EDITORIAL

# Developing a Human Rights-Based Approach to Tuberculosis

Brian Citro, Evan Lyon, Mihir Mankad, Kiran Raj Pandey, and Camila Gianella

This special section of Health and Human Rights Journal focuses much-needed attention on tuberculosis (TB) and human rights—particularly the right to health. Even as TB has surpassed HIV as the top infectious disease killer in the world and the global threat from multidrug-resistant TB (MDR-TB) continues to grow, approaches to fighting the disease remain primarily biomedical and public health-based.[1] These traditional approaches dominate global and national TB programs and research on the disease, and they largely ignore the underlying social, economic, and structural factors driving the epidemic and drug resistance. All the while, the highest TB burdens exist where vulnerability and marginalization increase the risk of infection and disease and erect barriers to accessing testing and treatment services.

Unsurprisingly, developing countries account for 95% of all TB cases and deaths.[2] Disease prevalence within countries reflects the same startling disparities between the wealthy and the poor. In India, which accounts for 23% of all TB cases in the world, data from a Demographic and Health Survey study reveals that members of the poorest quintile are at a 5.5-fold higher risk for self-reported prevalent TB than those in the wealthiest quintile.[3] Key affected populations—the poor, people living with HIV/AIDS, mobile populations, prisoners, miners, people who use drugs, and children—face entrenched stigma and discrimination, further restricting access to services, discouraging health-seeking behavior, and making it difficult for them to mobilize and demand their rights.

Despite this, and in stark contrast with efforts to combat HIV, human rights have played only a peripheral role in efforts to prevent and treat TB. This is evident in the limited role rights play in global advocacy efforts, the dearth of TB-specific legislation articulating the rights of people with TB, the underdeveloped jurisprudence involving TB and human rights in courts around the world, and the lack of funding for rights-based TB programming. More generally, the role the law plays in supporting or hindering efforts

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to combat TB has not been fully examined. As one prominent example illustrates, even where funding is available for human rights programming for TB, there is a lack of demand. The Global Fund to Fight AIDS, TB and Malaria advised the authors that it has analyzed approximately 50 country funding requests for TB submitted during the past two years and found that, while the majority identified human rights-related barriers to services, including high levels of stigma and discrimination, only a few included any investment in human rights programs to address those barriers.

A human rights-based approach to TB is grounded in international and regional treaties and national constitutions.[4] These laws establish the rights of people living with and vulnerable to TB, including the rights to life, health, nondiscrimination, privacy, participation, information, freedom of movement, housing, food, water, and to enjoy the benefits of scientific progress. Human rights law also creates corresponding legal obligations of governments and responsibilities of private actors, promoting accountability and access to remedies for rights violations. Moreover, as has been demonstrated in the fight against HIV, respecting and promoting the human rights of people with TB is likely to foster more sustainable interventions, improved prevention and treatment outcomes, and reductions in drug resistance.

The six papers and two perspectives in this special section cover diverse topics and concerns related to TB and the right to health, with a broad geographic scope. Nonetheless, key issues and themes emerge and cut across multiple papers. These include:

- the lack of adequate research and development of health technologies for TB and the right to benefit from scientific progress;
- imprisonment and compulsory treatment of people with TB;
- human rights-based approaches to TB in advocacy, litigation, and assessment strategies; and
- accountability and the human rights obligations of governments and international organizations to prevent and treat TB.

Several papers also examine problems in specific contexts around the world, including in Kenya, North Korea, Peru, and India.

## Lack of adequate research and development of health technologies for TB and the right to benefit from scientific progress

Two papers explore the relationship between the right to health, the right to benefit from scientific progress, and research and development of health technologies for TB. Mike Frick, Ian Henry, and Erica Lessem set the stage for the discussion by pointing out that the majority of TB drugs are decades old and several have never been studied for use against TB in randomized controlled trials. In fact, only two new drugs have been approved to treat TB in the last 40 years—delamanid and bedaquiline—and both are still largely unavailable to patients who need them. Approximately 2% of the estimated 150,000 people each year who would benefit from bedaquiline or delamanid under current WHO guidance have received them.[5] Moreover, Frick et al. note that the limitations of current treatment options leave patients reliant on lengthy regimens that are difficult to tolerate, making adherence difficult and creating the conditions under which drug resistant strains flourish. Underlying these problems is the acute global deficit in investment for TB research and development. By the end of 2014, the world had invested less than one-third of the $9.8 billion needed to develop the necessary tools to eliminate TB.[6]

In light of this, Frick et al. analyze state obligations under the rights to health and to benefit from scientific progress, both to consider practical means of improving government responses to TB and to articulate the content of obligations to address the lack of research and development for the disease. They emphasize governments' obligations to take steps necessary for the development and diffusion of science, including public investment, public participation, and public planning and accountability for research and development of health technologies. In particular, they call

upon states, in the short term, to support research to address gaps in TB drug development, including improved pediatric formulations and capacity-building for clinical trials and, in the long term, to increase support for basic TB science, new drug discovery initiatives, and phase III clinical trials of new drug regimens.

Leslie London, Helen Cox, and Fons Coomans present a similar analysis, but focus more squarely on MDR-TB and the right to benefit from scientific progress. They assert that, while the right does not provide an individual entitlement to development of a new drug for MDR-TB, it "entails a right for people to have a legislative and policy framework adopted and implemented which aims at making the benefits of scientific progress available and accessible—both through encouraging new scientific discoveries, and through removing barriers for existing scientific knowledge to be used for public benefit." To fulfill this right, governments should increase direct state investments in research and development of new medicines and provide subsidies and tax benefits to incentivize research and development by private companies, research institutes, and universities. They also emphasize the need to ensure regulatory approvals of new TB medicines are expedited and that systems are in place to ensure new medicines can be quickly integrated into existing operational protocols.

London et al. also consider whether wealthy countries have obligations pursuant to the right to benefit from scientific progress that extend beyond their own borders. They contend that, in an era of economic globalization and shifting alliances in global health governance, wealthy countries may have both positive and negative extraterritorial obligations. Negative obligations include the duty not to promote policies that infringe the rights of people in poorer countries, such as price protections for medicines at the expense of local access. Positive obligations include strengthening research infrastructure and capacity in poorer countries through the free transfer of knowledge and the development of drug and vaccine funds with contributions from wealthy countries, the corporate sector, and donor organizations.

## Imprisonment and compulsory treatment of people with TB

Traditional biomedical and public health approaches to TB have at times sought to control the spread of the disease in ways that are at odds with a human rights-based approach. Public health laws in many countries allow for the sanction and punishment of people with TB who refuse treatment or are lost to treatment follow-up. Gitau Mburu, Enrique Restoy, Evaline Kibuchi, Paula Holland, and Anthony D. Harries' paper and Allan Maleche and Nerima Were's perspective essay explore the imprisonment of people with TB in Kenya who are lost to treatment follow-up, including an analysis of the recent landmark decision on this issue from the High Court of Kenya at Nairobi.[7]

Kenya is one of WHO's 22 high TB-burden countries. The Public Health Act of Kenya allows for the isolation and detention of any person that "has recently been exposed to the infection, and may be in the incubation stage, of any notifiable infectious disease," including TB, if that person is "not accommodated in such manner as adequately to guard against the spread of the disease."[8] The Act also creates a penalty for those who "willfully expose" themselves in public "without proper precautions against spreading the disease."[9] The application of the law has resulted in the imprisonment and compulsory treatment of people with TB who are lost to treatment follow-up. In some cases, people with TB do not receive appropriate treatment in prison and the risk of disease transmission to other prisoners is high, due to overcrowded and poorly ventilated detention conditions.

Mburu et al. explore the potential risks of incarceration and compulsory treatment as a means of enforcing treatment adherence, both from a public health perspective and in light of patients' human rights. They provide several reasons to reject the practice of imprisoning people with TB and offer human rights-based alternatives. The authors note that people with TB are often denied access to health goods and services in prison that are scientifically appropriate and of good quality, as required by the right to health. They also assert that limitations of the right to freedom of movement

are not justified under the UN Siracusa Principles, because imprisonment "fail[s] to effectively contribute to effective TB control and sound public health response."[10] Finally, they note that imprisonment is likely to exacerbate existing socioeconomic deprivations of people with TB and that the stress and social exclusion associated with criminalization could adversely impact patients' psychological well-being, leading to substance abuse and other poor health outcomes.

Mburu et al. suggest three broad categories of human rights-based alternatives to imprisonment of people with TB lost to treatment follow-up: (1) preventing primary loss to follow-up, (2) improving the premises and conditions of isolation, and (3) amending public health laws to exclude prison as a setting for mandatory isolation. The third suggestion is addressed in Maleche's essay on the decision in *Daniel Ng'etich v. Attorney General* from the High Court of Kenya at Nairobi. The case involved a challenge to the arrest and imprisonment of two TB patients—pursuant to the Public Health Act discussed above—for interrupting their treatment. The petitioners argued that imprisonment was not authorized by the Act and that it violated their constitutional rights to health, dignity, and liberty, among others. The court noted that, in accordance with the UN Siracusa Principles, isolation and detention are permissible in some instances, where a person with TB poses a threat to public health. However, the court rejected an interpretation of the Public Health Act that allows prison to be used as a setting for mandatory isolation and held that the practice violates the Constitution of Kenya. Importantly, the court ordered the Cabinet Secretary for Health to develop a new involuntary confinement policy that does not involve imprisonment and that protects the constitutional rights of people with TB. The decision represents a concrete application of a human rights-based approach to TB that effectively considers both the individual rights of people with TB and concerns for public health.

## Human rights-based approaches to TB in advocacy, litigation, and assessment strategies

Although application of human rights-based approaches to TB have thus far been limited, a few papers in this section analyze situations involving TB and human rights and present potential means of addressing rights violations. One striking feature of these papers is their deeply context-specific nature. In this respect, they suggest that taking a rights-based approach to TB requires a context-driven analysis guided by human rights principles.

Camila Gianella, César Ugarte-Gil, Godofredo Caro, Rula Aylas, César Castro, and Claudia Lema examine the situation of the Ashaninka, an indigenous group in the Peruvian Amazon that is especially vulnerable to TB. Although Peru is classified as a middle-income country, it is highly unequal, with indigenous populations generally much poorer and experiencing worse health outcomes than non-indigenous Peruvians. In their assessment, Gianella et al. make use of the OPERA framework, developed by the Center for Economic and Social Rights. The framework provides guidance on human rights analysis of outcomes, policy efforts, resources, and assessment. The authors find that it allows for a holistic and deeply embedded examination of the factors giving rise to the increased vulnerability of the Ashaninka to TB and helps in identifying potential human rights violations in the Ashaninka community. In particular, they demonstrate that political decisions in the provision of TB care are largely responsible for the increased vulnerability of the Ashaninka. The paper highlights the importance of a human rights-based approach to TB that focuses on the structural determinants of health, including the distribution of economic resources and access to health information, rather than narrowly focused biomedical interventions.

Along similar lines, Sandra Fahy's perspective essay provides insight into the experience of migrants and prisoners in the Democratic People's Republic of Korea (North Korea) and demonstrates

the urgent need to implement a human rights-based approach to TB in the country. While data is extremely limited, TB is by all accounts a major concern within North Korean prisons, where approximately 1 in every 200 citizens is held. Fahy describes a near-total disregard for the treatment of prisoners with TB in North Korea. Reports range from spraying sterilizing cleaning solutions directly on prisoners with TB, to the near absence of testing and treatment services in prison health facilities. Significant restrictions on the movement of people in and out of North Korea contribute to a high prevalence of TB in mobile populations as well. Approximately 300,000 North Koreans reside illegally in China and 27,000 have gone through a difficult process to live legally in South Korea. These populations have highly restricted access to health care because they fear that attention will result in deportation and incarceration in North Korea.

In her paper, Kerry McBroom examines the utility of human rights litigation as one component of a larger strategy to realize the rights of people with TB in India. In particular, she considers the benefits (and potential adverse impacts) of a specialized litigation known as public interest litigation (PIL). McBroom considers as a case study a recent PIL in the High Court of Delhi, *Sanjai Sharma v. NCT of Delhi*, that sought to hold the Government of Delhi accountable for violations of the rights of people with TB to health, food, and to be free from discrimination.[11] The petition, filed by the Human Rights Law Network, relied on years of data collection and interviews with affected communities. It revealed serious barriers to accessing good quality TB testing and treatment in Delhi. These included physically inaccessible and understaffed clinics, drug stock-outs, use of outdated testing methods, and an acute lack of understanding of the disease and its treatment among vulnerable communities. The petition asserted that the government had several constitutional obligations: to make available and accessible, on a non-discriminatory basis, good quality facilities, goods, and services for TB; to ensure conditions of treatment are acceptable to all people with TB, including providing gender-sensitive treatment; and to provide nutritional supplements to people with TB who need them.

McBroom explains that the petition requested the court, among other things, to direct the government to conduct an independent audit and quality control survey of all government-run TB clinics in Delhi. The court's ruling, however, simply noted that the petition had pointed out several shortcomings in the government's TB program and ordered the government to meet with the petitioners, allowing for a revival of the case if the government did not act. McBroom acknowledges that this outcome creates a valuable space for dialogue with the state, but she laments that the court failed to address any of the specific claims raised in the case. She also highlights the frequent failure of the government to respond adequately to court orders in PILs more generally. With these limitations in mind, the paper concludes that litigation can play a critical role in realizing the human rights of people with TB, but it must be thoughtfully integrated into a broader, comprehensive advocacy strategy.

## Accountability and the human rights obligations of governments and international organizations to prevent and treat TB

Accountability is a central feature of a human rights-based approach to TB, and to health more generally. It distinguishes the approach from more traditional biomedical and public health-based approaches in requiring that governments and other actors be held accountable in law for the failure to uphold their obligations and in providing remedies for rights violations. The Kenyan High Court decision discussed above provides an instructive example. The government violated the rights of people with TB when it imprisoned them for stopping their treatment. The court recognized this as a rights violation and ordered the government to change its behavior, both holding the state accountable and providing a remedy in the form of a

revised involuntary confinement policy.

Several papers in this special section grapple with the task of articulating human rights obligations in the context of TB and ensuring accountability when rights are violated. Most notably, Thomas Nicholson, Catherine Admay, Aaron Shakow, and Salmaan Keshavjee consider the obligations of WHO with regard to its global MDR-TB program. Frick et al. and London et al. carefully articulate state obligations under the rights to health and to benefit from scientific progress in the area of research and development of health technologies for TB. Gianella et al. and McBroom prioritize accountability in their analyses of human rights-based approaches to TB advocacy, litigation, and assessment in the contexts of Peru and New Delhi, India. And, as noted, Maleche and Were provide a recent concrete example of accountability won through the courts.

Nicholson et al. examine WHO's MDR-TB policy decisions between 1993 and 2002, in light of alternative approaches available at the time and legal standards in the WHO Constitution and the International Covenant on Economic, Social and Cultural Rights (ICESCR). Their stated aim is to "foster transformative accountability" for past violations and to "mov[e] away from double standards" in TB care. They argue that during the period examined, the standard of care recommended by WHO for MDR-TB patients in low-resource settings was less effective than available alternatives used to contain and defeat MDR-TB in rich countries. The authors contend these policies resulted in potentially hundreds of thousands of avoidable deaths. In particular, they allege that cost considerations, driven by relationships with the World Bank and other donors, led to a global "double standard of care" for MDR-TB. In support of this claim, they cite statements made by WHO representatives and specific policy decisions, such as including "comparative cost effectiveness," rather than simply "effectiveness," as a criterion for inclusion of a drug on the 2002 WHO Model List of Essential Drugs.

In essence, Nicholson et al. claim WHO did not meet its obligations under the right to health in its own constitution and the ICESCR. They acknowledge, however, that WHO does not have direct obligations under international human rights law, as do states. Instead, they argue the organization has "responsibilities regarding the realization of the right to health," referring to, among other things, the UN Statement of Common Understanding on Human Rights-Based Approaches to Development Cooperation and Programming. They also maintain that WHO stands to lose institutional legitimacy if it denies the relevance of human rights law to the content of its policies.

## Developing a human rights-based approach to TB

The papers and perspectives in this special section illustrate the breadth of issues related to TB and the right to health, and human rights more generally. From the lack of research and development of new health technologies needed to better diagnose and treat TB, to the imprisonment of people with TB who stop their treatment, to the development of human rights-based approaches to the disease in Peru, India, and North Korea, and the accountability of WHO for global MDR-TB policies, this section highlights diverse issues facing the global community in its fight against TB. However, the pieces represent the beginning of a long-overdue conversation rather than a reflection on a long-standing movement. The global community can no longer afford to combat TB exclusively through biomedical and public health-based approaches—not when millions continue to suffer and die each year from an age-old illness that is both preventable and treatable. Recognizing and realizing the rights of people with TB, and enforcing the corresponding obligations of governments and other key actors, is a necessary and essential part of our ongoing efforts to eliminate the disease and to treat those who suffer from it now.

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