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Critique

Economics & ethics of the COVID-19 vaccine: How prepared are we?

The crisis due to the COVID-19 pandemic in India and elsewhere has required putting enormous amounts of resources in prevention, control and treatment, on the one hand, and social welfare and livelihood programmes on the other. The health sector was largely unprepared to tackle the pandemic, and policies had to be made in real time to deal with the evolving situation. Despite the scale of response, India has seen a rapid rise in cases; as on September; it had more than 800,000 active cases, and was in the third position in terms of total cases and first in terms of total new cases, globally[1,2]. Waiting for herd immunity to occur naturally will be time-consuming and costly in terms of not only increased morbidity and mortality but also from the impact on livelihoods due to the continued containment measures that would be required to prevent a faster spread of the virus[3]. Clearly, a vaccine is going to help in building immunity quickly and reduce significantly the socio-economic costs of the pandemic. This gives a sound economic rationale for fast-tracking COVID-19 vaccine trials, and the unprecedented scale of the global pandemic unparalleled in human history, has brought forward a global mandate for hastening the process of vaccine discovery.

With this understanding, the race for developing vaccines has begun, with national governments, pharmaceutical companies and scientific communities getting into partnerships across the globe[4]. However, both the science and the public policies around vaccines are fraught with uncertainties and ethical concerns. The COVID-19 pandemic itself has been marked by uncertainties across multiple domains - nature of the virus, alternative treatment options, clinical outcomes and prevention methods. The world is still grappling with these uncertainties, which are yet to be acknowledged fully and adequately by the scientific and policy establishments across the globe. On the top of these existing uncertainties, the vaccine concerns have added another layer of difficulties in global and domestic policies around COVID-19.

Despite this, the urgency of developing a suitable vaccine is an unchallengeable position for the global community, and many countries including India have currently initiated vaccine trials on a war footing. The urgency to fast-track the COVID-19 vaccine trials has raised concerns in the scientific community[5,6]. What does fast-tracking of trials actually mean? What are the various steps and components of this particular approach? The devil, as usual, is in the details.

For India, there is an urgent need to draw up a plan with details that can broadly be categorized under four domains: (*i*) production and financing, (*ii*) safety and efficacy of each candidate vaccine, (*iii*) distributional aspects including availability and equity, and (*iv*) accountability. We briefly discuss each of these points below.

While a number of steps have been taken to tackle the pandemic in India, one area that has remained unclear is that of public financing. Testing and treatment have been steadily ramped up, but it is not clear how funds have been raised and resources allocated across different needs. From a public finance perspective, resource allocation decisions are critical, especially in the face of low overall public health spending, because of potentially high opportunity costs of resource use. This pertains to both Centre and the States, and to date it remains unclear what the price tag of dealing with COVID-19 has been so far.

This opacity in public financing and policy should be avoided at all costs in the case of vaccines. On the positive side, there is already a global mandate for the development of one or more vaccines for COVID-19, and India is at the centre of the vaccine wave, leading one to presume that the government of India has a plan already drawn up on funding, production and

distribution of the potential vaccine(s). Some key areas that would need addressing much ahead of the actual trial results are the following:

Which vaccines are already under production? Which companies are producing these vaccines and in what quantities? Who is going to bear the loss in case the trials fail? What will be the loss to the government if the trials do not succeed? How much has the government invested so far in vaccine trials and production? How does the government plan to procure other incidentals that would be required for a COVID-19 vaccination programme? Vaccine development is a complicated and lengthy process with complex intertwining of the scientific and ethical dimensions. Generally, the six stages of the development cycle are exploratory, pre-clinical, clinical development, regulatory review, approval and manufacturing[7]. There are scientific and ethical issues in all these stages that require expert oversight, and need to be open to public scrutiny and accountability.

The ethical issues differ in each category; for example, ethical guidelines for clinical research is a critical area that has been much discussed and debated with focus on areas such as informed consent[8]. Transparency in the way the trials are being conducted and the ability to adhere to the various guidelines on clinical trials due to the fast tracking are important areas of scrutiny from a public accountability point of view. Similarly, the licencing process is fraught with ethical concerns because it involves adherence to safety standards and also efficacy of the vaccine. Given that globally several large pharmaceutical companies have partnered with governments and researchers, this raises concerns about the ethics in production, pricing and distribution.

Scientists and social scientists have raised concerns that elimination of proper and hitherto ratified steps in vaccine development could have repercussions on a variety of health and non-health parameters[9]. The government needs to reassure citizens that fast tracking has not been at the cost of scientific and ethical values.

The distributional aspects - once the vaccines are approved and ready to be used - are challenging. The pandemic has already exposed the fault lines in terms of accessibility and availability of health services across and within countries. Countries like India operate in resource-constrained settings with imperfect health systems and glaring inequities based on social determinants such as wealth, class, race, gender and religion. In these circumstances, the questions around who gets the vaccine, how and at what cost cannot be addressed in real time, but would require months of advanced planning and structures that would have to be put in place before the vaccines become available. With serious inequities in access to health services, will the vaccine distribution be based on different sets of parameters of ethics and justice?

The distributional issues take on daunting proportions when one considers vaccine allocations across the countries. Despite being a global public good, it is clear that the allocation across countries would not be an easy process because supply is likely to remain much below the demand, especially in the initial stages. Will the distribution follow the principle of fairness based on collectively approved criteria? While the WHO lays down rules about such principles that need to be followed[10], these are not binding on countries. In addition, the uncertainty around global public health policy has increased due to the withdrawal of the USA from the WHO[11,12]. Structures for supranational governance are yet to emerge and will be critical for equity and transparency.

The dangers of 'vaccine nationalism'[13], where deals are being struck between powerful countries and manufacturers to garner the initial and major shares possibly, of doses being produced, have been heard. In such a scenario, how will India safeguard its own interests? How much does it plan to procure and what will be the remaining estimated gaps in demand and supply? While the Coalition for Epidemic Preparedness Innovations (CEPI), Global Alliance for Vaccines and Immunizations (GAVI) and the WHO have launched COVAX to ensure equitable access to COVID-19 vaccines[4,14], what role will India play in this and other coalitions that are attempting to protect the interests of poor and middle-income countries? What role will the private sector play in vaccine supply, and to what extent will the government be willing and able to regulate the price and quantity of vaccines that would be available with the private sector?

There is evidence from media that the government has been focusing on many of these issues in any case[15,16]. However, like never before, the COVID-19 vaccine distributional issues may get intertwined with global politics and governance, making strategizing an important tool at the vaccine allocation stage. Options and moves need to be thought out it in advance to avoid troubleshooting in real time, which can result in

imperfect decision-making to the detriment of public welfare.

Thus, it might be useful for India to bring out a White Paper on COVID-19 vaccine and share it with citizens. All policies around the vaccine must be guided by the principles of accountability and transparency. In a world where science and politics are intertwined, it is the responsibility of the larger public health community and the main stakeholders *i.e.* the users of the vaccine, to raise difficult questions, demand transparency from the government and ensure that all data and information, including results of trials, quality of vaccines, efficacy and safety, the licencing process, demand estimation, rationing criteria, pricing and role of the private sector, are made available in the public domain. A separate website on the COVID-19 vaccine may be created where the White Paper (which should be a dynamic document) would be uploaded and supplemented with updates from time to time. There should be scope to invite and potentially include opinions and suggestions from the public as well. Transparency and full information will actually enhance the effectiveness of policymaking on the COVID-19 vaccine.

We hope that the government will hear these concerns presented here on behalf of many, and take adequate steps to make the process of COVID-19 vaccine adoption easier and acceptable to the main stakeholders of the country - its citizens.

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