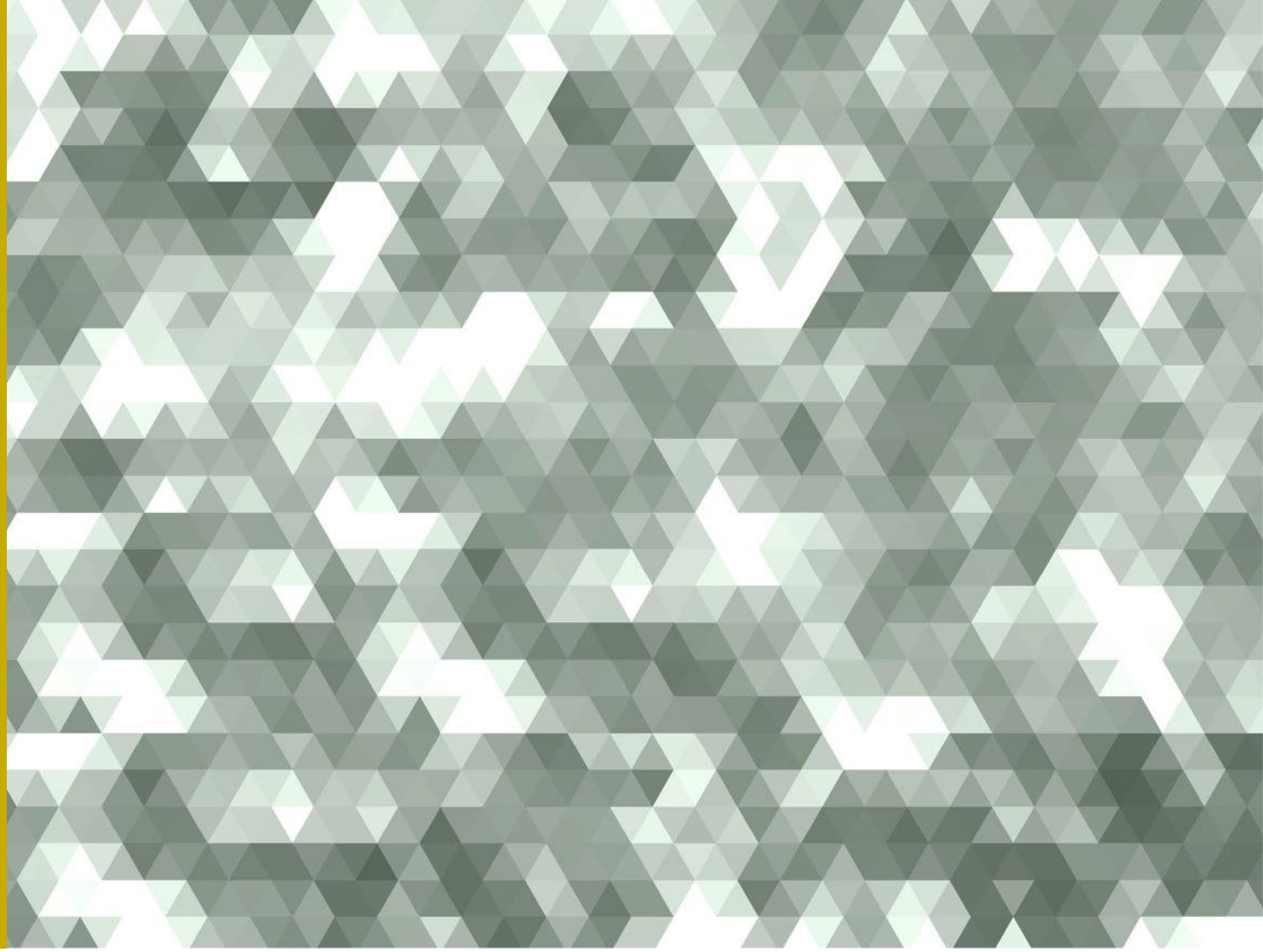

Audit Report

Global Fund Grants to the Republic of India

GF-OIG-16-023
5 October 2016
Geneva, Switzerland

The Global Fund
Office of the Inspector General

Table of Contents

I. Background

Country Context

With a population of over 1.2 billion people, India is currently the world's second most populous country.[1] Following reforms and 5.8% Gross Domestic Product (GDP) growth over the last two decades, the Indian economy is now the world's seventh-largest by nominal GDP, and third-largest by purchasing power parity.[1]

The three diseases in India

India's large size also translates into a heavy disease burden, especially for tuberculosis (TB) and HIV. With 36 states and union territories spread across 3.3 million square kilometers, India is highly diverse in population and ethnicity; geography and accessibility; climate and disease susceptibility; disease distribution and modes of transmission; and program staff qualification and capacity. These directly impact the three diseases, and translate into complex disease programs. The India portfolio, as one of the countries that receives the most funding from the Global Fund, requires well-informed and focused grant management, based on risk and materiality with reliance on country systems.

Tuberculosis
Based on WHO estimates, 1.6 million out of the 6.3 million new TB case notifications a year occur in India. This corresponds to more than 23% of global annual cases and by far the highest number of cases for any country in the world.[2] Multidrug-resistant TB is also a major health threat, with 1.4 million new smear-positive TB cases detected and treated annually, also the highest in the world.[3]

HIV
India has the third largest number of people living with HIV in the world.[4] Estimates from 2015 suggest national adult HIV prevalence in India is approximately 0.26%, equivalent to 2.1 million people living with HIV and AIDS.[5] The HIV epidemic in India is concentrated among high risk groups and is heterogeneous in its distribution. However, recent surveys show that 35 of the 36 states have less than 1% HIV prevalence among ante-natal care clinic attendees.[6] A considerable decline in HIV prevalence has been recorded among female sex workers at the national level (from 5.06% in 2007 to 2.67% in 2011) and among men who have sex with men (from 7.41% in 2007 to 4.43% in 2011).[7]

Malaria
Malaria in India is complex because of the country's geographical, ethnic and ecological diversity. The overall annual number of confirmed cases decreased from 1.6 million to 1.1 million between 2010 and 2014.[8] Although approximately 82% of the country's population lives in malaria transmission risk areas, 80% of malaria occurs among 20% of the people classified as "high risk." These high risk populations are found in 16 states, with 97% of confirmed malaria cases occurring in endemic states/ districts. [9]

These disease statistics mean that any meaningful global impact against the three diseases is highly contingent on successful disease programs in India.

[1] World Bank 2014 http://data.worldbank.org/country/india

[2] WHO TB Global report 2015
[3] http://www.tbfacts.org/tb-statistics-india/
[4] http://aidsinfo.unaids.org/
[5] India HIV estimation 2015 http://naco.gov.in/upload/2015%20MSLNS/HSS/India%20HIV%20Estimations%202015.pdf
[6] HIV Sentinel Surveillance 2014-15 http://www.naco.gov.in/upload/2016%20Data/SIMU/HIV_Sentinel_Surveillance_report.pdf
[7] UNAIDS http://www.unaids.org/sites/default/files/country/documents/IND_narrative_report_2015.pdf
[8] http://nvbdcp.gov.in/malaria3.html
[9] http://nvbdcp.gov.in/Doc/mal-situation-Apr-16.pdf.

Government and Global Fund spending on three diseases

With an estimated GDP of US$2,049 billion, public spending on health in India increased from 1.2% to 1.4% of GDP between 2011 and 2015.[1] It currently stands at around US$28.6 billion annually.[10]

The Government of India has shown strong ownership of the three disease programs by funding over 70% of interventions over the last 10 years. Approximately US$440 million is budgeted annually for the three diseases.[11] For the period 2014-2015, Global Fund contributions made up 22% of the total budget for HIV, 26% for TB and 8% for malaria. For the period 2015-2016, Global Fund contributions provide around 30% of the public budget for HIV and 23% for TB.[11]

Given the magnitude of investments required, and since the Global Fund is the only major contributor to the three diseases in India besides the Government, the country has been the Global Fund's largest cumulative portfolio in terms of funding since its creation, with details as follows:

Disease	Grants signed since 2004 (US$ million)	Grants committed in 2004-16 (US$ million)	Grants disbursed in 2004-16 (US$ million)	No of grants signed since 2004
HIV/AIDS	1,304	1,119	1,090	17
Malaria	199	134	118	5
TB	690	519	490	10
TB/HIV	15	15	15	1
Total	**2,208**	**1,786**	**1,713**	**33**

Under the new funding model, India has a total allocation (including incentive funding) of US$905 million approximately, broken down per disease as follows:

Disease component	Total allocation for 2014-17 (US$ million)	Proportion of allocation	Active grant implementers	Number of existing active grants
HIV/AIDS	444	49%	The National AIDS Control Program, Solidarity and Action Against the HIV Infection in India, Plan International and India HIV/AIDS Alliance	4
TB	337[12]	37%	Central TB Division, International Union Against Tuberculosis and Lung Disease and World Vision India	3
Malaria	124	14%	National Vector Borne Disease Control program and Caritas	2
Total	**905**	**100%**		**9**

[10] World Bank 2014 http://data.worldbank.org/indicator/SH.XPD.PUBL.ZS

[11] Demand for Grant (National Budget) and supporting budget documents provided by NVBDCP and CTD for 2014-2015 (INR26.8 billion)) and 2015-2016 (INR29.8 billion). Percentage of Global Fund share in the national budget for Malaria for the period of 2015-2016 was not submitted by the program.

[12] TB allocation includes additional USD 55 million as incentive funding.

The main Principal Recipient is the Government of India, through the Department of Economic Affairs of the Ministry of Finance, which accounts for more than 80% of existing allocations.

Accordingly, although India is a critical portfolio for the Global Fund in terms of both disease burden and funding, the ownership, impact, financial and programmatic sustainability for the three diseases country programs are primarily reliant on the Government of India. The Indian pharmaceutical manufacturing sector is the third largest in the world, growing at approximately 14% in 2012-16. The country currently exports about US$11.4 billion worth of drugs annually, which is almost half of its total pharmaceutical revenue.[13] Manufacturers have made significant investments in upgrading their manufacturing plants to international standards. Being a major producer and exporter of drugs for the three diseases, Indian drug manufacturing also has a major influence on the global fight against the three diseases.

Grant implementation through community outreach

India's vast geographical landscape, population spread, diversity within regions, and the stigma attached to HIV and TB present unique challenges in the management of the three diseases. In the administration of Global Fund's grants, these challenges have been partly addressed through the establishment of counselling programs to improve community outreach, diagnosis and treatment adherence.

Accredited social health activists have been identified and trained through the malaria program to improve outreach in the seven North Eastern states, specifically due to the difficult terrain. In the TB and HIV programs, counselling projects have similarly been launched by both government and civil society. For example, The Vihaan Care & Support Program for people living with HIV has been implemented through almost 50% of the sub-recipients and 80% of the sub-sub recipients that provide help to people living with HIV.

[13] International Federation of Pharmaceutical Manufacturers & Associations- Facts and Figures 2015

II. Scope and Rating

Scope

The Office of the Inspector General (OIG) audited Global Fund grants to the Republic of India including:

1. Assessing the Secretariat's risk management and assurance mechanisms in place to ensure the efficiency and effective management of:
   a) procurement and supply chain risks;
   b) program and data management risks;
   c) financial risks.

2. Assessing the adequacy of the funding arrangements in ensuring a sustainable contribution in the fight against AIDS, tuberculosis and malaria in India.

The audit focused on the existing active grants and activities for the period January 2014 to March 2016. The audit covered eight states representing 51% of the total population of India,[14] 33% of India's total HIV/AIDS burden, 46% of its TB burden and 35% of its malaria burden. As part of the audit, the OIG visited 125 projects/programs of Principal Recipients, sub-recipients and other implementing entities including selected health facilities, treatment centers, warehouses and stores.

Rating[15]

Below are the OIG's overall ratings of the risk management and assurance mechanisms in place to ensure the efficiency and effective management of the following risks to the Global Fund grants to India:

Audit objectives	Rating	Reference to findings
Procurement and supply chain risks	Needs significant improvement	5,6
Program and data management risks	Partially effective	1,2,3,4
Financial management risks	Effective	N/A
Adequacy of the funding arrangements in ensuring a sustainable and significant contribution in the fight against the three diseases	Partially effective	7

[14] http://mospi.gov.in/national_data_bank/Population_22oct2012/Census_2001_table_22oct12/1.%20Population%20by%20Religious%20Community.pdf. The states covered by the audit were Delhi, Andhra Pradesh, Assam, Karnataka, Maharashtra, Tamil Nadu, Orissa and Uttar Pradesh.
[15] See Annex A for the rating definitions.

III. Executive Summary

Implementing grants in India is critical if the Global Fund is to achieve its objective to end the epidemics of AIDS, tuberculosis and malaria. The grants are implemented in a vast territory with a population of over 1.2 billion people. Despite a growing economy, over 21% of the population are below the poverty line, and over 65 million people live in slums.[16] The size, variability and diversity of the country contribute to a high disease burden – India has the highest burden of TB in the world and the third largest HIV burden. The Government of India makes significant investments in the health sector, providing 80% of the annual budget for the HIV, tuberculosis and malaria programs, which are implemented at state level.

Based on the OIG's assessment of the key risks, the audit focused on evaluating the efficiency and effectiveness of two specific areas: firstly the assurance mechanisms put in place by the Secretariat to ensure the efficient and effective management of key risks; and secondly, the adequacy of the funding arrangements to ensure a sustainable contribution against the three diseases.

1. Secretariat's risk and assurance mechanisms for the management of key risks

The OIG examined the risk and assurance mechanisms in place at the Secretariat to identify, mitigate and manage key risks. The effectiveness of risk management processes was evaluated following an OIG review of implementation processes. The auditors noted that, although most risks in the India portfolio have been identified by the Secretariat, mitigating actions through risk and assurance mechanisms have not adequately addressed them. Nor have they been escalated through the risk management process for formal acceptance or resolution.

Procurement and supply chain risks

The OIG found that the Secretariat's mechanisms to manage and mitigate risks around procurement **require significant improvement** in the following key areas:

Significant delays in the procurement of essential commodities
80% of Global Fund grants to India are spent on the procurement of health commodities and medicines managed through one procurement agent. In a 2013 audit, the OIG had already highlighted delays of up to one year in health commodities procurement leading to stock-outs. In the 2016 audit, delays in procurement processes increased. Procurement of HIV and TB commodities now take an average of over 18 months and 24 months respectively, whilst commodities for the malaria program can take up to four years. This has resulted in significant under absorption of funds (84% of the malaria grant budget) over the last two years.

These procurement delays have resulted in stock-outs of commodities, particularly for HIV patients, and under performance of some key program activities since 2011. For example, there has been no distribution of bed nets under the Global Fund program since 2011. Anticipating procurement delays led to over ordering of multi-drug resistant TB commodities by program implementers, resulting in overstocking, expiries, and the inability of the disease programs to adapt to updated treatment regimens.

The root cause of these issues is a slow procurement process which includes multiple administrative approvals at different levels, weak monitoring of procurement timelines, and a lack of accountability for delays. Additionally, measures put in place in the past have only provided ad hoc solutions. For example, the Global Fund's Pooled Procurement Mechanism was used to buy bed nets, but only after four years of procurement bottlenecks. However, this has not been embedded as a permanent

[16] World Bank Poverty data 2011.

solution by the Ministry of Health, and is subject to case-by-case lengthy approval processes. For example, a new order of bed nets initiated in 2016 is currently undergoing approval for pooled procurement. Although the Secretariat is aware of the risks related to delays in procurement and country implementers have agreed to change the procurement agent under the new grants, significant delays remain. At the time of the audit, the Government of India had begun to address these delays in the long term by appointing a new procurement agent. However, timelines for the transfer of procurements financed by the Global Fund to the new procurement agent have not yet been decided.

Diverging quality assurance standards
Risks related to the quality of drugs used in disease programs have not been adequately resolved through the Secretariat's risk management processes. As per its requirements, the Global Fund supports only procurements from pharmaceutical companies that meet the Global Fund quality assurance requirements,[17] whereas drugs procured using domestic funds are not subject to these requirements.[18] The co-mingling of drugs at all levels in the TB program has meant that patients receive drugs from both sources. For the HIV program, given the planned transition to government funding of drugs in 2018, patients who previously received antiretroviral treatment compliant with the Global Fund quality assurance requirements will be switching to drugs that do not comply with those standards. It is unclear whether any difference exists in the quality of drugs from these two sources and, to the extent such difference exists, the programmatic impact is unknown. No assessments to evaluate the implications of these divergent quality assurance standards have been conducted. In the event that the government-funded drugs are of quality similar to those of the Global Fund, the Global Fund bears higher costs. Based on a sample of four main TB and a comparison of unit costs and quantities procured by the Global Fund and the government, the estimated cost differential is US$5 million out of U$13 million in last three years. However, in the event that the government-funded drugs are of poorer quality, this arrangement could also lead to drug resistance, despite the significantly higher cost of the Global Fund quality-assured drugs.[19] Although this issue is known at the Global Fund Secretariat, this risk has not been formally evaluated or accepted, and no mitigation actions have been implemented. More generally, Global Fund policy does not stipulate how the quality of health products is ensured when health products are bought outside of Global Fund programs.

Program and data quality risks

Programs funded by the Global Fund in India made significant advances between 2012 and 2015 with increases in the number of patients on TB treatment from 1.2 million to 1.5 million and those on antiretroviral treatment from 540,000 to 773,000. The procurement of 500 Gene Expert machines has also significantly reduced delays for TB diagnosis although they are not yet utilized optimally as installation only began in 2016. Despite these gains, the OIG noted challenges in the quality of services provided and in prevalence data:

Unknown prevalence information for the world's highest TB burden
There has been no TB prevalence survey in India since 1958 to evaluate the extent of the disease burden and the required response. This means that, although updates have been made periodically,

[17] As per WHO Quality Assurance policy detailed at http://www.theglobalfund.org/en/sourcing/qa/medicines/, there are three options for implementers to ensure that medicines fulfil the Global Fund Quality Assurance requirements, i.e. they are either: (1.) prequalified by the WHO Prequalification Program; (2.) authorized for use by a stringent drug regulatory authority; or (3.) recommended by the Expert Review Panel.
[18] WHO also promotes and recommends Good Manufacturing Practices (GMP), which are administered directly by national regulatory authorities. However, these certificates are not issued by WHO, and do not constitute WHO prequalification. WHO prequalification program requires direct inspection by WHO of the manufacturing premises or sites to determine the degree of compliance with WHO recommendations.
[19] Multiple studies and articles indicate higher risks of drug resistance developing from low quality of drugs. Some of them include Pharmacokinetic determinants of the window of selection for antimalarial drug resistance (Stepniewska K, White NJ, Antimicrob Agents Chemother. 2008 May; 52(5):1589-96); http://www.who.int/features/qa/79/en/; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2845817/; http://www.wwarn.org/about-us/malaria-drug-resistance.

calculations for the TB control programme in India are now approximately 60 years old. Recent surveys in specific states have also shown a two-fold increase over previous estimates. Given that the country accounts for 25% of the global TB burden, significant variation in the estimates and actual burden could affect global disease estimates as well as India's future level of support from the Global Fund. While this risk has been identified through various studies at the country level, it has not been escalated through the risk assessment and action planning tool at the Global Fund (known as QUART) or capacity assessments for the TB program.

Quality of services
There are significant delays in the diagnosis and referral for treatment of new HIV patients. 80% of the patients sampled in the audit are put on treatment when CD4 cell count was lower than 100. This is significantly less than national as well as international standards, indicating general ineffectiveness of detection, advocacy and awareness mechanisms. Approximately half of TB patients are treated through the private sector, which is currently largely unregulated and does not report patients into national data systems. This leads to the risks of incorrect treatment regimens, weak follow-ups and treatment disruption, in turn leading to drug resistance. Low public sector patient detection compared to their targets (55% detection for smear-positive patients against a 100% performance target)[20] and other quality of service issues are likely contributing causes.

Although the Secretariat's risk assessment and action planning tools noted several of the above key risks, management processes have not adequately or effectively taken action to mitigate their impact on program effectiveness. The Secretariat's management of program and data related risks is therefore rated **partially effective** by the OIG**.**

Financial risks

In 2013, the OIG audit identified significant risks in the financial management of the portfolio. Consequently, the Secretariat and the country made improvements to minimize the level of ineligible expenditures from the Global Fund grants. The OIG noted that this has effectively addressed the financial risks relating to ineligible expenditures on the grants in India. The government budgeting, payment and accounting systems are used for managing the Global Fund grants, which are generally well-designed and operationally effective, though some delays exist in transferring funds from the national level to the state level. The Secretariat's management of the financial risks is therefore rated as **generally effective**.

2. Adequacy of the funding arrangements to ensure sustainable impact

In February 2016, the Global Fund Secretariat notified the Government of India of its intention to progressively transition out Global Fund support for the three diseases over the next three replenishment phases. The government already contributes significantly to interventions for the three diseases. However, with the Global Fund providing US$905 million in the current grant cycle of four years, future investments will require careful planning. As the world's seventh largest economy spending 1.3% of gross domestic product on health,[21] there are further opportunities for increased government ownership and gradual transition of the Global Fund in India. However, the Secretariat and the country have yet to finalize transition planning, holistically analyzing all opportunities and contingencies, and laying out short and long term targets. The adequacy of the funding arrangements in place to ensure sustainable impact is therefore rated as **partially effective**.

[20] Progress Updates Disbursement Request form September 2015
[21] World bank 2014 http://data.worldbank.org/indicator/SH.XPD.PUBL.ZS

IV. Findings and Agreed Management Actions

01. There has been no measurement of TB prevalence in India, limiting the assessment of actual program impact. There are risks of significant increases in national and global disease estimates, funding requirements and disease elimination timelines.

The World Health Organization (WHO) currently estimates that India has approximately 25% of new annual TB global cases and the highest TB burden in the world, underlining India's importance in meeting global TB elimination targets.[22] However, there have been no surveys to measure the prevalence of all forms of TB in India since 1958. This means that although updates have been made periodically, formulations of the TB control programme in India are now approximately 60 years old. The WHO recommends prevalence surveys once every five years.

A recent state-level survey in Gujrat indicated double the previous estimates of prevalence.[23] Similarly, household surveys held in Tamil Nadu showed an increase of 70%.[24] The performance of TB prevalence surveys in various high burden countries after a significant time gap have resulted in doubling or in some cases trebling the original estimates.[25] This creates a risk of significant increases in prevalence estimates as a result of the recently approved nation-wide survey.

The last risk assessment and action planning tool (known as QUART) for TB was completed in 2014. Subsequently, a capacity assessment tool was completed in 2015 for the concept note submitted under the new funding model. While the absence of a TB survey risk was identified through various studies and reviews, this risk was not escalated or resolved through the risk management mechanisms of the Global Fund. In the absence of accurate disease burden estimates, coupled with the considerable uncertainty about the quality and quantity of overall treatment coverage in the country (see findings 02 and 03), the Revised National TB Control Program and the Secretariat may be unable to measure trends of TB burden, assess the impact of the program and devise future TB control strategies. [26]

Given India's existing disease burden, any increase in prevalence estimates could in turn significantly increase global disease estimates as well as the funding requirements of the TB program in India.[27] In April 2016, following the launch of the WHO End TB strategy, the Ministry of Health decided to carry out a national survey that will also examine prevalence at a state and regional level. The planning process has been initiated and, given its complexity, the survey is estimated to cost US$18 million. However, no funding commitments have been made by any of the stakeholders and a timeline has not yet been determined.[28]

Additionally, India currently has a national strategy to end TB by 2035.[29] The country is also expected to transition out of Global Fund funding in less than a decade.[30] A significant increase in prevalence can create the risk that the national strategy could fail as well as challenges in achieving the transition objectives for the Global Fund and fiscal challenges for the Government of India.

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22 Source: Global TB report 2015 http://www.who.int/tb/publications/global_report/en/

23 Population based survey to assess prevalence of pulmonary tuberculosis cases in the state of Gujarat, India (2011-12), released in December 2013 showed a 214% increase.

24 Household surveys held in Chennai for tribal communities, city and Tamil Nadu showed a prevalence of on average of 170% above the current national estimates.

25 Nigeria, Indonesia and Tanzania surveys resulted in prevalence revised to 202%, 217% and 306% of the previous national estimates respectively. Source: www.who.int/tb/publications

26 WHO End TB Strategy that has been adopted by the Revised National TB Control Program (RNTCP)

27 Based on 2015 budget. Source: http://www.who.int/tb/country/data/profiles/en/

28 As per communication between Revised National TB Control Program (RNTCP) and Global Funds Country Team including formalized budget for survey

29 WHO End TB Strategy that has been adopted by the Revised National TB Control Program (RNTCP)

30 Verified through official communications between the Secretariat and the Government of India.

Agreed Management Action 1:

The Secretariat will, in collaboration with the Ministry of Health and pertinent development partners and other stakeholders, support efforts to develop a plan and budget for a bespoke prevalence survey, identifying activities to be undertaken, cost, timelines and sources of funding.

Owner: Head Grant Management Division
Timeline: 30 June 2017

02. Achievement of impact on HIV and TB programs is adversely affected by limitations in program coverage

India's HIV and TB programs have improved patient coverage over the past years. The HIV program increased the number of patients treated from 540,000 to 773,000 between 2012 and 2015. Similarly, the TB program increased national coverage from 1.2 million to 1.5 million cases treated annually by 2015. However, the overall achievement of impact is limited by the following:

Delayed initiation of patients on HIV treatment

There are persistent delays in the diagnosis and referral of new patients for treatment, compared to the requirements of the existing national policy. Possible contributing causes include the low effectiveness of advocacy for voluntary patient testing, few testing machines in the past, and staff vacancies.

Of all 14 HIV facilities visited by the OIG, 80% of the sampled patients on treatment were referred through hospital/ medical referral systems with a CD4 cell count of less than 100. This is significantly lower than the national standards that require treatment as soon as the CD4 cell count drop below 350, and the latest international WHO standards that advocate treatment as soon as a patient is tested HIV positive, regardless of CD4 count. Low CD4 count leads to low immunity and high susceptibility against diseases.[31] This late detection of patients, whose diagnosis is generally only known when they seek treatment for illnesses, needs improving through effective advocacy for voluntary patient testing.

The OIG auditors noted an insufficient number of CD4 machines, used for testing HIV cases, in six of the 14 HIV facilities visited. As a result, patients had waited for more than a year and half for testing, as measured from the dates of patient notification and their CD4 tests in the health facility records. Furthermore, in all 14 HIV facilities visited, an average of 30% of approved staff positions were vacant. One of the reasons for the vacancies is a historical embargo on further recruitments by the government authorities.

Current national targets are based on the 2010 WHO guidelines for diagnosis and treatment of people living with HIV, which required patients below a 350 CD4 count be put on treatment. The National AIDS Control Programme (NACO) has committed to increasing the coverage in line with the 2013 WHO guidelines (patients below 500 CD4 count become eligible for treatment). This will further increase the targets by approximately 200,000 patients under a new grant. This spike is likely to further stretch the program and compound the existing coverage challenges due to lack of staffing and ineffective patient detection mechanisms.[32]

The reasons behind delayed initiation of treatment for new HIV patients have existed for many years and are known by the national programs and the Secretariat. These risks have been identified in various in-country program evaluations as well as in the risk assessment and action planning tool (QUART) for HIV in 2014. However, the Secretariat has not effectively monitored compliance with the performance measures agreed by the country.

Unregulated private sector TB coverage

Although the national coverage for TB has increased, a number of studies and surveys have suggested that up to 46% of patients, treated privately, may not be currently uploaded in the national data

[31] The CD4 count is a laboratory test that indicates measures the health of the immune system against diseases. HIV/ AIDS attacks and weakens the immune system.
[32] As per the TB-HIV single concept note for India submitted to Global Fund dated 19th February 2015.

systems.[33] Possible reasons that explain high private sector patient coverage include the convenience of service and the desire for confidentiality and personalized care.

In order to increase coverage and measure results better, the indicator for patients detected and registered for treatment has been changed. It now also includes patients from the private sector as well as those reported in the national TB program. However, since the change was made in 2014, the program has reported an average of 55% target achievement for patients detected and registered for treatment, through grant progress updates (PUDRs). This illustrates the program's challenges in achieving impact by increasing the number of patients tested and put on treatment for TB, in a country with the highest annual new TB cases globally.

The private sector is required to notify new TB cases into the national system. The TB program has started registration pilots in three states with the aim of encouraging private sector notification of all cases by providing incentives such as free testing and medication to patients while the private clinics retain the patients. However, so far, only approximately 3,200 private healthcare providers have been engaged by the national program. The total number of private TB treatment providers is unknown in a country with over 761,000 doctors in 2009.[34]

The private sector currently remains largely unregulated with no oversight on treatment protocol by the national program. This leads to the possible risks of incorrect treatment regimens, weak patient follow-ups and disruption during treatment, all of which could contribute to higher drug resistance. Furthermore, the lack of regulation for over-the-counter drugs for TB increases the risk of drug overuse and resistance, particularly for the private sector treatment cases.

[33] Satyanarayana, S "From where are Tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts", PLoS ONE www.plosone.org/article/info:doi/10.1371/journal.pone.0024160 - See more at: http://www.tbfacts.org/tb-india/#sthash.jtI1a1ot.dpuf

[34] WHO South East Asia Journal of Public Health

03. Impact of HIV and TB programs is affected by limitations on quality of services.

A policy framework exists for both TB and HIV programs, with detailed policies and procedures governing all aspects of TB and HIV prevention, treatment and care. Furthermore, there is effective coordination in setting policies and guidelines between the National AIDS Control Organization and India HIV/AIDS Alliance (the Principal Recipient responsible for the Vihaan program which provides patient support activities). The Vihaan program has shown innovation and success in providing additional support services such as income generating activities to patients on treatment. Similarly, the TB counseling program by the private sector TB Principal Recipient, Union against TB and Lung Diseases, improved patient adherence to treatment through both the health facilities and home-based visits.

However, the following issues were noted in the quality of services provided to patients by the HIV and/or TB programs in India:

Non-compliance with standards for TB care

- Fixed daily dose regimens for drug sensitive TB patients are not implemented in all 35 health facilities visited. WHO recommends daily regimens for all patients with TB as an effective mechanism to monitor the patient's treatment adherence.[35]
- Additionally, a pharmacovigilance system has not yet been implemented. Although training started in 2014, monitoring of adverse reactions to medication has not been embedded in the treatment of patients. This leads to the risk of patients not taking medication and dropping out of treatment, in turn leading to drug resistance.
- Contrary to the treatment protocols, preventive treatment is not provided to people living with HIV who test negative for TB in all the 35 facilities visited.[36] This increases the risk of co-infection, which is a challenge to the treatment and elimination of TB.
- Testing delays were also registered in all 35 health facilities visited. For example, the OIG review of the TB registers revealed that 39% of TB patients with indications of treatment failure were tested late, out of which 22% received tests after a 1-5 month delay. 5% were not tested at all.[37]
- Due to the delays in these tests, treatment for multi-drug resistant TB started for 29% of the sampled patients before test results had been received in all 35 health facilities visited. This leads to a risk that patients are given the incorrect treatment or dosage, which also increases the risk of drug resistance.

One of the main root causes for these issues is non-compliance with updated standards of TB care. This was not identified in the Secretariat's risk assessment for TB in 2014. The Ministry of Health released the Standards for TB Care in 2014, which sets out the standard of TB treatment and TB testing & diagnosis that should be provided by the RNTCP in all parts of India.[38] However, the proposed changes in the treatment regimens were not updated in the national guidelines until March 2016. Furthermore, training under the new guidelines had not yet been rolled out in seven out of the eight states reviewed in the audit. These gaps in compliance were not noted in the Secretariat's capacity assessment for the national TB program in 2015.

The historical shortage of **GeneXpert** has also contributed to the delays in testing.[39] This was noted by the Secretariat and has recently been addressed with the procurement of 500 machines. Their

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[35] World Health Organization. Treatment of Tuberculosis, Guidelines. 2010
[36] Isoniazed (INH) Preventive Therapy (IPT), as per Ministry of Health 2014 Standards of TB Care.
[37] TB patients who are found positive on any follow-up sputum smear examination during treatment with first line drugs, diagnosed TB patients with prior history of anti-TB treatment, TB patients with HIV co infection and all presumptive TB cases among PLHIV, and defaulters who return for treatment
[38] Standards for TB care in India www.searo.who.int/india/publications/en/
[39] The Xpert MTB/RIF detects DNA sequences specific for Mycobacterium tuberculosis and rifampicin resistance by polymerase chain reaction It is based on the Cepheid **GeneXpert** system, a platform for rapid and simple-to-use nucleic acid amplification tests (NAAT).

optimal utilization had not yet been achieved at the time of the audit as the machines had just been installed. There is therefore a need for the Secretariat to monitor use to ensure that testing delays are addressed.

Another contributing factor to challenges in the quality of services is the lack of counsellors in the national TB program. Conscious of this, the Secretariat is funding counselors in the new TB grant; however, these counsellors have not been trained to ensure and monitor the quality of services provided to patients, including follow-up through home-based visits. A review of data showed an improvement of treatment adherence when civil society counsellors visited homes. This represents a missed opportunity for coordination between the national and civil society programs to make the most of trainings already offered through the civil society Principal Recipient.

HIV patients lost to follow-up after treatment initiation

30% of patients were lost after starting treatment as noted in all 14 HIV facilities visited. Furthermore, a 'lost-to-follow up program'[40] only measures and focuses on patients who discontinue after initiating treatment, but does not include those patients who are tested positive at the Integrated Counseling and Testing Center (ICTC) and do not reach antiretroviral centers to initiate treatment.

The large number of vacant positions, with an average of 30% vacancies identified in the 14 HIV facilities visited is a key contributing factor. Despite the vacancies, a strong commitment from the health workers was observed in workload management and treatment continuation. The audit team observed long patient queues in six out of the 14 HIV facilities visited, which risks affecting patient adherence.

Furthermore, efforts to bring the lost patients back to treatment have registered low successes, as measured through program progress updates. Limited coordination between National AIDS Control Program and the other Principal Recipient (India HIV/AIDS Alliance) at the state and district levels, is also a likely contributing factor. For example, the auditors observed that the records for patients brought back from follow-up and those transferred between facilities were not updated or reconciled between facilities or between the two Principal Recipients.

Most of these risks were not captured with clear improvement plans by the Secretariat in its 2014 risk assessment, nor in a 2015 capacity assessment.

[40] Lost to follow up program is managed by India HIV/AIDS Alliance, the goal of this program is to bring back the lost to follow up patients to treatment with the assistance of Civil Society Organizations (CSOs)

04. Impact in HIV and TB programs is affected by limitations of data systems.

For national programs of both HIV and TB, various data automation efforts are ongoing. For example, under the TB program, there is an initiative to automate patient cards. All three disease programs are also in the process of automating the inventory management systems to include consumption data. However, these processes are not integrated and remain incomplete, resulting in some missed opportunities on the benefits of monitoring and data analytics at national levels and accurate patient records at lower service delivery levels. These gaps affect the programs' ability to achieve impact through the effective management of program data due to the following:

Data reporting errors in HIV program

While most facilities visited did not have material data inaccuracies, data reporting errors were noted during field visits, which can adversely affect disease estimates, drug and care forecasts as well as prevention activities. For example, 21% of the visited facilities had more than 10% errors in the patients' pre-antiretroviral treatment reports, and 14% of the visited facilities had more than 10% errors in patients on antiretroviral reports.

Possible root causes include vacant staff positions. For example, in the Maharashtra and Telangana states, the State Coordinator position had been vacant for more than two years, leading to the suspension of supervision missions from the states to districts and health facilities in 2015 and 2016. Limited supervision increases the risks of undetected data inaccuracies.

While data reporting errors had been identified in the Secretariat's risk assessment for HIV in 2014, and the capacity assessment of the national HIV program in 2015, the root causes were not adequately analyzed and resolved to enable remedial actions to be formulated and implemented.

Inconsistent data records in TB program

Although a monitoring and evaluation system has been developed, it has not been fully implemented and, as such, the program is unable to benefit from its use. For example, when patients became drug resistant and are added to list of multi-drug resistant patients, they are not automatically removed from list of normal TB patients, and can be duplicated.

Similarly, the absence of automation results in the need for four to five different patient cards per patient, with inconsistencies in updates, errors in data accuracy and additional effort for program staff. For example, 65% of drug resistant TB patient cards sampled in all four states visited did not update weights recorded, 80% of district TB center patient cards had follow-up culture results missing, multiple templates were used for drug resistant TB patient cards with 50% of drug resistant TB registers not updated with follow-up culture results. These data quality risks have been identified in the capacity assessment tools and the Secretariat supports the automation initiatives. However, the benefits of their integration have not been fully explored to ensure that these systems address the data quality risks noted.

Weak follow-up of supervision mission findings by the national programs was also identified as a possible contributing factor. For example, the reports of supervision missions conducted by monitoring teams were not followed up to ensure that recommendations were implemented. Although these risks have been identified, mitigating actions for this risk have not been included in the Secretariat's capacity assessment and risk assessment and, as such, progressive targets have not been set to enable implementation of remedial actions to address these risks.

Agreed Management Action 2:

The Secretariat will:

- In collaboration with the Ministry of Health's Central Tuberculosis Division and other relevant technical partners, and using the results of the completed pilots on the private sector engagement under the TB program, develop a plan to expand the coverage of the private practitioners and their case notification and treatment outcomes into the national system. The plan will include progressive targets, timelines, and access to diagnostics and drugs to help the program measure treatment outcomes. In addition, the Secretariat will, in collaboration with National AIDS Control Organization, India HIV/AIDS Alliance and Solidarity and Action Against the HIV Infection in India, develop a plan to enhance outreach for lost to follow-up (LFU), data cleaning and reporting for LFUs; and
- In collaboration with National AIDS Control Organization, ensure that the distribution plan for CD4 machines to the states is developed and the approved number of CD4 machines is procured.

Owner: Head Grant Management Division
Timeline: 30 June 2017

05. Diverging quality assurance arrangements of health commodities have adverse programmatic and financial implications for the disease programs.

As per the Global Fund policy on "Implementing the Quality Assurance Policies for Pharmaceutical, Diagnostics and Other Health Products", all procurements of drugs and health products financed from the Global Fund grants should meet the Global Fund quality assurance standards.[17] This practice is to ensure the quality of health commodities delivered to patients, which should translate into high success rates for patient treatment as well as effective disease prevention.

For India, the Global Fund finances 50% of first line and 40% of second line TB drugs and 100% of HIV drugs in line with this policy.[41] For all health commodities financed through domestic financing, the Government of India currently does not require compliance with the Global Fund quality assurance requirements, which is not considered sufficient by the Global Fund.[18] However, drugs from all sources of funding are co-mingled at national and sub-national levels, with no distinction during state-, facility- or patient-level distribution. This means that the same patient is likely to receive medicines adhering to different quality standards over the course of treatment. This arrangement could have the following programmatic and/ or financial implications for the TB program in India as well as globally:

- In the event that the government-funded drugs are of effective quality, the Global Fund bears higher costs for its quality assurance without assurance or measurement of any related benefits to the patients. For the past three years, for the procurements of a sample of TB drugs amounting to US$13 million, the Global Fund has paid an estimated US$5 million in excess of what would have been paid if the commodities had been domestically quality-assured.[42]
- In the event that the government-funded drugs are of poorer quality, this arrangement exposes the patients to the risks associated with low quality of drugs, despite receiving part of the treatment through the Global Fund quality-assured drugs. This is because both the Government of India and the Global Fund are major contributors towards TB and will be the same for HIV medicines in future in India.[43] There is therefore a risk of developing drug resistance,[19] despite the significantly higher cost of the Global Fund quality assurance of drugs.
- The difference in standards entail significant additional government approvals for the procurements of higher-cost drugs procured through the Global Fund investments. This contributed to procurement delays, adversely impacting the program implementation and results, with details in Finding 06.

All of the first line drugs are compliant only with the Government of India quality assurance standards. Therefore any material issue with their quality increases the risks of higher multidrug resistant TB prevalence, and limits the impact of the Global Fund investments in the treatment of drug resistant TB.

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[41] Concept Note- Modular Template pages 27 & 31

[42] Calculation based on comparison of unit costs and quantities of the Global Fund and Government procured drugs for a sample of 4 main TB drugs.

[43] Global Fund finances approximately 50% of first-line and 40% of second-line TB drugs in India currently, with the rest financed by Government of India. HIV drugs are historically been financed 100% by the Global Fund, but as per the concept note, Government of India will increase their share of drugs funding by 20% of total HIV drugs every year.

The Indian Pharmaceutical sector is the third largest in the world, growing at approximately 14% percent in 2012-16. The country is currently exporting about US$11.4 billion worth drugs annually, which is almost half of its total pharmaceutical revenue. It is expected to generate revenues worth US$55 billion by 2020.[44] & [45] India has made significant investments in upgrading its manufacturing plants to various international standards. However, as in the case of domestically consumed TB drugs, there is no assurance that all exports from India meet the Global Fund quality assurance standards. In the event that these exported drugs are of poor quality, there are global, adverse programmatic ramifications.

While there is evidence of discussion on this subject between the Global Fund and the Government of India, it did not contain a comprehensive analysis of all the risks inherent to the diverging quality standards. There has been no formal resolution or acceptance of this risk by the senior management or escalation to the Board.

Agreed Management Action 3:

With respect to the issue of potential impact due to the existing divergence in quality assurance standards of health commodities funded between various countries and the Global Fund, the Secretariat will submit a policy paper to the Strategy Committee leadership for consideration and will recommend that it be on the agenda.

Owner: Head Strategy and Policy
Timeline: 30 June 2017

[44] India Brand Equity Foundation - http://www.ibef.org/download/pharmaceuticals-august-2013.pdf
[45] International Federation of Pharmaceutical Manufacturers & Associations- Facts and Figures 2015

06. Systemic delays on the procurement of health commodities, adversely affecting program effectiveness and leading to missed opportunities on program efficiencies.

All 14 procurements for the three programs were reviewed. The OIG noted lengthy procurement processes for all three. The total average times for the full procurement cycle were 16 and 24 months respectively for the HIV and TB programs. For the malaria program, bed net procurement took four years[46] from 2011, with some procurements still ongoing. The procurement of artemisinin-based combination therapy has similarly taken over three years.

These delays have adversely affected program effectiveness and have led to the following challenges:

Lack of bed nets for a distribution campaign

For malaria, there has been no mass distribution of bed nets in the states covered by the Global Fund malaria grants since 2011, although mass distributions should take place every three years.[47] A mass campaign for bed nets, procured in October 2015 and started in February 2016, registered delays due to state elections. As a result, 45% of bed nets were not distributed at the time of the OIG's review. Bed nets for Odisha, a state that is now covered under a Global Fund new funding model grant, have not yet been procured. Malaria cases have increased from 2,950,000 in 2013, to 3,950,000 in 2014, and to 4,330,000 in 2015. One of the likely contributing causes is the lack of bed nets.

Shortages of HIV drugs

For the HIV/AIDS program, the supply chain Standard Operational Procedures state that 20% of stocks received at the State AIDS Control (SAC) warehouse should be kept as a buffer in order to avoid treatment disruption at the facility level. This was not the case in the three warehouses that were visited in Mumbai District AIDS Control Society (MDACS), Maharashtra State AIDS Control Society (MSACS) and Telangana State AIDS Control Society (SACS). Low stock supply and the need to dispatch all stock to the facilities caused stock-outs in all visited warehouses. Furthermore, the auditors also found stock-outs in three of the 14 facilities visited and constantly low stock in 12 out of 14 facilities. This led to minimizing the prescribed quantity to patients as per NACO's treatment guidelines (one month) to smaller batches, sometimes as low as five days' dosage. While this practice helps to avoid stock-outs of drugs, it leads to the additional physical burden and travel costs for the patient, with a risk of treatment disruptions and low treatment adherence.

Drug overstocking leads to inadequate storage and lack of regimen adaptability

Given lengthy procurement processes, program implementers order more stock for longer periods of time, which limits the adaptability of the program to change its estimates, including adjusting the estimates of patients on treatment. For example, for the TB program, the initial estimates for second line treatment scale-up have not materialized. This has contributed to excess quantities of multi-drug resistant and extensively drug-resistant TB drugs. As at April 2016, out of a sample of four second-line drugs, the auditors noted stocks of commodities worth approximately US$35 million, with an average of two years' worth of medicines based on current consumption levels.

The treatment regimen has recently been changed to daily treatment, which is likely to be more effective for the patients for treatment adherence. However, the existing stock of excess drugs is as

[46] The procurement agent RITES Ltd ended up canceling a tender in which foreign and Indian-based companies were to bid for contracts for 10.2 million nets in 2012, as well as another auction in 2013 for 14.8 million nets — both of which would have been paid for with assistance from the World Bank and the Global Fund.
[47] The Global Fund has historically covered the seven north eastern provinces under previous grant, while new funding model grant has extended to Odisha. Universal campaign has not happened in six north eastern states and in Odisha since 2011, and has been initiated but not completed in one north eastern state (Assam).

per the old regimen. This means that a daily treatment regimen cannot be initiated until these drugs have been used up, leading to lower quality of services for the TB patients.

Drug overstocks have also led to additional stress on the current storage facilities at the district levels. These quantities of second line drugs require air-conditioning and additional storage space. Drugs were stored in sub-optimal conditions in all district stores visited, leading to the risk of drug quality deterioration and/or drug expiries.

Various possible root causes contribute to the persistence of procurement delays:

- The differences in domestic and Global Fund requirements on quality assurance of health commodities have contributed to various procurement delays. In one example, for the malaria grant for the North Eastern states, the WHO pre-qualified procurements of 7.2 million bed nets initiated in 2012 required special government approval, since the prices were significantly higher than the government procurements. These approvals were never finalized, and the procurement was eventually made through the Global Fund's Pooled Procurement Mechanism, with the bed nets delivered in February 2016. In another example, the procurement of 11.4 million bed nets for Odisha was originally supported by a World Bank loan in 2011. However, these procurements have since not materialized, mainly due to a judicial complaint against the Principal Recipient alleging restrictive practice. This is because the quality standard required in the advertisement for the procurement was WHO Pesticide Evaluation Scheme to which only one manufacturer complied. Odisha State was subsequently included in the new funding model grant of the Global Fund and a solution to procure the bed nets is currently being explored.

- The National Procurement Guidelines clearly articulate which steps to follow in conducting procurements. However, these processes are often cumbersome and multi-staged. For example, initial government approval of procurements, before requesting proposals from bidders, takes approximately four months on average for the HIV program and for the TB program. In addition, the procurement process from requests for proposals to contract signature stage takes 11 months on average for the HIV program and 15 months for the TB program. Again most of the delays come from the government system approval of the selected bidder and the unit costs.

- The National Procurement Guidelines do not specify the maximum time to be taken for each step of procurement. Also, there is no internal process or mechanism to systematically follow-up procurements at all stages of approval and performance, identify and minimize delays, and assign accountability of timeliness of procurements at different tiers. This has affected the programs' ability to understand the root causes of the delays and effective remediation.

- As per the National Procurement Guidelines, the three disease programs use the services of a procurement agent, Rail India Technical and Economic Services (RITES) Ltd. However, various capacity gaps have been identified for this procurement agent in the latest assessment performed by the disease programs. While various capacity building initiatives have already been undertaken, further improvements are necessary to ensure the adequate quality and timeliness of procurement processes by RITES;

- Further delays were observed by the suppliers in delivering the health commodities to the warehouses, with an average of five months for the HIV program and nine months for the TB program.

The Secretariat has been aware of the issues leading to procurement delays and their implications as noted in the risk assessment and capacity assessments completed under the new grants in 2015. Their efforts have catalyzed the Government of India into committing to change its procurement

agent under the new grants. This is to put in place an efficient procurement process to avoid multiple approvals by the Ministry of Health and Family Welfare. However, so far, the Government of India has only transferred its own health product procurements to the new procurement agent. Timelines for a similar transfer of procurements financed by the Global Fund to this new procurement agent have not yet been decided. The response to these risks has been slow, with no actions taken to resolve these issues in the short-term. As such, the Secretariat's risk management mechanisms have not materially reversed the persistent procurement delays.

Agreed Management Action 4:

The Secretariat, in collaboration with the national disease programs, will develop a plan for the transfer of procurements of health commodities supported by the Global Fund to the new procurement agent (CMSS).

Owner: Head Grant Management Division and Chief Financial Officer
Timeline: 30 June 2017

07. Funding arrangements may affect a sustainable and significant contribution in the fight against the three diseases.

The Global Fund Secretariat formally notified the Government of India in May 2016 about its intention to transition out of India over the next three replenishment phases. The Government of India already contributes 80% of the funding required to fight the three diseases. However, the Secretariat is yet to agree on a transition plan for the portfolio that includes an analysis of the risks. 80% of the Global Fund's funding of the HIV, TB and malaria programs is currently made up of health commodities which will make the transition more complex. For example:

- Current Global Fund grants finance 100% of the antiretroviral medicines of the national HIV program and bed nets for eight states. The Secretariat planned to transfer funding for these medicines under the new grants with the Government of India providing 20% of funding in 2016, and increasing proportions at an incremental rate of 30% annually for the next two years. However, the government did make any contributions to drug purchases during the first year, and it has been agreed between the HIV program and the Global Fund Secretariat that its contributions will be deferred.

- In the TB program, the Global Fund contributes 50% of the first line and 40% of the second line drugs for 16 states. However, there is currently no method used to identify drugs procured under the grants. The auditors noted that drugs procured using Global Fund grants are not limited to the 16 focus states but instead are used throughout the country.

- Additionally, under the malaria program, bed nets are entirely funded in the eight states supported by the Global Fund. No specific interventions have been planned to replace this investment. No bed nets have been distributed in the past four years in the eight states.

The Global Fund currently funds US$905 million in the existing grant cycle of four years, with similarly high historical investments in the past given India's size and importance for the three diseases. Therefore, replacing Global Fund investments of drug procurement and distribution will require significant additional funds and careful planning by the Government of India.

There are risks of significant increases in disease prevalence estimates resulting from the future TB prevalence survey. Furthermore, the TB and HIV programs are scaling up adherence to global treatment standards and enhanced public sector patient coverage. This can lead to much higher overall national program investments in the three diseases.

The India portfolio is central in the fight against the three diseases with the world's highest TB burden and third highest HIV burden. If core program activities are not transferred progressively to the Government of India, after ensuring adequate measurement of disease burden and treatment coverage, there is a risk of adverse impact on the achievement of global targets against the three diseases. In April 2016, the Global Fund Board approved a transition policy providing guidance for countries affected.[48] This policy should be applied to develop a transition strategy for India. This strategy should identify specific areas for investment to maximize impact in the next three grant cycles.

Agreed Management Action 5:

Applying the principal of the recent Global Fund Strategy, transition and counterpart financing policy, the Secretariat will support the Government of India to develop a transition plan showing a

[48] file://prodmeteorfs.gf.theglobalfund.org/UserDocuments/oloukili/Documents/Downloads/BM35_04 SustainabilityTransitionAndCoFinancing_Policy_en.pdf

progressive phase out of the Global Fund support, for the national HIV/AIDS, tuberculosis and malaria programs.

Owner: Head Grant Management Division and Chief Financial Officer
Timeline: 30 June 2017

V. Table of Agreed Actions

#	Agreed Management Action	Target date	Owner
1	The Secretariat will, in collaboration with the Ministry of Health and pertinent development partners and other stakeholders, support efforts to develop a plan and budget for a bespoke prevalence survey, identifying activities to be undertaken, cost, timelines and sources of funding.	30 June 2017	Head Grant Management Division
2	The Secretariat will: • In collaboration with the Ministry of Health's Central Tuberculosis Division and other relevant technical partners, and using the results of the completed pilot on private sector engagement under the TB program, develop a plan to expand the coverage of the private practitioners and their case notification and treatment outcomes into the national system; • In collaboration with NACO, ensure procurement of the approved number of CD4 machines and develop a distribution plan for the machines to the States; and • In collaboration with NACO, Alliance India and SAATHII, develop a plan on how to improve early detection through voluntary testing, enhance outreach for lost to follow up (LFU), data cleaning and reporting for LFUs.	30 June 2017	Head Grant Management Division
3	With respect to the issue of potential impact due to the existing divergence in quality assurance standards of health commodities funded between various countries and the Global Fund, the Secretariat will submit a policy paper to the Strategy Committee leadership for consideration and will recommend that it be on the agenda.	30 June 2017	Head Strategy and Policy
4	The Secretariat will ensure transfer of procurements of health commodities financed by the Global Fund to the new procurement agent (CMSS) and monitor its effectiveness in addressing procurement delays.	30 June 2017	Head Grant Management Division
5	Applying the principal of the recent Global Fund Strategy, transition and counterpart financing policy, the Secretariat will support the Government of India to develop a transition plan showing a progressive phase out of the Global Fund support, for the national HIV/AIDS, tuberculosis and malaria programs	30 June 2017	Head Grant Management Division

Annex A: General Audit Rating Classification

Effective	**No issues or few minor issues noted**. 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.
Partially Effective	**Moderate issues noted**. 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.
Needs significant improvement	**One or few significant issues noted**. 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.
Ineffective	**Multiple significant and/or (a) material issue(s) noted.** 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**.**

Annex B: Methodology

The Office of the Inspector General (OIG) performs its audits in accordance with the global Institute of Internal Auditors' (IIA) definition of internal auditing, international standards for the professional practice of internal auditing (Standards) 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 help our auditors to provide high quality professional work, and to operate efficiently and effectively. They also help safeguard the independence of the OIG's auditors and the integrity of their work. The OIG's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

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 takes place across the Global Fund as well as of grant recipients, and is used to provide specific assessments of the different areas of the organization's' activities. 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 and supply chain management, change management, and key financial and fiduciary controls.