Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus. TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

Submission to the Office of the United Nations High Commissioner for Human Rights to Report on Sustainable Development Goals and Health
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Organization description:

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TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

TAG is a science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

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Introduction

1. In this submission, TAG stipulates that achieving the targets and overall impact of Sustainable Development Goal 3 (SDG 3) to "ensure healthy lives and promote well-being for all at all ages" requires all States and non-state actors to respect, protect, and fulfill the Right to Science.
2. The right of all people to take part in cultural life, enjoy the arts, and share in the benefits of scientific progress is enshrined in Article 27 of the Universal Declaration of Human Rights (UDHR).
3. Article 15 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) similarly asserts the right of everyone "to enjoy the benefits of scientific progress and its applications."
4. Article 15 of the ICESCR lays out State Parties' responsibilities (a) to include "the conservation, the development and the diffusion of science […] " (Art. 15.4); (b) "to respect the freedom indispensable for scientific research and creative activity" (Art. 15.3); and (c) to "recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields" (Art. 15.4).
5. Currently, the Committee on Economic, Social and Cultural Rights is developing a General Comment on the Right to Science. Other actors within and external to the UN system have explored the various dimensions of the Right to Science, how it may be read in conjunction with other human rights, and its application to health.

The Right to Science and Health

6. The Special Rapporteur (SR) in the field of cultural rights has previously noted the strong interdependence of the Right to Science and other human rights, including the obvious linkage with the Right to Health.[i]
7. In the above May 2012 report, the SR describes equitable and non-discriminatory access to scientific knowledge and its advances as essential benefits of scientific progress. The concept of access here connotes not only to the final results of research, but also to the processes, methodologies, and tools of scientific inquiry as part of the benefits deriving from the Right to Science.[ii]
8. Article 15 of the ICESCR speaks of "development and diffusion of science and culture" as State obligations. Together with the SR's reading of access, development in Article 15 must be understood as a State's obligation to support scientific research and innovation; and diffusion as the ability to enjoy scientific benefits in a non-discriminatory manner.[iii]
9. It thus becomes the duty of States to take measures that advance the diffusion of the benefits of scientific progress in an equitable manner. Part of these measures includes steps to guarantee not only availability, but also affordability of tangible health technologies, such as medicines.
10. The 2016 final report of the Secretary General's High-Level Panel on Access to Medicines calls SDG 3 "an important vehicle for realizing the right to health and the right to share in the benefits of scientific advancements."[iv] It further highlights the utility of States drawing on both rights to "remedy the policy incoherence between

the justifiable rights of inventors, international human rights law, trade rules, and public health in the context of health technologies."

11. This definition of the Right to Science undeniably establishes that without respect, protection and fulfillment of the Right to Science, States cannot guarantee to achieve the Right to Health, nor the health-related targets and goals of SDG 3.
12. Similarly, the American Society for the Advancement of Science (AAAS) determined through a multi-year survey of thousands of scientists that one of the two most cited benefits of the Right to Science was in relation to health.[v]
13. Surveyed scientists noted scientific infrastructure and research funding; public science education and a positive view of science; open access to scientific information; academic freedom; and technology transfer as important areas for State action.[vi]
14. As a science-based organization that works to expand and accelerate vital research and effective community engagement with research and policy institutions, TAG welcomes this opportunity to discuss the pivotal role the Right to Science has in achieving the goals and targets of SDG 3 in the context of HIV, TB, and viral hepatitis specifically; show how the Right to Science interacts with the Right to Health to aid the realization of SDG 3 with regards to development as well accessibility, affordability, acceptability, and quality of essential medicines more broadly; and the role affected communities should play in research and policy-making.

<u>The Indelible Connections between the Right to Science and SDG 3</u>

15. SDG 3 aims to ensure healthy lives and promote well-being for all at all ages. TAG's analysis of the Right to Science in the context of health and infectious diseases establishes that States cannot achieve SDG 3 goals and targets without observing obligations derived from the Right to Science.
16. Further, TAG's analysis of the Right to Science indicates that universal access to the benefits of scientific advancement and the workers rights' of scientists are essential to achieving the health-related SDGs.
17. In terms of universal access, it has become clear that framing the right to health primarily in terms of consumer rights has created a barrier to advancing the health-related goals of the SDGs. Universal access consists both of availability and affordability. Thus, States and non-state actors must distinguish between, on the one hand, the mere availability of healthcare coverage that may or may not be affordable, and, on the other hand, the guaranteed provision of direct healthcare services.
18. For example, scientific technologies including new diagnostic tools that allow earlier diagnosis are essential for stopping onward transmission and linking e.g. people living with HIV to care and treatment. When these tools exist but are not available due to unaffordability, trade-related barriers, shortage of trained personnel etc., States deny themselves the chance to reach the targets of SDG 3.
19. The SR's May 2012 report mentions the necessity of a professional environment that enables scientists to freely engage in scientific inquiry, exchanges of information e.g. through collaborative research, and publications. It is impossible to practice science without a culture of open inquiry and access to specialized knowledge. Equally,

specialized equipment, institutions and financing are pillars of the scientific enterprise.

20. The role of public institutions and financing, as enablers of science and thus diffusion of the benefits of scientific advancement, is tremendously important from the perspective of achieving SDG 3. How research is financed and owned often determines who has access to the (tangible and intangible) products of science.

21. The prevailing research and development (R&D) system is market driven and defined by the maximalist approach to the intellectual property protection as established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

22. In a market-driven R&D system, research to address challenges of high public health impact but little monetary reward e.g. the unmet scientific needs of marginalized communities is either under-resourced or not pursued at all. This remains a grave challenge for the eradication of infectious diseases such as TB, viral hepatitis, and HIV.[vii]

23. TB remains a global epidemic precisely because decades of underfunding research has left treatment long and burdensome, lasting between 6 months for drug-susceptible TB (DS-TB) and 2 years for multidrug-resistant TB (MDR-TB), often with serious side-effects. Funding for TB R&D has now flat-lined and even lost ground to inflation. To a significant extent, the rise and spread of DR-TB is a consequence of the weak environment for TB R&D, which has left patients and public health programs to rely on lengthy, difficult-to-tolerate regimens that complicate adherence and help to give rise to the conditions under which DR-TB strains arise and are transmitted within communities.[viii]

24. As mentioned above, the report of the Secretary General's High-Level Panel on Access to Medicines notes the importance of Right to Science and Right to Health in "resolving the incoherence between market-driven approaches [to research and development] and public health needs." In many cases, State laws fail to account for how publicly funded research contributes to commercialized scientific results in which the intellectual property resides with private owners or private sector actors. In these situations, the public often must pay twice for research—first to develop the science, and again to make a new technology e.g. a drug or vaccine available at a price set by a private developer that benefitted from public funding.

25. In the context of human rights, science, and health, the Right to Science has to be upheld together with other rights, including the Right to Participation and the Right to Self-Determination. When science fails to acknowledge or facilitate the participation of the individuals and the communities it focuses on, scientific inquiry that takes human beings as its subject in particular, can contribute to stigma, and therefore discrimination or other egregious human rights violations. Human rights violations have been shown to hinder the response to any infectious disease.

26. Furthermore, community participation in the research process has played a critical role in the development of the interventions, e.g. antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP) that have contributed to progress toward SDG 3 goals for HIV. Continued and expanded participation, including support and education to foster informed participation, is essential for continued progress toward the goal of developing additional prevention options (including HIV vaccines).

27. The Right to Science ensures that with the advancement of science, new health technologies and procedures become available. The benchmark for policy-makers, i.e. any State's obligations according to the Right to Science, the Right to Health and SDG 3 are always changing alongside new discoveries. Our understanding of what exactly the "highest attainable standard of […] health" is, i.e. what we have at our disposal to "ensure healthy lives and promote well-being for all ages" must equally evolve.[ix]

28. The below recommendations collate TAG's combined expertise on recent scientific developments, accessibility and human rights that State's should emulate in order to meet SDG 3, and advance the Right to Science in conjunction with the Right to Health for all.

Recommendations

I. Community right to participation, self-determination, and inclusion

States should:

A. Promote the meaningful inclusion of affected communities in scientific decision-making and research processes. Here, States can draw guidance from the Good Participatory Guidelines developed for HIV biomedical prevention trial; TB drug trials; and TB vaccine trials. These guidelines should be integrated into research and implementation of HIV treatment and cure trials, observational cohorts, and the clinical study of interventions for sexually transmitted infections.

B. Take steps to guarantee the inclusion of people living with, and vulnerable to, the respective disease in all regulatory and public health decision-making processes that affect access to state-of-the-art interventions. Guiding examples include community engagement in stringent product approval mechanisms for all drugs, biologics, and diagnostic tools; formulary determinations; and best-practice guidelines.

C. Ensure science does not contribute to stigmatization and discrimination of people living with HCV, MSM, sex workers, prisoners, people who inject or use drugs, or other vulnerable populations. Equitable access must be insured for all regardless of gender identity, sex, sexual orientation, race, ethnicity, religious belief, ability, age, immigration or other protected status. Access should never be determined by the criminalization of behaviors, history of involvement with the legal system, incarceration or detention, specifically related to illicit drug use.

D. Ensure all research, development, and implementation evaluations of experimental and existing biomedical prevention modalities meaningfully prioritizes highly affected, but often neglected, populations including youth, unstably housed individuals, transgender men and women, sex workers, people of color, undocumented migrants, refugees, and people with disabilities.

II. Development and diffusion of scientific technologies related to viral hepatitis

States should:

A. Follow the WHO Global Hepatitis Elimination Strategy to go beyond SDG target 3.3 and *eliminate* viral hepatitis as a public health concern.[x]

B. Provide maternal hepatitis B (HBV) screening and universal birth vaccine access for children born to HBV antibody positive mothers.

C. Support the development of simple diagnostics tools, particularly rapid (RDT) and point-of-care confirmatory tests. This will allow States to expand hepatitis C (HCV) testing outside of traditional health care settings, particularly integrated into HIV testing sites targeting key populations, and using rapid point-of-care tests when appropriate.

D. Support HCV reflexive testing in national programs to facilitate ribonucleic acid (RNA) confirmative results from a single blood draw.

E. Include mandatory reporting of negative HCV RNA testing into monitoring and surveillance efforts for more accurate understanding of the HCV epidemic.

F. Provide equitable access to evidence-based harm reduction services and promote opioid substitution therapy as the standard of care, particularly buprenorphine.

III. Development and diffusion of scientific technologies for HIV and related sexual health research

States should:

A. Treat potential occupational and non-occupational exposures to HIV as emergencies, with immediate access to the best post exposure prophylaxis (PEP) regimens on demand, particularly tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) plus once daily dolutegravir (as opposed to raltegravir which has increased problems with adherence due to the twice daily pill requirement).

B. Ensure the universal availability of 4th generation antibody/antigen laboratory testing, which can detect new infections faster than antibody-only testing.

C. Make point-of-care rapid tests widely accessible. These include the Alere Determine HIV-1/2 Ab/Ag combo 4th generation assay, which can detect a possible infection around one to two weeks earlier than other rapid tests. Orasure oral swabs should remain available for individuals with an aversion to finger sticks, and INSTI tests, with results in one to two minutes, are extremely valuable in high volume testing scenarios, such as community testing outreach.

D. Prioritize, approve and quickly implement prevention options that show registrational trial efficacy and real-world effectiveness for cisgender women, such as the dapivirine ring.

E. Prioritize wider and more effective use of phylodynamic surveillance to efficiently target prevention resources to disrupt transmission "clusters."

F. Should not neglect other sexual health research while addressing HIV care, treatment, and prevention needs. States should prioritize research on a vaccine for syphilis given the significant challenges of penicillin stockouts. While there are a few hopeful candidates in the pipeline for treatment of drug resistant gonorrhea, more investment and research is needed.

G. Address worldwide challenges to access quality benzathine penicillin G for treatment of syphilis. Regulatory agencies and manufacturers should immediately address unnecessary shortages of both the active pharmaceutical ingredient and final product.

H. Guarantee access to treatment to all people living with HIV in low-, middle-, and high-income countries to minimize the risk of premature morbidity and mortality, and to eliminate the risk of ongoing transmission of the virus.

I. Provide access to essential genotypic and phenotypic drug-resistance testing. These are scientifically validated and cost-effective tools to strengthen informed antiretroviral therapy (ART) prescribing practices and public health guidance. Access particularly in countries where ART options are limited, is critical.

J. Prioritize clinical and optimization research on emerging ART options, including long-acting formulations and drugs and biologics for treatment-experienced people living with cross-class-resistant HIV, to ensure their regulatory approval and uptake by public health guidelines. This must include confirmations of safety and efficacy, and evaluations in key populations, including pregnant women and people receiving treatment for TB. States should provide affordable access through optimization research, price concessions, voluntary licensing, and donor/government commitments.

K. Support development and rapidly make available interventions for individuals with HIV who remain at elevated risk for a spectrum of comorbidities and mortality compared to their HIV-negative counterparts; particularly those who initiate ART later in the course of infection,

L. Guarantee global access to TDF/FTC Pre-Exposure Prophylaxis (PrEP) for any individual who may benefit from it. The evidence and efficacy for TDF/FTC as HIV PrEP for sexual transmission is unparalleled by any other prevention modality currently available for HIV-negative individuals.

IV. Development and diffusion of scientific technologies for tuberculosis

States should:

A. Significantly increase financing for TB research and development, including for the full spectrum of TB research from basic science to product development to operational research and implementation science.

B. Provide funding for TB research that supports the "purposive development" of technologies that meet the innovation needs of those groups most vulnerable to TB. These groups are often left out of TB research and include people with HIV, children and adolescents, pregnant women, and people who use drugs.

C. Test and deploy innovative financing mechanisms and incentives in funding TB research, including those outlined in the 2012 report of the WHO Consultative Expert Working Group on Research and Development (CEWG)[xi] and the final report of the U.N. Secretary General's High-Level Panel on Access to Medicines.

D. Ensure that all people with and at risk of TB have access to the highest available standard of prevention, diagnosis, and treatment. This must include States making available TB drugs included on the Model List of Essential Medicines. States should scale up use new DR-TB drugs bedaquiline and delamanid, particularly as alternatives to older therapeutic agents that can cause irreversible, debilitating effects e.g. deafness in many patients with DR-TB.

E. Increase the availability and implementation of TB prevention services, including prophylaxis for high risk groups including people living with HIV, young children, pregnant women, and people who live in the same household or have close contact with persons with TB. States should take steps to strengthen infection control in communities impacted by TB and other high transmission settings e.g. hospitals with respect for human rights and ethics.

F. Provide universal access to GeneXpert MTB/RIF or the new GeneXpert MTB/RIF Ultra as the first diagnostic test for adults. TB LAM should be used as a preliminary test to rule in TB in people with HIV with CD4 counts below 100/mm^3 or who are seriously ill. States should work to end diagnostic delays and implement strategies to find the estimated four million people who develop TB each year but are either never diagnosed or reported to health systems.

G. Implement person-centered and community centered care to facilitate successful TB prevention and treatment in recognition of social and economic factors. All TB programs should implement interventions in accordance with the WHO TB Ethics Guidance (2017), which states: "Governments have an ethical obligation to provide universal access to TB care according to international standards, […]. This is grounded in their duty to promote the common good and to fulfill the human right to health."[xii]

V. Access to Medicines, Affordability, Intellectual Property and Access to Information

States should:

A. End data exclusivity agreements on drug formulations to promote universal treatment access via generic bioequivalent drugs.

B. End treatment rationing or treatment restrictions due to high prices of direct-acting antivirals (DAAs).

C. Provide voluntary licensing to generic manufacturers when the intellectual property owner is unable to meet the affordability demands set by government payors. States should not suffer any penalties for pressure if they enact the recommendations within the UN Secretary General's High Level Panel Report on Access to Medicines and TRIPS flexibilities.[xiii]

D. Make new biomedical prevention technologies immediately affordable to all individuals who need them once they receive regulatory approval. This includes new prevention options, long acting injectables, vaginal rings, etc. States should require manufacturers, perhaps in partnership with public and private payers, to develop, monitor, and evaluate a plan for access to all individuals who may benefit.

E. Work with institutions and companies to set and adhere to industry standards that allow transparent and public access to clinical trial data, with safeguards for patient anonymity.[xiv]

[i] http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf p.8.
[ii] ibid.
[iii] https://www.hhrjournal.org/2016/06/falling-short-of-the-rights-to-health-and-scientific-progress-inadequate-tb-drug-research-and-access/.
[iv] http://apps.who.int/medicinedocs/documents/s23068en/s23068en.pdf pp. 13.
[v] https://www.aaas.org/news/human-rights-coalition-deepens-understanding-right-science. See report at https://mcmprodaaas.s3.amazonaws.com/s3fs-public/reports/Right_to_Science_Report.pdf .
[vi] https://mcmprodaaas.s3.amazonaws.com/s3fs-public/reports/Right_to_Science_Report.pdf p.16.
[vii] For recommendations on specific topics for scientific inquiry please see recommendation section.
[viii] https://www.hhrjournal.org/2016/06/falling-short-of-the-rights-to-health-and-scientific-progress-inadequate-tb-drug-research-and-access/
[ix] For a discussion on the minimum core, human rights and scientific advancement see for example https://www.hhrjournal.org/2015/06/evolving-human-rights-and-the-science-of-antiretroviral-medicine/.
[x] See the Strategy at http://apps.who.int/iris/bitstream/10665/206453/1/WHO_HIV_2016.04_eng.pdf
[xi] http://www.who.int/phi/cewg_report/en/
[xii] http://www.who.int/tb/publications/2017/ethics-guidance/en/
[xiii]https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf
[xiv]For discussion of a recent court case see https://publichealth.yale.edu/news/article.aspx?id=15794