Ethical considerations on COVID-19 immunization and vaccines

Statement of the World Emergency COVID19 Pandemic Ethics (WeCope) Committee (10 May 2021)

a. Preamble

As an independent, multidisciplinary, and cross-cultural committee comprised of ethicists from cultures and nations across the world, we offer the following statement and recommendations on ethical issues associated with COVID-19 vaccines and immunization.[1]

The COVID-19 pandemic has raised several ethical challenges. It is therefore unsurprising that public health authorities have turned to ethicists for advice when developing and implementing policies and measures in their pandemic response. This has created many opportunities for ethicists to enhance the moral quality of public health decision-making. The statement includes reflections on the moral responsibility of getting vaccinated, sharing information on the side effects and efficacy of vaccines, and the rights and responsibilities of each person in decision making. The discussion includes considerations over the economic, political, commercial, and financial implications related to the distribution of the vaccines. There are recommendations on the distribution of vaccines, immunization, immunity, justice, and ethical procedures related to public health information.

b. Immunization, immunity, and justice

We write this during one of the most dreadful pandemics in modern human history caused by the coronavirus-19 (SARS-CoV-2) disease (COVID-19), which continues to have international, national, and local impacts. The moral and ethical responsibilities, obligations and abilities of all persons, communities, and nations of the international community, to cooperate are especially significant in situations of emergency[2] (WeCope. 2020a).

A vaccine is a substance used to stimulate the production of antibodies and provide immunity against one or several diseases, prepared from the causative agent of a disease, its products, or a synthetic substitute, treated to act as an antigen without inducing the disease. Vaccines are scientifically proven tools for controlling life-threatening infectious diseases by the active immunization. They are among the most cost-effective healthcare investments for public health services in world history. Vaccination has not only provided health protection, but also contributed to the development and maintenance of education, economy, and preventing impoverishment (Dubé et al., 2013).

The approval of COVID-19 vaccines has added one further disease to the list of 26 diseases that have a vaccine approved as a preventive therapy (Gravagna et al., 2020).

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https://www.eubios.info/world_emergency_covid19_pandemic_ethics_committee

[2] These were explored in our earlier Statement on Autonomy and Responsbility (WeCope, 2020a).

We note that there is an expanding list of vaccines against COVID-19 that have been granted emergency use authorization in many countries, and we do not discuss the technical aspects of clinical trials assessed by appropriate regulatory authorities in many sovereign nations. The global focus has shifted to vaccines as a significant means to bring the pandemic under control. The timeliness of scientific research initiatives will be one of the main "hallmarks" of the COVID-19 pandemic. The U.S. National Library of Medicine and U.S. National Institutes of Health (NIH) lists over seven thousand studies related to COVID-19.[3] From a medical and pharmaceutical point of view, the main issue is the quality, which is being assessed through the results of ongoing research in the global immunization drive. Quality is dependent on the safety and efficiency of the vaccines. The more effective the vaccine is, the more impact it will have to control the pandemic.

There are certain key technical issues that will not be addressed further in this report. First even though a growing number of vaccines have been approved for emergency use in different countries, there is less data with respect to the potential side effects of the vaccines to some vulnerable groups e.g., pregnant women, children, and persons with disabilities such as autism, and whether there are risks of blood clots to certain subpopulations, and so on. Governments must exercise caution, while also gathering data and monitoring the evolution of recommendations for various groups. Especially while there are safety doubts, governments should not make vaccinations for anyone, particularly children with intellectual disabilities, compulsory. Children were underrepresented during the vaccine trials (Branswell, 2020). However, after sufficient information and knowledge becomes available regarding the safety concerns, then any state or government may evaluate the situation and prescribe a morally acceptable approach.

Pregnant healthcare workers were provided options to take the experimentally approved vaccines in late 2020 because they face a high risk from infection, but the general recommendation for pregnant women was given after just six months of collecting safety data. In most countries the vaccine immunization programs are being conducted as extensive clinical trials. Some countries with high immunization rates such as Israel, were provided access to a high number of vaccine doses in return for thorough clinical trial reporting.

Another technical issue is the scientific and medical understanding of “herd immunity”. The percentage of population immunity needed to suppress community transmission has been estimated at 25%-70% (Peiris and Leung, 2020). Vaccination and immunization have impacts on healthcare systems including reducing deaths, hospitalizations, and the severity of the disease. However, vaccines may not eliminate community transmission of SARS-CoV-2 until a very high proportion of the population is immunized. Vaccine efficacy can be defined as “percent reduction in disease incidence in a vaccinated group compared to an unvaccinated group under optimal conditions” (McNeill, 2006). It shouldn’t be confounded with vaccine effectiveness: “ability of vaccine to prevent outcomes of interest in the “real world””. In terms of public health strategy, vaccination is a proven means to protect a population, without being sufficient in itself: *"first-generation vaccines are only one tool in the overall public health response to COVID-19 and are unlikely to be the ultimate solution that many expect"* (Peiris and Leung, 2020). The other strategy to “find-test-isolate-trace-support” remains until the

[3] NIH - U.S. National Library of Medicine. ClinicalTRials.gov URL: https://clinicaltrials.gov/ct2/results?cond=COVID-19 (Date to update)

risks are definitively controlled (Rajan et al., 2020) while vaccine distribution began in a few countries at the very end of 2020 and is steadily growing.

An unavoidable question in resource allocation in health systems is that who should bear the cost? Different countries have different standards: public health insurance schemes, private insurances, and so on. It seems that countries that have invested more will have more vaccines rapidly. Countries that have manufacturing capacities have advantages. The need for universal coverage and universal vaccination to control the pandemic is a moral and ethical question, challenging conceptions of justice and the effectiveness of just actions at the political, financial, corporate, and democratic scales.

This raises a few questions. Should the vaccine be provided on a non-for-profit basis during the pandemic? Or only in 2021? Like the flu vaccine, it is probable that a new vaccine will be needed every year, with the virus strains mutating. Already there are significant variants that have been detected that are expected to require a third dose for some of the two dose regimes being adopted. The cost of producing the vaccine is estimated at USD 5-10 a dose (Kollewe, 2020), although some are costlier. Analysts estimate the revenue generated, assuming an annual jab at an average unit price of USD20 [$3-37] at between USD 10B to 25B per year globally. Free universal coverage remains an objective of some national health policies. It seems, however, that in the current paradigm these costs will be absorbed, and vaccine expenditures are still affordable. Many governments provide the vaccines free of charge, especially those mandated for their own citizens. Serbia has offered vaccines to persons from neighboring countries as a strategy for economic recovery, and for regional solidarity. In most cases around the world tourists and applicants for immigrant visas need to pay for their vaccines as required by each country (See the section on "travel immunizations and immigration immunizations").

c. The global need for a COVID-19 vaccine, as a global public good

Oxfam (2020) has reported that *"the wealthiest nations in the world comprising of 13% of the global population have placed 51% of the orders for Covid-19 vaccines."* This is expected given the uneven structures in the global economic order (Maboloc, 2019). Oxfam (2020) also notes that 61% of the world population will not have access to the vaccine until 2022. The question of vaccination is a global justice issue. It is necessary to evaluate the matter of prioritization when it comes to making the vaccines available on a global scale and the prioritization plan is often agreed upon by experts in different countries. The World Health Organization (WHO) has taken a strong stand when it comes to the flow of vaccine distribution, and this is increasingly being recognized by different countries. However, we can see vaccine nationalism continues, as evidenced by the European Union's implementation of laws requiring export licenses for COVID-19 vaccines from manufacturers in Europe. India, as the world's major manufacturer of COVID-19 vaccine in 2021 also imposed some restrictions on the exports of vaccine in March 2021 as it encountered higher COVID-19 rates domestically.

A public good is defined as one meant to benefit everyone. However, how this public good is viewed and distributed is often a matter of politics. The states decide who gets to receive the vaccine and who does not. Since the sovereign rights of nations determine their conception of a just entitlement, there is a gap in terms of how to define the public good on a global scale. There may be cases where refuges or persons living in foreign lands may not be treated fairly. While it is true that every human being on earth must have access to the vaccines, it is the politics that actually decides what may happen. For this reason, the less powerful nations have no option but to wait (Oxfam, 2020). This is

counter to the principles of justice. The issue of which population is offered what vaccine may be seen as discriminatory. Societies can appeal to the principle of the equality of persons, not just the equality of citizens, in pursuing a more equitable global norm in terms of vaccines distribution.

The utilitarian principle helps in justifying a more equitable distribution of vaccines. For instance, globalization was put to a stop because of the interconnectedness of transport systems around the world (Mansueto, 2020). It is beneficial, in this respect, for wealthy societies to also deliver to poor countries, specifically to frontline healthcare workers in poor nations, to protect them in the same way that wealthy nations initially prioritized health professionals and the most vulnerable (e.g., the elderly). The vaccines were generally not made based on economic profit but from emergency public funds from many countries, but the consequence of their discovery and subsequent distribution undeniably has some utilitarian intent in terms of the desire to go back to normal or even to a post-normal scenario when it comes to global trade, travel, and migration. The overarching goal is for COVID-19 vaccines to contribute significantly to the protection and promotion of human wellbeing among all people of the world.

d. Global solidarity and global structural barriers to equity approach

The principle of solidarity is accepted globally on paper, as written in the Universal Declaration on Bioethics and Human Rights, Article 13: *"Solidarity among human beings and international cooperation towards that end are to be encouraged."*, as is the principle of equity in Article 10: *"The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably."* (UNESCO, 2005). There are a number of structural barriers to implementation of global solidarity such as discriminatory social arrangements that, when encoded into laws, policies and norms, unduly privileges some social groups while harming others (Farmer et al., 2006; Büyüm et al., 2020). Power imbalances and structural violence can lead to disproportionate suffering and premature death.

Pogge (2007) has proposed that rich countries must recognize their negative duties toward justice. A negative duty not to harm implies a positive right on another party. For instance, global poverty is a result of unjust trade policies and global economic structures that benefit the rich countries at the expense of poor nations. Globalization and the perverted nature of capitalism have resulted in an unjust global economic order (Stiglitz 2015). This reality has an impact with respect to the acquisition and distribution of vaccines since poorer nations may not have the sufficient funds to purchase the vaccines from pharmaceutical firms that are usually based in the West. The acquisition of vaccines must not be tainted with any politics but must be grounded solely in the interest of global health and the solidarity of nations.

One proposal is that global financial institutions should help financing the purchase of the vaccines. Incidentally, this has already been started by the World Bank and the Asian Development Bank. The World Bank has approved the allocation of USD 12 billion. Meanwhile, the ADB has allocated 9 billion US dollars for the acquisition and allocation of vaccines (adb.org). The next step is to be able to identify those countries who need the financing facility. An important aspect is to make the loan available to poor nations at zero interest rate. The reason for this is that many developing countries are saddled with long-term and short-term loans that have undermined their ability to attain any real economic progress and well-being for their people. The pandemic has only exacerbated this situation. From a moral end, it is incumbent upon rich countries as part

of rectificatory justice, to help governments with no real access to funds for the vaccines to be able to avail of such aid all for the sake of global health and public safety.

Recommendation 1:
COVID-19 vaccines are global public goods and therefore efforts should be made to make them available to any human in need of vaccines, irrespective of their socio-economic status. Global vaccine manufacturing capacity should be enhanced.

e. Public participation vis-à-vis COVID-19 vaccines

What is said to be crucial in the government's procurement of vaccines to contain Covid-19 is transparency. The role of the government is to inform and update the public regularly about the planned total number of doses to be acquired, the current contracted quantity, the plans for obtaining the remaining balance and the period of the expected deliveries (Punongbayan, 2020). In the global scale, governments should have clear, transparent, and objective criteria for beneficiaries and those who will be prioritized and communicate this widely to the population. (UNODC Policy Paper, p.8)

It is incumbent upon every government to inform citizens about its plans to procure whatever total quantity it believes is necessary, and the expected dates of delivery. The government must also inform everyone about what to expect regarding the movement of people in terms of plans for any continued restriction in public movement (Galvez, 2020). This is especially important as some people are questioning the vaccines' safety, particularly what side effects do they really bring. Transparency is important, wherein all results are released and discussed in scientific journals (Tamesis, 2020). In lieu of informed consent, which many countries have waived because it is an emergency use approval, a fact sheet explaining everything should be given to potential recipients prior to obtaining the vaccine in question.

Public institutions should identify and address any potential gaps and barriers, such as the risk of corruption in distribution and allocation processes, to ensure that populations have equitable access to vaccines. Addressing corruption is a priority in times of crisis, and the pandemic is creating new opportunities for corruption (UNODC Policy Paper, p.2). Civil society participation in the formulation of policies, a system of checks and balances, and monitoring of the overall health system is a necessary element in efforts to curb corruption in the health sector at every level. During the COVID-19 pandemic, civil society, non-governmental organizations, and community-based organizations can support government efforts to counter corruption. Promoting the active participation of civil society should include enabling and encouraging civil society participation in relevant decision-making processes related to the allocation and distribution of COVID-19 vaccines, including those related to the prioritization of recipients, the procurement of vaccines, and the flow of emergency funds for vaccine programs (UNODC Policy Paper, p.9).

There may be conflicts of interest related to the funding of the research and development of a COVID-19 vaccine prevents risk of corruption. An example of this could be when a high-level officer of a government's COVID-19 vaccine research and development program, who used to work for a private vaccine company that is bidding for a large contract under the government program to manufacture a vaccine candidate, participates in a decision-making process on that contract. Some countries have created special commissions to negotiate the purchase of COVID-19 vaccines with the laboratories and universities conducting research and development on potential vaccine

candidates. There can be a lack of transparency, and thus a potential risk of corruption in what these agreements entail. These laboratories and universities have frequently had to sign confidentiality declarations as part of their agreements with the special commissions to secure a vaccine for the populations of high-income countries. Such agreements risk undercutting fair global access of low-income countries to a COVID-19 vaccine (UNODC Policy Paper, p.3).

Recommendation 2:
Public participation in overseeing an equitable access to vaccines is a desirable approach to public health and this may reduce the risks of corruption.

f. Just allocation, distribution, and prioritization of COVID-19 vaccines

As the number of cases rise, and the longer the duration of the pandemic, questions on just allocation and distribution of the vaccines are intensified. Every sovereign state needs to decide who will be the first ones to get the vaccine. Although multidisciplinary teams and health authorities in different countries are working in prioritization of vaccines, as long as there is a shortage of the vaccine and a capacity gap in immunization, problems may arise. High success of an immunization program is only possible if distribution and allocation is well organized and planned with a clear preparation and administration plan, and an efficient immunization service. Occasionally there will be issues, such as the failure of a freezer, that have resulted in the immediate need to attempt to distribute doses before they expire, and there is consensus that all efforts should be made to avoid wastage of the vaccine. In addition, sometimes additional doses could be recovered from vials of vaccine.

All countries have prioritized healthcare workers and hospital staff. Most countries have then prioritized older people and critically ill and medically compromised patients. Most countries have also elevated persons in occupations that involve direct contact with people like dental professionals, ophthalmologists, and workers in essential services such as municipal garbage collectors to get the vaccine because they are more at risk to get the coronavirus. Allocation criteria should be determined according to occupation, and people at high risk of transmitting SARS-CoV-2, e.g., health workers, people most essential to maintaining core societal, and economic functions, and groups of people unable to physically distance such as disabled persons and their caregivers, people living in dense neighborhoods, multigenerational households, nursing homes and prisons. In addition, age and health situation should be considered, e.g., older adults, people with certain comorbid conditions, socio-demographic groups at disproportionately higher risks. For example, Indonesia is prioritizing working adults, who are at higher risk of contracting the virus, over some elderly persons who stay at home.

Although there are uncertainties about the fair distribution of the Covid 19 vaccine among countries, many national leaders, international organizations, and vaccine manufacturers recognize that one of the central factors in this decision-making process is ethical values (AstraZeneca, 2020; Trudeau et al., 2020). Fair distribution of the COVID 19 vaccine across countries is an important ethical issue. Prioritizing disadvantaged people is highlighted as a core value in ethics and global health (Ottersen et al., 2008; Sharp and Millum, 2018). National governments also have cross-border responsibilities to help provide basic needs such as basic healthcare, especially in global health emergencies (Sangiovanni, 2007).

The vaccines pillar of the ACT-Accelerator, convened by CEPI GAVI and WHO, were speeding up the search for an effective vaccine for all countries. At the same time, it has supported the building of manufacturing capabilities, and buying supply, ahead of time so that 2 billion doses can be fairly distributed by the end of 2021 (WHO, 2020b). COVAX is an association formed by the World Health Organization and non-governmental organizations GAVI (Global Alliance for Vaccines and Immunization) and CEPI (Coalition for Epidemic Preparedness Innovations). It has also considered the fair and effective distribution of Covid 19 vaccine to the world.

COVAX is one of three pillars of the Access to COVID-19 Tools (ACT) Accelerator, which was launched in April by the World Health Organization (WHO), the European Commission and France in response to this pandemic, bringing together governments, global health organizations, manufacturers, scientists, private sector, civil society, and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments, and vaccines. The COVAX pillar is focused on the latter. It is a global solution to this pandemic because it is the only effort to ensure that people in all corners of the world will get access to COVID-19 vaccines once they are available, regardless of their wealth.

For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as several higher-income self-financing countries that have no bilateral deals with manufacturers, COVAX is quite literally a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines. For the wealthiest self-financing countries, some of which may also be negotiating bilateral deals with vaccine manufacturers, it serves as an invaluable insurance policy to protect their citizens, both directly and indirectly. On the one hand it will provide direct protection by increasing their chances of securing vaccine doses. Yet, at the same time by procuring COVID-19 vaccines through COVAX, these nations will also indirectly protect their citizens by reducing the chances of resurgence by ensuring that the rest of the world gets access to doses too.

COVAX is necessary because without it there is a real risk that most people in the world will go unprotected against SARS-CoV-2, and this would allow the virus and its impact to continue unabated. COVAX has been created to maximize our chances of successfully developing COVID-19 vaccines and manufacture them in the quantities needed to end this crisis, and in doing so ensure that ability to pay does not become a barrier to accessing them. There are currently more than 170 candidate vaccines in development, but most of these efforts are likely to fail. To increase the chances of success, COVAX has created the world's largest and most diverse portfolio of these vaccines, with nine candidate vaccines already in development and a further nine under evaluation. Gavi has created the COVAX Facility through which self-financing economies and funded economies can participate. Within this also sits an entirely separate funding mechanism, the Gavi COVAX Advance Market Commitment (AMC), which will support access to COVID-19 vaccines for lower-income economies. Combined, these make possible the participation of all countries, regardless of ability to pay. The fact that the global community has come so far so quickly and built such a comprehensive and effective global solution to this pandemic is a remarkable accomplishment. Now we need to implement it, and this hinges on countries buying into the COVAX Facility so that it can make urgent investments now.[4]

[4] https://www.gavi.org/vaccineswork/covax-explained

The ACIP (Vaccination Practices Advisory Committee) highlighted the ethical principles and approved some recommendations for the use of the COVID-19 vaccine in September 2020. These principles express equity and justice, maximizing benefits and minimizing harm. In principle, they emphasized the importance of transparency in vaccination practices and ethical decisions. Transparency ensures that allocation decisions are open and open to scrutiny as well as public participation. Transparency is also required to increase public confidence (Bell et al., 2019).

One of the most striking conceptual initiatives proposed in the global distribution of the Covid-19 vaccine is a fair priority model. The fair priority model refers to three core values. These values encompass the concepts of maximizing utility and minimizing harm, prioritizing the disadvantaged, and equal moral concern. The WHO (2020a) approach recommends that countries receive vaccine doses in proportion to the size of their population. The WHO's initial dose allocation expectation for each country varies between 3-20% of the population. However, this rate may vary depending on the countries' position in pandemic struggle. This creates a distinct ethical challenge. As a matter of fact, the problem of allocating more vaccines to countries that do not manage the epidemic well, compared to strong countries that implement health measures well, comes to the fore. This situation poses a particular difficulty in ethical decision making (Emanuel et al., 2020).

The issue of the distribution of vaccines is a serious problem, so there is a need for guidelines based on ethical values and human rights in order to improve world health and ensure immunization and to reduce the problems that public health professionals will face in this context (National Academies of Sciences, 2020). SARS-CoV-2 pandemic has led to an increase in basic social, economic, education and health needs, and the existing imbalances and inequalities both between countries and people living in the same country. For these reasons, the distribution of vaccines must be transparent and inclusive, and all information on this issue must be made available to the public in a clear and understandable way, with justifications provided on the legality of such decisions. Failing to do so will reduce public trust in healthcare providers and systems, as well as government leadership, and may lead to chaos. Therefore, the common benefit should be determined as a goal and encouraged, and people should be treated equally and fairly, that is, every individual should have access to vaccines, and societies' legitimacy, trust, and sense of ownership should be encouraged (Toner et al., 2020). As stated in a report of the World Health Organization (WHO), international vaccine distribution should be carried out in accordance with the equality value of ethics, and each country should follow immunization by determining priority groups in order to control the pandemic (WHO Working Group on Ethics and COVID-19, WHO 2020a). The following principles are among the most important ones regarding vaccine allocation during the pandemic:

Human-wellbeing: The aim of getting vaccinated is to protect and promote human well-being, including physical, psycho-social, and social health, economic security, human rights and civil liberties, and the protection of all vulnerable groups (National Academies of Sciences, 2020).

Equal respect: Acknowledge and vaccinate all people without prejudice, as having equal moral and rights status and interests, and worthy of equal ethical/legal consideration (National Academies of Sciences, 2020).

Global equity should aspire to achieve equality in vaccine access by ensuring that people living in all countries, especially people living in low and middle-income countries have access to vaccines.

National equity: Ensure equality in vaccine access in the distribution and priority of the vaccine in accordance with basic ethical and scientific criteria, avoiding biological and social discrimination such as over political, religious, and ethnic affiliation, socioeconomic status, and gender (National Academies of Sciences, 2020).
Legitimacy: It involves transparency, trust, and nonprejudice in the process of making evidence-based allocation decisions (National Academies of Sciences, 2020).
Communication-media ethics: Media plays a vital role during pandemic and disasters. Therefore, they should use impartial and reliable sources, clear language, and explain all terms, report the numbers, explain side effects, using appropriate visuals, and reminding the benefits of the vaccine.

Recommendation 3:
The pandemic is a global challenge, therefore international and national ethical values and principles must overlap in vaccine distribution and setting priorities that can help contain the pandemic, even if the virus cannot be eliminated. All countries should be called upon in this regard. These principles should be applied in the framework of human well-being, equal respect, global equity, national equity, legitimacy and ethical communication.
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Recommendation 4:
Ethical values should be taken into consideration in vaccine distribution programs, and in the case of limited resources, priorities should be determined according to explicit ethical criteria. These criteria should take priority to protect and improve the health of society, according to vulnerability, occupation, age, health situation, population density and factors such as people living in multigenerational households. Especially, healthcare workers who face the most serious risks and burdens in the pandemic, providing material and moral support to alleviate their burden and risks should be considered on a world scale. Prioritization should be adjusted according to risk groups and be considered in other professions too.

Recommendation 5:
Governments have a moral obligation to be transparent about any vaccine they are providing and the reasons for choosing the vaccine, and about the right of people to choose another vaccine if available. The public should be informed about the vaccination and the technique of the vaccine, the tests performed and the results of each phase, and the questions and discussions of independent scientists, journalists, broadcasters, students, and other community leaders should be encouraged, as part of a meaningful process that can be trusted. Thus, the community should clearly understand the criteria for vaccines, different techniques of vaccines, autonomous approach to recipient selection, the priority reasons of vaccine distribution, to be able to trust the authorities in vaccine distribution.

g. Vaccination as a moral responsibility

Vaccination remains one of the most economical and effective interventions for preventing an array of infectious diseases and the associated disabilities and deaths, thus fostering public health (Afolabi, 2016). However, it is very important to highlight that vaccination should be voluntary unless it becomes critical to *"prevent a concrete and serious harm" and if so; visual aids and other media can be used to convey accurate and important information to the public in a time-efficient manner"* (Moodley et al., 2013).

One of the reasonable means for ensuring individual autonomy is to provide people accurate information related to positive and negative impacts regarding any vaccination program that is expected to be implemented in the society as a moral responsibility, in order to facilitate the individual decision-making process. The lack of accurate information about a given vaccination program can raise mistrust, weaken autonomy and the process of individual decision making. The current strategies used can be improved by giving the citizens the rights to make their own decisions with transparent and clear information from the government or the community leadership.

From an ethical perspective, decisions made by an individual's moral consciousness should be open to dialogue, and the procedures should be fair (Lenhardt and Nicholsen, 1999). Considering a broader perspective, the value of every individual life is significant, with particular care for vulnerable communities (e.g., people with special needs, those living in poverty, indigenous communities, and so on) should be protected by the government and that should become the priority of every government.

To ensure the respect to autonomy, the need of providing accurate information on the risks and benefits of vaccination to target populations should be regarded as vital, and it should done adequately to allow individuals to make informed decisions, while bearing in mind that many will lack a basic understanding of germ theory and immunology (Moodley et al., 2013). As it is well known *"Vaccines produce benefits but can also cause individual or social harm. Side-effects are an example of individual harm. These range from mild, common reactions, such as inflammation and pain at the injection site, to more severe but extremely rare events."* Thus, providing accurate information related to the risks and benefits of vaccination to target populations should always be regarded as fundamental for ensuring the respect for autonomy and allowing individuals to make informed decisions.

Philosophical views in many parts of Asia and Africa emphasize the idea of 'relational autonomy' which, is as an alternative conception of what it means for one to be a free and self-governing person, in that a person is socially constituted and embedded in a social environment, culture, or tradition that indicates value commitments, social obligations, interpersonal relationships, and mutual dependencies (Ikuenobe, 2015). For example, *Ubuntu ethics is relational ethics, that prizes relationships of interdependence, fellowship, reconciliation, relationality, community friendliness, harmonious relationships and other-regarding actions such as compassion and actions that are likely to be good for others, in which actions are morally right to the extent that they honour the capacity to relate communally, reduce discord or promote friendly relationships with others, and in which the physical world and the spiritual world are fundamentally united"* (Ewuoso and Hall, 2019).

Recommendation 6:

Receiving the immunization during a public health emergency can be a moral responsibility.

h. Compulsory vaccination by government authorities

There are circumstances in which governments have made immunization legally compulsory, and we can expect some of these policies to apply to COVID-19 vaccination regulations. The World Health Organization (WHO) has no official policy on mandatory vaccinations. Discussion of the ethical issues of voluntary versus compulsory immunization (Salmon et al., 2006) are discussed above in the section on voluntary immunization.

Gravagna et al. (2020) surveyed 195 countries and found that 105 countries had a national mandate for vaccines as of December 2018. 62 countries defined a penalty for non-compliance and 43 limited entry to school based on immunization. Among these 62 countries, 12 countries included the penalty of jail time for non-compliance, and 2 of these had immediate jail time more than 6 months in duration. Even though some nations have a compulsory immunization policy in law, they may decide not to enforce that policy; for example, local authorities may decide not to fine or imprison violators (Walkinshaw, 2011).

If a nation mandates immunization, they usually have a national no-fault compensation program for those who have medical problems because of these. Among G7 countries, Canada was the last country to introduce a no-fault compensation plan for immunization, as recently as December 2020.[5] The province of Quebec had a no-fault compensation scheme for 30 years, like many other OECD countries. In the case of a pandemic there are additional justifications for compulsory vaccination that apply in some legal circumstances, consistent with national law. Countries such as Australia and USA which have semi-mandatory programs argue on utilitarian grounds that the public benefit from higher immunization rates justifies the mandate (Salmon et al., 2006).

Some national and local governments require compulsory immunization for employees that have contact with certain populations (See Employee Mandated Immunization). Given that to date COVID-19 vaccines have only been granted emergency authorization, it is too early yet to mandate compulsory immunization, even if that should ever be implemented.

Travel mandated immunizations: Countries have legal authority to impose compulsory vaccination on immigrants and tourists. Immigrants to many countries around the world are required to have a set of immunizations and it has been announced by the European Commission and some other countries that a COVID-19 vaccine will be added to this list by mid-2021 (Murphy, 2021; Stevis-Gridneff, 2021). There are existing rules on international immunizations, and several immunizations are legally required for tourists.[6] The existing certification scheme can be adapted to include SARS-CoV-2 Virus and several countries have announced that they are considering

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[5] https://www.cbc.ca/news/health/vaccine-compensation-1.5837406

[6] An International Certificate of Vaccination Against Yellow Fever is an official record and a legal requirement for entry into some countries. There is an official list on the World Health Organization's International Travel and Health website of countries as requiring proof of vaccination for yellow fever for all travelers entering the country (currently: Angola, Burundi, Cameroon, Central African Republic, Congo, Republic of Cote d'Ivoire (Ivory Coast), Democratic Republic of Congo, French Guiana, Gabon, Ghana, Guinea-Bissau, Liberia, Mali, Niger, Sierra Leone, Togo, Uganda). In addition, many other countries require certification when travelling from a country with endemic Yellow Fever only, for example a traveller from Brazil to Columbia may require certification. The requirements also vary over time depending on the status of outbreaks of the disease. https://www.iamat.org/world-immunization-chart

whether to make it mandatory for tourists. The requirements for travel vary by each country.[7]

Immigration mandated immunizations: Generally, there are stricter requirements for immigrants as opposed to short-term business travelers and tourists. Simply put, no immunization may mean no immigration! In the light of the CDC guidance "*Any future vaccines recommended by ACIP for the general U.S. public will be subject to the new vaccination criteria. If the recommended vaccines fit the new criteria, they will be added to the list of required vaccines for immigrant applicants."*[8], thus a SARS-CoV-2 vaccine is expected to be added soon. However, the European Union does not have a unified policy as surveyed by Bica and Clemens (2017): *"With some notable exceptions immunization policies to contain spread of infectious diseases through migration are either non-existent or vary widely between countries in the EU/EEA. With freedom of movement within the EU/EEA there ought to be harmonization and a common EU/EEA vaccination strategy to replace national policies for immigrant populations."*

Some countries do not require immunizations for immigration, such as Japan. The COVID-19 pandemic may lead to pressure on some countries to introduce such regulations on the grounds of public health emergency laws that exist in many more countries than those which require immunization for immigration.

Immunization policies for schools: In some countries compulsory vaccination policies apply to teachers and students attending public school or private school. In the United States students attending school are required to have immunization against several diseases. The state of Mississippi and West Virginia only allow medical exemptions for students attending school, but other states also allow religious and philosophical exemptions.[9] In March 2020 Germany passed a law that requires all children to be vaccinated against measles before they can go to kindergarten or school. Since attending school is obligatory in Germany, that means the country already has a de facto mandatory measles vaccination.[10]

Some countries such as Australia offer financial incentives for students who attend school who have met the immunization requirements as an incentive to encourage vaccination under the Maternity Immunization Allowance and Childcare Benefit Act. Ethically it is more acceptable to offer financial incentives than to impose penalties such as jail time or loss of parental custody of children, as discussed in the Section on voluntary immunization.

For most children, in-person instruction is better than on-line teaching. A return to physical schools is expected, at the latest with the availability of immunization. Private universities with enough financial resources can take the initiative to vaccinate

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[7] A searchable country list for clinicians and for travelers is available at: https://wwwnc.cdc.gov/travel/destinations/list/

[8] https://www.cdc.gov/immigrantrefugeehealth/laws-regs/vaccination-immigration/revised-vaccination-immigration-faq.html#whatvaccines For example, to apply for an immigrant visa to the United States the following immunizations are required (Mumps, Measles, Rubella, Polio, Tetanus and diphtheria, Pertussis, *Haemophilus influenzae* type B (Hib), Hepatitis A, Hepatitis B, Rotavirus, Meningococcal disease, Varicella, Pneumococcal disease, Seasonal influenza).

[9] State Vaccination Requirements. Centers for disease control and prevention. Available at: https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html

[10] https://www.dw.com/en/germany-makes-measles-vaccination-compulsory/a-51243094

university students. Governments can provide funding to ensure that students from public colleges and universities can have access to the vaccines. Immunization, however, should not be compulsory. The parents will have to make the decisions for students who are not yet of legal age. Risk assessment should also be conducted scientifically. For instance, the government should select schools where the Covid infection is highest. In some cases, these are metropolitan cities where there are millions of people who interact on a daily basis.

Employer mandated immunization: In some countries compulsory vaccination policies apply to members of the military, or certain other occupations. In effect if you live in a country with universal military conscription, and the military requires immunization, in effect immunization is compulsory unless someone has an exemption against military service. In the United States case, it has been announced that COVID-19 vaccine will not be compulsory for all employees until it receives general FDA approval, because currently it is approved on an emergency basis.[11]

Some other employers mandate vaccination for their employees, and there is no legal question when this comes to recruitment of new employees, if it is made clear to applicants and new employees that is the policy. There are more complex legal questions whether current employees are required to have a vaccination in order to continue employment, although if employment is based on renewable contracts, then such additional requirements could be added to the new contracts.

Generally compulsory employee immunizations will be an attractive policy among consumers and customers of service industries, especially healthcare providers, staff of long-term care facilities, domestic help, and travel companies, for example. In the private marketplace, we can expect such marketing by companies. In a recent survey of medical students in Austria, 80% of medical students supported compulsory immunizations for medical doctors (Kunze and Schweinzer, 2020).

Because some consumers are expected to have privileged access to businesses with a vaccination passport, those businesses are also expected to require employees to be vaccinated. Dr. Frank Ulrich Montgomery, president of the World Medical Association, and Dr. Thomas Mertens, virologist and head of Germany's Standing Commission on Vaccination (STIKO), have suggested that “people who have been immunized against COVID-19 could use a vaccine "passport" to get access to flights, restaurants, concerts, and cinemas.”[12] Many Germans, like persons in some other countries, already have an "immunization passport" that records all immunizations they have had.

Compulsory immunizations for employees of travel companies: Employees of travel companies that cross international borders, such as flight crews, are already subject to meeting international law on travel health restrictions. Some airline companies, starting with the CEO of Qantas, have announced that they will make COVID-19 immunization compulsory for all passengers to all destinations, as well as all their cabin crew.

The *International Air Transport Association* (*IATA*) (2020) is considering a consistent international policy and has recommended: “Governments should put procedures in place to ensure that travelers who have been vaccinated should not need to undergo COVID testing.” Some countries are considering mandatory immunization as an entry

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[11]https://www.militarytimes.com/news/your-military/2020/12/09/troops-could-begin-getting-covid-19-vaccines-as-early-as-next-week-and-they-wont-be-mandatory/

[12] https://www.dw.com/en/covid-special-privileges-for-the-vaccinated/a-56077470

requirement, but in December 2020 IATA stated, "While IATA expects that a significant majority of international travelers will be willing to get vaccinated, COVID vaccination should not be a mandatory government requirement for international travel." However, as the IATA acknowledges, some countries will waive requirements for COVID-19 testing and mandatory quarantine periods for those with vaccination certification. We can expect some countries will add COVID-19 immunization to other required immunizations that exist as entry requirements. In the case of paper certification for COVID-19 vaccines, there are already a number of cases of reported forgeries and fraud in 2021.

Recommendation 7:
Experience from existing immunization programs, both mandatory and voluntary, should be assessed to consider whether vaccines against SARS-CoV-2 should be added to the list of mandated or elective immunizations, while considering the cultural and legal milieu, and the situation of the pandemic.

Recommendation 8:
Existing international travel certification systems should be extended to ensure just and transparent requirements for COVID-19 immunizations. Research should be conducted to determine whether digital vaccine certification is effective.

Recommendation 9:
When applying mandatory immunization policies, employers and travel companies should apply existing legal requirements fairly for their employees and customers. There is an urgent need to further elaborate ethical procedures, based on the experiences that global society is gathering during 2021.

i. Global funding and initiatives: affordable and available COVID-19 vaccines
As well as reducing the tragic loss of life and helping to get the pandemic under control, introduction of a vaccine will prevent the loss of US$ 375 billion to the global economy every month (WHO, 2020b). Equitable access to Covid-19 tests, treatments and vaccines in all countries will lead to the pandemic ending sooner, many lives saved, a return of international mobility and trade, and a start to economic recovery. The $28.1 billion investment still needed to develop these lifesaving tools could be recouped in 36 hours once international mobility and trade are restored. This investment is less than 1% of what G20 countries have already unlocked to support businesses and national economies.[13]

There is an extraordinary need to manufacture and distribute safe and effective vaccines to protect the entire global community from the ongoing threat of SARS-Cov 2 coronavirus infection, morbidity, and mortality (Corey et al., 2020). Cold chain requirements, cost and providing wide coverage are understood as potential restriction points in the delivery of vaccines to individuals and communities. Because of these problems, global cooperation between healthcare delivery and economic organizations is vital.

As an example, the Asian Development Bank (ADB) said it will only fund vaccines that have satisfied any of the following criteria: selected for procurement via COVAX on

[13] Wellcome.org, Equitable access to vaccines, tests and treatments for Covid-19, https://wellcome.org/what-we-do/our-work/coronavirus-covid-19/access

behalf of participating countries, prequalified by the World Health Organization, authorized by a Stringent Regulatory Authority (SRA) for manufacture in an SRA country or the SRA has authorized its manufacture in a non-SRA country. The funds will be available for ADB developing members to support vaccine-related health system assessments and the development of country readiness plans to strengthen the capacity to access, introduce, monitor vaccines, safely and effectively. Funds will help members assess and strengthen vaccine cold chain and logistics, infection control, supply and skills of health workers, risk communications, and real-time data capturing and monitoring (ADB,2020b).

The principle of solidarity and social responsibility is adopted, and countries with the ability to produce vaccines are expected to first provide vaccines to their own citizens, but also to allocate part of the supply to other countries (National Academies of Sciences, 2020).

Recommendation 10:

Investments should be made immediately to strengthen supply chains, allocating sustainable and adequate financing, and empowering community and frontline health workers to ensure no one is left behind. Investment is needed to enhance the Access to COVID-19 Tools (ACT) Accelerator. By investing in the ACT-Accelerator, governments will have a better chance of accessing the successful tools

j. Prioritization of persons with special vulnerability

In addition to the vulnerabilities discuss above, a double disaster occurs when a natural disaster happens in an area affected by the COVID-19 pandemic. During natural disasters including earthquakes, fire, flooding, severe storms such as a typhoon or a cyclone, evacuation of people in disaster prone ares and sheltering them in larger public buildings have been common strategies to save the lives of communities. However, such shelters may face serious issues related to the risk of infection spread especially in the urgency and panic of a natural disaster. Authorities have to prepare methods to deal with such situations (Shahul et al., 2020), and vaccination of communities living in areas at risks of such disasters, especially in flood prone areas should be a priority.

Recommendation 11:

Communities living in disaster prone areas, such as low-lying coastal areas that have been hit before with severe natural disasters requiring evacuation would benefit from having received COVID-19 vaccines in case evacuation is required during another disaster.

j. Hope for a better and healthier future should not be hinged only on vaccines

While vaccines are a critical tool to save lives, the immune system is dependent upon all aspects of health – physical, mental, and social. Food sustains our life, and we need to pay more attention to making nutritious food available to as many people as possible around the world. Exposure levels are critical for social groups who run a high risk of associated complications, as in settings where environmental protections are loose, healthcare spending is low, there is poor access to running water, and where is poor nutrition.

Evidence shows that a better life can be secured through higher physical and mental health standards, which in turn can reduce the risk of infection, and the best and easiest way toward this public goal is to help all people adopt conscious thoughts and behaviors that foster their wellness. Moreover, as social norms and values shift selection pressures to wider groups, clarity about the determinants of morbidity and mortality through lifestyles can help restore individual and community immune systems and vitality so people adapt and continue contributing to glocal communities in harmonious and ethical ways.

While it is encouraging to see so many vaccines proving successful scientists from across the world are also collaborating and innovating to develop better tests, treatments and vaccines that will collectively save lives, especially when combined with holistic approaches to enhance our immune systems. At the same time, still simple hygiene, wearing masks and physically distancing when close to other persons who might be infected, can protect ourselves and others.

Recommendation 12:

Vaccines are only one part of the global responses to COVID-19 that are necessary. The lessons that we can draw for improving equity and justice can be applied in all aspects of public health promotion.

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