The New Diagnostics WG and The Global Plan to Stop TB 2011-2015

Working Group on New Diagnostics

Annual Meeting

11th November 2010, Berlin

Christian Lienhardt
Stop TB Partnership
Geneva
Aims of this presentation

- Background: the TB situation today
- The Stop TB strategy and the Global Plan to Stop TB 2006-2015
- The revised Global Plan to Stop TB 2011-2015
- The role of new drugs in contributing to the goal of TB elimination by 2050
- The future
The global burden of TB in 2008

**Estimated number of cases**

- **All forms of TB**: 9.4 million (range 8.9–9.9 million)
- **HIV-associated TB**: 1.4 million (15%) (1.3–1.6 million)
- **Multidrug-resistant TB (MDR-TB)**: 440,000 (0.39-0.51 million)

**Estimated number of deaths**

- 1.9 million (range 1.6–2.3 million)
- 520,000 (0.45–0.62 million)
- 150,000 (0.05–0.27 million)
TB Control Global Targets

2015: Goal 6: Combat HIV/AIDS, malaria and other diseases

Target 8: to have halted by 2015 and begun to reverse the incidence...

Indicator 23: incidence, prevalence and deaths associated with TB

Indicator 24: proportion of TB cases detected and cured under DOTS

2015: 50% reduction in TB prevalence and deaths relative to 1990 levels

2050: elimination (<1 case per million population)
The Global Plan 2006-15 proposed achievements

1. MDGs for TB and the Partnership’s 2015 targets to halve prevalence and death rates globally

2. Treatment of 50 million people with TB, 3 million TB/HIV co-infected patients on ARV, and 1.6 million with MDR


4. The first new TB drug introduced by 2010

5. The "point of care" diagnostics introduced by 2010

6. Develop a new vaccine by 2015

US$ 56 billion needed to control TB in endemic countries

US$ 11 billion needed to develop new tools
Full implementation of Global Plan: 2015 MDG target reached but TB not eliminated by 2050

Projected incidence 10x lower than today, but 100x bigger than elimination target in 2050

Elimination target: 1 / million / year by 2050
Potential impact of new TB vaccines, diagnostics and drugs in SE Asia

Source: L. Abu Raddad et al, PNAS 2009
Global Plan targets – Research and Development

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The Global Plan 2006-2015 defined direction and costs

11 billion US$ to develop new tools

The Global Plan 2011-2015 strengthens the fight

9.8 billion US$ to develop new tools
Improve TB Control

Point of Care Diagnostics of TB

Diagnose all forms of TB in all populations

Improved diagnostics at all health care levels

Basic Science
Translational Studies
Preclinical Studies
Clinical Studies/Trials
Operational Studies/Trials

Improve TB Control

Operational Studies/Trials

Improved diagnostics at all health care levels

Basic Science
Translational Studies
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Improve TB Control
Objectives for New Diagnostics R&D

1. To address existing knowledge gaps obstructing development of new diagnostic tools
   - biomarkers and platform discovery

2. To develop a portfolio of new diagnostic tests
   - identify candidates for detection of all forms of TB in all age groups, including MDR-TB and LTBI founded on 1.
   - address specific diagnostic needs at various levels of public health systems in high-burden countries
Objectives for New Diagnostics R&D

3. To evaluate the portfolio of new diagnostic tools, demonstrate patient benefit and predict likely impact
   – conduct accuracy and validity studies
   – assess effectiveness of any new diagnostic tool at the required level of health service and in all target populations
   – assess the impact of new tests on case-finding, and access to treatment

4. To ensure wide availability of new diagnostic tools in endemic countries
   – operational and impact assessments studies to inform on the benefits for the patient and health systems.
   – ensure implementation and uptake of new tests at requested level of health care
   – harmonize regulatory requirements for TB diagnosis
Targets for introduction of new diagnostic tests 2006-2015

- Liquid culture & DST
- Non-commercial cultures (MODS, NRA, CRI)
- Rapid speciation
- LPAs - manual NAAT (DST)*
- LED microscopy & same-day diagnosis
- Automated NAAT (detection & DST)
- Rapid colorimetric DST
- Manual NAAT (detection)**
- POC test (detection)
- Predictive LTBI
- Manual NAAT (detection)***

% Access after 5 years:
- First Referral Level: 10-40%
- Peripheral Lab: 70%
- Community Health Care: 95%
TB diagnostics pathway, from need assessment to delivery
Expected Achievements 2015

• New markers for determination of LTBI, disease progression, active disease, and first- and second-line drug resistance are identified and validated;

• Improved and new technical platforms to meet required target specifications are developed;

• A portfolio of new and improved diagnostics tests meeting the disease target specifications up to validated design-locked products is developed;

• Evaluation and demonstration studies, specifically in paediatric and TB/HIV co-infection patient groups, are conducted:
Expected Achievements 2015

• Impact of new diagnostics on case-finding, access to treatment, patient benefit, cost-effectiveness, equity and poverty has been evaluated;
• Operational research studies carried out to evaluate how to optimally deliver novel diagnostic services in routine TB programmatic settings, including related costs and resources needed;
• Newly validated tools for TB diagnostics are fully registered, and methods for registration harmonized
Integration of new tools in the tiered health system

**Expected 2012 (Gen 1) / 2014 (Gen 2)**

- **Surveillance**
- **Reference methods**
- **Network supervision**

- **Resolution testing** (screening-test negative drug resistance)

- **Screening**
- **Passive case finding**
- **Detect and treat**

- **Clinical screening**
- **Primary care**

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<th>Level</th>
<th>Tools</th>
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<td>Community Level</td>
<td>Integrated NAAT +40% /2h, RDT Gen1 / Gen 2</td>
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<tr>
<td>SubDistrict Level</td>
<td>LED FM +10%, LPA Rif / INH 2d, Integrated NAAT +40% /2h</td>
</tr>
<tr>
<td>District Level</td>
<td>LC / DST 15d / 30d, ZN 2-3d</td>
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<tr>
<td>Regional Labs</td>
<td>Reference methods, Network supervision</td>
</tr>
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<td>Reference Labs</td>
<td>Special settings and conditions</td>
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Strategic focus 1

Strategic focus 2 & 3
Funding required for New Diagnostics, 2011-2015
Total: USD 1.9 billion

- Ensuring availability and use
- Evaluation and demonstration
- Portfolio development
- Closing the knowledge gap

Total: USD 1.9 billion

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<th>Year</th>
<th>Drugs</th>
<th>Basic Science</th>
<th>Vaccines</th>
<th>Unspecified</th>
<th>Diagnostics</th>
<th>Operational</th>
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<td>2005</td>
<td>$114,862,738</td>
<td>$81,892,167</td>
<td>$68,351,530</td>
<td>$40,741,527</td>
<td>$19,408,124</td>
<td>$32,170,084</td>
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<tr>
<td>2006</td>
<td>$144,336,532</td>
<td>$91,643,009</td>
<td>$76,555,111</td>
<td>$43,205,600</td>
<td>$31,890,329</td>
<td>$30,194,127</td>
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<td>2007</td>
<td>$170,233,497</td>
<td>$113,325,202</td>
<td>$73,225,383</td>
<td>$40,734,199</td>
<td>$42,435,113</td>
<td>$33,967,288</td>
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<td>2008</td>
<td>$174,178,052</td>
<td>$98,728,019</td>
<td>$109,337,224</td>
<td>$25,032,930</td>
<td>$49,788,950</td>
<td>$34,411,742</td>
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Key challenges and opportunities that can facilitate or impede the Plan’s success

• Increased investment in R&D since 2005 (71 %!) and commitment to research expressed by various bodies

• However, insufficient funds overall

• TB community needs to present the case better to political leaders and stakeholders;

• Development of a *Roadmap for International Research to eliminate TB*

• Based on consensus-driven global TB research agendas and systematic reviews;

• Promote the need for harmonized funding of TB research so as to target revolutionary discoveries that will foster better care and control for the elimination of TB
Many thanks to

• Madhukar Pai
• Andy Ramsay
• Giorgio Roscigno
• Core Group of NDWG
• Karin Weyer

• Christopher Fitzpatrick
• Katherine Floyd
• Inés Garcia-Baena
Thank you for your attention!