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**Title of manuscript-** COVID-19 vaccination in India: an ethical perspective

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**COVID-19 vaccination in India: an ethical perspective**

**Abstract**

Coronavirus diseases (COVID-19) had put world to a standstill with enormous morbidity and mortality. Vaccines’ development against this provided a beacon of hope globally. Many countries approved different vaccines under emergency use authorization, including India. But distribution of vaccines and vaccination of huge population was a challenging task for the country. There were many ethical concerns related to it including the accelerated approval of vaccines, choice of the vaccine to be approved, whom to provide it in initial phases and how to ensure transparency in this whole procedure, etc. We attempted to study the vaccination program for COVID-19 from an ethics perspective. Although the program tried addressing many of the ethical principles laid out in various international documents like utility, equity, fair procedures, beneficence, justice, non-maleficence and autonomy, but there were few gaps which still exist. These should be taken care of as the country advances further into vaccination program to garner enhanced public trust in the scientific, regulatory and administrative authorities.

**Introduction**

The coronavirus disease (COVID-19) pandemic and its control efforts have posed unique challenges for the medical field and even scientific, political, economic, and ethical spheres. For example, in India, some interventions for managing the pandemic, like the national lockdown and use of hydroxychloroquine, led to heated debates on many fora. The recent roll-out of the COVID-19 vaccination program in the country is another such topic. Considering the circumstances that led to decision making, planning, and implementation of the vaccination campaign, we must assess its compliance with ethical principles as these principles help in thinking through complicated moral issues and aid in resulting decision making. [1] Towards this end, in this paper, we review the vaccination drive using the core ethical principles of healthcare [2] and other tenets put forth in discussion papers on addressing ethical issues in pandemic influenza planning, [3] ethical considerations in developing a public health response to pandemic influenza [4] and World Health Organization (WHO) Scientific Advisory Group for Emergencies (SAGE) values framework for the allocation and prioritization of COVID-19 vaccination. [5]

1. **Principle of utility/efficiency**

The utility principle essentially means that the greatest possible balance must be produced between value and disvalue for all the affected people in all circumstances. This implies that if given a choice between equally effective but distinct interventions, patients' benefits have to be maximized, and the costs and risks involved should be minimized. [6] This principle is key while deciding the candidate vaccines for the COVID-19 vaccination in the country. Out of all the available and potential vaccine candidates, Covishield and Covaxin were chosen as they had acceptable safety and efficacy and were cheaper than other vaccine candidates. [7] Their indigenous production further reduced transportation costs, making them more cost-efficient than other available options. These vaccines were compatible with existing cold chain equipment used for routine immunization in India, obviating the need for stricter cold chain equipment.

The utility principle means the aggregate benefit of public health interventions should be maximized with available means to save the most significant number of lives. [3,4] The majority of COVID-19 mortality was amongst the elderly and those with co-existing morbidities like diabetes, hypertension, and cancers. Hence, the population over the age of 50 years was included in early phases of India's vaccination drive. [8] It would ensure a maximum number of lives can be saved, thereby again employing this crucial ethical principle. It also fulfills the objective of reducing deaths and disease burden from the COVID-19 pandemic under the principle of human well-being mentioned in the WHO SAGE values framework. [5] However, this age group is relatively less economically productive and employed than younger age groups, which are not included in the first phase. Also, the vaccines are yet to be proven effective against asymptomatic COVID-19 infection. These issues might not fulfill the objective of containing the disease transmission to reduce economic and societal disruption under the principle of human well-being. [5]

Another critical issue is of indirect health benefits. The non-health benefits of such public health interventions can be overlooked for a while, but indirect health benefits should be considered depending on the situation. It justifies giving priority access to preventive and treatment interventions in certain circumstances to groups or people involved in saving lives. [3, 4, 5] This reasoning was used in prioritizing health care and frontline workers for phase one of the vaccination program as they are involved in patient care or maintaining the country's essential infrastructure and services and are at high risk of getting and transmitting the infection. [8] It will satisfy a necessary objective of protecting the continuing functioning of essential services under the principle of human well-being. [5] It will also serve as an incentive for them as they were the ones who risked their lives most during the pandemic. It will also boost their confidence, and they will not be hesitant to care for infected people.

1. **Principle of equity**

Equity is the absence of avoidable or remediable differences among groups of people, which could be defined socially, economically, demographically, or geographically. Health inequities, therefore, involve more than inequality with respect to health determinants, access to the resources needed to improve and maintain health or health outcomes. They also entail a failure to avoid or overcome inequalities that infringe on fairness and human rights norms. [9] This principle implies giving equal weight to equal claims. It renounces discrimination, lessens unfairness and supports prioritization of groups who are at high risk of severe disease and death. [3, 4] Priorities should be set according to the criteria that are justifiable and relevant to all and not only to those who are in a position to make decisions. The prioritization for vaccination in India employed this principle by including the high-risk population in the first phase of the vaccination drive and didn't include politicians and other senior officials. Equity also decreases the chances of unfairness. If the vaccine had been given only to states and cities worst affected by the disease, that would have been unfair, leaving the rest of the cities unprotected and leading to distrust amongst them. The central government allotted the vaccines to all States/UTs in the proportion of the Health Care Workers database, ruling out the possibility of prejudice against any state. [10] Also, no discrimination was made between public and private healthcare and frontline workers, permanent or contractual employees, or rich and poor. The only criteria used for prioritization that is most at risk had only one focus- saving most lives, irrespective of other personal characteristics. Equal respect is henceforth provided and meaningful opportunity is being offered to everyone who is prioritized for first phase of vaccination.

Another important consideration while employing equitable distribution is reciprocity towards those groups who accepted risk for the common good of saving lives. [3, 4, 5] Healthcare workers and many sections of frontline workers played a significant role in tackling the pandemic. While doing so, they had put themselves at higher risk than the general population in contracting the infection. Therefore, they had a strong claim to be prioritized for the first phase under reciprocity consideration.

Among the prioritized population for first phase, there were two options for obtaining data of people aged more than 50 years - electoral roll or through self-registration. It will be uploaded on COVID Vaccine Intelligence Network (Co-WIN) application and used for the vaccination program. The beneficiaries are to be intimated about the vaccination site and time through short message service (SMS) notification. [8] However, the electoral roll data doesn’t contain the contact numbers of the voters. Illiteracy, disability, psychological factors, poverty, digital divide, etc. are some of the hindrances to the self-registration process. How these issues will be addressed is not clearly outlined yet. It might lead to a compromise in the objective of taking proactive action in ensuring equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations under the principle of national equity. One more objective outlined under the same principle is while prioritization, countries should consider the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic. The COVID-19 vaccination program in India falls short on this objective as no special provisions are defined as of now on how to reach such vulnerable populations, including tribal and slum population.

Similar to national equity, it is worth considering the principle of global equity outlined in the WHO SAGE framework. Ministry of Health and Family Welfare (MoHFW), India conducted training covering all aspects of vaccine roll-out for immunization programme managers of 13 foreign countries using Indian vaccines. [11]

Additionally, India supplied vaccines on a gratis basis to many low and middle-income countries (LMICs) like Bhutan, Myanmar, Bangladesh, Maldives, Seychelles, Mauritius, etc. in January. Commercial agreements were also made by many of the countries, including South Africa, Saudi Arabia and United Arab Emirates, with Indian manufacturers for the vaccines. [12] India’s ‘Vaccine Maitri’ Mission, thereby, accomplishes the principle of global equity, ensuring access to vaccines to people living mainly in LMICs.

1. **Principle of accountability and procedural fairness**

Pandemics are times of panic, anger, frustration, distrust, and resistance amongst the general population. The policies which are formulated to manage the pandemic should be justified and follow transparent and fair procedures. It can help in maintaining trust and garnering support from the public. The information on the preparedness plans, the justification for policies, decisions taken, and agencies involved in this process should be transparent and available in the public domain for scrutiny and understanding. [3, 4, 5] MoHFW, India utilized this principle in a righteous manner. The operational guidelines, training modules, videos, frequently asked questions, etc. were published on the official website and were accessible to all. [13]

However, only availability in the public domain is not enough, but additional measures should be taken to inform the public about the procedures involved and devised policies. For this, the Government of India took support from news agencies, media channels, eminent personalities in the health sector who gave interviews and publicized the vaccination drive. Regular and frequent press briefings were also done to address the upcoming challenges. Once vaccination was started, a daily update of the total number of beneficiaries vaccinated and the occurrence of Adverse Events Following Immunization (AEFIs) was published through Press Information Bureau, MoHFW, India. [11] It helped in decreasing the vaccine hesitancy and regaining trust in the vaccine approval procedure of the country.

The procedures used for devising the vaccination program also fulfilled the criteria of reasonableness and relevance. Experts from various fields were called and the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) was constituted on 7th August 2020 and held its first meeting on 12th August 2020, which provided consultations and justifications for program implementation. [14]

However, much of the important information related to NEGVAC was not available in the public domain. It raises concerns about procedures involved in the planning and roll-out of the vaccination and questions the NEGVAC itself. It is imperative to address this concern to comply with the principle of procedural fairness and rebuild the trust for the vaccination process among citizens of the country. [15]

Decisions once made should be amenable to change in the future based on available and updated scientific evidence and ethics or politics. In general, the public should be aware of the probability of change in such decisions in the future. Initially, when operational guidelines were formulated, there were no contraindications listed for vaccine use in pregnancy, lactation, people who are on blood thinner drugs, etc. But as the vaccines were rolled out and more data became available, the vaccine manufacturers released their fact sheets citing exclusion criteria for vaccine use in certain groups. [16, 17] Moreover, if new scientific evidence becomes available or due to the new COVID-19 strain, there is a possibility that these exclusion criteria be narrowed down or broadened further.

Covaxin approval, without completion of phase 3 trial generated a lot of controversy. Though, such approvals don’t undermine the scrutiny process by regulatory authority of India, but if the phase 2 trial results were made available in public domain prior to approval, it would have resulted in improved acceptance of Covaxin and increased trust in vaccine approval authority. In this way, transparency of this approval process could have been better appreciated, which seems to be compromised in present scenario. [18]

Additionally, contemplation is required that only formulation of fair procedures, policies, and criteria will fulfill the purpose, but also, compliance to them should be ensured. Therefore, it is required to have separate authorities to enforce and control this compliance. NEGVAC at the national level, task forces at state, district, and block-level are formed to monitor and supervise the vaccination program. Similarly, core groups are constituted at state, district and block level to ensure implementation. There is also a provision for independent external monitors and prioritization of concurrent monitoring in high risk or hard to reach and low performing areas. [8]

1. **Principle of autonomy**

Autonomy in healthcare is the right of the patient to exercise control over his or her body. The patient must be authorized to make decisions related to his/her healthcare, independently and as per his/her beliefs and judgments, irrespective of what the healthcare provider feels is in the patient's best interest. Although health care providers can advise or suggest, there should be no coercion, either overt or covert, in any form. [2] Example of this principle in the COVID-19 vaccination program in India is keeping the vaccination completely voluntary. Although there was no choice given between receipt of Covaxin or Covishield, there also was no coercion or incentive for taking the vaccine and no penalty for those denying it. To reduce vaccine hesitancy, senior health care professionals like Medical Superintendents, Deans of medical colleges took vaccine live on camera.

A consent form was also provided to the vaccine recipients of Covaxin, stating that the phase 3 trials are underway, and compensation will be provided for serious AEFI, if proven, are due to Covaxin. Factsheets of the available vaccines were also widely circulated to help beneficiaries in decision making. [16, 17] This autonomy principle helped build trust among people about the vaccine and its safety, and gradually, the vaccination campaign sped up, with India becoming the fastest country in vaccinating 40 lakh beneficiaries. [19]

1. **Principle of beneficence**

Beneficence implies good deeds, goodwill, or kindness. According to this principle, healthcare providers are obliged to do everything they can to benefit the patient in all circumstances. All prescribed and recommended treatment and interventions must intend to do the best for that patient. Therefore, healthcare providers should be highly skilled and knowledgeable and trained in current and updated best practices of medicine to help patients get the best care. [2] Before starting the most extensive vaccination program globally, against a novel virus, with newly developed vaccines and limited data about their long-term efficacy, the Government of India conducted cascade training at all healthcare administration levels from the national level to district and block level. The workforce from various sectors was trained with the help of operational guidelines, which were updated later on and the same was shared with the trainers and trainees. Dry runs were conducted before initiating the actual vaccination drive for on-field gap analysis, which can be improved when the vaccination process starts. Co-WIN, an IT platform, was used to monitor supply chain logistics, beneficiary management, AEFI reporting, etc. [20] In this way, the government ensured that beneficiaries get the best possible care according to the most recently available evidence as a skilled workforce, strengthened logistics and infrastructure are essential components for providing adequate healthcare. Prioritization of such beneficiaries, which are crucial for the sustenance of delivering care to diseased individuals and those who carry a high risk of severe disease and death, ensures the beneficence principle's implication.

1. **Principle of non-maleficence**

Non-maleficence is one of the most critical principles both in healthcare and in research. This principle means "to do no harm". It is the end goal for all the decisions made by healthcare providers and professionals. The decisions taken for the benefit of an individual patient should not harm other patients or society at large. Similarly, no individual should be harmed for the benefit of the larger section of society. [2] Providing emergency use authorization to the vaccines which are of proven safety and acceptable safety was an essential step in realizing this principle in spirit.

Additionally, the exclusion criteria decided for recipients of both the vaccines also fulfill this principle. Exclusion of pregnant and lactating women, children less than 18 years, people with a history of COVID-19 in the preceding three months, etc., protects these groups from any harm that the vaccine can cause them because the safety and efficacy of the vaccine is yet to be proven in these groups. The majority of the vaccine trials didn't include these groups, thereby limiting the data availability. In this way, both the society and certain individual groups were protected from any harm caused due to the disease and vaccine, respectively. Reiterating the importance of exercising COVID-19 appropriate behavior even after vaccination is another example as the vaccinated people might get an asymptomatic infection and infect other non-vaccinated individuals through direct or indirect route of transmission. Provision of compensation for any untoward event resulting from vaccination by Bharat Biotech for Covaxin is an ancillary step towards the principle of non-maleficence. [21]

Providing vaccine free of cost in the first phase of vaccination ensures financial safety. [22] The government of India also announced a separate budget for this vaccination program. [23] Both these actions restated the principle of not harming any individual or community, even in terms of economic matters.

1. **Principle of justice**

The principle of justice could be described as the moral obligation to act based on fair adjudication between competing claims. As such, it is linked to fairness, entitlement, and equality. In health care ethics, this can be subdivided into three categories: fair distribution of scarce resources (distributive justice), respect for people's rights (rights-based justice) and respect for morally acceptable laws (legal justice). [24]

If this principle is not implemented in healthcare, it can lead to misconduct and unfair distribution. It can generate agitation and distrust amongst the people against the government machinery and result in the program's failure. Distributive justice has already been discussed under the sub-head of the principle of fair procedures.

Rights-based justice or respect for people's rights was taken care of in this vaccination program. Keeping the vaccination voluntary without associated incentive or punitive action, getting informed written consent for Covaxin for which phase 3 results are not yet available in the public domain, and dissemination of fact sheets of both the vaccines are examples of some of the rights of patients' mentioned under Consumer Protection Act in India. It includes the right to choose, the right to safety, the right to be informed, and consumer education. [25] However, there was no choice between the available vaccines and the only available option was either to take the vaccine from a particular brand or not take it at all. It has already aggravated hesitancy amongst the beneficiaries and needs re-evaluation from a rights-based perspective.

Legal justice or respect for morally acceptable laws was practiced while giving accelerated approval to the candidate vaccines. The Drugs and Cosmetics Act and Rules of India has provisions for such accelerated approvals provided certain conditions are met. [26] The DCGI approval came only when the authority was satisfied that the vaccines fulfill the pre-requisites stated under the law. [27]

**Conclusion**

Ethical principles must be employed while preparing a response for an emergency situation like COVID-19 and allocating scarce resources like a vaccine. Although India’s vaccination program seems well-spelled out for the first phase, few gaps still exist. These should be addressed concurrently to have a more ethically robust response to the pandemic. When India moves further in vaccination drive and opens it for the general population, these ethical principles should be incorporated in future planning and implementation.

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