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COMMENTAIRE CRITIQUE / CRITICAL COMMENTARY (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Lessons from the COVID-19 Pandemic: A Call to Implement (and Reimagine) Bioethical Principles

Vugar Mammadov^a, Lala Jafarova^b

Résumé

Ce commentaire analyse les dilemmes éthiques auxquels la communauté mondiale a été confrontée pendant la pandémie de coronavirus. L'importance des droits de propriété intellectuelle dans le contexte de la distribution des vaccins est particulièrement soulignée. Les auteurs mentionnent les principes bioéthiques – « oubliés » mais si importants – dans le contexte de la distribution des vaccins.

Mots-clés

COVID-19, pandémie, principes bioéthiques, vaccins, propriété intellectuelle, santé mondiale

Abstract

The commentary analyses ethical dilemmas faced by the global community during the coronavirus pandemic. The importance of the intellectual property rights in the context of vaccine distribution is particularly emphasized. The authors highlight bioethical principles – “forgotten” but so significant – in the context of vaccine distribution.

Keywords

COVID-19, pandemic, bioethical principles, vaccines, intellectual property, global health

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INTRODUCTION

The coronavirus 2019 (COVID-19) pandemic revealed the vulnerability, not only of the medical and social spheres of life, but also of the practical implementation of bioethical principles. Historically, the development of modern bioethical principles was in response to the infamous events of World War II. The Nuremberg Code, adopted after the Nazi doctors' trial in Nuremberg, Germany, was the starting point for a new international medical-legal and bioethical discourse. It proclaimed the need for special protection of the research participants (1), an ethical concept articulated as respect for autonomy and informed consent to participate in research. However, modern bioethical principles address much broader issues than individual consent to medical research, as become evident during the COVID-19 pandemic. For example, internationally recognized individual-oriented bioethical principles turned out to be practically unrealizable during the emergency of a global scale, especially where conceptions of global justice are still in their infancy. These gaps in bioethics discourse resulted in declarative (non-legally binding) bioethical principles being mostly left out of the international response to the virus.

To address this situation, we argue that the Universal Declaration on Bioethics and Human Rights (UDBHR) should evolve into a component of international law – i.e., be the predecessor of a new document, an “International Convention on Bioethics” (2). The COVID-19 pandemic should become a starting point for both reimagining bioethical principles and developing the legal mechanisms for their practical implementation. A parallel development in political and scientific circles is the widely discussed need for a pandemic treaty (3,4). The International Convention on Bioethics and the Pandemic Treaty should thus develop in tandem. Specifically, the Treaty's provisions ought to be articulated through the lens of newly envisioned bioethical principles. The COVID-19 pandemic allowed us to identify both weaknesses and omissions in bioethical principles and offers a unique opportunity to re-think their practical implementation on an international scale. We propose that an International Convention on Bioethics include 4 principles: *global sharing of benefits*, *global health equity*, *social responsibility for health*, and *global solidarity and cooperation*.

PRINCIPLE 1: GLOBAL SHARING OF BENEFITS

A bioethical principle of *Global sharing of benefits* would ensure that the benefits “resulting from any scientific research and its applications” are shared not only domestically but within the global community, especially with economically developing countries (5). In current practice, the vaccines (and other medications) are granted Intellectual Property (IP) rights and protected by the World Trade Organization's TRIPS agreement (6), and these monopoly rights are very often used to limit sharing. On the one hand, transnational corporations, e.g., the leading multinational pharmaceutical companies, spend considerable resources (primarily financial) to pay scientists, conduct research, purchase modern equipment and create an infrastructure for conducting clinical trials. On the other hand, these innovations result from considerable public investment (principally governments) and may involve clinical research in low- and middle-income countries. As such, states should arguably have the authority to share resources (innovations) to which they contributed, while low-income countries that helped with the development of vaccines deserve reciprocity and access. The low-income countries often cannot afford to pay costly licensing agreements to patent holders, nor produce vaccines on their own; neither can they fund vaccine development due to a lack of resources, both scientific and financial. Thus, vaccines, especially during the pandemic, can become a “stumbling

block” for the implementation of an effective fight against a pandemic, for those countries. The fact that funding for the development of most COVID-19 vaccines came largely from national governments (7) and charitable foundations challenges the idea that the control (i.e., patents) and financial benefits should be the exclusive province of private pharmaceutical companies. This public source of financing gives grounds for calling these “people’s vaccines” (8), thereby implying equal access rights by all people.

Operating on the possibility of waiving exclusive rights, in October 2020, India and the Republic of South Africa came up with a joint proposal to abandon certain types of intellectual property rights during the pandemic (9). However, the proposal has not gained the unanimous support of members states at the World Trade Organization, which is required to amend TRIPS (10). Unfortunately, the principles of fair sharing have not been implemented and applied during the COVID-19 pandemic. Instead, high-income countries have launched mass vaccination programs, which today also cover children and booster doses, whereas in many low-income countries, even vulnerable groups and individuals at increased risk of infection are still waiting for their first dose. This situation has widened vaccine inequality and prolonged the pandemic.

Unfortunately, in terms of bioethical principles, vaccine distribution has not been a case for the “*sharing of benefits*”. Attention was focused more on economic-legal aspects instead of ethical; some media have even called upon the need to discontinue the “practice of treating drugs as a commodity” (11). The bioethical aspect of the issue was not widely discussed, although bioethical principles, due to their “universality” and as internationally recognized values, have the potential to form the basis in this regard. In June 2021, the European Union made a new proposal to the WTO, which includes a “multilateral trade action plan to expand the production of COVID-19 vaccines and treatments and ensure universal and fair access” instead of waiving IP rights (12). Proposals include expanding the production and supply of vaccines and medicines for COVID-19. Further, the EU recently drafted a Declaration concerning IP rights (13), and according to the TRIPS Council, debates about the IP response to COVID-19 will continue (14).

However, it is not only vaccines that should be considered as a “common good” – also included should be drugs, masks, ventilators etc., as these are all necessary to save patients’ lives during the pandemic. Unfortunately, in countries where there is a shortage of even basic medical masks or a lack of stable electrical supply necessary to maintain the operation of refrigeration units, it is difficult to talk about access to or the production of innovative vaccines, especially those that require special cooling units for storage and transportation. In the current pandemic, a significant obstacle to the acquisition of vaccines was precisely the lack of appropriate infrastructure in the purchasing country. Through foreign economic intervention, many African countries have even been provided with solar-powered refrigerators; however, their temperature did not match the storage requirements of many COVID-19 vaccines (15). Complicated vaccine storage requirements have discouraged even the most modern hospitals in the United States and had a negatively affected availability in rural areas (16). It is not surprising that for countries where resources are far more limited, such a task is practically impossible without the help of donor states or the world community. Thus, the TRIPS agreement is not the only obstacle to the provision of vaccines; even if self-production rights are granted, many countries do not have the capacity to start this process. The issue is not just technology transfer, but also training, development of regional capacity, infrastructure, etc. Vaccine production, purchase and distribution cover many issues within healthcare that may have direct or indirect implications for the fight against the pandemic; there are not only medical but also social aspects underlying this problematic situation. Therefore, we are now seeing, in debates about the pros and cons of the IP waiver, discussions of logistics, technology pooling and opposition from the pharmaceutical sector (17). By mobilizing a principle of global sharing of benefits in a “pandemic treaty on the bioethical principles”, it would then be possible to adopt and implement numerous collective measures/strategies, including conditions for temporary IP rights waivers or the creation of a universal vaccine database and production infrastructure.

PRINCIPLE 2: GLOBAL HEALTH EQUITY

The economic development of states has had a direct impact on their ability to respond to the COVID-19 pandemic, as well as contributing to global economic inequality. A 2020 study conducted by the Health Foundation showed that the population living in the wealthiest regions was 50% less likely to die from COVID-19 than those in the poorest regions (18). High-income countries purchased much more than the required amount of COVID-19 vaccine for their populations. According to data for November 2020, “developed countries, where 14% of the world’s population lives, purchased 53% of all world stocks of promising vaccines” (19). As a result, many low-income countries, especially in Africa, were left without access to vaccines or with major shortages, and so mass vaccinations in these countries are not expected to begin before the end of 2022. Some have called COVID-19 a “*syndemic*”, a convergence of biosocial forces that interact with one another to produce and exacerbate clinical disease and prognosis” (20), thus pointing to its numerous synergistic features. The crisis has demonstrated that social factors such as poverty are one of the decisive factors when it comes to public health. In addition, the level of socio-economic development itself raises *ethical* issues. Eliminating the roots of inequality among different groups and countries, i.e., striving for global health equity, should become a primary goal for an eventual pandemic treaty.

PRINCIPLE 3: SOCIAL RESPONSIBILITY FOR HEALTH

A further bioethical concern regarding vaccines relates to social responsibility for health. Given the emergency context, vaccines began to be distributed before they went through the full phases of clinical trials, under “emergency authorization” (21), with the result that populations were both patients and real-time research participants. There is no doubt that, amidst high rates of mortality, states were ethically compelled to release vaccines prior to trial completion. However, was

the bioethical principle of respect for autonomy, operationalised through *informed consent*, implemented appropriately? During an emergency, setting aside this principle can be ethically justified; however, do all people consider the pandemic to be an emergency? Did the doctors have enough time to explain all aspects of vaccination to the patient, to take blood tests in case of potential health-related conditions? Unfortunately, in the background of the pandemic has been a mass of false and misleading information about vaccines (22), which made many people reluctant or frightened to be vaccinated. How can one measure a person's responsibility for refusing vaccination? Does the person understand and fully realize the responsibility to other members of society? Further, how can a state "promote health and social development" during such an extreme situation as a pandemic? Is it possible to supersede individual interests for the interests of society? During the COVID-19 pandemic these concerns were not adequately addressed and point to the need for two interconnected bioethical principles: *solidarity and cooperation* and *social responsibility for health*. It is a social responsibility to protect people's informed consent and choice, which requires regulating social media and ensuring public health campaigns that are culturally appropriate and meet the needs of a diverse public. And it requires social solidarity and cooperation to agree on collective responses; but this solidarity cannot be simply local (within a community or country), it must also be global.

PRINCIPLES 4: GLOBAL SOLIDARITY AND COOPERATION

Vaccine distribution has become a prime example of the urgency of implementing bioethical principles, and it illustrates their interconnection. Adopted in 2005, the UDBHR principles outlined the general mechanisms for international solidarity and cooperation in the field of science and medicine. The bioethical principles of *global solidarity and cooperation* promote international cooperation aimed at the encouragement of public health practices and collaborative agreements that are not only local, but also global. The distribution of vaccines was a perfect example of a failure of such global solidarity. Discord between countries was rooted in concerns to defend and respond first to national interests. The purchase and distribution of vaccines between high-income countries has left low-income countries at the end of the vaccine cue, dependent on international aid. According to the data from July 2021, "only 1.1% of people in low-income countries have received at least one dose" (23). This data should be cause for concern all countries, because pandemic viral disease can be stopped only when most of the world's population is vaccinated – "No one is safe, until everyone is" (24,25).

The UDBHR, unfortunately, does not include definitions of the bioethical principles; the meaning and application of solidarity, in practice, thus remains somewhat vague. While some authors describe it as "enacted commitments to accept costs to assist others with whom a person or persons recognise similarity in a relevant respect", they also stress that in practice it may include more factors of "social interconnectedness" (20). The bioethics literature covers different contexts of solidarity but in terms of national and global interests, values of solidarity may clash with a struggle for survival. During the COVID-19 pandemic, where risks and interests are very unevenly disturbed, it is unlikely that the entire population "will accept the costs of containing pandemics *out of solidarity with each other*" (26). If there is inadequate or limited solidarity among the population of one country, how can we expect all countries to act in global solidarity? Collective struggle "is particularly pertinent to situations where no other ties exist to bind people together" (27). In the context of global health, solidarity during the early stages of the COVID-19 pandemic was significantly disrupted, especially with regards to vaccination – each country tried to obtain as much as possible. Today we see that even in the face of a common threat, human solidarity ends where health issues begin; the same applies to countries protecting their own population first.

The COVID-19 pandemic, in addition to mobilizing purely medical aspects, should be also considered from the bioethical point of view in its broadest context. Nunes describes the pandemic as a "global vulnerability" (28) because it showed that public health is the key to a sustainable life of *solidarity* at the global level. Building on this analysis, the pandemic emphasized the *vulnerability of the global* community and showed that during the emergency no state can return to "normal" unless the entire world is protected – this should be accepted as a basis for both local and global solidarity.

CONCLUSION

The unequal global distribution of COVID-19 vaccines showed how the bioethical principles of the UDBHR and other treaties were incomplete and inadequate, and so readily "forgotten". From the point of view of international relations, a sharp tension emerged between state and international interests, which led to self-defeating actions. During a global pandemic, no one's interests are served by forgetting ethics or by acting out of narrow national self-interest. The practical difficulty of implementing bioethical principles during an emergency has challenged states and international groups alike and so points to the need for a joint International Pandemic Treaty and an International Convention on Bioethics. Following the African Ebola epidemic, an Independent Panel on the Global Response to Ebola analysed the global response to the outbreak and produced 10 recommendations that provided a roadmap for strengthening disease prevention and improving response (29). However, as the COVID-19 pandemic demonstrated so clearly, these recommendations were not put into practice. It is urgent that declarative bioethics principles be implemented in global treaties and policies so that they can lead to better collective practices, and thus a better world. The need to do this is part of our larger *responsibility to future generations*. We can and must do better.

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