

TB AND HIV

CONCEPT NOTE

Investing for impact against tuberculosis and HIV

Applicant Information			
Country	India		
Funding Request Start Date for HIV	April 2015	Funding Request End Date for HIV	December 2017
Principal Recipient(s) for HIV	1. Department of Economic Affairs: Department of AIDS Control 2. Plan India 3. Solidarity and Action Against The HIV Infection in India (SAATHII) 4. India HIV/AIDS Alliance		
Funding Request Start Date for TB	April 2015	Funding Request End Date for TB	December 2017
Principal Recipient(s) for TB	1. Department of Economic Affairs: Central Tuberculosis Division 2. International Union Against Tuberculosis and Lung Disease 3. World Vision India		

Preamble:

India has the highest TB burden in the world with an estimated 2.2 million new cases and 270,000 deaths annually and third highest burden of HIV with an estimated 2.1 million people living with HIV. An estimated 130,000, in India suffer from both diseases, making India the second highest burden of TB-HIV co-infected cases; 42,000 of these patients are likely not to survive.

The HIV epidemic is mature and declining, with new pockets of emerging epidemic. Epidemic response is also having limited progress with Key Population such as men who have sex with men, transgender and people who inject drugs. The main mode of transmission is through sexual route with 5.4% from parent to child transmission as reported from public health facilities. The TB epidemic response needs are large given India's immense population, poverty, living conditions and other risk factors. There is a rise in cases of drug resistant TB fuelled, in part by unorganized private sector where diagnostic and treatment facilities are of variable quality. TB and HIV co-infection affects those PLHIV who typically have delayed access to testing and treatment.

India's National TB and HIV programs are built on the principles of gender and equity, human rights, public private partnership, and community ownership particularly with participation of key affected populations.

India has made significant strides in both National Programmes, addressing requirements for HIV and TB separately and to a limited extent together. Large portions of both programmes are domestically funded (showing a strong country ownership), additional resources are required to leverage the gains - in terms of depth (quality) and breadth (reach) of the Programme and as well as integrate the programmes at various levels, with a clear client focus. India's quest for strengthening its health systems through enhanced collaboration and integration of TB-HIV, better diagnostics, providing universal access to TB and HIV treatment, linkages between public and private sector and strengthening community systems are areas and innovative approaches which can significantly improve the programme quality and save lives.

The research agenda focuses on improved diagnostics, management studies on enhancing supply chain, involvement of community to enhance demand generation and access to services including community testing, operations research on potential efficiencies and effectiveness etc.

Through this investment, India proposes to improve access to vulnerable and hard to reach populations which include tribal populations, refugees and vulnerable migrants, urban slum dwellers, prison population, key populations in both urban and rural areas. The efforts do not stop in reaching but builds on earlier efforts to sustain health-seeking behaviour, treatment literacy and specifically work to address individual empowerment and self-realisation to access health services and care earlier than later.

Both programmes have a long and good track record of being able to convene, consult and draw consensus from a wide variety of stakeholders on critical matters like health priorities. These stakeholders range from top-level government officials, private sector, bilateral and multi-lateral partners, academic institutions, civil society organisations including those who represent affected communities. Inclusive programming is practiced and is now part of India's response and internationally recognized for its efforts in working with Community Systems.

Through the various country dialogues that have happened over the years in India, during the development of the National Strategic Plans for both TB and HIV, as well as the development of the National Joint TB HIV Collaborative Framework and most recently within the CCM and with Global fund country teams, the areas for resource mobilisation through Global Fund were prioritized. Thus given the epidemiology, the various Global Guidance on tackling TB and HIV, the funding gaps, India requests Global Fund to support its health systems strengthening efforts – to enhance availability and access to quality diagnostics, drugs, linkages and referral systems, health management information systems, outreach to socially and clinically vulnerable and marginalised communities and by working closely with community organisations and private sector, in improving treatment outcomes and quality of life.

India CCM requests a full expression of need of a total of 721 million USD

SECTION 1: COUNTRY CONTEXT

This section requests information on the country context, including descriptions of the TB and HIV disease epidemiology and their overlaps, the health systems and community systems setting, and the human rights situation.

1.1 Country Disease, Health Systems and Community Systems Context

With reference to the latest available epidemiological information for TB and HIV, and in addition to the portfolio analysis provided by the Global Fund, highlight:

- a. The current and evolving epidemiology of the two diseases, including trends and any significant geographic variations in incidence or prevalence of TB and HIV. Include information on the prevalence of HIV among TB patients and TB incidence among people living with HIV/AIDS.
- b. Key populations that may have disproportionately low access to prevention, treatment, care and support services, and the contributing factors to this inequity.
- c. Key human rights barriers and gender inequalities that may impede access to health services.
- d. The health systems and community systems context in the country, including any constraints relevant to effective implementation of the national TB and HIV programs including joint areas of both programs.

India, with 1.23 billion people, has the second largest population in the world. Between 2005 and 2010, rapid economic growth lifted an estimated 50 million people over the poverty line, yet with 400 million still living in poverty, the country accounts for one third of the global poor.¹ Health and livelihoods have reciprocal effects on each other and Tuberculosis and HIV, diseases that disproportionately affect the country's poor and socially marginalised, remain two of the most important health challenges the country faces. India has the highest TB burden in the world with an estimated 2.2 million new cases and 270,000 deaths annually. India has the third highest burden of HIV with 2.1 million people living with HIV. With an estimated 130,000 people, India has the second highest burden of those suffer from both diseases each year, where about 42,000 patients are likely to die.

India has made significant strides towards MDG 6, responding to HIV, TB and other communicable diseases. While India's health system is working towards achieving universal coverage, the access to prevention, treatment, care and support for both TB and HIV remains hindered by human rights and socio-economic barriers (including discrimination and poverty), relative lack of infrastructure, and geographical barriers to health services. Furthermore, ingrained gender inequity for women and sexual minorities is often manifested limited access to healthcare, and physical and sexual abuse making victims more vulnerable to sexually transmitted infections.

The Revised National Tuberculosis Control Programme (RNTCP) and the National AIDS Control Programme (NACP-IV) guides India's national response to TB and HIV. Both programmes, supported by civil society organisations in implementing services and increasing coverage, promote prevention among Key Populations that are most at-risk for the diseases and are hard to reach by health services, as well as provide efficient and comprehensive access to treatment, care, and support. In addition to this, India has formulated in 2013 a Joint Framework for National HIV/TB Collaborative Activities that seeks to strengthen coordination and referral systems and reduce the burden of co-

¹The World Bank. (2014). India: Country Snapshot. Retrieved from <http://siteresources.worldbank.org/SOUTHASIAEXT/Resources/223546-1398285132254/India-Country-SnapshotSpringMeetings-2014.pdf>

morbidity.

TB and HIV have distinct epidemiological profiles in India and managed differently under the Ministry of Health and Family Welfare (MOHFW) manages the national programs. However, both India and the Global Fund (GF) recognise the overlap in both the characteristics of TB and HIV disease manifestation, approaches to disease control, and the need to address co-morbidity. In this Concept Note under Global Fund's New Funding Model (NFM), we acknowledge the different needs and patterns of the diseases while presenting increased coordination and combined strategies to approach them, according to the Joint Framework and the strengthening of it. Most importantly, we present the important focus points identified by the national programmes in order to obtain optimal coverage and provide the most comprehensive and well tailored treatment, care and support.

Epidemiological Profile

TB, long associated with poverty, crowding and poor living conditions, remains a significant source of suffering in India. Even though there has been progress over the last 15 years in controlling the disease, much due to the work of the national program, India still has more TB cases annually than any other country. In 2012, TB prevalence in India was 230 per 100,000 (down from 465 in 1990) with an absolute prevalence of 2.8 million currently. The incidence in the same year was 176 per 100,000, which translates into estimated incidence of 2.2 million (which reduced from 216 in 1990).² In 2013, paediatric cases accounted for 5% of all cases, with 63,919 notified.³

TB mortality per 100,000 people has also reduced from 38 in 1990 to 22 in 2012. In absolute numbers, mortality due to TB has reduced from 0.3 million to 0.27 million annually.⁴ Despite these gains, TB remained the 6th most important cause of death in 2010, down from being the 5th in 1990.⁵ In 2013, a total of 8,121,514 TB suspects were examined, for sputum smear microscopy and 1,416,014 cases were initiated on treatment. Case detection rate of new smear-positive TB cases was 68% with a treatment success rate of 88%. To add to the problem of Tuberculosis, there could be up to 99,000 new Multi Drug Resistant-TB (MDR-TB) cases in India annually. It is estimated that 2.2% (1.9 – 2.6) of new patients and 15% (11 – 19) of re-treatment patients are multi-drug resistant⁶. Cases of extensively drug resistant TB (XDR-TB), resistant to drugs used to treat MDR-TB, have also been reported from most states in India. Effective and accurate diagnosis and appropriate treatment of TB can prevent both mortality and incidence of new cases as scale of mortality prevention depends on the number of TB cases that are accurately diagnosed and subsequent treatment and care.

² WHO. (2013). *Global Tuberculosis Report 2013*, Geneva

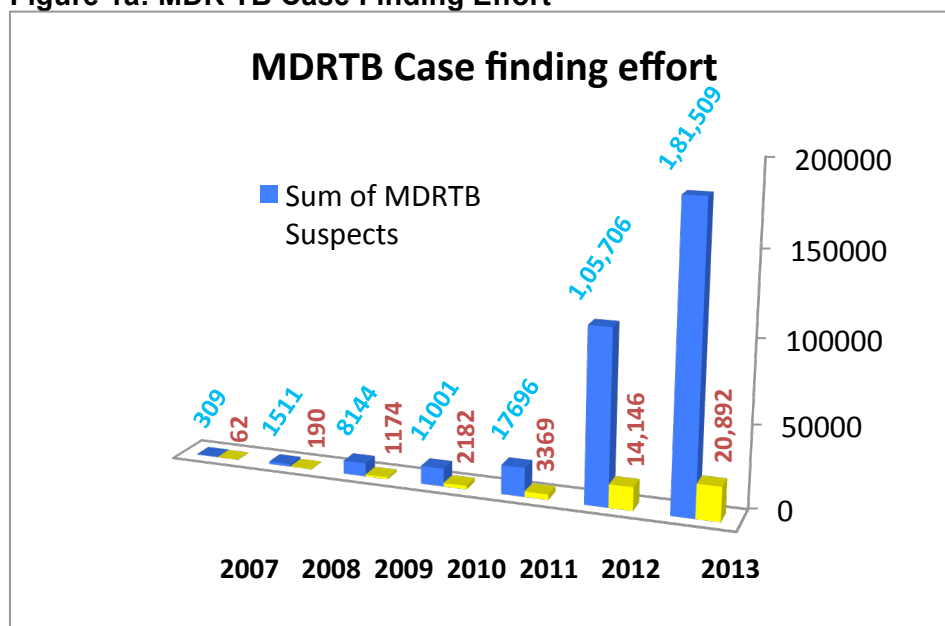
³ RNCTP (2014). *National TB Control Programme Annual Status Report*. Retrieved from http://www.tbcindia.nic.in/pdfs/tb_india_2013.pdf

⁴ RNCTP (2014). *National TB Control Programme Annual Status Report*. Retrieved from http://www.tbcindia.nic.in/pdfs/tb_india_2013.pdf

⁵ Institute for Health Metrics and Evaluation, University of Washington (2013) "Global Burden of Diseases, Injuries, and Risk Factors Study 2013," accessed at <http://www.healthmetricsandevaluation.org/gbd/2013>

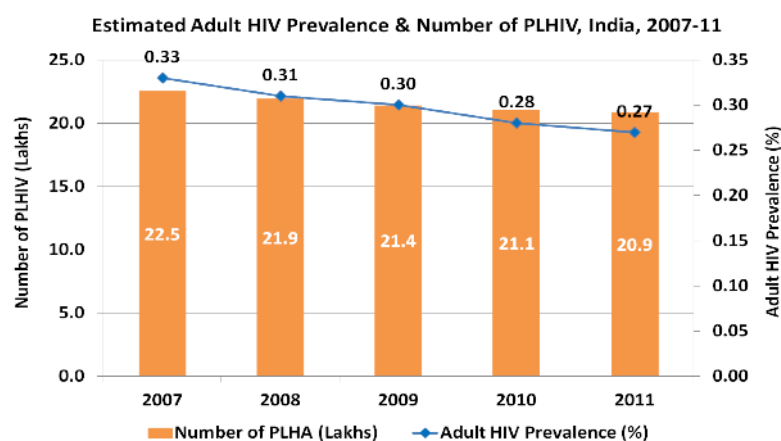
⁶ RNCTP (2014). *National TB Control Programme Annual Status Report*. Retrieved from http://www.tbcindia.nic.in/pdfs/tb_india_2013.pdf

Figure 1a: MDR TB Case Finding Effort⁷



India has a concentrated **HIV/AIDS** epidemic with marked differences between geographies and populations. Prevalence has decreased over the last decade, also attributed to the success of the national program (now in its fourth phase); however, India continues to have the third highest burden of HIV in the world.⁸ Latest prevalence data (GARPR, 2011) estimates the countrywide adult HIV prevalence at 0.27%, showing a steady decline from an estimated 0.41% in 2001 for both in men and women.⁹ In Figure 2, it is shown that there is a big variance in prevalence between the different states of India, with traditionally a high prevalence in the south and a lower prevalence in the north. In 2011 about 0.12 million new HIV infections occurred among adults and about 14,000 among children in India.¹⁰

Figure 1b: Adult Prevalence 2007-2011 (NACO2013)



Of the total burden of HIV infections, 39% (816,000) are among women. The new HIV infections among adults have reduced by 57% from an estimated 0.27 million in 2000, the bulk of the decrease being in the traditionally high HIV prevalence states, which saw a 76% decline during the same period.¹¹ Mortality associated with HIV/AIDS also declined 29% from 2007 to 2011, with about 148,000 deaths in 2011.¹²

⁷ RNTCP Annual Report 2014

⁸ AIDS Healthcare Foundation, n.d. *India*. Retrieved from: <http://www.aidshealth.org/asia/india>

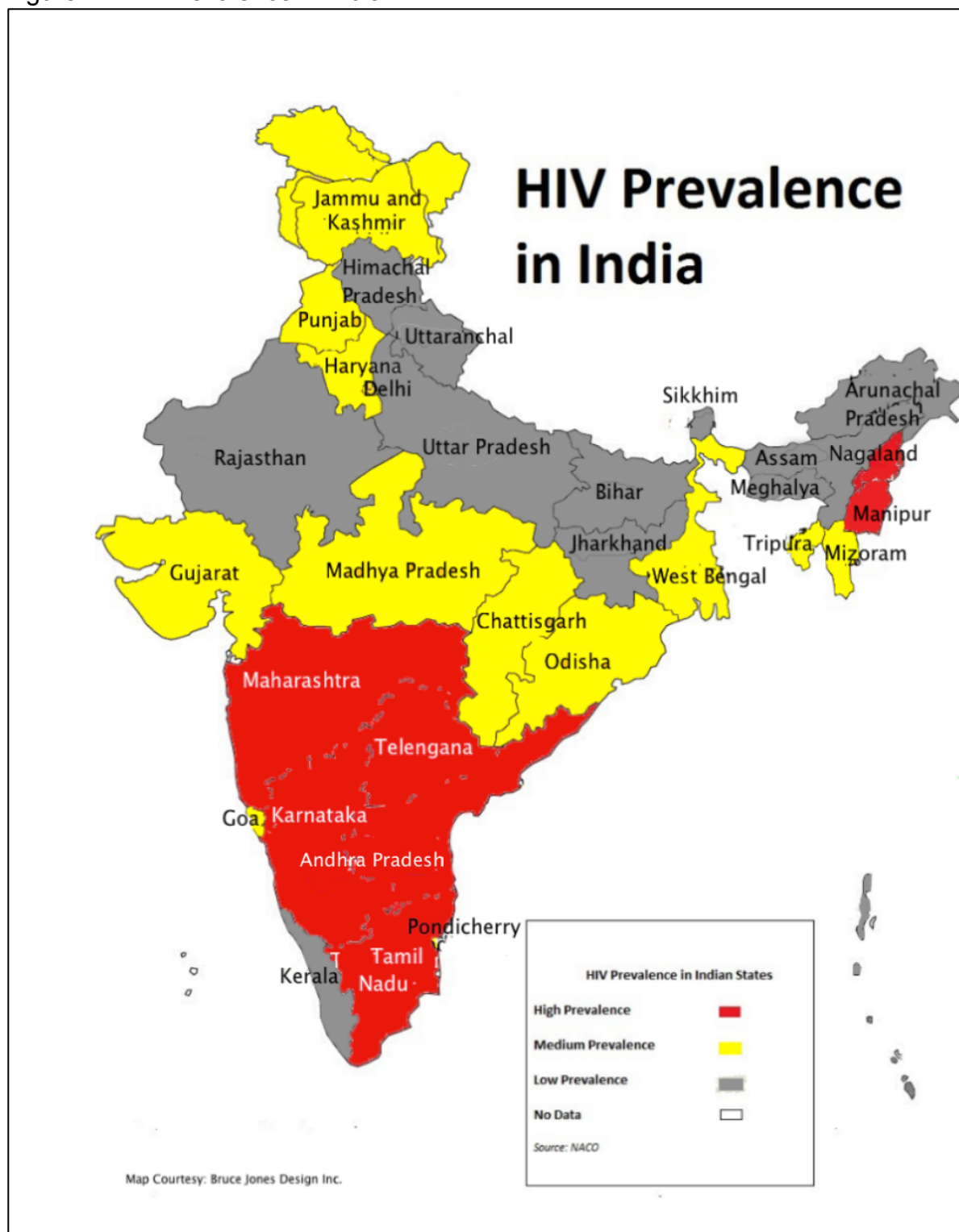
⁹ NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Pg. 12 Para 1 & 2 Retrieved from NACO - 2013 - National Strategic plan.pdf

¹⁰ NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Pg. 12 Para 1 & 2 Retrieved from NACO - 2013 - National Strategic plan.pdf

¹¹ NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Pg. 6 Para 5 Pg. 7 Para 1 Retrieved from NACO - 2013 - National Strategic plan.pdf

¹² NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Pg. 9 Para 4 Retrieved from NACO - 2013 - National Strategic plan.pdf

Figure 2: HIV Prevalence in India¹³



The five high HIV prevalence states in south India (Andhra Pradesh, Telangana¹⁴, Karnataka, Maharashtra and Tamil Nadu) currently still carry 53% of the country's burden. However, Odisha, Jharkhand, Bihar, Uttar Pradesh, West Bengal, Gujarat, Chhattisgarh, Rajasthan, Punjab and Uttarakhand together account for around 57% of new infections, whereas the high prevalence states account for 31% of new infections.¹⁵

¹³ NACO 2013

¹⁴ Newly created state in 2014, carved out of what was earlier undivided Andhra Pradesh

¹⁵ NACO. (2013). *Annual Report 2012-2013*. Pg. 6 Para 4 Retrieved from [http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf](http://www.naco.gov.in/upload/Publication/Annual%20Report/Annual%20report%202012-13_English.pdf)

Given that India is a concentrated epidemic, it is important to note the changes in trends among Key Populations (KP) who have been the primary focus of NACP and targeted interventions. The primary KPs in India most at-risk for HIV and the drivers of the epidemic include: Female Sex Workers (FSWs), Men who have Sex with Men (MSM), People who Inject Drugs (PWIDs), and Transgenders (TGs). Bridge populations include clients of FSWs, migrants, and long distance truck drivers. Patterns of decline and incline in prevalence of the different KP vary for the different states. While prevalence among FSW, in traditionally high prevalence states is in decline, the prevalence among PWID is increasing in other areas like Punjab, Delhi and Mumbai city.¹⁶

An estimated 14,000 infants acquire HIV each year,¹⁷ indicating a continued and high level of transmission of HIV from infected mothers to their children.¹⁸ The vertical transmission rate is 20-45% without any intervention and can be reduced to 10% or less when the mother is initiated on lifelong ART. In 2013-14 9.7 million pregnant mothers were tested and about 12,000 pregnant women were detected positive.

Uptake of ART services for adults has steadily increased, but optimal retention of PLHIV in HIV care once diagnosed for HIV remains a major concern. Wider access to ART has led to reduction in estimated annual AIDS-related deaths by 29% overall during the NACP-III period (2007-2011). Greater declines in estimated annual deaths are noted where significant scale up of ART services has been achieved, as high as 42% in some states between 2007 and 2011. It is estimated that around 150,000 lives have been saved due to ART till 2011.¹⁹ In addition, 870 Link ART Centres (LAC) and LAC Plus Centres are functioning in the country to provide decentralised ART services to PLHIV.

With PLHIV living longer, healthier lives, the need has arisen for more and sustained care, support and social protection. To date, there are 350 Care & Support Centres (CSCs) run by community networks of PLHIV or civil society organisations, 870 Link ART Centres (LAC) and 228 LAC Plus Centres are functioning in the country under the direction of DAC and managed by respective State AIDS Control Societies (SACS).²⁰

TB and HIV forms a deadly duo, with TB being the disease most responsible for deaths of HIV patients (25% deaths of PLHIV).²¹ Although only 5% of TB patients are HIV infected, in absolute terms India ranks 2nd in the world and accounts for about 10% of the global burden of HIV associated TB.²² As per the Global Tuberculosis Report (2013), approximately 130,000 HIV associated TB cases emerge in India annually, out of which 42,000 TB/HIV co-infected patients die each year.²³ The heterogeneous distribution of the disease within the country is a challenge for joint delivery of integrated services. In the RNTCP, about 61% of the registered patients know their HIV status, and among them, 5% are HIV positive.²⁴

¹⁶ NACO. (2013). *Annual Report 2012-2013*. Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

¹⁷ NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Retrieved from NACO - 2013 - National Strategic plan.pdf

¹⁸ NACO. (2013). *Annual Report 2012-2013*. Pg 12 Para 1 Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

¹⁹ NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Pg.VII Para 4 Retrieved from NACO - 2013 - National Strategic plan.pdf

²⁰ NACO. (2013). *Annual Report 2012-2013*. Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

²¹ Central TB Division. (2009). *National Framework For Joint HIV/TB Collaborative Activities*. Retrieved from <http://www.tbncindia.nic.in/pdfs/Final National Framework for TB HIV Collaboration 2009.pdf>

²² RNTCP (2014). *National TB Control Programme Annual Status Report*. Retrieved from <http://www.tbncindia.nic.in/pdfs/tb india 2013.pdf>

²³ Institute for Health Metrics and Evaluation, University of Washington (2013) "Global Burden of Diseases, Injuries, and Risk Factors Study 2013," accessed at <http://www.healthmetricsandevaluation.org/gbd/2013>

²⁴ NACO. (2013). *Annual Report 2012-2013*. Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

TB is difficult to diagnose and treat owing to challenges related to co-morbidity, pill burden, co-toxicity and drug interactions. The case fatality rate among the notified HIV positive TB patients in India is about 13%, which is 4 times that among HIV negative TB patients.²⁵

Human rights, gender inequity and barriers to access for Key Populations

In India, Key Populations with disproportionately low access to prevention, care and support services are, for the most part, those populations that face barriers due to existing legislation, human rights discriminations, gender inequities and their internal barriers (self esteem, knowledge, health seeking behaviour). These barriers, in turn, increase vulnerabilities to TB, HIV and co-infection of both diseases. RNTCP and NACP-IV respond to these challenges through a targeted focus on these populations for prevention, care, and support. The focus is not only for social inclusion, but also for program impact since these populations account for significant proportions of TB and HIV incidence.

Besides key populations, TB disproportionately affects socially vulnerable and clinically vulnerable populations. Some of the socially vulnerable populations include tribal populations who have high rates of poverty, illiteracy, smoking and alcohol use. Urban slum dwellers including refugees have additional social determinants of health to deal with that includes overcrowding, pollution, and poor access to health care. Other socially vulnerable groups include migrants, and prisoners. The clinically vulnerable includes people living with HIV, household contacts of TB cases, malnourished children, diabetics, tobacco users, the elderly and those living in houses with indoor air pollution. Human rights factors that affect access to TB services relate to socioeconomic factors that cause certain populations to be more at-risk, including poverty, social stigma around the disease, and gender barriers to health care.

Gender: Rates of TB notification are higher in men, which may partly reflect epidemiological differences in exposure, risk of infection, and progression from infection to disease. However, some studies indicate that women may have higher rates of progression from infection to disease and higher case fatality in their early reproductive ages. Evidence from India suggests that TB among mothers living with HIV associated more than double the risk of vertical transmission of HIV to the unborn child. Also, women with TB are twice as likely to give birth to premature or low-birth-weight babies and four times more likely to die during child birth. Social taboos that affect access of women to health services, lead to absence in detection of TB or detection at late stages of the disease.

Social stigma continues to be a barrier to access for both men and women, more so the latter. Almost a third of the cases have been known to face stigma from closed groups like family, neighbourhood and communities as well as public and private health care providers.

Studies that show majority of women get infection from their spouse's needs special mention. This is likely because of low power of negotiation for safer sex and deciding family planning options. Both have relevance to PPTCT²⁶, in terms of first prong of primary prevention of HIV among young women and second prong of avoiding unintended pregnancies.

Stigma and Discrimination: Stigma and discrimination within families, communities and health systems, compounded by gender inequities, impedes access to the full cascade of PPTCT services for women diagnosed positive. Further, women living in low prevalence states are an underserved population with disproportionately low access to PPTCT compared to high-prevalence states because of the unavailability of counselling and testing at sub-district level. Pregnant women who are sex workers or female partners of other key

²⁵ WHO (2013) *Global Tuberculosis Report 2013*

²⁶ Global Fund refers to Prevention of Parent to Child Transmission as Prevention of Mother to Child Transmission.

populations are likely to face further barriers to access because of multiple layers of stigma. This stigma is not just present in the public sector but particularly private sector. Those women who get diagnosed in private sector are the ones known to most likely miss the entire PPTCT treatment cascade.

Access to *HIV prevention, treatment and care services* by high-risk groups (MSM, TG, FSW and PWID) in India is impeded by pervasive systemic barriers to accessing services due to stigma and discrimination, gender norms, punitive laws and social-cultural attitudes around morality and sexuality.²⁷

For sexual minorities there are challenges of HIV prevention interventions such as condom distribution and behaviour change communication that are documented barriers to HIV prevention work, particularly with MSM and transgender women.

Alignment between the de-addiction and harm reduction approaches among Ministries of Health and Family Welfare, Social Justice and Empowerment and Home, and upscale of OST clinics has improvised the linkages of IDU with prevention care & treatment program. There are emerging cases on high rates of TB among PWID, as a result of the social determinants that foster communicable diseases including TB.

Overall, people living with HIV and TB are key populations with unique needs for prevention, treatment, care, and support and face additional needs in preventing co-infections and accessing services. Given that PLHIV are at-risk for TB, and in fact, India accounts for about 10% of the burden of HIV-associated TB cases, there is need for airborne prevention measures in ART centres and early testing of TB for PLHIV. These guidelines are noted in the National Framework for Joint HIV/TB Collaborative Activities.²⁸

Health Systems: Despite the gains made by the RNTCP in controlling TB and NACP in preventing HIV from becoming a generalized epidemic, there remain serious gaps in program delivery and coordination of health services. With an investment in health of 1.4²⁹% of the Gross Domestic Product (GDP), India is significantly short of the modest norm of 6.5% of GDP suggested by the World Health Organisation (WHO) for its category of countries. Only 25% of the total population is covered by some form of public or private health insurance. There is a dearth of infrastructure and equipment, especially in tribal and urban areas, making coordination of TB/HIV activities particularly challenging in areas not targeted for prevention and treatment health services.

RNTCP rapidly expanded to address the needs of India's population; however, given its current strategies and available resources, it has now maximized the number of TB patients that it supports while many more exist outside the purview of the programme. Furthermore, while systems for drug-sensitive TB are relatively well established, improvement is needed in the diagnosis and treatment MDR-TB. NACP has done well with engaging non-governmental organisations (NGOs) and community-based organisations (CBOs) for implementation of prevention programmes. Facilities such as Integrated Counselling and Testing Centre (ICTC) and ART Centres, function as a part of public health system and efforts are being taken to mainstream and integrate HIV services, where appropriate, within general health systems for long-term sustainability of the programme. The programme itself could benefit from a less vertical composition and enhanced integration. As of now, facilities such as Integrated Counselling and Testing Centre (ICTC) and ART Centres function as semi-autonomous units within the public sector.

An August 2010, a government order mandated integration between HIV and reproductive and child health (RCH) services provided through the health system. However, only a few

²⁷ UNAIDS, Evidence To Action, UNODC, UNFPA, & UNDP. (2013). *Punitive laws hindering the HIV response in Asia and the Pacific in July 2013*. Page 2013.

²⁸ DOT & NACO. (2013). National Framework for Joint HIV/TB Collaborative Activities.

²⁹ 12th Five Year Plan, Government of India

states have worked proactively towards such integration (e.g. Karnataka). Challenges to integration include lack of policy initiatives at state-level, pervasive stigma, limited knowledge and awareness on HIV issues, among the 'mainstream' health workforce in facilities and the community, no clarity of roles and between HIV frontline health workers and other frontline health workers who may be best positioned to converge HIV with outreach to pregnant and recently delivered women.

Private sector: Around 73% of India's Total Health Expenditure (THE) is private. Private health expenditure provides 80% of the outpatient care and 55% of the inpatient care. For example, even though RNTCP is widely acknowledged as successful, only about 50% of TB patients get diagnosed in the public sector and the remaining in the largely unregulated private sector. Private sector is vast and lack of private sector regulation and reporting of HIV /ART details gives a skewed picture of the actual problem. It is estimated that nearly 50% of all TB patients are treated in the private sector without notification to the national programme. There are 1 million missed TB cases in India (WHO Global TB Report 2013). The private sector treatment regimens are non-standardised and sub optimal follow-ups that lead to unfavourable outcomes and amplification of drug resistance.

Strengthening coordination between TB and HIV: In 2007, the first National Framework for Joint TB-HIV Collaborative Activities was developed. Through this coordinated effort, TB and HIV interventions were implemented, including establishment of a National Technical Working Group (NTWG). Collaborative interventions have focused on improving services for HIV-infected patients, with intensified TB case finding and linking with TB treatment. For TB patients, interventions instituted by the TB program include provider initiated HIV testing and counselling and decentralised provision of HIV treatment. In reality, TB/HIV collaborative activities are not yet at desired levels: only 50% of TB patients know their HIV status; inadequate diagnostic tools are used because sputum smear microscopy is not a sensitive tool to diagnose TB among PLHIV; there is uneven implementation (worse in the low HIV prevalence states); and there are still issues with the supply chain.

Procurement and Supply Management: There is a need for greater focus on improving pharmaceutical and health product management to address the procurement and supply management (PSM) challenges of both NACP-IV and RNTCP. India's pharmaceuticals have done well in supplying 85% of the world's ARV drugs.³⁰ However, within the country's own PSM system, challenges exist with stock-outs and quality assurance monitoring of TB and HIV drugs. There also continue to be inadequacies in the Management Information System (MIS) to inform forecasting (with reliable patient- and inventory-related data) and program planning.

Health Systems Strengthening: NACP aims at Integrating HIV services with health systems to ensure sustainability. However, there is also a need to address the challenge of competing priorities and varying capacities of health systems in different states to provide access to quality HIV/AIDS services. In this regard efforts are being made by programme to strengthen and capacitate health systems on prevention, early diagnosis and management of HIV.

The programme is working towards strengthening health systems by providing technical capacity, trainings, additional manpower and M & E systems. The facility integrated ICTCs are a step in this direction. For management of HIV and provision of care & treatment, Link ART Centres and Facility Integrated ART Centres are being established as a part of larger health systems with minimal support from the program. The Centres of Excellence have also been established to provide trainings to health care providers in health systems and conduct research studies to feed into program policy and planning. Mainstreaming of HIV

³⁰HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare? Colleen V. Chien, PLoS ONE. 2007; 2(3): e278. Published online 2007 March 14. doi: 10.1371/journal.pone.0000278,PMCID: PMC1805689

activities with all key central/state level ministries/departments is given a high priority and resources of the respective departments are being leveraged. Memorandums of Understanding (MoU) with various ministries and departments (Shipping, Defence, Railways, Information Technology, etc.) have already been signed. Social protection and insurance mechanisms for PLHIV are also being explored and rolled-out in some states. Furthermore, DAC is also engaging with private and corporate sectors for Public Private Partnership (PPP) model service delivery mechanism. Nearly 22 ART Centres are already functioning under the PPP model. These efforts will be further strengthened under the proposed NFM grant. Further to this, it is planned to have large-scale trainings of health care providers, both in the public and private sector on early diagnosis, management and linkages for HIV.

Community Systems: Particularly in the case of HIV, key population groups have been some of the most successful at ensuring services and obtaining their rights through effective community systems strengthening. Many communities, especially the sexual minority and sex worker communities, have played key advocacy roles to protect their rights. Given the stigma around TB, there is need for these networks to integrate advocacy around TB through community systems strengthening to empower people living with the disease to access their rights. Health systems improvements, including training additional health workers on TB and TB/HIV co-infection, can help promote community activism that encourages greater access to health services.

Going forward, regions with different maturity levels of HIV programming will require different resources and services. Emerging epidemics in selected regions will need greater prevention focus while care and support in the setting of matured epidemic, particularly management of 2nd line ART, will need a robust management and financing strategy. These emerging epidemics, as well as TB and TB/HIV communities can benefit from the work of HIV key populations in community systems strengthening to access required and rightful health services.

1.2 National Disease Strategic Plans

With clear references to the **current** TB and HIV national disease strategic plan(s) and supporting documentation (including the name of the annexed documents and specific page reference), briefly summarize:

- a. The key goals, objectives and priority program areas under each of the TB and HIV programs including those that address joint areas.
- b. Implementation to date, including the main outcomes and impact achieved under the HIV and TB programs. In your response, also include the current implementation of TB/HIV collaborative activities under the national programs.
- c. Limitations to implementation and any lessons learned that would inform future implementation. In particular, highlight how the inequalities and key constraints and barriers described in question 1.1 are currently being addressed.
- d. The main areas of linkage with the national health strategy, including how implementation of this strategy impacts the relevant disease outcomes.
- e. Country processes for reviewing and revising the national disease strategic plan(s). Explain the process and timeline for the development of a new plan and describe how key populations will be meaningfully engaged.

India's healthcare system aims to ensure universal healthcare; this strategy also guides the national response to TB and HIV/AIDS. Even though there are healthcare facilities (primary and community health centres) all throughout the country, the actual accessibility of healthcare services remains challenging due to a lack of resources, geographical coverage difficulties and stigma and discrimination.

Tuberculosis

The Revised National Tuberculosis Control Program (RNTCP) has entered into an ambitious National Strategic Plan (NSP) 2012-17 as part of the country's 12th Five year Plan. The theme of the NSP 2012-17 is "Universal Access for quality diagnosis and treatment for all TB patients in the community" with a target of "reaching the unreached". The NSP is backed by Government of India's (GoI) commitment for substantial increase in the investment for TB control, with a four-fold increase in budgetary allocation.

Goal: The goal of RNTCP is Universal Access to quality TB Care for all TB patients in the community.³¹

Objectives: Specific objectives include: (1) To reduce the incidence of and mortality due to TB, (2) To prevent further emergence of drug resistance and effectively manage drug-resistant TB cases, (3) To improve outcomes among HIV-infected TB patients, (4) To involve private sector on a scale commensurate with their dominant presence in health care services, and (5) To further decentralize and align basic RNTCP management units with National Health Mission (NHM) block level units within the general health system for effective supervision and monitoring.³²

Priority programme areas: The major focus is early and complete detection of all TB cases in the community, including drug resistant TB and HIV-associated TB, with greater engagement of private sector for improving care to all TB patients.

Current strategy: In this NFM proposal, the RNTCP objectives of focus include improving access to early diagnosis and treatment of Drug Resistant Tuberculosis (DRTB) services, improving access and outcomes among HIV-infected TB patients, improving access and outcome among at risk (social and clinical: urban, tribal, paediatric, migrant and refugee), engaging with providers outside RNTCP for public health impact for TB control, and generating evidence for guiding future policy for better TB care and control.

HIV

The National Strategic Plan for HIV in India is the National AIDS Control Programme (NACP-IV), currently in its 4th phase (2012-2017). The guiding principles of the NACP-IV have been and continue to be: equity, rights for gender equality and PLHIV, civil society organization (CSO) representation, establishing public-private partnerships, and rights-based, evidence-based and result oriented program implementation. NACP IV puts primary focus on working with key populations like sex workers, MSM, transgender and people who use drugs, towards prevention of HIV. In addition, NACP-IV implements comprehensive HIV care for all those who are in need of such services and facilitate additional support systems for women and children. With a wide network of treatment facilities and collaborative support from PLHIV and civil society groups, it is envisaged that greater adherence and compliance would be possible. Activities include building more ART Centres for high-quality and follow-up services, facilitating social protection, reducing stigma and discrimination, and developing PPPs.

Goal: Accelerate reversal of HIV infection and integrate programme response.³³

Objectives: The main objectives are: the reduction of new infections with 50% of 2007

³¹ Directorate General of Health Services, Ministry of Health and Family Welfare. Retrieved August 6, 2014, from <http://www.tbcindia.nic.in/rntcp.html>

³² Directorate General of Health Services, Ministry of Health and Family Welfare. Retrieved August 6, 2014, from <http://www.tbcindia.nic.in/rntcp.html>

³³ DAC. (n.d.). *National AIDS Control Programme Phase-IV (2012-2017)*, Page 3. Retrieved from [http://www.naco.gov.in/upload/NACP-IV/NACP-IV Strategy Document .pdf](http://www.naco.gov.in/upload/NACP-IV/NACP-IV%20Strategy%20Document.pdf)

Baseline of NACP III and comprehensive care, support and treatment to all persons living with HIV/AIDS.³⁴

Key Strategies: Key Strategies include Intensifying and consolidating prevention services with a focus on HRG and vulnerable populations, Expanding IEC services for (a) general population and (b) high risk groups with a focus on behaviour change and demand generation, Increasing access and promoting comprehensive care, support and treatment, Building capacities at National, State and district levels and Strengthening and use of Strategic Information Management Systems.³⁵

Cross-cutting areas of focus are quality innovation, integration , leveraging partnerships, stigma and discrimination

Current strategy: Strategies under NACP-IV that have been identified in the current Global Fund NFM proposal include increasing access and promoting comprehensive care, support and treatment, building capacities, strengthening HIV-TB collaborative activities, building capacities and strengthen systems for linkages, quality care at service delivery points , monitoring and evaluation of services.

Joint TB/HIV National Framework

Existing TB/HIV Collaborative activities consist of the strong RNTCP-NACP coordination mechanisms at national, state and district level with joint: Monitoring and evaluation (M and E), training of field staff, operational research, and implementation of basic infection control measures. It is reported that one TB client can infect up to 15 people. People who are infected and affected by HIV are more vulnerable to contract TB including DR-TB. This shows the importance of a joint strategy and programme.³⁶

Specific Activities to reduce the burden of HIV among TB patients are testing of TB patients for HIV and offering them treatment for TB as well as HIV (co-trimoxazole preventive therapy (CPT) and ART). Activities to reduce burden of TB among HIV infected individuals are intensified case finding at Integrated Counselling and Testing Centres (ICTC) and ART centres; prevention of airborne TB infection at such centres and implementation of Isoniazid Preventive Treatment (IPT) for all PLHIV (On ART + Pre-ART).³⁷ To ensure adherence for both TB and HIV treatment, there needs to be social and economic support mechanisms in place, like counselling, financial incentives etc.

Outcomes and impact achieved under the HIV and TB programs

Prevention of mortality by curing TB has been the biggest achievement of RNTCP, saving more than 2.8 million additional lives since its inception in 1997.³⁸

Implementation to date: Diagnosis and treatment of TB including Drug Resistant TB (DRTB) is provided free of cost to patients. For quality diagnosis, over 13,000 designated microscopy centres have been established in the country, with special norms for tribal, hilly and difficult areas. To ensure appropriate treatment 650,000 Directly Observed Treatment (DOTS) centres have been established in public private and NGO sectors. Uninterrupted

³⁴ DAC. (n.d.). *National AIDS Control Programme Phase-IV (2012-2017)*, Page 9. Retrieved from <http://www.naco.gov.in/upload/NACP - IV/NACP-IV Strategy Document .pdf>

³⁵ NACO, & DAC. (2013). *Annual Report 2012-2013*. Page 9. Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

³⁶ World Health Organization (WHO). (2014). Tuberculosis Fact Sheet. Retrieved from <http://www.who.int/mediacentre/factsheets/fs104/en/>

³⁷ DOTS, & NACO. (2013). *National Framework for Joint HIV / TB Collaborative Activities*, Page.3. Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

³⁸ RNCTP (2014). *National TB Control Programme Annual Status Report: Reach the UnReach*. Retrieved from <http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf>

supply of quality assured drugs is ensured by timely procurement, a robust supply chain management system and issuing drugs in patient-wise boxes ear marked to each patient. Programmatic Management of Drug Resistant TB (PMDT) achieved nation-wide coverage by March 2013.

Outcome/Impact: RNTCP has evaluated over 55 million persons for TB and treated more than 15.8 million TB patients an average of 1.5 million cases annually. About 3.8 million presumptive Drug Resistant TB cases were screened and more than 47,000 MDRTB and about 700 XDRTB cases were treated through 111 DRTB centres.³⁹ As per WHO estimations, Tuberculosis prevalence per million has reduced from 465 in year 1990 to 230 in 2012. Incidence per 100,000 people has reduced from 216 in year 1990 to 176 in 2012. Tuberculosis mortality per million has reduced from 38 in year 1990 to 22 in 2012.⁴⁰

HIV

In most states where long-standing targeted interventions have focussed on behaviour change and increasing condom use, considerable declines are recorded for high-risk populations. However, rising trends of new infections have been noted in some of the traditionally low prevalence states.⁴¹ Implementation is also uneven for treatment and care services between traditionally high and low prevalence states.

Implementation to date: The percentage of PLHIV that receive ART is nearly 67% of the estimated need (based on CD4 cut off of 350). There is need for better access to testing facilities and also linkages with ART centres and. Figure 2 show the scale up for ART centres in India. The PPTCT program under NACP-IV targets 140,00,000 pregnant women to be tested for HIV. According to available data with NACO 14,000 new HIV infections among children are seen annually. Currently only about 70% of estimated pregnant women in India are enrolled into antenatal care (ANC) at national level and less than 60% of all deliveries are institutional deliveries. Out of these about 30% women have their HIV status known due to suboptimal access to testing facilities.

During the later phase of NACP-III, the PPTCT program expanded the services in collaboration with the National Rural Health Mission (NRHM) and piloted provider initiated testing and counselling services in Primary Health Care (PHCs) centres of A and B districts⁴² through the facility integrated ICTC model. The program also piloted sub-centre level HIV screening through front line health workers in high prevalent districts.

Figure 3 : ART Scale up for PLHIV in India, NACO ⁴³

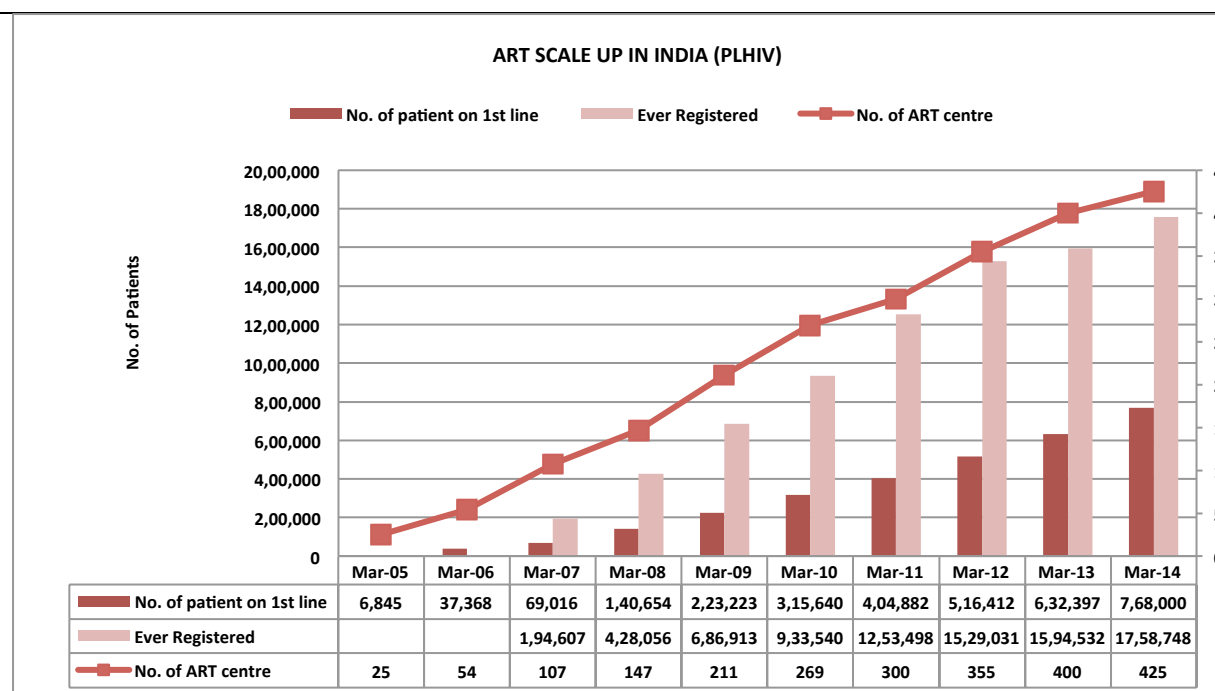
³⁹ RNTCP (2014). *National TB Control Programme Annual Status Report: Reach the UnReached*. Retrieved from <http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf>

⁴⁰ RNTCP (2014). *National TB Control Programme Annual Status Report: Reach the UnReached*, Page. 19 Para 4. Retrieved from <http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf>

⁴¹ NACO. (2013). *Annual Report 2012-2013*. Retrieved from [http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf](http://www.naco.gov.in/upload/Publication/Annual%20Report/Annual%20report%202012-13_English.pdf)

⁴² In the NACP document, Districts are categorized based on epidemiology into A,B, C and D districts where A and B are higher prevalent.

⁴³ NACO. (2013). *Annual Report 2012-2013*. Page 53. Retrieved from [http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf](http://www.naco.gov.in/upload/Publication/Annual%20Report/Annual%20report%202012-13_English.pdf)



Outcome/Impact: Wider access to ART has led to a 29% reduction in estimated annual AIDS-related deaths between 2007 and 2011. It is estimated that the scale-up of free ART since 2004 has saved over 150,000 (2011).⁴⁴ The current pace of scale-up of ART services is estimated to avert around 50,000 – 60,000 deaths annually in the next five years.

India has demonstrated an overall reduction of 57% in estimated annual new HIV infections (among adult population) from 274,000 in 2000 to 116,000 in 2011, reflecting the impact NACP's scaled-up prevention interventions.

TB/HIV

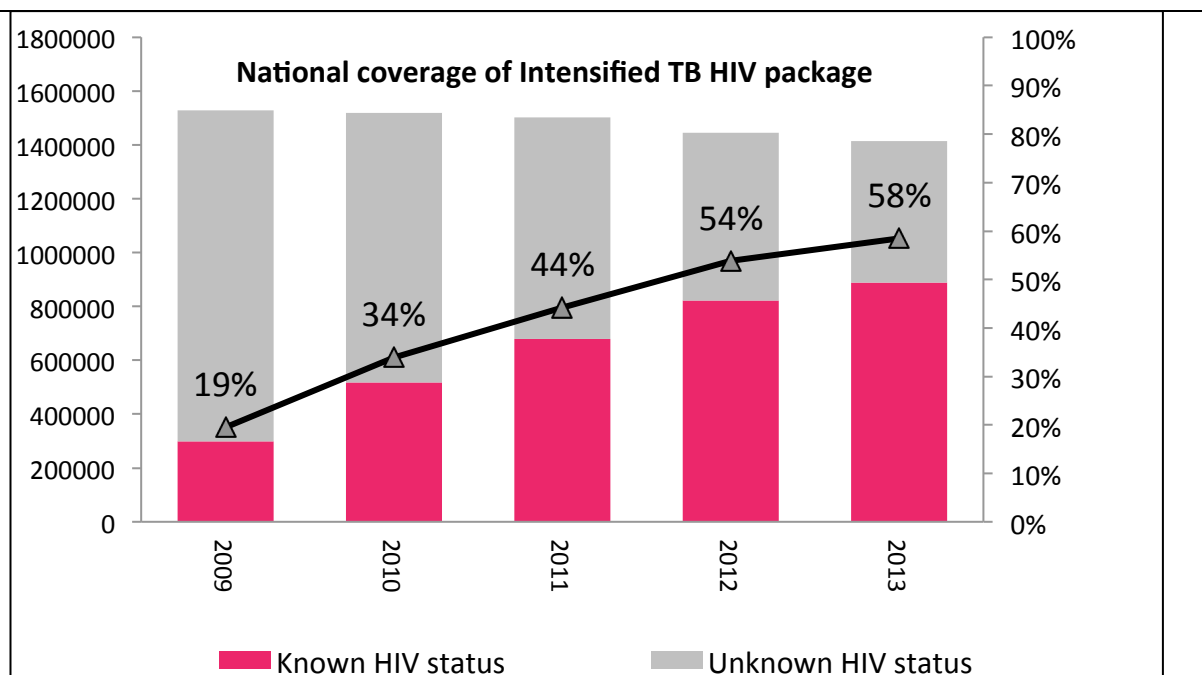
The RNTCP and NACP have significantly expanded joint TB/HIV services to all states in India. The main interventions have been to reduce TB among all PLHIV and to have PLHIV regularly screened for TB. All TB cases are counselled and tested for HIV.

Implementation to date: Provider initiated HIV counselling and testing (PITC) is accessible to all presumptive TB cases. All PLHIV have access to Anti-Retroviral Therapy (ART) and co-trimoxazole preventive therapy (CPT). Isoniazid preventive therapy (IPT) is accessible to all PLHIV who do not have active TB (estimated at 50% of those newly enrolled in HIV care).

Figure 4: National Coverage of Intensified TB HIV Package, Central TB Division⁴⁵

⁴⁴ NACO. (2013). *Annual Report 2012-2013*, Page. 7. Retrieved from [http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf](http://www.naco.gov.in/upload/Publication/Annual%20Report/Annual%20report%2012-13_English.pdf)

⁴⁵ IBID



Outcome/Impact: TB-HIV coordination is incrementally improving. At present 60% of the TB patients know their HIV status, and 90% of the HIV positive TB patients receive CPT, and 84% receive ART. However, TB-related outcomes have remained poor among PLHIVs with treatment success rate of less than 80%.⁴⁶

Limitations and lessons learned

TB

Treatment adherence amongst the retreatment cases is low which is known to amplify drug resistance. The lack of treatment adherence can be attributed to lack of support mechanism including counselling, and sub-optimal programming to address other determinants like alcohol and other substance abuse. Thus through the proposed Global Fund investment, India seeks to respond to this challenge.

Treatment success rates amongst the DR-TB patients are low (~50%), which can be attributed to delays in diagnosis, long treatment durations compounded by addressed stigma and discrimination. Newer diagnostics, counselling services and creation of enabling environment are proposed to address these challenges.

For nearly 60% of the TB patients the first points of contact are private providers who are yet to fully be within the ambit of the national program. Quality of care is a concern for a large proportion of these providers, which generates a strong need for engaging private sectors beyond the traditional Public Private Mix (PPM) approach.

Though programmatic management of drug resistant TB (PMDT) scale-up was massive, the laboratory capacity for DRTB care still does not match the demand. This is particularly important in the context of drug susceptibility testing (DST) for second-line drugs to all MDRTB cases at diagnosis. A lesson learned is that with deployment of Cartridge based Nucleic Acid Amplification test)-TB (CBNAAT) technology, it is important that the existing laboratory capacity for Line Probe Assay, and Solid and Liquid DST should not be redundant. This requires a well-balanced laboratory scale-up plan. The same has been taken care of in India's new lab scale-up plan.

Due to the massive scale up of PMDT and newer initiatives, human resources (HR)

⁴⁶RNCTP (2014). *National TB Control Programme Annual Status Report: Reach the UnReach*. Page. 2, Para 2. Retrieved from <http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf>

capacity is overstretched. There is a dearth of counselling services generally to TB patients and particularly to DRTB patients. This is in spite of significant proportion of time being invested by the general health system HR in the program. Also Infrastructure and conditions for storage of second line anti-TB drugs is not up to the desired standards.

Awareness about TB and the determinants among the vulnerable and marginalised populations is very low. Therefore from the years of TB response in the country, India recognizes the need to increase the demand and access to services for the vulnerable and marginalized communities through partnerships with civil society organizations.

HIV

The third phase of NACP and previous rounds of Global fund grant have been able to achieve the intended targets, outcome and impact to a large extent. Now there is need to consolidate successes gained, by sustaining prevention focus besides effectively addressing the challenges. Given the experience of previous phases where the programme focused on saturating the coverage, NACP- IV needs to advance towards focusing on ensuring higher quality of services under interventions while sustaining the coverage. With increasing coverage of treatment & decreasing AIDS-related mortality, a significant number of people are likely to require first and second line ART treatment during the 12th Plan period. Major challenge for the programme will be to ensure that the treatment requirements are fully met without sacrificing the needs of prevention regions with different maturity levels of the epidemic will require different resources and services. Emerging epidemics in selected regions will need greater prevention focus while care and support in the setting of matured epidemic, particularly management of 2nd line ART, will need a robust management and financing strategy. Integration with larger health system to ensure sustainability. Need to address the challenge of competing priorities and varying capacities of health systems in different states to provide access to quality HIV/AIDS services. There is address the need for innovation within all key programme strategies for integration of services, quality assurance at all service delivery points, coverage saturation, treatment adherence, data quality and use etc. Keeping these implementation challenges in mind and lesson learnt from

The implementation of universal treatment for PLHIV is still low. There is need to scale up, strengthen and decentralize service delivery mechanisms to improve coverage especially for Key populations, women, rural population and hard to reach population. Also, the systems for ensuring retention of PLHIV each stage of care. India has made great progress already in reducing the issues with stigma and discrimination by introducing advocacy at many different levels of government and in the healthcare facilities. Inequities identified in the prevention, care, and treatment of vulnerabilities requires ensuring social protection schemes for people infected and affected with HIV/AIDS through mainstreaming of HIV/AIDS with other ministries. increasing more ART centres and link ART centres will give better access to these centres for PLHIV. Implementing this successful strategy in more states and scaling up the facilities and advocacy activities in the country will improve the number of PLHIV receiving ART.

The primary challenge to the PPTCT program continues to be reaching out to pregnant mothers who do not reach health care institutions and do not contact the health system and those who avail the services of the private sector where PPTCT services are not available. Young people (aged 10-24 years) constituted almost 400 million and represented one third of the Indian population.⁴⁷ Adolescents and youth constitute a large proportion of the HIV

⁴⁷ Secondary analysis of data from National Family Health Surveys of India – 1, 2, 3 for the age group 15-24 years- MoHFW-GOI, 2009)

positive population; it is estimated that over 35 percent of all reported HIV incidences in India occur among young people 15-24 years of age⁴⁸.

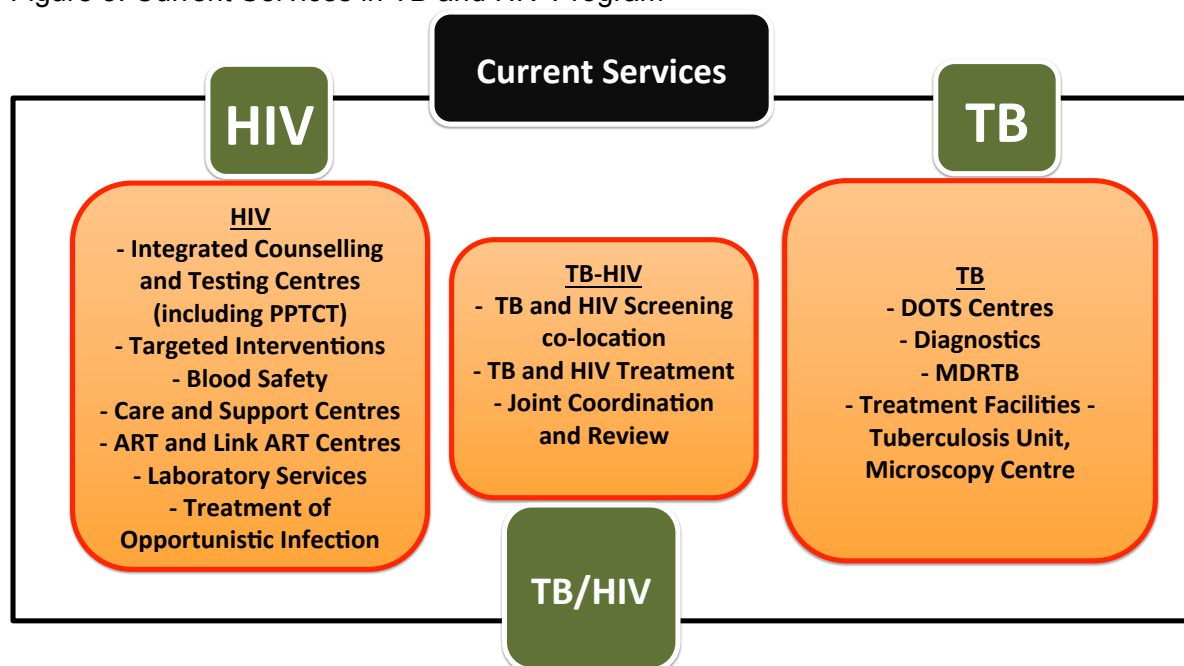
NACP-IV will address the need for innovation within all key programme strategies for integration of services, quality assurance at all service delivery points, coverage saturation, treatment adherence, data quality and use, etc. NACP-IV will also need to focus on integration with larger health system to ensure sustainability. There is a need to address the challenge of competing priorities and varying capacities of health systems in different states to provide access to quality HIV/AIDS services.

TB/HIV

HIV's shifting geographic epidemic poses some challenges for current joint efforts. As most of the infrastructures have been deployed in areas with high prevalence of HIV, there is a demand-supply mismatch of HIV TB collaborative services in these areas.

All services offered in NACP-IV, RNTCP and the joint programme are rights-based, meaning that no one has to accept the services offered and that an informed consent will be given at all times.

Figure 5: Current Services in TB and HIV Program



Areas of linkage with the national health strategy

The Indian healthcare system aims for universal coverage and has many systems in place to supply healthcare to the people. The healthcare systems include: healthcare facilities, the production and supply of medication, laboratories and trained medical personnel. Reaching the poor and marginalized with this public health system is key, even though this aim is not always reached. TB as well as HIV have traditionally been vertically oriented programmes with insufficient linkages between them.

Two key levels of linkages are envisioned (i) between HIV-related services and routine ANC services for pregnant women and (ii) between the national HIV and TB programs. Linkages among National AIDS Control Programme (NACP-IV), the Revised National TB Control Program and the National Health Strategy (NHS), as reflected in the National

⁴⁸www.unaids.org.

Health Mission (formerly two programs – National Rural Health Mission and National Urban Health Mission) are envisioned to ensure sustainability of response, quality assurance at all service delivery points, coverage saturation, treatment adherence, data quality and use. The strategy is envisioned to include:

- Mobilization of front-line health workers including Auxiliary Nurse Midwives (ANM), Village Health Nurses (VHNs), and Accredited Social Health Activists (ASHAs) for providing HIV-inclusive community and home base care for pregnant women and mother-baby pairs, and promoting institutional deliveries.
- HIV-inclusion in the Reproductive Maternal Neonatal Child and Adolescent (RMNCH+A) strategy.

Through the NFM investment, this infrastructure will enable the joint TB/HIV programme to scale-up services in the many states of India at high pace. The strong focus on treatment and care and the necessity to work on a more integrated strategy for HIV/TB makes this integration in the existing healthcare system a priority.

Country processes for reviewing and revising the national disease strategic plan(s)

TB

RNTCP developed its strategic plan through a cyclical process, incorporating monitoring and reviewing the operational processes of current plan and special consultative processes. The first level of review was through MIS, initiated monthly at the most peripheral institution level, which was validated by the program supervisors during their monthly visits. TB units submit quarterly reports on case finding, case holding, and infrastructure, resources and program management. Composite indicators are developed to monitor input, through put and output of program at TB Unit, district and state levels. Districts and states are monitored at national level through quarterly reports, with the same composite indicators. Presently, the program is fast migrating into real time monitoring through intelligent deployment of information, communication and technology (ICT).

Based on the information through these processes of supervision, monitoring, evaluation, specific intervention visits, periodic reviews, special reviews, analysis of MIS, and gaps are identified in focus areas. A consultative process is initiated with 100-150 national experts and state/district program managers with representation from all stakeholders including civil society. The NSP working group drafts the new strategic plan, which passes through the process of approval by the government. Once approved, it enters the next cycle of review and revision from the most peripheral program implementation unit to national program management unit.

HIV

The strategy and plan for NACP-IV (2012-2017) was developed through an elaborate and extensive process. The process has adopted an inclusive, participatory and widely consultative approach with 15 Working Groups and 30 sub-groups covering all thematic areas involving around 650 representatives from central and state governments, representatives of key population communities, people living with HIV/AIDS, civil society, subject experts, experts from NRHM and other government departments, development partners and other stakeholders. Regional and state level consultations, e-consultations and special studies/ assessments were also undertaken to develop the strategic plan.

1.3 Joint planning and alignment of TB and HIV Strategies, Policies and Interventions

In order to understand the **future** plans for joint TB and HIV planning and programming,

briefly describe:

- a. Plans for further alignment of the TB and HIV strategies, policies and interventions at different levels of the health systems and community systems. This should include a description of i) steps for the improvement of coverage and quality of services, ii) opportunities for joint implementation of crosscutting activities, and iii) expected efficiencies that will result from this joint implementation.
- b. The barriers that need to be addressed in this alignment process.

Through the various initiatives of the Government of India, the Joint Collaborative TB HIV Action Framework lays out the plan. The New Funding Model will provide the much needed resources to further the joint programming. Until now there has been collaborative activities between HIV and TB program but they have either not been communicated clearly across the states, and the districts, or sufficient guidance has not been given on the framework's roll out. The overall purpose of the national framework is to articulate the national policy for TB/HIV Collaborative Activities between RNTCP and NACP so as to ensure reduction of TB and HIV burden in India. The objectives of the framework are⁴⁹:

1. To maintain close coordination between RNTCP and NACP at national, state and district levels.
2. To decrease morbidity and mortality due to TB among persons living with HIV/AIDS.
3. To decrease impact of HIV in TB patients and provide access to HIV related care and support to HIV-infected TB patients.
4. To significantly reduce morbidity and mortality due to HIV/TB through prevention, early detection and prompt management of HIV and TB together.

Coordinating mechanisms

National Level: The National Technical Working Group (TWG) on TB/HIV helped develop the national framework. Moving forward, the national TWG will not only review national programs but also programs implemented by civil society and private sector. The TWG comprises of TB, HIV, and TB/HIV experts, community representatives affected by both, experts from the public sector, private sector and civil society as well as UN technical partners like WHO. This Group will identify bottlenecks in policy, program design and service delivery, explore solutions to address the bottlenecks and hold an oversight responsibility to the joint implementation.⁵⁰ There is already a guiding framework developed by Central TB Division and the Department of AIDS Control- National Framework for Joint HIV/TB Collaborative Activities, which has laid out the strategy and roadmap.

State Level: State Coordination Committees (SCC) are in place to ensure smooth implementation and regular review of TB-HIV Collaborative activities. SCCs, chaired by Principal Health Secretary are established at the State level. The State Working Group (SWG) is another body at state level, composed of key officials from SACS (PD and APD) and State TB Cell (STO, second MO if present), along with other officials dealing with TB/HIV collaborative activities and consultants involved in TB/HIV collaborative activities.⁵¹

District level: District Coordination Committees (DCC), chaired by the District Magistrate, have been formed in most districts of the country. In addition, monthly joint coordination

⁴⁹DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 2 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

⁵⁰DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 5 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

⁵¹DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 5 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

meetings are held between RNTCP and NACP staff. Currently, about 60-65% of the districts report having conducted a DCC meeting every quarter.⁵²

Program implementation Level: The mechanisms for TB/HIV collaboration are a well-entrenched part of RNTCP and NACP and a few dedicated staff are involved with improving supervision and monitoring. These include:

- A full-time regular government officer is in-charge of TB/HIV collaborative activities in the programs at the National and State level in NACP and RNTCP.
- National Consultants for TB/HIV (RNTCP & NACP) are available through WHO technical assistance.
- Technical officers at SACS for basic services (including TB-HIV) are available across the country (1-2 per state).
- State TB-HIV Coordinators are positioned in all the states.
- District level TB-HIV and DOTS-Plus supervisors have been placed for all districts by RNTCP.

Steps for the improvement of coverage and quality of services

To bridge the gap in infrastructure NACP and RNTCP are making concerted efforts. The following actions are planned:

- All District Microscopy Centres will have Facility linked-ICTC where HIV screening facility will be available
- Strengthening of State Coordination committees and State Working Group
- Strengthening of Coordination committees at all Districts
- Designating Nodal Persons for TB HIV co-ordination from both RNTCP & HIV/AIDS program at State and District level
- Strengthening joint review and monitoring of TB HIV collaborative activities at State and District level by Program Managers of RNTCP and HIV/AIDS.
- Kit storage

To improve and maintain optimum quality the joined TB/HIV Program envisages the following:

- Intensified TB case finding (currently only at ICTCs and ART centres) will be expanded to TI NGOs, Link ART Centres. ICF at ART Centres will be strengthened.
- Prioritize offer of rapid molecular test **Xpert-MTB-Rifampicin** to all presumptive TB cases among PLHIV for early diagnosis of TB as well as Rifampicin resistance. This will be implemented pan India in phased manner.
- Early detection and treatment of at least 90% of estimated HIV-associated TB in the community.
- Improved diagnostics to achieve program's universal access targets among HIV-infected TB patients
- The trainings on the standard operating procedures for collecting samples for PLHIV–Smear Negative TB / Extra Pulmonary TB will be imparted.
- Capacity building of RNTCP District microscopy centres laboratory technicians in HIV testing in coordination with DAC will be taken as a regular activity. The HIV component will be thoroughly included in the training curriculum of Laboratory technician
- Different civil society partners like Catholic Bishop Conference of India are involved with the TB program through the public private mix model , where ICTC centres will be integrated within facilities.
- For improved supervision, standardized supervision and monitoring tools for TB/HIV supervision will be updated on regular basis.

⁵²DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 6 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

- Mobility support to Senior DOTS Plus and TB HIV Supervisors will be provided for better TB HIV coordination.

Opportunities for joint implementation of cross-cutting activities

Collaboration through sharing facilities: To improve coverage while maintaining quality, NACP is currently enhancing HIV testing and ART services by establishing stand-alone Integrated Counselling and Testing Centres and ART centres in emerging HIV burden areas and establishing facility integrated testing and treatment centres (F-ICTC) and Link ART Centres (LAC). The TB program is facilitating the establishment of HIV testing facilities in all District Microscopy Centres, using existing facilities and manpower.⁵³

Collaboration in service delivery: The following mechanisms exist in the service delivery level to ensure smooth TB HIV collaborative activities:

- Routine referral of all TB patients for HIV counselling and testing.
- Provision of decentralized co-trimoxazole preventive therapy (CPT) to HIV-infected TB patients.
- Referral of HIV-infected TB patients to ART centres for initiation of ART.
- Expanded recording and reporting, including recording HIV status in the TB treatment cards and TB registers.

Collaboration through Information systems: Integration of surveillance of HIV prevalence among TB patients through the routine reporting system of RNTCP is another key area of coordination. This is being done by reporting HIV status of TB patients as anonymous data through the quarterly reports and TB status in HIV infected individuals attending ART centres.⁵⁴

Collaboration in M&E: Joint planning, supervision, monitoring and review are conducted through joint TB/HIV visits to states/districts and joint program reviews conducted at national and state level. National targets for assessing TB/HIV collaborative activities have been defined. The performance of TB/HIV collaborative activities is analysed and indicators are published in the performance reports of RNTCP every quarter. RNTCP conducts regular program reviews at the national and state levels. It is planned that at one of these reviews at the national level, an annual review of the TB/HIV collaborative activities is held with the participation of state program managers of both programs. Similar annual reviews are held at the state level by adding an additional day to one of the quarterly RNTCP review meetings and inviting the District Nodal Officers for HIV/AIDS and SACS officials.⁵⁵

Collaboration in Capacity building: All the training modules for training various cadres of staff have been jointly prepared by CTD and DAC. Staff of RNTCP and NACP conducts all the trainings jointly.

Expected efficiencies that will result from this joint implementation

Such efforts help in optimizing utilization of existing resources and make interventions sustainable. Availability of both HIV and TB testing facilities and the ART centres, preferably under one roof or at least in close vicinity ensures increase in coverage of HIV testing of TB patient as well as early linkage and prompt initiation to ART. Thus strengthening of infrastructure combined with close supervision and monitoring along with strong collaboration between NACP and RNTCP will result in consistent increase in

⁵³DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 9 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

⁵⁴DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 15 & 16 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

⁵⁵DOTS, & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 15 and 16 Retrieved from <http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf>

detection treatment and thus reduce mortality due to HIV associated TB.

The barriers that need to be addressed in this alignment process.

The challenge in India is that two separate and strong national programmes execute these two programmes. The nature of the two disease programmes are varied, while the HIV program is a vertical program with multi-sectoral partnerships for mainstreaming its programming, the TB program is integrated with the National Health Mission. Some of the barriers as a result of the structure includes close coordination, information sharing, and leadership styles. At the implementation level, often well-intended national and state policies on collaborative action do not get implemented on the ground due to unclear communication and roles. For patient centric services, co-location of facilities is sorely lacking, and the current available co-located facilities do not commensurate with the need. Only about 56% of facilities have both services, and that too some but not all services.

To ensure both the 100% detection of HIV associated TB and provision of ART and TB treatment to all those detected, a close collaboration between these programs is necessary. NACP and RNTCP have realized this and established mechanisms for collaboration at national, state and district level. The two programs have also invested significant resources to strengthen this collaboration. The national strategic plans of RNTCP and NACP offer several opportunities to address major program challenges over the next five years. The proposed NFM investment seeks to address some of the major barriers in alignment in particular Health Information Management Systems and co-location of facilities and services.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

To achieve lasting impact against the diseases, financial commitments from domestic sources must play a key role in a national strategy. Global Fund allocates resources that are insufficient to address the full cost of a technically sound program. It is therefore critical to assess how the funding requested fits within the overall funding landscape and how the national government plans to commit increased resources to the national disease program and health sector each year.

2.1 Overall Funding Landscape for Upcoming Implementation Period

In order to understand the overall funding landscape of the TB and HIV national programs and how this funding request fits within these, briefly describe:

- a. The availability of funds for each program area and the source of such funding (government and/or donor). Highlight any program areas that are adequately resourced (and are therefore not included in the request to the Global Fund).
- b. How the proposed Global Fund investment has leveraged other donor resources.
- c. For program areas that have significant funding gaps, planned actions to address these gaps.

The country has estimated an amount of USD 3,069 million towards HIV and TB services with an allocation of 73% for HIV (USD 2,236 million) and 27% for TB (USD 833 million). The estimates are drawn from the National Strategic Plans (2012-2017). In case of HIV, the Department of AIDS Control has drafted the NACP-IV strategy document and for TB, the National strategic Plan document for RNTCP document has been referenced.

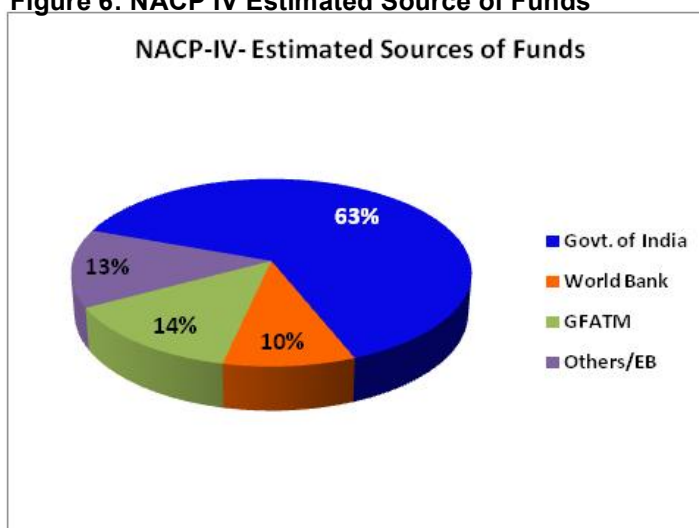
Availability and Sources of Funds: GOI under NACP-IV (2012-17) has earmarked an

amount of USD 2,236 million (Note: At an exchange rate of INR 60 per USD). It is estimated that 63% of the funds will be generated through budgetary sources of Government, 14% from the Global Fund, 10% from the World Bank, and 13% from other development partners.

The programme components of the NACP-IV indicate that 63% (USD 1,416 million) of the overall estimated budget is allocated for prevention services and 30% towards care, support and treatment services. The balance of 7% is bifurcated among the components of Institutional Strengthening (4%) and the Strategic Information Management Systems (SIMS) (3%). This indicates that the primary focus of the government is towards prevention that has been the case in the previous phases of the NACP.

The programme will implement comprehensive HIV care services for all those who are in need and facilitate additional care and support systems, including women and children. NACP-IV will work towards increasing access and demand for services, particularly for hard to reach populations. It will continue work to ensure improved access to CST services provided by the programme for PLHIV to reduce HIV-related morbidity and mortality. To achieve the objectives of the NACP, it is

Figure 6: NACP IV Estimated Source of Funds



required to further upscale and strengthen the existing systems. In the same context, WHO also recommends revised global guidelines for ART initiation and monitoring in 2013. Implementation of the revised guidelines will help reduce HIV-related morbidity, mortality and incidence of Opportunistic Infections (OIs), particularly TB in PLHIV. However, adoption of these revised guidelines adds to the overall ARV drug requirement in the country. It further necessitates the need to strengthen ARV service delivery mechanisms, lab capacity for PLHIV monitoring, supply chain systems for ARV drugs and other commodities, quality assurance systems, and supervision and monitoring of the programme in tandem with the ARV needs and scale up. In this context, the total requirement will be higher by an estimated amount of USD 841 million than the current estimates made in NACP-IV thereby creating a total funding gap of USD 463 million. The current Concept Note is prepared for USD 255 million as allocation amount (including an estimated saving of USD 32 million from previous Global Fund grants and an above allocation of budget request of USD 77 million. This totals to an overall request of USD 332 million.

Table 1 provides an overview of the budgetary support estimated across different components

Table 1: Overview of sources of budgetary support

Components	Budgetary Support	Extra-budgetary Support
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Targeted Intervention	DBS, World Bank	BMGF, USAID, AusAID, UNAIDS
STI services	DBS	BMGF
Lab Services	DBS	CDC
Blood Safety	DBS	CDC
Link Worker Scheme	DBS, Global Fund	UNDP
ICTC	DBS, Global Fund	UNICEF, WHO
IEC/Management Support	DBS, World Bank, Global Fund	USAID, UNDP, UNICEF
Condom Program	DBS	None
SIMS	DBS	CDC
Care support treatment	DBS, Global Fund	CDC, WHO

The GoI under the NACP–III, successfully managed to generate resources amounting to USD 453 million. It is estimated that along with the committed resources by the agencies other than Government, including technical support that is extra-budgetary the total amount of resources available to the country is USD 513 million that can be leveraged for the current NFM.

Leveraging Other Resources: Several multi-lateral, bi-lateral and international agencies including WHO, UNICEF, Centre for Disease Control, USAID and Clinton Health Access provide high-level technical assistance to the national and state governments. The Department of AIDS Control has a long standing relationship with several corporate foundations as well as public sector companies who conduct HIV prevention activities within their corporate activities like information, education and communication (IEC), counselling, behaviour change, condom programming and testing. Some examples are Tata Trust, Indian Airlines, Reliance Foundation, Standard Chartered Bank etc.

In addition to this, both TB and HIV programmes can tap into corporates' social funds, as India recently introduced a legislation mandating 2% of the new profits as corporate social responsibility (CSR).

TB:

Availability and Sources of Funds: The overall fund approved for the five-year period is USD 833 million for the period of 2012-17. In due course, these funding estimates have been revised due to emerging drug resistance, Urban TB, PPM etc. As per the new estimates, the total required funding for RNTCP for 3 years (2015-17) would be 1,200 million. The committed funding is only USD 614 million that includes donor commitment of 70 million USD. This committed funding is from 2 donors: 9.33 million from GFATM under Phase SSF till September 15 and the second from World Bank USD 61million till March 2016. The committed funding from GFATM will be utilised for laboratory related services that through FIND and for technical support from WHO, and does not include provision for drugs. The World Bank funding primarily supports procurement of drugs (80% of total committed WB funding). However, it is worth mentioning here that GoI through its domestic budgetary support still funds procurement of drugs.

RNTCP has nineteen budgetary heads and external funding is mainly being sought in areas of procurement of first and second line drugs, CB-NAAT technologies, scale up of DST services, urban TB & PPM, NGO support research etc. The areas that have been covered from domestic resources will be human resources, operations, and training, ACSM etc.

Proposed Global Fund investment has leveraged other donor resources as follows:

The TB control programme historically has been achieving implementation efficiencies through careful appraisal of activities of PRs and SRs followed by separation of activities of similar nature and ensuring that there is no overlap in the geographical coverage for a similar activity between various SR, PRs and activities financed through other sources. Further similar exercise is also carried out to ensure efficiencies by leveraging resources from other partners, creditors and donors (domestic budgetary resources, extra budgetary resources, World Bank and UNITAID). It is not out of place to mention here that activities/resources are also synergized not only between various programme within the health ministry (National AIDS Control Programme, child health programme including immunization, maternal health, tobacco control programme, non- communicable disease programme, National Health Mission etc.) but also activities and resources are synergised with other ministries (Ministry of Women and Child Development, Ministry of Rural development; Ministry of Tribal affairs etc.). The TB control programme has well exemplified these implementation efficiencies earlier through consolidation of grants under Round, 2, 4, 6 into Rolling Continuation Channel (RCC) and subsequently converged all existing grant into Single Stream funding TB (RCC+R9). The TB control programme currently also leverages through UNITAID funding support for scale up of labs and seeking grant funding in those laboratory areas that are not supported through UNITAID funding thus operationalizing efficiencies. The TB control programme proposes to achieve further efficiencies under NFM by continuing high impact activities under NFM and proposing new activities that were hitherto not addressed through earlier grants or other resources.

For the HIV investments, there are no other donors supporting ART. However, UNICEF, Clinton Foundation and WHO provide human resources and technical support for ART and PPTCT. Further discussion is planned on how these resources can be leveraged for the proposed investment.

For programme areas that have significant funding gaps, planned actions to address these gaps: Current challenges for the TB programme include MDR-TB, Universal DST and involvement of private sector and urban TB care and control. A significant portion of donor funding has been requested for these 3 components. Any funding gaps will be met through the domestic route.

The estimates are drawn from the National Strategic Plans (2012-2017).

Table 2: Funding gaps and Resource Mobilisation Plan

	Required funding	Available funding	Gap in funding	How do we plan to address
Categories	Total	Total	Total	
ACSM	33.77	1.5	32.27	Domestic resources
Diagnostics	183.3	10.34	172.96	under NFM and Domestic resources
FLD	129.03	13.69	115.34	Under NFM for 9 states and for others through domestic resources
HR	291.46	0	291.46	Domestic resources
M&E	27.77	0	27.77	100% through Domestic resources
Operations	150.76		150.76	100% through Domestic resources
PPM	147.84	0	147.84	Under NFM for 9 states and for other through domestic resources

Research	24.09	2.3	21.79	5 million under NFM rest through Domestic resources
SLD	183.76	35.53	148.23	GFATM for 50 %of the total gap
Technical Assistance	7.83	7.1	0.73	Under NFM
Training	21.16	0	21.16	100% through Domestic resources
Total	1200.77	70.46	1130.31	

2.2 Counterpart Financing Requirements

Complete the Financial Gap Analysis and Counterpart Financing Table (Table 1) The counterpart financing requirements are set forth in the Global Fund Eligibility and Counterpart Financing Policy.

- a. For TB and HIV, indicate below whether the counterpart financing requirements have been met. If not, provide a justification that includes actions planned during implementation to reach compliance.

Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
iii. Increasing government contribution to disease program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

- b. Compared to previous years, what additional government investments are committed to the national programs in the next implementation period that counts towards accessing the willingness-to-pay allocation from the Global Fund. Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.
- c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.

HIV: The funding allocation from the GoI from NACP- III to NACP-IV for HIV has increased by 15%. In absolute terms the increase is of USD 305 million. In addition, the GoI commits to meeting the overall estimates through domestic sources. Under the NACP-III, the funding by the government was 18% of the total spending. Against this in the NACP-IV, Government plans to allocate 63% of the total estimate through government spending. This is a substantial increase in the plan expenditure. In terms of the activities that are expected to be financed by the government, additional resources represents the bulk of the resources required under NACP-IV. Blood transfusion services, Condom promotion, Scale up of multi-drug regimen for PPTCT, Early infant diagnosis for HIV exposed infants and children below 18 months, mainstreaming activities, Strategic Information Management Services and institutional building activities are the major areas where government plans to allocate its resources.

Realisation of these commitments and its tracking: A nation-wide Strategic Information Management System (SIMS) has been developed and implemented during NACP-III for effective monitoring and evaluation of the programme. The NACP-IV proposes the maintenance of SIMS and providing support to around 20 institutions for analysis of the programme and also to create a knowledge hub. This includes tracking of funds disbursed based on the commitments.

TB Funding: Contribution to overall health programme by the Government of India has increased six times the budget of the 10th Five Year plans to the proposed 12th Five Year plan. The increase in RNTCP funding in absolute terms is in line with planned increases in overall central government health spending (see Table 4). At the same time, the proportion allocated to RNTCP will also increase in relative terms, from 1.4% of the total during the 11th Plan to a proposed 1.5% in the 12th Plan. (This proportion, however, can perhaps be compared to TB burden, as the disease causes an estimated 2.8% of all deaths in India and 6.4% of deaths among the 15-49 age groups). In per capita terms, during the 12th Plan, average annual central government spending on TB control is proposed to be about USD 0.18, which represents a tripling in absolute terms from the 11th Plan average.

DOTS implementation, human resources for other than 9 states, operational expenses like maintenance, and infrastructure expenses in all the states and union territory will be funded from the government sources. In addition, if there are any emergencies that the country faces, it will be met from the government sources. Activities to address the Urban TB are also financed from the government resources.

Table 3: Spending pattern of Revised National Tuberculosis Programme

Central Government health spending and RNTCP funding 10th , 11 and 12th 5 year plan							
Five year plan	Years	US \$ million			RNTCP as % of total of spending	US \$ per capita per year	
		Total central Govt. Spending	RNTCP Spending	% increase		Central Government	RNTCP
10	2002-07	13,093	168	-	1.28%	2.38	0.03
11	2007-12	24,076	358	113%	1.49%	4.01	0.06
12	2012-17	63,400	950	165%	1.50%	9.75	0.18

The commitment towards RNTCP from Gol and other donors are monitored on a regular basis. RNTCP submits annual Budgetary Estimate for the upcoming financial year where funding to RNTCP from all the sources is mentioned. Moreover, based on spending in the first half of the year, a six-monthly re-estimation of budgets is conducted mid-financial year in September/October. Subsequently, reports are shared with Department of Economic Affairs and the Planning Commission.

The assessment of the completeness and reliability of financial data reported, including any assumptions and caveats: The reported financial data is reliable. These data are audited by the respective State Health System, State National Health Mission Societies, and Auditor and Comptroller General before getting compiled at national programme management unit. These data are published in form of Annual Report of CTD as well as MoHFW, Annual Health Survey- Gol. Also these are available in the public

domain. No assumptions are made for the past years whereas logical assumptions are made for the future requirement.

Actual performance in the proposed areas may depend on the external environment, including the political and administrative changes at state level and capacity differentials of the individual state health systems.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

This section details the request for funding and outlines how the investment is strategically targeted to achieve greater impact on the diseases and health systems. While the investments for both the HIV and TB programs should be described, the applicant should also provide information on the expected impact and efficiencies achieved from planned joint programming for the two diseases including cross-cutting health systems strengthening as relevant.

3.1 Programmatic Gap Analysis

A programmatic gap analysis should be conducted for the six to twelve priority modules within the applicant's funding request. These modules should appropriately reflect the two separate disease programs in addition to crosscutting modules for both programs such as Health System and Community Systems Strengthening.

Complete a programmatic gap table (Table 2) for the quantifiable priority modules within the applicant's funding request. Ensure that the coverage levels for the priority modules selected are consistent with the coverage targets in section D of the modular template (Table3).

For any selected priority modules that are difficult to quantify (i.e. not service delivery modules), explain the gaps, the types of activities in place, the populations or groups involved, and the current funding sources and gaps in the narrative section below.

The national programmes completed Programmatic Gap analyses for the 6 priority modules across TB, HIV and TB/HIV. The section below elaborates on aspects of modules and interventions that require additional explanation to fully illustrate the programmatic gaps and the present need.

TB-HIV. Airborne infection control at ART centres and associated HIV care settings (community care centres and “Link” ART centres) has been identified as an area of increasing importance. Studies have shown high rates of exogenous re-infection among HIV-infected persons with recurrent TB, suggesting that these patients have been re-exposed to TB after being cured. The current programme does not have budgetary allocation for up-gradation of the facilities in accordance to the National Airborne Infection Control guidelines presenting a major gap in control of co-infection.

TB Care and Prevention. The country envisions universal access to TB care; however, the detection of New Sputum Smear Positive cases has declined from 70% to 66% of the estimated cases during the recent past years. Notification of all TB cases, including smear negative and extra-pulmonary shows similar decline. Approximately one million TB cases are missed, i.e. a third of the global estimates for missed cases. However, this number also includes cases diagnosed and treated by non-programme providers, but not notified to the programme. While it's expected that the RNTCP patients will be captured in the notification database by the recently vitalized notification system and additional effort of all

care providers, identification of patients outside RNTCP is the major gap. The problem of patient identification is particularly present in urban slums, where TB prevalence is high but service delivery is weak. Community outreach targeting key populations is a weak area across the country. Project Axshya is currently implemented in selected low-performing areas in 374 districts to address this issue, and mostly rural-centric whereas there is a growing need to mobilize and engage the key affected populations of the urban sites into appropriate TB care and control activities. Secondly, there is also a need to replicate Axshya in the other low-performing rural areas targeting key affected populations that are currently not under the coverage of the project and subsequently missing cases mostly from key affected populations. Thirdly, there is an urgent need of an inter-phase mechanism to establish coordinated and sustained linkages between private sector and RNTCP to promote TB case notification and adherence to standards for TB control in India during TB case management within private sector. In all these three aspects, civil society organizations' role is vital and can perfectly complement the efforts of RNTCP to reach the maximum number of missing cases and bring them under standardized TB care.

This gap is being addressed with high priority in the current strategic plan. Through this allocation, linkages will be strengthened between public and private sectors. Gaps will be addressed through interventions described in the Modular Template.

MDR-TB: Even after achieving the set targets as per the Programmatic Management Drug Resistant TB plan, the RNTCP has considerable gaps in capacity for diagnosing and treating all incident cases of MDR. The notification of drug resistance cases both MDR and XDR-TB as per WHO-annual report-2013 is only one-fifth of the total estimated burden of MDR and XDR-TB cases. In addition to the challenges in the notification of the drug resistant TB (MDR-TB and XDR-TB), diagnosis of Extra-pulmonary Tuberculosis (Drug sensitive and Drug Resistant), Non-tuberculosis mycobacterium and mono and poly resistance TB are also a challenge and need to be addressed effectively for comprehensive TB control strategy. To achieve this target, the current programme will build the capacity of laboratory networks to perform molecular diagnostics and second-line drug susceptibility tests.

Urban TB: A priority intervention area in the proposed programme addresses the need for a dedicated infrastructure for Urban TB. The Urban TB strategy is only recently articulated in the National Strategic Plan, and hence yet to be rolled out. There is a lack of dedicated infrastructure and resources as the available resources do not commensurate with the problem of urban TB. Case detection has clearly plateaued since 2011, despite increasing attention to improving the quality of diagnosis in the public sector, and delays in diagnosis are an average duration of 40 days. Stopping TB transmission in cities will require comprehensive and wide-reaching services including early diagnosis, which necessitates large-scale engagement of private providers and deployment of improved diagnostics across all points of care. The clear emerging need is massive support for and resourcing of enhanced case finding, particularly among vulnerable populations, and a specific focus on urban slums.

Treatment, Care and Support. Out of the almost 3,000 facilities where HIV detection is conducted, only 409 ART centres have the facility for baseline CD4 testing. Furthermore, facilities do not adequately meet the needs of patients who may be traveling long distances and lack access to transportation, thus creating barriers for access to drugs and treatment for PLHIV. To bridge this gap, it is proposed that low load point of care

equipment for CD4 testing and assessing eligibility for ART are provided to all low load ART centres and LACs at district level hospitals to increase accessible services for PLHIV. Additionally, the experience in our country shows that immunological failure is detected very late and the uptake of second line ART is not optimal. Therefore, the introduction of viral load testing is essential to meet the needs of patients and will play an important role in detecting failure early and reducing accumulations of mutations. The PLHIV networks have expressed their urgent need for increased access to viral load testing.

At the onset of NACP IV, based on expert committee reports, Community Care Centres were closed and care and support mechanism to Care and support centres, with focus on outreach for early treatment and adherence support. Right now there are 350 CSCs linked to 411 ART centres out of the existing 448 ART centres. In addition, under NACP IV, DAC plans to scale up the ART centres to 600, through additional 125 CSCs effort is to link maximum ART centres to support adherence and reduce lost to follow up. This responds to strong need expressed by community networks of key populations and PLHIV to increase access to treatment in particular in certain regions of the country (e.g. north east states)

Health Management Information Systems (HMIS) and M & E: India has a strong HIV surveillance system, however quality strengthening and upgrading is required. Gaps exist in the integration and harmonization with Strategic Information Management Systems (from Department of AIDS Control). The tracking of treatment, care, and support is relatively weak, and this is similar for the RNTCP programme as well. Due to the environment of stigma, mortality due to TB/HIV comorbidity or even morbidity is seldom accurately reported. An atmosphere of trust, data quality for improvement in impact, and attitude and capacity building on data quality assurance is much required. Innovations have been identified to track cases through mobile applications and will be implemented through this programme.

Program management. Grant management for large programmes, such as those supported, by Global Fund require systems development, support and monitoring. Apart from aligning earlier GF reporting, systems strengthening activities must include strengthening of the Management Information Systems, supportive supervision, documentation and impact evaluations. Since this is a first-of-its-kind Joint Programming at such a large scale funded through external support, a review of the National Framework of Joint Collaboration between TB and HIV, along with the Global Fund TB/HIV activities, governance, leadership, and collaboration is required. Due to the timing of this New Fund model, mid term and end term reviews of the National Strategic Plan of TB and HIV may also be planned during this three-year period.

We envision the NFM funding to address health systems constraints to quality treatment, care and support of TB and HIV services. Recognizing and filling these gaps with high impact and empirically tested programming will help to create a full realization of the national strategic plans' goals and priorities.

3.2 Applicant Funding Request

Provide a strategic overview of the applicant's funding request for TB and HIV, including both the proposed investment of the allocation amount and the request above this amount. Include the specific elements related to joint programming such as health systems and community systems strengthening. Describe how the request addresses the gaps and constraints described in sections 1, 2 and 3.1. If the Global Fund is supporting existing programs, explain how they will be adapted to maximize impact.

The India CCM requests a full expression of need of total of 721 million USD including savings from previous grants, over three years starting April 2015, for life saving health systems and community strengthening responses. The current Global Fund investment is being viewed as a critical need based support as the epidemiology and new information demands rapid scale and enhanced coverage of TB and HIV treatment, care and support. The National strategic plans of both TB and HIV programmes are in their third year and had not accounted for the revisions in Global guidelines on ART, PPTCT and MDR-TB treatments. It has also not accounted for an acute rise of drug resistance TB. As a result there is a huge gap that cannot be filled domestically as funds have already been allocated according to the need and the information available in 2012. The India CCM lauds Global Fund for recognizing the impetus required for a joint TB and HIV programming at the same time acknowledging the fact that the systems, funding and programming are fairly different, this is the need of the hour to prevent further morbidity and mortality while focusing on strengthening both health and community systems.

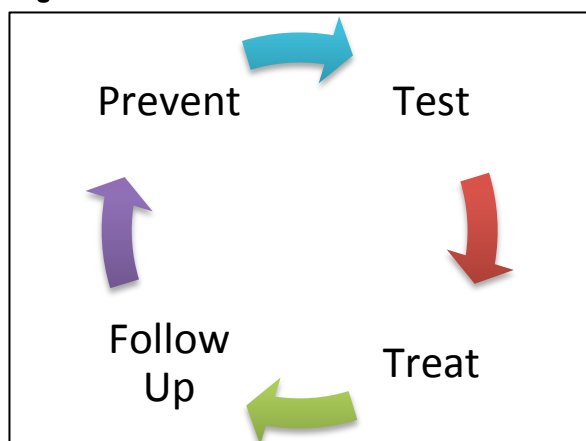
For the last 3 years, India has been unequivocally focused on various interventions and reforms that would lead towards Universal Health Coverage. It is with this intent that both the TB and HIV programme seek the support of Global Fund to address the unmet needs despite having domestic investments to address all key population targeted interventions and garnering other external support for key support areas. Towards achieving Universal Health coverage India has committed to the Global targets and revised WHO treatment guidelines of putting 1 million people on ART, addressing in scale drug resistant TB, ensuring demand and subsequent access for HIV services, to vulnerable populations including pregnant women.

This investment by Global Fund, will allow India to address its systemic weaknesses, strengthen community and health systems, and scale up coverage to life saving TB and HIV drugs, while domestic and other funds invest fully in key population interventions taking human rights, gender and equity as guiding principles. Through this investment not only will community and health systems form a continuum for enhanced access and sustainability but also integration of TB and HIV programming as the leading cause of death among HIV positive people is TB.

The vulnerable communities that will benefit from this investment include key populations like sex workers, men who have sex with men, transgenders, people who inject drugs, prisoners, vulnerable migrants and hard to reach tribal population, urban slum dwellers, prisoners, refugees and migrants and immune compromised individuals including those infected by HIV.

This TB and HIV joint programme comprises of joint TB and HIV programming for comprehensive responses in high burden areas, as well as those that are hard to reach and vulnerable to TB HIV co-morbidity. The strategic approach follows a Test, Treat, Follow up and Prevent lifecycle approach.

Figure 7



The core of the approach is an integrative care system for the PLHIV networks and those key affected populations, and highly vulnerable to both TB and HIV. As much as it is a challenge for prevention services to reach these populations, treatment access is even less given poor infrastructure, assets, quality human resources, and stigma environments. The proposal puts adequate focus on building demand and strengthening supply of treatment, care and support to communities in need. By integrating services at the centres, and by enhancing treatment literacy we envision communities to receive one-stop shop of

services, making it convenient, cost effective and addressing Loss to Follow up. It is this Loss to Follow up due to timely unavailability of appropriate diagnostics and treatment that has rendered resistance and worsening of conditions, that are in the long run more expensive to treat. Earlier Global Fund grants where nurses and counsellors were trained will be leveraged to bring about this integration and provide the much-needed key population friendly services particularly in the general health setting and those in the TB diagnostics and DOTS centres.

Test: Investments are being proposed to enhance testing of HIV, Viral Load, CD4 counts, drug resistance TB, referrals from ante-natal care clinics in high burden districts, urban centres and hard to reach geographies (in particular for enhancing the ART centres with TB services). A significant part of the proposed investment includes Early Infant Diagnosis. Strong referral linkages between targeted interventions and ICTC centres are proposed. ICTCs will have TB diagnosis integrated within them. Under Vihaan programme, CSCs will rigorously refer PLHIV and their families for testing and treatment through Intensive Case Finding (ICF) method

To enhance testing of TB and DR TB the investment proposes laboratory strengthening to scale up both diagnostics including second line and follow up examination. The new laboratories will augment the existing capacity for diagnosis and follow-up of TB and DR-TB cases. The proposed plan includes further strengthening of existing laboratories and establishment of new laboratories with automated liquid culture systems. The laboratories to be upgraded would include identified medical colleges and tertiary care facilities identified in consultation with the respective states. The Cartridge Based Nucleic Acid Amplification tests (CBNAAT) machine will be deployed across the country for rapid and early diagnosis of MDR-TB and TB in high risk population e.g. PLHIV and Paediatric presumptive cases. This proposal is in accordance with the “Laboratory Scale-up plan to address the problem of MDR/ XDR-TB for 2015-2019” of the RNTCP. As mentioned in the programme gaps, the testing in the private sector in unorganised and faulty, both the civil society PR will work towards training and sensitization of private providers to provide B services as per the National Programme.

Treat: High Impact Investment in the form of drugs (first line, second line, TB and MDR TB drugs) has been proposed. As much as ARV, first line is being scaled and will reach more eligible persons, second line ARV is also being scaled up. Currently program is covering only 67 % of estimated need for ART. Expanded eligibility for ART as per WHO guidelines will provide new opportunities to save lives, improve clinical outcomes and reduce HIV incidence but at the same time, it poses challenges to national programmes in terms of implementation. It is also planned to roll out Second line ART for PLHIV who need this. Option B has been adopted in three high prevalent states as well as Option B+ just started rolling out but needs critical support to continue. Much needed, life saving support in the form of medication and infrastructure has been proposed in this investment. MDR TB requires special counselling, which is critical to the care of MDR TB, hence

capacity building and staffing particularly for MDR TB (which is rising exponentially) has been proposed. Private health provides 80% of OPD and 55% of in patient care, e.g. only 50% of TB patients were diagnosed in private sector. Hence high impact interventions focusing on strengthening the reporting and quality of care in the private sector, is of particular importance in the proposed Global Fund investment.

Follow Up: Loss to follow up has been the second most significant cause of developing drug resistance disease and eventual mortality. The proposed investment requests community system strengthening particularly of PLHIV networks at the district, state and national levels. We also propose uniform MIS established at all levels- facilities, SRs and PRs, with formats prescribed by Department of AIDS Control, which would collect longitudinal data for tracking.

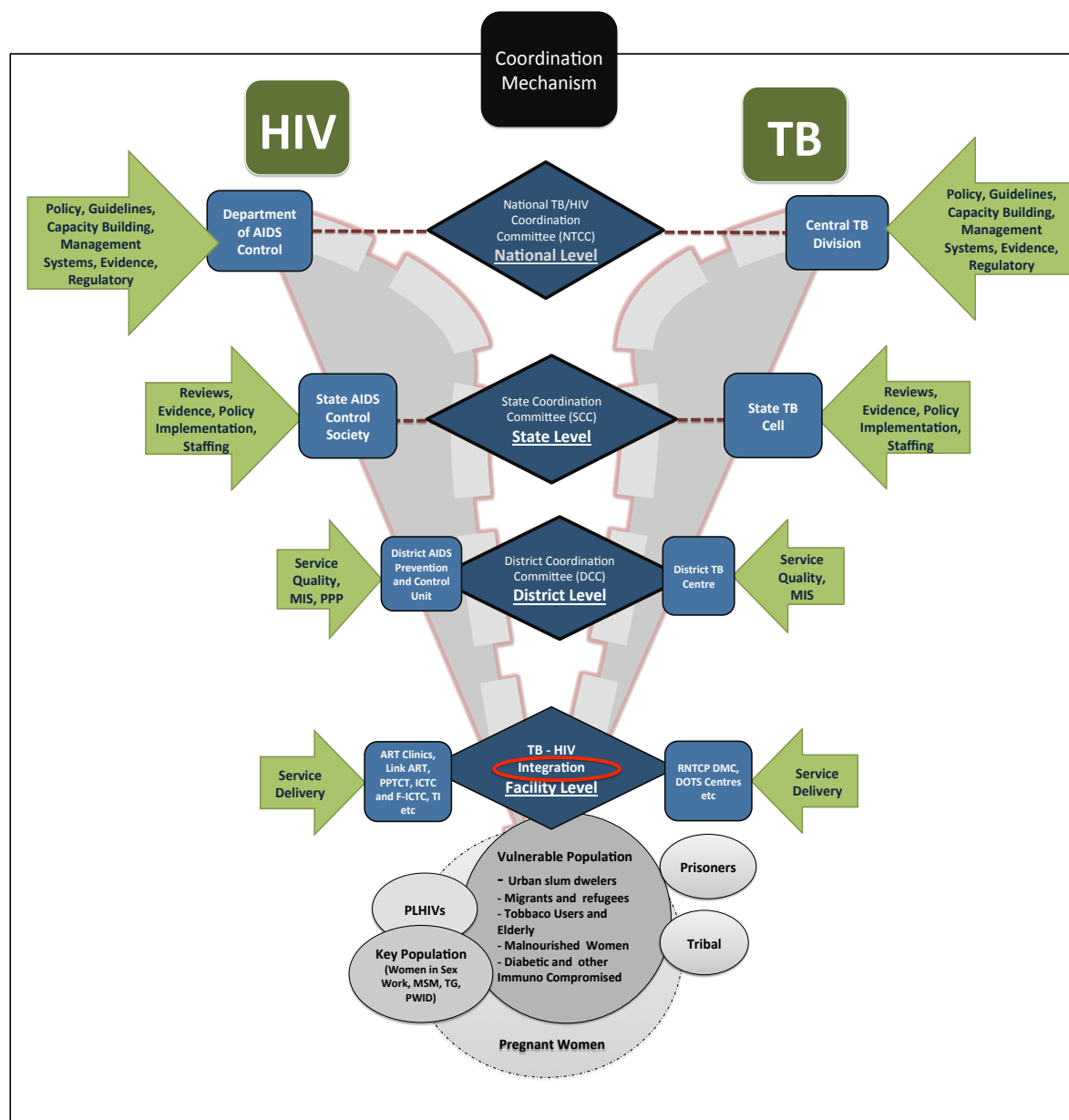
In this proposed investment, for those who are under treatment of MDR TB will avail of counselling services that were earlier piloted now scaled up across the country. This flagship programme will be implemented in both facilities and community settings endeavouring to improve the Quality of life of DR TB patients and their families.

Prevent: Timely TB diagnosis, viral load and CD4 count testing, Early Infant Diagnosis, prevents further transmission, disease and subsequent death. Prevention also includes prevention of parent to child transmission. Stronger referral systems, capacity building of health workers at community and facility level has been proposed in this much-required investment. In prevention of TB, proposed intervention includes air borne infection control is being proposed in high risk facilities through promotion of administrative (cough hygiene, fast tracking chest symptomatic), environment control (architectural structures, and adequate and appropriate ventilation), and personal protection like usage of masks. In addition, Isoniazid preventive therapy (IPT) will be made accessible to all PLHIV (estimated at 50% of those newly enrolled in HIV care) who do not have active TB.

Health Systems Strengthening Approach. The overall programme will establish and build upon coordination techniques between TB and HIV programmes. Figure 8 illustrates the proposed coordination framework to reach vulnerable populations affected by TB, HIV, and co-infection. While most service delivery mechanisms are already in place, the proposed funding would strengthen the systems to obtain maximum coverage with quality services, including national, state, district, and facility level coordination efforts. Health systems strengthening at the national level will include policy, guidelines, capacity building, management systems, and regulation; State TB Cells will include reviews, building evidence, policy implementation, and staffing; district level will include service delivery improvements and to promote integration at facility level. There would be efforts in larger health systems integration, particularly reporting between TB and HIV and public and private sector.

To respond to the poor public health infrastructure in urban areas particularly urban slums, this programme endeavours to provide TB services and to a limited extent HIV services.

Figure 8: TB and HIV Coordination Mechanism



Community Systems Strengthening

For vulnerable community groups including key populations and those living with HIV, there are currently no community level initiatives for HIV counselling of the TB cases and referral for HIV testing with follow-up as well as TB referrals for those infected and affected by HIV. Community awareness building on TB/HIV co-infection is also woefully inadequate. The current efforts of Intensified TB Case Finding (ICF) among people living with HIV & AIDS (PLHIV) and HIV high-risk groups (IDUs, sex workers, migrants, MSM, Transgender) are mostly restricted to TB sensitization of the district level PLHIV networks and HIV TI (Targeted Intervention) project managers with sub-optimal follow-up largely due to limited resources. The lack of inter-linkages between the rural HIV intervention (Link worker scheme) with TB control activities is a missed opportunity in achieving far reaching impact in rural areas.

There is a need for strengthening the engagement of civil society for TB control, specially related to providing support to the key populations to enhance their access to TB services.

In addition to this, there is a lack of evidence concerning the role of PLHIV networks and community based organisation and their role in prevention-testing-treatment-care continuum, hence in this funding request we propose Operational Research on Community led testing and care continuum. This investment will have far reaching implications on policy, programmatic and health impact.

PLHIV networks at the district, state and national levels are one of the key integrators between TB services and HIV services, post facto morbidity. Hence it will be critical to strengthen these networks in terms of treatment literacy, advocacy, referral system, counselling and peer support. The proposed Global Fund investment will focus on strengthening the PLHIV networks, so that they can form effective referral and follow up systems between both HIV and TB services, and offer much needed counselling and peer support.

In summary, the unmet needs are well within the framework of the National TB and HIV strategic plans, however, the financial gaps are relatively recent, due to epidemiological shifts and revised treatment guidelines. India will benefit immensely from the high impact investment requested from Global Fund, which will have far reaching impact on populations in need, in the second most populous country in the world.

3.3 Modular Template

Complete the **modular template (Table3)**. Note that the template allows access to modules that are specifically relevant to TB and HIV components, in addition to modules that are crosscutting for both diseases.

To accompany the modular template, for both the allocation amount and the request above this amount, explain:

- a. The rationale for the selection and prioritization of modules and interventions for TB and HIV, including those that are crosscutting for both diseases.
- b. The expected impact and outcomes of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

The strategies under the RNTCP, NACP-IV, and Joint Framework for HIV/TB are comprehensive prevention, treatment, and care responses to the epidemiological context (described in Section 1.1) of the diseases in India. The rationale for prioritizing the modules and interventions requested in the current proposal is dictated by unmet and emergent needs within these frameworks and identified in the Programmatic Gaps (Table 2, Section 3.1). The 6 modules have been selected on the basis of interventions that will lead to early diagnosis, timely treatment and care of TB and HIV in an integrated, comprehensive manner. The comprehensive approach will facilitate improved collaboration and knowledge integration of service providers at national, state, and community levels to reach key populations most at risk for TB, HIV, and co-infection.

Throughout the modules, the disease specific and crosscutting interventions provide community and health systems strengthening solutions that further integrate the work of RNTCP and NACP, as well as responses to gender inequities and human rights barriers. Programme management costs are also being proposed to ensure good grant management, financial and programme monitoring of NFM activities, regular reporting, seamless procurement and supply chain management. The modules and key interventions are summarized in Table 4.

Table 4. Summary of modules and key interventions

	Modules	Key Interventions
1	TB Care and Prevention	Community mobilization, community-based sputum collection; infrastructure improvements; treatment monitoring and counselling for adherence; focus on marginalised and vulnerable populations (tribals, refugees, slum dwellers, women & children); laboratory facilities, capacity building among care providers; private sector engagement
2	HIV Treatment, Care, and Support	Pre-ART care and counselling; counselling and psychosocial support for ART patients and families including peer outreach; laboratory systems strengthening; adherence to WHO 2013 guidelines for ART treatment; key population centric HIV services, including mobile outreach and referrals from TI; grant management services
3	TB/HIV	Intensified TB case findings among PLHIV and HIV among TB patients, including TB testing and care in ICTC and ART centres; air borne infection control; capacity building among community health workers; strengthening coordination and referrals; monitoring programme management
4	HMIS and M&E	HIV surveillance system interoperability; strengthening of routine surveillance and case reporting; expanding reporting to private sector; analysis, review and transparency
5	MDR-TB	Case detection, laboratory facilities, diagnosis, and treatment along with counselling and follow-up; treatment education and prevention among patients; technical support for scale-up of services
6	PMTCT	Early Infant diagnosis; prevention of vertical transmission; building capacity of public and private health systems; social mobilization; building community linkages; grant management

The budget that is above allocation will allow for increased coverage and enhanced impact of TB, HIV, and combined TB/HIV activities. The national programme has identified empirically supported activities that will create high impact results in key geographic areas.

With above allocation funding, RNTCP can increase coverage and provide life saving treatment to socially and clinically vulnerable populations including sex workers, MSM, trans genders and people who inject drugs in hard to reach geographies as well as improve programme management for quality and sustained service provision. The modular template outlines interventions requiring above allocation funding so that an additional **1.18 million presumptive MDR-TB suspects** will get rapid molecular testing and approximately **660,000 HIV positive patients** could be covered for early diagnosis through this testing. Additional funding would also allow drug courses to be accessed for

early treatment for 23,107 MDR & 1,605 XDR cases. Approximately **400,000 additional MDRTB and co-infected** patients would be reached for counselling to improve treatment adherence, substantially decreasing mortality rates. Funding would allow increased reach to **43 additional tribal districts** resulting in access to early screening, diagnosis, treatment and adherence support for around **13,000 TB/MDRTB patients**. Programme management and operations would also be strengthened to create efficiencies and shape policy towards better programme delivery and coverage.

Funding amounts going above allocation would also allow HIV prevention, treatment, and care services to **increase coverage**, particularly with the pressing issues of prevention of parent to child transmission and TB and HIV co-infection. For example, it would expand PPTCT outreach to an additional **176 districts in 20 States/Union Territories** and allow the possibility of ensuring approximately **5 million more women** are tested for HIV per year. Furthermore, the above allocation amount would help to **test additional 0.2 million pregnant women in the private sector** and identify and serve an additional target of **14% (5,336)** of the country's estimated positive pregnant women with **PPTCT cascade** of services till 18 months post delivery. Above allocation funding will also improve care and support services, and thereby quality of life and prevention, for PLHIV, by increasing service coverage for pre-ART, ART and follow-up counselling.

The impact expected from these comprehensive investments includes:

- Reduction of new HIV infections by 50% (from the NACP III 2007 Baseline data)
- Provision of comprehensive care and support to **all** persons living with HIV and treatment services for those who require it
- Achieve **universal access** to TB Care and Treatment
- Increase TB case detection and notification in urban areas

These impacts are based on the objectives of the NSPs for both programmes as well as the prerogatives of civil society PRs.

Anticipated outcomes from the integrated programme include (1) increased access to ART according to the WHO 2013 guidelines for all requiring it, (2) strengthened health systems for early diagnosis of TB and improved treatment outcomes among PLHIV, (3) enhanced access and coverage of PPTCT services in public and private sector to decrease vertical transmission from parent to child, (4) strengthened community systems to enhance access to both TB and HIV services, and (5) enhanced and up-scaled high impact TB diagnostics, treatment and prevention high among priority vulnerable population in both urban and rural districts. Indicators to track these outcomes come from surveillance systems and programme monitoring reports that fit the disease context and health systems needs and capacities in India. RNTCP and NACP modelling estimates are used to provide the majority of baseline information.

3.4 Focus on Key Populations and/or Highest Impact Interventions

This question is not applicable for Low Income Countries.

For TB and HIV, describe whether the focus of the funding request meets the Global Fund's Eligibility and Counterpart Financing Policy requirements as listed below:

- a. If the applicant is a lower-middle income country, describe how the funding request focuses at least 50% of the budget on underserved and most-at-risk populations and/or highest-impact interventions.
- b. If the applicant is an upper-middle income country, describe how the funding request focuses 100% of the budget on underserved and most-at-risk populations and/or highest-impact interventions.

India is a lower middle-income country and has provisions for 20% counterpart financing under the Global Funds Eligibility and Counterpart Financing policy requirements. The proposed investment seeks to address the needs of the deserving population with an allocation above the desired 50% of the total budget. The PRs have identified priority areas to tackle the disease burden. The key populations such as sex workers, MSM, TGs, Migrants, PLHIV, People living with TB, tribal populations, prisoners, refugees, and women and children have been identified across the high and increasing disease prevalence areas.

The PRs in alignment with the National Strategy seeks to attempt coverage of 1,253,004 PLHIV cases by providing them timely access to ART services by 2017. A total of 67,000 PLHIV cases will be identified, so that they will be provided with IPT. The programme will facilitate care services in the form of peer counselling, to monitoring the CD4 count once in 6 months, and home-based care for the communities.

In the private sector, the HIV incidence among children will be reduced by 90%, and the percentage of child HIV infections from HIV-positive women, delivering in the past 12 months, will be reduced to less than 5% by the end of year three. The funding will be utilized to increase the PPTCT coverage in the private sector from a staggering 10% to 80%, to identify more positive pregnant women. There will be a scale of the PPTCT services to 16 states and 5 Union territories in the country that account for 95% of the total affected population most of whom are from key affected populations.

RNTCP has a Social Action Plan, including a Tribal Action Plan in alignment with the National Strategic Plan for TB Control with the objective of ensuring "universal access to quality TB diagnosis and treatment for all TB patients" with special focus on special populations such as migrants and tribal groups, vulnerable and high-risk population and TB-HIV infected population. This entails sustaining the achievements of the programme to date, finding undetected TB cases, treating all cases appropriately, and responding to MDR-TB. RNTCP will continue to implement the Tribal Action Plan (2005) to increase access to and utilization of TB services by tribal people. The Tribal Action Plan emphasizes: (a) strengthening early reporting, (b) enhancing treatment outcomes, and (iii) closer supervision of tribal areas. Specific measures include: increasing case detection in targeted districts with higher proportions of the population who are from tribal groups; reducing default rates of female patients compared to male patients; promoting locally adapted information, education and communication (IEC) messages and patient education material; and operational research to assist in planning and implementation of RNTCP in tribal districts. The program will reach 25000 cases from tribal population.

Apart from this, there will be field practitioners to cover households in 450 urban slums across 90 districts to enhance door-to-door TB awareness and detect TB presumptive cases among adults and children, and linking them to sputum microscopy for sputum testing and follow-up as well as laboratories with better diagnostic services.

Most vulnerable TB patients are largely those who become drug resistant, about 150,000 will be reached. About 100,000 refugees will be reached through the TB programme.

The programme has a provision to sensitize qualified doctors, pharmacists, laboratories, AYUSH practitioners, corporates and other key stakeholders to tackle the stigma faced and as a result increase the potential of resources accessible to the vulnerable populations across rural and urban areas. There will be systems to ensure TB and HIV patients receive access to test for the other disease.

SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

This section requests information regarding the proposed implementation arrangements for this funding request. Defining the implementation arrangements for the program including the nominated Principle Recipients (PRs) and other key implementers is essential to ensure the success of the programs and service delivery. For the concept note for TB and HIV, the Country Coordinating Mechanism (CCM) can nominate one or more PRs, as appropriate given the country context.

4.1 Overview of Implementation Arrangements

For TB and HIV (including HSS if relevant), provide an overview of the proposed implementation arrangements for the funding request. In the response, describe:

- a. If applicable, the reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement (i.e. both government and non-government sector PRs).
- b. If more than one PR is nominated, how co-ordination will occur between PR(s) for the same disease and across the two diseases and crosscutting HSS as relevant.
- c. The type of sub-recipient management arrangements likely to be put into place and whether sub-recipient(s) have been identified.
- d. How coordination will occur between each nominated PR and its respective sub-recipient(s).
- e. How representatives of women's organizations, people living with the two diseases and other key populations will actively participate in the implementation of this funding request.

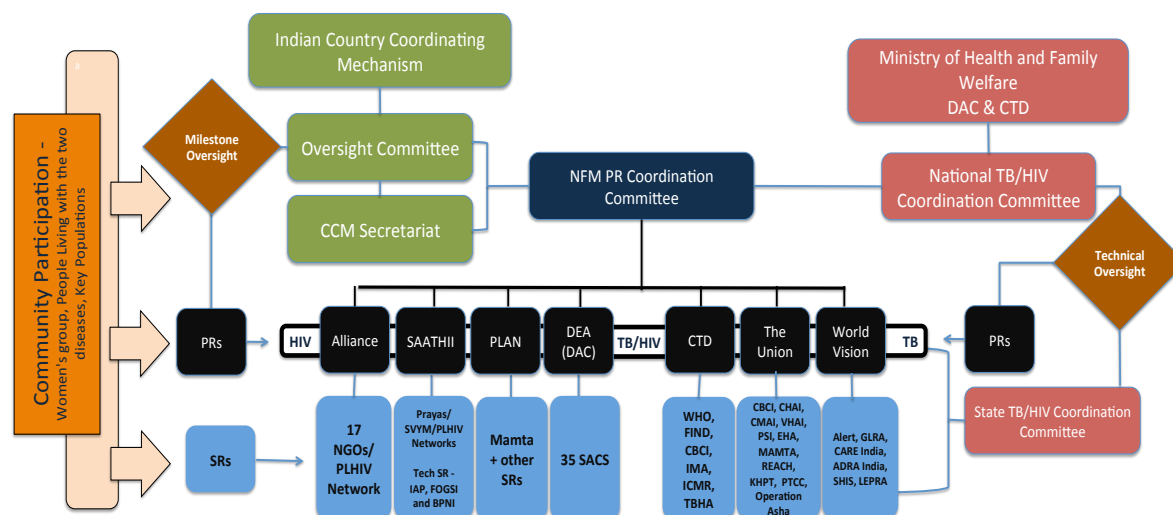
The India Country Coordinating Mechanism (ICCM) proposes Dual-Track Financing (DTF) implementation arrangements. In order to ensure a high impact intervention at scale and quality in the country across both HIV and TB diseases response system, the ICCM strongly believes in the need for DTF. Past experience of implementing DTF in the country has ensured better coverage of affected populations ensuring sustainability of these efforts. India CCM is proposing **two Government PRs** (Department of AIDS Control (DAC) and Central TB Division (CTD)) and **five Non-Government sector PRs** (Solidarity and Action Against The HIV Infection in India (SAATHII), PLAN India, India HIV/AIDS Alliance, The Union and World Vision India) who have been selected through a transparent bid process.

Being a proposal focussed on strengthening the health system and improving access to treatment and care for the community, there is a large procurement component in the proposed investment, in particular, life saving drugs and strengthening laboratory facilities.

The GoI PRs have the capacity and the footprint for such large volumes of procurement and extensive distribution channels across the country. In addition, the government is accountable to the public for quality and timely delivery of medical services and supplies. With respect to the funding allocation, the ratio between government PR and non-government PRs is 63:37 after accounting for the procurement and supply. In addition to this one of the Government PRs i.e. Central TB Department, has a sizeable portion allocated to civil society sub-recipients.

The coordination process under this Global Fund investment will be aligned to the existing coordination systems in the country. National TB/HIV Coordination Committee (NTCC), which has been already established and operational at national level, will continue to play a key role in facilitating coordination among the PRs. The State Coordination Committees will also be looking into the operations of proposed Global Fund supported programmes. The role of these two committees at national and state level will be primarily for technical oversight and guidance. The National Technical Working Groups working under these two committees will play a key role in ensuring technical quality of the programmes being implemented. The National Framework for Joint HIV TB Collaborative Activities is in Annex 3. Besides the above, for better coordination within this proposed Global Fund investment, a national level NFM PR Coordination Body, which will directly report to ICCM Oversight Committee, will be set up. The detail of the coordination mechanism is captured in the diagram below.

Figure 9: Implementation Arrangements



Abbreviations: Alert India - TB Alert, CCM – Country Coordinating Mechanism, DAC – Department of AIDS Control, CTD – Central TB Division, SAATHII - Solidarity and Action Against The HIV Infection in India, DEA - Department of Economic Affairs, SVYM – Swami Vivekananda Youth Movement, IAP - Indian Association of Paediatrics, IMA - Indian Medical Association, FOGSI - Federation of Obstetrics and Gynaecological Societies of India, BPNI - Breastfeeding Promotion Network of India, SACS – State AIDS Control Society, WHO – World Health Organization, FIND - Foundation for Innovative Diagnostics, CBCI - Catholic Bishop Conference of India, ICMR - Indian Council for Medical Research, TBHA - Tibetan Voluntary Health Association, GLRA - German Leprosy and TB Relief Association, ADRA – Adventist Development and Relief Agency, SHIS - Southern Health Improvement Samity, CHAI – Catholic Health Association of India, CMAI - Christian Medical Association of India, VHAI - Voluntary Health Association of India, PSI - Population Services International, EHA - Emmanuel Hospitals Association, KHPT - Karnataka Health Promotion Trust, CHAI - Clinton Health Access Initiative, PTC - Partnership for TB care and Control

PR Coordination Committee will be the mechanism that will be represented by PRs, Representative from CCM Oversight Committee, National TB/HIV Coordinating Committee (NTCC), beneficiary groups (PLHIV networks) etc. This will be a platform for coordination, technical discussion, trouble shooting on any ground level coordination issues and learning and sharing platform for the PRs. Oversight Committee of the CCM will be responsible for the milestone oversight. The NTCC along with its Technical Working Group and State level Coordination Committee will provide technical oversight and quality

assurance at both PR and SR level.

The National Coordination Committee (NCC) has been set up to manage the Global Fund supported TB programmes. NCC will also include the NFM grant within its review process and discuss the progress during the review meetings. The RNTCP also conducts Joint Monitoring Missions (JMM) at regular intervals of 3 years, which also include all the Global Fund supported programmes in addition.

Plan has identified one of the SRs (MAMTA) and others will be selected later through a transparent process. Other PRs have selected their SRs based on their technical expertise and experience in managing health programmes and in particular HIV and TB. All the SRs will be directly reporting to the PRs. Each of the PRs will put in place the MEAL (Monitoring, Evaluation and Learning) system for monitoring the performance of the SRs as well sharing learning from implementation experience. State TB/HIV Coordination Committee will be brought into picture to provide technical support to the SRs.

Management arrangements and coordination between respective PRs and SRs will be ensured through a comprehensive system for oversight (both technical and delivery related) in keeping with the principles of supportive supervision. A system of Project Management Unit (PMU) will be established within each PR in order to manage the programme. The system will include contracts management, financial management and controls, regular assessments and reviews through the M&E mechanisms, establishing procurement and supply management system, asset management system, technical support, capacity building etc. In addition to close monitoring of the programme through the PMU, a provision of technical support will also made available by creating a panel of technical resource pool locally by each of the PRs to support the SRs in ensuring implementation quality on the ground.

Efforts will be made to systematically assess capacities of the SR as well as implement specific and need based technical assistance plan to address the capacity gaps. While managing and monitoring the SRs, community participation and community perspectives will be sought as an important input to ensure results at the level of the service provision and quality. are achieved by the SRs. The information generated through the MIS system will be used to provide feedback, reflect and learn, and make appropriate and timely programmatic course corrections. PR will support the SRs to set right internal programme management systems (through appropriate system guidelines) so as to deliver results, maintain quality while achieving quicker scale up and coverage, achieve execution excellence and ensure results which are linked to achievements of outcomes. Management arrangements will ensure performance is ensured across all the SRs and additional support is provided to those SRs that require intense technical support. The Global Fund rating system will be effectively used to determine the intensity and focus of support to each SR.

The system of PR-SR coordination will be clearly laid out in the Supportive Supervision guideline that will be prepared by each of the PRs. This will include regular meetings, oversight field visits, regular submission of report by SR and feedback by PR etc. A robust Financial Management system will be put in place to ensure timely, transparent and accurate disbursement of funds to the SRs. Regular analysis of financial and programme information will be done that will help to make an appropriate technical support plan and contract management decisions.

Community participation will also be ensured at all levels of coordination and decision-making. Representation of the PLHIV network and other key population groups such as women in sex work, MSM, Transgender and Person Who Inject Drugs will be brought into the PR coordination mechanisms, state level coordination meetings and also at the level of the implementation. This will be included in the monitoring system and regularly measured to ensure commitment to participation of the community member is given utmost priority at all levels of coordination.

4.2 Ensuring Implementation Efficiencies

Complete this question only if the CCM is overseeing other Global Fund grants.

From a program management perspective, describe how the funding requested links to any existing Global Fund grants, or other funding requests being submitted by the CCM at a different time. In particular, explain how this request complements (and does not duplicate) any human resources, training, monitoring and evaluation, and supervision activities.

The Global Fund's current portfolio of grants in India comprises 8 active HIV grants, 3 active TB grants and 3 active malaria grants. The HIV programme in India is in its 4th phase of implementation and according to Global Fund's own preliminary calculation, the programme is "under resourced" by up to 33%. While the number of people who are on ART through 100% of the support coming from Global Fund stands at 710,000. But with the new of treatment protocol of WHO there is an increase in number of people who require treatment to 1.5 million. The NFM proposal seeks to raise the additional resources needed. Hence, there is no duplication of effort but instead it is for further scaling up of the reach for the ARV treatment. Currently, RCC of Round 4 and Round 6 support of the Global fund is focused on ARV treatment, with the increased need in the country to scale up and cover number of people who require ART treatment, this funding request that includes scale up of ART support actually complements the existing grants and is not a duplication. The country is also requesting for 2nd and 3rd line ART drugs.

The Global Fund supports a large part of the PPTCT programme in India. This proposal builds on past work. It looks at reaching out to young vulnerable mothers who are missing out on maternal and child health. It looks at strengthening existing health systems by building human capacity to work with young mothers in a sensitive manner, thus increasing uptake of PPTCT, creating access to maternal and child health care for young mothers, and preventing transmission of HIV. The investment sought through this proposal looks at developing BCC and advocacy strategies for young parents and training peripheral health care workers in using the same. The project aims to create greater understanding among young parents on pregnancy and HIV and increase uptake of PPTCT services.

PPTCT staff will link PLHIV to CSCs in their districts, CSC staff will follow up pregnant women in districts without PPTCT outreach. SACS mainstream division will train doctors based on resources developed by the this fund in districts where project is not working, etc. The Link Workers who were commissioned through Round 7 grant are trained in working on HIV matters and hence will be leveraged in linking the targeted interventions, key populations and vulnerable populations to services in rural areas.

Project Axshya supported by Global Fund is being implemented in 374 Districts by The Union and World Vision India (WVI), demonstrating the importance of civil society participation in supporting RNTCP. The key assets of the project in the community are engagement of 30,000 Rural Health Care (RHC) and AYUSH Providers, 1600 NGOs, 15,000 community volunteers, district TB Forums, community based sputum collection and transportation for early diagnosis and treatment. There is an increased community ownership and functional systems establishment involving NGOs and government health facilities at community level. Under NFM, non-government PRs will optimize the resources built over past project activities. The newer activities will aim to integrate with existing available resources to enhance the performance of systems built in the past to have higher returns.

The TB control programme has well exemplified these implementation efficiencies earlier through consolidation of grants under Round, 2, 4, 6 into Rolling Continuation Channel (RCC) and subsequently converged all existing grant into Single Stream funding TB (RCC+R9). The TB control programme proposes to achieve further efficiencies under

NFM by continuing high impact activities under NFM and proposing new activities that were hitherto not addressed through earlier grants or other resources.

In addition to the above, the PRs will meet specifically around this issue and map out further synergies and leveraging that is possible. The PRs plan to develop a matrix around various GF rounds and how they address geography, priority groups, staff, and facility and then arrive at a roadmap for optimising efforts and maximising returns on GF rounds. This will be carried out during the negotiation.

4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery

For both TB and HIV complete the table below for each nominated PR. For more information on Minimum Standards refer to the Concept Note Instructions.

PR 1 Name	Department of Economic Affairs Implementing Agency: Central TB Division	Sector	TB
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone crosscutting HSS grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
1. The Principal Recipient demonstrates effective management structures and planning		<p>The Central Tuberculosis Division (CTD) of the Ministry of Health and Family Welfare (MOHFW), led by the Deputy Director General (TB), manages the Revised National Tuberculosis Control Programme (RNTCP) at the central level. The Deputy Director General (TB) reports to the Director General of Health Services. A Joint Secretary (Public Health) is responsible for the programme, reporting to the Additional Secretary and Director of the National Health Mission (formerly the National Rural Health Mission) who in turn reports to the Secretary of Health and Family Welfare. CTD is organized in three divisions, each under the responsibility of an Additional Deputy Director General: (i) Programme Management, Research, Donor Coordination, and coordination with the National Health Mission (ii) Supervision, Monitoring and Evaluation, Epidemiology and Human Resource Development; Advocacy & Communication; Partnerships and (iii) Procurement & Supply Management; Finance, Contractual Manpower management. CTD focuses on policy development, technical oversight, monitoring and evaluation and capacity building. It also has responsibility national-level planning and budgeting, financial management of funds utilized at the central level and transferred to the states for RNTCP activities, central procurement of anti-TB drugs, and coordination</p>	

	<p>with external partners and other government departments. Several committees and research institutes provide technical guidance to CTD.</p> <p>CTD has a remarkable track record of successfully implementing global fund grants and consistent good ratings since 2002 in various rounds of global fund mechanism, which is a testimony to the excellent managerial capacity of the organization.</p>
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)	The PR has demonstrated effective management and oversight of the SR partners since 2002. SR management plan is also attached.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	Over a decade of experience in implementation of Global Fund Grants has enriched the programme with valuable lessons, experience and best practices. Over the years, actions on lessons learnt have lead to strengthening of internal control systems to detect early warning signs of misuse or fraud. The current financial management systems are robust and periodic external and internal audits further provide a good means of financial guidance and oversight

<p>4. The financial management system of the Principal Recipient is effective and accurate</p>	<p>The administrative and financial management structures of RNTCP are part of the National Health Mission. MOHFW and each state and union territory have entered into a memorandum of understanding for implementation of the National Health Mission, including RNTCP. At the state level, the State TB Officer in the State TB Cell is part of the National Health Mission State Programme Management Unit, reporting to the Director of Health Services and the Director of the National Health Mission in the state. The State TB officer with the support of a team oversees district level programme implementation, reviews staff training, undertakes minor procurement, prepares technical and financial reports, ensures quality control, and monitors programme indicators. In bigger states of the country, a State TB Training and Demonstration Centre supports the State TB Cell, encompassing three units: (i) training unit, (ii) supervision and monitoring unit and (iii) Intermediate Reference Laboratory (IRL) supporting the RNTCP's quality assurance system for the sputum smear microscopy network in the state.</p> <p>The PR follows high standards in financial management at different levels. It ensures that Global Fund conditions are fulfilled. The PR conducts regular periodic reviews of financial management systems of SRs and undertakes field visits to ensure that project goals are attained and guidelines are adhered to. The accounts of each district health society and state dedicated officials specializing in financial management manage health society. They are also subject to annual audits. The Comptroller and Auditor General of India conduct an audit at national level.</p>
<p>5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>There are 6 GMSD (General Medical Stores Depot) which act as National warehouses. The State drug stores are regional warehouses under the programme. CTD has developed standardized storage guidelines based on which the State Drug Stores and District Drug Stores have been upgraded. CTD has developed Standard Operating Procedures Manuals for State and District Drug Stores. The trainings are being conducted by CTD at the State level for the SDS and District level staff managing drug logistics.</p> <p>Recently, Guidelines for Storage of 2nd Line Anti-TB Drugs for RNTCP have also been finalized and disseminated to the states and districts for further implementation. This Guideline reflects the space requirements, specification for the drug store, Shelves, Racks & Storage Arrangements, stacking arrangements,</p>

	Control of Humidity and Temperature, Packing Instructions and the systems to be adopted for adequate security. These guidelines are also available at RNTCP website www.tbcindia.org .
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	A dedicated supply management agency is in place under the program for more than a decade reporting to a senior level officer. The stock and supply positions up to the peripheral level are monitored regularly through an established management information system. In addition the programme has a mechanism to continually monitor supplies and initiate prompt corrective actions. The personnel handling supplies and distributions chain national, state, district and at peripheral level are trained and equipped to handle exigencies. A provision of buffer stocks ensures that there are no disruptions on account of supplies of health products. There are also dedicated warehouses at national, state and district level for storage of health products with financial provisions to ensure transportation in time.
7. Data-collection capacity and tools are in place to monitor program performance	RNTCP has a well developed Monitoring and Evaluation strategy (document attached). The programme performance is routinely monitored through a multi-pronged approach of (1) Quarterly reporting from all Tuberculosis Units (TUs) to national level through EPI info. This is being diligently analysed and states are provided a feedback for improving performance. (2) The new real time web based software NIKSHAY is in an advanced stage and all TUs are also simultaneously reporting in this mechanism. NIKSHAY also has provision to report notification from private sector, laboratories among others. Over time this will also enable programme to follow individual patients for enhanced public health outcomes.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	A fully functional routine reporting system is already in place. Each peripheral health institute (PHI) submits a monthly report to TU. TU consolidates monthly reports of all PHIs reporting to it and transmits a report every quarter to the district. The district further transmits quarterly report to state and national level. The state consolidates all district quarterly reports and shares the same at national level. All this data is being routinely validated for its accuracy and CTD also provides quarterly feedback to states on their program performance.
9. Implementers have capacity to comply with quality requirements and	The Procurement, Supply & Logistics Unit in the Central TB Division (CTD) fulfils the procurement and supply

to monitor product quality throughout the in-country supply chain		chain management functions at the central level. The unit is under the supervision of an Additional Deputy Director General. The inbuilt safeguards of product quality through mechanism of formulations of technical specifications by an expert committee, floatation's of bids to vendors who fulfil mandatory qualification criteria to comply with quality, the pre-dispatch inspection of products, a certificate of quality assurance from an authorized laboratory ensures that products meet the specified quality criteria. Further to ensure that products meet the quality parameters during their use at decentralized level during their shelf life, random quality testing of drugs from the field through a certified quality assurance laboratory is an additional safeguard under the programme.	
PR 2 Name	The Union	Sector	TB
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a crosscutting health system strengthening grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
1. The Principal Recipient demonstrates effective management structures and planning		The Union has established a Project Management Unit (PMU) with adequate technical, financial and administrative capacity. The PMU is managing the current grant coordinating with 8 Sub-recipient partners working in 300 districts across 21 states. The PMU ensures adequate planning and timely implementation of project activities which is demonstrated by the continued achievement of 'A' rating	
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)		The PR has demonstrated effective management and oversight of the SR partners working in 300 districts over the last 4 years.	

3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	The Union has a robust internal control mechanism to prevent and detect misuse or fraud at various levels. This is ensured through benchmarks for the PR and SRs detailed in the technical, financial and operational guidelines and regular monitoring of the project activities.
4. The financial management system of the Principal Recipient is effective and accurate	The PR follows high standards in financial management at different levels. It ensures that Global Fund conditions are fulfilled at all levels. PR conducts regular periodic reviews of financial management systems of SRs and undertakes regular field visits to ensure that project goals are attained and guidelines are adhered to.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	Not applicable as The Union will not be procuring any drugs or consumables under the grant.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/me disruptions	There is no distribution/transportation of drugs and consumables planned in the grant. However the project will transport sputum specimens to the microscopy centres for which adequate transportation mechanisms have been established under the existing grant. These will be further strengthened for improving efficiency.
7. Data-collection capacity and tools are in place to monitor program performance	The PR has developed an in-house web based tool to monitor the programme performance at all levels in real time. Project staff have been oriented on these tools and provided guidelines. PR and SRs are experienced in Strategic Information (SI) management.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Project activities are being reported to PMU by SRs on quarterly basis. The performance of the project being reviewed with project managers of SRs on quarterly basis apart from routine field visits by PMU.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	PR and SRs have the capacity to ensure that project activities are implemented in a quality manner.

PR3 Name	World Vision India	Sector	TB
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a crosscutting health system strengthening grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Minimum Standards	CCM assessment
10. The Principal Recipient demonstrates effective management structures and planning	<p>The PR has a PMU (Project Management Unit) led by a Project Director who is further assisted by one Technical Advisor, one Finance Manager and one M&E Manager to provide the overall administrative, managerial and technical directions to the project along with its regular review, monitoring and supervision. Besides, the PMU has three more Finance Officer and one more M&E Officer to carry out programmatic and financial monitoring sub-recipient wise. PMU is further assisted and guided time to time by WVI's National Office located in Chennai. PMU functions as per a specific plan that each PMU members has to develop on regular fashion in consultation with the Project Director and as per the requirements of the SR-partners.</p>
11. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	<p>The PR has developed the following systems for the effective management and oversight of the SRs :</p> <ul style="list-style-type: none"> • Planned field-visits by PMU members for direct supervision and monitoring of the project activities and data verification, providing feedback to SRs and recommendations for betterment with regular follow-up. • On-job and on-site training of the SR/SSR partners for on-the-spot rectification of the emerging issues • Review of the quarterly reports and other reports (both programmatic and financial) submitted by the SRs, giving feedback and follow-up • Rolled out Standard-Operating-Procedures (SoPs) for standardization in project implementation, monitoring and financial management across the SRs • Conducting central level SR-review meetings quarterly-basis for the review of the project • Capacity building of the SR-partners on various aspects of the project and updating of the newer developments in the TB control and care • Under-taking administrative actions when required and streamlining the discrepancies.
12. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	<p>The internal control system developed by the PR to prevent and detect misuse or fraud comprises the following activities:</p> <p>(I) Cross-checking of the vouchers, bills and related financial documents with programmatic plans and activities; any mismatch found is clarified immediately from the</p>

	<p>respective SR/SSR</p> <p>(ii) Stringent data verification in the field which compulsorily includes verification at the beneficiary level to know the extent of benefit provided by the project to them</p> <p>(iii) Administrative actions directly against SR-level project staff and SSRs in case of the slightest financial irregularities detected</p> <p>(iv) SoPs as mentioned earlier guides the PR to detect financial mismatch with the already implemented activities by SR/SSRs in the field as implementation of every activity under the project is monitoring by following the guidelines adopted in the SoPs. The SoPs have been developed to ensure standardized</p> <p>(v) Implementation of the activities across the project.</p>
<p>13. The financial management system of the Principal Recipient is effective and accurate</p>	<p>The project has developed following financial management system:</p> <p>(I) FPMS software for de-centralized data recording</p> <p>(ii) Monitoring visits by the PMU finance team for data verification and validation</p> <p>(iii) SoP finance is utilized for cross-checking if policy and procedures are being followed by the SRs/SSRs</p> <p>(iv) Analysis of quarterly financial reports</p>
<p>14. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>Not applicable as the PR doesn't deal with health products of any kind in the project.</p>
<p>15. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions</p>	<p>Not applicable as the PR doesn't deal with health products of any kind in the project.</p>
<p>16. Data-collection capacity and tools are in place to monitor program performance</p>	<p>The following system has been built in the project for data collection and monitor project performance :</p> <p>Baseline database: All the districts (currently 74) have 5 district-level registers kept under the custody of the respective District-Coordinators of the SRs. These registers document detailed accounts of the every project-level</p>

	<p>activity performed at the district/sub-district level on behalf of the project in the standardized templates provided by the PR. These registers constitute the baseline database of the project. Similar registers are maintained by the Project Managers of the SRs to record the state-level activities. These registers are regularly checked by the PMU members on field-visit for accurateness, verification and updating</p>
<p>17. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately</p>	<p>Reporting system: Reports are developed compiling the data registered in the registers in the standardized reporting formats supplied by the PR. Following is the flow of reporting of the project:</p> <p>SSR (Sub Sub Recipient) to DC (District Coordinator) on monthly basis</p> <p>↓</p> <p>DC to Project Manager of the SR on quarterly basis</p> <p>↓Project Manager to PMU on quarterly basis</p> <p>A strict timeliness is maintained across the project to ensure timely reporting. Clarification is asked for delayed reporting and documented.</p> <p>Moreover the progress reports along with project action plans are shared with the RNTCP program managers like DTOs and STOs on quarterly basis. PMU also shares progress reports with CTD in the same fashion.</p> <p>The project is also reviewed by RNTCP through the Central Internal Evaluation of RNTCP and National Coordination Committee of the TB-grant PRs.</p> <p>Feedback systems:</p> <p>Feedbacks are routinely provided under the following situations:</p> <ul style="list-style-type: none"> • After any field visit • Review of the reports • Review of records • Meetings with SRs/SSRs • Interaction with community in the field • Meetings with RNTCP-staff • Recommendations given in the feedbacks are followed up on regular fashion.
<p>18. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain</p>	<p>Not applicable as the PR does not deal with health products of any kind in the project.</p>

PR 4 Name	Department of Economic Affairs Implementing Agency: Department of AIDS Control (DAC)	Sector	HIV/AIDS
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone crosscutting HSS grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
19. The Principal Recipient demonstrates effective management structures and planning		Department of AIDS Control, Ministry of Health and Family Welfare, Government of India provides leadership to HIV/AIDS control in India through 35 State AIDS Control Societies (SACS) which will be the main sub recipient. Secretary to the Government of India heads Department of AIDS Control. For administrative and non-technical divisions, officers of the rank of Joint Secretary, Director Finance, one Deputy Secretary and a number of Under Secretaries, who are officers with several years of managerial/administrative experience, are deputed. In addition, there are Deputy Director Generals, Assistant Director Generals and Joint Director (IEC) for technical divisions. Further, experts from relevant fields support DAC managerially and technically. DAC's remarkable track record of successfully implementing global fund grants from five rounds is a testimony to the excellent techno-managerial capacity of the organization.	
20. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)		SR management plan is attached	
21. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud		Being in the third year of implementation of this grant and programme, several lessons have been learnt and mid-course corrections made. The current financial management systems are robust and periodic external and internal audits further provide a good means of financial guidance and oversight.	

<p>22. The financial management system of the Principal Recipient is effective and accurate</p>	<p>Under NACP, expenditure is incurred at national, state (SACS) and field levels (at government health facilities where ART Centres & SACs are located). The spending at the national level is aimed at central procurement of goods and services and is appropriately captured in national budget of the Ministry of Health & Family Welfare. Release of funds to states is also captured there.</p> <p>NACP is implementing self- devised Computerized Project Financial Management System (CPFMS) to capture the project accounts. Receipt of central funds by states is captured on CPFMS as well as releases to field units (govt. hospitals and health care delivery points) for expenditure in the field. Detailed line items of each activity are available on CPFMS for capturing expenditure under each component.</p>
<p>23. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>DAC does not maintain any Central Warehousing. The supplies centrally procured are directly supplied to the Consignees i.e. State AIDS Control Societies (SACS). At the state level, the SACS maintain warehouses complying to good storage practices to ensure adequate condition, integrity and security of health products. Designated Store Officers are appointed in each SACS for ensuring maintenance, supervision, monitoring and efficient supply chain management systems. The Standard Operating Procedures (SOPs) for storage, distribution, monitoring and reporting are prescribed as part of the Operational Guidelines.</p>
<p>24. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions</p>	<p>The supplies of commodities are delivered at stores of SACS and are then further distributed to service facilities, based on their consumption patterns in such a manner that the facilities should have at least 3 months stock in hand at any point of time. The facilities send reports of availability of commodities to SACS on monthly basis. The SACS Officers in turn compile these reports & send it to DAC. The state officers with the support of Regional / District officers monitor the stock position at commodities to ensure that there is no stock out /expiry. The Logistics Coordinators and Assistant Logistics Coordinator at DAC monitor the stock position at SACS level as well as facilities to ensure that there is no stock out /expiry. The short expiry drugs/kits are transferred from one place to another place based on consumption and future needs.</p>

25. Data-collection capacity and tools are in place to monitor program performance		The Central monitoring and Information system has been used so far as the mechanism to report on key activities by the states. Since 2010, an improved system called Strategic Information and management system has been designed and is being implemented in a phased plan. This has been a challenge given the geographical diversity and the health system status of the country. However, the programme has managed to scale up significantly and will further strengthen the M&E systems to ensure correct, consistent and complete data.	
26. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately		As explained above, significant scaling up under the programme has managed to further strengthen the M&E systems to ensure availability of accurate, consistent and complete data sets.	
27. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		The PR is comprehensively responsible for ensuring that the products being purchased under the Global Fund financing meet requirements under the GFATM's "Quality Assurance Policy" .	
PR 5 Name	Plan India	Sector	HIV/AIDS
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a crosscutting health system strengthening grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
28. The Principal Recipient demonstrates effective management structures and planning		A Country Management Team (CMT) under the leadership of the Executive Director manages the operations of Plan India. The members CMT are Directors in charge of Programs, Strategy, Administration, Finance, Grant management and Human Resources. Plan India has team of Technical Advisors including Health, Early Childhood Care Development (ECCD), Child Protection, Household and Economic Security (HES), Water and Sanitation Advisor (WASH) as well as a number of mid-level management staff for areas of field operation, research, administration, financial management, logistics, and ICT. The Country team is also composed of internal auditors. Eleven decentralized state offices headed by State Managers handle Plan India's field operations. These state Managers are	

	<p>responsible for day-to-day program implementation through the grass root level NGO partners. The Plan India has an annual program planning cycle and a 5-year strategic planning cycle. The annual plan cycle is a part of the 5-year program cycle. The annual program cycle is developed in consultation with the SR's, key stakeholders and the beneficiaries and then approved at the appropriate authority level and signed out in the form of Program Outlines.</p>
<p>29. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)</p>	<p>The Operational model of Plan India is based on the concept of decentralized functioning where the field level implementation is pitched in by the field level NGO partners also called as SR's. The systems and procedures for monitoring and reporting have been developed by keeping in mind this model of working with SR's and SSR's. The authority levels have also been devolved in the similar manner and complete automated systems have been placed at strategic locations to capture data on implementation to generate reports and activate an online monitoring system called PPM (Program and Project Model).</p>
<p>30. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</p>	<p>Plan India employs Internal Auditors to assure the transparency and conformity of day-to-day operations. Additional auditors may be employed if there is a demand generated by a large volume of grants. Furthermore, an internal audit team is based at the global associates of Plan India that are also level of Plan's International Headquarters with staff at each Regional Office. The team visits Plan India every 12 months to verify adherence to organizational policies and procedures in all records, programs and transactions.</p> <p>An international audit firm contracted through competitive tender audits the operations of Plan India annually. Additional external audits are commissioned for individual grants as specified in the grant agreement. Plan India assures in its agreements with implementing partners that these organizations meet the same stringent audit standards.</p>
<p>31. The financial management system of the Principal Recipient is effective and accurate</p>	<p>A team of 18 regular staff members, headed by the Director – Finance and Operation, manages plan India's finance department. The finance staffs are</p>

based both at the Country Office and state office while the SR's have their own Finance staff.

All financial transactions are recorded daily in the General Ledger (GL) accounting software. The system allows all departments to automatically generate real-time reports and analyses that can act as basis for planning, budgeting and for producing financial reports by project and by department. GL has various levels of access to ensure sufficient segregation of tasks: recording, control, consolidation and reporting. An accounts assistant on the basis of approved supporting documents that are posted in the system after verification by the GL Accountant and the Accounts Manager makes all accounting entries.

The financial accounting system of Plan India has a long history of competent management of grants by a number of international donor agencies. A number of grants involved the signing of sub-recipient agreements. In these cases, Plan India provides sub-recipients with start-up workshops and intensive coaching and mentoring to ensure efficient grant disbursements and to manage identified financial risks. For the financial management of large grants, Plan India establishes separate finance and accounting teams reporting to the Director –Finance and Operations. This approach has been successfully implemented by Plan Country Offices in many countries for the financial administration of Global Fund grants.

To ensure good quality and timeliness of financial deliverables, Plan India has at its disposal the relevant instruments, tools and software. These combined with sound expertise, account for excellent credentials for a rigorous management of finances and more specifically, of cash flow. The cash flow monitoring goes beyond the level of Plan India as each program/project has a cash flow schedule that is equally tracked at the level of Global and regional level. And in the framework of the donor's requirement, Plan India is flexible in adopting its systems and procedures for a particular program to ensure timely disbursement of funds to local grantees and beneficiaries as necessary, purchase of materials, equipment and supplies, recruitment of

	project staff and timely implementation of all activities.
32. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	Not applicable as the PR doesn't deal with health products of any kind in the project.
33. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
34. Data-collection capacity and tools are in place to monitor program performance	<p>Plan India utilizes an established system of grants administration and monitoring, which guarantees a sound and rigorous tracking of project outputs and expenditures. Plan India implements a monitoring and evaluation system known as Program Accountability and Learning System (PALS) under the direction of monitoring and evaluation officers at the Country Office and in each of its Program Unit offices. PALS use a participatory approach to assure the accountability of programs to both the beneficiaries and to the financial donors. Monitoring focuses on the quality of services provided and on the changes in the lives of children and communities achieved. One of the PALS tools is the software-based Program and Projects Module (PPM) that concurrently monitors programs and finances to generate reports relating outputs to expenditures, planned versus actual implementation and reasons for variances.</p> <p>Mid-term and final evaluations of Plan India's programs and strategies are an integral part of the regular program cycle. In addition, evaluations of grant-funded programs and projects are implemented according to the grant contribution agreement. Most of the operational research conducted by Plan India over the last years has been in the context of regional Plan research projects on adolescent sexuality and reproductive health, violence against children, birth registration and other global thematic areas of Plan's work.</p>

	<p>Plan India has invested extensively in its ICT infrastructure. The Country Office and three regional hubs managing 11 Program Unit offices are fully networked with 24-hour internet access. Each office has a domain and a security server. Full-time ICT user support is available at each office. Some of Plan's corporate information systems, as for instance the General Ledger accounting system, are web-based so that they can be accessed at all times by all Plan Departments worldwide. Security of all data is maintained through user access rights and passwords.</p>
<p>35. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately</p>	<p>The Project reporting in Plan India is done on key activities and milestones.</p> <p>Standard monitoring information that all projects must collect includes:</p> <ul style="list-style-type: none"> • Project implementation progress. • Budget versus actual. • Output delivery. • Output location. <p>'Project implementation progress' report focuses on the quality of the project's processes and outputs viewed from the perspectives of different stakeholders. The report highlights the project's adherence to Plan's values and its contribution to PU Programme Objectives. The project progress log (a project diary) provides an opportunity to record this information in the Plan India's in built software called as Program and Projects Module (PPM) management information system. A project completion report (PCR) is prepared by the Plan project point person in consultation with the stakeholders involved, at the end of each assignment. The report highlights strengths and weaknesses of the project process and results (including its contribution to PU Programme Objectives) and identifies any lessons learned and recommendations for future work doing similar projects or following similar approaches. The report also details planned vs. actual (budget, output, location, community/partner contribution) and provides an explanation for significant variances. A key input to the PCR is information recorded in the project progress log. The periodicity of the report is donor dependent and a report scheduler is prepared at the beginning of the grant and a reminder system</p>

		is set to inform the implementing staff of the due date of the reports.	
36. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		Plan India has a Procurement Policy to guide the procurement of goods and services. Processes for bids and tenders are clearly outlined based on their value. Finance and Admin division jointly along with the Purchase Committee (PC) that has members from different departments provide oversight for the policy. The Quality Assurance Team, with a team of Internal Auditors is responsible for verification. Each year, the PC is reconstituted and the members are trained in the procedures and systems involved in the procurement of assets and services within the organization. For large grants, Plan India recruits the appropriate number of procurement and logistics specialists as members of the grant management team. The procurement experience of Plan as a Global Fund Principal Recipient can also be mobilized to support procurement under a potential Global Fund contract in India.	
PR 6 Name	SAATHII	Sector	HIV/AIDS
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a crosscutting health system strengthening grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (but has been SR for two GFATM grants)	
Minimum Standards		CCM assessment	
37. The Principal Recipient demonstrates effective management structures and planning		A Board of Trustees (Boot), Management Committee (MC) at organizational level and Local Management Committee (LMC) at office level governs SAATHII. The Boot comprises of experts from the field of HIV/AIDS, corporate governance, human rights, education and development. The MC which comprises of the president, two country directors and three associate directors is responsible for implementing policy decisions taken by the Booth MC is also responsible for overall coordination of programs, administration and finances of the organization. Towards this, MC conducts monthly programmatic and administrative reviews and addresses grievances put forward by employees and volunteers. At the beginning of every financial year, the Management Committee (MC) undertakes an annual	

	<p>administrative, financial and programme planning exercise in consultation with the Trustees, and relevant Consultants, Advisors and Employees across all city offices. The plan identifies major expenses anticipated in relation to administration, programmatic and in-house capacity building activities. This information is used for preparing a tentative budget as part of the annual plan of the organization.</p> <p>As a result of long-term staff retention and involvement, SAATHII has the second generation of leaders in place. There is considerable range in individual skills among the various tiers of staff in the organization. The skills and experience of the staff can be classified as: technical expertise and experience in gender, sexuality, reproductive health, HIV/AIDS and STI prevention, care, support and treatment, managerial and directorial skills, procurement and finance control, monitoring and evaluation, and research and documentation.</p> <p>SAATHII's organization systems and governance practices are documented in its comprehensive Administrative-Finance-HR policy manual and have formed the basis of successful comprehensive systems audits for pre-grant for two Global Fund grants, two evaluations by NACO, and program-specific audits conducted by such consultancies as KPMG and PWC.</p> <p>Project management and planning have helped SAATHII grow its staff strength from 17 to 111, portfolio of grants from 4 to 54, offices from 2 to 9, and grant award amounts from USD 11, 933 to USD 1.31 million the last 12 years</p>
<p>38. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)</p>	<p>SAATHII's partner profile has grown over the past 12 years to encompass over 75 as of date. These include NGOs, community based organizations and networks of PLHIV, private sector healthcare providers, in addition to non-funding relationships with professional medical associations and government departments. of 2014, almost 100% of SAATHII's project deliverables are partnership driven and partner agency dependent. Of direct relevance to the proposed project, SAATHII works with four state partners in private sector PPTCT, and more than 1000 private hospitals who provided counselling and treatment to pregnant women and report data to the National AIDS Control Programme and to SAATHII.</p> <p>Thus, a core competency is partner management,</p>

	<p>which includes partner capacity building, criteria for partner selection, partnership renewal and visibility actions that are in line with government protocols.</p> <p>Existing Project Management and MIS systems provide templates for developing systems and tools for the proposed project. Key Management Systems consist of processes, SOPs, Guidelines, templates, check-lists and tools that enable the adherence, timeliness, data collection, reporting and flagging of program activities, partners, organizations and situations, including anticipating and responding to adverse events. Besides providing an ability to comply with all the mandated and agreed reports and documentation, Management Systems provide an ability to forecast and manage resources, budget and people processes.</p> <p>Key instruments used for effective management and oversight of partner organizations (sub-recipients) include: (I) Checklists, periodic, comprehensive and in-depth reviews are used to ensure timeliness, quality assurance, compliance with goals and milestones, early warnings on issues and deviations from plan (ii) Besides routine monitoring and process evaluation, mentorship, experience-sharing and review forums are integral parts of SAATHII's management approach. During these, development and revision of shared vision and goal for upcoming years are reviewed and modified as needed, and sharing of learning conducted to enable achievement towards the shared goals, (iii) Partner specific (sub-recipient) quarterly financial audits (internal) and annual statutory audits are part of the financial management. In addition comprehensive project-specific systems and process-wide audits are conducted periodically as part of the M&E</p>
<p>39. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</p>	<p>Internal control systems include a system of multiple signatories on cheques and other instruments, interim audits and statutory annual audits, procurement systems designed to ensure objectivity, rigorous approval systems for payments, centralized banking operations. The same standards apply to grantees.</p> <p>Given the nature of SAATHII's work, several of its projects require collaborations or partnerships with civil society organizations (CSOs) of varying nature. These collaborations involve provision of micro- to large sub-grants to these CSOs, which include both Non-governmental Organizations (NGOs) and</p>

	<p>Community-based Organizations (CBOs).</p> <p>Financial management of partners is carried out as per the statutory requirements of the country and in accordance with SAATHII's financial policy and Sub-granting management procedures. SAATHII ensures that sub-grant funds are released as per agreement terms and conditions. Funds are released on submission of detailed forecasts (with explanations), periodic financial reports, related accounting documents, and progress report of the program. The release of second instalment is based on satisfactory performance at the first quarter. The systems set forth in the financial and accounting policy and the partner capacity build on the same, the periodic financial reports, periodic partner visits and evidence verification is geared towards preventing or detecting misuse of fraud.</p>
<p>40. The financial management system of the Principal Recipient is effective and accurate</p>	<p>SAATHII has a cash-based accounting system that correctly and promptly records all transactions and balances making clear reference to the budget and work plan of the grant agreement. Account payee cheques pay all the payments above INR 5000. More than one individual signs banking instruments. Separate set of books of account maintained for each project and centralized banking and funder management system is in place. All the payment vouchers and receipts are recorded within one week of the transaction and standard vouchering process is followed. Monthly Bank reconciliation statement is generated and approved by the authority and included in reporting to funders. SAATHII adopted internal auditing systems from the financial year 2008-09. The internal auditing committee comprising of selected finance staff with defined scope of auditing carries out the internal auditing. Regular financial reviews are held at branch offices and at central office. The Finance Head (FH) of each office conducts accounts and financial review, including program-finance variance analysis, once in a month before sending MIS. This includes verification of vouchers, supporting documents, Trial Balances and ledger. Details of these procedures are available in the financial and accounting policies document of SAATHII. Financial systems and controls have been scrutinized and have passed pre-grant and program audits by external consultants and auditors of acting on behalf of Government of India, bilateral and private foundation donors.</p>

<p>41. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>Not applicable as the PR doesn't deal with health products of any kind in the project.</p>
<p>42. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions</p>	<p>Not applicable as the PR doesn't deal with health products of any kind in the project.</p>
<p>43. Data-collection capacity and tools are in place to monitor program performance</p>	<p>SAATHII has experience managing multi-state, multi-year, multi-partner projects. Each project has its Monitoring and Evaluation (M&E) framework that spells out indicators, means of verification and validation processes. In case of projects where SAATHII is the PR, we develop the M&E framework. For instance, SAATHII has developed a comprehensive MIS system in its private sector PPTCT program which collects data under various indicators and used for analysis and reporting. The data of the PPTCT program are shared with the government within the given government format. In other cases (such as the GFATM projects of which we serve as SR), we follow the framework and tools developed by the PR.</p> <p>These systems assist in systematic tracking of project course, and enable evidence-based correction. SAATHII has specific, time-bound analysis of key indicators to assess the progress made along a desired pathway within any given time frame. Project MIS systems are developed for the current projects and the Key Management Systems consist of processes, SOPs, Guidelines, templates, check-lists and tools that enable the adherence, timeliness, data collection, reporting and flagging of program activities.</p>
<p>44. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately</p>	<p>SAATHII has a systematic review and reporting mechanism for all its projects. Monthly reports are generated and shared within a specific timeframe. Quarterly narrative reports, Quarterly quantitative reports and financial reports are generated at the end of each quarter and the reports are shared with the donors and significant stakeholders. The project admin team follows up on the timely submission of these reports. SAATHII also reports in time to state and national government</p>

45. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		Not applicable as the PR doesn't deal with health products of any kind in the project.	
PR 7 Name	India HIV/AIDS Alliance	Sector	HIV/AIDS
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a crosscutting health system strengthening grant(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
46. The Principal Recipient demonstrates effective management structures and planning		PR has built an efficient team having demonstrated managerial skill to operate effectively from M&E, Program and Finance point of view. Senior Management Team of the organization efficiently guides the team.	

47. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	PR through regular monitoring visits at SRs and SSRs has established sound systems of oversight for management and operations of SRs and SSRs. Detailed analysis of quarterly reports, received from SRs, provide an important tool for strong control over the operations at SR and SSR level on regular basis.
48. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	PR has established a strong internal control system, in compliance with accounting standards and generally accepted accounting principles in India. Regular monitoring visits by finance team at SR/SSR level, coupled with periodic review by external professional accounting firm leads to prevention and early detection for misuse or fraud at SR level. This has been validated when the OIG carried out its review in 2012.
49. The financial management system of the Principal Recipient is effective and accurate	PR has established strong financial controls and management at the organization, which is regularly monitored and updated by professional finance team and reviewed by external professional accounting firm at regular intervals.
50. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	Not applicable as the PR doesn't deal with health products of any kind in the project.
51. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
52. Data-collection capacity and tools are in place to monitor program performance	Through systematic flow of data in a pre-designed reporting template from SR to PR, its analysis, interaction with SR/SSR personnel, coupled with data validation visits by PR provides efficient monitoring of program performance. The PR is also now implementing a dashboard to monitor the grant performance since early 2014.
53. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Yes, there is a routine quarterly reporting system in place from SR to PR with regard to M&E, Program and Finance
54. Implementers have capacity to comply with quality	Not applicable as the PR doesn't deal with health products of any kind in the project.

requirements and to monitor product quality throughout the in-country supply chain	
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4.4 Current or Anticipated Risks to Program Delivery and PR(s) Performance

- a. With reference to the portfolio analysis, describe any major risks in the country and implementation environment that might negatively affect the performance of the proposed interventions including external risks, PR(s) and key implementers' capacity, past and current performance issues.
- b. Describe the proposed risk mitigation measures (including technical assistance) included in the funding request.

The portfolio analysis prepared by the GF India Country Team identifies four major risks:

1. Insufficient programmatic data quality that can influence public health decisions;
2. Weaknesses in financial reporting and audit compliance that have resulted in disbursement disallowances and other financial losses to the grant programs;
3. Inadequate quality assurance of pharmaceuticals and diagnostic products that potentially contribute towards drug resistance and poor treatment outcomes; and
4. Governance and capacity issues characterized by conflicts of interest and restricted information flow.

While the CCM and the PRs take cognizance of the above findings India is NOT in full agreement with the above findings and analysis. Given below are responses to these issues:

1. Insufficient Programme Data: Both the HIV and TB Programmes in India have extensive Programme data – which includes one of world's largest HIV surveillance, extensive MIS data and studies / research. The data emerging from these are regularly used in strategizing and financial allocations. As in any programme data, there is scope for improvement and we have identified the following areas:
 - Inclusion of Private sector data
 - Review and further simplification of programme data, based on usage and a multi-level Information Needs Analysis.
 - Cloud based solutions and dashboard, which make information real time, which enhances utilization.
 - Building capacities at local levels to analyse and use information
 - To improve sharing of data between HIV and TB programmes, including interoperability of systems.
2. Weakness in financial reporting: The TB program does not have any issues regarding financial reporting. The HIV grants however have had some issues. However, we feel that our responses and actions to the comments on financial reporting and compliances, given the size of grant and complexity of the country, have been sufficient. CAG audits, combined with CSO PR audits have both been very strong inputs. HIV programme in particular has less compliance and reporting issues in general, as pointed by LFA. India CCM has identified areas for improvement and actions that are being taken including:
 - At PR (central) level, in addition to regular audit, Comptroller Auditor General now

conducts claim audit based on details of yearly sanctions issued under Global Fund the different Rounds. The claims submitted before CAG indicate specifically the total amount of sanctions, taxes and duties and net claim excluding taxes & duties. Further, backlog of unadjusted advances given to Procurement Agents has been largely cleared during the last round audit of accounts and accordingly CAG has issued audit certificate.

- For improvement at SRs level, we have modified the TORs of Internal Auditors and selection procedure has been modified. Instead of selecting Internal Auditors on least cost selection criteria, the selection of Internal Auditors has been done on Quality and Cost Based Selection criteria. Further, on Computerized Financial Management System, efforts are on going to train all the financial staff on concurrent basis.
- Regarding reconciliation of earlier funds flow. India CCM would like to submit that disallowance and the processes for it would be significantly reduced if the verification were done earlier than after 12-24 months as staff turnover and storage of information affects information flow at the SR and SSR levels.
- Taking cognizance of earlier disallowances and re-training teams to understand and avoid in future.

Progress has already been made in all the above and India CCM and the PRs are committed to making this above happen quickly and comprehensively.

3. Inadequate quality control assurance: Drugs and supplies including diagnostics are subject to a number of quality assurance systems. India CCM would like to highlight improvements and progress underway:

- DAC has been ensuring that the pharmaceuticals and diagnostic products being purchased are meeting the statutory requirements as prescribed by the National Drug Regulatory Authority (NDRA) in terms of the registration of the vendor, observance of Good Manufacturing Practices (GMP) etc. The procurement of pharmaceutical products is in accordance with the principles set out in the GF's QA policy. This includes procuring all health products manufactured in a site meeting 13485:2003 ISO standard.
- As far as HIV rapid diagnostic tests are concerned, these were procured using National Standards. When they were procured through Global Fund support, DAC had ensured adherence to the Quality Assurance policies of Global Fund. There are inbuilt internal and external quality assurance systems in place for ensuring compliance to quality standards at all levels including pre dispatch at the central level for every batch procured and post dispatch at the storage and facility levels.
- RNTCP is taking due care in ensuring quality of Anti TB drugs reaching the field for consumption by the patients, under the National Programme. For the first line drugs procured under World Bank - GoI funding, procurement of Patient Wise Boxes (Adult and Paediatric) is made from the WHO pre-qualified sources. Although the specific drug formulations (strength wise) are not WHO pre-qualified, the co-blisters or co-formulations are considered as surrogate sources, although they may be in different strengths. The Global fund supported procurement of first line drugs (patient wise boxes) is made through the ERP sources as per Global Fund policy on quality assurance of pharmaceutical products. For the procurement of second line drugs through World Bank- GoI funding, pre-dispatch testing of all batches of drugs is carried out before they are sent to the field for consumption by the patients under the programme. Global Fund supported procurement is made through Global Drug Facility (GDF) as required and recommended under Global Fund funding.

4. Governance and conflict of interests: Here, we understand that the CCM governance is being commented on and not whole national governance. India CCM was selected as one of the case studies by the GF team in 2008. CCM has constantly made improvements, including having a Col policy and implementing the same. We have also inducted PLHIV

leaders into the CCM. We propose to continue the improvements in the following areas:

- Provide induction training to new CCM members and alternates
- Revisit the COI policy, update and share with CCM members for endorsement and follow through
- Strengthening of the CCM Secretariat through additional capacitated staff
- Expression of community participation

5. Issues with Procurement and Supply management in both TB and HIV departments:

Procurement and Supply Management of both TB and HIV departments are problematic. A new line of credit of a USD 100 million for this purpose, was signed with World Bank recently, as part of this a risk assessment was carried out. This assessment referred to various issues regarding procurement and supply management including bottlenecks in supply, quality of drugs- that documented minimal risks and adequate mitigation strategies in place.⁵⁶

The HIV programme has planned and commissioned reviews and technical support to strengthen the PSM systems. This has been commissioned already and therefore beyond the scope of the proposed Global Fund investments.

The epidemiology of these diseases in India clearly depicts the need of focussed prevention initiatives for key populations. Given the situation, one expects the country to request additional funding to tackle the issue. Instead India has channelized funds from domestic sources towards prevention initiatives, considering the criticality of the issue. However under this grant there are several other activities that involve working with key populations.

In addition to the risks identified by the GF India Country Team, the PRs identify some additional risks, and mitigation methods:

A. Both HIV and TB disease programs work in relative isolation, hence the collaborative activities thus far have been transactional and have made only a beginning, as is with many other countries. The risk of not articulating a comprehensive TB/HIV program is that there would never be a true integration of services unless the implementation is comprehensive. Given this scenario, through the Global Fund investments, specific dedicated resources will now be channelized to co-locate facilities, put in much needed air borne infection control measures, strengthen community systems to facilitate comprehensive approaches and integrated response.

B. Approximately one million TB cases per year are unreported, and may remain either undiagnosed or ineffectively treated. Patients diagnosed in the private sector remain outside the awareness and reach of the program, and patients bear high costs for diagnosis and treatment that is unsupervised, unsupported, and frequently far short of national and international standards. Variable quality of treatment in the private sector drive the development of drug resistance, which endangers patients and creates a costly public health threat for the future. The private market for TB diagnostics remains chaotic and centered on inappropriate blood tests, and limited capacity exists for GOI to evaluate and approve improved new diagnostic tests. The RNTCP is engaging the private sector through the activities of Indian Medical Association and Catholic Bishops Conference of India Catholic Association for Rural Development as part of the GF grant SR. The program

⁵⁶ The TB program can provide this assessment report if the Global Fund requires

has also planned to identify and implement appropriate strategies for involving the private sector as per the NSP 2012 - 2017.

C. Government of India has not articulated a clear Public Private Partnership Policy within the Health Ministry. There is also deep distrust between Government and Private players. Despite a vibrant private sector, collaboration has been limited due to the above factors. However, both programmes have been working on improving this area of work by developing policies, trying pilots, working with and through partners who have capacities to deal with Private sector and improving collaboration with Civil Society.

D. Though engagement civil society has been strong, the current environment of shrinking aid, and the disappearance of the erstwhile platforms of intense CSO engagement at the national level and in varying degree at the regional, state and district levels compound the lack of voice response and equity focused discourse, planning, design and monitoring. In addition to this, recent issues surrounding financial misappropriation of a national network of positive people, which was investigated by the Office of the Inspector General, set back the PLHIV movement. A revival of the movement has been seen and the India CCM is working closely with various stakeholders, particularly UNAIDS to get more momentum in this area.

E. For PPTCT there are particular risks, with regard to private health sector involvement- the board members of professional medical associations change on annual basis and hence their involvement on an annual basis at national, state and district levels will affect the involvement as it needs reorientation to new board members (2) government policies on regulating private health sector and their reporting is key to eliminate paediatric HIV, as just establishing PPP sites will increase the detection rates but will not lead us to elimination (3) even after policy change in mandatory reporting, it will take time for entire private sector to report data and hence there are expected delays. Risk mitigation strategies include closely engaging with new leaders and continuous and consistent advocacy on what is required for India to address both TB and HIV.

There are currently plans for technical support, supportive supervision mechanism, learning and sharing as performance enhancers and risk mitigation strategies to be proposed in the implementation New Funding Model Concept Note.