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# Scaling up Antiretroviral Treatment in the South-East Asia Region

*Report of the National AIDS Programme Managers' Meeting, SEARO, New Delhi, India 19-21 November 2003*

WHO Project: ICP HIV 001

World Health Organization
Regional Office for South-East Asia
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## ACRONYMS

| | |
|---|---|
| AIDS | **A**cquired **I**mmuno **D**eficiency **S**yndrome |
| ART | **A**nti **R**etroviral **T**reatment |
| ARV | **A**nti **R**etro**V**iral |
| CCM | **C**ountry **C**oordinated **M**echanism |
| CUP | **C**ondom **U**se **P**rogramme |
| d4T | **S**tavudine |
| GFATM | **G**lobal **F**und to fight **A**IDS, **T**uberculosis and **M**alaria |
| HIV | **H**uman **I**mmunodeficiency **V**irus |
| HIV/ TB | The intersecting epidemics of **HIV** and **TB** |
| LFA | **L**ocal **F**und **A**gent |
| NACO | **N**ational **A**IDS **C**ontrol **O**rganization, India |
| NAP | **N**ational **A**IDS **P**rogramme |
| NAS | **N**ational **A**IDS **S**trategy |
| NGO | **N**on **G**overnmental **O**rganization |
| NVP | **N**evirapine |
| OI | **O**pportunistic **I**nfection |
| PR | **P**rincipal **R**ecipient |
| RNTCP | **R**evised **N**ational **T**uberculosis **P**rogramme |
| RSCM | **RS C**iptomangunkusumo Hospital |
| SEA | **S**outh-**E**ast **A**sia |
| SEAR | **S**outh-**E**ast **A**sia **R**egion |
| SEARO | **S**outh **E**ast **A**sia **R**egional **O**ffice |

| | |
|---|---|
| STI | **S**exually **T**ransmitted **I**nfection |
| TB | **T**u**B**erculosis |
| 3TC | **L**amivudine |
| TRP | **T**echnical **R**eview **P**anel |
| UNAIDS | The joint **U**nited **N**ations programme on HIV/**AIDS** |
| UNGASS | The **U**nited **N**ations **G**eneral **A**ssembly **S**pecial **S**ession on HIV/AIDS |
| VCCT | **V**oluntary **C**onfidential **C**ounselling & **T**esting (HIV) |
| VCT | **V**oluntary **C**ounselling and **T**esting (HIV) |
| WHO | **W**orld **H**ealth **O**rganization |
| YRG Care | **Y R G**aitonde **C**entre for **A**IDS **R**esearch and **E**ducation |
| ZDV | Zidovudine |

## CONTENTS

# 1. INTRODUCTION

Globally, five to six million people infected with HIV in the developing world need access to antiretroviral treatment (ART) but only 300 000 are receiving it. The failure to deliver antiretroviral drugs (ARV) to the millions of people who need them is a global health emergency. To address this emergency, WHO is fully committed to getting three million people on ARVs by the end of 2005 – the "3 by 5" target. This is an intermediate target and a means to achieving the treatment goal of universal access to ARVs for all who need them.

In the South-East Asia Region (SEAR), nearly six million people are living with HIV/AIDS making it the second most affected Region in the world after sub-Saharan Africa. Approximately 800 000 people living with HIV/AIDS in the Region are in immediate need of ART; however, less than 30 000 are receiving it. India, Indonesia, Myanmar and Thailand account for an overwhelming majority of the burden of HIV/AIDS in the Region.

Two remarkable developments in the past couple of years have had profound implications for HIV prevention and care around the world. First, the prices of ARV drugs have plummeted to as low as US$ 150 per patient per year, and are expected to further come down as antiretroviral treatment is scaled up in developing countries. Second, experiences in Brazil, Thailand, Botswana and other parts of Africa indicate that it is indeed feasible to implement affordable and replicable ART programmes in resource-poor settings.

Scaling up ART was the central theme of the third National AIDS Programme Managers' Meeting of the WHO South-East Asia Region held from 19 to 21 November 2003 in New Delhi, India. The meeting was attended by 52 participants including country representatives from Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka,

Thailand and Timor-Leste; nongovernment organizations (MSF, YRG Care); People Living with HIV/AIDS group (INP plus); bilateral donors (DFID, Canadian High Commission); WHO/HQ, SEARO and Country Offices, UNICEF, UNDP and UNAIDS South-Asia Inter-country-team (Annex 1).

The specific objectives of the meeting were:

(1) To exchange country experience in scaling-up antiretroviral therapy;

(2) To brief the participants on the "3 by 5" initiative proposed by WHO and the partners;

(3) To identify priority actions needed to implement "3 by 5" initiatives at country level during 2004-2005;

(4) To provide an update on the Global Fund to fight AIDS, TB and Malaria and on issues relating to programme implementation.

The agenda of the three-day meeting is attached (Annex 2).

## 2. INAUGURAL ADDRESS

The meeting was opened by Dr Poonam Khetrapal Singh, Acting Regional Director, WHO/SEARO. It was stressed that control of HIV/AIDS is one of WHO's priority programmes and that the "3 by 5" initiative would guide much of WHO's work on HIV/AIDS. Along with the renewed emphasis on treatment, work on prevention, counselling and care would continue.

The urgent need to increase coverage of quality HIV/AIDS care including ART in the public and private sectors was highlighted. Less than 5% of People Living with HIV/AIDS (PHA) in this Region are receiving ART despite the fact that prices for ARVs have dropped more than 90% in some cases. It is well known that the majority of manufacturers of WHO/UNICEF pre-qualified generic ARVs are from this Region, namely India and Thailand. Thailand is the first country in Asia to set the target of providing more than 50 000 people living with HIV/AIDS with ART by 2005 using different sources for financing.

All efforts must be made to strengthen the capacity of programmes, health services and communities to administer ART. HIV/AIDS prevention efforts must be maintained. The major modes of HIV transmission in the

Region are: sexual transmission, mainly through unprotected sex with commercial sex workers, followed by needle-sharing injecting drug users, and mother to child transmission. Experience in countries of this Region has shown that a number of interventions do work successfully to prevent the spread of HIV. Examples include ensuring targeted condom programmes among commercial sex workers and their clients, combined with the syndromic management of sexually transmitted infections. Prevention of mother-to-child transmission programmes have also been implemented in many countries on a national scale resulting in reduction of HIV/AIDS among children. HIV transmission among IDUs continues to rise in some Member Countries and this must be addressed using harm reduction approaches in tandem with programmes to decrease demand and supply of drugs.

The meeting elected Dr P L Joshi as the Chairman, Dr Manit Teeratantikanont as the Co-chairman and Dr Sujatha Samarakoon as the Rapporteur.

## 3. GLOBAL "3 BY 5" INITIATIVE

While "3 by 5" is a new initiative and WHO's top priority, it will not replace prevention efforts. Prevention efforts are very important and WHO believes that with a good implementation of ART programme, HIV prevention efforts will also be strengthened. WHO has set a fairly ambitious target and is taking the lead in this initiative, but it cannot do it alone. The "3 by 5" initiative will be driven by countries and by WHO as well as other developmental partners.

WHO's strategy will be to catalyze rapid uptake of ART in communities by adopting a two-pronged approach:

(1) Supporting countries to recognize and respond to their HIV/AIDS treatment gap and leveraging the necessary resources to enable ART to be scaled up rapidly in line with 3x5 target.

(2) Simplifying and standardizing ART as far as possible without compromising effectiveness, so that it could be universally scaled up and delivered in resource-constrained settings.

The global strategic framework has 14 elements grouped into five categories, as shown in Table 1.

***Table 1:** WHO global strategy for "3 by 5"*

| Strategy | Specific Activities |
|---|---|
| **Category 1: WHO and global level activities**<br>1. Visible WHO leadership and commitment to urgent action to reach the goal of universal access to ART.<br>2. Locate the rights-based 3x5 initiative within the broader development context.<br>3. Support all national efforts whilst focusing WHO resources on high-burden and strategic countries to achieve maximal impact of 3x5 initiative.<br>4. Align and mobilize partner support to achieve 3x5 target at global level | • Announce the global 3x5 target;<br>• Declare global health emergency;<br>• Allocate resources, with a majority channelled to countries;<br>• Develop a global strategy and work plan;<br>• Revise staff policy to provide ART to all WHO staff<br>• Publish ethics and equity guidelines;<br>• Respond to appeals from countries for assistance;<br>• Increase capacity of WHO country offices by deploying additional, competent staff; and<br>• Agree on specific roles with all stakeholders, including the private sector, in the scale-up process and establish mechanisms for ongoing collaboration. |
| **Category 2: Country Support Efforts**<br>5. Ensure the key elements required at the national level to deliver the 3x5 target as part of a comprehensive response to HIV/AIDS<br>6. Strengthen and support the renewal of health systems and national operational capacity for scaling up ART programmes<br>7. Strengthen and build human capacity for scaling up ART<br>8. Expand capacity of communities to be fully involved in ART programme planning and delivery | • Advocate with countries to set targets in line with 3x5;<br>• Support countries in the development of national scale-up plans;<br>• Broker additional resources to close funding gaps at country level;<br>• Accelerate HIV prevention activities to reduce stigma and discrimination;<br>• Develop technical brief on "Prevention for positives";<br>• Technical and operational guidelines for country implementation;<br>• Clinical treatment guidelines (IMAI);<br>• Develop methods for accreditation of service delivery points;<br>• Develop standardized training packages;<br>• Support countries in training of key groups; and<br>• Produce guidelines for support quality service provision. |

| Strategy | Specific Activities |
|---|---|
| **Category 3: Simplified, standardised tools**<br>9. Simplify and standardize procedures to identify individuals in need of therapy and facilitate entry to ART programme<br>10. Simplify and standardize ART to facilitate adherence and enable rapid scale-up to be implemented<br>11. Simplify and standardize tools for tracking ART programme performance including drug resistance surveillance<br>**Category 4: Effective, reliable supply of medicines and diagnostics** | • Simplified guidelines for HIV counselling and testing;<br>• Guidelines for better use of "entry points";<br>• Recommendation for standard first and second line regimens;<br>• Guidelines for adherence support;<br>• Guidelines on requirements for laboratory monitoring;<br>• Guidelines for nutritional support of adults and children on ART;<br>• Monitoring and evaluation programme indicators;<br>• Guidelines and networks for drug resistance surveillance; and<br>• An "incident room" to track activities and progress towards 3x5. |
| 12. Support country access to , and efficient distribution of high quality, low cost medicines and diagnostics | Form the AMF – AIDS Medicine and Diagnostics Facility - with three major functions:<br>a) Provide important information on selection, market intelligence (sources, prices, registration status, patent status, forecasting of needs, forecasting of production capacity), product specification and prequalification;<br>b) Arrange for technical support to Member States (market intelligence, procurement, supply management, local production, and<br>c) Convene a buyers' group (common principles, information support, rate tendering, procurement of diagnostics. |
| **Category 5: Success stories and learning by doing**<br>13. Build on success<br>14. Continuously learn by doing - with ongoing evaluation and analysis of programme performance<br>15. and a focused operational research agenda. | • Document experiences and lessons learnt from successful ART programmes (e.g., Brazil, Thailand, Botswana);<br>• Document experiences and lessons learnt from other successful programmes (e.g.,TB, Polio, SARS);<br>• Set up south -to - south networks to disseminate models and exchange information, and<br>• Coordinate and develop Operations Research agenda document influence of ART scale up on health systems and impact on prevention and at-risk behaviour. |

# 4. SCALING-UP OF ART IN SOUTH-EAST ASIA: CURRENT STATUS

WHO/SEARO conducted a rapid assessment of country preparedness for scaling-up ART. Seven of the 11 countries in SEAR have included ART in their national AIDS policy and four countries have ARV medicines added to the national essential drug list. Indonesia and Thailand are providing ART through provincial AIDS committees and their respective national programmes. India, Myanmar and Nepal will soon be starting national ART programmes.

All countries except Thailand lack laboratory facilities to perform CD4 counting. VCT and private practitioners are the entry points for the administration of ART in most countries. India and Thailand have the capacity to monitor ARV drug resistance.

Many generic drugs are manufactured in India and Thailand. Drug costs vary from country to country, the lowest price of about US$ 30-50 per month are found in India and Thailand where locally produced generic drugs are being used. Countries have different sources of drug financing ranging from public to private. Strong involvement of civil society including people with HIV/AIDS is necessary in the initiation and implementation of ART at all levels.

Some countries including India, Indonesia, Myanmar, Nepal and Thailand have been successful in mobilizing resources for ARV from the Global Fund, with support from WHO/SEARO. Many meetings on HIV/AIDS care including ARV have been conducted within the Region to enhance implementation at country level and collaboration among partners.

While some ground work has been done, major investments and acceleration of efforts will be required by all partners, in particular high-burden Member Countries such as India, Indonesia, Myanmar and Thailand, to attain the ambitious target of putting 400 000 people on ART.

***Table 2:*** *Estimated HIV prevalence and ART needs in SEAR, 2003*

| Country | HIV prevalence | Total number of people needing ART | Number of people on ART in 2003 | Proposed WHO target by 2005 | Treatment gap (number on treatment and WHO target ) |
|---|---|---|---|---|---|
| Bangladesh | 13 000 | 1 800 | 5 | 900 | 895 |
| Bhutan | <100 | 14 | 5 | 7 | 2 |
| DPR Korea | n/a | 0 | 0 | 0 | 0 |
| Indonesia | 130 000 | 18 400 | 500 | 9 200 | 8 700 |
| India | 4 580 000 | 600 000 | 13 000 | 300 000 | 287 000 |
| Maldives | 100 | 14 | 0 | 7 | 7 |
| Myanmar | 420 000 | 60 000 | 1 000 | 30 000 | 29 000 |
| Nepal | 60 000 | 8 000 | < 100 | 4 000 | 3 750 |
| Thailand | 670 000 | 98 000 | 13 000 | 48 000 | 25 000 |
| Sri Lanka | 4 800 | 680 | 25 | 340 | 315 |
| Timor–Leste | n/a | n/a | n/a | n/a | n/a |
| Total | 6 million | 800 000 | 30 000 | 400 000 | 360 000 |

# 5. TECHNICAL ISSUES AND CHALLENGES IN SCALING UP ART

## 5.1 Access to Drugs, Procurement and Supply

The objective of the procurement and supply system is to ensure that good quality medicines are obtained at competitive prices and the drugs are available without interruption. Supply and procurement systems are influenced by several regulatory regimes, such as, the drug registration system and the intellectual property/patent system. Both of these affect the possible sources of supply, and, therefore, affect access.

Countries like Brazil, Thailand and India have initiated local production of those ARVs that are not protected by a patent in their territory. In addition, Brazil is using the 'threat' of issuing a compulsory licence to negotiate steep price reductions for those ARVs that are patented. Several other countries have already implemented small scale or pilot projects. Lessons from their experience include:

- Registration is not a major constraint; usually there is an exemption mechanism, and it is used when necessary. However, while such exemptions are useful in the short term, in the long term, it is preferable to encourage registration. Registration is more secure and reinforces rather than bypasses the drug supply and quality control system.
- Although it might be possible to ignore patents in small-scale or trial projects, when scaling up, the provision of ARVs should have a sound legal basis. Thus, for patented ARVs, countries may have to opt to provide exclusively innovator drugs. Alternatively, they could make use of 'safeguard mechanisms' such as compulsory licensing or parallel importation.

Challenges with regard to procurement include inaccurate quantification of requirements; lack of information on prices and sources of good quality medicines and on reliable suppliers; lack of expertise and experience with pharmaceutical procurement and inefficiencies due to procurement being dispersed among several programmes and organizations.

In order to address these challenges, it is important that HIV/AIDS programmes communicate their scaling up targets clearly to procurement offices. Moreover, if at all possible, countries should use experienced procurement officers following good procurement practices and having access to the necessary market intelligence. Countries should also consider pooled procurement, and pooling of procurement expertise.

## 5.2 Simplifying Treatment Guidelines

The present updated and simplified treatment guidelines are the cornerstone of the WHO's "3-by-5 Strategy", and are more directive than its predecessor with respect to first and second line therapies. They take into account not only the evidence generated by clinical trials and

observational studies on the efficacy and side effects of the treatment regimens discussed, but also the experience gained with ART by programme and the cost and availability of drugs in resource-limited settings. These guidelines deal only with recommendations for ART and monitoring, but are meant to be a component of a comprehensive package of care at the country level including opportunistic infection prevention and treatment, nutritional programmes, and psychosocial support for infected persons.

The topics addressed in these treatment guidelines include when to start ART, which ARV regimens to start, reasons for changing ART and what regimens to continue if treatment needs to be changed. It also addresses how treatment should be monitored, with specific reference to the side effects of ART and drug adherence, and makes specific recommendations for certain patient subgroups. All recommendations are made bearing in mind the needs of health systems that often lack sophisticated manpower and monitoring facilities, without compromising the quality and outcomes of the treatments offered. A first innovative feature is significant simplification of the recommendations for the treatment regimen, with a recommendation to opt for one, single three-drug first-line treatment regimen, using either d4T or ZDV, 3TC, and either NVP or EFV as the first-line drugs. Further new features include more liberal recommendations on when to start treatment, new definitions of treatment failure, new recommendations on second-line treatment, increased clarity in the laboratory monitoring section, and a new section on adherence support.

## 5.3 Treatment Adherence and Antiretroviral Drug Resistance Monitoring

Drug compliance is a very important factor in any ART programme. Mechanisms for monitoring of drug adherence and drug resistance should be in place before scaling up ART. Using a fixed drug combination like GPO-vir (d4T/3TC/NVP), as in Thailand, can help improve drug adherence.

Several factors are related to drug adherence, e.g., knowledge about the disease, length and complexity of the treatment; perceived benefits versus barriers; social support; depression; interactions between the patient and the provider; substance use; self-efficacy regarding adherence. From the experience gained by treating patients in YRG Care, poor adherence is

associated with costs of drugs (cannot continue to buy/afford ARV). Therefore, free/subsidized drugs should be important considerations in improving treatment compliance.

Most importantly, national programme managers must ensure that distribution of ARVs occurs in the context of policies, practices and procedures that promote rational ARV use and encourage patient adherence. In collaboration with partners, WHO is in the process of initiating a global ARV drug resistance surveillance programme. The WHO programme will assess geographical and temporal drug resistance prevalence, improve understanding of the factors that lead to resistance, and help identify strategies to minimize the appearance, evolution and spread of drug resistance.

ARV treatment programmes should actively involve patients, their families, PHAs and the communities in improving treatment compliance. In Thailand, advocacy campaigns with key messages are used to improve treatment compliance. Examples of advocacy messages include, "AIDS is a chronic disease like diabetes", "ART can improve the quality of life of people with HIV".

Additional research is needed to identify optimal strategies to promote patient adherence. One formidable challenge will be how to get a buy-in from the private sector, where drugs are being provided without monitoring. There is need for national guidelines for simplified and standardized drug regimens to regulate the use of antiretroviral drugs and prevent the emergence of drug resistance.

## 5.4 Laboratory Monitoring of ART

The role of the laboratory is central for successful ART. Laboratory support is required both to guarantee safe and effective drug treatment and assess ARV drug resistance. Flow cytometry is the gold standard for CD4+ count measurement and is the recommended method; however, it is extremely expensive and requires infrastructure and trained human resources.

Issues and challenges for laboratory support of ART include development of uniform guidelines, creation of infrastructure, cost of equipment, continuous supply of reagents, quality assurance, training of human resources, and ongoing operations research. Back up of laboratory

support is extremely important - e.g. generator, continuous supply of resources, reagents, trained laboratory workers. Good management is very important at all levels of the programme. The high cost of maintenance of machines is also an issue - the cost of annual maintenance for big machines is up to 6-7% of its total cost. Another important area is quality assurance of both public and private laboratories. Private laboratories are dominated by market forces and would require external quality control through a method of accreditation to ensure that the quality of diagnostics is not compromised.

WHO is supporting Member Countries by developing regional guidelines, training human resources in CD4 count and quality assurance, providing technical support to countries in creating infrastructure and networking, promotion of quality systems, and resource mobilization.

Diagnostic technology is evolving at a rapid pace. Countries must strengthen their health systems and be ready to absorb the new technology without worrying too much about the cost at this point. It is likely that cost of diagnostics will eventually come down. Networking of laboratories (at different levels, and across different sectors) is required to overcome resource limitations. Brazil is a successful example of optimally creating a laboratory network for ARV. Brazil has a network of 70 laboratories for assessing viral load, 63 laboratories for CD4 count, and has placed on treatment more than 100 000 patients.

## 5.5 VCT as an Entry Point for ART

India's National AIDS Control Organisation (NACO) has been establishing Voluntary Counselling and Testing (VCT) Centres since 1997, initially attached to blood banks. Over the past three years, the number of VCTs has rapidly accelerated from 108 in 2001 to 445 in 2002. As of December 2003, 542 VCT Centres have been established in all districts in high prevalence states and are being progressively established in districts in low prevalence states. NACO aims to establish at least one VCT in each district of India by 2004. Each VCT is staffed with two counsellors (one male and one female), one laboratory technician and with the appropriate infrastructure and consumables for HIV testing. However, currently, only 30-40% of VCTs are functioning according to national guidelines.

In 2002, a total number of 425 205 clients were tested in VCTs in India. 24% were voluntary walk-in clients, 62% of all clients tested received pre-test counseling and around 13% of all clients tested positive for HIV.

Selected high prevalence states (Andhra Pradesh, Karnataka) have established VCTs at the sub-district level using state level funds. The third round of GFATM funding is earmarked for the establishment of sub-district level VCTs in rural areas of all six high prevalence states (Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland, Tamil Nadu) in close coordination with the RNTCP (Revised National TB Control Programme).

A pilot study on TB-HIV collaborative activities from six high HIV prevalence states conducted over nine months until August 2003 followed 249 386 new VCCT clients. 20% of these clients were HIV-positive. 41% of HIV positive clients (with cough) had been referred to TB Microscopy Centres and 38% of the referred HIV-positive clients also had TB.

## 5.6 Involvement of PHAs in ART

PHAs are no longer just passive consumers of health care, but should be involved actively in providing care and support to peers. In scaling up of ART, PHAs can play a crucial role and reduce workload on health staff by motivating other PHAs to come forward for treatment, and by supporting treatment adherence. For this, they would need to be trained in ARV, opportunistic infections, communication skills, and recording and reporting. National programmes should take concerted steps to develop and support PHA networks.

PHAs play an important role both in policy development and implementation in the ART programme. In Thailand, MSF successfully collaborated with PHAs and this experience could be used by other countries. Involvement of PHAs in the co-trimoxazole prophylaxis campaign was a key stepping stone in the collaboration. In India, the government is providing funds to PHA groups to set up networks. As a result, 14 states in India have a network of PHAs. ARV is increasingly being identified as a need by PHAs. In Indonesia, NGOs are playing an important role in engaging PHAs, particularly IDUs.

Several issues still need to be addressed. ART gives PHAs a second life. So they want to get back to work, have relationships, and have sex and family. In order to ensure long-term adherence, it would be important to address these issues.

## 6. THE "3 BY 5" INITIATIVE IN THE CONTEXT OF HIV-TB

The South-East Asia Region bears 40% of the global TB burden and ranks second after sub-Saharan Africa in the number of HIV/AIDS cases. HIV-TB is an important priority in the Region. Collaboration between HIV and TB programmes are beginning to take shape in several countries based on a clear and comprehensive policy and strategy on HIV-TB. The "3 by 5" initiative provides considerable additional opportunities to enhance HIV/TB collaboration.

The TB programmes and the DOTS strategy in countries have a well established system of drug delivery that can serve as a model for ARV delivery. TB patients in high HIV settings are likely to be co-infected. They constitute a readily identifiable group in the health system for HIV testing and ART thus can contribute strongly to the "3 by 5" target. Draft guidelines for treatment of HIV/TB co-infection are being finalized (Table 3).

***Table 3:*** *Recommended treatment strategy for patients with TB disease and HIV co-infection*

| CD4 (mm3) | TB and ART | Recommend |
|---|---|---|
| < 200 | 1. Start TB Rx<br>2. Start ART as soon TB Rx tolerated | Recommend ART |
| 200 - 350 | 1. Start TB Rx<br>2. Start ART after initiation phase | Consider ART |
| > 350 | Start TB Rx | Defer ART |

*WHO: Scaling-Up Antiretroviral Therapy in Resource-Limited Settings, 2003*

It is important to learn how lessons from TB can be packaged for scaling up ART. Examples of successful lessons from the TB programme

include the setting of national targets for coverage of services and adherence to treatment; simplified and standardized diagnosis and treatment approach, the use of community resources for improving treatment adherence, including the use of family members with supervision from the health system; ensuring uninterrupted drug supply, and tracking progress against targets by quarterly cohort analysis.

## 7. GFATM UPDATE

Since the Global Fund was established in 2001, the WHO Regional Office has been providing support to Member Countries in terms of information and communication, technical assistance in proposal development and implementation, convening regional meetings, and organizing mock Technical Review Panels (TRPs).

To date, US$ 409 595 687 have been committed to HIV/AIDS programmes in the SEA Region through the Global Fund (Table 4). The national governments are the main Principal Recipients (PRs) in the countries. However, in Myanmar and DPR Korea, the PR is unknown. Given the need for additional and ongoing technical assistance from WHO requiring staff commitment and resources, Country Coordination Mechanism (CCMs) may be encouraged to request funding to be set aside during grant agreement negotiations, to support multilateral agencies such as WHO to undertake operational, advisory and monitoring and evaluation services as required by countries during the implementation stage.

***Table 4**. Proposals approved and funds allocated to South-East Asia Region*

| APPROVED BUDGET | | | | |
|---|---|---|---|---|
| | **Component** | **Round 1** | **Round 2** | **Round 3** |
| Bangladesh | AIDS | | 19 961 030 | |
| India | AIDS | | 100 081 000 | |
| | HIV/TB | | | 14 819 773 |
| Indonesia | AIDS | 15 960 103 | | |
| Myanmar | AIDS | | | 54 300 034 |

| APPROVED BUDGET | | | | |
|---|---|---|---|---|
| | **Component** | **Round 1** | **Round 2** | **Round 3** |
| Nepal | AIDS | | 11 173 542 | |
| Thailand | AIDS | 109 505 316 | 81 348 535 | 1 371 348 |
| MMR-THA NGO | AIDS | 1 075 006 | | |
| Total | | 126 540 425 | 212 564 107 | 70 491 155 |
| **Total (Round 1, 2 & 3): 409 595 687** | | | | |

The pre-requisite for PRs to set up credible financial systems and build up new supply distribution systems before the first disbursements for medicine purchases has caused many delays between grant agreements and disbursements. Another concern is the high costs of international Local Fund Agents (LFAs) versus local options. The Global Fund intends to award a number of Local Fund Agent Framework Contracts and invites suitably qualified organizations to submit proposals for provision of services as LFA. The discussion that other kinds of organizations besides private sector accounting firms should also be considered as LFA is ongoing.

The fourth round of GF will be primarily a "3 by 5" round. Calls for applications will be made by the first week of April 2004 and the deadline for submission would be the first week of April. Technical support missions will be made available from the Regional Office and regional review and mock TRP will be provided.

In summary, GF presents an excellent opportunity to mobilize resources; priority will be given to ensure GF support for countries without approved proposals. Countries with approved proposals need to build PR capacity and ensure performance-based implementation.

# 8. SITUATIONAL ANALYSIS AND PRIORITY ACTIONS FOR SCALING UP ART IN HIGH BURDEN COUNTRIES

## 8.1 Thailand

More than 1 million people have been infected with HIV to date causing an estimated 450 742 deaths. While a declining trend in the number of new

HIV infections is noted in the recent years, it is expected that more than 50 000 AIDS cases will continue to occur each year for the next five years due to the large number of those already infected with HIV.

To mitigate the impact of the epidemic, the ART programme in Thailand began as early as 1992. The programme was developed in three phases: in the first phase (1992-1997), AZT monotherapy was introduced and a limited number of cases were treated at a few sites. In the second phase (1998-2000), the capacity and networking of clinical service centres were strengthened with the strategy to integrate ARV into a comprehensive care and support programme. Dual therapy was introduced as a standard treatment in 1998 before changing to ART in 2000. The number of patients accessible to the therapy, however, was still limited. In the third phase, it has been possible to expand the ART programme due to lowered prices and local production of generic medicines.

Currently, the National Access to ARV Programme aims to cover all cases who are in need of ARV. The core components of the programme include: simplified standard regimens (d4T+3TC+nevirapine as the first line of treatment); infrastructure development and capacity building through continuous training for medical doctors, nurses, counsellors or social workers, laboratory technicians and pharmacists; drug procurement and distribution; monitoring and evaluation of ARV programme; development of CD4 count laboratory networks; and involvement of civil society, PHA and family care givers in improving adherence to treatment.

More than 800 hospitals are currently involved in providing ARVs. Up to September 2003, 14 677 patients have been initiated on ARV, of whom 13 279 are currently on treatment. The government allocated US$ 25 million in 2004 to scale up access from 13 000 to 50 000 next year. The policy has been laid to provide ARV to cover all AIDS patients through the Social Security Fund and Universal Health Insurance programme. Necessary infrastructure development including human resource development will be built up. Currently there are 19 CD4 machines available for ARV in 19 centres. This year, an additional 20 centres will come up from GF to support expansion of ART. The cost of diagnosis and monitoring is still very high. 80% of the required budget for ARV would come from the government and the rest from the Global Fund.

The challenges and priority actions remaining for ensuring ARV access to all include sustaining the programme by building capacity, strengthening partnerships, maintaining financial commitment, reduction of cost for CD4 count, adherence to ARV, long term follow-up, surveillance for clinical failure and drug resistance.

## 8.2 India

There are an estimated 4.58 million persons living with HIV/AIDS. It is estimated that around 13 000 PHA are receiving ART in the private sector. The public sector provides free ARVs (under certain circumstances) in the Central Health Services, ESI (Employees State Insurance Scheme), and the Ministry of Defence. The government supports provision of ARV for post-exposure prophylaxis in Government hospitals and for the Prevention of Parent to Child Transmission programme for preventive treatment.

Scaling up treatment to 300 000 PHAs who need treatment will be a challenging task and will require the following urgent actions: (1) development of a national policy on ART; (2) sensitization of the political and administrative leadership and other stakeholders; (3) development of a strategic national plan for scaling up ART; (4) mobilization of financial resources in conjunction with partners; (5) exploration of mechanisms to procure generic drugs and strengthen existing systems for distribution and inventory control; (6) development or adaptation of guidelines for diagnosis, treatment, and monitoring; (7) development of plans for capacity building of medical, paramedical and programme staff; (8) mobilization of communities, PHA networks and other international and national partners, and (9) review of existing monitoring and evaluation plan to include indicators for monitoring ART.

## 8.3 Myanmar

A total of 45 033 people in Myanmar were diagnosed with HIV infection up to December 2002, although it is estimated by UNAIDS that between 170 000 and 420 000 people are currently living with HIV/AIDS. Access to treatments for opportunistic infections and antiretroviral combination therapy is currently very limited due to resource constraints.

HIV/AIDS along with TB and malaria is among the three priority diseases addressed in the National Health Plan. The government has increased funding for AIDS/STD programme five fold in the past three years to 22.5 million Kyats and plans to increase this thrice in the next four years (73.9 million Kyats).

There are 40 AIDS/STD prevention and control teams in 30 towns (including Yangon) covering 28 districts. The teams of eight people consist of doctors, nurses, nurse assistants, counsellors/health educators, and laboratory technicians. The teams are based in public sector STD clinics. The teams provide outreach education, VCCT, STI diagnosis and treatment, contact tracing, local administration of the 100% CUP, PMCT services (in some sites), sentinel surveillance, HIV outpatients treatment (including drugs for opportunistic infections), and home care. Currently 35 districts do not have prevention and control teams.

In these districts, local medical officers provide limited HIV/AIDS/STI services. Over the next five years, AIDS/STD prevention and control teams will be established in each of the 35 districts not currently covered. The salary component of the planned expansion will be funded by the NAP, as part of the budgetary commitment of the Myanmar Government to responding to HIV/AIDS/STIs.

Three priority areas have been identified to be urgently addressed with the support of the Global Fund:

(1) To reduce the risk of HIV infection through sexual transmission by expansion of the 100% Condom Use Programme (CUP);

(2) To reduce the risk of HIV infection among injecting drug users through a range of harm reduction interventions, and

(3) To build capacity for voluntary confidential counselling, HIV testing (VCCT), and care and support including ART services.

The expansion and promotion of VCCT services to 200 towns nationwide over five years will be used to very significantly increase the number of people in 'at risk' groups and the general population who will have ready access to HIV counselling and testing. VCCT services have been designed as an entry point to enable the direct delivery of education and

prevention messages and linking people who are infected with care and treatment services, including access to ART and OI treatments. Expected results will be a reduction in HIV transmission through education and prevention, and improved access to care and support services resulting in a better quality of life. Number of PLWHA receiving ART will cover 550 persons during the first year, 2 619 in the second year and up to 6 548 by the fifth year.

## 8.4 Indonesia

There are an estimated 90 000 – 130 000 PLWHA in Indonesia. The Ministry of Health is increasingly engaging the local governments and other stakeholders in mobilizing financial and human resources for comprehensive HIV/AIDS activities, including ART. There are currently 30 ART delivery points in Indonesia. To date, an estimated 1 100 PHAs have been put on ART. In terms of diagnostic capacity, there are currently two CD4 centres, both in Jakarta. Drug adherence monitoring has not yet been initiated.

At present, the cost of ART is around Rp. 500 000 – 650 000/month. Cost of ART support is considered through three mechanisms: 1) 100% support from government through the social safety net, i.e., free service for poor with poverty card; 2) 50% subsidy, and 3) full payment by patients themselves. Currently, 90% of patients are paying by themselves. The government has committed to allocate subsidy funding for 2 000 patients @ Rp 200 000/month in the year 2004.

The government plans to set up reference hospitals for HIV/AIDS management, including facilities for CD4 count in at least six priority provinces (Jakarta, Bali, Riau, Papua, West Java –Bandung, and East Java – Surabaya), where HIV prevalence is highest. The government will work closely with NGOs and the drug dependence hospitals to scale up access to IDUs.

The RSCM under the assistance of the Pokdisus has long initiated HIV/AIDS care and now is expanding its commitment to act as a training hospital for other groups of HIV care providers from various parts of Indonesia. Training in laboratory procedure is also being followed through WHO support and national level training will follow to strengthen

laboratory support. Some medical professionals have been sent to regional collaborating training centres through WHO assistance and Indonesia has a plan to send at least 20 health care providers as soon as possible to build capacity in ART provision. VCT training modules have been developed and massive training of counsellors needs to be scaled up.

Indonesia recognizes the urgent need to be ready for treatment, care and support of PHAs, and has already identified it as an important and priority need in the NAS as well as the MoH National AIDS Strategy. However, it is also recognized that it is important to have technical guidelines, tools and sufficient capacity for delivering of such a programme. The WHO commitment and proposed leadership is very timely and very much appreciated.

At present, 1 100 PHAs are already on ARV through community support and it's expected that by the end of 2005, at least 10 000 will be on ARVs if appropriate support is available. Priority activities for Indonesia will be as follows:

(1) To mobilize national political commitment for Indonesia's partnership and contribution to reach the WHO 3 by 5 target. This advocacy is essential, as Indonesia has a decentralized system, which means that local governments have a major decision- making power.

(2) To develop a comprehensive plan including monitoring and evaluation, and partnership plans will have to be developed by end January 2004.

(3) To build the capacity of health services to deliver ART. While WHO is already involving some Indonesian personnel in regional training, the country will need to build a massive pool of human resources with good understanding of the right approach to scaling up ART.

(4) To identify a focal agency and develop a system and coordination mechanisms with partners for ensuring uninterrupted supply of ARV and diagnostics.

(5) To develop national guidelines for treatment, adherence, monitoring as proposed in the regional strategic framework.

(6) To establish monitoring, evaluation, surveillance and operational research.

# 9. REGIONAL STRATEGY FOR SCALING UP ART

To attain the ambitious target of putting 400 000 people in the Region on ART will require major investments and acceleration of efforts by all partners in other high-burden Member Countries, such as India, Indonesia, Myanmar and Thailand. Currently in SEAR, only 30 000 PHAs are on antiretroviral treatment against a target of 400 000. Thus, treatment coverage has to be scaled by a factor of 10 by 2005.

The success of the regional strategy for scaling-up ART depends on the implementation of a policy package which includes the following six strategy elements:

(1) **High-level government commitment to scaling-up ART aiming at 50% coverage** and ultimately at universal coverage. Effective leadership requires a permanent national core group for scaling-up ART qualified in the planning and management of the treatment programme. The core group's tasks are to initiate, coordinate, supervise and evaluate the key activities of the treatment programme at all levels through the primary health care system wherever it exists. The team should consist of partners from government, technical experts, nongovernmental organizations, private medical associations, civil society, PHAs, international partners and donors.

(2) **Establishment of a system of regular drug supply of all essential first-line and second line ARV.** Advanced planning for drug procurement and timely delivery should be based on the targeted number of patients and stock levels. Stock outs must not occur, since treatment interruptions will result in the emergence of drug resistance.

(3) **Building capacity of health services to deliver through the development, strengthening and sustaining of the workforce.** A capacity building plan must be developed to ensure the availability of sufficient number of appropriately qualified individuals for the scale-up and maintenance of ART services for 400 000 people by the end of 2005.

(4) **Mechanisms for proper case management to ensuring treatment adherence.** Service delivery models, peer support, increasing treatment literacy of People Living with HIV/AIDS, in order to avoid the emergence of resistant HIV strains should be developed. This is of utmost importance, since only a limited number of ARVs for second line treatment are available in Member Countries.

(5) **Community mobilization including People Living with HIV/AIDS.** Reducing stigma and discrimination through community mobilization, establishing community groups and ensuring their involvement in planning, and overseeing enrollment, service delivery and treatment adherence, establishing referral/linkages between services within health facilities and between health facility and home/community, and increasing demand for VCT including prevention, care and treatment through social mobilization are necessary.

(6) **Establishment and maintenance of a monitoring, evaluation, and surveillance system as well as operational research to be used for programme supervision and evaluation.** This system should be based on recording individual patient information in registers and on regularly reporting, preferably on a quarterly basis at district level. The flow of data to central level and feedback as well as the analysis of data at all levels must be determined. ARV drug resistance surveillance at national level is recommended.

## 10. SUMMARY AND RECOMMENDATIONS

The meeting concluded that scaling-up of antiretroviral treatment will be a part of the comprehensive care package for PHAs and reaffirmed that HIV prevention efforts will be maintained. Participants worked in smaller groups to initiate work plans for starting and scaling-up ART which will be fine-tuned and submitted to WHO in due course.

### For WHO and other developmental partners:

(1) While maintaining its overall support for HIV prevention activities, WHO should fully advocate for “3 by 5”, the setting of national targets and the development of national strategic plans.

(2) Full-fledged technical support for antiretroviral treatment should be provided to the four high burden countries (India, Thailand, Myanmar and Indonesia) while ensuring sustained support to all countries in the Region for comprehensive HIV prevention and care, including ART.

(3) Mechanisms for intercountry exchange of information and experiences should be established and reinforced, lessons learned for "3 by 5" documented.

(4) Development of tools and guidelines for voluntary counseling and testing, clinical management, drug management, and monitoring and evaluation should be finalized; their distribution to countries expedited, and provide assistance in adaptation and application of these tools and guidelines, as necessary, for country use.

(5) Countries should be supported to strengthen capacity for the core technical and programmatic areas, specifically monitoring, supervision and evaluation of care and treatment programmes, and in identifying priority areas for operational research.

(6) WHO should assist Countries in advocacy for additional financial support to fill the current funding gaps, and help them in preparing proposals for the fourth round of GFATM, where requested.

(7) Staff capacity at the regional and country levels should be strengthened to support efforts to achieve the "3 by 5" target.

**For Member States:**

(1) National targets should be set for the number of people living with HIV/AIDS to receive antiretroviral treatment by 2005, in line with the global target of 3 million by 2005 (i.e., at least 50% coverage of the persons requiring treatment).

(2) Comprehensive national plans and strategies for the "3 by 5" target should be developed by strengthening the existing health care systems.

(3) PLWHAs, NGOs, and civil society, media and the private sector, and international partners should be fully involved in planning, implementation and evaluation of HIV/AIDS care with an emphasis on equitable access.

(4) Uninterrupted supply should be ensured with sufficient buffer stock of diagnostics, antiretroviral drugs and other supportive treatment (drugs for prevention and treatment of opportunistic infections).

(5) Comprehensive mechanisms for adherence to antiretroviral treatment and drug resistance monitoring should be included in the national plans.

(6) Increased national resources should be allocated and additional external resources mobilized in order to ensure adequate and sustainable financing and access to HIV/AIDS care and antiretroviral treatment.

(7) Strategic plans should be implemented for capacity building, targeting programme managers, medical doctors, counsellors, nurses, paramedics, laboratory technicians, pharmacists and PHAs.

(8) Monitoring and evaluation indicators recommended by WHO and other partners should be adopted in order to monitor coverage and quality of services.

# Annex 1

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# Annex 2

## PROGRAMME

**Monday, 19 November 2003**

0900-1230 hrs

- Welcome/Opening remarks – Poonam Khetrapal Singh, DRD/SEARO
- Objectives of the meeting – Jai P Narain, Coordinator(HIVAIDS & TB), SEARO
- Sharing global, regional and country experience with ART (15 min. presentations)
  - Global "3 by 5" initiative – WHO HQ
  - Progress made in SEAR – Jai P Narain, WHO SEARO
  - Progress made in Thailand – NAP Thailand

1400-1700 hrs

- Discussion
- "3 by 5 initiative": Issues and challenges for scaling up ART(Presentations 15 minutes)
  - New simplified treatment regimens – Ying-Ru Lo, WHO SEARO
  - Access to drugs, procurement and supply – Karin Timmermann, WHO Indonesia

**Tuesday, 20 November 2003**

0900-1230 hrs

- "3 by 5" initiative: Issues and challenges for scaling up ART (Presentations 15 minutes)
  - Simplified laboratory monitoring of ART (CD4, TLC) Sudarshan Kumari, WHO SEARO
  - Involvement of PHA and communities for ensuring treatment adherence Paisan Tan-Ud TNP Plus, David Wilson MSF
  - Treatment adherence and ARV drug resistance – N. Kumarasamy, India

- Country missions
- Check list for country missions
  WHO HQ/WHO SEARO

1400-1700 hrs Group Work

- To identify priorities for action at country level during 2004-2005, followed by Country presentations
- Synthesis of country workplans Rapporteur
- GFATM update – Jai P. Narain, WHO SEARO

**Wednesday, 21 November 2003**

0900-1230 hrs

- Welcome/Opening remarks *
  DRD, SEARO
- Objectives of the meeting
  Jai Narain, Coordinator HIV/AIDS &TB, SEARO
- Global "3 By 5" strategy
  WHO HQ
- Country target and needs in four priority countries
  - India
  - Thailand
  - Myanmar
  - Indonesia
- Conclusions and Recommendations
  Jai P Narain, WHO/SEARO
- Closing of NAP Meeting
  N Kumara Rai, WHO/SEARO