



Up To 300% More Antibodies When Second Dose Delayed, Says Study



Levels of antibodies produced to fight off the virus are 20% to 300% higher when the follow-up vaccine comes later, new research shows. Faced with a limited supply of shots and anxious populations waiting their turn, more countries are turning to an initially controversial strategy that's now been vindicated by scientific studies: doubling or tripling the intervals between the first and second Covid vaccine dose.

A delay in getting the second shot not only allows the existing supply of shots to be more widely distributed, it boosts their protective power by giving the immune system more time to respond to the first inoculation. Levels of antibodies produced to fight off the virus are 20% to 300% higher when the follow-up vaccine comes

later, new research shows. That's welcome news for places like Singapore, which is grappling with a rare, albeit small, rise in cases after strict mitigation measures contained the virus last year. The city-state is now extending dose intervals -- previously three to four weeks -- to six to eight weeks, in order to reach a goal of covering its entire adult population with at least one shot by the end of August. India, facing a catastrophic outbreak, is advising 12 to 16 weeks between shots.

Other nations in similar straits - with few vaccine doses and antsy populations - are likely to follow. "If I could, I would push a button that says right now, this second, we give one dose to everybody we can reach," Gregory Poland, a virologist and director of the Mayo Clinic's Vaccine Research Group. "We'll get around to second doses later." "In the midst of a world on fire, you put out as many fires as you can, as quickly as you can," Poland said. The reassuring evidence on longer dosing intervals wasn't available when the vaccine rollout first started at the end of 2020. Then, countries limited their use to the highest-risk people and guaranteed a second shot was waiting for those segments. The U.K. was the first to abandon those constraints amid a massive outbreak in late 2020 - a move that was initially criticized but has now proved prescient. The research suggests that the first shot primes the immune system, allowing it to start making protective antibodies against the virus. The longer that response is allowed to mature, the better the reaction to the second booster shot that comes weeks or months later.

The benefits from longer dose intervals is being seen across all types of vaccines. People over 80 given a powerful mRNA vaccine from Pfizer Inc. and BioNTech SE had an antibody response that was 3.5-fold higher if the second shot came after three months, rather than three weeks. Other studies concluded that delaying the final shot for nine to 15 weeks averted more hospitalizations, infections and deaths, while one from Canada suggested the biggest benefit came from a six month delay.

There are drawbacks. The additional time between doses means it will take longer for countries to protect their populations. While one shot offers some level of benefit, people aren't considered fully immunized until several weeks after their second dose. The interval is particularly dangerous when less potent vaccines are being used or more transmissible variants of the virus are circulating. Some countries are pushing the boundaries. India's delay of three to four months between doses, among the longest in the world, means those scrambling to get vaccinated amid its current outbreak won't be fully protected until the summer or the fall. While studies suggest the optimal spacing between AstraZeneca shots is 12 weeks, there is scant data on the impact of stretching that to 16 weeks. The British drugmaker's shot accounts for the majority of inoculations in India now. The greater delay can also increase the logistical hurdles involved in getting millions of people to return to complete the series, especially if they feel they already have some coverage from the first shot. It's already difficult to get people in developing countries to return given transportation and communication challenges.

"When you have any kind of a two-dose schedule, it's hard logistically," said Gigi Gronvall, a senior scholar at the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health. "You worry about when people will come back for a second shot, or if you will lose them entirely." It's a tradeoff many places are willing to make, particularly given the limits on vaccine availability. With a new variant first identified in India already spreading in Singapore, officials want to administer a first dose to about 4.7 million people by the end of the summer. "We're vaccinating 40,000 people a day at the moment, so you can do the math and work out how long that'll last," said Dale Fisher, an infectious diseases professor at the National University of Singapore. "And that's a fairly rigid pipeline. It's not like you can just order more." By delaying the second dose, several hundred thousand people will get their first injection sooner, he said. "We're comfortable that there's no downside to this." (Source: NDTV)

E-pharmacies Are Signing Bulk Deals to Acquire COVID-19 Vaccines – But Are They Allowed to Do So?



Prashant Tandon, founder and CEO of 1mg, said they have roped in 600 corporates as partners and are now in talks with apartment complexes, societies and local clinics to provide vaccinations. Jefferies India in fact notes that private vaccinations in India can generate up to \$1.4 billion in revenues in FY22 – with the vaccine purchase ratio at 50:40:10 for Centre, states and private sector, respectively. E-pharmacies are in a race to secure deals with corporates, old-age homes, small clinics and residential complexes as the Indian government opened up COVID-19 vaccinations for the private sector from May 1. The development is being viewed as a

\$1.4 billion opportunity in FY22 for private healthcare service providers and talks are on with manufacturers — Bharat Biotech (homegrown Covaxin), Dr Reddy's (imported Sputnik V), and the Serum Institute of India (AstraZeneca's Covishield), for the stock, Mint reported. Prashant Tandon, founder and CEO of 1mg, told Mint that they have signed over 600 corporates as partners and are now in talks with apartment complexes and societies and local clinics to provide vaccinations. Practo, a digital health services company, saw expressions from 500 corporates for the first phase of its 'Corporate Suraksha' vaccination programme launched on May 3. Jefferies India in fact notes that private vaccinations in India can generate up to \$1.4 billion in revenues in FY22 – with the vaccine purchase ratio at 50:40:10 for Centre, states and private sector, respectively. Permissions worked out?

It was earlier reported that health aggregators were expecting to join the country's expanded vaccination drive and that players are in talks with the Centre-run CoWin platform to integrate systems and ensure that all vaccinations are counted. "We are waiting to get some clarity from the government as to when and how the private sector can participate; at 1mg we are keen to participate," Tandon told Moneycontrol. He said that besides vaccines, the company has put in place four key things like information about the vaccine, administration, supply chain and doctor consultation for a successful rollout. It isn't 1mg alone, other private sector players such as Apollo Hospitals, Portea Medical, Medlife, Reliance-Netmeds, and Pharmeasy have evinced interest to be part of COVID-19 vaccination, but are awaiting more clarity from the government.

But the government has not yet given any indication of allowing private sector participation in the COVID-19 vaccination drive. Is participation likely to be approved? Vaccinations have so far been opened up for private hospitals and clinics in India. But government sources are divided on whether pharmacies, clinics and e-pharmacies will be allowed. By regulation, pharmacists are not allowed to administer vaccines. However, an official told the Hindustan Times that since this was allowed for flu shots, it could be opened up for COVID-19 jabs too – but with riders. "This is something that was also done for the influenza vaccine; those who can pay are allowed to access the vaccine in private (market) with certain riders," said a senior official, who is part of the vaccine delivery process. On the other hand, another source told the Times of India that this is unlikely since COVID-19 vaccines are so far only listed for "emergency use", which removes the possibility of over-the-counter purchases.

"COVID vaccines are allowed under emergency licensure and, therefore, they cannot be sold at chemists. It is important to administer them in a proper set-up and follow the guidelines during immunisation. Besides, all these vaccination centres, including the ones at workplaces, are linked with AEFI management centres to ensure identification and investigation of any adverse reaction," an official said. While the government allowed the sale of COVID vaccines in the open market from May 1, the shots would not be available for sale at chemists or pharmacies. Only hospitals and approved vaccination centres can administer the vaccines. Another source told the Business Standard in January that pharmacies' participation is already under consideration. "We want the COVID-19 vaccine drive to be a mass movement and we would need participation from all walks of life. Pharmacists, too, are likely to be roped in," said the official in New Delhi.

Some are of the opinion that pharmacists will be allowed to join in the efforts only if India is able to secure enough vaccines. "The involvement of pharmacists will depend on the number of doses India gets," officials told Mint, adding that even if India gets enough doses, training will be a key part of the plan. By regulation, pharmacists are not allowed to administer vaccines. A move in this direction would likely require amendment or caveats to existing rules. Pharmacies do provide regular vaccine shots for flu, pneumonia and hepatitis-B, Tandon told Moneycontrol, adding: "We do vaccinations for flu shots, pneumococcal vaccine and hepatitis-B, we have the expertise." He added that training is also something they have taken into account. "What we are doing now is we are investing in setting up a cold chain for vaccine supplies; currently we have 500 trained technicians who can administer the vaccine, we are training a network of 5,000 to 10,000 vaccinators, we are in touch with a bunch of vaccine manufacturers for possible tie-ups," he added.

Besides India, the US is using its 'The Federal Retail Pharmacy Program' for COVID-19 vaccination, where the government has collaborated with 21 national pharmacy partners and independent pharmacy networks to increase access to vaccination across the country, as per the US CDC. Support to understaffed healthcare system. The move would infuse human resources in form of doctors, clinics and healthcare workers into the healthcare system beyond the 7,000 government and 7,000 private centres offering vaccinations at present. However, players are still awaiting clarity on Co-WIN integration. Jagannath Shinde, chairman, All India Origin Chemists and Distributors told BS that the country's 800,000-odd pharmacies would "enthusiastically participate if asked"

"If asked to participate, they are likely to be enthusiastic. Pharmacists are already training people to administer insulin injections. They are trained to administer a basic injection. We can plan to have refresher courses for the pharmacists and select a set of pharmacies in every city which would administer the COVID-19 vaccine," Shinde added. Rajiv Singhal, general secretary of All India Organisation of Chemists and Druggists also told BS that they are "ready to come forward if the training is given". He also noted that pharmacists "know very well how to maintain the cold chain and to keep the vaccine intact".

Gurpreet Sandhu, president, Council for Healthcare and Pharma and founder, Reva Pharma, said that while training will be needed and there is a requirement to change related laws and regulations, "8 lakh-strong pharmacists could play an important role in this". Experts are also of the opinion that adding pharmacists to the mix will allow larger coverage – subject to proper and mandatory training. "Training must include administering all types of injections—intramuscular, intravenous, subcutaneous, intradermal—so that the trained resources can be used for all types of vaccination programmes. They must also be trained for management of all untoward and adverse reactions to an injection," Raghavendra Prasad TS, founder, StepOne said. (Source: Money Control)

US Backs Covid Vaccine Patent Waiver Plan Proposed By India, South Africa



Biden had been under intense pressure to waive protections for vaccine manufacturers, especially amid criticism that rich nations were hoarding shots. Washington: US President Joe Biden's administration on Wednesday announced support for a global waiver on patent protections for Covid-19 vaccines, offering hope to poor nations that have struggled to access the life-saving doses.

India, where the death count hit a new daily record amid fears the peak is still to come, has been leading the fight within the World Trade Organization (WTO) to allow more drugmakers to manufacture the vaccines -- a move pharma giants oppose. US Trade Representative Katherine Tai said that while intellectual property rights for businesses are important, Washington "supports the waiver of those protections for Covid-19 vaccines" in order to end the pandemic.

"This is a global health crisis, and the extraordinary circumstances of the Covid-19 pandemic call for extraordinary measures," she said in a statement. Biden had been under intense pressure to waive protections for vaccine manufacturers, especially amid criticism that rich nations were hoarding shots. Tedros Adhanom Ghebreyesus, head of the World Health Organization (WHO), called the US decision "historic" and said it marked "a monumental moment in the fight against COVID19."

Tai cautioned however that negotiations "will take time given the consensus-based nature" of the WTO. With supplies for Americans secured, the Biden administration will continue efforts "to expand vaccine manufacturing and distribution," and will work to "increase the raw materials needed to produce those vaccines."

For months the WTO has been facing calls to temporarily remove the intellectual property protections on Covid-19 vaccines, known as a TRIPS waiver in reference to the agreement on Trade-Related Aspects of Intellectual Property. But that notion has been fiercely opposed by pharmaceutical giants and their host countries, which insist the patents are not the main roadblocks to scaling up production, and warned the move could hamper innovation.

"A waiver is the simple but the wrong answer to what is a complex problem," the Geneva-based International Federation of Pharmaceutical Manufacturers and Associations lobby group said, describing the US move as "disappointing." Countries such as New Zealand, however, welcomed the US announcement, while Australian Prime Minister Scott Morrison called the move "tremendous news," adding that it would help his country manufacture mRNA vaccines locally. France, on the other hand, has said it is opposed to the waiver, stating it prefers instead a donation-based model to help poor countries overcome a lack of vaccines. While the United States has reached the point of offering donuts and beer to entice vaccine holdouts to get their shots, India reported 3,780 new pandemic deaths and not enough doses to inoculate its people.

India has in recent weeks endured a devastating surge in coronavirus cases, with more than 380,000 infections reported on Wednesday. K Vijay Raghavan, the Indian government's principal scientific advisor, said the country of 1.3 billion people had to prepare for a new wave of infections even after beating down the current wave, which has taken the country's caseload above 20 million. In an effort to boost the country's collapsing health system, India's reserve bank announced \$6.7 billion in cheap financing for vaccine makers, hospitals and health firms. India's crisis has been partly fueled by a lack of vaccines. This has in turn exacerbated the global shortage as India is the world's biggest producer of Covid shots.

In London, foreign ministers from the Group of Seven wealthy democracies committed to financially support the vaccine-sharing program, Covax. But there was no immediate announcement on fresh funding. On the opposite end of the spectrum, Denmark, where the spread of the virus has been deemed under control, will open up cinemas and theaters plus gyms and fitness centers Thursday. And bars, cafes and restaurants, which have already reopened, will no longer require reservations.

All patrons, however, must present a "corona pass" certificate confirming they have either tested negative in the past 72 hours, been vaccinated or recently recovered from Covid-19. The pandemic has claimed more than 3.2 million lives worldwide since it first emerged in late 2019, but many wealthy nations have made progress in suppressing the virus as mass vaccination campaigns gather steam. More than 1.2 billion doses have been administered globally, but fewer than one percent in the least developed countries.

Vaccine shortages are not an issue in the United States, which could soon be sitting on as many as 300 million extra doses -- nearly equivalent to its entire population. Biden on Tuesday said he wanted 70 percent of US adults to have received at least one shot by the July 4 Independence Day holiday. He also said his administration was "ready to move immediately" if regulators authorize the Pfizer-BioNTech vaccine for 12- to 15-year-olds. But some experts question the wisdom of devoting limited vaccine supplies to a low-risk group instead of sharing them with high-risk groups abroad. In the Middle East, Egypt announced a partial shutdown of malls and restaurants and called off festivities for the Muslim holiday of Eid al-Fitr to curb rising coronavirus cases. And on Wednesday Argentina broke its record for Covid-19 deaths with 633 recorded fatalities in 24 hours, despite stepped-up measures to reduce movement of people across the country. (Source: NDTV)

Pharma Industry Warns Of Covid Drug Shortages As Raw Materials Prices Surge 200%



New Delhi: As India struggles with the worst surge in Covid cases since the beginning of the pandemic last year, the price of raw materials used to manufacture key Covid drugs has jumped by up to 200 per cent in the past one month. Drug makers have voiced their concern about the price hike to the government, and many have also talked about the possibility of shortage of key medicines in the coming months, owing to the price rise and unavailability of raw materials in the market.

According to data accessed by ThePrint from the pharmaceuticals industry, the prices of many active pharmaceutical ingredients (APIs), such as ivermectin, methylprednisolone, doxycycline, enoxaparin, paracetamol, azithromycin, meropenem and piperazine, needed for the production of key Covid medicines, have gone up by approximately 30-200 per cent in the past one month, between March to April 2021. Drug-makers are struggling with the frequent fluctuations in prices and termed the situation as “alarming”.

“Traders and manufacturers of these raw materials are quoting different prices, sometimes within a span of four hours. The situation is very bad. If there is no intervention [from the government], there is a high probability of shortages of medicines in the coming months,” said Sandeep Arora, chief executive officer of the Baddi-based, Ultra Drugs. Baddi, in Himachal Pradesh, is the hub of medicine production in India. The suspension of Chinese cargo services to India, impacting the import of pharmaceutical raw materials, has added to the industry’s worries.

India imports 70 per cent of its pharmaceutical raw materials from China. On 26 April, China suspended for 15 days cargo flights by Sichuan Airlines that had been transporting medical supplies to India. This, according to industry insiders, has led to a hoarding of important pharmaceutical raw materials. In a letter written to Minister of External Affairs Dr S. Jaishankar on 29 April, the IDMA termed China’s move as “worrisome” and expressed concern that it would have “cascading effects on its entire supply chain leading to shortage of essential medicines for the nation’s population as well as severe impact on exports”.

Arora too said that “with China suspending cargoes to India, there is going to be a huge shortage [of vital drugs], especially in June and July. Even simple products such as azithromycin, paracetamol, and montelukast [needed for manufacturing medicines] might be in short supply.” ThePrint reached S. Aparna, secretary, Department of Pharmaceuticals (DoP) and Shubhra Singh, chairman of drug availability watchdog National Pharmaceutical Pricing Authority (NPPA) for comment over text messages, but there was no response till the publication of this report. The shortage of oxygen needed in manufacturing APIs — India is currently facing a huge shortage of medical oxygen owing to the demands of Covid patients — and shortage in manpower for production, because of the pandemic, are other reasons being forwarded for the short supply of pharmaceutical raw materials.

The pharmaceuticals industry had already presented their concerns to the government about the “unprecedented” hike in raw material prices on 5 April. The Indian Drug Manufacturers Association (IDMA) — the country’s biggest lobby of drug-makers — in a presentation to the Centre on 5 April, raised the issue of “unprecedented” increase in prices of raw materials needed for the production of key drugs. The presentation, accessed by ThePrint, also mentioned that “the gyrating prices of many raw materials are a cause of serious concern”. “The huge escalation in input and transportation cost and their cascading effect on the pharmaceutical value chain throws up severe challenges in maintaining the viability of the pharma business for many of our members,” Ashok Madan, executive director, IDMA told ThePrint. The association represents over 1,000 pharma companies. Its members include Torrent Pharmaceuticals, Lupin, Cipla, Sun Pharma and Jubilant Life Sciences.

A senior official at one of the country’s leading pharmaceutical companies told ThePrint, on condition of anonymity, that the “pricing situation is very bad. Prices have increased drastically and availability [of raw materials] is also a big issue.” The official also warned of possible shortage of critical medicines in the near future. “Of course, if raw materials are not available or are highly expensive, many drug-makers will stop the production.

This will lead to a shortage. The situation is very alarming,” he said. Why the price surge? The main reason behind the surge in prices, according to industry insiders, is a huge demand for drugs, followed by anticipated shortages of raw material (owing to the suspension of cargo services by China), resulting in the hoarding of stocks here. “The news of cargoes to India being suspended by China led to the stocking up of raw materials and escalation of prices. In fact, artificial shortages were created by some traders,” said Arora of Ultra Drugs. Another reason is the reduced supply of oxygen for raw material manufacturing within the country.

“The production of many APIs and intermediates — needed for manufacturing drugs — require oxygen supply. But there is limited oxygen supply now,” said an executive at a Mumbai-based listed pharma company, on the condition of anonymity. The other big problem, according to him, “is none of the manufacturing plants are working on full manpower capacity, because either the employees or their family members are infected with Covid.” (Source: The Print)