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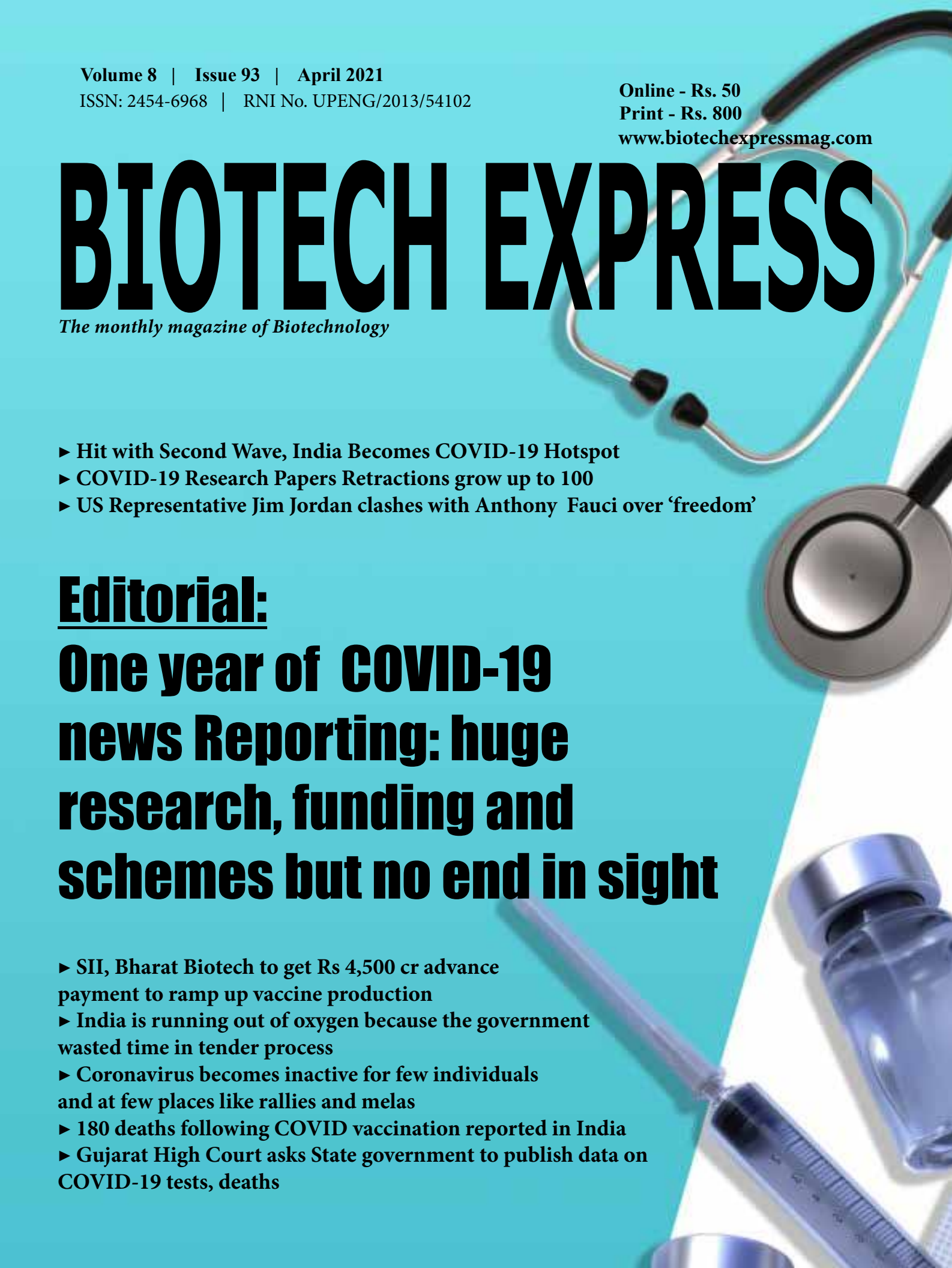
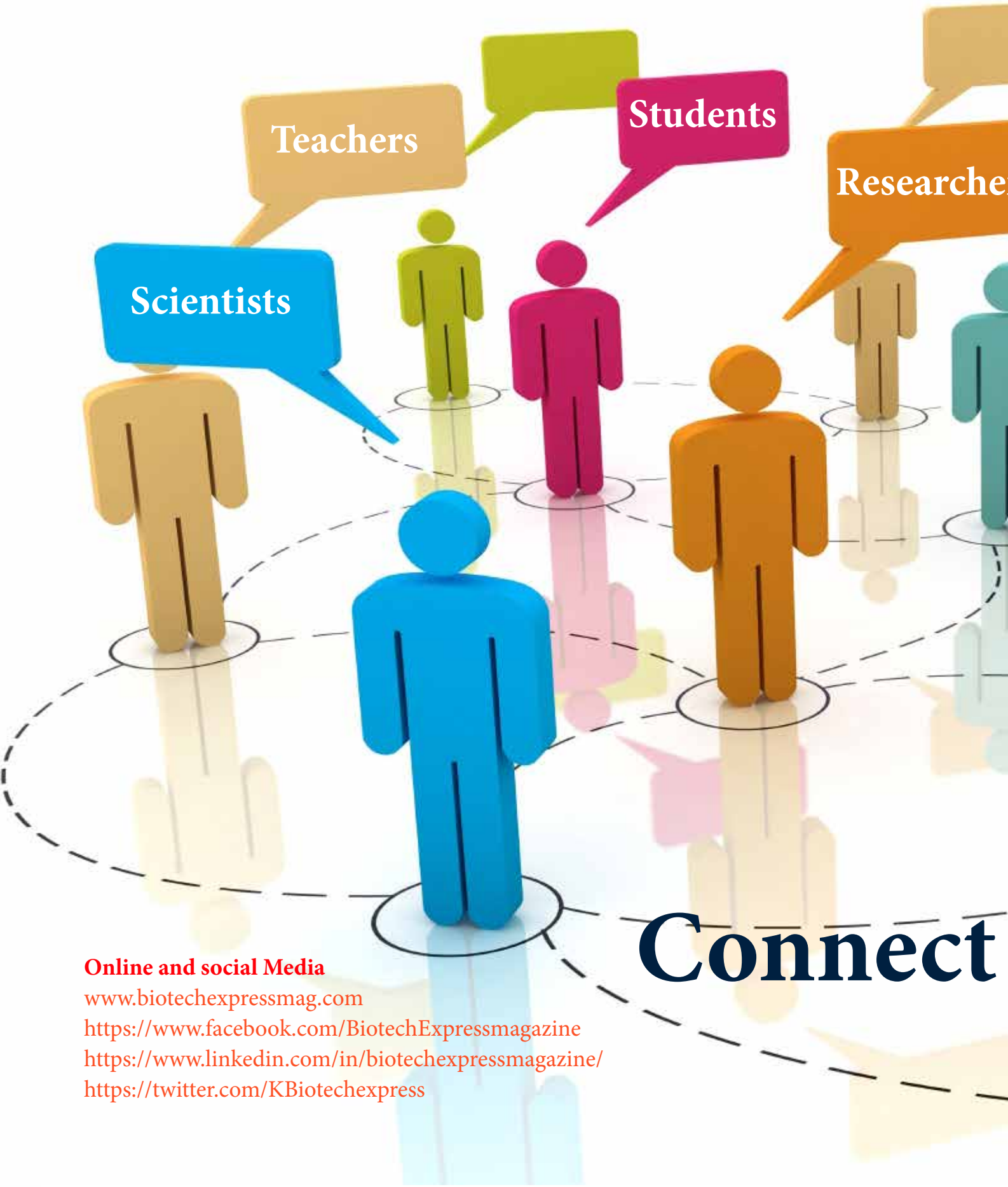


- Hit with Second Wave, India Becomes COVID-19 Hotspot
- COVID-19 Research Papers Retractions grow up to 100
- US Representative Jim Jordan clashes with Anthony Fauci over 'freedom'

Editorial:

One year of COVID-19 news Reporting: huge research, funding and schemes but no end in sight

- SII, Bharat Biotech to get Rs 4,500 cr advance payment to ramp up vaccine production
- India is running out of oxygen because the government wasted time in tender process
- Coronavirus becomes inactive for few individuals and at few places like rallies and melas
- 180 deaths following COVID vaccination reported in India
- Gujarat High Court asks State government to publish data on COVID-19 tests, deaths



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BIOTECH EXPRESS

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From the desk of Editor

Entrepreneurship and startups are only a recent phenomenon in the country. It is only in the last decade and half that people in the country have moved from being job seekers to job creators. Doing a startup is tough and every country sees more failures than success. More often than not an entrepreneur needs to be prepared to face failures and unprecedented hardship.

Having a brilliant idea is different from making that idea a business success. For a startup, it is very important to have mentors who have been through a similar process of starting or have business experience. A great mentor is often what separates success from failure by providing valuable inputs. However, there is no formal mechanism to mentor startups in the country. Every mentoring that happens is on an ad-hoc basis. A startup that has raised funds can count the investors for some form of support.

Government is the single largest enabler for the entrepreneurial ecosystem. Government's role in ease of doing business and helping companies start is vital to ensuring success.

In this and subsequent issues we will discuss various aspects that need discussion around start-up culture in biotechnology in India and welcome suggestions and comments from our readers in this respect so to gather and disseminate different opinions from diverse background of people involved in this field.

Dr. Seema P. Upadhye

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From the very first issue, Biotech Express team has been delivering what's best for Biosciences community. The audience of this magazine includes students, researchers, faculties and executives of highly prestigious organizations of India. In year 2016, BEM has made new editorial Board combining experience of eminent Advisory Board Members who have been into Award winning Research and head prestigious Administrative positions.

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Editorial

One year of COVID-19: huge research, funding and schemes but no end in sight

Kamal Pratap Singh

Dr. Anthony Fauci during House of Representatives panel on the COVID-19 pandemic on 13th April 2021, faced angry questions from Republican congressman Jim Jordan, who demanded to know when Americans could "get their liberty and freedoms back."

Source: Reuters on YouTube-https://www.youtube.com/watch?v=PiuOAA5esCc

Abstract: The COVID- 19 is in existence since more than a year and still no one, not even Anthony Fauci himself is sure to answer that how much time it will take to come to normal. Scientific claims and political scenarios have made the situation worst in some parts of the world and thus common man has been suffering from all of this. In this article, the author has been trying to understand various aspects that can clear our doubts about coronavirus and handling of future activities in regard to this or any other similar biological pandemic. Here the author has articulated points that may raise the doubts over the COVID- 19 and its lethality and thus compel us to analyze situation if it needs more attention or should become normal like many other viruses that exists on the earth. The huge misinformation spread around the pandemic but Biotech Express(BE) always put forward science based articles even when the misinformation spread by scientific leaders around the world. Biotech Express has always tried to contain fact checked information about CoV because we understand the importance of misinformation. Here in this article, I have analyzed our article and news reporting over the past one year to make forecast about the pandemic.

It all started after the statement from Tedros which then created so much chaos around the world because he was head of most prestigious health organization i.e WHO, when he came to conclusion of declaring pandemic without any concrete scientific evidence. We will discuss how common man suffered from scientific community in later sections.

Firstly, we have covered all important aspects of COVID-19 pandemic be it scientific and non-scientific through editorials and guestorials **(Table 1).** Let us see what different aspects are covered and analyze the facts in conclusion.

The first article on CoV in Biotech Express appeared in February 2020 as short article, long before COVID-19 was

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Table 1: List of COVID-19 related articles published in Biotech Express from March 2020-March2021

S.No Article	Issue -Year	Type of Article	Title of Article	Author(s)
1	Feb-20	Guest Article	Novel Coronavirus: A Biological bombshell	Sonia Goel and Jasina Arora from SGT University, Gurugram, Haryana
2	Apr-20	Editorial	All you need to know about SARS-CoV2 and COVID-19 disease	Kamal Pratap Singh, Managing Editor, Biotech Express
3	Apr-20	Expert Views: Virology	How to Tackle Coronavirus Transmission and Possible Route of Exit from Lockdown	Expert: Prof Ramareddy V Guntaka, Professor, Microbiology, Immunology & Biochemistry, University of Tennessee, USA and Owner, Sudarshan Biotech, India
4	Apr-20	Editorial	Why India has gain advantage over COVID-19 pandemic? A lesson till now	Kamal Pratap Singh and Vaibhav Sharma, PhD fellow, AIIMS
5	Apr-20	Expert Views: Mental Health	Meet your mental health experts for COVID-19 related stress	Experts: Dr Rachna Agarwal, Dr Om Prakash from IHBAS
6	Apr-20	Analysis	Impact of COVID 19 on global and Indian Economy	Biotech Express Bureau
7	Apr-20	Analysis	SARS COVID-19 Diagnosis: Past present and future	Biotech Express Bureau
8	Apr-20	Analysis	Race against COVID-19 Treatment	Biotech Express Bureau
9	May-20	Editorial	Why Indian Bioscience Response is Not Enough to Curb Global "COVID-19" Biological Pandemic: What Are We Missing?	Kamal Pratap Singh and Seema Pavgi Upadhye
10	May-20	Letter	To PM, India, from Virology Expert	Prof Ramareddy V Guntaka, Professor, Microbiology, Immunology & Biochemistry, University of Tennessee, USA and Owner, Sudarshan Biotech, India
11	May-20	Editorial in News:	India's Pioneer Scientific Work towards the COVID-19 vaccine	Prof Shailendra K Saxena, King George Medical University
12	May-20	Editorial	Detection of Viruses in Sludge, Effluents and Waters - The Case of COVID-19	Sunita Varjani et al. from Gujarat Pollution Control Board,
13	May-20	Expert Views: Stem Cells	Stem Cells as Clinical and Research Tools For COVID-19	S Dravida, PhD, Founder, CEO, Transcell Biologics
14	May-20	Policy:	No Funds for Science in Atma Nirbhar 20 lakh crore Package	by Biotech Express Bureau
15	Jun-20	Editorial:	Does information from preprints servers serves purpose in a pandemic like COVID-19?	Kamal Pratap Singh
16	Jun-20	Editorial:	A correlation between environmental deterioration and Pandemic	Seema Pavgi Upadhye
17	Jun-20	Guest Article:	Coronavirus and the heat - A realistic perspective	Rama S Verma and Steffi SV from Department of Biotechnology, IIT- Madras, Chennai
18	Jun-20	Guest Article:	COVID-19 and Primary Health Infrastructure: Is Rural India in Ruins?	Sukanya Chakraborty and Aparajita Chattopadhyay from IISER- Berhampur & International Institute of Population Sciences, Mumbai

19	Jun-20	Guest Article:	Disinfection – A silent soldier	Hridya Susan Varughese, Veterinary College, Bengaluru
20	Jun-20	Views:	Are FDA and WHO Puppet of The Lancet, NEJM and such journals? The case of HCQ in COVID-19	Anonymous Writer
21	Jul-20	Update	List of COVID-19 drugs from India	Update on July 16, 2020 by Dr Seema Pavgi Upadhye
22	Jul-20	Views	Rs. 100 crore from PM CARES Fund for COVID-19 vaccine to PSA to PMO: Progress till now?	Sumit Kumar
23	Jul-20	Analysis	Fake Misleading And Controversial News Surrounding COVID-19 Pandemic	Kamal Pratap Singh
24	Aug-20	Interview	How to approach COVID-19 as biopreneur? Talk with Dr Ram S Upadhayaye	Interview - Dr Ram S Upadhayaye
25	Aug-20	Review Article	An Insight About COVID-19: The Deadly Pandemic	Arti Pandey from Ram Sewak Singh Mahila College, BRABU Muzaffarpur, Bihar
26	Sep-20	Editorial in News	FIRST BOOK on COVID-19 edited and authored by Professor Shailendra Kumar Saxena and published by Springer Nature	Kamal Pratap Singh
27	Sep-20	Guestorial	Mental Health Hazards during and after COVID-19 like Pandemics	Dr. Maneesha Phadke

declared an emergency (Article 1, Table 1), the article was an introductory article only because BE has covered many viruses like Zika, MERS etc. during their outbreaks and those subsided soon.

Since COVID-19 was declared emergency on March 11, an info article was then published in March 2020 issue to give complete scientific information to scientists and audience about origin, classification, identification, naming, structure, genome, transmission, infection, diagnostic tests, treatment and other important aspects of novel CoV (Article 2, Table 1). In the same issue BE published an interview of Prof Ramareddy V Guntaka who was the then Professor in Department of Microbiology, Immunology & Biochemistry at University of Tennessee, USA, was pioneer of recombinant Hepatitis B vaccine R&D in Shantha Biotech, India and was the first scientist to molecularly clone the entire genome of Rous Sarcoma Virus. In this interview, he discussed how to do contact tracing and other alternatives to exit lockdown situation (Article 3, Table 1). In another article, BE discussed how India because of its obedient citizens have gained advantage over COVID-19 situation when many developed nations were reporting high incidence and mortality (Article 4, Table 1). Because it was the first time that the whole world was under lockdown, we discussed mental health aspects with two neurobiologists of India from the dedicated hospital of mind and brain i.e. Institute of Human Behaviour and Allied Sciences (IHBAS) wherein we discussed how to keep check anxiety, distress, insomnia, hopelessness, loneliness, worry, apprehension, fear, anger, sadness, lethargy etc. in stress that has been caused by lockdown each for general population, mental health workers, caretakers of children, older adults & people with underlying health conditions, people in isolation/quarantine their families, substance users etc. (Article 5, Table 1)

In the same April 2020 issue, BE did preliminary analysis to see Impact of COVID-19 on global and Indian Economy where we concluded that the Hospitality industry i.e. hotel, restaurant & tourism industry had been badly damaged, with airlines cutting flights and tourists cancelling business trips and holidays. There were many other industries that have suffered and have been suffering a lot after coronavirus attack. The list includes education, sports & entertainment, hyperlocal marketplaces, fintech, textile and apparel, consumer durables and electronics, poultry and seafood, movie theatres, fitness centers, commercial real estate, shipping, automakers, oil and gas, conventions, online food service, theme parks etc. (Article 6, Table 1). In analysis of SARS COVID-19 Diagnosis, we discussed the past, present and future of it and new assays like PCR-based protocol, CRISPR-based diagnostic Protocol, serology, radiographic tests, rapid antibody test etc. (Article 7, Table 1). In another

28	Sep-20	Opinion	Role of confidence in coping up with COVID-19	Suhana Mishra and Amir Mohammad Arsh, Affiliation: School of Biotechnology, Gautam Buddha University, Greater NOIDA, Uttar Pradesh, India
29	Sep-20	PRESS RELEASE	Highlights of initiatives of ASPIRE BioNest UOH bioincubator to curb COVID-19 situation	Biotech Express Bureau
30	Oct-20	Guest Article	COVID-19 in the light of ayurveda: A pharmacognostic approach	Amir Mohammad Arsh and Suhana Mishra Affiliation: School of Biotechnology, Gautam Buddha University, Greater NOIDA, Uttar Pradesh, India
31	Nov-20	Guest Article	Indian Medical Institutions need to break the bottleneck of their research activities: Unmet need for health care	Saurabh Mandal
32	Dec-20	Editorial	Why every nation is in hurry to release COVID-19 drug/ vaccine despite many concerns? Editorial	Kamal Pratap Singh
33	Dec-20	Editorial	Vaccine can be harmful: Side effects and clinical trial errors	Dr Seema P Upadhaye
34	Jan-21	Guest Article:	COVID -19 Vaccine: A Race of Time, Technology and Nations	Saurabh Mandal
35	Jan-21	Press Release:	"Supply Chain Challenges of COVID -19 Vaccines: Indian Imperative"- International Virtual	Biotech Express Bureau
36	Feb-21	Conference Report	Press Release: Event: BioAsia 2021 to focus on COVID-19 & Medtech	Biotech Express Bureau
37	Mar-21	REVIEW ARTICLE	Cross reactivity and neutralization: SARS CoV-2 triggers antibodies from previous coronavirus infections	Suhana Mishra, Amir Mohammad Arsh and Varnit Chauhan from School of Biotechnology, Gautam Buddha University, Greater NOIDA, Uttar Pradesh, India

analysis of SARS COVID-19 treatment BE discussed what could be the treatment when no treatment options were available and what would be the vaccine candidates among available like Remdesivir, intranasal coronavirus vaccine, mRNA-1273 vaccine by Moderna etc. (Article 8, Table 1)

In an article, Why Indian Bioscience Response is "Not Enough" to curb Global "COVID-19" Biological Pandemic: What are We Missing? We discussed that how lockdown which was proposed for 21 days after scientific advises was not lifted up until 6 months and thus lead to sufferings to common man. We discussed how different task forces were fighting with each other and praising themselves when entire country was suffering. Analysis of various task forces revealed lack of harmony among these groups. It was imperative that India did not have any promising innovative product nor its scientists could utilize the time they were seeking for preparation by putting lockdown in place; India was using diagnostic kits of other nations and in treatment too India was not in the hit lists of COVID-19 Landscape drugs at the time. How the committee chaos was creating problem can understand by taking excerpts from one article - "Everything is fine as long as you take action," Naveet Wig, head of the department of medicine at the AIIMS, Delhi told other members of the government's task force of public health experts on COVID-19 on 29 March 2020. He added "This discussion has gone on for too long and no action has been taken. No. No. We will have to tell the truth." The records also showed, while imposing the lockdown, the government had ignored recommendations from its top scientists. Instead of the current coercive lockdown, these scientists had advised "community and civil-society led self-quarantine and self-monitoring, through their research in February 2020. According to a survey by Biotech Express magazine many senior scientists of concerned field were not imbibed in the commit-

Table-2: - List of COVID-19 news covered in Biotech Express from February 2020 to April 2021

Issue	Research	Featured News	News in Focus	Controversial
February 2020		• China's Wuhan Institute Files to Patent the Use of Gilead's Remdesivir for CoV		
March 2020	• Remdesivir prevents MERS CoV in monkeys • Chest CT findings in COVID-19 pneumonia	• First CoV vaccine trial in the US is recruiting volunteers		
April 2020	• BCG vaccination for COVID-19 • FDA Authorizes Blood Purification Device to treat COVID-19 • World's biggest trial of drug to treat COVID-19 begins in UK	• Scientists, led by Shailendra K. Saxena is the first Indian group to work on CoV vaccine • A Wuhan shrimp seller identified as CoV'patient zero'	• HCQ in CoV pandemic • NIV Pune Scientists first to deposit gene sequence of CoV from the India	• China death toll jumps dramatically • Trump suspends World Health Organization funding

tees. Lack of appropriate choice of expertise was revealed as an important factor which was seen while formations of task forces. It mainly revolved around current employees irrespective of their specialization whereas many famous Indian Microbiology and Biotechnology vaccine researchers like Jacob John, G Padmanabhan, Rajeev Bhargava, N K Ganguly, Satyajit Rath and many more had not appeared in any of the task forces. Concept of domination by misinformation in science came from an observation of a video of Prof K Vijayraghavan where he was seen ignoring his expertise when news anchor called him a 'Microbiologist'. Our observation found that he is not a Microbiologist but a Drosophila Developmental Geneticist who has never experienced virus research, at least not in his published research studies (Article 9, Table 1).

In the same May issue we published a letter from Prof Ramareddy V Guntaka to Prime Minister of India where he suggested some points as virologist like death rate from other diseases, inaccuracy of diagnostic kits, giving highest priority to high quality research without political interference and some other measures for the benefit of Indians. He also suggested that locking down 130 crores of people in their homes and putting millions of policemen to achieve this, will not solve the problem (Article 10, Table 1).

Biotech Express editorial board member also appeared in news for his pioneer scientific work toward CoV. Collectively, for the first time Prof Shailendra K Saxena, KGMU, and his team in a paper exhibited that the emergence of human 2019-nCoV is closely related to predecessor SARS-CoV and provide the evidence that 2019-nCoV uses various novel glycosylation sites as SARS-CoV does and may have a potential to become pandemic owing its antigenic discrepancy. The same news was very well covered by Nature Asia and many other reputed Journals (Article 11, Table 1).

Water is an essential resource and can be a potential reservoir of CoV was discussed in another editorial written by Sunita Varjani et al., from Gujarat Pollution Control Board. She discussed how pathogens, if not removed properly from wastewater may enter in water bodies and cause infections. She also discussed occurrence, detection, survival, disease outbreaks, elimination and protective measures due to waterborne viruses and suggested measures for wastewater treatment facility operators/Heath care facility operators (Article 12, Table 1). How stem cells can be a potential tool to devise the treatment was discussed by S Dravida, PhD, Founder, CEO, Transcell Biologics the biggest stem cell company of India (Article 13, Table 1).

Despite having huge money flow in biological pandemic Indian Bioscience sector looked at the backfront when announcement of G.O.I of Atma Nirbhar Package was made. In all mentioned schemes biological science was not discussed for even a single time when we had have victimized of biological pandemic which compel us to think if it was a punishment to Indian scientists or the ignorance of government (Article 14, Table 1). Later 35,000 crore rupees

May 2020	• HCQ linked to increased risk of cardiac arrhythmias • Scientists discovered Antibody blocks infection by the SARSCoV- 2 in cells • Blood clotting a significant cause of death in patients with COVID-19 • Blood thinners may improve survival among hospitalized COVID-19 patients • High blood pressure medications safe for patients with COVID-19 disease, study finds • Most critically ill patients with COVID-19 survive with standard treatment, study reveals • Mutations in SARSCoV- 2 offer insights into virus evolution • Indian Researchers Submit 53 Genome Sequences of Coronavirus	• Overall strategy of DBT-BIRAC COVID-19 Research Consortium for funding in Vaccines, Diagnostics, Therapeutics and other Technologies • Complications in Plasma therapy for COVID- 19 • Paper strip based COVID-19 test kit developed in India? • After Remdesivir 2 out of 4 COVID-19 Solidarity trial drug candidates failed to achieve results • What's new about Italy and Israel's first COVID-19 vaccine • Chinese scientists said they have successfully tested the country's first vaccine against COVID-19 in monkeys • Two repuprposed drugs from Korea showed promise against COVID-19	• DBT Launched 1000 Genome sequencing project of SARS Cov-2 • IICT to make affordable RT-PCR kits • CSIR pins hope on repurposed Sepsivac • An exponential blast of Covid-19 scientific research • Nearly Everyone Who Recovers From COVID-19 Makes CoV Antibodies: Dr. Francis Collins on NIH Blog • CSIR NMITLI program approves a multi institutional project to develop human monoclonal antibodies (hmAbs) to neutralize SARS-CoV-2	• Why India is throwing out Rapid testing kits for COVID-19 worth Rs. 30 Crore? • CoV antibody tests have 'really terrible' accuracy, says US researchers • Flawed Covid-19 Database Source to Ease Lockdown • COVID-19 has unmasked significant health disparities in the U.S. • Another Hype of world's first Covid-19 vaccine: Italy's claims • US study on remdesivir inconclusive: Indian Health Ministry

were sanctioned in budget for vaccine manufacturing and distribution.

Preprints publish articles without peer review which is seen in case of COVID-19. Important articles were retracted from these publishing servers too. Unlike normal journal which shows only published articles, preprints accumulates unpublished and unverified research on their servers which becomes available for public interpretation. Several articles from these servers were quoted for decision making in COVID-19. The total controversial articles on COVID-19 on Retraction Watch website at that time were 19 (now >100), out of these total, 7 (now 16) were from either BioRxiv or MedRxiv which makes around 36 (now 16) percent. (Source:https://retractionwatch.com/retracted-coronavirus-covid-19-papers/) (Article 15, Table 1).

Heat and coronavirus was topic of great heat in June 2020 when everyone was waiting for summer end but no relief was seen in any part of the world because another hypothesis of scientists failed. At this special scientific conjecture Biotech Express published an article by Rama S Verma and Steffi SV from IIT, Madras on Coronavirus and the heat - A realistic perspective ". The authors concluded that though some handful of lab experiments in China and the United States suggest the coronavirus decays more quickly in summer versus winter conditions but neither the hot temperature nor the cold temperature can kill the virus (Article 17, Table 1).

Guest Article on COVID-19 and Primary Health Infrastructure: Is Rural India in Ruins? by "Sukanya Chakraborty from IISER, Berhampur and Aparajita Chattopadhyay from International Institute of Population Sciences, Mumbai talked about pitfalls in current healthcare infrastructure of India (Article 18, Table 1).

FDA, WHO, CDC and many other organizations were seen being puppets of some journal that owes great reputation like The Lancet, NEJM but case of HCQ was heavily criticized and retracted and so the decisions of these organizations and heads which raised questions of their scientific judgement. It was observed that HCQ was proposed through social media then became widely accepted by various clinical studies around the world. COVID 19 was declared as emergent and fast changing situation but from

June 2020	• New report examines challenges and implications of false negative COVID-19 tests • Why doctors remain cautious about chloroquine/ hydroxychloroquine for treating COVID-19 • Clues to COVID-19 in the brain uncovered in new study • Hospitalized COVID-19 patients with diabetes represent more than 20 percent of ICU population • New model to predicts the peaks of the COVID-19 pandemic • Survey finds increase in psychological distress in US adults during the COVID-19 pandemic	• Dexamethasone proves first life-saving drug in UK • International Summit Aims to Raise $7.4 Billion for Vaccine Alliance • ICMR has notified 16 bio-repositories for clinical samples of COVID-19 patients • DBT/Wellcome Trust India Alliance and RTI International India set up a 'COVID-19 Catalytic Partnership' for India • EU secure $2.7 Billion emergency Fund for COVID-19 Vaccines • COVID-19 drug development could benefit from approach used against flu	• New COVID-19 test developed by the CCMB • Vaccine for COVID-19 would be available latest by next year: N K Ganguly • DST, India launches awareness programme on Science & Health with focus on COVID-19 • Eli Lilly Begins Phase III Study of RA Drug to Treat COVID-19 • Excelra Releases COVID-19 Biomarker Database	• Questions raised over the Integrity of The Lancet and NEJM? • Los Angeles attorney is suing Wellness Matrix Group for "fraudulent scheme" related to the COVID-19 • Social isolation in olders linked to more severe COVID-19 outbreaks

March 12 to June 14 the decision over HCQ was accepted and rejected several times, because someone was saying something while FDA and WHO scientists could not get the time to verify the facts by them before going to further conclusion. First, HCQ was accepted because of several reports from different trials but was rejected just because Lancet published a heart attack story of bogus trial. When this Lancet story was unsurfaced, FDA and WHO once again gained trust and start advocating HCQ. Lastly, without any further solid basis they rejected HCQ trials again. So the facts raises the questions over the working of world's reputed organizations like WHO, FDA etc. and publishing platforms like The Lancet, NEJM etc. (Article 20, Table 1)

A list of approved drugs for COVID-19 were discussed in article ''List of COVID-19 drugs from India" which was Updated on July 16, 2020. Now there are more than 100 treatments as per news headlines which are too non-scientific in their reporting (Article 21, Table 1).

PSA office to PM, headed by Dr K Vijayraghavan got Rs. 100 crore from PM CARES Fund for the development of vaccine against COVID-19. To know more about vaccine development, we communicated questions posed by Sumit Kumar but despite several attempts we could not get any response from PSA to PMO, India (Article 22, Table 1).

Because fake news had been floating on the market (or happening now), we covered some of the fake news and their reactions on the society in fact check analysis article ''Fake, Misleading and Controversial News Surrounding Covid19 Pandemic. Some of the fake news resulted in serious injury when several people were hospitalized after they consumed household disinfectant after U.S. President Donald Trump suggested that scientists should investigate inserting the cleaning agent into the body as a way to cure COVID-19. Others fake news that emerged were - Can bathing in hot water prevent covid-19? / Video shows COVID-19 victim's bodies removed from Iran hospital. Questionable/controversial news surrounding COVID-19 pandemic like diagnosis, clinical trials, research methodology, research publications, treatments, accusations of money making, Governments' actions, media bias were covered in this article (Article 23, Table 1).

During the talks with Dr Ram S Upadhayaye whose company Laxai just collaborated with CSIR at that time to conduct clinical trials of combinatorial therapies against COVID-19, discussed how to approach COVID-19 as biopreneur. He emphasized that lung damage is the most common reported occurrence post-recovery, yet reports of cardiac and neurological damage are in multitude. Syncytia formation leading to cellular fusion, alveolar clotting, heme dysregulation and fibrotic deposition are major areas

July 2020	• Researchers find rise in broken heart syndrome during COVID-19 pandemic • New research confirms higher rates of new coronavirus in Latinx populations and in BAME populations • Hamsters develop protective immunity to COVID-19 and are protected by convalescent sera • Cell 'membrane on a chip' could speed up screening of drug candidates for COVID-19 • About half of health care workers positive for COVID-19 by serology have no symptoms, study finds • CT of CoV disease (COVID-19) versus CT of influenza virus pneumonia • Global COVID-19 registry finds strokes associated with COVID-19 are more severe	• Zydus COVID-19 vaccine got approval from DCGI to starts human dosing of its vaccine 'ZyCoV-D' • Brazil's President Bolsonaro tests positive but is fine now after HCQ dose • Dexamethasone approved for use in India • No reason to say that Indian CoV strain is less virulent: Dr Raman Gangakhedkar	• BioNTech, Pfizer COVID-19 Vaccine Candidates • Biopharma Giants Launch AMR Fund of $1 Billion • International leaders who got sick of SARS CoV2 • Sanofi and Regeneron's Kevzara fails in Phase III COVID-19 trial • NIAID Creates Clinical Trials Network COVPN • Novavax Secures $1.6 Billion from U.S. Government for COVID-19 Vaccine Program • Tesla to Build Mobile RNA Microfactories for CureVac's COVID-19 Vaccine • WHO acknowledges 'evidence emerging' of airborne spread of COVID-19	• Biocon Itolizumab attract criticism from experts • Gagandeep Kang resigned from director's position of DBT- THSTI amid COVAXIN turmoil • CORONIL: Magical medicine from self proclaimed ayurveda doctor • New journal launched to scrutinize Covid-19 preprints papers • Meerut hospital in India sealed, licence revoked for providing fake COVID-19 negative report for Rs 2,500

of concern and may be probable reasons for post-recovery damage (Article 24, Table 1).

Arti Pandey from Ram Sewak Singh Mahila College, BRABU Muzaffarpur, Bihar in an article "An Insight About COVID-19: The Deadly Pandemic" attempted to explore findings on the symptoms, causes, clinical diagnosis, spread, as well as prevention and control of COVID-19 (Article 25, Table 1).

Professor Shailendra Kumar Saxena, Vice Dean and Professor at King George's Medical University, Lucknow, once again appeared in international news because of his book which was FIRST BOOK on COVID-19 and published by Springer Nature. The book "Coronavirus Disease 2019 (COVID-19): Epidemiology, Pathogenesis, Diagnosis, and Therapeutics (Medical Virology: From Pathogenesis to Disease Control)" provided a detailed comprehensive overview of recent novel coronavirus (SARSCoV-2) infection (Article 26, Table 1).

Mental Health Hazards were again discussed after extended lockdown was imposed. The guest author implied that lockdown across the globe due to high infectivity and fatality rate resulting in a plethora of psychological consequences. Some of the effects seen as a result may be experienced in the long run, such as depression, excessive worry, acute panic, anxiety, stress, obsessive behaviors, hoarding, paranoia and some serious effects, such as post-traumatic stress disorder (PTSD). News spread via different platforms of social media has added to people's anxiety and stigmatization at times. There is an urgent need to set up research and mental healthcare delivery at community level by dedicated helpline and websites with regards to medical and psychological issues (Article 27, Table 1).

COVID-19 affects not just the individual infected but all those who were or are present around them. People feels

August 2020	• Blood test may point to patients at higher risk for COVID-19 deterioration, death • COVID-19: The longer term effect of COVID-19 recovery • COVID-19: The virus and the vasculature • Electric cooker an easy, efficient way to sanitize N95 masks • Human Trials Begin for COVID-19 Plant-Based Technology Vaccine • In cell studies, seaweed extract outperforms remdesivir in blocking COVID-19 virus • Lab-made virus mimics COVID-19 virus • Pasteurization inactivates COVID-19 virus in human milk: new research • Strong link found between abnormal liver tests and poor COVID-19 outcomes	• Cipla receives regulatory approval for launch of Ciplenza (Favipiravir 200 mg) • World's Cheapest COVID-19 Testing Kit developed in India by IIT-Delhi • DBT seed funds Gennova Biopharmaceuticals' • novel mRNA-based COVID-19 vaccine • Nearly 200 Indian Doctors Have Succumbed to COVID-19 So Far: IMA • COVID-19: Angry Health Workers in India Launch a Strike	• GSK and Sanofi Strike $2.1 Billion Deal with U.S. Government for COVID-19 Vaccine • Pfizer and BioNTech Begin Global Phase II/III COVID-19 Vaccine Trial • JLL Report: COVID-19 Related Vaccines Stimulate Life Sciences Real Estate Market • Moderna Launches Phase III COVID-19 Vaccine Trial with $472 Million More in BARDA Funding • Novartis Launches Initiative to Supply COVID-19 therapies to Low and Middle-Income Countries • Novavax and SIPL to Develop 1 Billion COVID-19 Vaccine Doses for India, other countries • Octapharma Uses IVIG as Potential Treatment for COVID-19 • Synairgen's Inhaled COVID-19 Treatment Appears to Decrease Disease Risk by 79%	• DCGI Rejects Mylan's Request to Waive Phase 3 Trials for COVID-19 Drug • Russia Plans Mass COVID-19 Vaccination Program in October but draws criticism • Roche's Actemra Misses the Mark in Phase III COVID-19 Associated Pneumonia Study

lonely because of quarantine that causes depression, tension, sorrow, boredom and how can be coped up by the self-confidence, inner peace, social help, proper knowledge about COVID-19 etc. was communicated by young researchers in an opinion "Role of confidence in coping up with COVID-19" (Article 28, Table 1).

To see what start ups are doing in this pandemic we saw some of the startup incubated at ASPIRE-BioNest, University of Hyderabad (UoH) which is among the best Bioincubator in the country. OncoSeek Bio Pvt Ltd., a was selected for financial support for developing an *invitro* Lung Organoid model by DBT-BIRAC, ReaGene along with INDRAS Pvt. Ltd., Hyderabad collaborated with Tech Mahindra, the IT giant, to identify FDA approved drugs which can be redeployed as therapeutics for COVID-19 etc. (Article 29, Table 1).

The herbal formulations found in Ayurveda for 'immunity enhancement like Herbal tea / decoction (Kadha) made from Tulsi (Basil), Dalchini (Cinnamon), Shunthi (Dry Ginger), Golden Milk- Haldi (turmeric) powder in hot milk and their roles in immunity boost were briefly discussed after Ministry of AYUSH, Government of India promoted ayurveda for COVID treatment (Article 30, Table 1).

Guest Article on "Indian Medical Institutions need to break the bottleneck of their research activities: Unmet need for health care" by Saurabh Mandal discussed how the COVID-19 pandemic has exposed the country's inadequate healthcare infrastructure, poor access to medical facilities, high-cost treatment, and shortage of doctors, medical staff wuth reference to population, low health investment etc. The article figured out a Lancet report which showed that from 2005 to 2014, 332 out of 576 (~57%) medical institutions have not published even a single research paper. Over the same ten years, the total research output of the Massachusetts General Hospital, USA has 46311 and and Mayo Clinic, USA has 37633 publications. These many

September 2020	• FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment • Vir Bio and GSK Join the Race for a COVID-19 Monoclonal Antibody • Translate Bio and Sanofi's COVID-19 Vaccine Positive in Animal Studies	• Bangalore Bioinnovation Center launches 7 new products for COVID-19 • U.S. says it won't join WHO-linked effort to develop, distribute CoV vaccine • Sanofi, GSK Move COVID-19 Vaccine Candidate into the Clinic	• Merck is Building $1.3 Billion Research Hub in London • Regeneron and Roche Partner to Supply COVID-19 Antibody Cocktail • COVID-19 has likely tripled depression rate, study finds • Metabolic syndrome linked to worse outcomes for COVID-19 patients	• Improving FDA's COVID-19 vaccine authorization and approval process: Lessons from HCQ • AstraZeneca Pauses Phase III COVID-19 Vaccine Trial after Patient Illness • 9 CEOs Pledge to Stand Behind Science, Not Politics in Potential Vaccine Approval • Former FDA Commissioner Questions COVID-19 Vaccine Fast-Track Statement says it is politics
October 2020	• Policy Research into Mapping of Indian and Chinese Vendors for Supply of Biologicals to Indian Labs • 17-year-old Delhi boy becomes youngest winner of Aatmanirbhar Bharat Ideathon with app that detects COVID-19 in seconds • COVID-19 vaccine prospects that have made it to phase three trials and beyond • CRISPR COVID-19 test 'FELUDA' commercially launched in India	• ICMR's newly launched COVID-19 vaccine online portal revealed no vaccine form govt. labs • PM Modi Pledges to Use India Vaccine-Production Capacity • J&J's One-Dose COVID-19 Vaccine Candidate Begins Phase III Trial	• Novavax Begin Phase III Study of COVID-19 Vaccine Candidate in the U.K. • White House defies COVID-19 restrictions even after Trump tests positive • India declines proposal to test Russia COVID-19 vaccine Sputnik-V in large study	• ICMR COVID-19 seroprevalence data differs significantly and may be of no use? • COVID-19: China gives 'unproven' vaccine to thousands, makes them sign 'secrecy' agreement • Trump officials interfered with CDC reports on COVID-19 • Turkish scientists and physicians face criminal investigations after criticizing COVID-19

publications were nearly four times more than what India's prestigious medical Institute, All India Institute of Medical Sciences (AIIMS), New Delhi has published at that time (Article 31, Table 1).

BE wrote an editorial to check Why every nation is in hurry to release COVID-19 drug/ vaccine despite many concerns? Despite various questions about effectiveness, safety and availability of drug/vaccine there seems a hurry to release COVID-19 treatment by individuals, scientists, organizations and Nations. Numerous examples of failures exists like Solidarity trial candidates – remdesivir, hydroxychloroquine, lopinavir/ ritonavir and interferon, AstraZeneca's Calquence, Novartis' Ilaris, Sanofi & Regeneron's Kevzara, Eli Lilly antibody drug, Roche's Actemra, Glenmark's Favipiravir, Biocon's Itolizumab, Patanjali's Coronil and many more. Not only companies but world's renowned doctor Anthony Fauci first suggested (In a CBS interview) that the British regulators had failed to scrutinise the data carefully enough and had waved the vaccine through. Later he apologized for casting doubt over UK's approval of Pfizer vaccine. Pharma lobbying was also discussed, according to the sources for the study, published in the Journal of General Internal Medicine, the team looked at lobbying expenditures in the fourth quarter of 2019 and the first quarter of 2020. Results showed that lobbying spending hit $248.4 million between January 1 and March 31, and 357 new lobbyist registrations were filed during this period. Researchers found the biggest increases came from the pharmaceutical industry, making up 16 of the top 30 healthcare organizations in lobbyist spending (Article

November 2020	• American Medical Association declares racism an 'urgent public health threat' • Moderna's COVID-19 Vaccine Interim Readout Suggests 94.5% Efficacy • AstraZeneca's Calquence Fails Pair of Phase II COVID-19 Trials • Novartis' Ilaris Fails to Meet Endpoints in COVID-19 Study	• FM Nirmala Sitharaman announces Rs 900 crore grant for COVID-19 vaccine research • J&J Secures Additional $1 Billion in Funding for COVID-19 Vaccine • Dr Harsh Vardhan launches CSIR partnered clinical trials website "CUReD" on Repurposed Drugs for COVID- 19	• FDA COVID-19 Vaccine Advisory Committee: Lots of Talk, No Decisions, Some Reassurance • IAVI, Merck KGaA, Darmstadt, Germany, and Serum Institute of India Join Forces to Develop Monoclonal Antibodies for COVID-19 • Lilly and NIAID Halt COVID-19 Antibody Trial in Hospitalized Patients	• WHO shows no effect on patients but Veklury has become the First FDA Approved Treatment for COVID-19
December 2020	• FDA Issued Emergency Use Authorization for Second COVID-19 Vaccine • COVID-19 pneumonia paper earns expression of concern • Public health journal "seeking further expert advice" on January paper about COVID-19 PCR testing by high-profile virologist • Prof Said Jade Amulets May Block COVID—and Became a Science Supervillain	• COVID-19 Antibody Discovery Company Preps for Massive $391 Million IPO • Incyte and Novartis' Jakafi (Ruxolitinib) fails to reduce COVID-19 associated Cytokine Storm Complications • Boston Biogen Superspreader Conference Led To Over 300,000 COVID-19 CoV Cases • UK Investigates Reports of Allergic reactions to Pfizer-BioNTech COVID-19 Shot	• Pfizer's COVID-19 vaccine may not be needed, says Harsh Vardhan • Expert committee of CDSCO has sought more data from Serum Institute and Bharat Biotech on their vaccine trials • Anthony Fauci will continue as Chief Medical Adviser in the Biden administration	• Are Bill Gates's Billions Distorting Public Health Data? • Haryana Minister, Who Participated In Bharat Biotech COVID Vaccine Trial, Tests Positive • Health Ministry Does Not Know Where COVID Vaccine Expert Group's Records Are? revealed RTI • Oxford and Serum Institute of India (SII) vaccine has serious adverse effects? • COVID vaccine can turns you into a crocodile?: Brazilian President's remarks

32, Table 1).

Vaccine side effects were separately discussed in an article where experts' opinions were pointed out that the lack of transparency in releasing crucial information and data could lead to stricter scrutiny by regulators in many countries and mistrust among people. Historical incidents of side effects of vaccines and current CoV vaccine side effects were discussed. There seem considerable cases of side effects of vaccines like the Oxford/AstraZeneca COVID-19 vaccine trial was voluntarily put on hold at one stage to investigate why one participant - out of many thousands – had died, patients suffered from transverse myelitis, a rare neurological condition that causes inflammation of the the spinal cord. The results of the early trials of the Sputnik V vaccine were published in The Lancet Study on September 4, no serious adverse effects were reported. However, the results have been criticised by several scientists around the world, including a group of researchers who wrote an open letter against the published trial results of Sputnik V. We have seen loopholes in existing system of FDA and EU when they approved certain medications without any sufficient evidences and later these studies were challenged and retracted (Article 33, Table 1).

Guest Article on COVID -19 Vaccine: A Race of Time, Technology and Nations discussed how different nations and companies are competing to bring out their treatment (Article 34, Table 1).

BE covered the event of Supply Chain Challenges of COVID-19 Vaccines which was discussed in an International Virtual conference. The event was organized by a consortium of Global Bio Supply Chain Association of Life Sciences, involving the Federation of Asian Biotech Associations (FABA), Bio Supply Management Alliance (BSMA) USA and Europe, BIRAC, ABLE, NITIE Mumbai, Indian Oil etc. Prof. Pallu Reddanna, the Executive President of FABA thanked various academic institutions, Government organizations, particularly the DBT, CSIR, CDSCO,

January 2021	• Air pollution much bigger killer than COVID -19 in India, finds study	• DCGI approval of Bharat Biotech & Serum Institute COVID-19 vaccines	• Covaxin Phase-3 trial: COVID vaccine volunteer's death	• Science advocacy groups join call for Trump's removal • Scientists criticized 'rushed' approval of Indian COVID-19 vaccine without efficacy data • List of retracted COVID-19 papers grows past 70
February 2021	• Variants mutations of SARS-CoV-2 • Covaxin Neutralizes UK Variant Of COVID-19 in lab Setting: ICMR • CCMB scientists find different variant of SARS CoV-2 in India • Phase I Clinical Trial Data pertaining to Bharat Biotech COVAXIN BBV152 Finally Published	• India Budget 2021 – Healthcare and research • India has 30 COVID-19 vaccine candidates under development • Tatas may partner with Moderna to launch COVID-19 vaccine in India • India received 2.5 billion dollars from World Bank to fight COVID-19	• Eli Lilly's Antibody Combo Wins FDA Approval for Mild to Moderate COVID-19 • GSK and CureVac Take Aim at COVID-19 Variants with Second-Generation mRNA Vaccine	• False phone numbers, fake names: How Bihar COVID testing data got infected and led to termination of officials • Millions earmarked for public health emergencies were used to pay for unrelated projects, US inspector general says • India: Lack of transparency on COVID vaccine goes against Centre's draft science policy
March 2021	• COVID-19 isolation linked to increased domestic violence, researchers suggest• Indian Medical Association furious after Union Health Minister Harsh Vardhan 'promoting' Patanjali's Coronil	• Convalescent Plasma Doesn't Prevent Progression of COVID-19 • Frontiers Removes Controversial Ivermectin Paper Pre-Publication	• 65% of world's vaccines manufactured in Hyderabad Bharat's Next-Gen • COVID-19 NasalVaccine Moving Toward Human Testing	• Some Countries Pause Dosing of AstraZeneca Vaccine Due to Clotting Concerns • Russia Engaging in Anti-Pfizer Disinformation Campaign to Boost Sales of Sputnik Vaccine, U.S. Alleges

vaccine manufacturers, cold storage and supply chain organisations. The eminent person who attended this online conference were Dr. Renu Swarup, Dr K. Srinath Reddy, Dr. Varaprasad Reddy, Dr. Krishna Ella, Prof. Gagan Deep Kang and Dr. S. Eswara Reddy (Article 35, Table 1).

A look to the summary of all article we have covered till now on cov shows that all major topics were covered in this biotechnology periodical be it scientic or non- scientific w.r.t. the biggest biological pandemic of history. Now because everything was not covered in article we are looking at other aspects through our various other sections like research and news (Table 2). The broad topics we covered under scientific (diagnosis, treatment, regulatory aspects of drugs; science failure; pharma lobbying) and non-scientific (lockdown; science funding; relief packages; racism; misinformation; cultural favours; industry growth, political favours) aspects of COVID-19 pandemic.

We have seen different kind of news and article that a biotechnology magazine obeyed to cover. We will see an another picture but first let us study the current scenario which is the emergence of 2nd wave in India.

Present Scenario

India has become the global hotspot for the COVID-19 pandemic, counting the world's highest numbers of daily new infections in recent days as it grapples with a second wave of the pandemic weeks after witnessing a dramatic decline. Health experts blame many people including PM and Home Minister, India abandoning COVID protocols. Huge crowds, mostly without masks, have been jostling at

April 2021	• Clinical trial completion rates decline during COVID-19 pandemic • COVID-19 patients can be categorized into three groups • COVID-19 vaccines may not produce sufficient antibody response in transplant recipients • Flu shot associated with fewer, less severe COVID cases, study finds • Increased rates of organ damage after discharge from hospital with COVID-19 • Prolonged immune response may contribute to post-COVID-19 blood clots	• Hit with Second Wave, India Becomes COVID-19 Hotspot • COVID-19 Research Papers Retractions grow up to 100 • US Representative Jim Jordan clashes with Anthony Fauci over 'freedom' • Is the AstraZeneca Vaccine Safe or Not? Questined raised after blood clots • Second coronavirus wave will push India's middle class toward poverty • SII, Bharat Biotech to get Rs 4,500 cr advance payment to ramp up vaccine production • Experts clear Russia's Sputnik Covid-19 vaccine for use in India • India is running out of oxygen because the government wasted time in tender process • Coronavirus becomes inactive for few individuals and at few places like rallies and melas • Why Remdesivir? Its already out from WHO solidarity trial • The ex-Pfizer scientist who became an anti-vax hero • 180 deaths following COVID vaccination reported in India	• Coronavirus Vaccinations cross 13 crore doses in India • Longer lockdown only tool to break the chain of COVID transmission • Large-Scale Study Finds One-Third of COVID-19 Patients Suffer Neurological Damage • Likely Legal, 'Vaccine Passports' Emerge as the Next Coronavirus Divide in US and other parts of world • Young survivors of Coronavirus can get reinfected with CoV for second time: Lancet study • Plant-Based COVID-19 Vaccine Candidate Starts Phase 3 Trial • WHO Report: Wildlife Farms, Not Market, Likely Source Of Coronavirus Pandemic • FDA Authorizes First Machine Learning-Based Screening Device to Identify Certain Biomarkers That May Indicate COVID-19 • After Emergent COVID-19 Manufacturing Mess, J&J Team Takes Charge • AstraZeneca's Diabetes Drug Farxiga Faled in COVID-19 Study • Regeneron's Antibody Cocktail Cuts Progression to Symptomatic COVID-19 • Zydus Cadila seeks DCGI approval for use of PegIFN in treating COVID-19	• Elsevier pulls 26 COVID-19 papers by Victor Grech • Gujarat High Court asks State government to publish data on COVID-19 tests, deaths • Paper claiming presence of SARS-CoV-2 in Italy in 2019 earns expression of concern • Scandal over COVID vaccine trial at Peruvian universities prompts outrage

massive political rallies being held in five states holding local elections.

This is happening when more than 10 crore people have vaccinated and government has spent thousands of crores of rupees in healthcare spending. Both Media houses and public are now criticizing govt and questioning the very existence of virus. According to a source, following questions were asked by some individuals, which are just tip of iceberg and led to think why CoV is not a serious thing among common man now.

1. No vaccine is working – people are becoming positive after vaccination.

2. Some people are enjoying liberty from masks and safe distancing but others are compelled to follow by fine.

3. People are getting positive and negative in alternate fashion.

4. COVID-19 has no cure but its recovery is 99 %.

5. Now people are not getting infected for other common diseases like flu, dengue, malaria etc.

Conclusion

So far we have covered the topics under two broad headings i.e. scientific and non-scientific issues around coronavirus pandemic. We are not concluding much here but leave it on reader to read, think and cross-check the available information from a regarded source like Biotech Express which has covered the pandemic's each and every perspective from verified sources. Now there can be two possibilities, either coronavirus exists and it is deadly like we have been told and it is there but not that much deadly as we were told. What if it is not deadly, then, if it is game, China has already played the game once or twice before using SARS-CoV-1. This time it reported healthcare emergency for SARS-CoV-2 in December 2019. Though the number of cases increased in China initially, but they became stagnant and later doubled suddenly when some countries blamed that it is hiding its deaths from COVID-19.

1. Diagnosis- The very first genome of CoV sequence study from China was retracted; Accuracy and precision of diagnostic kits which were based on this sequence were questioned several times.

2. Treatment- Drugs/Vaccines were rush approved despite safety and efficacy studies. Many drugs like HCQ and now vaccines which were quoted as magical treatment were abandoned and even proved unsafe for consumption.

3. Infection Data- So called coronavirus dashboards were reporting without any reference and based on news stories.

4. Death reporting- Deaths were reported from many countries but the CDC data suggested co-morbidities in almost all the cases.

5. Misleading and Controversial News- Misinformation floated by leaders and social media created panic among masses.

6. Vaccine diplomacy- It has been seen that vaccines which were produced in last the past one year have gone under heavy criticism but were released subsequently even when safety data and data on clinical trials was not in public domain for scrutiny.

7. Working of top health organizations- Working of FDA and WHO were questioned several times when they approved a product or issued guidelines, for instance, the case of HCQ and the retractions from The Lancet and NEJM.,

8. Research Publications- Much of the early information on CoV and pandemic came from Preprints servers like MedArxiv and BioArxiv. Many of these studies were unverified and later either retracted or could not find place in any scientific journal.

9. False Scientific claims- Temperature was earlier considered by many eminent scientists as the determining factor for CoV transmission, this was later disapproved when infection rates did not go down in summer.

10. Monetary gains- China increased supplies of masks, sanitizers and also applied for approval of first vaccine which led others to run in this direction. There was a steep increase in the rates of medical supplies like masks, sanitizers, PPE kits and OTC medicines. Due to lockdown most of the grocery items also became costlier.

Disclaimer: These are strictly views of author of this article, Biotech Express and its Editorial board is not responsible for any error and view of the article.

Event Report

Panel Discussion on Pharma & Biopharma Industries in India: Opportunities & Challenges in Innovative Drug Discovery & Development

Panelists :
1. Anand Anandkumar (CEO, Bugworks)
2. Dr. Tanjore Balganesh (President, GangaGen)
3. Dr.Srikar Raman (VP and Head R&D, Levim Biotech)
4. Dr. Manish Diwan (Head - Strategy Partnership & Entrepreneurship Development, BIRAC)
5. Dr. Nishith Tyagi (Director, AI and Data Science, Novartis)

Moderator: Dr. Uday Saxena, ReaGene Innovations

Other Contributors:
Professor P. Reddanna (University of Hyderabad)
Dr. Ajith Kamath (Advisor Pandorum Technologies) and
Dr. Bindu Madhava Reddy (Assistant Professor, University of Hyderabad)

Q1: India has done very well in development of generic and biosimilars. However, we have not produced an innovation-based first in class medicine yet. Please name one reason for this and a possible solution

Anand:
Innovation takes funds and risk-taking ability but Indian Biopharma still does not have that ecosystem yet. Secondly the supply of validated targets that can be used in drug discovery come from Academia and Industry collaboration in the USA, but no such activity is prevalent in India. This is a big gap in Indian Innovation ecosystem. Things are changing and will get better soon but, we are not there yet.

Nishith
The risk-taking ecosystem is not there in India. Secondly, academia normally leads the way in innovative science, where India is still lagging. Disease biology and medical science towards innovation is lacking in India and unless we work more in this area we will lag behind.

Balganesh
We tend to work in silos, there is hardly any cross disciplinary interaction between biology and say, chemistry. This is important for translational and product research. The second aspect is that we do not have clinicians participate in the innovation process, either in understanding disease biology or in epidemiology. The third point is that our best brains are post-doctoral candidates in the US and tend to stay there.

Srikar
There is no dearth of funding in India – our generics and biosimilar sales are huge and we are the third largest economy in the world. Also, our young talent is very good, but we do not have experienced people in the Indian regulatory system or guidelines to assess and support innovative approaches to treat diseases. We need feedback from them

and need positive but critical advice from them. We have to be patient and things will improve and the biopharma will grow.

Manish
The status of first in class discovery in India is pathetic. Preclinical discovery and clinical development form two pillars of innovation. We do not have much experience in clinical development – as seen by our product pipeline, hardly few molecules are in clinical development. We need larger numbers in clinical development. The experience that we have acquired in biosimilar space is excellent and clinical development of novel drugs should follow a similar pathway. We can expect to see many large international pharma companies set up shop here and that will help us.

Q2: Is our academic training good enough to support Innovative and translational science?

Anand:
Few years back when we looked at the PhD talent pool for industry it was not very good, but quality is improving. our scientists have to think about data, ability to comprehend and use data. They have to think like a startup and think in a big picture and explore getting training in data sciences as a tool.

Nishith:
We have excellent QA scientists and they all come from academia but still not ready for the future. We should be offering integrated courses that involve computer training very early. Secondly, medical institutions have to be involved to provide a clinical perspective. Finally, AI/ML skills need to be included in the drug discovery process to absorb the vast amount of information that is out there. So, students need to be trained in AI/ML as well as exposure medical sciences.

Balganesh:
We are not there yet – but we can get there. Late 80's there was no value attached to patents, but slowly patenting is improving. But its only being done as a mandatory activity without understanding the importance. This has to change. Secondly, in the past there were a handful of Institutions that trained talent pools very well and the number is still small. One element is rotational training of PhDs across discipline like it is done in the USA. Finally, we need to have academia go work at the industry and create a highway of knowledge sharing.

Srikar
PhD trains you to do research, it's an enabling tool but not means to innovation excellence. What is needed is a leader/mentor who can see the big picture and bring everything together and think uniquely. It's not just PhD but focus has to be on training in innovation skills.

Manish
Twenty years ago I did a postdoc in South Korea. It was eye opening because every faculty there had links with industry and had a spin off. Similarly, in Japan, PI who did not have industry collaboration was looked down upon. This is something we need to have in Indian academies, without which quality exposure to innovation will not be there. We have very few students/PIs in India that venture into new areas but spend their lifetime working on the same problem. However newer and younger faculty are aggressive and are more collaborative and students from such labs are better prepared. The Government now tends to fund multidisciplinary and industry connected projects.

Dr. Reddanna
A number of academic institutions in the country with highly qualified faculty and excellent infrastructure are working on various biomedical problems but they have very limited interactions with industry due to lack of push from academia and pull from industry. Secondly, no institution has medical schools attached, which is critical for innovation research. This is a major challenge in pushing biomedical ideas into products. Industry in India is risk averse and thus have very limited opportunities for fresh PhDs for innovative research. In contrast, in the IT industry, in view of plenty of opportunities, they recruit and train fresh students and make a productive workforce.. BIRAC has helped a large number of start-ups and that's where young scientists are getting training. But startups are not funded deep and VC funding is needed for further development of their innovative products However, Venture financing ecosystem is yet to evolve in India.

Anand
We need a triangle of three sections to come together - regulatory, funding and we need to hear from Indian big pharma why there is a lack of interest in innovation.

Dr. Bindu M. Reddy
Clinicians do not have an opportunity to interact and train in research. Very few discoveries are happening in the world so let's not harp on it. Instead, let's not focus on it alone but focus on providing BIG grants to younger scientists to train them rather than fund huge grants to estab-

lished PI's. INSPIRE fellowships can be given to clinicians and young minds.

Selected suggestions from Q/A

1. Pallavi – Industry internship is needed for young students
2. Balganesh/Anand – smaller companies can partner with CRO's to provide fully integrated programs
3. Abhishek- what is industry ready mean for a PhD ?- Srikar suggested problem solvingskills as a key and look for jobs that are aligned with your interests and training. Anand suggested that be open to change and newer skill learning
4. Meenakshi – training in coding, etc. is critical even for biologists but not available as a course right now
5. Manish – New educational policy to be rolled out soon where interdisciplinary skills can be included into one degree
6. Jagan – should we focus on affordable medicines or high-risk innovation – Nishith favors going to breakthrough innovation/ precision medicines and be game changers despite the challenges. Commercially new drugs are far more profitable than generics which can fuel innovation. Anand says a judicious mix of both to solve our own Indian problems
7. Balganesh– Industry wants people who can think laterally and practice how you approach a problem
8. Dr. Reddanna – there is a skill gap between academia and industry needs and FABA academy was designed to fill this void thru training courses
9. Jagat -Corporate in India should have training internships like in the USA
10. Ajith – Many CROs are doing their own drug discovery in India now
11. Ajith – How to go from basic science to product innovation for young scientists? It's mainly your interest and passion for the field of R&D, if you have a good idea or data just present it at the interview.

Major Take home messages:

1. It is important that we don't deny the existence of an innovation ecosystem in the country. It will take time to mature to bear fruits all year long. The ecosystem is evolving and several sporadic examples of bio-innovations can be seen - Covaxin, various covid and AMR diagnostic kits, Hanugen, Aten Porus, Rotavac, many clinical leads developed from India's BMS labs, various clinical leads developed from India's pharmas/CROs - Daiichi Sanyo, Zydus, Rhizen, Syngene, Jubilant, to name a few.
2. Clinicians/Hospitals need to be involved in innovation process along with the basic scientists to work on disease biology
3. Both industry and academia have to work together to promote this ecosystem thru collaborations to create knowledge and skill highways
4. Regulatory and clinical development skills/pathways are not well established in India hampering novel product development
5. Training of young scientists for innovation has to be more well-rounded and include interdisciplinary education, internships at Industry and working at start-ups

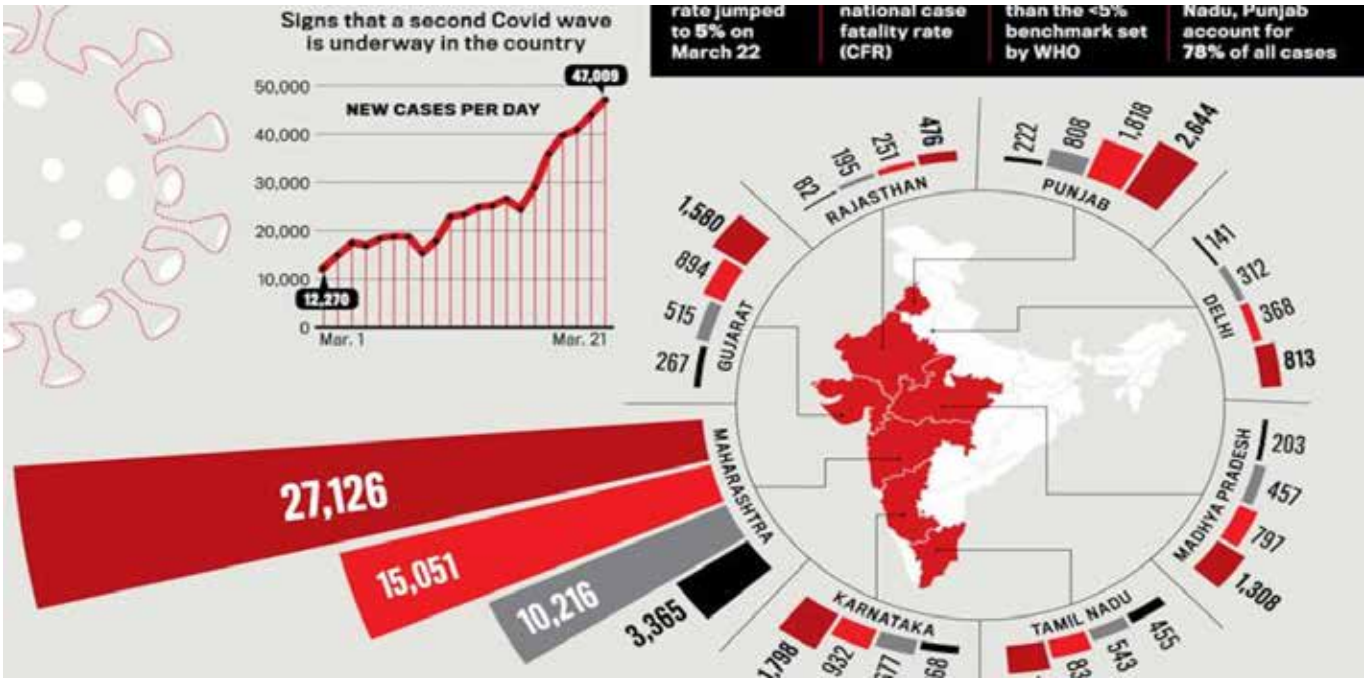
The readers can also view the panel discussion on You tube, using the following link:

https://youtu.be/hpZBwwxpoFU

Featured News
Biotech Industry and Govt

Hit with Second Wave, India Becomes COVID-19 Hotspot

APRIL 10, 2021



India has become the global hotspot for the COVID-19 pandemic, counting the world's highest numbers of daily new infections in recent days as it grapples with a second wave of the pandemic weeks after witnessing a dramatic decline. The impact of the swift surge in the virus, in the world's biggest vaccine maker, will be felt far beyond its shores as India slows vaccine shipments to other countries.

Health experts blame many people in the vast populous country for virtually abandoning COVID protocols as cases tumbled.

Huge crowds, mostly without masks, have been jostling at massive political rallies being held in five states holding local elections. A month-long religious festival that sees hundreds congregate daily to take a dip in the river Ganges that Hindus consider holy is underway in the northern state of Uttarakhand. Weddings and family events have become bigger. Now, experts say the country is paying the price — the number of infections during this second wave has climbed far more swiftly than the first with daily cases topping the 100,000 mark for the first time.

India is unlikely to impose a national lockdown that extracted a huge economic cost, but worst affected areas in the country are reimposing restrictions. The western state of Maharashtra, the country's most economically developed state, is the epicenter of the new wave reporting nearly 60% of the country's cases. Its capital, Mumbai, reimposed a partial lockdown this week shutting down shops, restaurants and monuments and ordering a complete shutdown on weekends. The Indian capital, New Delhi has imposed a night curfew.

COVID-19 Research Papers Retractions grow up to 100

APRIL 11, 2021

Retraction Watch readers may know, as part of keeping their database of retractions up to date, they've been publishing a running list of COVID-19 papers that have been retracted. Retraction Watch divided the list of retractions into three groups: Retracted, Retracted due to journal error, and Retracted and reinstated. Those in the last category have simply been replaced without notice.

The most spectacular flameouts involved a pair of articles that appeared in two of the world's most prestigious medical journals. Both The Lancet and The New England Journal of Medicine were forced to remove articles that relied on data from a questionable firm called Surgisphere, which refused to share its results with coauthors and the editors involved, leading to the suspension of clinical trials on hydroxychloroquine.

PLOS ONE issued an expression of concern for a paper it published in September suggesting that vitamin D might protect against severe COVID-19.after an epidemiologist in Sydney who pointed out, among other issues, that the study relied on a small number of patients and appeared to show a null result. If lack of data was a problem for some papers, others suffered from a complete lack of common sense. Like this article, which claimed that COVID-19 resulted from 5G telecom energy. The quickly retracted paper earned the title of the "worst paper of 2020" from data-sleuth Elisabeth Bik.

Cellular & Molecular Immunology took three days to accept a paper about how COVID-19 might infect white blood cells—similar to HIV's strategy—and then took three months to retract it after a researcher sent them a letter critiquing the study.

The retractions "are great examples of why science needs more of a 'In God We Trust, everyone else needs to show their data' approach," said Ivan Oransky, vice president of editorial at Medscape and co-founder of the Retraction Watch blog.

"The most spectacular flameouts involved a pair of articles that appeared in two of the world's most prestigious medical journals. Both The Lancet and The New England Journal of Medicine".

US Representative Jim Jordan clashes with Anthony Fauci over 'freedom'

APRIL 9, 2021

Jordan he repeatedly asked National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci when Americans will "get their freedoms back." "Fifteen days to slow the spread turned into one year of lost liberty," Jordan said before asking Fauci: "What metrics, what measures, what has to happen before Americans get more freedoms?"

Rep. Jim Jordan, R-Ohio, questions Dr. Anthony Fauci, the nation's top infectious disease expert, during a House Select Subcommittee hearing on Capitol Hill in Washington, Thursday, April 15, 2021, on the coronavirus crisis.

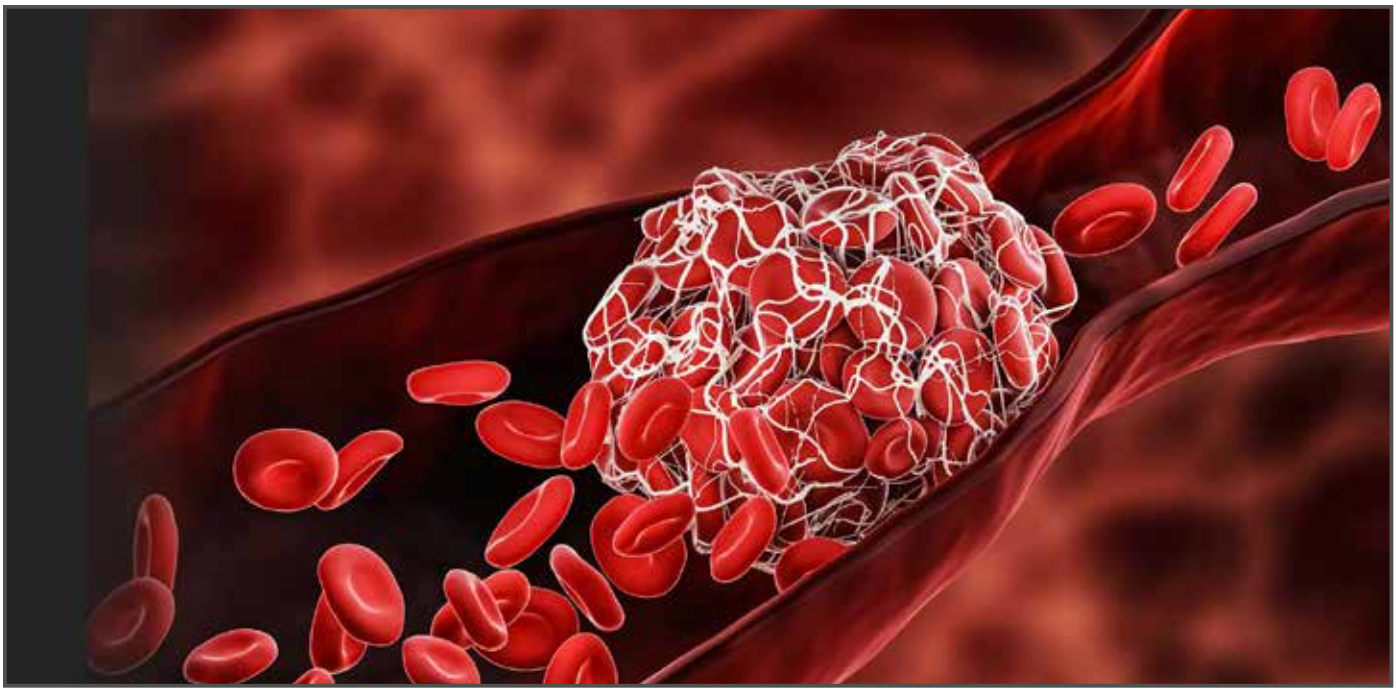
Ohio's Rep. Jim Jordan got into a shouting match at a Wednesday hearing of the House Select Committee on the Coronavirus

After Fauci told him that precautions to prevent spreading he virus can be lifted after the nation vaccinates as many people as soon as it can and infections decrease, Jordan again demanded "What measure, what standard, what objective outcome, do we have to reach before before Americans get their liberty and freedoms back?" He declared "First Amendment rights," and rights to attend church, petition one's government, freedom of the press and freedom of speech have "all been assaulted."

More than two hours into the hearing, Jordan returned to the same line of questions, demanding a "specific measurement that will have to be attained...so that Americans know they're going to get their liberties back and be able to move on with their lives."

Is the AstraZeneca Vaccine Safe or Not? Questined raised after blood clots

APRIL 9, 2021



Several European countries suspended use of the AstraZeneca Plc Covid-19 vaccine amid safety concerns after some blood-clotting events that regulators feared might be tied to the shot.

Given all the information shared by European Union and U.K. regulators, there is a reasonable chance that the AstraZeneca vaccine is associated with an increased risk of a rare condition that is characterized by blood clotting coupled with a fall in platelet counts. These divergent symptoms are what makes this a serious and difficult-to-treat reaction. The reported number in the EU calculates to about 1 per 100,000 vaccinations.

Australia and the Philippines also limited use of AstraZeneca's COVID-19 vaccine on Thursday, while the African Union dropped plans to buy the shot amid global shortages, dealing further blows to the company's hopes to deliver a vaccine for the world.

Australia recommended people under 50 should get Pfizer's COVID-19 vaccine in preference to AstraZeneca's, a policy shift it warned would hold up its inoculation campaign.

Italy recommends the AstraZeneca coronavirus vaccine only for people aged over 60 from now on, an ordinance by the Health Ministry showed. Up to April 8, Italy has administered 11.7 million doses of the vaccines authorized in the country, including 3.9 million doses of AstraZeneca, according to government data. Some 3.6 million people have received both vaccine jabs.

Globally, 269 candidate vaccines are still being developed — 85 of them in clinical trials — in countries including Germany, China, Russia, Britain, and the United States, according to information released by the World Health Organization on April 2.

Second coronavirus wave will push India's middle class toward poverty

April 17, 2021

Ashish Anand had dreams of becoming a fashion designer. A former flight attendant, he borrowed from relatives and poured his $5,000 life savings into opening a clothing shop on the outskirts of Delhi selling custom-designed suits, shirts and pants. The shop, called the Right Fit, opened in February 2020, just weeks before the coronavirus struck India. Prime Minister Narendra Modi abruptly enacted one of the world's toughest nationwide lockdowns to stop it. Unable to pay the rent, Mr. Anand closed the Right Fit two months later. Now Mr. Anand, his wife and his two children are among millions of people in India in danger of sliding out of the middle class and into poverty. They depend on handouts from his aging in-laws. Khichdi, or watery lentils cooked with rice, has replaced eggs and chicken at the dinner table. Sometimes, he said, the children go to bed hungry.

"I have nothing left in my pocket," said Mr. Anand, 38. "How can I not give food to my children?" Already, about 32 million people in India were driven into poverty by the pandemic last year, according to the Pew Research Center.

"It's very bad news in every possible way," said Jayati Ghosh, a development economist and professor at the University of Massachusetts Amherst. "It has set back our growth trajectory hugely and created much greater inequality."

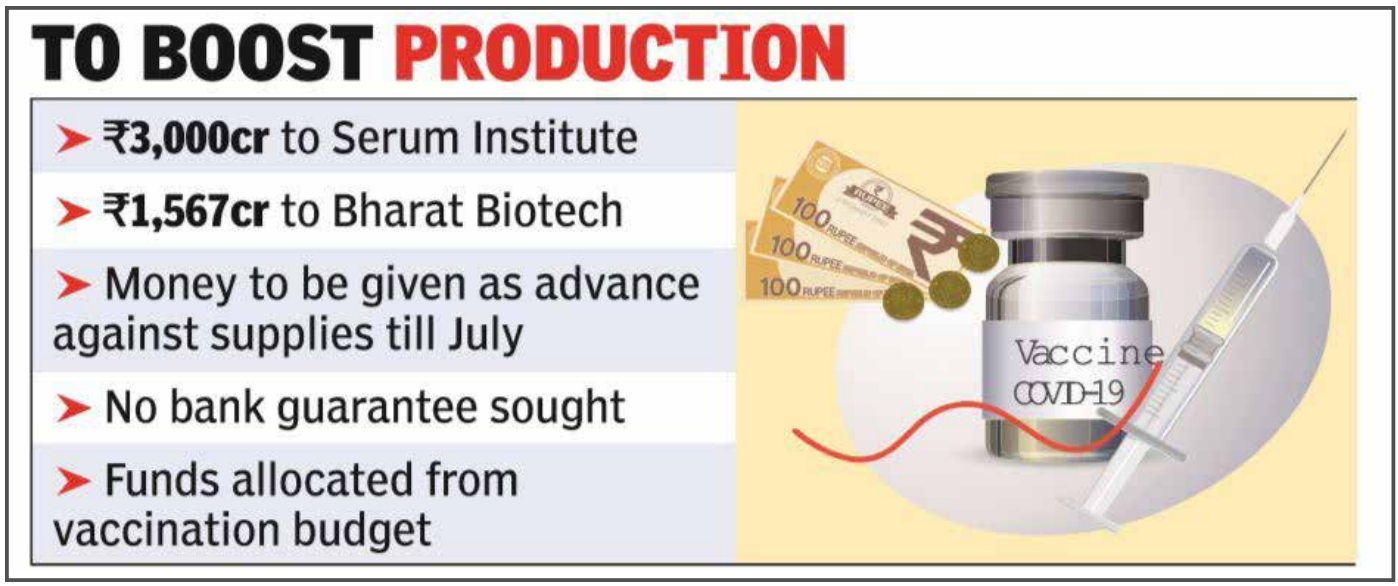
Pfizer-BioNTech COVID-19 vaccine will be Effective for Six Months only

The current Phase III trial of the Pfizer-BioNTech COVID-19 vaccine has confirmed the protection remains high for at least six months after the second dose. In a statement, Pfizer and BioNTech reported the vaccine, BNT162b2, was 91.3% effective against the disease, measured seven days through up to six months after the second dose.

The data was based on an analysis of 46,307 trial participants. Out of the 927 confirmed symptomatic COVID-19 cases in the trial, 850 were in the placebo group and 77 were in the vaccine group, which provides a vaccine efficacy of 91.3%. Efficacy was consistent no matter the age, gender, race and ethnicity, as well as in people with various comorbidities.

SII, Bharat Biotech to get Rs 4,500 cr advance payment to ramp up vaccine production

Apr 20, 2021



The finance ministry has given in-principle nod for advance payment of Rs 4,567.50 crore to Covid-19 vaccine manufacturers Bharat Biotech and Serum Institute of India (SII) to boost the production of the vaccines in India. This constitutes 100 per cent advance to two of India's Covid vaccine manufacturers till July.

While Rs 3,000 crore has been approved for Pune-based SII—the manufacturer of AstraZeneca COVID-19 vaccine Covishield, Rs 1567.50 crore has been granted to Hyderabad-based Bharat Biotech to boost the production of Covaxin.

The finance ministry has reportedly relaxed the general financial rules to allow the advance payment against future supplies of Covid-19 vaccines without any bank guarantees.

The credit will be sanctioned to the nodal ministers incharge for Covid-19 who will then pass it on to the two companies to ramp up vaccine production, reports said. Reports also said that the payment will be released at the earliest.

The decision comes days after SII CEO Adar Poonawalla requested the government for Rs 3,000 crore grant for ramping up capacity of the Covid-19 vaccine beyond 100 million doses a month. The SII is the largest vaccine manufacturer in the world. The company will also manufacture the Novavax vaccine in India.

SII will supply 200 million doses and Bharat Biotech is to supply another 90 million doses to the government by July at a pre-agreed rate of Rs 150 per dose.

Experts clear Russia's Sputnik Covid-19 vaccine for use in India

A committee of experts has granted emergency use approval to Sputnik-V, the vaccine against the coronavirus disease (Covid-19) developed by Russia, in India, which is in the middle of the second wave of the pandemic.

After Covishield and Covaxin, this will become the third Covid-19 vaccine to be used in the country if it is given a go-ahead by the Drugs Controller General of India (DCGI).

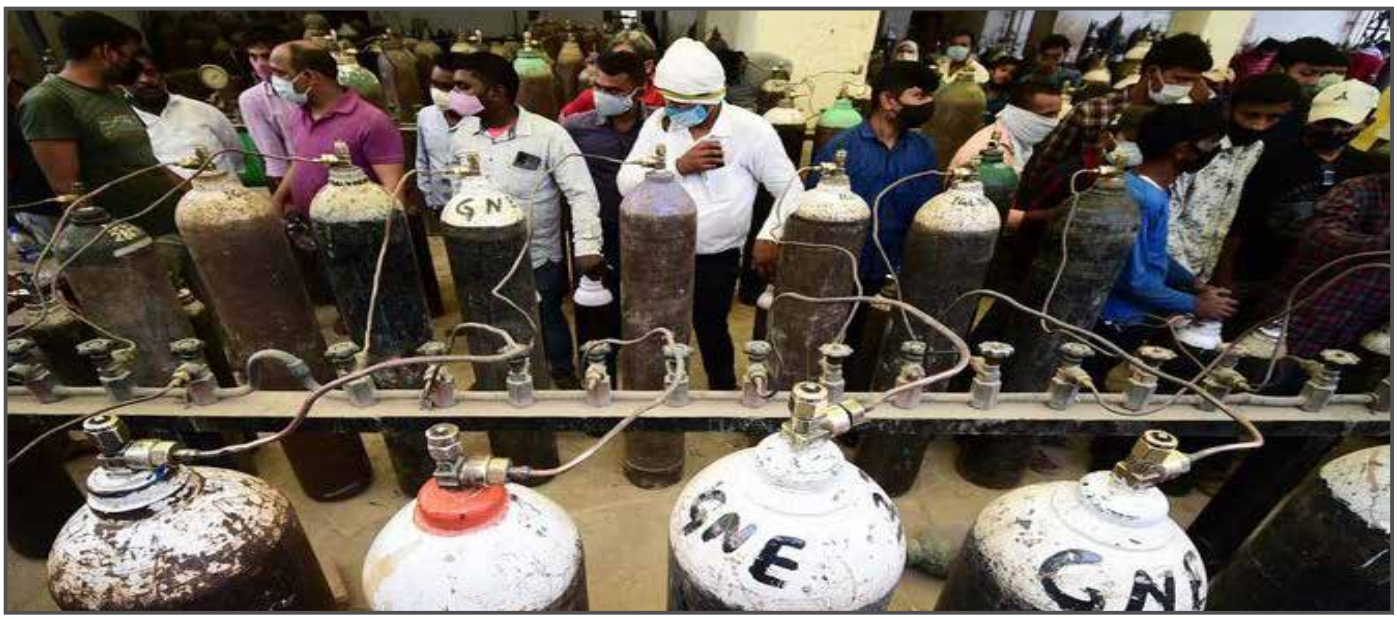
Dr Reddy's Laboratories, the Hyderabad-based pharmaceutical company, last week sought the government's approval for the vaccine to be used in India. The Russian Direct Investment Fund (RDIF) partnered with Dr Reddy's in September 2020 to conduct clinical trials of Sputnik V in India.

The Russian vaccine has an efficacy of 91.6% based on the interim analysis of phase III clinical trials, which included data from 19,866 volunteers in Russia. and is conducting its Phase III clinical trials in the UAE, India, Venezuela and Belarus, according to the Sputnik-V's website.

Along with Dr Reddy's, RDIF partnered with Hyderabad-based Virchow Biotech Private Limited in March to produce up to 200 million doses per year of Sputnik V in India, according to news agency PTI.

RDIF has also partnered with Stelis Biopharma Pvt Ltd and Panacea Biotec earlier in April as well to produce 200 million and 100 million doses per year of Sputnik V in the country.

India is running out of oxygen because the government wasted time in tender process



It took eight months to invite bids for over 150 oxygen generation plants costing just Rs 200 crore. Six months later, most still aren't up and running.

As the 65-year-old freelance journalist's complaint went viral on Twitter, the Uttar Pradesh chief minister's media advisor responded to him next afternoon, asking for more details. By then, Srivastava's oxygen levels had fallen to 31. At 4.20 pm on Saturday, his son, Harshit Srivastava, tweeted to say his father had died – waiting for an ambulance. "We did not get anything," he told Scroll.in on the phone. "I called every number for an oxygen cylinder but no one picked up."

About 7 km from their home, the government-run Shyama Prasad Mukherjee Civil Hospital has been waiting for an oxygen generation plant. It is one of 150 district hospitals across India for which the Central government floated tenders in October, eight months into the coronavirus pandemic, to create units that can produce medical oxygen on site.

But six months later, the oxygen plant is yet to be installed. Had it been in place, breathless Lucknow residents like Srivastava would have stood a better chance of surviving Covid-19. In Navsari, Gujarat, another district hospital due to get an oxygen generation plant has had to refuse admission in the last few days to several Covid-19 patients who required oxygen.

On October 21, the Central Medical Services Society, an autonomous institution under the Union health ministry, floated a tender online calling for bidders to establish Pressure Swing Adsorption oxygen plants in 150 district hospitals across the country. The PSA technology separates gases from a mixture in the atmosphere to generate concentrated oxygen that can be supplied to hospital beds through a pipeline, negating the need for hospitals to buy pressurised liquid oxygen from other sources.

An independent investigation by Scroll.in revealed a disturbing picture of mounting delays. We called more than 60 hospitals across 14 states where the new oxygen plants are expected to come up. Only 11 units had been installed and just five were operational, as per interviews with hospital officials.

Coronavirus becomes inactive for few individuals and at few places like rallies and melas

The alarming surge in COVID-19 cases in India can be blamed largely on Prime Minister Narendra Modi and Home Minister Amit Shah, and their reckless messaging through overcrowded, unmasked election rallies as well as the Kumbh Mela, said many people on social media and news channels.

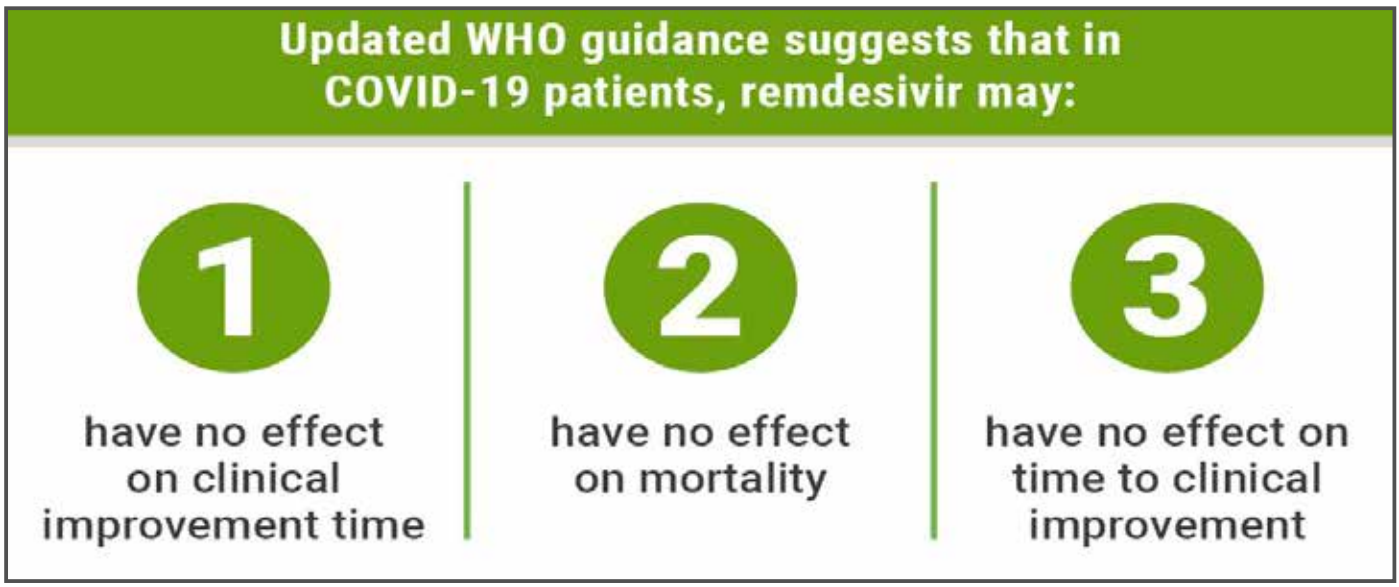
With the two Bharatiya Janata Party (BJP) leaders addressing 'massive' rallies and roadshows without masks, an illusion of normality was created. A message was sent to the masses that Covid is a nightmare of the past. The virus loves crowds, as the saying goes, but it particularly adores crowds that don't bother with masks or physical distancing. And the crowds at mega rallies in Assam or West Bengal suggest that both masks and distancing have become unfashionable.

It is rather facile for a prime minister like Modi with unparalleled popularity and devotion across the country to address people on his monthly radio talk show Mann Ki Baat and pontificate about 'mask zaroori'. But contrast this with Modi addressing thousands of people crammed into rally tents, sitting close to each other, so many without masks and say "amazing atmosphere" and not utter a word about Covid-safe behaviour.

Similar was the scene at the Haridwar Kumbh Mela on Monday as nearly 31 lakh people thronged to the Kumbh Mela for a holy dip in river Ganga at Haridwar's Har Ki Pauri. Regarding the ongoing Kumbh Mela, experts have warned that holding such a large gathering in the midst of a raging pandemic can prove to be catastrophic and severely impede India's fight against the deadly viral disease that has claimed millions of lives globally.

What is also of concern is that people attending the Kumbh Mela come from different parts of the country. Experts fear non-observance of Covid-19 protocol may result in the infection spreading to several states.

Why Remdesivir? Its already out from WHO solidarity trial



The Solidarity Trial published interim results on 15 October 2020. It found that all 4 treatments evaluated (remdesivir, hydroxychloroquine, lopinavir/ritonavir and interferon) had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay in hospitalized patients.

Interim results from the World Health Organization's solidarity trial showed that Gilead Sciences Inc's remdesivir showed little or no effect for covid-19 patients, a result which was significantly different from the positive results shown by Gilead's own trial.

In fact, the mega trial, which also studied the effect of hydroxychloroquine, a combination of HIV drugs lopinavir and ritonavir, as well as a combination of lopinavir and interferon, showed that none of the drugs actually showed any effect, according to the study.

Despite failure many doctors are prescribing remdesivir and it is leading to black marketing of drug.
CoV A drug tout India Today TV investigated at Gurugram offered remdesivir, purportedly manufactured by Hetero, for Rs 20,000 a vial, almost six times its new MRP.

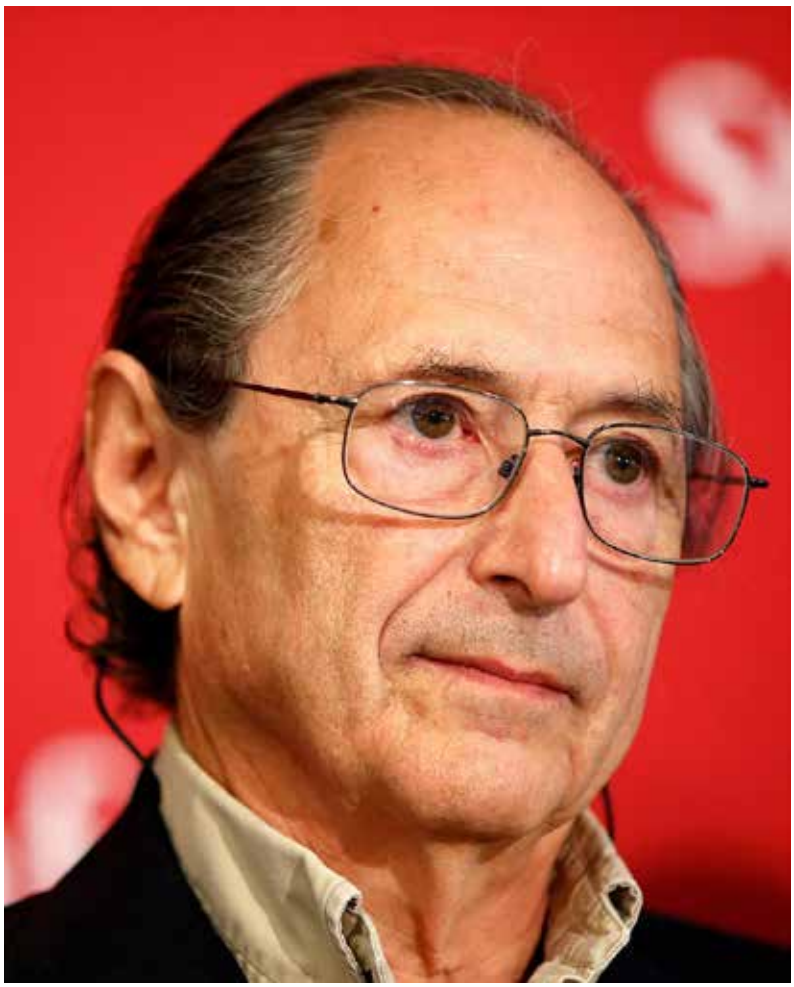
At Delhi's Yusuf Sarai market, vendor Ravindra at the Helpline Medical Store agreed to supply remdesivir for around Rs 14,000 a vial. He claimed the product would be smuggled out of a hospital.

A 100-mg vial of the drug manufactured by Cadila now has a maximum retail price of Rs 899, Syngene's Rs 2,450, Dr. Reddy's Rs 2,700, Cipla's Rs 3,000, Mylan's Rs 3,400, Jubilant's Rs 3,400, and Hetero's Rs 3,490.

The UP government on Monday claimed there was no scarcity of Remdesivir injections in UP, and added that 25,000 vials of the anti-viral drug would reach the state by Tuesday evening.

The ex-Pfizer scientist who became an anti-vax hero

March 18, 2021



Late last year, a semi-retired British scientist co-authored a petition to Europe's medicines regulator. The petitioners made a bold demand: Halt COVID-19 vaccine clinical trials.

Michael Yeadon, wasn't just any scientist. The 60-year-old is a former vice president of Pfizer, where he spent 16 years as an allergy and respiratory researcher. He later co-founded a biotech firm that the Swiss drugmaker Novartis purchased for at least $325 million.

Recent reports of blood clots and abnormal bleeding in a small number of recipients of AstraZeneca's COVID-19 vaccine have cast doubt on that shot's safety, leading several European countries to suspend its use.

Yeadon isn't the only respected scientist to have challenged the scientific consensus on COVID-19 and expressed controversial views. Michael Levitt, a winner of the Nobel Prize for chemistry, told the Stanford Daily last summer that he expected the pandemic would end in the United States in 2020 and kill no more than 175,000 Americans – a third of the current total – and "when we come to look back, we're going to say that wasn't such a terrible disease." And Luc Montagnier, another Nobel Prize winner, said last year that he believed the coronavirus was created in a Chinese lab. Many experts doubt that, but so far there is no way to prove or disprove it.

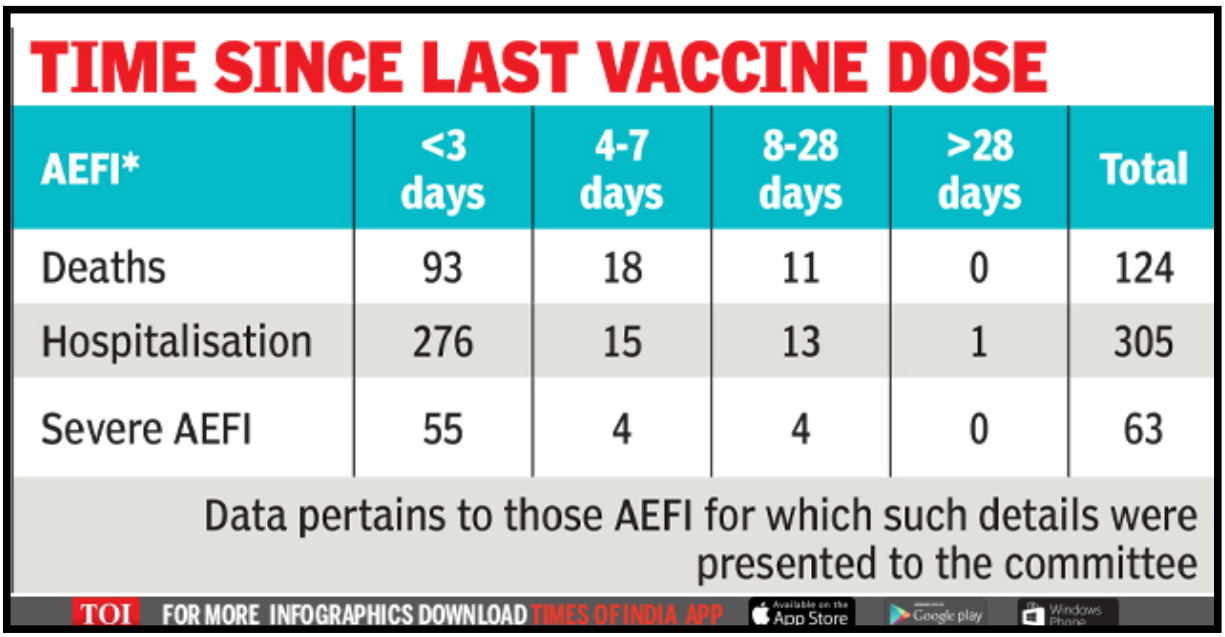
Levitt told Reuters that his projections about the pandemic in the United States were wrong, but he still believes COVID-19 eventually won't be seen as "a terrible disease" and that lockdowns "caused a great deal of collateral damage and may not have been needed."

In a debate last fall in Britain's House of Commons about the government's response to the pandemic, parliamentarian Richard Drax called Yeadon an "eminent" scientist, and cited his view "that the virus is both manageable and nearing its end."

Yeadon called for an end to mass testing and claimed that 30% of the population was already immune to COVID-19 even before the pandemic started. By the time of the recording, he said, there was little scope for the virus to spread further in the UK because most people had already been infected or were immune.

180 deaths following COVID vaccination reported in India

APRIL 09, 2021



TIME SINCE LAST VACCINE DOSE

AEFI*	<3 days	4-7 days	8-28 days	>28 days	Total
Deaths	93	18	11	0	124
Hospitalisation	276	15	13	1	305
Severe AEFI	55	4	4	0	63

Data pertains to those AEFI for which such details were presented to the committee

According to a presentation made to the National AEFI Committee during a meeting held on March 31, there have been 617 severe and serious (including deaths) adverse events following immunisation (AEFI).

As on March 29, a total of 180 deaths (29.2%) have been reported following vaccination across the country. Complete documentation is available only for 236 (38.3%) cases.

In all, 492 severe and serious AEFI have been classified by the AEFI Secretariat of the Immunisation Technical Support Unit (ITSU) at the Health Ministry. Classification has been completed for 124 deaths, 305 serious events that required hospitalisation, and 63 severe events that did not require hospitalisation.

Of the 124 deaths, more than 63 deaths (nearly 51%) have been categorised as being caused due to acute coronary syndrome (a range of conditions associated with sudden, reduced blood flow to the heart) or heart attack. Another 11 deaths (12%) of deaths are due to stroke.

As on March 17, the details of the causality assessment of only 13 AEFI including 10 deaths have already been made public by the national AEFI committee. The vaccine was not found to have caused death in any of the 10 vaccinated people.

However, in many cases post mortems have not been conducted. For example, in at least six out of 10 cases where the National AEFI Committee has completed causality assessment, no post mortem has been done, says Malini Aisola, a Public Health Researcher based in Delhi.

Virologist Dr. Jacob John, formerly of CMC Vellore, says that if deaths are not associated with vaccination, then they would be nearly evenly distributed across weeks post vaccination. However, there are 93 deaths in the first three days (31 deaths per day) and 18 deaths in four-seven days (4.5 deaths per day) after vaccination.

There have been 11 deaths in 8-28 days (0.5 deaths per day) post-vaccination. "Deaths are not evenly distributed," he says. There is hence a compulsion to investigate the deaths more thoroughly for any association.

Latest Biotech News

Coronavirus Vaccinations cross 13 crore doses in India

APRIL 20, 2021

Amidst complaints of vaccine shortages raised by several States, India crossed a milestone of administering 10 crore doses as on Saturday. The Health Ministry claimed that India had administered these doses within 85 days, faster than the United States' 89 days and China's 103 days.

Data from the CoWin database, that displays vaccination trends over a monthly timeline, shows that except for the weekends, the number of vaccinations on a given day is usually more than the previous day.

This particularly coincides with a steady increase in daily vaccinations that went down to 6.2 lakh on March 29 but then accelerated everyday to reach 41 lakh on April 3.

However, from March 29 to April 10, the number of daily infections has zoomed from about 58,000 to over 115,000.

This also coincides with vaccinations being opened for everyone above 45.

Health Minister Harsh Vardhan said on Thursday that 13.5 crore doses of vaccines were available, of which 10 crore had been administered until Saturday. The rest were either in the 'pipeline' or in stock. With India administering 30 lakh to 40 lakhs doses every day, it suggests that the existing stockpile should be available for 10-13 days, though every State gets varying replenishments based on past usage, vulnerable population and requirement.

Covishield, which constitutes around 90% of the doses administered in India, is facing serious supply constraints. Cutting across party lines, several States have flagged shortages in the last few days.

Longer lockdown only tool to break the chain of Covid transmission

APR 18, 2021

According to a study of the molecular basis, 60 per cent of strain is double mutant which is extremely dangerous, and who knows if the number of cases in the country will cross three to four lakh mark in the future.

As India reported its highest-ever single-day spike of COVID-19 cases with over 2.34 lakh new cases and more than 1,300 deaths on Saturday, Dr Shyam Agrawal of Del-

hi's Sir Gangaram Hospital stressed that only a longer period of lockdown can break the chain of transmission. "It is taking four to five days to double the number of cases now, so the chain of transmission can be broken only with a longer period of lockdown," Dr Agrawal said.

The doctor further cited the example of Maharashtra and said we need to do likewise. He also added that this mutant of the virus is extremely contagious.

He further said that according to a study of the molecular basis, 60 per cent of strain is double mutant which is extremely dangerous, and who knows if the number of cases in the country will cross three to four lakh mark in the future.

Large-Scale Study Finds One-Third of COVID-19 Patients Suffer Neurological Damage

Apr 12, 2021

Six months after a COVID-19 diagnosis, more than 33% of people exhibited some form of brain damage, according to a study appearing in Lancet Psychiatry. Mortality, therefore, is not the only concern. While COVID-19 can lead to serious respiratory, pulmonary and cardiac issues, it also has other severe, far-reaching neurological consequences.

Concern about related neurological and psychological sequalae have been raised since COVID-19 first appeared on medicine's radar screen. They were underscored with small studies and punctuated with case studies and anecdotal reports that reported increases risks of moodiness and anxiety disorders. There were few large-scale studies of COVID-19 and it consequences until now.

Researchers from the University of Oxford have completed a large-scale study confirming those early concerns. They analyzed the health records of 236,379 COVID-19 survivors six months after their COVID-19 diagnoses. Of the total, 46,302 were hospitalized and, of those, 8,945 were admitted to the intensive care unit (ICU).

While 33.62% of all the patients had some form of neurological or psychiatric disorder in their records, for 12.84% of them, the diagnosis was new. The most common diagnoses were anxiety disorder (17.4%), followed by ischemic stroke (2.1%) and psychiatric disorder (1.4%).

Among patients who were admitted to an (ICU), the incidence of neurological or psychological sequelae rose to 46.42%. For more than 25% of patients admitted to an ICU for COVID-19, the diagnosis of neurological or psychiatric issues was new. Specific diagnoses were anxiety disorder (19.15%), ischemic stroke (6.92%), and psychotic disorder (2.77%).

Other conditions were found in both groups, and included intracranial hemorrhage, dementia, and parkinsonism (a group of conditions with manifestations similar to Parkinson's disease).

The researchers reported these diagnoses, overall, were somewhat more common in COVID-19 patients than in patients diagnosed with influenza (1.44%) or those diagnosed with other respiratory tract infections (1.16%). Rates for first diagnoses were slightly higher, as well (1.78% and 1.32, respectively). Not surprisingly, the hazard rate for neurological and psychological conditions increased in step with the severity of their COVID-19 experience.

Likely Legal, 'Vaccine Passports' Emerge as the Next Coronavirus Divide in US and other parts of world

April 6, 2021

Businesses and universities want fast, easy ways to see if students and customers are vaccinated, but conservative politicians have turned "vaccine passports" into a cultural flash point.

Cathay Pacific airlines, convinced that digital proof of coronavirus vaccination will bring about the return of safe international travel, asked its pilots and crew to try out a new mobile app that showed their vaccination status on a recent flight from Hong Kong to Los Angeles.

New York has rolled out "Excelsior Pass," billed by the state as "a free, fast and secure way to present digital proof of Covid-19 vaccination" in case reopening sports and entertainment venues require proof of attendees' status.

And Walmart, the nation's largest private employer, is offering electronic verification apps to patients vaccinated in its stores so they "can easily access their vaccine status as needed," the company says.

Around the country, businesses, schools and politicians are considering "vaccine passports" — digital proof of vaccination against the coronavirus — as a path to reviving the economy and getting Americans back to work and play. Businesses especially fear that too many customers will stay away unless they can be assured that the other patrons have been inoculated.

But the idea is raising charged legal and ethical questions: Can businesses require employees or customers to provide proof — digital or otherwise — that they have been vaccinated when the coronavirus vaccine is ostensibly voluntary?

Can schools require that students prove they have been injected with what is still officially an experimental prophylaxis the same way they require long-approved vaccines for measles and polio? And finally, can governments mandate vaccinations — or stand in the way of businesses or educational institutions that demand proof?

Young survivors of Coronavirus can get reinfected with CoV for second time: Lancet study

Young patients who have recovered from Coronavirus once are not completely immune from contracting Covid-19 for the second time, a recent study conducted by The Lancet Respiratory Medicine has found. The subjects of the study were more than 3000 healthy members of the US Marines Corps most of whom were 18-20 years old. Out of the 3000 total about 2346 members were followed throughout the period of the study, the Indian Express reported.

At the start of the study in May 2020, a total of 189 Marines were seropositive whereas 2247 Marines were found to be seronegative. At the end of the study in November 2020, about 19 individuals out of the 189 Marines were found

re-infected with Coronavirus. On the other hand, about 50 percent of Marines who were seronegative earlier were infected with Coronavirus.

As per the study findings, the participants of the study who got reinfected with the Coronavirus were those who had lower antibody levels against the virus. In addition to this prime reason, the participants who got reinfected also had less common neutralising antibodies.

Bharat Biotech to make 6 crore Covaxin doses by July
The Department of Biotechnology (DBT) on Friday announced financial support to four firms including Bharat Biotech International and Haffkine Biopharmaceutical Corporation Ltd, to ramp up production of the indigenously-developed Covid-19 vaccine Covaxin.
Among the grants, Bharat Biotech, the co-developer of the vaccine, would get ₹65 crore to repurpose its new Bangalore facility to increase the capacity of Covaxin production, while Maharashtra state-owned Haffkine will also be provided around ₹65 crore for setting up a facility to make the inactivated vaccine.

Apart from these two companies, two more public sector undertakings Indian Immunologicals Ltd and Bharat Immunologicals and Biologicals Ltd will also be getting funds to produce 10-15 million dozes per month by August or September.

Plant-Based COVID-19 Vaccine Candidate Starts Phase 3 Trial

March 31, 2021

Medicago, the Quebec City-based biopharmaceutical company, and GlaxoSmithKline (GSK) have announced the start of Phase 3 clinical testing of Medicago's plant-derived COVID-19 vaccine candidate in combination with GSK's pandemic adjuvant, as part of the ongoing Phase 2/3 study.

Medicago received approval from Canadian and US regulatory authorities to proceed with the enrollment of healthy adults in the Phase 3 portion of the trial based on positive interim Phase 2 results. The vaccine candidate, in combination with the pandemic adjuvant, was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) on February 17, 2021. Fast Track designation allows the FDA to expedite the development and review of new medicines and vaccines intended to treat or prevent serious conditions and address an unmet medical need.

The Phase 3 portion of the study is an event-driven, randomized, observer-blinded, placebo-controlled, two-way cross-over design that will evaluate the efficacy and safety of the adjuvanted CoVLP formulation, compared to placebo. The study will enroll up to 30,000 subjects initially composed of healthy adults (18y to 65y), followed by elderly adults (65y+), and adults with comorbidities. The trial will take place in 10 countries pending regulatory approvals, starting with Canada and the United States, and will enroll males and females from ethnically and racially diverse populations. Medicago's plant-derived COVID-19 vaccine candidate uses Coronavirus-Like-Particle (CoVLP) technology with the vaccine composed of recombinant spike (S) glycoprotein expressed as virus-like-particles (VLPs) co-administered with GSK's pandemic adjuvant. Two doses of 3.75 micrograms of CoVLP are administered 21 days apart.

WHO Report: Wildlife Farms, Not Market, Likely Source Of Coronavirus Pandemic

The highly anticipated World Health Organization report on the origins of the coronavirus that sparked a global pandemic was released on Tuesday.

According to the report, data suggests that the Huanan Seafood Wholesale Market in Wuhan was not the original source of the outbreak.

In addition, the report noted that "introduction through a laboratory incident" — a leak from the lab in Wuhan — "was considered to be an extremely unlikely pathway."

The report further suggests that animals in livestock farms in southeast Asia could be "linked to early human cases" and that further study on these farms is needed.

In an exclusive interview with NPR last week, Peter Daszak, a disease ecologist who was part of the investigative team that did two weeks of research in China, noted that wildlife farms supply vendors at the Wuhan market, which early had been identified as a possible starting point of the pandemic.

The WHO report is likely to generate controversy. Jamie Metzl, a geopolitics expert who serves on a WHO genetic engineering advisory committee, called the investigation a "highly chaperoned, highly curated study tour" in an interview Sunday with 60 Minutes.

FDA Authorizes First Machine Learning-Based Screening Device to Identify Certain Biomarkers That May Indicate COVID-19

March 30, 2021

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first machine learning-based Coronavirus Disease 2019 (COVID-19) non-diagnostic screening device that identifies certain biomarkers that are indicative of some types of conditions, such as hypercoagulation (a condition causing blood to clot more easily than normal).

The Tiger Tech COVID Plus Monitor is intended for use by trained personnel to help prevent exposure to and spread of SARS-CoV-2, the virus that causes COVID-19. The device identifies certain biomarkers that may be indicative of SARS-CoV-2 infection as well as other hypercoagulable conditions (such as sepsis or cancer) or hyper-inflammatory states (such as severe allergic reactions), in asymptomatic individuals over the age of 5.

The Tiger Tech COVID Plus Monitor is designed for use following a temperature reading that does not meet criteria for fever in settings where temperature check is being conducted in accordance with Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines. This device is not a substitute for a COVID-19 diagnostic test and is not intended for use in individuals with symptoms of COVID-19.

The device is an armband with embedded light sensors and a small computer processor. The armband is wrapped around a person's bare left arm above the elbow during use. The sensors first obtain pulsatile signals from blood flow over a period of three to five minutes. Once the measurement is completed, the processor extracts some key features of the pulsatile signals, such as pulse rate, and feeds them into a probabilistic machine learning model that has been trained to make predictions on whether the individual is showing certain signals, such as hypercoagulation in blood.

Hypercoagulation is known to be a common abnormality in COVID-19 patients. The result is provided in the form of different colored lights used to indicate if an individual is demonstrating certain biomarkers, or if the result is inconclusive.

After Emergent COVID-19 Manufacturing Mess, J&J Team Takes Charge

Apr 05, 2021

Emergent BioSolutions' production facility in Baltimore botched production for an ingredient for Johnson & Johnson's COVID-19 vaccine. J&J has a contract with Emergent for its production plant in Baltimore. The problem involved one batch of an ingredient in the vaccine.

Now, J&J is taking over the production at that facility. In order to have full control of J&J's product, the production of the AstraZeneca vaccine, which was being conducted at the same facility, will move elsewhere.

Emergent is part of J&J's manufacturing network but did not yet have FDA authorization to produce part of the COVID-19 vaccine. Emergent wasn't part of the supply chain, but was scaling up to be. If the batch had been successful, it would have been used in the vaccine and distributed.

"It's important to note that these wouldn't be finished doses, just key ingredients ultimately bound for another facility to be put into vials and prepared for distribution," reported NPR's Sydney Lupkin.

The problem was first reported by The New York Times, which indicated that 15 million vaccine doses were potentially affected. Apparently there was a mix-up by Emergent between vaccine materials it is producing for both J&J and AstraZeneca.

AstraZeneca's Diabetes Drug Farxiga Faled in COVID-19 Study

Apr 12, 2021

AstraZeneca's diabetes drug Farxiga (dapagliflozin) failed to reach endpoints in a Phase III study as a potential treatment for hospitalized COVID-19 patients serious risk of developing complications.

AstraZeneca, which had partnered with Saint Luke's Mid America Heart Institute to conduct the study, announced the negative outcome this morning. The failure follows the continued difficulties the U.K.-based pharma company has had with its COVID-19 vaccine in parts of Europe and Asia.

In the announcement, AstraZeneca said Farxiga did not achieve statistical significance in the Phase III DARE-19 study after a 30-day period. The primary endpoint of the study was the prevention measuring organ dysfunction and all-cause mortality. Additionally, AstraZeneca said Farxiga fell short in assisting hospitalized patients with recovery.

The safety and tolerability of Farxiga remained consistent with the well-established safety profile of the medicine.

Farxiga is a first-in-class, oral, once-daily SGLT2 inhibitor. The drug has been approved by the U.S. Food and Drug Administration to reduce the risk of hospitalization for heart failure in patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors.

The DARE-19 study was the first late-stage study that evaluated the safety and efficacy of SGLT2 inhibitors in 1,250 hospitalized COVID-19 patients who had the risk factors in developing severe complications.

Patients who were enrolled in the study had a medical history of cardiac, renal, and metabolic comorbidities, including hypertension, heart failure, chronic kidney disease and atherosclerotic cardiovascular disease. These comorbidities can lead to the death of patients.

The full data from the study was not provided by AstraZeneca this morning. The company said it intends to share the complete data at the American College of Cardiology Scientific Sessions in May. Mene Pangalos, AstraZeneca's executive vice president of BioPharmaceuticals R&D, noted that until AstraZeneca launched the Phase III study, there was little data on the use of SGLT2 inhibitors in hospitalized COVID-19 patients. Even with missing the study's primary endpoints, Pangalos said the study has helped fill a "knowledge gap" as the world continues to grapple with the COVID-19 pandemic.

Regeneron's Antibody Cocktail Cuts Progression to Symptomatic COVID-19

Apr 12, 2021

Regeneron Pharmaceuticals announced the results from its Phase III trial of recently infected asymptomatic COVID-19 patients for its REGEN-COV (casirivimab with imdevimab) antibody cocktail.

The therapy decreased the overall risk of the patients progressing to symptomatic COVID-19 by 31%, which was the trial's primary endpoint. It also decreased the overall risk of progression by 76% after the third day. In addition, REGEN-COV decreased the duration of symptoms and significantly reduced viral levels.

The trial hit both primary and key secondary endpoints, demonstrating the antibody cocktail decreased the risk of symptomatic infections by 81% in people who were not infected when they began the trial. On average, people receiving the antibody therapy who had symptomatic infection resolved their symptoms in one week, compared to three weeks with placebo.

"These data suggest that REGEN-COV can complement widespread vaccination strategies, particularly for those at high risk of infection," said Myron Cohen, who heads the monoclonal antibody programs for the NIH-sponsored COVID Prevention Network (CoVPN) and is director of the Institute for Global Health & Infectious Diseases at the University of North Carolina at Chapel Hill. "Despite standard precautions to reduce transmission, nearly 10% of unvaccinated individuals living with an infected person developed symptomatic infections if they did not receive REGEN-COV. If authorized, convenient subcutaneous administration of REGEN-COV could help control outbreaks in high-risk settings where individuals have not yet been vaccinated, including individual households and group living settings."

In the first trial, adverse events (AE) occurred in 34% of patients receiving REGEN-COV and 48% of placebo patients, with serious adverse events occurring in 0% of the REGEN-COV cohort and 3% of the placebo patients. No patients dropped out of the test from AEs, and there were no deaths.

In the second trial, adverse events occurred in 20% of patients receiving REGEN-COV and 29% in the placebo group, with serious adverse events in 1% of the REGEN-COV cohort and 1% in the placebo group. Zero REGEN-COV participants were either hospitalized or visited the emergency room because of COVID-19 during the 29-day efficacy assessment period, while four in the placebo group did. None withdrew from the trial from adverse events, and none of the deaths in the trial—two in the antibody group and two in the placebo group, were related to COVID-19 or the study drug.

REGEN-COV is still being studied in clinical trials in mul-

tiple settings. These include for prevention of COVID-19 in households contacts of infected people; in non-hospitalized and certain hospitalized patients, including the open-label RECOVERY trial of hospitalized patients being run in the U.K.

Zydus Cadila seeks DCGI approval for use of PegIFN in treating COVID-19

Zydus Cadila announced that its Phase III clinical trials with Pegylated Interferon Alpha 2b, PegiHepTM has shown promising results in treating COVID-19. In what could be a breakthrough in the disease management of COVID-19, the interim results indicate that PegIFN when administered early on, could help patients recover faster and avoiding much of the complications seen in the advanced stages of the disease. PegIFN in COVID19 has several add-on advantages compared to other anti-viral agents. The treatment regimen would be less cumbersome and more affordable for patients as Pegylated Interferon Alpha 2b, is a single dose regimen.

It would also ensure better compliance. PegIFN has very well-established safety with multiple doses in chronic hepatitis B and C patients since many years. Patients on Pegylated Interferon Alpha 2b during the trial also showed lesser need for supplemental oxygen, clearly indicating that it was able to control respiratory distress and failure which has been one of the major challenges in treating COVID-19. The findings are in line with recently reported importance of early IFN treatment given in combination with steroids in the treatment of COVID-19 (Lu et al, Signal Transduction and Targeted Therapy (2021) 6:107, a Nature publication. With these positive results, the Company has applied for an approval for additional indication with the DCGI for the use of PegIFN in the treatment of COVID 19.

Latest Biotech Research

Clinical trial completion rates decline during COVID-19 pandemic

Researchers previously reported that more than 80% of clinical trials suspended between March 1 and April 26, 2020, noted the pandemic as their chief reason for halting activity. Patient enrollment in studies was lower in April 2020, compared to April 2019. Arthur Berg, associate professor of public health sciences, and Nour Hawila, a biostatistics doctoral candidate, investigated how these trends may have affected the completion of clinical trials.

The researchers examined more than 117,000 trials in the United States, Europe, Asia and other regions to study whether the pandemic affected clinical research. Their goal was to assess how the pandemic's mitigation efforts and financial setbacks may have contributed to decreased clinical trial enrollment and completion.

"The pandemic has made it more difficult for researchers to recruit and follow up on patients in clinical trials," said Hawila, a research assistant from the Department of Public Health Sciences. "This analysis revealed that the impact was substantial -- particularly for trials funded by government, academic or medical entities."

Hawila and Berg analyzed data from ClinicalTrials.gov, a website that contains information on the status of thousands of clinical trials in the U.S. Pre-COVID-19 enrollment and completion data was pulled from March 2017 to February 2020. The post-COVID-19 period was defined as April through October 2020.

According to researchers, the pandemic reduced the number of new interventional clinical trial submissions to ClinicalTrials.gov by about 10%. Completed trials were down 13% to 23%, depending on the sector and location of the trial source. Clinical trials sponsored by pharmaceutical, biotechnology and therapeutic companies were more likely to complete enrollment.

Journal Reference:
Nour Hawila, Arthur Berg. Assessing the Impact of COVID-19 on Registered Interventional Clinical Trials. Clinical and Translational Science, 2021; DOI: 10.1111/cts.13034

COVID-19 patients can be categorized into three groups

In a new study, researchers identify three clinical COVID-19 phenotypes, reflecting patient populations with different comorbidities, complications and clinical outcomes. The three phenotypes are described in a paper published this week in the open-access journal PLOS ONE by first authors Elizabeth Lusczek and Nicholas Ingraham of University of Minnesota Medical School, US, and colleagues.

Journal Reference:
Elizabeth R. Lusczek, Nicholas E. Ingraham, Basil S. Karam, Jennifer Proper, Lianne Siegel, Erika S. Helgeson, Sahar Lotfi-Emran, Emily J. Zolfaghari, Emma Jones, Michael G. Usher, Jeffrey G. Chipman, R. Adams Dudley, Bradley Benson, Genevieve B. Melton, Anthony Charles, Monica I. Lupei, Christopher J. Tignanelli. Characterizing COVID-19 clinical phenotypes and associated comorbidities and complication profiles. PLOS ONE, 2021; 16 (3): e0248956
DOI: 10.1371/journal.pone.0248956

COVID-19 vaccines may not produce sufficient antibody response in transplant recipients

Now, Johns Hopkins Medicine researchers have tried to rectify that inequity, taking one of the first looks at how people who are immunocompromised respond to their first dose of one of the two mRNA vaccines -- Moderna and Pfizer-BioNTech -- currently being administered worldwide. Their findings, as published March 15, 2021, in a research letter in the Journal of the American Medical Association, disappointingly show that only 17% produced detectable antibodies against the SARS-CoV-2 virus.

"This is in stark contrast to people with healthy immune systems who are vaccinated, nearly all of whom mount a sufficient antibody defense against COVID-19," says study lead author Brian Boyarsky, M.D., a surgery resident at the Johns Hopkins University School of Medicine.

The study evaluated the vaccine immunogenic response for 436 transplant recipients, none of whom had a prior diagnosis of COVID-19 or tested positively for SARS-CoV-2 antibodies. The median age was 55.9 years and 61% were women. Fifty-two percent were administered a single dose of the Pfizer-BioNTech vaccine and 48% received one shot of the Moderna vaccine. The median time since transplant for the participants was 6.2 years.

At a median time of 20 days after the first dose of vaccine, the researchers report that only 76 of the 436 participants (17%) had detectable antibodies to the SARS-CoV-2 virus. The researchers also found that among the 76 transplant recipients, the most likely to develop an antibody response were those younger than age 60 who did not take anti-metabolites for immunosuppression and who received the Moderna vaccine.

Journal Reference:
Brian J. Boyarsky, William A. Werbel, Robin K. Avery, Aaron A. R. Tobian, Allan B. Massie, Dorry L. Segev, Jacqueline M. Garonzik-Wang. Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients. JAMA, 2021;
DOI: 10.1001/jama.2021.4385

Flu shot associated with fewer, less severe COVID cases, study finds

People who received a flu shot last flu season were significantly less likely to test positive for a COVID-19 infection when the pandemic hit, according to a new study. And those who did test positive for COVID-19 had fewer complications if they received their flu shot.

Researchers reviewed medical charts for more than

27,000 patients who were tested for a COVID-19 infection at Michigan Medicine between March and mid-July of 2020. Of the nearly 13,000 who got a flu shot in the previous year, 4% tested positive for COVID-19. Of the 14,000 who hadn't gotten a flu shot, nearly 5% tested positive for COVID-19. The association remained significant after controlling for other variables including ethnicity, race, gender, age, BMI, smoking status and many comorbid conditions, Hofmann says.

People who received their flu shot were also significantly less likely to require hospitalization, although the researchers didn't find a significant difference in mortality between the two groups. No one in the study tested positive for both infections at the same time.

The underlying mechanism behind the association isn't yet clear, Hofmann says.

Prospective longitudinal studies to examine the effect of the flu vaccine on respiratory illness are ongoing, including the Household Influenza Vaccine Evaluation (HIVE) study through the University of Michigan's School of Public Health.

"It's powerful to give providers another tool to encourage their patients to take advantage of available, effective, safe immunizations," says co-first author Carmel Ashur, M.D., M.S., an assistant professor of internal medicine and a hospitalist at Michigan Medicine.

Journal Reference:
Anna Conlon, Carmel Ashur, Laraine Washer, Kim A. Eagle, Marion A. Hofmann Bowman. Impact of the influenza vaccine on COVID-19 infection rates and severity. American Journal of Infection Control, 2021; DOI: 10.1016/j.ajic.2021.02.012

Increased rates of organ damage after discharge from hospital with COVID-19

People discharged from hospital after covid-19 appear to have increased rates of organ damage ("multiorgan dysfunction") compared with similar individuals in the general population, finds a study published by The BMJ

The increase in risk was not confined to the elderly and was not uniform across ethnic groups, prompting the researchers to suggest that the long-term burden of covid-19-related illness on hospitals and broader healthcare systems is likely to be substantial.

Although covid-19 is most well known for causing serious respiratory problems, it can affect other organs and systems within the body, including the heart, kidneys, and liver.

Several unexplained symptoms that continue for more than 12 weeks after covid-19 are said to be part of post-covid syndrome (also known as "long covid"), but the long term pattern of organ damage after infection is still unclear.

To investigate this, a team of UK researchers from the Office for National Statistics, University College London and University of Leicester set out to compare rates of organ dysfunction in individuals with covid-19 several months after discharge from hospital with a matched control group from the general population.

Their findings are based on 47,780 individuals (average age 65, 55% men) in hospital in England with covid-19 who were discharged alive by 31 August 2020.

Participants were matched with controls, based on personal characteristics and medical history. Health records were then used to track rates of hospital readmission (or any admission for controls), death from any cause, and diagnoses of respiratory, cardiovascular, metabolic, kidney, and liver diseases until 30 September 2020.

Over an average follow-up of 140 days, nearly a third of individuals who were discharged from hospital af-

ter acute covid-19 were readmitted (14,060 of 47,780) and more than 1 in 10 (5,875) died after discharge.

These events occurred at rates of 766 readmissions and 320 deaths per 1,000 person years, which were four and eight times greater, respectively, than those in matched controls.

Rates of respiratory disease, cardiovascular disease, and diabetes were also significantly raised in patients with covid-19, with 539, 66, and 29 new onset diagnoses per 1,000 person years, respectively (equivalent to 27, three, and 1.5 times greater than in matched controls).

Differences in rates of multiorgan dysfunction between patients with covid-19 and matched controls were greater for individuals aged less than 70 than for those aged 70 or older, and in ethnic minority groups compared with the white population, with the largest differences seen for respiratory disease.

Journal Reference:
Daniel Ayoubkhani, Kamlesh Khunti, Vahé Nafilyan, Thomas Maddox, Ben Humberstone, Ian Diamond, Amitava Banerjee. Post-covid syndrome in individuals admitted to hospital with covid-19: retrospective cohort study. BMJ, 2021; n693 DOI: 10.1136/bmj.n693

Mango Genome Sequence Leads to Candidate Genes for Fruit Quality

Mango Genome Consortium decoded the genome of mango cultivar Tommy Atkins which can help in global efforts in understanding mango genetics.

Mango is a tropical fruit that is known for its sweet and aromatic characteristics. It has been an orphan crop with limited molecular information. Recent studies have been conducted to develop linkage maps, transcriptomes, and diversity analysis of large collections. Combined analysis of genomic and phenotypic information could help in the improvement of mango breeding.

An international team of researchers of the Mango Genome Consortium sequenced, analyzed, and annotated the genome of Tommy Atkins mango. The genome sequence showed 20 pseudomolecules representing the 20 chromosomes of mango and included ~86% of the ~439 Mb haploid mango genome. Two regions were found to be linked with the commercially important fruit size characteristics.

BMC Plant Biology.

Prolonged immune response may contribute to post-COVID-19 blood clots

Serious complications due to blood clots, such as heart attacks and strokes, that are experienced by some COVID-19 survivors may be caused by a lingering immune response in the blood vessels after recovery, suggests a study published today in eLife.

The findings may help explain why some COVID-19 survivors, so-called 'long-haulers', report lasting COVID-19 symptoms or why some experience strokes or heart attacks weeks or months after recovery. They may also suggest potential strategies to help prevent these complications.

"During the initial stages of infection, SARS-CoV-2, the virus that causes COVID-19, may attack the lining of the blood vessels which can trigger inflammation and an immune response. This can result in blood vessel damage in the short term," explains first author Florence Chioh, Research Assistant at the Lee Kong Chian School of Medicine (LKCMedicine), Nanyang Technological University, Singapore. "For our study,

we wanted to investigate what happens in the blood vessels of COVID-19 survivors over the longer term."

Chioh and colleagues collected blood samples from COVID-19 survivors within a month of their recovery and discharge from the hospital. They found that, in comparison with healthy individuals, COVID-19 survivors have twice as many damaged blood vessel cells, called circulating endothelial cells, floating in their blood. Even more of these damaged blood vessel cells were found in survivors who had conditions such as hypertension or diabetes that can also damage the blood vessels.

In addition to signs of blood vessel damage, the team found that survivors had an abundance of inflammatory proteins called cytokines that are produced by immune cells. They also found unusually high numbers of immune cells called T cells, which help destroy viruses, despite the fact that the virus was already gone.

"We show that an overactive immune system is the likely cause of blood vessel damage seen in some COVID-19 survivors," Chioh says. "This may cause 'leakiness' in the blood vessels that increases the risk of blood clots."

A novel marker of adult human neural stem cells discovered

While there are increasing number of tools available to study NSCs and neurogenesis in mouse models, one of the major hurdles in exploring this fundamental biological process in the human brain is the lack of specific NSCs markers amenable for advanced imaging and in vivo analysis. A team of researchers led by Dr. Mirjana Maletic-Savatic, associate professor at Baylor College of Medicine and investigator at the Jan and Dan Duncan Neurological Research Institute at Texas Children's Hospital, and Dr. Louis Manganas, associate professor at the Stony Brook University, decided to tackle this problem in a rather unusual way. They reasoned that if they could find proteins that are present on the surface of NSCs, then they could eventually make agents to "see" NSCs in the human brain.

"The ultimate goal of our research is to maintain neurogenesis throughout life at the same level as it is in the young brains, to prevent the decline in our cognitive capabilities and reduce the tendency towards mood disorders such as depression, as we age. To do that, however, we first need to better understand this elusive, yet fundamental process in humans. However, we do not have the tools to study this process in live humans and all the knowledge we have gathered so far comes from analyses of the postmortem brains. And we cannot develop tools to detect this process in people because existing NSC markers are present within cells and unreachable for in vivo visualization," Maleti -Savati said. "So, in collaboration with our colleagues from New York and Spain, we undertook this study to find surface markers and then develop tools such as ligands for positron emission tomography (PET) to visualize them using advanced real-time in vivo brain imaging."

Typically, antibodies are made against known antigens but the team set out to generate antibodies for unknown target proteins, which made their mission rather challenging. They solved this problem by relying on an age-old method of generating antibodies by injecting mice with whole-cell or membrane preparations. This resulted in 1648 clones out of which 39 reacted with NSCs. Upon closer examination, one potential candidate most strongly labeled NSCs. Mass spectrometric analysis of the human hippocampal tissue identified the target protein as the Brain-Abundant Signal Protein 1 (BASP-1), previously shown to be present in the neurons of the mouse brain but not in NSCs. Interestingly, the specific antibody that recognizes BASP-1 in NSCs did not label neurons or any other cells apart from NSCs, indicating that it could be used to visualize these cells in the live mammalian brain.

"Using our new antibody, we found that BASP-1 is restricted to NSCs in neurogenic niches in the mammalian brains, including humans, during development in utero and after birth. Thus, our work identified mem-

brane-bound BASP-1 protein as a possible biomarker of NSCs that would allow us to examine the mechanisms of adult human neurogenesis as well as to explore its role in the process," Maleti -Savati concluded.

Journal Reference:
Louis N. Manganas, Irene Durá, Sivan Osenberg, Faith Semerci, Mehmet Tosun, Rachana Mishra, Luke Parkitny, Juan M. Encinas, Mirjana Maletic-Savatic. BASP1 labels neural stem cells in the neurogenic niches of mammalian brain. Scientific Reports, 2021; 11 (1) DOI: 10.1038/s41598-021-85129-1

PLD3 gene contributes to risk of Alzheimer's disease

A rare and controversial mutation in the phospholipase D3 (PLD3) protein -- previously linked to Alzheimer's disease -- interferes with PLD3's vital recycling function inside neurons. Matthew Schrag of Vanderbilt University Medical Center and colleagues report these new findings in a paper published April 8th in PLOS Genetics.

About 1 percent of people with Alzheimer's disease carry a specific mutation in their PLD3 gene. The question of whether or not this mutation leads to Alzheimer's disease has remained controversial, however, due to its rarity and because the protein's function was previously unknown. In the new study, Schrag's team delved deeper into the function of this gene and its link to the disease. The researchers found that PLD3 is located in lysosomes inside neurons. Lysosomes are highly acidic sacs of enzymes that act as the recycling system of the cell. PLD3 produces an important component of the membrane of these acidic organelles, and this function is lost in the mutant form. In the brains of people with Alzheimer's disease, PLD3 occurred near buildups of toxic proteins called β-amyloid plaques. Furthermore, people with high levels of PLD3 had fewer β-amyloid plaques and less cognitive decline, suggesting that normal PLD3 helps protect against the disease.

Together, these discoveries establish the PLD3 mutation places a person at higher risk of developing Alzheimer's disease, most likely by disrupting its role in the lysosome. The researchers propose that future studies should focus on investigating whether boosting PLD3 can have a protective effect that reduces the effects of the disease. Ultimately, these findings may yield new drug targets for Alzheimer's disease therapies and improve our understanding of the role of the lysosome in this common and burdensome disease.

"The discovery of Phospholipase D3 as a genetic risk factor for Alzheimer's disease points to the critically important role of the lysosome in dementia," the authors add. "Targeting experimental therapies to these lysosomes could lead us to new approaches to treat this disease."

Journal Reference:
Alex G. Nackenoff, Timothy J. Hohman, Sarah M. Neuner, Carolyn S. Akers, Nicole C. Weitzel, Alena Shostak, Shawn M. Ferguson, Bret Mobley, David A. Bennett, Julie A. Schneider, Angela L. Jefferson, Catherine C. Kaczorowski, Matthew S. Schrag. PLD3 is a neuronal lysosomal phospholipase D associated with β-amyloid plaques and cognitive function in Alzheimer's disease. PLOS Genetics, 2021; 17 (4): e1009406 DOI: 10.1371/journal.pgen.1009406

Women accumulate Alzheimer's-related protein faster

Alzheimer's disease seems to progress faster in women than in men. The protein tau accumulates at a higher rate in women, according to research from Lund University in Sweden. The study was recently published in Brain.

The first protein to aggregate in Alzheimer's is beta-amyloid. Men and women are equally affected by the first disease stages, and the analysis did not show any differences in the accumulation of beta-amyloid.

Memory dysfunction arises later, when tau starts to accumulate. More women than men are affected by memory problems due to Alzheimer's, and it was for tau that the researchers found a higher rate of accumulation in women.

"Tau accumulation rates vary greatly between individuals of the same sex, but in the temporal lobe, which is affected in Alzheimer's disease, we found a 75% higher accumulation rate in women as a group compared to men," explains Ruben Smith, first author of the study.

The accumulation of tau is faster in patients who already have a pathological accumulation of beta-amyloid, and are in the early phase of the disease. The discovery that the accumulation rate of tau is higher in women remained even after adjusting for age and the levels of tau they had at the beginning. Together with data from three similar cohorts in the USA, the project contains 209 women and 210 men.

"The next step would be to examine why this accumulation is faster in women," says Sebastian Palmqvist, the researcher responsible for the cognitive assessment of the patients.

The study did not investigate the reasons for the higher rate of tau accumulation in women.

"Our study strongly indicates that the faster spread of tau makes women more prone to develop dementia because of Alzheimer's pathology compared to men. Future experimental studies will be important to understand the reasons behind this," concludes Professor Oskar Hansson.

Journal Reference:
Ruben Smith, Olof Strandberg, Niklas Mattsson-Carlgren, Antoine Leuzy, Sebastian Palmqvist, Michael J Pontecorvo, Michael D Devous, Rik Ossenkoppele, Oskar Hansson. The accumulation rate of tau aggregates is higher in females and younger amyloid-positive subjects. Brain, 2020; 143 (12): 3805 DOI: 10.1093/brain/awaa327

Bio Controversies

Elsevier pulls 26 COVID-19 papers by Victor Grech

March 31, 2021

An Elsevier journal has retracted more than two dozen Covid-19 papers by a researcher in Malta with a fondness for Star Trek after determining that the articles did not meet its standards for publication.

The move comes several months after we reported that Hampton Gaddy, a student at the University of Oxford, had raised questions about more than 100 articles written by a pediatric cardiologist named Victor Grech. The papers appeared in Early Human Development (EHD), which Grech managed to turn into something of a vanity press — including for papers about how the lessons of Star Trek shed light on everything from the evolving role of nurses to the horrors of Nazi doctors.

As Gaddy pointed out to Elsevier last December, Grech has written at least 113 papers in EHD, 57 as sole author:

19 of these 113 articles focus on various aspects of the TV series Star Trek. They generally discuss topics within the series that are relevant to the field of medicine, but the extent of this stops at discussing the potrayals [sic] of doctors, 2 medical practices, 3 medical technology, 4 etc., in the series.1 Many of

these articles were confusingly published in the category of 'Best practice guidelines' [BPGs].

The April issue of EHD has an editor's note addressing 17 of the "Star Trek BPG" papers. The note reads:

Upon publication of this BPG series, concerns were raised regarding its appropriateness for inclusion in a peer-reviewed academic journal. It is the Editor's judgement that this series of articles should not have been accepted for publication by the journal since it is not within its scope. The idea was to engage topics that the ordinary reader of Early Human Development might not normally come across – but could find interesting. The journal has re-designed its editorial and review workflow to ensure that this will not happen again in future.

Gujarat High Court asks State government to publish data on COVID-19 tests, deaths

A day after raising doubts about the actual number of COVID-19 cases and the numbers given by the State government during its hearing on the suo motu petition initiated by it, the Gujarat High Court on Friday asked the State to publish actual data on RT-PCR tests and people found positive for COVID-19.

The Court observed that transparency is needed to remove general conception from the minds of people that data shared by the government on COVID-19 tests and positive cases was not accurate.

"Accurate reporting of RT-PCR testing (considered gold standard in diagnostic testing) with correct figures of positive results be made public. The State should not feel shy of publishing the correct data of RT-PCR testing results, if such figures are not being correctly reported," said the bench.

The court has posted the matter for further hearing in April 20. The court initiated suo motu petition based on the newspaper reports about the worsening COVID-19 situation in the State amidst surge in cases and deaths.

Paper claiming presence of SARS-CoV-2 in Italy in 2019 earns expression of concern

March 24, 2021

When researchers in Italy published a paper last November claiming to have found evidence of SARS-CoV-2 in that country as early as September 2019 — four months before the first official case of Covid-19 — the World Health Organization took immediate notice. According to Reuters, the WHO asked the group — with ties to Italy's National Cancer Institute (INT) — for more information and a chance "to discuss and arrange for further analyses of available samples and verification of the neutralization results".

As WebMD reported then:
If the initial history of the pandemic shifts, public health officials may need to consider new screening tools to test people who don't have COVID-19 symptoms. Better screening could contain future waves of the pandemic and asymptomatic spread, the authors wrote.

Now, Tumori Journal, which published the study, has expressed concern about the findings. More precisely, the journal says it has doubts about the peer review process that vetted the paper.

According to the notice:
The Editor and SAGE were alerted to a potential issue regarding the peer review carried out for this paper. SAGE and the Editor are investigating the matter.

The Editor and SAGE strive to uphold the very highest standards of publication ethics and are commit-

ted to supporting the high standards of integrity of Tumori Journal. Authors, reviewers, editors and interested readers should consult the ethics section of the SAGE website and the Committee on Publication Ethics (COPE) website for guidelines on publication ethics. Tumori Journal is a member of COPE.

A spokesperson for SAGE, which publishes the journal, told us that the journal does not suspect that the review was "compromised":

Tumori is currently fast-tracking research related to COVID-19 while still striving to maintain high standards of robust review. The journal and SAGE received an inquiry about the peer review on the article as a result of its rapid publication. While we don't currently have reason to believe that the review was compromised, we are investigating further as part of our commitment to maintaining the highest standard of quality review in line with COPE guidelines.

Scandal over COVID vaccine trial at Peruvian universities prompts outrage

March 26, 2021

A clinical trial of COVID-19 vaccines in Peru has sparked outrage and triggered a series of high-profile resignations at universities and in government. Politicians, researchers and some of their family members who were not enrolled as trial participants nevertheless received vaccines — breaching standard protocols. Investigations are ongoing as the country struggles to inoculate its general population with limited doses.

The scandal emerged on 10 February, when local media revealed that in October 2020, then-president Martín Vizcarra had received two doses of a vaccine developed by the Chinese state-owned pharmaceutical group Sinopharm. At the time, a phase III clinical trial was under way to test the vaccine at two universities in Peru; Vizcarra was not part of the trial.

Days later, it emerged that a group of around 470 other people — including 100 high-profile individuals such as Peru's minister of health and Vizcarra's wife and brother — also got a jab while the trial was in progress. The shots came from a batch of about 2,000 doses that Peruvian officials reportedly negotiated with Sinopharm to protect the medical staff running the trial.

It is not standard practice to vaccinate anyone other than trial participants while a trial is under way — including the medical staff running it, says Euzebiusz Jamrozik, a bioethicist at the Ethox Centre at the University of Oxford, UK.

The laws regulating clinical trials in Peru state that imported, experimental research products such as unapproved vaccines are to be used exclusively for research.

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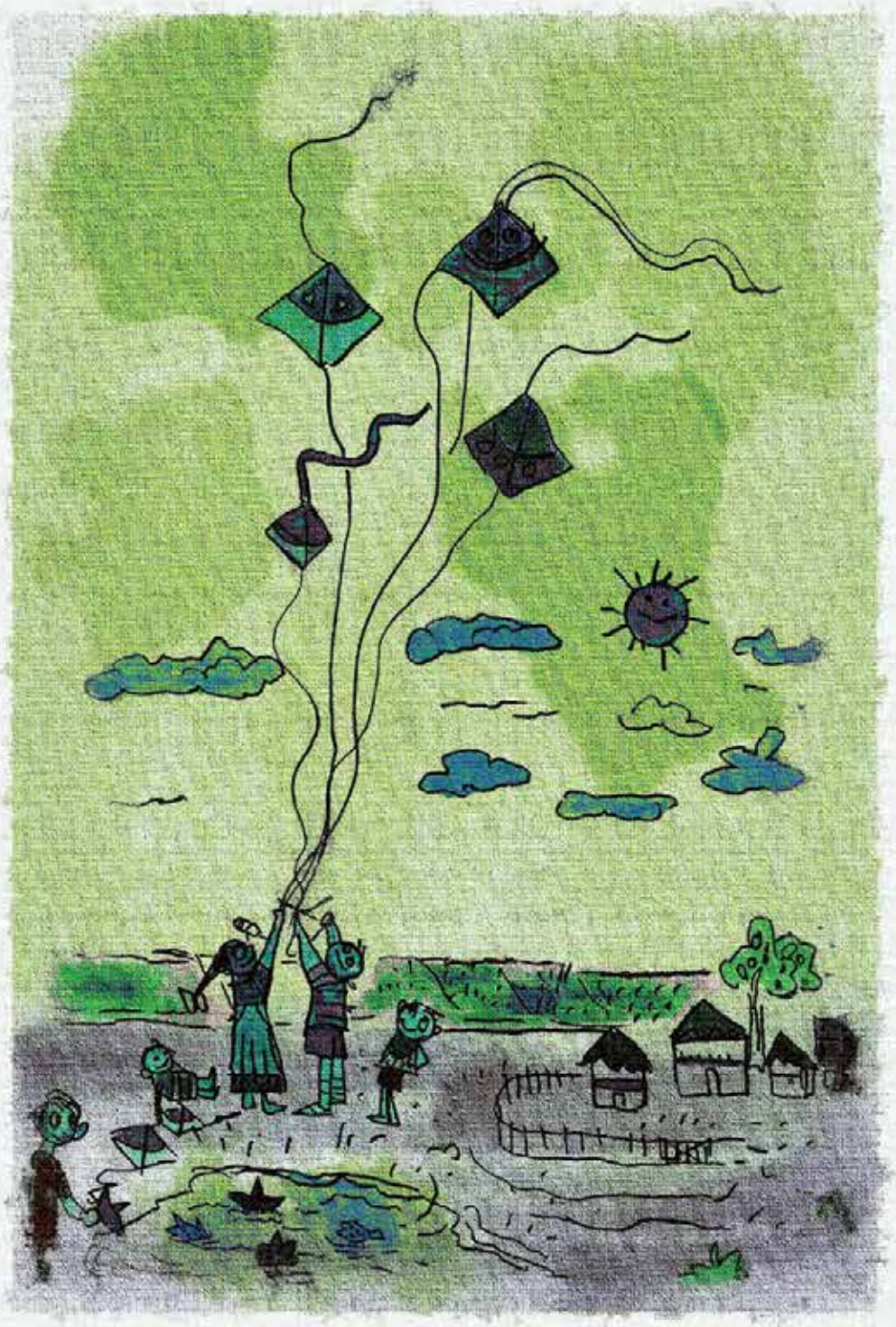

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