

Berlin TB Summit: Outcomes Document

We, members of parliament from across the Group of 20 (G20) countries, meeting in Berlin, Germany on 20-22 March 2017, call for G20 leaders:

- 1. To prioritize TB within all initiatives to combat antimicrobial resistance, to ensure TB is recognised as a priority pathogen within the AMR agenda, and to devote all necessary efforts to tackling the disease within the G20 and across the world.*
- 2. To recognize in the G20 Heads of State Declaration: the global burden of TB as the world's leading infectious disease killer; as both a cause and consequence of poverty; as a leading threat from antimicrobial resistance through drug-resistant TB; and the need to increase support for TB research and development and for the scale up and implementation of new and improved tools.*
- 3. To establish a G20 supported mechanism to fast-track the development of a shorter and more effective TB treatment regimen, a point of care rapid molecular test and an effective vaccine which will be available and affordable for all.*

Explanatory Notes:

Tuberculosis (TB) is the world's deadliest infectious disease. It is airborne, drug-resistant and found in nearly every country in the world. It predominantly affects people in their most productive years, robbing children of their parents and families of their major earners. It is both a driver, and a consequence, of poverty. If we are to achieve the ambitious vision articulated in the Sustainable Development Goals (SDGs)¹ of a world free from poverty by 2030, we must first end TB.

Headline statistics on TB and drug-resistant TB (DR-TB)²

1. Tuberculosis (TB) is the world's leading infectious disease killer. In 2015, 1.8 million people died from TB and 10.4 million people fell ill. 4.3 million people with TB were 'missed' by their healthcare systems; that is, they were not diagnosed or treated in officially recognised settings.
2. 46 per cent (816,000) of all deaths from TB, and 54 per cent (5.6 million) of all cases of TB in 2015, were in G20 nations. The majority of these occur in Brazil, China, India, Indonesia, the Russian Federation and South Africa, but high rates are found in many other G20 countries.
3. TB is the leading cause of death among people infected with HIV and is responsible for 1-in-3 deaths from HIV (400,000). Since 2000 over 8 million people have died from TB-HIV co-infection.
4. Drug-resistant TB (DR-TB) remains a major challenge. In 2015 there were 580,000 cases of DR-TB, more than any other form of antimicrobial resistance. Overall, 55 per cent (322,000) of MDR-TB cases were in G20 countries.

TB funding worldwide

¹ Sustainable Development Goals: <http://www.un.org/sustainabledevelopment/sustainable-development-goals/> accessed 01/03/17

² All data taken from the World Health Organization Global TB Report 2016: http://www.who.int/tb/publications/global_report/en/ accessed 01/03/17

5. The World Health Organization (WHO) estimates that only US\$6.6 billion of the US\$8.3 billion required to fully fund the response to TB was provided in 2015. The majority of this funding comes from national governments, but the lowest income countries are dependent on international donors for 90 per cent of the funding for their TB programmes. Largely due to the lack of funding, the number of global cases of TB every year is falling at only 1.5 per cent a year. At this rate, TB will continue to be a threat to global public health into the next century.³
6. TB research and development (R&D) is critically underfunded. “The 2016 Report on Tuberculosis Research Funding Trends, 2005–2015: No Time to Lose” by the Treatment Action Group (TAG) and the Stop TB Partnership estimated that of the US\$9.84 billion needed for R&D between 2011–2015 – identified by the Stop TB Partnership’s Global Plan to End TB 2011–2015 - actual funding amounted to only US\$3.3 billion.⁴⁵ According to the G-Finder 2016 Report only \$98 million was invested in TB vaccine research in 2015 and funding for TB diagnostics research fell by 39 per cent in the last year.⁶

Market failure

7. The incentives that currently exist for commercial R&D have failed for TB. As the disease predominantly affects poor people there is little prospective financial return from new TB medicines to encourage commercial entities to make the major investments needed to develop new drugs.
8. No new drugs have entered the standard TB treatment for close to 50 years. In that period only two drugs have been developed to fight DR-TB: bedaquiline by Johnson & Johnson and delamanid by Otsuka. These drugs have both been demonstrated to improve treatment outcomes when added to treatment for DR-TB, however, it can be challenging to integrate individual drugs into existing regimens, because extensive trials are required to understand how the new combinations of drugs work together.
9. R&D for TB vaccines and diagnostics is also hampered by market failure. The current BCG vaccine was developed in 1921 and is only moderately effective in preventing severe TB in infants and young children – and it does not adequately protect teens and adults, who are most at risk for developing and spreading TB. The majority of diagnoses of TB today rely on technology and techniques pioneered in the 19th century.

TB and AMR

10. One-third of all deaths worldwide from AMR are due to DR-TB. Experts have estimated that, in a worst case scenario, an additional 75 million people could die as a result of DR-TB by 2050. Of these, 33 million would be in the G20. The cumulative economic impact of these deaths could equal US\$16.7 trillion, of which US\$10.5 trillion would be in the G20. The Gross Domestic Product (GDP) of sub-Saharan Africa could be 3.21% lower in 2050 as a consequence of DR-TB, and in low-income countries as a whole it could be 2.45% lower.⁷
11. DR-TB is driven by a combination of market failure and sub-standard TB care and prevention programmes. Due to the lack of development of new and better drugs, the current treatment for drug sensitive TB requires patients to take four different types of medicines associated with strong side

³ See 2 above

⁴ Treatment Action Group’s “2016 Report on TB Research Funding Trends, 2005-2015: No Time to Lose: <http://www.treatmentactiongroup.org/tbrd2016> accessed 01/03/17

⁵ Stop TB Partnership’s “Global Plan to End TB 2011-2015” <http://www.stoptb.org/global/plan/plan1115.asp> accessed 01/03/17

⁶ G-Finder 2016, Policy Cures, <http://www.policycuresresearch.org/g-finder/> accessed 01/03/17

⁷ Extracted from a report prepared by KPMG LLP in the UK, derived from research commissioned by the Wellcome Trust, as part of an independent review into anti-microbial resistance supported by the Department of Health and the Wellcome Trust

effects over six months. This is a major driver of the DR-TB epidemic: patients struggle to finish the full treatment course and therefore are at risk of developing resistance. Treatments for DR-TB are even more difficult than drug sensitive TB, with a very low success rate.

12. TB efforts continue to be limited by a lack of implementation and scale-up of currently available TB tools in countries. Of the 10.4 million people with TB in 2015, only 6.1 million were reached with TB care, resulting in 4.3 million being missed.⁸ Only 1-in-5 people who needed treatment for MDR-TB in 2015 received it, and only half of those starting MDR-TB treatment were cured. Many high-burden TB countries are underutilizing effective new tools in the fight against TB, including rapid diagnostic tests such as GeneXpert, and new treatments for MDR-TB such as bedaquiline and delamanid.

The role of the G20

13. Leaders at the Hangzhou G20 Summit agreed that AMR “poses a serious threat to public health, growth and global economic stability,” and committed to exploring options to prevent and mitigate resistance from a “G20 value-added perspective.”⁹ As the source of the majority of public funding for medical research and development, and home to nearly all the world’s major pharmaceutical companies, G20 countries are well-positioned to address the market failure that hampers antimicrobial R&D – and through carefully tailoring the intervention, could generate a significant value-add for their existing R&D efforts.
14. G20 nations are home to over half of the global TB burden. If the G20 oversees a dramatic scale-up in investment to tackle the disease, in line with the strategies above, millions of lives could be saved with existing tools. To eliminate the disease and achieve the SDGs, however, new drugs, diagnostics and vaccines must be made available to patients by 2025. To do this, the market failure hampering TB R&D must be overcome.
15. The G20 could, and should, support a new mechanism to fast-track the development of an anti-TB regimen. TB can only be successfully treated through the use of a combination of drugs, so a regimen is required. There are a number of prospective compounds already in pre-clinical development for TB, but progress has been hampered by a lack of support for further development. With the right combination of incentives, these compounds could advance relatively quickly.
16. Any mechanism should be driven by the principles of affordability, effectiveness, efficiency and equity. Where significant public funding is invested in unlocking new R&D efforts, these products should be considered as a shared responsibility and as public goods and all efforts made to ensure access and provide appropriate stewardship. Efforts must be made to incentivise knowledge sharing, collaboration and the trialling of combination of drugs as early as possible. In this perspective, we support innovative initiatives such as UNITAID that fosters innovation, fast-tracks access and reduces costs of new and more effective medicines. Such an approach will lead to faster development of a new regimen and help to ensure that all new products are accessible, affordable and appropriate for all.
17. Such an approach would serve to coordinate existing efforts to develop new drugs for the disease, ensure any new drugs developed by these mechanisms reached patients as quickly and safely as possible, and have an immediate and tangible impact on the health of people across G20 countries and around the world.

⁸ See 2 above

⁹ G20 Leaders’ Communique Hangzhou Summit: http://www.g20chn.org/English/Documents/Current/201609/t20160906_3395.html accessed 01/03/17