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Vaccine T20 World Cup

With UK giving approval to the Pfizer vaccine, the race for regulatory nod begins. Which of the Covid-19 vaccines will be suitable, available and affordable for countries like India?

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England can justly claim the credit for inventing the T20 format in cricket. Can it claim the Covid-19 vaccine world cup too, as Gavin Williamson, the British education secretary, has declared that his country has better science than Europe or the US? He claimed that the speed with which British regulators appraised trial evidence on the Pfizer-BioNTech vaccine for Covid-19, ahead of others, was proof of superior scientific expertise. This was macho "regulatory nationalism" joining "vaccine nationalism" on Covid-19's political frontlines. Irked by this dismissive comment, Dr Anthony Fauci initially remarked that the British regulators had perhaps not done as thorough a review as US regulators do. He later politely apologised, expressing his respect for the British regulatory process in general.

Leaving aside this storm in the British teacup, was this vaccine itself a triumph of British science?

The idea of mRNA vaccines was conceived first by Katalin Kariko, a Hungarian scientist who emigrated to the US to pursue that effort. There she faced rejection of research grant proposals by funding agencies, which thought the concept was outlandish, and serially suffered academic demotions in her university career as she tried to pursue her idea. Forty years later, she is now being hailed as a Nobel-worthy visionary scientist. The Pfizer-BioNTech vaccine itself has been developed by the husband-wife duo Ugur Sahin and Özlem Türeci, entrepreneurial scientists who founded BioNTech. They are Germans who are Turkish by birth. The vaccine has been manufactured in Belgium. So, the UK may wish to thank Europe for the vaccine, even as it Brexits. The Oxford vaccine, when it is approved, will be more worthy of a British boast.

Now that an approved vaccine has arrived, setting a speed record of 11 months from the first description of the genetic sequence of the new virus, what does it mean for India and most other low- and middle-income countries? Will it be suitable, available and affordable for us? These questions have been raised after a Pfizer spokesperson claimed that they have begun discussion with the Indian authorities for supporting a rollout in this country.

Usually, the trial data need to be published in scientific journals, after peer review. Here, an emergency use authorisation has been issued by the regulator after an expedited review. The vaccine appears to have passed the efficacy test, for preventing severe Covid-19 infection, in a trial of 44,000 subjects in the age range of 18-85 years. The duration of protection is uncertain but both antibody and cell-mediated immunity appear to be sufficiently stimulated. The vaccine has to be administered by intramuscular injection in doses set 21 days apart.

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The mRNA platform for vaccine development is a new one, even for the regulators. The safety of these vaccines is a challenging area for any regulator to assess. Indian regulators have no prior experience with this platform. Even if short-term safety has been reassuringly assessed, longer-term safety is also an issue that merits attention in vaccine trials. Social media alarm has already been sparked by posts purported to arise from concerns of pharmaceutical industry insiders on possible long-term effects on the reproductive health of women. These concerns are not backed by evidence.

The fear that the mRNA vaccine will alter the human genetic code is without basis. In a normal cell, mRNA is a "messenger" that carries the instructions of the DNA to the protein making ribosomes. In this case, the instruction from the vaccine's mRNA is to make a spike protein resembling that of the virus, to create a foundation for immunity against the real virus. The vaccine's mRNA does not track back to the DNA, just as the cell's own mRNA does not. However, long-term safety is still an unanswered question. While it is possible that the vaccine may be safe even in the long run, that is a box yet to be ticked.

Even as we await an answer to the question of long-term safety, the immediate challenge lies in the logistics of storage and transport, under highly demanding cold chain conditions of -70 degree Celsius. Even if a few facilities in India are equipped for that, a nationwide immunisation programme cannot pass that roadblock. Other than for a few select groups of people, if at all, the vaccine is unsuitable for India. The Moderna vaccine too is an mRNA vaccine. Though the cold chain requirements are less demanding, at -20 degree Celsius, it is still unsuitable for Indian conditions and the cost too will be a barrier.

So, India has to wait for the vaccines being manufactured in India. It is likely that the Oxford-AstraZeneca vaccine will get the British regulator's approval soon. Since the two standard (full) doses have been used in the Indian arm of the trial and the international data too will be available for the Indian regulator to review, the approval process in India should not take long. The adenovirus platform is also one that is familiar to our regulators. This vaccine is already under manufacture in India.

If the initial rollout commences with the Oxford vaccine, the domestically developed and manufactured vaccines are likely to be lining up for regulatory review from February 2021. If one or more of them gain approval, the production volumes will assure a steady supply. They too will not pose formidable cold chain barriers. As familiarity breeds confidence, the immunisation programme can proceed without vaccine supply constraints. However, the need for each vaccine to demonstrate safety and efficacy, through convincing clinical trials, has to remain an inviolate rule of science-guided public health. We wait, with hope tempered by caution. ■

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