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FINAL REPORT OF THE 5TH MEETING OF THE DOTS EXPANSION WORKING GROUP

27–28 October 2004
Paris, France

World Health Organization
Geneva

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Abbreviations and acronyms

AFB	Acid fast bacilli
ART	Antiretroviral therapy
ATS	American Thoracic Society
CDC	Centers for Disease Control and Prevention, USA
CIDA	Canadian International Development Agency
COMBI	Communication for behaviour impact
DEWG	DOTS Expansion Working Group
DFID	Department for International Development, United Kingdom
DOTS	The internationally recommended strategy for TB control
DRS	Drug resistance surveillance
DST	Drug susceptibility testing
EQA	External quality assurance
FDC	Fixed-dose combination
FIDELIS	Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
HBC	High burden country
HIV	Human immunodeficiency virus
HR	Human resources
HRD	Human resources development
IEC	Information, education, and communication
ISAC	Intensified support and action countries
IUATLD	International Union Against Tuberculosis and Lung Disease
KNCV	Royal Netherlands Tuberculosis Association
MDG	Millennium Development Goal
MDR	Multidrug resistant
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NGO	Nongovernmental organization
NRL	National reference laboratory
NTP	National tuberculosis programme
PPM	Public-Private Mix
PSI	Population Services International, Myanmar
QA	Quality assurance
SCC	Short course chemotherapy
SQH	Sun Quality Health franchise, Myanmar
TB	Tuberculosis
TBCTA	Tuberculosis Coalition for Technical Assistance
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WEF	World Economic Forum
WHA	World Health Assembly
WHO	World Health Organization
ZN	Ziehl-Neelsen (stain)

1. Introduction

The fifth meeting of the DOTS Expansion Working Group (DEWG) was held on 27 and 28 October 2004 in Paris, France in conjunction with the 35th International Union Against Tuberculosis and Lung Disease (IUATLD) World Conference on Lung Health. The first day of the meeting was closed, to include only the representatives of the 22 high burden countries (HBCs) for tuberculosis (TB), financial and technical partners, and regional and country offices of the World Health Organization (WHO).

The second day of the meeting – which was hosted by the IUATLD – was open to all participants of the IUATLD conference. The final agenda of the meeting, and the complete list of participants are included as annexes to this report. The meeting was financially supported in part by the Global Bureau for Population, Health and Nutrition of the United States Agency for International Development (USAID); IUATLD; the World Bank; and WHO.

The objectives of the meeting were to:

- review the status of TB control and DOTS expansion in the world;
- identify and discuss constraints of the 22 HBCs in achieving the 2005 targets and the Millennium Development Goals (MDGs), and discuss solutions and activities to be implemented in 2005 – the last year for corrective and innovative actions for achieving the global TB targets;
- review the national laboratory systems and networks and develop a plan to strengthen laboratories;
- discuss collaboration with other health-care providers, including public-private mix, public-public mix, TB control in the workplace, and community TB; and
- present and discuss the intensified support and action countries (ISAC) initiative.

The expected outcome was an up-to-date plan to support country activities for DOTS expansion, outlining action needed by countries and their international partners to reach the 2005 targets.

2. Report of the DEWG Secretariat

2.1 **Status of DOTS expansion in HBCs**

Information on DOTS expansion, progress, and activities between 1 July 2003 and 30 June 2004 was collected from the 22 HBCs, based on a questionnaire developed by the WHO Stop TB Department. Many countries reported rapid expansion of DOTS in various aspects of their health systems during the past year. India has expanded DOTS coverage to an additional 179 million people (approximate 76% total population coverage) and has an approved national plan for 100% DOTS coverage by 2005.

Moreover, a major scaling-up of Public-Private Mix (PPM) DOTS – and involvement of medical colleges and health facilities under other than governmental ministries – has taken place over the past year. Myanmar achieved 100% DOTS coverage in December 2003, and has reached the global targets for case detection at 73%. The Government of China has pledged to greatly increase funding for TB control and continued DOTS expansion. In the African region, Nigeria has further expanded DOTS and Uganda has expanded community-based DOTS. The Russian Federation has gradually expanded DOTS in accordance with its five-year plan, and has implemented a new recording and reporting system based on a WHO cohort analysis. In that country, the World Bank loan and the Global Fund to Fight AIDS, TB and Malaria (GFATM) grant for TB have been approved and will significantly impact DOTS expansion and TB control activities. South Africa has also implemented a uniform cohort-based recording and reporting system in all provinces. Pakistan has

had rapid expansion of DOTS, including PPM DOTS, through the nongovernmental organization (NGO) network. Viet Nam has expanded DOTS to cover remote areas, the Philippines has further expanded DOTS into the private sector and hospitals, and Cambodia has doubled the number of health centres providing DOTS in 2003 and has introduced community DOTS in collaboration with NGOs in remote areas. The Philippines has also developed guidelines on childhood TB.

The National TB Control Plan for 2004–2007 to expand DOTS was approved in Brazil. Bangladesh achieved 84% treatment success, and the National Tuberculosis Programme (NTP) has strengthened its collaboration with numerous NGOs that provide DOTS services countrywide. Greater involvement of other public health providers in DOTS as part of public-public DOTS, and improved supervision and monitoring, are adding to the success of TB control in Indonesia. Kenya has expanded PPM DOTS, and developed and implemented a communication for behaviour impact (COMBI) plan to improve early case detection. Both Pakistan and Uganda have launched Stop TB Partnerships, and in Pakistan this launch has resulted in increased funding from the government for further TB control activities.

There have been positive changes in the national TB programmes of several countries. The organizational structure of the NTP in Afghanistan at the national, provincial, and district levels was formulated, and NTP guidelines and other materials have been developed. There has been a major strengthening of NTP capacity in Indonesia at both central and provincial levels, and the national TB laboratory has been reinstated in Kenya. In Viet Nam, both a nationwide external quality assurance (EQA) system and a mechanism to ensure quality of anti-TB drugs was established.

Development of human resources (HR) was a main activity for many HBCs during the year. Major plans to strengthen HR were developed in China and India. Training activities and capacity building were significant activities in Ethiopia, Indonesia, Nigeria, the Russian Federation, South Africa, and the United Republic of Tanzania. TB/HIV collaborative activities have begun in some areas. In Kenya, a TB/HIV working group and guidelines were established. A TB/HIV coordinator was appointed and collaborative activities were launched in Mozambique. In South Africa, national guidelines for the care of co-infected TB patients were developed, which include access to antiretroviral therapy (ART).

2.2 **Epidemiological update**

Preliminary data suggest that by the end of 2003, 77% of the world's population lived in countries – or parts of countries – covered by DOTS: an increase from 69% in 2002. In 2002, 180 countries were implementing DOTS. Among those countries (170 out of 210) who had reported to the World Health Organization by 12 October, two new countries had adopted the DOTS strategy in 2003.

Many countries have made progress towards achieving the 2005 global TB targets of 70% case detection and 85% treatment success. The global case-detection rate continues to accelerate: preliminary figures suggest a rate of 43% for 2003 (37% in 2002). The treatment success rate for patients registered in 2002 is close to the target, at 82%. However, treatment success is below average in Africa (71%) and in eastern Europe (70%). The case-detection rate for 2003 was above 70% in only three HBCs (Myanmar, South Africa, and Viet Nam). Only in Viet Nam have both targets (70% case detection and 85% treatment success) been achieved. Two HBCs with high HIV prevalence – Kenya and the United Republic of Tanzania – have reported treatment success rates above 80%. Myanmar and the Philippines are also close to the targets.

WHO is now routinely reporting on progress towards the MDGs for 2015 (halving TB prevalence and deaths), as well the global TB targets for 2005 (70% case detection and 85% treatment success). WHO is continuing to carry out a series of case studies to evaluate the impact of TB control on incidence, prevalence, and deaths. These case studies are identifying a wide range of approaches to improving case detection. Through a series of regional workshops, WHO has

provided countries and partners with guidance on best practices and tools for analysing routine and survey data and using results to form policy.

2.3 **Financial situation**

2.3.1 Expenditures and funding gaps

Expenditure on TB control in the HBCs in 2002 was US$ 834–884 million. This was lower than the anticipated expenditure of US$ 976 million, the sum that would have been required – in WHO's estimation – to achieve 70% case detection by 2005. Estimated expenditures for the HBCs in 2003 totalled approximately US$ 1 billion. This figure reflects an increase of about US$ 150 million from 2002 expenditures, but is probably still too low to meet the target for case detection by 2005.

In 2003, the governments of HBCs contributed (from national funds and loans) 70% of funds specified in NTP budgets, and 87% of total costs. But government contributions to total costs varied from 0% (Afghanistan) to 100% (e.g. Brazil), and tended to be greater in richer countries. External grants contributed about one half or more of the NTP budgets of Afghanistan, Bangladesh, the Democratic Republic of the Congo, Ethiopia, Pakistan, and the United Republic of Tanzania.

The overall funding gap reported by HBCs (excluding South Africa and Zimbabwe, for which there were no data) was US$ 41 million in 2003, about 4% of total costs, but a much larger fraction of the costs in poorer countries. Between 2002 and 2003, the funding gap narrowed in seven countries, mainly because more funds were promised by governments (including loans) and the GFATM. The gap increased in five countries because more (unfunded) activities were planned to accelerate DOTS expansion.

WHO estimated that, if the 2005 targets for case detection and treatment success are to be met, US$ 0.95 billion must be spent in the HBCs (except the Russian Federation) in 2004, and US$ 1.1 billion in 2005, compared with US$ 0.65 billion spent in 2002 and US$ 0.85 billion budgeted for 2003. The Russian Federation reported a budget of around US$ 400 million for 2004, of which US$ 200 million is yet to be found.

2.3.2 Resource mobilization

Funding for DOTS expansion activities is being mobilized through links with bilateral financial partners from the Canadian International Development Agency (CIDA), Italy, Japan, and USAID, among others. DOTS expansion should also be linked with the GFATM to coordinate support through technical partners, to provide in-country support to prepare proposals, and to stimulate applications in countries with large funding gaps. All except three of the HBCs have received TB funding from the GFATM. The Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB (FIDELIS) is also supporting new approaches to increase case detection.

- The GFATM will make a major contribution to TB control in some countries, provided that the money can be disbursed and absorbed quickly. By the end of 2003, the GFATM had approved grants (for up to 5 years) of US$ 608 million for TB control activities, and US$ 319 million for TB/HIV control, in 56 countries. The total contribution for the first two years was US$ 294 million for TB control and US$ 90 million for TB/HIV, but only 16% had been disbursed by the end of 2003. The launching of the fifth round of proposals is planned for mid-2005. To better support countries that intend to apply for grants in the upcoming round, a workshop was held in Geneva during the first quarter of 2005. The purpose of this workshop was to instruct country experts and consultants from the partner organizations in the elements of a well-prepared proposal and to provide recommendations on the essential technical areas to be included in those proposals.

- FIDELIS is a new funding mechanism, initiated by CIDA in 2003 and managed by IUATLD. Specifically, FIDELIS aims to cure new sputum-positive cases, prioritizing those with limited access to health services. This mechanism provides support to countries for implementing innovative approaches to TB control, focusing on improving case detection – especially among hard-to-reach populations. At the time of the presentation of this Report of the DEWG Secretariat, 16 projects were being implemented and an additional 16 approved projects were likely to start implementation by October 2004. Innovations in these projects included decentralizing existing services, improving referrals, promoting community-based DOTS, intensifying information, education, and communication (IEC), involving private health-care providers, encouraging joint ventures between national tuberculosis programmes (NTPs) and NGOs, and providing for the payment of performance-based incentives to peripheral health-care workers.

2.4 **Intensified support and action countries (ISAC)**

ISAC is a special emergency Stop TB initiative – implemented through the DEWG – to accelerate DOTS expansion and reach the 2005 targets within the Global Plan to Stop TB, and ultimately the 2015 Millennium Development Goals (MDGs). ISAC is an extraordinary and additional effort to accelerate TB control – regular efforts by the DEWG continue to support all 22 HBCs and other countries in need.

Countries were selected based on the following criteria:

- burden of disease and/or of TB/HIV dual infection;
- presence of – or desire to have – in-country WHO or Stop TB partners' staff and intensified support;
- clear commitment and potential capacity to implement the programme at the country level and provide an enabling environment;
- availability of funding for TB or TB/HIV control activities from GFATM, bilateral donors, and/or banks; and
- the potential for collaboration with the Global Drug Facility (GDF) for drug procurement.

The first tier of ISAC countries includes China, India, Indonesia, Kenya, Pakistan, Peru, Romania, the Russian Federation, and Uganda, (although the plan for Peru is not yet available). The main ISAC donors to date are CIDA, the Department for International Development, United Kingdom (DFID), GFATM, USAID, and the governments of Italy, Japan, and Norway. The next steps anticipated for ISAC are to review activities and estimate potential outcomes, to review and confirm the list for the second year of ISAC activities, and to review and start the activities of the second-tier countries (Bangladesh, the Democratic Republic of the Congo, Mozambique, Myanmar, Rwanda, Sri Lanka, the United Republic of Tanzania, and Zambia).

2.5 **DEWG subgroups**

2.5.1 Childhood TB

The progress and achievements of the Childhood TB Subgroup, established in 2003, were presented. The goal of the subgroup is to decrease the global burden of mortality and morbidity caused by TB in children. The objectives are to promote research and policy development, formulate and implement guidelines, mobilize human and financial resources, and collaborate with partners working in relevant fields – including maternal and child health, the Expanded Programme on Immunization (EPI), and HIV/AIDS. The main activities are:

- developing guidance for NTPs, on promoting childhood TB prevention and care;
- advising on acceptable case definitions and recording of childhood TB cases
- advising on child-friendly formulations and preparations of anti-TB drugs; and
- developing a proposal for implementation and research activities.

2.5.2 Laboratory capacity strengthening

The activities conducted in 2004 by the Subgroup on Laboratory Capacity Strengthening were presented. The group performed assessments in Bangladesh, Kenya, Pakistan, Romania, and Uganda. Assessments were planned for the Russian Federation (November 2004), Indonesia (December 2004) and Egypt (December 2004).

Other activities included development of the global strategy to improve the capacity of TB diagnostic services, revision of the laboratory assessment tool, and a review (and repackaging) of available international and national training materials. Members of the subgroup participated in several NTP reviews in collaboration with partners, translated the external quality assessment component of the *AFB Smear Microscopy Guidelines* into French, organized laboratory management training for managers of the national reference laboratories from the WHO Eastern Mediterranean Region, and organized the annual subgroup meeting in Paris in conjunction with the 5th meeting of the DEWG and the IUATLD World Conference on Health.

2.5.3 Public-Private Mix (PPM) DOTS

The activities of the Subgroup on PPM DOTS were presented. Two reports were published in 2003–2004: one on the cost-effectiveness of PPM, and a second on a cross-site analysis entitled *What makes PPM work?* The 2nd PPM-DOTS Subgroup meeting was held in India in February 2004. Intensified support for PPM-DOTS has been given to countries through missions to Bangladesh, China, India, Kenya, and Myanmar. A PPM-DOTS surveillance system is being piloted in 12 of 14 cities, scaling up PPM DOTS. Draft PPM guidelines are in preparation.

Since 1995, more than 40 PPM-DOTS projects have been initiated and more than 20 000 patients evaluated. Treatment success of new sputum-smear-positive cases in the private sector has increased substantially from baseline in a number of evaluated projects (i.e. Bangladesh, India, Indonesia, Myanmar, Nepal, the Philippines, and the Republic of Korea). Economic analysis has shown that patient costs have been reduced by more than 60% in PPM DOTS projects in Hyderabad and New Delhi, India, compared with private non-PPM DOTS. There is a high level of sustainability in PPM-DOTS projects such as Hyderabad (since 1995), the Damien Foundation in Bangladesh (since 1997), Nepal (since 1998), and several projects in India and the Philippines (which have been operational for between three and five years).

The way forward for the subgroup includes: continuing to decentralize and strengthen technical capacity for PPM DOTS; mainstreaming PPM DOTS into DOTS expansion; disseminating and emphasizing the international standard of TB care; facilitating resource mobilization through strengthening the PPM-DOTS component in GFATM proposals; exploring PPM DOTS-Plus and PPM for TB/HIV; developing documentation and guidelines for various PPM strategies (e.g. medical colleges, NGOs, individual private practices), and continuing operational research on PPM and poverty-related MDGs.

3. Evolution of DOTS

3.1 **TB care for all: evolution of the DOTS strategy**

Substantial progress has been made towards the 2005 global targets: the case-detection rate is 43% and the treatment success rate is 82%. The best forecast suggests that the treatment success global target will be achieved; however, DOTS expansion must be accelerated to reach the case-detection target.

The main directions for accelerating DOTS expansion and for adapting outreach to all are as follows.

- Continue to expand and sustain DOTS achievements, supporting countries in building capacity and mobilizing resources, within strengthened health systems.
- Advocate for:
  – DOTS, as the recognized public health strategy for TB control; and
  – the importance of individual patient care within DOTS.
- Engage all care providers, public and private, to increase access and use of an essential *standard of care* – especially among the poorest.
- Promote community participation and mobilize societies to increase:
  – demand for proper care; and
  – involvement in care.
- Adapt DOTS to high-HIV and multidrug resistant (MDR)-TB settings, and strengthen capacity to diagnose and manage sputum-smear-negative TB and drug-resistant cases.
- Strengthen monitoring and evaluation for problem-solving and for measuring achievements vis-à-vis World Health Assembly and MDG targets.
- Sustain the Stop TB Partnership and its working groups.

In addition to the essential public-health approach to TB, a care approach is also needed. Patient care to cure and prevent TB is the ultimate goal of DOTS. The foundation of DOTS is *effective patient care* – to alleviate suffering, as well as to control and prevent TB in a community. A standard of care for TB exists within DOTS, but that standard needs further promotion among all care providers. Stated simply, each care provider – public or private – should:

- diagnose TB quickly (i.e. bacteriological confirmation);
- treat TB properly (i.e. short course chemotherapy (SCC) and treatment support); and
- report TB cases and treatment outcomes.

3.2 **Developing an international standard for TB care**

The following resolution (WHA58.14) was presented and adopted by the Fifty-eighth World Health Assembly in May 2005.

> The 58th World Health Assembly—stressing the importance of the engagement of the full range of health providers in delivering the *international standard of tuberculosis care* in line with the strategy of DOTS—encourages all Member States to ensure that all TB patients have access to the *universal standard of care* based on proper diagnosis, treatment and reporting consistent with the DOTS strategy by promoting both supply and demand …

A standard is needed to bridge the apparent gap between tuberculosis care and tuberculosis control, and to provide a framework for both public-sector and private-sector providers that builds on the principles of DOTS. The Tuberculosis Coalition for Technical Assistance (TBCTA), which is

funded by USAID, will fund a 12-month project to develop this universal standard of care by an appointed steering/writing committee of 15 members. The launch of the final consensus document is planned for the IUATLD Conference to be convened in October 2005.

3.3 **The second Global Plan to Stop TB (2006–2015)**

The second Global Plan to Stop TB will build on the first Global Plan and Progress Report. This second Global Plan is needed to provide:

- a vision of what can be achieved;
- a road map to achieve targets;
- a tool for advocacy and fund-raising;
- support for long-term national planning; and
- stimulation for research and development.

The key features of the second Global Plan lie in its provisions which:

- lead to the 2015 Millennium Development Goals;
- have a10-year time frame;
- build on the first Global Plan and Progress Report;
- are complementary to the MDGs TB Working Group report;
- are consistent with the 2005 World Health Assembly resolution;
- support country needs for long-term planning and financial sustainability;
- develop strategic directions set out by the 2nd *ad hoc* Committee on the TB Epidemic;
- are based on contributions of the Stop TB working groups.

The development of the plan is coordinated by the Stop TB Partnership Secretariat, guided by a steering committee and based on contributions of the seven Stop TB Partnership working groups (DOTS Expansion, DOTS-Plus, TB/HIV, Drugs, Diagnostics, Vaccines, and Advocacy and Communications). Each working group will develop its work plan as a contribution to the Global Plan, facilitated by the secretariat of each working group. The second Global Plan will be finalized by September 2005 and launched by the end of 2005.

4. Laboratory services in the 22 HBCs

All 22 HBCs were asked to develop and prepare a poster presentation according to a template. The theme of the presentation was laboratory services and issues. These issues were presented and discussed in the following six groups.

Group 1: Afghanistan, Brazil, Nigeria, and the Russian Federation.
Group 2: Mozambique, Pakistan, and Thailand.
Group 3: Bangladesh, Kenya, Myanmar, and the United Republic of Tanzania.
Group 4: South Africa, Uganda, and Zimbabwe.
Group 5: Cambodia, India, the Philippines, and Viet Nam.
Group 6: China, the Democratic Republic of the Congo, Ethiopia, and Indonesia.

Summaries of the group discussions are presented in Annex 1.

4.1 **Laboratory issues: proposed action by the DEWG**

The group discussions led to consensus of the following proposed actions to be taken by the DEWG.

- **Advocacy strategy to enhance political commitment**: advocate to all partners (including governments, NTPs, and technical and financial agencies) the important role of the laboratory in TB control. Increase resources for laboratories (e.g. GFATM applications, World Bank, bilateral donors).
- **Strengthening of the human resources component**: ensure that enough human resources are available. Ensure competency of staff at all levels through standardized training, improved supervision and evaluation activities, and development and implementation of standard operating procedures.
- **External quality assurance (EQA**): ensure high-quality supervision and feedback mechanisms. Develop and implement slide re-checking/proficiency schemes. Link with the supranational reference laboratory.
- **Procure high-quality equipment and laboratory supplies.**
- **Improve communication between the NTP and laboratory management**: involve national reference laboratories in planning and budgeting. Invite laboratory managers to NTP meetings.
- **Facilitate field evaluation of new diagnostic tools**.

It is recommended that the DEWG Subroup on Laboratory Strengthening Capacity should:

- continue assessing laboratory systems in the HBCs;
- develop standardized training packages;
- strengthen the managerial capacity of national reference laboratory managers (training of trainers).

5. Key issues in DOTS implementation

5.1 **Human resources: the role of nurses**

Some challenges faced by nurses in TB control include the lack of nursing guidelines and research evidence; the lack of an international voice; and the large variation in resources, environment, and qualifications. Nurses should play an important role in TB control, because they work globally and they share common ideas and values.

Nurses can play a key role in obtaining the goal of at least 70% case detection and 85% treatment success in a community for a number of reasons. They are a first point of call in primary care services, and are involved directly in health education. They can follow the patient from presentation to registration, and perform many of the recording and reporting functions of a health facility.

Nurses may not be reaching their full potential in TB control because of the lack of strategic level representation, research evidence, and consistent training and materials. The TB control community should take full advantage of the potential of nurses by identifying leaders in the field and developing research and training opportunities.

5.2 **Collaboration with other health-care providers**

5.2.1 Scaling-up PPM DOTS in India

The Revised National TB Control Programme (RNTCP) of India has expanded implementation of DOTS from 87 districts (with a population of 188 million) in the first quarter of 2000, to 521 districts (906 million) in September 2004. The first PPM model began in Hyderabad in 1995; and between 2000 and 2003, PPM models were established in New Delhi, Kannur, Kollam, Mumbai, and the tea

gardens of the north-east. In 2002, private practitioners schemes were published, and in 2003 new PPM-DOTS activities were initiated in many districts.

An intensified PPM scaling-up began in 14 urban sites in 2003. By September 2004, more than 160 medical colleges, 800 NGOs, 5000 private practitioners and 80 corporate houses were involved in DOTS. Health-care facilities under ministries other than that of health have started implementing DOTS; these include the Ministries of the Railways, Employees State Insurance, and Mining, Coal, and Shipping.

In the second and third quarters of 2004, 61% of new sputum-smear-positive cases were detected by health providers, 18% by medical colleges, 8% each by private practitioners and NGOs, 4% by government facilities, and 0.2% by the corporate sector. With the scaling-up of PPM-DOTS projects, case detection and treatment success are on course to meet the 2005 global targets.

5.2.2 Business sector contributions to the global effort to Stop TB

The global health initiative is a partnership between the World Economic Forum, WHO (specifically Roll Back Malaria and the Stop TB Partnership) and UNAIDS, to increase the quality and quantity of private sector activity to fight HIV, TB, and malaria. Until two years ago, however, there was no real collective business action against TB.

The business sector should be involved in TB control because companies can reach related but diverse groups (e.g. workers, families, surrounding communities, suppliers and contractors, and consumers), bring expertise to people (through communication and marketing, distribution, project management, and research and development), and provide resources (in-kind contributions, people and cash). The private sector can help national TB programmes by reaching different segments of the population, often in difficult-to-reach rural, remote or dense urban areas. Synergistic outcomes include increased case detection and a maintained treatment success rate, better NTP country coverage and more available public health and private employers services. Two examples of successful business sector involvement in TB control are Chevron Texaco in Angola and the Indian Business Alliance to Stop TB. Within a 12-month period in Angola, the programme has detected an additional 555 cases with 92% treatment success. The Indian programme has led to raised awareness about TB, the implementation of DOTS in many workplaces, and a growing number of member companies.

5.2.3 Strengthening TB control through social franchising: experiences from Myanmar

Social franchising of DOTS has started in Myanmar using the Sun Quality Health (SQH) franchise through Population Services International/Myanmar (PSI). The SQH franchise has 470 clinics with over 500 doctors trained in 8 of 14 states/divisions, covering a combined township population of more than 17 million. The SQH franchise has had positive results in the reproductive health community and this model was used to integrate DOTS into SQH.

PSI worked with the national tuberculosis programme to develop the social franchising strategy. The NTP defined diagnostic and treatment protocols and private provider roles; reviewed training materials; provided laboratory training; conducted laboratory quality assurance and monitoring visits; provided fixed-dose combination (FDC) drugs; and facilitated government approvals. PSI defined the strategy for engaging private providers; selected and trained private providers; selected laboratories; facilitated laboratory quality assurance; collected data; branded and packaged FDC drugs; and designed, pre-tested, and produced print and video communications. In the first seven months of the project, 102 private providers were trained in DOTS; seven private laboratories were provided with training and accredited; and 1500 cases were detected (40% new smear positive). There are signs of a positive impact on overall case detection.

5.2.4 National partnership: Uganda

There has been an upward trend in TB case notifications in Uganda since 1995. The idea of a Stop TB Partnership came about as the need to coordinate the various activities of TB control stakeholders became apparent. The partnership has a number of objectives including those to:

- raise the profile of TB as a major public health problem in Uganda;
- improve the coordination of efforts by various stakeholders;
- harmonize work plans for a concerted effort to reach 2005 global targets and MDGs;
- mobilize extra financial and human resources;
- guide relevant operational research for TB control.

A commitment by the Minister of Health to meet global 2005 targets and the need to utilize available funds from CIDA, FIDELIS, GFATM, and USAID created the impetus to start the process of developing a partnership. WHO has offered to house the partnership and an interim executive secretary has been appointed. Terms of reference have been developed and approved. To date, several technical and financial partners have agreed to the partnership, with more expected to join. The partnership was to be launched in December 2004.

5.3 **Important issues for DOTS expansion**

5.3.1 TB and poverty

The World Development Report for 2004 summarized the fact that services in general fail for poor people within the contexts of access, quantity, and quality, but that services do work when the poor are put at the centre of service provision. Specifically, TB control programmes do not always reach the poor, but can be improved by putting TB control on the agenda in poverty reduction strategy papers, by accelerating development and implementation of pro-poor strategies, and by pursuing research and response on poverty.

The Network for Action on TB and Poverty is a platform for TB-control and poverty experts to coordinate actions in support of countries and the poor. The objectives of the network are to:

- assist pro-poor mainstreaming in DOTS expansion and TB;
- foster research to inform TB control operations and policy control; and
- advocate pro-poor approaches using DOTS and link up with other initiatives and funding.

The network will be governed by the Core Group on TB and Poverty, a subgroup of the DEWG. Terms of reference for the secretary have been developed and guidelines for NTP managers on TB and poverty will provide strategic and practical guidance to countries.

5.3.2 TB Diagnostic Kits Initiative

Rapid DOTS expansion to meet the 2005 global targets requires reliable and quality-assured laboratory diagnosis of TB. Supply constraints at the country level often threaten appropriate diagnosis, and have led the GDF to develop laboratory kits. Preliminary research has shown that laboratory kits may benefit HBCs by providing standardized high-quality products at cheaper prices, an easier procurement process, and a reduced incidence of stock outages and service disruptions.

Proposed laboratory kits include microscope kits, consumables kits (with ready-to-use ZN stains for 1000 smears), sputum-collection containers, and equipment starter kits. In-country piloting of kits will take place in the Congo (Brazzaville), Nigeria, and Sierra Leone. This piloting will evaluate the application process, provide comprehensive data collection, determine sustainability of kits, and evaluate opinions of NTP and laboratory staff.

5.3.3 Tuberculosis and HIV – future directions

The fourth meeting of the DEWG held in 2003, concluded that joint TB/HIV activities are necessary for TB control, because HIV drives TB incidence and mortality in high-HIV prevalence areas, TB is a

significant cause of mortality among HIV/AIDS patients, and – where the incidence of HIV is high and rising – DOTS alone is insufficient to control TB.

TB/HIV collaborative activities will establish mechanisms for collaboration, decrease the burden of TB in people living with HIV/AIDS, and decrease the burden of HIV in TB patients. The fourth meeting of the TB/HIV Working Group was held in September 2004, with the theme "Two diseases – one patient: scaling-up prevention and treatment for TB and HIV". The conclusions of that meeting were as follows.

- Significant progress has been made since Montreux.
- Current movement is good, but there is still a long way to go.
- The HIV-activist community is engaging in the effort.
- The partnership is expanding, and support for joint TB/HIV activities is coming from the African Union, the Prime Minister of Ethiopia, and the Director of the Centres for Disease Control and Prevention (CDC) in the USA.
- Focus is now on implementation in countries.
- Systems for measuring progress need to be strengthened.

Future directions of the TB/HIV Working Group include country implementation (e.g. technical assistance, expansion of evidence base, GFATM round 5 applications), advocacy at the country level (through supporting alliance with advocates), increased partnership activity, new tools, and sustainable funding.

5.4 **Integrating DOTS-Plus components into DOTS programmes**

The final session of the fifth meeting of the DEWG included a presentation on the magnitude of the MDR-TB problem, the availability of second-line drugs, the Green Light Committee (GLC) mechanism, and future plans and challenges. Based on resistance surveys in 64 countries and predictive data from 72 countries, the number of estimated new cases of MDR-TB in 2000 was 273 000. From June 2000 to August 2004, the GLC held 26 meetings and reviewed 38 applications – over 8000 patients are enrolled in 25 approved projects.

Advantages to applying the GLC mechanism are many, including the following:

- access to a continuous supply of quality-assured, low-cost drugs;
- access to technical assistance;
- access to an external monitoring mechanism;
- increased rational use of drugs;
- creation of wide evidence base for policy development;
- ensured consolidation of DOTS as the strategy to control TB.

While DOTS-Plus is more complicated than DOTS, it is feasible under routine programme conditions. Indeed, mainstreaming of DOTS and DOTS-Plus is already taking place in many settings. Future plans include development of new guidelines, training courses and field training; increased technical assistance; improved laboratory capacity-building; maintaining and upgrading GLC operations; resource mobilization; and continued policy development.

Three examples of countries in different stages of DOTS-Plus were presented.

1. **The United Republic of Tanzania**. DOTS-Plus preparation phase.
   The set of essential conditions (determined by the GLC as prerequisite to the introduction of DOTS-Plus into the country) was described, and the progress the country had been making to meet these conditions was assessed.

2. **The Philippines**. DOTS-Plus expansion and mainstreaming.

The status of DOTS-Plus in the country, and the issues and challenges involved in turning the DOTS-Plus pilot project into policy, were detailed.

3. **Latvia**. Full implementation and integration.
   A presentation was made on how full DOTS-Plus implementation has positively affected TB control and MDR-TB in the country.

6. Conclusions

The conclusions of the 5th meeting of the DEWG – presented by its Chairman – were as follows.

- Important laboratory issues should be addressed in all countries for further effective TB control and DOTS expansion. Proposals for action to be taken by the DEWG include:
  - countries must increase resources for laboratories;
  - laboratory human resources (quantity and quality) must be strengthened;
  - external quality assurance systems must be established;
  - high-quality equipment and laboratory supplies are needed;
  - collaboration is necessary between the NTP and laboratory managers;
  - standardized training packages must be developed;
  - managerial capacity of national reference laboratory managers needs to be strengthened;
  - field evaluation of new diagnostic tools must be facilitated.

- DOTS has evolved from the mid-1990s. The first standardized framework for TB control and DOTS branding were introduced to the expanded DOTS framework in early 2000.

- The TB control strategy used today is based on the *Expanded DOTS framework for TB control*, published in 2002. That framework includes the following approaches.
  - political commitment;
  - diagnosis with bacteriology confirmation – microscopy, culture and drug-susceptibility testing (DST);
  - standardized treatment under proper case-management conditions, including directly observed treatment (DOT);
  - uninterrupted drug supply to the patient;
  - an adequate recording and reporting of cases and treatment outcomes.

- The main directions needed to accelerate DOTS expansion and reach all patients involve:
  - expanding and sustaining DOTS achievements within strengthened health systems;
  - emphasizing, first, DOTS as the public health strategy for TB control, and second, the importance of individual patient care with DOTS;
  - improving diagnostic capacity and reliability;
  - engaging all care providers – public and private – to increase access and use of standard of care, especially among the poorest;
  - promoting participation of community and social mobilization for TB care;
  - streamlining TB/HIV activities and treatment of MDR-TB with DOTS programme activities;
  - strengthening monitoring and evaluation for problem-solving and to measure achievements vis-à-vis World Health Assembly and MDG targets;

- increasing communication among Stop TB Partnership working groups;

- The DEWG must continue to link with the GFATM, World Bank, and bilateral and multilateral donors, to broaden the scope of activities, which include:
  - laboratory strengthening
  - PPM-DOTS (engaging all health-care providers)
  - ISAC (human resources/capacity building)
  - GDF (quality drug supply)
  - advocacy, communication, and social mobilization
  - building and funding partnerships
  - drug resistance surveillance (DRS) and MDR-TB
  - TB/HIV
  - monitoring (internal, external, MDGs).

7. Next meeting

The next meeting of the DEWG will be held jointly with the TB/HIV Working Group and the DOTS-Plus for MDR-TB Working Group and will take place from 15 to 17 October in the Palais des Congrés, Versailles, France. A symposium will be held on 18 October as part of the 36th Union World Conference on Lung Health of the IUATLD.

Annex 1
Summaries of group discussions on laboratory services in the 22 HBCs

Group 1. Afghanistan, Brazil, Nigeria, and the Russian Federation

DOTS coverage varies in these countries from 17% in the Russian Federation to 60% in Nigeria, but remains low in all. The case-detection rate also varies widely – from 20% in Afghanistan to 81% in Brazil – although the DOTS detection rate is low in all countries. All countries rely on chest x-ray for diagnosing sputum-smear-negative patients. Brazil and the Russian Federation also refer the patient for culture; however, the capacity and quality assurance (QA) of culture in the Russian Federation is inadequate.

Data on MDR-TB is lacking in both Afghanistan and Nigeria. Brazil has a low percentage of patients with MDR-TB because they use fixed-dose combination drugs. Parts of the Russian Federation have high rates of MDR-TB (3–11% in new cases; 26–30% in retreatment cases).

All of these countries face challenges to their laboratory services.

- **Afghanistan**. The main issue is the lack of a reference laboratory. Overall, there are few laboratories and diagnostic centres. Those that do exist lack sufficient quantity and quality of staff and quality assurance. Increased government commitment is needed.
- **Brazil** has a centralized laboratory network with approximately 4000 local laboratories which are performing sputum-smear microscopy, 137 laboratories which are performing culture, and 33 which are capable of performing drug susceptibility testing (DST). The main challenge is the development of an information system to cover the large number of laboratories in the country. The recent decentralization of the health system did not take laboratories into account, which has resulted in shortages of funding for the laboratory network.
- **Nigeria** has a laboratory network with over 500 microscopy centres. However, quality assurance of sputum-smear microscopy is a major challenge due to lack of funding. Government commitment needs to be increased. The establishment of two national reference laboratories is a priority.
- **The Russian Federation** has a weak laboratory network that needs better links to the five federal-level laboratories. Currently, an administrative reform is in progress that will have effects at the laboratory level. There is a continued lack of human resources and quality assurance, and necessary training is needed.

In general, national reference laboratories and reference laboratories below the national level are either weak or do not exist. Information systems and human resource capacities are inadequate. Supplies and equipment are insufficient. All countries need to establish or improve their quality assurance systems.

Group 2. Mozambique, Pakistan, and Thailand

The case-detection rate varies from 32% in Pakistan, to 55% in Mozambique, to a high of 81% in Thailand. All countries have treatment success rates of approximately 75–78%. Mozambique and Pakistan diagnose smear-negative patients through clinical symptoms and chest x-ray. Thailand diagnoses some of its smear-negative cases with culture in the national laboratory. All three countries have national reference laboratories with DST capability.

Additionally, some private laboratories in Pakistan and seven laboratories in Thailand also perform drug susceptibility testing. All of these countries face challenges to their laboratory services.

- **Mozambique**. There are constraints to human resources development and training, and additional reference laboratories are needed in the central and northern parts of the country. Quality assurance remains inadequate, and the laboratory capacity of peripheral health centres needs to be improved. Planned activities for 2005 include establishing two new reference laboratories and exploring ways to increase human resources for laboratory services.
- **Pakistan**. An intermediate-level laboratory service and standardization of training and laboratory supplies are needed. Quality assurance remains inadequate, and human resources are lacking. In 2005, Pakistan plans to implement external quality assurance (EQA) and develop an intermediate laboratory network.
- **Thailand**. There is good capacity for smear microscopy, although culture capacity needs to be strengthened at provincial hospitals. Building capacity for DST in the regions also remains a challenge. Training is needed for non-licensed staff for smear microscopy. In 2005, Thailand will build additional capacity for culture and DST, and explore ways to incorporate rapid diagnostic methods for detection of *M. tuberculosis* and drug resistance.

Group 3. Bangladesh, Kenya, Myanmar, and United Republic of Tanzania

The case-detection rate varies from 41% in Bangladesh to 74% in Myanmar. All four countries have treatment success rates at or above 80%. All of these countries face challenges to their laboratory services.

- **Bangladesh**. The major challenges are to increase and maintain high levels of commitment at policy levels for microscopy quality, to supervise and extend the implementation of QA of sputum microscopy, and to expand acid-fast bacilli (AFB) culture and DST for drug resistance surveillance. The planned priority actions in 2005 are to build capacity through basic and refresher training, expand diagnostic services by establishing new microscopy centres in all *Upazilas* with populations over 300 000, and implement quality assurance of sputum microscopy in all urban and rural diagnostic centres.
- **Myanmar** lacks quantity and quality of staff in the laboratory services, has a weak EQA system, and weak overall supervision of laboratories. The planned priority actions in 2005 are human resources development, strengthening of the EQA system, strengthening of culture and DST at the national reference laboratories in Yangon and Upper Myanmar, and expansion of culture facilities to four state/divisional laboratories.
- **Kenya**. The major challenge is inadequate human resources, which is hampering the decentralization process. There is also an inadequate budgetary allocation for supervision of laboratory services. The priorities for laboratory services in 2005 are to strengthen the EQA system and supervision, increase the laboratory technical staff to support decentralization, expand the linkage between public and private laboratory networks, and improve the technical capacity of the central reference laboratory.
- **The United Republic of Tanzania** has a shortage of qualified laboratory staff and unsatisfactory implementation of the QA programme for smear microscopy. In 2005, the priorities are drug resistance surveillance, improvement of the quality of supervision of peripheral laboratories, minimization of laboratory cross-contamination, and validation of "Ora-Quick" for TB/HIV surveillance.

In general, the main constraints within these countries are human resources (quantity and quality), quality assurance of smear microscopy, and equipment/supplies.

Group 4. South Africa, Uganda, and Zimbabwe

The case-detection rate varies from 47% in Zimbabwe to 53% in Uganda to over 90% in South Africa. All three countries have treatment success rates below the 85% target: Uganda at 61%, South Africa at 65%, and Zimbabwe at 70%. The estimated percentage of MDR-TB in new cases is below 2% for all these countries. The challenges faced by the laboratory services, and planned actions include the following.

- **Uganda**. The main challenges include the lack of an EQA system and lack of trained technicians. The priority actions for 2005 include drug resistance surveillance, EQA implementation, and recruitment of staff.
- **South Africa** has a reference laboratory but it is not integrated with the NTP. The turn-around time for sputum smear microscopy needs to be improved. The country plans to establish a national reference laboratory and improve turn-around times.
- **Zimbabwe** lacks trained laboratory staff and improvements are needed in supervision. The planned priority actions for 2005 are to establish and strengthen the EQA system, strengthen capacity for culture and DST, and improve supervision.

Group 5. Cambodia, India, Philippines, and Viet Nam

DOTS coverage is high in all four countries: 73% in India, 83% in Cambodia, and 100% for both the Philippines and Viet Nam. With the exception of Viet Nam, these countries have not met the global target of 70% case detection (54% in India – 69% in DOTS areas, 59% in Cambodia, and 61% in the Philippines). Treatment success rates are above the global target in all countries (in all DOTS areas in India).

Since 2000, drug-resistance surveys have been completed in Cambodia, the Philippines, and Viet Nam. The percentage of TB/HIV dual infection varies from 3.2% in Viet Nam, to 4.6% in India, to a high of 12% in Cambodia. All countries are either implementing or in the planning stages of PPM-DOTS projects. All of these countries face challenges to their laboratory services.

- **Cambodia**. Procurement of equipment and supplies, quality of staff, and low salaries are the main challenges.
- **India**. Shortage of laboratory technicians and capacity building are the main challenges.
- **The Philippines**. Guidelines for the laboratory network and strict definitions of laboratory functions are needed.
- **Viet Nam**. An EQA system needs to be implemented.

EQA has been implemented in Cambodia, India, and the Philippines. Viet Nam uses traditional QA. All countries have functioning national reference laboratories for QA, training, monitoring, and surveillance. Smear microscopy is the priority for all countries, though culture is performed for specific purposes. However, all countries need better definitions or criteria for the use of culture.

Group 6. China, Democratic Republic of the Congo, Ethiopia, and Indonesia

The case-detection rate varies from 40% in Indonesia, to 46% in Ethiopia, to 65% in the Democratic Republic of the Congo. Treatment success rates are above the global target only in China (92%). That rate is 82% in Ethiopia and 78% in the Democratic Republic of the Congo. The percentage of MDR-TB in new cases varies from 1.3% in Ethiopia to 7.6% in China.

- **China**. The government is highly committed to improving laboratory services for DOTS expansion. There are one central reference laboratory and 31 provincial reference laboratories.
- **The Democratic Republic of the Congo**. In the one national reference laboratory and 20 provincial laboratories, services are challenged since 50% of smear-positive TB patients are HIV-positive. There is also instability among the health staff due to country conflict and war.

- **Ethiopia**. Intermediate management of laboratory services is greatly needed. Standardized training, which includes training modules and regional training teams, has been established.

The main challenges for laboratory services in all four countries include shortage of trained laboratory staff, absence or weakness of laboratory networks at the regional and provincial levels, supply problems, and absence or weakness of QA systems. Plans to address these challenges include human resources development, establishing and strengthening national reference laboratories, supportive supervision of intermediate and peripheral laboratories, operational research, and focused attention to logistics.

Annex 2
Agenda

27 October 2004 – by invitation

7:30–8:30	Registration	
8:30–9:15	Welcome	K. Shah (DEWG Chair)
	TB care for all: evolution of DOTS strategy	M. Raviglione (Director, WHO/STB)
	Evidence for standard of care	P. Hopewell (ATS/TBCTA)
9:15–10:00	Progress towards the 2005 targets and next steps	C. Watt (WHO, HQ)
	The Global Plan to Stop TB, part 2 (2006–2015)	D. Maher (WHO, HQ)
	Discussion	
10:00–10:30	Report from the secretariat: Achievements in 2003/2004	L. Blanc (WHO, HQ)
	Discussion	
10:30–11:00	*Coffee break*	
11:00–11:45	Reports from the DEWG subgroups	
	11:00–11:15 Childhood TB	R. Gie (South Africa)
	11:15–11:30 Laboratory strengthening	F. Portaels (Belgium)
	11:30–11:45 PPM	K. Lönnroth (WHO, HQ)
11:45–12:15	Quality of care for all	F. Matthys (MSF)
12:15–13:30	*Lunch*	
13:30–15:30	Country presentations and group discussions on increasing case detection with a special focus on laboratories.	
15:30–16:00	*Coffee break*	
16:00–18:00	Report from the group discussions, including outline of needs to strengthen laboratories.	

Group	Room	Countries	Facilitator
Group 1	351	Afghanistan, Brazil, Nigeria, Russian Federation	S. Bacheller (USAID)
Group 2	330/331	Mozambique, Pakistan, Thailand	C. Wells (CDC)
Group 3	332/333	Bangladesh, Kenya, Myanmar, United Republic of Tanzania	C. Hanson (PATH)
Group 4	336/337	South Africa, Uganda, Zimbabwe	A. Trébucq (IUATLD)
Group 5	353	Cambodia, India, Philippines, Vietnam	I. Onozaki (Chiba Foundation)
Group 6	352A	China, Democratic Republic of the Congo, Ethiopia, Indonesia	J. Broekmans (KNCV)

28 October 2004 – open meeting

8:30–9:00	Welcome	K. Shah (DEWG Chair) N. Billo (IUATLD)
	Report of day 1	C. Basri (Rapporteur)
9:00–9:30	Progress towards the Millennium Development Goals	C. Dye (WHO)
9:30–10:00	Human resources: the role of nurses in TB control Discussion	G. Williams (IUATLD)
10:00–10:30	*Coffee break*	

Session Chair: M.J. Chakaya (Kenya)

10:30–11:00	Report from the secretariat: Intensified support and action countries (ISAC) initiative Discussion	K. Shah (DEWG Chair)
11:00–12:30	Collaboration with other health-care providers	
11:00–11:15	1. Scaling up PPM	L.S. Chauhan (India)
11:15–11:30	2. TB management in the workplace	F. Boldrini (WEF)
11:30–11:45	3. Strengthening TB control through social franchising/marketing: experiences from Myanmar	G. Stallworthy (PSI)
11:45–12:00	4. National partnership	F. Adatu-Engwau (Uganda)
12:00–12:30	Discussion	
12:30–13:45	*Lunch*	
13:45	Working groups of Stop TB Partnership	M. Espinal (Executive Secretary, STB Partnership)

Session Chair: E. Luna (Brazil)

13:45–14:15	TB and poverty	P. Gondrie (KNCV) M. van Cleeff (KNCV)
14:15–14:30	The Global TB Drug Facility's diagnostic kits for AFB microscopy	C. Mundy (MSH)
14:30–15:30	TB/HIV: future directions after the 4th Working Group Meeting in Addis Ababa	P. Nunn (WHO, HQ)
15:30–16:00	*Coffee break*	

Session Chair: J. Lagahid (Philippines)

16:00–17:30	Integrating DOTS-Plus components into DOTS programmes	K. Lambregts (WHO, HQ)
16:30–16:45	1. United Republic of Tanzania: DOTS-Plus preparation phase	S. Egwaga (United Republic of Tanzania)
16:45–17:00	2. Philippines: DOTS-Plus expansion and mainstreaming	T. Tupasi (Philippines) R. Vianzon (Philippines)
17:00–17:15	3. Latvia: full implementation and integration	V. Leimane (Latvia)
17:15–17:30	Panel discussion	
17:30–18:00	Conclusions	K. Shah (DEWG Chair)

Annex 3
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