

Essentials steps for introduction and scale-up of the BPaL containing regimens

Date: Thursday, 18 November 2021

Time: 13:00 to 16:00 CEST

Registration link for course:

<https://us06web.zoom.us/meeting/register/tZEqcemvpj8rGdfiqvhlzzSDz9vPEIEmB1La>

Description: Careful planning and preparations for the successful introduction and scale-up of new drugs and regimens (ND&R) is essential. The National Tuberculosis programs and partners should ensure rational use of the ND&R, adequate diagnostic capacity for appropriate treatment allocation, clinical management, monitoring of safety and effectiveness, treatment adherence, provision of patient support when implementing a new TB treatment including BPaL containing regimens for highly resistant tuberculosis. Adequate surveillance systems including drug resistance surveillance and aDSM should be in place to generate data for evidence-based policy decisions. Mechanisms should be in place to assess the total cost of treatment with the new regimen.

Learning objectives: Participants will be able to

- Define essential steps for the introduction and scale-up of BPaL containing regimens in different country settings across the world.
- Understand the patient perspective and patient support needs regarding treatment with BPaL containing regimens.
- Familiarize themselves with the tools to assist planning for the introduction and scale-up of BPaL containing regimens.

This is a very hands-on workshop conducted in English without translation during which participants will

- be handed a checklist for BPaL introduction and scale-up planning, which they will use throughout the workshop.
- have an action plan to lead them through the BPaL introduction and programmatic scale-up in their own country in line with international guidance and based on the experience of early implementing countries.
- be able to make programmatic and policy decisions based on the BPaL Operational Research (OR) and surveillance data in their country settings.

Session sponsor: Thomas Lynch, TB Alliance

Chairs: Askar Yedilbayev, WHO; Fraser Wares, KNCV Tuberculosis Foundation

Coordinators: Veriko Mirtskhulava (KNCV Tuberculosis Foundation), Mansa Mbenga (KNCV Tuberculosis Foundation)

Audience: Tuberculosis Program Managers, Clinicians, Epidemiologists, Laboratory professionals, TB/DR-TB International Consultants

Speakers:

- **Victor Babawale** (National Tuberculosis and Leprosy Control Programme in Nigeria): *Preliminary Data on the BPaL Regimen Safety from Nigeria*
Nigeria is, after South Africa, the second country in Africa to provide the new BPaL regimen under operational research (OR) conditions to patients with highly resistant tuberculosis from April 2021. The OR aims to enroll 50 patients. A functional aDSM framework is an essential part of the BPaL regimen introduction and scale-up. This presentation will report the early safety outcomes and the experienced challenges. During a QA session, a patient will share his experience on the BPaL treatment process, and the need for support to improve better outcomes, and thereby helping countries develop a patient care and support system strategy.
- **Mansa Mbenga** (KNCV Tuberculosis Foundation): *BPaL Introduction and Scale-up Protocol development*
Highlight the key areas that need attention in terms of the BPaL introduction and scale-up protocol development such as tuberculosis patient triage, provision of adequate care for a patient on the BPaL containing regimens, including criteria for the regimen modification, interruption and discontinuation, proper adverse event monitoring and management, define a list of adverse events of special interest.
- **Veriko Mirtskhulava** (KNCV Tuberculosis Foundation): *BPaL Implementation Program Monitoring and Evaluation*
We will present a core set of variables to be collected for monitoring and evaluation of the BPaL containing regimen implementation, program monitoring indicators for coverage, safety, and effectiveness. The steps to be taken to integrate the BPaL implementation program monitoring in the existing TB surveillance and aDSM systems in the different country settings will be discussed at the breakout sessions. Furthermore, the BPaL operational research and data analysis and results interpretation will be discussed.
- **Jong Seok Lee** (International Tuberculosis Research Center (ITRC): *Laboratory Readiness Assessment Toolkit*
ITRC will present its approach for toolkit development to assess the laboratory readiness for the BPaL regimen at both implementation/OR sites and reference lab. Specific factors required to be identified per level of laboratory and diagnostic method would also be presented.
- **Suzanne Staples** (THINK): *BPaL Implementation Guide*
The BPaL implementation guide, developed by THINK with support from the Stop TB Partnership's TB REACH, is a comprehensive guide to the operationalization of the BPaL regimen globally with an aim to assist countries with the successful and safe implementation suggestions of the BPaL regimen supported by the experience of healthcare workers and program coordinators. This presentation will give an overview of the Guide, including an overview of the individual drugs, toxicity management, pharmacovigilance, regulatory implementation, and lessons learned from earlier trials and clinicians.

Chairs and Speakers' biographies



Chair 1: Fraser Wares KNCV Tuberculosis Foundation

Dr Fraser Wares is a British trained public health physician. After working for various INGOs in different countries (1988-2001), he joined the WHO in India (2002-2010) and then in Geneva (2010-2016), providing technical assistance mainly on DR-TB.

Since 2016, he has been a PMDT Consultant with KNCV TB Foundation. Until 2019, he co-ordinated the “Core bedaquiline project”, under the USAID-supported Challenge TB Project.

Currently he co-ordinates KNCV’s BPAL-related activities in 10 countries.

From 2018, he has been part of the Global Drug-resistant TB Initiative’s Core Group and Vice-Chair (2018–2020), and as member and Chair of the SEAR Advisory Committee on DR-TB (2019 onwards).



Chair Askar Yedilbayev WHO Regional Office for Europe

Dr. Askar Yedilbayev is a TB Team Lead at Joint Programme for TB, HIV and viral Hepatitis at the WHO Regional Office for Europe, leading the regional support to countries on planning, implementation, monitoring and evaluation of all aspects of TB prevention and control. Dr Yedilbayev is a Medical Doctor and Public Health professional with 20 years of

professional, practical and research experience management of TB, DR-TB and TB/HIV co-infection in high-burden countries and resource-poor settings (WHO EURO and AFRO regions).

SPEAKERS



Victor Babawale

Dr. Babawale Victor is a Medical Doctor at the National Tuberculosis and Leprosy Control Programme in Nigeria with 12 years of experience focusing on drug-resistant (DR-) TB. He anchors the operational researches on the modified all oral shorter treatment regimens supported by TDR| WHO and the BPAL regimen supported by KNCV. He played a vital role in developing the first national guideline for DR-TB clinical and programmatic

management. He was a member of the Global Guideline Development Group (GDG) for the DR-TB in 2011 and currently is a member of the drug-sensitive (DS-) TB GDG.

**Mansa Mbenga**

Dr. Mansa is a PMDT consultant at KNCV Tuberculosis Foundation, He graduated as Medical Doctor from the People's Friendship University of Russia, pursued a postgraduate degree in Phthisiology from the same University, and a Diploma in Tropical Medicine and Hygiene for Royal College of Physicians in London. He has more than 10 years of experience in tuberculosis (TB) with 6 years of clinical trial experience. He successfully led the implementation of TB-PRACTECAL with MSF in Uzbekistan. He is supporting the introduction of the BPaL regimen under operational research conditions in KNCV supported countries under the LIFT-TB project.& nbsp;

**Veriko Mirtskhulava**

Veriko Mirtskhulava is a Medical Doctor with MPH and Ph.D. in Epidemiology and Global Health with more than ten years of experience in tuberculosis (TB) research, programmatic management, and capacity building. As a freelancer, She provided consultancies for WHO, USAID, ESDC, focusing on TB control program reviews and translational and operational research in Eastern Europe and Central Asia. Veriko joined KNCV in April 2017, currently, works as Senior Epidemiologist, and supports countries in introducing new drugs and regimens and in building translation research capacity.

**Jong Seok Lee**

Dr. Jong Seok Lee is the head of the Division of Microbiology Research at the International Tuberculosis Research Center(ITRC). He has been committed to the LIFT-TB BPaL OR project as a technical lead of laboratory capacity building. He identified the pathogenic factor of tuberculosis at the Max-Planck Institute in Germany and is currently participating in the research of the genetic characteristics of Mycobacterium tuberculosis and the development of the rapid tuberculosis diagnosis system based on Korean technology.

**Suzanne Staples**

Dr Suzanne Staples is a medical doctor and Head of Research at THINK: TB and HIV Investigative Network, South Africa. She started doing research in 2012 working as Principal Investigator of global clinical trials as well as conducting independent research. She completed a Masters degree in Transdisciplinary health and development studies in 2017 complementing her biomedical knowledge for a holistic approach. She received recognition for her work when awarded an international research fellowship in 2017 through the EDCTP. Currently she heads her own research department looking at the social impact of TB as well as technological advances in healthcare.