

## In Europe, the Availability and Cost of Drugs to Treat Tuberculosis

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### Abstract

In countries in the WHO European region, where rates of drug-resistant tuberculosis are the highest of all WHO regions, we looked into access to genotypic and phenotypic *Mycobacterium tuberculosis* drug susceptibility testing, the availability of antituberculosis drugs, and the cost of drugs and treatment regimens. Results were divided into groups based on low- and high-income nations.

43 treatment facilities overall, representing 43 nations, took part in the study. The percentage of nations offering phenotypic drug susceptibility testing for WHO group A medications was as follows (a) 75% (30/40) for levofloxacin, (b) 82% (33/40) for moxifloxacin, (c) 48% (19/40) for bedaquiline, and (d) 72% (29/40) for linezolid. Overall, 36 (84%) of the 43 nations had access to bedaquiline, while 24 (56%) had access to delamanid, and just 6 (14%) had access to rifapentine [1-5]. Many drug-resistant TB patients receiving a treatment plan that includes Only 17 (40%) of the 43 countries have access to a carbapenem. In middle-income countries (n = 12), the median cost of regimens for drug-susceptible tuberculosis, multidrug-resistant/rifampicin-resistant tuberculosis (shorter regimen, including bedaquiline for 6 months), and extensively drug-resistant tuberculosis (including bedaquiline, delamanid, and a carbapenem) was €44 (minimum-maximum, €15-152).

### Introduction

The most common bacterial pathogen-related cause of death worldwide is tuberculosis (TB). In 2020, 9.9 million persons contracted TB, and 1.5 million TB patients passed away. The WHO's END-TB strategy is under jeopardy due to *Mycobacterium tuberculosis* developing antimicrobial medication resistance. The proportion of patients with drug-resistant TB is higher in the European region of the WHO compared to all other regions [6]. In 2020, there were 34 778 patients with rifampicin- and multidrug-resistant (MDR) tuberculosis, including 11 072 patients with Both extensively drug-resistant (XDR) and pre-XDR TB are prevalent in the WHO European area. The WHO reports that more than 85% of TB patients worldwide experience a good treatment outcome; however, the prognosis for patients with MDR/RR-TB is less encouraging, with less than 60% of patients experiencing such success

The care of patients with drug-resistant TB has undergone a significant change as a result of diagnostic advancements and the availability of novel anti-TB medications [7-13]. In many nations, clinical routines now include molecular drug susceptibility testing (DST) based on nucleic acid amplification technologies. Along with significant modifications to treatment guidelines and regimens, new anti-TB medications, such as bedaquiline, delamanid, and pretomanid, have been approved for the treatment of drug-resistant TB. If patients and programmes have access to these advancements, TB control can be improved. All new anti-TB drugs must be priced reasonably to increase access, and this is a hot-button issue in politics and advocacy.

There is limited information available regarding the availability of pharmaceuticals and DST for new and repurposed anti-TB therapies following a recent change of the hierarchy of anti-TB drugs for the treatment of patients with drug-resistant TB by the WHO in 2020. The same is true of the price of various medications and treatment plans

### Subjective Heading

Through the distribution of a standardised questionnaire to TBNET representatives with knowledge of the management of drug-resistant TB at referral treatment facilities in nations of the WHO European region, data on TB drug availability, cost, and availability of DST for all anti-TB drugs were surveyed. If there were no TBNET representatives

in a country, we searched PubMed for significant papers on drug-resistant TB and contacted the authors from those countries. From June 2020 through December, data on medicine availability, price, and DST availability were collected, revised in October 2021 from 2020. The list of medications included in the survey was created using those made available through the Global Drug Facility. When obtaining TB medications through pharmacies, paying at the Global Drug Facility, or through other country-specific suppliers, hospitals or other treatment providers incur drug costs.

The price of a single unit (a tablet or a vial) of the medicine was used to calculate drug costs. According to WHO-recommended drug doses, we calculated the quantity of units needed to provide individuals with 70 kg of body weight with a sufficient level of daily treatment. Fixed-dose drug combinations were taken into account when determining the cost of the regimen where available, and the least expensive regimen choice was reported. For medications that are not taken every day, such as bedaquiline, the daily treatment cost was calculated by dividing the weekly cost by seven. Cost information was gathered in local money or US dollars using conversion rates as of July 1, 2020. When costs are reported in Euro No direct country-to-country comparison exists. Drug costs were translated to international dollars for direct country comparisons using the purchasing power parity conversion factor from the international comparison programme 2017. Income stratification was done in accordance with the World Bank classification, which classifies middle-income nations as include both upper- and lower-middle-income ratio. If not otherwise mentioned,

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costs for medications and regimens are shown as the median with minimum and maximum values.

## Discussion

We offer a report on the availability of anti-TB DST as well as an updated data on the availability and pricing of anti-TB medications in the WHO European region as a result of a survey conducted in 2013. The key finding of this study is that second-line anti-TB drug supply in Europe is extremely constrained, particularly for new and repurposed therapies, and that new drugs are more frequently accessible than their specific DST. Drug-resistant tuberculosis treatment regimens and medications are relatively expensive in comparison to those prescribed to treat DS-TB. In addition, the cost of regimens is highly variable across different countries. Pre-XDR and XDR-TB treatment regimens are difficult to obtain, especially in middle-income nations. Finally, nearly no nation in Europe has access to the medications, including rifapentine and pretomanid, that are a part of the new, promising regimens for DS and drug-resistant TB.

Based on the most recent recommendations from the WHO and the American Thoracic Society/Centers for Disease Control/European Respiratory Society/Infectious Diseases Society of America we chose regimens for drug-susceptible (DS) TB, MDR/RR-TB, pre-XDR TB, and XDR-TB; regimen compositions are shown in Table S2. All first-line TB medicines were considered to be effective against DS-TB. According to the WHO 2020 definitions, XDR-TB, pre-XDR-TB, and MDR/RR-TB were all defined .display the outcomes for eight priority regimens, while Table S5 displays the outcomes for additional regimens. and S4 Tables, respectively. We do not include the price for a standard treatment plan containing bedaquiline, linezolid, and pretomanid or rifapentine, moxifloxacin, isoniazid, and pyrazinamide as information on the drug's price was only available in three high-income countries for pretomanid and in two middle-income and three high-income countries for rifapentine, respectively. For the same set of medications as the pricing data, DST accessibility was assessed and stratified using phenotypic and genotypic testing.

In general, phenotypic DST was more accessible than genotypic testing. Phenotypic DST for all first-line medications was available in 38 (95%) of the 40 countries, genotypic DST for rifampicin was available in 40 (100%), isoniazid was available in 38 (95%), ethambutol was available in 21 (53%), and pyrazinamide was available in 12 (30%) of the 40 countries. For WHO group A medications, the proportion of nations offering phenotypic and/or genotypic DST was 75% (30/40) for levofloxacin, 82% (33/40) for moxifloxacin, 48% (19/40) for bedaquiline, and 72% (29/40) for linezolid, respectively (Fig. 1, Fig. 2). Countries that frequently use group B medications include For clofazimine, the availability of phenotypic and/or genotypic DST was 63% (25/40) and 28% (11/40), respectively, while for cycloserine/terizidone, it was 58% (23/40) and 20% (8/40). For group C medications, phenotypic and/or genotypic DST was only available in 6 (15%), 1 (2.5%), 17 (42%) and 10 (25%) of the 40 countries, respectively, for carbapenems (meropenem and imipenem) and delamanid. Rifapentine genotypic DST was only accessible in 6 (15%) of the 40 countries, and phenotypic DST could not be analysed in any of the countries. Similar to genotypic DST, only 2 (5%) and 4 (10%) of the 40 nations offered phenotypic DST for pretomanid.

## Conclusion

We are aware of the study's various shortcomings. First, information on drug accessibility, drug price, and DST was available for 43, 41,

and 40 of the WHO European region's 53 nations, respectively. The poll excluded nations with tiny cities and those in Central Asia [14-15]. Second, information was gathered from MDR/RR-TB centres in nations having the capability of reporting representative data. Despite the fact that none of the participating centres reported differences in the price of medications at This possibility cannot be ruled out because of their respective countries' various centres. Third, we failed to examine how potential stock outs may affect medicine availability. Fourth, while various regimen compositions might be conceivable, the regimens used for cost calculations adhered to the guidelines of the WHO and the American Thoracic Society/Centers for Disease Control/European Respiratory Society/Infectious Diseases Society of America .Fifth, there is no discussion of paediatric TB regimens. Finally, the coronavirus disease 2019 pandemic may have caused a delay in the installation of newer diagnostics capabilities and the accessibility of new treatment regimens in several nations of the region.

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## Conflict of Interest

The authors declare that they are no conflict of interest.

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