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SRK FOUNDATION VIJAYAWADA

A Newsletter on Pharmacy Practice

Dear reader

The novel coronavirus disease (covid-19) lockdown has led to disruptions on a scale we have never seen before. It is not clear how the new normal of our lives will be. we are living in unprecedented times the covid-19 pandemic has profoundly changed our personal and professional lives. The national push to get people vaccinated against covid-19 represents an arms race – the faster the shots arrive in arms, the closer we are to reopening society. Regarding vaccination many apprehensions existing among public have to be removed and knowledge on this will lead to better functioning of the society.

The Coronavirus Disease 2019 (COVID-19) pandemic has presented a major threat to public health worldwide alongside unprecedented global economic and social implications. In the absence of a "gold standard" treatment, the rapid development of a safe and effective vaccine is considered the most promising way to control the pandemic. Over 200 COVID-19 vaccine varieties are under trails worldwide. Vaccine development targeting the SARS-CoV-2 virus poses several challenges. The following are the vaccine varities currently under development or authorized for emergency use to reduce infection associated with SARS-CoV-2.

Messenger RNA Vaccines

Vaccines with the greatest potential for rapid development are RNA-based platforms. Pfizer-BioNTech (BNT162b2) Comirnaty® (tozinameran) and Moderna (mRNA-1273) are newly developed mRNA vaccines. These vaccines function on the premise that mRNA coded for pathogen antigen can be delivered into human cells and result in production of antigen within the cell. Unlike other vaccines, this triggers an immune response without the introduction of live, killed, or subunit portions of the virus. The mRNA cannot cause infection, does not alter human DNA, and is broken down by normal processes in human cells. One of the main concerns of utilizing mRNA-based platforms is the potential of synthetically formulated mRNA to cause a severe adverse reaction due to its inherent inflammatory nature. In addition, mRNA is highly susceptible to extra cellular ribonucleases and is rapidly degraded, so it must be encapsulated in a protective lipid system to facilitate delivery into human cells. Because mRNA is naturally unstable, it must be stored in frozen form below -20 °C, which complicates the shipping, storage, and administration of mRNA vaccines.

Viral Vector Vaccines

Two SARS-CoV-2 vaccines Astra Zeneca Oxford (AZD1222), Janssen/Johnson & Johnson (Ad26.COV2-S) under development use nonreplicating viral vectors to transport recombinant SARS-CoV2 spike protein genes into the human cell. The infected cells display the coronavirus spike protein on their surfaces, which stimulate the immune system to develop antibodies. This transient viral DNA protein is not incorporated into the host cell DNA. The AstraZeneca vaccine uses a simian adenovirus and the Janssen/Johnson & Johnson vaccine uses a human adenovirus. Because these adenoviruses do not replicate, a high dose is required, producing about 12 hours of flu-like symptoms as the immune system responds to the vaccine. The Janssen/Johnson & Johnson vaccine was administered as a single dose in the first phase 3 trial. A second phase 3 trial has been using 2 doses of the vaccine to evaluate safety and efficacy.

Recombinant Protein-Based Vaccines

The Novavax and Sanofi/GlaxoSmithKline (GSK) immunizations include SARS-CoV-2 proteins, but no genetic material. Since this method actually produces a unique protein, it is harder to manufacture than other vaccines and requires more time to ensure production meets high -quality standards. The proteins are recognized by T-cells as target antigens, which generate an immune response. The Novavax product has shown efficacy in initial trials. The Sanofi/GSK vaccine has not produced the desired level of response in subjects over the age of 50 years.

Conclusion

At this time, data are not available to determine how long the mRNA vaccines will provide protection, nor is there evidence that these vaccines prevent transmission of SARS-CoV-2 from person to person.

Source: https://www.gavi.org/vaccineswork/covid-19-vaccine-race

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

SARS-CoV-2 MUTATIONS AND ITS VARIANTS

SARS-CoV-2, the virus that causes COVID-19, has had a major impact on human health globally; infecting a large number of people; causing severe disease and associated long-term health complications resulting in death and excess mortality, especially among older and vulnerable populations; interrupting routine healthcare services, disruptions to travel, trade, education and many other societal functions; and more broadly has a negative impact on people's physical and mental health. Since the start of the COVID-19 pandemic, WHO has received several reports of unusual public health events possibly due to variants of SARS-CoV-2.

B.1.1.7 lineage (a.k.a. 20I/501Y.V1 Variant of Concern (VOC) 202012/01) :

On 14 December 2020, authorities of the United Kingdom reported to WHO a variant referred to by the United Kingdom as B.1.1.7 or SARS-CoV-2 VOC 202012/01 (Variant of Concern, year 2020, month 12, variant 01) emerged with a large number of mutations. This variant has since been detected in numerous countries around the world, including the United States (US). This variant has a mutation in the receptor binding domain (RBD) of the spike protein at position 501, where the amino acid asparagine (N) has been replaced with tyrosine (Y). The shorthand for this mutation is N501Y. This variant also has several other mutations, including:

- 69/70 deletion occurs spontaneously many times and likely leads to a conformational change in the spike protein
- P681H: near the S1/S2 furin cleavage site, a site with high variability in coronaviruses. This mutation has also emerged spontaneously multiple times.

Preliminary epidemiologic, modelling, phylogenetic and clinical findings suggest that SARS-CoV-2 VOC 202012/01 has increased transmissibility. However, preliminary analyses also indicate that there is no change in disease severity (as measured by length of hospitalization and 28-day case fatality), or occurrence of reinfection between variant cases compared to other SARS-CoV-2 viruses circulating in the United Kingdom. This variant is reported in the US at the end of December 2020.

B.1.351 lineage (a.k.a. 20H/501Y.V2):

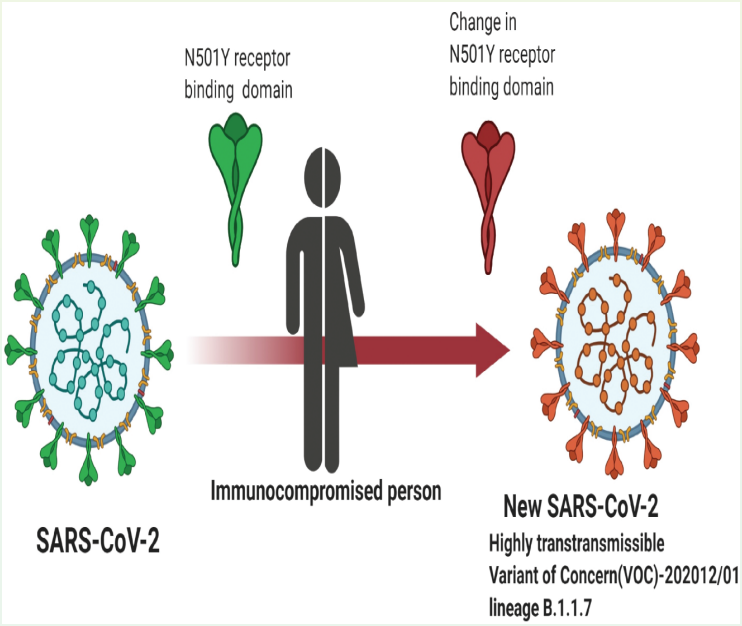
On 18 December, national authorities in South Africa announced the detection of a new variant of SARS-CoV-2 that is rapidly spreading in three provinces of South Africa. South Africa has named this variant 501Y.V2, because of a N501Y mutation. This variant shares some mutations with B.1.1.7. It has multiple mutations in the spike protein, including K417N, E484K, N501Y.

Unlike the B.1.1.7 lineage detected in the UK, this variant does not contain the deletion at 69/70. Cases attributed to this variant have been detected in multiple countries outside of South Africa. The variant is associated with a higher viral load, which may suggest potential for increased transmissibility, as well as other factors that influence transmissibility, are subject of further investigation. Moreover, at this stage, there is no clear evidence of the new variant being associated with more severe disease or worse outcomes. Further investigations are needed to understand the impact on transmission, clinical severity of infection, laboratory diagnostics, therapeutics, vaccines, or public health preventive measures.

P.1 lineage (a.k.a. 20J/501Y.V3) :

In Brazil, a variant of SARS-CoV-2 (known as P.1) emerged that was first was identified in four travelers from Brazil, who were tested during routine screening at Haneda airport outside Tokyo, Japan. This variant has 17 unique mutations, including three in the receptor binding domain of the spike protein. While mutations of SARS-CoV-2 are expected, it is important to continue to monitor the public health implications of new virus variants. Any increased in transmissibility associated with SARS-CoV-2 variants could make control more difficult. Current disease control measures recommended by WHO continue to be effective and should be adapted in response to increasing disease incidence, whether associated with a new variant or not.

Prevention advice and communications for the public should be further strengthened, including precautions to protect oneself and others such as physical distancing, wearing a mask, keeping rooms well ventilated, avoiding crowds, cleaning hands, and coughing into a bent elbow or tissue.



Source : https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

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REGULATORY NEWS

TINIDAZOLE

Risk of skin hyper pigmentation

The NCC-PvPI has made a recommendation to the CDSCO to request that the PIL (Prescribing information leaflet) for tinidazole is revised to incorporate skin hyperpigmentation as a clinically significant adverse drug reaction. Tinidazole is used for the treatment of amoebiasis and giardiasis in adult patients only and in the treatment of anaerobic infections. Between July 2011 and November 2019, the NCC-PvPI received a total of 13 ICSRs of tinidazole associated skin hyperpigmentation. The cases were evaluated by the SRP, PvPI, and IPC who found a strong causal relationship between tinidazole use and skin hyperpigmentation.

Reference: Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

HYDROXYCHLOROQUINE

Risk of prolonged QT, ventricular tachycardia

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for hydroxychloroquine (Plaquenil®) should be revised to include prolonged QT and ventricular tachycardia as adverse drug reactions. Hydroxychloroquine is indicated for cutaneous lupus erythematosus and systemic lupus erythematosus. A total of four cases of prolonged QT and ventricular tachycardia (including torsades de pointes) were reported in patients who used hydroxychloroquine in Japan during the previous three years. A causal relationship between the drug and event could not be established for any of these cases. One case of patient mortality has been reported and a causal relationship could not be established. The MHLW and PMDA have concluded that a revision of the package insert is necessary.

Reference: Revision of Precautions, MHLW/PMDA, 8 September 2020 (www.pmda.go.jp/english/)

DENOSUMAB

Increased risk of multiple vertebral fractures

The MHRA has announced that the Commission on Human Medicines' Pharmacovigilance Expert Advisory Group suggested that there is an increased risk of multiple vertebral fractures after stopping denosumab (Prolia®) for osteoporosis. Denosumab is indicated for treatment of osteoporosis and bone loss associated with hormone ablation in men with prostate cancer or with long-term systemic glucocorticoid therapy in adult patients. From 2015 to June 2020, 44 cases of vertebral fracture, including multiple fractures, have been reported in the UK in post-marketing settings in patients after stopping or delaying ongoing treatment with denosumab. Healthcare professionals should evaluate a patient's individual factors for benefits and risks before initiating treatment with denosumab, particularly in patients at increased risk of vertebral fractures (e.g. previous vertebral fracture). Patients should not stop denosumab without specialist review.

Reference: Drug Safety Update, MHRA, 26 August 2020 (www.gov.uk/mhra)

NOVEL DRUG APPROVALS FOR 2020

DRUG NAME	ACTIVE INGREDIENT	APPROVAL DATE	USES
Detectnet	copper Cu 64 dotatate injection	03.09.20	To help detect certain types of neuroendocrine tumors
Inmazeb	atoltivimab, maftivimab, and odesivimab-ebgn	14.10.20	To treat Ebola virus
Oxlumo	lumasiran	23.11.20	To treat hyperoxaluria type -1
Imcivree	setmelanotide	25.11.20	To treat obesity and the control of hunger associated with pro-opiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age
Gallium 68 PSMA-11	Gallium 68 PSMA-11	01.12.20	For detection and localization of prostate cancer
Orladeyo	berotralstat	03.12.20	To treat patients with hereditary angioedema
Margenza	margetuximab (anti-HER2 mAb	16.12.20	To treat HER2+ breast cancer
Gemtesa	vibegron	23.12.20	To treat overactive bladder

Source : https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020.

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

Campus News

- During lockdown the institution has taken up many activities like social service and participated in awareness program.
- On 24.09.2020 students and staff visited Nirmal hruday bhavan Vijayawada orphanage for the old and sick. They distributed snacks to the inmates of the house.
- During national pharmacy week celebrations i.,e from 16.11.2020 to 23.11.2020 students have created videos Pamphlets and posters to spread awareness on preventive measures of covid-19.
- On 17.11.2020 students visited medical stores in the villages of Ramavarapadu and Nidamanuru to make the pharmacist's role significance.
- On 18.11.2020 students visited Pratap and Prakash industries in the village of Enikepadu to create awareness on preventive measures of covid-19.

To,

We are pleased to receive your feedback and suggestions to :

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