

**2nd Meeting of the Core Group of the Global
Drug-resistant TB Initiative
27 October 2014, Barcelona, Spain**

**Update on WHO policy development
for MDR-TB response**

Ernesto Jaramillo
Global TB Programme

THE
END TB
STRATEGY



**World Health
Organization**

Guidelines for the programmatic

The use of bedaquiline in

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

Interim policy guidance



Guidelines for the programmatic management of drug-resistant tuberculosis

EXECUTIVE SUMMARY

Emergency Update 2008

Companion Handbook

to the WHO guidelines for
the programmatic management of
drug-resistant tuberculosis





**Framework for Engagement of All Health Care Providers
in Management of Drug Resistant Tuberculosis**

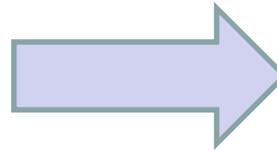
THE
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STRATEGY

**A PRACTICAL HANDBOOK
ON THE PHARMACOVIGILANCE
OF MEDICINES USED
IN THE TREATMENT OF
TUBERCULOSIS**

ENHANCING THE SAFETY OF THE TB PATIENT



World Health
Organization



**PHARMACOVIGILANCE
DES MÉDICAMENTS UTILISÉS
DANS LE TRAITEMENT
DE LA TUBERCULOSE :
GUIDE PRATIQUE**

AMÉLIORER LA SÉCURITÉ DU PATIENT TUBERCULEUX



Organisation
mondiale de la Santé

**ПРАКТИЧЕСКОЕ ПОСОБИЕ
ПО ФАРМАКОНАДЗОРУ
ЗА ПРОТИВОТУБЕРКУЛЕЗ-
НЫМИ ЛЕКАРСТВЕННЫМИ
СРЕДСТВАМИ**

ПОВЫШЕНИЕ БЕЗОПАСНОСТИ БОЛЬНЫХ ТБ



Министерство
здравоохранения
Российской Федерации



Management of drug-resistant tuberculosis

Training for staff working at
DR-TB management centres

Facilitator's guide



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Tuberculosis (TB)

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The use of short regimens for treatment of multidrug-resistant tuberculosis

10 August 2012 | The current WHO guidelines on treatment regimens for MDR-TB recommend an intensive phase of treatment of 8 months and a total duration of treatment of 20 months for most patients(1). The guidelines were developed following the GRADE process for guideline development that has been adopted by WHO, and recommendations were based on an analysis of more than 9,000 cases treated in observational studies. The results from an observational study in Bangladesh showed much better rates of treatment success using regimens having a duration of 12 months or less compared with those usually achieved when the longer regimens are used (2). However, there is much less evidence on the effectiveness and safety of these so-called "short-regimens" compared with regimens lasting 20 months.

WHO's position is that regimens which are markedly different from the ones which represent the current norm and have undergone GRADE review should only be used within the context of research and under close monitoring for a period of at least 12 months beyond the end of treatment. This follow-up after treatment completion is aimed at early identification of those patients who may have a high risk of relapse and acquired resistance. Proper attention to drug regulatory and ethical issues will be needed to facilitate the gathering of additional evidence that can be used for future updates of current WHO guidelines on the treatment of MDR-TB. Until sufficient evidence is available to inform a policy update, WHO is advising countries to introduce short MDR-TB treatment regimens only in projects that adhere to the following criteria:

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http://www.who.int/tb/challenges/mdr/short_regimen_use/en/index.html

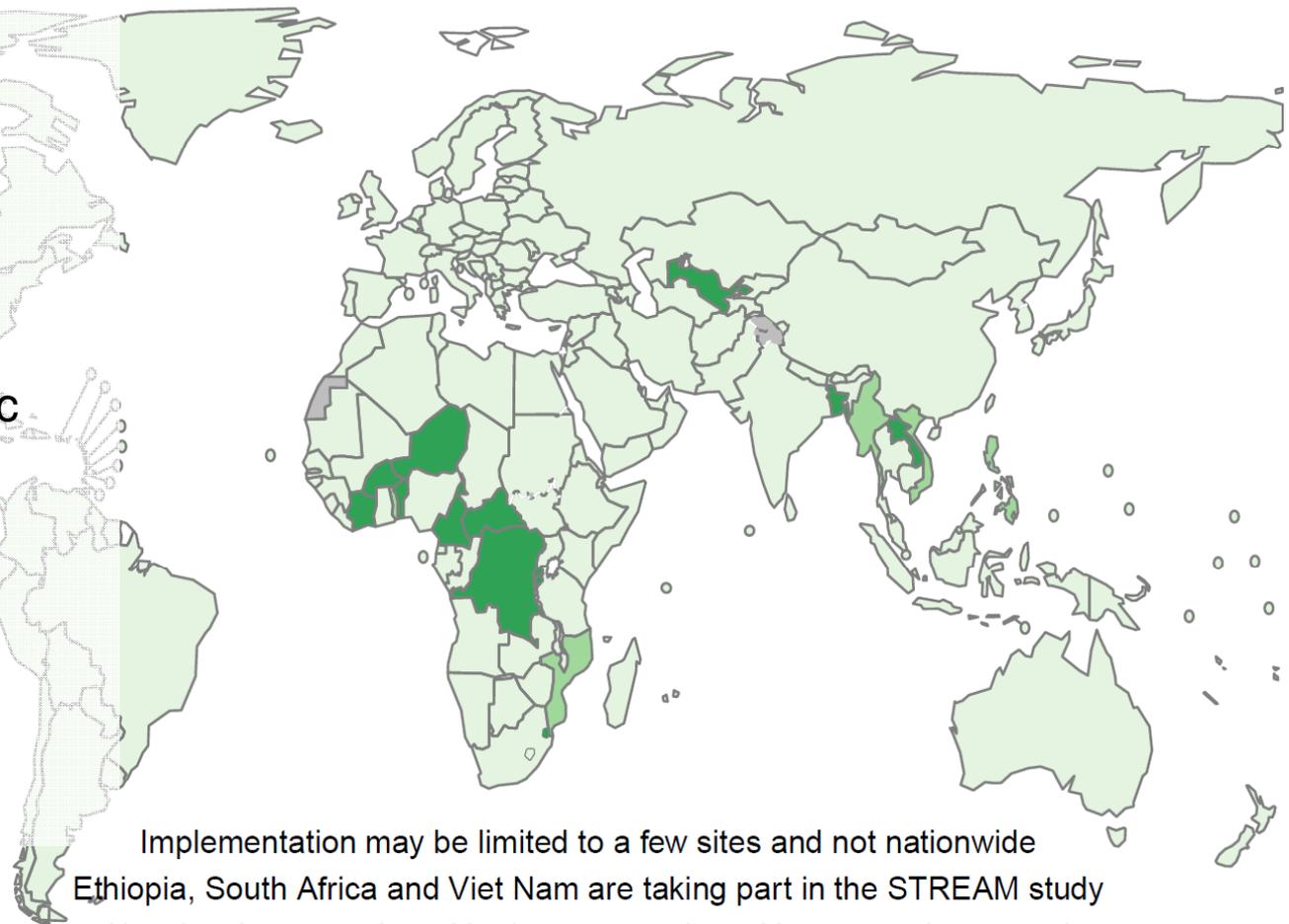
Use of shorter regimens for MDR-TB

Countries using shorter MDR-TB regimens under observational study conditions, by October 2014

No Planning to start Started

Study protocols compliant with WHO position

Benin
Burkina Faso
Burundi
Cameroon
Central African Republic
Côte d'Ivoire
DR Congo
Lao PDR
Niger
Rwanda
Swaziland
Uzbekistan



Implementation may be limited to a few sites and not nationwide

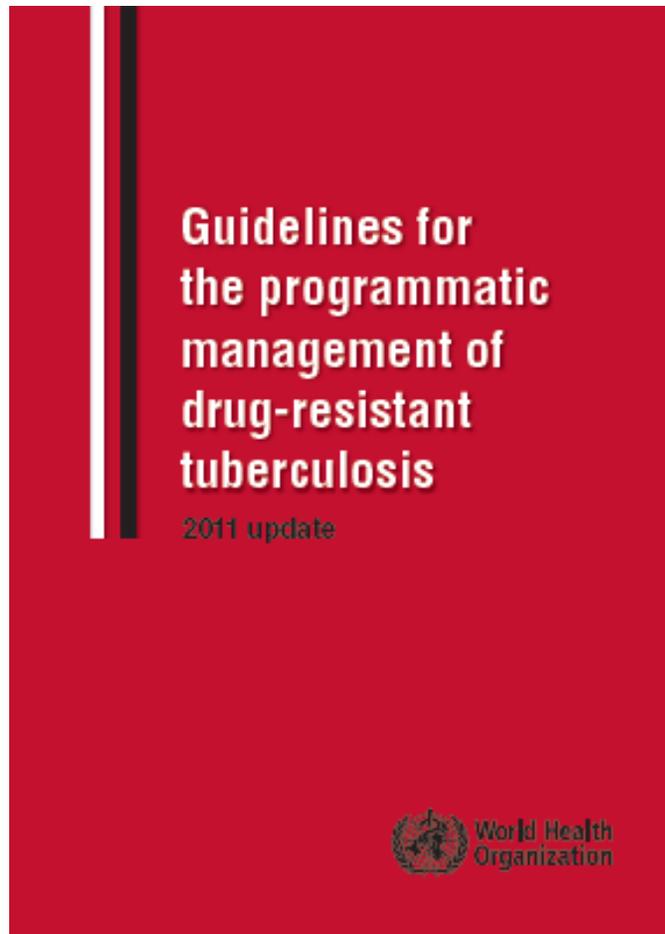
Ethiopia, South Africa and Viet Nam are taking part in the STREAM study

Not showing countries with plans to start but without a study protocol

Promoting access to quality-assured drugs for MDR-TB management

- WHO Essential Medicines List (April 2015)
- WHO Expression of Interest (ongoing)

Next steps: updating of policies in 2015



- Safety and efficacy of group 5 second-line drugs (SLDs)
- Re-grouping of SLDs
- Treatment of XDR-TB
- Treatment of mono/polyresistance
- Models of care for patients without treatment options
- Social support to enhance treatment adherence and improve quality of life

Emerging ethical issues in MDR-TB management: updating the guidance in 2015

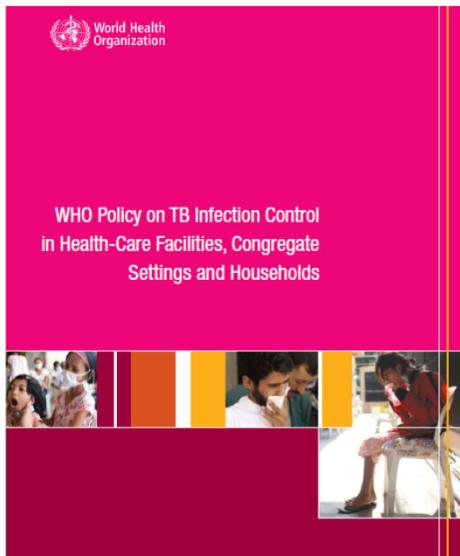
Guidance on ethics
of tuberculosis prevention,
care and control



- Caring for patients who are a source of infection but have no effective treatment alternatives
- Forced repatriation of legal and illegal migrant TB patients
- TB management in prisons
- Advocacy for TB in the era of DR
- Ethics of preventive therapy in the context of the TB elimination
- Management of MDR-TB in children

LET'S NOT FORGET TB INFECTION CONTROL! (the vice-chair of that group is around!)

- Infection control through means other than early diagnosis and effective treatment is also paramount when:
 - diagnosis is made in the absence of effective treatment
 - treatment fails in patients with XDR-TB
 - health care workforce faces avoidable infection risks



- Updating of WHO policy on TB infection will start in 2015 following well established process

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