Viewpoint

Applying the right to health to medical research: Opportunities for advocacy

Mike Watson Frick[a]

a TB/HIV Project, Treatment Action Group, New York

The right to the highest attainable standard of health offers a strong conceptual foundation for advocacy in response to emerging and established infectious diseases. Much of this advocacy draws on core obligations under the right to health as outlined in article 12 of the International Covenant on Economic, Social and Cultural Rights [1] and its normative content as discussed in General Comment 14 of the Committee on Economic, Social and Cultural Rights (CESCR) [2]. The CESCR's interpretation of article 12 opens many entry points for advocacy, and the right-to-health framework that has emerged from treaty interpretation and normative practice has proved versatile in helping activists respond to a range of diseases. These include diseases for which there is treatment but no cure (e.g. HIV) as well as those that continue to exact a heavy toll on human well-being despite the discovery of curative therapies decades ago (e.g. tuberculosis).

Within the tuberculosis (TB) and HIV epidemics, most activists working under a right-to-health framework have focused on extending and securing access to life-saving medical products (i.e. drugs, drug regimens, prevention methods, and diagnostic tools). This framework has provided fertile ground for building the social movements that spurred governments, pharmaceutical companies, and multilateral organizations to scale up access to antiretroviral therapy in response to HIV [3]. Less often have these advocacy movements applied the right to health at the upstream point where medical technologies are conceived, designed and researched. As science-based treatment activists, my colleagues and I at Treatment Action Group (TAG) believe that the right to health holds the potential to bolster advocacy aimed at shaping and accelerating vital research, just as it has strengthened advocacy aimed at resolving inequities in access.

As a starting point, human rights scholars and activists should recognize that upholding the right to health requires engagement with the design and conduct of health and medical research (traditionally a territory left to medical ethics). Here, human rights concepts such as participation, transparency, accountability, and nondiscrimination are central to what TAG and others call "good participatory research practices". The *Good Participatory Practice Guidelines for TB Drug Trials* (GPP-TB) and the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* (GPP-HIV) refer to the human rights principles above to outline why and how researchers should engage affected communities at each stage of research – from drafting study protocols to enrolling participants into studies to disseminating results and facilitating access to investigational products after a trial ends [4].

The GPP-TB and GPP-HIV guidelines advance the claim that research conducted in accordance with good participatory practices is more likely to produce results that meet the needs of affected communities. In this way, meaningful community engagement can help to ensure that medical research upholds the principles of availability, accessibility, acceptability, and quality, each of which is an "essential element" of the right to health described in General Comment 14 [2]. Together, these principles form the concept of 3AQ, which holds that health facilities, goods, and services must be available, accessible (including affordable), acceptable, and of good quality to individuals and communities. Each of these considerations forms a focal point around which activists can organize. The quality component of 3AQ specifies that health goods must be "scientifically and medically appropriate" for a given context [2]. This idea reinforces the importance of including communities in research as more than just trial participants, a notion that is central to good participatory practice. Research in which the public engages is more likely to produce goods that are ethically and culturally acceptable and designed to improve the health of communities affected by TB and HIV.

The other two components of 3AQ – accessibility and availability – provide a bridge for advocacy that spans clinical research and public health practice. Advocacy related to concerns of availability and accessibility occurs at the intersection where science meets the public – a contested space occupied by governments, pharmaceutical companies, multilateral organizations, civil-society groups, and individual patients and their communities. Within this space, the human rights principles of equity and nondiscrimination can guide efforts to hold both government and non-government actors accountable for connecting individuals and communities to the outcomes of successful research. Employing human rights as a higher standard to which governments can be held accountable continues the activist tradition of invoking rights to name obligations, document failures to fulfill these obligations, and recommend solutions [5]. Recent work by TB advocacy groups related to bedaquiline and delamanid, new drugs to treat drug-resistant tuberculosis (DR-TB), illustrates how drawing on these tactics can advance the right to health.

Globally, cure rates for DR-TB range from 11% to 79% dependent on the extent of drug resistance [6]. Access to new drugs is therefore critical for reducing mortality from DR-TB and expanding treatment options for patients stuck on failing regimens. An estimated one-third of the 1.5 million people with DR-TB worldwide would be eligible to receive either bedaquiline or delamanid (Jennifer Furin, personal communication, 2015 June 9). Activists have pushed for wider access to bedaquiline and delamanid by advocating for their release under compassionate use, registration with and approval by drug regulatory authorities, price reductions, and scale-up in national TB programs. This work started with specifying the obligations of different parties, a critical step given the diffusion of accountability among so many global actors – from the World Health Organization to country governments to the pharmaceutical companies, each of which plays a role in drug access and delivery. A new coalition called DR-TB Scale-up Treatment Action Team (DR-TB STAT), organized by Médecins Sans Frontières, TAG, SWIFT Response Project, and others, has formed to track country-level progress toward wider access to bedaquiline and delamanid, playing the documentation function that is critical for building accountability [7].

Activists have also been vocal about recommending solutions to filling the research gaps on bedaquiline's safety, efficacy, and use. Many of these recommendations concern the future research that will be necessary to validate bedaquiline's safety and efficacy in phase III clinical trials. (Confirmation of bedaquiline's safety and efficacy is especially important given the higher mortality observed among patients taking bedaquiline in one phase II trial that led to the drug's conditional approval [8].) As an example, activists successfully intervened to change the design of the bedaquiline phase III investigation plan over concerns about an insufficiently robust control arm in the original design [9]. Activists have also weighed in on the ethics of studying bedaquiline in regimens for drug-sensitive TB by urging investigators to carefully consider issues of equipoise when assessing the risk/benefit trade-off of taking a new drug into first-line regimens [10].

Extending the right to health to the research context can help to illuminate its interrelation with other rights – particularly article 15 on the right to enjoy the benefits of scientific progress and its applications. Although the normative content of article 15 remains less fully defined than the right to health [11], provisions within the article create grounds for framing access to medicines as part of States Parties' obligations to connect individuals to the benefits of scientific advancement. This case is particularly strong in TB, where over 60% of all funding for TB research comes from public institutions [12]. Further articulating the synergies between articles 12 and 15 would strengthen the argument for conducting rights-based advocacy that jointly addresses research and access issues.

Areas of potential action include evaluating whether research questions address unmet community needs; ensuring that the design of clinical trials will provide outcome data that are sufficiently comprehensive and robust to enable swift regulatory review and approval; and building access provisions into early- and late-stage research. Advocacy in this last area would include securing, in early research stages, non-restrictive intellectual property agreements, arrangements for technology transfer, and platforms for knowledge-sharing. In late stages, the focus of research advocacy would shift to obtaining upfront commitments to post-trial access via compassionate use, regulatory registrations and pricing agreements. Failure to anticipate these aspects of research has slowed the rollout of new TB drugs. By linking the normative content of articles 12 and 15, activists may be better equipped to hold governments accountable not only for the outcomes of health interventions, but also for the ways in which these interventions are designed, researched, financed and implemented.

Correspondence
Mike Watson Frick
TB/HIV Project
Treatment Action Group
261 5th Avenue, Suite 2110, New York, NY 10016

E-mail: mike.frick[at]treatmentactiongroup.org

References
1. United Nations. International Covenant on Economic, Social and Cultural Rights (ICESCR). New York, United Nations, 1966. United Nations General Assembly resolution 2200 (CCI), UN GAOR, 21st Session, Supp. No. 16, at 49, UN Doc. A/6316, entered into force 3 January 1976. New York: United Nations; 1976.
2. Committee on Economic, Social and Cultural Rights. The right to the highest attainable standard of health: 11/08/2000. E/C/12/2000/4, CESCR General Comment 14. Twenty-second session Geneva, 25 April–12 May 2000 Agenda item 3.
3. Kavanagh M, Cohn J, Mabote L, et al. Evolving human rights and the science of antiretroviral medicine. Health and Human Rights. 2015;17(1):76–90.
4. Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens. Good Participatory Practice Guidelines for TB Drug Trials. Washington, D.C.: Critical Path to TB Drug Regimens; 2012.
5. Gruskin S, Mills E, Tarntola D. History, principles and practice of health and human rights. Lancet. 2007;370(9585):449–55.
6. Pietersen E, Ignatius E, Streicher EM, et al. Long-term outcomes of patients with extensively drug-resistant tuberculosis in South Africa: a cohort study. Lancet. 2014;383:1230–9.
7. Médecins Sans Frontières, et al. Open Letter Re: Accelerate access to DR-TB drugs. 2015 March 10. www.msfaccess.org/content/call-action-accelerate-access-dr-tb-drugs (accessed 3/7/2015).
8. Diacon A, Pym A, Grobusch M, et al. Multidrug-resistant tuberculosis and culture conversion with bedaquiline. NEJM. 2014;371:723–32.
9. Frick M. Sound science of redesigned STREAM trial. 18 December 2014. Available at: www.treatmentactiongroup.org/tagline/2014/spring/fool%E2%80%99s-errand-sloppy-science-mdr-tb-stream-trial (accessed 03/07/2015).
10. Ruiz Mingote L, Namutamba D, Apina F, et al. The use of bedaquiline in regimens to treat drug-resistant and drug-susceptible tuberculosis: a perspective from tuberculosis-affected communities. Lancet. 2015;385(9966):477–79.
11. Chapman A. Towards an understanding of the right to enjoy the benefits of scientific progress and its applications. Journal of Human Rights. 2009;8(1):1–36.
12. Frick M. The 2014 Report on Tuberculosis. In: Andrea Benzacar (ed.). Research Funding Trends, 2005–2013. New York: Treatment Action Group; 2014.