ACT UP. FIGHT BACK. FIGHT TB: POTENTIAL PATHWAYS TO R&D FUNDING ADVOCACY FOR THE U.S. TB COMMUNITY

By Elizabeth Lovinger and Suraj Madoori

Since the beginning of the HIV epidemic in the United States–before HIV even had a name–those most affected have been vocal activists, and better access to treatment and prevention innovations have long been among their concerns. In many ways, TB-affected communities face similar challenges as people living with HIV (PLHIV) did in the early days of the epidemic. TB is also a communicable disease that ravages marginalized populations. As with HIV in the 1980s and early 1990s, TB receives very little political and private attention, despite being a public health crisis with limited tools to stop it. TB today has surpassed HIV as the world's leading infectious killer and is the most common cause of death among PLHIV globally. Like HIV, TB is concentrated among low-income communities and disproportionately affects people of color, people who are homeless, and immigrants.

TB keeps its grip on these communities in part because research funding, which increasingly comes from publicly funded institutions, has been stagnant. Underinvestment in research and development (R&D) has led to the use of arcane TB treatments with multiple pills and daily injections, which produce debilitating side effects such as hearing loss and mental health issues. As Mike Frick notes, limited resources for TB R&D limits equity from the outset: Scant funding forces researchers to compromise on conducting research that truly reflects the needs and characteristics of key populations. For example, to get the biggest results with the smallest, least expensive trials, researchers may prioritize patients with the "easiest to treat" profile, e.g., those with very little cavitation in the lungs, or PLHIV with high CD4 counts. Very few TB studies include those most vulnerable to TB, including children, pregnant and lactating people, and people who use drugs. Limited funding for TB R&D thus excludes the particular needs of these populations from the beginning, leading to data and policy decisions that exclude the very people we should prioritize for treatment.[1]

There are many lessons to be learned from the successes of HIV activism. In the HIV movement, activists brought attention to the dearth of research on HIV, contributing to a dramatic increase in R&D funding, as well as influencing research design.[2] For example, the U.S. Food and Drug Administration (FDA) licensed zidovudine (AZT) in 1987 based on data from a placebo-controlled study that was stopped early because of a disproportionate death rate in the placebo arm. After that, activists and PLHIV worked to minimize the use of placebo arms.

Over the next 10 years, activists and scientists worked to evolve and improve both clinical trials and the underlying standards of HIV care. These came to allow the use of concomitant medications, including prophylaxis for opportunistic infections such as Pneumocystis pneumonia, cytomegalovirus, toxoplasmosis, and Mycobacterium avium complex. Through activists' pressure, scientists created new regulatory pathways: expanded access and parallel track programs to allow preapproval access to experimental therapies when people were ineligible for controlled clinical trials, and accelerated approval, through which the FDA could offer preliminary approval for a drug based on favorable changes in surrogate markers (requiring that these be confirmed later in controlled clinical trials).

These initiatives both broadened access to and sped up approval of experimental therapies for HIV, thus significantly increasing the speed of innovation.[3] These and many other successes forever changed the landscape of HIV science. The current level of HIV research funding at the National Institutes of Health amounts to nearly $3 billion, having doubled from $1.5 billion in 1995 to its current level in 2004.[4]

Research on TB is ripe for similar changes, and global communities of TB survivors are better poised than ever to mobilize and call for these changes. They are finding connections through partner organizations and social media, and they have demonstrated solidarity in advocating for the R&D funding necessary to defeat the aforementioned treatment toxicities, inaccessibility, and inequities.

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There's a global annual TB R&D funding gap of $1.3 billion, with only $772 million in total research funding committed worldwide in 2017. At the United Nations, the September 2018 UN High-Level Meeting on TB signaled the need for action, including scaling up contributions to TB R&D—but member states made little in the way of concrete commitments. So how can the TB advocacy community in the U.S. catalyze much-needed investments in TB R&D?

The role of TB survivors and community advocates in the U.S. is particularly important. With 40 percent of total TB R&D funding coming from U.S. government agencies, the U.S. TB advocacy community is well-positioned to influence these institutions to advance R&D for new TB tools that will have an impact in the U.S. and globally. In part, this will mean messaging the successes and global implications of U.S. investment to policymakers as reasons to continue momentum and strengthen TB research investments. These successes include: 4-week and 12-week regimens to treat latent TB infection (which are shorter than, and just as effective as, previous regimens); bedaquiline; and potential future therapeutics for TB such as pretomanid, the latest TB drug to be submitted to the FDA for evaluation. As the administration continues to vocalize the need for other countries to "pay their fair share," U.S. TB advocates are well-positioned to advance a globally accepted, TAG-developed fair share target for TB R&D in Congress and among agencies. This target, for U.S. and other member states to each devote 0.1% of existing gross domestic expenditure on R&D overall toward TB-specific research, would bring the world to a funding amount that could end TB by 2030. For the U.S., this amounts to a manageable $131 million in additional funding from the government, split across several institutions.[5]

Lastly, mirroring the HIV activist legacy, the U.S. TB community should deepen its involvement in TB research conducted by U.S. institutions to ensure that studies continue to answer critical questions and engage communities in research. Doing so requires investment in building the capacity and leadership of members in nascent constituency-based advocacy networks such as We Are TB (see textbox)—including increased funding for advocacy trainings and participation in policy conversations at the regional and national levels, as well as connecting them to other TB advocacy groups with a strong research orientation, such as the Global TB Community Advisory Board (see Sound Off). This, in turn, would change many of the benefits from U.S. research institutions and ensure that funding is never the reason why critical TB R&D is compromised.

Endnotes

1 Frick M. Using human rights to strengthen TB research and access [transcript of TB2016 plenary address]. TAGline. 2016 Fall. http://www.treatmentactiongroup.org/tagline/2016/fall/science-and-solidarity.

2. Colvin CJ. Evidence and AIDS activism: HIV scale-up and the contemporary politics of knowledge in global public health. Glob Public Health. 2014;9(1-2):57-72. doi: 10.1080/17441692.2014.881519.

3. Jonsen AR, Stryker J. The social impact of AIDS in the United States. Washington: National Academies Press (US), 1993.

4. Summers T, Kates J. Trends in U.S. Government Funding for HIV/AIDS Fiscal Years 1981 to 2004. Henry J. Kaiser Family Foundation. 2004 March. https://kaiserfamilyfoundation.files.wordpress.com/2013/01/issue-brief-trends-in-u-s-government-funding-for-hiv-aids-fiscal-years-1981-to-2004.pdf

5. Low M. Tuberculosis research funding trends, 2005-2017. New York: Treatment Action Group; 2018 December. http://www.treatmentactiongroup.org/content/tbrd2018

We Are TB

We Are TB is a national patient-survivor community with about 40 members across the United States. We Are TB connects TB survivors with each other and with local and state departments of health to share information about the issues that have directly affected them, including TB R&D. Members can access capacity-building and advocacy opportunities to educate elected officials about their experiences and explain how increased R&D funding would have made a difference for them. There are members across the country in almost 30 cities, from Los Angeles to Birmingham and Denver to Burlington. Members of this group have proven to be effective in advocacy: They've contributed to a slew of victories to support TB R&D funding, from protecting the Centers for Disease Control and Prevention's domestic TB program from budget cuts in FY17 through FY19, to increasing funding for the U.S. Agency for International Development's global TB program to its highest level at $306 million in FY19, to influencing policies on the inclusion of pregnant people with TB in clinical trials by testifying before the Task Force on Research Specific to Pregnant and Lactating Women.