

**World Health Organization**  
Perspectives in Public Health

# **HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region**



**World Health  
Organization**  
Western Pacific Region



CHINESE CENTER FOR DISEASE CONTROL AND PREVENTION  
NATIONAL CENTER FOR AIDS/STD CONTROL AND PREVENTION



**HIV Drug Resistance  
Prevention, Surveillance and  
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# Acronyms

<b>AIDS</b>	Acquired immunodeficiency syndrome
<b>ANC</b>	Antenatal care
<b>ART</b>	Antiretroviral therapy
<b>ARV</b>	Antiretroviral
<b>CDC-GAP</b>	Centers for Disease Control and Prevention, Global AIDS Project (USA)
<b>EWIs</b>	Early warning indicators
<b>HIV</b>	Human immunodeficiency virus
<b>IDU</b>	Injecting drug users
<b>HIVDR</b>	HIV drug resistance
<b>MSD</b>	Merck Sharp & Dohme
<b>MSF</b>	Médecins sans Frontières (Doctors without Borders)
<b>MSM</b>	Men who have sex with men
<b>NCAIDS</b>	National Center for AIDS/STD Control and Prevention (China)
<b>STI</b>	Sexually transmitted infection
<b>SW</b>	Sex workers
<b>TB</b>	Tuberculosis
<b>VCT</b>	Voluntary counselling and testing

# Executive Summary

In response to the growing need to address issues related to HIV drug resistance (HIVDR) in the Asia Pacific Region, a Technical Consultation on HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region was held in Beijing, China, from 14 to 16 November 2007.

About 100 participants from six countries and two regions (Cambodia, China, Hong Kong [China], Macau [China], Indonesia, Papua New Guinea, Thailand and Viet Nam), discussed the critical actions required to minimize the emergence of HIVDR and to assess its prevention and emergence in the Region. The participants included a mixture of epidemiologists, clinicians, laboratory scientists, antiretroviral therapy (ART) and HIVDR programme managers and policy-makers representing government, civil society, academic institutions and international development agencies.

The primary objectives of the meeting were:

- (1) to update participants on progress in the HIVDR situation in the Region and share experiences and lessons learnt since the Ha Noi HIVDR meeting;
- (2) to share WHO-recommended HIVDR strategies and methodologies;
- (3) to develop outlines for country reports for 2007 and agree upon a process for regular, sustainable reporting over the coming years;
- (4) to develop country strategies and work plans in line with the WHO recommendations for HIVDR prevention and assessment strategies, including actual and prospective partnerships; and
- (5) to consolidate regional and global linkages through the WHO Global HIV Drug Resistance Surveillance Network (HIVResNet) laboratory and epidemiology networks, including establishing links between national HIVDR working groups and accredited laboratories and putting in place mechanisms for data entry, data quality assurance, data sharing and data analysis.

Over the course of the Consultation, experts and participants discussed technical briefs on core WHO HIVDR strategies and methodologies. They shared progress in scaling up their antiretroviral therapy (ART) programmes and acknowledged the need to minimize preventable HIVDR and keep patients on first-line regimens for as long as possible. Although most countries have established HIVDR technical working groups (TWG) and are implementing some HIVDR prevention activities, most have not yet begun to regularly assess the recommended early warning indicators (EWIs) and very few have initiated WHO-recommended surveys to monitor HIVDR prevention and associated factors in sentinel ART clinics. In countries where WHO HIVDR transmission threshold surveys have been conducted, the prevalence of transmitted HIVDR is low, under 5%.

Countries prepared national HIVDR prevention and assessment plans for the next three to five years and consolidated regional and global HIVResNet linkages. The following next steps were agreed upon:

- Dissemination of the report of the Beijing Technical Consultation on HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region.
- Distribution of templates for the 2007 country reports, designed by WHO Headquarters.
- Publication of country and regional HIVDR reports for 2007.
- Discussion and finalization of country work plans with national HIVDR technical working groups and with the WHO Western Pacific Regional Office to aid development of a regional HIVDR plan.
- Establishment of operational linkages with accredited laboratories in the Region. At the time of the Consultation, the only accredited regional laboratory in the Western Pacific Region was the Burnet Institute, Melbourne, Australia.
- Submission of requests for further accreditation of laboratories through the WHO Western Pacific Regional Office.
- Provision of technical support from WHO country offices, the WHO Western Pacific Regional Office and WHO Headquarters to assist in the implementation of country plans.
- Enhancement of partnerships within the HIVResNet to support country plan implementation and resource mobilization.
- Expansion of HIVDR networks to additional countries in the Western Pacific Region.
- Planning for a joint WHO Western Pacific Region/South-East Asia Region HIVDR technical consultation, to be held early in 2009.



# Introduction

An estimated 1.3 million people in 37 countries of the Western Pacific Region were living with HIV/AIDS as of December 2006, with Cambodia, China, Papua New Guinea and Viet Nam accounting for over 75%. Antiretroviral therapy (ART) is being scaled up in these countries and, by December 2007, over 40 000 patients in China, 27 000 in Cambodia, 17 000 in Viet Nam and 2300 in Papua New Guinea were receiving ART.

With the number of people receiving ART increasing, the need to minimize the emergence and transmission of HIV drug resistance (HIVDR) has become crucial. Failure to do so could lead to the need for more complicated and expensive regimens that many countries could not afford. Indeed, many of these non first-line regimens are so prohibitively expensive for resource-constrained countries that the emergence of widespread HIVDR could severely jeopardize country ART services.

To strengthen the prevention and assessment of HIVDR in Asia, the Viet Nam National Institute of Hygiene and Epidemiology, in collaboration with the United States Centers for Disease Control (CDC) Global AIDS Program (GAP), organized a technical consultation in Ha Noi, Viet Nam, in April 2006 to discuss HIVDR. Representatives from Cambodia, China, India, Indonesia, the Lao People's Democratic Republic, the Philippines, Thailand and Viet Nam developed draft country work plans for 2006-2007 and agreed to document their progress.

As a follow-up, the Ministry of Health of the People's Republic of China hosted the Technical Consultation on HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region in Beijing, China, from the 14 to 16 November 2007. The Consultation was organized jointly by WHO and the National Center for AIDS/STD Control & Prevention (NCAIDS), Chinese Center for Disease Control & Prevention (China CDC), to discuss critical actions required to minimize the emergence of HIVDR in the Asia-Pacific Region.

# Meeting participants and objectives

About 100 participants (epidemiologists, clinicians, laboratory scientists, antiretroviral therapy [ART] and HIVDR programme managers and policy-makers) from six countries and two regions (Cambodia, China, Hong Kong [China], Macau [China], Indonesia, Papua New Guinea, Thailand and Viet Nam) took part in the Consultation. They came from the organizing agencies (WHO and China CDC), government and civil society institutions (Treat Asia and Pangea AIDS Foundation). Some were members of, or had been sponsored by international agencies, such as United States CDC-GAP, Medicine San Frontiers (MSF) and the Clinton Foundation, academic institutions (Universities of Maryland [Baltimore], California [San Diego] and Hong Kong, the Pasteur Institute in Ha Noi and the National Institute of Epidemiology and Hygiene in Ho Chi Minh City in Viet Nam). Local partners who participated in the consultation included: MSF (Belgium, France and Access Campaign), United States CDC-GAP and National Institutes of Health, Family Health International, the Clinton Foundation, the Bill and Melinda Gates Foundation and the China-MSD HIV/AIDS Partnership. See Annex 2 for the list of participants.

The primary objectives of the meeting were:

- (1) to update participants on progress in the HIVDR situation in the Region and share experiences and lessons learnt since the Ha Noi HIVDR meeting;
- (2) to share WHO HIVDR strategies and methodologies;
- (3) to develop outlines for country reports for 2007 and agree upon a process for regular, sustainable reporting over the coming years;
- (4) to develop country strategies and work plans in line with the WHO recommendations for HIVDR prevention and assessment strategies, including actual and prospective partnerships; and
- (5) to consolidate regional and global linkages through the WHO HIVResNet laboratory and epidemiology networks, including establishing links between national HIVDR working groups and accredited laboratories and putting in place mechanisms for data entry, data quality assurance, data sharing and data analysis.

The Consultation was conducted over three days (see Annex 1 for Agenda). On day three, participants had the opportunity to visit one of two NCAIDS departments (Division of Care and Treatment or the Division of Virology and Immunology) or Beijing You'an Hospital. In addition, on the afternoon of day three, an optional database training session was conducted for interested participants. In the closing session, the organizers presented the conclusions and next steps agreed upon by the Consultation and closing statements were made by representatives from Treat Asia, United States CDC-GAP, National Institutes of Health-China, MSF Belgium, the WHO Western Pacific Regional Office and China CDC, as well as a participant from one of the countries.

# Update on treatment scale up and HIVDR prevention and assessment strategies

Updates by key experts on scaling up global and regional antiretroviral treatment and on WHO-recommended HIVDR prevention and assessment strategies set the stage for the Consultation. In addition, two presentations—one on lessons learnt and the implications of scaling up HIVDR for ART and another on China's national AIDS treatment framework and key work in 2007—highlighted and prompted discussion on issues such as: the availability of second-line ARVs; early versus late switching to second-line regimens due to failure of first-line therapy; and drug toxicities and programmatic implications of HIVDR for scaling up of ART.

Participants called for more data on early versus late switching and WHO informed participants that, because of the many still unanswered questions related to treatment failure, a global consultation to review the definition of and recommendations for treatment failure was scheduled for early 2008. The HIVDR experts pointed out the often overlooked fact that switching to a second-line regimen would be futile if full support for treatment could not be guaranteed.

Table 1 shows the current status of ART scaling up in participating countries and regions.

**Table 1: Current status of ART scaling up in participating countries and regions**

Country	Population (in millions)	Estimated number of persons living with HIV	Estimated number of people in need of treatment based on country reports, 2007	Estimated number of people receiving treatment, Dec 2007	Availability of a second-line ART regimen
China	1300	700 000	85 000	41 777*	Limited to pilot sites
Hong Kong (China)	7	3600	1704	1384	Readily available
Cambodia	14	61 400	29 200	27 000	Available
Viet Nam	84	290 000	49 960	17 000	Available
Papua New Guinea	6	46 000	6348	2300	Not available
Thailand	63	500 000	250 000	153 000	Available
Indonesia	224	169 000	43 000	6600	Not available

\* China's number of patients receiving ART is actual number by end of Dec 2007.

Given HIV's high mutation rate and the need for life-long treatment, the emergence of HIVDR in the Asia-Pacific Region, as elsewhere in the world, is considered to be inevitable. Countries were therefore urged to include prevention and assessment of HIVDR in their universal ART access plans if they had not already done so. The goal of the WHO HIVDR strategy is to support ART programme practices that minimize preventable HIVDR and to limit the extent to which resistance threatens the effectiveness of the ART regimens available. (See Box 1).

Participants discussed WHO protocols for HIVDR early warning indicators, surveys to monitor HIVDR prevention and associated factors in sentinel ART sites, and surveys to assess transmitted HIVDR. For countries with limited resources, WHO recommends that collection of HIVDR early warning indicators (EWI) should be prioritized. HIVDR EWI assesses the extent to which ART programmes are functioning to optimize prevention of HIVDR and can be used as the basis for preventive action. Monitoring of EWI can be coordinated with ART site quality assurance activities and data quality assurance programmes to evaluate recording of information in ART medical records.

#### **Box 1. WHO-recommended HIVDR prevention and assessment strategies**

WHO recommends that the following eight national HIVDR strategic elements should be included for all countries scaling up ART:

- (a) Development of a national HIVDR Strategy Working Group, five-year plan and budget;
- (b) regular assessment of HIVDR 'early warning' indicators from all antiretroviral treatment (ART) sites (or representative sites);
- (c) surveys to monitor HIVDR prevention and associated factors in sentinel ART sites
- (d) HIVDR transmission threshold surveys in geographical areas where ART has been widespread for >3 years;
- (e) HIVDR database development;
- (f) designation of an in-country or regional WHO-accredited HIVDR genotyping laboratory;
- (g) review of and support for HIVDR prevention activities; and
- (h) preparation of annual HIVDR reports and recommendations, and use of data for ART and prevention planning.

### **Post-Ha Noi country updates on planning and implementation of the WHO-recommended HIVDR strategy and other HIVDR-related activities**

The last three to five years have seen rapid scaling up of access to ART by people living with HIV in the Region. Countries shared experiences as regards

the planning and implementation of the WHO-recommended HIVDR strategy and other HIVDR-related activities since the Ha Noi Consultation.

Reports demonstrated that countries are at different stages in planning and implementing their HIVDR prevention and assessment strategies. Four countries (China, Cambodia, Indonesia and Viet Nam) have established national HIVDR Technical Working Groups (TWG) or similar bodies. Although Thailand has not yet formally established a working group, its Ministry of Health has developed a national HIVDR strategy and plan, including the terms of reference for such a group. All national HIVDR TWGs have a multidisciplinary membership including: clinicians, epidemiologists, laboratory scientists and data statisticians. None of the shared HIVDR TWG plans presented were budgeted. All countries are performing at least some WHO-recommended HIVDR prevention activities (See Box 2).

### **Box 2. WHO-recommended HIVDR prevention elements**

WHO-recommended HIVDR prevention elements:

- Appropriate ART prescribing practices, national prescribing guidelines and appropriate ART eligibility definitions in place.
- Support for and monitoring of adherence.
- Removal of barriers to continuous access to care.
- Resources and personnel for follow-up of ART patients.
- Ongoing quality assurance for drugs (not only initial QA).
- An adequate and continuous drug supply; monitoring at site and regional levels of drug supply shortages.
- Standard ART patient records or minimum standard data recording to facilitate ART patient and cohort monitoring.
- Prevention programmes to reduce HIV transmission from persons undergoing treatment.
- Collection of strategic information to support HIVDR prevention.

**Note:** Do not perform surveys/collect indicators if results will not lead to dissemination of information, recommendations and action!

Cambodia, China, Indonesia, Thailand and Viet Nam all initiated HIVDR assessment activities after the Ha Noi meeting. None of the countries who participated in the Ha Noi meeting have begun to collect EWIs on a regular basis, however, Thailand has piloted monitoring of selected EWIs, and China, Thailand and Viet Nam have identified ART sites at which sentinel HIVDR prevention monitoring surveys will be piloted. China, Indonesia, Thailand and Viet Nam have performed at least one threshold survey to evaluate transmitted resistance, although China's sequences have not yet gone through the WHO quality assurance check.

The following summarizes the presentations made by individual countries on their experiences with planning and implementation of the WHO-recommended HIVDR strategy, as well as other HIVDR-related activities taking place.

**Cambodia.** An HIVDR working group was established in November 2006 and has developed a protocol for an HIVDR transmission threshold survey, to be conducted at five VCT sites in Phnom Penh in 2008. A draft EWI monitoring plan has been created and piloting will occur at representative ART sites in 2008. The working group is planning to adapt the generic WHO/CDC protocol for monitoring of HIVDR emerging during treatment and to select sites for piloting of the survey. The working group will identify an appropriate accredited regional or specialized laboratory for drug-resistance testing, and will begin the mobilization of financial and technical resources to support HIVDR activities.

**China.** Work in HIVDR in China began in 2003 when four laboratories (NCAIDS, Division of Research on Virology and Immunology; China Medical University, AIDS Research Center; Chinese Academy of Military Medical Science, Military Center for Disease Control & Prevention; and Shanghai Municipal Center for Disease Control & Prevention, Department of AIDS/STD ) were nominated to serve as national HIVDR laboratories. The National HIVDR Network was established in July 2004 and, from 2004–2006, China conducted nationwide cross-sectional HIVDR surveys, provided training to provincial HIVDR laboratories, linked the national HIVDR database with the national ARV treatment database and actively communicated with WHO HIVResNet. Furthermore, in 2006, China participated in a multicountry HIVDR initiative to validate the then proposed HIVResNet accreditation criteria. The four core laboratories were assessed during that exercise.

China has been strengthening its core laboratories to provide better technical support to other laboratories in the country. Currently, there are 10 provincial laboratories that can support HIVDR genotyping and 13 locations have been chosen as sentinel ART sites for monitoring of HIVDR emerging during treatment. Drug resistance threshold surveys in three provinces have all indicated that the rate of transmitted HIVDR is still less than 5%. In addition, China shared its progress in HIVDR-related research including: ART adherence, HIVDR among MSM, phenotype assay for HIVDR and the genotype characteristics of the HIV viruses prevailing in China.

**Hong Kong (China).** Unlike other countries that made presentations, Hong Kong (China) is not a resource-limited setting. Hong Kong has not yet collaborated

with WHO in planning an HIVDR prevention and assessment strategy, but is implementing some elements of the recommended strategy and also performing research activities that are not included in the WHO recommendations. In Hong Kong, there were a total of 1385 new infections reported between 2003 and the first half of 2007, and 290 of these were selected for genotypic resistance testing. Overall drug resistance among these newly reported HIV cases was found to be between 2% and 3%, depending on the reference mutation database used. Resistance was found only to the NNRTI drug class. In addition, data were presented on a retrospective study to assess the frequency and patterns of HIVDR among patients failing ART at the Integrated Treatment Center, where 913 patients are currently on ART. The goals of the Hong Kong HIVDR Working Group include monitoring of EWIs at two pilot sites; monitoring the quality of laboratory HIVDR testing; undertaking regular threshold surveys; and determining patterns of HIVDR in treatment failure.

**Indonesia.** Indonesia shared its progress in ART scaling up. As part of the HIVDR activities in the country, IDU populations in Jakarta were selected for a threshold survey. Analysis indicated that transmitted resistance was below the threshold of 5%. Plans to collect EWIs and conduct surveys in sentinel sites to monitor the emergence of HIVDR are being prioritized for 2008.

**Thailand.** Thailand's HIVDR strategy has three components: (1) minimizing the occurrence and transmission of drug-resistant HIV through prevention programmes; (2) strengthening HIVDR surveillance and monitoring and; (3) ensuring that qualified genotypic testing and interpretation are readily available.

Thailand conducted an HIVDR transmission threshold survey in 2005 and found HIVDR prevalence to be less than 5%. It was noted that six hospitals were involved in the 2006 EWI pilot test; in the national plan for 2008–2010, 36 sentinel sites will be established. Thailand also plans to increase its laboratory capacity and is hoping to establish a WHO-accredited HIVDR genotyping laboratory. Existing data suggest that, among monitored patients receiving ART, baseline resistance is 4.6%, with HIVDR emergence rates of 1.8% at six months and 1.2% at 12 months. A threshold survey among female sex workers was integrated with existing serosurveillance efforts in 36 of 76 provinces in 2007, building on work already done in 2005 among VCT clinic attendees, seroconverted blood donors and female sex workers.



**Viet Nam.** Drug resistance work is coordinated by a national HIVDR working group that began its work in 2006. Pilot data extraction for EWIs is forecasted to begin in November-December 2007 at 16 ART sites. A national protocol for sentinel monitoring of the emergence of HIVDR during treatment is being developed from the WHO/CDC generic protocols and will be implemented in 2008 in four pilot sites with  $\geq 20$  new ART patients each month. Viet Nam conducted a threshold survey in Ha Noi in 2006 at two VCT sites. The survey demonstrated a prevalence of transmitted HIVDR of  $< 5\%$  for all drugs and drug classes. A second threshold survey at six VCT sites was initiated in October 2007 in Ho Chi Minh City. It is interesting to note that several institutions are building laboratory capacity in Viet Nam with the goal of establishing a national WHO-accredited genotyping laboratory in the near future. Additional HIVDR activities that were shared included: a study on 200 treatment-naïve patients to determine the prevalence of HIVDR mutations; an observational study on the emergence of HIVDR among HIV-positive, pregnant women following administration of ARVs for prevention of mother-to-child transmission; and two clinical studies related to treatment failure of first-line regimen.

Table 2 in the following page summarizes the progress of countries in implementing their HIVDR prevention and assessment strategies. Much work remains for all countries attending the Consultation.

**Table 2: Implementation status of the WHO-recommended HIVDR Strategy in five countries**

HIVDR strategic element	Cambodia	China	Indonesia	Thailand	Viet Nam
National HIVDR TWG and 3–5 year workplan and budget	TWG established in 2006. Workplan and budget in development.	TWG established in 2004.  2004–2006 plan completed. 2007–2008 plan ongoing – budget includes government and Global Fund monies.	TWG established in 2006.	No TWG but terms of reference and a national HIVDR strategy and plan developed.	TWG established in 2006. 2008–2012 workplan and budget to be finalized.
Regular assessment of WHO HIVDR EWIs	EWI study protocol to include 20 ART sites (10 with patient monitoring database and 10 without) developed and will collect 1-7 EWIs.	Pilot assessment to be conducted in 2008.	Not yet.	Ongoing in six hospitals. Planning to scale up to 36 in 2008-2010.	Pilot EWI data collection on five selected indicators in 16 ART sites planned.
Sentinel HIVDR prevention surveys	Sentinel monitoring protocol in development.	13 monitoring sites in 10 provinces (Anhui, Henan, Hunan, Hubei, Sichuan, Yunnan, Guangxi, Guizhou, Xinjiang, Jiangxi) identified.	Planned.	Ongoing in six sites in four provinces. 14 more sites in five provinces identified.	Sentinel monitoring protocol in development.
HIVDR transmission threshold surveys	Threshold survey protocol developed and will soon be implemented in Phnom Penh.	Threshold surveys conducted in three provinces (Hunan, Sichuan and Xinjiang).	One survey done in IDU population.	Threshold survey conducted in 2005.	Two threshold surveys conducted. One in 2006 in two VCT sites in Ha Noi and the second still ongoing in six VCT sites in HCMC.
HIVDR database development	Not yet.	Done.	Not yet.	Planned.	Not yet.
Designation of an in-country or regional WHO-accredited genotyping Lab	Not yet.	Three laboratories to be assessed in early 2008.	Not yet.	Designation of an in-country WHO-accredited genotyping laboratory planned.	Designation of an in-country WHO-accredited genotyping laboratory planned.
HIVDR prevention activities	Ongoing.	Ongoing.	Ongoing.	Ongoing.	Ongoing.
Preparation of 2007 annual HIVDR report	In progress. Awaiting the WHO template.	In progress. Awaiting the WHO template.	In progress. Awaiting the WHO template.	In progress. Awaiting the WHO template.	In progress. Awaiting the WHO template.

# HIVDR partner presentation: Treat Asia

Treat Asia, a nongovernmental organization (NGO) funded by the Dutch umbrella NGO AIDS Funds, participated in the 2006 meeting in Ha Noi, Viet Nam. Treat Asia supports the TAASER project, which operates in select Asian countries to evaluate drug resistance and build laboratory capacity. TAASER surveys are performed in private sector and academic sites. Although the surveys contain additional research elements that do not appear in WHO protocols, the TAASER protocols to monitor HIVDR prevention and emergence in sentinel ART sites, and to evaluate transmitted resistance, have been harmonized with WHO protocols. Treat Asia sites are committed to sharing relevant data with national HIVDR working groups.

As of April 2007, three rounds of laboratory proficiency assessments had been performed, with a forecasted 17 laboratories participating in the fourth round in November 2007. A total of 900 patients were enrolled in sentinel ART site surveys in 2007, a number that is planned to increase to 3000 by 2011. While only one site is currently implementing the protocol to evaluate transmitted HIVDR, an additional Centre is expected to enroll by the end of 2007, with a total of six centers and 480 patients envisioned by 2010. Treat Asia is also supporting laboratory training. Countries wishing to develop genotyping capacity in one or more national laboratories should enquire whether collaboration with Treat Asia is feasible.

# Challenges in setting up and managing patient-tracking systems

Panelists for this session included one HIVDR expert and two country participants. The Consultation noted that, when ART failure occurs and drug resistance emerges, more often than not, there are both individual and programmatic factors at play. Individual patient monitoring and ART site and programme monitoring should be coordinated and, ideally, supported by one information system.

Challenges shared and discussed included: the large numbers of patients; record systems that require unreasonably large amounts of data entry; poor data quality and collection strategies; little or no communication between providers and database managers; complicated and unstandardized patient record systems; determining an appropriate frequency for monitoring; a lack of a standardized lost-to-follow-up definition and insufficient documentation; and little or no feedback to providers from national monitoring systems. In addition, some countries sited the impracticality of having electronically collected data and language issues where data have to be translated into English.

Shared solutions that some countries have implemented include: using both electronic and paper-based systems; standardization and simplification of patient records and report forms; full-time employment of data managers and clerks; and involvement of people living with HIV/AIDS and civil society to discuss patient monitoring and programmatic challenges. Piloting of the EWI is often useful as a data quality assurance exercise, to point out difficulties in data recording at sites and insufficiencies in general ART monitoring systems.

# Update on the WHO HIVDR Laboratory Network

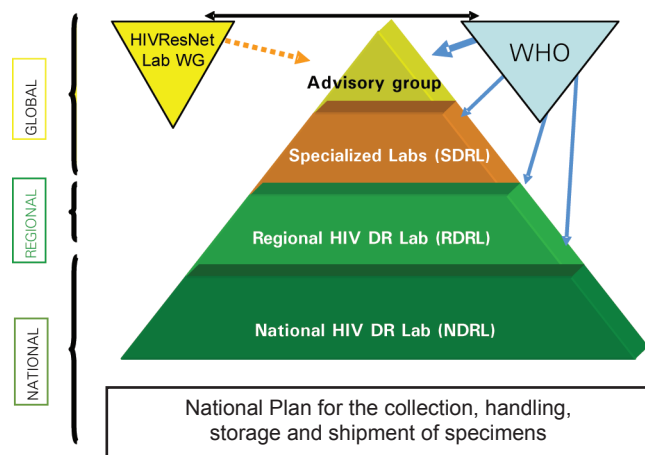
The Consultation noted that the overall goal of the Global WHO HIVDR Laboratory Network is to support national, regional and global HIVDR surveillance and monitoring by the timely provision of quality-assured genotyping results in a standardized format that meets WHO specifications. Box 3 provides the key elements of the Global WHO HIVDR Laboratory Network and Figure 1 shows the structure of the Network.

### Box 3. Key elements of the Global WHO HIVDR Laboratory Network

To promote standardization and quality in HIVDR genotyping for HIVDR surveillance and monitoring by:

- (1) guiding the laboratory component of the national HIVDR plan for collection/handling/shipment/storage of specimens for HIVDR testing;
- (2) promoting a WHO accreditation process for laboratories performing HIVDR genotyping for the purpose of HIVDR surveillance and monitoring;
- (3) establishing a network of accredited laboratories to ensure that each country adopting the WHO strategy for national surveillance and monitoring has access to a quality-assured genotyping laboratory services for this purpose; and
- (4) supporting capacity-building for laboratories applying for accreditation through guidelines, technical assistance and training (e.g. Twinning programme).

Figure 1. Structure of the WHO HIVDR Laboratory Network



In addition to the laboratory accreditation system, all sequences produced by laboratories for surveys and studies are run through quality assurance checks at WHO Headquarters and the regional offices (the Regional Offices for South-East Asia and the Western Pacific). Any queries produced by the system are resolved by an external WHO HIVResNet virologist in communication with a virologist at the laboratory. HIVDR committee members, and WHO regional and Headquarters staff also participate in the discussions.

# Update on the China HIVDR Laboratory Network

China showcased the experience gained in building its national HIVDR Laboratory Network and further elaborated, through two presentations, the Network's activities. The country has four national HIVDR laboratories designated by the Ministry of Health. Three of these (NCAIDS, Division of Research on Virology and Immunology; China Medical University, AIDS Research Center; Shanghai CDC, Department of AIDS/STD) had, at the time of the Consultation, begun the process of preparing to be assessed by the WHO/HIVResnet for accreditation. China has also developed a national HIVDR database that compiles data from all the national laboratories and designated provincial laboratories belonging to the HIVDR Laboratory Network. The database contains information on epidemiology, ART adherence, CD4 count, viral load, HIV clades and HIV genotype and phenotype, and is used to produce the HIVDR country report and provide feedback to local CDCs and hospitals. A newsletter, edited by the Chinese HIVDR Network, is widely distributed.

# Country planning and country plans

An objective of the Beijing HIVDR Technical Consultation was to support participating countries to develop and/or strengthen their national strategies and five-year plans in line with the WHO-recommended HIVDR prevention and assessment strategy. Days 1 and 2 morning and early afternoon sessions prepared participants for this work.

Boxes 3, 4 and 5 provide: (1) the WHO-recommended site selection criteria for collection of EWIs; (2) the WHO-recommended site selection criteria for sentinel monitoring of HIVDR prevention and related ART programme factors; and (3) WHO-recommended participant eligibility and site selection criteria for HIVDR transmission threshold surveys, respectively.

### **Box 3. WHO-recommended ART site selection for EWI**

Countries should monitor only those EWI for which information is readily available from data currently recorded routinely at sites. It is not necessary for countries to monitor all EWIs.

Initial pilot collection of EWI may focus on sites where EWI collection is easiest\*, but WHO recommends that some sites be included to represent challenges that will be found when the system is expanded. Plans should include expansion to a representative system following the pilot test. The representative system should include a sufficient number of sites to represent important site characteristics in the country, including geographic area, patient populations, partner support, level of technology and resources, and other factors that, in the judgment of the HIVDR working group, are likely to affect site functioning substantially.

EWI should be monitored at:

- (1) all ART sites in the country, or
- (2) representative sentinel sites: the country should formally develop a selection method for representative sites. Either a formal sampling method or the use of a grid with relevant characteristics is recommended. In either case, all sites in the country must be classified according to the relevant characteristics noted by the HIVDR working group before the selection is made.

\*Reports should discuss the limitations of unrepresentative reporting systems.



#### Box 4. WHO-recommended criteria for surveys to monitor HIVDR prevention and related factors in sentinel ART sites

- Cohorts of approximately 100–130 patients beginning ART, followed for 12 months at representative sentinel sites (may extend the survey to 24/36/48 months).
- Sites selected based on patient load, staffing ratio, resources available on-site, geographic area, other relevant issues.
- Genotyping of residual specimens at baseline and viral load + genotyping at 12 months or at regimen switch.
- HIVDR outcome measures:
  - HIVDR prevention (defined as viral load suppression)
  - HIVDR mutations evaluated if viral load is detectable.
- Factors potentially associated with outcome evaluated (previous ARV experience, baseline mutations, regimens, adherence, on-time drug pick-up, on-time appointment-keeping, site factors).
- Data abstracted at baseline and at endpoint.
- Site profile data collected on the day the survey starts and then annually on that date, and also on the day the last patient reaches his/her endpoint. The site profile data are qualitative and support interpretation of results.

#### Box 5. HIVDR threshold survey—participant eligibility, site selection criteria and result interpretation

- Participant eligibility criteria:
  - Documented positive HIV test result, aged <25 years and no previous pregnancy if female
  - If numbers are sufficient, <22 years of age
  - Or laboratory evidence of recent infection (if reliable and valid) or seroconversion
  - No previous positive HIV test\*\*
  - No known exposure to antiretroviral drugs\*\*
  - No known AIDS-defining illness\*\*
  - Not eligible to start ART\*\*
  - CD4 count >500 (where available)\*\*
  - First risk-defining event within the past three years (e.g., drug injection, STI)
- \*\*use these criteria only if routinely available
- Target site characteristics:
  - Sufficient numbers of HIV-positive persons, high percentage relatively recently infected
  - Representative of persons infected with HIV in the geographic area of interest (or a group in that area)
  - Every eligible person has an equal chance of being included (all individuals receive HIV tests)
  - Individuals diagnosed with HIV are likely to be “newly diagnosed”
  - Most newly diagnosed individuals are unlikely to be ART-experienced
  - The majority of HIV tests are **not** performed because individuals are ill with HIV-related symptoms
- Result interpretation
  - Low HIVDR prevalence <5%
  - Moderate HIVDR prevalence 5–15%
  - High HIVDR prevalence >15%

Countries had the opportunity to work on their three to five year national HIVDR prevention and assessment plans and representatives from each country presented the draft plans and discussed the potential challenges.

**Cambodia.** Of the 32 000 people living with HIV/AIDS who were eligible for ART, slightly over 25 000 were receiving treatment at the time of the Consultation. Cambodia plans to conduct a feasibility assessment for collection of EWIs at four sites, after which the number of pilot sites for 2008 will be decided. Over the next three to five years, the number of sites collecting EWIs will increase from 16 to 35. For monitoring of HIVDR emerging during treatment, two pilot sites in Phnom Penh will initiate surveys in 2008, with an additional two sites at Takeo and Battambang in 2009, and two more at Siem Reap and Kampong Thom in 2010. Five VCT clinics in Phnom Penh have been selected for the first threshold surveys in 2008. Cambodia plans to use an appropriate regional HIVDR laboratory for genotyping and the WHO database for data management.

**China.** Approximately 42 000 people living with HIV/AIDS were receiving ART at the time of the Consultation. China is planning to collect WHO-recommended EWIs at six to eight pilot sites, after which a plan for selecting appropriate sites for regular EWI collection will be developed. Surveys at six sites in the first year and eight sites in years two and three are planned to monitor HIVDR prevention at sentinel ART sites. The sentinel sites will include sites where the predominant patient populations represent the following HIV exposure categories: past history of plasma donation, injecting drug use and homosexual and heterosexual sex were each predominant modes of HIV transmission. For surveillance of HIVDR transmission, separate threshold surveys will be performed among populations with different exposure categories and among other vulnerable groups: i.e., IDU for sites in Xinjiang, Sichuan, Guangxi, and Yunnan; MSM in Beijing and Shanghai; sex workers in Guangdong and Fujian; and discordant couples among former plasma donors in Henan and Anhui.

In 2008, three of the four core laboratories of the National HIVDR Network will be assessed for possible accreditation by the WHO HIVDR Laboratory Network. In addition, the China HIVDR Network intends to improve the national HIVDR quality control panel and guidelines. All provincial HIVDR laboratories are expected to eventually participate in a national quality control programme, beginning with six to eight laboratories in 2008 and increasing to 25 to 30 by 2010.

**Hong Kong (China).** Approximately 3600 people are living with HIV/AIDS in Hong Kong. Among them, approximately 1400 individuals of the 1700 individuals eligible for ART are receiving it. Collection of EWIs will begin in one site starting in early 2008, with quarterly reporting of EWIs. The second site will begin EWI data collection in mid-2008. Threshold surveys will then be conducted in different risk populations throughout Hong Kong. There are plans for one laboratory to apply for accreditation from the WHO HIVDR Laboratory Network, and the working group will be responsible for the development and maintenance of an HIVDR database.

**Indonesia.** Planned activities by the National HIVDR Working Group will encompass the following: revision of HIVDR prevention monitoring and threshold survey protocols; collection of EWIs; regular HIVDR surveillance and monitoring; capacity-building for genotyping; support for ART adherence and other prevention activities and HIVDR research.

Since EWI collection is still in the preliminary stage, the HIVDR working group will initially select which EWIs to collect, outline pilot plans and site selection, and develop a three- to five-year implementation plan. For monitoring of HIVDR prevention, five to 10 sites will be identified and surveys will be conducted each year on a rolling three-year cycle. The threshold surveys will be conducted in Jakarta, Surabaya and Bali. A WHO-accredited regional laboratory will be used for genotyping in the interim, with plans to build in-country laboratory capacity and to achieve WHO HIVDR Laboratory Network accreditation. Indonesia is planning to improve its database management by consolidating existing data input streams into a more organized system.

**Papua New Guinea.** As of June 2007, 1647 people living with HIV were on treatment out of the 5600 people living with HIV estimated to need ART. The three overarching tasks of the HIVDR Technical Working Group will include the development and implementation of a national HIVDR prevention and assessment plan for 2008-2010, incorporating: EWIs, sentinel monitoring of HIVDR prevention and HIVDR transmission threshold surveys; the development of a memorandum of understanding with partners to assist in HIVDR national plan implementation; and the development of a plan for building national laboratory capacity for genotyping.

The current Epidemiology Information database that the ART programme is using is not user-friendly and a proposal has been put forward for the creation of a new database system. In the meantime, five EWIs will be piloted at four regional HIV care and treatment Centers. Four additional sites will then be added

in the second year to achieve coverage of more than 75% of patients currently receiving ART. Sentinel monitoring of HIVDR prevention will occur on a three-year cycle at representative sites, with a new site being added in each of the three years. Threshold surveys are planned at antenatal (ANC), VCT and STI clinics in Port Moresby. The interim plan for genotyping is to use the regionally accredited laboratory at the Burnet Institute in Melbourne, Australia, with plans to build local capacity shortly.

**Thailand.** More than 80% of the 92 000 persons eligible for ART were receiving it at the time of the Consultation. Thailand plans to collect all the WHO-recommended EWIs and to scale up collection from three provinces to 24 representative provinces. A rolling three-year cycle for the implementation of HIVDR prevention monitoring at sentinel ART sites is also planned, with three, then eight and then 24 sites planning to conduct prevention monitoring surveys in the first, second and third years, respectively. The Ministry of Health plans to nominate one laboratory for accreditation as a national HIVDR laboratory and one laboratory as a regional laboratory. A national database for genotyped mutations will be established using in-house software.

**Viet Nam.** Approximately 30% of the estimated 50 000 people eligible for ART were receiving it at the time of the Consultation. Five EWIs will be collected at 21 pilot sites (17 adult and four paediatric sites) around the country in late 2007. EWI collection will then be expanded to 30 sites by 2008, 40 by 2009 and 50 by 2010. A national protocol for surveys to monitor HIVDR prevention at sentinel ART sites is being developed and the four sites for the 2008 pilot have already been selected, with future plans for surveys in six sites by 2009 and 10 sites in 2010. A second threshold survey began in October 2007 at six VCT sites in Ho Chi Minh City, with plans for further surveys in Ha Noi, Hai Phong, and Quang Ning in 2008 and Ho Chi Minh City and An Giang in 2010. Viet Nam hopes that the National Institute of Hygiene and Epidemiology and/or the Pasteur Institute in HCMC will be accredited by the WHO HIVDR Laboratory Network to provide laboratory genotyping support to HIVDR efforts.

# Conclusions and next steps

The Beijing Technical Consultation on HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region provided a forum for countries to share their experiences in scaling up ART and in HIVDR prevention and assessment activities. HIVDR experts provided updates on planning and implementation of HIVDR activities globally and in the Region. Countries recognize the importance of including HIVDR prevention and assessment activities in their plans for scaling up of HIV ART.

During the development of draft national HIVDR prevention and assessment plans, countries were encouraged to develop national strategies that include establishment of an HIVDR technical working group and development of a three- to five-year budget and workplan. Key conclusions from the technical presentations and discussions included the following:

- HIVDR prevention and assessment strategies, as well as ART pharmacovigilance, are critical elements in supporting public health scaling up of ART.
- For countries with limited resources available for HIVDR activities, it is recommended that monitoring of EWI should be prioritized, since the EWI will support earlier action to prevent HIVDR than genotyping surveys, and will also provide more information to guide action. EWI monitoring can also be used for ART programme quality assurance and improvement.
- In developing EWIs, it is important that countries focus on simplicity, ideally by collecting those indicators readily available through existing patient and pharmacy record systems.
- For ART site surveys to monitor HIVDR prevention and for threshold surveys to evaluate HIVDR transmission, it is important to recognize the various methodological restrictions in terms of eligibility criteria, site selection and data analysis.
- Countries are encouraged to build national laboratory capacity for genotyping only if more important laboratory priorities, such as providing HIV tests and CD4

counts for all adults and children requiring them, have already been addressed. Regional or specialized laboratories can provide quality-assured genotyping for surveillance and monitoring if capacity-building for genotyping is not prioritized, or if it is ongoing but accreditation has not yet been achieved.

- Currently, genotyping is not recommended for individual patient management in resource-limited settings.

The following next steps were agreed upon:

- Dissemination of the report of the Beijing Technical Consultation on HIV Drug Resistance Prevention, Surveillance and Monitoring in the Western Pacific Region.
- Distribution of templates designed by WHO Headquarters for the 2007 country reports.
- Publication of country and regional HIVDR reports for 2007.
- Discussion and finalization of country work plans with national HIVDR Technical Working Groups and with the WHO Western Pacific Regional Office to aid development of a regional HIVDR plan.
- Establishment of operational linkages with accredited laboratories in the Region. At the time of the Consultation, the only accredited regional laboratory in the Western Pacific Region was the Burnet Institute, Melbourne, Australia.
- Submission of requests for further accreditation of laboratories through the WHO Western Pacific Regional Office.
- Provision of technical support from WHO country offices, the WHO Western Pacific Regional Office and WHO Headquarters to assist in the implementation of country plans.
- Enhancement of partnerships within the HIVResNet to support country plan implementation and resource mobilization.
- Expansion of HIVDR networks to additional countries in the Western Pacific Region.
- Planning for a joint WHO Western Pacific Region/South-East Asia Region HIVDR technical consultation, to be held early in 2009.

# Technical Consultation Agenda

## Day 1: Wednesday, 14 November 2007

08:00 – 08:30	Registration	
<b>Opening Session</b>		
08:30 – 09:00	Opening remarks	
	<ul style="list-style-type: none"> <li>• Ministry of Health</li> <li>• WHO Representative, China</li> <li>• China CDC</li> </ul>	Dr Yang Hao Dr Cristobal Tunon Dr Xiaoping Dong Dr Ning Wang
	Purpose, objectives, and overview of conference agenda	Dr Connie Osborne
<b>Session 1: Update on treatment scale-up and HIVDR treatment and assessment strategies</b>		
09:00 – 09:45	Presentations (15' each)	
	<ul style="list-style-type: none"> <li>• Global and regional ART scale-up: A public health approach</li> <li>• China national AIDS treatment framework and key work in 2007</li> <li>• Implications of HIVDR for ART scale-up: Lessons learned</li> </ul>	Dr Charles Gilks Dr Fujie Zhang Dr Bruce Gilliam
09:45 – 10:15	The WHO HIVDR strategy: Country and regional approaches	Dr Donald Sutherland
10:15 – 10:30	COFFEE – TEA BREAK	
<b>Session 2a: Post Ha Noi country updates on planning and implementation of the WHO HIVDR strategy and other HIVDR activities</b>		
10:40 – 12:00	Country presentations (25 ' each)	
	<ul style="list-style-type: none"> <li>• China</li> <li>• Cambodia</li> <li>• Viet Nam</li> </ul>	Dr Yiming Shao Dr Saphonn Vonthanak Dr Van Kinh Nguyen
	Questions and answers (5' each )	
12:00 – 13:30	LUNCH	
13:30 – 14:20	Country presentations continued (25 ' each)	
	<ul style="list-style-type: none"> <li>• Thailand</li> <li>• Indonesia</li> </ul>	Dr Tanarak Plipat & Dr Kunjanakorn Phokhasawad Dr Dyah Mustikawati
<b>Session 2b: Partner experiences with HIVDR studies</b>		
14:20 – 14:45	TREAT Asia: Studies to evaluate resistance	Mr Jeffery Smith
14:45 – 15:10	HIV Testing on Hong Kong SAR HIV-1 drug resistance in HIV-infected treatment experienced patients, Hong Kong	Dr Wilina Lim Dr Fernando Bogнар
15:10 – 15:30	COFFEE – TEA BREAK	

### **Session 3: Challenges in setting-up and managing patient tracking systems: A panel discussion**

15:30 – 17:30	Pre-panel discussion presentations <ul style="list-style-type: none"><li>• ART patient and program monitoring</li><li>• Challenges in setting-up and managing patient tracking systems in Thailand</li><li>• China pediatric HIV/AIDS treatment and resistance pilot</li></ul> Panel discussion	Dr Diane Bennett Dr Achara Teeratakul  Dr Yan Zhao
17:30 – 18:00	Secretariat Meeting	
18:00	BANQUET	

### **Day 2: Thursday, 15 November 2007**

08:15 – 08:30	Summary and conclusions from Day 1	Katharine Poundstone
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#### **Session 4: Updates on WHO HIVDR networks and activities**

08:30 – 09:00	Introduction to the WHO HIVDR global laboratory network	Dr Charles Gilks
09:30 – 9:30	The experience of building China's national HIVDR network	Dr Ping Zhong
09:30 – 10:00	Discussion	
10:00 – 10:30	COFFEE – TEA BREAK	
10:30 – 11:10	WHO recommendations for HIVDR monitoring and surveillance	Dr Diane Bennett
11:10 – 11:30	China's experiences: <ul style="list-style-type: none"><li>• Development of Chinese national plan for HIVDR early warning indicators</li><li>• HIVDR threshold surveys in China</li></ul>	Dr Yuhua Ruan Dr Jue Li
11:30 – 12:00	Discussion	
12:00 – 13:15	LUNCH	

#### **Session 5: Country planning and country presentations**

13:15 – 15:30	Country planning and country reporting elements <ul style="list-style-type: none"><li>• Country planning and annual reporting elements</li><li>• How the balance and prioritize resources for country-level HIVDR activities</li></ul> Country planning group work	Dr Masaya Kato Dr Zeenat Patel
15:30 – 15:45	COFFEE – TEA BREAK	
15:45 – 17:30	Country presentations <ul style="list-style-type: none"><li>• Papua New Guinea</li><li>• Indonesia</li><li>• Hong Kong</li><li>• Thailand</li><li>• Cambodia</li></ul>	
17:30 – 18:00	Secretariat Meeting	
18:00	BANQUET	



### Day 3: Friday, 16 November 2007

#### Session 6: Country planning and country presentations continued

08:30 – 09:30	Country presentations continued <ul style="list-style-type: none"><li>• Viet Nam</li><li>• China</li></ul> Panel discussion on issues emerging from developing country plans and reports	
09:30 – 10:00	Summary of technical consultation	Dr Massimo Ghidinelli
10:00 – 10:30	Closing remarks <ul style="list-style-type: none"><li>• TREAT Asia</li><li>• US CDC GAP</li><li>• US National Institutes of Health</li><li>• Participant Representative (from MSF-Belgium)</li><li>• WHO WPRO</li><li>• China CDC</li></ul>	Mr Jeffery Smith Dr Carol Ciesielski Dr Ray Chen Dr Philip Tavernier  Dr Massimo Ghidinelli Dr Yiming Shao
10:30 – 10:45	COFFEE – TEA BREAK	
10:45 – 12:00	Field visit: <ul style="list-style-type: none"><li>• You'an hospital for patient care and hospital lab</li><li>• China CDC HIVDR national lab</li><li>• China CDC patient tracking system</li></ul>	
12:30 – 14:00	LUNCH	
14:00 – 17:30	Satellite database training meeting <ul style="list-style-type: none"><li>• Database applications for surveillance and monitoring of HIVDR: Focus on threshold survey analyses</li><li>• HIV sequence quality assessment tool</li><li>• Mutation lists and interpretation of sequence results</li><li>• WHO global HIVDR strategy: Data management and informatics</li></ul>	Dr Diane Bennett

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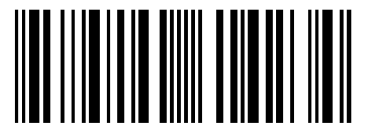
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### **Conflict of Interest Disclosure Information**

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