

EDITORIAL

Vaccination during a pandemic - a public health challenge

Faruqueuddin Ahmed

Former Professor & Head of Department Community Medicine Assam Medical College, Pro-Vice Chancellor, Khaja Bandanawaz University, Kalaburagi, Karnataka-585104

Corresponding Author

Dr. Faruqueuddin Ahmed, Former Professor & HOD Community Medicine Assam Medical College, Pro-Vice Chancellor, Khaja Bandanawaz University, Kalaburagi, Karnataka-585104.
E Mail ID: karufalim@gmail.com



Citation

Ahmed FU. Vaccination during a pandemic - a public health challenge. Indian J Comm Health. 2020;32(4):617-619. <https://doi.org/10.47203/IJCH.2020.v32i04.001>

Source of Funding: Nil **Conflict of Interest:** None declared

Article Cycle

Received: 31/10/2020; **Revision:** 16/11/2020; **Accepted:** 05/12/2020; **Published:** 30/12/2020

This work is licensed under a [Creative Commons Attribution 4.0 International License](https://creativecommons.org/licenses/by/4.0/).

Introduction

Since the emergence of COVID 19 virus, scientists all over the world are working at breakneck speed to develop a vaccine. Development of a vaccine is not a competitive race to the finish as it must pass through a stringent process of evaluation. The process includes vaccines' immunogenicity, duration of immunity, efficacy of protection, interaction with other antigens, dosage, route of administration, packaging, and thermostability and expected adverse events and safety. Efficacy of a new vaccine is measured in clinical trials under ideal conditions, whereas its effectiveness is measured in the field under actual program conditions. (1) In normal circumstances, vaccine development is a prolonged process, averaging over 10 years from start to finish (2). To meet the urgent, need a COVID 19 vaccine may be available in a much shorter-term frame, at the earliest in 18 months. (1,3,4) This will be possible as a result of the unprecedented coordinated and combined global effort of the scientific and National Regulatory Authority (NRA). The conclusive proof of vaccine safety and efficacy is "standard correlates of protection of vaccinees" (SCPV) set by WHO and NRA. One of the major criteria for authorization of a vaccine is its protective efficacy measured by the outcome of disease occurrence (clinical end point) in experimental and control group. As it is a lengthy process instead of the clinical endpoint (i.e. disease

"intermediate end point" of antibody generation is used as a surrogate. (1) The Food & Drug administration (FDA) of US department of Health and Human services has set the recommended Primary efficacy end point (PEEP) estimates at 50% with an alpha-adjusted confidence interval of >30% around the primary efficacy endpoint point estimate. (5). A few of the COVID 219 vaccines under investigation may soon be qualifying the set criteria of efficacy and safety for "emergency use authorization" (EUA), based on a "Benefit-risk ratio" (BRR). The ratio is between the available evidence of known and potential benefit against its known and potential risks of developing adverse reaction in Phase III trial. [6] Public confidence on any Covid-19 vaccine available under an emergency use authorization (EUA) will depend on the rigor of the clinical criteria, including the duration of follow-up, used to evaluate it. (6). Once a new vaccine is authorized the public health authority must plan for its introduction with a clear objective, & goal (personal/ community protection) scope of application and target population (area/people) of and selection of an introduction strategy (at risk/universal/ campaign or routine mode) for the health care delivery system of the country. (1) If there are more than one vaccine available with different safety and efficacy profile against different groups of people the selection will depend on "Benefit Risk Ratio" of individual vaccine.

In India one vaccine is in phase III trial and may soon be licensed under the provision of EUA. The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) constituted by the Government of India in consultation with state government and all relevant stake holder have already prepared a detailed blueprint of vaccine storage and administration and was presented in the Prime Minister's review meeting on 21st. October 2020. (7). In a pandemic situation introduction of a new vaccine under EUA is a political and public health priority, which is a public health challenge. In an ongoing pandemic, the demand for a vaccine is urgent -. more so when there is no specific drug to treat and when available non pharmaceutical measures fails to contain the spread. The politician, public health professional, people at large are eagerly waiting for a vaccine. Once available everyone will make a beeline for getting vaccinated. In the current socio-political backdrop of India after a sustained period of social and economic disruption, and disproportionate suffering of a large section of the disadvantaged communities across the country during "Lockdown", any strategy other than the anticipated universal coverage of vaccination may be misconstrued by the people, and may be exploited for political gain. The legitimacy of a policy emerges from people's perceptions of the integrity of the process and participants in policy development. Given the widespread negative perception of the governments "lock down policy" legitimacy of vaccination policy developed by a government constituted body requires the support of professional bodies, autonomous research and academic institutions, legal experts, and social activists. To boost the public confidence on government's COVID 19 vaccination program public health bodies of IPHA, IAP&SM, must come together and put their recommendation on COVID 19 vaccination policy in public domain. The core theme for any recommendation for a vaccine policy should be to of achieve maximal benefit with minimal harms, in a setting of a constrained supply, and based on principles of equity justice and fairness. Safe and effective vaccines are needed for all. Initially number of available doses will be constrained due to a global demand but will increase over time which, necessitates phased increase in coverage. The first phase includes the period of constrained supply, when more targeted administration among the at-risk group and place

determined by the epidemiological data viz. front-line health care providers, security personal including elderly may be included. An effective vaccination surveillance program will provide the safety data which will be essential for expanding the coverage. In the second phase, supply will likely increase to meet increase demand, allowing for wider coverage. In the third phase, with adequate and ongoing vaccine supply, efforts will continue to improve vaccination coverage and make it universal. Even though India is the largest manufacturer of vaccine in the world but due to international obligation during a pandemic the constraint of vaccine supply will be there.

Despite apparent high demand for vaccination, participation in a vaccination program depends on the perception and attitude of the people, civil society, and health care providers. The perception is influenced by the available information from the technical discourses in the electronic and print media by experts whose effect is unknown. A well-planned Information. Communication and education program based on the prevailing perception on COVID 19 vaccination will help to develop a positive attitude among people and help in removing the existing myths and confusion. To meet the communication need, the communication package must be developed based on the existing level of knowledge, perception of the disease, available measures of prevention and the role of vaccination. Health system of India has a robust cold chain system for vaccine transportation and storage and a well-trained health worker all over the country. As per the deliberation of the expert committee it will be utilized effectively in the new program. But it will need a meticulous planning and augmentation so that the ongoing routine immunization program is not affected.

From the ethical perspective of vaccination with a EUA vaccine, informed consent requirement is ideal. An alternative method of providing a fact sheet that describes the investigational nature of the product, the known and potential benefits and risks, available alternatives, and the option to refuse vaccination may be used. (9) Obligatory vaccination in any form is unethical.

References

1. Field Guide_ New Vaccine 1st. Edition, Scientific & Technical Publication No632, Pan American Health Organization, Washington 2010. <https://www.paho.org/hq/dmdocuments/2010/FieldGuid>

- e_NewVaccines_1stEd_e.pdf? Accessed on August 27, 2020.
2. Thanh Le T, Andreadakis Z, Kumar A, et al. The COVID-19 vaccine development landscape. *Nat Rev Drug Discov* 2020; published online April 9. DOI:10.1038/d41573-020-00073-5. Accessed on July29 2020
 3. Pronker ES, Weenen TC, Commandeur H, Claassen EH, Osterhaus AD. Risk in vaccine research and development quantified. *PLoS One*. 2013;8(3):e57755. doi: 10.1371/journal.pone.0057755. Epub 2013 Mar 20. PMID: 23526951; PMCID: PMC3603987. [[PubMed](#)].
 4. Amanat F, Krammer F. SARS-CoV-2 Vaccines: Status Report. *Immunity*. 2020 Apr 14;52(4):583-589. doi: 10.1016/j.immuni.2020.03.007. Epub 2020 Apr 6. PMID: 32259480; PMCID: PMC7136867. [[PubMed](#)].
 5. Eyal N, Lipsitch M, Smith PG. Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure. *J Infect Dis*. 2020 May 11;221(11):1752-1756. doi:10.1093/infdis/jiaa152. PMID: 32232474; PMCID: PMC7184325. [[PubMed](#)].
 6. Development and Licensure of Vaccines to Prevent COVID-19 Guidance for industry. US Food and Drug Administration. June 2020. <https://fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>. Accessed on August 10, 2020.
 7. Krause P, Fleming TR, Longini I, Henao-Restrepo AM, Peto R; World Health Organization Solidarity Vaccines Trial Expert Group. COVID-19 vaccine trials should seek worthwhile efficacy. *Lancet*. 2020 Sep 12;396(10253):741-743. doi: 10.1016/S0140-6736(20)31821-3. Epub 2020 Aug 27. PMID: 32861315; PMCID: PMC7832749. [[PubMed](#)].
 8. Pandemic-situation-and vaccine delivery- distribution-and -administration -551929; Prime Minister's Office no-reply@sampark.gov.in dated 21-102020.
 9. Philip R. Krause, M.D., and Marion F. Gruber, Ph.D. The New England Journal of Medicine. 16th. October. <https://www.nejm.org/toc/nejm/383/16>, Accessed on October 24, 2020.