

## Reasoning behind experimental booster shots

02 November 2021 | Features

**Studies have shown a reduction in the efficacy of vaccines with newer variants. As the world moves towards boosters doses, the efficacy of the COVID vaccines is becoming a concern. According to researchers from the University of Oxford, UK, and the country's Office for National Statistics, Pfizer/BioNTech COVID-19 vaccine efficacy fell to 90 per cent, 85 per cent, and 78 per cent after 30, 60, and 90 days, respectively, and AstraZeneca vaccine efficacy dropped to 61 per cent by 90 days with the Delta variant. There are ongoing studies for booster doses but certain governments and vaccine manufactures have advocated for booster doses. Booster doses can become a burden for nations when some are struggling to obtain vaccines for first and second doses.**



With the second wave of COVID-19 in the rearview, the cumulative COVID-19 vaccine doses administered in the country has surpassed the 100-crore milestone on October 21, 2021. On this historic achievement, in a tweet, Prime Minister Narendra Modi congratulated the countrymen and expressed gratitude to the country's scientific community and health professionals for working towards achieving this stupendous feat.

India has been adding more vaccines to its armoury to beat COVID-19. The Drug Controller General of India has granted emergency use authorisation to vaccines manufactured by Serum Institute India (Covisheild), Bharat Biotech (Covaxin), Zydus Cadila (ZyCoV-D), Moderna (mRNA-1273), Gamaleya (Sputnik V), and Johnson & Johnson's (Ad26.COV2.S).

The vaccines have been effective in protecting those who have been vaccinated from death and hospitalisation with severe bouts of COVID-19 infection. But as time has progressed since the approval of the vaccines globally there have been several cases of breakthrough infections, amongst those who have been fully vaccinated. Then there have been cases reported, of deaths of those who were fully vaccinated (two doses) and also cases where fully vaccinated individuals were admitted with severe cases of COVID-19 infections. The vaccines as far as the data is concerned have been protecting against the virus.

Efficacy of the vaccines with newer emerging variants is another issue of concern. The SARS-COV-2 virus has mutated since it was first reported from Wuhan in China, also known as the Wuhan virus which caused the first wave globally, followed by the second wave with the Delta variant in India. Globally there have been reports of emerging variants as the virus tends to mutate quickly. The mutating characteristic of the virus has impacted the efficacy of the currently approved vaccines and the

number of cases that are being reported has seen a steep incline. Several countries are struggling with the rise in the number of cases even after a majority of their population has been vaccinated.

### **Developed nations pushing for booster doses**

Countries like the UAE, France, the US, Germany, the United Kingdom, and Israel are providing booster shots to the vulnerable population. Countries like India, Singapore, Switzerland, and several other countries are mulling over the third dose (booster shot). The World Health Organisation is yet to release a statement on the booster dose, but more variants emerging and the efficacy of vaccines reducing due to the emerging variants could probably change in due course.

According to the fourth serosurvey conducted by the Indian Council of Medical Research (ICMR) approximately 67 per cent of the population surveyed had developed antibodies for COVID-19.

The results of the survey were made public after the second wave had peaked in India, at the time the vaccination drive hadn't gained a lot of momentum as citizens were skeptical to get vaccinated. India has completed nine months of the world's largest COVID-19 vaccination drive but still, there are no approved tests to check for the efficacy of the vaccines or if antibodies have developed in those who have been vaccinated.

The only data that is available on the efficacy of the vaccines is based on the clinical trials that were conducted when the vaccine was being tested to check whether it was effective against the coronavirus variant at the time. The ICMR has approved antigen tests to check if an individual has had prior exposure to the coronavirus or not.

Even experts believe that antibody tests to check for the antibodies cannot determine if an individual is protected against COVID-19 or not, or there is no gold standard to gauge the efficacy of the vaccines. This raises a lot of questions as there is a gold standard to determine whether an individual is infected with COVID-19, but there are no approved tests globally to check the efficacy of the vaccines that have been administered.

Pharma majors manufacturing COVID-19 vaccines had conducted clinical trials to determine the efficacy of the vaccines and shared figures on the efficacy of the vaccines once the clinical trials were complete. However, there have neither been any follow-ups, nor have the manufacturers addressed this important piece of information.

### **Big pharma monopoly**

COVID-19 cases are escalating and a very large population, especially in Low and Low Middle-Income Countries (LMIC) remains vulnerable as the governments of these nations haven't been able to procure vaccines. Pfizer/BioNTech and Moderna have sold over 90 per cent of their vaccines so far to rich countries, charging up to 24 times the potential cost of production. mRNA-type vaccines produced by Pfizer/BioNTech and Moderna have been developed through public funding to the tune of \$8.3 billion.

Analysis of production techniques for the leading mRNA suggests these vaccines could be made for as little as \$1.20 a dose. COVAX has been paying, on average, nearly five times more. COVAX has also struggled to get enough doses and at the speed required, because of the inadequate supply and the fact that rich nations have pushed their way to the front of the queue by willingly paying excessive prices.

An analysis done by the People's Vaccine Alliance firms Pfizer/BioNTech and Moderna are charging governments as much as \$41 billion above the estimated cost of production. Earlier this year according to The Bureau of Investigative Journalism pharma major Pfizer/BioNTech was accused of bullying Latin American countries to provide them with sovereign assets as a guarantee against the cost of any future legal cases.

Anna Marriott, Health Policy Manager, Oxfam, United Kingdom said, "Pharmaceutical companies are holding the world to ransom at a time of unprecedented global crisis. This is perhaps one of the most lethal cases of profiteering in history. Precious budgets that could be used for building more health facilities in poorer countries are instead being raided by CEOs and shareholders of these all-powerful corporations."

Winnie Byanyima, Executive Director, UNAIDS, Uganda, shared, "I see lives being saved in vaccinated countries, even as the Delta variant spreads, and I want the same for developing countries. It is criminal that the majority of humanity is still facing this cruel disease unprotected because pharma monopolies and super-profits are being put first."

### **Efficacy and affordability**

Studies have shown a reduction in the efficacy of vaccines with newer variants. As the world moves towards booster doses, the efficacy of these vaccines is becoming a concern. According to researchers from the University of Oxford, UK, and the country's Office for National Statistics Pfizer/BioNTech COVID-19 vaccine efficacy fell to 90 per cent, 85 per cent, and 78 per cent after 30, 60, and 90 days, respectively, and AstraZeneca vaccine efficacy dropped to 61 per cent by 90 days with the Delta variant. There are ongoing studies for booster doses but certain governments and vaccine manufacturers have advocated for booster doses.

Earlier in the year the Government of India (GoI) had fixed the prices at Rs 200 per dose (without taxes) for Covishield and Rs 295 per dose (without taxes) for Covaxin which have been revised over the months and the current rates being Rs 780 for Covishield, Rs 1,410 for Covaxin, and Rs 1,145 for Sputnik V (approved by Drugs Controller General of India in April 2021) was approved in private hospitals. Prime Minister Narendra Modi in his address on June 7, 2021, stated that free vaccines would be available to all those who wanted them from June 21, 2021, but there have been major hurdles in obtaining free vaccines. Government vaccination centres across India have had to shut down their vaccination drive on several occasions due to the shortage of vaccines.

Recently Tedros Adhanom Ghebreyesus, Director-General, WHO in an address in Budapest expressed disappointment on the approval of booster doses by countries that have excess stock of the COVID-19 vaccines, while many poorer countries are struggling to administer their citizens with the first and second dose. He said, "Some countries are administering booster doses to people who are already fully vaccinated, while many people in the poorest countries are yet to receive a single dose, including health workers, older people, and other vulnerable groups."

Ghebreyesus further commented, "That's why I have called for a global moratorium on booster vaccines until at least the end of September, to allow those countries that are furthest behind to catch up."

Dr Soumya Swaminathan, Chief Scientist, World Health Organisation has also echoed similar sentiments. She is opposed to the idea of booster doses as several countries are suffering from acute shortages of COVID-19 vaccines.

In August 2021, Dr Cyrus Poonawalla, Chairman, Serum Institute of India (SII), Pune along with 7000-8000 employees of SII were administered the third dose of Covishield. Dr Poonawalla had also expressed concerns about the reduced efficacy of vaccines after six months post the second dose. A month after Dr Cyrus Poonawalla's statement, Adar Poonawalla, CEO, Serum Institute of India, Pune has expressed that a third booster dose would be 'unethical' as various countries have not been able to administer two doses to those who are eligible. He commented "The third dose of vaccine is not right, at least till significant part of the other countries get two doses and then, of course, we look into third dose or an annual booster shot or something like that," at a media interaction along with Kiran Majumdar Shaw, Chairperson, Biocon after the announcement of the strategic partnership forged between Biocon Biologics Ltd (BBL) and the Serum Institute Life Sciences (SILS). He also clarified his father's statement about a booster dose by mentioning that it may be required by the population that has weakened immunity.

Poonawalla commented, "Maybe some very vulnerable sections, immuno-compromised people could do with some booster shots. There is no evidence to show Covishield requires a third dose."

Addressing the issue of booster doses in the future, Priya Abraham, Director, National Institute of Virology, Pune mentioned, "Studies on booster dose have been going on overseas and at least seven different vaccines have been tried out for booster dose. Now, the WHO has put a stop to it till more countries catch up with vaccination. This is because there is an alarming vaccine gap between high-income and low-income countries. But, in future, recommendations for boosters will definitely come."

### **How wise is the 3rd dose?**

The GoI hasn't approved a booster dose yet but SII's initiative to provide booster doses to its employees and several countries approving a booster dose there is a possibility of a booster dose being approved in the future. This also highlights the issue of affordability of the vaccines that have been approved. Lockdowns imposed to curb the spread of COVID-19 have impacted economies globally and driven millions into poverty. Third-world countries have been facing issues with the availability and affordability of COVID-19 vaccines. Booster doses can become a burden for nations when some are struggling to obtain vaccines for first and second doses.

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