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The Equitability of Universal Vaccine Mandates – A Bioethical Analysis of COVID-19 Vaccine

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ABSTRACT

In public health emergencies that warrant mass vaccination, vaccine mandates are sometimes imposed. There is historical evidence of the effectiveness of vaccination mandates, but varying strategies in policy implementation. The COVID-19 vaccine mandate presents an ethical imbroglio that poses these bioethical questions, "Is there ethical justification for a vaccine mandate?", and "Whose responsibility is it to ensure the equitability of a vaccine mandate in a pandemic?" Using ethical principles and theories, this paper focuses on the health equity of vaccine mandates, considering both the global and local implications.

Vaccination mandate, in a pandemic, is driven by the need to accelerate the achievement of public health goals of herd immunity, protecting the most vulnerable in terms of case fatality and hospitalization rates, protecting the capacity of the acute health care system, as well as circumventing the economic impact. These mandates must still be guided by appropriate stakeholder involvement and bioethical considerations, to assess their validity and equitability, as vaccine mandates may impose restrictions on the freedoms and rights of an individual. Using COVID-19 as a case study, we argued the equitability of vaccine mandates based on the WHO framework of ethical considerations and caveats for mandatory vaccination. Necessity and proportionality of the vaccine, sufficient evidence of safety, efficacy, and effectiveness, sufficient supply, and public trust are key during ethical processes of decision-making. We conclude that vaccine mandates are more equitable as population-specific mandates, as opposed to global or universal mandates, even in pandemics. This is due to varying geographic, socio-cultural, and economic characteristics. Bioethicists should be actively engaged in discussions on the vaccine mandate, as its equitability is a function of critically analyzing the proposed mandate based on ethical recommendations prior to being issued. Retrospective bioethical analysis is warranted to identify shortfalls and make recommendations for future decision-making.

KEYWORDS
vaccines, mandate, COVID, fairness, equity.

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Introduction

Vaccination has been instrumental in reducing the burden on some infectious diseases, resulting in the eradication of some diseases like smallpox and eliminating others. There are well-established immunization programs that allow for systematic vaccination. However, in emergent situations, mass vaccination may be warranted leading to vaccine mandates. Vaccine mandate,

also known as mandatory vaccination, in its contemporary form entails policies that adjure the use of direct and indirect threats of sanctions in cases of noncompliance with few recognized legitimate exceptions.(WHO Ethics and COVID-19 Working Group, 2021) The vaccination mandate is not uncharted territory as there is historical evidence of mass vaccination campaigns dating back to the ultimate eradication of smallpox in the 20th century (Horton, 2020). This paper will focus on equity – particularly health equity of vaccine mandates, considering both the global and local implications. Using the recent debate and calls for a vaccine mandate to mitigate the COVID-19 pandemic as a case study, we seek to undertake a bioethical analysis based on the equity of vaccine mandate. This article summarizes the COVID-19 pandemic and uses its experiences to make an argument for and against vaccine mandates.

Historical Perspective

The vaccination mandate is not uncharted territory as there is historical evidence of mass vaccination campaigns dating back to the ultimate eradication of smallpox in the 20th century (Horton, 2020). Especially in the United States, there was a clear depiction of the positive effects of vaccine mandates on smallpox eradication. A comparison of the incidence from 1919 and 1928- of states that issued vaccine mandates, states that provided local options for laws on vaccination, and those that prohibited vaccine mandates; shows that the incidence was higher (115.2 per 10, 000 cases) in the 4 states the ten states where mandatory vaccination was prohibited and least (6.6. per 10, 000 cases) in the 10 states that enforced mandatory vaccinations (Batniji, 2021).

The prevalence of infectious diseases is high in low-income countries. As a result of this, there are various strategies in place for mandatory childhood vaccination programs. School-based outbreaks have warranted several vaccine mandates over the years, backed by state laws for school entry. These have targeted diseases such as smallpox, diphtheria, polio, tetanus, pertussis, and measles, resulting in significant disease control and prevention (Malone and Hinman, 2007). Thus, vaccine mandate is not a foreign concept in both high and low-income countries.

What varies, however, is the strategy employed to enforce the policy- persuasion (education or incentivization) versus coercion. Societal interest is pitched against individual interest in mass vaccination programs and if this conflict is not well-managed it results in a "tragedy of commons" where more individuals choose to do what is in their “best” individual interest and undermine the herd immunity for community disease prevention resulting in disease outbreaks (Malone and Hinman, 2007).

The Covid 19 Mandate Case Study

The COVID-19 infection was declared a public health emergency of international concern by the World Health Organization (WHO) on 30th January 2020 and a pandemic by 11th March 2020. As of December 2020, Ayoub and colleagues (2021) estimated the global percentage of infected persons at 12.56% (95% CI: 11.17–14.05%), global infection fatality rate was 10.73 (95% CI: 10.21–11.29) per 10,000 infections.(Ayoub et al., 2021) They projected 8.18 million deaths from the pandemic, without intervention, by the time the herd immunity threshold is reached at 60–70% infection exposure.(Ayoub et al., 2021) It was therefore imperative to accelerate the achievement of public health goals of herd immunity, protecting the most vulnerable in terms of case fatality and hospitalization rates, protecting the capacity of the acute health care system, as well as circumventing the economic impact.

The alternative to herd immunity via natural infection/exposure is vaccination. There was a prompt response by major pharmaceutical companies like NIH-Moderna and Pfizer-BioNTech SE, such that by March 2020, vaccine candidates had entered their first phase of clinical trials. By December 2020, these two vaccines were authorized by the U.S. Food and Drug Administration (FDA) for emergency use.(AJMC Staff, 2021) A framework was developed to ensure equity in the COVID-19 vaccine allocation and distribution.(Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, Board on Health Sciences Policy, Board on Population Health and Public Health Practice, Health and Medicine Division, & National Academies of Sciences, Engineering, and Medicine, 2020) Vaccine reception, uptake, and vaccination rates however varied among countries.(Mathieu et al., 2021)(Mathieu et al., 2020) As of 13th September 2022, "a total of 12,613,484,608 vaccine doses have been administered, with 5,361,962,048 having received at least one dose of the vaccine, and 4,908,532,010 have been fully vaccinated".(WHO, 2022) The low uptake led to calls for a COVID-19 vaccine mandate that seeks to bridge this gap and ensure herd immunity is attained globally. The proposed vaccine mandate assumed that vaccination per-protocol results in immunity and thus does not require the testing of anti-RBD IgG titers, rather using vaccine certificates as a proxy. One wonders, "Scientifically, beyond the contextual framework, is there enough scientific data to validate a vaccine mandate as the sole way of achieving public health goals?"

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Bioethical Question

A central tenet of bioethics is to marry the rights of humans with the quest for medical and scientific innovation and progression. This is done by honoring the four main principles of ethics: autonomy, justice, beneficence, and non-maleficence. Stemming from these, other principles like honesty (truth telling), confidentiality, fairness (equity), leadership, integrity, compassion, respect, responsibility, loyalty, law-abiding, transparency, and environmental concerns, have emerged. A singular way of describing the harmony of these principles is fairness- otherwise known as equity. Similar to the conflicts of ethical theories, there may be conflicting principles in any given ethical or moral issue. Although the focus of this paper is the "equitability" of universal vaccine mandates, several of these principles will lend either support or dissent to either arm of the argument. The collision of theories and/or principles emphasizes the need for models of resolving such conflicts. This ethical analysis aims to create a forum of discourse to develop a suitable model for future resolution of conflicts pertaining to vaccine mandates.

Using the shared ethical framework designed for allocating scarce resources, equity can simply be viewed as mitigating unfair disadvantage. The dimensions of disadvantages are varied and may include ill health, poverty, discrimination, and exclusion from opportunity. The evolution of COVID-19 has been accompanied by a plethora of ethical debates and contemplations. The COVID-19 vaccine mandate presents an ethical imbroglio that poses these bioethical questions, "Is there ethical justification for a vaccine mandate?", and "Whose responsibility is it to ensure the equitability of a vaccine mandate in a pandemic?"

Interpreting fairness may be subject to the theory of ethics being subscribed to; Laar et al (2020), discussed utilitarianism, equity, equal worth, urgent need, and the prioritarian principles as moral

considerations in a crisis.(Laar et al., 2021) Although a utilitarian approach may be a good guiding principle in rationing and allocation in some aspects of the pandemic, equity may be a more appropriate guide in other aspects. In the face of hardship, the ability to remain fair is put under significant test. Inequitable decisions may have negative effects on the susceptible population and perpetuate adversity for all. In ethical decision making the interest, motives, and power of each stakeholder must be considered to address ethical biases and logical fallacies.

The main stakeholders involved in mass vaccination exercises are the people (the consumer), the service providers (pharmaceutical companies and the scientific/medical fraternity), and the policymakers (governments and regulatory bodies). From the perspective of the consumer, under the principle of autonomy, vaccine mandates can be argued as an infringement of one's rights. However, the policymaker has the responsibility to make decisions on behalf of a group of people that will impact their lives as individuals and as a community. Pharmaceutical companies and the medical fraternity, as a group, have been greatly relied on for therapeutic and preventive interventions in this COVID-19 pandemic. The role of these stakeholders may be considered independently or collectively; either way, it presents a complexity that bioethicists must navigate cautiously when discussing vaccine mandates.

Mello and colleagues presented six criteria for the COVID-19 vaccine mandate: inadequate containment, Advisory Committee on Immunization Practices vaccination recommendation for the specific population; adequate supply for coverage of the population; evidence of safety and efficacy of vaccine which has been transparently communicated; accessibility of vaccines without financial or logistic barriers and surveillance and compensation for vaccine adverse effects; when voluntary uptake has fallen short of the level required to prevent epidemic spread.(Mello, Silverman, & Omer, 2020) This mirrors the WHO framework of ethical considerations and caveats for mandatory vaccination.(WHO Ethics and COVID-19 Working Group, 2021)

To make an informed and objective stand on equity of vaccine mandate, I shall discuss arguments both for and against vaccine mandate, using COVID-19 pandemic as a case study. This will be based on the WHO framework of ethical considerations and caveats for mandatory vaccination – necessity and proportionality, sufficient evidence of vaccine safety, efficacy and effectiveness, sufficient supply, public trust, and ethical processes of decision making. (WHO Ethics and COVID-19 Working Group, 2021)

Arguments for the Motion

Necessity and Proportionality of the COVID-19 Vaccine

As of 2021, data showed that only 13% of the global population had been infected with SARS-CoV-2 by the end of 2020.(Ayoub et al., 2021) Global projections predicted a potential ten million COVID-19 deaths and 200 million hospitalizations without interventions to increase vaccination coverage to match global needs.(Ayoub et al., 2021) The global incidence, hospitalization, mortality rates, and risks were of significant concern and substantiated the need for accelerated immunization through vaccine mandates.

The COVID-19 vaccines, as opposed to natural infection, offer the opportunity of immunity without causing illness or major complications such that health care systems are not overwhelmed, and can be administered in a controlled and well-monitored manner. The historical evidence of the feasibility and benefits of achieving herd immunity through vaccination makes it the more viable alternative.

Voluntary vaccination upon introduction of vaccination was suboptimal, varying among countries and various jurisdictions. (Mathieu et al., 2021) Even among health care workers, who are at significant risk and were expected to take up ambassadorial roles to promote vaccine acceptance, there was significant vaccine hesitancy. Thus, vaccine mandate for health care workers, as well as other groups of workers, can be seen as a social justice policy. (Hagan et al., 2022)

Despite the resistance to vaccine mandates, several population-specific and nation/state-specific mandates were issued. Recent statistics show that vaccine coverage has improved, with WHO States reaching on average 60% of their populations.(WHO, 2022) Major reductions in severe disease, hospitalization, and mortality, and the easing of stringent public health interventions to allow societies to re-open, may be attributable to vaccination rates.(Karaivanov, Kim, Lu, & Shigeoka, 2022) This is reflected in the WHO statistics shown in the table 1.

Sufficient Evidence of Covid-19 Vaccine Safety, Efficacy and Effectiveness

The available data on the authorized the COVID-19 vaccines upon their introduction, at the time, showed that these vaccines were safe and efficacious in reducing the severity of disease and mortality (Wong, 2021). However, there was a need for concerted effort to achieve herd immunity in the shortest possible time to decrease the likelihood of viral genetic mutations to strains less susceptible to the vaccine. It was purported that insufficient coverage contributed to the development of the Delta strain and other strains. (Wynia, Harter, & Eberl, n.d.) Vaccine production for SARS Cov-2 was based on long standing research and experience, going through the necessary phases of trials before approval for use (Lurie et al., 2020). The apparent accelerated development and authorization does not imply a compromise in quality or safety of vaccines produced during a pandemic. It is important to note that, marketing authorization were issued to Pfizer-BioNTech and Moderna was on condition of legally binding post-authorization obligations for further research into vaccine safety. (Prugger, Spelsberg, Keil, Erviti, & Doshi, 2021)

With the emergence of new strains of concern, such as the Omicron variant, coupled with evidence of waning vaccine-induced immunity, there were concerns about the effectiveness of vaccines. However, studies have shown that COVID-19 vaccination still conferred higher protection against hospitalization and death, comparing fully unvaccinated, fully vaccinated without booster doses and fully vaccinated with booster doses. (Rubin, 2021) (Johnson et al., 2022)

Sufficient Supply

The COVID-19 Vaccines Global Access Facility (COVAX), co-led by Gavi (the Vaccine Alliance), the Coalition for Epidemic Preparedness Innovations, and the World Health Organization (WHO), provides the framework to ensure fair and dynamic vaccine allocations across countries in response to variations in urgency. This pre-emptive intervention utilized the WHO "proportional allocation scheme" (PAS) to promote fair vaccine distribution based on its two phased framework of first equal proportional allocation to coverage of 20%, then subsequent weighted allocation.(Emanuel, Luna, Schaefer, Tan, & Wolff, 2021) The Fair Priority Model (FPM), proposed by Emanuel et al (2020, 2021), provides further ethical considerations guided by three basic values of benefiting individuals and limiting harm, prioritizing the disadvantaged, and global equal concern.(Emanuel et al., 2021)(Emanuel et al., 2020) The combined effect of these two frameworks was consideration of fairness among individuals across state boundaries and global fairness among countries, to ensure equitable vaccine supply and allocation. What informed

these frameworks is experienced from past allocation efforts like the H1N1 influenza campaign, the Ebola campaign, and other pandemics.(National Academies of Sciences et al., 2020) In the most recent report on Global COVID-19 Vaccine Strategy (2022), the WHO states that "...despite remaining impediments to vaccination delivery, opportunities for all countries to achieve global vaccine coverage goals are largely being achieved".(WHO, 2022)

Public Trust

There were significant efforts at public engagement through education to court public trust in the COVID-19 vaccines. Campaigns co-opted celebrities, opinion, and religious leaders, as well as medical and scientific experts, to propagate information about the COVID19 vaccines with emphasis on safety and effectiveness. Myths and misinformation about vaccines and the developmental process were addressed in a bid to resolve vaccine hesitancy. Medical and religious exemptions in vaccine mandates also helped to engender public trust in the motives of the vaccine mandate. The collaborative effort invested in tackling COVID-19 might have helped address the long-standing health disparity due to socioeconomic determinants.

Ethical Processes of Decision making

There is a need to address the scope of autonomy beyond individualistic gains in the context of community impact. (Wynia et al., n.d.) (Barugahare, Nakwagala, Sabakaki, Ochieng, & K Sewankambo, 2020) The legitimate derogation and limitation of some human rights to meet public health goals during public health emergencies may emphasize other principles of justice, beneficence, and non-maleficence as warranted. This explains the ethical propriety of vaccine mandates. In the case of COVID-19, though sharing similarities with other epidemics and pandemics, it remains unique as a novel virus needing to be studied as it evolves while concurrently being controlled. The WHO Policy Brief on Ethical Considerations for COVID-19 and Mandatory Vaccination (2021), stipulates that vaccine mandates must be guided by ethical deliberations, as proposed by their framework. (WHO Ethics and COVID-19 Working Group, 2021) These deliberations pertaining to a mandate must be transparent and well communicated- to explain the evidence and importance/rationale, and consequences of lack of mandates and non-compliance. The collaboration between the WHO Global Ethics team and other bioethical societies and organizations- such as the Global Network of WHO Collaborating Centers for Bioethics, National Ethics Committees, Public Health Emergency Preparedness and Response Ethics Network (PHEPREN) and The Access to COVID-19 Tools (ACT) Accelerator; is evidence of ethical processes and considerations that have been involved in the decision making for a vaccine mandate. These have provided advice, policy briefs, guidelines, systems of monitoring, et cetera to ensure equity.

Arguments Against the Motion

Necessity and Proportionality of the COVID-19 Vaccine

Although the studies used are mainly observational with some inconsistencies, "national surveys covering 2020–2021 documented that a previous SARS-CoV-2 infection is associated with a significantly reduced risk of reinfections with efficacy lasting for at least one year and only relatively moderate waning immunity".(Pilz, Theiler-Schwetz, Trummer, Krause, & Ioannidis, 2022) The immunity against most respiratory viruses is fluid- ranging from complete long-lasting immunity that protects against infection, to immunity that only mitigates disease severity without protecting against transmission and reinfection.(Morens, Folkers, & Fauci, 2022) The latter depicts the immunity profile of COVID-19, either by natural infection or vaccination.

Development of SARS Cov-2 virus variants capable of escaping immunity from either infection or vaccination, coupled with the waning immunity may result in potential endemicity of the virus as was the case with the 1918 influenzas virus pandemic. (Morens et al., 2022) The afore-mentioned points question the necessity of the COVID-19 vaccine and the need to enforce a global vaccine mandate. It can be argued that the efficacy of natural immunity is being downplayed by "big pharma" to advance the cause of vaccine production and use.

Also, the epidemiology of COVID-19 has been variable in various jurisdictions – regions, countries, and localities; and not always comparable to global proportions. (Ayoub et al., 2021) In this context, necessity and proportionality cannot be generalized to justify a global vaccine mandate. In countries where population dynamics depict a smaller proportion of the population as vulnerable and high-risk populations, inequity can be argued based on proportion. There is also a need to consider the evolution of the disease with the emergence of different strains/variants with different effects on viral transmission, clinical manifestations, morbidity as well as mortality, and the other relevant findings. For the above reasons, a global vaccine mandate is neither feasible nor justifiable. Even state-specific or region-specific mandates remain controversial.

Sufficient Evidence of the COVID-19 Vaccine safety, efficacy, and effectiveness

Classical herd immunity may be unattainable for COVID-19, due to antigenic shifts resulting in potential vaccine-escape mutant strains that may render vaccines less efficacious. (Rubin, 2021) (Morens et al., 2022) This has warranted the need for booster shots and further development of vaccines that can combat both the original strain and emerging strain effectively. The vaccination regimen appears to be evolving with no clear end, and a vaccine mandate under these circumstances. The evidence on vaccine safety, efficacy, and effectiveness continue to evolve, correlatively, the vaccination regimen is evolving with no clear end. There is a risk of perpetuating the development of new strains by natural selection or vaccine selective pressure which can cause these mutations. (SeyedAlinaghi et al., 2021) Also, the evidence about the efficacy and effectiveness of the authorized vaccines against new strains is controversial as there is the possibility of potential mutations that might escape vaccine-induced immunity. Pertinent questions about the duration of vaccine-induced immunity, risks of infection after vaccination, the impact of emerging variant strains on the targeted herd immunity, and feasibility of herd immunity need to be addressed if vaccine hesitancy is to be overcome. The imposition of a vaccine mandate without addressing these legitimate concerns is coercive and likely to reinforce vaccine refusal. (Wong, 2021)

Sufficient Supply

Globally, the inequitable vaccine distribution and coverage despite projections of continuous increase in vaccine supply and frameworks for equitable allocation, challenges the sufficient supply consideration of a vaccine mandate. There has been a longstanding racial and socioeconomic health disparity that undermines equitable supply and access to vaccines. (Bruce & Tallman, 2021) Citizens of low and middle-income countries whose lack of vaccination may be attributable to insufficient supply and coverage as opposed to vaccine hesitancy suffered restrictions when traveling to countries with high coverage and vaccination rates with imposed mandates. See Table 1. A global vaccine mandate targeting the general public, or even specific populations like schools, large businesses and health workers, will be fair only when it can be ensured that every eligible member in that setting can be appropriately vaccinated based on the vaccine supply. (WHO Ethics and COVID-19 Working Group, 2021)

Public Trust

Mistrust of authorities and the scientific community stems from the history of unethical practices suffered by vulnerable and minority populations, especially black and African American populations. (Scharff et al., 2010) Mistrust is also due to prevailing health disparity and inequity of minority groups. The proposed framework for equitable allocation and tiered administration based on risk groups by combining PAS and FPM may appear logical. However, when this approach selects vulnerable groups to be early recipients of an accelerated vaccine with emergency use FDA approval, especially without appropriate engagement and education, it may trigger insecurities and vaccine hesitancy. Statistics in the US identified a relatively high risk of infection with poorer outcomes among the African American population (Reyes, 2020). It has been argued that the predisposition is due to racism, rather than race, and socioeconomic determinants of health.(Vasquez Reyes, 2020)(Laurencin, 2021)(Sina-Odunsi, 2021) However, the most vaccine hesitancy is experienced among these populations which may be attributable to the racial precedence informing allocation which reinforces insecurities due to racial biases and long-standing health inequities.(Sina-Odunsi, 2021)

Ethical Stand Statement

On consideration of both arguments, I make an ethical stand against a universal vaccine mandate until all the ethical considerations have been duly addressed. However, in select populations where the risks posed by lack of vaccination are detrimental to the individual and/or society, population-specific mandates may be warranted.

Personal Argument

When subjected to the ethical lens to make a decision that is fair to all stakeholders in consideration of the available data, it is obvious there is no one size fits all answer to the bioethical question, or the scientific questions posed. There was a significant gap in scientific knowledge informing COVID-19 vaccination. Leaning on a personal background in medical practice and historical evidence of the positive outcome of vaccination exercises, COVID-19 vaccination is a feasible alternative to achieving public health goals. However, some form of strategy needs to be employed to encourage mass vaccination other than a coercive mandate. As no one ethical theory presents a conclusive justification for a vaccine mandates, strategies should be informed by applying different theories where appropriate.

The following recommendations are being made to address the gaps identified by applying the considerations proposed by the WHO Ethics and COVID-19 Working Group (2021):

- Policymakers
  i. Further epidemiological studies need to be undertaken to better define the proportionality of disease burden that will inform the necessity for any particular public health intervention. This will also help identify and stratify risk populations to inform risk-based vaccine mandates.
  ii. Further research and monitoring of the vaccination exercise would be useful in providing further information to better characterize the outcomes, to provide sufficient evidence of vaccine safety, efficacy, and effectiveness.
  iii. Sustainable vaccine production, supply and allocation should be ensured to facilitate universal coverage. Health disparity can be addressed by capacity building and decentralization of vaccine and therapeutic manufacturing plants with well-defined distribution frameworks.

iv. Continuing stakeholder engagement and collaboration to develop guidelines for crises and decision-making should be prioritized to garner public trust in the scientific, bioethical, and legal basis of proposed policies. Healthcare reforms must focus on the integration of science, sociocultural and other factors to drive the success of public health interventions.

v. Developing good social mobilization and engagement strategy to improve understanding and reduce vaccine hesitancy.

- **Healthcare providers**
  i. There should be transparency and oversight of post-authorization safety and efficacy studies for vaccines following conditional authorization.
  ii. There is need for fundamental innovation in the development of improved, durable, and broadly protective "universal" SARS C0v-2 vaccines is of high importance.
- **Public:** There should be opportunity for open dialogue and dissemination of accurate information to dispel misconceptions and doubts.

Conclusion

The dynamics of an evolving pandemic present a challenge to equitable decision-making. Bioethicists should be actively involved in decision-making to ensure ethical consideration is not overlooked. Decisions may be reviewed as indicated by emerging evidence and disease evolution. This does not undermine the value of bioethical analysis as said by Cropper in Suits "Ethics is not about never doing anything wrong; it's about making choices".

Limitations of the study

The authors tried to combine both empirical and theoretical bioethics for an objective analysis. Both required making assumptions and claims on moral utility. There is still significant chance of influence by individual moral inclinations. There were aspects where the authors had dissenting views.

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Tables

Table 1: Current COVID-19 and vaccination statistics (WHO, 2022b)

	Cumulative cases	New cases in past 7 days	Fully vaccinated persons with last dose of primary series per 100 population	Persons boosted per 100 population
Global	607,083,820	3,188,184	62.97	28.37
High income	365,400,111	2,241,138	74.41	40.63
Upper-middle income	157,017,581	843,728	74.78	40.63
Lower-middle income	81,149,081	90,856	56.88	14.92
Lower income	1,955,569	2,966	18.71	2.08

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