TECHNICAL BRIEF

HIDDEN COSTS: GENEXPERT TESTS AND DANAHER'S DELAYED AUDIT

GENEXPERT TESTS

Accurate and affordable diagnostic medical tests are an essential first step toward treating deadly infectious diseases such as tuberculosis (TB), HIV, and hepatitis, among others. The GeneXpert diagnostic system is a self-contained, fully integrated, automated platform that can be used to diagnose these diseases near the point of care. The combination of high accuracy and simplicity allows GeneXpert to be used in decentralised health systems, which is particularly important for low- and middle-income countries (LMICs) where laboratory capacities are limited, and many people live far away from reference hospitals.

GeneXpert is manufactured by Cepheid, a diagnostics corporation owned by the US-based conglomerate Danaher, which ranked 132nd on the "Fortune 500" list in 2023 and reported revenues of more than US$31 billion. GeneXpert tests for TB, HIV, and hepatitis are among the tests recommended by the World Health Organization (WHO) for diagnosing these diseases. While the India-based diagnostic corporation Molbio also has WHO-recommended tests for TB, and similar technologies from other corporations are entering the market, most national disease programmes in LMICs are currently highly dependent on GeneXpert systems and cartridges.

The research and development (R&D) of GeneXpert tests was supported by financial investments to the tune of at least $250 million from public and philanthropic organisations such as the US Department of Health and Human Services and the global non-profit FIND, among others.[1] The tests entered the LMIC market progressively from 2012 onwards at different prices: $9.98 for the standard TB test; $19.80 ($14.90 since 2022) for the extensively drug-resistant TB (XDR-TB) test; and $14.90 for the HIV and hepatitis tests.

Activists calling for a reduction of GeneXpert test prices at the 2024 International AIDS Conference in Munich, Germany.

September 2024 | www.msfaccess.org

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The $9.98 price of the TB test was the result of a 10 years' "buy down agreement", an arrangement to lower prices for buyers through an upfront payment to the seller, negotiated by WHO and Unitaid in 2012.[2] The prices of this and other GeneXpert tests are not based on any evidence of their cost of production, remain largely unchanged despite growing sales for more than a decade, and are too high for governments and healthcare providers to roll out at the scale needed.[3]

In 2018, faced with high prices and lack of transparency from Cepheid, Médecins Sans Frontières/Doctors Without Borders (MSF) commissioned an independent consultancy company to estimate the cost of production for GeneXpert tests. The analysis showed that at 10 million annual sales volumes, the cost to produce one GeneXpert test is estimated to be between $3 and $4.60.[4] Sales figures had already crossed this mark in 2018, and stand at at least 20 million for TB tests alone today.[4]

The analysis measured the direct cost of production of the GeneXpert tests, including the cost of materials, labour, manufacturing overhead, intellectual property royalties, and various indirect expenses. Aside from the $250 million invested by public and philanthropic organisations, investments into the tests' R&D have not been disclosed by Cepheid and therefore could not be included in the analysis. The study also showed there is no major difference in cost between producing tests for TB and other diseases, and that volumes can be aggregated across tests for different diseases to reduce costs. Cepheid has therefore been charging LMICs more than 2-4 times what it has been estimated to cost to produce each test.

The "Time For $5" campaign, a coalition of 150+ civil society organisations and activists coordinated by MSF, Partners in Health and Treatment Action Group, calls for a price of $5 per GeneXpert test, which would make them much more accessible and affordable for LMICs and still earn Cepheid profits of 8-40% per test.[5]

TB TEST PRICE REDUCTION AND COST-OF-PRODUCTION AUDIT COMMITMENT

On 19 September 2023, under unprecedented public pressure from the Time For $5 campaign and TB activists, Danaher announced they will sell Cepheid's standard TB test "at cost" and reduced the price by 20%, from $9.98 to $7.97 per test.[6] The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) projected that the price reduction will free up $32 million, which could allow the procurement of an additional 3.6 million Xpert TB tests each year. MSF is also saving hundreds of thousands of dollars annually as a result of the price drop, enabling these funds to be redirected to other critical medical operations.

Danaher also committed that "Going forward, Cepheid will validate its actual cost annually with an internationally accredited third-party assessment and adjust pricing accordingly, if necessary, so that Danaher can assure that it continues to earn no profit from these cartridge sales." This pledged annual audit on GeneXpert production costs is an opportunity to demonstrate best practices for a credible, publicly verifiable result that can build trust with countries, procurers and end users, and lead to more rational pricing for these and other lifesaving medical tests.

Almost a year later, despite repeated attempts by the Time For $5 coalition to reach out to key decision makers at the corporations, no information has been made available by Danaher or Cepheid about how the audit will be conducted and by whom. In March 2024, 18 investors in Danaher with over $400 billion in assets sent an open letter to Danaher requesting full transparency of the audit they pledged to carry out.[7] To date, the corporation has not responded in writing.

RECOMMENDATIONS

To maximise the audit's benefits for disease-affected countries, the Time for $5 coalition urges Danaher and Cepheid to take the following actions by December 2024 to ensure an independent, rigorous, and transparent audit process on an annual basis:

- Establish an audit advisory committee to keep all stakeholders informed and consulted throughout the audit process, from design to reporting.

  The committee should include, at least, The Global Fund, Stop TB Partnership and the Global Drug Facility, USAID, WHO, FIND, and civil society organisations representing affected communities.

- Use an audit methodology that follows best practices for assessing the production costs of molecular diagnostics. Such a methodology has been developed, but not published, by FIND.

- Include all GeneXpert tests eligible for Cepheid's Access Programme for high-burden disease countries in the audit.[8]

- Develop, in collaboration with the advisory committee, a public information-sharing approach that prioritises transparency of the audit.

  This includes disclosing the audit request to the third party, the methodology used, raw data, and audit outcomes in a publicly available report. Conducting audits in a transparent manner, with oversight from key stakeholders including civil society organisations, is essential to uphold credibility and trust in the audit outcomes.

THE ROLE OF GLOBAL HEALTH ACTORS AND GOVERNMENTS

While Danaher and Cepheid are primarily responsible for the GeneXpert cost-of-production audit, governments and global health actors must also ensure the audit is conducted transparently and helps guarantee affordability of these lifesaving tests.

THE GLOBAL FUND

The Global Fund jointly announced the September 2023 price reduction with Danaher and shares responsibility for ensuring that Danaher conducts the audit in line with best practices, as described above. In addition, The Global Fund is responsible for good stewardship of funds it receives from governments. As such, **it must ensure that countries can procure lifesaving diagnostic tests at the most economical price to maximise their funding for expanding testing and saving more lives, ensuring impactful value for money.**

FIND

Currently, no publicly available guidance exists for assessing the production cost of diagnostic tests like GeneXpert. This gap is evident in Danaher's "at cost" price of $7.97 for the standard TB test, which contrasts sharply with the $3 to $4.60 cost estimated by MSF's independent analysis. Danaher/Cepheid contest this estimate but have not made publicly available a methods-based critique or methodology and results of a different estimation process. These discrepancies highlight the urgent need for a consistent methodology in estimating diagnostic production costs.

To address this issue, FIND, a non-profit public private partnership dedicated to accelerating equitable access to reliable diagnostics for LMICs, should take the lead. **FIND should make publicly available a standardised methodology and guidance for estimating diagnostic production costs.** This framework will not only assist in guiding Danaher's cost-of-production audit but will also set a precedent for future audits of diagnostic production costs conducted by other manufacturers.

WHO

In 2019, the World Health Assembly passed resolution WHA72.8 to improve the transparency of markets for medicines, vaccines, and other health products. It requested the WHO Director-General "to continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products".[9] **As part of this objective, WHO should issue normative guidance on when audits of diagnostic test production costs should be conducted and reported.**

WHO should also establish criteria to identify diagnostic tests and medical products that need cost-of-production analysis and publish priority lists for these products. Priority should be given to products that are urgently needed to address major burdens of disease in LMICs but whose high prices limit access, and to products for which there is only a single supplier.

GOVERNMENTS

Ahead of the next Global Fund replenishment in 2025, **donor governments should request that The Global Fund commit to maximising the impact of their official development assistance (ODA) investments by auditing the cost of production of GeneXpert tests.**

Governments of countries in which national procurement laws and bureaucracy result in price mark-ups for GeneXpert tests (and other lifesaving medical products) should take immediate action to lower prices. The landing prices—prices after accounting for shipping, duties and other fees—of GeneXpert tests in LMICs are sometimes two or three times the prices set by the manufacturer. Uncontrolled price setting by local distributors of GeneXpert tests, often without any alternative local supplier, can be another factor contributing to high prices for end users. **Governments should regulate distributor mark-ups, and minimise importation fees and taxes on medical tests, to maximise health benefits of procurement.**

Governments and other public funders of R&D of diagnostic tests and other medical products should require cost-of-production data to be made publicly available as a transparency condition when funding R&D, or as a condition attached to rewards such as tax credits. The requirement should include using a standardised methodology to assess production costs with the analysis conducted by an agreed independent third party.

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