



Review Article

Will COVID vaccine be a game changer in current pandemic situation?

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ABSTRACT

Most daunting threat for humankind is the corona virus disease 2019 (COVID-19) pandemic caused by SARS-CoV-2. Various vaccine production platforms are available, each with distinct advantages and obstacles. Pharmaceutical formulation science plays a critical role in the race for a safe, effective coronavirus disease vaccine (COVID)-19. The target population of vaccinees includes high-risk individuals over the age of 60, those with chronic co-morbid conditions, frontline healthcare workers, and those involved in critical industries. Once a safe and reliable vaccine policy becomes available, pre-pandemic normalcy will never return. As COVID-19 continues to wreak havoc on people's health and livelihoods around the world, the prospect of an effective vaccine may appear to be a silver bullet. Despite this, a number of challenges remain, each of which necessitates careful and ongoing debate to ensure that vaccination strategies are safe, appropriate, and realistic. So the best way forward is simply to register oneself on Aarogya Setu and get vaccinated as soon as possible, regardless of Covishield or Covaxin.

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1. Introduction

The most daunting threat for humankind is the coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).¹ As of 7:19 p.m. CEST on April 21, 2021, there had been 142,557,268 confirmed cases of COVID-19 reported to WHO, including 3,037,398 deaths. A total of 889,827,023 vaccine doses had been administered as of April 20, 2021.² It is generally accepted that once a safe and reliable vaccine policy becomes available, and a global vaccination program is successfully introduced, pre-pandemic normalcy will never return.³ The COVID-19 pandemic, which is potentially the most destructive one in the last 100 years after the Spanish flu, involves the rapid assessment of the multiple approaches to the ability to evoke protective

immunity and protection to minimize unnecessary immune potentiation, which plays a vital role in the pathogenesis of this virus. An effective COVID-19 vaccine will require careful confirmation of efficacy and adverse reactivity, as the target population of vaccinees includes high-risk individuals over the age of 60, particularly those with chronic co-morbid conditions, frontline healthcare workers, and those involved in critical industries.⁴ Various vaccine production platforms are available, namely: virus vector vaccines, protein subunit vaccines, genetic vaccines, and passive immunization monoclonal antibodies under evaluation for SARS-CoV-2, each with distinct advantages and obstacles.³ Bacillus Calmette-Guérin (BCG) vaccines, DNA and RNA dependent vaccines, inactivated vaccines, protein subunits, and viral vectors are the various vaccine platforms being studied.^{3,4} Pharmaceutical formulation science plays a critical role in the race for a safe and effective coronavirus disease vaccine (COVID)-19 in the

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production, manufacturing, distribution, and vaccination processes. Proper selection of the type of vaccine, carrier or vector, adjuvant, excipient, dosage form, and route of administration directly affects the induced immune responses and the subsequent efficacy against COVID-19 and the production, storage, and distribution logistics and mass vaccination of the vaccine. Companies have progressed beyond their initial safety and immunogenicity studies into clinical trials with Moderna, CanSino, the University of Oxford, BioNTech, Sinovac, Sinopharm, Anhui Zhifei Longcom, Inovio, Novavax, Vaxine, Zydus Cadila, the Institute of Medical Biology, and the Gamaleya Research Institute.⁵

A vaccine that is both safe and effective against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) will be paramount. WHO global target product profile of critical characteristics for prequalification of a COVID-19 vaccine. Candidates must be targeted at the most vulnerable populations, including older adults. Individuals at high risk of SARS-CoV-2 exposure must be protected for at least six months with the vaccine.⁶ The structural and immunological dimensions of SARS-CoV-2, which are similar to SARS-CoV, have been demonstrated in a study by Wang et al.⁷ SARSCoV immunodominant epitopes, such as Spikeprotein S, for example, have been strongly preserved in SARS-CoV 2 and have the potential to elicit a T-cell response. Clinical studies using many different vaccine platforms have demonstrated neutralising antibody responses after immunisation, including mRNA, adenoviral vectored vaccines, inactivated viruses, and adjuvanted spike glycoprotein.

1.1. Phases of testing a vaccine

The various phases of vaccine testing Include-Preclinical Testing, in which Scientists test another immunization on cells and afterward offer it to creatures, for example, mice or monkeys, to check whether it delivers an immune response.

1. Stage 1 is called Safety Trials- Scientists give the vaccine to few individuals to test well-being to affirm that it invigorates the safe framework and stimulates an immune response.
2. Stage 2 is Expanded Trials. Scientists give the vaccine to several individuals split into gatherings, for example, youngsters and the older, to check whether the immunization demonstrations diversely in them. These preliminaries further test the safety of vaccines and the generation of an immune response.⁸
3. Stage 3 is Efficacy Trials: Scientists give the vaccines to many individuals and hold on to perceive the number of becoming contaminated, compared to volunteers who receive a placebo. These preliminaries can decide whether the immunization ensures against the COVID infection. Likewise, Phase 3 preliminaries are

sufficiently enormous to uncover side effects that may be missed in earlier studies.

Early or Limited Approval: China and Russia have approved vaccines without waiting for the results of phase 3 trials. Experts say it is likely to be associated with severe risks.

Endorsement: Regulators in every nation audit the preliminary outcomes and conclude if to affirm the vaccine. During a pandemic, a vaccine may get crisis use approval before getting the formal endorsement. When an immunization is authorized, scientists keep on checking individuals who bring it to ensure it's effective and safe.

Consolidated PHASES: One approach to quicken antibody improvement is to join stages.

1.2. Vaccine efficacy

Its efficacy characterizes the adequacy of a new vaccine. Effectiveness of less than 60% may lead to failure to create herd immunity. Host-("vaccinee")- related determinants that render an individual susceptible to infection, for example, hereditary factors, well-being status (chronic illness, nourishment, pregnancy, sensitivities or hypersensitivities), immunocompromised, age, and economic effect or social climate can be essential or auxiliary components influencing the seriousness of disease and response to a vaccine. Elderly (above age 60), allergen-hyperreactivity, and obese individuals have a susceptibility to compromised immunogenicity, which may prevent vaccine efficacy. Further, mutation of the virus may alter its structure, making the immunization ineffective.⁹

1.3. For what reason do we need an immunization?

Mass vaccination induction of herd immunity has proven to be an effective method for preventing the spread of many infectious diseases, protecting the most vulnerable population groups that are unable to develop immunity, such as people with immunodeficiency or a compromised immune system due to underlying medical or weakening circumstances.¹⁰ Therefore, one of the most promising counter-pandemic steps to COVID 19 is vaccination.

Pfizer/BioNTech vaccine -The enormous advancement came when Pfizer/BioNTech distributed its first outcomes in November. Immunization is up to 95% powerful and is given in two dosages, three weeks separated. About 43,000 individuals have had the vaccine, with no security concerns. However, a vaccine must be put away at a temperature of around - 70C. It should be shipped in an uncommon box, stuffed in dry ice, and introduced with GPS trackers. On 2 December, the UK turned into the primary nation on the planet to affirm the Pfizer/BioNTech Covid immunization for certain use.¹¹

Oxford University/AstraZeneca immunization - Preliminaries of the Oxford antibody suggested it stops 70% of individuals from creating COVID manifestations.

The information additionally shows a reliable, safe reaction in more seasoned individuals. There is also fascinating information that proposes consummating the portion could build assurance up to 90%. The UK has requested 100 million dosages, and it is given in two dosages. Trials with more than 20,000 volunteers are as yet proceeding. This might be probably the most straightforward immunization to disseminate, because it shouldn't be put away at freezing temperatures.¹¹

Moderna vaccine - Moderna utilizes a similar methodology as the Pfizer vaccine. It secures 94.5% of individuals; the organization says the UK will have 5,000,000 dosages by the spring. It is given in two dosages, a month separated, 30,000 have been engaged with the preliminaries, with half getting the antibody and half fake infusions. It is simpler to store than Pfizer's, because it remains stable at - 20C for as long as a half year.

COVAXIN™, India's indigenous COVID-19 immunization by Bharat Biotech is created in a joint effort with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). Inactivated immunization is designed and fabricated in Bharat Biotech's BSL-3 (Bio-Safety Level 3) high containment facility. The vaccine got DCGI endorsement for Phase I and II Human Clinical Trials and the preliminaries initiated across India from July 2020. After fruitful consummation of the interval investigation from the Phase 1 and 2 clinical preliminaries of COVAXIN™, Bharat Biotech got DCGI endorsement for Phase 3 clinical preliminaries in 26,000 members in more than 25 focuses across India.¹²

1.4. Covishield vs covaxin

The viral vector platform serves as the foundation for the Covishield. Simply put, it is a weakened version of a common cold virus called adenovirus derived from chimps that has been modified to look more like coronavirus. Covaxin, on the other hand, is an inactivated vaccine. It contains a dead virus that causes an immune response but does not infect or make the person sick. Both vaccines require two doses administered 28 days apart and can be stored in a standard refrigerator at 2-8 degrees Celsius. The Government of India extended the time between the first and second doses of Covishield from 4 to 8 weeks in the last week of March. The Covishield's Phase-III trials show that it is up to 90% efficient, according to peer-reviewed findings. The vaccine was only 62 percent effective when participants received two full doses, but it increased to 90 percent when a half dose followed by a full dose was administered. The vaccine will almost certainly be effective against the new strain as well. Covaxin demonstrated 80.6 percent efficacy in Phase 3 trials, according to Bharat Biotech and Ocugen. The vaccine can induce antibodies that are capable of neutralising the UK strain as well as other heterologous strains. Covishield is effective against the UK

strain and is currently being tested against the Brazilian variant. Covaxin effectively protects against both the UK and Brazilian variants. The eligible age group is one area where Covaxin clearly has an advantage. Covaxin can be given to anyone over the age of 12, whereas Covishield is only safe for people over the age of 18. Covishield does have a few side effects, including pain, redness, itching, swelling, or bruising, feeling ill, fatigue, chills, fever, headache, nausea, joint pain, and muscle ache, and they're mostly mild to moderate in nature and it can be handled with over-the-counter medications. It has also been linked to allergic reactions such as itchy skin rash, shortness of breath, and swelling of the face or tongue, so if you have a history of allergies, talk to your doctor first. Along the same lines, Covaxin has caused side effects such as injection site pain, swelling, redness, itching, stiffness in the upper arm, weakness in the injection arm, body ache, headache, fever, malaise, weakness, rashes, nausea, and vomiting. Covaxin, on the other hand, is less likely to cause an allergic reaction. If one is pregnant, breastfeeding, immune-compromised, or dealing with any serious health issue, it is better to notify your vaccine provider beforehand. Serum Institute will supply India with 110 lakh doses for INR 200 each. The government will also purchase 55 lakh doses from Bharat Biotech at a cost of about INR 206 per dose. However, as of now, both vaccines are provided free of charge to citizens in government hospitals. A single dose of either vaccine costs INR 250 in private hospitals. While both Covishield and Covaxin have advantages and disadvantages, neither is superior to the other. Both are equally safe to use and have been recommended by the Drugs Controller General of India only after careful consideration (DCGI). In light of the current situation, being immunised against the coronavirus is the most important thing, regardless of which vaccine was used. Furthermore, the Indian government has not given its citizens the option of choosing which vaccine jab they want to receive.

1.5. Cost

A compelling immunization for COVID 19 could spare trillions of dollars in worldwide monetary effect, as indicated by one master. It would, hence, make any sticker price in the billions look little in comparison. It isn't known whether it is conceivable to create a protected, dependable, and reasonable antibody for this infection, and it isn't known precisely how much the immunization advancement will cost. The European Commission coordinated and held a video meeting of world pioneers on 4 May 2020, at which US\$8 billion was raised for COVID 19 immunization development. After a vaccine is made, billions of portions should be fabricated and disseminated around the world. In April 2020, the Gates Foundation assessed that assembling and conveyance could cost as much as US\$25 billion.¹³

1.6. Vaccination obstacles

Individual decision-making for COVID-19 is complex and multifaceted, and should be considered when planning any vaccination programme. Specifically, the proclivity to vaccinate against SARS-CoV-2 is dependent on the availability of an effective vaccine, i.e. the virus's actual existence and country of origin; access to a vaccine, which may be hampered by individual or government budgetary constraints to finance public health preventive measures; and the perceived risk to health, which varies depending on the strength and intensity of the virus.¹⁴

1.7. Investigating options for operational priority

Health care staff is a specific first-tier category that protects health care services by defending those who manage them. Another priority is to directly protect those who, if infected, are most at risk of death or hospitalisation, particularly those over 65 and those with certain comorbid conditions. Even if the vaccine is far less effective in these populations, this approach could be ideal for lowering mortality. However, if a vaccine in high-risk groups provides little to no protection while reducing infection or infectiousness in younger people, an indirect approach may be preferred as vaccine supplies become sufficiently widespread. A successful vaccine that eliminates illness in younger adults but leaves the most vulnerable at risk by providing neither direct nor indirect protection to high-risk groups is a worst-case scenario. It is necessary to understand these vaccine characteristics when evaluating the relative merits of other items. Fortunately, several vaccine candidates are being developed using a combination of new and existing technologies. Although vaccine characteristics vary, providing clear proof of direct and indirect safety may aid in planning how these vaccines can be used in an organised manner. The CDC is working with its Immunization Practices Advisory Committee to develop guidelines for prioritising vaccination delivery, recognising that there may not be enough vaccinations for everyone at first. Priority is given to vulnerable groups, such as those in high-risk occupations such as healthcare professionals and security, emergency, and response personnel, including first responders, or those at medical risk, such as long-term care facility residents, people with chronic illnesses, and adults 65 and older. Priority can also be given to minority groups who have been disproportionately affected by the virus.¹⁵

1.8. Trials in humans

Other solutions are being considered by researchers at the National Institutes of Health in the United States, the World Health Organization, and elsewhere. It is possible to use challenge trials, in which volunteers are vaccinated and then infected with a live virus. Meanwhile, umbrella trials

could be used in conjunction with a single trial protocol. By standardising decisions such as recruitment standards and endpoints, these experiments make it easier to compare and contrast any results.¹⁶ Formalized paraphrase Pragmatic benefits, such as the ability to use a single placebo arm to reduce the overall size and cost of these trials, may also be possible. According to Maheshi et al., ChAdOx1 nCoV-19 is better tolerated in older adults than in younger adults and has comparable immunogenicity following a boosted dose across all age groups.

2. Conclusion

As COVID-19 continues to wreak havoc on people's health and livelihoods around the world, the prospect of an effective vaccine may appear to be a silver bullet. Despite this, a number of challenges remain, each of which necessitates careful and ongoing debate to ensure that vaccination strategies are safe, appropriate, and realistic. So the best way forward is simply to register yourself on Aarogya Setu and get vaccinated as soon as possible, regardless of Covishield or Covaxin.

3. Source of Funding

None.

4. Conflict of Interest

None.

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