

**Fourth annual meeting of the
Stop TB Working Group on
DOTS-Plus for MDR-TB**

**Paris, France
27–28 October 2003**



**World Health Organization
Geneva**

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Summary

The fourth annual meeting of the Stop TB Working Group on DOTS-Plus for MDR-TB (multidrug-resistant tuberculosis) was held 27–28 October 2003 in Paris, France. Its purpose was to review the progress made since the previous meeting of the Working Group, held in Tallinn, Estonia, 10–12 April 2002, and to discuss future directions. More than 130 people attended the meeting, representing 36 countries, bilateral and multilateral agencies, international organizations, nongovernmental organizations, the pharmaceutical industry, and universities. This document summarizes the presentations, discussions, conclusions, and recommendations of the meeting.

The meeting was divided into three sessions:

1. From Tallinn to Paris
2. The Green Light Committee (GLC) and DOTS-Plus
3. Future steps: from research to policy.

The first session outlined the overall progress made by the Working Group and focused on access to and quality of second-line drugs. The second session was devoted to the achievements and challenges of the DOTS-Plus pilot projects and the GLC. The future of DOTS-Plus, including the plan for developing guidelines on MDR-TB management, was discussed during the final session. In addition, partner organizations outlined their future perspectives on MDR-TB control.

Background

MDR-TB is one of the greatest threats to TB control. Although DOTS is the most effective strategy for preventing the development of MDR-TB, short-course chemotherapy – one of the five components of DOTS – does not cure the majority of MDR-TB cases. Control of MDR-TB requires sound implementation of DOTS to prevent the occurrence of new cases and a careful introduction of second-line drugs, with adequate laboratory support, to stop the creation and circulation of resistant strains. In 1999, the World Health Organization (WHO) and its partners launched DOTS-Plus to develop global policy on the management of MDR-TB and to foster rational access to second-line drugs. As part of this process, and with continuous monitoring by the GLC, several DOTS-Plus pilot projects have been established to evaluate the feasibility and cost-effectiveness of using second-line drugs for managing MDR-TB in resource-limited settings. Projects approved by the GLC have access to quality-assured, concessionally priced, second-line drugs and benefit from technical support and monitoring.

In 1999, the WHO Working Group on DOTS-Plus for MDR-TB (later renamed the Stop TB Working Group on DOTS-Plus for MDR-TB) was established with the following objectives:

- to assist in producing policy recommendations for Member States on the management of MDR-TB, based on assessment of the feasibility, effectiveness, and cost-effectiveness

data generated by pilot projects implemented by the agencies/institutions participating in the Working Group, or by WHO;

- to coordinate and monitor the implementation of internationally comparable pilot projects for the management of MDR-TB – representatives of participating agencies/institutions will in most cases be acting as principal investigators on behalf of the bodies they represent;
- to establish a system that allows WHO Member States to have access to high-quality second-line drugs at reduced prices and, at the same time, prevents misuse of such drugs;
- to review progress achieved within the DOTS-Plus initiative;
- to identify resources to fund and implement DOTS-Plus pilot projects and to assist with global coordination of the initiative.

Five subgroups have been created under the Working Group:

- A core group – to assist the Secretariat in rapidly implementing the recommendations of the Working Group and in pursuing its objectives and aims.
- The GLC – to foster access to and rational use of concessionally priced second-line drugs.
- A subgroup on drug procurement – to address issues related to increasing access to second-line drugs.
- A scientific panel on clinical, laboratory, and programmatic issues – to offer guidance to the GLC.
- A subgroup on laboratory issues – to standardize drug susceptibility testing (DST) methods for second-line drugs.

Objectives of the meeting

The objectives of the meeting were to:

- present the progress of the Working Group and its subgroups;
- present the newly developed collaboration between the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the GLC;
- discuss the progress of the GLC-approved DOTS-Plus pilot projects;
- outline a plan for mainstreaming DOTS-Plus with DOTS expansion;
- provide updates on aspects of the control, research, and monitoring of MDR-TB;
- elect a new chair of the Working Group.

Opening of the meeting and welcoming remarks

Dr Léopold Blanc, Coordinator, TB Strategy and Operations, WHO, opened the meeting and welcomed the participants on behalf of WHO. He stressed that the merger of DOTS-Plus with DOTS is a priority for WHO – in the future there will be no special DOTS-Plus projects but rather routine MDR-TB management as part of the general activities of national tuberculosis control programmes (NTPs).

Dr Marcos Espinal, Executive Secretary of the Stop TB Partnership, emphasized that the activities of the Working Group have given more people from resource-limited countries access to adequate MDR-TB treatment. The future challenge for the Working Group is to develop the global policy on MDR-TB management for comprehensive TB control, building on the experiences gained in the DOTS-Plus pilot projects.

As Acting Chair of the Working Group, Dr Kai Vink, Estonia, welcomed the participants and outlined once more the urgent need to obtain evidence from the pilot projects to develop the future policy on MDR-TB management.

Session 1: From Tallinn to Paris

Session 1 was chaired by Dr Kitty Lambregts, Royal Netherlands Tuberculosis Association (KNCV); Mr Rajesh Gupta, WHO, served as rapporteur.

Progress of the Working Group

Dr Vink reported on the progress made by the Working Group since the meeting in Tallinn. The approval of eight new DOTS-Plus pilot projects by the GLC has granted treatment with concessionally priced drugs to 1864 additional MDR-TB patients. So far, projects covering approximately 4000 MDR-TB patients have received approval by the GLC.

At the GFATM board meeting in October 2002, it was decided that requests for second-line drugs for MDR-TB should go through the GLC to prevent their misuse and allow access to high-quality drugs and GLC technical assistance. This collaboration will increase the access to second-line drugs in resource-limited settings. In July 2003, the convergence of the Global TB Drug Facility (GDF) and the GLC was completed. On 5 June 2003, Eli Lilly announced that they will share their manufacturing technology for capreomycin and cycloserine with companies in high MDR-TB settings.

With regard to progress on laboratory issues, the determination of clinically relevant in vitro resistance criteria of second-line drugs is continuing. To ensure quality of drugs, WHO has started the process of pre-qualifying manufacturers of second-line drugs. One of the recommendations of the previous Working Group meeting was that the MDR-TB research agenda should be finalized. An article has been published in the *International Journal of Tuberculosis and Lung Diseases* and an internet database on global MDR-TB research has

been developed that covers more than 76 projects from 27 countries. Finally, Dr Vink presented the following future plans of the Working Group:

- mainstream DOTS-Plus with DOTS expansion;
- decentralize DOTS-Plus technical assistance to WHO regional and country offices and partners;
- collect and analyse data from pilot projects to serve as an evidence base for future guidelines on MDR-TB management;
- develop practical guidelines on DST of second-line drugs;
- continue to pursue second-line drug price reduction and technology transfer and ensure adequate quality of second-line drugs;
- promote research activities within the framework of the prioritized research agenda.

The need to push for reduced prices not only of second-line drugs but also of MDR-TB diagnostics and infection control in order to be able to implement MDR-TB control in low-income settings was stressed by several participants. Discussions also dealt with the need to create a second-line drug stock – at a cost of US\$ 1.3 million – to ensure timely procurement for DOTS-Plus pilot projects.

GFATM and GLC: role in increasing access to second-line drugs for MDR-TB

A presentation by Mr Guido Bakker, GFATM procurement manager, GFATM, focused on the collaboration between the GFATM and GLC. The GFATM is a funding mechanism, not an implementing agency. Its overall purpose is to attract, manage, and disburse resources to fight HIV/AIDS, TB and malaria. As mentioned by Dr Vink, the GFATM board has decided that all procurement of second-line drugs must be done through the GLC. A country that obtains funding approval from the GFATM on management of MDR-TB has to submit an application to the GLC in order to receive funding for second-line drugs. To date, 14 countries have been approved by the GFATM for second-line drugs, of which six have also submitted applications to the GLC: funds totalling US\$ 38 million have been granted to these countries for MDR-TB treatment for five years.

Before the GFATM was established, few resources were available for second-line drugs – and manufacturers were reluctant to invest in the production of these drugs. Now, with funding available from the GFATM, manufacturers are more likely to produce these drugs competitively and with assured quality. Mr Bakker expressed concern that the new WHO initiative to pre-qualify manufacturers of second-line drugs may have a negative impact on the supply.

It was pointed out that the agreement between the GFATM and GLC is unique; there are no similar agreements for first-line TB drugs or for drugs to treat HIV/AIDS and malaria. Countries that are granted GFATM support follow their own procurement mechanisms for first-line TB drugs. However, the GFATM has established a procurement assessment group that makes informal evaluations of national regulations: if these are found to be inadequate, the GFATM recommends drug purchase through the GDF or other agencies. Dr Lembit Rägo, Coordinator, Quality Assurance and Safety of Medicines (QSM), WHO, urged the GFATM to support the strengthening of quality assurance and national regulatory systems.

Procurement of second-line drugs for MDR-TB – status, challenges, and future prospects

The presentation by Mr Henk van den Besten, International Dispensary Association (IDA), focused on the status of, and challenges and future prospects for, second-line drug procurement. In July 2001, an agreement was signed between WHO and IDA for the procurement, quality assurance, and distribution of second-line drugs for projects approved by the GLC. The purpose of this agreement is to ensure uninterrupted supply of high-quality products at the lowest price achievable through economies of scale. The challenges faced by IDA may be summarized as follows:

- The limited market for second-line drugs means that they are not kept in stock but have to be ordered in response to a request comes.
- Some of the products have short shelf-lives.
- The products may not be registered in the countries where they are to be used.

Mr den Besten stated that IDA has its own quality assurance and quality control mechanisms and studies product protocols and conducts site visits. Future priorities for IDA include identifying new drug sources, further lowering of prices, and supporting technology transfer projects. Questions were raised as to whether IDA has the same quality requirements as QSM; Mr van den Besten informed the meeting that IDA has its own specific procedures but has initiated discussions on collaboration with QSM.

Quality and pre-qualification of second-line drugs for MDR-TB

Dr Rågo presented WHO's work in the field of quality and pre-qualification of drugs. In collaboration with other United Nations agencies, WHO has recently completed the first phase of a project to ensure the quality, safety, and efficacy of HIV/AIDS medicines and diagnostics. This work has yielded a list of suppliers whose products have been found acceptable for procurement by United Nations agencies, which can be used for guidance in the selection of suppliers of HIV/AIDS products. Based on the experience of the pre-qualification of HIV/AIDS drugs, WHO has started the same process for anti-TB and antimalarial medicines.

The pre-qualification project involves two major components – evaluation of product data and information provided by manufacturers and suppliers, and inspection of manufacturing sites. The process is voluntary and transparent and does not imply any cost for the manufacturers. With regard to second-line drugs, one expression of interest was published in June 2003 but no application has yet been received from a manufacturer of second-line drugs. It was hoped that this situation would change after the next assessment in November 2003.

The pre-qualification project in general and the experience gained from HIV/AIDS provide quite positive indications that good-quality generic products do exist. A relatively large number of antiretroviral products and suppliers are included on the WHO "white list" of manufacturers, and many potential suppliers have appreciated the feedback from the project and shown willingness to improve. On the negative side, only a limited number of products have met the standards, and it takes time for non-compliant manufacturers to improve. In conclusion, Dr Rågo urged IDA and the Working Group to encourage second-line drug manufacturers to apply for pre-qualification, to provide manufacturers with technical assistance to achieve compliance with required standards, and to be committed to creating a pool of suppliers whose products meet international standards.

Eli Lilly/Partners/WHO initiative on MDR-TB control

Dr Patrizia Carlevaro, Eli Lilly, gave a presentation on the Lilly MDR-TB Partnership. The company has initiated a US\$ 70 million MDR-TB programme with the following aims:

- To transfer technology for the manufacture of capreomycin and cycloserine to China, India, and South Africa and possibly the Russian Federation. This will ensure the long-term availability of second-line drugs at a low cost and will increase the local capacity in developing countries for the production, distribution, and sales of high-quality drugs.
- To increase the production of capreomycin and cycloserine and continue to provide these drugs at a fraction of their cost to GLC-approved DOTS-Plus pilot projects.
- To support training in and treatment and surveillance of MDR-TB as follows. WHO will develop a global MDR-TB monitoring system and provide technical assistance to DOTS-Plus pilot projects; the Centers for Disease Control and Prevention (CDC) will monitor MDR-TB, Harvard University will develop two MDR-TB centres of excellence, and the International Council of Nurses will develop guidelines for nurses on treating MDR-TB.

Dr Lambregts expressed concern that the technology transfer will also mean that the manufacturing plants will sell products to non-GLC approved projects; she mentioned China as an example. Dr Carlevaro informed the meeting that the plant in China will produce only the active pharmaceutical ingredient and that the capacity will still be limited to fit the GLC demands. However, it cannot be guaranteed that sales to non-GLC approved projects will be prevented.

Session 2: GLC and DOTS-Plus – achievements, challenges, and constraints

Dr Charles Wells, CDC, chaired the session and Dr Ernesto Jaramillo, WHO, served as rapporteur.

GLC update

Dr Lambregts presented the achievements of the GLC since the Tallinn meeting. Currently, there are 16 GLC-approved DOTS-Plus pilot project with a cohort size in excess of 4000 patients. In addition, 11 projects are under review (3000 patients) and another 10 countries are planning to apply (3000 patients). This total of 10 000 MDR-TB patients shows that the number of patients treated with approval and support from the GLC could increase significantly in the near future. At the same time, Dr Lambregts stressed that most countries in the world are already using second-line drugs – often without representative drug resistance surveillance (DRS) data, without quality assurance of the drugs, without proper guidelines, without a regular and adequate supply of drugs, and without treatment outcome monitoring. She mentioned the important agreement between the GFATM and the GLC and also stressed that the GFATM would save approximately US\$ 20 million by purchasing second-line drugs through the GLC for the countries it has already approved. The GLC has been instrumental in providing technical assistance to 17 countries for the preparation of applications to the GLC. There have been 11 missions as part of the GLC review mechanism and 13 DOTS-Plus pilot project monitoring missions. The GLC has been

operational for three years – the time has now come to produce the global policy on MDR-TB management. Future challenges include: adequate financial support to the GLC and for DOTS-Plus coordination, capacity building, laboratory strengthening, mainstreaming of DOTS and DOTS-Plus, and acceleration of DRS activities.

Results from DOTS-Plus pilot projects

Ms Eva Nathanson, WHO, presented the results of a survey among GLC-approved DOTS-Plus pilot projects on MDR-TB policy and practice, epidemiology, laboratory aspects, DRS, clinical characteristics, treatment regimens and outcomes, drugs and side-effects, and infection control. Although nine pilot projects replied to the questionnaire, the presentation focused on the pilot projects with treatment outcome results – Estonia, Latvia, Peru, the Philippines and the Russian Federation (Tomsk oblast).

By October 2003, 2577 MDR-TB patients had been enrolled for treatment in these projects and 1103 had finished treatment. Prevalence data show that the levels of MDR-TB and of resistance to second-line drugs are extremely high, particularly in Estonia, Latvia, and Tomsk. Estonia, Latvia, and Tomsk hospitalize all MDR-TB patients at the start of treatment, while Peru and the Philippines provide MDR-TB treatment on an ambulatory basis. All the projects use surgery except for the Philippines. Incentives and enablers are used for the patients in all projects except in the Philippines, and in Estonia, Peru, and Tomsk, incentives are also given to DOT (directly observed treatment) providers. All projects use individualized treatment regimens based on DST of first- and second-line drugs. The average number of drugs used per MDR-TB patient ranges from 5.5 to 6.1.

Studying the drug resistance pattern in MDR-TB patients shows that only a fraction are resistant to rifampicin (R) and isoniazid (H) only, while most are resistant to all first- and second-line drugs (57%). Moreover, the profile of MDR-TB cases shows that 53% and 35% of the MDR-TB patients in Estonia and Latvia are new, while in Peru and Tomsk most patients are re-treatment cases. Interim analysis of treatment outcomes from Latvia, the Philippines, Peru and Tomsk shows promising results: default rates are under 11% and cure rates range from 61% to 82%. Among 924 patients enrolled from Estonia, Latvia, Orel (Russian Federation, data included on adverse events), Philippines and Tomsk, only 2% have had to stop treatment due to severe adverse events.

It was pointed out that the figures on adverse events are difficult to interpret as there are no standard definitions used across the projects for adverse events. DST of second-line drugs is not standardized, and resistance data should therefore be treated with caution. In addition, the average number of drugs used is not standardized. If one drug is replaced as a result of adverse reactions does that count as one drug or two? If the patient starts on an empiric regimen and then continues with an individualized treatment regimen, should all those drugs be counted?

Panel discussion with pilot project representatives: lessons learnt and constraints

Drs Manfred Danilovits (Estonia), Vaira Leimane (Latvia), Jaime Bayona (Peru), Thelma Tupasi (Philippines) and Alexander Pasechnikov (Tomsk) briefly presented their main challenges to DOTS-Plus implementation. A panel discussion followed. The main impediments to DOTS-Plus implementation are the following:

- high default rates due to poor adherence among the large number of alcohol-dependent patients in Estonia, Latvia and Tomsk;
- rapid increase in HIV infection in Estonia and Latvia, which may have a negative impact on the MDR-TB epidemic;
- the need for infection control and protection of health care workers
- the urgent need for rapid diagnostic methods to detect MDR-TB;
- the lack of standardization of DST of second-line drugs;
- the need to manage adverse drug reactions.

Adverse events in the treatment of MDR-TB: results from five DOTS-Plus pilot projects

Dr Leimane presented the Latvian experience on adverse reactions to second-line drugs and data on a comparative study between five DOTS-Plus pilot projects. In Latvia there is a clinical protocol for the registration of adverse reactions, which are classified as mild (treatment regimen not changed), moderate (interruption of causative drug or all drugs for a short time) or severe (discontinuation of causative drug). Among 367 MDR-TB patients treated, 39% experienced moderate or severe adverse reactions: of this proportion, 24% had to discontinue the causative agent and 13% had to alter the treatment. Of the patients with adverse reactions, 1.6% of those with severe co-morbidities and/or extensive drug resistance completely interrupted treatment. Adverse reactions were reported more often among female patients than male (87% compared with 37%).

The most common adverse events were gastrointestinal problems, hearing disturbance, allergic reactions and arthralgia. In order of importance, the main causative second-line drugs were *p*-aminosalicylic acid (PAS), protionamide, capreomycin and kanamycin. Dr Leimane pointed out the limitations imposed by the lack of standardization in defining the nature and severity of adverse events and the difficulty of identifying the causative drug in multiple drug regimens. She also reported the results of a study on adverse events among 818 patients from the DOTS-Plus pilot projects in Estonia, Latvia, Peru, the Philippines and Tomsk. Only 2% of these patients stopped treatment but 30% required removal from the regimen of the drug(s) thought to have caused the adverse events. The five most common adverse events were nausea/vomiting (33%), diarrhoea (21%), arthralgia (16%), dizziness/vertigo (14%) and hearing disturbances (12%). Dr Leimane concluded that adverse events are manageable in the treatment of MDR-TB in resource-limited settings provided that standard management strategies are applied.

Special session: MDR-TB treatment in South Africa

Dr Karin Weyer, South Africa, shared the experiences of MDR-TB management in South Africa, a country where TB incidence is 556 per 100 000 population and 55% of TB cases are also infected with HIV. A national survey in 2001–2002 revealed 1.6% MDR-TB among new cases (provincial range 1–2.6%) and 6.6% in re-treatment cases (provincial range 4–13.9%). Since 2001, the NTP has had a national policy on MDR-TB: a standardized regimen is given to all cases (4 months of kanamycin, ofloxacin, ethionamide, pyrazinamide and ethambutol or cycloserine/12–18 months of ofloxacin, ethionamide, ethambutol or cycloserine). Each province has an MDR-TB treatment centre. The cost of the standardized regimen is US\$ 3000 if ethambutol-based and US\$ 4000 if cycloserine-based.

The rationale for using a standardized regimen is due to the high MDR-TB burden and limited expertise and experience in using second-line drugs. DST for rifampicin, isoniazid and ethambutol is conducted on all re-treatment failures and non-converting patients and in risk groups.

A total of 315 patients have finished treatment (80% re-treatment cases) and results indicate high efficacy (90% success). However, the effectiveness of the programme is low because of high default rates (almost 30%), which bring the treatment success rate down to 50%. Four factors have been linked with the treatment outcome: the regimen (the cycloserine-based regimen is more likely to succeed), HIV status (outcomes were more favourable in HIV-negative and HIV-positive patients than in patients of unknown status), provincial differences in TB control, and age (older patients more likely to succeed). Dr Weyer mentioned the following activities as important for improving the programme: identification of risk factors for default; greater on case-holding; strengthening of voluntary counselling and testing for HIV; and stricter regulations for second-line drugs. South Africa has not applied to the GLC for MDR-TB control.

Session 3: Future steps – from research to policy

Dr Michael Kimerling, Gorgas Initiative for Tuberculosis Control at the University of Alabama, chaired the session and Ms Eva Nathanson served as rapporteur.

Second-line drug susceptibility testing: status and next steps on validation criteria study

Dr Sang Jae Kim, WHO, reported on current problems of DST for second-line drugs. There is a lack of correlation between DST results and the clinical response in patients. In addition, the reproducibility of the tests is poor – probably because the testing methods for some of the second-line drugs have not yet been calibrated with representative samples of clinical isolates of *Mycobacterium tuberculosis*. It is also possible that the poor reproducibility of DST is the result of the lack of standardization of testing methods within the fragile test environment. To investigate current DST practices for second-line drugs and plan further activities, a questionnaire was developed and sent to 21 supranational reference laboratories (SRLs). Aspects of testing methods covered by the questionnaire included medium, the critical resistance proportions and/or critical concentrations for each drug tested, and any proficiency testing exercise performed. Responses from 10 SRLs revealed significant variation in testing systems and methods used and reflected the difficulty in securing reproducibility and optimizing the clinical relevance of the results. A proficiency testing exercise of SRLs to improve understanding of the reproducibility of DST and a study designed to optimize the clinical relevance of DST results with clinical isolates collected at four TB institutes are currently under way.

MDR-TB community of practice

Drs Margaret McIntyre and Mark Rosenberg from the Task Force for Child Survival and Development presented their work on promoting collaboration across organizations to address complex public health problems. In order to share the MDR-TB knowledge that exists within the Working Group, Drs McIntyre and Rosenberg proposed setting up a “community of practice” – a group of people who share a concern, a set of problems or a

profound interest in a particular topic and who interact with each other on a continuous basis to deepen their understanding and knowledge. The presenters informed the meeting that the Task Force for Child Survival and Development is willing to take the lead in setting up an MDR-TB community of practice. Among other activities, this would involve the creation of special interest/discussion groups and the design of a web site with possibilities for information sharing and interactive discussions.

Mainstreaming DOTS-Plus with DOTS expansion: the roadmap to 2005–2006

Mr Gupta proposed a roadmap for activities related to MDR-TB policy development. Since the launch of DOTS-Plus in 1999 and the creation of the Working Group, several MDR-TB management activities have been undertaken, and preliminary results are now available from GLC-approved DOTS-Plus pilot projects and from non-GLC reviewed programmes managing MDR-TB. As yet, however, there is no formal evidence of the outcomes of projects reviewed and monitored by the GLC. Moreover, the *Guidelines for establishing DOTS-Plus pilot projects for the management of MDR-TB* are outdated as the Working Group has gained more experience since their publication in 2000. Thus it is now possible to begin the next stage of global policy development. Mr Gupta presented four products that would serve as tools for global MDR-TB management and increase political commitment, the first three to be finalized in 2004 and the fourth in 2005:

- a publication based on the results of the first GLC-approved DOTS-Plus pilot projects;
- a monograph outlining the global scenario of MDR-TB management, including country profiles specific for MDR-TB that will reflect the use of second-line drugs globally and the urgency of implementing cost-effective measures to control MDR-TB;
- guidelines for MDR-TB management,
- guidelines for DST to second-line drugs.

WHO proposes to take the lead in the development of these four products in collaboration with the Working Group. As part of the mainstreaming process, WHO regional and country offices and partners will need to be more involved in the technical implementation of DOTS-Plus. In the future, the Working Group should become a part of the global DOTS Expansion Working Group and MDR-TB management should be integrated into regular NTP activities.

It was pointed out that the new guidelines on MDR-TB management will need to be sufficiently flexible to allow for the human and financial capacities of individual countries and that different models will need to be recommended. Although most GLC-approved DOTS-Plus pilot projects use individualized treatment regimens, the standardized approach should not be ruled out. The GLC needs more experience from settings that are applying standardized treatment regimens.

International collaboration in MDR-TB control: present and future perspectives

Partners in Health

Dr Paul Zintl presented the work of Partners in Health (PIH). The organization supports DOTS-Plus projects in Haiti, Peru and Tomsik. Through the projects in Peru and Tomsik, it is planned to create generic models for DOTS-Plus implementation. In Lima, Peru, 1450 MDR-TB patients have been enrolled and, with support from the GFATM, DOTS-Plus will be expanded to the whole country. In Tomsik, where 412 patients have been enrolled, the

project includes prison populations. Funding has been granted by the GFATM. Together with WHO and partners, PIH is assisting the authorities in the Russian Federation to standardize and improve MDR-TB management in the country. The DOTS-Plus pilot project in Haiti recently received the green light from the GLC and the country has also been awarded funds for TB control by GFATM.

Future challenges include supporting partners in Haiti, Peru and Tomsk to make a success of the investments granted by the GFATM, and helping countries and partners to promote these models of care in DOTS and DOTS-Plus programmes to stimulate investment and commitment to reaching the global TB control targets.

Centers for Disease Control and Prevention

Dr Peter Cegielski presented CDC's involvement in MDR-TB control. Country support for MDR-TB control is provided to Brazil, Estonia, Latvia, Lithuania, Peru, the Russian Federation (mainly Ivanovo and Orel oblasts but also at national level to develop MDR-TB policy) and South Africa. Country support activities include technical assistance for policy development, MDR-TB capacity building, DRS, laboratory strengthening, infection control and operational research in MDR-TB epidemiology and diagnostics. In addition, CDC is working with the following specific technical issues:

- paediatric MDR-TB, including the development of guidelines for the diagnosis and management of MDR-TB in children;
- infection control, including training and technical assistance to a number of countries and development of guidelines;
- epidemiology and evaluation, including training, information system development and operational research.

CDC is also a member institution of the GLC.

Médecins Sans Frontières (MSF)

Dr Henkens outlined MSF's activities on MDR-TB control. MSF was directly involved in both price negotiations and supply of the first 2000 treatments for the GLC: it was also a member of the GLC during the first two years. Two applications submitted by MSF have been approved – Kemerovo, Russian Federation, and Karakalpakstan, Uzbekistan. Unfortunately, after seven years of work, the project in Kemerovo had to end because the treatment regimen approved by the GLC was not approved by the Russian authorities. The project in Karakalpakstan has just started to enrol MDR-TB patients. In future, MSF intends to apply to the GLC from other supported TB control projects in the world. The organization fully supports the WHO pre-qualification project on second-line drugs.

Gorgas Initiative

Dr Kimerling presented the Gorgas TB Initiative and its activities to support the creation of an MDR-TB management system in Kazakhstan. The strengths of the TB control programme in Kazakhstan are commitment to TB control, availability of first- and second-line drugs, and availability of resources for basic DOTS. The weaknesses are that DST is unreliable, case management is inadequate, and DOT is not functioning optimally. After approval by the authorities, the Initiative started activities in October 2003. The project includes support to capacity building, laboratory strengthening, drug management, improving infection control, and revision of protocols and information systems. It is initially planned to last for one year.

The Norwegian Heart and Lung Association (LHL)

Ms Torunn Hasler presented LHL's work in Arkhangelsk oblast, Russian Federation. The collaboration started in 1995, since when a revised TB control system based on DOTS has been introduced in the whole oblast, including prisons. Preliminary DRS results indicate that the MDR-TB rates are extremely high in the oblast (well over 10% in new cases). At present, there are about 500 registered MDR-TB cases. Since 2002, the oblast has funded treatment of 220 MDR-TB cases. In May 2003, the project obtained approval from the GLC to treat an initial 300 MDR-TB cases. The main challenges faced are improving DST, preventing the transmission of MDR-TB, reducing default rates and, finally, securing long-term funding of the project.

US Agency for International Development (USAID)

Dr Amy Bloom presented USAID's support to global TB control in general and MDR-TB control in particular. USAID supports activities geared to improving the procurement and management of high-quality second-line drugs, improving the monitoring of treatment failures, expanding DRS, strengthening laboratory capacity to monitor resistance, introducing new drugs and regimens, and supporting DOTS-Plus operational research. In 2002, USAID invested almost US\$ 19 million in global TB control, 15% of which was spent on drug resistance. In addition, a sum of almost US\$ 78 million was allocated to regions, countries and the GFATM for TB control.

Conclusions and recommendations

Conclusions

- The Working Group acknowledges that the funds coming from the GFATM will potentially increase access to second-line drugs. This will result in increasing demand on monitoring and technical assistance activities.
- The Working Group endorses the WHO project on pre-qualification of manufacturers of second-line drugs.
- The Working Group acknowledges that suppliers will probably invest in improving both production capacity and the quality of second-line drugs when demand increases and is quantified (i.e. through GLC-approved pilot projects), rather than vice versa.
- The Working Group supports the continued efforts of Eli Lilly and the new MDR-TB initiative launched by the company.
- The GLC is facing several challenges as a result of the scaling-up of operations and the mainstreaming of DOTS-Plus into the DOTS strategy. Among these challenges are the need to mobilize additional funding, the training of consultants, closer involvement of WHO regional offices, acceleration of DRS, and assistance to WHO in furthering the progress in drug procurement for the DOTS-Plus projects.
- Interim analysis of the GLC-approved DOTS-Plus pilot projects shows promising results. Default rates are less than 11% and cure rates range from 61% to 82%. However, it is still too early to draw any definitive conclusion to be reached: more detailed analyses are needed in order to avoid biased conclusions.
- The experiences of the first GLC-approved DOTS-Plus projects indicate that adverse drug reactions are not an obstacle to MDR-TB control. A sound plan that includes education and training of patients and health care workers in early detection and management of adverse reactions is key to treatment success.

- Research and innovative thinking is required to deal with several unresolved clinical and programmatic issues faced by the GLC-approved DOTS-Plus projects, such as management of MDR-TB in children, rapid diagnosis of MDR-TB, DST of second-line drugs, infection risk protection for health care workers, case-holding of alcohol-dependent and other difficult-to-treat patients, and sustaining political commitment to the DOTS strategy.
- The Working Group recognizes the difficulties of interpreting second-line DST because the tests are not standardized and reproducibility is poor, which leads to low reliability.
- Overall laboratory capacity needs to be strengthened, and more technical, human and financial resources are needed for efficient MDR-TB management.
- The Working Group recognizes that DOTS-Plus provides an opportunity to strengthen laboratory capacity and improve the collaboration between the laboratory and clinicians.
- MDR-TB management is a key component of TB control and should be seen within the broader health system development rather than as an isolated element.
- DOTS-Plus, closely linked with DRS, is necessary to facilitate DOTS expansion in some regions (for example, the WHO European Region). However, it should be considered only as an additional input to the DOTS strategy and not as the main focus of TB control activities.
- The Working Group supports the plan for mainstreaming DOTS-Plus with DOTS Expansion in a carefully designed, stepwise process that will lead to new policy development on global MDR-TB management.
- The new Chair of the Working Group is Dr Vink.
- Next year's Working Group meeting should take place back-to-back with the annual conference of the International Union Against Tuberculosis and Lung Diseases to obviate the need for additional travel by many participants.

Recommendations

- Measures to increase the human and financial resources needed for DOTS-Plus should be explored in view of the potential rapid scaling up made possible by the increased funding from the GFATM.
- A meeting should be organized of WHO, GLC, GFATM, IDA, and other interested partners should be organized to explore the short- and long-term consequences of the pre-qualification project for the second-line drug supply. A plan should be developed to ensure the availability of high-quality drugs.
- WHO and partners should work closely with countries to develop national drug regulatory mechanisms for the supply of first- and second-line drugs and to promote use of drug sources on the WHO "white list" of manufacturers.
- The Working Group and IDA should encourage manufacturers to apply to the WHO project on pre-qualification of manufacturers of second-line drugs.
- Standardized MDR-TB treatment regimens should be explored to facilitate DOTS programme delivery and reduce costs. These efforts should go hand-in-hand with accelerating DRS.
- Attention should be given to quality assurance of laboratory functions, and MDR-TB isolates from DOTS-Plus pilot projects should be preserved as they are essential for correct diagnosis, follow-up of patients and future studies on MDR-TB.
- The WHO secretariat should continue the project on the development of guidelines for second-line DST.

Annex 1. Agenda

Monday, 27 October 2003

12:30–13:30	Registration	
13:30–13:45	Opening of the meeting and welcoming remarks	L. Blanc, M. Espinal, K. Vink

Session 1 – From Tallinn to Paris

Chairperson: K. Lambregts

Rapporteur: R. Gupta

13:45–14:00	Progress of the Working Group	K. Vink
14:00–14:30	Discussion	
14:30–14:45	The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the Green Light Committee (GLC): role in increasing access to second-line drugs for MDR-TB	G. Bakker
14:45–15:30	Discussion	
15:30–16:00	Coffee break	
16:00–16:15	Status, challenges and future prospects in the procurement of second-line drugs for MDR-TB	H. den Besten
16:15–16:45	Discussion	
16:45–17:00	Quality and pre-qualification of second-line drugs for MDR-TB	L. Rägo
17:00–17:30	Discussion	
17:30–17:40	Eli Lilly/Partners/WHO initiative on MDR-TB control	P. Carlevaro
17:40–18:00	Discussion	
18:00–19:30	Reception	

Tuesday 28 October 2003

Session 2 – GLC and DOTS-Plus: achievements, challenges and constraints

Chairperson: C. Wells

Rapporteur: E. Jaramillo

08:30–08:45	GLC update	K. Lambregts
08:45–09:00	Results from DOTS-Plus pilot projects	E. Nathanson
09:00–09:10	Questions and answers	
09:10–10:30	Panel discussion with pilot project representatives	M. Dailovits V. Leimane A. Pasechnikov T. Tupasi J. Bayona
10:30–11:00	Coffee break	
11:00–11:15	Adverse events in the treatment of MDR-TB: results from five DOTS-Plus pilot projects	V. Leimane
11:15–11:45	Discussion	
11:45–12:00	Special session: MDR-TB treatment in South Africa	K. Weyer
12:00–12:30	Discussion	
12:30–14:00	Lunch	

Session 2 – Future steps: from research to policy

Chairperson: M. Kimerling

Rapporteur: E. Nathanson

14:00–14:15	Second-line drug susceptibility testing: status and next steps on validation criteria study	S.J. Kim
14:15–14:30	Discussion	
14:30–14:45	MDR-TB community of practice	M. Rosenberg M. McIntyre
14:45–15:00	Discussion	
15:00–15:15	Mainstreaming DOTS-Plus with DOTS expansion: the roadmap to 2005–2006	R. Gupta
15:15–15:30	Discussion	
15:30–16:00	Coffee break	

16:00–16:45	International collaboration in MDR-TB control: present and future perspectives	<ul style="list-style-type: none"> • Partners in Health • CDC • MSF • Gorgas Initiative • Norwegian Heart & Lung Association • USAID
16:45–17:15	Discussion	
17:15–17:30	Election of Chairperson	
17:30–18:00	Recommendations, next meeting, closing remarks	

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