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Ethical challenges in health and biomedical research: lessons from the COVID-19 pandemic

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ABSTRACT

The COVID-19 pandemic has created unprecedented health and economic challenges in mankind's history. At the same time, human civilization is facing a great ethical crisis. The duty- vs. right-based moral values led to justified dilemmas in the ethical decision-making process of health care providers, especially physicians. On the one hand, the duty towards the patients affected by the highly contagious virus (often in the face of PPE shortages) and the right (as individuals) to preserve themselves and family members, on the other hand, is difficult to solve only by a legal framework. The rationing of life-saving measures (like HFNC, ICU beds, or Ventilators) in the context of acute shortages is another example of physicians and managers needing to make very difficult ethical choices. Revelation of the self-centered nature of individual human beings, families, social groups, and even countries has been widely noticed during the pandemic, and it may not be a surprising phenomenon. However, the crisis has brought to the forefront the traditional debates on the relative merits of utility-, duty- and right-based ethics from a wider social perspective. The illusory blessings of the globalized market economy and associated neoliberal ethical principles have faced critical questions throughout these years. The rise of ultranationalism has been exposed with its vulgar faces worldwide. It is now obvious that the worst sufferers of the pandemic are poorer and marginalized people (forming the major bulk of the world population) who are now increasingly subject to rapidly increasing health and socioeconomic inequality and injustice due to the existing world order. Managing the pandemic through authoritarian approaches (lockdown, tracking, etc.) has also raised certain fundamental ethical issues related to human dignity, freedom, and autonomy, and, in many cases, the pandemic has been used to justify specific ideological platforms. Ethics of biomedical and health-related research (and their dissemination) also face some basic questions regarding the sacrifice of some age-old scientific and moral practices in the face of humanity's urgent need. Critical discussion and working consensus on those ethical issues have become urgent for biomedical research's future advancement.

Introduction

The COVID-19 pandemic created unprecedented health and economic challenges in the history of humanity. The well-being of the global population has been profoundly affected by the pandemic in all dimensions, including morbidity, mortality, poverty, and education. In a post-pandemic analysis, Decerf et al. (2024) have recently estimated these losses (using a common metric) for 122 countries. The Authors have covered around 95% of the global population using country-specific WHO data. With an

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assumption of equal distribution among the worldwide population, every person would have spent about two weeks in poverty in 2020–2021 (the *CPY* estimate), lost eight days of life (*YLL*, discounted to the present), and would expect to spend an additional month in poverty (*FPY*, again discounted to the present) after 2021 due to the pandemic. In practice, however, the distribution of these losses was inequitable; people of lower- and middle-income countries suffered from a disproportionate burden.

Apart from being a technical challenge, the COVID-19 Pandemic has compelled the global human community to address some difficult ethical issues (Ezekiel et al., 2022). Distribution of scarce resources, mandatory imposition of certain restrictions, including long-term lockdowns and travel (with the consequent fear of violating human rights), skipping some well-established steps during clinical trials of vaccines or drugs, and inequitable distribution of vaccines among various countries are among the instances where the mere technical judgment was not sufficient to take the 'right' decision. Instead, well-thought value judgments (and thus ethics) became essential to address the issues. In addition to traditional ethical ideas, the unique nature of the COVID-19 pandemic compelled the global community with some newer ethical dilemmas (Smith et al., 2021).

In recent centuries, right-based ethics (from utilitarian and liberal systems of philosophy, leading to democratic political systems) has mostly replaced duty-based ethics (traditionally followed by various ideologies, leading to ideology-based states). The health systems and biomedical research are now mainly designed to revolve around that concept. As per this design, every citizen of the state, individually, has some constitutionally guaranteed basic rights. Many rights, such as medical care, nutrition, autonomy, and privacy, are directly related to health and biomedical research. The state's major institutions are designed to protect *individual rights* with authorities and obligations divided and balanced among legislative, executive, and judiciary wings. Under this system, like other citizens, healthcare providers and researchers operate under a 'rule of law' that prevails in a particular context.

In contrast to this system, duty-based ethics highlights collective rights where individuals may have to compromise some of their rights for the community's interest. While right-based ethics prioritizes individual rights and freedoms, emphasizing what individuals are entitled to, duty-based ethics centers on moral obligations and responsibilities, highlighting what individuals must do, often regardless of the consequences. Rights focus on 'what you can do' while duties focus on 'what you must do.'There has been an ongoing debate between these two ethical systems for centuries, and no empirical or logical instrument has been available to resolve the controversy (Moyn, 2016). The COVID-19 pandemic has raised awkward questions that perplex both systems. It has emphasized the need for rethinking and reconciling these two systems of ethics. The dichotomous issues, such as self-preservation versus duty towards patients and prioritization of patients in the case of critical shortages, may illustrate the problems.

Self-preservation vs. Duty Toward Patients

It is well-known that SARS-COV-2 (the causative agent of COVID-19) was a highly contagious virus with lethal consequences in a considerable proportion of affected patients. The healthcare providers or HCPs (especially those in close contact with patients, such as managing physicians, nurses, and certain groups of technologists) also became potential patients, and the risk extended to their family members. As per strict right-based ethics, self-preservation is an individual's fundamental right, and an HCP is no exception. Accordingly, self-preservation supersedes the duty-related obligation of

patient care. Even if an HCP remains morally committed to caring services (following duty-based ethics), s/he violates the self-preservation right of the jointly living family members or other associates in the living space (frequently congested in a developing country setting like Bangladesh). The problem was further complicated by the substantial shortage (by quantity or quality) of Personal Protective Equipment or PPEs, and this became a common phenomenon in countries like Bangladesh (Joarder et al., 2021; Parveen et al., 2024). Even with the arrangement of isolated residential facilities in hotels (which was financially and socially demanding), the risk of contamination among the family members or other associates could not be reduced optimally, and a situation of 'burning-out' phenomenon was observed among the HCPs, both physically and psychologically (Parveen et al., 2021). A simplistic legal framework is insufficient to solve the dilemma related to the self-preservation rights of the HCPs.

Rationing of Life-saving Measures

It is well-known that there was a shortage of life-saving equipment and other commodities [like high flow nasal cannula (HFNC), Intensive Care Unit Beds (ICU Beds), or Ventilators] in most healthcare facilities, and the shortage was acute in resource-constrained countries like Bangladesh (Sakib, 2021). In such a situation, even in the absence of any irregularity or undue pressure, difficulty arises in rationally choosing the correct recipient of the life-saving resource in the face of limited availability. We can imagine a situation where only one Ventilator is available, and it is simultaneously needed by an elderly above 80 years of age and a young adult below 40 years of age. From one argument, older people should get priority as their risk for morbidity is greater than the younger ones, and they may also be considered to belong to a disadvantaged group. On the other hand, compared to older adults, younger adults have a much better chance of survival, which is desired from the outcome point of view (a preferred option as per utility-based ethics, which has close links with liberalism). It creates a substantial dilemma for physicians and managers to set priorities in the distribution decision. No law under the presently prevailing neoliberal political system can solve this dilemma, and an ethical judgment is mandatory in such a situation.

Instances of Other Ethical Challenges during the Pandemic

Revelation of the self-centered nature of individual human beings, families, social groups, and even countries has been widely noticed during the pandemic, and it may not be a surprising phenomenon. In Bangladesh, there were several reports where children abandoned parents, wives abandoned husbands (or vice-versa). At times, even the burial of dead bodies became a problem, and a charitable organization came forward with support. Such crisis has brought to the forefront the traditional debates on the relative merits of utility-, duty- and right-based ethics in a wider social perspective. The illusory blessings of the globalized market economy and associated neoliberal ethical principles have faced critical questions throughout the year.

During the period, the rise of ultranationalism was exposed with its vulgar faces worldwide. Almost every nation became conservative to protect its resources, and the so-called spirit of a 'global village' just vanished from the solidarity and unity points of view. We may remember the example when India deferred the delivery of COVID-19 vaccines to create a stock of its own vaccines. Some countries even increased the stock of essential commodities by 2-3 times the estimated actual need. These situations contrast the need for more cooperation as COVID-19 spread quickly due to a globalized world (Heilinger et al., 2020), and interconnectedness among nationalities was much more required in such situations (The Lancet, 2007).

It is now obvious that the worst sufferers of the pandemic are poorer and marginalized people (forming the major bulk of the world population) who are increasingly subject to rapidly increasing

health and socioeconomic inequality and injustice due to the existing world order. The pandemic exposed inequality in a much more straightforward way and increased inequality and injustice.

Managing the pandemic through authoritarian approaches (lockdown, tracking, etc.) has also raised certain fundamental ethical issues related to human dignity, freedom, and autonomy. All authoritarian/ dictatorial regimes in the world tried to suppress real information and promoted disinformation in indirect and direct ways. In many cases, the pandemic was used to justify certain ideological platforms.

Revitalization of Public Health Ethics

Bioethics, in general, is discussed and emphasized more in terms of medical care and clinical research. This fact is particularly true in developing and underdeveloped countries like Bangladesh. In practice, the subdiscipline of public health ethics occupies a marginal position in the overall sphere of bioethics. The issues, as mentioned above, necessitate the revitalization of the discipline in the interest of national and global health justice (Working Group Ethics, 2020; Jamrozik and Heriot, 2020; Jamrozik, 2022). As per this ethical subsystem, a public health intervention cannot be ethically justified merely by expecting to produce a (net) improvement in public health (over and above the harms of the intervention). A public health policy is ethically justified only when two sets of key values are considered in addition to health: fairness, e.g., regarding the distribution of benefits and harms of an intervention in a population, and freedom, e.g., to move and interact with others without unjustified externally-imposed restrictions (Selgelid, 2009).

From the public health point of view, the pandemic has raised fundamental and practical issues regarding the violation of general principles of public health ethics (Jamrozik, 2022). During the pandemic, mental health and other harms increased, which, in many cases, is related to the narrow alignment of the moral value of health to the avoidance of one particular virus. The socioeconomic inequalities were exacerbated, and civil liberties were subject to sometimes undue limitations. Sometimes, without any strong justification, the interests of children were ignored in multiple ways in the name of reducing harm from a virus that poses extremely low risks to healthy children. There was a rapid rise in inequality; the public health interventions and their economic effects often disproportionately benefitted the rich sections of the population. The poor sections benefited little, were usually harmed, and were sometimes placed at higher risk of infection. There was a lack of scientific evidence that the benefits of many non-pharmacological interventions (NPIs) outweighed their harms, and there was also a failure to collect unbiased data. Transparency and legal checks on power were often limited.

Revisiting the Ethics of Biomedical and Health-System Research

Ethics of biomedical and health-related research (and their dissemination) also faced some basic questions regarding the sacrifice of some age-old scientific and moral practices in the face of the urgent need of humanity (Dawson et al, 2020; Parker et al, 2020). For example, the approval of the human trial of the mRNA-based vaccines against COVID-19 was done by skipping the preclinical trial on higher animals, which is a prerequisite in usual times. Also, scientific evidence was considered for policy and planning, even from the non-peer-reviewed publications in pre-print journals, which is not the case in normal times. Publication norms were becoming relaxed at this time. Lack of deeper understanding (apart from other irregularities) of these ethical issues among the relevant professionals in the Bangladesh Medical Research Council (BMRC) contributed to the delay (and missed opportunity) in developing the COVID-19 vaccine by the Bangladeshi company 'Globe Pharmaceuticals Ltd.'

Conclusions and Future Directions

The COVID-19 pandemic has shaken the confidence in the ethical basis of liberalism. The limitations of the solely right-based ethical systems have now been questioned, especially concerning individuals' autonomy and duty toward society and nature. The debate on the overdependence on 'utilitarian' and 'legalistic' systems (ignoring the 'moralistic' aspects

and normative values) is now live again, even in societies with functional democracies. It has emphasized the need for rethinking and reconciling these two major systems of ethics. The importance of a cultural revolution, at an equal pace with a political, technological, and economic revolution, is more realized now in this post-pandemic period. The need to strengthen the oversight of the ethical review or institutional review systems in biomedical research is now felt more than ever. These issues are vital to address, particularly in transitional societies like Bangladesh, where they are given only marginal importance. Critical discussion and working consensus on those ethical issues have become urgent for future healthcare and biomedical research advancement.

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