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Time for the ethical management of COVID-19 vaccines

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The ethical distribution of life-saving medical and public health interventions to vulnerable groups has often been overlooked. Valuation of life linked to an individual's country of origin, the pharmaceutical industry's prioritisation of profit, the exploitation of vulnerable groups in clinical trials, and the resulting hesitancy towards drugs and vaccines have, among other factors, made the human right to health unattainable for many people. The COVID-19 pandemic presents itself as an opportunity to reverse this long-standing trajectory of unethical practices in global health. By ensuring the ethical inclusion of vulnerable groups in the vaccine development process and making a safe, effective vaccine accessible to all, pharmaceutical companies, governments, and international organisations can usher in a new era of global health that relies solely on ethical decision making.

Introduction

With several COVID-19 vaccines approved worldwide, the ethical principles guiding their distribution should be reflected on and considered, especially for those at high risk (ie, vulnerable groups). From late December, 2020, countries started vaccinating their populations with vaccines that were approved by various regulatory institutions. As of March 24, 2021, 468 million doses have been administered in 135 countries.¹ However, these doses are concentrated in high-income countries, which have purchased 54% of secured doses but which account for only 19% of the global population.² The COVAX initiative was established to serve as a safety net for all countries—to pre-empt this inequitable distribution of vaccines by ensuring coverage for 20% of member countries' populations and by prioritising at-risk groups such as front-line health-care workers. Despite this goal, vaccine nationalism exemplified by countries' decisions to hoard vaccines and inoculate groups that are not at high risk has substantially reduced the supply of available vaccines. At this rate, it is estimated that many low-income countries will not be vaccinated until late 2023. This inequitable distribution of COVID-19 vaccines is a manifestation of unethical decisions and actions that have historical roots and threaten to stall our return to a state of normality.

Discrepancies in valuation of life

Historically, ethical principles in health policy have often been disregarded when they have concerned vulnerable groups, with the distribution of life-saving drugs considered too expensive and unsustainable and the recipients deemed unfit and unworthy.³ For example, this was the case with multidrug-resistant tuberculosis, a disease that was once considered as one of the deadliest diseases for vulnerable groups.⁴ The inadequacy of care and treatment for some non-communicable diseases (NCDs), such as cancer, is another more recent example of how access to treatment is often overshadowed by the push for a prevention-only approach to diseases, with care and treatment deemed too expensive for low-income countries to provide. This tendency continues despite the growing evidence of the burden of NCDs in low-income countries. In fact, the *Lancet* NCDs and Injuries Poverty

Commission⁵ showed that more than a third of the disease burden in the poorest billion is due to NCDs.

Another unethical approach to access to health services is evident from recommendations on countries' health expenditure. For instance, WHO recommends that countries increase their expenditure on primary health care by 1% to achieve greater health outcomes.⁶ Similarly, heads of African Union states came together in 2001 and pledged their commitment to the Abuja Declaration—a target of 15% of their budgets to be allocated towards the improvement of the health sector.⁷ However, these blanket, percentage-wise recommendations result in vast differences in expenditure in absolute terms when comparing low-income and high-income countries. This bypasses global solidarity and suggests that low-income countries should spend substantially less on saving the lives of vulnerable groups, thereby intentionally or unintentionally indicating that the value of one's life is linked to their country's income. Consequently, this suggests that the lives of those in low-income countries are worth less than the lives of those in high-income countries. The valuation of life solely based on where an individual lives contributes to unethical guidelines and health policies that negate an individual's human right to health.

Unethical pricing

Research and development by pharmaceutical firms is substantially supported by government subsidies,⁸ yet the price cited for most medical products is multiple times the production cost. For instance, Gardasil-4 (Merck Sharp & Dohme, Kenilworth, NJ, USA), one of the vaccines against human-papillomavirus-related cancers, is estimated to cost US\$4·50 per dose but was initially sold for \$150–190.⁹ Even when Merck Sharp & Dohme provided a reduced rate to GAVI for \$4·50, a cost estimation exercise showed that the true manufacturing cost was likely to be between \$0·48 and \$0·59, not \$4·50. Keeping in mind that subsidies given to big pharmaceutical companies comprise of taxes paid for by citizens including vulnerable groups, this exorbitant pricing of drugs and vaccines is unethical and denies vulnerable groups their right to health.

This unethical practice is further emphasised by the fact that most pharmaceutical firms are more profitable than most large companies in other industries.¹⁰ For an

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industry that is supposed to be saving lives, its deliberate decision to sell drugs at extremely high prices while letting vulnerable groups who can't afford them die is counterintuitive and highly unethical.

As we have received nearly global approval of several COVID-19 vaccines, we need to ensure that pharmaceutical companies are held accountable for their pricing and that financial and political leaders ensure accessibility for all, especially the most vulnerable groups in all countries. We have promising signs of ethical costing with Pfizer's Chief Executive Officer, Albert Bourla, indicating that the company will be using tiered pricing for middle-income countries while providing the vaccine for free in Africa.¹¹ However, Pfizer's contract with the Dominican Republic, guaranteeing the company indemnity and forcing the government to compensate for any adverse effects of the vaccine, undermines the company's efforts to ensure ethical costing. Vaccine manufacturers should work with governments and ensure little to no out-of-pocket costs for citizens.

However, when it comes to the sharing and transfer of technology, history seems to be repeating itself. The US Government is losing its opportunity to ensure equitable global distribution through the patent issued on March 30, 2021, on the government-sponsored vaccine technology used in at least five of the successful vaccines.¹² On a global scale, governments of high-income countries are blocking the World Trade Organization COVID-19 Trade-Related Aspects of Intellectual Property waiver that would temporarily suspend intellectual property rights and monopoly over COVID-19 vaccines to increase global supply and reduce prices until global herd immunity is achieved.¹³ Although this pandemic provides an opportunity for the world to redeem itself by avoiding mistakes of the past, we do not seem to be succeeding thus far.

Exploitation of vulnerable groups in clinical trials

For scientific and ethical appropriateness, we must ensure that vaccines are tested in more diverse locations and among diverse populations both nationally and globally. For instance, Oxford University, Oxford, UK, has partnered with the University of Witwatersrand in Johannesburg, South Africa, to do ethical clinical trials of this COVID-19 vaccine. However, often unethically, marginalised populations have historically been excluded from clinical trials, and when included have often been exploited extensively, for drugs they later have no access to.¹⁴ This use of vulnerable groups as so-called guinea pigs for the benefit of the rich is a prime example of how vulnerable groups are considered dispensable. Examples of such practice with impunity range from the Tuskegee Study of Untreated Syphilis in the Negro Male¹⁵ to the stolen cells of Henrietta Lacks.¹⁶ With the COVID-19 vaccine, we have seen efforts to continue such unethical practices when French doctors suggested testing the vaccine first in African populations.¹⁷ However, this time, they retracted

their statements because of the outrage of African communities and global health activists worldwide who were quick to denounce these racist remarks.

Anti-scientific, anti-vaccine discourse

Despite the currently approved vaccines being tested through rigorous clinical trials, political discourse and the propagation of anti-scientific information have derailed the vaccination campaign globally, potentially harming the lives of many. The vaccine development process has been linked to election cycles in countries such as the USA, with politicians promising that the vaccine will be ready in time for the election.¹⁸ This link not only politicises a medical product, but also reduces the trust that individuals have in the results of what appear to be rushed clinical trials.¹⁹ Moreover, anti-vaccine groups have gained increased momentum during the COVID-19 pandemic, spreading inaccurate information about the vaccine development process and its potential side-effects. In fact, anti-vaccine groups on social media have increased their followership base by 7·8 million people since 2019.²⁰ Although certain social media platforms are implementing measures, such as removing inaccurate posts by political leaders and hiring fact checkers for COVID-19 information, much remains to be done. Given the risk of illness and death associated with misinformation, anti-vaccine groups need to be held accountable for their actions and governments need to have an active role in designing and enforcing such regulations.

Vaccine hesitancy: a result of exploitation and miscommunication

The result of the exploitation of vulnerable groups is distrust and hesitancy towards potentially life-saving medical interventions. If minority groups distrust big pharmaceutical companies, researchers, policy makers, and the judiciary system, it is because they might see these cynical players, even in the most respected democracies, as unapologetic accomplices to various human rights violations and to the perpetuation of structural violence. This hesitancy is evident when considering the COVID-19 vaccine. Although the COVID-19 vaccine is being distributed in the USA and Europe, a Kaiser Family Foundation survey²¹ has shown that 35% of African Americans would probably not or definitely not get the vaccine. One of the explanations for this finding was the lack of trust in the vaccine development process, with only 11% of African Americans and 16% of Latinx very confident that the development process accounted for their needs.²² A similar survey done by the Africa Centres for Disease Control and Prevention, in partnership with the London School of Hygiene & Tropical Medicine (London, UK), in 15 African countries shows that, on average, 21% of the population is not willing to take the vaccine, with reasons ranging from distrust of the vaccine to perceptions of its importance and efficacy.²³ Vaccine hesitancy caused by

unethical exploitation of vulnerable groups increases the risk of death and unnecessary pain from a disease. Such unethical practices remind us that as we continue to test, develop, and distribute the needed vaccines, the rush for a so-called magic bullet should never undermine individuals' rights to health. We need to ensure the transparency of clinical trial results to approve a safe and effective vaccine for all.

The role of regulatory agencies

Institutions such as WHO and regulatory bodies including the US Food and Drug Administration and the European Medicines Agency should play their part in ensuring that the history of exploitation in the testing and distribution of drugs and vaccines does not repeat itself. In light of WHO's approval of the Pfizer–BioNTech vaccine and the two versions of the AstraZeneca vaccines for emergency use,²⁴ WHO should realise the paramount influence and responsibility it has as a multilateral normative agency and make careful decisions based only on scientific evidence. For example, WHO recommended oseltamivir during the 2009 H1N1 influenza pandemic—a drug that was used despite a lack of sufficient data to prove its safety and efficacy and was later downgraded.²⁵

Worldwide, various players have greatly undermined and discriminated against vulnerable groups, refusing their right to health and instead standing in their way of achieving it. This pandemic is an occasion to correct historical wrongs and set forth a path in global health that solely relies on the ethical production and distribution of life-saving care and treatment. We need to examine our moral principles when it comes to vulnerable groups, keeping pharmaceutical companies, normative agencies, and political leaders in check and continuously advocating for initiatives that first and foremost promote ethical and equitable solutions. It is only by doing so that we can remove the unethical barriers that stand between vulnerable groups and life-saving medical and public health interventions.

Contributors

AB and KM conceptualised this Viewpoint. All authors wrote the original draft, and reviewed and edited it, with AB supervising.

Declaration of interests

We declare no competing interests.

References

- Bloomberg. More than 468 million shots given: Covid-19 tracker. <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> (accessed on March 24, 2021).
- Rouw A, Wexler A, Kates J, Michaud J. Global COVID-19 vaccine access: a snapshot of inequality. <https://www.kff.org/policy-watch/global-covid-19-vaccine-access-snapshot-of-inequality/> (accessed March 24, 2021).
- Partners in Health. New guidelines and goals for treating MDR-TB announced. <https://www.pih.org/article/new-guidelines-and-goals-for-treating-mdr-tb-announced> (accessed Dec 13, 2020).
- Herbert N, George A, Baroness Masham of Ilton, et al. World TB Day 2014: finding the missing 3 million. *Lancet* 2014; **383**: 1016–18.
- Bukhman G, Mocumbi AO, Atun R, et al. The Lancet NCDI Poverty Commission: bridging a gap in universal health coverage for the poorest billion. *Lancet* 2020; **396**: 991–1044.
- Lindmeier C. Countries must invest at least 1% more of GDP on primary health care to eliminate glaring coverage gaps. <https://www.who.int/news/item/22-09-2019-countries-must-invest-at-least-1-more-of-gdp-on-primary-health-care-to-eliminate-glaring-coverage-gaps> (accessed Jan 19, 2021).
- WHO. The Abuja Declaration: ten years on. http://www.who.int/healthsystems/publications/abuja_declaration/en/ (accessed Jan 19, 2021).
- OECD. Research and development in the pharmaceutical sector. https://www.oecd-ilibrary.org/content/component/health_glance-2017-72-en (accessed Jan 19, 2021).
- Clendinen C, Zhang Y, Warburton RN, Light DW. Manufacturing costs of HPV vaccines for developing countries. *Vaccine* 2016; **34**: 5984–89.
- McCall R. Big pharma companies earn more profits than most other industries, study suggests. <https://www.newsweek.com/big-pharma-companies-profits-industries-study-1490407> (accessed Jan 19, 2021).
- Business Today. Pfizer's coronavirus vaccine price may differ depending on country's GDP. <https://www.businesstoday.in/sectors/pharma/pfizer-coronavirus-vaccine-price-may-differ-depending-on-country-gdp-pfizer-price/story/424303.html> (accessed Jan 19, 2021).
- Gebrekidan S, Apuzzo M. Rich countries signed away a chance to vaccinate the world. <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html> (accessed March 24, 2021).
- Médecins Sans Frontières. Countries obstructing COVID-19 patent waiver must allow negotiations. <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations> (accessed March 24, 2021).
- Dal-Ré R, Rid A, Emanuel E, Wendler D. The potential exploitation of research participants in high income countries who lack access to health care. *Br J Clin Pharmacol* 2016; **81**: 857–64.
- McVean A. 40 Years of human experimentation in America: the Tuskegee Study. <https://www.mcgill.ca/oss/article/history/40-years-human-experimentation-america-tuskegee-study> (accessed Jan 19, 2021).
- Nature. Henrietta Lacks: science must right a historical wrong. *Nature* 2020; **585**: 7.
- Roseman R. Racism row as French doctors suggest virus vaccine test in Africa. <https://www.aljazeera.com/news/2020/4/4/racism-row-as-french-doctors-suggest-virus-vaccine-test-in-africa> (accessed Jan 19, 2021).
- Brewster J. Trump says vaccine will be ready in as little as 'four weeks' — scientists say that's aggressive. <https://www.forbes.com/sites/jackbrewster/2020/09/15/trump-says-vaccine-will-be-ready-in-as-little-as-four-weeks---scientists-say-thats-aggressive/> (accessed March 24, 2021).
- Bokemper SE, Huber GA, Gerber AS, James EK, Omer SB. Timing of COVID-19 vaccine approval and endorsement by public figures. *Vaccine* 2021; **39**: 825–29.
- Burki T. The online anti-vaccine movement in the age of COVID-19. *Lancet Digit Health* 2020; **2**: e504–05.
- Hamel L, Kirzinger A, Muñana C, Brodie M. KFF COVID-19 vaccine monitor: December 2020. <https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/> (accessed Jan 19, 2021).
- Langmaid V, Grayer A. Most Americans will likely get a Covid-19 vaccine, Kaiser Family Foundation survey finds. <https://www.cnn.com/2020/12/15/health/survey-covid-vaccine-kaiser-monitor/index.html> (accessed Jan 19, 2021).
- Africa CDC. Majority of Africans would take a safe and effective COVID-19 vaccine. <https://africacdc.org/news-item/majority-of-africans-would-take-a-safe-and-effective-covid-19-vaccine/> (accessed Jan 19, 2021).
- WHO. WHO lists two additional COVID-19 vaccines for emergency use and COVAX roll-out. <https://www.who.int/news/item/15-02-2021-who-lists-two-additional-covid-19-vaccines-for-emergency-use-and-covax-roll-out> (accessed Feb 18, 2021).
- Ebell MH. WHO downgrades status of oseltamivir. *BMJ* 2017; **358**: j3266.

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