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UNESCO'S ETHICS COMMISSIONS' CALL FOR GLOBAL VACCINES EQUITY AND SOLIDARITY

Joint Statement by the
UNESCO International Bioethics Committee (IBC)
and the
UNESCO World Commission on the Ethics of Scientific Knowledge and
Technology (COMEST)

Introduction

As previously expressed in our [Statement on COVID-19: Ethical Considerations from a Global Perspective](#), the COVID-19 pandemic represents a dramatic and urgent threat to global health and a **challenge to global bioethics**. In addition to major health challenges such as diseases associated with poverty and the 6.3 million children under 15 who died in 2017 from hunger and preventable causes¹, more than 100 million people have contracted Sars-Cov-2, more than 2 million have died, and the threat is higher than ever with the evolution of variants, which are more transmissible and dangerous. The global effort to develop a **vaccine** has been unprecedented in terms of scale and speed. The rapid development of various vaccines, already available and approved, is a scientific and technological success and represents a real hope for controlling the pandemic. However, **their availability for all** will take time and require a global effort. Furthermore, we remain without effective therapies, and the few existing treatments for severe cases are neither easily available nor affordable for many people. Ethics must play an important role in the prioritization of vaccine beneficiaries.

The continuing rapid changes in the behaviour of the virus and the efforts towards its mitigation justify the need for **UNESCO's ethics bodies, the IBC and COMEST, to provide an update of their earlier Statement. There is a need to draw once again, attention to the ethical aspects concerning education and science; research and financing, production, quality and deployment of vaccines; vulnerable populations and countries, taking into account increased inequalities of income and opportunity; vaccine hesitancy; information and communication; data-sharing and privacy; availability to all and sustainability.**

These are the ethical requirements in order to concretely respect the fundamental right to health of every human being.

1. Persisting COVID-19 threats despite vaccine deployment

The several waves of the disease and the emergence of new Sars-Cov-2 variants reinforce the imperative that *health and social policies should be based on solid scientific evidence*, taking into account the uncertainties that exist during a pandemic, especially when caused by

¹ UNICEF, WHO, World Bank Group, "[A child under 15 dies every five seconds around the world – UN report](#)," Press release (September 2018).

a novel pathogen. Political decisions should be based on sound scientific knowledge, but never legitimized by science alone. An open dialogue which includes politics, science, diplomacy, ethics and law is particularly necessary.

There is also a *need to consider the economic perspective*. Socioeconomic status is one of the main determinants of health. Impoverishment due to the pandemic is affecting many communities and will affect their health. COVID-19 clearly exposes the weaknesses of healthcare systems in different countries: the insufficient number of health professionals, the lack of basics such as anaesthetics, oxygen and ventilators, the shortage of beds in intensive care units (ICU), as well as obstacles and inequities of access to healthcare. *The IBC and COMEST call for international coordination in a joint effort to provide access to adequate health care for all, as an unequivocal right.*

Vulnerabilities become more profound and individuals become even more vulnerable in times of pandemic. It is particularly important to take note of vulnerabilities related to poverty, discrimination, gender, race, sexual orientation, co-morbidities, loss of autonomy or functionality, advanced age, disability, ethnicity, incarceration (prisoners), homelessness, undocumented migration, and the status of refugees and stateless persons (see [Report of the IBC on the Bioethical Response to the Situation of Refugees](#), 2017). The IBC and COMEST re-affirm the recognition of our collective responsibilities for the protection of the most vulnerable and the need to confront and avoid any form of stigmatization and discrimination, both verbal and physical (see the [Report of the IBC on the Principle of Non-Discrimination and Non-Stigmatization](#) (2014); and the [Report of the IBC on The Principle of Respect for Human Vulnerability and Personal Integrity](#) (2013)). Measures such as isolation and quarantine impact vulnerable persons heavily. Specific attention should be paid to intra-familial violence, and to persons living in precarious economic and social situations, especially in middle- and low-income countries. Unfortunately, millions of displaced persons and refugees are practically excluded from vaccination programmes to the point that their rights and dignity are violated. Little has been made public about vaccination programmes directed at these groups, which constitute a substantial part of the population.

The urgency of finding a cure should not preclude responsible research practices. Researchers must comply with the ethical principles of research, and all research activities should be subject to scrutiny by competent research ethics committees. Such independent committees must continue to function uninterrupted.

Prevention

Even with a vaccination plan, preventive measures must continue. It is of note that the Inter-American Commission on Human Rights (AICHR) resolved that states must consider all kinds of prevention measures².

Given that there are currently no available therapeutic treatments for COVID-19, and that vaccination may take one year or more to immunize the population in many countries, particularly those in low- and middle-income categories, prevention is key. So far, states have been focusing on containment measures to address and prevent the effects of the pandemic, which includes quarantine, social distancing, isolation, the closing of schools and businesses, national and international travel restrictions, and guidance on preventive personal and community hygiene. States should also support public campaigns to guide people on how they can improve their physical and mental health through simple practices that are proven to be useful: physical exercise, better nutrition, breathing techniques, meditation or mindfulness,

² Resolution 1/2020 “Pandemic and Human Rights in the Americas” and Resolution 4/2020 “Human Rights of persons with COVID-19”.

exposure to sunlight. These practices are free or inexpensive and will also reduce the impact of chronic diseases associated with more severe cases of COVID-19.

2. Ethical concerns for research on vaccines

The first ethical requirement is to ensure the supply for **safe, effective, available and affordable vaccines, which** means research and clinical trials that comply with sound scientific methodology. The enormous pressure to find a vaccine should not impact the time needed to ensure the quality of the result and the primacy of safety and wellbeing of each participant during trials. The same is true for regulators, who should not compromise the quality of their evaluation and follow-up during the transition from the experimental phase toward the industrial-scale production and distribution.

There is an expected problem, both scientific and ethical, of **comparative evaluation of different vaccines that are already approved. Such an evaluation must be on a case-by-case basis, using all the data that are being accumulated.** It should be mandatory that all studies be published without any delay in peer-reviewed journals. As the number of approved vaccines increases, the use of placebos becomes an issue. An ad-hoc expert group of the World Health Organization (WHO) has defended the use of placebos for upcoming phase studies, as the proportion of people vaccinated worldwide is still minimal.³ With the emergence of fast-spreading variants, there is a pressing need to speed up the vaccine development process and have as many alternatives as possible. The feasibility of human challenge trials has even been debated⁴. In any case, all trials should be conducted under the scrutiny of independent ethics committees with appropriate risk-benefit analyses, and researchers must fully inform volunteers of all risks associated with the study.

When a vaccination campaign is waged on a global scale, success depends not only on the efficacy of a product, but on how it is deployed in the field. Therefore, research on pharmacoepidemiology, logistics, and supply chains should not be overlooked and should be supported. Special provisions are required for the transportation, storage, and distribution of high-tech vaccines. Some countries lack adequate infrastructure for such vaccine deployment, which creates an inequality of access, even if the financial bottleneck is resolved through donations. The shortcomings in the infrastructure and logistics needed to ensure equitable vaccine distribution exacerbate the existing divides between the rich and the poor, restricting the access of the low and middle income countries only to certain types of vaccines. The COVID-19 Vaccines Global Access (COVAX) initiative should not breed discrimination, nor create a situation in which donors would benefit from "first-class" vaccines and recipients from "second-class" ones. The unequivocal establishment of efficacy and safety with stringent scientific criteria for all vaccines would alleviate this burden.

All ethical concerns raised for vaccine research are also valid for research related to pharmacological treatments, many of which have been proven useless after having made headlines and having been intensively marketed. It must be noted that one of the pillars of the COVAX initiative concerns drug development and the support for improved accessibility and affordability.

Despite the urgency of rapidly finding responses to the pandemic, principles of research integrity should never be violated. Responsible research practices, under the supervision of qualified ethics committees, are the only truly reliable bases for finding sustainable solutions.

³ WHO Ad Hoc Expert Group on the Next Steps for COVID-19 Vaccine Evaluation, 2021. Placebo-Controlled Trials of COVID-19 Vaccines – Why We Still Need Them. *New England Journal of Medicine*, 384(2), p.e2.

⁴ WHO, 2020. [Key criteria for the ethical acceptability of COVID-19 human challenge studies](#).

3. Cost, production and distribution: Vaccines as a “global common good”

Availability of vaccines to all, in all countries, is an essential ethical issue. *The need to ensure that all individuals access affordable vaccines is of paramount ethical importance.*

There are risks that the most developed countries may buy the still incipient production of vaccines, to the detriment of LMICs. *The IBC and COMEST support the COVAX initiative (WHO, GAVI, CEPI) to overcome this risk.* More financial support is needed to allow COVAX to cover the needs of the LMICs.

Pandemics show the interdependency of countries. The IBC and COMEST call for international cooperation and solidarity. **The IBC and COMEST firmly reject “vaccine nationalism”**, as the “predatory rush” – in other words the political-economic power to pay for large quantities of vaccines in order to distribute them to one’s own citizens - is unfair on a global level (Canada bought enough doses to vaccinate its population five times⁵, the United States four times, the European Union three times). National and regional governments have cross-border responsibilities. We also call for measures against all forms of trafficking and/or corruption that might be associated with individuals or groups trying to undermine the needed solidarity. It is understandable to prioritize certain populations in an initial stage, such as front-line health workers and elderly people. These vulnerable populations are similar in every country, with certain variations in different countries allowing for specific considerations.

However, as the vaccine production accelerates, it is necessary to ensure that everyone, in all countries, will have access to it.

The extraordinary circumstances of the global pandemic raise ethical concerns on the appropriateness of the current **regulation of patenting and ownership rights**. The global challenge of this pandemic requires responses built on equality, justice, and solidarity.

We recognize that ownership rights protect some fundamental liberties such as freedom of research and the right to property, however, **an extraordinary context implies the need for extraordinary measures**. Furthermore, we call attention to the fact that the rapid development of vaccines would not have been possible without key contributions made by initial research conducted by scientists in public institutions (such as universities and public research institutions). Private companies have made a great effort to rapidly develop and transform academic discoveries into clinically relevant products, and to set up large scale clinical trials. The subsequent development of vaccines by the pharmaceutical industry was also supported by public funds, often in collaboration with public academic institutions. **This private-public partnership has enabled vaccines** to be produced in a record time, giving private companies a historical opportunity to contribute to the common good from a global perspective. Ultimately the goal should be to make vaccines available to all at a reasonable cost. It is important to share intellectual property, so that manufacturers in other countries can also upscale the delivery of vaccines to all. **Vaccines should be considered global common goods.**

For real equity in the global access to vaccines, a shared ethical recognition of health as a **global common good** with no territorial limit is needed, as well as new global legal instruments for economic and political agreements and treaties. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the agreements of the World Trade Organization (WTO) were not designed to manage situations such as pandemics. One

⁵ Sandrine Rastello, Kait Bolongaro, “[Canada Has Reserved More Vaccine Doses Per Person Than Anywhere](#),” Bloomberg News, 7 December 2020.

possibility is to use the Doha Declaration on the TRIPS agreement⁶ in public health to ensure the rights of everyone to access to these scientific developments. However, the solution to the issue of the availability, affordability and distribution of the COVID-19 vaccine should not be sought only in these existing agreements. New global approaches and mechanisms should be urgently put in place to allow efficient development and production of vaccines, while at the same time supporting the necessary investments that would guarantee access to all under fair conditions. The COVAX initiative, for instance, has secured the participation of over 190 countries, with the goal of working together for "equitable access to all the tools available to prevent, detect, treat and defeat COVID- 19". As of January 2021, COVAX had secured contracts amounting to two billion doses of vaccines.

Another issue is the business model of the vaccine production. The IBC and COMEST also underline the **responsibility of pharmaceutical industries** to invest in facilities that are able to produce vaccines of the highest possible efficacy and to facilitate rapid distribution to where they are needed. The massive pre-orders by certain national and regional structures such as the European Union and the African Union demonstrate that health must be treated differently from other markets, and require international economic, scientific and ethical frameworks to regulate investments and returns in this essential field, in a way that does not compromise the wellbeing of the marginalized.

4. Vulnerabilities and fair distribution

In the event that vaccines are produced in sufficient numbers to meet global demand, it will still be impossible to ensure simultaneous distribution around the world. What is the ethical criterion for a just/fair distribution? Who should be the first in line? The IBC and COMEST have drawn attention to the necessity of an open international dialogue to **decide how to fairly allocate and distribute COVID-19 vaccines** that are being produced, combining principles from both clinical and public health ethics, and taking into account issues arising both at the national and at the global levels.

The main goal of vaccination is to prevent the disease from spreading and to reduce its severity (direct protection). The pandemic is eventually controlled when a sufficient percentage of the population has been vaccinated, in order to achieve "herd immunity" (indirect protection).

It is important to note that vaccine clinical trials do not measure the transmissibility of SARS-CoV-2 and its variants, and that the efficacy of current vaccines against recently discovered variants may not be known at the time the vaccines are authorized.

Another effect of vaccination is to reduce the pressure on healthcare workers and the risk of oversaturating the demand for resources, which could lead to the collapse of the healthcare system. Finally, it will facilitate the recovery of economic activity. LMICs have less financial leverage to manage the impacts of quarantine measures, and will therefore take a double hit. The health impact is amplified by the economic impact, which is made more acute due to the lower resources and less-developed social protection systems.

Therefore, there are four main risks related to this pandemic which should be considered in order to develop a vaccination strategy in the context of scarce resources:

⁶ DOHA Declaration – it refers to several aspects of TRIPS, including the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property right. Available at https://www.who.int/medicines/areas/policy/doha_declaration/en/

- Comorbidity and mortality-associated risks;
- Risk of exposure;
- Transmission risk;
- Socioeconomic risk (including mental health, education and travel restrictions).

Each of these could have a different hierarchy or prevalence, depending on the context of the pandemic. For instance, in a context where a wave has devastating effects on people's health and lives, the risk of comorbidity and mortality must prevail. In addition, the risk of exposure must play an important role, considering the position of healthcare and essential workers and the principle of reciprocity and solidarity. The most exposed professionals should be adequately compensated by the community.

A utilitarian approach based on the benefit of the greatest number of people is not acceptable as the sole criterion from an ethical perspective. Other relevant ethical principles and values, such as the principles of equality, equity, protection from vulnerability, reciprocity and the best interest of children must also be considered. Furthermore, decisions on fair distribution and prioritization should be based on the advice of a multidisciplinary group of experts. The opinion of scientists is directly relevant in these matters, but not enough to solve such multi-faceted dilemmas which require ethical considerations and decision-making. The participation of experts in the area of bioethics, law, economics and sociology is indispensable to develop a prioritization based on a multidisciplinary proposal. The existing structure of bioethics committees such as the IBC and COMEST, bring together experts from different disciplines, is a good example.

The vulnerability of specific groups should play a **central role** in setting vaccination priorities. Ethicists and scientists should work in an interdisciplinary context (in order to focus also on psycho-social vulnerabilities), taking into consideration the perspective of citizens. In this regard, the IBC and COMEST consider that it is necessary to respect general ethical principles (justice, equality, solidarity), to be flexible in cultural/local-specific contexts, and to develop transparent interdisciplinary guidelines with scientific and ethical justification, recognizing both the role of experts and broad community engagement.

Two main areas for consideration:

- the clinical trials of vaccines, and the categories of people included/excluded (people excluded may be more vulnerable e.g. marginalized communities; LMICs).
- the risk/benefit analysis both direct for the individual and indirect for society: that is the risk for the health of the individual, the risk of transmission to others; the psycho-social risks.

Specific ethical guidelines for achieving just distribution of vaccines:

- *Occupational activities*: frontline healthcare workers; high-risk group, both for individuals more exposed to contagion, and for society, transmitting infection; public service workers of essential services (i.e. teachers, public security, community services considered as essential).
- *Individual vulnerability*: those most at risk medically—people most likely to suffer serious illness and to die if they become infected (vulnerability consideration based on severity of illness and their irreversibility); old people living in residences for the elderly; patients with comorbidities; those most likely to become severely ill if infected (e.g. immuno-suppressed individuals and chronic disease patients); people living in poor conditions, the homeless, those in precarious situations, including prisoners, migrants, refugees, asylum seekers;

- *Social vulnerability*: people at greatest risk of spreading/transmitting infection (e.g. emergency service providers).
- *Economical vulnerability*: lower income groups are the most affected. In LMICs, the high level of economic vulnerability and informality means that low socio-economic groups face higher risks. COVID-19 has magnified the pre-existing inequalities. Furthermore, low-income groups have less trust in the government, and therefore efforts to get them vaccinated need more attention.

These should be done in close agreement with the proposal emanating from WHO's COVAX initiative, which recommends three phases for initial vaccine distribution: in phase 1, the need to acquire enough vaccines to immunize 20% of the first three target populations: health care workers, the elderly and individuals with co-morbidities⁷. Transparency and public participation also play an important role in developing a strategy for vaccination. Confidence is not only related to the vaccine, but also to the prioritization strategy. Solidarity needs confidence, and transparency is essential to reach both confidence and solidarity.

Governments are called upon to declare their policies regarding the prioritization of vaccinations transparently and openly. Public policy implementation should be inclusive and based on the aforementioned ethical principles.

5. Mandatory/spontaneous adhesion

The IBC and COMEST underline the importance of information, communication and education campaigns aimed at illustrating the importance of vaccinations at an individual and societal levels. **This aims at reaching spontaneous participation on a global level.** The greater the educational effort and the communicative commitment (health literacy) are, the greater the number of people who will voluntarily get vaccinated. Public trust in vaccines is essential in achieving group/herd immunity. The challenges of promoting vaccine confidence may be heightened and clearly tackled in the context of the development of efficacious COVID-19 vaccines.

According to the epidemiology and medical and socio-economic sustainability of each country, the need for compulsory vaccination may generate discussion. However, the IBC and COMEST consider that the strategy for vaccination should be based on a non-compulsory, non-punitive model, based on information and education. In addition, nudges could play an interesting role in the strategy as a way to keep autonomy while promoting the most virtuous and solidarity decision from an ethical perspective. As explained in the [Report of the IBC on the principle of individual responsibility as related to health](#) (2019), through nudges, we try to promote healthy behaviours without adopting any kind of restriction or prohibition. Nudging could therefore be an option, as it is offered as an intermediate proposal between education and information on the one hand, and coercion and prohibition on the other hand. Since the most vulnerable often have less confidence in public institutions, we need public campaigns to assure citizens that all the validated information on vaccines are easily accessible. Hard to reach communities, like migrants and minorities, deserve our greatest effort. On the other hand, language and terms used in a strategy to address the issue of a pandemic are very important to promote a virtuous decision. For example, the expression "non-compulsory vaccination" could be more appropriate than "voluntary vaccination", since using the first one emphasizes the comparison between the two decisions of accepting or not accepting the vaccination. Therefore, only the first should be correct, ethically, even though both are acceptable from a legal perspective.

⁷ WHO, [Access and allocation: how will there be fair and equitable allocation of limited supplies?](#) Online article, 12 January 2021.

A non-compulsory model means, among other things, that the refusal of vaccination will not have any consequences for the individual from the perspective of his or her fundamental rights and, specifically, in relation to his or her right to healthcare or to access jobs. In the IBC Report on individual responsibility, we acknowledge that public health policies should not unnecessarily discriminate against individuals who, of their own volition, choose to partake in unhealthy lifestyle behaviours. Article 5 of the Universal Declaration on Bioethics and Human Rights (UDBHR) demands that such individuals also have a right to be respected for their decisions. The IBC report also adds the following: “to use responsibility in a retrospective way, punishing the patient for his/her behaviour (on top of his/her health condition) is ethically indefensible.” It is also unethical to deny treatment to individuals, abandoning them to their own devices, if they are unable to afford the healthcare they need, on the pretext of respecting their autonomy and individual responsibility. Health inequities exist; whether it is as a result of an individual’s own choice, socio-economic conditions, political situation, environmental conditions, or even genetic predispositions. Promoting individual responsibility for health does not mean permitting such health care inequities to be perpetuated.

Nevertheless, as indicated in the Report of the IBC on the principle of individual responsibility, and reframing the words of WHO, some believe that strong coercion or restrictions on liberty might be justified in exceptional conditions of urgency and security, such as in outbreaks of particularly dangerous communicable diseases.⁸ This was true for Ebola outbreak but seems different for COVID-19 until now. The emergence of new and more contagious variants may change this stance. However, restrictions on human rights, even in the context of a pandemic must respect international legal standards as articulated by IACHR Res. 1/2020: states must ensure that “any and all restrictions or limitations placed on human rights to protect health in the context of the COVID-19 pandemic comply with the requirements of international human rights law. In particular, such restrictions must comply with the principle of legality, be necessary for a democratic society and therefore be strictly proportionate to achieving the legitimate purpose of protecting health”.

6. Information and communication to raise awareness and responsibility

The IBC and COMEST underline the high importance of adequate information and communication to society, and that it should be:

- based on scientific evidence and updated on safety and security;
- clear, transparent, understandable (considering different cultural contexts and languages);
- consistent and coherent;
- inclusive;
- realistic about benefit/risk (underlining the necessity to continue preventive measures).

Anti-vaccination movements should be approached with openness, not with scientific arrogance: trust can only grow from a respectful dialogue and an invitation to critically and openly discuss the scientific practices behind vaccines.

The strategies for immunization programmes should differentiate between “no vax” and “vaccines hesitancy”, considering the individual social and cultural attitude towards vaccines. A specific need is the **monitoring of sources of disinformation and misinformation** (fake news) and the provision of counter-arguments to these.

⁸ WHO, 2020. [Key criteria for the ethical acceptability of COVID-19 human challenge studies](#).

Transparency and public responsibility are the main ways to convince people about the benefits for the individual, as well as the common good of accepting vaccinations.

7. Data-sharing and results-sharing (openness of science)

In light of the truly global nature of the pandemic, **international cooperation across all different sectors** working on COVID-19 is needed, in order **to share the benefits of research**. Greater transparency and data-sharing between companies and researchers is important for the evaluation of a drug's safety and efficacy but can also play an essential role in increasing access to vaccines. Global cooperation between industry, academic and research institutions, and governments could speed the development of vaccines.

As the IBC said in its Report on Big Data and Health, Big Data can be framed as a common good of humankind. So, solidarity should play also a main role in the context of secondary use of data. The solidarity of all as members of our communities, far from constituting a limit or obstacle to the development of our personal life, is the condition for the possibility of its realization. The Universal Declaration of Human Rights summarizes this idea: "Everyone has duties to the community in which alone, the free and full development of his{her} personality is possible" (art. 29.1).

The IBC has also reiterated the need to improve solidarity not only to allow citizens to share or donate their data for the common good, but also to urge companies and private actors to share their work to the same end.

Sharing our health data through techniques which guarantee our privacy such as pseudonymization is one of the best ways to develop treatments and strategies to address COVID-19. Pseudonymization could be a way to balance individual rights and the common good.

Digital technologies have come to play a central role in the pandemic. They are already widely used for contact-tracing and self-reporting and are increasingly being used to register test results and vaccination status. It is of crucial importance that these technologies always respect human rights and support individual values such as privacy and autonomy as well as collective values such as solidarity and inclusiveness. Moreover, these technologies should never be seen as the final solution: technological interventions should always be complemented with societal interventions like the development of resilient and flexible health facilities, the promotion of better housing for the elderly, more investments in public transport, and resettlement plans for people living in deprived areas.

8. Sustainability

The current pandemic reveals the urgency of shaping the conditions for sustainable ecosystems, in order to reduce the risk of zoonosis and to minimize the harmful impacts of future pandemics. Both from a human and from an environmental perspective, therefore, sustainability should have a central priority in policy-making.