

BIOTECH EXPRESS

Editorial:
Detrimental consequences of not approving eligible and safe COVID-19 vaccine on world's health: the case of COVAXIN


Editorial: The Role of Judicial courts in catastrophe: the case of COVID -19 pandemic

Guest Article:
Leprosy Drug Clofazimine Set For New Roles

Editorial:
Is NIH, USA Head Dr Anthony Fauci a serial liar and manipulative over COVID-19? Yes! Says US Ministers

Guest Article:
The Enigma of Gut Microbiome in COVID-19

Event Highlights:
Workshop on Biologics and Biosimilars Upstream and Downstream Technologies



Editorial:
Prof. Pallu Reddanna
Joins Advisory Board of Biotech Express

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Event: Summary and Highlights of the Workshop on 10th - 18th July 2021 Biologics and Biosimilars Upstream and Downstream Technologies | p20

BRSI Upcoming Event



18th BRSI Convention

The 18th Convention of the Society will be held as the International Conference on Biotechnology for Resource Efficiency, Energy, Environment, Chemicals and Health (BRE3CH-2021) during December 1-4, 2021 at Dehradun.

The event will be jointly organized by the CSIR-Indian Institute of Petroleum, Dehradun, Uttarakhand, India in association with the International Bioprocessing Association, France; the Centre for Energy and Environmental Sustainability (CEES)-India; CDC Jaipur and International Solid Waste Association (India chapter).

The event will be held at IIP, Dehradun. Prof Sudhir Sopory, President of the BRSI is the conference chair and Prof Huu Hao Ngo, University of Technology Sydney, Australia; Prof Claude Gilles Dussap, Universite Clermont Auvergne, France and Prof Samir Khanal, University of Hawaii, USA are conference international chairs. Dr Debashish Ghosh is the convener of the conference, Dr T Bhaskar is the Chairman of the local organizing committee, and Dr P Binod, COE, BRSI, Dr Bhavya Balahurumurthy, CSIR-IIP, Dehradun and Dr Kamlesh Choure, AKS University, Satna are its co-convener.

Details can be found at <https://www.bre3ch2021.in/>

Important Dates

01 July, 2021
Abstract Submission Opens
31 August, 2021
Abstract Submission Closes
10 September, 2021
Acceptance Notification
15 October, 2021
Registration at Normal Rates
31 October, 2021
Registration Cancellation

Booking of Accommodation
Registration may close earlier if
maximum numbers of participants
have been reached

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BIOTECH EXPRESS

Featured Biotech News | p32

- ▶ 56% of hand sanitiser samples in Uttarakhand ineffective
- ▶ China pressured WHO team to dismiss lab leak theory: Chief investigator
- ▶ Indian Govt approves Bharat Biotech's Ankle-shwar plant to produce Covaxin
- ▶ Rs 1,600 cr allocated for COVID research and development: Dr Jitendra
- ▶ Vaccines may do more harm than good to those who recovered from COVID-19: Experts
- ▶ UK relaxes travel curbs for Indian passengers, no mandatory quarantine for fully vaccinated
- ▶ Vaccines and strategies under scrutiny as Delta drives COVID surge
- ▶ US-based Adagio Therapeutics gives Biocon licence to make antibody treatment for COVID-19
- ▶ Advantages of Intranasal Vaccine Over Intramuscular Shots
- ▶ Central Govt, India advises States to conduct State specific Sero Surveys in consultation with ICMR
- ▶ FDA Clears Vaxart's S-Only Oral Tablet for COVID-19 Vaccine Candidate
- ▶ No application received yet for Covishield approval: European health regulator

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Doctor Who Complained About Faulty PM-CARES Ventilators Suspended for 'Medical Negligence'

News...

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- ▶ U.S. authorizes third shot of COVID-19 vaccines for the immunocompromised people
- ▶ Delhi, India Inaugurated the first ICU Tele Medicine Centre of India
- ▶ ICMR validates 6 self testing kits for COVID-19
- ▶ 50 researchers awarded Prof M K Bhan 2021 fellowship
- ▶ Bharat Biotech's Rotavac 5D gets WHO Prequalification
- ▶ Fiona Godlee to step down as The BMJ's editor in chief after 16 years
- ▶ India first biobank for heart failure research inaugurated
- ▶ J&J's single-shot COVID vaccine receives EUA in India
- ▶ Disaster If COVID Vaccines Administered To Children Without Proper Research: Court
- ▶ Meth Abuse Drove Huge Surge in Heart Failure Crises in California, USA
- ▶ More than 1.5 million children lost a primary or secondary caregiver due to the COVID-19 pandemic
- ▶ Novel researchers have a lower chance of winning funding, according to a study
- ▶ Sanofi intent to buy Translate Bio in \$3.2B
- ▶ SoftBank Acquires \$5 Billion Stake in Roche
- ▶ mRNA Disruptor Goes Public in \$1.5 Billion SPAC Deal

Biotech Research | p52

- ▶ Bio-inspired, blood repelling tissue glue seal wounds quickly
- ▶ Brain cholesterol regulates Alzheimer's plaques, study reveals
- ▶ For psoriasis, targeting skin protein may help control inflammation
- ▶ Light therapy helps burn injuries heal faster by triggering growth protein
- ▶ Researchers solve structure of BRCA2 protein complex important in DNA repair
- ▶ New drug combo shows potential for treating pancreatic cancer
- ▶ Study identifies DNA genes linked to heart disease
- ▶ Potential COVID-19 medication found among tapeworm drugs

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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 of prestigious Administrative positions.

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Editorial

The Role of Judicial courts in catastrophe: the case of COVID -19 pandemic

by Kamal Pratap Singh

The rapid spread of this virus has led to the closing down of Courts and Tribunals in the country to avoid human association and to curb the spread of novel coronavirus in the country. The outbreak of COVID -19 is affecting litigation in multiple ways and has also crippled the courts across the country as judges, advocates and litigants are trying to achieve justice under the law while balancing public safety but courts are working and bringing judiciary to its best when it is required utmost. There have been instances where decision of Judiciary has been appreciated and brought justice to the democratic country like India in COVID-19 pandemic. Though the judgements on single topic came from several courts, here are the compilation of news articles giving one example of each that covered such judgements under the following broad topics:

1. **Inaccurate COVID -19 vaccination figures**

Around July 10, 2021, the Tripura High Court has termed as inaccurate the state government's claim that it had covered 98 per cent of the 45-plus age group and 80 per cent of the eligible population with the first dose of the COVID -19 vaccine and directed it to issue a clarification.

When the Mission Director made these claims, the total vaccines administered were 24,26,803 of which 5,66,458 were of second dose. Total number of people vaccinated was thus 18,60,345.

Perhaps, he has taken the total doses of vaccines ad-

ministered for arriving at this 80% coverage, forgetting that substantial part of it was administered to the same person as a second doze," the court order reads.

The court also observed that 14,36,595 doses were administered to the 45-plus age group with 5,66,458 people being given the second doses. This would mean that around 9 lakh people got the first dose—which would not come up to 98 per cent of the eligible 12.36 lakh population.

A Health Department official, who wished to stay anonymous, said the state's actual target for the 45-plus category is just under 10 lakh and not 12 lakh.



“There seems to be some miscommunication between the court and NHM office. We are sticking to our figure of 98 percent coverage in the 45-plus category. We will be submitting an affidavit soon.”

The court’s observation came in the wake of reports published in two local English newspapers on June 25 that quoted the NHM director as saying that around 80 per cent of the eligible population and 98 per cent of the 45-plus age group were vaccinated with the first dose.

2. Mismatch of information on hospital beds

Around May 6, 2021 Allahabad High Court had exposed the Uttar Pradesh administration’s claims about the reliability of its COVID information system by demonstrating a mismatch between the government helpline and online portal on the availability of hospital beds.

During a virtual hearing the bench of Justices Siddhartha Varma and Ajit Kumar asked an advocate, Anuj Singh, to call up the COVID helpline number, he dialled the number and when connected reply was that there was no Level-2 (or) Level-3 bed available, whereas the online portal, during the course of hearing of the case, was showing that there were vacant positions of beds in both Level-2 and Level-3 category,” the high court observed, according to records of the proceedings.

3. Treatment Strategies

The same bench of Justices Siddhartha Varma and Ajit Kumar has also sought a clarification on allegations that a sitting high court judge, Justice V.K. Srivastava, who had died last week in Lucknow, had not received proper treatment.

The bench asked additional advocate-general Manish

Goyal to file an affidavit on the treatment given to Justice Srivastava at the Ram Manohar Lohia Hospital and explain why he had not been taken to the Sanjay Gandhi Institute straightaway.

4. Oxygen Demand

On May 5, 2021, the Delhi high court issued a show-cause notice to the Centre as to why contempt proceedings should not be initiated after it sought to wriggle out of its liability to supply 700 tonnes of medical-grade oxygen to the national capital.

We don't want to hear anything besides compliance. Enough is enough. We mean business and give it by whatever means. Your officers will face the notice," a bench of Justices Vipin Sanghi and Rekha Palli said. They added, we are facing the grim reality every day of people not able to secure oxygen beds, even ICU beds. Situation has come to this that hospitals have had to reduce beds offered by them because they are not able to service due to shortage of oxygen".

5. Audit Of COVID Deaths

In June 2021, a petition has been filed in the Orissa High Court seeking a high-level independent audit of COVID deaths in the state. Along with records of all COVID-19 deaths in the state, the petition filed by senior advocate Nishikant Mishra also seeks details on COVID testing and vaccination in rural areas of Odisha. In his petition, Nishikant has alleged discrepancies in the COVID fatality data provided by district-level authorities and the state government's health department.

He has also cited media reports on the disparity in deaths between actual cremations performed in accordance with COVID protocol and the district administration's tally, which was significantly lower.

Speaking to India Today, Gajendra Kabat, a relative of the deceased Kuntala Singh, said the patient was transferred to Balasore COVID hospital on May 18 after developing COVID -19 symptoms and was later transferred to Aditya Aswini COVID hospital in Cuttack after her condition deteriorated. She

was declared dead after almost 22 days due to post COVID-19 complications. However, the hospital administration mentioned pneumonia as the cause of death, not COVID -19.

6. Compensation to the kin of COVID-19 deceased

In last week of June 2021, the Supreme Court directed the government to frame rules within six weeks on payment of *ex gratia* to the families of those who have died of COVID -19, noting that the Prime Minister-headed National Disaster Management Authority (NDMA) "failed to perform its statutory duty" by not envisaging a compensation scheme.

"We direct NDMA to recommend guidelines for *ex gratia* assistance on account of loss of life to family members of the persons who died due to COVID-19 as mandated under Section 12(iii) of Disaster Management Act (DMA), 2005 for the minimum standards of relief to be provided to the persons affected by disaster, over and above the guidelines already recommended," ordered the bench.

The court rejected the Centre's contention that it was not bound to make *ex gratia* payments since COVID was different from natural disasters such as floods and earthquakes, and therefore, the Disaster Management Act will have to be interpreted to mean that such a scheme on *ex gratia* was only recommendatory and not mandatory.

Dissatisfied with these submissions, the bench underlined that section 12 of the DMA used the word 'shall' twice in propounding that guidelines have to be made "*ex gratia* assistance on account of loss of life", damage to houses and restoration of means of livelihood.

7. Take charge of kids orphaned by COVID

Hearing an urgent application filed by Amicus Curiae Advocate Gaurav Agrawal expressing anguish over the plight of children orphaned by COVID or abandoned during the pandemic, the Supreme Court asked district authorities to "immediately take charge of such children and attend to their basic needs without

waiting for any further orders” from the court.

A bench of Justices L Nageswara Rao and Anirudha Bose also directed authorities to upload data on the number of affected children since March 2020 on the ‘Bal Swaraj’ portal set up by the National Commission for Protection of Children’s Rights (NCP-CR). The court pointed out that the Provisions of the Juvenile Justice (Care and Protection of Children) Act, 2015 make it clear that there is an obligation on part of authorities to ensure that children in need are taken care of.

The Amicus Curiae had filed an application seeking direction in respect of children orphaned by COVID and faced increased chances of trafficking.

8. Vaccine Procurement and availability

In the end of May 2021, the Supreme Court bench headed by Justice DY Chandrachud asked the Centre that several state governments are now issuing global tenders to procure vaccines, is this the central policy on vaccine procurement. The court also observed that till date, the Centre has failed to submit a national policy document on COVID vaccines.

The Supreme Court also questioned the logistics of picking up and distributing vaccines and why the government is not supplying for the 18+ age group as well.

The Supreme Court cited the case of Maharashtra and said, “We are seeing a spectacle now where municipal corporations and states are issuing global tenders. Is it a government policy that each municipal corporation and state will be left to their own devices and procure global tenders?”

“Compare the budget of the Mumbai municipal corporation with that of some city municipal corporation in a UP or Bihar or any other state. The BMC budget is more than that of some of the states. Are you allowing as a policy for the municipal corporations to open tenders,” asked the Supreme Court.

The Supreme Court further questioned the rationale behind not supplying vaccines for the population be-

low 45 years. For the population above 45 years, we will supply vaccine, but for under 45 years, states are left to make arrangements,” observed the court.

It further added, “Your rationale for doing this was that the rate of mortality is higher for above 45 years. In the second wave of the pandemic, it’s not merely the above 45 age group that is affected. Those under 45 years are also suffering.”

The Supreme Court further questioned how is the Centre addressing the digital divide and its constraints in rural India.

9. Differential COVID-19 vaccine pricing

In the first week of May 2021, a bench, headed by justice Dhananjaya Y Chandrachud, maintained that “there are several aspects of the vaccine pricing policy adopted by the Central government which require that policy be revisited,” in particular the rationale behind letting the manufacturers determine the vaccine prices for states and other private entities.

“All vaccines, whether in the quantity of 50% purchased by the Central government or the remaining 50%, are to be used for vaccinating citizens. The end use is the same,” noted the bench, adding that to compel the states to negotiate with manufacturers on the ground of promoting competition and making it attractive for new vaccine manufactures will result in a serious detriment to those in the age group of 18 to 44 years, who will be vaccinated by the state governments.

“While we are not passing a conclusive determination on the constitutionality of the current policy, the manner in which the current policy has been framed would *prima facie* result in a detriment to the right to public health which is an integral element of Article 21 (right to life) of the Constitution. Therefore, we believe that the Central government should consider revisiting its current vaccine policy to ensure that it withstands the scrutiny of Articles 14 (equality) and Article 21 of the Constitution,” said the bench, in its order.



Editorial

Prof. Pallu Reddanna joins Advisory Board of Biotech Express

It is my immense pleasure to announce that Prof Pallu Reddanna has joined the Advisory Board of Biotech Express magazine. He is an eminent personality in Life Sciences and a well known name in Biotech Industry. Prof Reddanna is Executive president of FABA and is actively involved in promoting Indian biotech in Asia and around the world.

Kamal Pratap Singh, Managing Editor



Brief Profile

Prof. Pallu Reddanna

BSR Faculty Fellow, School of Life Sciences
University of Hyderabad, Hyderabad, India
President, Federation of Asian Biotech Associations
Email: prsl@uohyd.ac.in; preddanna@gmail.com

Prof. Reddanna was born in Reddivaripalli village, Lakkireddipalle in Kadapa District, Andhra Pradesh, in the year 1954, completed schooling from ZPH School, graduation (1974), post-graduation(1976) and doctoral studies (1979) from Sri Venkateswara University, Tirupati, Andhra Pradesh.

He started his career as lecturer in Zoology (1982-1990) in Sri Venkateswara University before joining as Reader in the School of Life Sciences, University of Hyderabad in 1990. He became Professor in 1998, and later managed the department of Animal Sciences as Head (now Department of Animal Biology) during 1999-2002, Coordinator, Centre for

Biotechnology, (now Department of Biotechnology and Bioinformatics) during 2006-2008 and as the Dean, School of Life Sciences (2015-2018) and served as a member of the Executive Council of University of Hyderabad.

Prof. Reddanna served as the Founding Director (2010-2014) of National Institute of Animal Biotechnology (NIAB), Department of Biotechnology, Ministry of Science & Technology, Government of India. Dr. Reddanna was instrumental in establishing the infrastructure, recruiting the scientists and establishing the NIAB in about 100 acres in a record time.

Prof. Reddanna played a key role in promoting innovation and entrepreneurship activities in the University of Hyderabad by establishing NSTEDB supported Technology Business Incubator (TBI) in 2010 and BIRAC supported Biotech Incubation Center (UoH-BioNEST) in 2018. Within a span of three years of the establishment of BioNEST incubator, it has been recognized as the Best BioNEST incubator in the country, under emerging incubators category, in 2021.

As one of the founder members of the Federation of Asian Biotech Associations (FABA) he provided a platform for interactions for the academy, industry and Government bodies not only in India but also in a number of Asian countries. During the 17th edition of BioAsia, BioAsia 2020, FABA Academy was launched, mainly to bridge the gap between academia and industry in Human Resources Development. As part of FABA Academy a number of webinars and workshops are being conducted to help the science graduates in career guidance and skill development activities. More details are available at: <https://biofaba.org.in/>

Areas of Research:

Prof. Reddanna's main research focus is on bioactive lipids, prostaglandins and leukotrienes (eicosanoids) formed via cyclooxygenase (COX) and lipoxygenase (LOX) pathways. These eicosanoids play a role in the regulation of variety of physiological processes and their uncontrolled production in some cases is associated with many of the inflammatory disorders, including cancer. As a result, the enzymes- COX and LOX, have become the targets for the development of anti-inflammatory and anti-cancer drugs.

Prof. Reddanna, during his research career over 35 years, has published around 200 papers, guided 41 students for Ph.D and mentored several masters and post-doctoral students. He was successful in collaborating with

leading Pharma and Biotech industries like Dr Reddy's Laboratories Ltd., Dabur India Ltd, Shantha Biotechnics Ltd, Indian Immunologicals, Natco Pharma Ltd, Surya Pharmaceuticals, Onconova Therapeutics, USA etc. Similarly, his service to the promotion of Pharma and Biotech industry in the country was recognized with "Outstanding Contribution Award (Pharma)" in 2005 by the ChemTECH Foundation and "Outstanding Scientist Award for the Benefit of Industry" in 2007 by Federation of Andhra Pradesh Chamber of Commerce and Industry (FAPCCI).

International Exposure

He has visited Countries like USA, Canada, China, UK, Germany, Portugal, Pakistan, France, Israel, Singapore, Malaysia and Iran, Sri Lanka, Japan for academic and industrial purposes. As exchange visitor (1984-87) and as The Rockefeller Foundation Biotechnology Career Awardee (summers of 1992 - 96, 2003 & 2005) at The Penn State University, Prof. Reddanna made significant contributions to the field of eicosanoids. His contributions to the field of lipoxygenases and cyclooxygenases and thus on eicosanoids were recognized with "Royan International Award" in the year 2007.

Research Grants

- Government of India - Completed 18 projects funded by: DST (5), DBT (4), CSIR (3), UGC (1), ICMR (4), NMPB (2)
- Industries- Completed 13 projects funded by various Biotech and Pharma Industries: Dr Reddy's Laboratories, Unique Biotech, Shantha Biotechnics Pvt. Ltd., Natco Pharma, Indian Immunologicals, Medgene Biotech, Surya Pharmaceuticals, Laila Impex, Pacific Hospital Pvt Ltd, Institute of Life Sciences, ABL Biotechnologies and Dabur Research Foundation and Onconova Therapeutics (USA), Celestial Labs.
- International - Completed 5 projects funded by: Netherlands Biotech Program, The Rockefeller Foundation, Asian Office of Air Force Research and Development (AOARD), Japan; DST-DAAD Sandwich program; IRTG program, Germany



Photo: Prof. Pallu Reddanna receiving the FAPCCI 2007 Outstanding Scientist Award for Benefit of Industry from late Dr. YS Rajasekhar Reddy, former CM of Andhra Pradesh.

Publications:

- Published around 200 papers in peer reviewed journals. H index: 49, i10 index: 137; Total citations: 8541 (Source: Google Scholar: <https://scholar.google.com/citations?user=xCp2iFoAAAAJ>).
- <https://pubmed.ncbi.nlm.nih.gov/?term=reddanna>

Promotion of Biotech Industry:

On behalf of AIBA (All India Biotech Association) & FABA (Federation of Asian Biotech Associations), he was actively involved in organizing various scientific meetings/workshops/conferences. As the Vice-President of AIBA-SC and Member Secretary of FABA, one such major event organized annually is BioAsia, an event promoted by the Government of Andhra Pradesh. BioAsia provides the platform for academia-industry interaction and promotes business partnerships and collaborations. It provides an opportunity for life science companies from around the world to showcase their products, services, technologies and facilitates interactions and business transactions. BioAsia was successful in putting Andhra Pradesh state on world radar and attracting many Pharma and Biotech

companies to set up their facilities in the state. To promote entrepreneurship among the scientists, he was instrumental in introducing “BioAsia Innovation Award” for young scientists with a cash prize of Rs. 1,00,000/- and “Young Minds Award” for the best innovations by the High School children with a cash prize of Rs50,000/-. During BioAsia 2020, FABA Academy was launched, mainly to help science graduates in career guidance and skill development activities, through webinars, workshops and conferences.

Important Honours and Awards:

- **Founder Director, National Institute of Animal Biotechnology, a Unit of the Department of Biotechnology, Government of India (2010-2014).**
- **Founder Director, ASPIRE (Association for Scientific Pursuits for Innovative Research Enterprises), a section-8 company established in the University of Hyderabad.**
- **Executive President, Federation of Asian Biotech Associations (FABA), 2016 onwards**
- **Vice President, FABA- 2013 to 2016**
- **Federation of Andhra Pradesh Chambers of Commerce and Industry (FAPCCI) ‘Outstanding Scientist for the Benefit of Industry -2007’**
- **Royan International Foundation, “ Best Research Project Award- 2007”**
- **Chemtech Foundation “Pharma Bio Excellence Award” 2005**
- **The Rockefeller Foundation Biotechnology Career Award (1993-96)**
- **Ministry of Education & Culture, Govt. of India “ Overseas Post-doctoral Fellowship” (1984-87)**
- **Council of Scientific & Industrial Research (CSIR), Govt. of India, JRF, SRF & Research Associate Fellowships**



Editorial

Detrimental consequences of not approving eligible and safe COVID-19 vaccine on world's health: the case of COVAXIN

by Seema Pavgi Upadhye

Keeping away the desperate from the needed resources in emergency is equivalent to crime which is under commitment when the organizations like USFDA and WHO are not approving a vaccine because it is Made in India. Politicization of COVID is not new since the beginning of pandemic but here the points have been discussed to understand what it cost to ignore COVAXIN when whole world is suffering from this catastrophe.

Rise of Variants- All viruses like every living thing evolve over time, due to the replication errors, some mutations are beneficial but some can be dangerous too. Pathogens if develop a mutation that can affect host then it is a matter of concern for health professionals. In SARS- CoV 2 too it has been seen that delayed eradication has given rise to variants which appeared in different countries. This is due to the fact that the virus has been

stuck between politics. At many instances delaying vaccination by any means gave virus chances to replicate and thus become more dangerous.

Travel Prohibition Non approval of Indian vaccine has lessen the chance of foreign visit by Indians in other countries. This has hampered community to much extent, for example the students are not able to go back to their foreign institutions, businessman are not able to meet supply chain people etc. This has greatly shrunk international economic activities which in some cases is applicable to life saving commodities like food and medicines.

Quarantine Cost Because Indian vaccine are not allowed outside India, vaccinee have to quarantine themselves for 14-28 days depending on the country. Again this step has greatly increased the budget of international travellers.

Unavailability to Poor Countries

– Since the whole world is struggling to get rid of CoV-2, many countries specially the wealthy ones, have stockpiled vaccines in advance. Since this vaccine business is highly capital intensive, only wealthy nations could afford to buy it and thus the poor/poorer nations are not able to get it which again is posing danger because these unvaccinated people would again make the transmission chain possible.

Doubt Over Credibility of Health Agencies'

- It has also been seen that drugs have been approved based on the country of origin and have given special privileges. EUA approval by FDA and WHO of several drugs in lack of evidence is a proof of this. Now, COVAXIN which is available after rigorous studies and clinical trials have been seeking for approval and this has been delayed because of political turmoil.

■■■

Editorial

Is NIH, USA Head Dr Anthony Fauci a serial liar and manipulative over COVID-19? Yes! Says US Ministers

Dr. Anthony Fauci has flip-flopped or been proven wrong on a host of different coronavirus measures and recommendations since the virus first hit the United States last winter. Fauci, the leading White House coronavirus task force member, has changed positions or faced scientific data proving his stances are flawed on issues ranging from mask wearing to the severity of the virus and from asymptomatic spread to effective treatments for patients, among other issues.

Keywords: Origin of CoV funding, Mask mandates, Vaccine doses, Lockdown mandate

On March 8 2020, Fauci described lockdown measures in China as “draconian” and stated that such restrictions wouldn’t be “feasible” in the U.S., more than a month after on Jan. 30, the World Health Organization (WHO) had declared a global health emergency. One week later on March 15, he changed positions and said he was open to a national 14-day shutdown to help stop the spread.

In April, when pressed in a CNN interview on why social distancing and lockdowns weren’t implemented sooner, he sparked confusion when he said more lives “obviously” could have been saved if there hadn’t been “pushback” to lockdowns at the start of the pandemic. The very next day, he backtracked, saying that he used “the wrong choice of words.”

Perhaps Fauci’s most notable flip-flop has been on the efficacy of masks, saying in March 2020 that there was “no reason” to wear a mask. By April, he joined the chorus of doctors and health agencies encouraging the use of face masks.

He also downplayed asymptomatic transmission on Jan. 28, 2020 saying what “people need to realize” is that in “all the history” of respiratory-borne viruses, asymptomatic transmission has never been the driver of outbreaks. By August, Fauci did a complete 180, saying asymptomatic cases were a driving factor in the community spread of COVID-19 despite a WHO advice that more evidence was needed to make this determination.

Fauci’s recommendations for treating COVID-19 have also been challenged by scientific data. Fauci advocated the use of remdesivir in April, citing one trial prior to it being peer-reviewed, lauding it as a breakthrough “in diminishing time to recovery” for patients with COVID-19 and predicting it “will be the standard of care.” In November 2020, however, the WHO warned against using remdesivir, after many setbacks, saying that “there is currently no evidence that remdesivir improves survival and other outcomes in these patients.” The news came after Trump took



Republican Senator, an ophthalmologist and member of the Senate Health Committee Rand Paul confronted with Dr. Anthony Fauci, director of the NIAID and the chief medical advisor to the president alleging that coronavirus gain of function research was funded by NIH during a testimony before a Senate on July 20, 2021. He also suggested that Fauci and the NIH could be partly responsible for the pandemic and the deaths of 4 million people worldwide.

the medication when he was diagnosed with COVID-19 in October 2020 and after the Food and Drug Administration approved it for the treatment of COVID-19.

Sen. Rand Paul, who went after Fauci in a Senate hearing on March 18 2021, peppering him with questions about masks and why immune people are forced to wear them. “Given that no scientific studies have shown significant numbers of reinfections of patients previously infected, or previously vaccinated, what specific studies do you cite to argue that the public should still be wearing masks well into 2022?” Paul said. It’s simple: Fauci is trying to manipulate you.

In March 2020 when Fauci told CBS News, “There’s no reason to be walking around with a mask” ([https://](https://www.cbsnews.com/news/preventing-coronavirus-face-mask-60-minutes-2020-03-08/)

www.cbsnews.com/news/preventing-coronavirus-face-mask-60-minutes-2020-03-08/). He very explicitly characterized mask-wearing as a performative gesture that “might make people feel a little bit better and it might even block a droplet, but it’s not providing the perfect protection that people think that it is.”

Months later, fact-doctorer Fauci performed a whiplash-inducing 180-degree turnaround and became the planet’s No. 1 mask cheerleader. He rationalized that he needed to mislead the nation about the efficacy of masks in order “to save the masks for the people who really needed them because it was felt that there was a shortage of masks.” You could argue this was a reasonable non-scientific decision, but you cannot argue that it was anything other than manipulation.

Fauci further disclosed on CNN that his herd immunity pronouncement was nothing more than a “guesstimate.” (<https://edition.cnn.com/videos/health/2020/12/27/fauci-coronavirus-herd-immunity-range-estimate-shift-in-tv-sotu-vpx.cnn>). The Erroneous Experts shut down playgrounds, ordered to stop singing and dancing, and canceled Easter, Thanksgiving and Christmas in the name of social distancing — but gave the green light to Black Lives Matter marches, antifa protests and post-election celebrations by Joe Biden supporters.

“When polls said only about half of all Americans would take a vaccine, I was saying herd immunity would take 70 to 75% ... Then, when newer surveys said 60% or more would take it, I thought, ‘I can nudge this up a bit,’ so I went to 80, 85. We need to have some humility here ... We really don’t know what the real number is. I think the real range is somewhere between 70 to 90%. But, I’m not going to say 90%.” Fauci continues to ignore those who have already been infected in his herd immunity calculations, according to Dr. Marty Makary at the John Hopkins School of Medicine.

The lead author of a seminal paper promoting the theory that SARS-CoV-2 evolved in nature deleted 5,000 tweets — and then his entire Twitter account on June 6 — after a trove of emails obtained by BuzzFeed News revealed the researcher, who originally believed the virus originated in a lab, changed his mind after corresponding with Dr. Anthony Fauci. Emails show Dr. Kristian Andersen, author of “The Proximal Origin of SARS-CoV-2,” published March 17, 2020 in Nature, was thanked by Fauci after he flipped his position on the origin of COVID. Five months later, Andersen received nearly \$2 million in government funding for virus research. The emails also show Fauci admitted masks are best suited for sick people to help stop the spread of the virus and are not effective in protecting healthy people from COVID, and that those who have had COVID have natural immunity, so they don’t need the vaccine.

Fauci on the “Morning Joe” show said that while he was concerned about the variants and about the possibility of a surge, he said that the national vaccination effort should be enough to keep any spike from becoming a full-blown

outbreak (<https://thehill.com/policy/healthcare/public-global-health/546620-fauci-tamps-down-fears-of-another-coronavirus-wave>). But next day, Fauci backtracked, telling CNN that the number of COVID cases was “disturbing” and that there was “a risk of getting a surge back up (<https://edition.cnn.com/2021/04/08/health/us-coronavirus-thursday/index.html>).”

Fox News host Martha MacCallum pushed back against Dr. Anthony Fauci after he claimed that the public has been “misunderstanding” the threat of additional lockdowns. “I don’t think all these businesses are misunderstanding what’s going on,” MacCallum interjected. “They are not allowed to open, many of the schools are closed, you’ve got college kids who have been literally prisoners in their dorm rooms, they can’t leave. And little kids whose mothers have had to quit their jobs. Tell them there’s no lockdown, doctor,” she said.

Earlier in the segment, Fauci criticized the United Kingdom for jumping the gun on granting approval to the Pfizer and BioNTech’s COVID-19 vaccine. Next day he apologized for the statement he made about the approval.

Peter Navarro, a senior trade adviser to President Donald Trump, has taken aim at Anthony Fauci. Dr. Anthony Fauci has a good bedside manner with the

public, but he has been wrong about everything I have interacted with him on. In late January 2020, when I was making the case on behalf of the president to take down the flights from China, Fauci fought against the president’s courageous decision — which might well have saved hundreds of thousands of American lives. When I warned in late January in a memo of a possibly deadly pandemic, the Fauci was telling the news media not to worry.

Navarro added that when we were building new mask capacity in record time, Fauci was flip-flopping on the use of masks. On Feb. 17, weeks before the coronavirus was declared a pandemic, Fauci told USA TODAY that “in the United States, there is absolutely no reason whatsoever to wear a mask.” Now in current times Fauci says a falling mortality rate doesn’t matter when it is the single most im-

The Erroneous Experts Fauci shut down playgrounds, ordered to stop singing and dancing, and canceled Easter, Thanksgiving and Christmas in the name of social distancing — but gave the green light to Black Lives Matter marches, antifa protests and post-election celebrations by Joe Biden supporters.

portant statistic to help guide the pace of our economic reopening.

Senator Rand Paul also allege that Fauci helped fund research and lied to Congress while under oath about Gain of Function research, he added that it was a crime to lie to Congress, a felony that could lead up to five years in prison. Paul cited an academic paper published in Nature in 2015 (<https://doi.org/10.1038/nm.3985>) that shows the lab was conducting illegal research to create “potential pandemic pathogens that exist only in the lab, not in nature.”. Earlier this paper did not reveal funding source but after many objections Dr Shi declared its funding source which is from NIAID and the National Institute of Aging of the US National Institutes of Health (NIH).

Paul said there’s no question that the NIH was funding this research in Wuhan. “The only real debate is over whether or not it was gain of function. But in the research, we presented the evidence that she took two viruses, the genes for the S protein to two viruses, bat viruses that she found in a cave, and she melded them or merged or recombined them with the backbone of a virus called the SARS virus. Now the SARS virus is like the one we are dealing with now. COVID-19 was a virus from 2004 that had 15% mortality. It wasn’t very transmissible, but it was much more deadly than what we have. So she was experimenting with a virus that had a 15% mortality, merging it with two new viruses she found in a cave to create a virus that does not exist in nature. And then she proves that it can infect human cells.”

NIH’s RePORTER website said the agency provided \$15.2 million to Peter Daszak’s EcoHealth Alliance over the years, with \$3.74 million toward understanding bat coronavirus emergence. Daszak maintained a long working relationship with Wuhan lab “bat lady” Shi Zhengli, sending her lab at least \$600,000 in NIH funding. Daszak was also part of the World Health Organization-China team that dismissed the lab leak hypothesis as “extremely unlikely” earlier this year.

Sen. Rand Paul is not alone to question Fauci, many scientists with differing opinions about COVID-19 are raising questions to Fauci. Republican Senator and Florida man Marco have also accused Dr. Anthony Fauci of lying about coronavirus in general and masks in particular.

USA Ohio’s Rep. Jim Jordan got into a shouting match during hearing of the House Select Committee on the Coronavirus where he repeatedly asked Anthony Fauci when Americans will “get their freedoms back.” Fifteen days to slow the spread turned into one year of lost liberty.

What metrics, what measures, what has to happen before Americans get more freedoms?” Jim Jordan has claimed Dr. Anthony Fauci is unwilling to appear in public to speak about the COVID-19 pandemic following the release of his emails.

Dr. Anthony Fauci keep it to themselves because the top disease expert controls much of their funding, Sen. Rand Paul added. He said that he receives letters from scientists that routinely contradict Fauci’s prescriptions and public statements, but that they all offer the same regret: that they are afraid to speak out against what the health care bureaucrat says. “They are very distrustful of what he is saying. They don’t think he is making sense and reading the science accurately.

Senator Rand Paul, who recovered from the virus last year and has said he will not be vaccinated, has called Fauci a “petty tyrant” and accused him of writing “science fiction” while promoting unnecessary health restrictions. Rand is accusing Fauci of fear-mongering rhetoric and what he says is incorrect praise of so-called lockdown measures implemented to stem the spread of the virus since the pandemic began.

Adding to the fury one individual wrote “Yes and he was in charge of getting a vaccine for HIV about 50 years ago. Still no vaccine for it”!

Timeline of Clashes between Paul and Fauci

June 30, 2020: Paul tells Fauci to provide ‘more optimism’ on virus

September 23, 2020: Fauci corrects Paul on herd immunity

March 18, 2021: Paul argues wearing a mask is ‘theater’

May 11, 2021: Fauci and Paul argue over the origins of the virus

July 20, 2021: Paul accuses Fauci of lying to Congress



Summary and Highlights of
the Workshop on

Biologics and Biosimilars

Upstream and Downstream
Technologies

10th - 18th July 2021

ORGANISERS



Syngene



SCHRÖDINGER

SPEAKERS

Keynote Speaker



Dr. Mahesh Bhalgat
Chief Operating Officer,
Syngene International Ltd.

Valedictory Address



Dr. Rajan Sriraman
Head R&D - Vaccines
Reliance Life Sciences



Prof. Pallu Reddanna
Senior Professor,
Dept. of Animal Biology,
University of Hyderabad.



Dr. Sunit Maity
Director - Product
Development
Zumutor Biologics Inc



Dr. Smita Kale
Manager-
Bioincubation
Venture Center



Prof. S Dayananda
Dean, School of Life Sciences
University of Hyderabad



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The Federation of Asian Biotech Associations (FABA) Academy conducted a workshop on “Biologics & Biosimilars: Upstream and Downstream Technologies” from 10th-18th July 2021 as part of a continuing education program, open to students, mentors and the scientific community.

This workshop was conducted by the Federation of Asian Biotech Associations (FABA) Academy, in association with the University of Hyderabad BioNEST incubation centre, Syngene International, Centers for Biopharma Analysis at Pune and Bangalore, Cytiva Life Sciences and Ingenuity Biosciences Ltd.

Nearly 110 participants from various Asian countries, including Japan, Bangladesh, Pakistan, Iran, Indonesia and Malaysia attended the workshop. Of these nearly 40% were from various leading biopharma industries, including Dr. Reddy's Laboratories, Biological E, Aurobindo Pharma, Syngene International, Laurus Labs, MSN Laboratories and BioBeams, participated in the workshop. Nearly 26 experts from the academy, industry and Government agencies participated as resource persons.

The tone for the workshop was set with the inaugural address by Dr. Mahesh Bhargat, COO, Syngene International Ltd., on “Quo Vadis – Where Is Biotechnology heading” (link to the video: https://youtu.be/WYS0ogXm2_A) on the 1st day, 10th July. Dr. Mahesh presented an overview of the historical perspective on Biotechnology, the present status on how the healthcare industry is shifting from pharma to bio-

pharma and the predictions to the future of biotechnology in addressing the needs of society. Additionally, Dr. Mahesh highlighted few key points about the innovativeness of the biologics industry, the efficacy of the products, safety, costs are of paramount importance and the quality of biologics processing has to be supreme to reach industries better and bigger heights.

This was followed by introductory lectures on topics such as “Overview of biopharma product development” by Dr. Nithya Kalyani Srirangan, Head, Center for Advances Protein Studies (CAPS), Syngene International Ltd; “Roadmap for biologics development” by Dr. Ravi Krovidi, CEO, Ingenuity Biosciences Pvt. Ltd., and “Approval of 100 mAb by the FDA” by Dr. Nandakumar, Head, Analytical Development Services, Kemwell Biopharma Pvt. Ltd.

The day 2 session on “Biologics by Design” was conducted by Schrodinger on in silico Modelling Solutions for Biologics – BioLuminate. BioLuminate is a next-generation simple intuitive structure-based biologics research platform for antibody sequence to structure prediction, antibody humanization and antibody-antigen interaction prediction. For these sessions, Schrodinger provided hands-on training on their software by providing access to cloud computing.

In addition to the step-wise hands-on training on their software, Schrodinger provided one month of free access for the software for utilisation by the participants to practice and use in their project/PhD work and publish their works.

The day 3 sessions on “Upstream and Harvesting Technologies” started with a talk on “Overview of Prokaryotic Expression Systems: Advantages and Disadvantages” by Prof. Dayananda Siddavattam from the University of Hyderabad. He emphasized the components of the gene, gene synthesis, signal peptide, expression vector structure and function. This was followed by Dr. Muralidharan Vasudevan’s (Cytiva) insightful lecture on “Cell types of Industrial importance”. Dr Vasudevan talked about different cell types used in industries and upstream processing development strategies, Bioreactors per se optimization of processing, software/tools and sensors and primary downstream processing.

The day 4 sessions on “Downstream processing Technologies” began with a talk by Dr. Ashok (Cytiva), who delivered an interesting talk on Ion exchange chromatography, the principle, usages of different resins and functions followed by video demonstration by his team for “Purification strategy, process development from R&D to pilot and manufacturing”.

Further, “Downstream Processing Technologies-scale-up and Bioprocess Unit Operations” was elaborated by Dr. Anurag Rathore (IIT Delhi), followed by a talk by Dr. Saji Menon (Nano Temper Technologies) on “multiple parameter stability characterizations of biologics in formation and development”.

The day 6 session on “Analytical Characterization” was coordinated by 3 speakers. Dr. Mohan Krishna Reddy Mudium (CSIR-IICT) presented an “Overview of Analytical

Techniques for Protein Characterization” such as liquid chromatographic modes, FTIR, CD and capillary electrophoresis. This was followed by Dr. Nithyakalyani Sri Rangan (CAPS, Syngene), who delivered an enlightening talk on the “Mass spectral Techniques” followed by a video demonstration of CAPS infrastructure for protein purification and characterisation. The last lecture of this session was delivered by Dr. Smita Kale (BVC, Pune) on “Higher-order Protein Structure and Characterization” who elaborated on the use of CD and fluorescence spectroscopy in protein characterisation.

The day 7 sessions were also on “Analytical Characterization”, which began with a talk by Dr. Ravi Krovidi (Ingenuity Biosciences) on “Overview and Strategies of Immunogenicity and Flow-cytometry assays, functional characterisation by ELISA and method development of neutralizing antibody assay and finally on the growth of Biosimilars. This was followed by Dr. Shubendu Seal (Cytiva) who covered video demonstration of the entire process of “Biacore Applications” such as binding kinetics and affinity analysis on the Biacore system.

The sessions on day 8th were initiated by Dr. Nandakumar (Kemwell BioPharma) who presented the “In-Process Analytics”. This was followed by a talk on “Biologics and Biosimilars: Regulatory Requirements” by Dr. Mohana Kumar Reddy Mudium (IICT). He elaborated on the importance of analytical characterisation data for regulatory submissions. The session ended with a talk by Dr. Madhavi (DBT-BIRAC) who briefed

the participants on the “National Biopharma Mission (NBM)” for promoting novel drug discovery programs in the country. She also presented the other schemes of BIRAC for promoting the innovation and entrepreneurship ecosystem and academy–industry interactions.

The workshop concluded on the day 9th with the sessions on “Characterisation and regulations” with key presentations. The session began with a talk by Dr. Sunit Maity (Director, Zumutor Biologics) who delivered an insightful lecture on “Novel Immune Nontherapeutic” (link to the video: <https://youtu.be/B9SVYO6KfQs>). This was followed by Dr. Rajan Sriraman (Head, Reliance Life Sciences) who stated “Trends in Vaccines-Virus like particle” (link to the video: <https://youtu.be/hCdalnAQRhY>). Interestingly, the highlights of the closing ceremony include a panel discussion on “Issue and challenges in Bioprocess Technologies for Biopharmaceuticals” (link to the video: <https://youtu.be/8me52JQOITI>) involving the panelists from industries and academics moderated by Dr. Partha Kumar Sarkar, Associate Vice President, Technical Operations, Bharat Biotech International Ltd.

The panel discussion was initiated with an introductory presentation by panelists which emphasized on biopharmaceutical various aspects i.e., pharmaceutical drug products manufactured from biological sources, engineered macromolecular products, recombinant therapeutic proteins and monoclonal antibodies, vaccines, biosimilars and advance therapy medicinal products, gene therapy medicines. The

panel discussion session was found very informative and interactive and the panel members were Dr. Guhan Jayaraman (Professor, IIT Madras), Dr. Ravi Krovidi (CEO, Ingenuity Biosciences), Mr. Bedadyuti Chakraborty (Dr. Reddy’s), Dr. Mirage Singh (DBT-BIRAC), Dr. Samir Kulkarni (NCNN, University of Mumbai). Feedback from the participants regarding the workshop was extremely encouraging and positive with productive concepts.

The workshop illustrated an efficacious closing ceremony concluded by a welcome address by Dr. Hemalatha Reddy (Former Principal, Delhi University) and feedback by the participants and efforts of FABA to introduce filling the gap between academia and industry. To conclude, the vote of thanks by Dr. S. Harinarayana Rao (Consultant and Officer) to the principal sponsors of the workshop i.e., CuraTeQ Biologics, Biological E. Limited, Dr. Reddy’s Institute of Life Sciences and co-sponsored by BioBeams. He also thanked organizers, FABA president (Dr. Asadulghani) and executive president (Prof. P. Reddana), who made this entire workshop extremely successful and appreciated several important insights and action that were accomplished through this workshop.

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Guest Article

The Enigma of Gut Microbiome in COVID-19

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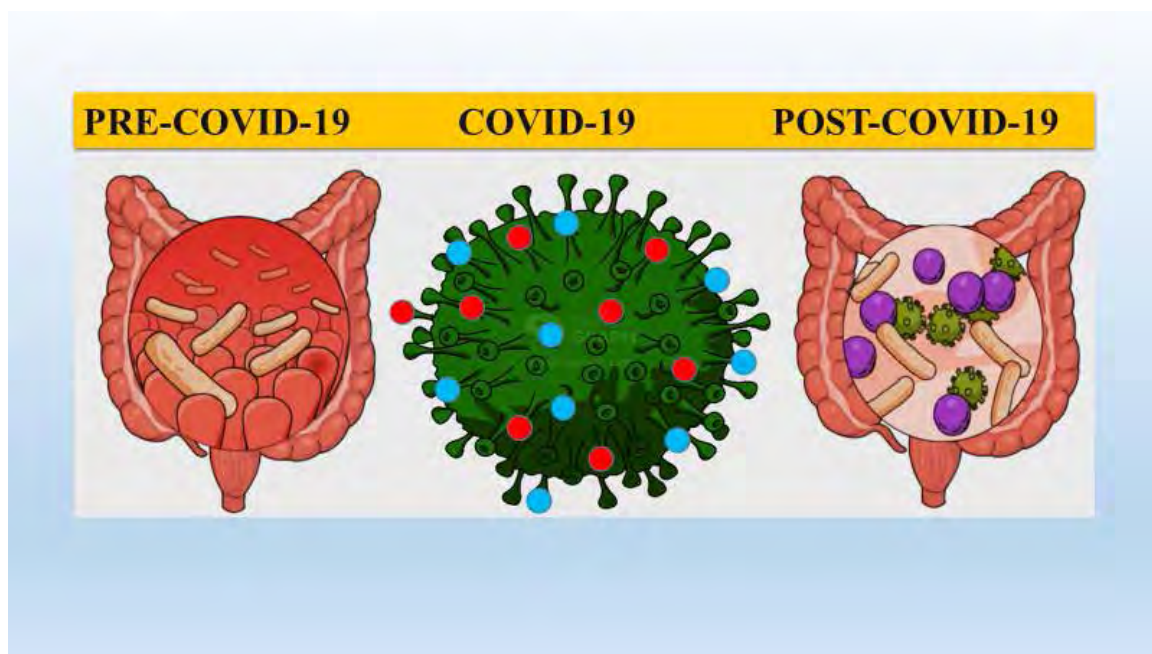
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Abstract

Gut is the reservoir of trillions of diversified cells creating complex ecosystem but maintaining marvelous balance in the form of homeostasis in humans. The global scientific literature gives convincing evidence of the role of different microbes and their genetic constitution (gut microbiome) is associated with variety of good health as well as pathological conditions. Simultaneously gut serves as welcome mat for SARS-CoV and acting as good reservoir for their survival and prolong infection. Though the research in this field is in its infancy but this article gives a taste of the breadth of this burgeoning area.



Gut and COVID-19

Introduction

The COVID-19 pandemic crippled all over the world now-a-days caused by novel severe acute respiratory syndrome corona virus-2 (SARS-CoV-2). The global scientific community have been continuously thriving for finding various pharmacological solutions for combating this menace by identifying various drug molecules, vaccine candidates, drug repurposing strategies. On the other hand, recently SARS-CoV-2 posits other technical challenges by evolving new variants that might be more harmful or infectious as compared with earlier strain. Therefore, maintaining certain medical and social advisories like social distancing, wearing masks and keeping high immunity is the safest option in the current scenario as preventive measures. The intriguing outcome of COVID-19 infection can be assessed through various respiratory manifestations such as pneumonia, acute respiratory distress syndrome (ARDS), but recently 50% of patients suffering from COVID-19 displayed gastrointestinal (GI) symptoms, including diarrhea, nausea and vomiting. Apart from that, detection of SARS-CoV-2 virus in stool and anal swab samples confirmed the ensuing role of digestive tract for corona virus entry as well as their replication. The digestive tract comprises of trillions of microorganisms that include, bacteria, fungi, viruses as well as other life forms that plays pivotal role in maintaining the balanced physiological state. These microorganisms are coevolved with humans and formed a living ecosystem inside our gut affecting metabolism, immunity, digestion and behavioral status of cells. The entire microbial world within the gut is commonly known as "gut microbiota" and their combined genome is termed as "gut microbiome". However, its worthy to mention here that now-a-days with increasing importance gut microbiota has been considered as an "essential organ" and comprising 150 times more genes than present in the human genome. The research studies highlighting the role of gut microbiome reminded me a very old adage of our ancestors that "Its all about gut feelings". Thus, their considerable role cannot be defied in the context of current pandemic.

Composition of gut microbiome in COVID-19 patients

The journey of the development of gut -microbiota begin from the birth of an individual however, its development is severely affected by the diet, pathological conditions and antibiotic treatment and more prominently mode of delivery in humans. In the early development two major phyla *Proteobacteria* and *Actinobacteria* dominated but at the age of 3-5 years major development of gut microbiota has been taken place that is further subjected to change

with differential environmental cues. Recently, the analysis of COVID-19 patients from various countries revealed the fact that at the onset of COVID-19 infection from mild to severe progression there is considerable increment in the abundance of opportunistic pathogens like *Streptococcus*, *Actinomyces*, *Coprobacillus* and *Candida albicans*, *Candida auris* and *Aspergillus flavus* and reduction in the population of commensals or symbionts in the gut. Therefore, these studies evidenced that the gut microbiome as a contributory factor to the pathogenesis of COVID-19 infection.

Factors affecting gut microbiome in COVID-19

Currently, there are various risk factors that have been identified for acquisition of COVID-19 but little is explicit about how these factors can be linked to gut microbiome. The growing continuum of studies related to the linking of unrecognized role of gut microbiome with COVID-19 certainly enhanced our understanding towards this perspective. One of the prominent factors is age and it was proven previously that the elderly microbiome comprises of *Parabacteroides* and *Alistipes* genera that has been shifted from *Firmicutes* present in adults and healthy individuals. Similar gut microbiome profile has been observed in COVID-19 patients in which the diversity of microbial population has been reduced and more populated by *Bacteroidetes*. In addition to that, ethnicity can also be considered as an important factor in COVID-19 because ethnic minorities have been documented with high mortality rate from COVID-19. The genetics, dietary, lifestyle and socioeconomic factors and geographical region may profoundly impact the variation in the profiles of gut microbiome. At global context, it was explored and confirmed that the abundant genus was found to be in *Prevotella* in Turkish, Moroccan and Ghanaian ethnicities while Surinamese South-Asian Surinamese and African ethnicities are richer in *Bacteroides* population while Dutch ethnicities are found to be rich in *Clostridiales*. In Indian context, *Prevotella* abundance was observed in North Indian population due to plant-based diet while enrichment of *Bacteroides* have been observed in Southern Indian population due to an omnivorous diet. Furthermore, overwhelming use of drugs and antibiotics also alter the profile of gut microbiome as these are acting as double-edged sword eliminating both beneficial and harmful microbes. The destruction of beneficial microbes paved the way for the growth of unwanted microbes and shifting from state of symbiosis to gut dysbiosis. An overview of impact of COVID-19 in gut microbiome is represented in **Fig. 1**.

Apart from that, various comorbidities like diabetes, hypertension have been realized to enhance the severity of COVID-19 outcome. The gut microbiome profile of

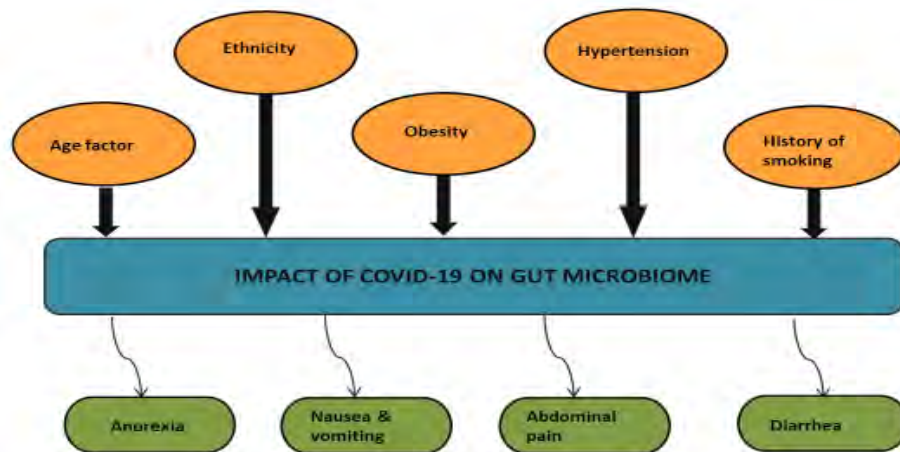


Fig. 1 Impact and outcome of COVID-19 in gut microbiome

patients from diabetic and hypertension revealed the reduction in *Firmicutes* and short chain fatty acid producers (SCFA) producers in the gut and found to be enriched in *Bacteroidetes* and *Parabacteroides*, respectively. In addition to that, cellular entry point of SARS-CoV-2 that is ACE-2 receptors also expressed in extra-pulmonary sites like kidney and gastrointestinal tract. It has been already proven that gut microbiota regulates colonic ACE-2 receptors. Therefore, it's quite apparent that gut is providing a welcome mat for the virus for their prolonged survival and proliferation thus can be directly correlated with severity of COVID-19. Recently, it has also been in limelight that cytokine storm one of the serious outcomes of COVID-19 has been maintained by the gut microbiome through Toll-like receptors (TLRs)-mediated immune responses. Though further prodigious research must be needed for understanding the comprehensive mechanism behind these alterations.

How we can improve the gut microbiome in COVID-19

It has been evidenced that vegetarian diet promotes the growth of commensal microbes that have capacity for eliminating pathogens through competitive exclusion and conferring anti-inflammatory response. The Hippocrates were never credited for their statement "let thy food be thy medicine and thy medicine be thy food" but in today's context it seems to be worth remembering. Research studies also corroborated that intake of probiotics was found to reduce the severity of ventilation-associated complexities

in COVID-19. The most commonly used probiotic species are *Lactobacillus*, *Bifidobacteria* and *Saccharomyces boulardii*. The probiotics induce immune responses, protect the integrity of intestinal epithelium, secrete anti-viral compounds, increase serum antibody IgA and reduce the inflammation. The colonization of probiotics has also been envisaged in upper and lower respiratory tract to alleviate the anti-viral infection. Though the recommendation of probiotics is not acclaimed at International level as more than 25 clinical trials are under progress for assessing their efficacy in COVID-19 but still they are the prime factors for improvement of gut microbiota.

Further, the improvement of gut microbiota can be done by prebiotics defined as the non-digestible carbohydrates, short polysaccharides and oligosaccharides like inulin, galacto-oligosaccharides, oligofructose, galacto-fructose and xylo-oligosaccharides. These prebiotics promote the growth of probiotics and other gut microbiota followed by production of short chain fatty acids and antimicrobial compounds. The prebiotics act as a substrate for the fermentation of gut microbiota to release various anti-inflammatory compounds that protect the integrity of gastrointestinal epithelium. More recently, "oral bacteriotherapy" or "fecal microbiota transplantation (FMT)" in which the transplantation of fecal microbiota from healthy individuals to patients with gut dysbiosis has been performed. The history of this therapy dates back in 4th century but it was successfully applied for treatment of *Clostridium difficile* infection (CDI) and Inflammatory bowel disorder (IBD). Currently gut dysbiosis is one of the prime factors in

COVID-19 therefore the application of this treatment modality holds great potential to restore the healthy microbial community for executing their normal function. There are various ways by which transplantation took place either in the form of enema, capsular insertion, colonoscopy but still more validation is needed from extensive clinical studies of COVID-19 patients with comparison of healthy individuals.

Current challenges and Future perspectives

The above discussion clearly states that gut microbiome confers indispensable role in COVID-19 but their comprehensive studies amid this pandemic seems to be quite challenging. Due to the global lock down and restriction in routine research activities and other hospital procedures like stool sample collection, surgery, endoscopic practices inhibit their wider assessment and adoption. The future research studies can be directed in evaluation of safety and efficacy of probiotics as well as FMT in COVID-19. That will further pave the way for finding therapeutic avenues in gut microbiome and reduce the burden of drugs and antibiotics.

Conclusion

The journey of COVID-19 is still going on and their long-term effects yet need to be elucidated more precisely. It may be clearly seen that overwhelming utilization of repurposed drugs and antibiotics will be detrimental to our gut microbiome. Thus, understanding the microbiome-based strategies will certainly be helpful and more beneficial for the treatment of COVID-19. At the end we can say that we should be vigilant about our gut microbiome by keeping “Buddy bugs to eradicate harmful bugs”.

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Guest Article

Leprosy Drug Clofazimine Set For New Roles

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Abstract

Development of a brand new drug takes enormous toll on time, money and effort, due to bottlenecks in therapeutic development. Strategically repurposing drugs for other uses can save time and money, as their pharmacology, formulation and potential toxicity are already known. The preclinical phase includes a demonstration of its efficacy in *invitro* or *in vivo* model system and then filing the experimental new drug application with the U.S. Food and Drug Administration (FDA), it typically enters into clinical phase II trials. The cost of launching a repurposed drug is approximately 85% less than for a *de novo* drug. Besides repurposed drugs, repositioned and rescued drugs generate 25% of annual revenues for the pharmaceutical industry as per the estimate. There are multiple illustrations of drug repurposing to date, the pioneer was the repurposing of thalidomide, initially a sedative and anti-leprosy, later approved for the treatment of multiple myeloma by USFDA in 2012.

Clofazimine (CFZ), primarily known for its anti-leprosy activity is shown to be effective against primary interventions for multidrug-resistant tuberculosis, chronic myelogenous leukemia (CML), and more recently SARS-CoV-2. CFZ was discovered during 1950s at Trinity College, Dublin, was approved for use in the United States in 1986, presently it is in WHO list of essential medicines.

The efficacy of CFZ against Mycobacterium Avium Complex (MAC) was demonstrated by *Jarand et. al.* from University of Calgary, Canada in 2016. CFZ administered in combination with macrolide and ethambutol was shown to be highly effective in treatment of MAC. The work was recognized and published in the renowned journal CHEST.

The research group at CSIR-Central Drug Research

Institute, Lucknow in collaboration with Zydus Research Centre, Ahmedabad and King Georges Medical University, Lucknow has demonstrated that CFZ can defeat leukemic stem cells (LSCs) and resists relapse in CML patients.

CML, a type of cancer affecting blood and bone marrow developed due to chromosomal aberrations is one of most recurrent adult leukemia in Indian population, which accounts for 30%-60% of all leukemia. The management of CML was revolutionized by the targeted treatment with imatinib that has become the standard treatment of choice. The second-generation of medicine includes nilotinib, dasatinib administered to patients resistant or intolerant to first-generation of drugs. However, although effective, second-line therapy comes at a significant expense. It has been estimated that the cost can measure up to \$800000 per

quality-adjusted life-year compared to generic imatinib. Moreover, a considerable number of patients suffer from relapse and progression when the first/second-line therapy stops due to the activity of leukemic stem cells (LSCs).

The breakthrough research from the group shows CFZ is particularly effective in imatinib-resistant patients and terminates LSCs including notorious quiescent stem cells derived from CML patients without causing harm to hematopoietic cells derived from healthy individuals. The drug could successfully over empower cellular leukemic/ oncogenic factors often associated with multidrug-resistant patients. Interestingly CFZ when administered in combination with imatinib at a significantly low physiological dose known so far, proved exceptionally effective in comparison to monotherapy. The outcome of the study was published in a reputed journal, HAEMATOLOGICA. Leukemic stem cells possess immense hindrance to the existing drugs, as they are incapable of targeting quiescent stem cells. The identified drug from the study could overcome this hindrance and can be proposed for its further clinical evaluation.

The future of this comprehensive study depends directly on clinical evaluation in humans because preclinical validations, pharmacokinetics and toxicity studies have already been performed in detail. Successful execution of clinical trials will render healthcare much more affordable for CML patients of Indian origin. The research team with their disease-centric viewpoint screened over most possible repurposing candidates for the treatment of chronic myeloid leukemia and has come across CFZ. Again, they have explored the use of novel combination therapies, where the repurposed drug increases the efficiency of imatinib, a well-known treatment and could dramatic improvements in outcomes. This research promises that in the future treatment of CML who are resistant to existing drugs or relapse patients will benefit from it as the cure will become within reach in economically backward parts of India. Clinicians can bank on CFZ repurposing for the treatment of chronic myeloid leukemia.

Most recently in 2020, researchers from Sanford Burnham Prebys Medical Discovery Institute and the University of Hong Kong demonstrated that CFZ was capable of inhibiting SARS-CoV-2 multiplication in hamsters. Their research published in the highly reputed journal NATURE reports CFZ to be effective against several coronaviruses including the novel coronavirus. Novel emerging

infectious diseases like the present COVID-19 possess extreme challenges to the healthcare systems. This creates an urgent need for effective pharmacological treatments. The demand can only be fulfilled by repurposing drugs due to the lack of available time for new drug formulation. The antiviral synergism between clofazimine and remdesivir, the first ever-pharmacological approach towards prevention of Covid-19 has a promising future. Repurposing clofazimine thus brings a ray of hope for combating the prevalent pandemic situation.

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The Merck logo is displayed in a bold, pink, sans-serif font in the top right corner of the page. The background of the entire top half of the page is a dark blue space with a starry pattern and several glowing blue, spherical molecular or cellular structures of varying sizes and opacities.

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Detailed description of the challenges, the application process and timing of the **deep dive** workshops **are** available at:

researchgrants.merckgroup.com

Applications deadline **Aug. 31st, 2021.**



Featured Biotech News

56% of hand sanitiser samples in Uttarakhand ineffective

August 5, 2021

Several sanitisers in the market, including known brands, may be “completely ineffective” at killing Sars-Cov-2 and preventing Covid-19, researchers have warned after they tested 1,050 samples from 50 different brand names in Uttarakhand and found that over half of them were of no use against the coronavirus.

In fact, the sanitisers might actually be causing harm as many of them contained toxic chemicals over the permissible limit, said researchers from the Dehradun-based Society of Pollution & Environmental Conservation Scientists (SPECS) who tested them in their laboratory which is approved by the Centre.

Dr NS Bisht, senior physician based in Dehradun commenting on the issue said, “Medical Council of India has set the norms for ingredient/chemical composition for sanitizer to be used in these pandemic times. Sub-standard quality of sanitizer is damaging for individual as well as collective society.”



Maximum number of sanitizer samples failed in Champawat and Chamoli districts with 64% failure followed by Rudraprayag (60%), Tehri (58%), Almora, Nainital, Udham Singh Nagar with 56% each, Pauri (54%), 52% each in Haridwar, Uttarkashi and 49% in Pithoragarh district.

Researchers have warned after they tested 1,050 samples from 50 different brand that over half of them were of no use against the coronavirus.

China pressured WHO team to dismiss lab leak theory: Chief investigator

August 12, 2021

The World Health Organization expert who led a controversial joint probe into the origins of the coronavirus pandemic says in a documentary airing Thursday night on Danish television that Chinese colleagues influenced the presentation of their findings.

Speaking to Danish documentarians, Peter Ben Embarek said Chinese researchers on the team had pushed back against linking the origins of the pandemic to a research laboratory in Wuhan in a report about the investigation.

“In the beginning, they didn’t want anything about the lab [in the report], because it was impossible, so there was no need to waste time on that,” Ben Embarek said during the interview. “We insisted on including it, because it was part of the whole issue about where the virus originated.”

A discussion of whether to include the lab-leak theory at all lasted until 48 hours before the conclusion of the mission, Ben Embarek told the Danish reporters. In the end, Ben Embarek’s Chinese counterpart eventually agreed to discuss the lab-leak theory in the report “on the condition we didn’t recommend any specific studies to further that hypothesis.”

Asked in the documentary whether the report’s “extremely unlikely” wording about the lab-leak theory was a Chinese requirement, Ben Embarek said “it was the category we chose to put it in at the end, yes.” But he added that this meant it was not impossible, just not likely.

In further comments during the interview that were not included in the documentary but were incorporated in an account by the Danish channel TV2 on its website, Ben Embarek suggested that there could have been “human error” but that the Chinese politi-



cal system does not allow authorities to acknowledge that and they’re not very happy to admit that.

A Chinese official Chinese respiratory specialist Zhong Nanshan and Zhao Lijian who has a history of attacking the United States online has lent a voice to a conspiracy theory that blames American soldiers for bringing COVID-19 to China, though the science does not support that narrative.

The article was published in BMJ 2021;374:n2023

Leaked documents show that some early commercial batches of Pfizer-BioNTech’s covid-19 vaccine had lower than expected levels of intact mRNA, prompting wider questions about how to assess this novel vaccine platform.

Indian Govt approves Bharat Biotech's Ankleshwar plant to produce Covaxin

August 10, 2021



Bharat Biotech's Ankleshwar facility has been given the go-ahead to produce Covaxin doses, Union Health Minister Mansukh Mandaviya announced.

"Govt of India approves vaccine manufacturing facility for production of BharatBiotech's Covaxin in Ankleshwar, Gujarat," the Minister tweeted.

In 2019, Bharat Biotech had acquired Chiron Behring Vaccines Pvt Ltd, located in Ankleshwar, from GlaxoSmithKline Asia. While production is already on at the Ankleshwar facility, supplies are expected from the fourth quarter of the calendar year.

Last week, referring to Covaxin supplies, VK Paul, Member - Health, NITI Aayog, had said that the standardisation process was being fine-tuned at Bharat Biotech's Bengaluru facility. "Soon, another unit at Ankleshwar (Gujarat) would add 6 million doses," he

had said, adding that the target of 51 crore doses up to July-end had been met and the year-end target of 135 crore jabs would also be met.

Covaxin has recently received Good Manufacturing Practices (GMP) compliance certificate from Hungary, The approval was received from the National Institute of Pharmacy and Nutrition, Hungary certifying the GMP for the manufacture of Covaxin.

Rs 1,600 cr allocated for COVID research and development: Dr Jitendra

August 4, 2021



Union Minister of State (Independent Charge) Science & Technology, Minister of State (Independent Charge) Earth Sciences, MoS PMO, Personnel, Public Grievances, Pensions, Atomic Energy and Space, Dr Jitendra Singh today informed the Rajya Sabha that Government has allocated over Rs 1,600 crore for COVID related research through different Science Ministries and Departments.

In an elaborate reply to a question, the Minister stated that the Department of Biotechnology and its Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), have allocated an amount of appx. Rs 1,300 Crore for COVID-19 Research and Product Development.

Similarly, the Department of Science and Technology (DST) earmarked an amount of approximately Rs 200 crore for COVID-19 related research for implementation through its different programmes, autonomous institutions and statutory bodies like Science and Engineering Research Board and Technology Development Board. At the same time, Council of Scientific and Industrial Research (CSIR) has allocated Rs.10444.39 lakhs from its Government budgetary support and internal resources for imple-

menting projects related to COVID-19 related research. Under the COVID-19 Research Consortium as a part of the comprehensive efforts to facilitate development of indigenous research solutions to tackle COVID-19, 107 projects were supported in thematic areas of COVID-19 vaccines (17), diagnostics (45), therapeutics (22) and biomedical interventions (23).

The reply further stated that to advance biomedical research, DBT has supported five COVID-19 biorepositories. Further, the Indian SARS-CoV-2 Genomic Consortium (INSACOG), a Consortium of 28 regional sequencing labs, was launched, to ascertain the status of new variants of SARS-CoV-2. “Mission COVID Suraksha – The Indian COVID-19 vaccine development Mission” is being implemented at a total cost of Rs. 900 crore.

The Mission is supporting the development of COVID-19 vaccine candidates (05), facilities for animal challenge studies (03), facilities for immunogenicity assays (03), clinical trial sites (19). Additionally, facility enhancement of Bharat Biotech and 3 Public Sector Undertakings to support augmented production of Covaxin, is also being supported under the Mission.

Vaccines may do more harm than good To those who recovered from COVID-19: Experts

August 10, 2021



Experts argue that when the current evidence shows that people recovered naturally from Covid-19 are well-protected from future infection or severity of the disease, there is no point including them in the current vaccination drive.

Dr Sanjay Rai, Professor, Community Medicine in All India Institute of Medical Sciences, New Delhi, says that all available evidence demonstrates that the natural infection provides better and longer protection that may even be lifelong.

”There is no need to vaccinate individuals who had documented COVID-19 infection in the past. These individuals may be vaccinated after generating evidence that vaccine is beneficial after natural infection,” Dr Rai said.

He added, ”Based on the available shreds of evidence, we can say that there is no additional benefit of vaccination in COVID recovered individuals. Actually, it may cause

harm due to few known and unknown severe adverse events following immunization.”

Dr Rai also believes that vaccines are precious resources that should be used to save other vulnerable persons’ lives rather than wasting them on well-protected individuals.

Noted epidemiologist Dr Jayaprakash Muliyl, who is a core member of the National Technical Advisory Group on Immunization (NTAGI), agrees that vaccinating a confirmed Covid-19 recovered person doesn’t have any additional benefit “but there is some small chance of adverse reaction.”

As the current vaccination drive in India doesn’t have any provision to exclude naturally-recovered persons, a lot of such people say that they have to get vaccinated even if they didn’t want because they were under pressure from their employers.

UK relaxes travel curbs for Indian passengers, no mandatory quarantine for fully vaccinated

August 08, 2021



The UK eased travel restrictions for India by moving the country from its “red” to “amber” list, which means fully vaccinated Indian passengers will no longer be subjected to a compulsory 10-day hotel quarantine on their arrival in Britain.

The Department of Health and Social Care (DHSC) has confirmed that all arrivals from India who have been vaccinated in India, which is on the amber list as at 4 am local time on Sunday, are required to isolate at home or their designated location mentioned on the compulsory locator form.

“We recognise there are a large variety of Covid-19 vaccines being administered worldwide and work is ongoing to determine which non-UK vaccines and certification solutions to recognise,” a DHSC source said.

There had been some speculation over Covishield, the

Serum Institute of India made Oxford/AstraZeneca vaccine, being considered within the wider UK-approved vaccines ambit.

However, the government has clarified that the India-made version of the Oxford/AstraZeneca vaccine so far approved by the UK’s Medicine and Healthcare products Regulatory Agency (MHRA) is branded as Vaxzevria and that is the only one currently recognised under the exemption rules.

The Department of Health and Social Care (DHSC) has confirmed that all arrivals from India who have been vaccinated in India

Vaccines and strategies under scrutiny as Delta drives COVID surge

August 2, 2021



China's hardline zero Covid strategy is facing a fresh challenge from the rapid spread of the Delta variant, amid concerns over the efficacy of Chinese vaccines against the highly contagious strain.

The Delta variant, which appears to cause more severe illness and spreads as easily as chickenpox according to an internal document from the US Centers for Disease Control and Prevention (CDC), has wreaked havoc across the world. Now, it is causing China's worst outbreak in months.

Malaysia's health ministry has announced that it will stop using the COVID-19 vaccine produced by China's Sinovac once its supplies end, while other Southeast Asian countries have said they are looking to mix and match the Chinese-made shots with those from western manufacturers amid a surge in cases driven

by the highly-transmissible Delta variant.

Elsewhere in the world, countries with relatively high vaccination rates are increasingly choosing to tolerate a degree of transmission, as long as it doesn't translate into a surge in hospitalizations and deaths.

Breakthrough cases have also been reported among people fully immunized with more effective vaccines, such as those produced by Pfizer/BioNTech and Moderna.

Questions raised about level of efficacy of WHO-approved shots from China by several countries

US-based Adagio Therapeutics gives Biocon licence to make antibody treatment for COVID-19

July 27, 2021



The US-based Adagio Therapeutics has granted Biocon Biologics Ltd., a biosimilars company and a subsidiary of Biocon Ltd, an exclusive licence to manufacture and commercialise an antibody treatment based on ADG20 for India and select emerging markets.

ADG20, a novel monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is in global clinical development by Adagio as a single agent for both the treatment and prevention of Covid-19, the disease caused by the SARS-CoV-2 virus, its variants, as well as future variants that may emerge, a statement from the company said on Monday.

Kiran Mazumdar-Shaw, the executive chairperson of Biocon Biologics Ltd, said: "This partnership with Adagio aligns our joint vision of bringing superior biologic therapies to millions of patients in low and

middle-income countries. Vaccines alone will not protect and make the world safer. Biologic therapies that arrest the virus in its path of devastation is a necessity for sustainable protection and safety."

"We believe that Covid-19 will become an endemic disease requiring a variety of effective, safe and convenient treatment and prevention options for years to come," the statement said.

ADG20, a novel monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses

Advantages of Intranasal Vaccine Over Intramuscular Shots

July 25, 2021



Nearly 100 Covid-19 vaccines are currently in clinical trials around the world, out of which only seven are delivered intranasally. Injection pain is one of the reasons for vaccine hesitancy among people. Intranasal Covid-19 vaccines are needle-free, means pain-free. In a new article published in the journal Science, two immunologists from the University of Alabama at Birmingham (UAB) have highlighted several advantages of using an intranasal vaccine against the SARS-CoV-2 virus in the fight against COVID-19 pandemic.

In the article, UAB researchers - Fran Lund and Troy Randall also pointed out individual advantages and challenges of each of the seven intranasal vaccine candidates under clinical trials. Lund is a professor of microbiology and Randall is a professor of medicine in the Division of Clinical Immunology and Rheumatology at UAB.

According to the UAB researchers, the main advantages of intranasal vaccines are needle-free administration, delivery of antigen to the site of infection, and

the elicitation of mucosal immunity in the respiratory tract.

Compared to intramuscular shots, intranasal vaccination also gives two additional layers of protection. A vaccine administered through the nose produces: 1) immunoglobulin A and resident memory B and T cells in the respiratory mucosa that are an effective barrier to infection at those sites, and 2) cross-reactive resident memory B and T cells that can respond earlier than other immune cells if a viral variant does start an infection.

Bharat Biotech is working on a nasal vaccine, which is expected to be launched by the end of the year.

Central Govt, India advises States to conduct State specific Sero Surveys in consultation with ICMR

July 28, 2021



The Centre has advised States to conduct State-specific Sero Surveys in consultation with Indian Council of Medical Research, ICMR to generate district-level data on sero-prevalence.

Union Health Secretary Rajesh Bhushan has written a letter to Additional Chief Secretary, Principal Secretary and Health Secretaries of all States. Mr Bhushan said, this Survey is essential in formulating localized public health response measures.

Health Ministry has referred to the findings of the 4th round of National Sero-Prevalence Survey done by ICMR and has advised the States to conduct the sero-prevalence studies in their own States and Union Territories. He said, the findings of such studies can be utilized by them to guide objective, transparent and

evidence-based public health response to COVID-19.

Mr Bhushan pointed that the ICMR has conducted the recent National Sero-survey in 70 districts of the country.

The national sero-survey by ICMR was designed to capture the extent of the spread of COVID infection at the national level.

The national sero-survey by ICMR was designed to capture the extent of the spread of Covid infection at the national level.

FDA Clears Vaxart's S-Only Oral Tablet for COVID-19 Vaccine Candidate

August 02, 2021



A clinical-stage biotechnology company developing oral vaccines administered by tablet, announced today that the U.S. Food and Drug Administration has cleared Vaxart's Investigational New Drug application for an S-only oral tablet SARS-CoV-2 vaccine candidate.

“This is great news because it allows us to move forward with our first S-only vaccine construct,” said Andrei Floroiu, Vaxart's Chief Executive Officer. “As we said at the end of the first quarter, we will explore multiple S-only constructs in clinical trials alongside the S+N construct that has already completed its Phase I trial.

Vaxart announced in February that it had completed a Phase 1 clinical trial for its oral S+N COVID-19 vaccine. The results from that study found that the investigational oral vaccine triggered multiple immune responses against SARS-CoV-2 antigens, while reaching primary and secondary endpoints of safety and immunogenicity, respectively.

Vaxart (www.vaxart.com) is a clinical-stage biotechnology company developing a range of oral recombi-

nant vaccines based on its proprietary delivery platform. Vaxart vaccines are designed to be administered using tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury.

Vaxart believes that its proprietary tablet vaccine delivery platform is suitable to deliver recombinant vaccines, positioning the company to develop oral versions of currently marketed vaccines and to design recombinant vaccines for new indications. Its development programs currently include tablet vaccines designed to protect against coronavirus, Norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immuno-oncology indication. Vaxart has filed broad domestic and international patents covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

No application received yet for Covishield approval: European health regulator

20 July, 2021



The approval of Covishield vaccine by the European Medicines Agency (EMA) will help fully vaccinated Indians travel to European Union countries without any ban. But Europe’s health regulator said Thursday it is yet to receive any formal request for the evaluation and marketing authorisation of Covishield.

In a tweet posted on its official handle, the EMA clarified its position: “For the #COVID19vaccine Covishield to be evaluated for use in the EU, the developer needs to submit a formal marketing authorisation application to EMA, which to date has not been received.”

SII CEO Adar Poonawalla had said there was “no controversy” and that he was expecting to receive approval from the EMA for Covishield in a month.

“We are quite confident that in a month EMA will approve Covishield,” he had stated in various statements to the press.

An SII official, requesting anonymity, however, told The Print Friday, that “we have applied through AstraZeneca and we are confident”. The company is expected to release an official statement on the matter soon.

While SII says it has applied for the approval through its partner, AstraZeneca, the EMA says it is yet to receive any formal request for the evaluation of

Latest Biotech News



U.S. authorizes third shot of COVID-19 vaccines for the immunocompromised people

August 14, 2021

U.S. regulators authorized a third dose of COVID-19 vaccines by Pfizer Inc (PFE.N)-BioNTech and Moderna Inc (MRNA.O) on Friday for people with compromised immune systems who are likely to have weaker protection from the two-dose regimens.

The U.S. Food and Drug Administration amended its emergency use authorization for both vaccines on Thursday, paving the way for people who have had an organ transplant, or those with a similar level of weakened immune system, to get an extra dose of the same shot they have initially received.

An advisory panel to the U.S. Centers for Disease Control and Prevention (CDC) voted to recommend the additional shots, and the agency's director signed off on that recommendation on Friday. Immunocompromised individuals can begin receiving the shots immediately, according to an agency spokesperson.

Mixing of mRNA vaccines is permitted for the third shot if their original vaccine is not available.

The vulnerable group makes up less than 3% of U.S. adults, Rochelle Walensky, director of the CDC, had said before the authorization.

The FDA's decision does not apply to people who received the one-dose Johnson & Johnson (JNJ.N) vaccine, the CDC said, because there is not enough data to support additional doses yet.

Scientists are still divided over the broad use of COVID-19 vaccine boosters among those without underlying problems as benefits of the boosters remain undetermined.

Reports of infections among vaccinated people and concerns about diminishing protection have galvanized wealthy nations to distribute booster shots, even as many countries struggle to access first vaccine doses.

The World Health Organization last week called for a moratorium on COVID-19 vaccine booster shots until at least the end of September.

Delhi, India Inaugurated the first ICU Tele Medicine Centre of India

August 12, 2021



Shri. Satyendar Kumar Jain, Hon'ble Minister of Health & Family Welfare, Govt. of NCT of Delhi Inaugurated the first ICU Tele Medicine Centre of India in a field hospital at Ujala Cygnus Covid Center, Burari, New Delhi

Telehealth Project for COVID India is the joint effort of Health Committee, PHD Chamber, Rotary club of Delhi Central, BAPIO Training Academy (BTA), UK and Ujala Cygnus Healthcare Services to provide the Tele-Consultation & Tele-Reporting (internet and mobile based) services and support Indian health care professionals looking after COVID / Non-Covid patients. The Tele Medicine Centre was inaugurated at Ujala Cygnus Healthcare Services, Burari, New Delhi.

The telemedicine centre was inaugurated by Shri. Satyendar Kumar Jain, Hon'ble Minister of Health & Family Welfare, Govt. of NCT of Delhi & Shri. Dilip Kr. Pandey, Chief Whip Legislative Assembly & MLA Timarpur Assembly.

Speaking on the initiative, Mr. Sanjay Aggarwal, President, PHDCCI, welcomed Hon'ble Minister for sparing his valuable time to inaugurate the center and other dignitaries present physically as well as through virtual platform. He congratulated all the partners for taking this wonderful step and mentioned that rural India, where the access to medical specialists opinion and advance healthcare amenities are limited, telemedicine will bring access of health-

care and specialist doctors while reducing the time of consultations and improve the quality of healthcare services. It will also provide psychological support to the exhausted Indian healthcare professionals enabling safe & best quality within shortest possible time.

ICMR validates 6 self testing kits for COVID-19

August 9, 2021



Indian Council of Medical Research (ICMR), Department of Health Research, Ministry of Health, and Family Welfare, Government of India has recently issued a notification on the validation of COVID-19 Home Testing using Rapid Antigen (Ag) Tests (RATs). The US-FDA approved antigen-based COVID-19 Home/Self tests are exempted from ICMR validation.

To date, six Rapid Ag-based Home / Self Test Kits have been validated. These are Mylab Discovery Solutions, Pune for CoviSelf™ (PathoCatch) COVID-19 OTC Antigen LF device; Abbott Rapid Diagnostics Division, Chicago (Alere Medical, Gurugram) for PanBio COVID-19 Antigen Rapid Test Device and Meril Diagnostics, Vapi (Gujarat), for CoviFind COVID-19 Rapid Ag Self Test.

The other validated Rapid Ag-based Home/self Test Kits kits but not yet approved by ICMR are as follows: Trivitron Healthcare for MyCoviTest Self Test Kit, Oscar Medicare, Delhi for OSKIT Corona Ag Home Test and Oscar Medicare, Haridwar (Uttarakhand) for OS-KIT Corona Ag Home Test.

50 researchers awarded Prof M K Bhan 2021 fellowship

August 5, 2021



The Department of Biotechnology on Thursday announced the results of the first M K Bhan Fellowship-Young Researcher Fellowship Programme, a statement said.

A total of 358 applications were received through the Department of Biotechnology's (DBT) eProMIS portal for the fellowship, out of which 50 researchers were selected.

The department established the M K Bhan Fellowship-Young Researcher Fellowship Programme (MKB-

YRFP) to encourage young bright researchers, below 35 years of age, to continue their research in the country after PhD in any branch of Life Sciences/Biotechnology/allied areas.

The fellowship was instituted to honour eminent scientist and former DBT secretary M K Bhan.

The scheme offers an independent research grant for three years to the young post-doctoral fellows to enable them to emerge as future leaders and take up cutting edge research focused on issues of national relevance.

The fellowship also entails a monthly emolument of Rs 75,000 along with a generous Research/Contingency grant to carry out cutting edge research.

Bharat Biotech's Rotavac 5D gets WHO Prequalification

August 2, 2021

Bharat Biotech on Monday announced that the World Health Organisation (WHO) has awarded prequalification to its rotavirus vaccine, Rotavac 5D to prevent rotavirus diarrhea.

Rotavac 5D, new variant of Rotavac, is a unique rotavirus vaccine formulation that can be administered without a buffer and its low dose volume (0.5 mL) facilitates easy vaccine logistics, cold chain management and low biomedical waste disposal post-vaccination, the company said in a press statement.

WHO Prequalification enables the procurement of Rotavac 5D by agencies such as UNICEF and PAHO (Pan American Health Organisation) and will fast-track global access to this life saving vaccine.

Commenting on the development, Suchitra Ella, Joint Managing Director- Bharat Biotech, said that Rotavac and Rotavac 5D are projects conceived, innovated and executed in India, in collaboration with Indian and global partners.

Rotavirus is the leading cause of severe diarrhea among children less than five years of age around the world, re-

sulting in more than 200,000 deaths and 2 million hospitalizations worldwide. Vaccinations are an important part of global public health efforts to meet the Sustainable Developmental Goals of UNDP.

Fiona Godlee to step down as The BMJ's editor in chief after 16 years

August 2, 2021



Fiona Godlee is to resign as editor in chief of The BMJ at the end of this year, after more than 16 years in the role.

Godlee first joined the journal as an assistant editor in 1990 and became editor in chief in March 2005, the first woman to lead it since its inception in 1840.

Under her editorship The BMJ has become firmly established as one of the world's most influential and most widely read medical journals, defined by its mission to work towards a healthier world for all. The journal's impact factor, a measure of the importance or rank of a journal, has risen from 7 in 2005 to 39.8 today, and in the past five years worldwide usage on bmj.com has grown from around a million unique users a month to nearly six million.

Most recently Godlee was instrumental in the UK government's decision to abandon plans to allow

households to mix over Christmas, almost certainly helping to prevent deaths from covid-19.

Her work during the pandemic was recognised last week when she won editor of the year in the Association of British Science Writers awards. The judges said, "There was nothing more that anyone could ask for the title of editor of the year: vision, creativity, leadership, execution, and impact."

Today a third of BMJ's 70 journals are open access, promoting the exchange of ideas and rapid access to knowledge, to improve health and healthcare globally.

India first biobank for heart failure research inaugurated

August 6, 2021



The first National Heart Failure Biobank (NHFB) in the country that would collect blood, biopsies, and clinical data as a guide to future therapies was inaugurated at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST).

"There are no heart failure biobanks in the country, and this would greatly help in guiding future therapies and technologies and would benefit the heart failure patients significantly," said Prof. Balram Bharga-

va, Secretary, Department of Health Research (DHR) and DG, Indian Council of Medical Research (ICMR) while inaugurating the NHFB virtually on 5th August.

“The facility will be useful for the research and treatment of post-covid heart failure. The increase in the observed prevalence of long-COVID symptoms and post-COVID heart failure calls for long-COVID clinics to collect patient data and biospecimens that can be biobank for future research. Through the NHFB, researchers can get access to well-annotated biological specimens linked to clinical data while maintaining appropriate standards of quality and security. I sincerely hope that the NHFB will facilitate research both in India and abroad, helping clinicians and scientists to work together to understand and find solutions to heart failure-related morbidity and mortality.” Prof. Ashutosh Sharma, Secretary, Department of Science & Technology (DST) pointed out in his message.

The principal investigator of the project and Prof. of cardiology at SCTIMST, Dr. Harikrishnan S, informed that the storage facilities include -20, -80-degree mechanical freezers and a liquid nitrogen storage system which can store bio-samples at -140 degrees perpetually for years. Currently, there are facilities to store nearly 25000 biosamples.

The biosamples include the blood, serum, tissue samples obtained during open-heart surgery and peripheral blood mononuclear cells (PBMCs) and genomic DNA collected from heart failure patients. The biobank activity is supervised by a Technical Advisory Committee (TAC) with a member from ICMR.

J&J's single-shot COVID vaccine receives EUA in India

August 7, 2021

Healthcare major Johnson & Johnson has received Emergency Use Authorisation (EUA) for its sin-



gle-dose covid-19 vaccine in India, health minister Mansukh Mandaviya said in a press conference. Now India has 5 EUA vaccines. This will further boost our nation's collective fight against #COVID19,” Mandaviya tweeted.

The company's COVID-19 vaccine leverages the Ad-Vac vaccine platform proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV and HIV vaccines.

The Johnson & Johnson /Janssen vaccine was listed for emergency use by WHO on 12 March 2021. The vaccine has been authorized for use in Europe, the United States and other countries, with the widest experience to date in the United States. The WHO later reviewed thromboembolic events (blood clots) and thrombocytopenia (low platelets) after vaccination with the adenoviral vectored J&J vaccine.

India mainly has three covid-19 vaccines available for administration currently-- Bharat Biotech's Covaxin, Russia's Sputnik V. Moderna vaccine (mRNA-1273) and Oxford-AstraZeneca developed vaccine being manufactured by Serum Institute of India under brand name Covishield.

Other covid-19 vaccines awaiting approval in India are Zydus Cadila's ZyCOV-D, Gennova's mRNA vaccine, Biological E's Corbevax, Covaxin's nasal vaccine and Novovax's Covovax.

Disaster If COVID Vaccines Administered To Children Without Proper Research: Court

July 20, 2021

A division bench of Chief Justice D N Patel and Justice Jyoti Singh said, “It would be a disaster if vaccines are administered on children without proper research.”

Appearing for the petitioner, advocate Kailash Vasudev argued that there shall be a specific timeline as to when the vaccine trials for children would conclude. The court warned that it would dispose of the matter if the petitioner makes such kinds of submissions and said that there cannot be a timeline for the research.

The affidavit further submitted that vaccination is the Centre’s topmost priority and all efforts are being made to achieve 100 per cent vaccination in the shortest time possible, keeping the availability of vaccine doses in mind.

Meth Abuse Drove Huge Surge in Heart Failure Crises in California, USA

July 17, 2021

In a finding that demonstrates methamphetamine’s power to destroy the human heart, new research shows hospitalizations for heart failure related to the illicit drug have soared by 585% in California.

“Our study results should bring urgent attention to this insidious, yet rapidly growing, form of severe heart failure — methamphetamine-related heart failure [MethHF], which is taking the lives of young people, straining health care resources and threatening to spread like wildfire in California, the West and to the rest of the nation,” said study author Dr. Susan Zhao. She is a cardiologist at the Santa

Clara Valley Medical Center in San Jose, Calif.

For the study, the researchers analyzed data on more than one million people in a statewide database who were hospitalized with heart failure from 2008 to 2018. While hospitalizations for methamphetamine-related heart failure rose nearly 600%, those unrelated to methamphetamine use fell by 6%, the study showed.

More than 1.5 million children lost a primary or secondary caregiver due to the COVID-19 pandemic

July 20, 2021



More than 1.5 million children around the world are estimated to have lost at least one parent, custodial grandparent, or grandparent who lived with them due to death related to COVID-19 during the first 14 months of the pandemic, according to a study published in The Lancet. The study highlights orphanhood as an urgent and overlooked consequence of the pandemic and emphasizes that providing evidence-based psychosocial and economic support to children who have lost a caregiver must be a key

part of responding to the pandemic.

The analysis used mortality and fertility data to model rates of COVID-19-associated orphanhood (death of one or both parents) and deaths of custodial and co-residing grandparents (ages 60-84) from March 1, 2020 to April 30, 2021, across 21 countries. This study was funded in part by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health.

Traumatic experiences, such as the loss of a parent or caregiver, are associated with increases in substance use, mental health conditions, and other behavioral and chronic health conditions. NIDA supports research aimed at understanding the impact of trauma on young people, preventing substance use after experiencing hardship, and treating substance use in populations that experience trauma.

The countries with the highest numbers of children who lost primary caregivers (parents or custodial grandparents) included South Africa, Peru, United States, India, Brazil, and Mexico. The countries with rates of COVID-19-associated deaths among primary caregivers (>1/1000 children) included Peru, South Africa, Mexico, Brazil, Colombia, Iran, United States, Argentina, and Russia.

The study found that for every country, COVID-19 associated deaths were greater in men than women, particularly in middle- and older-ages. Overall, there were up to five times more children who lost a father than who lost a mother.

Novel researchers have a lower chance of winning funding, according to a study

July 22, 2021

In a 2012 Nature article, provocatively titled 'Conform and be funded', Joshua Nicholson and John Ioannidis showed that few of the most highly cited US biomedical scientists received funding from the country's National Institutes of Health. They attributed this to a reluctance at the agency to support potentially groundbreaking work. Since then, the sense that research funding is risk-averse and biased against novel work has become increasingly

widespread within the scientific community.

The possible causes for this include: increasing competition for funding, making funders reluctant to gamble on unusual, high-risk studies; a growing focus among policymakers and agencies on more applied problems with obvious societal relevance over speculative blue-skies work; and the biases of expert reviewers who prefer ideas in the mainstream of their disciplines to more left-field ideas.

What has been missing, however, is concrete evidence of the existence and size of potential biases in the funding system against researchers pursuing novel ideas. In a recent study, we provide this evidence, showing that, in a prestigious Swiss funding programme, researchers with a history of publishing novel research are less likely to win grants.

Sanofi intent to buy Translate Bio in \$3.2B

August 6, 2021

Sanofi is betting the genetic technology behind the fast development of two highly effective coronavirus shots last year will lead to vaccines for other viruses as well as drugs for diseases of the lung and liver, announcing Tuesday a deal to buy research partner Translate Bio for \$3.2 billion.

The acquisition is the latest sign large pharmaceutical



companies view messenger RNA, which BioNTech and Moderna used to create the COVID-19 vaccines now cleared for use in dozens of countries, as a crucial drugmaking platform.

For Sanofi, buying Translate Bio follows a recent commitment to spend nearly \$500 million a year on mRNA vaccine development through a new research unit that the French drugmaker plans to staff with 400 employees in the U.S. and France.

Under deal terms, Sanofi will pay \$38 per Translate share, a premium of 30% over yesterday's closing price and 56% over the volume-weighted average price of the past 60 days.

At \$3.2 billion, the purchase price for Translate is far below the lofty market valuations commanded by Moderna, BioNTech and, to a lesser extent, CureVac. Moderna is now worth \$140 billion, about \$10 billion more than Sanofi despite the latter company's international reach and dozens of approved medicines.

SoftBank Acquires \$5 Billion Stake in Roche

August 4, 2021

First reported by Bloomberg, SoftBank's investment

in Roche is something of a departure for the company, which often looks to technology companies and early-stage biotechs. According to the Financial Times, SoftBank's chief executive officer is bolstering the investments after a series of strategic missteps for its SB Northstar unit.

With the acquisition of the Roche stake, SoftBank has become one of the company's biggest stakeholders, Bloomberg reported. Shares that SoftBank acquired are non-voting shares, the Financial Times reported. SB Northstar was launched last year by SoftBank founder Masayoshi Son. According to Bloomberg, it was a means to put the company's massive cash pile to use. Son personally holds a one-third stake in SB Northstar. SoftBank has nearly \$20 billion in liquid capabilities for investments, Bloomberg said.

This year alone, SoftBank has made several significant investments in companies like Pacific Biosciences, Unoja Biopharma, Invitae and CMR Surgical. The \$5 billion invested in Roche will be among its biggest investments.

mRNA Disruptor Goes Public in \$1.5 Billion SPAC Deal

Aug 10, 2021

The Boston-based company is also out to save the earth with sustainable alternatives to pesticides and by protecting the bees. After raking in over \$122 million last year in funds, GreenLight is now headed to the NASDAQ by way of a \$1.5 billion SPAC deal.

While the pandemic has shown us that mRNA type vaccines can be produced much quicker than the traditional vaccines of the past, the technology faces some massive bottlenecks when it comes to scaling up. Obtaining the quantities of raw materials needed to vaccinate a large portion of the world isn't easy.



Biotech Research

Bio-inspired, blood repelling tissue glue seal wounds quickly

August 9, 2021



The new paste can adhere to surfaces even when they are covered with blood, and can form a tight seal within about 15 seconds of application. Such a glue could offer a much more effective way to treat traumatic injuries and to help control bleeding during surgery, the researchers say.

Zhao's lab has been working to address the problem for several years. In 2019, his team developed a double-sided tissue tape and showed that it could be used to close surgical incisions. This tape, inspired by the sticky material that spiders use to capture their prey

in wet conditions, includes charged polysaccharides that can absorb water from a surface almost instantaneously, clearing off a small dry patch that the glue can adhere to. For their new tissue glue, the researchers once again drew inspiration from the natural world. This time, they focused their attention on the barnacle, a small crustacean that attaches itself to rocks, ship hulls, and even other animals such as whales. These surfaces are wet and often dirty -- conditions that make adhesion difficult.

This sticky material consists of a polymer called poly(acrylic acid) embedded with an organic compound called an NHS ester, which provides adhesion, and chitosan, a sugar that strengthens the material. The researchers froze sheets of this material, ground it into microparticles, and then suspended those particles in medical grade silicone oil.

When the resulting paste is applied to a wet surface such as blood-covered tissue, the oil repels the blood and other substances that may be present, allowing the adhesive microparticles to crosslink and form a tight seal over the wound. Within 15 to 30 seconds of applying the glue, with gentle pressure applied, the glue sets and bleeding stops, the researchers showed in tests in rats.

Journal Reference:

Rapid and coagulation-independent haemostatic sealing by a paste inspired by barnacle glue. *Nature Biomedical Engineering*, 2021; DOI: 10.1038/s41551-021-00769-y

Brain cholesterol regulates Alzheimer's plaques, study reveals

August 13, 2021

A team co-led by scientists at Scripps Research has used advanced imaging methods to reveal how the production of the Alzheimer's-associated protein amyloid beta (A β) in the brain is tightly regulated by

cholesterol.

In the new study, Hansen and his colleagues take a close look cholesterol's connection to A β production. Cholesterol's role has been suggested by various prior studies but never confirmed directly, due to technological limitations.

The scientists used an advanced microscopy technique called super-resolution imaging to "see," in cells and in the brains of live mice and tracked how cholesterol regulates A β production.

They focused on cholesterol produced in the brain by essential helper cells called astrocytes, and saw it was carried by apoE proteins to the outer membranes of neurons. There, it appeared to help maintain clusters of cholesterol and related molecules colloquially referred to as "lipid rafts."

The researchers showed that apoE and its cholesterol cargo bring APP into contact with nearby lipid rafts. There, in the rafts, enzymes that cleave APP to form A β are found. They found that blocking the flow of cholesterol would take APP out of contact with lipid rafts, thereby effectively preventing A β production.

The scientists then did a series of experiments in aged "3xTg-AD" mice, which are genetically engineered to overproduce A β , to develop A β plaques, and broadly to model Alzheimer's.

They found that when they shut off astrocyte cholesterol production in the mice, A β production plummeted to near-normal, and A β plaques virtually disappeared.

Another classic Alzheimer's sign usually seen in these mice is the accumulation of tangled aggregates of a neuronal protein called tau -- and those disappeared too.

Journal Reference:

Regulation of beta-amyloid production in neurons by astrocyte-derived cholesterol. Proceedings of the National Academy of Sciences, 2021; 118 (33): e2102191118 DOI: 10.1073/pnas.2102191118

For psoriasis, targeting skin protein may help control inflammation

August 12, 2021



Psoriasis is an autoimmune disease that causes overproduction of skin cells and impacts nearly 30 million people in the world.

Using a model that mimics psoriasis in mice, researchers found that changing the levels of interferon kappa, a protein made by skin cells, altered the severity of inflammation and production of cell signaling molecules, called cytokines, that induce inflammation characteristic of psoriasis. Investigators found more psoriasis-like inflammation when more interferon kappa was present, while decreasing interferon kappa levels reduced disease.

The research team induced psoriasis in mouse models, splitting them into groups with interferon kappa at low, normal or elevated levels. The overexpressed protein alone didn't induce the disease, but it primed the skin for the inflammatory response that followed.

Journal Reference:

Interferon Kappa Is a Rheostat for Development of Psoriasiform Inflammation. Journal of Investigative Dermatology, 2021; DOI: 10.1016/j.jid.2021.05.029

Light therapy helps burn injuries heal faster by triggering growth protein

August 6, 2021



The research, published in *Scientific Reports*, found that photobiomodulation therapy -- a form of low-dose light therapy capable of relieving pain and promoting healing and tissue regeneration -- sped up recovery from burns and reduced inflammation in mice by activating endogenous TGF-beta 1, a protein that controls cell growth and division.

“Photobiomodulation therapy has been effectively used in supportive cancer care, age-related macular degeneration and Alzheimer’s disease,” says Arany. “A common feature among these ailments is the central role of inflammation. This work provides evidence for the ability of photobiomodulation-activated TGF-beta 1 in mitigating the inflammation, while promoting tissue regeneration utilizing an elegant, transgenic burn wound model.”

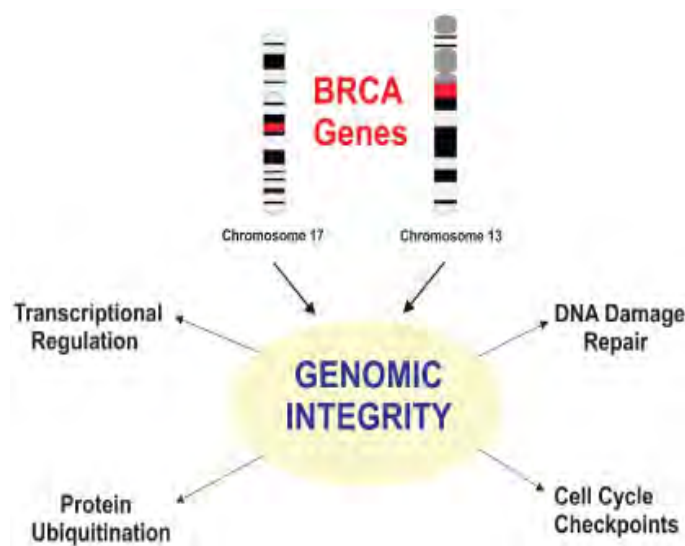
The study measured the effect of photobiomodulation on the closure of third-degree burns over a period of nine days.

Journal Reference:

Accelerated burn wound healing with photobiomodulation therapy involves activation of endogenous latent TGF- β 1. *Scientific Reports*, 2021; 11 (1) DOI: 10.1038/s41598-021-92650-w

Researchers solve structure of BRCA2 protein complex important in DNA repair

August 13, 2021



The initials BRCA2 may be best known for a gene associated with many cases of breast cancer, and the protein encoded by the BRCA2 gene is critical to repairing breaks in DNA. The breakdown of this interaction is a hallmark of many cancers. Now scientists have determined the structure of a complex of two proteins -- BRCA2 together with MEILB2 -- that allows repairs to happen efficiently in cells undergoing cell-splitting, called meiosis. Their results have major implications for cancer and infertility.

To determine the structure of this BRCA2 complex, the researchers used X-ray crystallography. In this

process, the protein crystal is bombarded with X-rays and the patterns that are generated when the X-rays deflect off the atoms in the crystal allow the researchers to figure out where each atom is located in the 3D structure of the molecule. That would help them figure out how the BRCA2 protein is connected to the MEILB2 protein.

From the X-ray crystallography data and additional experiments by MCDB graduate student Ritvija Agrawal, the team determined the structure of the protein complex and how the two proteins worked together. To validate their findings, they created mutant versions of BRCA2 and MEILB2 based on their structure and showed how these mutants failed to form this complex with each other.

In further validation of the MEILB2-BRCA2 complex structure, collaborators at the University of Gothenburg in Sweden introduced equivalent mutant versions in mouse cells undergoing meiosis. Mutant BRCA2 or MEILB2 failed to get to the DNA breaks that needed to be rejoined.

Journal Reference:

Structure of a meiosis-specific complex central to BRCA2 localization at recombination sites. *Nature Structural & Molecular Biology*, 2021; 28 (8): 671 DOI: 10.1038/s41594-021-00635-0

New drug combo shows potential for treating pancreatic cancer

August 6, 2021

A team of MIT researchers has now developed an immunotherapy strategy and shown that it can eliminate pancreatic tumors in mice.

Immune checkpoint therapy (the most common form of immunotherapy currently being used clinically) works by removing the brakes on these T cells, rejuve-



nating them so they can destroy tumors.

One class of immunotherapy drug that has shown success in treating many types of cancer targets the interactions between PD-L1, a cancer-linked protein that turns off T cells, and PD-1, the T cell protein that PD-L1 binds to. Drugs that block PD-L1 or PD-1, also called checkpoint inhibitors, have been approved to treat cancers such as melanoma and lung cancer, but they have very little effect on pancreatic tumors.

In a study using mouse models of pancreatic cancer, the researchers found that in fact, PD-L1 is not highly expressed on pancreatic cancer cells. Instead, most pancreatic cancer cells express a protein called CD155, which activates a receptor on T cells known as TIGIT.

When TIGIT is activated, the T cells enter a state known as “T cell exhaustion,” in which they are unable to mount an attack on pancreatic tumor cells. In an analysis of tumors removed from pancreatic cancer patients, the researchers observed TIGIT expression and T cell exhaustion from about 60 percent of patients, and they also found high levels of CD155 on tumor cells from patients.

Working with the Lustgarten Foundation for Pancreatic Cancer Research, which helped to fund this study,

the MIT team sought out two pharmaceutical companies who between them have a PD-1 inhibitor, TIGIT inhibitor, and CD40 agonist antibody in development.

None of these drugs are FDA-approved yet, but they have each reached phase 2 clinical trials. A clinical trial on the triple combination is expected to begin later this year.

Journal Reference:

The CD155/TIGIT axis promotes and maintains immune evasion in neoantigen-expressing pancreatic cancer. *Cancer Cell*, 2021; DOI: 10.1016/j.ccell.2021.07.007

Study identifies DNA genes linked to heart disease

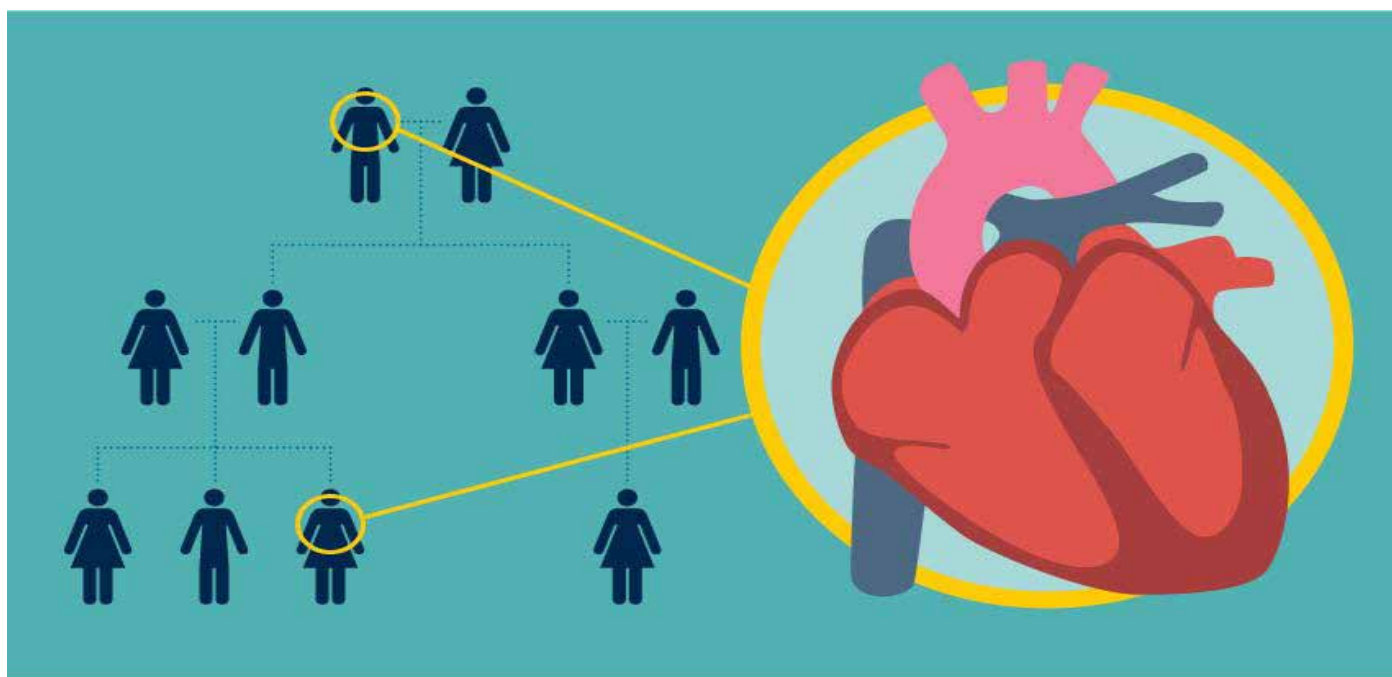
August 4, 2021

A new study identifies DNA signatures associated with risk for cardiovascular disease, a discovery that could lead to opportunities for clinical intervention

years before symptoms manifest. Based on analyses of data from five large heart cohort studies of diverse populations, the findings are published in the journal *JAMA Cardiology*.

The researchers began their analysis with data from the Strong Heart Study, the largest study of cardiovascular disease in American Indians, conducted in partnership with communities across the Great Plains and the Southwest since 1988. They analyzed blood samples to identify specific locations on DNA where methylation activity was associated with incidents of coronary heart disease, including heart attack and coronary deaths

In the initial analysis of Strong Heart data, they identified 506 epigenetic marks linked to cardiovascular risk. Of these, 33 were also linked to cardiovascular risk in three or more of the other cohorts, although some of these sites were associated with higher risk of disease in one cohort but with lower risk of disease in other cohorts. Among the 33 methylation sites are those previously linked to cardiovascular risk and smoking, as well as novel sites that the researchers say are worthy of future investigation. Further analysis of the commonalities between the 33 marks found that many of them are connected with EGFR gene, which is involved in cell growth and cell survival.



“The overlap of these methylation sites across diverse cohorts supports the idea of interconnected biological pathways for cardiovascular risk,” says Yuling Hong, MD, PhD, chief of the epidemiology branch within the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute.

Journal Reference:

Blood DNA Methylation and Incident Coronary Heart Disease. *JAMA Cardiology*, 2021; DOI: 10.1001/jamacardio.2021.2704



Potential COVID-19 medication found among tapeworm drugs

August 6, 2021

A group of medications long prescribed to treat tapeworm has inspired a compound that shows two-pronged effectiveness against COVID-19 in laboratory studies, according to a new publication appeared online in the journal *ACS Infectious Disease*.

The compound, part of a class of molecules called salicylanilides, was designed in the laboratory of Professor Kim Janda, PhD, the Ely R. Callaway, Jr. Professor of Chemistry and director of the Worm Institute for Research and Medicine at Scripps Research, in La Jolla, CA.

Salicylanilides were first discovered in Germany in the 1950s and used to address worm infections in cattle. Versions including the drug niclosamide are used in animals and humans today to treat tapeworm. They have also been studied for anti-cancer and antimicrobial properties.

The modified salicylanilide compound that Janda created was one of about 60 that he built years ago for another project. When the SARS-CoV-2 virus became a global pandemic in early 2020, knowing that they may have antiviral properties, he started screening his old collection, first in cells with collaborators from Sor-

rento Therapeutics and The University of Texas Medical Branch, and later, after seeing promising results, working with Scripps Research immunologist John Teijaro, PhD, who conducted rodent studies.

One compound stood out. Dubbed simply “No. 11,” it differs from the commercial tapeworm medicines in key ways, including its ability to pass beyond the gut and be absorbed into the bloodstream -- and without the worrisome toxicity.

The experiments showed that of the many modified salicylanilides he had built in his laboratory, No. 11 affected pandemic coronavirus infections in two ways. First, it interfered with how the virus deposited its genetic material into infected cells, a process called endocytosis. In addition, No. 11 helped quiet potentially toxic inflammation in the research animals.

Journal Reference:

Salicylanilides Reduce SARS-CoV-2 Replication and Suppress Induction of Inflammatory Cytokines in a Rodent Model. *ACS Infectious Diseases*, 2021; DOI: 10.1021/acsinfectdis.1c00253

Bio Controversies

Doctor Who Complained About Faulty PM-CARES Ventilators Suspended for ‘Medical Negligence’

August 4, 2021

A doctor in Kanpur who raised her voice against sub-standard ventilators provided under the PM-CARES Fund has been suspended for “medical negligence” which allegedly caused a child’s death.

According to the state administration, orders for Dr Neha Agarwal’s suspension have been sent to the Ganesh Shankar Vidyarthi Memorial Medical College (GSVM).

Dr Agarwal, who was in charge of the paediatric intensive care unit (PICU) in GSVM, had written a let

ter to her head of the department (HoD) informing him about two faulty ventilators. In her letter, the doctor said that the ventilators from Aqva Healthcare company, received by the department under the PM-CARES Fund, work only intermittently.

The HoD, Yashwant K. Rao, had then written a letter to the then principal, R.B. Kamal, on July 6, informing him about the faulty ventilators. Rao also refused to use the ventilators in the future, citing a child’s death allegedly because one such ventilator stopped working abruptly.

Rao also demanded a ventilator from another company. He also informed the GSVM administration that despite the ventilator being repaired several times, the problem could not be solved. These two letters stirred the medical college as well as the state administration.— The Light 0 min panel for 1um MB No light appears to partially overlap with the Light 40 Min panel of the same row, and partially overlap with the Light 0 Min panel for No MB.



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