TB in India:
burden, progress and needs

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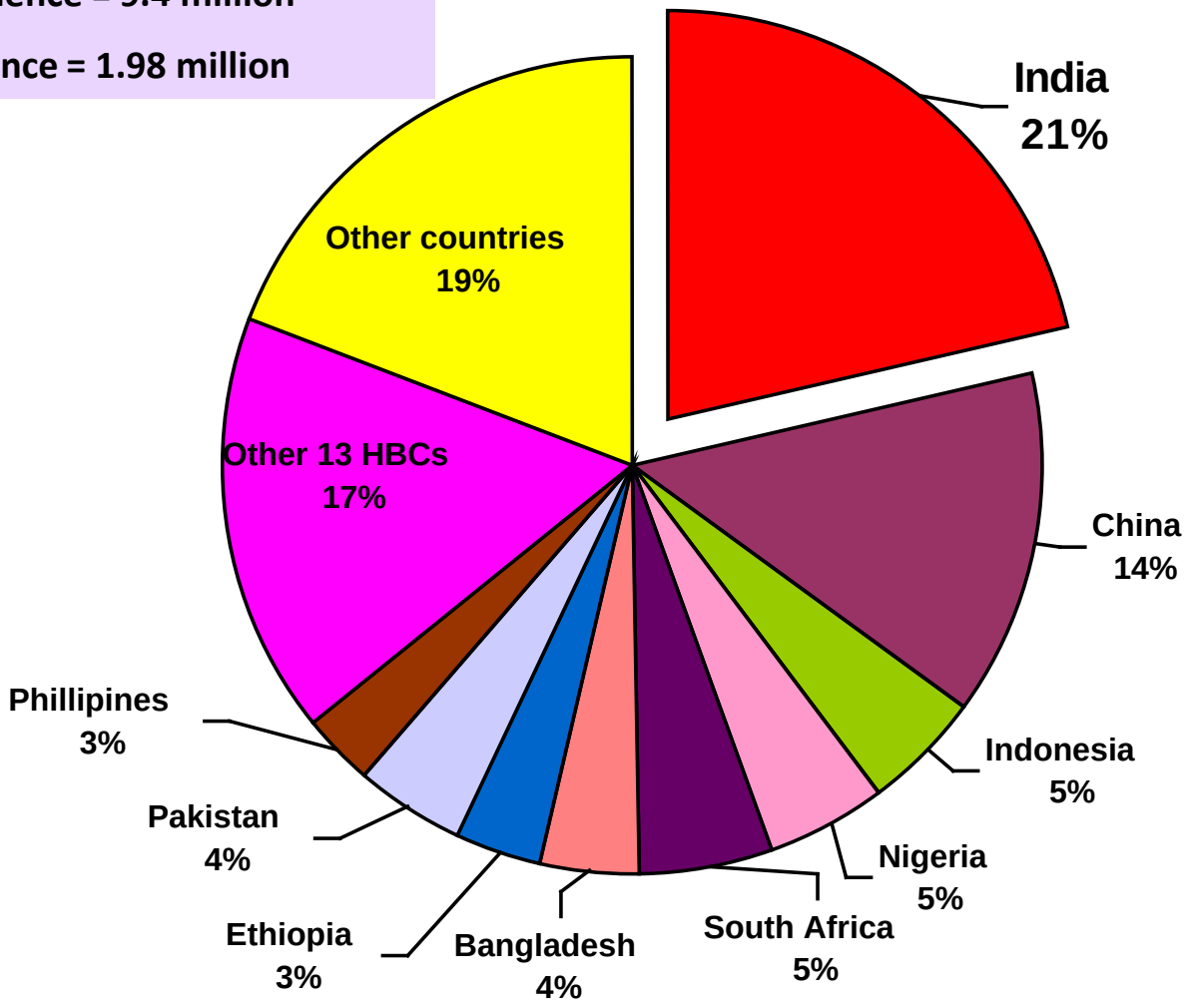
India is the highest TB burden country accounting for one fifth of the global incidence

Global annual incidence = 9.4 million

India annual incidence = 1.98 million



Source: WHO Geneva; WHO Report 2010: Global Tuberculosis Control; Surveillance, Planning and Financing

TB Burden in India

- **Incidence of TB disease:** 1.98 million new TB cases annually
- **Prevalence of TB disease:** 3 million total cases
- **Deaths:** about 280,000 deaths due to TB each year
- **TB/HIV:** 2.3 million people with HIV; ~95 thousand co-infected with HIV & TB
  - About 4.85% of TB patients estimated to be HIV positive
- **MDR-TB** in new TB cases 2-3% **and** 12-17% in Re-treatment cases
- Affects predominantly economically productive age group leading to huge **socio- economic** impact

Goal

- The goal of TB control Programme is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem in India

Vision

Universal Access-reaching the unreached

The vision of the Government of India is a "TB-free India - through achieving Universal Access by provision of quality diagnosis and treatment for all TB patients in the community".

Programme Objectives
(2012-17)

- Early detection and treatment of at least 90% of estimated all type of TB cases in the community, including TB associated with HIV
- Successful treatment of at least 90% of new TB patients, and at least 85% of previously-treated TB patients
- Reduction in default rate of new TB cases to less than 5% and re-treatment TB cases to less than 10%
- Initial screening of all re-treatment smear-positive till 2015 and all Smear positive TB patients by year 2017 for drug-resistant TB and provision of treatment services for MDR-TB patients;

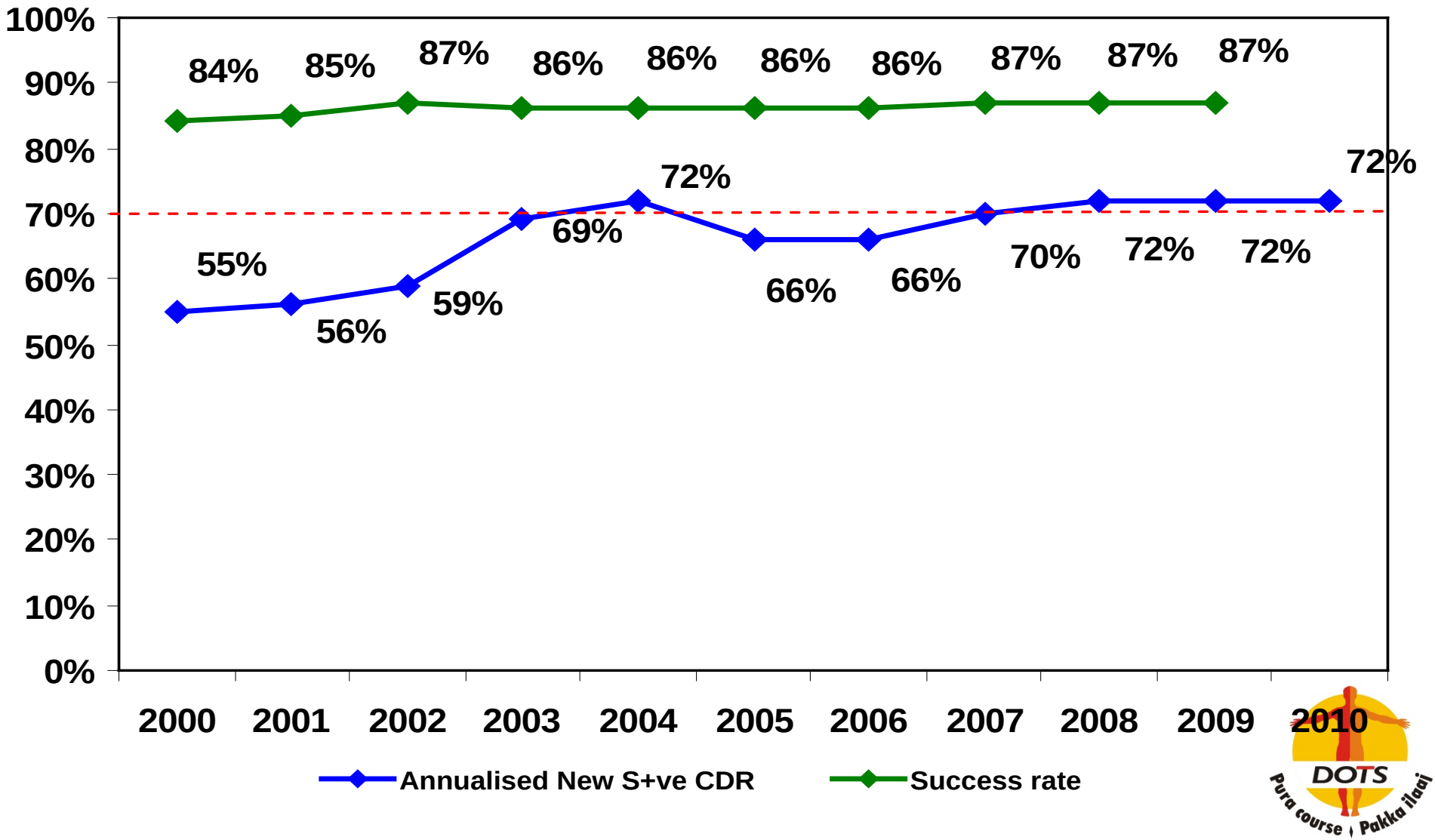
National Strategic Plan
Thematic sub-groups

S.No	Thematic groups	Key thrust areas
1	ACSM	Reach the unreached
2	TB/HIV	Intensified TB-HIV Package
3	Health Systems strengthening	Re-alignment of TU's
4	Human Resource Development	Sustaining existing and addl HR
5	Public Private Mix	Enhanced PP/NGO involvement
6	PSM/Logistics	MDR drugs
7	Case finding	Rapid diagnostics and Lab scale up
8	Treatment	DOTS Plus scale up
9	Research	Ensuring OR projects uptake
10	Epidemiology	ARTI, Prevalence studies
11	Budgeting and Finance	Revising costing and norms

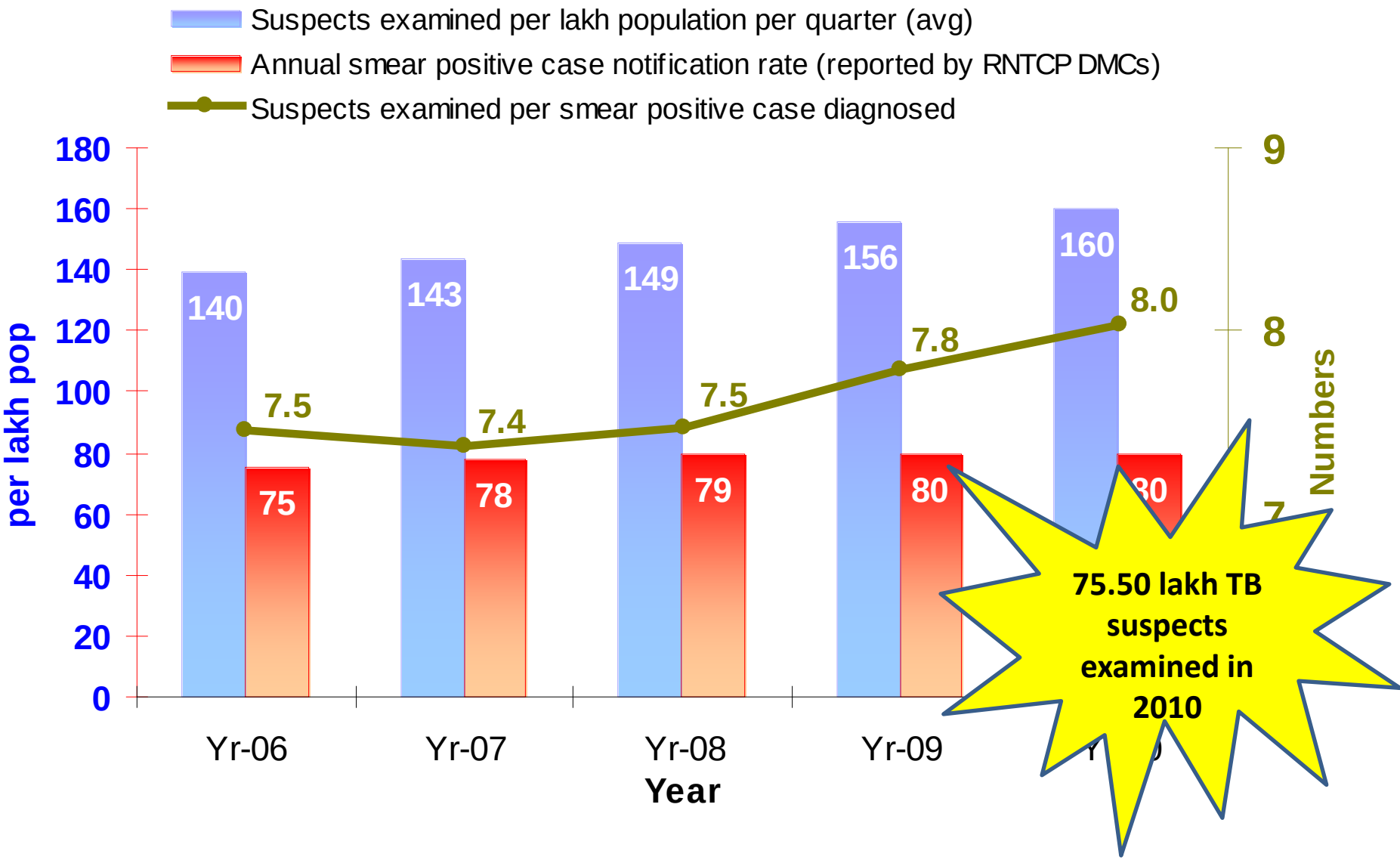
Millennium Development Goals

- **Goal 6**: Combat HIV/AIDS, malaria and other diseases
  - **Target 8**: By 2015, 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 at least 70% of new infectious cases and to cure at least 85% of detected sputum positive patients

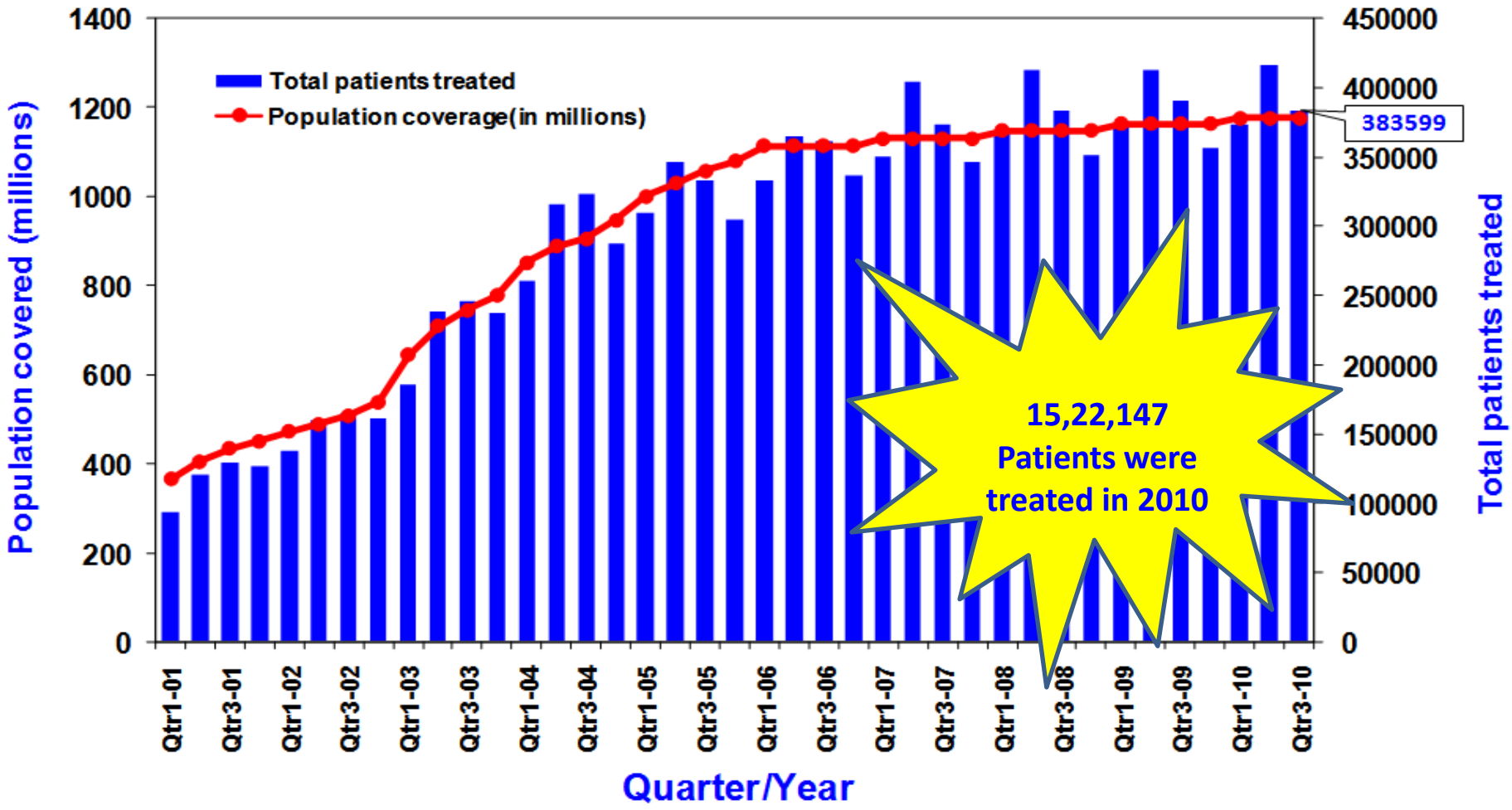
New Smear Positive (NSP) case detection and treatment success rate



TB Case finding efforts, 2006-10



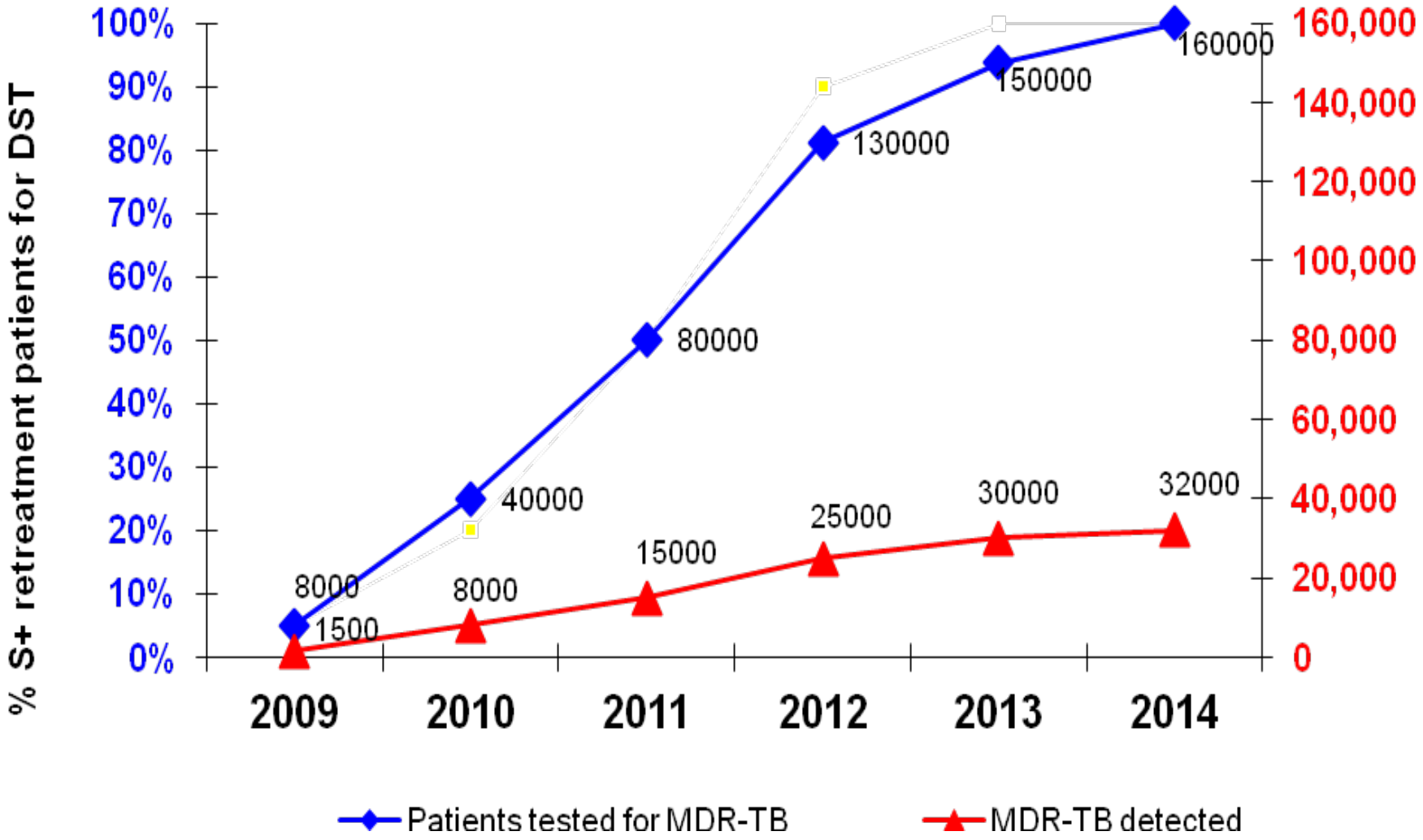
Population in India covered under DOTS and Total Tuberculosis Patients put on treatment each quarter



Key achievements

- Since implementation,
  - > 44 million TB suspects examined
  - > 12.8 million TB patients placed on treatment
  - > 2.3 million additional lives saved
- Achievements in line with the global targets

Projections/Estimates for MDR-TB suspects to be tested and Patients detected (2009-2014) under RNTCP



Numbers of patients to be evaluated

- India would require scale-up of laboratory capacity by 2015 to conduct
  - Primary culture for 160,000 patients
  - DST for 143,000-160,000 patients
  - Follow-up cultures 325,000 patient evaluations

Currently available TB diagnostics

- Smear Microscopy – by ZN
- Solid Culture and DST by LJ Medium
- Line Probe Assay and Liquid Culture systems in few reference labs
- Conventional FM in a few reference Labs

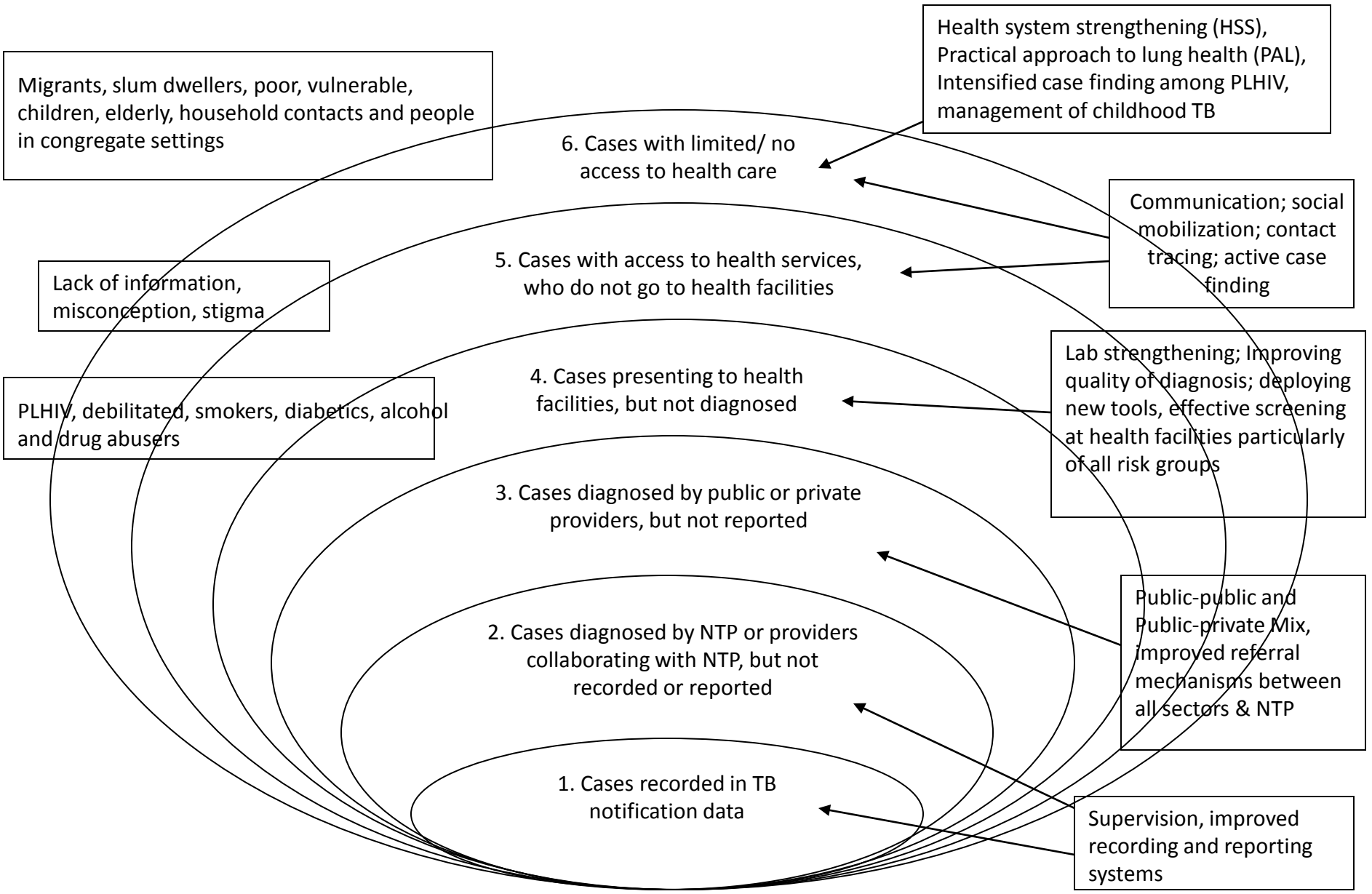
Expansion of C & DST labs : Number –Year wise

Lab unit	2010-11	2011-12	2012-13	Total
Enhanced capacity for solid culture and sputum processing	12	13	18	43
Establish Molecular unit-LPA	12	13	18	43
Establish liquid culture systems	13	9	11	33

Planned service delivery for Drug resistant TB

- By 2012
  - Complete geographical coverage
  - Drug susceptibility testing for patients failing first line treatment and DR TB contacts
  - DST for all smear positive retreatment TB cases at the time of diagnosis
- By 2015,
  - DST for all smear positive TB (new and re-treatment) cases registered under RNTCP
- Start at least 30,000 DR TB cases on treatment annually by 2013

Early and Improved Case Detection: using the " ONION MODEL"



Source of Previous treatment for Re-treatment TB cases registered under the National TB Control Programme, India, 2010

- To assess the source of previous treatment for re-treatment TB patients registered under RNTCP
- Nationally representative cross sectional study -sample of 36 districts selected by PPS sampling

Kuldeep Singh Sachdeva (1), Srinath Satyanarayana (1,2), Puneet Dewan (3), Sreenivas A (2), Raveendra Reddy (3), Debasish Kundu (3), Sarabjit S Chadha (2), Ajay Kumar MV (1,3), Malik Parmar (1,3), Lakhbir S Chauhan (1)

Result

- 1712 retreatment TB patients
- Source of previous treatment
  - RNTCP- 958 [56% (95% CI; 50.1%-61.8%)]
  - Non-RNTCP- 754 [44 % (95% CI, 38.2%-49.9%)]

From where are tuberculosis patients accessing treatment in India? Results of a community based survey – (under publication)

- Cross sectional community based survey in 30 districts of India
- 75,000 households enumerated, 73,249 households (97.6%) visited
- 371,174 household members, 761 TB patients identified (~205 cases per 100,000 populations)
- Data collected from 609 (80%) TB patients
  - 331 [54.3% (95% CI: 42.3%-66.4%)] on treatment 'under DOTS/RNTCP'.
  - 278 [45.7% (95% CI: 33.6% to 56.7%)] on treatment from 'outside DOTS/ RNTCP' sources.

Srinath Satyanarayana, Sreenivas A, Sarabjit Singh Chadha , Roopa Shivashankar , Geetanjali Sharma , Subhash Yadav , Subrat Mohanty , Vishnuvardhan Kamineni , Nevin Charles Wilson , Anthony David Harries, Puneet Dewan.

Summary

- ~45% of TB Patients are treated outside RNTCP in India
- It is possible (though challenging) to estimate Incident cases based on notification + estimation using drug sale survey
- Qualitative research techniques including Delphi method is useful to estimate TB Incidence (for the outer layers of onion model)

Serological Testing Versus Other Strategies for Diagnosis of Active Tuberculosis in India: A Cost-Effectiveness Analysis

David W. Dowdy[1], Karen R. Steingart[2], Madhukar Pai[3]*

Table 3. Cost-effectiveness of diagnostic strategies for 1.5 million persons with suspected active TB in India.

Diagnostic Test	Cost (US$)	Additional TB Cases Treated	Additional False-Positive Cases Treated	Secondary Cases Averted	DALYs Averted	Incremental DALYs Averted	Incremental Cost per DALY Averted (US$)
Performed alone, relative to no microbiological testing							
Sputum smear microscopy	11.9 million	44,000	36,000	443,000	623,000	623,000	19
anda-TB serology	47.5 million	58,000	157,000	411,000	520,000	(Dominated)	(Dominated)
Performed on smear-negative specimens only, relative to sputum smear alone							
MGIT culture	27.6 million	26,000	12,000	112,000	130,000	130,000	213
anda-TB serology	39.0 million	24,000	152,000	112,000	110,000	(Dominated)	(Dominated)

Size and Usage Patterns of Private TB Drug Markets in the High Burden Countries

William A. Wells[1]*, Colin Fan Ge[2], Nitin Patel[2], Teresa Oh[2], Elizabeth Gardiner[1], Michael E. Kimerling[3]

1 Global Alliance for TB Drug Development, New York, New York, United States of America, **2** IMS Health, New York, New York, United States of America, **3** Bill and Melinda Gates Foundation, Seattle, Washington, United States of America

Table 1. Size and characteristics of private TB drug market.

Country	Incident cases (2008)	Coverage by first line, private sector drugs*	% change in volume 2004–9	% of private market that is loose drugs	Number of manufacturers with >3% of private first line market share	Fluoroquinolone coverage of incident MDR-TB cases#	Fluoroquinolone coverage of all incident cases&
India	1,982,628	117%	−3%	23%	6	41%	6.1%
Indonesia^	429,730	116%	−5%	91%	6	12%	1.0%
Philippines	257,317	86%	−16%	16%	6		
Pakistan	409,392	65%	−7%	36%	4	13%	1.3%
China^	1,301,322	23%	59%	98%	9		
Thailand^	92,087	17%	−10%	94%	9		
Russia^	150,898	13%	5%	100%	7		
Vietnam^	174,593	7%	−28%	90%	11		
Bangladesh	359,671	7%	−51%	11%	2		
South Africa	476,732	3%	2%	34%	2		
Weighted average		66%	5%	52%			
Global Total	9,369,038						
10 country total, as % of global incidence	60%	39%					

Role of Private Sector in Providing Tuberculosis Care: Evidence from a Population-based Survey in India

Hazarika I.

J Glob Infect Dis. 2011 Jan;3(1):19-24.

CONCLUSION:

- In India, much of the population, across all socioeconomic strata, consult private providers at some time during their illness. These private providers outnumber public health care providers and often offer better geographical access and more personalized care than the public facilities. The involvement of the private sector has, therefore, become extremely important to improve the effectiveness and outreach of TB control efforts in India.

From Threat to Reality

The Real Face of Multidrug-resistant Tuberculosis

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AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE VOL 178 2008

In this issue of the *Journal* (pp. 306–312), Mak and colleagues show the negative impact of MDR-TB on current TB control efforts. In a well-designed ecological study, the authors have shown that a prevalence of initial MDR-TB of 3% or greater was strongly correlated with higher failure and relapse rates among new cases receiving initial treatment with first-line drugs (3). More importantly, the proportion of cases of TB requiring retreatment doubled where the prevalence of initial MDR-TB was greater than 3%, as compared with 1% or less. Furthermore, the higher the prevalence of MDR-TB in previously treated cases, the higher the failure rate among cases retreated using first-line drugs.

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The article by Mak and colleagues should serve as a reminder that the fight against TB and MDR-TB is now becoming more complex. MDR-TB needs first to be prevented at all costs by proper practices of TB care and control. For this, the DOTS strategy and its emphasis on strict supervision of treatment are essential. Second, MDR-TB needs to be managed effectively maximizing the use of current tools. Last, research must be urgently intensified to make the diagnosis and treatment of TB more user friendly than they are today. Unless those with the

Critical issues in TB diagnostics

- Smear Microscopy is not very sensitive to detect all smear positive cases
  - *Improving Smear Microscopy by technology, approach*
- Early and complete case detection (Smear Negative Pulmonary and extra-pulmonary TB, pediatric and PLHA)
  - *Rapid Culture Techniques – Automated/manual Liquid culture systems*
  - *Rapid automated Molecular- Xpert TB/RIF*
- Rapid methods for detection of DR especially MDR/XDR
  - *Molecular methods – LPA, Xpert TB/RIF*

WHO Recommendations on New Technologies 2006-2010

Year	Policy Recommended
2006	2 smears instead of 3 for screening PTB and 1+ve smear as TB case definition (equivalent to 1 or more AFB/100 fields) Conventional FM for high load settings
2007	Commercial Liquid Cultures (Automated and Manual) and DST Rapid Speciation –using immuno-chromatographic assays
2008	Line Probe Assays (LPA)
2009	LED based FM and Dual Mode Systems including low load settings Non-Commercial Methods for Culture & DST (MODS, CRI, NRA etc)
2010	Automated Cartridge Based Nucleic acid technologies – Xpert

Role of New Tools in RNTCP

- Increase through-put: A given lab can conduct DST on many more patients by molecular, liquid than solid
- Rapid diagnosis: Reduce patient loss, mortality, and operational complexity of current system.
- Infrastructure requires *flexible* capacity, with molecular, solid, and liquid capacity
- General approach
  - Initial DST molecular>liquid>solid, depending on availability
  - Follow up cultures by solid media
  - Liquid culture for critical follow up time points (where liquid available)

Challenges

- Large unregulated Private sector – market driven diagnostics usage
- Increased cost to the programme per specimen examination for first and second line DST
- Non-availability of same day diagnosis for pulmonary TB

Needs….

- New Point of care test that is simple, easy, cheap and can be performed with very minimal training at PHI level

- Indigenous, economical, simple, automated (battery operated) or manual Molecular test to detect drug resistance that can be done in a peripheral lab with minimal training

Thank You