

January 2024

Dear Esteemed Members of the Board of The Global Fund to Fight AIDS, Tuberculosis and Malaria,

This message is about the Value for Money Audit report of the Global Fund Office of the Inspector General (OIG) on Global Fund investments in Health and Laboratory-related equipment.

Over the past months, the Stop TB Partnership has collaborated with colleagues from the WHO Global TB Programme, USAID and country programmes to share our joint concerns with the OIG regarding the scope, methods and findings of the audit.

While the OIG has made some improvements to the first version of the draft report shared with Board Members, Alternate Board Members and Focal Points in June 2023, we want to clarify and share that there are many points of disagreement and concerns.

Even though the OIG has amended the report to describe the critical role GeneXpert plays as an enabler for national TB programmes to rapidly diagnose TB and drug-resistant TB, the report does not acknowledge the challenges that programmes have faced in securing adequate funding to provide a rapid molecular test to everyone who needs one. This is evident from the unfunded demand for GeneXpert products of approximately 111 million USD and 213 million USD in Global Fund Grant Cycles 6 and 7, respectively. Furthermore, many high TB burden countries have had no choice but to develop algorithms that restrict cartridges for use with specific risk groups or at certain facilities. From the 2020 Stop TB Partnership Step Up for TB report, which included a survey of high TB burden countries' policies conducted during the time of the OIG report's 2016-2021 timeframe, half of countries (17/34) had policies that either did not call for universal access to rapid molecular testing or that restricted such testing to certain facilities. This is the sad reality that country programmes have had to resort to when faced with limited budget envelopes.

Despite arguments from Stop TB and partners, the report's conclusions around effectiveness continue to center on a sole indicator: the percentage of people with TB that were tested with GeneXpert. The focus on this indicator's trends, particularly during the Covid pandemic when services were being diverted and supply chain challenges were contributing to stockouts in many countries, is highly questionable and disturbing.

www.stoptb.org

Stop TB Partnership
Global Health Campus
Chemin du Pommier 40
1218 Grand-Saconnex
Geneva, Switzerland



GeneXpert has contributed significantly to the diagnosis of drug-resistant TB and reductions in time to diagnosis and start of treatment, indicators that were not considered in the report. Furthermore, the report makes conclusions around limited effectiveness based on an arbitrary threshold that was not reached in 3 of 5 countries, one of which entailed use of data that differs from that reported to WHO. Even the mathematics and assumptions used in defining the arbitrary threshold are incorrect.

We question the representativeness of the 6 countries included in the review, given known variations between countries and possible confounding factors. We also consider that the report does not recognize the importance of the cost of cartridges, and absence of comprehensive service and maintenance packages as a constraint on full utilisation or the extent to which GeneXpert machines were procured to be used for the COVID-19 pandemic response.

We, at the Stop TB Partnership, recognize there are operational challenges on roll-out of rapid molecular diagnosis and have been working diligently alongside countries, partners and donors to overcome them, with multiple examples of success stories. We are proud to have worked closely over the past year with the Global Fund and USAID to negotiate improvements in service and maintenance, with Cepheid for the first time ever committing to make comprehensive packages widely available. We are optimistic that these efforts can lead to increased instrument uptime across more countries so that people in need of testing can reliably have access. We are also advocating tirelessly on behalf of countries to increase TB funding from the Global Fund so that countries can buy enough cartridges to meet the ambitious targets of their strategic plans and overcome the access challenges highlighted in the report.

However, we are very worried that this report leaves open the door to misinterpretation and some readers may falsely conclude that GeneXpert is not an effective tool and that countries have too many instruments.

We simply can not accept that country programmes can be pushed back to microscopy for the diagnosis of TB. We must collectively support all efforts of countries to increase access to diagnosis using rapid molecular tests including with GeneXpert and other instruments.

This means more funding for instruments, cartridges, comprehensive service and maintenance contracts, specimen referral systems and other health system components.

The report reviews data and trends between 2016-2021, and today we are in 2024 and several things are clearer than ever:

1. The TB response is grossly underfunded.
2. Countries' programmes struggle to buy enough cartridges for their insufficient number of instruments, even with the recent significant price decrease for Xpert cartridges achieved with the support of the Global Fund. Therefore, sadly, there are countries even today still resorting to restrictive

algorithms and limited roll-out of instruments to make due with the number of cartridges that they can afford under their budget envelope.

3. We cannot accept underfunding of TB molecular diagnostic networks as the only standard for diagnosis must be a molecular test for all.

We do not see any added value of this report of OIG in supporting the work done by country programmes towards ending TB by 2030.

Best regards,



Dr Lucica Ditiu
Executive Director
Stop TB Partnership