Treatment Action Group

Ms. Karima Bennoune
Special Rapporteur in the field of Cultural Rights

9 November 2020

Re: Update on COVID-19 and the right of everyone to participate in and enjoy the benefits of scientific progress and its applications

Dear Madame Special Rapporteur,

Treatment Action Group (TAG) thanks you for your invitation to submit an update to our 23 June 2020 letter regarding COVID-19 and the right of everyone to participate in and enjoy the benefits of scientific progress and its applications (right to science). In 2019, the Special Rapporteur remarked on the intricate relationship between public spaces and the realization of cultural rights (A/74/255). In many countries across the globe, COVID-19 has not only devastated cultural institutions, but also shattered public life and cultural expression by severely limiting access to public spaces and by inhibiting people's ability to physically gather. At this junction, asserting the interrelation between cultural rights, the right to science, the right to health and other human rights (rights to food, adequate housing, education, privacy, liberty among others) is crucial.

The General Comment 25 (E/C.12/GC/25) on the right to science, published in April 2020, lays out state obligations with respect to scientific progress, which, if followed, would enable states to develop an effective, rights-based response to the COVID-19 pandemic. Our previous letter discussed state obligations to science and emphasized four elements with particular relevance to COVID-19: participation, access, non-discrimination, and international cooperation. In the present letter, we outline specific instances in each of these areas where states have fallen short of their obligation to ensure the right of everyone to participate in and enjoy the benefits and applications of scientific progress. Because the right to science remains largely unknown, we strongly encourage the Special Rapporteur to counsel states to respect, protect, and fulfill right to science principles in order to strengthen the global COVID-19 response. States have an opportunity to resolutely curb the current pandemic and future health emergencies by placing equity at the center of innovation.

It is thus imperative in our view that the Special Rapporteur explicitly acknowledge the human rights dimensions of science and reaffirm the right of everyone to participate in and enjoy the

benefits of scientific progress and its applications in her forthcoming communication with the United Nations General Assembly.

Through our ongoing work on COVID-19 and other infectious diseases, we have observed the below situations and would like to make the following recommendations for consideration by the Special Rapporteur to put forward in her upcoming report to the General Assembly:

1. **Participation** is the foundation of effective public health responses. Similarly, participation is the animating value of the right to science as expressed in General Comment 25, which states that the right "encompasses not only a right to receive the benefits of the applications of scientific progress but also a right to participate in scientific progress."[1] The discussion of participation in General Comment 25 validates the rich tradition of community engagement in global health research and policy formulation. Unlike the positive global experience with implementing participation in other pandemics—for example through the formation of community advisory boards in the responses to AIDS, TB, and Ebola—scientific efforts to counter COVID-19 have been carried out without the participation of affected communities and without the commitment to transparency that enables effectives participation.

   We are concerned that States are ignoring hard-won lessons from previous pandemic responses and even regressing in some areas. In too many state-supported COVID-19 research initiatives, opacity is replacing transparency, keeping the public from receiving timely and vital information and preempting civil society from holding both state and non-state actors accountable on issues such as scientific decision making, priority setting, financing, ethical research conduct, and access to scientific benefits.

   For example, despite the best efforts of civil society, there have been no opportunities for community input into COVID-19 vaccine clinical trials protocols (something that is standard e.g. in HIV vaccine trials). Only on 17 September 2020 was the first protocol from the Moderna phase 3 COVE study publicized—months after the trial began.[2] The lack of transparency and participation may be undermining the willingness of certain communities to participate in this and similar trials, which could lead to an absence of evidence that new vaccines work in populations experiencing the worst effects of the pandemic. Only 28% of participants in Moderna's vaccine trial are from non-white communities. In another example, networks of people living with HIV successfully advocated for COVID-19 vaccine trials to lift rules disqualifying people living with HIV from enrolling.[3] This temporary exclusion could have been avoided altogether if states had compelled pharmaceutical companies to make their protocols publicly available and open to community review and input.

[1] GC 25 paragraph 11
[2] https://www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html
[3] See: https://www.treatmentactiongroup.org/wp-content/uploads/2020/08/covid_19_1273_collins_nih_7_27_20.pdf AND https://www.positivelyaware.com/articles/hiv-activists-win-fight-inclusion-major-covid-19-vaccine-trial

The populations disproportionately affected by COVID-19 are also those historically underrepresented in biomedical research. Underrepresentation in research can result in exclusion from the enjoyment of scientific benefits. COVID-19 has compounded this historic injustice. Many trials of COVID-19 vaccines and therapeutics appear to exclude key populations. This suggests that states are regressing on tenuous gains in research participation made in other pandemic responses to e.g., HIV and TB. For instance, a recent study of sex and gender representation in registered COVID-19 trials found that a) trials do not disaggregate data for sex or gender, despite knowing that "sex and gender differences impact incidence of SARS-CoV-2 infection and COVID-19 mortality", and b) very few consider sex/gender in recruitment of trial participants. As the authors of the study state, "excluding one sex from clinical trials and omitting to disaggregate results by sex can lead to an increased incidence of unwanted side effects in the untested population due to overmedication and other factors […]."[4]

One form of community participation that has been highly effective in other infectious diseases, e.g., TB and HIV/AIDS, is the formation of community advisory boards (CAB). CABs play an important oversight and advisory role by "providing input [to research funders and sponsors] on study design, early access, regulatory approval, post marketing, and implementation strategies."[5] The National Institutes for Health (NIH) in the United States has recently announced that its COVID Prevention Trials Network (CoVPN) had built a platform to engage thousands of volunteers to enable participation, but this can only be the first step.[6] COVID-19 science needs participatory structures that look beyond convincing communities to enroll in studies and instead create space for community representatives to participate in decision-making at each stage of the research process—from designing trial protocols to monitoring study conduct to translating results into policy and practice. Participation is an important measure to avoid unethical approaches to developing vaccines and treatments.

Public participation has suffered because trials are progressing too quickly for meaningful community involvement and are too often operating under a blanket of non-transparency. We have learned from other infectious disease epidemics that states should not approach COVID-19 science as a sprint; instead, the world will need long term scientific investments to overcome the COVID-19 pandemic and sustain the fights against other ongoing epidemics such as TB, HIV/AIDS and hepatitis C. A sudden and dramatic shift in global resource allocation threatens to rollback previous gains made against TB, HIV, and hepatitis C.[7]

---

[4] https://www.medrxiv.org/content/10.1101/2020.09.13.20193680v1.full.pdf
[5] See for example Global TB CAP http://www.tbonline.info/tbcab/
[6] https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-covid-19-vaccines-other-prevention-tools
[7]https://www.who.int/docs/default-source/hq-tuberculosis/global-tuberculosis-report-2020/executive-summary.pdf?sfvrsn=2466d0dd_2 AND

The development of a vaccine or cure for COVID-19 will not be the "magic bullet" states appear to be counting on. We should not exceptionalize the scientific process and expect its results to offer up a panacea. For illustration, a cure for hepatitis C exists. However, even in the state of Vermont (USA), current modeling suggests that hepatitis C will not be eradicated until after 2050 due to social determinants of health and the righteous distrust that many communities have with the current healthcare system. Triple therapy for TB was once heralded as the therapeutic breakthrough of the century, but now drug-resistant TB has become a global threat. And despite four decades of investments and tremendous progress there is still no cure for HIV. For all these diseases, the full representation and participation of affected communities and publics has driven the advances in knowledge, information, and biomedical interventions that have allowed us to arrive at this point.

We call on the Special Rapporteur to recommend that states take all necessary steps to enable the participation of communities affected by COVID-19, in particular marginalized and vulnerable populations, in all aspects of COVID-19 research and development.

2. **Access, intellectual property, and international cooperation** are closely related components at the heart of the right to science. Access not only encompasses knowledge and information, but also the material results of scientific progress such as medicines and vaccines as well as the means, methods, and materials of scientific discovery, as described by General Comment 25.[8] With the intensity of a global search for a COVID-19 vaccine, civil society has raised concerns that high-income countries are fleeing solidarity mechanisms for vaccine development and distribution. This so-called "vaccine nationalism" includes bilateral agreements between states and the pharmaceutical industry, to allocate a certain amount of future vaccine doses in exchange for research funding, i.e. advance market commitments (AMC). The fact that the United States and the United Kingdom, two large sources for public research funding, have already abandoned the WHO technology pool illustrates that such mechanisms require a clear mandate and cannot solely operate as voluntary mechanisms.

   Advocates have been pointing out for years the challenges with equitable access to existing health commodities due to high prices deriving from patents and intellectual property rights, illustrating the importance of global calls for a People's Vaccine for COVID-19.[9] Another important call is the proposal by South Africa and India asking the World Trade Organization to allow all countries to choose to neither grant nor enforce patents and other intellectual

http://www.stoptb.org/assets/documents/covid/TB%20and%20COVID19_Modelling%20Study_5%20May%202020.pdf

[8] GC 25 paragraph 70

[9] https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine?utm_source=UNAIDS+Newsletter&utm_campaign=1ad04ac900-20200929_covid-19-survivors&utm_medium=email&utm_term=0_e7a6256e25-1ad04ac900-114193989

property (IP) related to COVID-19 drugs, vaccines, and other technologies for the duration of the pandemic.[1011] Engendering an Open Science approach to data sharing and research collaboration is just as important as removing IP barriers. The ability to participate in the scientific process, including access to data, would provide the transparency needed to judge the fairness and affordability of vaccine pricing. A recent white paper by New York University and Médecins Sans Frontières outlines several demands for needed cost transparency of clinical trials, that would foster equitable access through adequate pricing.[12] General Comment 25 notes that the right to science can mediate tensions between IP protections and other human rights, e.g. the right to health, right to education, and right to food. All of these human rights have already been negatively impacted by COVID-19.

We call on the Special Rapporteur to recommend that OHCHR works with states to develop approaches to intellectual property governance that incorporate Open Science principles, including but not limited to the exercise of existing flexibilities, that promote access to the benefits and applications of scientific research. States should recognize the primacy of the human rights to health and science over intellectual property rights.

3. **Non-discrimination** in the enjoyment of scientific progress and its benefits is fundamental, as it is with all human rights. At the beginning of the pandemic, COVID-19 was dubbed the "great equalizer" by some observers, based on the assumption that everyone is at risk of contracting the virus. It quickly became clear that assumption this was not reflective of reality. Underlying determinants of health shape vulnerability, and not everyone has equal access to quality healthcare services, essential health technologies, or knowledge and information. Similarly, not everyone has the same access to public spaces; expressions of cultural life; or ability to adjust work settings. One of the starkest examples of this is how the pandemic has affected people of different races to a differing degree. To take just on example: the United States Census Bureau reports that several months into the pandemic in the United States "23 percent of white Americans said they were not confident they could make rent in August […]. Among Black and Latinx Americans, though, the number was double that: 46 percent didn't think they could pay for the roof over their head."[13]

   Applying the right of everyone to participate in and enjoy the benefits of scientific progress and its applications to the COVID-19 response is integral to formulating equitable and non-discriminatory health interventions. General Comment 25 requires that "[S]tates must adopt the measures necessary to eliminate conditions and combat attitudes that perpetuate inequality and discrimination in order to enable all individuals and groups to enjoy this right without

[10] https://msfaccess.org/overcoming-intellectual-property-monopolies-covid-19-pandemic
[11] https://msfaccess.org/covid-19-vaccine-6-recommendations-equitable-access
[12] https://www.law.nyu.edu/sites/default/files/Clinical_Trial_Cost_Transparency_at_the_NIH-Law_and_Policy_Recommendations.pdf
[13] https://www.forbes.com/sites/madhukarpai/2020/09/26/tuberculosis-and-covid-19-fighting-a-deadly-syndemic/#634743c24c59

discrimination, including on the grounds of religion, national origin, sex, sexual orientation and gender identity, race and ethnic identity, disability, poverty and any other relevant status."[14] TAG would like to raise attention to the status of migrants, asylum-seekers, and people in all forms of detention as particularly vulnerable to a wide array of discrimination in the context of COVID-19.[15]

However, as mentioned in the above discussion of participation, the effectiveness of global health technologies can suffer when clinical trials privilege the participation of some groups above others. For example, pulse oximetry, a small device heralded as an important tool in diagnosing COVID-19, is more prone to inaccurate readings on black and brown skin.[16] The paradigm of non-discrimination must therefore include states' obligation to take steps to ensure that vulnerable and marginalized groups can participate in and access science and the fruits of its advancement, i.e. "actively overcome exclusion from such progress and applications, especially in the health sectors and education."[17]

Another decisive challenge to equitable, non-discriminatory access to a future COVID-19 vaccine derives from global manufacturing capacity versus the AMC contracted to specific countries. To date, there is not enough manufacturing capacity to provide vaccine access to everyone globally. A recent commentary expected "significant impediments […] on the manufacturing side, including issues regarding manufacturing scale-up, the risk of shortages, supply chain management, and other logistical hurdles. […] administrative distribution […], or vaccine skepticism that are bound to dog implementation of a COVID-19 vaccine."[18] Importantly, the world will not be able to overcome COVID-19 without embracing a non-discriminatory approach to vaccine development and rollout, i.e. collaborating on research based on Open Science principles and distributing vaccines according to equitable allocation frameworks. Recent research shows that "[a]ccording to modeling from Northeastern University, if rich countries buy up the first 2 billion doses of vaccine instead of making sure they are distributed in proportion to the global population, then almost twice as many people could die from COVID-19." Only collaboration as required by the right to science thus becomes inevitable, if not mandatory, for overcoming the COVID-19 pandemic.

<u>We call on the Special Rapporteur to endorse the call for a People's Vaccine shepherded by UNAIDS to make available to all without discrimination and free of charge all COVID-19 vaccines and essential health commodities; and to provide guidance to states on how to realize the enjoyment of scientific benefits for all without discrimination.</u>

[14] E/C.12/GC/25 paragraph 25
[15] See for example: Treatment Action Group. Public Comment Opposing Proposed Rules on Security Bars and Processing. 10 August 2020. In response to RIN 1615-AC57/USCIS Docket No. 2020-0013; RIN 1125-AB08/A.G. Order No. 4747-2020.
[16] http://bostonreview.net/science-nature-race/amy-moran-thomas-how-popular-medical-device-encodes-racial-bias.
[17] E/C.12/GC/25 paragraph 47
[18] https://blog.petrieflom.law.harvard.edu/2020/08/11/covid19-vaccine-advance-purchases-explained/

4. **Freedom of scientific research:** the right to science calls for the freedom to conduct necessary systematic investigation and study to establish facts and reach conclusions that may have an impact on multiple realms of human health. However, a worrying trend accelerated by the current pandemic are ideologically-motivated directives that govern what research scientists are able to do, and how they are allowed to pursue research. Sometimes these ideologically-drive directives take the form of regulation, in other instances states have enacted laws limiting the freedom of scientific research. For example, in 2019, the U.S. administration effectively initiated a ban on the use of fetal tissue in biomedical research by denying the award of federal funding to such research (even when the research has been judged ethically-compliant by rigorous ethics and other procedural reviews). This ban extends to research that is integral for preventing or treating infectious diseases, including COVID-19. The irony is not lost on us that contrary to this practice, the President of the United States was recently treated with experimental treatment derived from fetal tissue research. Obligations under the right to science require states to develop and diffuse scientific advances equally to all without discrimination. Furthermore, denying scientists an important and ethically cleared research strategy and tool such as fetal tissue on the basis of ideology, limits the potential to discover novel vaccines and therapeutic to address COVID-19 and other infectious disease epidemics.

   We call on the Special Rapporteur to stress that as part of the right to science, states have the obligation to respect and protect the freedom of research as discussed in the General Comment 25, including the freedom of researchers to pursue their scientific inquiry without undue influence, as long as the research respects ethics and human rights.

We invite the opportunity for further dialogue on the right to science. Please do not hesitate to contact us should you seek further clarification.

Respectfully,

Mike Frick	Gisa Dang	Suraj Madoori
Treatment Action Group	Treatment Action Group	Treatment Action Group