

Issue 2 - November 2015

TB RESISTANCE RESPONSE

Newsletter of the GDI



The GDI is a Working Group of the Stop TB Partnership with the secretariat provided by the Global TB Programme of the World Health Organization

About the GDI

The GDI serves as a multi-institutional multi-disciplinary platform organizing and coordinating the efforts of stakeholders to assist countries to build capacity for programmatic management of DR-TB (PMDT) in the public and private sector.

Strategic priorities

1. Facilitate integration and coordination of efforts to align diagnostic services for patients with access to high-quality care
2. Develop targeted advocacy strategies and resource mobilization for DR-TB management scale-up
3. Build global consensus on the management of DR -TB for patient centred care delivery ("care for cure")
4. Promote strategies to facilitate patient access to high-quality DR-TB care, through a long-term, in-country capacity building approach targeting both the public and private sector
5. Facilitate effective knowledge sharing among partners and harmonise coordination with existing technical assistance TA mechanisms
6. Support prioritization of research to generate evidence for PMDT.

The GDI Core Group

Core Group members and represented constituency

1. Raimond Armengol, The Union, France. Chair, Regional Green Light Committee (rGLC) of the Americas
2. Amy Bloom, USAID, USA, Donor/ funding agencies
3. Chen-Yuan Chiang, The Union, France, Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
4. Daniela Cirillo, Fondazione Centro San Raffaele, Italy, Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
5. Charles Daley, National Jewish Health, USA (Chair), Academic institutions, institutions of high scientific and technical standing having attained international recognition in the area of DR-TB management
6. Dalene von Delft, TB Proof, South Africa, Civil society, patients and affected communities
7. Essam Elmoghazy, National TB Programme, Egypt. Chair, Eastern Mediterranean rGLC
8. Agnes Gebhard, KNCV, The Netherlands, Non-governmental sector partners
9. Saira Khawaja, Interactive Research and Development, Pakistan, Private for profit sector
10. Andrey Olegovich Maryandyshev, Northern State Medical University, Arkhangelsk, The Russian Federation. Chair, rGLC for the European Region
11. Lee B. Reichman, New Jersey Medical School Global Tuberculosis Institute, The United States of America. Chair, Western Pacific Region rGLC
12. Kuldeep Singh Sachdeva, NTP, India, National TB programmes of high DR-TB burden countries
13. Rohit Sarin, LRS Institute of TB and Respiratory Diseases, New Delhi, India. Chair, South East Asian Regional Advisory Committee on MDR-TB (rGLC SEAR)
14. Hind Satti, Partners In Health, Boston, The United States of America. Chair, rGLC for the African Region
15. KJ Seung, Partners In Health, USA, Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
16. Gini Williams, International Counsel of Nurses, Switzerland, National/international/ scientific/professional medical associations and nursing associations (Resigned in December 2014)"
17. Sirinappa Jitmanee, NTP of Thailand, National TB programmes of high DR-TB burden countries, Nursing association (Joined in May 2015)
18. Carrie Tudor, Chair, Infection Prevention and Control, GDI Infection Control sub-Group

GDI Secretariat

Fraser Wares, Global TB Programme, World Health Organization

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Chair of the GDI

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TB Proof

Phumeza cured from Extensively Drug Resistant TB (XDR-TB)

The SWIFT Response Project

Closing the treatment gap – implementation tools for new medications for the treatment of Drug-Resistant TB

Contributors

Thank you to GDI Core Group members who have contributed to this issue.

Cover photo: Phumeza Tisile
Photo credit: Arne von Delft from TB Proof

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Message from the Chair



Welcome to the newsletter of the Global Drug-Resistant TB Initiative (GDI)! The purpose of the Newsletter is to communicate updates to the many Partners and Stakeholders involved in the care of patients with drug-resistant tuberculosis.

Since the first Newsletter, a great deal has happened in the global fight against drug-resistant tuberculosis (TB). The GDI and GLI Partners Forum was held in Geneva in April 2015. This was an exciting event bringing together two working groups of the Stop TB Partnership that focus on drug resistant TB. One of the areas addressed during the Forum was the issue of a growing gap between patients diagnosed with multidrug-resistant TB (MDR-TB) and those enrolled on therapy. Among those enrolled on therapy, partners and stakeholders discussed the frustratingly slow uptake of new drugs such as bedaquiline and delamanid.

The GDI Core Group met after the Forum for the third time and reviewed the progress of its Task Forces and discussed the “Call for Action” (see the SWIFT response below). All were in agreement that the roll out and use of new drugs for MDR and XDR-TB was inadequate. Based on discussions at the Forum and GDI CG meeting it was felt that the best way forward was through use of current infrastructure and development of a new Task Force called DR-STAT. I am happy to say that the new Task Force has hit the ground running!

In this edition of the TB Resistance Response, partners describe current and planned activities and the poignant yet courageous story of Phumeza, one that highlights many of the issues we face in treating patients with drug-resistant TB. I hope you find the newsletter interesting and we look forward to your contributions to future editions!

Sincerely,

Charles L. Daley,
MD, Chair, GDI Core Group

STREAM clinical trial update

STREAM, which stands for Standardised Treatment Regimen of Anti-Tuberculosis Drugs for Patients with MDR-TB, is a clinical trial, assessing a nine-month standardised treatment regimen for multidrug-resistant tuberculosis (MDR-TB). The trial is being conducted by TREAT-TB, an initiative managed by the International Union Against Tuberculosis and Lung Disease (The Union), and will involve 400 patients in Africa and Asia.

The regimen to be tested is modelled on one used in a non-randomised observational study in Bangladesh, which demonstrated excellent outcomes, including an 87% cure rate. The trial is designed to determine whether comparable results can be achieved in different settings. The aim is to show that this shorter treatment regimen is at least as effective as the current lengthier treatments used throughout the world to treat MDR-TB.

Patients treated with the STREAM regimen will receive moxifloxacin, clofazimine, ethambutol and pyrazinamide for nine months, supplemented by prothionamide, kanamycin and isoniazid during an intensive phase of four months. Once the full complement of patients has been enrolled, the trial is expected to run for two years, with results available in late 2017.

STREAM Stage I Recruitment Complete

Since its launch in 2012 through July 2015, STREAM has enrolled 424 patients in Ethiopia, South Africa, Viet Nam and Mongolia – exceeding the trial's recruitment target. Patient follow up continues and results are expected in early 2018.

Preparation for STREAM Stage II Underway

The success of the trial's Stage I presented the opportunity to consider additional regimens for evaluation in the clinical trial. After discussions with investigators and experts in the field it was decided that two regimens would be of particular interest and relevance. Both the new regimens will include a recently licensed drug, bedaquiline and will be compared to the 9-month regimen studied in Stage I. The first of the new regimens will be completely oral; the kanamycin in the original 9-month regimen will be replaced by bedaquiline. In the second new regimen, total treatment duration will be reduced to 6 months, and kanamycin will be given for only 2 months.

In preparation for Stage II, The Union and MRC CTU at UCL have developed an amended trial protocol, which was approved by the US FDA and the EMA and the Ethics Advisory Group of The Union. STREAM Stage II will be conducted in close association with Janssen Research & Development. The STREAM research team is currently evaluating potential sites for Stage II of the trial and preparing for trial initiation which is expected in late 2015.

Multidrug-resistant tuberculosis (MDR-TB) activities at The Union



Addressing the MDR-TB crisis is a major priority for The Union with activities ranging from clinical research to education and outreach aimed at improving prevention, control and treatment of drug-resistant tuberculosis.

Research highlights:

Preliminary data from an observational cohort study coordinated by The Union and conducted in nine African countries show positive outcomes for the use of a shortened, 9-month treatment regimen used to treat MDR-TB. Patient enrolment was concluded in March 2015, and more than 1,000 patients are now receiving treatment through the study. Encouraging preliminary results were presented at the 2014 Union World Conference in Barcelona and at the GDI meeting in April 2015, with 83% treatment success in the first cohort of 356 patients. Further results will be presented at the 2015 conference in Cape Town this December.

In addition, The Union is evaluating the effectiveness of two new treatment regimens for MDR-TB, as part of the STREAM clinical trial, which is entering its second stage. If successful, the study will provide robust new evidence on the effectiveness of an all-oral 9-month treatment regimen and a 6-month treatment regimen for MDR-TB, which will both include bedaquiline. STREAM Stage II will be conducted in close association with Janssen Research & Development.

Education & training highlights:

The Union recently offered International Courses on the Clinical and Operational Management of MDR-TB in Mozambique in July, in India in August and in Peru in September 2015. The Union taught its annual International TB Course in French in Benin in September 2015. There is an International Course on the Clinical Management of DR-TB in English scheduled for mid-November in Thailand (this course is full). Curricula cover both theory and international best practices with emphasis on the challenges presented by limited-resource settings and the work environments where participants will apply their new skills. In addition to these international courses, The Union also offers National courses at the request of National TB Programmes.

Technical assistance highlights:

The Union regularly assists national tuberculosis programmes in Africa, Asia, Latin America and the Middle East, at their request, to review their strategic planning and policies, budgets, programmatic management of MDR-TB, laboratory networks, procurement plans, monitoring and evaluation and other issues. Since 2012 The Union has been involved in the FHI360 CAP TB project in Yunnan (China) focusing among other things on prevention, diagnosis and management of MDR-TB; in order to strengthen TB control programmes in the region.

TB case finding and outreach/ education Projects include Project Axshya (India), Program to Increase Catchment of Tuberculosis Suspects (PICTS, Myanmar), Slum Partnerships to Actively Respond to Tuberculosis in Kampala (SPARK-TB and SPARK-TB Plus, Uganda), TB CARE (Zimbabwe) and more recently Challenge TB (Zimbabwe). Challenge TB and TB CARE are not acronyms.

www.theunion.org

The Union brings innovation, expertise, solutions and support to address health challenges in low- and middle-income population.

**The third face-to-face
Global Drug-resistant
TB initiative (GDI)
meeting core group
meeting - Geneva,
Switzerland, 1 May
2015**

The third Core Group (CG) meeting of the Global Drug-resistant TB Initiative (GDI) was held on 1 May 2015 in Geneva, Switzerland. All members of the CG, attended the meeting, along with observers from the Global Laboratory Initiative (GLI), Global TB Drugs Facility (GDF), Global Fund (GF), Infection Prevention and Control (IC) sub-group and the USAID.

The objectives of the meeting were:

- **To follow up on recommendations from the GDI/GLI forum, including the issue of the “call to action on the introduction of new anti-TB drugs”**
- **To follow up on recommendations and action points agreed upon during 2nd GDI CG meeting and subsequent monthly teleconferences**
- **To provide an update on the progress of the GDI Task Forces, and the Infection Control (IC) sub-group**
- **To review the strategic priorities of GDI and plan subsequent activities for the next year; and**
- **To discuss the GDI “costed framework” and the work plan**

The participants were briefed about the activities of the GDI Secretariat since the second CG meeting held in October 2014.

Following discussions between the GDI CG members and interested participants from the Joint GDI/GLI Partners Forum, there was general consensus that no-one wanted any “new” structures outside of considering a new Task Force. Hence GDI CG agreed that the creation of a GDI Task Force to address the introduction of new drugs for DR TB was the best solution.

A joint session of the GDI and GLI CGs discussed the issue of growing gaps between the number of MDR-TB cases detected and the numbers started on treatment. GDI and GLI chairs also reviewed the recommendations from the previous joint meeting, as well as relevant issues raised during the Joint GDI/GLI partners forum.

**The third face-to-face GDI
meeting report and the
participants presentations are
available at GDI webpage at:
www.stoptb.org/wg/mdrtb/default**





The joint GLI / GDI Partners Forum

The joint GLI/GDI partners forum was organized by the World Health Organization Global TB Programme in Geneva, Switzerland, 27-30 April, 2015.

The overall goal of the Joint Partners Forum was to bring together representatives from country TB control programmes, international institutions and initiatives, non-governmental organizations, academic and research institutes from developed and developing countries, patient communities, the TB Supranational Reference Laboratory network, industry representatives and funding agencies, working in partnership to address the challenges of increasing access to early diagnosis and treatment of all persons with TB, including drug-resistant TB and TB/HIV.

Meeting objectives included the following:

- **Provide an overview of the WHO End TB strategy to control the global TB epidemic post-2015;**
- **Present priorities and achievements of the Global Laboratory Initiative and Global Drug-resistant TB Initiative;**
- **Disseminate developments in WHO policy guidance on TB diagnostics and new drugs, and provide updates on the TB diagnostics pipeline and clinical trials for new drugs and regimens;**
- **Share lessons learned and challenges for wide-scale implementation of Xpert MTB/RIF and other rapid diagnostic tests to ensure effective use of resources and identify synergies with TB/HIV integrated activities;**
- **Evaluate the status of the SRL network and its activities;**
- **Share best practices for the alignment of diagnosis and treatment for the programmatic management of drug-resistant TB (PMDT); and**
- **Present progress of regional initiatives for scale-up of laboratory strengthening and PMDT.**

Case Report

Author: **Jennifer Hughes**
(**Medecins Sans Frontieres**
(**MSF**) **Khayelitsha**)



Phumeza cured from **Extensively Drug Resistant TB** **(XDR-TB)**

Phumeza Tisile was 21 years old when she first presented to a private doctor in May 2010, with a recent history of significant, unintentional weight loss but no other specific symptoms. She was referred to the local primary healthcare clinic for tuberculosis (TB) screening. She had never received treatment for TB before, had no significant personal or family medical history, and was not taking any regular medications. At that time, Phumeza was single, had no children and lived with 6 adult members of her family in a 3-bedroomed house in Khayelitsha, Cape Town, South Africa. She reported no known TB contacts, however she was in her first year of college in Cape Town and travelled by local minibus taxi into town every day from her home in Khayelitsha. On presentation at her local clinic, a sputum sample was requested and only direct smear microscopy examination was carried out. As she had no high risk factors for drug-resistant TB (DR-TB), culture and drug sensitivity test (DST) was not carried out. The smear microscopy result was negative, but TB was confirmed clinically and she started treatment with rifampicin, isoniazid, pyrazinamide and ethambutol (RHZE) on 25 May 2010. After one month of treatment she had not improved, and sputum microscopy examination was conducted again but it was negative once again. However this time, culture and DST were also carried out. The culture was positive and the line probe assay (LPA) revealed resistance to rifampicin (R) and isoniazid (H).

After 2 months of relatively ineffective TB treatment, Phumeza commenced the standard MDR-TB treatment regimen (pyrazinamide [Z] / kanamycin [Km] / moxifloxacin [Mfx] / ethionamide [Eto] / terizidone [Trd]) in July 2010, which she received daily in her local clinic under Directly Observed Therapy (DOT). However, less than one week later she deteriorated dramatically and was referred to the local district hospital with a right hemiparesis and inability to walk. A CT scan suggested TB meningitis, and indicated a left midbrain granuloma and secondary hydrocephalus. A few weeks later, she improved sufficiently to be transferred to the nearest specialist TB hospital. Meanwhile, the injectable drug (Km) was withdrawn due to renal impairment and sudden onset, severe, sensorineural hearing loss. Only after this event was the second-line DST result received, which revealed resistance to amikacin, but susceptibility to ofloxacin and ethionamide. Therefore, Phumeza had again been receiving inadequate treatment for over 4 months, and also she had suffered permanent hearing loss from a drug that she need not ever have received. In October 2010, a mediastinal mass was noted on her chest radiograph and she underwent an operation in a tertiary hospital. The surgery led to the fracture of her 4th anterior rib, as well as a pneumothorax and empyema, requiring an intercostal drain and long term low pressure suction. These complications resolved after a prolonged stay in the tertiary hospital, and three months later she recovered sufficiently to be transferred back to the local specialist TB hospital. Monthly sputum cultures have remained negative since culture conversion in August 2010. Phumeza was eventually discharged from the TB hospital in April 2011, clinically well but profoundly deaf, to continue treatment in Khayelitsha.

Despite excellent adherence, another routine sputum sample taken in clinic in May 2011 was culture positive for Mtb. Phumeza was clinically stable and reported no symptoms of active TB disease. A repeat sample taken in June 2011 was 2+ positive on direct smear microscopy, culture positive for Mtb and resistant to R and N with presence of both inhA and KatG mutations, however molecular evidence of a mixed infection was observed. Second-line DST results arrived in the clinic only one month later, and these reported phenotypic resistance to both amikacin and ofloxacin, but susceptibility to ethionamide. Given the extensive drug resistance and apparent bacteriological failure of treatment, the following treatment regimen was commenced on: E / Mfx / capreomycin (Cm) / Trd / Eto / para-aminosalicylic acid (PAS) / clofazimine (Cfz) / linezolid (Lzd). Sputum samples from 1 August 2011 were smear negative, but remained culture positive for Mtb. Results of genetic sequencing carried out on the initial sputum cultures revealed resistance to Z and E and hence, both drugs were stopped.



This year, through an unprecedented crowd funding effort, # Defeat The Silence, Phumeza received bilateral cochlear implants and could hear her mother's voice again for the first time in 5 years!

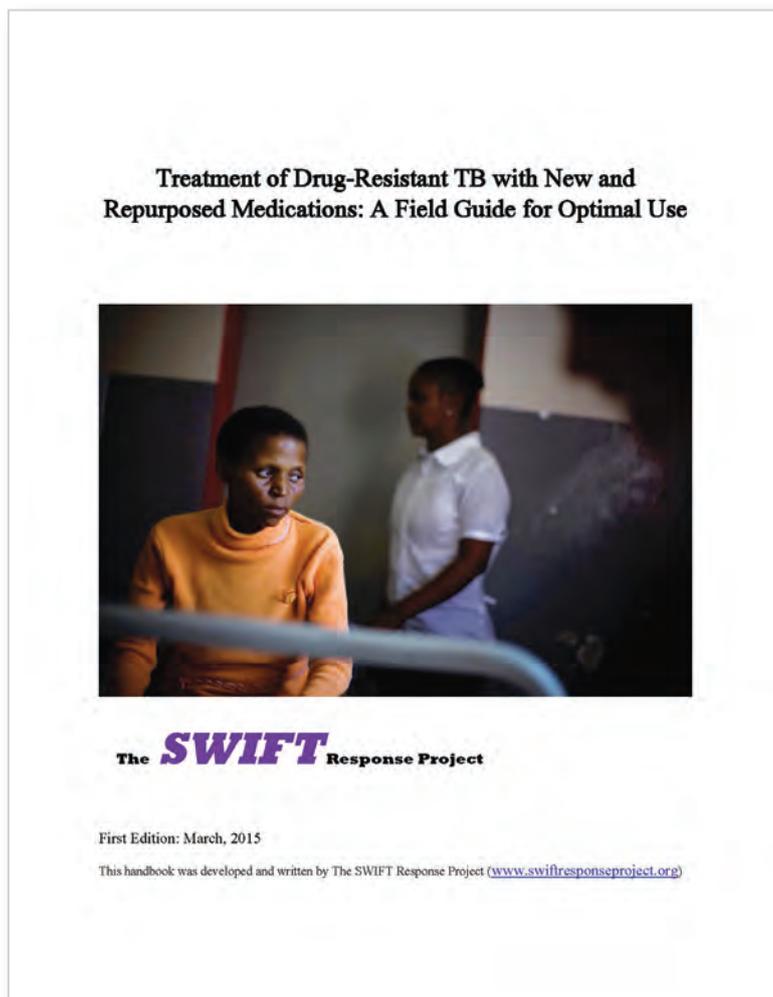
After 4 months on the new 'strengthened regimen', Phumeza's clinical condition improved compared to previously, but with persistent lower zone opacifications. At this point, capreomycin was withdrawn from the regimen as the extensively drug resistant TB (XDR-TB) was likely resistant to the capreomycin, and the persistent electrolyte abnormalities (assumed to be due to the drug) were difficult to manage and required close monitoring. Despite Phumeza's disappointment at the news that her treatment was likely to be failing, she opted to continue treatment with Mfx / Trd / Eto / PAS / Cfz / Lzd and agreed to be assessed for surgery (she was later considered ineligible). However in February 2012, her sputum sample was reported culture negative. Over the next 4 months on treatment in the sub-acute inpatient facility, Phumeza continued to gain weight up and had a further 3 negative sputum cultures between March and June 2012. Moxifloxacin was withdrawn in June 2012 due to a skin rash and arthralgia. At this point, she was otherwise well and ready to go home to continue receiving treatment at her local clinic. However her family were concerned about her infectious risk and refused for her to return to the household. MSF constructed a 2-room shack for Phumeza and her mother to live in on a plot of a friend of theirs, and Phumeza was discharged from the facility at the end of June 2012.

Phumeza remained adherent on treatment and in August 2013, 18 months after the most recent culture conversion, Phumeza celebrated the cure of her XDR-TB.

Over the past three years, Phumeza has been, and continues to be, an active advocate for development of better TB diagnostics and improved access to second line drugs for DR-TB.

The SWIFT Response Project:

Closing the treatment gap – implementation tools for new medications for the treatment of Drug-Resistant TB



In the past, the global TB community has been slow to respond to opportunities and challenges in treating drug-resistant disease. We now have an unprecedented chance to join forces and effectively respond to this public health crisis, notes Dr. Jennifer Furin, one of the funding members of SWIFT.

One of the most disturbing trends reported in the field of MDR-TB is the growing gap between those diagnosed with DR-TB and those offered therapy for their disease. To date, treatment strategies have not kept up with the introduction of novel and more sensitive diagnostics. For the first time in almost 50 years, however, there are new drugs for the treatment of DR-TB that offer hope to patients suffering from this disease and their providers. For new drugs to reach these patients, however, there is a need for implementation tools that take the policy guidance developed by international organizations and help patients, providers and programmes use these new drugs in the field.

To address the implementation gap, a pioneering group of 77 international DR-TB experts from 21 countries has created the SWIFT Response Project. SWIFT stands for “**Society Working on Implementation to Fight TB**”. The goal of the group is to rapidly develop implementation tools to ensure optimal use of new TB drugs in order to provide the best possible outcomes for patients and programmes. These drugs include bedaquiline, delamanid, linezolid and clofazimine. The group consists of volunteers and was announced on 18 December 2014.

“The policy guidance for new drugs has been developed, but there is an urgent need for effective field tools in order to move from the conference room to the clinic. These new drugs offer opportunities for better treatment of highly-resistant disease and to manage some of the disabling side effects of current therapy. This is great news for our colleagues and, most importantly, the men, women and children affected by DR-TB” – notes Jennifer Furin.

Since coming together in December of 2014, the SWIFT Response Project has developed a field guide for new drug implementation, a patient workbook to facilitate better communication between providers and patients, and a training

curriculum covering relevant topics for the use of new and re-purposed drugs. The group is also working on developing practical tools for pharmacovigilance and training materials for nurses and treatment supporters. The project also hosts a monthly webinar to share information and lessons learned on new and repurposed drugs.

The group is open to anyone who wishes to join, and the only criteria for membership is a desire to see the fruits of modern medicine benefit those most in need. For more information please visit our website at www.swiftresponseproject.org or contact Dr Jennifer Furin at jenniferfurin@gmail.com

“In the past, the global TB community has been slow to respond to opportunities and challenges in treating drug-resistant disease. We now have an unprecedented chance to join forces and effectively respond to this public health crisis,” notes Dr. Jennifer Furin, one of the funding members of SWIFT.

News

Upcoming events

- **DR STAT meeting 28 Nov 2015(closed), Cape Town, South Africa**
- **End TB Strategy Summit for national Programmes of the highest TB burden countries (closed meeting), 30 November, 2015, Cape Town, South Africa**
- **4th GDI Core Group meeting (closed meeting), 1 December 2015, Cape Town, South Africa**
- **GLI Core Group meeting (closed meeting), 1 December 2015, Cape Town, South Africa**
- **Stop TB Symposium (open meeting), 2 December 2015, Cape Town, South Africa**
- **46th Union World Conference on Lung Health in Cape Town, South Africa, 2–6 December 2015, Cape Town, South Africa**

Recent publications

- **Digital health for the End TB Strategy - an agenda for action, World Health Organization, 2015**
- **ENGAGE-TB: Training of community health workers and community volunteers: facilitators' guide, World Health Organization, 2015**
- **Guidelines for surveillance of drug resistance in tuberculosis - 5th edition, World Health Organization, 2015**
- **Implementing tuberculosis diagnostics: A policy framework, World Health Organization, 2015**
- **Guidelines on the management of latent tuberculosis infection, World Health Organization, 2015**

Resources

For additional resources from partners, please visit: <http://www.stoptb.org/wg/mdrtb/resources/home.html>

Contact

gdi_secretariat@who.int
www.stoptb.org/wg/mdrtb/

Recent articles

Ahmad N, Javaid A, Basit A, Afridi AK, Khan MA, Ahmad I, Sulaiman SA, Khan AH. Management and treatment outcomes of MDR-TB: results from a setting with high rates of drug resistance. *Int J Tuberc Lung Dis.* 2015 Sep;19(9):1109-14

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