Regional Workshop on Recording and Reporting of Drug-Resistant Tuberculosis in the Western Pacific

24–26 November 2010
Manila, Philippines
REPORT

REGIONAL WORKSHOP ON RECORDING AND REPORTING OF DRUG-RESISTANT TUBERCULOSIS IN THE WESTERN PACIFIC

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NOTE

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Key words: Tuberculosis, Multidrug-resistant - prevention and control / Western Pacific
The new STOP TB strategy identifies management of drug-resistant tuberculosis as an important element of effective tuberculosis control in the world. In May 2009, the Sixty-second World Health Assembly (WHA) adopted resolution WHA62.15, which urged Member States to strengthen "health information and surveillance systems to ensure detection and monitoring of multidrug-resistant and extensively drug-resistant tuberculosis and monitor achievement in its prevention and control". Improved information allows managers to monitor programme performance and trends in cases notified, plan drug supply and develop programmes and policy. It also helps clinical providers with the management of individual patients.

It was therefore planned to hold a workshop to train key health workers involved in the monitoring and evaluation of drug-resistant tuberculosis (TB) in countries with a high burden of multidrug-resistant (MDR) TB as well as other countries treating substantial numbers of MDR-TB patients. This three-day workshop was focused on the methodology of recording and reporting (R&R) of MDR-TB patients on treatment, and on the use of data for analysis to strengthen programme management. Of particular importance are:

1. drug-resistant TB registration has additional data requirements to the basic directly observed treatment, short-course (DOTS) information system;
2. accurate record-keeping is crucial both for patient care and for surveillance; and
3. standardized monitoring of treatment outcomes both at national and regional levels will help with understanding the impact of drug-resistant TB control interventions and identify problems.

The objectives of the workshop were:

1. to improve information on TB control in Member States through strengthened national capacity in surveillance, registration, monitoring and evaluation of drug-resistant tuberculosis cases;
2. to understand the need for standardized patient registration and case definitions as well as the importance of cohort analysis of registered MDR-TB patients on treatment and their outcomes; and
3. to understand the importance of case evaluation for improved patient management.

About 20 participants from 12 countries in the Western Pacific Region attended the workshop. Most countries were represented by a senior National TB Programme (NTP) managerial staff and one person dealing with registration of multidrug- and extensively drug-resistant (M/XDR) TB patients. The agenda consisted of four sessions: (1) Introduction to the rationale of MDR surveillance and recording and reporting; (2) Parameters for standardized recording and reporting; (3) Electronic solutions for recording and reporting; and (4) Increasing capacity in analysis and planning. The sessions included formal lectures, directed reading and hands-on practical sessions with group discussions and demonstrations including software. Participants presented posters according to a template sent out before the workshop.
The main conclusions of the workshop were as follows:

(1) The routine recording and reporting system for the basic TB programmes (e.g. DOTS) is well-established in the Region; however, many countries face challenges in maintaining the good quality, in monitoring trends, and in identifying and monitoring groups defined as MDR suspects who should have drug-susceptibility testing (DST).

(2) The routine recording and reporting system for MDR-TB is clearly defined in WHO guidelines, but its implementation is still weak in many countries in the Region. It is difficult to assess trends in the MDR situation, e.g. incidence and burden of MDR-TB, since data on MDR cases by category are incomplete. In the absence of well-functioning surveillance systems, periodic surveys have provided key information, but the overall picture remains incomplete.

(3) NTPs lack data on coverage of culture and DST in MDR suspects, partly because groups that are considered to be MDR suspects and have DST are not yet well-defined, and because the routine R&R system does not include all relevant groups such as so-called chronics and early failures.

(4) The number of reported MDR cases is often incomplete because laboratories usually do not register category of patients. Often there is no direct link between laboratories and the TB programme, which manages the MDR registry. Also, different dates are used for the registration of cases.

(5) The Green Light Committee (GLC) has approved treatment for a considerable number of MDR cases in the Region, but so far, only a minority of cases have been enrolled. The number of cases, however, has been rapidly increasing. There is a lack of solid data on MDR treatment coverage and delay, inside and outside the GLC mechanism.

(6) NTP data on MDR treatment outcome are incomplete in most countries. This information is especially needed to monitor levels of defaults, deaths and failures in a timely way, so that the strategy can be modified when needed (e.g. social support, regimens);

(7) Supply of second-line drugs is affected by lack of reliable data on current MDR cases and reasonable projections, which are based on reported cases and not on estimates. The new drug procurement system promoted by the Global Drug Facility (GDF) is based on quarterly routine data from the TB programmes, and should coincide with strengthening of the R&R system.

(8) The R&R system for MDR-TB is paper-based in five countries and computerized with data linkage over the web in the Philippines and the four Pacific Islands. These paper-based systems may work well as long as the number of patients is limited. Computerized systems, however, may prove to be very useful especially for tabulation and analysis.

(9) The two main computer systems for MDR-TB presented, OpenMRS and e-TB Manager, are extensive electronic medical record systems, which, according to the WHO guidelines and list of indicators, contain more information than the minimum required.
The recommendations of the workshop were as follows:

(1) In line with recommendations from the Workshop on Surveillance and Impact Monitoring in Ho Chi Minh City, Viet Nam, June 2010, NTPs should ensure a well-functioning R&R system for basic TB programmes (e.g. DOTS) through training, regular supervision and use of data for analysis and management at all levels.

(2) NTPs should ensure a well-functioning R&R system for MDR-TB as an extension of the basic R&R system in line with WHO recommendations. Budgeting for programmatic management of drug-resistant TB (PMDRTB) should include proper R&R, through training and supervision. NTPs should use data for analysis at all levels as part of routine supervision visits, to stimulate better quality.

(3) NTPs should monitor closely the coverage of culture and DST in MDR suspects through a strengthened basic R&R system, and special collection of data on chronics and early failures using MDR suspects, laboratory and district TB registers.

(4) NTPs should strengthen the use of MDR registers and keep updated links with laboratory registers to ensure completeness.

(5) NTPs should take advantage of the new GDF system for improved drug procurement of first- and second-line drugs, as an integrated part of NTP routine quarterly R&R data.

(6) NTPs should take maximum advantage of computerized systems for R&R. Challenges that need to be considered include high cost and high demand of technical competence and back-up. Countries with established computerized systems for normal TB may add on an integrated MDR component in the same system. The countries without a computerized system may develop their own based on local competence or use of one of the already developed electronic medical record systems such as OpenMRS or e-TB Manager. It is important to keep systems simple and compliant with the WHO requirements for reporting.

(7) Technical assistance needs to be provided for country staff to: (1) ensure good data quality in the R&R system; (2) tabulate, analyse and manage data; and (3) introduce feasible options for electronic systems.
1. INTRODUCTION

The new STOP TB strategy identifies management of drug-resistant tuberculosis as an important element of effective tuberculosis control in the world. In May 2009, the Sixty-second World Health Assembly (WHA) adopted resolution WHA62.15, which urged Member States to strengthen "health information and surveillance systems to ensure detection and monitoring of multidrug-resistant and extensively drug-resistant tuberculosis and monitor achievement in its prevention and control". Improved information allows managers to monitor programme performance and trends in cases notified, plan drug supply and develop programmes and policy. It also helps clinical providers with the management of individual patients.

It was therefore planned to hold a workshop to train key health workers involved in the monitoring and evaluation of drug-resistant TB in countries with a high burden of multidrug-resistant (MDR) TB as well as other countries treating substantial numbers of MDR-TB patients. This three-day workshop was focused on the methodology of recording and reporting (R&R) of MDR-TB patients on treatment, and on the use of data for analysis to strengthen programme management. Of particular importance are:

1. drug-resistant TB registration has more data requirements than the basic directly observed treatment, short-course (DOTS) information system;
2. accurate record-keeping is crucial both for patient care and for surveillance; and
3. standardized monitoring of treatment outcomes at both national and regional levels will help with understanding the impact of drug-resistant TB control interventions and identifying problems.

1.1 Objectives

1. To improve information on TB control in Member States through strengthened national capacity in surveillance, registration, monitoring and evaluation of drug-resistant tuberculosis cases.

2. To understand the need for standardized patient registration and case definitions as well as the importance of cohort analysis of registered MDR-TB patients on treatment and their outcomes.

3. To understand the importance of case evaluation for improved patient management.

1.2 Resource persons

The Stop TB Unit of the WHO Western Pacific Regional Office planned and conducted the workshop in close coordination with the Stop TB Department, WHO Headquarters.

Eight facilitators made presentations and supervised the practical sessions. They included three temporary advisers who were invited to present computer systems used to manage MDR-TB, and a consultant to provide support to the workshop.
1.3 Participants

About 20 participants from 12 countries in the Western Pacific Region attended the workshop. Most countries were represented by a senior National TB Programme (NTP) manager and one person dealing with the registration of multidrug- and extensively drug-resistant (M/XDR) TB patients. Seven national programme officers and medical officers based in five country offices also participated. The full list of participants is in Annex 1.

1.4 Agenda

The agenda consisted of four sessions: (1) Introduction to the rationale of MDR surveillance and recording and reporting; (2) Parameters for standardized recording and reporting; (3) Electronic solutions for recording and reporting; and (4) Increasing capacity in analysis and planning.

The sessions included formal lectures, directed reading and hands-on practical sessions with group discussions and demonstrations (including software). Participants also presented posters according to a template sent out before the workshop. For more details see Annex 2 (agenda and timetable).

2. PROCEEDINGS

2.1 Surveillance of MDR-TB: Global and regional situation (Agenda item 3)

Dr Dennis Falzon, WHO Headquarters, presented surveillance data on the M/XDR-TB situation, in line with the 2010 global report on surveillance and response. Although the amount of surveillance data has increased, 40% of countries globally have no data. More than half of the countries in the Region (14/27) have data on first-line drug susceptibility testing (DST). Few MDR-TB cases have been notified in the Region through routine continuous TB surveillance. WHO has developed estimates for the number of MDR cases among new and previously treated TB cases in each country in 2009. While 122 212 MDR cases were estimated, only 1993 were reported (1.6%).

Modern diagnostics are promoted through Expanding Access to New Diagnostics for TB (EXPAND-TB). Many countries report MDR treatment outcome, but with modest success rates and high numbers of deaths. The high cost of second-line drugs is a major limitation for the countries. The Global Plan to Stop TB 2011–2015 has as its goal to reduce the incidence of MDR-TB. By 2015 all re-treatment cases and 20% of new TB cases should have drug resistance testing as MDR suspects, and all those diagnosed should be started on treatment. WHO Headquarters collects annual drug-resistant TB data through the WHO Global TB data collection system.

2.2 Why monitor drug-resistant tuberculosis, aim of R&R, indicators, strategies for detection of MDR-TB (Agenda item 4)

Dr Einar Heldal announced that the aim of the R&R system was (1) to allow TB managers at different levels to monitor programme performance, follow trends in number of cases notified, plan drug supply and provide the basis for programme and policy development, and (2) to aid clinical providers in the management of individual patients.
In recent years, a few countries have documented a decline in MDR from high levels, such as Latvia and Estonia in the Baltic region. The main reason seemed to be a decline in the number of re-treatment cases, while the proportion of MDR in new cases did not clearly decline. One main approach to control MDR is to strengthen the basic DOTS programme to prevent the creation and transmission of MDR in the first place.

Each TB programme needs to define clearly the groups of patients that should have DST done as MDR suspects. In most countries, the groups include all re-treatment cases and a few new cases such as close contacts of confirmed MDR cases.

The routine R&R system for DOTS provides the number of re-treatment cases, although the quality of data may be low. Two groups of MDR suspects are not reported in the DOTS R&R system, namely: (1) "chronics" or "backlog" cases who have failed re-treatment in the past; and (2) early failures, i.e. cases with positive smear after three to four months of treatment. So far, hardly any data are available on the proportion of re-treatment cases with DST result, and reported MDR cases are very few. NTPs at all levels should use the R&R system more actively for programme management to motivate better quality. However, in some settings, defining targets and use of incentives have affected the quality of data (political reporting). Real data are needed to detect low-performing areas so that improvements can be made.

2.3 On anti-TB drug-resistance surveillance and drug-resistance surveys, followed by group work (Agenda items 5 and 6)

Dr Falzon described the background and prerequisites for anti-tuberculosis drug-resistance surveillance and surveys. Minimum requirements are regular surveys among new cases and continuous surveillance among previously treated cases. DST should include rifampicin and isoniazid, and, in case of rifampicin resistance, should also include fluoroquinolone, second-line injectable and ethambutol. The need to clearly separate new and previously treated cases was emphasized, including assurance of laboratory quality. Focus should be on smear-positive cases, but new tests will change this to focus on all cases. Ethical issues must be addressed to ensure that adequate treatment is made available to all drug-resistant cases detected.

The planning and implementation of drug-resistance surveys were described in detail. Routine surveillance data have been grouped into class A and B depending on culture and DST coverage. EXPAND-TB provides an opportunity to collect laboratory DST information and then report it to NTP more efficiently. The laboratory information management system needs strengthening. Data and information management is not given priority, services are specimen-focused and new diagnostics may change surveillance methods. There is a critical need to integrate laboratory, clinical, and population health programme information systems.

In the first group work session, participants discussed plans to set up routine surveillance or nationwide surveys, and learnt how to write a drug-resistance survey protocol.

2.4 Regional activities of the Eli Lilly Foundation (Agenda item 7)

Ms Sunita Prasad, Eli Lilly Foundation, India, presented The Eli Lilly MDR-TB Partnership, which addresses TB burden in some of the hardest-hit countries, including China, India, the Russian Federation and South Africa. The programme reaches 80 countries on five continents. The Eli Lilly Foundation has organized health professionals, businesses, academic institutions and communities in a comprehensive US$ 135 million MDR-TB programme. Activities include health care professional training; community support with the International Federation of Red Cross (IFRC) and Red Crescent Societies; country support and technical assistance with WHO, the Centers for Disease Control and Prevention (CDC) and Stop TB
Partnership and Workplace programmes; communications and advocacy; transfer of technology; and research and development.

2.5 Definitions for case registration and treatment (Agenda item 8)

Dr Heldal presented definitions for case registration and treatment according to the *WHO guidelines for the programmatic management of drug-resistant tuberculosis* (emergency update, 2008) in chapter 4 (i.e. definitions of case registration, bacteriology and treatment outcomes). He followed that with a presentation of chapter 18 (i.e. content of the recording and reporting system) and the forms. A revision of the guidelines will be finalized in early 2011.

Definitions of drug resistance, category IV, empiric treatment and conversion were also discussed. According to Dr Heldal, MDR registration groups are separated according to previous use of first- and second-line drugs to stratify analysis of treatment result. They are separated by result of previous treatment (very similar to the DOTS R&R system) in order to assess trends in case finding and to assess the coverage of DST in risk groups for MDR-TB. Definitions of cohort analysis of treatment outcome were discussed.

Some key definitions are causing confusion. For example, identifying an MDR case can be difficult since the MDR treatment regimen may be changed one or more times because of later information of DST. It is not quite clear when changes are so substantial that they should be considered when starting a new treatment period and the MDR patients should be registered again. This is related to the definition of failure of MDR treatment, which does not specify when to declare failure, i.e. after how many months on ineffective treatment. Some projects may consider several treatment periods in a row as one treatment, causing one treatment to last much more than two years. "Chronics" or "backlog" patients (mainly patients who failed category II treatment in the past) are an important group of MDR suspects, but they are not included in the DOTS R&R system. Therefore incidence and prevalence of MDR-TB are often not clearly distinguished. XDR in case finding and treatment outcome are still not included in WHO guidelines.

2.6 Presentation of Chapter 18 and forms, followed by group work (Agenda items 9 and 10)

Dr Heldal presented the following MDR forms, registers and reports: sputum request form (including culture and DST), laboratory register for culture and DST, MDR treatment card and MDR register. For clarity of data, it is important to use dates correctly. Date of TB register (when entered in the TB register) should be used for assessing the size of MDR risk groups, coverage of culture and DST, and proportion of cases with MDR. Date of MDR register (when entered in the MDR register) is used to assess MDR case finding. Date of MDR diagnosis is when the result of DST showing MDR is available. Date of MDR treatment start is used for cohort analysis of treatment result. The *Guidelines for the surveillance of drug resistance in tuberculosis* (2009) contains other key standard tables with resistance patterns in patients (pages 77-78).

The MDR register allows quick assessment of MDR management in the unit. It facilitates comparison with the laboratory register to ensure completeness when updated with outcome and sm/cu controls allow intermediate assessment. All MDR cases (including those who started treatment on suspicion) are entered by date of registration, but analysis of treatment is easier if a computerized system is used to sort MDR cases by date of treatment start.

The R&R system should be kept simple by requesting and recording only data that are absolutely needed – R&R is not research! It is necessary to train staff, to provide supervisory support, to conduct visits regularly (not only for R&R), and to maintain telephone contact.
As seen from the incomplete data in the 2010 M/XDR surveillance report, most countries have had difficulties implementing the MDR-TB R&R system fully.

There is underreporting of confirmed MDR cases and limited data on treatment outcome. Accurate counting of MDR cases requires both DST of acceptable quality and a DOTS R&R system providing correct numbers of MDR suspects in defined risk groups.

In the second group work sessions, participants discussed problems/bottlenecks in implementing the R&R system in each country and suggested interventions for strengthening, and specified at which levels the different forms and registers would be used.

2.7 Forecasting system for improved procurement (Agenda item 14)

Mr Thierry Cordier-Lasalle from the Global Development Fund (GDF) described challenges in forecasting, planning and rapid response for supply of second-line drugs. Lack of real-time forecast data affects manufacturers’ willingness to produce second-line drugs, thus, increasing prices and limiting the supply of quality assured products. The current stockpile is not sufficient for all emergencies. The Green Light Committee (GLC) / TB Monitoring and Evaluation (TME) annual survey does not enable rapid adjustment of plans and corrective-preventive actions. National TB Programmes’ enrolments do not follow the Global Fund and UNITAID plan, which may lead to funding gap and bottlenecks. There was discrepancy between data and issues of data quality.

GDF was therefore starting up a new forecasting system for first-line drugs and MDR-TB procurement. It requires countries to provide quarterly data on enrolments (number of patients by regimen, number of patients on treatment per regimen, and weight bands distribution) and diagnostics (number TB cultures, first- and second-line DSTs, line probe assays (LPAs), first-line drug and MDR patients diagnosed) and a quarterly report including drug/diagnostics forecasts, funding, stock levels and shelf-life. GDF is planning to start pilots soon in selected countries.

2.8 Reporting of MDR-TB cases: Presentation of standard tools for deriving MDR-TB indicators, followed by group work (Agenda items 15, 16 and 17)

Dr Falzon presented data and information systems, individualized and aggregated, paper-based and computerized. A system that uses individualized data offers more detailed information, can streamline and improve accuracy, and allows more in-depth analyses. The disadvantages of such a system are that it is labour-intensive and raises concerns on confidentiality. The reasons for using computerized systems are such that it facilitates checks and controls, data storage and transmission, management of patients and drugs, surveillance and monitoring (reports), and statistical analysis. Challenges include cost, reliability, changing landscape and the process of communications.

All countries had completed a questionnaire on the situation of R&R in their countries. Five countries rely on paper systems, while only the four Pacific island countries and the Philippines use computerized systems with data linkage over the Web. Eight countries proposed to revise their data management systems; four of them have allocations from the Global Fund and other sources will be mobilized to reinforce R&R for drug-resistant TB.

Dr Falzon then presented the recent WHO publication, *MDR-TB indicators: a minimal set of indicators for the programmatic management of MDR-TB in national TB control programmes* (2010), which uses the same definitions, registers or treatment cards as the guidelines, but
focuses on indicators and templates rather than forms. The four areas are detection, enrolment, interim result and final outcome.

The indicators include the number and proportion of MDR suspects with DST result of isoniazid and rifampicin, and the proportion of MDR cases tested for fluoroquinolones and second-line injectible drugs. Changes introduced in the indicator publication include: separate stratifications for risk categories, children, females and HIV-positive individuals (+/- antiretrovirals (ART)), no stratification of outcome by prior treatment history, separate outcomes for XDR and HIV-positive individuals where indicated, intervals (delays) in diagnosis and in start of treatment, detection and enrolment reported every six months instead of every three months, ratio of enrolled patients to identified MDR cases, and outcomes including cases started on treatment for M/XDR-TB incorrectly.

Exercise III focussed on the MDR-TB indicators, specifically, on detection and enrolment, interim results and final outcomes.

2.9 OpenMRS (Agenda item 18)

Dr Hamish Fraser from Partners in Health (PIH) presented OpenMRS (medical record system). Core functions include: clinical care and quality improvement, monitoring and reporting, and drug supply management. A general purpose medical record system architecture is required. Local users can create forms and reports. It is web-based but can also be run on a local computer. There are open standards for data exchange and integration with other systems. It is not limited to one disease. It is fully open source and is supported by a community of programmers.

Countries that have OpenMRS sites include: Pakistan (see next agenda item), Haiti (PIH), Rwanda (PIH, Global Fund, Government of Rwanda, WHO), Botswana (NTP and University of Pennsylvania), and Nepal (WHO/IRD in progress).

Standard OpenMRS software is free and a basic package with WHO forms and reports can be installed quickly. However, countries nearly always want to customize the system, and modifications with new forms, reports and custom workflow are expected. Programmer time is the main cost as well as training.

Challenges for OpenMRS include reliability and support for equipment, power supplies and software, data management and quality control, training, evaluation and sustainability.

2.10 OpenXdata (Agenda item 19)

Mr Aamir Khan from the Indus Hospital Research Center, Karachi Pakistan (current chair of MDR working group of Stop TB Partnership), Interactive Research Development, presented innovations using mobile phones for DOT and community-based management of MDR-TB, including interoperability with OpenMRS MDR-TB module. Others collaborating on mobile OpenMRS include the University of Makarere (Uganda) and the University of Bergen (Norway).

Mr Khan described the use of mobile OpenMRS by Indus Hospital MDR-TB Control Programme in Karachi, Pakistan, which began DOTS and programmatic management of drug-resistant TB (PMDRTB) in November 2007, approved by GLC in November 2008. The hospital was chosen as an NTP pilot site for Round 6, Global Fund (100 patients) from June 2010 and a subrecipient for Round 9, Global Fund from December 2010.
Mobile OpenMRS is also using OpenMRS to manage MDR patients. Mobile OpenMRS was developed in-house as a mobile phone-based application that uploads DOT data directly into an electronic medical record. Health staff are using mobile phones to enter patient data during field visits, including DOT data. The system is improving patient care and enhancing operations. A mobile DOT form is currently being piloted. Proposed work includes: enhance mobile DOT form and given ability to collect real-time programmatic data; and build reporting and management tools (e.g. clinician alerts, operational flags). There is also a Geographic Information System (GIS) Data Visualization showing the localization of health facilities and individual patients.

2.11 e-TB Manager, followed by group work (Agenda items 20 and 21)

Dr Nerizza Muñes, representative of Management Sciences for Health in the Philippines, presented e-TB Manager: a comprehensive web-based tool for strengthening TB programmes by integrating case notification and management, medicine supply and stock control and epidemiological surveillance/reports information into a single platform.

The case module allows real-time case management and information-sharing. Key functionalities include: (1) case management tool, (2) search tool that allows patient monitoring and avoids entry duplication, and (3) validation tool that checks data consistency before recording on database. The medicine module allows first- and second-line medicines management. Key functionalities include: (1) medicine management tool, and (2) forecasting tool that estimates future stock levels, consumption levels and procurement needs. Key functionalities of the management module, which provides the information required for timely interventions, include: (1) comprehensive reporting tool, (2) data extraction tool that exports the system’s database to MS Excel, and (3) other statistical tools.

The e-TB Manager has been adopted as national TB surveillance management information system (MIS) for drug-resistant TB in Brazil. The drug management module has been integrated with the national drug-resistant TB MIS in Romania and in the Republic of Moldova. Final field-testing has been done for the advanced version in English for the Philippines (drug-resistant TB) and in Ukraine. Implementation has been initiated in the Dominican Republic, in Indonesia (in cooperation with KNCV) and the Caucasus region. In Asia, there are plans to start using e-TB Manager in Viet Nam and Bangladesh in cooperation with WHO.

System implementation in a new country usually requires one to two years depending on counterparts’ preparedness and inputs.

New upcoming developments include a desktop version for countries with low Internet coverage, automatic e-mail alerts (in case of low stock of medicines to launch a new order, make a new appointment for case follow-up or realize a new exam), link with GIS, use of Short Message Service (SMS) or text messages for rapid data exchange, and enhanced laboratory module.

Practical work in using key system functionalities of OpenMRS MDR Module and e-TB Manager was carried out in agenda items 21 and 25.

2.12 Principles of laboratory information system (Agenda Item 22)

Dr Hamish Fraser presented general information on the electronic laboratory information system (LIMS). An LIMS is the goal of larger laboratories, especially those with automated analysers. Open source systems include: (1) OpenElis (Viet Nam, Haiti, Cote d’Ivoire), (2) E-Chasqui (Peru), and (3) OpenMRS-TB (Haiti, Rwanda, Pakistan, others). The system is
free but costs are incurred from: customizations, hardware and system software, and human resources needed to support the customized system.

TB laboratory reporting systems include personal digital assistant (PDA) data management: collecting laboratory data in sites without Internet, palm project, E-Chasqui laboratory reporting system, and potential components of integrated national eHealth architecture in Rwanda.

2.13 EpiAnywhere (Agenda Item 25)

Dr Maylee Ekiek, Federated States of Micronesia, presented EpiAnywhere, an electronic solution supported by CDC and used in some Pacific island countries. Before EpiAnywhere was developed, United States-affiliated Pacific islands used a paper-based reporting form that required six pages for each TB case to be faxed to CDC. Data were then entered electronically by staff at CDC. Negotiating changes or discrepancies with data was challenging and time-consuming.

With EpiAnywhere, users only require access to the Internet to enter and approve case data, conduct analysis, and generate reports. Electronic forms with built-in validation and error-checking improve the accuracy and standardization of TB case data. Once data are entered and approved, they are available immediately for local analysis and reporting. This reduces the resources needed to meet CDC, Secretariat of the Pacific Community (SPC) and/or WHO reporting requirements and removes the need to return to logs and charts for reporting.

Future development includes expanded surveillance reports, additional and/or co-morbid disorders, multilingual versions, operability on handheld devices, and geographic mapping.

Users of EpiAnywhere need to have Internet access, need to know how to use a computer and need to be trained to input data. Computers need to be registered and data need to be inputted on a timely basis.

2.14 Data cleaning, validation and cross-checking (Agenda item 26)

Dr Falzon presented routines for managing surveillance data. Routines for data validation were discussed, including definitions, data entry errors, missing data and invalid data. Data cleaning and challenges in data processing and data reporting were covered, as well as two types of software for data analysis: Epi Info for Windows and “R”.

2.15 Principles in developing a national plan for R&R for TB/MDR-TB in countries: Introduction of the TB surveillance system in China (Agenda item 27)

Dr Fei Huang, National Center for TB Control and Prevention, China CDC, presented China's TB surveillance system. In 2004, the Ministry of Health launched a web-based infectious disease reporting system (IDRS). About 37 notifiable infectious diseases, including TB, can be reported in real-time by all health facilities. This system was updated in 2008 and the second version was used in 2009. All information and data on TB suspects and TB cases are entered at TB facility level (township and county, including hospitals) and the key information and data are stored in a relational database management system at central level. It also allows producing standard or customized analyses.

While TB in general is diagnosed and treated at county TB dispensaries, MDR suspects are referred to prefecture TB dispensaries for diagnosis and treatment. So far, MDR R&R is basically paper-based. The weaknesses of the current MDR system include: only MDR-TB cases
are generated from on-treatment, pulmonary tuberculosis (PTB) can be entered into the system, very limited information from MDR-TB cases is collected, MDR-TB and PTB data are stored in one database, and poor output cannot meet the requirements of NTP and WHO.

This system is being revised again, mainly focusing on drug-resistant TB. The plan is to include: (1) drug-resistant TB suspects - PTB case on treatment retrieved from normal TB record, chronic TB cases entered by county and/or prefecture TB dispensary, and cases generated automatically by system from on-treatment MDR-TB case; and (2) all drug-resistant TB cases - mono-resistant, poly-resistant, MDR, and XDR.

Advantages of the new surveillance system include: (1) IDRS, TBIMS and DR-TB system are linked with each other and are exchanging data in real-time; (2) drug-resistant TB suspects, drug-resistant TB cases and PTB cases are integrated into one web-based system, but data for each are stored in different databases; (3) all kinds of drug-resistant TB suspects and cases can be captured by this system; (4) combined search can identify any specific suspects/cases in the database; and (5) enhanced output, including WHO form 5/6/7, etc.

Improvements to this TB R&R system were funded by the Central Government with financial support from the Ministry of Health/WHO Regional Office collaborative project (regular budget) and the Bill & Melinda Gates Foundation project. Technical support was provided by the WHO country office and Management Sciences for Health.

2.16 On pharmacovigilance (Agenda item 28)

Dr Falzon presented pharmacovigilance for tuberculosis. The World Health Assembly (WHA) invited Members States to do systematic collection of serious drug reactions in 1963, and WHO's International Drug Monitoring Programme had 96 full members and 30 associate members in 2009. Minimum requirements for a functional national pharmacovigilance system have been defined. WHO is currently raising awareness on this issue, including developing a practical handbook on the pharmacovigilance of antituberculosis medication.

2.17 Approaches toward data description, graphing and analysis – Using data for programme management of drug-resistant TB (PMDT) – Philippines, followed by GLC approval in the Region (Agenda item 29)

Dr Anna Marie Celina G. Garfin, NTP – Philippines, described how MDR management had evolved from pilot phase 1999-2003 in Metro Manila, to expansion phase 2003-2006 in Metro Manila with Global Fund Round 2 support, to mainstreaming phase 2006-2008 in Metro Manila (regionwide) and Region 7 (Cebu) with Global Fund Round 5, to the current scale-up phase 2009-2014 in more than five regions with the Global Fund Rolling Continuation Channel.

In the pilot and expansion phases, an electronic medical record was used, and in the scale-up phase, the Philippines e-TB Manager (merging DOTS and MDRTB) was used. Treatment outcome data are therefore available from the start, with 608 cases evaluated during the period 1999–2006, with cure rate increasing in 2006 to 78%, with 25% deaths, 22% default and 2% failure. The categories of MDR cases during the period 2000–2009 were: “others” (60%), failure of category II (17%) and relapses (12%). Data were also available by category on the number of MDR suspects (9744), confirmed (2125) and enrolled (1116). In 2007–2009, 22% of suspects were confirmed overall, ranging from 67% of those treated after failure, 28% of relapses, 25% of others, 24% of those after default, and to 3% of new cases. The proportion enrolled was 53% overall, ranging from 74% of those treated after failure, 7% of others, 65% of relapses, and to 48% of new cases.
Based on the DST pattern, the treatment regimen in MDR cases among new, relapses and after default cases included: Lfx, Km, Cs, Pto and Z, while MDR cases treated after failure of category I or II and others replaced Z with PAS. Among 45 patients who started standard MDR treatment in the second and third quarter 2010, 34 (76%) were confirmed with MDR, while four had mono or poly-resistance and seven were pan-sensitive.

Dr Angelito Bravo, WHO Headquarters, Stop TB Department, provided updated information about GLC approvals in seven countries in the Region (see Table 1). So far, only a minority of approved patients have been enrolled on treatment. Treatment success among patients starting in 2007 was 63.1% (but numbers not shown) (GLC annual report, 2009).

Table 1: GLC-approved countries in the Western Pacific Region by December 2010

<table>
<thead>
<tr>
<th>Country</th>
<th>Year approved</th>
<th>Total approved cohort</th>
<th>Preliminary cumulative number of patients enrolled a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>2006</td>
<td>560</td>
<td>73</td>
</tr>
<tr>
<td>China</td>
<td>2006</td>
<td>17 231</td>
<td>600</td>
</tr>
<tr>
<td>Lao People's Democratic Republic</td>
<td>2010</td>
<td>45</td>
<td>-</td>
</tr>
<tr>
<td>Federated States of Micronesia</td>
<td>2007</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Mongolia</td>
<td>2005</td>
<td>1 563</td>
<td>372</td>
</tr>
<tr>
<td>Philippines (includes TDF, Department of Health and Tibotec project)</td>
<td>2000</td>
<td>7 183</td>
<td>1 843</td>
</tr>
<tr>
<td>Samoa</td>
<td>2007</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>2007</td>
<td>600</td>
<td>101</td>
</tr>
</tbody>
</table>

a As reported to GLC Secretariat

2.18 Practical exercises in data analysis – posters (Agenda item 30)

Participants discussed the posters very actively as they were briefly presented. Almost all of the countries presented data on case finding during the period 2005–2009 (including different groups of re-treatments) and treatment outcome. For some countries, the number of cases notified and the number of cases with treatment outcome did not quite correspond, suggesting challenges in the quality of the R&R system. Data on MDR cases and treatment outcome were more limited. Here are MDR data from some selected countries:

- Philippines (refer also to agenda item 29): MDR treatment status at the sixth month was available for a subgroup of patients (TBC+ at baseline) who started treatment in 2007–2008. MDR treatment final outcomes were available for the period 2000–2008, although many patients were still on treatment in 2007-2008. The success rate ranged
from 57% to 74%, default rate ranged from 7% to 23% (already 17% in 2007), failure rate ranged from 5% to 19% (already 11% in 2007 and 10% 2008), with very few deaths.

- China: Data on MDR cases were available for the first six months of 2010: total 1950 confirmed cases: mainly relapses (758), after failure of category II (463), “chronics” classified as others (371), after failure of category I (209), new (134) and after default (15). During the same period, 1049 confirmed MDR cases had started treatment. The difference between total cases started on treatment and those with interim outcome reported was discussed.

- Viet Nam: A total of 101 confirmed MDR cases were reported in 2009 – 52 chronics, 36 after failure category II and 13 after failure category I. All 101 registered in 2009 had started treatment and their six-month status was available. In 2010, so far, 300 have been registered; among them, 16 after failure category II have started MDR treatment.

- Mongolia: MDR data were available for the period 2006–2010. In 2007-2010, 702 confirmed MDR cases were reported and 357 started on MDR treatment, including 224 after failure category II, 78 after failure category I, and 17 relapses. At the sixth month of treatment, 10% were smear-positive.

- Malaysia provided data from the Sabah region only, while Cambodia, the Lao People's Democratic Republic and Papua New Guinea did not provide data on MDR-TB.

- The Pacific island countries and areas had few TB cases but in general provided data on MDR-TB, including treatment outcome.

2.19 Course assessment (Agenda item 31)

About 20 participants completed the questionnaire and expressed overall satisfaction. Some individual suggestions were as follows:

1. Field visits to health centres should be included in the workshop to see the R&R system in use.

2. For calculating the indicators, a concrete example should be given in order to limit or prevent confusion.

3. More sessions on data analysis, e.g. hands-on practical session on the Philippines should be provided.

4. It should be kept in mind that some of the participants are not computer literate.

5. There should have been more practice than lectures.
3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The main conclusions of the workshop were as follows:

3.1.1 The routine recording and reporting system for the basic TB programmes (e.g. DOTS) is well-established in the Region; however, many countries face challenges in maintaining the good quality, in monitoring trends, and in identifying and monitoring groups defined as MDR suspects who should have drug-susceptibility testing (DST).

3.1.2 The routine recording and reporting system for MDR-TB is clearly defined in WHO guidelines, but its implementation is still weak in many countries in the Region. It is difficult to assess trends in the MDR situation, e.g. incidence and burden of MDR-TB, since data on reported MDR cases by category are incomplete. In the absence of well-functioning surveillance systems, periodic surveys have provided key information, but the overall picture remains incomplete.

3.1.3 NTPs lack data on coverage of culture and DST in MDR suspects, partly because groups that are considered to be MDR suspects and have DST are not yet well-defined, and because the routine R&R system does not include all relevant groups such as so-called chronics and early failures.

3.1.4 The number of reported MDR cases is often incomplete because laboratories usually do not register the category of patients. Often there is no direct link between laboratories and the TB programme, which manages the MDR registry. Also, different dates are used for the registration of cases.

3.1.5 GLC has approved treatment for a considerable number of MDR cases in the Region, but so far, only a minority of cases have been enrolled. The number of cases, however, has been rapidly increasing. There is lack of solid data on MDR treatment coverage and delay, inside and outside the GLC mechanism.

3.1.6 NTP data on MDR treatment outcome are incomplete in most countries. This information is especially needed to monitor levels of defaults, deaths and failures in a timely way, so that the strategy can be modified when needed (e.g. social support, regimens).

3.1.7 Supply of second-line drugs is affected by lack of reliable data on current MDR cases and reasonable projections, which are based on reported cases and not on estimates. The new drug procurement system promoted by GDF is based on quarterly routine data from the TB programmes, and should coincide with the strengthening of the R&R system.

3.1.8 The R&R system for MDR-TB is paper-based in five countries and computerized with data linkage over the web in the Philippines and the four Pacific Islands. These paper-based systems may work well as long as the number of patients is limited. Computerized systems, however, may prove to be very useful especially for tabulation and analysis.

3.1.9 The two main computer systems for MDR-TB presented, OpenMRS and e-TB Manager, are extensive electronic medical record systems, which, according to the WHO guidelines and list of indicators, contain more information than the minimum required.
3.2 **Recommendations**

The recommendations of the workshop were as follows:

3.2.1 In line with recommendations from the Workshop on Surveillance and Impact Monitoring in Ho Chi Minh City, Viet Nam, June 2010, NTPs should ensure a well-functioning R&R system for basic TB programmes (e.g. DOTS) through training, regular supervision and use of data for analysis and management at all levels.

3.2.2 NTPs should ensure a well-functioning R&R system for MDR-TB as an extension of the basic R&R system in line with WHO recommendations. Budgeting for PMDRTB should include proper R&R, through training and supervision. NTPs should use data for analysis at all levels as part of routine supervision visits, to stimulate better quality.

3.2.3 NTPs should monitor closely the coverage of culture and DST in MDR suspects through a strengthened basic R&R system, and special collection of data on chronics and early failures using MDR suspects, laboratory and district TB registers.

3.2.4 NTPs should strengthen the use of MDR registers and keep updated links with laboratory registers to ensure completeness. The projected expansion in the use of rapid drug-susceptibility testing (e.g. line probe assay and Xpert MTB/RIF) should make this need even more relevant.

3.2.5 NTPs should take advantage of the new GDF system for improved drug procurement of first- and second-line drugs, as an integrated part of NTP routine quarterly R&R data.

3.2.6 NTPs should take maximum advantage of computerized systems for R&R. Challenges that needs to be considered include high cost and high demand of technical competence and back-up. Countries with established computerized systems for normal TB may add on an integrated MDR component in the same system. The countries without a computerized system may develop their own based on local competence or use of one of the already developed electronic medical record system such as OpenMRS or e-TB Manager. It is important to keep systems simple and compliant with the WHO requirements for reporting.

3.2.7 Technical assistance needs to be provided for country staff to: (1) ensure good data quality in the R&R system; (2) tabulate, analyse and manage data; and (3) introduce feasible options for electronic systems.
INFORMATION BULLETIN NO. 2

FINAL LIST OF PARTICIPANTS

1. PARTICIPANTS

CAMBODIA

Dr Keo Sokonth
Chief of Technical Bureau
National Center for TB and Leprosy Control (CENAT)
Ministry of Health
No. 151-153 Kampuchea Krom Str
Phnom Penh
Tel: (855) 12 870 042
Fax: (855) 23 218090
E-mail: ksokonth@yahoo.com

Dr Narith Ratha
Technical Bureau Officer
Training, Supervision and Research Section
Chief of National TB Reference Laboratory
National Center for TB and Leprosy Control (CENAT)
Ministry of Health
No. 1, Str. 278-95, Boeung Keng Kang 2
Khan Chamkar Morn
Phnom Penh
Tel.: (855) 23 219 274 / 275 / 219
Fax: (855) 23 218090
Email: narith.ratha@yahoo.com
Annex 1

CHINA, PEOPLE'S REPUBLIC OF

Dr Huang Fei
Assistant Researcher
Surveillance Department
National Center for TB Control and Prevention
China CDC
No. 155 ChangBaï, Road
Changping District
Beijing 102206
Tel.: (8610) 58900536
Fax: (8610) 58900533
E-mail: boyoffline@chinatb.org

Dr Zhao Jin
Practitioner-Researcher
National Center for TB Prevention and Control
China CDC
No. 155 ChangBaï, Road
Changping District
Beijing 102206
Tel.: (8610) 68792661
Fax: (8610) 68792662
E-mail: zhaojin@chinatb.org

GUAM

Ms Estelle-Marie Alig
Coordinator
Communicable Disease Control
TB Control Programme
Department of Public Health and Social Services
123 Chalan Karefa
Mangilao 96913-6304
Tel.: (671) 735-7157
Fax: (671) 735-7318
Email: Estelle_alig@dphss.guam.gov
E_alig@hotmail.com

LAO PEOPLE'S DEMOCRATIC REPUBLIC

Dr Bounkong Fongosa
Chief of Technical Division
National Tuberculosis Centre
Ministry of Health
Vientiane
Tel.: (856) 21 414259
Fax: (856) 21 452855
E-mail: bounkongfongosa@yahoo.com

Dr Khamloune Choumlivong
Deputy Chief
Infectious Disease and Tuberculosis Department
Setthathirat Hospital
Ministry of Health
Dongpalane thong Village, Sisattanak District
Vientiane
Tel.: (856) 305 262053
Fax: (856) 021 351160
Email: kamlouch@yahoo.fr
MALAYSIA
Dr Rafidah Baharudin
Principal Assistant Director
Disease Control Division
Ministry of Health
Level 3, Block E10, Complex E
Federal Government Administrative Centre
62590 Putrajaya
Tel: (603) 8883 4527
Mobile: (6013) 8602897
Fax: (603) 8889 1013
Email: rafidahb@moh.gov.my

Ms Zirwatul Adilah Aziz
Science Officer
National Public Health Laboratory
Ministry of Health
Lot 1853, Kg. Melayu Sg. Buloh
47000 Sungai Buloh
Selangor
Tel: (603) 61261200
Fax: (603) 61402249
Email: adilahaziz@moh.gov.my

MARSHALL ISLANDS,
REPUBLIC OF
Dr Kennar Briand
Director of Public Health
TB/Leprosy National Manager
Ministry of Health
PO Box 16
Majuro 96960
Tel.: (692) 625 3355
Fax: (692) 625-4372 / 3422
Email: kbrriand@yahoo.com

MICRONESIA, FEDERATED
STATES OF
Dr Mayleen Jack Ekiek
National TB/HD/STD Programme Manager
(Communicable Disease Physician)
Department of Health and Social Affairs
Palikir, Pohnpei 96941
Tel.: (691) 320 2619
Fax: ((691) 320 8632
Email: mkiek@fsmhealth.fm

MONGOLIA
Ms Khongorzul Byambajav
Deputy Director
Department of Information, Monitoring and Evaluation
Ministry of Health
Government Building 8
Olympic Street-2, Sukhbaatar District
Ulaanbaatar
Tel: (976-51) 263681
Fax: (976-11) 320916
E-mail: khongorzul@moh.mn
Annex 1

Ms Tserenkhand Tserenjav
Quality Manager
Shastin Hospital
Bayangol District
Ulaanbaatar 210648
Tel.: (976) 687900
Fax: (976-11) 450492
E-mail: munkhuuleiz@yahoo.com

NORTHERN MARIANA ISLANDS
Dr Shirish Balachandra
Acting TB Controller
Commonwealth Health Centre
Department of Public Health
1 Lower Navy Hill Rd.
Saipan, MP 96950
Tel.: (670) 287 2222
Fax: (670) 236-8608
Email: saipanbala@gnail.com

PAPUA NEW GUINEA
Dr Margaret Kal
Medical Officer
TB for Highlands Region
Department of Health
P.O.Box 807
Waigani, NCD
Tel: (675) 301 3808
Fax: (675) 325 0368
Email: margaretkal@gmail.com

Dr Paul Harino
Clinical Researcher
Papua New Guinea Institute of Medical Research
P.O. Box 378
Madang 511 MP
Tel.: (675) 422 2909
Fax: (675) 422 3289
Email: nuen09@gmail.com

PHILIPPINES
Dr Anna Marie Celina Garfin
Medical Specialist IV
National Center for Disease Prevention and Control
Department of Health
Sta. Cruz
Manila
Telefax: (632) 711 7846
E-mail: garfinamc@yahoo.com

Mr Roberto Belches
Programme Management Office Staff
Lung Center of the Philippines
Quezon City
Telefax: (632) 924 6101 extn. 305
Email: robbelchez@yahoo.com
VIET NAM, SOCIALIST REPUBLIC OF

Dr Tran Van Thieu
Medical Doctor
National TB Programme
National Lung Hospital
Ministry of Health
463 Hoang Hoa Tham, Badinh
Ha Noi
Tel.: 84-4-37618396
Fax: 84-4-37614901
E-mail: tienthieu60@yahoo.com.vn

Dr Pham The Anh
Vice Chief
Networking Department
Hospital 74 Central
Trung Wong
Ha Noi
Tel.: 84-02116-268 623
Fax: 84-02116-268 674
Email: chidaotuyen74@gmail.com

2. TEMPORARY ADVISERS

Dr Hamish Fraser
Director of Informatics and Telemedicine
Partners in Health
888 Commonwealth Avenue, 3rd Floor
Boston, Massachusetts 02215
United States of America
Tel.: (1-617) 432-3930
(1-617) 998-8973
Email: elda_heldal@hms.harvard.edu

Mr Aamir Khan
Director
MDR-TB Control Programme
The Indus Hospital Research Center
Korangi Crossing
75190 – Karachi
Pakistan
Tel: 92 21 511 2709
Fax: 92 21 511 2718
Email: ajkhan@jhsp.edu

3. CONSULTANT

Dr Einar Heldal
TB consultant
Arvollveien 60D
0590 Oslo
Norway
Tel.: +47-97517465
Mobile: +47 97517465
Email: elda.heldal@c2i.net
Annex 1

4. REPRESENTATIVES OF PARTNER AGENCIES AND OBSERVERS

ELI LILLY AND COMPANY

Ms Sunita Prasad  
MDR-TB Partnership Director  
Eli Lilly and Company (India) Pvt. Ltd.  
Plot No. 92, Sector 32  
Gurgaon – 122001  
Haryana, India  
Tel.: +91-124-4753213  
+91-9910491578  
Fax: +91-124-47753012  
Email: prasadsu@lilly.com

MANAGEMENT SCIENCES FOR HEALTH

Dr Nerizza Muñez  
Drug Management Consultant  
270 Benito St., Kauswagan,  
Cagayan de Oro City, Philippines 9000  
Tel.: +63-08822-711811  
Email: zaza.munez@gmail.com

DEPARTMENT OF HEALTH, PHILIPPINES

Ms Virna C. Turbolencia, RN  
Bldg 9, San Lazaro Compound  
National Epidemiology Center  
Department of Health  
Rizal Avenue, Sta. Cruz, Manila  
Tel.: +632 - 7436076  
Email: v_c_t13@yahoo.com; vcturbolencia@gmail.com

Ms Evangeline De Keyser  
Bldg 9, San Lazaro Compound  
National Epidemiology Center  
Department of Health  
Rizal Avenue, Sta. Cruz, Manila  
Tel.: +632 - 7436076  
Email: vangie0415@yahoo.com

Dr Mary Rose Santiago  
Clinic Physician  
Lung Center of the Philippines  
Public Health and Domiciliary Unit Bldg.  
Quezon Avenue Extension, Quezon City  
Philippines 1100  
Tel.: +632 – 9271126  
Fax: +632 – 9271126  
Email: maryrosarytaguinod@yahoo.com
5. SECRETARIAT

Dr John Ehrenberg  
Director  
Combating Communicable Diseases  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9701  
Fax: (632) 521 1036  
Email: ehrenbergj@wpro.who.int

Dr Catharina van Weezenbeek  
(Responsible Officer)  
Team Leader  
Stop TB and Leprosy Elimination  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9706  
Fax: (632) 521 1036  
E-mail: vanwezenbeekc@wpro.who.int

Dr Daniel Sagebiei  
(Co-Responsible Officer)  
Medical Officer  
Stop TB and Leprosy Elimination  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9720  
Fax: (632) 521 1036  
E-mail: sagebield@wpro.who.int

Dr Katsunori Osuga  
Medical Officer  
Stop TB & Leprosy Elimination  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9709  
Fax: (632) 521 1036  
E-mail: osugak@wpro.who.int

Dr Nobuyuki Nishikiori  
Medical Officer  
Stop TB & Leprosy Elimination  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9726  
Fax: (632) 521 1036  
E-mail: mishikiorin@wpro.who.int
Annex 1

Ms Catherine Lijinsky  
Technical Officer  
Stop TB & Leprosy Elimination  
WHO/WPRO  
U.N. Avenue  
1000 Manila  
Philippines  
Tel.: (632) 528 9726  
Fax: (632) 521 1036  
E-mail: lijinskyc@wpro.who.int

WHO/WPRO COUNTRY OFFICES

Dr Fabio Scano  
Medical Officer, Stop TB & Leprosy Elimination  
Office of the WHO Representative in China  
401, Dongwai Diplomatic Office Building  
23, Dongzhimenwai Dajie  
Chaoyang District  
Beijing 100600  
China  
Tel.: (8610) 6532 1288  
Fax: (8610) 6532 2359  
Email: scanof@chn.wpro.who.int

Dr Wang Xuejing  
National Professional Officer, Stop TB & Leprosy Elimination  
Office of the WHO Representative in China  
401, Dongwai Diplomatic Office Building  
23, Dongzhimenwai Dajie  
Chaoyang District  
Beijing 100600  
China  
Tel.: (8610) 6532 7189  
Fax.: (8610) 6532 2359  
E-mail: wangxu@chn.wpro.who.int

Dr Jadambaa Narantuya  
National Professional Officer  
Office of the WHO Representative in Mongolia  
Ministry of Health  
Government Building – 8  
Ulaanbaatar, Mongolia  
Tel.: (976) 11-327870  
Fax: (976) 11-324683  
E-mail: narantuyaj@mog.wpro.who.int

Dr Woo-jin Lew  
Medical Officer, Stop TB and Leprosy Elimination  
Office of the WHO Representative in the Philippines  
P.O. Box 2932  
Manila  
Philippines  
Tel. No.: (632) 5289767  
Fax No.: (632) 7313914  
E-mail: leww@phl.wpro.who.int
Annex 1

Dr Mariquita Mantala
National Professional Officer, Tuberculosis
Office of the WHO Representative
in the Philippines
P.O. Box 2932
Manila
Philippines
Tel. No.: (632) 5289767
Fax No.: (632) 7313914
E-mail: mantalam@phl.wpro.who.int

Dr Nguyen Nhat Linh
Medical Officer, Stop TB & Leprosy Elimination
Office of the WHO Representative in the South Pacific
Level 4 Provident Plaza One
Downtown Boulevard
33 Ellery Street
Suva, Fiji
Tel.: (679) 3-304600; 304631
Fax: (679) 330 0462; 331-1530
Email: nguyenli@wpro.who.int

Dr Pham Huyen Khanh
National Professional Officer
Stop TB & Leprosy Elimination
Office of the WHO Representative in Viet Nam
63 Tran Hung Dao Street
Hoan Kiem District
Ha Noi
Socialist Republic of Viet Nam
Tel.: (844) 943 3734
Fax: (844) 943 3740
Email: phamh@vtn.wpro.who.int

WHO HEADQUARTERS

Dr Dennis Falzon
Stop TB Department
World Health Organization
Avenue Appia 20
CH – 1211 Geneva 27
Switzerland
Tel.: 4122 791 1469
Fax: 4122 791 1589
E-mail: falzond@who.int

Mr Thierry Cordier-Lassalle
GDF Principal Officer
Stop TB Partnership
Global Drug Facility
World Health Organization
Avenue Appia 20
CH – 1211 Geneva 27
Switzerland
Tel.: 4122 791 4541
Fax: 4122 791 4886
E-mail: cordierlassallet@who.int
Annex 1

Dr Angelito Bravo
Technical Officer
TB Operations and Coordination (TBC)
Stop TB Department
World Health Organization
Avenue Appia 20
CH – 1211 Geneva 27
Switzerland
Tel.: 4122 791 3627
Fax: 4122 791 4199
E-mail: bravoa@who.int
AGENDA

1. Opening ceremony
2. Objectives and expected outcomes of the workshop
   
   **Session 1: Introduction to the rationale of MDR surveillance and recording and reporting**

3. Surveillance of MDR-TB: Global and regional situation
5. On anti-TB drug resistance surveillance (DR) and DR surveys
6. Exercise 1: Strengthening the surveillance for DR-TB
7. Regional activities of the Eli Lilly Foundation

   **Session 2: Parameters for standardized recording and reporting**

8. Definitions for case registration and treatment
9. Presentation of Chapter 18 and forms (part 1: Case finding): Case finding forms and registers (Form 1), Treatment register (Form 02), Request for sputum examination form (Form 03), Lab register for culture and DST (Form 04), MDR-TB suspect register
10. Exercise 2: Familiarization and use of standard tools in recording of MDR-TB cases
11. Plenary discussion
12. Assessment of each day's proceedings
13. Summary of presentations from each day
Annex 2

14. Forecasting system for improved procurement

15. Reporting of MDR-TB cases: Presentation of standard tools for deriving MDR-TB indicators

16-17. Exercise 3: Familiarization and use of standard tools for deriving MDR-TB indicators

18. OpenMRS – Demonstration
   (to present the software, its costs, prerequisites to be in place, quality assurance, and some models of how countries have used these packages, obtained support and dealt with problems)

   **Session 3: Electronic solutions for recording and reporting**

19. **openXdata** – Innovations in use of mobile phones for DOT and community-based management of MDR-TB, interoperability with OpenMRS MDR-TB module

20. **e-TB Manager** – Demonstration
   (An integrated web-based platform for case management, drug management and epidemiological surveillance for TB/MDR-TB country experiences, data QA, overview of implementation process)

21. Practical work in using key system functionalities – 1

22. Principles of laboratory information systems

23. Assessment of each day's proceedings

24. Summary of presentations from each day

25. Practical work in using key system functionalities – 2
   EpiAnywhere

26. Data cleaning, validation and cross-checking

   **Session 4: Increasing capacity in analysis and planning**

27. Principles in developing a national plan for recording R&R for TB/MDR-TB in countries – The Introduction to TB Surveillance System in China

28. On pharmacovigilance

29. Approaches towards data description, graphing and analysis – Using data for PMDT-Philippines GLC Approval in the Region

30. Practical exercise on data analysis

31. Course assessment
   Distribution of certificates
   Closing
<table>
<thead>
<tr>
<th>Time</th>
<th>24 November, Wednesday</th>
<th>Time</th>
<th>25 November, Thursday</th>
<th>Time</th>
<th>26 November Friday</th>
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</thead>
<tbody>
<tr>
<td>08:30</td>
<td>Registration</td>
<td>08:30</td>
<td>(13) Summary of presentations from Day 1</td>
<td>08:30</td>
<td>(24) Summary of presentations from Day 2</td>
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<tr>
<td>09:00</td>
<td>(1) Opening ceremony</td>
<td>08:45</td>
<td>(14) Forecasting system for improved procurement</td>
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<td>(25) Practical work in using key system functionalities – 2</td>
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<td></td>
<td>- Welcome remarks: Dr John Ehremberg, Director, Combating Communicable Diseases (in behalf of Dr Shin Young-soo, Regional Director, WHO/WPRO)</td>
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<td>(15) Reporting of MDR-TB cases: Presentation of standard tools for deriving MDR-TB indicators</td>
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<td>(26) Data cleaning, validation and cross-checking</td>
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<td></td>
<td>- Self-introduction of participants and facilitators</td>
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<td>(16) Exercise 3: Familiarization and use of standard tools for deriving MDR-TB indicators</td>
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<td>- Administrative announcements</td>
<td>09:15</td>
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<td>10:00</td>
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<td>09:30</td>
<td>PHOTO SESSION – COFFEE / TEA BREAK</td>
<td>10:45</td>
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<td>COFFEE / TEA BREAK</td>
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<td>10:00</td>
<td>Session 1: Introduction to the rationale of MDR surveillance and recording and reporting</td>
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<td>11:00</td>
<td>Session 4: Increasing capacity in analysis and planning</td>
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<td>11:00</td>
<td>(4) Why monitor drug-resistant TB, aim of R&amp;R, indicators, strategies for detection of MDR-TB</td>
<td>12:15</td>
<td>(18) OpenMRS – Demonstration (to present the software, its costs, prerequisites to be in place, quality assurance, and some models of how countries have used these packages, obtained support and dealt with problems)</td>
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<td>(6) Exercise 1: Strengthening the surveillance for DR-TB</td>
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<td>12:45</td>
<td>LUNCH BREAK</td>
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<td>13:45</td>
<td>(7) Regional activities of the Eli Lilly Foundation</td>
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<td>15:00</td>
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<td>(22) Principles of laboratory information systems</td>
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<td>(23) Day's assessment and closure</td>
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<td>17:30</td>
<td>Directed evening reading from the Guidelines and Revised MDR-TB indicators</td>
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<td>18:00</td>
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Regional Workshop on Recording and Reporting of Drug-Resistant Tuberculosis in the Western Pacific

24–26 November 2010
Manila, Philippines