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# Ethical Considerations and Challenges Duringthe COVID-19 Vaccine Deployment: Experiences from an Indian Perspective

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ABSTRACT

**Introduction:** There is a continued quest towards developing protective vaccines to halt and end the global pandemic of COVID-19 with the research predominantly driven by the developed world. Induction of herd immunity requires mass vaccination, and any avoidable delays would cause enormous health and economic losses. However, developing countries will experience extensive vaccine allocation challenges due to limited indigenous manufacturing and cold chain facilities. **Methods:** Literature searches were conducted on MEDLINE (accessed by PubMed).The reference list of the selected articles was also screened to find other relevant articles with an emphasis on ethical consideration in COVID-19 vaccine deployment and distribution. **Results:** Most developing countries are likely to face shortage and consequent uncertainty over timely COVID-19 vaccine availability. Developing countries are also at risk of significant pre-existing vaccine hesitancy and also compromising justice because of the socioeconomic divide, enabling the rich to access retail vaccines before the poor. Finally, the recommended measures for implementing a mandatory vaccination policy are mostly devoid of feasibility in the global south. We identified ethical challenges and their feasibility of resolution by establishing ethically valid mechanisms for allocation and distribution of COVID-19 vaccine as a scarce resource in these resource-constrained settings. Ethical frameworks for assessing government measures towards vaccinating their respective populations are limited in their scope due to scientific uncertainty with regards to the timeliness of vaccine availability and the unpredictable frequency and severity of vaccine-related adverse effects. **Conclusion:** governments may escape moral culpability despite failing to ensure adequacy and timeliness of vaccination coverage in the absence of specific and measurable ethical benchmarks developed as part of a robust ethical framework.

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## INTRODUCTION

There are operational problems in COVID-19 vaccine deployment in developing countries. The COVID-19 pandemic has caused more than 144 million cases and more than 3.07 million deaths as of April 22, 2021 [1]. Vaccination with effective COVID-19 vaccines to achieve herd immunity in the population is the key to ending the COVID-19 pandemic globally [2]. However, some major operational challenges in the vaccine deployment process that confront policy-makers have profound ethical implications. Some of these include fair allocation and prioritization of an efficacious COVID-19 vaccine among eligible beneficiaries [3], ethics of mandatory vaccination, and coercion in situations involving vaccine hesitancy [4].

Developed countries are primarily driving COVID-19 vaccine research, have high vaccine manufacturing capacity, advanced cold chain logistics, and a smaller population to immunize [3].

However, the challenges related to vaccine allocation are multiplied in resource-constrained healthcare settings in developing countries due to vaccine scarcity, problems of affordability, low pre-existing routine immunization coverage, and limited vaccine handling and cold chain facilities [5, 6]. The ethics of fair allocation and global solidarity entrust developed countries to allocate a share of these vaccines for other countries after meeting their requirements which have led to the expansion of the World Health Organization-supported COVAX initiative [7]. However, it is becoming clear, that



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while developed countries have mostly secured access to COVID-19 vaccines, the supply and access for most developing countries is uncertain with very low levels of coverage attained so far (https://ourworldindata.org/grapher/cumulative-covid-vaccinations). Moreover, vaccine nationalism has emerged as a big threat in fostering global cooperation for achieving vaccine equity. This occurs when governments with economic heft sign agreements with pharmaceutical companies for exclusive grant of vaccines for their own populations before others resulting in a situation when some developed countries have completely vaccinated a significant proportion of their population while most developing countries are yet to receive a single dose of the vaccine. For instance, the decision by the government of the USA to ban export of raw materials for vaccine manufacturing had undermined critical supply chains necessary to augment vaccine supply for the developing world [8].

Achieving vaccine induced herd immunity against COVID-19 would require vaccination of nearly 75-90% of the population considering 80% vaccine efficacy and Ro (basic reproductive number) between 2.5 to 3.5 [9]. Nevertheless, most vaccines show very high efficacy in preventing severe disease and mortality (~95-100%) which indicate the public health impact of vaccination is much higher in reducing the disease burden. Consequently, attaining vaccine adequacy and coverage especially in the absence of independent domestic vaccine manufacturing and deployment capacity are likely to be delayed in most of the developing world. These delays would entail enormous costs in terms of (i). The lives lost both directly due to COVID-19 and indirectly from excess mortality due to neglect of major non-COVID, health conditions, and prevalent public health problems, (ii). The continuing costs of hospitalization and treatment (iii). Economic costs from school and workplace closure with absenteeism that result in reduced academic, service, and industrial outputs, apart from the decline in the tourism industry. Furthermore, the failure to protect any vulnerable population through effective vaccination would subvert the ethical principle of justice. Consequently, ethical preparedness in identifying and resolving likely ethical dilemmas encountered during deployment of this scarce COVID-19 vaccine resource, particularly in the context of the unique circumstances of developing countries is acutely warranted. Furthermore, this should be accompanied by recognizing the specific challenges in the implementation of the available solutions towards enhancing COVID-19 vaccination coverage and their ethical consequences.

India, is globally, the second most populous country, and till date has reported over 16 million cases and 1.86 million deaths [1]. Currently, three COVID-19 vaccines have been authorized for use in India; the indigenous Covaxin (BBV152) developed by Bharat Biotech, Covishield – the Oxford AstraZeneca (ChAdOx1-S) vaccine manufactured by the Serum Institute of India (SII), and most recently the Russian Sputnik –V vaccine [10,11]. A second national wave of Covid-19 probably fuelled by mutant strains and complacency has caused India to record the highest number of cases recorded in a single day and high levels of mortality. Till date, India has administered nearly 138 million doses of any Covid-19 vaccine (mohfw.gov.in).

## MATERIALS AND METHODS

### Literature Searches

MEDLINE (accessed by PubMed) was used for the search terms: “Vaccine Hesitancy AND COVID-19” (MeSH and entry terms). The reference list of the selected articles was also screened to find other relevant articles.

## RESULTS

The ethical considerations duringCOVID-19 vaccine deployment and distribution can be summarized as follows:

### Ethical Challenges in Prioritization and Fair Allocation

Assuming the availability of a vaccine with high protective efficacy, initially, there would be limited vaccine supplies and resources for vaccinating the population, necessitating the need for prioritization with possible rationing. A fair allocation approach towards vaccine prioritization would require upholding utilitarian principles signifying ‘greater good for the greater number’ by maximizing medical outcomes and incorporating egalitarian considerations, including equity and social justice [12, 13].

### Prioritization by Occupational Risk Profile

This is a well-established ethical criterion during public health emergencies, especially among frontline health workers, since it enables a multiplier effect to protect the lives of patients under their care, while also meeting the principle of reciprocity [14]. However, in developing countries, high levels of pre-existing occupational hazards exist among sanitation workers, auxiliary health staff, and informal workers, who are involved in fulfilling essential community needs. This renders them eligible for vaccine prioritization due to their high social instrumental value, reciprocity, and for upholding social justice considering their socioeconomic disadvantages.

### Prioritization among Demographic Groups

Those with the highest medical risk of disease complications and death such as elderly, comorbid, and immunocompromised (especially, diabetes patients) populations should be prioritized for vaccination to increase the medical utility of the intervention and adhere to the principle of utilitarianism [12]. Furthermore, within these subgroups, the excess risk in those with both adverse medical and social determinants of health need recognition as a criterion for equitable vaccine prioritization. For instance, a diabetes patient living in urban slums with limited healthcare access, living in an overcrowding environment, and compelled to work outside his residence for meeting his or her livelihood needs is far more vulnerable compared to an affluent diabetes patient, working from home, and having avenues for practicing social distancing.

The Indian vaccination drive commenced from 16th January, 2021 and was initially restricted to healthcare and essential frontline workers including sanitation workers, with subsequent opening up for elderly (>60 years) and the comorbid (>45 years), all >45 years, and finally all adults (≥18 years) scheduled from 1st May 2021 [15].

### Prioritization among Available Vaccine Candidates and their Equitable Distribution

Several COVID-19 vaccine candidates are likely to be available in the future with varying protection and safety profiles. International agencies and national governments in developing countries have to confront issues related to early availability, the feasibility of meeting cold storage requirements, and ultimately affordability. The ethical propriety of government decisions in selecting vaccine candidates can also be validated only when based on objective scientific



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evidence and expert consensus. Distribution of COVID-19 vaccines and determining their mode of access in developing countries would involve major ethical implications. If multiple vaccines are available through private retail purchase, socioeconomically advantaged individuals will likely have a significantly easier path to purchase vaccines. However, during a pandemic, to achieve equity and justice, governments must ensure an effective vaccine must be available for free through the public sector universally, or at least to those who are unable to afford the same, before or simultaneously with retail vaccine availability.

In India, the Covishield – the Oxford AstraZeneca (ChAdOx1-S), was the first vaccine to be provided regulatory approved. Covaxin (BBV152), the indigenous COVID-19 vaccine was initially provided approval for restricted use in clinical trial mode even as Phase-III results were ongoing and final efficacy results pending. It reflected an improvisation suggestive of prudent pragmatism which enables the beneficiary to receive a guaranteed vaccine dose while also being protected through the clause on compensation, akin to a clinical trial. In contrast, a phase-3 trial participant has only half the probability of receiving the actual vaccine dose as against placebo [16]. Furthermore, since vaccination for COVID-19 is completely voluntary, the principle of autonomy was not compromised. Since then, interim phase-3 data showed high nearly 78-81% efficacy of Covaxin (BBV152) with an excellent safety profile [17].

**Resolving Issues with Vaccine Uptake**

Vaccine hesitancy is the delay in the acceptance or refusal of vaccination despite the availability of vaccination services, usually due to religious reasons, belief in pseudoscience, and the lack of trust in health systems [18]. Furthermore, concerns regarding the safety and efficacy of COVID-19 vaccines due to their unprecedented accelerated development and suspicion of cutting corners can manifest reluctance even in individuals who otherwise have no history of vaccine hesitancy. Surveys globally are showing that the intention to vaccinate against COVID-19 is suboptimal among both healthcare providers and the general population [19, 20]. In India, slow vaccine uptake and high vaccine wastage in the initial couple of months post vaccine deployment was primarily driven by irrational safety concerns fuelled by pseudoscientific theories, vested interests, and reduced perceived susceptibility from Covid-19 due to reduction in case load [21, 22].

Transparent risk communication by the government would be the cornerstone of combating potential vaccine hesitancy to COVID-19 vaccines by demonstrating trust and instilling vaccine confidence in the people. However, any delays in vaccine uptake would delay the attainment of herd immunity in the population [5]. Public health interventions focussing on overcoming COVID-19 vaccine hesitancy and restoring vaccine confidence therefore warrant high prioritization.

## DISCUSSION

Enforcing mandatory vaccination for achieving herd immunity in the population can be ethically justified considering the principles as recognized in the Faden-Shebaya framework, which include [23, 24]: (i) Collective action and societal benefit: from a public health perspective, vaccination in a critical population mass to break the chain of transmission and prevent future disease outbreaks is well-established. However, in the case of COVID-19, estimating the herd immunity threshold required through vaccination is problematic particularly on account of suspected immune escape in mutant strains [25]. Nevertheless, in absence of a mandatory policy for vaccination, diminished perceived susceptibility to disease in countries where COVID-19 infection burden is declining can cause the problem of free-riders from individuals who may consider delaying or avoiding vaccination. (ii). Proportionality in the distribution of burdens: elderly people with the highest risk of disease severity should be vaccinated first if vaccine candidates with proven efficacy and safety are available. However, vaccinating children, adolescents, and young adults who have a negligible risk of serious COVID-19 illness, can also benefit the elderly population at the highest risk of disease severity, by preventing disease transmission. (iii). Mill's No harm principle affirms that measures overriding individual autonomy (along with privacy, and liberty) are warranted only if they are necessary for preventing harm to others. Based on the same principle, compulsory vaccination can be possibly mandated among groups who are at risk of transmission of infection to vulnerable populations.

Nonetheless, the implementation of mandatory vaccine policies apart from the concern over the undermining of public trust is challenged by the lack of feasibility. Previously used measures such as fines, prohibiting non-vaccinated children from attending school, withholding child benefits, and restricting movement are impractical in poor developing countries as a majority of the vaccine-hesitant population are of low socioeconomic status, including a large out of school child and adolescent population, or experiencing threatened livelihoods. Furthermore, incentives for vaccination, including payments that have been advocated due to risk-uncertainty (Savulescu: 2020) [4] are a non-starter in most developing countries struggling in meeting the costs for procuring the vaccine. In conclusion, Rapid COVID-19 vaccination coverage in developing countries encounters several challenges primarily arising from vaccine scarcity, inadequate vaccination capacity, and prevalent inequity with poor social determinants of health. Furthermore, high occupational risk in several population subgroups, economic disparities in vaccine affordability, and living in intergeneration families create a large pool of vulnerable populations eligible for high prioritization for vaccine allocation. Ethical frameworks for assessing government measures towards vaccinating their respective populations involve multiple ethical principles but are also limited in their scope due to scientific uncertainty with regards to the timeliness of vaccine availability and the unpredictable frequency and severity of vaccine-related adverse effects (Table 1).

Consequently, similar to public health responses towards the management of other aspects of the COVID-19 pandemic, governments are likely to escape moral culpability despite failing to ensure adequacy and timeliness of vaccination coverage due to the lack of specific and measurable ethical benchmarks [29]. Evolving a robust ethical framework for assessing government and administrative response towards COVID-19 vaccination applicable in the developing world therefore represents an urgent ethical imperative.



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**Table 1.** Ethical considerations for COVID-19 vaccination in developing countries.

| Ethical issue | Reasoning | Ethical principles involved | Challenges in assessment and implementation |
|---|---|---|---|
| Preparedness towards procuring and/or manufacturing adequate vaccine stock for vaccinating the majority of the population or achieving herd immunity. | Governments need to take all feasible measures towards adequate vaccine procurement such as country participation in clinical trials towards vaccine development [19], upscaling domestic manufacturing, and collaboration with international organizations. | Duty to care, Stewardship Accountability, Transparency | Identifying indicators for assessing rapidity and adequacy of response from public domain data. Low vaccine stocks, cost-effectiveness, stringency of cold chain requirements [27], uncertainty over ongoing phase 3 trial results of vaccines suited for developing world Differentiating non-response because of lack of accessibility and that that due to vaccine hesitancy among vulnerable groups. |
| Preparedness towards implementing large-scale vaccination | Augmenting cold chain capacity across the country especially in underserved and hard to reach areas, training of staff to be involved in vaccination, registration of eligible beneficiaries in a transparent and time-bound manner. | Stewardship Effectiveness, Responsiveness Transparency | |
| Prioritization of population groups for vaccination<br><br>Incorporating social determinants of health as an additional criterion for vaccine prioritization. Social justice considerations towards vaccine prioritization | Evidence-based policy for identification of groups which would be prioritized for vaccination – frontline health workers, elderly, comorbid, etc. | Reciprocity, Inclusivity, Justice Trust | Lack of public health resources towards improving accessibility of vaccines in socially vulnerable and marginalized groups Lack of expert consensus and guidelines Socially vulnerable groups like ethnic minorities may have significant pre-existing vaccine hesitancy |
| Measures to dispel vaccine hesitancy | Low intention for vaccination due to misconceptions and myths related to COVID-19 vaccines is a serious public health threat. Health departments need to engage in effective communication and combat misinformation or fake news that jeopardize vaccination efforts with legal action if necessary. | Responsiveness, Stewardship Trust | Incidents such as unexpected side effects which increase vaccine hesitancy Governments may not be in a position to completely regulate false information circulated on social media networks and instant messaging platforms due to an infodemic situation [28]. Ethics and consequences of perusal of a mandatory vaccination policy |

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## CONFLICT OF INTEREST

The authors declare they have no conflict of interests.

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