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Covid vaccine goals

Does India have the doses to fulfil Phase-1 Covid vaccine goals? (The Tribune: 20210104)

https://www.tribuneindia.com/news/health/does-india-have-the-doses-to-fulfil-phase-1-covid-vaccine-goals-192661

Does India have the doses to fulfil Phase-1 Covid vaccine goals?
Reuters file photo

Given that India has set the goal of vaccinating 30 crore people with Covid-19 jabs by July, can the country procure enough doses to fulfil that goal?

To vaccinate 30 crore people, the country will need 60 crore doses as the two vaccines that are leading the race to get the approval from the government require two-doses per person for protection.

These two vaccines that the government is currently considering giving the approval are "Covishield" and "Covaxin" While the Pune-based Serum Institute of India has partnered with Oxford-AstraZeneca for conducting clinical trials and manufacturing "Covishield", Bharat Biotech has collaborated with the Indian Council of Medical Research (ICMR) for "Covaxin".

Approval for Covishield is expected soon as the Subject Expert Committee of the Central Drug Standard Control Organisation on Friday recommended its emergency use.

However, it now appears that the Serum Institute of India is planning to supply the government with 30 crore doses by July, enough for vaccinating 15 crore people, according to media reports.

If it works out that way, the government will be able to reach just half way of fulfilling the phase-1 goals with Covishield alone.

"For rolling out the vaccination campaign, cold chain equipment such as walk-in coolers, walk-in freezers, refrigerators, deep freezers are already procured and distributed to the states," Harshal R. Salve, Associate Professor at Centre for Community Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi, told IANS.
"Vaccine storage capacities at airports and major railway staions are being created.

"You may have approval for another vaccine too in the meanwhile that can be included in the mass the vaccination drive," Salve added.

It now appears that the success of India's vaccination drive may rely on the efficacy of Covaxin in protecting people against Covid-19.

This is specially in view of the fact that India did not sign early procurement deals for the other two vaccines that have got approval in several countries including the US -- the vaccines developed by Pfizer-BioNTech and Moderna.

As these two vaccines are now in great demand, they appear unprepared to supply India huge number of doses quickly even if New Delhi fast-tracks their approvals.

Pfizer has already sought the emergency use authorisation for its Covid-19 vaccine in India.

Now experts believe that to achieve herd immunity against Covid-19, about 70 per cent of the country's population will have to be vaccinated, meaning about 90 crore people.

If other vaccines that are approved in the future also require two doses per person, this will mean that India will need 180 crore doses of Covid-19 vaccines.

Union Health Minister Harsh Vardhan earlier this month said that about 30 vaccines against Covid-19 are in different stages of development in India.

How many of them get the required approval may say a lot about how quickly India achieves herd immunity against Covid-19.

Covishield, Covaxin

CDSCO approves Covishield, Covaxin for restricted emergency use in India Both Covishield, Covaxin are two-dose vaccines (The Tribune: 20210104)

https://www.tribuneindia.com/news/health/cdsco-approves-covishield-covaxin-for-restricted-emergency-use-in-india-193044

The stage is set for the commencement of COVID vaccination drive in India with the national regulator on Sunday approving both Covishield and indigenous COVAXIN for restricted use in emergency situations.

While Covishield is Serum Institute's vaccine developed in collaboration with Oxford University and AstraZeneca, COVAXIN has been made by Bharat Biotech with ICMR partnership.

"After adequate examination, the CDSCO has decided to approve Covishield and COVAXIN for restricted emergency use in India," Drug Controller General of India VG Somani said.

Also read: WHO welcomes India's COVID vaccine approvals; first in South-East Asia

Approval for vaccines accelerates India's journey to be COVID-free, says Modi

'Covishield' ready to roll out in coming weeks: Poonawalla

Bharat Biotech recruits 23,000 volunteers for COVID-19 vaccine trials

He said both vaccines would be stored at 2 to 8 degree and are two-dose vaccines.

"SII submitted safety, efficacy and immunogenicity data on 23744 subjects aged 18 or older from overseas and efficacy was found to be 70.42 per cent. Interim safety data from trials in India was found to be comparable with overseas data and SII's ongoing phase 2 and 3 clinical trials in India will continue," Somani said.

About Bharat Biotech vaccine he said it is based on the inactivated virus platform whose safety is well established in India and abroad.

(Click here for the latest developments on Covid-19 epidemic)

"Bharat Biotech submitted data from animal studies. Phase 1 and 2 trials were done on 800 subjects and results show safe, robust immune response. Phase 3 trials have been initiated on 25800 participants and 22500 have been vaccinated. The vaccine is safe as per data available. Subject experts have recommended restricted emergency use, which has been accepted," Somani added.
The government said it is prepared for COVID vaccine rollout.

As soon as the approvals were announced the Congress raised concerns over the safety of Bharat Biotech and Covishield.

Congress leader Jairam Ramesh said "Bharat Biotech is a first-rate enterprise, but it is puzzling that internationally-accepted protocols relating to phase 3 trials are being modified for Covaxin. Health Minister should clarify."

Former minister Anand Sharma also raised concerns asking for safety data to be made available in the public domain.

WHO

WHO welcomes India's COVID vaccine approvals; first in South-East Asia 'Decision will help intensify and strengthen the fight against COVID-19'(The Tribune: 20210104)

https://www.tribuneindia.com/news/health/who-welcomes-indias-covid-vaccine-approvals-first-in-south-east-asia-193049

WHO welcomes India's COVID vaccine approvals; first in South-East Asia
Image only for representational purposes. Reuters photo.

The WHO on Sunday welcomed the emergency use authorization given to COVID-19 vaccines in India, the first in the South-East Asia Region.

Also read: CDSCO approves Covishield, COVAXIN for restricted emergency use in India

'Covishield' ready to roll out in coming weeks: Poonawalla

Bharat Biotech recruits 23,000 volunteers for COVID-19 vaccine trials

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"This decision taken today by India will help intensify and strengthen the fight against COVID-19 pandemic in the Region.

(Click here for the latest developments on Covid-19 epidemic)

The use of the vaccine in prioritized populations, along with the continued implementation of other public health measures and community participation will be important in reducing the impact of COVID-19," said Dr Poonam Khetrapal Singh, Regional Director WHO South-East Asia Region

Pandemic winter: Cardiac issues

Pandemic winter: Cardiac issues, including heart attack, rise by 50% Doctors say extremely low temperature and post-COVID complications are key contributors behind the reported rise in cardiac issues (The Tribune: 20210104)

https://www.tribuneindia.com/news/health/pandemic-winter-cardiac-issues-including-heart-attack-rise-by-50-193146

As the mercury continues to fall in bone-chilling winter, a contrasting scenario is being reported in hospitals of Delhi-NCR. The fast-dipping temperature and the post-COVID trauma have led to a rise in cases of heart-related issues.

Hospitals are witnessing at least 50 per cent rise in such cases in comparison to last winter. The cases, including heart attacks and strokes have significantly increased, doctors told IANS.

Medanta Hospital in Gurugram said it has seen 50 per cent rise in patients coming with heart issues since the start of December.

Aakash Healthcare in Delhi said since the last two months, the average patient count coming with cardiac issues has increased in the hospital. It is now receiving an average 500 patients since November which was around 300 patients in previous years during winters.

Indraprastha Apollo Hospital is also witnessing a spike in cases of heart attacks and angina in the past 3 weeks.

Doctors said that extremely low temperature and post-COVID complications are the key contributors behind the reported rise in cardiac issues among the public.

(Click here for the latest developments on Covid-19 epidemic)

“Frigid temperatures constrict blood vessels that increase blood pressure which makes it suffer heart attack or stroke. Besides, Covid-19 is also playing a major factor since it affects the circulatory system of the body. If you catch the virus, you are at an increased risk of having a heart attack or stroke. COVID makes blood thicker and hence blocks arteries,” Dr Praveen Chandra, Chairman, Interventional Cardiology, at Medanta explained.

Dr Anil Saxena, Director, Cardiology, Fortis Escorts Heart Institute, Delhi, said that the risk of rise in heart-related cases is a common phenomenon during winters. However, Covid-19 is aggravating the issue further this year.

“Many patients with COVID infection are getting complications due to inflammation in the arteries and heart muscle itself. This may complicate matters for heart patients,” he added.

Dr Ashish Agarwal, Head, Department of Cardiology at Aakash said the COVID-19 has substantially affected the hearts of its patients, especially to those with pre-existing heart problems or other comorbidities.

“Having an incurable viral infection like COVID-19 during winters can increase the risk of heart failure or heart attack. This is because blood vessels in the body become more constricted due to exposure to extremely cold temperatures in winters that can restrict blood flow to the body and to the heart,” he informed.

A study published in JAMA Cardiology medical journal, claimed that 78 per cent of Covid recovered patients have abnormalities in the heart while 60 per cent have an 'ongoing myocardial inflammation'. It also found higher levels of Troponins, the blood enzyme which indicates heart damage, among the study subjects.

Meanwhile, Indraprastha Apollo Hospital said that the numbers are also increasing since the patients, with existing heart ailments, who have been delaying regular check-ups amid the pandemic, are now coming with aggrieved condition.

"While dip in temperature is the major cause here, the pandemic has made this situation even grimmer. The patients with existing heart ailments who have been delaying regular check-ups are the worst-hit. They are turning in with aggravated condition of their disease," said Dr Mukesh Goel, senior consultant, Cardio Thoracic Surgery at the hospital, told IANS.

Doctors advised that people with heart conditions and those who have recovered from COVID-19 in the past few months need to remain watchful and take extra care to prevent any fatal heart condition during winters.

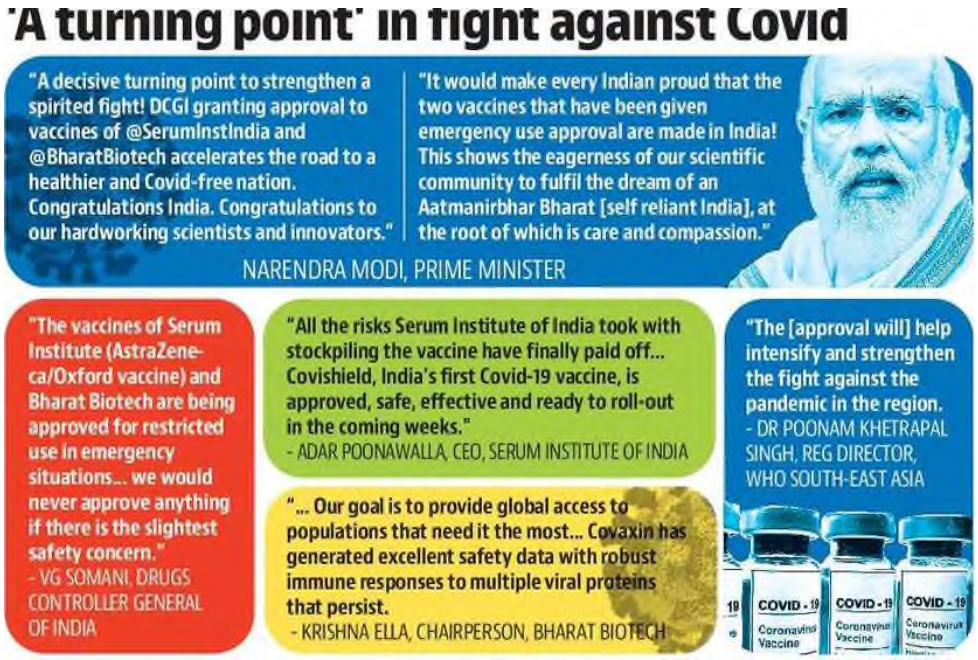
"It is important to note that many patients with COVID infection have minimal symptoms but can still have sudden and severe complications. Therefore, one has to be especially watchful for any symptoms of heart disease. Any chest discomfort or sudden difficulty in breathing should not be neglected. One should seek medical care whenever such symptoms occur. Prompt treatment of heart disease can minimise damage to the heart and save lives," Dr Saxena cautioned.

"Patients should undergo regular screening tests to check their heart health. Besides, standard of care practices should be applied, such as avoiding fried food and alcohol, layering of warm clothes, and regular exercise," Dr Agarwal advised. IANS

Oxford, Bharat Biotech vaccines

Oxford, Bharat Biotech vaccines cleared for use (Hindustan Times: 20210104)

https://epaper.hindustantimes.com/Home/ArticleView



India could roll out the world's largest vaccination drive against the coronavirus disease (Covid-19) in about 10 days after the national drug controller approved two vaccines for restricted emergency use in India on Sunday, officials with knowledge of the development said.

Drugs Controller General of India (DCGI) VG Somani on Sunday announced that he had approved both the Oxford University-AstraZeneca Plc. vaccine being manufactured in India by the Serum Institute of India (SII), and Bharat Biotech International Limited's locally developed vaccine candidate.

He said that he had accepted recommendations made by the subject expert committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO) on Friday and Saturday to grant restricted emergency approval to both the vaccines.

A top official with knowledge of the matter said the vaccination drive could begin as early as in 10 days. "It will take about a minimum of 10 days from now for the vaccine to be rolled out," the official said on condition of anonymity.

Soon after the approval was announced, Prime Minister Narendra Modi put out three tweets congratulating the country, scientists and innovators.

"A decisive turning point to strengthen a spirited fight! DCGI granting approval to vaccines of @SerumInstIndia and @BharatBiotech accelerates the road to a healthier and Covid-free nation. Congratulations India. Congratulations to our hardworking scientists and innovators," his first tweet said.

The Subject Expert Committee consists of domain experts from the fields of pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine and so on .

On SII's Oxford-AstraZeneca vaccine, Somani said: "After detailed deliberations Subject Expert Committee has recommended for the grant of permission for restricted use in emergency situation subject to certain regulatory conditions. The clinical trial ongoing within the country by the firm will continue."

Pune-based SII, which is manufacturing the Oxford-AstraZeneca Covid-19 vaccine and testing it in India, presented a recombinant chimpanzee adenovirus vector vaccine (Covishield) encoding the Sars-CoV-2 Spike (S) glycoprotein with technology transfer from AstraZeneca/Oxford University.

The firm submitted safety, immunogenicity and efficacy data generated on 23,745 participants aged 18 years or older from overseas clinical studies.

“The overall vaccine efficacy was found to be 70.42%. Further, M/s Serum was granted permission to conduct Phase-II/III clinical trial on 1,600 participants within the country. The firm also submitted the interim safety and immunogenicity data generated from this trial and the data was found comparable with the data from the overseas clinical studies,” Somani said.

Bharat Biotech has developed a whole virion inactivated coronavirus vaccine (Covaxin) in collaboration with the Indian Council of Medical Research (ICMR) and National Institute of Virology (Pune), from where it received the virus seed strains. The vaccine is developed on a vero cell platform, which has a well established track record of safety and efficacy in the country and globally.

The firm has generated safety and immunogenicity data in various animal species such as mice, rats, rabbits, Syrian hamster, and also conducted challenge studies on non-human primates (Rhesus macaques) and hamsters.

The company had shared the data with CDSCO, and also put out phase 1 and 2 trial results for publication in December.

Phase 1 and Phase 2 clinical trials were conducted in approximately 800 subjects, and the results have demonstrated that the vaccine is safe and provides a robust immune response. The Phase 3 efficacy trial was initiated in India in 25,800 volunteers and to date, 22,500 participants have been vaccinated across the country and the vaccine has been found to be safe as per the data available currently, according to the drugs controller.

“The Subject Expert Committee has reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. The clinical trial ongoing within the country by the firm will continue,” said Somani.

Both the vaccines have to be intramuscularly administered in two doses.

On the sidelines of a media briefing, Somani said that people of India must rest assured that all safety concerns have been met before the vaccines were approved.

“Even if there is smallest of doubt regarding safety of the vaccine, it won’t be approved. Of course, the ones approved are safe; I would say 110%. There are some side-effects but those are minor ones that are commonly seen in vaccines such as pain at the injection site, slight temperature, minor allergies, etc. Don’t believe in rumours as all scientific processes have been strictly adhered to,” he added.

Clinical trial mode condition means that the company will closely monitor and take full responsibility for any side-effects to any participants.

While there has been criticism from a large section of experts about the way approvals were given without adequate efficacy data, some experts say there is a provision for

such approvals in the Indian regulatory system during emergency situations such as a pandemic.

“There is a provision in the Drugs and Cosmetics Act for grant of approval even without the efficacy data but the terminology used is somewhat different from emergency use authorisation. The approval can be granted on the basis of phase 1 and 2 clinical trials’ safety and immunogenicity data. The data gradually has to be updated. I don’t see the fuss created around it by people, many of whom aren’t even domain experts,” said a senior public health expert, who requested anonymity.

Vaccines and transparency

A hurried gamble: On vaccines and transparency (The Hindu: 20210104)

https://www.thehindu.com/opinion/editorial/a-hurried-gamble-the-hindu-editorial-on-vaccines-and-transparency-amid-high-vaccine-hesitancy/article33488169.ece

Opacity in communication is dangerous when there is high vaccine hesitancy
The stage is set for the biggest vaccine rollout in India’s history with the Drugs Controller General of India formally approving two vaccines for restricted use under emergency conditions: Covishield by the Serum Institute of India (SII), and Covaxin by Bharat Biotech. Though other vaccine candidates are in the fray too, these two set a precedent for how future COVID-19 vaccines will be evaluated and administered. India has been long known as a manufacturer of vaccines but less so as one that can develop from scratch, test and then provide it to the world. The pandemic offers an unprecedented opportunity to establish those credentials, but already a key step — of establishing the vaccine’s efficacy in the Indian population before rollout — has been side-stepped. A double-blinded phase-3 trial — where some volunteers get the vaccine and some do not and the rate of disease in both arms is compared to determine the vaccine’s ability — is among the foundations of evidence-based medicine. The SII because of its agreement with AstraZeneca has furnished data from a phase-3 trial in the U.K. and Brazil, but nothing publicly on how protective the vaccine was in 1,600 Indian volunteers. All of the leading vaccine candidates — Pfizer, Moderna and AstraZeneca itself — made public at least partial results of the vaccine’s abilities in their own populations before these were given a go-ahead by the respective regulators. Bharat Biotech, which is conducting such a phase-3 trial in India, is yet to furnish similar data because it has not been able to finish recruiting the required number of volunteers. The Indian data furnished by the companies only attest to the vaccine’s safety and its evoking some immune response. However, this pandemic has revealed multiple instances of therapies and interventions — from convalescent plasma therapy to a slew of antivirals — that seemed to work well under idealised lab conditions but did not measurably protect in real-world hospital conditions.

The concern from approving an untested vaccine is that it makes it nearly impossible to conduct a proper phase-3 trial. It will be unethical to expect volunteers to participate in a trial where there is only a 50% chance of being administered the actual vaccine, when they have the option of the real dose elsewhere. Both SII and Bharat Biotech, given the pace of recruitment and potential pool of volunteers, would have been able to generate much more data within mere weeks. So, it is hard to imagine why an emergency use authorisation of these vaccines was hurried through. Opacity marks the government’s communication strategy in a country where

distrust of vaccines remains in spite of years of vaccination programmes and elimination of grave diseases. The government neglects this at the country's peril.

Covid-19 cases pass 2.8 mn

Africa's confirmed Covid-19 cases pass 2.8 mn: Africa CDC (New Kerala: 20210104)

https://www.newkerala.com/news/2021/1564.htm

The number of confirmed Covid-19 cases in the African continent has reached 28,07,864 on Sunday, the Africa Centers for Disease Control and Prevention (Africa CDC) said.

The continental disease control and prevention agency said in a statement that the death toll from the ongoing Covid-19 pandemic has reached 66,631 as of Sunday afternoon, the Xinhua news agency reported.

The Africa CDC, a specialised healthcare agency of the African Union (AU) Commission, also said that a total of 23,32,063 people infected with Covid-19 had recovered from the infectious virus across the continent so far.

The most affected African countries in terms of the number of positive cases include South Africa, Morocco, Tunisia, Egypt and Ethiopia, respectively, figures from the Africa CDC showed.

South Africa has the highest number of confirmed positive Covid-19 cases, at 10,88,889. The country also has the highest Covid-19-inflicted deaths at 29,175 according to the Africa CDC.

Meanwhile, Chairperson of the AU Commission, Moussa Faki Mahamat, on Friday called on the African continent to ensure economic recovery from the brunt of Covid-19 pandemic as the New Year begins.

"As we mark the end of the year 2020, we also mark the end of one of the most extraordinary and challenging years in living memory," the chairperson of the 55-member pan-African bloc said in a statement.

Mahamat warned that "the challenging task of protecting our health and livelihoods, while ensuring recovery of our economies, still lies ahead as we begin a new year."
Cellular immune dysregulation

COVID-19

Study: Individuals recovering from COVID-19 helpful for Sustained cellular immune dysregulation (New Kerala: 20210104)

https://www.newkerala.com/news/2021/1543.htm

A recent study has determined that Covid-19 patients might be helpful for clinicians to better understand how the unknown SARS-CoV-2 virus acts.

According to a study published in the Journal of Clinical Investigation, many infected patients remain asymptomatic or have mild symptoms. Others, especially those with comorbidities, can develop severe clinical disease with atypical pneumonia and multiple system organ failures.

Since the first cases were reported in December 2019, the SARS-CoV-2 virus that causes COVID-19 has surged into a pandemic, with cases and deaths still mounting. Ongoing observational clinical research has become a priority to better understand how this previously unknown virus acts, and findings from this research can better inform treatment and vaccine design.

The University of Alabama at Birmingham researchers, led by first-author Jacob "Jake" Files and co-senior authors Nathan Erdmann, M.D., Ph.D., and Paul Goepfert, M.D., have now reported their observational study, "Sustained cellular immune dysregulation in individuals recovering from SARS-CoV-2 infection."

In a commentary on the UAB study, published in the same issue, Phillip Mudd, M.D., Ph.D., and Kenneth Remy, M.D., both of Washington University, wrote, "The importance of these studies to provide context for the interpretation of immune responses generated by participants in COVID-19 vaccine trials, including how those responses change over time, cannot be over-emphasized. This information will be key in potential modifications to existing COVID-19 vaccines and treatments."

The UAB researchers obtained blood samples and clinical data from 46 hospitalized COVID-19 patients and 39 non-hospitalized individuals who had recovered from confirmed COVID-19 infection. Both groups were compared to healthy, COVID-19-negative controls. Importantly, most individuals in the hospitalized group had active SAR-CoV-2 viruses in their blood and were in the hospital at the time of sample collection. All individuals in the non-hospitalized group were convalescent at the time of sample collection.

From the blood samples, researchers were able to separate specific immune cell subsets and analyze cell surface markers. From this complex information, immunologists can analyze how each individual's immune system is responding during infection and during convalescence. Some of these results can reveal whether immune cells have become activated and exhausted by the infection. Exhausted immune cells may increase susceptibility to a secondary infection or hamper the development of protective immunity to COVID-19.

In addition, the researchers were able to analyze changes over time, in two ways. The first was observing changes in surface markers over time, defined as days since the onset of symptoms for non-hospitalized samples. The second was directly comparing the frequencies of these markers between the first and second clinic visits for non-hospitalized patients who had blood samples collected at two sequential time points.

The most surprising finding involved non-hospitalized patients. While the UAB researchers saw upregulated activation markers in hospitalized patients, they also found several activations and exhaustion markers were expressed at higher frequencies in non-hospitalized convalescent samples.

Looking at these markers over time, it was apparent that immune dysregulation in the non-hospitalized individuals did not quickly resolve. Furthermore, the dysregulation of T cell activation and exhaustion markers in the non-hospitalized cohort was more pronounced in the elderly. "To our knowledge," the researchers reported, "this is the first description of sustained immune dysregulation due to COVID-19 in a large group of non-hospitalized convalescent patients."

For details of the comprehensive look at immune cells subsets during and after COVID-19 infection in hospitalized and non-hospitalized people, see the study, which includes an in-depth characterization of the activation and exhaustion phenotype of CD4+ T cells, CD8+ T cells, and B cells.

The B and T cells from both patient cohorts had phenotypes consistent with activation and cellular exhaustion throughout the first two months of infection. And in the non-hospitalized individuals, the activation markers and cellular exhaustion increased over time. "These findings," Mudd and Remy said in their commentary, "illustrate the persistent nature of the adaptive immune system changes that have been noted in COVID-19 and suggest longer-term effects that may shape the maintenance of immunity to SARS-CoV-2."

A question now being explored, the UAB researchers say, is whether these observed immunologic changes are associated with symptoms experienced well beyond the acute infection, often described as "Long COVID."

Co-authors with Files, Erdmann and Goepfert in the Journal of Clinical Investigation report are Sushma Boppana, Mildred D. Perez, Sangita Sarkar, Kelsey E. Lowman, Kai Qin, Sarah Sterrett, Eric Carlin, Anju Bansal, Steffanie Sabbaj, Olaf Kutsch and James Kobie, Division of Infectious Diseases, UAB Department of Medicine; and Dustin M. Long, Department of Biostatistics, UAB School of Public Health.

Blood vessel

Blood vessel damage, inflammation in COVID-19 patients' brains: Study (New Kerala: 20210104)

https://www.newkerala.com/news/2021/1270.htm

A team of researchers from National Institutes of Health, in an in-depth study of how COVID-19 affects a patient's brain, have consistently spotted hallmarks of damage caused by thinning and leaky brain blood vessels in tissue samples. These damage hallmarks were spotted in patients who died shortly after contracting the disease.

In addition, they saw no signs of SARS-CoV-2 in the tissue samples, suggesting the damage was not caused by a direct viral attack on the brain. The results were published as correspondence in the New England Journal of Medicine.

"We found that the brains of patients who contract the infection from SARS-CoV-2 may be susceptible to microvascular blood vessel damage. Our results suggest that this may be caused by the body's inflammatory response to the virus" said Avindra Nath, M.D., clinical director at the NIH's National Institute of Neurological Disorders and Stroke (NINDS) and the senior author of the study. "We hope these results will help doctors understand the full spectrum of problems patients may suffer so that we can come up with better treatments."

Although COVID-19 is primarily a respiratory disease, patients often experience neurological problems including headaches, delirium, cognitive dysfunction, dizziness, fatigue, and loss of the sense of smell. The disease may also cause patients to suffer strokes and other neuropathologies. Several studies have shown that the disease can cause inflammation and blood vessel damage. In one of these studies, the researchers found evidence of small amounts of SARS-CoV-2 in some patients' brains. Nevertheless, scientists are still trying to understand how the disease affects the brain.

In this study, the researchers conducted an in-depth examination of brain tissue samples from 19 patients who had died after experiencing COVID-19 between March and July 2020. Samples from 16 of the patients were provided by the Office of the Chief Medical Examiner in New York City while the other 3 cases were provided by the department of pathology at the University of Iowa College of Medicine, Iowa City. The patients died at a wide range of ages, from 5 to 73 years old. They died within a few hours to two months after reporting symptoms. Many patients had one or more risk factors, including diabetes, obesity, and cardiovascular disease. Eight of the patients were found dead at home or in public settings. Another three patients collapsed and died suddenly.

Initially, the researchers used a special, high-powered magnetic resonance imaging (MRI) scanner that is 4 to 10 times more sensitive than most MRI scanners, to examine samples of the olfactory bulbs and brainstems from each patient. These regions are thought to be highly susceptible to COVID-19. Olfactory bulbs control our sense of smell while the brainstem controls our breathing and heart rate. The scans revealed that both regions had an abundance of bright spots, called hyperintensities, that often indicate inflammation, and dark spots, called hypointensities, that represent bleeding.

The researchers then used the scans as a guide to examine the spots more closely under a microscope. They found that the bright spots contained blood vessels that were thinner than normal and sometimes leaking blood proteins, like fibrinogen, into the brain. This appeared to trigger an immune reaction. The spots were surrounded by T cells from the blood and the brain's

own immune cells called microglia. In contrast, the dark spots contained both clotted and leaky blood vessels but no immune response.

"We were completely surprised. Originally, we expected to see the damage that is caused by a lack of oxygen. Instead, we saw multifocal areas of damage that is usually associated with strokes and neuroinflammatory diseases," said Dr. Nath.

Finally, the researchers saw no signs of infection in the brain tissue samples even though they used several methods for detecting genetic material or proteins from SARS-CoV-2.

"So far, our results suggest that the damage we saw may not have been not caused by the SARS-CoV-2 virus directly infecting the brain," said Dr. Nath. "In the future, we plan to study how COVID-19 harms the brain's blood vessels and whether that produces some of the short- and long-term symptoms we see in patients."

Coronavaccine (Hindustan: 20210104)

https://epaper.livehindustan.com/imageview_553125_53020408_4_1_04-01-2021_3_i_1_sf.html

• डीसीजीआई ने कोविशील्ड और कोवैक्सीन के आपात इस्तेमाल की मंजूरी दी • कहा-दोनों ही वैक्सीन 110 फीसदी सुरक्षित

सुखद : देश को मिले दो कोरोना कवच

नई दिल्ली | विशेष संवाददाता

देश में कोरोना टीके का इंतजार खत्म हो गया। भारत के औषधि महानियंत्रक (डीसीजीआई) ने रविवार को दो टीकों कोविशील्ड और कोवैक्सीन के सीमित आपात इस्तेमाल को मंजूरी दे दी। इसके साथ ही भारत दुनिया का पहला देश बन गया जिसने एक साथ दो वैक्सीन के इस्तेमाल को मंजूरी प्रदान की है।

ऑक्सफोर्ड और सीरम इंस्टीट्यूट ऑफ इंडिया द्वारा तैयार कोविशील्ड तथा पूरी तरह स्वदेशी भारत बायोटेक के कोवैक्सीन टीके को मंजूरी दी गई है। इसके साथ ही देश में कोरोना से बचाव के लिए जल्द टीकाकरण का रास्ता साफ हो गया है।

सिफारिश स्वीकार: डीसीजीआई डॉ. वीजी सोमानी ने रविवार सुबह संवाददाता सम्मेलन कर टीकों की मंजूरी दिए जाने का ऐलान किया। उन्होंने कहा कि केंद्रीय औषधि मानक नियंत्रण संगठन (सीडीएससीओ) ने अध्ययन के बाद विशेषज्ञ समिति की सिफारिशों को स्वीकार करने का फैसला किया है। इसके बाद ही सीमित उपयोग के लिए स्वीकृति दी गई है। नए साल के पहले दो दिनों में सीडीएससीओ की सब्जेक्ट एक्सपर्ट कमेटी ने दोनों टीकों को सशर्त मंजूरी देने की सिफारिश की थी।

09 टीकों का निर्माण हो रहा भारत में

07 का ट्रायल विभिन्न चरणों में

डीसीजीआई डॉ. वीजी सोमानी ने रविवार को टीके की मंजूरी की जानकारी दी। • पृट

कोवैक्सीन का बैकअप के रूप में इस्तेमाल

एम्स दिल्ली के निदेशक के मुताबिक, कोवैक्सीन टीके का इस्तेमाल बैकअप के रूप में हो सकता है। जब कोरोना मामलों में अचानक वृद्धि होती है तो आपात स्थिति में टीकाकरण की जरूरत होती है।

कोविशील्ड
- सीरम ने कोविशील्ड के लिए एस्ट्राजेनेका से साझेदारी की
- इसकी प्रभावकारिता 70.4% आंकी गई है

कोवैक्सीन
- भारत बायोटेक आईसीएमआर संग बना रहा कोवैक्सीन
- ट्रायल तीसरे चरण में
- टीका सुरक्षित और प्रभावी

टीके से जुड़ी प्रश्नोत्तरी

- **टीकाकरण कब शुरू होगा?** सभी राज्यों में टीकाकरण का पूर्वाभ्यास हो चुका है। केंद्र से अनुमति मिलते ही टीके लगेंगे।
- **टीके बाजार में कब आएंगे? इनकी कीमतें क्या रहेंगी?** सरकार टीके खरीद प्राथमिकता समूह का टीकाकरण करेगी। इसके बाद बाजार में आएगा। कोविशील्ड 200 में सरकार को और बाजार में 1000 रुपये में मिलेगा।
- **किसे कौन सा टीका लगेगा, यह कैसे तय होगा?** संभाव है कि सरकार राज्यों के हिसाब से अलग-अलग टीके लगाए। इससे दूसरी खुराक लगाने में गड़बड़ी नहीं होगी। कोविन सॉफ्टवेयर में दर्ज होगा कि किसे कौन सा टीका दिया गया है।
- **देश में कितने टीकों पर कार्य चल रहा है?** नौ। सात टीके विभिन्न चरणों में हैं। सात की दूसरी छमाही में और टीके आ चुके होंगे।
- **सबको मुफ्त टीके लगेंगे?** अभी एक करोड़ स्वास्थ्यकर्मी व दो करोड़ फ्रंटलाइन वर्कर को टीके लगेंगे। 27 करोड़ के बारे में अभी निर्णय होना बाकी है।

विशेषज्ञों से बातचीत पर आधारित

चीन में सर्वाधिक टीकों को इजाजत

चीन	4
भारत	2
ब्रिटेन	2
रूस	2
अमेरिका	2

स्वागत: मोदी ने बधाई दी

प्रधानमंत्री नरेंद्र मोदी ने कहा, बधाई भारत! यह हर भारतीय के लिए गर्व की बात है कि दोनों टीके भारत निर्मित हैं। यह वैज्ञानिकों की इच्छाशक्ति को दर्शाता है। > ब्योरा पेज 09

सवाल: वैक्सीन पर सियासत

आनंद शर्मा समेत कई कांग्रेस नेताओं ने टीके के सीमित उपयोग की मंजूरी पर कहा-यह अपरिपक्व है। भाजपा अध्यक्ष जेपी नड्डा बोले, मजाक उड़ाना विपक्ष की आदत। > ब्योरा पेज 09

उत्पादन की अनुमति: डॉ वीजी सोमानी ने कहा कि दोनों वैक्सीन 110 फीसदी सुरक्षित है। इस बीच, डीसीजीआई ने एक आदेश जारी करके भारत बायोटेक कंपनी को कोवैक्सीन टीके के उत्पादन को मंजूरी दे दी है।

लड़ाई मजबूत होगी: कोविड टीके को मंजूरी दिए जाने का विश्व स्वास्थ्य संगठन ने स्वागत किया। संगठन ने कहा कि इससे मौजूदा महामारी के खिलाफ लड़ाई और मजबूत होगी। > कोरोना से जंग पेज 2,8,9

जायडस कैडिला करेगी तीसरे चरण का परीक्षण

डीसीजीआई ने जाइडस कैडिला की डीएनए आधारित वैक्सीन के तीसरे चरण के परीक्षण की मंजूरी दे दी है।

आपात इस्तेमाल का अर्थ

इसका अर्थ है कि इस्तेमाल पूर्ण रूप से चिकित्सकीय निगरानी में होगा। ज्यादा प्रभावी दवा आने पर मंजूरी वापस होगी। निगरानी के दौरान सफल रहा है तो अंतिम मंजूरी दी जाएगी।

Active Patient (Hindustan: 20210104)

https://epaper.livehindustan.com/imageview_553125_53018214_4_1_04-01-2021_3_i_1_sf.html

सलाह : जो लोग बीमारी को मात देकर स्वस्थ हो चुके हैं उन्हें बचाव के लिए वैक्सीन लगवाना चाहिए

सावधान ! कोरोना के सक्रिय मरीज न लगवाएं टीका

नई दिल्ली | वरिष्ठ संवाददाता

कोरोना के सक्रिय मरीजों को वैक्सीन नहीं लगवानी चाहिए। संक्रमण खत्म होने के कम से कम 14 दिनों बाद ही टीका लगवाना उचित होगा। अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) दिल्ली के निदेशक डॉक्टर रणदीप गुलेरिया ने लोगों को यह सुझाव दिए हैं।

देश को दो टीकों का कोरोना कवच मिलने के साथ ही लोगों के मन में कई आशंकाएं भी हैं। ऐसे तमाम सवालों पर गुलेरिया ने जवाब दिए हैं। उनके मुताबिक, आने वाली वैक्सीन कोरोना के सक्रिय मरीजों पर क्या असर दिखाइएगा, इसके बारे में अभी हमें कुछ मालूम नहीं है।

टीका केंद्र पर न जाएं: उन्होंने यह भी कहा कि कोरोना के सक्रिय मरीजों को चाहिए कि वे टीकाकरण केंद्र पर नहीं जाएं। उनके वहां जाने से कोविड-19 के संक्रमण फैलने का खतरा बढ़ेगा।

वैक्सीन की दोनों खुराक जरूरी: कोरोना से ठीक होने के बाद भी लोगों को कोरोना का टीका लगवाना चाहिए। संक्रमण से पूरी तरह सुरक्षा के लिए स्वस्थ हो चुके लोगों को भी वैक्सीन की दोनों डोज लगवानी चाहिए। कुछ जगह ऐसा देखा गया है कि ठीक होने के बाद दोबारा संक्रमण हुआ है। ऐसे में वैक्सीन उन्हें फिर से कोरोना संक्रमित होने से बचाएगी।

कैंसर, मधुमेह और रक्तचाप के मरीज भी टीकाकरण कराएं

कैंसर, मधुमेह या रक्तचाप से पीड़ित मरीजों को जरूर टीका लगवाना चाहिए। ऐसे लोगों को कोरोना से गंभीर रूप से बीमार होने का खतरा बढ़ जाता है।

दूसरी दवाओं के रूटीन पर कोई असर नहीं पड़ेगा

अन्य बीमारियों से पीड़ित लोग अगर टीका लगवाते हैं तो इसके बाद उनके दवाओं के समय या नियम पर कोई असर नहीं पड़ेगा।

बिना पंजीकरण कराए नहीं मिलेगी वैक्सीन

पंजीकरण कराने पर ही वैक्सीन दी जाएगी। स्वास्थ्य मंत्रालय की वेबसाइट पर लोग पंजीकरण करा सकेंगे। इसके लिए फोटो पहचान पत्र चाहिए।

Vaccination (Hindustan: 20210104)

https://epaper.livehindustan.com/imageview_553126_53027430_4_1_04-01-2021_4_i_1_sf.html

तीन लाख स्वास्थ्य कर्मचारी और छह लाख अग्रिम पंक्ति के कोरोना योद्धाओं को प्राथमिकता मिलेगी

नौ लाख दिल्लीवालों को पहले टीका : जैन

नई दिल्ली | वरिष्ठ संवाददाता

दिल्ली के स्वास्थ्य मंत्री सत्येंद्र जैन ने कहा कि दिल्ली सरकार टीकाकरण की पूरी व्यवस्था कर चुकी है। दिल्ली में तीन लाख स्वास्थ्य कर्मचारी और छह लाख पहली पंक्ति के कोरोना योद्धा हैं। इन नौ लाख लोगों को टीका लगाना हमारी प्राथमिकता होगी।

जैन ने कहा कि हमारा प्रोटोकॉल होगा कि स्वास्थ्य कर्मियों, फ्रंटलाइन वर्कर्स, 50 वर्ष से अधिक उम्र वाले और गंभीर बीमारियों से पीड़ित लोगों को पहले टीका लगाया जाएगा।

तैयारी

- मंत्री ने वैक्सीन स्टोरेज की सभी तैयारी पूरी करने की बात कही
- गंभीर बीमारी वाले लोगों को भी टीकाकरण में प्राथमिकता रहेगी

डीजीसीआई द्वारा कोरोना वैक्सीन को मिली मंजूरी पर सत्येंद्र जैन ने कहा, हमें अभी-अभी बताया गया है कि भारत बायोटेक और सीरम इंस्टीट्यूट ऑफ इंडिया के टीकों को मंजूरी मिल गई है।

जैन ने कहा कि वैक्सीन लगाने के लिए पहले चरण में 500-600 कोविड केंद्र बनाए जाएंगे, इन केंद्रों की संख्या समय के साथ 1000 कर दी जाएगी। स्वास्थ्य मंत्री ने कहा कि शनिवार को सरकारी अस्पताल, निजी अस्पताल और सरकारी डिस्पेंसरी- इन तीन स्थानों पर बने केंद्रों पर टीकाकरण का पूर्वाभ्यास किया गया। वैक्सीन के स्टोरेज की भी सारी तैयारियां हो गई हैं।

कोरोना बेड की संख्या और घटेगी: स्वास्थ्य मंत्री ने कहा कि पिछले कुछ दिनों में हमने कोरोना बेडों की संख्या घटाई है। इसके तहत दिल्ली सरकार के अस्पतालों में 2500 और निजी अस्पतालों में 5000-6000 बेड कम किए गए। पहले हमारे पास 18,800 बेड उपलब्ध थे, लेकिन संख्या घटाने के बाद भी हमारे पास 10,500-12,000 बेड हैं। हम अगले सप्ताह बेडों की संख्या और घटाएंगे। जहां तक कोविड केंद्रों को बंद करने की बात है, दिल्ली सरकार विशेषज्ञों के साथ मिलकर बड़ी सतर्कता और सावधानियों को ध्यान में रखते हुए केंद्रों की संख्या घटा रही है।

भारत के औषधि महानियंत्रक ने दो टीकों के आपात इस्तेमाल की मंजूरी दे दी है। इसे संभव बनाने के लिए दिन रात काम करने वाले वैज्ञानिकों और अनुसंधानकर्ताओं को ढेर सारी बधाई। टीका पहुंचते ही दिल्ली सरकार टीकाकरण शुरू करने को तैयार है। पहले चरण में तीन लाख स्वास्थ्यकर्मियों और अग्रिम मोर्चे पर काम करने वाले करीब छह लाख लोगों को टीका लगाया जाएगा। - **सत्येंद्र जैन**, स्वास्थ्य मंत्री

कोरोना काबू में पर मास्क का साथ न छोड़ें

सत्येंद्र जैन ने बताया कि दिल्ली में साढ़े सात महीनों में पहली बार कोरोना के 500 से कम केस आए हैं। संक्रमण दर में भी लगातार गिरावट देखी जा रही है। उन्होंने कहा कि दिल्ली में अब कोरोना का प्रकोप काफी हद तक नियंत्रण में है, लेकिन फिर भी सभी को मास्क पहनना चाहिए और बाकी सावधानियां भी बरतनी चाहिए। क्योंकि लापरवाही भारी पड़ सकती है और फिर से कोरोना की चपेट में आ सकते हैं।

Vaccination Procedure (Hindustan: 20210104)

https://epaper.livehindustan.com/imageview_553126_53027740_4_1_04-01-2021_4_i_1_sf.html

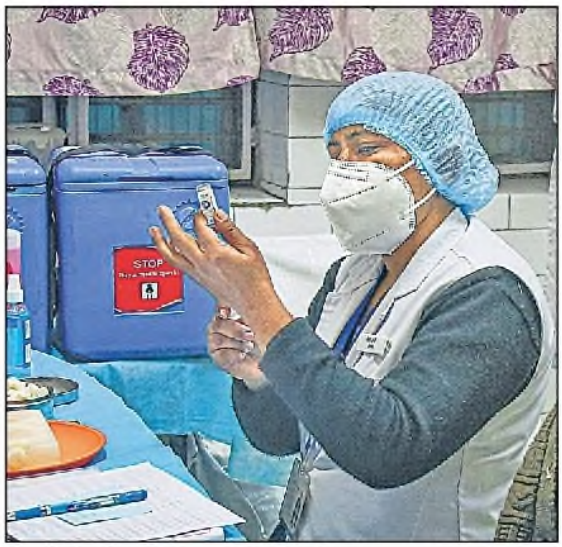
जानकारी

टीकाकरण प्रक्रिया को ऐसे समझें

कोरोना के दो वैक्सीन को आपात स्थिति के लिए भारत में मंजूरी दे दी गई है। जल्द ही वैक्सीन लगाने की प्रक्रिया शुरू भी कर दी जाएगी। दिल्ली में भी इसकी पूरी तैयारी की गई है। 600 से ज्यादा टीकाकरण केंद्र बनकर तैयार हो गए हैं और जल्द ही एक हजार केंद्र तैयार कर लिए जाएंगे। यहां आपको टीकाकरण की प्रक्रिया बताई जा रही है।

वैक्सीन

- सीरम इंस्टीट्यूट की कोविशील्ड और भारत बायोटेक की कोवैक्सीन को आपातकाल में इस्तेमाल के लिए मंजूरी मिली है।
- चार से 12 सप्ताह के अंदर वैक्सीन के दो डोज लेना जरूरी है।



दिल्ली के तीन केंद्रों पर शनिवार को टीकाकरण का पूर्वाभ्यास किया गया था, जो सफल रहा। ● फाइल फोटो

कोरोना वैक्सीन की यात्रा

केंद्रीय भंडार गृह : दिल्ली में कोरोना वैक्सीन के लिए दो केंद्रीय भंडार गृह बनाए गए हैं। पहला सिविल लाइंस में और दूसरा राजीव गांधी सुपर स्पेशियलिटी हॉस्पिटल ताहिरपुर में। इन दोनों स्थानों पर एक करोड़ से अधिक वैक्सीन डोज को सुरक्षित रखा जा सकता है।

जिला भंडारण केंद्र : जिला भंडारण केंद्रों तक पुलिस की निगरानी में तापमान नियंत्रित वाहनों में वैक्सीन को ले जाया जाएगा।

कोल्ड स्टोरेज प्वाइंट : जिला भंडारण केंद्रों से वैक्सीन को शहर भर के 621 छोटे कोल्ड चेन प्वाइंट तक पहुंचाया जाएगा।

टीकाकरण केंद्र : कोल्ड स्टोरेज प्वाइंट से वैक्सीन को एक हजार टीकाकरण केंद्रों तक पहुंचाया जाएगा। हर टीकाकरण केंद्र में वैक्सीन को रखने के लिए डीप फ्रीजर की व्यवस्था रहेगी।

फेज-1 के तहत लाभार्थी

51	03	06	42
लाख लोगों को टीका लगाया जाएगा	लाख स्वास्थ्यकर्मी इसमें शामिल	लाख अग्रिम पंक्ति के कोरोना योद्धा	लाख लोग जिनकी उम्र 50 वर्ष से अधिक है या वो गंभीर बीमारियों से पीड़ित हो

टीका लगाने के दौरान यह भी हैं चुनौतियां

1. सरकारी पोर्टल कोविन पर पंजीकरण जांच के लिए तेज स्पीड इंटरनेट जरूरी
2. कोई प्रतिकूल घटना होती हो उसे संभालने के लिए अतिरिक्त समय चाहिए
3. हर बूथ पर रोज 100 को टीका लगेगा, इसलिए अतिरिक्त कर्मचारी की जरूरत

Infection (Hindustan: 20210104)

https://epaper.livehindustan.com/imageview_553126_53028050_4_1_04-01-2021_4_i_1_sf.html

संक्रमण के 424 नए केस सामने आए

नई दिल्ली | वरिष्ठ संवाददाता

दिल्ली में कोरोना संक्रमित मरीजों की संख्या तेजी से कम हो रही है। दिल्ली के स्वास्थ्य विभाग के अनुसार रविवार को 424 नए मामलों की पुष्टि हुई। इन नए मामलों के साथ दिल्ली में कोरोना संक्रमितों की कुल संख्या बढ़कर 6,26,872 हो गई है।

रविवार को 708 मरीजों को छुट्टी दी गई, जबकि 14 मरीजों ने कोरोना के कारण दम तोड़ दिया। दिल्ली में अभी तक 611243 मरीज कोरोना से ठीक हो चुके हैं, जबकि 10585 मरीजों की कोरोना से मौत हो चुकी है। दिल्ली में कोरोना से मृत्युदर 1.69 फीसदी है। विभाग के अनुसार दिल्ली में कोरोना के कुल 5044 सक्रिय मरीज हैं। इनमें से दिल्ली के विभिन्न अस्पतालों में 1942 मरीज भर्ती हैं। कोविड केयर सेंटर में 51 और कोविड मेडिकल सेंटर में 27 मरीज हैं। होम आइसोलेशन में 2600 मरीज भर्ती हैं। वंदे भारत मिशन के तहत आए139 मरीज भी आइसोलेशन में हैं। दिल्ली में 97.5 फीसदी कोरोना मरीज ठीक हो चुके है।

शनिवार को आरटीपीसीआर से 39217 और रैपिड एंटीजन से 29542 टेस्ट हुए। दिल्ली में अभी तक 8876518 टेस्ट हो गए हैं। हॉटस्पॉट की संख्या घटकर 3623 रह गई है।

रिपोर्ट

- कोरोना संक्रमण के कारण 14 लोगों को अपनी जान गंवानी पड़ी
- 708 मरीजों ने स्वस्थ होकर कोरोना को मात दी

97 फीसदी से अधिक कोरोना मरीज अब तक दिल्ली में स्वस्थ हो चुके हैं

1.69 फीसदी संक्रमित होने वाले लोगों की मौत हो रही है