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EDITORIAL

Using existing data to illustrate—and close—the gap in access to new anti-tuberculosis drugs

IN THIS ISSUE OF THE *JOURNAL*,[1] Bonnet and colleagues provide the first empiric evidence that a large proportion of multidrug-resistant tuberculosis (MDR-TB) patients in some settings have indications for receiving bedaquiline or delamanid.[2,3] Across five sites in the former Soviet Union and Africa, nearly 35% of patients had extensively drug-resistant (XDR) or pre-XDR-TB, an indication for bedaquiline. Approximately two thirds had risk factors for poor outcomes, representing an indication for delamanid. This study suggests that demand for new drugs may be much higher than previously expected.[4]

Several other baseline risk factors for unfavourable outcomes or indications for new drug use were identified: previous incarceration, previous TB treatment, low body mass index (BMI) and higher grade smear. Although their distribution is heterogeneous, certain risk factors stand out: low BMI in approximately half of patients in the African sites, and XDR/pre-XDR in approximately one third of patients in the former Soviet sites. Applying these proportions to the number of estimated MDR-TB cases among notified TB cases in the World Health Organization Africa (32 000, 95%CI 15 000–49 000) and Europe regions (72 000, 95%CI 62 000–81 000])[5] gives low-bound estimates of 16 000 people in Africa and 24 000 in Europe requiring a new drug each year. This stands in sharp contrast to the total 1764 courses of bedaquiline ordered through the Global Drug Facility by early October 2015. Thus, the gap between need and access is still enormous.

Closing this gap will require additional supplies and resources and more affordable pricing than the current tiered-pricing strategy for bedaquiline: US$900 for 31 low-income and US$3000 for 104 middle-income countries. The cost of 16 000 courses of bedaquiline or delamanid—assuming the same low price—in Africa would be US$14.4 million, while for the mostly middle-income European region, the cost would be US$72 million. In addition, programmes require support to import and use new drugs, including guidance on how to perform pharmacovigilance, with ECG monitoring of QT interval unless the cardiac safety of the new drugs is established.

Programmatic evidence is also required to document the impact of new drug use on early and final treatment response, reducing loss to follow-up, morbidity and transmission of MDR-TB. On average 23% of the patients were lost to follow-up during treatment, despite patient support.

Countries would benefit from a simple scoring system that predicts the likelihood of poor outcome with current treatment and to identify MDR-TB patients who would benefit from these new drugs. Further efforts are needed to validate and refine a score based on the predictors identified in this study and MDR-TB patient heterogeneity, including human immunodeficiency virus serostatus.

The present article serves as an excellent reminder of the limitations of current MDR-TB treatment and sounds the alarm for a more extensive and proactively supported introduction of delamanid and bedaquiline for the patients who need them.

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