DRUG INFORMATION BULLETIN

Volume14, Number 22, 30th January, 2021
Drug Information Centre (DIC)
Indian Pharmaceutical Association, Bengal Branch
Tele fax: 033 24612776, Contact: 09830136291
E-mail: ipabengal.dic@gmail.com
Web: http://www.ipabengal.org
Regulatory Affairs Division, IPA (IPA-RAD)

Glorious Moment

India completed 28.5 lakhs vaccination to frontline health workers within a fortnight as on 28.01.2021

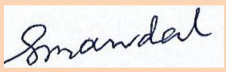
Editorial:

India is completing one year since COVID -19 detected in India. On 29th January 2021 India dropped to the fourth place in deaths from COVID virus infection tally of 1,54,184. India recorded death of less than 200 during last 15 days, which is better than at least eight countries round the world.

India started COVID vaccination since 16th January 2021 and vaccinated 191181 front line health workers using services of 16755 vaccinators from 3374 sites round the country. This number has reached to more than 28.5 lakh within a fortnight through 52,667 sessions. Now the number of sites were extended to 9994 around 37 states and vaccinated 4,91,615 in a single day on 28th January 2021.

As per the sources over 98.3 lakh health care workers and 53.9 lakh frontline workers are registered on the CO-WIN portal.

It is satisfying that Pharmacists are also receiving COVID vaccine along with doctors and nurses as frontline health worker in the first phase of vaccination.



Dr. Subhash C. Mandal, Editor
Email: Subhash.mandaldr@gmail.com
Mobile: 9830136291

CONTENTS

WHO updates guidance on clinical management of patients with COVID-19

The World Health Organization (WHO) has updated its guidance on clinical management of patients with coronavirus disease 2019 (COVID-19).

In the revised clinical management guidelines, the WHO recommends that patients who have COVID-19 - both confirmed and suspected - should have access to follow-up care if they have persistent, new or changing symptoms.

"Evidence was gathered on the post COVID condition, so-called 'long COVID', where people who have recovered from COVID-19 continue to have longer-term issues like extreme fatigue, persistent cough and exercise intolerance," the WHO noted. "Understanding this condition is one of WHO's priority areas of work. In February 2021, the WHO will organise a series of consultations to reach consensus on a description of this condition and its subtypes, and case definitions. This scientific understanding will inform the name of the condition. The consultations will include a broad range of stakeholders, including patient groups."

Meanwhile, for COVID-19 patients at home, the WHO suggests the use of pulse oximetry to measure oxygen levels in the blood.

Further, the WHO suggests using thromboprophylaxis dosing of anticoagulation, rather than intermediate or therapeutic dosing, in patients hospitalised with COVID-19, without an established indication for higher dose of anticoagulation.

For hospitalised patients who are taking supplemental oxygen (including high-flow nasal oxygen) or non-invasive ventilation, the WHO suggests the use of awake prone positioning.

The guidelines also include recommendations on the use of care bundles to systematise care provision for COVID-19 patients, as well as a recommendation to favour clinical judgement over models in making decisions for the patient's care.

The WHO said that the recommendations were made by an independent panel of experts, the Guideline Development Group, on the basis of detailed rapid reviews of all available evidence, and that the guidelines will be updated regularly as more data becomes available.

Reference: https://bit.ly/2MrwXr1

SOURCE: World Health Organization

Bharat Biotech's Covaxin Neutralises UK Strain Of Coronavirus

Bharat Biotech International's covid-19 vaccine Covaxin can protect against the new strain of novel coronavirus discovered in the UK, a pre-print of an in-vitro study conducted by the company showed.

The company had conducted a plaque reduction neutralization test (PRNT50) study, wherein it collected blood sera from the 26 individuals who had received Covaxin, and tested them against the new UK strain as well as another strain of the virus that the company had tested before.

Sera from vaccinated individuals showed comparable neutralisation antibody activity against both strains, which indicated that the vaccine worked against the new strain.

"It was reassuring from the PRNT50 data generated in our laboratory that the indigenous BBV152/ Covaxin, following its roll out in vaccination program, could be expected to work against the new UK-variant," the study, which has not yet been peer-reviewed, said. The study was supported by Bharat Biotech and Indian Council of Medical Research's National Institute of Virology at Pune.

The study inferred that the results indicated that Hyderabad-based Bharat Biotech's Covaxin worked against the new strain of the virus, which was a crucial factor for the company getting an

emergency licensure from the Drugs Controller General of India V.G. Somani earlier this month.

“It is unlikely that the mutation 501Y would be able to dampen the potential benefits of the vaccine in concern," the study said.

The 501Y mutation is a genetic change of the spike protein RNA of the novel coronavirus, found in a UK variant as well the South Africa variant, which sparked concern among experts over efficacy of vaccines and drugs because most of the medical treatments and jabs targeted that protein.

The mutant strain found in UK in December was especially concerning because it was found to be as much as 70% more transmissible and was one of the major reasons for the spike in covid-19 cases seen in UK. Last week, the UK government said that early evidence has also indicated that the strain could be about 30% more deadly.

So far, the mutant strain has been found in over 100 travellers who returned to India from UK.

Discovery of the new strain was the primary reason for the DCGI giving the emergency licensure to Covaxin even though there was criticism on lack of efficacy data even against the original strain. The DCGI had given authorisation to the vaccine “in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains".

“They have used sera from Covaxin vaccinated individuals, and while this is based on limited testing, it is the proof that the vaccine is likely to provide protection against this UK variant. This method was also used for mRNA vaccines. However, this is not a test against the South African variant, which appears to be more of a problem today based on other preliminary reports," Vineeta Bal, professor of biology at Indian Institute of Science Education and Research in Pune, said.

A new strain discovered in South Africa is similar to the one found in UK in terms of the mutation in the spike protein gene and is seen to be 50% more transmissible as compared to the original coronavirus strain.

To be sure, it is normal for viruses, like most living organisms, to mutate, and most variants globally observed so far in the coronavirus have made little difference to how these function. However, the UK and South Africa strains have been especially concerning due to the variation in the spike protein gene.

Source: Livemint

SEC clears Conduct of intranasal vaccine phase-I trials

The Subject Expert Committee (SEC) that advises the Indian drug regulator has asked vaccine maker Bharat Biotech to first conduct phase-I trials of its chimpanzee adenovirus vectored Covid-19 intranasal vaccine, codenamed BBV154, on 75 volunteers to ascertain its safety and immunogenicity before seeking approval for phase-II trials.

The SEC has also asked Bharat Biotech to submit a revised clinical trial protocol. This decision was taken after the company presented the animal toxicity and immunogenicity as well as CMC (chemistry, manufacturing and control) data along with protocol to conduct phase I/II clinical trials of the vaccine candidate. BBV154 is a single dose vaccine candidate that Bharat Biotech is developing in collaboration with the University of Washington School of Medicine at St Louis (WashU).

As per the minutes of the SEC meeting held on January 18 but uploaded recently, “After detailed deliberation the committee recommended that the firm should generate safety and immunogenicity data in phase-I clinical trial (75 subjects) in the proposed doses as per the protocol and submit the data for the consideration of the committee to proceed to phase-II clinical trial. Accordingly, firm should submit revised clinical trial protocol for consideration of the committee.”

Bharat Biotech had applied to DCGI for approval to begin phase I/II clinical trials of the intranasal

vaccine shortly after receiving emergency use authorisation (EUA) approval for indigenous vaccine Covaxin.

Airlifted Covid vaccines to Nine countries, will gradually supply to WHO's COVAX facility: India at UN

India has informed the UN Security Council that it will gradually supply vaccines to the COVAX facility of the World Health Organisation and undertake contractual supplies to various countries in a phased manner, as more than six million doses have been airlifted to nine countries under New Delhi's "vaccine diplomacy."

"As the largest vaccine-producing country of the world, we are fulfilling our commitment to make our vaccine production and delivery capacity available for the benefit of the entire humanity," India's Deputy Permanent Representative to the UN Ambassador K Nagaraj Naidu said on Monday.

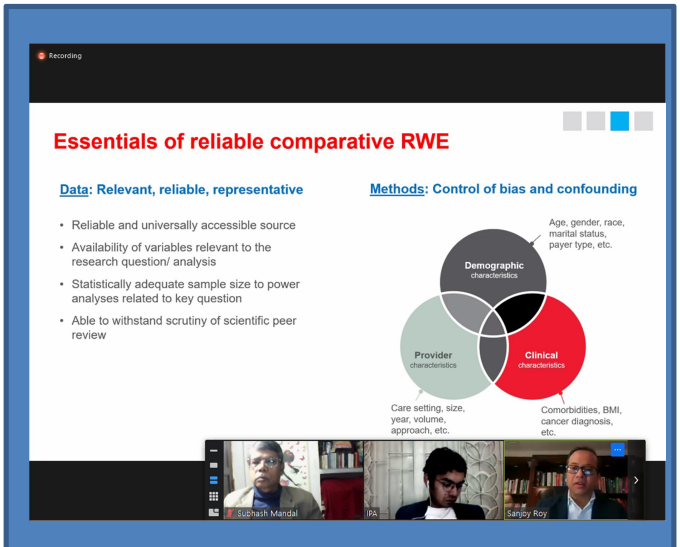
Speaking at the UN Security Council briefing on 'Maintenance of international peace and security : Follow-up on the implementation of resolution 2532', Naidu said two vaccines have already been granted approval for emergency use in India and the country plans to vaccinate about 300 million citizens in the first six months.

Resolution 2532 (2020), adopted in July 2020, expressed support for the Secretary-General's appeal for a global ceasefire to help unite efforts to fight Covid-19 in the world's most vulnerable countries.

"We have already airlifted more than 6 million doses to nine countries in Phase-I as grant assistance. Contractual supplies to various countries are also being undertaken in a phased manner. We will also gradually supply to the COVAX facility of the WHO," Naidu said, adding that India has also provided training to several partner countries to strengthen their clinical capabilities, as well as to enhance their capacities for vaccine administration.

COVAX is the global initiative to ensure rapid and equitable access to Covid-19 vaccines for all countries, regardless of income level.

For details:
https://health.economictimes.indiatimes.com



Glimpses of an International webinar on "Real World Evidence and its Utility"