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Covid-19 Vaccination 'Mother of Planning Exercises', Data Should be Compared Independently: Experts

As the government's national expert group decides on modalities that are key to the administration of a potential vaccine against coronavirus, experts and former top bureaucrats said that the size of the challenge is formidable. Globally, there are over 40 vaccines under various stages of trials whereas, in India, three vaccine candidates are undergoing clinical human trials. Two of them, developed by Bharat Biotech International Limited and Zydus Cadila, are being directly supported by the Indian government. Keshav Desiraju, who served as Secretary, Ministry of Health and Family Welfare for a year between 2013 and 2014 said that administration of the Covid-19 vaccine for over a billion people will be the mother of all planning and logistic exercises. Desiraju said that the biggest difference between past vaccination campaigns, ongoing immunization programmes and the one against coronavirus will be the sheer scale of the job at hand. "Campaigns to eradicate polio or universal immunization involved reaching out to a targeted population. But the vaccination against coronavirus will have to reach out to almost the entire population. Now, that will be a mother of all planning and logistic exercises," the retired bureaucrat said.

Desiraju said that the government will have to draw on all the previous major campaigns such as those against polio and HIV AIDS. He added that even as Serum Institute of India and Bharat Biotech are competent enough to manufacture vaccines, a lot of work will go into the processes such as storage, manufacture of devices needed to deliver the vaccine and last-mile delivery. Desiraju gave the example of cold-chains as one of the key logistical infrastructure issues that need to be addressed. "Cold-chains are important because the vaccine has to retain its potency and efficacy. They cannot be stored at room temperature. The ground level workers such as ASHA (Accredited Social Health Activists) need ice-boxes and uninterrupted supply of electricity at places where vaccines are stored before last-mile delivery. Our vaccination programmes have been a success in the past due to the diligence of healthcare workers and sound logistics makes their job easier," Desiraju said.

The many stages in vaccine administration and vaccination, especially in the case of a Covid-19 vaccine, begins from selecting a vaccine that will work. Last month, the Indian government constituted a national expert group on vaccine administration. This group has been tasked with the job of deciding on vaccine selection, procurement, delivery, prioritizing populations that would need first shots of the vaccine, sorting of logistics and inventory and planning for the funding of all these tasks. "There is a digital platform that is being enhanced to track on a real-time basis, the vaccine movement from procurement to storage to administration and last-mile delivery. Another intervention will be made to develop online training modules for ground workers as skilled manpower will be required to vaccinate people, to report adverse events post-vaccination," said Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare.

"A sub-group within the national expert groups is seized of issues such as logistics, syringes and associated equipment," he added.
India is part of GAVI, the public-private vaccine alliance that facilitates immunization and the Covax facility that has been formed to support research and development of Covid-19 vaccines, for negotiation of prices. The initial aim is to provide 2 billion doses by the end of 2021 to countries affiliated to the facility. More importantly, the facility is crucial for low and middle-income countries, including India, for getting equitable and affordable access to vaccines against Covid-19. India is eligible to receive vaccines from this facility and has pledged $15 mn to GAVI.

INNDEPENDENT ANALYSIS OF VACCINE TRIAL DATA

Eminent vaccine expert D Gagandeep Kang of the Christian Medical College, Vellore, said among many issues pertaining to vaccine administration, India needs to address two important issues relating to the independent review of data generated during vaccine trials and on what systems would be used to deliver it. Kang cited the example of 'Operation Warp Speed', the public-private partnership of the Trump administration to facilitate, develop and distribute Covid-19 vaccines. "In this operation, the US government is providing individually negotiated funding to vaccine companies but it is insisting that those vaccine companies need to have aligned protocols and their samples and data need to be reviewed by independent labs and independent statisticians decided by the US government," Dr Kang said. This ensures a head-to-head comparison of the different vaccine candidates and comparability of data and of biological readouts, Dr Kang said.

"The Indian government is not doing anything like that at the moment. It should be thinking about this issue. For instance, if you have a definition of a clinical outcome that is severe disease versus another example in which clinical outcome is a mild disease; can you compare the two vaccines?" Kang said. As far as delivery of vaccines is concerned, Kang said the government should consider at this stage what structure will be used to reach people; the existing immunization programme or a completely new one that perhaps uses Aadhaar, voter rolls or platforms? "Whatever we build should be new and rather not be repurposed from the existing system to prevent damage to it. We have already seen that ASHA workers are doing everything under the sun and that affected childbirths," Kang added. (Source: News18)

Huge Study of Coronavirus Cases in India Offers Some Surprises to Scientists

With 1.3 billion people jostling for space, India has always been a hospitable environment for infectious diseases. And the coronavirus has proved to be no exception: The country now has more than 6 million cases, second only to the United States.

An ambitious study of nearly 85,000 of those cases and nearly 600,000 of their contacts, published Wednesday in the journal Science, offers important insights not just for India but for other low- and middle-income countries.

Among the surprises: The median hospital stay before death from COVID-19, the illness caused by the coronavirus, was five days in India, compared with two weeks in the United States, possibly because of limited access to quality care. And the trend in increasing deaths with age seemed to drop off after age 65 — perhaps because Indians who live past that age tend to be relatively wealthy and have access to good health care.

The contact-tracing study also found that children of all ages can become infected with the coronavirus and spread it to others — offering compelling evidence on one of the most divisive questions about the virus. And the report confirmed, as other studies have, that a small number of people are responsible for seeding a vast majority of new infections.

An overwhelming majority of coronavirus cases globally have occurred in resource-poor countries, noted Joseph Lewnard, an epidemiologist at the University of California, Berkeley, who led the study. India recorded its first case of COVID-19 on Jan. 30 in an Indian citizen evacuated from China.

The study focused on two southern Indian states, Andhra Pradesh and Tamil Nadu, which together have a population of about 128 million and represent two of the five Indian states with the most cases. They also have among the most sophisticated health care systems in the country. Contact tracers reached more than 3 million contacts of the 435,539 cases in these two states. The researchers analyzed data for 575,071 contacts for whom test information was available.

The contact-tracing data revealed that the people infected first were more likely to be male and older than their contacts. Lewnard and his colleagues also looked at infections in contacts by age and sex and found that infected people tend to spread the virus to those of similar ages. Overall, the researchers found, just 5% of people accounted for 80% of the infections detected by contact tracing. (Source: News 18)

'Simply Unethical': WHO Chief Warns Against Pursuing Herd Immunity to Stop Coronavirus

The head of the World Health Organization warned against the idea that herd immunity might be a realistic strategy to stop the pandemic, dismissin such proposals as "simply unethical." At a media briefing on Monday, WHO Director-General Tedros Adhanom Ghebreyesus said health officials typically aim to achieve herd immunity by vaccination. Tedros noted that to obtain herd immunity from a highly infectious disease such as measles, for example, about 95% of the population must be immunized.

Herd immunity is achieved by protecting people from a virus, not by exposing them to it, he said. Some researchers have argued that allowing COVID-19 to spread in populations that are not obviously vulnerable will help build up herd immunity and is a more realistic way to stop the pandemic, instead of the restrictive lockdowns that have proved economically devastating. Never in the history of public health has herd immunity been used as a strategy for responding to an outbreak, Tedros said.

Tedros said that too little was known about immunity to COVID-19 to know if herd immunity is even achievable. We have some clues, but we dont have the complete picture, he said, noting that WHO had documented instances of people becoming reinfected with coronavirus after recovering from an initial bout of the virus. Tedros said that while most people appear to develop some kind of immune response, it's unclear how long that lasts or how robust that protection is and that different people have varying responses.

"Allowing a dangerous virus that we dont fully understand to run free is simply unethical," he said. WHO estimates less than 10% of the population has any immunity to the coronavirus, meaning the vast majority of the world remains susceptible.

Tedros also noted countries had reported record-high daily figures of COVID-19 to the U.N. health agency for the last four days, citing surges in Europe and the Americas in particular. (Source: News18)

Covid-19 Reduces Male Sex Hormone Levels Leading to More Deaths Among Men, Study Suggests

Anew study has linked more men dying of Covid-19 globally than women to the ability of SARS-CoV-2 in depleting testosterone levels in the body.

Initially the lower testosterone levels in the Covid-19 patients were associated with poor health condition, however a new study shows that it may be viral infection that is causing the level of male sex hormone to decrease, a report in The Print said.

“For the first time, our data suggest that Covid-19 might deteriorate serum testosterone level in SARS-CoV-2 infected male patients. Low serum total testosterone level at baseline has a significant increased risk for the ICU and mortality in patients with Covid-19,” researchers from University of Mersin, and the Mersin City Education and Research Hospital in Turkey, reported in The Aging Male journal.

Testosterone is the male sex hormone and decreases on an average by 0.8-2 percent a year after 40 years. The fact could be comprehended behind the outcome of coronavirus in older patients.

The study published earlier this month selected a sample of 438 patients, and 232 of them were men. “Future studies related to testosterone treatment in this population would discover possible improvement in clinical outcomes with the testosterone treatment in SARS-CoV-2 infected hypogonadal male patients,” the study added.

“Testosterone is associated with the immune system of respiratory organs, and low levels of testosterone might increase the risk of respiratory infections,” says Selahittin Çayan, professor of urology, who contributed to the study.

“Low testosterone is also associated with infection-related hospitalisation and all-cause mortality in male in ICU patients. So testosterone treatment may also have benefits beyond improving outcomes for Covid-19,” the professor added.

In India, the deaths among Covid-19 patients have mostly been among men, with reports indicating it at 69 per cent. It also noted that the severity of the Covid -19 was higher when the testosterone decreased. It noted that the testosterone level in the ICU patient were lower that the patients in the intermediate ICU level. (Source: News18)

Covid vaccine: 8,000 jumbo jets needed to deliver doses globally, says IATA

There is no Covid-19 vaccine yet, but IATA is already working with airlines, airports, global health bodies and drug firms on a global airlift plan. The distribution programme assumes only one dose person is needed.

"Safely delivering Covid-19 vaccines will be the mission of the century for the global air cargo industry. But it won't happen without careful advance planning. And the time for that is now," said IATA's chief executive Alexandre de Juniac.

While airlines have been shifting their focus onto delivering cargo during the severe downturn in passenger flights, shipping vaccines is far more complex.

Not all planes are suitable for delivering vaccines as they need a typical temperature range of between 2 and 8C for transporting drugs. Some vaccines may require frozen temperatures which would exclude more aircraft.

"We know the procedures well. What we need to do is scale them up to the magnitude that will be required," added Glyn Hughes, the industry body's head of cargo.

Flights to certain parts of the world, including some areas of South East Asia, will be critical as they lack vaccine-production capabilities, he added.

Military Precision

Distributing a vaccine across Africa would be "impossible" right now IATA says given the lack of cargo capacity, size of the region and the complexities of border crossings.

Transportation will need "almost military precision" and will require cool facilities across a network of locations where the vaccine will be stored.

About 140 vaccines are in early development, and around two dozen are now being tested on people in clinical trials.
One is being developed by the University of Oxford that is already in an advanced stage of testing.

IATA has urged governments to begin careful planning now to ensure they are fully prepared once vaccines are approved and available for distribution.

Along with making sure they are handled and transported at controlled temperatures, security is another issue.

"Vaccines will be highly valuable commodities. Arrangements must be in place to keep ensure that shipments remain secure from tampering and theft," added IATA. (Source:BBC)

UK Pharma Firm AstraZeneca Pauses Coronavirus Vaccine Trial After Unexpected Illness In Volunteer

London: Pharmaceutical company AstraZeneca said Tuesday it had "voluntarily paused" a randomized clinical trial of its coronavirus vaccine in what it called a routine action after a volunteer developed an unexplained illness.

The company, which is developing the drug alongside the University of Oxford, is a frontrunner in the global race for a Covid-19 vaccine. "As part of the ongoing randomized, controlled global trials of the Oxford coronavirus vaccine, our standard review process was triggered and we voluntarily paused vaccination to allow review of safety data by an independent committee," a spokesperson said.

"This is a routine action which has to happen whenever there is a potentially unexplained illness in one of the trials, while it is investigated, ensuring we maintain the integrity of the trials." It added that in large trials, illnesses will sometimes happen by chance but must be reviewed independently.

"We are working to expedite the review of the single event to minimise any potential impact on the trial timeline," the spokesperson added. It was not immediately clear where the patient was, or the nature and severity of their illness.
Holds during clinical trials are not uncommon, but this is thought to be the first time it has happened for a Covid-19 vaccine trial.

AstraZeneca is one of nine companies currently in late-stage Phase 3 trials for their vaccine candidates. In the US, the company began enrolling 30,000 volunteers across dozens of sites on August 31. The vaccine, called AZD1222, uses a weakened version of a common cold causing adenovirus that has been engineered to code for the spike protein that the novel coronavirus uses to invade cells.

After vaccination, this protein is produced inside the human body, which primes the immune system to attack the coronavirus if the person is later infected. (Source: NDTV)

Helping Russia Conduct Sputnik V Vaccine Trials, Make It In India

New Delhi: India has received Russia's request for conducting phase 3 human trials and manufacturing the Sputnik V coronavirus vaccine, the government said today. It said India is working to facilitate Russia's request.

"The government of Russia reached out to the government of India through appropriate channels and sought help on two fronts. One was to consider the manufacturing of the vaccine through a network of companies that are well-known for vaccine manufacturing and of size, volume and quality that is among the very best in the world. So the intention was that this can be manufactured by Indian companies at a large scale," said Dr VK Paul, who heads the national expert group on vaccine administration for COVID-19 and is also a member of the centre's think tank NITI Aayog.

"The second part of the request was that they have done phase 1 and 2 trials and the results were published in The Lancet last week. They want to know whether phase 3 trials could be conducted in India and for that what regulatory clearances are needed," Mr Paul said. "India attaches great importance to Russia's offer. It is an offer from a friend and one who has been a very special friend of the country. We reached out to several companies in India and three-four have responded well," Mr Paul said.

"Once a company is finalised and our regulatory clearances are in place, then trials will begin with Indian volunteers. The coming together of both nations is a win-win situation for both India and the world since we can produce in large quantities," he said. The Russian Health Ministry registered the first vaccine against COVID-19, named Sputnik V, on August 11. The vaccine has been developed by Moscow-based Gamaleya Research Institute of Epidemiology and Microbiology and triggered a "strong" immune response in phases 1 and 2 of the clinical trials on 76 people, according to researchers.

It is currently undergoing phase 3 trials in Russia. Russian Health minister Mikhail Murashko said the country will start mass inoculation from November or December, with a focus on high-risk groups. Trials of other vaccines are going on in India. The phase 3 human trials for Oxford University's vaccine Astra Zeneca will begin next week across 17 sites in India; 1,600 volunteers are participating. Currently, among India's two indigenous vaccines, Bharat Biotech's vaccine is about to begin phase 2 trial while Zydus Cadilla's vaccine is already in phase 2. (Source:NDTV)