

15th September, 2015

Sh. J. P. Nadda
Minister of Health & Family Welfare
Nirman Bhawan, C-Wing
New Delhi- 110001

Re: TB case detection: Urgent need to scale up Rapid TB Test Machines and cartridges

Dear Sir,

We are writing as organizations, associations, and individuals working with people and communities affected by tuberculosis (TB), to **call for the immediate scale up of rapid, cartridge-based nucleic acid amplification tests (CB NAATs) to detect TB disease and rifampicin resistance.**

As you know, India has the largest burden of TB in the world, with an estimated 2.6 million people living with TB in the country, as well as a high burden drug-resistant TB (DR-TB) and TB/HIV co-infection.¹

Yet according to a recently leaked draft report from the Joint Monitoring Mission (JMM) to India, only about 60% of TB cases are currently being detected in India² – a far cry from the goal set out in the National Strategic Plan of the Revised National Tuberculosis Control Programme (RNTCP) for the early detection of 90% of all incident TB case.

Fortunately, new technologies now exist to improve detection for TB disease, DR-TB, and TB/HIV coinfection. In December 2010, the World Health Organization recommended Xpert MTB/RIF as the initial diagnostic test for detection of HIV associated TB and MDR-TB.³ This rapid test Xpert MTB/RIF simultaneously detects TB and resistance to rifampicin in just two hours, and is to date the only WHO-endorsed cartridge based nucleic acid amplification based test. Further, the Global Fund has committed funding for the procurement of GeneXpert and cartridges.

However, while India's comparatively rapid scale up of second-line drug susceptibility testing has, according to the draft report, "shown how India can rapidly accelerate the development of laboratory capacity with adequate resources and partnerships," it highlights that TB case detection is one of the biggest challenges for India, with an estimated 1 million cases undiagnosed or not notified, and ranks the probability of achieving that goal "low" if the status quo continues.⁴

Critical delays in procurement of GeneXpert Rapid TB Test Machines and cartridges

India's National Strategic Plan's goal outlines plans to scale up GeneXpert to at least 950 sites in all of India's 500 districts and medical colleges nationwide by 2017, with 300 GeneXpert sites becoming operational by end of 2015 and additional 200 sites by 2016.⁵ For this, the CTD planned to procure 300 GeneXpert machines and 780,000 cartridges through the Global Fund.

¹ World Health Organization. Global Tuberculosis Report 2014. Annex 2: Country Profiles. Geneva: WHO; 2014.

² Draft Report of the Joint TB Monitoring Mission, India, 2015. Available at: <http://www.tbonline.info/media/uploads/documents/jmmdraft2015.pdf>

³ World Health Organization. Using the Xpert MTB/RIF assay to detect pulmonary and extrapulmonary tuberculosis and rifampicin resistance in adults and children. Geneva: WHO; 2013 Available at: http://who.int/tb/laboratory/expert_group_report.pdf?ua=1

⁴ Draft Report of the Joint TB Monitoring Mission, India, 2015.

⁵ Draft Report of the Joint TB Monitoring Mission, India, 2015.

Yet, despite initiating the procurement two years ago, only 119 Xpert devices are in the program today.⁶

Under-utilization of GeneXpert MTB/RIF technology

Even these available Xpert is available remain chronically underutilized, particularly for diagnosing extra-pulmonary TB and childhood TB.^{7,8} Stockouts of Xpert cartridges, including a ten-month stock-out in Andhra Pradesh documented by the draft JMM report, contribute further to the under-use of Xpert⁹.

Lack of access for people living with HIV

The lack of access to GeneXperts is particularly worrisome for people living with HIV. While the RNTCP has done an excellent job revising the diagnostic algorithm, and in 2014 prioritized GeneXpert as the first diagnostic test for people with HIV, this policy is not being implemented. GeneXpert is only available in 84 out of 7,742 co-located integrated counselling and testing centres (ICTCs), designated microscopy centres (DMCs) and antiretroviral therapy (ART) centres. Of those with HIV and chest symptoms in 2014, only 2% received a GeneXpert test as compared to the 50% target in the National Strategic Plan.¹⁰

Without concrete action for the procurement and systematic roll out of GeneXpert and cartridges, all the planning and revising of policies are meaningless, and TB—particularly among the most vulnerable, including children and people with HIV—will remain undetected and untreated.

As such, we call on you to bring the strong political commitment and resources necessary to hasten the roll out of GeneXpert testing in India.

In particular, we reiterate the recommendations of the JMM and request CTD and the Health Ministry to:

- 1) *Immediately finalize procurement of 300 GeneXpert devices and 780,000 GeneXpert MTB/RIF cartridges through the Global Fund and proceed with implementation;*
- 2) *Ensure a sustained supply of cartridges in all facilities using GeneXpert, especially in ART centres and in districts with high HIV and MDR-TB prevalence;*
- 3) *Rapidly implement new algorithms and scale-up the use of GeneXpert to detect TB and rifampicin resistance upfront, especially in children, people with HIV, people at risk of DR-TB, and people to be evaluated for extra-pulmonary TB;*
- 4) *Scale-up second-line drug susceptibility testing capacity and DR-TB treatment capacity in parallel, to guarantee that patients with GeneXpert-identified rifampicin resistance are linked to appropriate diagnosis, treatment, and care;*
- 5) *Provide full exemption from customs duty on GeneXpert devices and cartridges to reduce the cost of procurement for CTD and the private sector.*

Thanking you in advance for your cooperation.

For further communication and to provide information on progress on the above, please contact Loon Gangte, Treasurer, Delhi Network of Positive People, e-mail: tuckchapa@gmail.com; Mob: 09871029514

⁶ Draft Report of the Joint TB Monitoring Mission, India, 2015.

⁷ Qin ZZ, Pai M, Van Gemert W, Sahu S, Ghiasi M, Creswell J. How is Xpert MTB/RIF being implemented in 22 high tuberculosis burden countries? *Eur Respir J.* 2015 Feb;45(2):549-54. doi: 10.1183/09031936.00147714.

⁸ Draft Report of the Joint TB Monitoring Mission, India, 2015.

⁹ Draft Report of the Joint TB Monitoring Mission, India, 2015.

¹⁰ Draft Report of the Joint TB Monitoring Mission, India, 2015.

Signed and endorsed by:

Organizations:

Asia Pacific Network of Positive People (APN+)
Delhi Network of Positive People (DNP+)
Coalition of People Living with HIV in India (NCPI+)
Global Coalition of TB Activists (GCTA)
Gujarat State Network of People Living with HIV/AIDS (GSNP+)
International Treatment Prepared Coalition (ITPC) – South Asia
Nagaland Users' Network, India
Network of Maharashtra People with HIV (NMP+)
Resource Group for Education and Advocacy for Community Health
Treatment Action Group, USA
Sankalp Rehabilitation Trust

Public health experts, professionals and activists:

Dr. Anant Bhan, Researcher, Global Health and Bioethics, India
Almas Shamim, Public health professional, New Delhi
Imrana Qadeer, Retired Professor, School of Social Medicine, JNU
Jagdish Patel, Peoples Training and Research Centre
Leena Menghaney, Lawyer, Public Health and Human Rights, New Delhi
Dr. Rohan Thakur, Public health professional
Shailly Gupta, Activist working with people living with HIV/TB, New Delhi
Dr. Vijaysree H.Y., Institute of Public Health, Bengaluru

Cc:

Prime Minister's Office, India

Shri Shripad Yasso Naik, Hon' Minister of State (Health & Family Welfare), India

Shri Bhanu Pratap Sharma, Secretary, Dept. of Health and Family Welfare, India

Dr. Soumya Swaminathan, Director General, Indian Council of Medical Research

Shri Anshu Prakash, Joint Secretary, Dept. of Health and Family Welfare, India

Dr. Sunil Khaparde, DDG TB-CTD

Dr. K. S. Sachdeva, Addnl. DDG TB-CTD

Dr. Arun Thapa, WHO representative to India

Dr. Perry Mwangi, Senior Fund Portfolio Manager, Global Fund

Dr. Lucica Ditiu, Executive Secretary of the Stop TB Partnership

Dr. Mario Raviglione, Director of the Global Tuberculosis Programme, World Health Organization