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## HCFI Round Table Expert Zoom Meeting on “Double Mutation in Coronavirus and Revisiting Vaccine Adverse Effects – Anecdotal Reports”

### CONSENSUS STATEMENT OF HCFI EXPERT ROUND TABLE MEETING (27TH MARCH, 2021)

- The coronavirus keeps on changing in small ways as it passes from one person to another. The vast majority of these mutations are inconsequential and do not alter the virus behavior.
- Some mutations trigger changes in the spike protein and other key areas resulting in more infectiousness, severity and/or even evade vaccine.
- A double variant (E484Q and L452R) has been detected in India. It is a variant of concern. Majority have been detected in Maharashtra, while few have been detected from Delhi, Punjab and Gujarat.
- Mutations occur in the nucleotides and so the amino acid changes.
- The three major variants are the UK variant (B.1.1.7), South Africa variant (B.1.351) and Brazil variant (P.1). The N501Y mutation is common to all three.
- The UK variant has 69-70 and 144 deletions (in the NTD), N501Y substitution in the receptor-binding domain (RBD) and P681H substitution near S1 and S2 bifurcation. This variant may become the wild virus now.
- The South Africa strain has two mutations in the receptor-binding motif or RBM (E484K and K417N); the Brazil strain has K417T and E484K mutations.
- The E484Q and L452R mutation is a novel variant. It does not have NTD deletion so it may autocorrect itself and if this occurs then this mutation will not last long. It will cause a sudden rise in the number of cases, which may exceed the first wave. So, the second wave may be stronger than the first wave, but it may not become a wild virus. It may not develop as the UK strain and will remain a country-specific virus and not spread worldwide.
- The UK strain is causing S gene target failure.
- Does the new mutation cause E gene target failure? This is yet to be confirmed. If the test is based on E gene, then it may be false negative, even while other specific COVID genes may be positive. So, we must test for other markers too.
- Three phenotypes are being seen: Sudden infection with rapidly worsening pneumonia, diarrhea-predominant and the routine presentation of D614G strain. The phenotype of the double mutant virus is not yet known.

- COVID-19 infection is unexpectedly being reported after the first dose of the vaccine.
- The new mutation is double contagious but half as dangerous. It is spreading fast, but so far, no cause for panic. One must remain cautious though.
- Three cases of anaphylaxis have been reported in the media; possibly due to polysorbate 80 (also a constituent in Voveran injection) in one case.
- Non-IgE-mediated reactions within 6 hours: angioneurotic edema eye lid, rash on neck and urticaria; can be prevented by premedication.
- Type 4 reactions may be seen in 4-10 days on the site of injection and also a remote site.
- Other reactions seen include severe aphthous ulcers, local warmth/redness at the injection site on 2nd day, swelling/itching on ear and petechial rash in a patient with varicose veins, ear eczema, severe urticaria reaction on the leg, painful lymph nodes.
- Delayed local injection-site reactions to vaccine may occur, though they are uncommon (T-cell-mediated hypersensitivity) (NEJM).
- Sympathetic overactivity presenting as accelerated hypertension and transient atrial fibrillation, transient ventricular tachycardia, uncontrolled diabetes, precipitation of seizures, brain hemorrhage, exaggerated rheumatoid arthritis, worsening of Crohn's disease, superficial clots (increase in D-dimer).
- Vaccine may precipitate underlying allergy and inflammation: Ear eczema, herpes zoster, Bell's palsy, transverse myelitis.
- Vaccine can precipitate inflammation: Painful lymphadenitis, episcleritis, left eye conjunctivitis.
- Thrombotic thrombocytopenic purpura (TTP) – skin rash after 1 week.
- Post-COVID vaccine systemic inflammation with normal pulmonary function may occur manifesting as fever >101, significant rise in C-reactive protein (CRP). In antibodies after COVID infection, the first dose may act like the second dose and may precipitate systemic inflammation.
- Three cases of myocardial infarction (MI) reported; all deaths in Hong Kong, Malaysia and Sri Lanka are related to heart attacks.
- Post-vaccine COVID infection after the first dose can cause severe inflammation.
- Vaccine-induced loss of smell and taste may occur (RT-PCR negative).
- Anticipate a reaction and act accordingly. In a patient with severe thyrotoxicosis due to post-COVID severe thyroiditis, vaccine was deferred; vaccine would have precipitated a thyroid storm.
- Side effects are predictable and accordingly premedication may be taken to avoid the side effects.
- In its safety review of the AstraZeneca vaccine, the World Health Organization (WHO) has also said that the benefits are more than the risks.
- Evaluate the risks in every individual. In the high-risk and susceptible individuals, give the vaccine by doing appropriate risk reduction.
- Healthcare workers need to be sensitized about these adverse effects.
- The duration between the first and the second dose of Covishield has been increased from 4-6 weeks to 4-8 weeks. The second dose of Covaxin can also be given up to 6 weeks as per the Frequently Asked Questions on Co-WIN released by the Health Ministry (dated 22.3.21).

*With input from Dr Monica Vasudev*

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