

## **Tuberculosis (TB) Facts and the Need for New Tools**

### **About Tuberculosis**

Tuberculosis (TB) is a highly contagious disease that, like the common cold, is easily spread through the air. Only people with an active TB infection can transmit the disease; when a person with an active infection coughs, sneezes, talks or spits, TB germs, known as bacilli, are propelled into the air. A person needs only to inhale a small number of these to be infected.

### **TB is a Leading Killer Worldwide**

- TB kills nearly two million people every year, and is second only to HIV as the leading infectious killer of adults worldwide. Ninety-four percent of all TB cases and 98 percent of TB deaths occur in the developing world.
- While curable, someone dies roughly every 20 seconds due to TB. In 2010, there were more than 8.8 million new cases of TB and more than 1.4 million deaths.

### **The Rise of Drug-resistant TB**

- Globally, five percent of TB patients – 650,000 people – are estimated to have multi-drug resistant TB (MDR-TB), a more difficult to treat form of the illness. Extensively drug-resistant TB (XDR-TB), which can be incurable, has been reported in 58 countries worldwide, including the United States.
- In some TB hot-spots, including China and India, up to 30 percent of people with TB are infected with drug-resistant strains. In multiple regions in Eastern Europe, more than half of re-treatment TB cases are MDR-TB.
- Estimates indicate that as few as 10 percent of people with MDR-TB receive treatment in accordance with guidelines set forth by the World Health Organization.

### **The Impact of TB-HIV Co-Infection**

- One-third of the increase in global TB cases over the last five years can be attributed to the HIV epidemic.
- TB is the leading cause of death among people living with HIV in Africa and a major cause of death elsewhere. In 2010, there were an estimated 900,000 HIV-positive TB cases globally in Africa alone. This amounts to 40% of all new TB cases in the region
- At least one-third of the 34 million people living with HIV worldwide are infected with TB and they are 20-30 times more likely to develop TB than those without HIV; TB is the cause of death for ~25% of HIV-positive people.

### **The Financial Burden of TB in the U.S. and Globally**

- The annual global economic toll of TB is at least \$12 billion.<sup>1</sup>
  - MDR-TB costs between \$28,217 and \$1,278,066 per individual<sup>2</sup>
  - In the US, the average estimated hospitalization cost for treating a patient with extensively drug-resistant tuberculosis is \$600,000, and that does not include costs of outpatient care and related public health department interventions.<sup>3</sup>
  - In the US, about 50 percent of drug-sensitive TB patients are hospitalized for TB at a cost of \$19,000 per patient, with outpatient directly observed treatment costs of \$4,000<sup>4</sup>
  - DOT for drug sensitive TB costs \$4,000 per case.<sup>5</sup>

<sup>1</sup> Pricing infectious disease: The economic and health implications of infectious diseases. <http://www.nature.com/embor/journal/v9/n1s/full/embor2008110.html>

<sup>2</sup> Rajbhandary SS, Marks SM, Bock NN. Costs of patients hospitalized for multidrug-resistant tuberculosis. *Int J Tuberc Lung Dis.* 2004 Aug;8(8):1012-6.

<sup>3</sup> Banerjee R, Allen J, Westenhouse J, et al. Extensively drug-resistant tuberculosis in California, 1993-2006. *Clin Infect Dis.* 2008;47:450-7.

<sup>4</sup> Marks SM. Potential TB treatment cost savings using moxifloxacin-based regimens. *TB Notes.* Atlanta, GA: CDC, US Department of Health and Human Services; 2006;1:13-15.

<sup>5</sup> Marks SM. Potential TB treatment cost savings using moxifloxacin-based regimens. *TB Notes.* Atlanta, GA: CDC, US Department of Health and Human Services; 2006;1:13-15. (Costs are in 2004 dollars.)



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### The Need for New TB Drugs

- The current TB drug regimen, developed more than 40 years ago, is inadequate to address the ongoing challenges of treatment. Current treatment includes four drugs and requires six to 30 months of treatment for active, drug-susceptible TB. Unfortunately, many people do not or cannot complete this treatment.
- Shorter, simpler treatments hopefully will reduce the burden on individuals and the health system, and should result in more people successfully completing their treatment. In turn, less resistant disease should arise.
- Results of a previous study suggest that new and improved TB drugs, vaccines, and diagnostics could reduce the global incidence of TB by 71 percent by 2050, a reduction of more than 6.5 million annual cases.<sup>6</sup>

### The Need for TB Vaccines

- There is therefore an urgent need for a modern, safe and effective vaccine that would prevent all forms of TB, including the drug-resistant strains, in all age groups and among people with HIV.
- The Bacille Calmette-Guérin (BCG) vaccine, created in 1921, is the only existing vaccine against TB. Unfortunately, it is only partially effective. It provides some protection against severe forms of pediatric TB, but is unreliable against adult pulmonary TB, which accounts for most of the disease burden worldwide.

### The Need for New Diagnostics

- Sputum microscopy is over 100 years old and fails to diagnose the majority of worldwide TB cases. It cannot detect drug-resistant or extra-pulmonary TB, and is particularly ineffective for diagnosis of TB in children and HIV-positive individuals.
- Lack of proper diagnosis costs patients and their families valuable time and money, delays treatment and leads to continued TB transmission.
- Mounting drug resistance and a growing number of patients co-infected with TB and HIV have highlighted the urgent need for more accurate and rapid diagnostic tests.

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### Three public-private partnerships lead development of needed new tools.

Research is currently under way to develop these critically needed new tools through innovative partnerships that maximize the likelihood of success and minimize costs. The Aeras Global TB Vaccine Foundation (Aeras), the Foundation for Innovative New Diagnostics (FIND) and the Global Alliance for TB Drug Development (TB Alliance) — three not-for-profit Product Development Partnerships (PDPs) — are leading the global effort to develop new TB tools.

- The **TB Alliance** is developing new affordable TB drugs that will dramatically shorten treatment time, work against drug-resistant TB, be compatible with HIV antiretrovirals and improve treatment of latent TB.
- **Aeras** is developing new, safe, effective and affordable vaccine regimens to protect against all strains of TB – including those that are MDR or XDR, to prevent TB in children, adolescents and adults, and to be safe for use in people infected with HIV.
- **FIND** is developing rapid, accurate and affordable TB tests and point-of-care diagnostics to more efficiently detect TB and drug-resistant forms of TB.

**Harnessing the collective resources of government, industry, academics, and philanthropies, FIND, the TB Alliance and Aeras have created the largest pipeline of new TB drugs, diagnostics and vaccines in history. Nevertheless, increased investments and support for this research are needed to speed development of better TB tools and ensure access for those who need them most.**

<sup>6</sup> Epidemiological benefits of more-effective tuberculosis vaccines, drugs, and diagnostics. <http://www.pnas.org/content/106/33/13980.full>

\*\*All figures without citations were taken from the World Health Organization's TB Data