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NEWS LETTER
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# Vaccines: 200 years of progress and scepticism


Covid-19 has been a shot in the arm for vaccine research with several viable jabs in production less then a year after the disease emerged. Yet four in 10 Americans, and six in 10 French people say they will not get vaccinated against the virus, even if the shot is free. We look at the history of vaccines over the last two centuries, with scepticism about them never far away. - 1796: Eureka! - Deadly and highly contagious smallpox, transmitted through open sores that scarred millions for life, ravaged populations for centuries until English doctor Edward Jenner notices that milkmaids who got cowpox never get smallpox.

In 1796 he inoculates a child with the harmless version of the disease to stimulate an immune response. Despite repeated exposure, the child never falls ill. Vaccination is born. - 1853: Poxy policy - The smallpox vaccine becomes mandatory for all British children in 1853, but this provokes an immediate backlash. Many object for religious reasons or see the policy as infringing of individual liberties. A conscience clause is added to the law in 1898 to allow people to opt out. - 1885: Pasteur and rabies - French scientist Louis Pasteur develops a rabies vaccine from a more benign strain of the disease.

It appears successful when he gives it to a child bitten by a rabid dog. Vaccine sceptics however accuse Pasteur of trying to develop "laboratory rabies" to increase his profits. - 1920s: TB, diphtheria, tetanus - A vaccine against typhoid is developed at the end of the 19th century, followed by several crucial shots in the 1920s: the 1921 Bacille Calmette-Guerin (BCG) vaccine against tuberculosis and shots against diphtheria in 1923, tetanus in 1926 and whooping cough in 1926. It is also in the 1920s that aluminium-containing agents are first used in vaccines to increase their efficiency -- an ingredient that will spark vaccine scepticism later on, especially in France. - 1944: Flu vaccine - The first vaccine campaign against the seasonal flu targets US soldiers fighting in Europe in 1944-45, with a new shot developed each year.

In the 1950s, when polio vaccination was a US government priority, megastar Elvis Presley lent himself to the cause, getting the shot live on the primetime "Ed Sullivan Show". In the 1970s a campaign to innoculate Americans against a supposedly devastating strain of swine flu grounds to a halt, however, when the pandemic fails to materialise and some 450 of those vaccinated unnecessarily develop Guillain-Barre syndrome which can cause paralysis. The incident continues to fuel vaccine scepticism. - 1980: Smallpox wiped out - The last natural case of smallpox is diagnosed in Somalia on October 26, 1977 and the World Health Organization (WHO) declares the illness officially eradicated in 1989 thanks to a global vaccination campaign.

A similar campaign to eradicate polio has been hugely successful, wiping it out in Africa. The disease lingers on in Pakistan and Afghanistan because some religious leaders claim the shot is a plot to sterilise Muslim children. - 1998: Fake study, real damage - In 1998 a study published in the prestigious Lancet medical journal suggests a link between the MMR (measles, mumps and rubella) vaccine and autism. The main plank of it, however, had been falsified by its author Andrew Wakefield who was later barred from the profession. Yet the debunked study is still cited by "anti-vaxers". - 2009: H1N1 debacle - In 2009 an H1N1 -- or swine flu -- outbreak sets off alarm bells around the world. Although related to the infamous 1918 flu strain, the virus turns out to be far less consequential, killing just 18,500 people. The waste from millions of unused vaccines prompts criticism of the WHO's handling of the outbreak. In addition, Sweden, where more than 60 percent of the population were vaccinated, was traumatised when hundreds of people who got the jab were later diagnosed with narcolepsy. (Source: ET HealthWorld.com)

## Covid: How the War on the Virus Attacked Freedom in Asia

Safoora Zargar was more than three months pregnant when she was arrested in the Indian capital Delhi for participating in a protest against a controversial citizenship law. It was 10 April, and the pandemic was just beginning to take root in India. The government's own advice said pregnant women were particularly vulnerable to infection, but for more than two months she was held in the overcrowded Tihar jail. "They'd tell other prisoners not to talk to me. They'd told them I was a terrorist who'd killed Hindus. Now these people didn't know about the protests, they didn't know I was jailed for participating in a protest," she told the BBC's Geeta Pandey in Delhi after her release.

Her crime had been tking part in widespread protests against the law which critics say targets the Muslim community. The demonstrations had captured the imagination of the country and attracted global attention. But there were no protests in the street demanding her release. There couldn't be: India was under one of the world's strictest lockdowns, with people confined to their homes. Her arrest was one of many which took place during this time.

And it was not just India. Activists say numerous governments across Asia used the cloak of coronavirus to implement laws, carry out arrests, or push through controversial schemes which otherwise would have sparked a backlash, both at home and abroad. But instead of a backlash, many governments have seen their popularity increase as people turned to them for direction during the crisis. "The virus is the enemy and people are put on a war footing. This allows governments to pass oppressive laws in the name of 'battling' the pandemic," Josef Benedict of Civicus, a global alliance of civil society organisations and activists, told the BBC. (Source:BBC)

## Narayana Health, Mazumdar Shaw Medical Foundation launches MSMF MedTech Innovation Centre in Bangalore

New Delhi: Narayana Health in association with Mazumdar Shaw Medical Foundation announced the launch of a physical incubator called Mazumdar Shaw Medical Foundation (MSMF) MedTech Innovation Centre - BIRAC BIONEST.

A centre with a dedicated space of around 8000 sqft Mazumdar Shaw Medical Foundation (MSMF) MedTech Innovation Centre - BIRAC BIONEST will help MedTech entrepreneurs who are looking to address affordability, access and innovation challenges in the healthcare eco-system. The MedTech Innovation Centre will also augment further the initiatives undertaken by Mazumdar Shaw Medical Foundation and Narayana Health towards identifying, mentoring and handholding entrepreneurs and innovators in their journey to success. The space will facilitate close interaction and prototyping facility too for startups. “India has the potential to become the next global R&D hub for biomedical devices and health technologies, and the Mazumdar Shaw Medical Foundation (MSMF) MedTech Innovation Centreat Narayana Health City, in collaboration with BIRAC will help explore this potential. It will provide health tech entrepreneurs a well-equipped incubation space and a collaborative ecosystem. Through MSMF MedTech Innovation Centre we aim to fill the gap in healthcare innovation to have a single platform for entrepreneurs to co-create and identify clinical challenges in conjunction with doctors, scientists and technology enthusiasts.

The wealth of research and medical data generated at Narayana Health will provide a translational science model, accelerating the lab to market journey of innovative and promising solutions discovered and developed at MSMF MedTech Innovation Centre,” said Kiran Mazumdar-Shaw, Founder, Mazumdar Shaw Medical Foundation (MSMF) and Chairperson, Biocon. Inaugurating the centre Dr. Devi Prasad Shetty, Founder and Chairman, Narayana Health said, “Innovation is key to solve the healthcare concerns that we are currently facing and I am very glad that we have been able to create a platform that nurtures the creation of innovative solutions. MSMF’s vision is to fill the gap in healthcare innovation by creating a single platform for entrepreneurs to co-create solutions in conjunction with doctors, scientists and technology enthusiasts. We are hopeful the physical incubator will provide the much needed facilities that startup look for to progress with their innovation.

While we have been able to support over 25 startups through our other programs like Clinical Immersion Program (CIP) and our partnership with VC Firms like, Villgro and Axilor. We also have international collaborations too with Japanese and Korean startups through JETRO and GAIN respectively.The physical infrastructure will help us to further strengthen our mission as the infrastructure can support 39 start-ups at any given point of time with the total seating capacity of 82. We are looking at nurturing 10 startups in 2021.” An extension of the existing CIP, apart from providing physical infrastructure, the centre will continue to provide start-ups access to the clinical expertise of Narayana Health. Each of the startups incubated in the centre will be paired with a clinician with whom they can co-create the innovation, device the right clinical validation pathway to prove the product in a hospital setup.

The centre is also recognised by both Department of Science and Technology and Department of Biotechnology-BIRAC, hence the startups get access to multiple grant opportunities through these agencies. The Centre also has a prototyping lab comprising of - mechanical, electronics and AI labs. These labs give the startups a facility to build and iterate medical devices or healthcare AI platforms and test it within the departments of Narayana Health. (Source: ET HealthWorld)

# FDA approves second Covid Vaccine for emergency use as it clears Moderna's for U.S. distribution

The Food and Drug Administration has approved Moderna's coronavirus vaccine for emergency use. The vaccine — the second approved for use in the U.S. behind Pfizer and BioNTech's — bolsters the U.S. supply of doses. The potentially lifesaving shots are desperately needed to fend off the pandemic that has taken more than 300,000 American lives and overwhelmed hospitals. The FDA's emergency use authorization Friday approves the federal government's plan to distribute roughly 5.9 million doses of Moderna's vaccine to 64 states, territories and major cities across the nation next week. "We likely will see shots in the arm by the very early part of next week, I would hope Monday or Tuesday," Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, said on the "Today" show on Friday morning. President Donald Trump said in a tweet: "Congratulations, the Moderna vaccine is now available!"

In addition to Moderna's vaccine, the U.S. also plans to send out 2 million doses of Pfizer's vaccine after 2.9 million doses were cleared for shipment this week, Gen. Gustave Perna, who oversees logistics for the Operation Warp Speed vaccine project, said Monday. Both vaccines require two doses three to four weeks apart. Moderna's Covid vaccine is its first-ever FDA authorized product. "With the availability of two vaccines now for the prevention of COVID-19, the FDA has taken another crucial step in the fight against this global pandemic that is causing vast numbers of hospitalizations and deaths in the United States each day," FDA Commissioner Dr. Stephen Hahn said in a statement. U.S. officials hope to vaccinate at least 20 million Americans — mostly front-line health-care workers and nursing home residents — by the end of the year. Initial doses will be limited as manufacturing ramps up, with officials predicting it will take months to immunize everyone in the U.S. who wants to be vaccinated. The Centers for Disease Control and Prevention has provided states with an outline that recommends prioritizing health workers and nursing homes, but states can distribute the vaccine as they see fit. Already, states are reporting confusion about vaccine plans. In recent days, state officials said they learned their second shipment of Pfizer's vaccine would be smaller than expected or delayed. In Florida, for example, Republican Gov. Ron DeSantis said the federal government told him the state would receive 205,000 Pfizer vaccine doses next week and 247,000 the following week. Those shipments are now on hold, DeSantis said at a press conference Tuesday, and it's unclear when they will arrive. Moderna's vaccine, like Pfizer's, uses messenger RNA, or mRNA, technology. It's a new approach to vaccines that uses genetic material to provoke an immune response. Late-stage clinical trial data published last month shows Moderna's vaccine is more than 94% effective in preventing Covid, is safe and appears to fend off severe disease. To achieve maximum effectiveness, the vaccine requires two doses taken four weeks apart.

The FDA has indicated it would authorize a Covid-19 vaccine that's safe and at least 50% effective. The flu vaccine, by comparison, generally reduces people's risk of getting influenza by 40% to 60% compared with people who aren't inoculated, according to the CDC. The FDA authorized Moderna's vaccine for people who are 18 years old and older. Such an authorization from the agency isn't the same as full approval, which requires more data and can typically take several months longer. Moderna has submitted only two months of follow-up safety data. The agency usually requires six months for full approval and can always revoke an EUA for a drug if it doesn't work as intended or proves to be unsafe. The FDA approved the emergency use of hydroxychloroquine to treat Covid-19 in March, only to revoke it in June after additional data showed it provided "no evidence of benefit" in coronavirus patients. The FDA's announcement comes after a key agency advisory panel on Thursday voted 20-0 with one abstention to recommend the vaccine for emergency use. The Vaccines and Related Biological Products Advisory Committee plays a key role in approving flu and other vaccines in the U.S., verifying the shots are safe for public use. While the FDA doesn't have to follow the advisory committee's recommendation, it often does.

Prior to the vote, some members of the committee stressed that their endorsement of Moderna's vaccine was not for a full FDA approval, reiterating that the agency will still need to review more data on safety and effectiveness. At the meeting, outside medical experts asked the agency about allergic reactions reported in two Alaskan health-care workers who took Pfizer's vaccine. Doran Fink, deputy director of FDA's division of vaccines and related products applications, said the agency is looking into the issue. "As we continue to investigate and evaluate the data, we will consider whether additional recommendations need to be made," he said. "At this point, we don't have enough data to make a definitive recommendation one way or the other."

Fatigue, headaches and muscle pain are the most common side effects from Moderna's vaccine, along with some rare symptoms such as intractable nausea or vomiting and facial swelling that are likely triggered by the shots, according to the FDA. Some side effects were hard to shake, though most resolved within a week, the FDA said. The FDA said that, though it is not necessarily a side effect, it recommends monitoring people who get Pfizer's or Moderna's vaccine shots for possible cases of Bell's palsy, a condition that causes sudden freezing or weakness in facial muscles.

The agency also noted a higher prevalence of lymphadenopathy, a disease that can produce swollen or enlarged lymph nodes, in Pfizer's and Moderna's trials in the vaccine group compared with the placebo groups. Moderna has said its vaccine remains stable at 36 to 46 degrees Fahrenheit, the temperature of a standard home or medical refrigerator, for up to 30 days. It can be stored for up to six months at minus 4 degrees Fahrenheit. By comparison, Pfizer's vaccine requires a storage temperature of minus 94 degrees Fahrenheit. The federal government announced last week that it will purchase an additional 100 million doses of Moderna's vaccine. The U.S. entered into an agreement with Moderna in August to acquire 100 million doses for about $1.5 billion. Moderna said that month it was charging $32 to $37 per dose for its vaccine for some customers, under cheaper "pandemic pricing." The company said it was in discussion for larger volume agreements that will have a lower price. (Source: CNBC)

## US Steps Closer to Vaccine Approval Amid Row Over 'not Purchasing More Doses'


US regulators stepped closer to approving the Pfizer Covid-19 vaccine on Tuesday as a 90-year-old British woman became the first person outside of trials to receive the shot, offering hope of slowing a pandemic that has pushed hospitals to the brink.

Meanwhile, the Trump administration sought to shore up the US vaccine supply and Congress progressed toward a stopgap Covid-19 relief package on Monday, when another 203,474 infections were reported and 1,582 people died. Pfizer Inc is on the cusp of winning US approval for the vaccine it developed with Germany's BioNTech, clearing a hurdle on Tuesday when the US FDA released documents that did not raise any new issues about its safety or efficacy. Britain has already authorised the Pfizer vaccine, enabling Margaret Keenan, 90, to receive the first shot at her local hospital in Coventry in central England. While China and Russia have gone forward with their own vaccines, Britain is the first Western nation to begin mass inoculations.

The US could soon follow as an FDA panel of outside advisers will meet on Thursday to discuss whether to recommend emergency use authorisation of the Pfizer vaccine.US health officials predict a swift green light with inoculations starting days or weeks later. President Trump will sign an executive order on Tuesday to ensure that priority access for Covid-19 vaccines procured by the US government is given to the American people before assisting other nations. The signing follows a New York Times report that Pfizer may not be able to provide more of its vaccine to the US until next June because of its commitments to other countries.

The Washington Post also reported that the Trump administration months ago passed on the chance to buy twice as many as the 100 million doses they agreed to. Pfizer had urged the Trump'ss Operation Warp Speed program to purchase 200 million doses, enough for 100 million people as the vaccine is administered in two shots, the Post reported. White House press secretary Kayleigh McEnany denied the reports "The administration didn't pass. We contracted with many other firms." Moncef Slaoui, a leader of Operation Warp Speed, said on Tuesday: "We have committed to have enough vaccine doses to immunise the full population by middle of the year, 2021." (Source: ET Health World)

## WHO pre-qualifies Biological E's Typhoid Conjugate Vaccine

Hyderabad-based Biological E. Limited (BE) announced that its Tphoid Conjugate Vaccine (TCV) has been pre-qualified by the World Health Organisation (WHO). With this pre-qualification, BE became one of two pre-qualified suppliers of TCV to the UN agencies. BE's TCV is a single-dose injectable vaccine, which can be administered to children from 6 months of age to adults up to the age of 45 and it is formulated with Vi polysaccharide conjugated to a carrier protein (CRM197). The Vi polysaccharide antigen used in BE's TCV is derived from C. freundii, which is a non-pathogenic source (BSL 1 organism), compared to virulent Salmonella Typhi used by other manufacturers, and the carrier protein used for conjugation is a non-toxic CRM197 protein locally developed by BE through in-house R&D effort. Clinical studies conducted in India have shown that the safety and immunogenicity profiles of this vaccine are comparable with those of the other WHO pre-qualified TCV. BE offers this vaccine as single-dose and multi-dose vials for ease of administration.

The vaccine was developed in collaboration with the GSK Vaccines Institute for Global Health (GVGH), based in Siena, Italy, which first developed the vaccine strain and transferred the technology to BE in 2013. BE has further developed the vaccine, including manufacturing process optimization and scale up, pre-clinical studies and comprehensive clinical trials for Phase I, II/III in India. Today, this vaccine is being manufactured in BE's GMP manufacturing facilities in Hyderabad, India.

"This is a remarkable accomplishment and a significant milestone in the journey of our vaccines. I am delighted that we have been able to produce a new WHO pre-qualified vaccine. We believe that every year this vaccine would save about 1.5 Lakh people worldwide," said Mahima Datla, Managing Director, Biological E. Limited. "GSK, through its R&D efforts at GVGH, is proud to have played an essential role in providing technologies to Biological E for their Typhoid Conjugate Vaccine (TCV)," said Francesco Berlanda-Scorza, GVGH Director. For more than a decade, GVGH has been advancing vaccines for under-recognised diseases, and as a result of an innovative partnership with Biological E to develop this vaccine, and TCV prequalification by WHO, many more children will have access to a much-needed intervention for the prevention of typhoid fever."

In March 2020, BE received approval from India's health regulators to authorise and market a new TCV (BE's product TYPHIBEV) for infants, children and adults from 6 months. This pre-qualification from WHO allows BE to make a significant contribution to unmet public health needs in developing countries by helping to protect children against typhoid and helping to secure the supply of vaccines against typhoid. (Source: ET HealthWorld)