

SESSION 5
1 June 2017, 14:00-17.00
New and repurposed anti-TB drug introduction

WHO policies related with management of drug-resistant tuberculosis

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ENDING TB IN THE SUSTAINABLE DEVELOPMENT ERA: A MULTISECTORAL RESPONSE



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THE ISSUE

... of 580,000 incident cases globally -

480 000



incident cases of MDR-TB in 2015
(with another 100 000 rifampicin-resistant
TB cases eligible for second-line treatment)

132 000



MDR/RR-TB cases detected in 2015

125 000



patients started on MDR-TB
treatment in 2015

52%



treatment success in MDR/RR-TB
patients starting treatment in 2013

250,000

• deaths per year

23%

• tested and treated

11%

• treated successfully

In summary

480 000



incident cases of MDR-TB in 2015
(with another 100 000 rifampicin-resistant
TB cases eligible for second-line treatment)

132 000



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CHALLENGES AND OPPORTUNITIES

• Challenges

- **Patients:** agonising, prolonged suffering, often permanent disability, excess mortality, devastating economic hardship, stigma and discrimination
- **Health systems:** ethical, legal and human rights challenges, critical human resource and skills gaps, deficient infection control, suboptimal contact follow-up, transmission becoming the main driver of M/XDR-TB epidemics

• Opportunities

- Innovations in diagnostic platforms, digital technologies, regimens
- Existing, cross-cutting systems to link AMR and MDR-TB
- Innovative funding mechanisms, multisectoral approaches and catalytic interventions
 - WHO Global Action Plan on Antimicrobial Resistance
 - Global Health Security Agenda



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ACTIONS

National level

- **Declare MDR-TB as a national public health crisis requiring an emergency response**
- **Prepare urgent MDR-TB Emergency Response Plans**
- **Accelerate specific, targeted and coordinated actions**

Global level

- **Establish urgent and prominent space for the MDR-TB crisis within the global AMR agenda and the GHSA (WHO with AMR and GHSA secretariats);**
- **Commit to increased funding and flexibility of investment (Multilateral donors);**
- **Track progress in the MDR-TB emergency response and intensify corrective actions to barriers detected (WHO and technical partners)**

Guidelines for the programmatic

The use of bedaquiline in the treatment of multidrug-resistant

The use of delamanid in

The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents

WHO treatment guidelines for drug-resistant tuberculosis

2016 update
OCTOBER 2016 REVISION

THE END TB STRATEGY

THE END TB STRATEGY

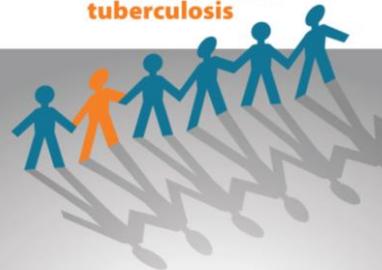


Companion handbook

THE END TB STRATEGY

Active tuberculosis drug-safety monitoring and management (aDSM)

Guideline: Nutritional care and support for patients with tuberculosis



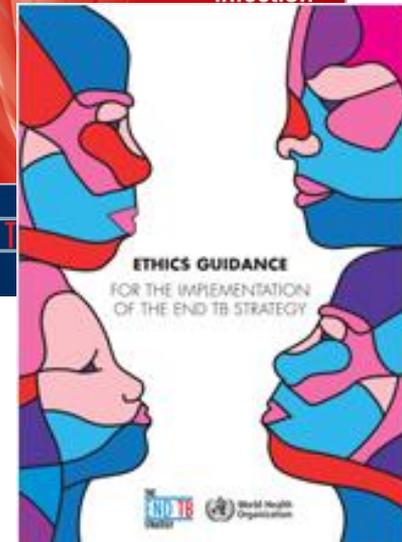
WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households



Guidelines on the management of latent tuberculosis infection

THE END TB STRATEGY

ETHICS GUIDANCE FOR THE IMPLEMENTATION OF THE END TB STRATEGY



Types of recommendation

- Positive recommendation
- No recommendation
- Negative recommendation

WHO guidelines for the treatment of drug-resistant tuberculosis. 2016 update

For all recommendations...

Strength : conditional

Certainty of evidence : very low

WHO guidelines for the treatment of drug-resistant tuberculosis. 2016 update

Key changes

- *A shorter MDR-TB treatment regimen* is recommended for RR-/MDR-TB patients, under several conditions
- The design of conventional MDR-TB regimens uses a different *regrouping of second-line medicines*
- *Treatment of children with RR-/MDR-TB* based on a first-ever meta-analysis of individual-level paediatric patient data for treatment outcomes
- Recommendation on *partial lung resection surgery*

Regrouping of the medicines used for RR-/MDR-TB

| | | |
|--|---|---|
| <p>GROUP A</p> <p>Fluoroquinolones</p> | <p>Levofloxacin Moxifloxacin Gatifloxacin</p> | |
| <p>GROUP B</p> <p>Second-line injectable agents</p> | <p>Amikacin Capreomycin Kanamycin (Streptomycin)</p> | |
| <p>GROUP C</p> <p>Other Second-line Agents</p> | <p>Ethionamide / Prothionamide Cycloserine / Terizidone <i>Linezolid</i> <i>Clofazimine</i></p> | |
| <p>GROUP D</p> <p>Add-on agents</p> | <p>D1</p> | <p>Pyrazinamide Ethambutol High-dose isoniazid</p> |
| | <p>D2</p> | <p>Bedaquiline Delamanid</p> |
| | <p>D3</p> | <p><i>p-aminosalicylic acid</i> Imipenem-Cilastatin Meropenem Amoxicillin-Clavulanate (Thioacetazone)</p> |

www.who.int/tb/areas-of-work/drug-resistant-tb/treatment/FAQshorter_MDR_regimen.pdf



Frequently asked questions about the implementation of the new WHO recommendation on the use of the shorter MDR-TB regimen under programmatic conditions

Version: 20 December 2016

These FAQs are to be read alongside the *WHO treatment guidelines for drug-resistant tuberculosis, 2016 update* (WHO/HTM/TB/2016.04) and their online annexes released by the Global TB Programme of the World Health Organization (WHO) in May 2016(1),(2). The 2016 guidelines provide more background about the updated WHO recommendation on the shorter MDR-TB regimen since the previous guidelines of 2011(3).

Why are shorter MDR-TB regimens needed?

About 580,000 new cases of rifampicin-resistant (RR-TB) or multidrug-resistant (MDR-TB; RR-TB with additional resistance to isoniazid) emerge each year globally(4). RR-/MDR-TB cannot be treated with the recommended 6-month standard course of medication which is effective in most TB patients(5). Patients with MDR-TB are typically treated with more medicines and for much longer (conventionally 20 months or more(3)). Despite this, these regimens are not as effective as standard first-line regimens for drug-susceptible TB.

The duration of the longer MDR-TB treatment regimens and the toxicity of certain agents composing

Recommendation on longer MDR-TB regimen

- Evidence relies mostly on observational studies; RCTs rare
- All RR-TB cases to be treated with a recommended MDR-TB regimen, regardless if isoniazid resistance is confirmed or not (caution on InhA mutation)
- The detection of resistance to fluoroquinolones and to 2nd line injectable agents is important for regimen design.
- Access to reliable DST for pyrazinamide would be helpful as well.
- Recommendations apply to adults and children;

WHO interim policy guidance on new drugs

The use of bedaquiline in the treatment of multidrug-resistant tuberculosis

Interim policy guidance



The use of delamanid in the treatment of multidrug-resistant tuberculosis

Interim policy

The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents

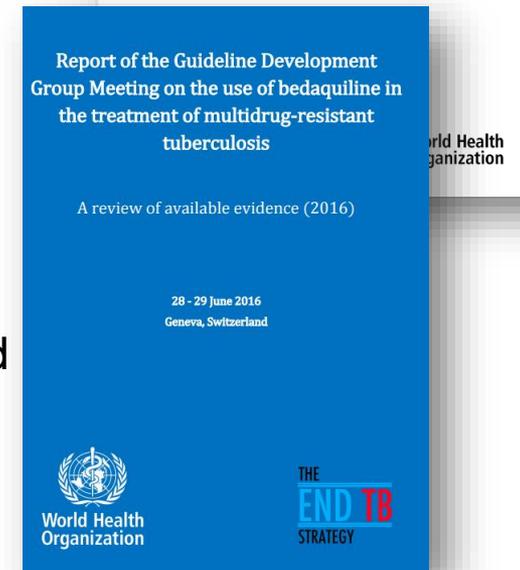
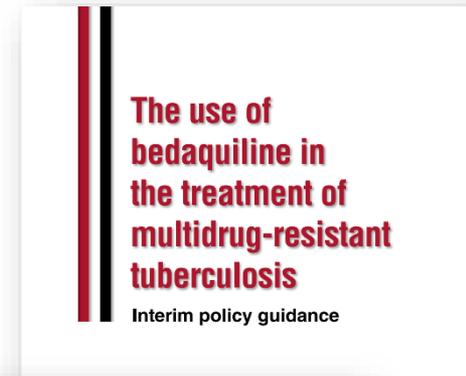
Interim policy guidance

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Interim guidance on introduction and use of Bedaquiline within MDR-TB treatment

- Bedaquiline is the first new drug developed specifically to treat TB in nearly 50 years.
- Granted accelerated approval by the U.S. FDA in 2013.
- WHO issued *Interim Policy Guidance* on its use as part of MDR-TB treatment in 2013.
- As new evidence became available, WHO undertook the revision of the interim guidance which led to confirm existing recommendation for the use of bedaquiline, including the following conditions:
 - Proper patient inclusion
 - Patient informed consent
 - Adherence to principles to design a WHO-recommended *longer* regimen
 - Treatment administered under closely monitored conditions
 - Active pharmacovigilance* and management of adverse events



*In recent documents, *active pharmacovigilance* has been replaced with "active TB drug safety monitoring and management"

Interim guidance on introduction and use of Delamanid within MDR-TB treatment

- Delamanid, a mycobacterial cell wall synthesis inhibitor, received a conditional approval from European Medicines Agency (EMA) in 2013, leading to the issuance of the WHO *Interim policy guidance* on delamanid use for treatment of adult MDR-TB patients in the following year.
- The availability of new PK/PD data on delamanid in paediatric populations led the WHO to review these data, and issue an interim policy for the use of delamanid in children and adolescents (>6 years old)

Conditions

- Proper patient inclusion
- Adherence to the principles of designing a WHO-recommended *longer* MDR-TB regimen
- Close monitoring of patients
- Active TB drug safety monitoring and management
- Informed decision-making process ensured

The use of delamanid in the treatment of multidrug-resistant tuberculosis

Interim policy guidance

The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents

Interim policy guidance

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Recommendations on treatment of drug susceptible tuberculosis

New recommendations on treatment of DS-TB

Effectiveness of shortened fluoroquinolone-containing regimens

- *In patients with drug-susceptible pulmonary TB, 4-month fluoroquinolone-containing regimens should not be used and the 6-month rifampicin-based regimen 2HRZE/4HR remains the recommended regimen.*

Effectiveness of TB treatment using fixed-dose combination pills

- *The use of fixed-dose combination (FDC) tablets is recommended over separate drug formulations in treatment of patients with drug-susceptible TB.*

Effectiveness of intermittent dosing of TB medications

- *In all patients with drug-susceptible pulmonary TB, the use of thrice-weekly dosing is not recommended in both the intensive and continuation phases of therapy, and daily dosing remains the recommended dosing frequency*

Initiation of antiretroviral treatment in TB patients living with HIV

- *ART should be started in all TB patients living with HIV regardless of their CD4 cell count.*
- *TB treatment should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment. HIV-positive patients with profound immunosuppression (e.g. CD4 counts less than 50 cells/mm³) should receive ART within the first 2 weeks of initiating TB treatment.*

New recommendations on treatment of DS-TB

The duration of TB treatment for HIV co-infected patients

- *In patients with drug-susceptible pulmonary TB who are living with HIV and receiving antiretroviral therapy during TB treatment, a 6-month standard treatment regimen is recommended over an extended treatment for 8 months or more.*

The use of adjuvant steroids in the treatment of extrapulmonary TB disease

- *In patients with tuberculous meningitis, an initial adjuvant corticosteroid therapy with dexamethasone or prednisolone tapered over 6–8 weeks should be used.*
- *In patients with tuberculous pericarditis, an initial adjuvant corticosteroid therapy may be used.*

The empirical use of the WHO category II regimen in patients who require retreatment for TB

- *In patients who require TB retreatment, the category II regimen should no longer be prescribed and drug-susceptibility testing should be conducted to inform the choice of treatment regimen.*

Recommendations on patient care and support

(cross-cutting interventions for DS-TB and DR-TB)

1. Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment
2. A package of treatment adherence intervention may be offered for patients on TB treatment in conjunction with the selection of a suitable treatment administration option
3. One or more of the following treatment adherence interventions (complementary and not mutually exclusive) may be offered to patients on TB treatment or to health-care providers:
 - material support to patient
 - psychological support to patient
 - communication with patient
 - digital medication monitor
 - staff education

Recommendations on patient care and support

(cross-cutting interventions for DS-TB and DR-TB)

4. The following treatment administration options may be offered to patients on TB treatment:

- Community- or home-based directly observed treatment (DOT) is recommended over health facility-based DOT or unsupervised treatment;
- DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members or unsupervised treatment;
- Video observed treatment (VOT) can replace DOT when the video communication technology is available and can be appropriately organized and operated by health-care providers and patients.

Recommended treatment adherence interventions (individual or combined interventions)

| intervention | Description |
|--------------------------------|--|
| Patient education | Health education and counselling. |
| Staff education | Education, chart or visual reminder, educational tool and desktop aid for decision-making and reminder. |
| Material support | <p>Food or financial support such as meals, food baskets, food supplements, food vouchers, transport subsidies, living allowance, housing incentives or financial bonus.</p> <p>This support addresses indirect costs incurred by patients or their attendants in accessing health services and, possibly, tries to mitigate the consequences of income loss related to the disease.</p> |
| Psychological support | Counselling sessions or peer-group support. |
| Communication with the patient | Home visit or via mobile telephone communication such as SMS or telephone (voice) call. |
| Digital medication monitor | A digital medication monitor is a device that can measure the time between openings of the pill box. The medication monitor can give audio reminders or send SMS to remind patient to take medications, along with recording when the pill box is opened. |

Implementation considerations on patient care and support

Assessments need to be done prior to the start of treatment for every patient on:

- Patient needs for social support - for the decision on what kind of support to be provided to the patient
- Risk of treatment interruption - for the decision of an appropriate treatment administration option
- Resources and conditions for implementation of individual intervention - for the decision on a package of patient support interventions and model of care



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Model of care for drug-resistant TB

A decentralized model of care is recommended over a centralized model for patients on MDR-TB treatment.

Active tuberculosis drug-safety monitoring and management (aDSM)

Framework for implementation

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aDSM

“active and systematic clinical and laboratory assessment of patients on treatment with new TB drugs, novel MDR-TB regimens or XDR-TB regimens to detect, manage and report suspected or confirmed drug toxicities”

apps.who.int/iris/bitstream/10665/204465/1/WHO_HTM_TB_2015.28_eng.pdf

aDSM components

1. Clinical monitoring

- active and systematic clinical and laboratory assessment during treatment to detect drug toxicity and AEs

2. Management of AEs in a timely manner

3. Systematic and standardized recording and reporting of AEs

- Data collection to include safety data
- At least all SAEs reported and assessed for causality
- Close coordination between national TB and PV structures

Minimum monitoring : Serious AEs

- Core package of aDSM targets **serious adverse events (SAEs)**
- Other sites can register and report other AEs of clinical significance / special interest

Seriousness

Seriousness involves any of the following:

- death or a life-threatening experience;
- hospitalization or prolongation of hospitalization;
- persistent or significant disability;
- congenital anomaly.

Events which do not result immediately in one of these outcomes but which might require an intervention to prevent it from happening may also be considered serious

aDSM “packages”

- 1. Core:** requiring monitoring for and reporting of all SAEs
- 2. Intermediate:** includes SAEs as well as AEs of special interest
- 3. Advanced:** includes all AEs of clinical significance

aDSM eligibility

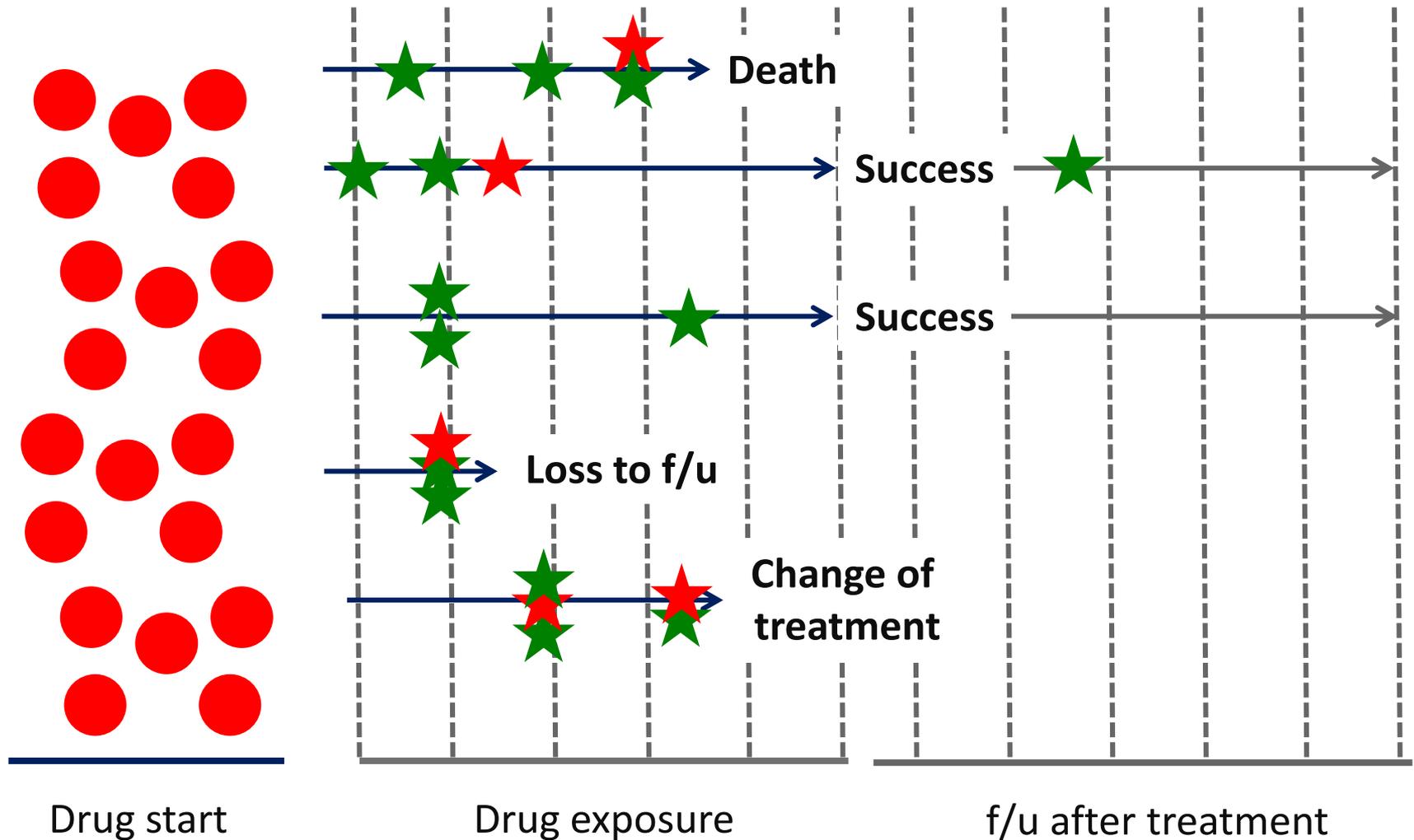
aDSM applies primarily to the following:

1. MDR-TB patients treated with bedaquiline, delamanid and other new medicines;
2. MDR-TB patients enrolled on treatment with novel regimens (including the shorter MDR-TB regimen);
3. All XDR-TB patients on second-line treatment, as these regimens usually include multiple repurposed drugs

Once coverage of these patient groups is reached, aDSM can extend to other MDR-TB patients on treatment

aDSM : cohort-based approach

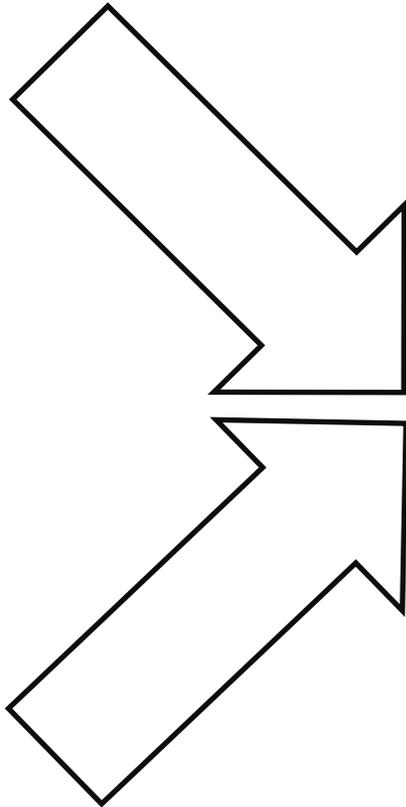
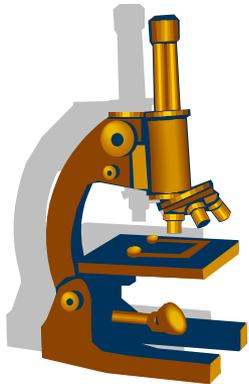
- ★ Serious AE
- ★ Other event



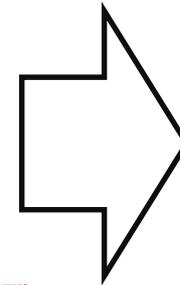


PATIENT HISTORY

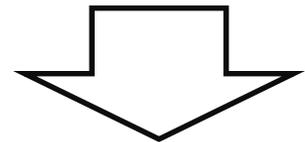
CLINICAL TESTS



SAE



DATA ENTRY



GLOBAL aDSM
DATABASE

CONFIDENTIAL - To be sent even upon suspicion of a serious adverse event

IS THIS REPORT A NEW EVENT? YES NO GIVE DATE WHEN PREVIOUS SAE FORM SENT: DD MM YYYY

1. PATIENT DETAILS

LAST NAME _____ FIRST NAME _____

SEX MALE FEMALE DATE OF BIRTH DD MM YYYY
age in yrs. if DOB unknown

PREGNANCY YES NO

ID NUMBER _____ PHONE NO. _____

ADDRESS _____

2. SUSPECTED and CONCOMITANT MEDICINE(S)

| NAME (Brand name or Generic) | Total | Date started | Date stopped | Continues |
|------------------------------|-------|--------------|--------------|-----------|
| | | | | |

Global aDSM database

- A global aDSM database was created in 2016
- Coordinated by the Special Programme for Research and Training in Tropical Diseases at WHO Headquarters (TDR) and the WHO/GTB
- The Luxembourg Institute of Health (LIH) is responsible for its day-to-day management
- National programmes and other bodies can report AEs to the database for patients treated with medicines which are new or repurposed for an indication other than TB
- Belarus has started to report

What happens to the data ?

- Programme indicators
- Causality assessment
- Signal detection
- Drug-safety profiles

Key steps in aDSM implementation

Create a national coordinating mechanism for aDSM

Develop a plan for aDSM

Define management and supervision roles and responsibilities

Create standard data collection materials

Train staff on the collection of data

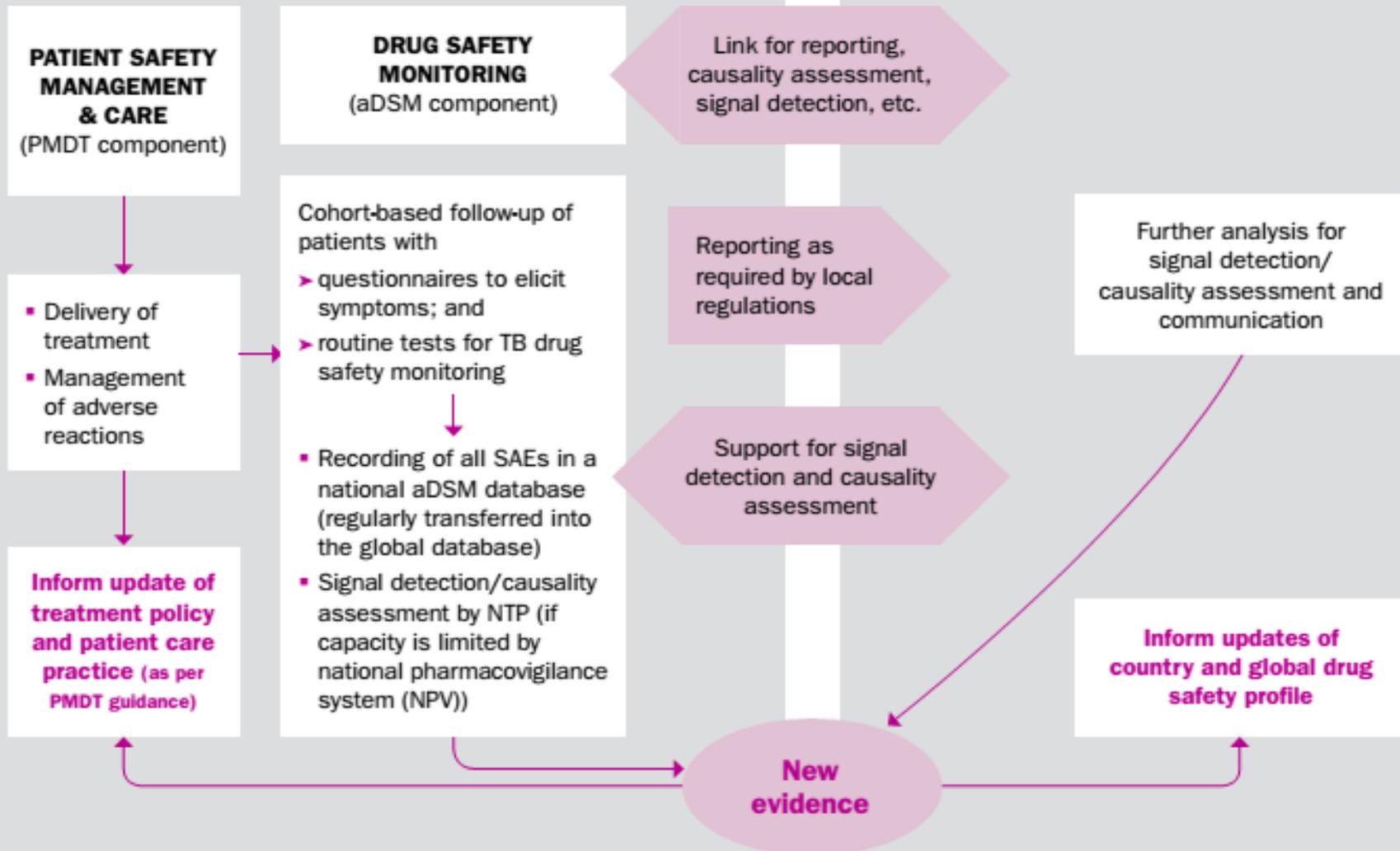
Define schedules and routes for data collection and reporting

Consolidate aDSM data electronically

Develop capacity for signal detection and causality assessment

National TB Programme

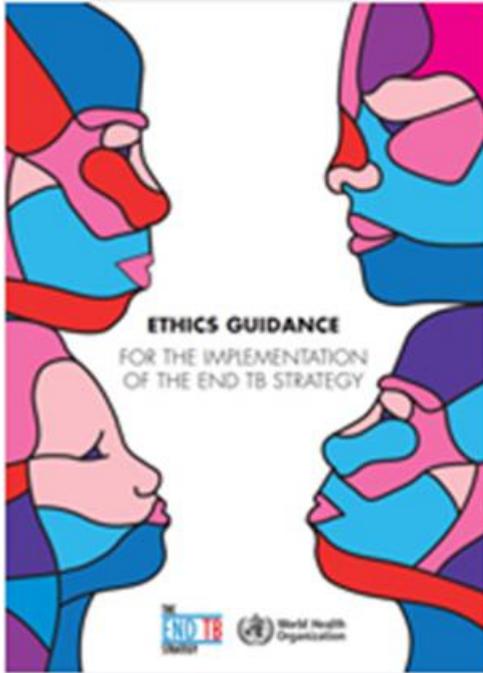
National Pharmacovigilance System



In conclusion ...

- The 2016 WHO policy updates aim to improve the assignment of patients to treatment regimens which can increase the likelihood of cure
- Important uncertainties remain on the effectiveness and safety of the treatment options, both regarding older and newer medications
- More evidence will be needed and new studies to ensure that treatment is better targeted according to the patient profile
- The global aDSM database is geared to detect signals of previously unknown or poorly documented adverse events in patients on MDR/XDR-TB regimens

Key messages



- Diagnosis in the absence of treatment
- DOT only with patient-centred care
- TB safe working environment
- Sharing of research data
- Hospitalizing of TB children without medical reason

CHAPTER 12

Patient-centred care, social support and adherence to treatment

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CHAPTER 13

Palliative and end-of-life care

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Ongoing work

- Update of the IPD MDR-TB longer regimen
- Guideline developing group meeting on INH-resistant TB
- Pharmacokinetics/pharmacodynamics
- Update of TB infection control guidelines
- TB Digital health agenda

Digital health and TB

Conceptual framework for digital health & TB

SIMpill

Home
The SIMpill Solution
How SIMpill Works
About Us
Contact Us
SIMpill Login

The SIMpill Medication Adherence Solution
The SIMpill Medication Adherence Solution helps patients and caregivers as necessary to take their medication as prescribed.

Copyright SIMpill © 2012

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VCP-DOT: Video Cell Phone - Directly Observed Therapy for Tuberculosis

Funded by NIAD, grant R21-AI088326-01; PI: Richard S. Garfield

The purpose of this study is to develop and pilot test a novel, cost-effective method of assuring high rates of patient adherence to anti-tuberculosis (TB) medication regimens. An estimated 2.2 billion persons are infected with M. tuberculosis, resulting in 9.2 million cases of disease and nearly 2 million deaths annually. TB is now the leading cause of death among persons with HIV. Reports of drug resistant TB cases – the result of poor adherence to antibiotic treatment – has led to an increasing demand for directly observed therapy (DOT) as a means of assuring high treatment adherence. While daily visits with a healthcare worker to receive DOT places significant costs on patients and providers, the consequences of poor adherence would be far costlier. The goal of our intervention will be to achieve treatment adherence at least as high as traditional DOT at a lower cost and reduced burden to patients and care providers.

The VCP-DOT program is a collaborative effort between the UCSD Division of Global Public Health and the TB Control Programs of San Diego County and the Municipality of Tijuana, BC, Mexico. This pilot study will evaluate the feasibility and acceptability of a novel approach to delivering DOT using cell-phones, through which patients send daily videos of themselves taking their TB medications. Videos are then viewed remotely by a DOT worker located at the TB Control Program office via a web-based video and data management system hosted by CALIT-2 at UCSD. By allowing patients to send videos at any time from any location via their cell phone, we anticipate that patients will miss fewer observed doses because they may face fewer on a technique that better suits their lifestyle and their time in no longer a supervisor to their

QuanTB 2.0.0 | USAID FROM THE AMERICAN PEOPLE | SIAPS

Reference date: Apr 1, 2014 Total enrolled cases: 89,811 Total expected cases: 222,339

Dashboard showing enrollment and expected cases across various categories.

Patient Cost Questionnaire

Phần 1. Things you believe most depend up to the doctor to do

Form with fields for patient information and checkboxes for beliefs.

Person at a computer workstation.

Patient care Surveillance

Programme management eLearning

EpiCollect+ BETA
For complex projects.

Features:

- Drag and Drop form Builder
- Define multiple linked forms(s)
- Any number of text questions
- Any number of media fields

Generated using Google Earth

Map showing locations like Mbabane Government hospital.

Person at a laptop.

Global Health: An Interdisciplinary Overview

This course proposes an overview of current global health challenge drawing on the insights of several academic disciplines including medicine, public health, law, economics, social sciences and humanities. This interdisciplinary approach will guide the student into seven critical topics in global health.

Sessions: Add to wishlist

About the Course

Course coordinators: Prof. Antoine Gessisburier, MD, Prof. Louis Louisa, MD and Dr. Didier Ntsems, MD, MSc
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CHILDHOOD TB TRAINING TOOLKIT

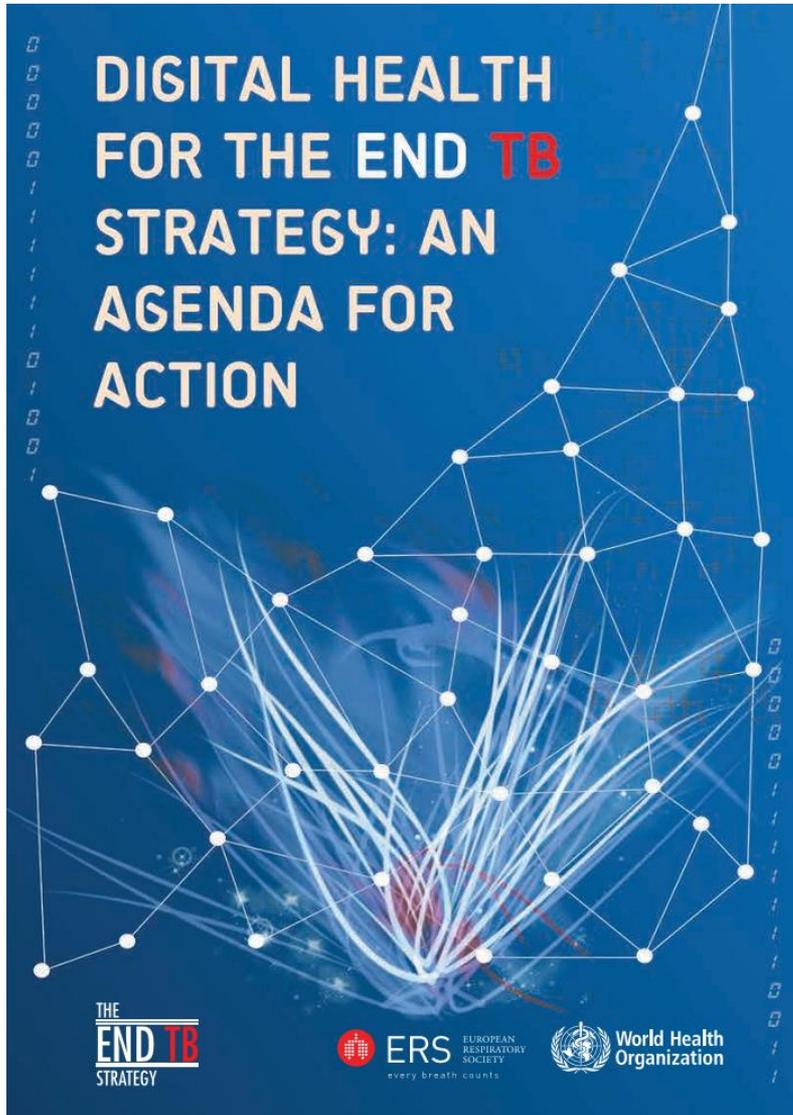
MDR-TB COURSE

1. Introduction to MDR-TB
2. Case Finding and Diagnosis of MDR-TB
3. Treatment of Patients with MDR-TB
4. Adverse Drug Effects
5. Patient-Provider Communication
6. Special Situations
7. MDR-TB and HIV-Co-infection
8. Infection Control

The «Agenda for Action» & the End TB Strategy



“Agenda for action”



The strategic direction that WHO is mapping out to integrate digital health into preventive and care activities for the different components of the End TB strategy

Comments on the evidence and an outline of the target product profiles

Sep 2015

Target product profiles (TPP) (1)

for priority digital technologies for TB

| <i>Function</i> | <i>TPP : short description</i> |
|--------------------------------------|---|
| Patient care | 1. Video treatment support (VOT) via mobiles |
| | 2. eHealth portal |
| Surveillance & monitoring | 3. Graphic dashboards |
| | 4. eNotify |
| | 5. eReporting of adverse events of treatment |
| Programme management | 6. Diagnostic device connectivity |
| eLearning | 7. Patient information platform |
| | 8. Web-based training for health care professionals |
| | 9. Clinical decision support systems |

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END TB

