

USING HUMAN RIGHTS TO ADVANCE TB RESEARCH & ACCESS

TB2016 | SCIENCE + SOLIDARITY

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Good morning. Thank you to the organizers for inviting me and to the chairs for the warm introduction. We've waited a long time to have a TB-specific gathering at an AIDS conference, and it is good to be here. And it's a particular honor to speak at this meeting, which has chosen as its theme science and solidarity. I hope to address both of these ideas in my talk and show how, through the lens of human rights, science and solidarity are the twin engines driving our path to TB elimination. And demonstrate how human rights can be harnessed to advance both TB research and access to its benefits, and in doing so maybe even build a bridge between basic science and outcomes in patient care, the problem that Cliff addressed in his talk.

So, as this first slide and the photo that I'm trying to bring up on the next one suggest, the close connection between TB research and human rights is something that the grassroots, civil society, TB-affected communities have already recognized and articulated. It's an idea that we TB activists, led by our comrades in South Africa's Treatment Action Campaign, have, in fact, taken into the streets. This is a photo from a march organized by the Treatment Action Campaign at last year's Union Conference in Cape Town, and the rallying cry of the march was "Invest in TB R&D." Specifically, the marchers in this photo staging this die-in were calling on political leaders of the BRICS countries—Brazil, Russia, India, China, South Africa plus Indonesia—to triple their funding for TB research, delivering an urgent reminder to these political leaders that we still die of TB, your people still die of TB.

The close connection between human rights and TB research has also been recognized in Geneva, where one of the foundational planks of the World Health Organization's End TB Strategy is protecting and promoting human rights, ethics, and equity, upholding the third pillar of the strategy, which is intensified research and innovation. So, TB activists have articulated demands for increased investment in TB science based on human rights consequences like the loss of life, and the WHO has suggested that there is a connection between protecting and promoting human rights and intensified TB research. But I think to really understand the demands of TB activists and the aspirations of the WHO's End TB Strategy, it's helpful that we understand what we talk about when we talk about rights—their specific nature. And just as science speaks in terms that are precise and specific in meaning, human rights are not just vague aspirations, ideals, or visions of the good life. They are specific in character and refer to specific entitlements that are timeless, fundamental to the human person, universal, inalienable, and indivisible. These entitlements are defined by international law, and as such they primarily concern the relationship between individuals and their governments.

Governments are the entities tasked with upholding human rights through a set of actions that we refer to as respecting, protecting, and fulfilling rights.

Now, many of us, including myself, come from countries where we tend to think of rights as being civil and political: suffrage, the right to freedom of movement, freedom of religion. But there is another branch of international human rights law that resonates more deeply with TB and the science of TB in particular, and those are the economic, social, and cultural rights, and I'm going to talk about two that have particular relevance for this scientific enterprise. The first is the right to the highest attainable standard of health, and the second is the right to enjoy the benefits of scientific progress and its applications.

When we talk about human rights and TB research at all, we usually start with the observation that the conduct of TB research needs to respect medical ethics and human rights, and hopefully this is a point of consensus among all of us. But beyond just ethical research conduct, TB research implicates human rights in a number of ways. TB research and access to its benefits can either reinforce or resolve ethical dilemmas in TB prevention, diagnosis, treatment, and care. Consider the ways that an underfunded R&D environment, slow progress in the clinical pipelines, have left TB patients reliant on poorly performing, poorly tolerated regimens that complicate adherence in a number of ways that raise a whole host of ethical issues that TB programs must navigate day to day. TB research can also change the way that TB is culturally perceived. Imagine the power to work against fear and stigma if the message that TB is preventable, treatable, and curable is widely known. And the corollary: the gains against stigma and fear that can be rolled back if, due to a lack of research, what was once curable becomes more chronic and deadly, as is happening with the rise of drug-resistant TB.

Research can also galvanize advocacy, it can clarify legal petitions for redress of TB related harms. And we've seen how that can happen in two landmark court cases here in Africa this year. The first in Kenya where the NGO KELIN just won a major case in the Kenyan High Court. The ruling basically comes down to the fact that TB is not a crime. KELIN was representing three men who had been imprisoned for poor adherence to TB medication, and the court ruled that promoting adherence is good, but sending people to jail to ensure adherence is not in accordance with human rights standards. The second case is right here in South Africa where miners recently won the right to act as a class in their litigation against South African mining companies for failing to offer them protection against silicosis and TB in the mines. Both cases drew heavily on the science of TB transmission, what we know about TB treatment and its effectiveness, and the science of patient care and support.

Research can also either reinforce or resolve the inequities that drive the TB epidemic, globally or locally. Think about who has access to clinical trials, who can participate in research, how that research is regulated in places where trials are not conducted, and the difficulties of ensuring that the products of research—new tools to fight TB—reach all people in need.

So, those are some of the human rights issues that research implicates, but there's also the potential for human rights to advance and strengthen the case for intensified research and innovation. A natural starting place for understanding how this can happen is the International Covenant on Economic, Social, and Cultural Rights, article 12, which is the right to the highest attainable standard of health. Importantly, the right to health is not a right to be healthy, and it's not just confined to discussions of healthcare. The right charges governments with ensuring that the conditions conducive to a healthy life are in place. This includes the availability of health goods and services, which must be made available within governments that have signed and ratified this convention. Sometimes, this availability may require promoting medical research or health education.

So I think within the right to health there is a really strong argument to be made that where inadequate or outdated tools hinder a vigorous public health response to an epidemic, fulfilling the right to health actually requires governments to ensure the availability of health technologies through the promotion of research required to create them. It is clear that inadequate and outdated tools hinder the global response to the TB epidemic. We are using diagnostic tests that are over 100 years old, we have a TB drug pipeline that has few new candidates from novel classes in it, and a vaccine that was introduced in 1921. So the right to health can point us strongly in the direction of tasking governments to promoting research in order to ensure the availability of the tools we need to beat TB.

But there's this other human right that speaks more directly to the scientific enterprise and the work of scientists—the work that many of you in this room are doing. It's article 15 of the International Covenant of Economic, Social and Cultural Rights: the right to enjoy the benefits of scientific progress and its applications. It is one of the least well-known human rights, often forgotten entirely. There has been very little litigation or court activity around this right, yet I think it has a deep potential to advance the TB research cause. When the right refers to scientific progress, it's not just talking about general knowledge advancement, the kind of knowledge that accrues from scientific discovery. It extends to the actual applications of that discovery. It's clear in the drafting history of the right, when countries came together to define it in the post-war period, that they were talking about tangible benefits when they were talking about applications of science. For medicine, that would mean access to new tools: new drugs, new diagnostics, new vaccines. In keeping with the human rights principle of non-discrimination, all people are entitled to enjoy the right and particular attention and innovation must be paid to vulnerable and marginalized groups. Certainly, people with TB are often from the most vulnerable quarters of society. What's most important is that the right tasks states with two obligations. They both have to develop science and they have to diffuse it. So it is significant that article 15 singles out development and diffusion as distinct yet related activities existing on the same plane of concern for governments.

So, what do development and diffusion actually mean? A report by the UN Special Rapporteur in the field of cultural rights provides some clarity. Development actually refers to investment, to funding, and because it's governments tasked with upholding human rights, it is publicly funded research that must be strengthened. This can include

cooperation with the private sector, and it should include things such as scientific freedom, what scientists need to do their work. Diffusion is then the dissemination of scientific knowledge and its applications, not just within the community of scientists through peer review or presentations at conferences such as this one, but within society at large. Because without diffusion there can be no public participation in scientific decision-making, participation being another key human rights concern, and without diffusion we cannot have future innovation. We have to share knowledge in order to create knowledge.

What can governments do specifically to promote development and diffusion of TB science? Human rights scholar Audrey Chapman has outlined a number of steps that governments can take, and they speak directly to the demands that are often voiced by TB activists. The first is funding. Governments must set priorities for public funding. They must channel sufficient investments in what Chapman calls a “purposive development of science and technology” to meet the needs of disadvantaged groups. Regulation, a concept that TB activists frequently invoke as a challenge toward access. That is, you need to have the ability to evaluate a product developed in clinical trials conducted elsewhere to allow for its importation to the benefit of your own people, something we often come up against in struggle. Community engagement is participation in science. It’s the work of community advisory boards and the acknowledgement that an individual has the right to participate in research as more than just a clinical trial participant. They have the right to participate in scientific agenda setting and the translation of science into policy and practice. Then, access mechanisms and ensuring that the tools and applications of science are equitably distributed, and accountability mechanisms to hold governments to task and to account for development and diffusion. We need all of these things and they’ve already been voiced by TB activists.

Here I am quoting just one instance of where the connection between human rights and scientific progress has been articulated. This by Anele Yawa, the General Secretary at the Treatment Action Campaign, in his closing remarks at last year’s Union Conference. Notice how he is speaking directly to governments: “We say to the government of China, we say to president Xi Jinping, ‘Your people are dying of TB. Why are you not investing in TB research?’”

What is Anele referring to and how are governments doing when it comes to the development and the diffusion of TB science? Not very well. We know that global funding for TB R&D is woefully inadequate. Ten years of data collected by Treatment Action Group, my organization, shows that global annual funding for all forms of TB research and development, from basic science to operational research, has never totaled more than US\$700 million a year. The trend has been flat since 2009, but these are nominal figures not adjusted for inflation, and of course we know that inflation does not stand still for a flat, public budget. So, in fact, the flat trend is a declining trend. We are expending less on TB research in real terms than we were in 2009, or even in 2006.

It’s not just that we have a little amount of money to spend, it’s that it is highly

concentrated among a few institutions. So the funding we have is precarious. When a big player pulls out of the field, it has an effect on everyone. Last year, US\$674 million was spent on TB R&D. Fifty percent of it came from just two organizations: the US National Institutes of Health and the Bill & Melinda Gates Foundation. So we don't have solidarity when it comes to funding TB research. Funding largely depends on public budgets, which is what makes human rights such a germane topic for us, because it is governments that are tasked with upholding human rights and it is governments that are funding TB research. The blue line at the top, which is far above the others, shows you the proportion of annual funding for TB research since 2005 that comes from public sector agencies. You can see that it's far above what other sectors give: philanthropic institutions in dark blue, the private sector in yellow, and multilateral institutions in orange. Last year, in 2014, public agencies gave 60 percent of all money spent on TB research globally. That is a reliance on public budgets that has only intensified since 2011, which is when the pharmaceutical industry began to pull out of TB research. Entire companies have shut down their anti-infectives divisions or TB research programs. Where is Pfizer? Where is Astra-zeneca? Starting in 2011, industry funding for TB research started falling. From the US\$145 million pharmaceutical companies spent on TB R&D in 2011, that total has now dropped to just under US\$100 million in 2014, and again, it's worse than it looks because this is highly concentrated: 60 percent of that US\$100 million came from a single company: Otsuka. We have little solidarity in funding our TB research.

So what are the consequences of limited funding for human rights? It's my opinion that limited funding limits the equity proposition of our TB research from the outset. It means that compromise is woven into the fabric of TB research itself. There is a real sense at TB research meetings that investigators are conditioned to think not just in terms of efficiencies but actually scarcities, and this has affected the way that we prioritize research. Think of the way we don't study new drugs in optimal combination, due to the way TB research is owned that doesn't always allow for optimal collaboration. So we have single new agents rather than the entirely new regimens that we need.

There is little money for research that focuses on the most vulnerable or includes them in clinical trials, the people most vulnerable to TB who are most urgently in need of innovation for new tools: pregnant women, children, people who use drugs, people with HIV, those with non-pulmonary forms of TB. When drugs are approved in TB, they are approved with minimal data on their use. Compare the number of studies behind the new TB drug delamanid with one of the newest ARVs—dolutegravir—by the time each received marketing approval—reached the market. It's the third box on this slide. By the time dolutegravir received FDA approval, it had completed or initiated 61 studies, compared to 6 with delamanid, a difference of 10-fold. We just have so little data on the drugs and how to use them. Partly, this is a consequence of differences in funding. Over US\$2 billion spent on HIV drug development in 2011, compared to under US\$300 million spent on TB drug development last year. We aren't keeping pace in terms of innovation with our sister epidemic. TB and HIV research are on almost totally different planets in terms of the amount of resources dedicated to each. That's born out by FDA approvals. The FDA since 1987 has approved over 37 drugs or drug combinations for

HIV compared to just 2 drugs for TB.

So that's the development story. How are we doing in terms of the other government obligation, diffusion, or access? Here, too, things are not looking so good. A survey of 24 countries conducted by MSF shows that national TB policies governing access to state-of-art TB care are seriously out of step with global guidelines. Of 24 countries surveyed by MSF, only 30 percent had policies ensuring rapid molecular tests are used as the initial test for everyone being evaluated for TB, especially important for those with forms of TB that aren't well-diagnosed with old technologies—people with HIV and children in particular. Most concerning to me, 60 percent of countries continued to offer the category II re-treatment regimen, which we know basically amounts to monotherapy and a signal that DST isn't necessary for someone. But, only 12 percent of countries had all existing drugs on their national essential medicines list, in terms of drugs available to treat DR-TB, and only 65 percent of countries had a process in place to access the newest TB drugs for TB patients who had run out of other options. So whether it's old technologies or new technologies, policies and practices are not reflecting the access needs of TB patients.

This is why, throughout the conference, you will be hearing from activists who are calling on you—that's everyone—to sign the dotted line to commit within 500 days to urge your country, your NTP program, and the other players that be in the TB field where you work to implement WHO guidelines on TB and DR-TB in these 5 critical areas. This is just one step to ensuring that the benefits of scientific progress extend to all people who need them with TB, and I have been told that you can actually sign on the dotted line if you go to the Stop TB Partnership's [website online](#).

I want to close with the words of Paul Farmer, who was writing in 1999 around the last time that the AIDS conference came to Durban. He was talking about the human rights agenda, and he singled out the need to focus on scientific progress and place it alongside the right to health in order to move forward and make progress. He was specifically writing with the example of drug-resistant TB in the Russian prison system in mind. He says, "[what we need is] an agenda for research and action grounded in the struggle for social and economic rights, an agenda suited to public health and medicine whose central contributions for future progress in human rights will be linked to the equitable distribution of the fruits of scientific advancement." I hope that we can spend today and tomorrow crafting this agenda for research and action together.

Thank you. And special thanks to my colleagues at TAG, Erica Lessem and Lindsay McKenna, and to Ian Henry at the University of Southern California, for helping to develop many of the ideas presented here.