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Are boosters another Shot in the Dark?

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Omicron and newer emerging variants have been portrayed as a cause of concern globally as several low and middle-income countries have not been able to immunise their citizens due to the shortage of COVID-19 vaccines. Notably, it was in the double-vaccinated South African individuals that the Omicron variant was first discovered. The COVID-19 Vaccines Global Access (COVAX) had promised two billion doses of COVID-19 vaccines by the end of 2021 to a total of 92 low-and middle-income countries that are eligible to receive COVID-19 vaccines through the COVAX mechanism. But, it has managed to deliver only about 95 million doses as developed nations hoarded surplus doses of the vaccines. Approximately 75 per cent of the 4.5 billion first doses of the COVID-19 vaccine that were rolled out, went to affluent countries. Can emerging variants make vaccine inequity a bigger challenge than it already is? Let's unravel.

2021 saw the approval of various vaccines and drugs for the treatment of COVID-19, in the new year, we are faced with another mutation of the COVID-19 virus, Omicron that is spreading rapidly across the globe. Omicron as per early research data is capable of escaping the immune response of vaccines adding fuel to the ever-increasing reasoning behind the need for booster doses to help maintain the efficacy of COVID-19 vaccines against severe infection and death.

So far approximately 89 countries have reported cases of Omicron with the United Kingdom reporting 12 deaths due to the variant. According to the World Health Organisation (WHO), COVID-19 cases are doubling every 1.5-3 days in countries that are dealing with community transmission of the variant. The growth advantage that Omicron has over the Delta variant that caused the second wave in India will soon become the most dominant variant globally.

Addressing vaccine inequity

Omicron and newer emerging variants are a cause of concern globally as several low and middle-income countries have not been able to immunise their citizens due to the shortage of COVID-19 vaccines globally. COVID-19 Vaccines Global Access (COVAX) promised to deliver two billion doses of COVID-19 vaccines by the end of 2021 to a total of 92 low-and middle-income countries that are eligible to receive COVID-19 vaccines through the COVAX mechanism but has managed to deliver about 95 million doses as developed nations hoarded surplus doses of the vaccines. Approximately 75 per cent of the 4.5 billion first doses of the COVID-19 vaccine that were rolled went to the people in affluent countries, emerging variants could make vaccine inequity a bigger challenge than it already is.

Expressing her views during the Global Technology Summit 2021 on the impact of vaccine inequity on the global population, **Dr Kiran Mazumdar Shaw, Executive Chairperson, Biocon Biologics, Bengaluru** expressed, “It is very interesting that the biggest vaccine makers in the world are in India but the western vaccine companies chose to use contract manufacturing organisations (CMOs) in the western world who didn’t have any experience with vaccines and I think many of the problems that we have today in the supply chain is because of that mistakes that vaccine companies have made.”

Sharing his views during the Bengaluru Tech Summit 2021 (BTS 2021), **Richard Hatchett, Chief Executive Officer, Coalition for Epidemic Preparedness Innovations (CEPI), London,** England commented, “We need to have equitable vaccine manufacturing capacity globally. If all regions have some access to these rapid response platforms and some ability to address their own national or regional health security, we will be much positioned to reduce the equity gap that has emerged during this pandemic.”

Dr Gagandeep Kang, Professor, Microbiology, Christian Medical College, Vellore, Tamil Nadu reiterated the importance of vaccine equity during the fireside chat with Hatchett during BTS 2021. She commented, “Partnerships are critical for vaccine equity and access, CEPI has shown the way and will be doing more in the next ten years.”

Hatchett further added, “We need new capacity in regions that don’t have the capacity and that capacity needs to be sustainable for the long term. The challenge that we face in ensuring that capacity can be sustainable, is the new COVID-19 vaccines on the new platforms. COVID-19 vaccines are the only vaccines currently authorised on those platforms, so we need to expand the application of those platforms to other diseases that are important for the region where vaccine manufacturing is occurring.”

Approval of booster doses

There is early evidence to support the fact there is reduced efficacy with time and a certain section of the population (elderly, immunocompromised, diabetic, etc.) may require booster doses to keep them protected against COVID-19 infection. The WHO’s interim statement on booster doses dated October 4, 2021, states: The degree of waning of immunity and need for booster doses of vaccine may differ between vaccine products, target populations, circulating SARS CoV-2 virus, in particular variants of concern (VoC), and intensity of exposure. For some vaccines, restricted booster indications have been included into the product label of some jurisdictions.

Mahima Datla, Managing Director and Chief Executive Officer, Vaccines and Branded Formulations, Biological E Limited, Hyderabad, Telangana shared, “The evidence is out there that different vaccines have waning antibody levels post four to six months post-vaccination some much more than others which is why there is a pretty determined need to include boosters. What is unclear is that a lot of information isn’t published or aren’t spoken of is how these vaccines are working against the existing variants and the new variants. One thing that seems to be clear is that if the antibody levels stay high, it seems to be preventing any kind of severe disease even if there is a variant change.”

As the debate for booster doses rages on, several countries have approved booster doses and several nations are mulling over approving booster doses. Speaking on whether India should approve booster doses or not Dr Kiran Mazumdar Shaw expressed, “I think we don’t have enough data of the waning antibody if it is not protecting us against severe disease. I think that data needs to be shared because right now it suits everyone to say let us go for an extra booster, but I would like to see

data that says that if you have two doses you are fairly well protected against severe disease and whilst it is nice to boost your antibody levels with a booster dose, can we not make sure that everybody in the world has at least has their shot of the vaccine."

A transparent, equitable approach

The pandemic is far from over and newer emerging variants, waning efficacy of vaccines, shortage of vaccines in developing nations is a cause of concern. Another cause of concern is the rising number of deaths due to adverse events post-vaccination. India as of December 21, 2021, has vaccinated 138 crore of its citizens, out of which 54.8 crore (39.7 per cent) are fully vaccinated. There have been about 10,664 deaths reported by the Indian mainstream media so far (Data collated by Awaken India Movement).

Scientists have been exploring a plethora of options for the treatment and prevention of COVID-19 infections, single-domain Variable New Antigen Receptors (VNARs) could be a possible therapeutic that is being explored, it is derived from the immune system of sharks. VNARs may not be available to treat COVID-19 as of this writing, but it could be helpful in future SARS CoV-2 outbreaks.

2022 may or may not be the end of the COVID-19 pandemic, the world is better prepared to handle a crisis on a global scale. 2021 saw pharma majors and academia coming together and forging partnerships to address the challenge at hand and fast-tracking, scaling of live-saving solutions. The newer generation of vaccines, drugs in development and late stages of clinical trials, which could eventually lead to the pandemic becoming endemic. However, there is a need to address concerns of transparency in vaccine and drug development, clinical trials and preventing deaths from the COVID-19 infections as well as adverse events.

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