Towards the 2018 UN High-level Meeting on TB in New York

Recommendations by German Civil Society Organizations

Introduction

Today, Tuberculosis (TB) is the leading cause of death due to a single infectious agent. Globally, it is the 9th most frequent killer. In 2016, there were 1.7 million TB-related deaths and 10.4 million new cases. In 600.000 of these cases drug-resistant forms of Tuberculosis (DR-TB) caused the infection. This means, that one third of the total global deaths associated with Anti-Microbial-Resistance are attributable to DR-TB. These dire figures underline the urgency of a massive scale-up of the global fight against tuberculosis and its underlying causes.

The WHO End TB Strategy aims to end the global TB epidemic by 2035. Its targets include reducing TB-related deaths by 95%, to reduce the number of new cases by 90% between 2015 and 2035 and to ensure that no family has to bear catastrophic expenses due to TB. To achieve these goals, no more time must be lost.

National governments and the international community will have the opportunity to commit to a strong and sustained combat against TB at the upcoming UN High-level Meeting "United to end Tuberculosis: An urgent global response to a global epidemic" (UN-HLM). Just like the global HIV-response received a boost after the first UN-HLM on HIV was held, the current event has the potential to elicit covenants to build a realistic perspective to eliminate TB. This must be backed by tangible, time-bound targets, the allocation of sufficient financial resources and efficient accountability mechanisms.

The role of Germany in Global Health has been growing in recent years. This great potential to demonstrate leadership in the global battle against TB and for action towards achieving the health related sustainable development goals (SDG3) must be handled responsibly.

Germany should be represented at the UN-HLM TB in New York by Chancellor Angela Merkel to express high-level political commitment and ownership of the TB agenda. The political representation must continue to reside at the highest political level in order to account for the urgency and gravity of the issue

People worldwide need to have better access to early testing and effective treatment for TB. There is an urgent need to scale up research for the development of effective and well tolerated vaccines, diagnostics and treatments. Tuberculosis is closely linked with structural and social determinants. Therefore, biomedical remedies must be implemented as part of multidisciplinary, intersectoral pathways.

This document was authored by German NGOs that address the topic of TB in their work in various forms. The following seven fields of action should be given specific emphasis and advocated for as part of the processes around the UN-HLM TB:

1. Decisive and accountable global leadership, including regular UN reporting and review are essential

A) Situation analysis:

In June 2001, the UN General Assembly Special Session on HIV/AIDS represented a decisive step forward for the global response to the pandemic. It had tremendous impact on the global AIDS response, including resource allocation, the establishment of efficient accountability mechanisms, as well as the formulation of concrete commitments and time bound roadmaps and work plans. Accountability, as we understand it, describes an individual's or organizations' obligation to provide reasons for their activities, accept responsibility for them and to disclose the outcome of their action in a transparent manner. The UN-HLM on TB and its declaration need to meet these requirements.

B) Recommendations:

- Express commitment and ownership by German high-level representation in the person of Chancellor Merkel at the UN-HLM TB in New York
- Convene a follow up High-Level Meeting on TB in 2023
- Convene Heads of States as part of a Global TB Cabinet in order to regularly assess and confront the epidemic dimensions of TB/DRTB and AMR as part of the "decade to defeat TB"
- Commit to developing an accountability framework with an independent review and reporting mechanism with quantifiable and verifiable indicators

2. The TB response has to be equitable, rights-based, and people-centred

A) Situation analysis:

A human rights dimension is implicated in the factors that determine a person's vulnerability to contract TB and their access to adequate TB treatment. Overarching poverty and unfavourable living conditions, including overcrowding and malnutrition, enhance the vulnerability to become infected and fall ill with TB. In order to reach everyone at risk and affected, programs need to be people-centered and put particular focus on groups that are most vulnerable and/or have limited access to information, prevention and treatment. These limitations frequently result from stigma, residency status, and inadequate resource allocations to those most in need.

One of the most vulnerable groups includes prisoners and people in other closed settings, like refugee centres. Due to multiple structural and setting related factors, such as overcrowding, insufficiently ventilated and/or moist buildings and insufficient exposure to sunlight etc., the TB prevalence can be considerably higher than in the general population. Due to these aforementioned factors in combination with a lack of prevention, diagnostics and inappropriate or interrupted treatment, as recorded in many countries, prisons become breeding grounds for new TB infections. Scientific evidence has shown an increasing likelihood to acquire a TB infection and fall ill with TB with the duration of imprisonment. People in custody are endowed with the right to safe living conditions just like everyone else. The risk of contracting diseases cannot form part of the punishment and governments have the obligation to ensure the safety of incarcerated people. Now is the time to better integrate prisons and other specific settings, where individuals are more prone to contracting TB, into global TB responses.
Governments must be held accountable, prison exceptionalism must be ended and prison health must be incorporated into general public health services. Equity and human rights principles, such as freedom from discrimination and the right to information and education must be at the centre of any TB response.

B) Recommendations:

- Recognise the rights of people to know their TB status and access TB diagnostics. Provide accessible, affordable, and equitable services and care to protect their health and that of their household members and contacts
- Facilitate and maintain equitable and affordable access to TB tools by invoking the flexibilities of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the rights of WTO Member States to protect public health, promote access to medical commodities for all and address barriers to generic competition and other strategies and safeguards

- Commit to empowering people affected by TB, including through education and counselling, proper social protection, people-centered models of service delivery such as integrated, decentralised, ambulatory care
- Provide adequate and integrated services for key populations, such as refugees and migrants, detainees, health care workers, people who use drugs and/or alcohol, persons with co-morbidities (including HIV and diabetes), indigenous populations and people living under precarious conditions
- Repeal laws that entail forced deportation of migrants with TB (latent or active) and incarceration of people with TB and end discrimination against people with TB (latent or active) by 2020
- Make sure that the final declaration highlights the need of a closer cooperation between the Ministry of Justice and the Ministry of Health to develop evidence-based approaches to address TB prevention and treatment in prisons
- Actively address setting-related aspects that create vulnerability of people in prisons and unhealthy workplaces and develop proposals how to challenge the situation

3.) Transform the TB response to be comprehensive and multisectoral

A) Situation analysis:

The German and global response to TB places a strong focus on biomedical interventions, frequently targeted at improving diagnosis, treatment and care. The need for improvements in these areas is beyond doubt. Yet, in order to put an end to the global TB epidemic, action beyond the health thematic area is required. Factors such as overarching poverty, nutrition, working and living conditions, as well as alcohol and tobacco use represent some of the social determinants of tuberculosis which have been identified as important drivers for the global TB burden. These aspects cut across the remit of different political domains and are situated within several of the SDGs, such as: SDG 1: social protection, SDG 2: hunger, SDG 7: indoor air pollution, SDG 8: working and living conditions, SDG 10 inequalities and SDG 11: urban slums.
It is therefore essential for actors from within and beyond governments to take action in a coordinated manner in order to enable a multisectoral TB response, acknowledging the need to address TB outside of the limited scope of health politics.

B) Recommendations:

- Recognise and address the need for a comprehensive TB approach, encompassing social determinants, such as overarching poverty, under- and malnutrition, working and living conditions, as well as smoking, and the use of alcohol and drugs
- Engage in dialogue and cooperation across different policy areas to foster a multisectoral and horizontal TB response
- An integrated response to TB must not only address co-morbidities with other infectious diseases, like HIV, but also make a strong commitment to the fight against NCDs, such as diabetes. In this context, strong alignment with the UN's and the WHO's efforts to combat NCDs must be sought

4. Speak out and act against TB related discrimination

A) Situation analysis:

Political and social stigmatization and discrimination of people living with TB is a global phenomenon. The framing of AMR as a challenge to global health can fuel stigmatization of TB patients. TB-related stigma can add to the burden of discrimination incurred by poverty, imprisonment, drug and alcohol use, HIV, homelessness or refugee status. Lessons learned from the HIV response include the insight that stigma can lead to isolation, has a negative impact on health outcomes and impedes access to health care services.

TB related discrimination can also be observed in Germany. Right-wing social media activists and parties like the AfD are misusing TB-related data from the Robert Koch Institute and individual cases for racist propaganda

purposes with negative repercussions for the affected people as explained above. It is within the responsibility of the Ministry of Health to prevent possible harm in this context.

B) Recommendations:

- Address TB related human rights violations, the stigmatization and criminalisation of people living with TB at the UN-HLM and develop concrete measures to counter their negative impact on access to services treatment outcomes and health seeking behaviour
- Actively object to the trend in law enforcement, as witnessed in several countries, whereby the numbers of imprisoned people without fair trial is rising, living conditions in many facilities are deteriorating and the lives of inmates are endangered due to exposure to infectious diseases - especially TB
- Reiterate that the realization of all human rights and fundamental freedoms for all forms an integral part of the global response to TB
- Take measures against the misuse of TB-data gathered by national surveillance institutes, take a clear stance and action against political fear mongering in the context of TB and take precautions against the acceleration of stigma and discrimination due to the framing of infectious diseases, such as TB, or AMR as global security threats

5. Increase access to testing, treatment and prevention

A) Situation analysis:

Far too many people have undetected TB for too long. But late detection of TB increases the risk of transmitting the infection to others, or for the patient and his/her family to suffer distress and economic hardship. To treat TB is to prevent additional cases. Hence, progress in controlling TB and mitigating its consequences can be expedited through early diagnosis and treatment.

About 40% of TB cases remain undiagnosed, illustrating a massive testing gap. The number of undiagnosed cases has stayed at about 4 million over the last 6 years. Less than 25% of MDR TB patients are being diagnosed and treated and globally only five percent of all DR TB patients have access to innovative, better tolerated, more effective and often life-saving medicines. The targets of the WHO End TB Strategy will not be reached if access to testing, treatment and prevention is not considerably improved.

TB in children is commonly neglected. It is often missed or overlooked due to non-specific symptoms and difficulties in diagnosis. Since children are also less likely to pose a risk of infection to others, childhood TB is simply not the priority in resource-scarce settings. However, the impact of TB in children is devastating: in 2017 one million children fell ill with TB and more than 200.000 died from it. In high burden TB settings 15-20 percent of all TB cases are among children, whereas the estimated figure lies at 2-7 percent in low burden TB settings. Children are also more likely to suffer severe disability due to TB, as they are more vulnerable to complex forms of the disease, such as TB meningitis. TB affects the youngest and weakest children; those living with HIV are particularly at risk, as are those suffering from malnutrition, common childhood infections and intestinal worms. Children are most likely to be infected with TB by their parents and other close relatives. Many families live in overcrowded living conditions, further increasing a child's risk to become infected. It is estimated that annually more than 30,000 children fall ill with strains of multi-drug-resistant TB (MDR-TB).

B) Recommendations:

- Commit to treating a cumulative total of 40 million people by 2023, including 1 million children annually and 500,000 people with drug-resistant TB [Final numbers to come from WHO]
- At the national level, commit to providing access to TB treatment for 90% of the people eligible by 2023 and, to prevent TB disease, to ensuring that 90% of people living with HIV/AIDS, children, and adult contacts eligible for treatment of latent TB receive it annually by 2022
- Ensure access to safer treatment and shorter regimens with better side-effect profiles for the treatment of drug-resistant TB
- Countries with less than 50% testing coverage should commit to increasing coverage by at least 20% annually

- Develop national strategic plans to reflect these goals, including separate goals and indicators for reaching vulnerable, at-risk, and key populations, including prisoners, children, household contacts, migrants, PLWHA, etc.
- Adopt and implement the latest evidence-based practices, including international standards recommended by WHO and support countries to be able to do so.

6. Accelerate research and development of essential new tools to end TB

A) Situation analysis:

Although TB is one of humankind's oldest diseases, the world still lacks adequate vaccines, diagnostics and antibiotics to fight it. The BCG vaccine for example is only recommended for children and unsuitable for persons living with HIV/ADIS. Additionally, there is the need for an easy-to-use and affordable diagnostic test for quick and effective detection of all forms of TB and all types of antibiotic resistances to reach populations particularly difficult to diagnose. Despite some positive impulses in research & development in recent years, many challenges largely remain unaddressed: The rise of multi and extreme resistant TB forms calls for the implementation of new treatment regimens and there is an urgent need for suitable treatment options in resource-limited settings and within the context of comorbidities like HIV/AIDS or diabetes. Diagnosing and treating TB in children still poses great challenges. TB is most commonly tested for by sputum microscopy. However, children less frequently have a productive cough and are therefore often unable to provide a sample. Child-friendly TB treatment formulations are rarely used and so children are often forced to take a bitter concoction of crushed-up adult pills – with the risk to trigger refusal against the medication, inadequate dosing and thereby the development of drug-resistance.

The treatment success rate for drug-resistant TB (MDR-TB and XDR-TB) presently lie at only 52% and 28% respectively on global average. The current standard treatment regimens often cause a great deal of pain and distress for patients and are regularly associated with serious adverse side effects. For example, about 50% of MDR-TB patients suffer from permanent hearing loss. As a consequence of the required long treatment duration of up to 24 months, many people face catastrophic healthcare costs, unemployment and patients are separated from families and communities, which again negatively impacts on treatment adherence.

The research focus currently lies on the development of single drugs, while TB has to be treated with a combination of medicines. Therefore, TB-research should be organized in a highly collaborative way, targeted at developing complete combination-therapy regimens instead of single substances.

B) Recommendations:

- Introduce new tools to prevent, diagnose, and treat all types of TB (pulmonary and extrapulmonary):
    - i Treatments: develop and deliver an effective short-course oral cure for TB, and its drug resistant forms before 2028 (two months shorter), as well as interim improvements in drug-sensitive and drug resistant TB
    - ii Vaccines: develop 2-3 novel vaccines to prevent infection and/or disease in late stage evaluation before 2025
    - iii Diagnostics: identify biomarkers to differentiate tuberculosis disease from latent tuberculosis infection (LTBI), to predict the risk of progression to clinical disease, response to treatment, and relapse, and develop and introduce multiple approaches to diagnosing TB at the point of care that are affordable, specific, and sensitive
- Acknowledge TB innovation as a shared global responsibility and as the cornerstone of the antimicrobial resistance (AMR) response. This requires including the cost of investment in research and development to be de-linked from price and volume of sales so as to facilitate equitable and affordable access to new tools for preventing, diagnosing and treating TB, while simultaneously preventing overuse
- Strengthen collaborative research initiatives such as the BRICS TB R&D Network, the G20 AMR R&D Collaboration Hub, and the Life Prize. Based on the research principles as agreed on in the UN Political Declaration on AMR, create collaborative approaches to research and data sharing, which promote the development of new regimens comprised of novel classes of drugs

- All countries should develop strategic plans for TB research or incorporate TB research into national health research plan by 2022
- Support models of innovation that de-link the cost of R&D from the final price, increase transparency in the costs of R&D, and R&D efforts that are needs-driven, evidence-based and guided by the principles of affordability, effectiveness, efficiency and equity.

7. Mobilize the funds necessary to end TB

A) Situation analysis:

There are massive gaps in the financing of TB care and in the funding of urgently needed research and development for new vaccines, diagnostics and medicines.
65% of all international financing in the global fight against TB is provided by the Global Fund to fight Aids, Tuberculosis and Malaria (GF). Its TB Catalytic Investment initiative pushes joint efforts with WHO, the Stop TB Partnership, and other implementing partners to find the missing TB cases and reach the global goal of ending TB as an epidemic by 2030. The initiative includes a strong focus on migrant and cross-border issues, the mining sector, refugees, improved laboratory services, and transition to domestically funded health programs.

B) Recommendations:

- Begin to raise the US$12.3 billion in annual funding needed to implement the TB care activities laid out in the WHO End TB Strategy and the Stop TB Partnership's Global Plan to End TB 2016-2020 and meet the financing target for international cooperation to close the funding gap in economically disadvantaged countries
- For TB R&D, immediately begin to allocate $2 billion annually in innovation to deliver the new tools and technologies needed to prevent, diagnose and treat TB, and ensure affordable access to new tools and technologies for all
- Make sure that the HLM addresses the financial implications of the global response to TB
- Accentuate the role of the GF in the fight against TB during the UN-HLM on TB
- Develop concrete proposals for a financial response supporting the fight against TB within the next 5 years and deliver a positive example by pledging a concrete amount. This amount should correspond to the economic capacity of Germany

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