



## EDITORIAL

## Implementation of Xpert® MTB/RIF in high-burden countries: voices from the field matter

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It is almost a decade since the Xpert® MTB/RIF assay (Cepheid Inc, Sunnyvale, CA, USA) was endorsed by the World Health Organization for tuberculosis (TB) diagnosis and rapid drug susceptibility testing (DST). We have learnt a lot in these years. We know that the Xpert is highly accurate and has played a big role in making it possible for high-burden countries advance towards the End TB goal of universal DST.<sup>1</sup> This has paved the way for the introduction of new drug regimens. The Xpert technology has inspired many fast followers to enter the TB diagnostics space.<sup>2</sup>

We have also learnt that the technology is no panacea. Countries have been slow to scale-up the test, although trend analyses do show progress.<sup>3</sup> We have also learnt that Xpert alone cannot have a big impact without improving the overall cascade of TB care.<sup>4</sup>

As newer versions of Xpert emerge (e.g., GeneXpert Edge, Omni and Xpert XDR), we need to continue to learn about practical barriers in the field and listen to the voices from the field. This will not only help develop better products that are fit for purpose, but also enhance uptake and impact.

In this context, the survey of stakeholders by England et al. from 16 high-burden countries provides valuable data and insights.<sup>5</sup> While previous studies have discussed concerns around cost<sup>6</sup> and the slow pace of policy change in countries,<sup>1</sup> England et al. provide interesting data on barriers created by the poor sensitisation of clinical staff, and a high turnover of trained laboratory staff.

Another useful finding is the cost inflation that occurs due to the distribution process in countries; added costs that include import duties, shipping costs and profit margins imposed by local distributors can add 7–50% to the cartridge price. The real price for countries is therefore much higher than the US\$9.98 sticker price.

Yet another key finding is challenges faced by countries for service and maintenance provision; only half the countries surveyed stated that they were fully satisfied with the services provided.<sup>5</sup> Turnaround times for module replacement ranged from 7 days to 1 year, with about 40% of countries having modules replaced in less than 1 month.<sup>5</sup>

Finally, England et al. describe the over-reliance on the Global Fund for Xpert implementation. They raise valid concerns about sustainability of the Xpert networks if/when countries transition out of Global Fund

support and adequate domestic financing does not kick in.

Cumulatively, these barriers could explain why countries tend to ration the use of Xpert and limit access to only select, high-risk groups.<sup>7</sup> To fully exploit this powerful technology and to improve TB outcomes at the population level, all stakeholders, especially Cepheid, donors (e.g., Global Fund) and country programmes should anticipate and address these barriers for sustained implementation.

One potential strategy to offset price escalation and sustainability is to share the procurement and maintenance costs for Xpert across multiple conditions (e.g., TB, HIV, hepatitis, cancer), and fully leverage the platform for offering a range of tests included in the WHO Essential Diagnostics List.<sup>8</sup> Indeed, access to essential diagnostics must be seen as a key component of universal health coverage (UHC).<sup>9,10</sup> To deliver on UHC, countries will need to think beyond siloed vertical programmes and think of system integration. In this context, platform technologies that can deliver a variety of tests in the Essential Diagnostics List are highly desirable. Today, thanks to their pathfinder MTB/RIF assay, Cepheid's GeneXpert is an obvious candidate. However, to realise this potential, Cepheid should continuously listen to voices from the field and do everything possible to address the barriers identified by stakeholders.

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