

The Ukraine Experience: Implementing the BPaL Regimen



Photo: Brendan Hoffman

A participant of Ukraine's BPaL operational research program taking treatment in Kyiv.

TB Alliance is the world's leading developer of new TB drugs and is the first non-profit organization to develop a new TB drug. TB Alliance's **pretomanid and the BPaL (bee-pal) regimen** is a therapy for people with drug-resistant tuberculosis (DR-TB), consisting of bedaquiline (B), pretomanid (Pa), and linezolid (L).

“Nataliia Lytvynenko, who has overseen BPaL treatments in Ukraine, said the more manageable amount of pills meant it was **easier for patients to continue treatment** after being displaced by the war in her country.”

AFP (August 31, 2022)

About Drug-Resistant TB

TB is one of the world's oldest and deadliest poverty-related neglected diseases. TB is now killing more than twice as many people every day as COVID-19 – 1.6 million per year.¹ Though present in every country in the world, TB preys disproportionately on the poorest of the poor. TB is also a significant driver of the increasing threat of antimicrobial resistance (AMR)—there are roughly half a million cases of DR-TB each year, and **is responsible for about 1 in 3 deaths from AMR infections.**^{1,2}

WATCH THE STORY FROM UKRAINE



About the BPaL Regimen

BPaL was first studied in TB Alliance's Nix-TB trial, which enrolled people with highly drug-resistant TB. Nix-TB data have demonstrated a favorable outcome in 90 percent of patients after six months of treatment with BPaL and six months of post-treatment follow-up.³ Pretomanid has been clinically studied in more than 1,100 participants in 19 clinical trials evaluating the drug's safety and efficacy. Pretomanid has been clinically studied in 14 countries.

Prior to the introduction of BPaL, treatment of highly DR-TB was lengthy, intolerable, and complex. Most patients with highly drug resistant-TB took a combination of up to eight antibiotics, some involving daily injections, for 18 months or longer.²

Success rates were lower than 6 in 10.¹

“[Ukraine's BPaL implementation team] has been offering patients with drug-resistant TB a shorter treatment regime that also involves taking fewer pills every day. And rather than asking patients to show up at a clinic to collect their medication, the doctors pop it in the post. Patients are then checked on through messaging apps such as Viber, Whatsapp and Telegram. **It proves that TB treatment can innovate to fit the needs of patients in new circumstances.**”

The Economist (November 2, 2022)



WATCH
MARIIA'S STORY



Photo: Brendan Hoffman

Mariia's Story of TB Courage

Mariia had gotten sick while she worked at a factory making doors. By the time she went to the doctor, she found out that she had been infected with drug-resistant TB for over a year. She began her treatment journey in Lviv, Ukraine, but her doctors recommended she go to Kyiv to join a research program that would give her access to “a better treatment.”

Mariia then went to Kyiv where she was enrolled in an operational research program to help expand access to BPaL in the country.

“I am happy because I got better fast,” Mariia said of her experience on BPaL. “I do not have weakness anymore.”

BPaL Enables Cure Amidst Crisis

Ukraine was the first high-burden country to adopt the BPaL regimen. A shortened, simplified treatment for DR-TB has been an especially welcome advance for patients who needed treatment amid wartime conditions. As the war began, Ukrainian patients were given the remainder of their full treatment course so the remaining duration of their treatment could be completed remotely. **47 of 50 such patients successfully completed treatment.** Overall, **more than 90% of Ukrainian patients who completed DR-TB with BPaL 6+ months ago remain TB-free.**⁴ These outcomes would have been extraordinarily difficult using the longer, more toxic, and less effective treatments that were in place prior to BPaL. Ukraine's National TB Program is now moving quickly to scale up access to BPaL on a nationwide basis.

Despite the ongoing war with Russia, patients on BPaL in Ukraine have been able to continue their treatment even when TB hospitals were under assault.



Photo: Brendan Hoffman

The National Center of Tuberculosis and Lung Disease in Kyiv in December 2021.



Photo: Dennis Matsko

The Chernihiv Regional TB Hospital in 2022 after the war with Russia began.

REFERENCES

1. World Health Organization (WHO). Global TB Report 2022.
2. The Review on Antimicrobial Resistance. Tackling Drug-Resistant Infections Globally. May 2016.
3. Conradie F, et al. Bedaquiline, pretomanid and linezolid for treatment of extensively drug resistant, intolerant or non-responsive multidrug resistant pulmonary tuberculosis. *N Eng J Med* 2020;382:893-902.
4. Lytvynenko N. (2022) November 10. *Practical considerations for implementing and scaling up a new DR-TB regimen: experience from early BPaL-adopting countries* [Conference presentation]. Union Conference 2022.

New advances in DR-TB treatment enable similar **success rates** and the **same treatment time** as DS-TB.

Implementing BPaL in and around Ukraine



● ZeNix trial sites

● BPaL OR site

● BPaL+ trial sites

■ WHO list of high-burden MDR/RR-TB countries

For more information, please visit www.tballiance.org