



Audit Report

Global Fund Grants in the

# Republic of India



GF-OIG-23-011  
9 May 2023  
Geneva, Switzerland

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The Office of the Inspector General (OIG) safeguards the assets, investments, reputation and sustainability of the Global Fund by ensuring that it takes the right action to end the epidemics of AIDS, tuberculosis and malaria. Through audits, investigations and advisory work, it promotes good practice, enhances risk management and reports fully and transparently on abuse.

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# 1. Executive Summary

## 1.1 Opinion

Achieving strong programmatic results in the fight against the three diseases in India is critical for the Global Fund to achieve its overall global mission. The country has a significant tuberculosis (TB) disease burden and a large number of People Living with HIV (PLHIV).

This has made India a key strategic partner to the Global Fund as both a major recipient of Global Fund investments (US\$3 billion<sup>1</sup> since 2002) and a donor with contributions totalling US\$60.5 million to date. As a major economic power with a large national health budget, Global Fund investments represent a small proportion of the total national response to the three diseases. This alters how Global Fund investments are positioned, supporting more innovative and catalytic areas within a broader landscape of domestic funding.

Overall, India has achieved strong programmatic results for both TB and HIV, with notable declines in morbidity and mortality. TB case notifications have increased, linked to innovative interventions with the private sector and active case finding. In addition, the TB program demonstrated resilience in recovering from the impact of COVID-19 with a strong rebound in TB case notifications in 2021.

However, issues were identified around the timely handover of interventions to domestic financing, operational challenges with key diagnostic equipment and poor results on Lost To Follow-Up (LTFU) targets. Therefore, the design of Global Fund interventions to support sustainable<sup>2</sup> programmatic results has been rated as **partially effective**. The Global Fund Secretariat determined that a management action is not needed due to the nature of the grants, the limited span of control of implementers, and the risks covered by existing grant and risk management processes of the Global Fund.

The Payment for Results (PfR) modality signals an innovative approach to strategically engage with the government by rewarding positive performance. PfR targets are mostly ambitious and aligned to national priorities. However, issues in the design of HIV targets and operational gaps and delays in risk assessment, mitigation and assurance mechanisms could impact PfR's effective implementation and limit potential benefits. Therefore, the design of the PfR modality under NFM3, to ensure catalytic impact, has been rated as **partially effective**.

The Global Fund approved US\$ 105 million from C19RM 2020 and 2021 to support India in mitigating the impact of COVID-19. Rapid approval of proposals was noted in response to India's urgent needs. However, significant issues were reported in the effectiveness and timely use of C19RM funds. As a result, the design and effectiveness of Global Fund support through C19RM investments in India has been rated as **needing significant improvement**.

Finally, partial gaps in risk management and oversight over some data quality and data system related risks were noted. This has exposed the portfolio to increased risks that can affect grant implementation. Therefore, the design and effectiveness of oversight and monitoring of Global Fund interventions has been rated as **partially effective**.

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<sup>1</sup> <https://data.theglobalfund.org/location/IND/overview> (accessed 13 May 2022)

<sup>2</sup> The Global Fund defines sustainability as the ability of a health program or country to both maintain and scale up service coverage to a level, in line with the epidemiological context, that will provide for continuing control of a public health problem and support efforts for elimination of the three diseases, even after the removal of external funding by the Global Fund and other major external donors - [https://www.theglobalfund.org/media/4221/bm35\\_04-sustainabilitytransitionandcofinancing\\_policy\\_en.pdf](https://www.theglobalfund.org/media/4221/bm35_04-sustainabilitytransitionandcofinancing_policy_en.pdf) (accessed 09 December 2022)

## 1.2 Key Achievements and Good Practice

### **Strong programmatic results for HIV and TB**

The HIV program has demonstrated solid progress in dealing with the key population-centered epidemic in the country, with declining trends for HIV prevalence, new infections, and mortality. India has made steady progress in reaching 95:95:95 targets, reporting 78:83:85 in 2021.<sup>3</sup> This progress reflects several innovations to improve HIV treatment care and support including: multi-month dispensing, the establishment of care and support centers (CSCs) and the introduction of self-verified treatment adherence. The TB program has demonstrated strong programmatic results with increases in treatment coverage and large increases in TB case notifications (46% increase since 2011). Although COVID-19 negatively impacted TB case notifications, the program has shown resilience in recovering with a strong rebound in case notifications in 2021 (19% increase year on year). Success was driven by significant private sector investment in TB case notifications through the JEET (Joint Effort for Elimination of Tuberculosis) project.

### **National survey improves understanding of India's TB burden**

The government completed its first national TB prevalence survey since 1958. It was finalized at the end of 2021 and published in Q1 2022. The survey showed that India's TB prevalence is larger than previously estimated and that there are also variances across various age groups, geographic locations, and populations. The detailed results allow the TB program to plan differentiated approaches with targeted interventions for TB care at the sub-national level.

### **Targeted investment in health system strengthening**

Continuous investments have helped to strengthen the laboratory and diagnostic capacity of both the HIV and TB programs. For the TB program, there has been significant scale-up in the number of laboratory sites, increases in diagnostic equipment in place and investment in a nationwide Laboratory Information Management System (LIMS).

## 1.3 Key Issues and Risks

### **Gaps and delays in hand-over activities to the Indian government risk the sustainability of investments**

Key HIV and TB interventions were originally due to be handed over to the Indian government at the end of NFM2 (31 March 2021), however, this has been significantly delayed. These interventions include a number of CSC sites for HIV and JEET sites for TB. The delays were linked to significant COVID-19 disruption, diverting efforts at the state level away from hand-over planning and execution, as well as a lack of up-to-date, costed and detailed transition plans at the sub-national level.

### **Gaps in the design of Payment for Result modality increases the risk of ineffective implementation**

The Global Fund signed Payment for Results (PfR) grants with India in NFM3 worth US\$300 million. This is only the second time that a country receives most of its Global Fund disbursements through this type of modality. PfR targets are mostly ambitious and aligned to national priorities, but some design gaps remain especially around targets set for HIV. In addition, gaps in assurance over data quality, as well as delays in finalizing key assurance processes and tools may negatively impact the modality during implementation. Subsequent to the audit, the verification protocols were approved to support timely assurance and disbursement.

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<sup>3</sup> NACO Sangkalak, 2021 - [http://naco.gov.in/sites/default/files/Sankalak\\_Booklet\\_2021\\_Third\\_Edition.pdf](http://naco.gov.in/sites/default/files/Sankalak_Booklet_2021_Third_Edition.pdf), page 36

## Low absorption of C19RM funds reduces investment impact

The Global Fund approved US\$105 million from C19RM in 2020 and 2021 to mitigate the impact of COVID-19 in India. The Secretariat ensured requests were rapidly approved in line with the country's urgent needs. However, there have been significant issues in the effectiveness and timely use of C19RM funds. Only 62% of the total 2020 award (US\$30 million) and 0% of the total 2021 fast-track award (US\$75 million) was used at the time of the audit (March 2022). As of September 2022, there had been minimal progress in using these funds with only a further US\$0.9 million expensed. This low utilization is linked to issues in grant design for key affected populations, as well as changes in the funding landscape, with substitute funding being used. There was also a lack of agile decision-making at both the country and Global Fund Secretariat levels, in addition to a lack of ownership and oversight by country stakeholders during implementation.<sup>4</sup> This was also balanced against the need to ensure COVID-19 funding was being used for the greatest impact and minimal risk.

### 1.4 Objectives, Ratings and Scope

The audit's overall objective was to provide reasonable assurance on the adequacy, effectiveness and efficiency of Global Fund grants to India. Specifically, the audit assessed the objectives below.

Objective	Rating	Scope
Design and implementation of Global Fund interventions to support sustainable programmatic results for HIV and TB programs.	Partially Effective	<b>Audit period:</b> The audit covered grants from January 2019 to December 2021, as well as the design of future arrangements for grant implementation in India.  <b>Coverage:</b> The audit covered the nine HIV and TB Principal Recipients of Global Fund-supported programs in India.  OIG auditors visited 106 sites, including 52 TB sites and 54 HIV sites, in 22 districts across three states (Delhi, Bihar and Uttar Pradesh).  <b>Scope exclusion:</b> The implementation and effectiveness of the Payment for Result modality and any C19RM awards not approved by 31 December 2021.
Design of the PfR modality for HIV and TB programs under NFM 3 to ensure catalytic impact.	Partially Effective	
Design and effectiveness of Global Fund support through C19RM investments.	Needs Significant Improvement	
Design and effectiveness of oversight and monitoring of Global Fund interventions.	Partially Effective	

Details about the general audit rating classification can be found in [Annex A](#) of this report.

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<sup>4</sup> However, it is noted that a CSO/KP Steering Committee was formed in country with representatives of various CSO networks related to the Key Affected Population grant that sought to push forward implementation. This committee is not a CCM committee and was not formally created as a part of the CCM.

## 2. Background and Context

### 2.1 Overall Context

India is a lower-middle-income country that has a health expenditure of US\$64 per capita. With a population of 1.38 billion, it is the second-most populous country in the world. India has a federal structure, meaning power is shared for health care financing and services between the central government and its 28 states and eight union territories. This requires both national- and state-level engagement to implement Global Fund-supported grants.

India has the largest economy of all beneficiary countries supported by the Global Fund, which impacts how it engages India in terms of co-financing, sustainability and transition. Domestic financing from the Indian government provides the main funding for HIV, TB and malaria activities, which significantly influences grant design.

Global Fund investments act as catalytic support to the government – accounting for only 6 to 8% of interventions for the three diseases. There are a few other donors with major investments in health, including the World Bank, which offers significant loans and grants to the country for a range of health and non-health priorities.

### 2.2 COVID-19 Situation

India is the second worst affected country in terms of reported cases in the world for COVID-19, and the third worst in terms of reported deaths. As shown below, there were three significant waves in the pandemic in India. Each had a substantially negative impact on health service provision overall and for the three diseases.

**Covid 19 snapshot (01.03.22)**  
**Cases:** 42,417,022  
**Active Cases:** 92,472  
**Recovered:** 42,324,550  
**Total vaccinated:** 1,777,025,914  
**Deaths:** 514,023

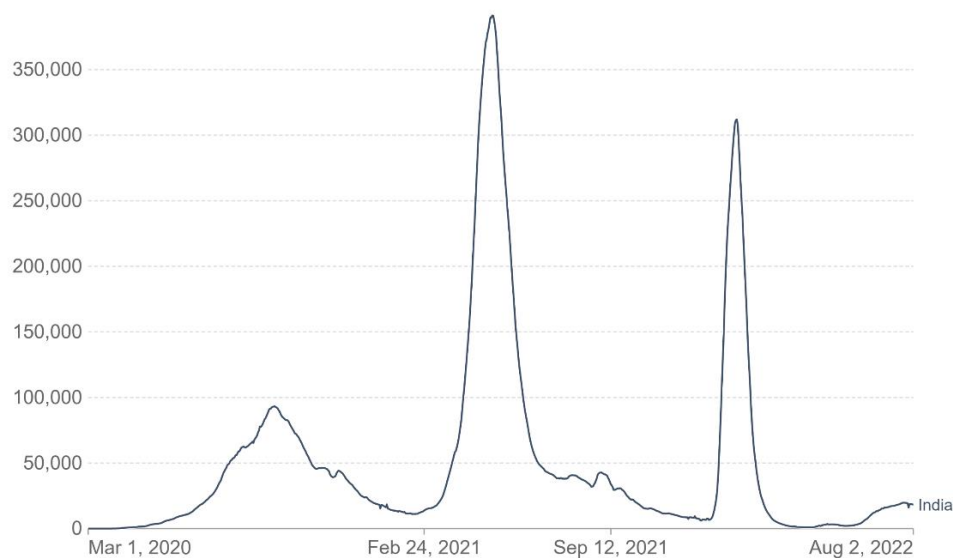


Figure 1: COVID-19 cases in India<sup>5</sup>

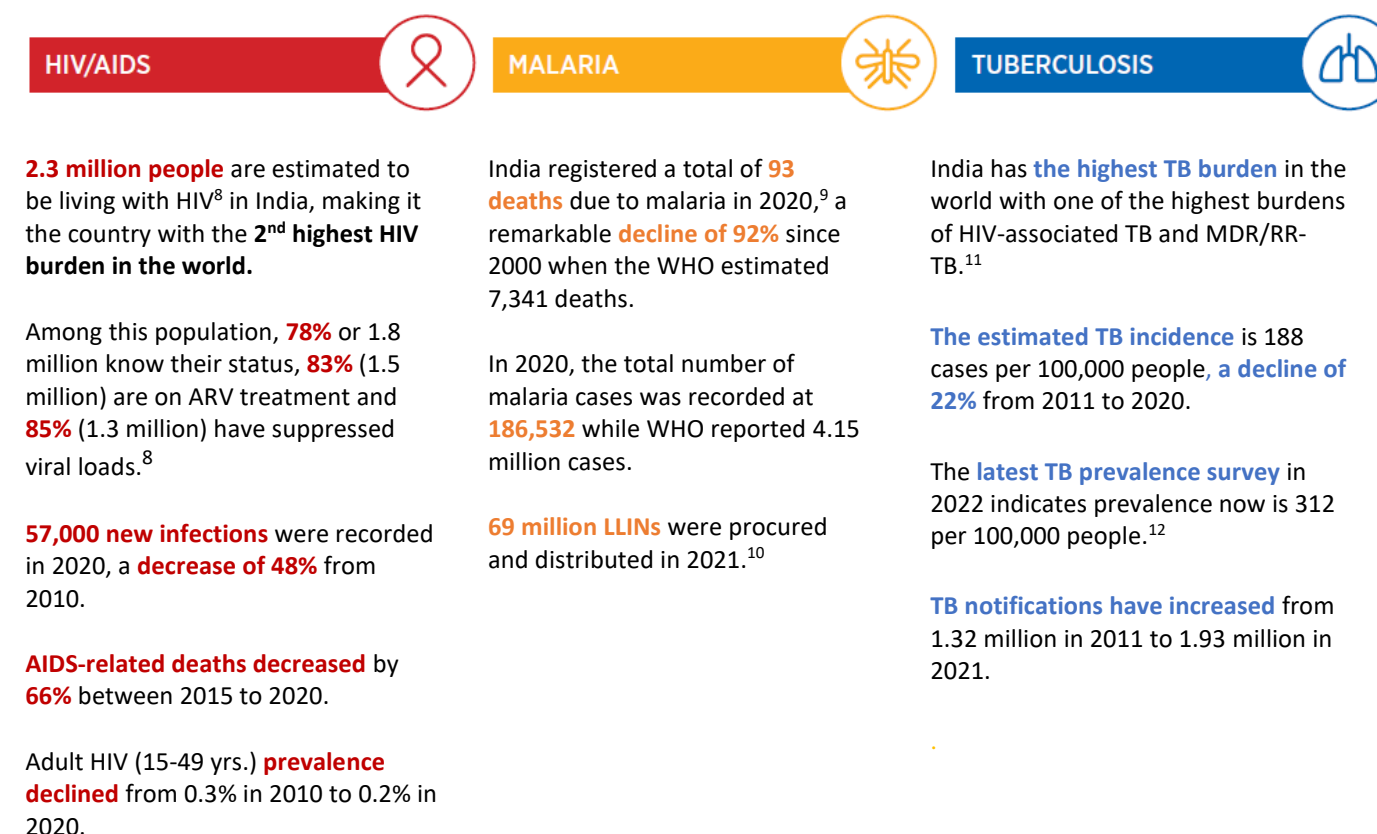
<sup>5</sup><https://ourworldindata.org/coronavirus/country/india> (Accessed on 03 August 2022)

## 2.3 Global Fund Grants in India

Since 2003, the Global Fund has disbursed more than US\$3 billion to India,<sup>6</sup> with a total allocation of US\$1 billion for the funding cycle 2017-2019 (NFM2) and 2020-2022 (NFM3). Full details on grants can be found in the Global Fund's Data Explorer.<sup>7</sup> There were 11 Principal Recipients in NFM2 and 10 in NFM3.

Implementation arrangements in place for NFM2, three of which leverage a blend of government and non-government Principal Recipients. For government implementers, grant agreements are signed with the Department of Economic Affairs in the Ministry of Finance (MoF). However, grant implementation and monitoring sits under the Ministry of Health. Several non-government Principal Recipients, including NGOs and private sector entities, support implementation of key activities across the three diseases.

## 2.4 The Three Diseases



<sup>6</sup> <https://data.theglobalfund.org/location/IND/overview> (accessed on 17 May 2022).

<sup>7</sup> Global Fund's Data Explorer, Nigeria profile - <https://data.theglobalfund.org/location/NGA/overview> (Accessed on 3 December 2021).

<sup>8</sup> NACO Sangkalak, 2021 - [http://naco.gov.in/sites/default/files/Sankalak\\_Booklet\\_2021\\_Third\\_Edition.pdf](http://naco.gov.in/sites/default/files/Sankalak_Booklet_2021_Third_Edition.pdf) - Sankalak: Status of National AIDS Response (Third edition, 2021)

<sup>9</sup> <https://nvbdcp.gov.in/WriteReadData/l892s/95833279891655805683.pdf>

<sup>10</sup> Data as per NFM2 grant

<sup>11</sup> WHO Global TB Report, 2021

<sup>12</sup> <https://tbcindia.gov.in/WriteReadData/l892s/25032022161020NATBPSReport.pdf>

### 3. Portfolio Risk and Performance Snapshot

#### 3.1 Portfolio Performance

Performance and grant ratings are shown below.

Com p	Grant	Principal recipient	Budget Amount (USD) NFM 2	Absorption as of 31 Mar 2021 NFM 2	Final Absorption as of 30 Sep 2021 NFM 2	Budget amount (USD) NFM 3 as of Mar 2022 (before C19RM 2021 integration)	Budget amount (USD) NFM 3 as of Sep 2022 (after C19RM 2021 integration)	Absorption as of 30 Sep 2021 NFM 3	Absorption as of 31 Mar 2022 NFM3	March 2021 rating	Sept 2021 rating
HIV & TB	IND-C-WJCF	William J. Clinton Foundation	18,283,889	70%	73%	N/A	N/A	N/A	N/A	A2	N/A
HIV	IND-C-PLAN	Plan International (India Chapter)	N/A	N/A	N/A	18,659,908	26,619,060	64%	75%	N/A	A2
HIV	IND-H-IHAA	India HIV/AIDS Alliance	24,447,187	88%	89%	9,619,064	36,691,267	57%	73%	B1	B2
HIV	IND-H-NACO	Department of Economic Affairs, Ministry of Finance of India	102,371,361	86%	86%	99,984,197	99,984,197	N/A	100%	A1	N/A
HIV	IND-H-PLAN	Plan International (India Chapter)	17,802,600	77%	80%	N/A	N/A	N/A	N/A	B1	N/A
HIV	IND-H-SAATH II	Solidarity and Action Against The HIV Infection in India	10,380,806	71%	73%	26,450,381	26,407,671	16%	69%	A2	B1
TB	IND-T-CHRI	Centre for Health Research and Innovation	15,596,592	73%	71%	N/A	N/A	N/A	N/A	B1	N/A
TB	IND-T-CTD	Department of Economic Affairs, Ministry of Finance of India	201,344,390	83%	100%	200,038,453	200,038,453	N/A	90%	B1	N/A
TB	IND-T-FIND	Foundation for Innovative New Diagnostics India	48,803,722	43%	57%	37,659,371	62,477,362	51%	93%*	B1	B1
TB	IND-T-IUATL D	International Union Against Tuberculosis	15,511,945	75%	76%	13,431,955	16,998,808	55%	82%	B1	B2



		s and Lung Disease									
TB	IND-T-WJCF	William J. Clinton Foundation	N/A	N/A	N/A	22,452,552	30,324,344	60%	90%	N/A	B1

## 3.2 Risk Appetite

The OIG compared the Global Fund Secretariat's aggregated assessed risk levels of key risk categories covered in the audit with the residual risk that exists based on the OIG's assessment, mapping risks to specific audit findings.

Please note that the OIG audit covered the Payment for Results (PfR) modality and risks relating to its design. Issues were noted for the modality in finding 4.3. The OIG noted moderate residual risks relating to the PfR modality, however these cannot be mapped to the key risk categories defined by the organization. This is because the Global Fund Secretariat's risk management framework considers the design of the PfR modality as an internal review process, not as a country-facing risk.

The full risk appetite methodology and explanation of differences are detailed in **Annex B** of this report.

Audit areas	Risks	Secretariat aggregated assessed risk level (As of 29 March 2022)	Assessed residual risk, based on audit results	Relevant audit issues
Global Fund interventions to support sustainable programmatic results for HIV and TB programs.	Program quality and efficiency	Moderate	Moderate	Findings 4.1 & 4.2
Global Fund support through C19RM investments to mitigate the impact of COVID-19 on communities and to maintain or scale-up program achievements.	Program design and relevance	Low	Moderate	Finding 4.4
	Procurement processes and outcomes	Moderate	Moderate	
Oversight and monitoring of Global Fund interventions related to HIV, TB and malaria programs, including routine monitoring mechanisms.	Design and operational capacity of M&E systems	Low	Moderate	Finding 4.5
	Data availability and data quality	Moderate	Moderate	

## 4. Findings



### 4.1 Global Fund supported interventions have contributed to strong programmatic results for TB, but sustainability risks persist

Global Fund supported interventions have contributed to strong programmatic results for the TB program. However, risks surrounding the handover of specific interventions from the Global Fund to domestic funding could derail progress if not monitored and mitigated.

India has made strong progress in the fight against tuberculosis, specifically reducing missing cases and increasing treatment coverage. For instance, TB case notifications have increased by 46% since 2011 to reach 1.93 million<sup>13</sup> in 2021. India has also demonstrated strong resilience in recovering from COVID-19. Although there was a 25%<sup>14</sup> drop in TB case notifications between 2019-2020, the country recovered in 2021 with a 19% increase year on year. A critical success factor for this progress has been the government's strong political commitment to, and ownership of, the TB program. The government has committed to reach the UN Sustainable Development Goals (SDGs) related to TB by 2025, five years ahead of the global target.

Global Fund investments for TB are designed to be innovative and catalytic, supporting a broader funding landscape dominated by domestic financing.<sup>15</sup> Investments have focused on strengthening innovation in key areas including:

- I. TB active case finding
- II. strengthening private sector case notification and treatment
- III. laboratory strengthening, including increasing drug resistant TB (DR-TB) diagnostic capacity

These investments strongly align with India's National Strategic Plan for TB. Under NFM2 in 2019, the Global Fund supported innovative financing for TB by providing US\$41.6 million as part of a loan buy-down agreement with the Indian government and the World Bank.

Overall, India has realized strong programmatic achievements with support from the Global Fund. However moderate issues have been noted in the operationalization of some interventions along with some challenges in handing over interventions to domestic funding. This puts the sustainability of programmatic achievements at risk.

#### **Strong results for TB active case finding with a successful handover to domestic funding**

India still has significant numbers of missing TB patients with over 750,000<sup>16</sup> total missing cases compared to the estimated TB incidence. Therefore, active case finding to reach at-risk and vulnerable populations is critical to ensure early detection and prompt treatment. The Global Fund invested in active case finding interventions during NFM2 with implementation activities in 128 districts across 14 states. Activities resulted in strong programmatic achievements against targets during NFM2, with 104% achievement for the number of TB cases notified among key affected populations, excluding prisoners.

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<sup>13</sup> India TB Report 2022, Central TB Division, Ministry of Health and Family Welfare.

<sup>14</sup> Global tuberculosis report 2021, World Health Organization.

<sup>15</sup> Global Fund funding accounts for approximately 9% TB NSP budget for NFM3 grant cycle with the majority coming from domestic financing.

<sup>16</sup> The gap between the total estimated TB incidence (2.56 million) and total cases notified (1.81 million) was 777k cases in 2020. Source: WHO TB data. [https://worldhealthorg.shinyapps.io/tb\\_profiles/?inputs\\_entity\\_type=%22country%22&lan=%22EN%22&iso2=%22IN%22](https://worldhealthorg.shinyapps.io/tb_profiles/?inputs_entity_type=%22country%22&lan=%22EN%22&iso2=%22IN%22) – accessed 27 June 2022.

The Global Fund was only to finance active case finding during NFM2 with handover to the Indian government in NFM3. Domestic funding was secured, and the OIG noted continued active case finding in over 75% (3/4) of districts visited. This shows a solid handover and that these activities can be sustained.

### **Increased private sector TB notifications under JEET initiative (NFM2) support a reduction in TB missing patients**

The Global Fund supported the scale-up of private sector engagement to increase TB case notifications through the Joint Effort for Elimination of Tuberculosis (JEET) project, which covered 488 districts across 24 states. Three Principal Recipients<sup>17</sup> implemented the project in close coordination with the National Tuberculosis Elimination Program (NTEP). The project achieved strong programmatic results with the percentage of microbiologically confirmed cases increasing from 19% in 2018 to 35% in 2020, outperforming the National Strategic Plan targets between 20-28%. Overall, the JEET project contributed to nearly a million TB case notifications from the private sector during the 2018-2020 period. This helped to reduce the total number of TB missing cases and to strengthen India's overall TB response.

### **JEET handover delays in NFM3 to domestic funding could impact program sustainability**

Global Fund support for JEET sites (both PPSA and PPSA lite districts<sup>18</sup>) was initially intended to stop at the end of NFM2<sup>19</sup> for handover to the Indian government. This was extended until December 2021 due to COVID-19 related challenges. As of March 2022, however, only 40% of states and districts had fully transitioned to domestic financing. It should be noted that handover support was provided through Technical Support Units funded by a World Bank loan in nine states after the end of NFM2. The Global Fund approved funding extensions for three states until June 2022. The handover delay can be attributed to COVID-19 disruptions and broader delays at the state level in completing the contracting process for PPSAs to continue receiving domestic financing support. COVID-19 had a significant impact at the state level in diverting human resources away from routine activities that would support a timely handover. There were also issues in transition planning. The OIG was not provided with evidence of up-to-date state-level transition plans or with the institutional and financial mechanisms needed to support successful handovers. However, transition guidance for states were developed, in addition to a State Program Implementation Plan that included budget lines for PPSAs. While the preparation and execution of transition plans are the responsibility of respective states and outside the direct control of the Global Fund and its implementers, transition plans are important to track progress, address bottlenecks and ensure a timely handover.

Among the nine JEET program sites visited, private sector contribution to TB case notification declined from 36% in Q1 2021 to 29% by end of Q4 2021.<sup>20</sup> This highlights a decline in notifications at the point of handover, potentially impacting future sustainability at a critical point on programmatic continuation. Considering the above and the severity of the COVID-19 situation, the Global Fund provided additional support to PPSA sites in three states under NFM3 with a budgeted cost of US\$0.7 million.

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<sup>17</sup> JEET has three Principal Recipients: Foundation for Innovative New Diagnostic India (FIND), the William J Clinton Foundation (WJCF) and the Centre for Health Research and Innovation (CHRI).

<sup>18</sup> PPSA is short for Patient Provider Support Agency, which operate in districts to engage with private providers and connect patients to TB diagnostic services and treatment. The PPSA model was a human-resource intensive model to provide end-to-end services in 105 districts. The PPSA lite model focused on provider engagement capacity building of National Tuberculosis Elimination Program staff to strengthen notification and treatment adherence in 383 districts.

<sup>19</sup> The National Tuberculosis Elimination Program NFM2 grant ended on 31 March 2021.

<sup>20</sup> Similarly, across all JEET sites, private sector contribution declined from 49% in Q1 2021 to 35% by end of Q4 2021.

## **Enhancements in handover planning, improved functioning of laboratories and key diagnostic equipment needed to support sustainable results**

The Global Fund has played a key role in strengthening laboratory systems and diagnostic equipment across India. This includes supporting the scale-up of laboratory services, establishing seven new labs and deploying a laboratory information system across multiple lab sites. This has contributed to increased presumptive testing for TB. But issues with the sustainability of investments in lab equipment and the underutilization of this equipment have been noted.

### *Gaps in sustainability planning to support use of key lab equipment*

Global Fund grants support maintenance<sup>21</sup> of diverse types of critical lab equipment across multiple TB Culture and Drug sensitivity Testing (C&DST) labs. A planned phase-out of support from the Global Fund is expected to start at the end of Q3 2022. However, at the time of the audit, there were no state-level situational and transition readiness/preparedness assessments and plans to support a successful handover. These are important to identify key challenges for laboratory human resources, procurement, supply chain management (PSM) and other systemic barriers. This increases the risk that key equipment will become non-functioning after Global Fund support has stopped, reversing progress made in TB diagnosis.

### *Low utilization of TB diagnostic equipment*

Low utilization<sup>22</sup> of Whole Genome Sequencing (WGS) and equipment supporting NAAT<sup>23</sup> was noted at labs and clinical sites visited. This has been linked to shortages of lab consumables, especially at the national and intermediate reference lab level<sup>24</sup> under the primary responsibility of the Indian government. Low use also relates to gaps in key human resources in lab sites. The Global Fund previously funded laboratory positions before handover to domestic funding. The OIG noted human resource constraints at intermediate lab sites for microbiologists, lab technicians (LTs) and data entry operators (DEOs). An analysis of national level data for staff vacancies highlighted large gaps with vacancies for 39% of microbiologist posts and 66% for senior lab technicians. These vacancies ultimately impact the coverage and assessment of TB diagnosis and act as a barrier to finding the missing cases needed to finally eliminate TB.

To mitigate the sustainability and transition risk, the OIG proposed that the National TB Program, with support from the Global Fund, engage sub-national actors to design, approve and implement handover plan(s) for key Global Fund-supported activities and investments to be transitioned to domestic financing and management.

However, the Secretariat determined that due to the nature of Global Fund grants in the Republic of India, the proposed action cannot be agreed given that this is a state responsibility outside the control of the National TB Program and the Global Fund Secretariat.

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<sup>21</sup> Supporting the maintenance, calibration and repairing of equipment

<sup>22</sup> With 0% use at Intermediate Reference Lab (IRL) and 7%-15% use across the 2 NRLs labs in two years. The audit also noted low NAAT use across facilities visited in 12 districts. 85% of sites covered had NAAT tests, with 38% use for CBNAAT and 32% for TrueNat tests.

<sup>23</sup> NAAT states for Nucleic Acid Amplification Test, a type of diagnostic tests used to detect TB and drug resistant TB

<sup>24</sup> OIG visited two National Reference labs (Delhi and Bangalore) and one Intermediate Reference lab in Delhi



## 4.2 Global Fund investments in HIV have supported solid programmatic results, but operational barriers persist to enhance and sustain them

Stable progress has been noted in the fight against HIV in India with investments supporting innovation in key areas including tackling Lost to Follow Up (LTFU) cases with care and support centres (CSCs). However, there were issues noted in handover to domestic financing, as well as operational issues impacting LTFU results and use of diagnostic equipment.

Led by clear national strategic plans and objectives, India has reduced HIV prevalence, new infections (48% since 2010<sup>8</sup>) and AIDs related deaths since 2010 (83% since 2010<sup>8</sup>). Like TB, Global Fund-supported HIV investments fit within a much broader landscape of domestic funded activities. The Global Fund aims to focus on activities that are catalytic in nature and align with national priorities including HIV treatment, care and support, as well as prevention of mother to child transmission. However, operational challenges in key areas and delays with handover activities to domestic funding risk future programmatic impact.

### **Roll out of new innovative approaches improves HIV treatment, care and support**

Several innovations in HIV treatment, care and support have been noted with key advances to support treatment adherence. Multi-month dispensing (MMD) of ARVs was introduced in 2020, along with decentralized ART refilling at the sub-national level and the introduction of self-verified adherence (SVA) in the first six months of taking ARVs.

In tackling issues with Lost to Follow-Up (LTFU) cases for antiretroviral treatment, the India HIV/AIDS Alliance implemented the Vihaan program. This supports ARV adherence by establishing and managing care and support centers (CSCs). These sites aim to enhance treatment adherence and retention in HIV care. During COVID-19 waves in 2020 and 2021, the centres provided especially vital support to people living with HIV by delivering treatment directly to homes and through other innovative approaches. Through consecutive rounds of funding from the Global Fund, 310 centres have been established and maintained with funding continuing throughout NFM2, with the aim to handover financial support to domestic funding in NFM3.

### **Gaps and delays in handover planning and execution to domestic funding undermines the sustainability of key HIV program activities**

Due to the relatively small share of Global Fund investments in the country compared to domestic funding, Global Fund investments focus on catalytic, innovative, and targeted interventions that, if proven successful, can be handed over to the government. This is meant to maximize the Global Fund's impact in India's complex environment. However, issues with the handover to domestic funding may risk the sustainability of programmatic achievements.

#### *Care and support centres*

Delays have occurred in handing over CSCs from the Global Fund to domestic funding. Of the 310 CSCs sites supported under NFM2 by the Global Fund, 110 were planned for handover to the government by end of NFM2 (31 March 2021) to establish new CSC entities.

However, at the time of the audit, 13 months after the end of NFM2, only 38 had been fully handed over. These delays were linked to:

- COVID-19 affecting the capacity of State AIDS Prevention and Control Societies (SACS) to support key steps of the handover process.
- The absence of costed detailed transition plans between the national and state level in states sampled by the OIG.

These handover delays have led to repeat requests for extended financial support from the Global Fund until September 2023, leveraging grant savings, as well as C19RM funding of US\$ 1.1 million. Continued reliance on the Global Fund and the lack of a clear operational roadmap to domestic funding threatens the sustainability of results in this area.

#### *Prevention of Mother to Child Transmission (PMTCT)*

The Global Fund supports two non-government Principal Recipients to conduct PMTCT interventions across all states in India. While support is secured for these activities in NFM3, handover to domestic funding is planned at the end of this period. To support this handover, a transition plan agreed between all Principal Recipients is required, as well as an assessment of preparedness for this transition. This was further enforced in a Secretariat management action that called on non-government Principal Recipients to develop transition plans by 31 December 2021. At the time of the audit (May 2022), however, the plans remained outstanding. This increased the likelihood of sustainability risks emerging at the end of NFM 3 as delays in handover planning could harm programmatic results in the long term.

#### **Implementation and quality of service challenges affect LTFU targets**

Adherence to HIV treatment protocols is critical to effective HIV programming. The Global Fund has supported key interventions to strengthen adherence during both NFM2 and NFM3. However, only moderate performance has been noted against approved performance targets during 2020 and 2021.<sup>25</sup> COVID-19 has affected implementation, altering how health workers and those seeking care could provide and access treatment. However, in addition to COVID-19, operational issues were noted in the HIV sites visited. Evidence of training and supervision of staff was lacking on LTFU at ART and CSC sites in nine out of 15 sites. In addition, lack of evidence of pre-ART LTFU from Integrated Counselling and Testing Centres (ICTC) to ART sites, (as suggested by the CSC operational guidelines) was noted by other assurance providers. Without strengthening ART adherence, the program will face challenges in achieving the second and third 95 targets of the treatment cascade. It also increases the risk of mortality if people are not effectively supported to stay on treatment.

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<sup>25</sup> April-September 2020 and October-March 2021 results reported to Global Fund on LTFU indicators at 54% and 59% against the target, and April-September 2021 (non-validated PU at time of audit) on LTFU indicator is 67% against the target

### **Delayed use and low utilization of key testing machines impact effectiveness of viral load monitoring**

Under grant funding, India's National Aids Control Organisation (NACO) has procured 64 RT-PCR machines to enhance HIV viral load testing. These machines were delivered to India under NFM1 (pre-March 2018). However, it took over three years (up to July 2021) for all machines to become operational. Even when operationalized, national program testing data highlighted that in 2021 the machines were only used at 20%<sup>26</sup> of their full testing capacity for HIV viral load monitoring. In sites visited by the OIG, the low utilization was driven by:

- COVID-19 diverting human resources away from the use of these machines.
- General gaps in human resources at site level to support timely sample collection and testing.
- Lack of evidence of an operational plan to support optimal use of VL Labs.

As a result, there is a need to ensure increased viral load testing to monitor for viral load suppression and to achieve the third 95 target of the treatment cascade in India. In addition to government lab sites, a private provider has been contracted to support testing.

To mitigate the sustainability and transition risk, the OIG proposed that the National HIV Program, with support from the Global Fund, will engage sub-national actors to design, approve and implement handover plan(s) for key Global Fund support activities and investments to be transitioned to domestic financing and management.

However, the Secretariat determined that this action was not necessary given the nature of Global Fund grants in the Republic of India. The Secretariat has deemed no further action is required above and beyond the existing grant and risk management processes of the Secretariat.

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<sup>26</sup> From the data shared by NACO for Viral Load testing undertaken in the previous 12 months in 2021, it was observed that 287,103 tests were run on the 64 Viral Load RT-PCR machines, representing 19.7% of optimal use for machines in the country



### 4.3 Payment for Results signals a move towards a strategic long-term relationship with India, but gaps in design could limit the benefits

Although the move to a Payment for Results (PfR) modality can provide long-term strategic benefits, some limitations in India's design of key HIV targets could negatively impact its effectiveness. In addition, weaknesses in the risk assessment, mitigation and assurance mechanisms over the modality may negatively impact grant implementation.

The Global Fund signed Payment for Results (PfR) grants with India in NFM3<sup>27</sup> worth US\$300 million (60% of the country allocation). This comprises two grants (US\$100 million for HIV and US\$200 million for TB).<sup>28</sup> This makes India the second country<sup>29</sup> to receive most of its Global Fund disbursements through this type of modality. The Department of Economic Affairs within the Ministry of Finance is the Principal Recipient.

DISBURSEMENT LINKED INDICATORS (DLIs) AND TOTAL ALLOCATION (US\$ M)
<b>HIV (\$100 million)</b>
<b>DLI 1:</b> Number of people on ART at the end of the reporting period (US\$44m)
<b>DLI 2:</b> Percentage of people living with HIV and on ART who are virologically suppressed (Total Budget US\$29.5m)
<b>DLI 3:</b> Proportion of 'Sampoorna' one-stop centers operational against the planned (Total Budget US\$5.90m)
<b>DLI 4:</b> Number of people who inject drugs reached with HIV prevention programs – defined package of services (Total Budget US\$20.57m)
<b>TB (\$200 million)</b>
<b>DLI 1:</b> MDR TB-3 <sup>(M)</sup> Number of cases with RR-TB and/or MDR-TB that began second-line treatments (Total Budget US\$79.63m)
<b>DLI 2:</b> Treatment success rate of RR-TB and/or MDR-TB: Percentage of cases with RR and/or MDR-TB successfully treated (Total Budget US\$39.96m)
<b>DLI 3:</b> Number of presumptive TB patients received molecular diagnostic test (Total Budget US\$80.44m)

**Figure 1: Summary of PfR DLIs for**

#### Key elements of PfR in India

PfR links the disbursement of funds directly to the achievement of specific program results defined in DLIs (Disbursement Led Indicators), see figure 1. This modality moves the focus away from inputs and more on programmatic performance, aligned to the strategic importance of India to the Global Fund's mission.<sup>31</sup> Targets have been set for each DLI for each year of the grant, with full payment possible per year if the country reaches 90% of the agreed target (the effective target).

In addition to DLI targets, there are also defined program boundaries<sup>32</sup> that tie the Principal Recipient to support specific intervention areas. The Principal Recipient is expected to report on expenditure relating to these program boundaries on an annual basis. If expenditure is less than the amount corresponding to the achieved results under the DLIs, the Global Fund may reduce subsequent disbursements or request reimbursement.

The move to PfR provides both strategic and operational benefits for how grants are implemented and monitored. This includes increased flexibility to reprogram interventions as required and incentivizing innovation and agility in the national response. However, design gaps have been noted for the HIV grant along with limitations in the risk management of the modality.

<sup>27</sup> NFM is short for New Funding Model. For India, NFM3 relates to active grants from April 2021 to March 2024.

<sup>28</sup> The remaining US\$200 million allocation was under malaria (fully non-PfR). Additional HIV and TB grants signed with non-government Principal Recipients still follow the traditional input-based modality.

<sup>29</sup> The first being Rwanda: [https://www.theglobalfund.org/media/2616/oig\\_gf-oig-14-023\\_report\\_en.pdf](https://www.theglobalfund.org/media/2616/oig_gf-oig-14-023_report_en.pdf)

<sup>31</sup> India accounts for approximately 26% of estimated global TB incidence (WHO Global TB Report 2021) and 6% of the global estimated people living with HIV/AIDS (2.3 million out of 37.7 million. Sankalak (Status of National AIDS Response 2021 and UNAIDS Data 2021 respectively).

<sup>32</sup> Defined program boundaries refer to specific activities for TB and HIV agreed with Principal Recipients and monitored by the Global Fund.

## **PfR targets are ambitious and aligned to national priorities, but some design limitations reduce the potential effectiveness over its full life cycle**

Overall, robust program boundaries and disbursement-linked indicators have been developed to ensure that the India PfR grants are strategically aligned to priority areas for both TB and HIV in the country, as defined in the National Strategic Plans (NSPs). The targets for disbursement-linked indicators for TB are ambitious and aligned to respective National Strategic Plan targets. However, the issues below were noted in the design of targets for HIV that could weaken the effectiveness of the modality to promote greater efficiencies during implementation and stronger programmatic performance.

### *HIV DLI 1: number of people on ART*

The targets set for this DLI fall slightly below the targets set in the April 2022 revised NSP for HIV. The DLI target is 5% lower than the revised NSP targets set in April 2022<sup>33</sup> for 2023/24. The effective target is even lower since full payment is triggered once 90% of the DLI target is reached. This means that full payment (US\$44 million) is possible even if performance is 17%<sup>34</sup> below the revised National Strategic Plan target. Though it is noted that the grant includes provisions to revise targets in case of significant epidemiological changes, including changes in National Strategic Plans.

### *HIV DLI 2: percentage of people living with HIV and on ART who are virologically suppressed*

The effective percentage target set for this DLI falls below the baseline set for this indicator.<sup>35</sup> The Principal Recipient can receive full payment even if they achieve results below the percentage baseline set for viral load suppression at the end of the grant period. This issue was not observed in the TB PfR grant, which had developed more sophisticated payment structures to ensure performance was incentivized year on year.<sup>36</sup>

### *HIV DLI 4: number of people who inject drugs (PWID) reached with HIV prevention programs*

The performance framework for DLI 4 is ambiguous regarding the definition of “reach” for people who inject drugs with HIV prevention programs.<sup>37</sup> Specifically, regarding if (i) all the defined services or (ii) a minimum number of HIV prevention services must be received before counting a beneficiary as “reached.”

Overall, the HIV PfR grant confirmation and performance framework do not clearly define the data sources for DLIs<sup>38</sup> and were still not defined at the time of the audit. In comparison, data sources for the World Bank TB loan DLIs were agreed with the implementers and included in the approved project documents prior to the program start.

## **Gaps and delays in risk assessment, mitigation and assurance may negatively impact modality**

The strategic decision to apply PfR in India was supported with clear direction from the Global Fund Secretariat. Underpinning this decision and modality development were numerous reviews, consultations, and inputs from a range of internal and external groups and specialists.<sup>39</sup> While this helped to strength the modality design in India, some gaps

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<sup>33</sup> At grant signing in April 2021, the DLI target for HIV DLI1 was 17% less than corresponding National Strategic Plan target before it was revised.

<sup>34</sup> The Global Fund requires at least 1.566 million (90% of HIV PfR grant target of 1.74 million) people on ART at the end of NFM3 for full payment. The effective target of therefore is 17% below the revised NSP target (1.825 million).

<sup>35</sup> The target is expressed as a percentage and this effective percentage target is below the indicator baseline although there are numerator and denominators not in the performance framework that progressively increase over the grant period.

<sup>36</sup> PfR involves a different disbursement methodology for TB DLI2 (percentage of cases with RR and/or MDR-TB successfully treated). Performance for treatment success rate is calculated as percentage point improvement against the DLI baseline for the first year of implementation and, thereafter, percentage point improvement is measured against achievement in the preceding years.

<sup>37</sup> While the performance framework is not clear, there is a NACO Standard Operating Procedure (SOP) titled 'Operationalizing Targeted Interventions for IDUs: Guidelines for NGOs' 2007 Edition that provides guidance

<sup>38</sup> The ultimate data system where results for HIV DLIs would be sourced was unclear at the time of the audit.

<sup>39</sup> This includes the Technical Review Panel (TRP), Executive Grant Management Committee (EGMC), Grants Approval Committee (GAC) and Portfolio Performance Committee (PPC) and other external and internal stakeholders.

were noted in how these inputs were factored into the final design. There were also limitations on how specific programmatic data risks were identified, mitigated and monitored.

*EGMC recommendations for detailed risk assessments were not completed prior to signing of PfR grants*

Key risk and mitigation measures and exceptions to operational policies were presented for approval to the Executive Grant Management Committee (EGMC) in Q4 2020. The committee then made specific recommendations for the country team to build on initial risk assessments to have a clearer view on the risk appetite and analyse how these exceptions impact the portfolio's risk profile. The committee's recommendations were not fully addressed prior to the signing of PfR grants and remained outstanding at the time of the audit. However, residual risks were presented to the GAC, but this did not include or address the risk trade-offs mentioned in the EGMC recommendations. The failure to fully consider all risks appetite implications could result in inadequate risk mitigation and assurance measures during implementation.

*Limited Global Fund assurance over data quality and gaps in use of assurance outputs to inform PfR design*

The availability of good and reliable programmatic data plays a critical role in the PfR modality since annual disbursements are directly tied to reported programmatic results. Despite this reliance, the Global Fund has not conducted an independent data quality review (DQR) for government Principal Recipients since 2017 (see finding 4.5 for further detail). Although, there was a government-led national ART data cleaning exercise completed in January 2018 that identified significant data quality issues and sought to address them. The last targeted DQR covering TB and HIV for government grants by independent assurance providers was performed in 2015 and 2017 with data quality issues flagged for TB. A planned targeted DQR for 2020 was cancelled due to COVID-19 disruptions. In Q1 2021, there was a Global Fund Secretariat-approved targeted review of the key Health Management and Information Systems (HMIS) for HIV and TB along with a non-representative spot check on TB data quality. The review highlighted that the HIV HMIS system was not operable. Variances in TB data were also found when comparing outputs from the HMIS system to source records at health facilities.

The identified gaps from the targeted review of key HMIS and M&E systems for HIV and TB by independent assurance providers were not fully factored into decision-making during modality design. Assurance was not leveraged to inform appropriate risk mitigation actions or to provide that future assurance helps to ensure data quality risks are kept within acceptable levels. This lack of assurance and robust risk management over data quality increases the likelihood of incorrect disbursement decisions and misalignment between actual and reported results.

*Key assurance processes, tools and protocols were outstanding a year after the start of PfR grants*

A key control over the PfR modality in India is the annual results verification process. This is where programmatic results linked to each DLI are independently verified in line with Secretariat-approved principles and methodologies. Detailed verification protocols should include how results are sampled, what tools and approaches to verification are applied and how the Global Fund will deal with discrepancies. These protocols were outstanding at the time of the audit, and thus could not be reviewed by the OIG. However, after the audit fieldwork, these protocols were approved (15 months after grant signing).<sup>40</sup> The review of year 1 results was then performed, and disbursements made to the country in September 2022 with no delays noted.

The HIV grant agreement also includes a requirement for annual financial audits on program boundaries to be conducted by the Comptroller and Auditor General of India (CAG). The ToRs should have been finalized by 30 September 2021. However, these were outstanding at the time of the audit by seven months.

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<sup>40</sup> Verification protocols were finalized and approved by Global Fund senior management following the completion of audit fieldwork in June 2022, this audit does not opine on the adequacy of the protocols.

### **Influencing context and root causes for gaps and delays**

The above design gaps and issues in risk management around the PfR modality should be considered in the context that this is a relatively new modality for the Global Fund Secretariat. Thus, new approaches had to be developed – with limited examples to leverage from other Global Fund portfolios – including the development of robust result verification protocols, thereby increasing the time needed to design these approaches.

There were and continue to be no dedicated operational policy notes (OPN), technical briefs and best practice/lessons learned guidelines for PfR. This is despite the significant monetary amounts now channelled through this modality. In future developing of these resources, there will be opportunities to elaborate on minimum standards around how results are verified, what constitutes a representative sample to inform disbursement and when protocols should be finalized. This is important in the context of India where there are trade-offs in the level of verification needed versus the significant costs to validate a representative data sample to inform disbursements. There are also opportunities to develop enhanced guidance on how value for money principles can be fully applied in the design of PfR grants (including the application of allocative and technical efficiency concepts).

Unlike for input-based financing, there is no clear definition of roles and responsibilities across the Secretariat during PfR design. Definitions and timelines are also lacking to help finalize the more bespoke PfR-related processes and milestones.

In addition, at the time of designing the India PfR grants, there was limited in-house expertise on innovative financing approaches.<sup>41</sup> As a result, country teams and in-country stakeholders were reliant on their own significant efforts to navigate a way forward and ensure the timely signing of grants for NFM3, though third-party practices were leveraged.

Agreed Management Action 1
<p>The Global Fund Secretariat will design and approve an operational policy note on the payment for results (PfR) modality with the aim to establish a framework and guiding principles to help future design and implementation in India and other geographic settings. This policy note would include the following:</p> <ul style="list-style-type: none"><li>▪ Establish an end-to-end process, set of requirements, and clear roles and responsibilities across the Global Fund Secretariat in designing, approving, and monitoring PfR grants.</li><li>▪ Key principles to guide country teams and countries on where PfR could be applicable as a modality.</li><li>▪ Define the risk management process to be followed at design stage and throughout implementation. This includes how risk trade-offs, mitigations and assurance considerations have been considered and documented before entering into a payment for results modality.</li><li>▪ Minimum standards around results verification processes that can be further tailored to specific country contexts.</li><li>▪ Enhanced guidance and operational tools to support operationalization of PFR grants.</li></ul>
OWNER: Head, Strategic Investment & Impact Division (SIID)
DUE DATE: 30 September 2023

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<sup>41</sup> The current Health Financing Department of the Global Fund Secretariat includes specialists in innovative financing, but this unit was only put in place in mid-2021.



#### 4.4 Significant issues in the timely and effective use of C19RM funds limit the intended impact of investments

By December 2021, the Global Fund had approved US\$105 million from C19RM 2020 and 2021 to mitigate the impact of COVID-19. Rapid approval of proposals was noted, in line with India's urgent needs. However, the use of these funds was neither effective nor timely: 62% from 2020 and 0% from 2021 were used as of March 2022.

India has been heavily impacted by COVID-19 and experienced multiple prolonged lockdowns. The pandemic's direct and indirect impact undermined the fight against the three diseases and led to severe strain on the national health system. In response, the Global Fund approved key investments through the COVID-19 Response Mechanism known as C19RM.

By the end of 2021, the Global Fund had approved US\$105 million to India through C19RM 2020 and 2021. Investments covered the purchase of Personal Protective Equipment (PPE), GeneXpert machines, PSA oxygen support and Direct Benefit Transfer (DBT) to marginalized communities and key populations (KAP grant). This investment was made within a broader and larger COVID-19 response funding landscape, with significant financial support coming from development banks, bilateral partners and domestic financing initiatives.

Mechanism version	Amount	IC Approval Date	Investment detail
C19RM 2020	USD 20m	June 2020	Personal Protective Equipment (PPE) and health equipment
C19RM 2020	USD 9.9m	Nov 2020	Key Affected Population (KAP) grant: Direct Benefit Transfer (DBT) and food ration support
C19RM 2021	USD 75m	May 2021	PSA oxygen support

There were positives in the Global Fund response in terms of the appropriately quick speed to approve requests, PPE cost saving with C19RM funds, and innovative community engagement in the funding request process. However, significant issues were noted in the overall timely utilization of funds as noted below.

##### **Rapid and innovative C19RM request and approval processes aligned to country needs**

All C19RM 2020 and 2021 funding requests received from India were approved by the Global Fund investment committee within 5 to 19 calendar days upon receipt.

- **C19RM 2020**

Direct lobbying and engagement by civil society contributed to the approval of US\$9.9 million to support key populations through Direct Benefit Transfers and food ration support. This was a unique instance in which civil society representatives empowered themselves to conceive, design and build a C19RM funding request tailored to the needs of the most marginalized in society.

- **C19RM 2021**

Due to India's significant oxygen crisis in May 2021, a fast-track funding request was approved within four working days, reflecting the urgency and magnitude of the crisis. This rapid response was enabled by the significant efforts of the Country Coordinating Mechanism, and other in-country stakeholders, to quickly develop and approve funding requests.

## Slow and low use of C19RM funds limits the impact of investments

While the upstream processes around funding request submission and approval was rapid and innovative, implementation itself has been weak. A key metric to help assess the benefit of C19RM investment is how quickly financing can generate impact at the country level. C19RM benefits are weakened if available funding is not used in a timely manner, as was noted in India.

As of March 2022,<sup>42</sup> only 62% of C19RM 2020 funds and 0% of C19RM 2021 funds had been absorbed. This was 16 months after the last investment committee approval for 2020 funds and 10 months after C19RM 2021 approval. This shows extremely slow and weak utilization of available funds intended for urgent and critical interventions. As of September 2022, subsequent to the audit fieldwork, there had been minimal progress in using these funds with only a further US\$0.9 million expended. The root causes of this low use of funds are complex and linked to a very broad range of interventions as described below.

### *Investments in DBT and PSA plants*

Both the US\$9.9 million KAP in 2020 and US\$75 million PSA in 2021 aimed to fund critical activities to mitigate the impact of COVID-19. They had the weakest utilization rate across all C19RM investments, with 23% of the KAP and 0% of the PSA investment utilized at the time of the audit.

- *Implementation challenges for KAP funding resulting in 77% of funds unutilized, limiting the impact of interventions*

The KAP investment aimed to provide cash transfers and food rations to 500,000 people in key affected populations. However, implementation challenges were noted linked to this being a new investment category for Principal Recipients, the broader context of the country being in lockdown due to COVID-19, and the elevated fiduciary risks linked to the use of cash transfers to individuals. The Secretariat's decisions sought to balance fiduciary risk and programmatic implementation in an emergency context, with the responsibility on implementers to ensure fiduciary control as a key condition of the Investment Committee's approval of funding.

In response, Principal Recipients built new processes to limit fiduciary risks, which increased the time it took to set up their response. However, the implementation processes were not aligned to the operational realities on the ground. Once finally in place, civil society groups could not adhere to these processes due to capacity gaps and lockdowns that impacted movement for staff and beneficiaries. This particularly affected the creation and validation of beneficiary bank accounts, resulting in significant funds not having reached beneficiaries for over 16 months at the time of the audit.

- *Funding source changes impact PSA investments due to original needs being met by domestic funds*

In response to the acute COVID-19 wave in 2021 that heavily impacted oxygen supplies, US\$75 million of fast-track funding was approved to support the procurement of PSA plants and oxygen concentrators. After approval, however, the oxygen need initially identified by the Ministry of Health and the Country Coordinating Mechanism was ultimately met through domestic financing initiatives. As such, the Global Fund-approved intervention could not be executed, and funds were not absorbed over 10 months. At the time of the audit, there was no approved plan to use the funding in the near future.

- *Lack of transparent oversight and agile decision-making by the full CCM and Global Fund Secretariat*

For both the KAP and PSA investments, the initial design of interventions was impacted by unforeseen factors during implementation at the country level. Once issues were identified, there were delays in decision-making to resolve

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<sup>42</sup> 30 March 2022 was the end of the last complete quarter at the time of audit fieldwork and was based on the latest financial information available to the OIG.

them. These delays were linked to COVID-19, including the need to focus on the broader COVID-19 response and additional funding requests. Yet the Country Coordinating Mechanism did not make timely or effective decisions that would address implementation challenges and redesign interventions to ensure impact. During CCM meetings held during 2020 and 2021, implementation issues were only discussed once in November 2021, nearly a year after funding was approved. Even after issues were raised, no mitigation decisions were taken, nor were proposals approved for the available funding. At the time of the audit, there were no clear timelines or approved proposals by the CCM to repurpose or refine the approach for KAP and PSA investments.

This lack of agile decision-making surrounding repurposing C19RM funds was evident at both the implementation and Global Fund Secretariat levels. This is linked to the core principle of country ownership, requiring CCM action before the Global Fund can act. This means the Secretariat cannot unilaterally trigger the repurposing of C19RM funding in a rapid manner. There was also limited guidance to country teams and countries on if/when unused awards should be reviewed, returned, and optimized across portfolios. In 2022, a corporate-wide portfolio optimization process for C19RM was developed and a roll-out initiated.

#### *Investments in PPE and health equipment*

US\$20 million was approved for critical Personal Protective Equipment (PPE) and health equipment to support the COVID-19 response in 2020. Overall absorption for these investments was strong with savings realized on PPE local procurements (US\$5.6 million). This highlights a focus on value for money even in a pandemic context.

Challenges were experienced, however, in the ordering process. Delays in regulatory approval and procurement of consumables for GeneXpert machines under C19RM delayed use of the machines. It took 375 days between initial quotations being received from suppliers and the delivery of all 159 machines. Even after this period, issues were noted in the use of machines (see below). The delay was primarily driven by WHO regulatory approval of the 10-color GeneXpert module model. It was only granted eight months after the procurement approval by the Global Fund, which prevented the completion of procurement orders and delayed the supply of commodities. These delays also occurred in a broader context of COVID-19 disruption to procurement and supply chains worldwide.

A Global Fund Secretariat-approved review noted limitations in the use of the machines. Of the 20 sites sampled in this review, 14 (70%) were not using the machines in place at all. The average use rate varied considerably between 16-69%. This issue was linked to gaps in infrastructure and hardware in multiple sites, including interrupted power supply systems and stock-outs of cartridges and consumables for machines. Both were the responsibility of the government of India. This had a negative impact on the total number of diagnostics used to identify COVID-19, as well as TB-related cases, weakening the response to both diseases.

Issues around re-prioritizing and re-purposing C19RM funds after they were initially awarded were covered in the C19RM 2021 Audit report.<sup>43</sup> Agreed Management Action 3 in the C19RM report focuses on developing a portfolio optimization framework for C19RM investments in line with the evolving nature of the COVID-19 pandemic. This framework will consider factors including absorption to date and the evolution of the external funding landscape.

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<sup>43</sup> [https://www.theglobalfund.org/media/11878/oig\\_gf-oig-22-007\\_report\\_en.pdf](https://www.theglobalfund.org/media/11878/oig_gf-oig-22-007_report_en.pdf)





## 4.5 Gaps in risk management and oversight leading to issues in data quality and HMIS data systems

Some delays and gaps in risk management and oversight have been noted relating to data quality and Health Management Information Systems (HMIS). This has exposed the portfolio to increased risks that can affect grant implementation, especially with PfR modalities.

Timely and effective grant oversight and risk management are key to ensuring grants are implemented as intended and risks do not materialize. Both are key enablers to ensure strong programmatic performance. Robust grant oversight and risk management are also linked to the availability of robust data and data systems, as well as timely assurance from the country level to inform decision-making.

### **Delays and gaps noted in completing key portfolio risk management processes by the Secretariat, impacting effective risk management over a key risk area**

Risk management is critical to support the implementation of grants and is even more crucial in the context of COVID-19. During this period, country teams were required to ensure key risk management process were adhered to, including: (i) the completion of the Country Risk Management Memorandum (CRMM) and (ii) maintaining a comprehensive risk tracker in the Integrated Risk Management (IRM)<sup>44</sup> module.

The Country Risk Management Memorandum (CRMM) is key in ensuring that Global Fund senior management have visibility over and can approve a country's risk profile and its management strategies. Completion is required within 90 days of GAC approval, which in the case of India meant by July 2021. At the time of the audit, however, the CRMM was over 2.5 years out of date.<sup>45</sup> An updated CRMM was fully approved in October 2022. The updated IRM was received during fieldwork and was under review by the second line.

There were also gaps in risk management and tracking within the Integrated Risk Management Module (IRM), particularly for data quality risks. At the time of the audit, the IRM did not include risks and risk mitigation relating to PfR raised in separate documents developed for the Portfolio Performance Committee and the Executive Grants Management Committee. In addition, data system and data quality risks identified in prior Global Fund assurance reviews and reports were not reflected in the IRM.

For NFM3, there were issues in how the IRM was completed for some high-risk areas<sup>46</sup> with no documented root causes and mitigating actions noted in the system. Subsequent to the audit fieldwork, the IRM was updated to include additional root causes. For NFM2, there were also instances of delayed assurance activities without justification documented in the system.<sup>47</sup> These gaps in the IRM limit the effectiveness of the system to support robust risk identification, mitigation and assurance planning and to ensure risk management processes are followed.

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<sup>44</sup> The Integrated Risk Management (IRM) module is an online platform that is part of the Global Fund's Grant Operating System (GOS). Country teams use the IRM to manage risks in their portfolios.

<sup>45</sup> At the time of the audit fieldwork, the IRM was updated in 2020 to include the new NFM3 risks, and the risk rating was updated in March 2021.

<sup>46</sup> These relate to six cross-cutting high-risk areas linked to program quality and efficiency, as well as program design and relevance (IND-T-CTD, IND-T-WJCF, and IND-T-IUATLD)

<sup>47</sup> By the end of NFM2 grants, 23% (14/61) of the assurance activities had a "delayed" status, 70% (43/61) were in progress and 7% (4/61) had not been started. However, 64% (9/14) of the delayed assurance activities did not have comment on the reason for delays.



The root causes for these delays and gaps in key portfolio risk management processes include:

- De-prioritization of key risk management processes by the country team, linked to increased workloads from COVID-19 at the country level
- Ineffective monitoring of risk management policies and processes by the risk department
- Outdated risk management guidelines and deficiencies in the IRM system itself<sup>48</sup>

This has led to gaps in monitoring and mitigation of data quality risks and limited Global Fund assurance over this area (highlighted also in Finding 4.3). All of which could contribute to allowing data quality issues on the ground to arise. This has been indicated in non-representative OIG site visits and other assurance reports. The OIG site visits to a non-representative sample of health facilities identified material data variances for key TB indicators.<sup>49</sup> These variances were noted in a period of high COVID-19 cases, as well when the TB data systems were being transitioned. For HIV, however, the OIG site visits indicated no material issues with data quality for key indicators.<sup>50</sup> The material data variances noted in TB site visits could indicate broader challenges with data quality that may require further assurance activities and risk mitigation.<sup>51</sup>

### **Delays in and suboptimal quality of HMIS development for HIV systems negatively impact the national program**

India has a mixed level of maturity in its Health Management Information Systems for TB and HIV programs. India uses a sophisticated system for TB data called Nikshay. It is operational across the country and allows for data to be captured and visualized in near real time. Nikshay is leveraged by both public and private sector health care providers, and elements of its reporting are fully available to the public.<sup>52</sup>

For HIV, however, there is a fragmented landscape of legacy systems that support different components of the HIV program. Due to this fragmentation, there has been a concerted effort by the Government to move towards a consolidated system called SOCH.<sup>53</sup> The Global Fund stepped in to fund this critical intervention with US\$3.9 million budgeted to a non-government Principal Recipient in NFM2 to support this government initiative. Funds were designated to support the design and rollout of the system. At the time of the audit, some quality gaps emerged.

- *SOCH was not fully operational at the point of handover to the government*  
25% of the agreed-upon system requirements were incomplete at the time of handover to the national HIV program.
- *Gaps in the software development process*  
Key system development steps and tests to ensure SOCH is fully functioning and stable were not performed. This includes no load and performance testing,<sup>54</sup> no regression testing and gaps in standards for SIT and UAT testing.

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<sup>48</sup> The current IRM tool does not prompt users to add comments, root causes and mitigation actions to high-risk areas and delayed assurance activities. However, a project to upgrade the IRM system is underway in the Secretariat.

<sup>49</sup> For TB DLI 1 (RR-TB and/or MDR-TB cases that began second-line treatment), total absolute variance of 39% was noted between data reported by CTD centrally and DRTB registers at the DR Sites (12 sites) visited. Google sheets was used as the main reporting tool for this indicator in 2021, with CTD planning a full transitioning to Nikshay in 2022.

For TB DLI 3 (presumptive TB patients received a molecular diagnostic test), variance of 47% was identified across 14 sites visited. This compared CTD records and primary records in the form of smear microscopy registers and NAAT registers.

<sup>50</sup> Data quality for the HIV indicator on the number of people on Anti-Retroviral Treatment (HIV DLI 1 under NFM3) only showed a minor variance of 1.4% when comparing central level data to primary source documents at health facilities.

<sup>51</sup> After the audit fieldwork, verification work on year 1 results conducted by the other assurance provider did not highlight material issues with data. However, this was not validated by the OIG.

<sup>52</sup> <https://reports.nikshay.in>

<sup>53</sup> SOCH: Strengthening Overall Care for HIV beneficiaries

<sup>54</sup> Load and performance testing is used to verify and validate a software performance capacity under maximum load (e.g., maximum users, maximum connections, maximum data requests and transfers among others).

These issues can be attributed to protracted negotiations between the Principal Recipient and country team on staffing and budgets that delayed the start of the project by nine months. In addition, the COVID-19 pandemic in 2020 negatively affected project delivery.

Issues in the software development process are linked to the lack of a detailed Software Development Lifecycle (SDLC) approach between the vendor and Principal Recipient. In addition, there was no evidence of approved and finalized software testing plans and procedures. There were also gaps (detailed below) in Global Fund monitoring of SOCH development during NFM2.

While work plan tracking measures (WPTMs) were defined to monitor system development, the delayed start of the project created misalignment between the project plan and execution. However, this was not reflected in the milestones tracked through WPTMs. Unmet or overdue SOCH development milestones were not effectively reported or followed up on in subsequent progress updates, creating a gap in formal progress reports. Updates were nonetheless informally communicated between the Principal Recipient and the country team.

All together, these issues and root causes contributed to SOCH not being fully functional at the point of transition to the national program. This has perpetuated the fragmentation of HIV systems and resulted in continued inefficient data collection, analysis and reporting in India.

Agreed Management Action 1 will address how risk management will be conducted for payment for results grants.

## Annex A: Audit rating classification and methodology

<b>Effective</b>	<b>No issues or few minor issues noted.</b> Internal controls, governance and risk management processes are adequately designed, consistently well implemented, and effective to provide reasonable assurance that the objectives will be met.
<b>Partially Effective</b>	<b>Moderate issues noted.</b> Internal controls, governance and risk management practices are adequately designed, generally well implemented, but one or a limited number of issues were identified that may present a moderate risk to the achievement of the objectives.
<b>Needs significant improvement</b>	<b>One or few significant issues noted.</b> Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met.
<b>Ineffective</b>	<b>Multiple significant and/or (a) material issue(s) noted.</b> Internal controls, governance and risk management processes are not adequately designed and/or are not generally effective. The nature of these issues is such that the achievement of objectives is seriously compromised.

The OIG audits in accordance with the Global Institute of Internal Auditors' definition of internal auditing, international standards for the professional practice of internal auditing and code of ethics. These standards help ensure the quality and professionalism of the OIG's work. The principles and details of the OIG's audit approach are described in its Charter, Audit Manual, Code of Conduct and specific terms of reference for each engagement. These documents help safeguard the independence of the OIG's auditors and the integrity of its work.

The scope of OIG audits may be specific or broad, depending on the context, and covers risk management, governance and internal controls. Audits test and evaluate supervisory and control systems to determine whether risk is managed appropriately. Detailed testing is used to provide specific assessments of these different areas. Other sources of evidence, such as the work of other auditors/assurance providers, are also used to support the conclusions.

OIG audits typically involve an examination of programs, operations, management systems and procedures of bodies and institutions that manage Global Fund funds, to assess whether they are achieving economy, efficiency and effectiveness in the use of those resources. They may include a review of inputs (financial, human, material, organizational or regulatory means needed for the implementation of the program), outputs (deliverables of the program), results (immediate effects of the program on beneficiaries) and impacts (long-term changes in society that are attributable to Global Fund support).

Audits cover a wide range of topics with a particular focus on issues related to the Impact of Global Fund investments, procurement, supply chain management, change management and key financial and fiduciary controls.

## Annex B: Risk Appetite and Risk Ratings

In 2018, the Global Fund operationalized a Risk Appetite Framework, setting recommended risk appetite levels for eight key risks affecting Global Fund grants, formed by aggregating 20 sub-risks. Each sub-risk is rated for each grant in a country using a standardized set of root causes and combining likelihood and severity scores to rate the risk as Very High, High, Moderate or Low. Individual grant risk ratings are weighted by the grant signed amounts to yield an aggregate Current Risk Level for a country portfolio. A cut-off methodology on high risks is applied (the riskiest 50% of grants are selected) to arrive at a country risk rating.

OIG incorporates risk appetite considerations into its assurance model. Key audit objectives are generally calibrated at broad grant or program levels, but OIG ratings also consider the extent to which individual risks are effectively assessed and mitigated.

Assessed residual risks are compared against the Secretariat's assessed risk levels at an aggregate level in the eight key risk areas that fall within the audit's scope. In addition, a narrative explanation is provided every time the OIG and the Secretariat's sub-risk ratings differ. For risk categories where there is no set formal risk appetite or levels, OIG opines on the design and effectiveness of the Secretariat's overall processes for assessing and managing those risks.

### Global Fund grants in India: Comparison of OIG and Secretariat risk levels

While OIG and Secretariat risk levels were aligned for program quality and efficiency as well as procurement processes and outcomes, they differ for other sub-risk areas. Below is a summary of the considerations for the OIG's assessed residual risk ratings.

- **Program design and relevance** is assessed as "Moderate" by the OIG due to gaps in program design and relevance of C19RM investments which have led to significant under absorption of C19RM funds, especially for key affected population interventions and procurement of PSA plants and oxygen concentrators (0% absorption at time of the audit).
- **Design and operational capacity of M&E Systems** is assessed as "Moderate" due to the continued reliance on multiple and diverse manual or MS Excel based data sources, especially for HIV programmatic data. The Global Fund investment in SOCH during NFM2 did not fully deliver with only 75% of the agreed upon system requirements finalized at the point of project transition to the Indian government (as of 31 March 2021).

The OIG audit identified strategic and operational gaps in the design of the Payment for Results modality. However, these have not affected any of the eight key risk areas as the Global Fund Secretariat's risk management framework does not currently consider risks related to the design and implementation of the PfR modality itself.