1,000 deaths a day:
The unbearable cost of TB in India

Report of Parliamentary Delegation
March 2007

RESULTS

The Power to End Hunger and Poverty

Report of Parliamentary Delegation March 2007

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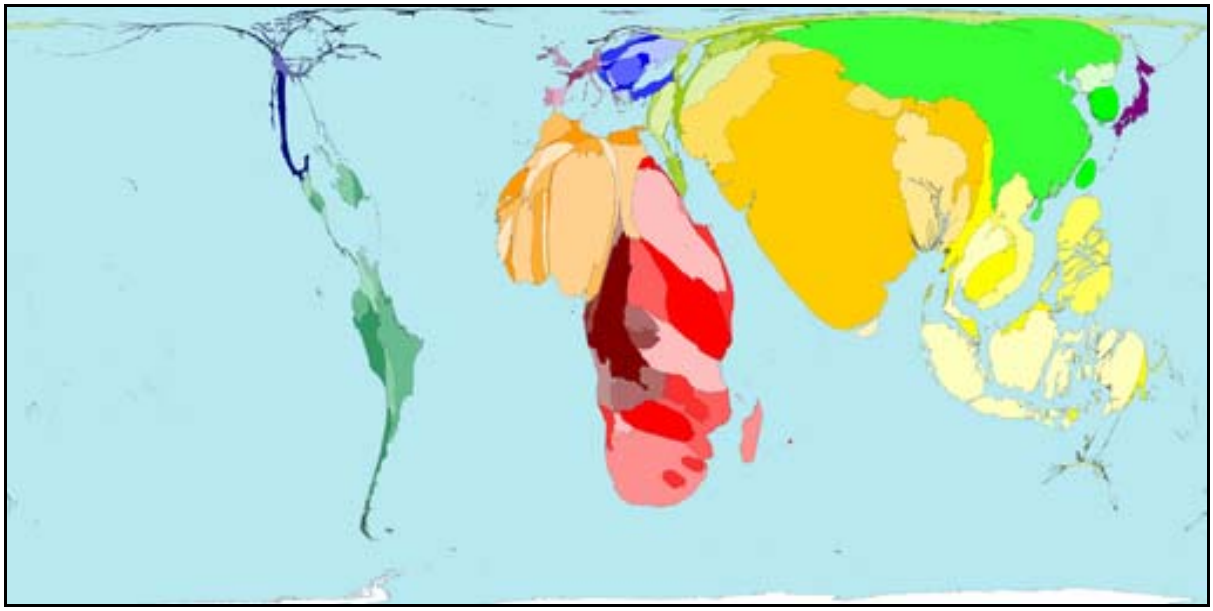
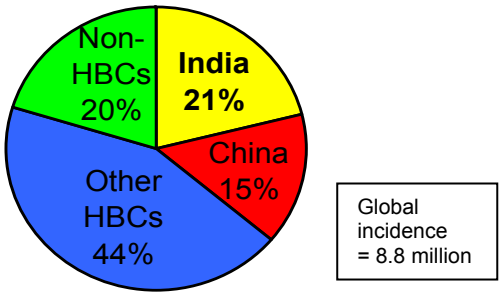
1,000 deaths a day: The unbearable cost of TB in India



Map showing each territory size adjusted according to the number of TB cases. India and sub-Saharan Africa are shown to have a disproportionately high number of TB cases. Source: worldmapper.org

TB in India: an overview

The scale of tuberculosis (TB) in India is immense. Annually, there are around 1.85 million new TB cases in India equating to one-fifth of the total global TB incidence.



Global incidence of TB showing India as the highest TB burden country (HBC).
Source: *WHO Report 2007, Global Tuberculosis Control*

Approximately 40% of the Indian population is infected with the TB bacillus of which around 10% will go on to develop the disease. Each untreated patient will go on to infect a further 10 to 15 people per year.

370,000 people in India die each year from TB – around 1,000 preventable deaths every day. Three per cent of new TB cases and around 12% of re-treatment cases are multi-drug resistant TB (MDR-TB).

TB has a huge social and economic burden on India. Almost three-quarters of TB cases are found among the most productive age group (15-54 years) resulting in more than 100 million work days lost to TB illness and 1.3 billion work days lost to TB deaths each year. The Revised National TB Control Programme (RNTCP) estimates that the indirect costs of TB to society are in the region of US$ 3 billion per year. Research carried out by the Tuberculosis Research Centre (TRC) in Chennai has also shown that malnutrition rates are higher among people with TB, exacerbating the cycle of poverty further.

UK parliamentary delegation to India

Members of the All-Party Parliamentary Group (APPG) on Global Tuberculosis were invited by advocacy organisation RESULTS UK to participate in a week-long delegation to look at the problem of TB in India. The purpose of this delegation was to give members of the APPG the opportunity to gain a fuller understanding of the range of issues and challenges relating to TB by experiencing TB control on the front line.

India was chosen because it is the country with the greatest TB burden in the world. India's TB programme is also hailed as an unprecedented success – it is the world's fastest expanding DOTS programme (see page 5), placing more than 100,000 patients on treatment every month. However the challenge of TB remains significant; more adults die from TB than any other infectious disease in India - equating to more than 1,000 lives lost every day.

The Government of India has demonstrated significant leadership in addressing its TB epidemic but emerging challenges threaten to reverse progress made in recent years. India also has the world's highest number of HIV/AIDS cases, creating a potentially deadly environment for a TB/HIV co-epidemic to accelerate the impact of both diseases further. Furthermore, the growing threats of MDR-TB and Extensively Drug-resistant TB (XDR-TB) taking hold in India mean that TB control must continue to be seen as a social and political priority both in India and internationally.

Delegates

The Parliamentary delegation was comprised of six members of the APPG on Global Tuberculosis:

Tom Clarke MP
Labour MP for Coatbridge, Chryston and Bellshill

Ann Cryer MP
Labour MP for Keighley

Nick Herbert MP
Conservative MP for Arundel and South Downs and co-Chair of the APPG on Global TB

Jeremy Hunt MP
Conservative MP for South West Surrey

Dr. Ashok Kumar MP
Labour MP for Middlesbrough South and East Cleveland

Baroness Lindsay Northover
Liberal Democrat Spokesperson on International Development in the House of Lords

Delegates were accompanied by staff from RESULTS UK and TB ACTION India.

Delegation programme

The delegation programme was designed to highlight the challenges that arise at the various stages of TB control and the role that different stakeholders are playing to address these challenges. Delegates were provided with opportunities to meet and

John Mathai (TB Action India), Ashok Kumar MP, Louise Holly (RESULTS), Tom Clarke MP, Sheila Davie (RESULTS), Ann Cryer MP, Baroness Lindsay Northover, Jeremy Hunt MP, Nick Herbert MP.

interact with a broad spectrum of individuals and organisations involved in the fight against TB – from TB patients to scientists trying to develop new drugs; health workers to politicians. Activities were organised in Delhi, Chennai and Bangalore (see map on page 9) to demonstrate the contrasts and coordination of TB control efforts across India. For the full delegation schedule see Appendix 1.

Microscope – the main tool still used for detecting TB in most parts of the world.

Diagnosis and treatment

Through visits to a variety of TB clinics, microscopy centres, community DOTS programmes and hospital wards, delegates were given the chance to see the processes and infrastructure involved in diagnosing TB and delivering treatment and to witness TB control in action. Interactions with patients and health workers allowed delegates to hear firsthand what impact TB has on the lives of individuals and the difficulties faced in trying to identify and successfully treat patients. The importance of education and awareness for increasing case detection and reducing stigma was raised throughout the delegation. Visits to voluntary counselling and testing (VCT) and antiretroviral therapy (ART) centres enabled delegates to learn more about the close links between TB and HIV. An overview of India's Revised TB Programme and its successes to date was given in Delhi by the National TB Programme Manager, Dr. L. S. Chauhan and his colleagues from the World Health Organization (WHO).

Research and development

Research into the impact of TB and the most effective way to fight the disease has been carried out in India for many decades. In Chennai, the UK delegation visited the TRC where they learned about the important role that this organisation has played in developing the TB control strategy in use today and their current research in areas such as TB/HIV co-infection. The discovery of new tools (particularly new drugs, diagnostics and vaccines) to control TB is essential for the long-term eradication of the disease. To learn more about this issue, the delegation visited AstraZeneca (AZ) who have a new facility in Bangalore dedicated to the discovery of new anti-TB drugs. Interactions throughout the delegation also reinforced the need for new and more effective diagnostic tools and a vaccine to prevent TB.

Political will

Significant progress has been made in TB control as a result of strong political support from the Government of India and assistance from the international community. In Delhi, the delegation was invited to receive a briefing from staff from the UK Department for International Development (DFID) in India about their work in partnership with the Indian Government towards the achievement of development targets and their support for the Indian TB programme (for more information about DFID India see page 8). The UK delegation also had the privilege of meeting with a group of Indian parliamentarians to discuss the role of policy-makers in the fight against TB and opportunities for further inter-parliamentary cooperation (see Appendix 2 for further details of this meeting). The APPG was extremely encouraged to hear that a new Caucus on TB was to be formed as an outcome of the meeting.

Brightly coloured poster produced by the RNTCP to inform people about the importance of practicing better hygiene in order to prevent the spread of TB.

The delegation demonstrated two sides of the TB story in India. On one hand a lot of progress has been made with TB prevalence and mortality on the decline; on the other hand the burden of TB in India is still enormous and there is a long way to go before the disease is no longer considered a public health problem. In the next section of this report, further background information is provided on the scale of the TB problem in India, the RNTCP and the role of the DFID in India. From page eight onwards, the report discusses in more detail some of the major themes and challenges that arose during the course of the delegation. The final section summarises the main findings and conclusions of the visit and looks to the future role that the APPG can play to support India in its battle against TB.

Case study:
New Delhi Municipal Council Chest Clinic

Within the New Delhi Municipal Council (NDMC) hospital there is a multi-health clinic providing a range of services including TB, VCT and maternal and child healthcare. The TB clinic, like all other district TB clinics serves a population of around 500,000 people.

A queue of patients could be seen at the front of the clinic who were either waiting to provide sputum samples for microscopy testing or returning to collect their results after two days. Waiting inside the clinic were patients there to receive their treatment. Each TB patient has his or her own box of drugs which are supplied by the Global TB Drug Facility (GDF) through a grant from DFID to the Government of India. In and around the clinic are brightly coloured posters displaying messages about the importance of practicing better hygiene – e.g. covering your mouth when coughing and not spitting – to prevent the spread of TB.

Shavana has been coming to the NDMC TB clinic for treatment for 2 months. She started to feel ill around 8 months ago but didn't visit a doctor until 2 months ago when a hospital referred her to the chest clinic for a TB test. She had not come forward for testing before because she had been looking after her sick husband rather than putting her own health first. Her daughter is currently the only wage earner in her family. Shavana feels much better already having started her TB treatment but knows that she must continue her treatment for the full 6 months to ensure that the TB goes away completely.

DOTS

The past decade has seen major progress in global TB control – mainly as a result of the development and widespread implementation of the Directly Observed Treatment Short-course (DOTS) strategy. DOTS is the internationally recommended strategy for delivering the basics of TB detection and treatment. It remains the most effective approach available for treating patients already infected with TB and preventing both new infections and the development of drug resistance. Pill taking is directly observed by a DOT provider to ensure that patients complete their treatment, thus reducing the risk of drug-resistance. A DOT provider can be anyone – a health worker, community volunteer or family member, for example – that is fully trained and acceptable to the patient.

The success of DOTS in India has contributed substantially to the success of TB control across the globe.

Community DOTS worker and patient in Jehangirpuri.

Case study:
Community DOTS programme, Delhi

Community DOTS programmes play an important role in identifying and treating TB patients in India. TB diagnosis and treatment usually requires frequent trips to a TB clinic. Patients need to provide at least three sputum samples for microscopy examination and then, once TB has been diagnosed, the patient will be required to make further return visits three times a week to a DOTS provider to take their treatment under supervision.

The opening hours of government DOTS centres are frequently incompatible with work schedules forcing poor patients to forfeit TB treatment in order not to lose wages. For many TB patients, taking time off work or away from the family home during the day to visit a clinic is simply not an option. Each DOTS centre covers approximately 5,000 people. In rural areas, people may need to travel some distance to reach their centre thus incurring additional expenses and loss of income.

Recognising the aforementioned challenges, the German Leprosy and TB Relief Association (GLRA) in partnership with the Government of India established a programme to bring DOTS to the community. GLRA has been coordinating a community DOTS programme in the slum area of Jehangirpuri in North-West Delhi for over two years. The programme was established to help residents complete their TB treatment by involving the whole community and by providing DOTS at times of the days that better suit TB patients.

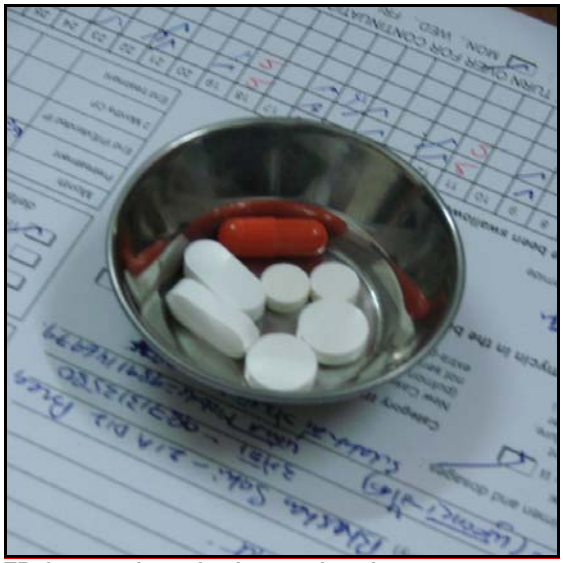
The UK delegation visited the homes of two young women who volunteer as community DOTS providers in the Jehangirpuri area. Their small homes doubled as stores for their patients' TB drugs, records and other equipment. Instead of going to a government TB clinic, patients can collect their drugs from the community worker's home as they travel to or from work. Community workers are also a source of social support to their patients and help to educate patients, their families and the wider community about TB. If a patient does not turn up to take their drugs, it is the duty of the community DOTS worker to go out and find them to ensure that they comply with their full course of treatment.

The Revised National TB Control Programme

In 1992, the Government of India launched its Revised National TB Control Programme after a review of the existing National TB Programme highlighted systematic weaknesses and poor results. At this time only 30% of TB patients were being diagnosed and, of those, only 30% were being treated successfully.

The RNTCP is an application in India of the DOTS strategy. Following the successful implementation of pilot programmes in five states, the RNTCP was rolled out as a national programme in 1997. Scaling-up was carried out in a phased manner to maintain quality of services. The RNTCP achieved full nationwide coverage of 1,114 million people in 632 districts by March 2006 and has been recognised as the fastest expansion of DOTS implementation in its history.

The RNTCP provides free, quality diagnosis by sputum microscopy through a network of laboratories across India. Drugs to treat TB are also provided free of charge and are provided in 'patient-wise' drug boxes which contain each patient's full six-month course of drugs. This initiative has considerably improved patient care, adherence to treatment, drug supply and stock management.



TB drugs and a patient's record card

Targets and achievements

A key objective of the RNTCP is to achieve the TB-related targets set by the WHO and included in the Millennium Development Goals (MDGs) for 2015 and to achieve total TB control in the longer term:

► **MDG Goal 6:** To combat HIV/AIDS, malaria and other diseases

► **Target 8:** By 2015, to have halted and begun to reverse the incidence of malaria and other major diseases

► **Indicator 23:** Between 1990 and 2015 to halve prevalence of TB disease and deaths due to TB

► **Indicator 24:** To detect 70% of new infectious cases and to successfully treat 85% of detected sputum positive patients

Achievements of the RNTCP to date include:

- 100,000 patients on treatment each month (6.7 million in total)
- Fastest DOTS expansion in the world
- 500,000 staff trained using standardised training modules
- TB/HIV collaborative activities implemented in 14 states. The number of HIV patients referred for TB services between increased by 114% rise between 2005 and 2006 (23,950 to 51,183)
- Special strategies developed for vulnerable groups e.g. tribal and urban communities; workplace DOTS services; and migratory populations

The RNTCP places great importance on properly documenting patient records. Quarterly reports are published on patient numbers and treatment outcomes. Evidence suggests that the RNTCP is having a major impact. The target to successfully treat 85% of sputum positive cases has been achieved and the target to detect 70% of new infectious cases has been narrowly missed (66%). The number of estimated TB deaths is on the decline from 500,000 per year in 2002 to 370,000 per year by the end of 2006. Further

evidence from the TRC in Chennai shows that TB prevalence rates are reducing by 9 - 11% annually suggesting that the MDG target to halve prevalence by 2015 could be attained if this trend continues.

India's TB programme is not completely vertical but part of the wider primary health system. By strengthening laboratories and drug delivery systems and by putting key staff in place who can deliver TB services plus a range of other services, the RNTCP continues to strengthen broader health systems in India.

Current financial support for the RNTCP

The resources required to implement the RNTCP over the period 2006-2011 will come from a range of bilateral and multilateral channels:

- US$ 170 million loan (2006-2010) from the World Bank to the Government of India
- US$ 62.5 million from DFID for the procurement of drugs through the GDF and US$ 13 million for technical assistance through WHO for the period 2005-2010
- US$ 64 million through grants from the Global Fund to Fight AIDS, TB and Malaria (GFATM) over three funding rounds
- US$ 6.58 million support for the State of Haryana between 03-07 from USAID
- Further resources will be provided by state governments for staff, infrastructure etc

The RNTCP programme is confident that it will have sufficient resources for its activities over the next five years provided that no new and unexpected challenges arise. The RNTCP will soon be looking to plan ahead for the next five- year period.

Challenges

The RNTCP has already begun collaborating with the National AIDS Control Programme (NACP) to address the challenges of TB/HIV co-infection. Guidelines have also been developed for the management of MDR-TB supporting the RNTCP's plans to treat more than 5,000 MDR cases over the next five years. The RNTCP recognises however that much greater effort is required to fully address the challenges of TB/HIV co-infection and MDR-TB.

The RNTCP also faces the challenge of ensuring that equitable TB services are available to all who need them in India, with a focus on those living in the poorest and most remote areas of the country, such as the States of Bihar and Uttar Pradesh. Much more needs to be done to coordinate the public and private sectors to ensure that standardised TB treatment is provided free of charge and pilot projects are being carried out to bring the private sector into the RNTCP programme.

TB patient collecting his drugs in Delhi.

A further challenge faced by the RNTCP is attracting qualified personnel to work and stay in the field of TB control. To try and counter some of these challenges, the RNTCP has developed a modular training programme. The wider health sector in India also has the added challenge of trying to retain staff and reduce the number of trained workers seeking employment in developed countries.

Ensuring long term and sustainable financial and technical support from partners will remain a challenge for the RNTCP in coming years. Even if the MDG targets on TB are met in India by 2015, TB will still pose a major problem and TB services will need to be continued until the disease is no longer a public health problem.

DFID India

DFID is the biggest bilateral donor in India. DFID India (DFIDI) currently implements DFID's largest single overseas programme contributing to poverty eradication (£253 million in 2005/06).

DFIDI works in partnership with the Government of India to achieve its national development targets and its commitment to the MDGs. Its main areas of work are health, education and rural livelihood with a focus on strengthening the public sector. DFIDI is supporting the Government of India's efforts to tackle diseases of poverty plus the growing burden of non-communicable diseases such as diabetes and heart disease. DFIDI has a national programme and four focus states: Andhra Pradesh, Madhya Pradesh, Orissa and West Bengal (see map on page 9). It is now looking at expanding its work into Bihar and Uttar Pradesh.

TB is recognised as a health and development priority by both the British and Indian Governments. DFIDI has a long history of support for TB control in the State of Andhra Pradesh, supporting the RNTCP to fight TB in that state between 1995 and 2005 (total commitment of £27.9 million). Since 2005 the programme has been continued by a grant from the GFATM and DFIDI's funding for TB now has a wider reach through support to the National Government. £41.7 million were committed in 2006 to support the procurement of TB drugs through the GDF and to provide technical support to the RNTCP through the WHO over five years.

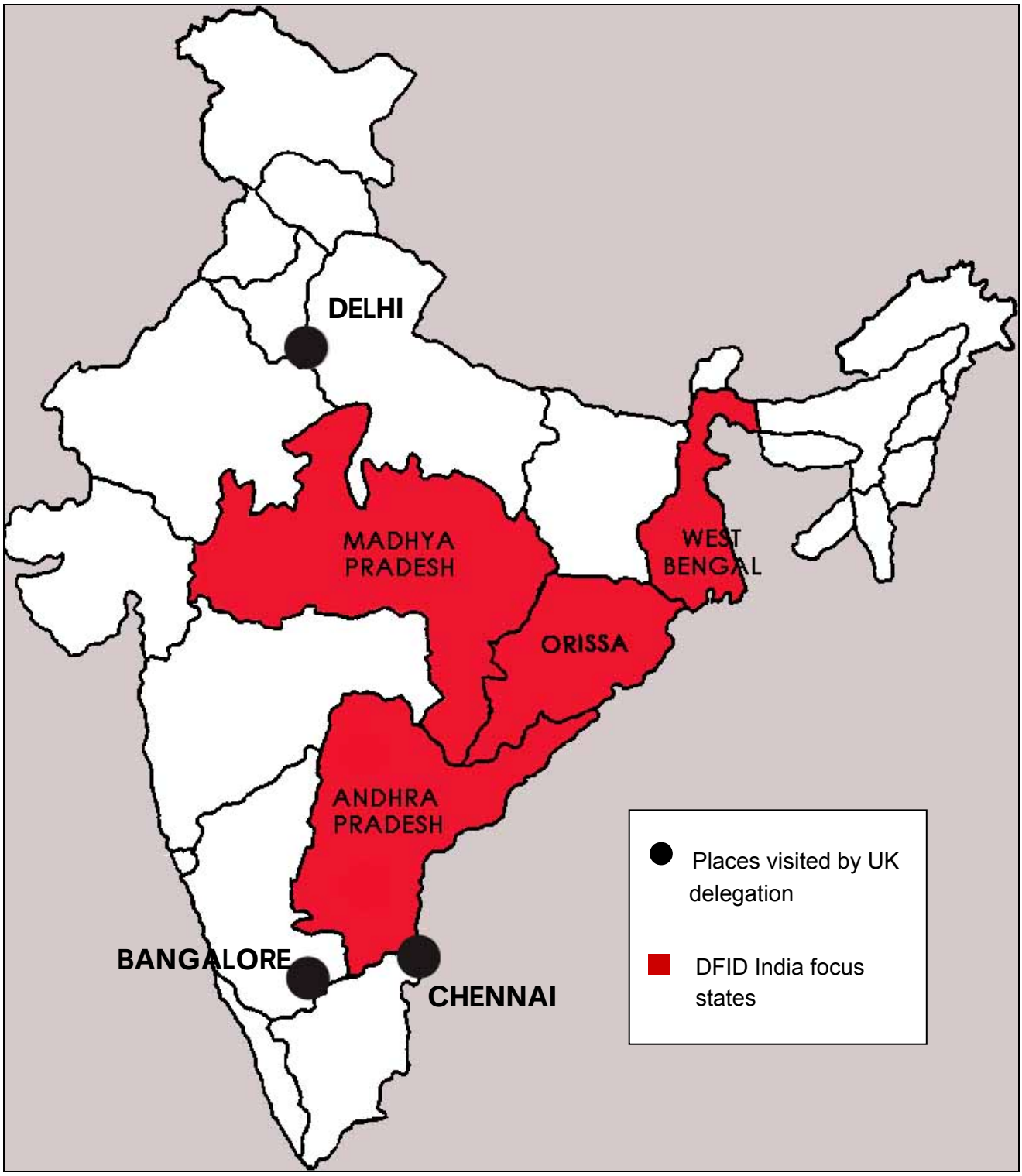
DFIDI has also supported the NACP in India for the last ten years. For the five year period 2007 to 2012, £95 million have been committed plus an additional £7 million for technical assistance. Recognising the link between TB and HIV, the NACP is developing standard TB/HIV protocols and delivers many of its components through the broader health system to enable more effective integration.

DFIDI is moving away from disease-specific support and is shifting its focus towards capacity building of Indian institutions. In its four focal states DFIDI is also supporting, or planning to support, broader health system strengthening programmes which will enable states to implement the national TB programme more effectively. By strengthening health systems, DFIDI will be helping to ensure that health workers are trained to correctly identify symptoms of TB and refer patients to TB specialists or manage TB treatment themselves if they are trained to do so properly.

At present, the RNTCP is heavily reliant on external funding and technical assistance which raises issues of sustainability. DFIDI is therefore looking to help build the capacity of the RNTCP and Indian Government as a whole in order to eventually reduce the need of foreign assistance. Beyond its current five-year commitment, DFID has not made any further commitments to India's TB programme but will continue to monitor progress towards the MDGs and the RNTCP's capacity.

DFID is exploring different ways of supporting the fight against TB in India and globally through investing in the research and development of new tools to control TB. DFID's Central Research Department in London already supports a range of Product Development Partnerships and is looking at incentive mechanisms such as Advanced Markets Commitments which will help stimulate greater interest in the development of new tools for the control of TB and other diseases of poverty.

Map of India


DELHI
MADHYA PRADESH
WEST BENGAL
ORISSA
ANDHRA PRADESH
BANGALORE
CHENNAI
Places visited by UK delegation
DFID India focus states

Key challenges

A number of common themes and challenges were highlighted during the various site visits and discussions with different stakeholders. Five key barriers were identified by the delegation that should be addressed with priority if the burden of TB in India is to be reversed.

1. Scaling up DOTS

The RNTCP has made considerable progress in expanding TB services under the DOTS strategy during its first phase and is now seeking to consolidate, maintain and improve achievements during phase two (2006-2011). Its main focus is now on widening the availability of good quality treatment and diagnostic services to all TB patients.

Baroness Northover, Tom Clarke and Ashok Kumar MPs with two community DOTS providers.

Health provision in India

The private health sector in India is an important source of care even with the availability of public health services. India has one of the largest private sectors in the world with around eight million Private Practitioners (PPs). The vast majority of expenditure on health in India (around 90%) is channelled through the private sector. Public spending on health is very low: the Government of India's target is to spend 2 - 3% of GDP on health by 2010. There is therefore chronic underinvestment in public health resulting in weak systems, staff shortages and absenteeism, fragile supply chains and poor infrastructure.

TB treatment is provided free of charge through public sector TB clinics but around half of all TB patients will access TB services through the private sector since they are not accustomed to using the public sector for other health-related matters or are simply not aware that quality TB treatment and testing is available for free elsewhere. About 88% of rural and 85% of urban patients with TB will approach a PP in the first instance. One day's TB treatment can cost as little as eight rupees (nine pence) in the private sector so it is often only the poorest people who will automatically go to a government DOTS centre because they cannot afford to buy drugs from the private sector.

There are many diverse health care facilities in India provided by different government ministries (e.g. prisons, railways, coal and steel etc) and a wide spectrum of PPs and non-governmental organisations (NGOs). All of these diverse health providers manage TB patients but a large proportion of them have not yet adopted the DOTS strategy resulting in variations in quality and treatment success rates. Only 2,200 NGOs and 14,500 PPs are currently involved in the provision of RNTCP services.

Case study:
REACH Project

The Resource Group for Education, Advocacy and Community Health (REACH) project began in 1998 in Chennai with the purpose of increasing awareness of community health issues, in particular TB.

In 2003 REACH was awarded a three year grant from the GFATM (the first given to an Indian NGO) to support the RNTCP in strengthening its model of a public-private partnership in TB control and also to support its TB advocacy work.

As a social disease with serious health, economic and social consequences, a variety of players need to be brought together in the fight against TB. REACH is working to try and bring private programmes into the National DOTS programme and to build links between different TB service providers including doctors (public and private), DOTS providers, NGOs and pharmacies who sell TB drugs over the counter. REACH runs workshops for

private practitioners to educate them about the DOTS strategy and to encourage them to work in partnership with the RNTCP.

The UK delegation was given the opportunity to visit The Hindu Employees Health and Welfare Centre in Chennai which is an establishment of *The Hindu* newspaper serving both employees and local residents. Since 1999 the centre has been working with REACH. Doctors and laboratory staff have been sensitised to the RNTCP programme and DOTS strategy and now provide free diagnosis and treatment to TB patients. Directly-observed therapy is currently provided by the centre's receptionist.

Participation of other health providers in the RNTCP is very important because of the large proportion of TB suspects and cases that they manage. The RNTCP is therefore developing Public-Private Mix (PPM) initiatives in collaboration with different public and private health care providers to bring them into the RNTCP and to make quality TB treatment and care through DOTS equitable and accessible to all.

2. TB and HIV

TB is one of the earliest opportunistic infections to develop amongst people infected with HIV. HIV weakens the immune system, increasing a person's vulnerability to TB and increasing the risk of progression from TB infection to active TB disease. Although TB can be cured among people with HIV, TB is one of the most common causes of HIV-related illnesses and deaths: globally more than 200,000 people living with HIV died from TB in 2005.

In Africa, HIV has been the key driving force behind the dramatically increased incidence of TB over the last decade. Whilst the TB epidemic in India is primarily driven by people not infected with HIV, increasing prevalence of HIV and AIDS in India creates the potential for a deadly environment in which the two diseases will fuel each other further. The WHO has estimated that around 5.2% of adult TB patients in India are HIV-positive. Conversely, around half of all opportunistic infections among people living with HIV in India are TB.

HIV in India

India has the largest number of people living with HIV in the world. UNAIDS estimates that there were 5.7 million people, or 0.91% of the adult population, living with HIV in India at the end of 2005. The majority of these people will not be aware of their HIV status.

In India, HIV prevalence is higher among men - the TRC in Chennai currently estimates that nationally around 40% of HIV cases are in women. In the NDMC Hospital in Delhi, for example, 57 out of 206 patients registered as HIV-positive were women. Heterosexual intercourse is the main source of transmission – accounting for almost 90% of infections in India – exacerbated by growing rates of infection among commercial sex workers. Other routes include blood transfusion and injecting drug use, particularly in the areas of India that border with Myanmar. Between 40,000 and 50,000 children are born with HIV each year mostly as a result of mother-to-child transmission. Approximately 57% of HIV cases are found in rural areas with Andhra Pradesh being the worst affected state. Like TB, HIV is closely linked to poverty and routes of migration.

Integrating TB and HIV control

Increasing HIV in India could have a huge impact on TB mortality rates and efforts to meet MDG targets on both TB and HIV unless more is done to tackle the two diseases in a more integrated way.

Delegates interacting with patients in a TB/HIV clinic.

The close relationship between HIV and TB has been well documented since the start of the HIV epidemic but programmes to implement collaborative TB/HIV activities in India and globally have been slow to develop.

TB and HIV programmes share mutual concerns since they often target the same patient yet have long worked in isolation from each other. Detection, prevention and treatment of HIV should be of concern for TB control programmes and, equally, TB care and prevention should be a priority for HIV and AIDS programmes.

Efforts to integrate TB and HIV services in India are being scaled up across the country. In Delhi, for example, the NDMC Hospital began their integrated TB/HIV project in 2001 which employs a system of cross-referral to ensure that every patient who comes in for VCT is encouraged to go for a TB test. HIV testing is not mandatory for patients who visit the TB clinic but counsellors will educate individuals about the links between TB and HIV and if the patient is considered to be at high risk of HIV infection they will be encouraged to visit the VCT centre for further counselling.

Case study:
Tuberculosis Research Centre, Chennai

The TRC is a leading research institution in the field of TB and the largest research centre in India. Established in 1956 with the support of UK experts Wallace Fox and Dennis Mitchison, the TRC is now a permanent institute of the Indian Council of Medical Research (ICMR). The strength of the TRC lies in its ability to identify and carefully characterise various populations of patients with tuberculosis and follow them up for periods as long as five to ten years.

In the last few years, TRC has initiated TB/HIV related studies and has established an HIV vaccine trial centre. Now 50% of TRC's current research is in field of TB/HIV. Clinical trials are being performed over five years to evaluate the effectiveness of TB isoniazid prophylaxis among 650 people with HIV. There are also a number of research projects being carried out to investigate if TB can be more successfully diagnosed in people with HIV.

TB clinics are an important entry point for identifying people with HIV and enabling them to go on to receive appropriate support and treatment. At the Lok Nayak Hospital in New Delhi, many patients are referred to the ART centre from the TB clinic and all patients are examined for signs of TB and other opportunistic infections. As the referral hospital for Northern India, many patients come to Lok Nayak for the treatment of extra-pulmonary TB which is more common in people with HIV and AIDS. Doctors from across India were participating in training courses at Lok Nayak Hospital at the time of the delegation's visits so that more ART centres can be opened throughout the country. At present there are 100 ART centres in India and it is hoped that a further 150 will be opened by 2010 to enable India to achieve Universal Access targets.

Further research is being carried out by the TRC in Chennai in the field of TB/HIV. The RNTCP recognises the need to do more to address the growing challenge of TB/HIV co-infection and is committed to scaling up joint TB/HIV activities in partnership with the NACP. This partnership has already produced positive results: the number of patients referred from HIV counselling and testing centres to RNTCP services increased by 114% between 2005 and 2006 (11 months). Integration between TB and HIV programmes must be accelerated and sustained so that growing HIV rates do not reverse the progress made by the RNTCP and unnecessary deaths among people living with HIV can be prevented.

3. MDR-TB

The emergence of strains of *Mycobacterium tuberculosis* that are resistant to standard anti-TB drugs pose an enormous challenge to TB control efforts worldwide. MDR-TB is a reflection of poor management of TB cases and is mainly due to a failure to ensure that standardised doses of TB drugs are taken for the full regimen rather than the failure of the medication to cure the disease. Once a drug-resistant strain of TB has developed it can then be transmitted on to others in the same way as 'standard' TB.

Continuous monitoring of drug-resistance trends is essential to assess the effectiveness of current interventions. A series of drug-resistance surveillance studies is being carried out in a number of states across India to provide more accurate information on the occurrence of MDR-TB. Available data from early surveys shows that 1 and 3% of new TB cases, and between 13 and 17% of

cases with a previous history of anti-TB treatment, are MDR-TB.

MDR-TB costs around 400 times more to treat than standard TB plus there are additional costs created by the need for more specialised and expensive diagnostic methods such as culture and drug-susceptibility testing. Stronger support systems are also required for MDR-TB patients who have to endure 18 to 24 months of treatment with drugs that cause more adverse side effects than first-line treatment. Most MDR-TB patients are also required to stay in hospital for the first stage of their treatment until they are no longer infectious creating both a burden on the broader health system and the patients themselves who lose income whilst they are in hospital.

Whilst the prevalence of MDR-TB is still low in India, this translates as a very large number of cases. At present, India is not fully equipped to manage all of its MDR-TB cases. Because of the duration, frequency and toxicity of MDR-TB treatment, many patients fail to complete the full course of drugs and thus the MDR cure rate in India is very low: between 50 and 60%.

Doctor wearing a mask to protect himself from MDR-TB.

The RNTCP is taking specific measures to enhance its existing programme to prevent the further spread of MDR-TB and to appropriately manage existing cases. Rolling out the DOTS strategy will help to prevent new MDR-TB cases but national guidelines have also been developed under a 'DOTS-Plus' strategy for the management of MDR-TB. DOTS-Plus promotes, for example, the timely procurement and rational use of second-line drugs to prevent more deadly strains of XDR-TB.

In early 2007, the RNTCP began to introduce second line anti-TB treatment for all MDR-TB cases. The RNTCP aims to establish a network of accredited Intermediate Reference Laboratories (IRL) for the provision of quality assured culture and drug susceptibility testing at state level. It is planned that there will be at least one IRL in the 20 largest states by 2010. The vision of the RNTCP is to provide care and management for up to 5,000 'new' MDR-TB cases per year. This will require sustained investment and commitment in order to integrate the management of MDR-TB into basic RNTCP activities alongside the continued strengthening of DOTS activities.

4. Education and stigma

In India, and in many parts of the world, lack of education and information about TB presents enormous barriers to the successful identification and treatment of TB cases. Among many communities in India there is considerable lack of awareness about the basic facts: that TB is an airborne disease which can affect anybody; that drugs are free and, most importantly, that TB is curable. In Bangalore, a group of women met by the delegation were asked if they knew what the symptoms of TB were. None of them knew. Misinformation about TB results in the stigmatisation of patients, continued transmission of the disease and many unnecessary deaths.

Fighting stigma

Street plays and other awareness activities aim to overcome numerous misconceptions and superstitions about TB. Many people believe that illness of any kind is the result of bad karma or punishment from gods or spirits and will be inclined to accept their lot rather than seek treatment. TB is also considered to be a disease of slum people (the majority of TB patients are from lower economic classes) exacerbating the feelings of shame and stigmatisation that TB patients experience in the community and workplace.

Views about the level of stigma related to TB differed among the parliamentarians and health workers met by the UK delegation. Some parliamentarians argued that there was

no longer stigma attached to TB and that everyone knew that TB was curable. Interactions with civil society, patients and TB service providers suggested that this was not the case in many parts of India.

Case study:
Street plays

A large proportion of the population in India, especially women and girls, are not educated, so a variety of tools are needed to ensure messages reach different sectors of the population. Street plays are an effective method of raising awareness of TB, particularly among poor communities who do not have televisions and radios. The GLRA works with young people in the Jehangirpuri district of Delhi to organise and perform street plays which increase awareness about TB and other issues such as HIV. Through role play, performers describe the symptoms of TB and explain that a person with those symptoms should visit a DOTS centre where they can receive testing and treatment free of charge. Audiences are told that TB is a treatable and curable disease. Street plays have helped to improve case detection rates. Before beginning their programme of street plays, GLRA carried out surveys on TB awareness and found that only 60% of the local population knew about TB. One year later, the figure had increased to 85% after street plays had been performed on a regular basis.

Increasing awareness

85% of TB in India is pulmonary. It is therefore important to detect and treat smear positive (infectious) cases as quickly as possible. Education and awareness campaigns are a key tool for informing people about how to recognise the symptoms of TB in themselves or others and to encourage them to present for testing.

Civil society has an important role to play in helping to increase awareness about TB. On World TB Day (24th March) the REACH project in Chennai distributed pamphlets and displayed banners to help raise awareness of TB. They also organised other local activities such as putting up posters in pharmacies and organising street plays. To target larger numbers of people, REACH has also involved a famous Tamil actor to produce TV spots, newspaper adverts and billboard posters. Initiatives such as these work: at a clinic in Chennai, patients told the UK delegation that they had come to the clinic because either they, or a relative, had seen a REACH poster or pamphlet.

Ann Cryer MP with a mother who had been abandoned by her husband because she had TB and HIV.

Women and TB

Women are particularly vulnerable to stigma and are more likely to ignore medical help not wanting to neglect household and family responsibilities. TB can impact the marriageability of young women so many will try to hide symptoms of illness fearing rejection by their families and in-laws. Research carried out by the TRC suggests that around 100,000 women have been thrown out of their homes because they had TB. In Chennai, the delegation met one such woman whose husband abandoned her and their two children because she was co-infected with TB and HIV. Much more needs to be done to reduce the stigma faced by women since TB among women also has major implications for child survival, economic productivity and family welfare. Children whose mothers die of TB are often found to have TB themselves.

Case study:
Sangama Centre, Bangalore

Prevalence of HIV and therefore TB and other opportunistic infections is greater among certain minority and high-risk groups. Sangama, a human rights organisation representing individuals from sexual minority groups has established a community drop-in centre in Bangalore with a grant from the Bill & Melinda Gates Foundation. A main objective of the organisation and the centre is to reduce stigma and provide support for vulnerable and oppressed minority groups.

Sangama estimates that HIV prevalence among its main constituency is as high as ten per cent. One in six clients with HIV has had TB. Sangama has therefore developed a programme to reduce the incidence of HIV and other sexually-transmitted infections through a range of outreach and awareness-raising activities. Sangama also provides care and support for people living with HIV and AIDS. The drop-in centre that the delegation visited houses its own HIV and sexually transmitted infections (STI) testing centre. Counseling and psychosocial support and HIV testing is provided through their Community-based Voluntary and Confidential Counseling and Testing Centre. Patients suspected of having TB are referred to a local government DOTS centre. The programme has reached out to at least 7,000 people in Bangalore City on a regular basis.

5. New tools

Current drugs and diagnostics can control TB if they are used correctly but it is widely acknowledged that TB will never be eliminated as a global health problem without new and more effective tools. Increasing rates of drug-resistant TB and rising TB/HIV co-infection have reinforced the need for a new approach to TB control.

The tools currently used to prevent, diagnose and treat TB are old. The Bacille Calmette-Guérin (BCG) vaccine which has been in use since the early twentieth century is only partially effective; the main diagnostic test for TB dates back to the 1880s and lacks precision, and no new anti-TB drugs have been developed since 1966. India is playing a key role in the development of new tools for TB control, particularly the discovery of new drugs.

Diagnostics

Diagnosis of TB in the majority of endemic countries, including India, is usually carried out by the examination of a patient's sputum through a microscope. Although high quality sputum smear microscopy is the cornerstone of the DOTS strategy, it has low sensitivity and can misdiagnose a large number of cases. Microscopy is also time consuming and labour intensive since laboratory technicians must be taught and trained to examine each slide thoroughly and rigorous quality control applied. Even more problematic is the correct diagnosis of TB in people with HIV and AIDS and drug susceptibility testing for MDR-TB.

The lack of accurate, robust, and rapid diagnostics impedes TB patient management and disease control. Patients are often diagnosed after weeks to months of waiting, at substantial cost to themselves, and at huge cost to society; many patients are never diagnosed at all. Research into the development of more simple, accurate and reliable diagnostic tools that can deliver fast results even in low resource settings is urgently needed. A variety of diagnostic methods are currently under development with new technologies expected to be made available within the next two years.

New drugs

The last TB drug to be developed was Rifampicin in 1966. Before this time treatment for TB was given for 18 to 24 months with two drugs. From the 1970s a 'short-course' became recommended using a combination of four drugs for six months under supervision. Attempts to shorten the treatment time further to three or four months have resulted in high relapse rates.

If completed properly, the six month regimen has extremely high success rates (95%). However, the length of treatment time and frequency of doses make it difficult for patients to complete treatment and can result in drug resistant strains of TB developing.

Ashok Kumar and TomClarkeMPs looking at TB bacillus through a microscope.

HIV and MDR-TB, plus a resurgence of TB in parts of the developed world, have led to an increase in interest in TB research and

development. Half a dozen new compounds for new TB drugs are currently being developed by a number of pharmaceutical companies but are unlikely to be available for clinical trials for at least six years. The success rate of drug development is less than ten per cent so there needs to be a number of drugs in the pipeline at the same time. Trials are also being carried out by institutions around the world, including the TRC in Chennai, to shorten or reduce the dose frequency of the existing regimen by introducing compounds such as quinolones.

Case study:
AstraZeneca

AstraZeneca (AZ) is one of the world's leading pharmaceutical companies, with a broad range of medicines designed to fight disease in different areas of healthcare. Over US$ 16 million is spent every working day on the research and development of new medicines.

AZ came to India in 1984 as a non-profit organisation and now employs 1,200 people. 100 of these work on research and development including more than 90 scientists based at a state of the art research and development facility in Bangalore, opened in 2007, dedicated to finding a new treatment for TB.

AZ decided to work on TB based on an analysis of six diseases. Looking at the global medical need, level of existing expertise and infrastructure, new science opportunities TB and malaria came out on top. TB was ultimately chosen because no new drugs had been developed for 40 years and in 2000 the complete genome for TB was made available.

AZ's objective is to develop compounds that are efficacious in the treatment of TB and that will shorten the treatment time to two months or less. AZ is committed to producing drugs that will be available at affordable prices for developing countries and hopes to have the first compound available by 2009 and candidates by 2010 to take into clinical trials as part of a Product Development Partnership.

Vaccines

A cure alone will not help to prevent people from developing TB again. Every child born in a registered facility in India is inoculated with the BCG vaccine within 72 hours of birth. However the BCG is not protective beyond adolescence and many children are born at home and will not receive the vaccination. Ultimately to eradicate TB, a new vaccine is needed. Efforts to develop a new vaccine, most likely to be delivered together with BCG, are progressing with encouraging results produced from research and field trials with early candidates.

Case study:
Aeras Global TB Vaccine Foundation

The Institute for Population Health and Clinical Research (IPHCR) based at St. John's National Academy of Health Sciences in Bangalore is working in partnership with the Aeras Global TB Vaccine Foundation to prepare clinical trials for new TB vaccine candidates in Palamaner Taluk, in Southern Andhra Pradesh.

Aeras chose India for the development of vaccine trial sites because of its sophisticated medical infrastructure and research facilities and for the high incidence of TB. The IPHCR and Aeras have designed two long-term studies to obtain information about the TB epidemic in the selected community firstly among infants and then adolescents, whilst building the skills and resources needed for a TB vaccine trial.

Aeras will be bringing as many as six candidate TB vaccines to clinical trials at their India site in the next five years. Initial trials will be relatively small (50 to 200 participants), but Phase III efficacy trials will be much larger, involving 20,000 or more participants. These larger trials will last for three years or longer.

Sputum samples in a laboratory.

Conclusion and recommendations

The delegation to India highlighted the significant progress made by the Indian Government and RNTCP with the support of a diverse range TB care providers in reducing India's TB burden. Evidence presented to the UK delegation and the testimonies of patients and health workers suggests that the new national TB control programme, based upon the DOTS strategy, is having a positive impact and is setting India on the right track to meet MDG targets on TB.

> ***"I am returning to the UK with hope about achieving MDG target 6."***
>
> Tom Clarke MP, on the significant progress being made to tackle TB in India

However, the scale of the TB problem in India is still great and mortality rates unacceptably high. A great many challenges remain to be addressed with urgency in order to prevent 370,000 unnecessary deaths each year.

The main challenges, described in more detail in the previous pages of this report, are increasing access to DOTS services, meeting the growing threats of TB/HIV and MDR-TB, fighting stigma and increasing awareness about TB and developing new TB control tools. A major concern of the delegation was that messages about TB were not being communicated widely enough and were not reaching the poorest sectors of the population, signifying that the RNTCP needs to do much more to increase basic education about the disease and to promote its services.

In addition to reducing the stigma frequently attached to TB, awareness raising activities are an important means of bringing people into the TB programme thus enabling patients to receive treatment quickly and providing early opportunities for identifying drug resistance and HIV co-infection. The RNTCP, whilst confident that it was making progress in this area, called upon the UK to support its efforts to create more cohesive awareness-raising activities particularly those targeted at marginalised groups such as tribal groups and slum dwellers.

Interactions with Indian Parliamentarians and ministry officials showed that fighting TB is given the highest level of political commitment in India. This was reinforced by the announcement of an Indian Caucus on TB at the roundtable meeting between Indian and British Parliamentarians in Delhi. This new Caucus will focus parliamentary activity around TB control and provide a platform for discussion and debate on key issues as well as a new ally for the UK APPG on Global TB.

Recommendations for further action

The purpose of the delegation to India was to give delegates the opportunity to learn about the scale of the TB problem in India in order to better inform future parliamentary activities. RESULTS has therefore asked that delegates utilise their experiences to raise awareness of the challenges of TB in India and to increase political commitment for global TB control.

Recommendations to delegates:

1. Share information gathered and lessons learned from the trip with parliamentary colleagues through informal discussions and parliamentary debates.
2. Organise a meeting with the Secretary of State for International Development to brief him on the findings of the trip.
3. Support the APPG on Global TB to campaign for TB to be made a greater political priority in the UK and internationally.
4. Continue to build relationship with new Indian Caucus on TB by inviting members of the Caucus to visit the UK to explore opportunities for collaboration and partnership further.

As the delegation heard directly from the RNTCP and staff from DFID, the UK is already playing an important role in helping India address its TB problem through building capacity in key states and providing resources and technical support for the procurement of TB drugs nationally. Ensuring long term and sustainable assistance has been identified as an upcoming challenge for the RNTCP and DFID should continue to assess how it is best placed to work with the Government of India towards the achievement of the MDGs and the eradication of TB as a public health problem in the longer term.

TB patient back at work thanks to a community DOTS provider who takes treatment to her each day.

A key objective of the APPG on Global Tuberculosis is to promote effective and sustainable solutions that will have a positive impact on meeting global TB control targets. In its recently published *Agenda for Action*, the APPG identified a number of key areas that the UK government should prioritise to take its support for global TB control to the next level. During the week spent in India, many of these areas were highlighted, reinforcing the need for action.

Recommendations to the UK Government:

1. Assess what further role the UK can play in providing long-term technical assistance to countries like India to enable them to address the growing problems of MDR-TB and TB/HIV co-infection.

2. Increase support for the development of new tools to control TB by promoting product development partnerships and advance market commitments to stimulate research in this area.

3. Support India to scale up education and awareness activities and develop a stronger public-private mix to bring other health care sectors into the DOTS strategy, reduce stigma and increase case detection and treatment rates further.

4. Replicate what has worked well in India, e.g. meeting the need for a guaranteed supply of quality TB drugs, in other parts of the world.

5. Work with the RNTCP to share lessons learned in India with other national TB programmes in order to promote best practice in TB control.

6. In the longer term, continue to evaluate UK policy towards giving aid to India. As India grows to become a middle income country, DFID will inevitably need to assess the level of development assistance it can continue to provide.

As the RNTCP noted, even if MDG targets on TB are met by 2015, it will be many decades before TB is no longer considered a public health problem in India. External assistance is still likely to be needed in the medium to long-term to successfully eradicate the disease both in India and worldwide. Furthermore, the delegation was reminded that whilst India's overall GDP is rising, this increased wealth only benefits a small proportion of the population. Many millions still live, and will continue to live, far beneath the poverty line and remain vulnerable to TB.

Appendix 1

Outline of schedule and activities

Saturday 24 March (World TB Day) - DELHI
- Visit to community DOTS centres in Jehangirpuri slum

Sunday 25 March - DELHI
- Visit to India International Centre for demonstration of street plays used to raise awareness of TB and roundtable discussion with members of Indian civil society

Monday 26 March - DELHI
- Visits to New Delhi Municipal Council (NDMC) chest clinic, microscopy and VCT centres and Lok Nayak Hospital TB clinic and ART centre
- Meeting with Dr. Chauhan, National TB Programme Manager
- Meeting with Sir Michael Arthur, British High Commissioner

Tuesday 27 March - DELHI
- Meeting with staff from DFID India office
- Roundtable meeting with Indian Parliamentarians followed by joint press briefing

Wednesday 28 March - CHENNAI
- Tour of TB Research Centre and presentations from staff
- Visits to MDR-TB and TB/HIV wards
- Visit to Hospital Andra Mahila Sabha and REACH DOTS programme

Thursday 29 March - BANGALORE
- Tour of AstraZeneca TB drug development plant including presentation on the need for new tools for TB
- Visit to St. John's Medical College and Hospital
- Visit to Sangama community centre

Friday 30 March - BANGALORE
- Visit to Grameen Koota microfinance groups and offices

Appendix 2

Meeting with Indian Parliamentarians

The UK delegation was invited to meet with six members of the Indian Medical Parliamentarians' Forum (IMPF) at a roundtable meeting co-hosted by the Rajiv Gandhi Institute for Contemporary Studies and the Center for Sustainable Health and Development.

The IMPF represents a group of around 30 Indian Parliamentarians with a background in medicine. As health providers directly involved in policy and decision-making, the IMPF's members recognise their unique position to bring about effective reform and initiate innovative activity in this sector.

Following an introduction from Dr. M. Jagannath MP, Chair of the IMPF, Dr. Bobby John from the Center for Sustainable Health and Development was invited to give an overview of the scale of the TB problem in India and acknowledged the UK APPG for its leadership in raising the political profile of the global TB problem.

Dr. Senthil MP, Convenor of the IMPF, then gave a presentation highlighting the need for both a further increase in state expenditure on health and for the private health sector to participate more in the public sector. He also commented that since independence many vertical health programmes have been developed and a more holistic approach is needed to address TB along with other health interventions. For example, the Indian Government established its Rural Health Mission in 2005 aimed at integrating different vertical programmes and decentralising health care service delivery at the village level. Dr. Senthil also spoke of the skewed distribution of resources in India. The majority of services and health workers are based in urban areas and there should be more focus on delivering quality health services to rural populations.

Nick Herbert MP, co-Chair of the APPG on Global TB reinforced the importance of political commitment for the eradication of TB and spoke about the UK's strong support for efforts to fight TB both in India and globally. He informed the Indian Parliamentarians that this is an issue that receives cross-party support and that whilst the UK already supports TB control efforts through a number of channels, there is still much more that can be done as highlighted in the APPG's recently published *Agenda for Action*.

Nick Herbert MP with the Director of the Rajiv Gandhi Institute (left), Dr. M. Jagannath MP and Dr. Bobby John.

Among the many points discussed throughout the meeting, the issues of improving laboratory facilities and ensuring completion of treatment figured prominently. The emergence of MDR-TB and XDR-TB and its consequences on the existing programme caused concern among speakers on both sides. UK parliamentarians also raised concerns about the level of stigma experienced by many TB patients and the lack of awareness evidenced in some parts of India.

Issues around the development of new tools were also high on the agenda. India was recognised as the 'pharmacy of the developing world' and an important actor in this field. Whilst new drugs, diagnostics and vaccines are urgently needed to dramatically reverse the burden of TB in India and worldwide, parliamentarians need to be aware of the potential challenges that will arise when they finally come onto the market including the registration of new products and patents, training staff to use new tools and ensuring that they are made

available to those people with the greatest need.

British and Indian Parliamentarians agreed that all countries should work together to address the global TB problem and that lessons on best practice should be shared between countries. The meeting was concluded with all Parliamentarians signing the international 'Call to Stop TB' urging more action on the part of all stakeholders to renew the fight against TB.

Speaking after the signing of the 'Call to Stop TB', Dr. R. Senthil MP and Convenor of the IMPF said: "We have to work on making TB control a priority in our constituencies. As leaders, it will be our responsibility to raise visibility for TB control within parliament, and to keep a track of the programme to ensure that lives are saved."

Nick Herbert MP and co-Chair of the APPG on Global TB said: "As people's representatives, it is our duty to press for action which will save 14 million lives worldwide … we are keen to work with our colleagues from other countries to help persuade our governments to step up the fight against TB. This is a global disease that does not respect borders."

Appendix 3

Glossary

APPG	All-Party Parliamentary Group on Global Tuberculosis
ART	Antiretroviral therapy (medication for the treatment of HIV)
BCG	Bacille Calmette-Guérin vaccine
DFID	UK Department for International Development
DFIDI	UK Department for International Development (India)
DOTS	The internationally recommended TB control strategy. Originally an acronym for 'Directly Observed Therapy, Short-Course'
GDF	Global Drug Facility – an initiative of the Stop TB Partnership to increase access to high quality TB drugs for DOTS implementation
GFATM	The Global Fund to Fight AIDS, TB and Malaria – a financing instrument established in 2001 to increase resources to fight three of the world's most devastating diseases.
GLRA	German Leprosy and Tuberculosis and Leprosy Relief Association
IMPF	Indian Medical Parliamentarian's Forum
MDG	Millennium Development Goals – eight goals adopted by all governments in 2000 with the aim of reducing extreme poverty
MDR-TB	Multi-drug resistant TB - a specific form of drug-resistant TB which is resistant to at least isoniazid and rifampicin, the two most powerful anti-TB drugs
NACP	National AIDS Control Programme
NDMC	New Delhi Municipal Council
PP	Private Practitioner
RNTCP	Revised National TB Control Programme
TB	Tuberculosis
TRC	Tuberculosis Research Centre, Chennai
VCT	Voluntary Counselling and Testing (for HIV)
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

RESULTS is an international grassroots advocacy organisation working to generate the public and political will to end hunger and the worst aspects of poverty

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