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Update

List of COVID-19 drugs from India

Updated 0n July 16, 2020 | Dr Seema Pavgi Upadhye

We are witnessing COVID19 pandemic since September 2019, when China first imposed lockdown and then every country had to do this because of growing number of cases and mortality. Since January, scientists all over the world are trying to develop a vaccine or cure against this deadly virus but there is no hope yet. Here, we are providing a list of drugs from India that are being considered for COVID-19 treatment with upto date status.

Note: This article does not endorse any drug/therapy for COVID19 or any other condition. To date, there are no specific vaccines or medicines for COVID-19. Treatments are under investigation, and will be tested through clinical trials.

Favipiravir

Patent (holding company) – Expired, generic version of Avigan, a Fujifilm drug commonly used in Japan for the treatment of influenza

Mode of action- oral antiviral drug
Clinical trial- Glenmark's clinical trial of 150 mild to moderate patients
Contraversies, if any - Cannot be given to patients with severe renal complications, hepatic impairment, pregnant and lactating women, according reports by Fujita Health University, Avigan has failed to show any ability to treat COVID-19.
Authorization by Global regulators – drug not approved in the EU or US, approved in Russia and parts of the Middle East
Authorization by Indian regulators - fast-tracked by Drug Controller General of India Received Emergency Use on 19.06.2020
Companies involved- Glenmark Pharmaceuticals
Price - Fabiflu, at Rs75 / tablet

Itolizumab

Patent (holding company) – Active, Biocon
Mode of action- humanized IgG1 anti-CD6 monoclonal antibody, earlier approved for the treatment of Psoriasis, handling the hyperactivity of the immune system and managing cytokine storm
Clinical trial- 30 patients' clinical trial where 20 patients were out on Itolizumab, 10 randomised on standard care.
Contraversies, if any – small sample size, The trial was also open-label without, which means there is good chance that the results were biased towards more favourable outcomes.
Authorization by Global regulators – drug not approved in the EU or US
Authorization by Indian regulators - fast-tracked by Drug Controller General of India received emergency use on 11.07.2020
Companies involved- Biocon
Price - Rs32000 for treatment (Rs8,000/vial)

Dexamethasone

Patent (holding company) - NA
Mode of action- Works as corticosteroid medication. It is used in the treatment of many conditions such as rheumatic problems, a number of skin diseases, severe allergies, asthma, chronic obstructive lung disease, croup, brain swelling, eye pain following eye surgery, and along with antibiotics in tuberculosis.
Clinical trial- Clinical trial ongoing – UK's RECOVERY Trial
Contraversies, if any – N.A
Authorization by Global regulators – U.K and U.S. issued an emergency use authorization
Authorization by Indian regulators - "off-label" drug for COVID-19 severe cases
Companies involved- Several
Price - below Rs 10 and is Rs. 2/ tablet

Remdesivir

Patent (holding company)- Upto 2035, Gilead Sciences
Mode of action- anti-viral drug, earlier tried on Ebola
Authorization by Global regulators- Hospital-only, Injectible drug,
Authorization by Indian regulators Has Emergency Use Authorisation in India on 01.06.2020 by CDSCO

Clinical trial- The first randomised double-blind study showed no statistically significant treatment efficacy in severe COVID-19 patients. Well-designed clinical trials show Remdesivir to be effective, shown to shorten recovery time & hospital stay but does not reduce mortality. A study published on May 22 – sponsored by NI-AID – showed that Remdesivir didn't affect the recovery of Asians.
Contraversies, if any – several like lobbying and money making
Price - $2,340, Rs 5400 for 5 day course
Companies involved- Gilead Sciences, USA; Hetero Pharma(Covifor), India; Cipla(Cipremi), India

Hydroxychloroquine

Patent (holding company) - NA
Mode of action- Approved as a treatment in mild cases and as prophylactic
Clinical trial- WHO's SOLIDARITY and UK's RECOVERY trials show HCQS does not show benefits in treatment
Contraversies, if any - Side-effects like Severe heart arrhythmia
Authorization by Global regulators – USFDA revoked Emergency Use Authorisation,
Authorization by Indian regulators - India moved the drug out of treatment protocol for severe cases
Companies involved- Several
Price - Rs. 1 to 10/tablet

Tocilizumab

Patent (holding company) – Active, Hoffmann La Roche
Mode of action- humanized IL-6 receptor inhibitor monoclonal antibody, counter the severe inflammation (cytokine storm)
Clinical trial- Phase II clinical trial will be carried out
Contraversies, if any - Can increase the risk of bacterial infections
Authorization by Global regulators – drug not approved in the EU or US
Authorization by Indian regulators – "restricted use" on severely ill COVID-19 patients on "emergency and compassionate grounds"
Companies involved- Roche Pharma, marketed by Cipla
Price - Rs 40,545 each/vial

Others

Convalescent Plasma Therapy - Approved as an "off-label" therapy and works best when given early on in the treatment cycle.

Methylprednisolone - For use as an anti-inflammatory drug, Low molecular weight Heparin, use to prevent blood clots & thrombogenic response.

Antibiotics - Azithromycin, Ivermectin - To deal with infections.

Commentary

Rs. 100 crore fund from PM CARES Fund for COVID19 vaccine to PSA to PMO : Progress till now?

Sumit Kumar

Dr K Vijayraghavan (PSA to PMO) was visible on national TVs to much extent until the announcement of 12 or 13 May, when he got 100 crore Rs. for the development of vaccine against COVID19. Since then it is very difficult to find him on any national news platform to see what developments he is directing toward the assigned tasks of vaccine development, communicated Sumit Kumar to Biotech Express. (https://www.livemint.com/news/india/pm-fund-allocates-rs-3-100-cr-to-boost-fight-against-covid-19-11589391319927.html)

As per the office's press release the following tasks were facilitated but how they were unique and useful we will check them later. Here is the complete List of initiatives by the Office of the Principal Scientific Adviser to the Government of India, on COVID-19

1. The office of the PSA has played coordinating role for government ministries/departments, scientific institutions,

academia and enterprises to accelerate decisions on dealing with research and innovation based actions to meet the COVID-19 challenges.

2. It has enabled ICMR to issue the required notification allowing institutions under DST, DBT, CSIR, DAE, DRDO and Indian Institute of Science (IISc) to self-assess and prepare their BSL labs for research and testing of corona virus.
3. The O/o PSA has been instrumental in the launch and outreach of the AarogyaSetu App.
4. The O/o PSA has issued a detailed manual on homemade masks for curbing the spread of Coronavirus.
5. The O/o PSA issued illustrative guidelines with precautions and measures for controlling the spread of COVID-19 in densely populated areas on April 13, 2020.
6. The Office of the PSA has converged efforts across various government departments and programme to identify innovations that can tackle COVID-19 challenges.
7. The O/o PSA worked with the Ministry of Corporate Affairs for issuing an enabling OM for the use of CSR funds for research and innovation projects for providing solutions to meet the COVID-19 challenges.
8. A "Science & Technology core team" has been set up in the office of the Principal Scientific Advisor to crowd-source ideas and solutions from experts, companies, academia and citizens to tackle the spread of the Covid-19 virus in the country.

Source: http://psa.gov.in/sites/default/files/pdf/PSA_Office_Initiatives_COVID-19.pdf

It is nowhere understood from the above points that why the scientist sitting on topmost scientific position of country is not talking about science and its development. For example, in this PR, it is not discussed what initiatives he has taken to identify vaccine candidate, what facilities they are using and when the vaccine will probably come.

Earlier a article written in Biotech Express show how different govt. department formed their own groups of expertise and then start taking their own initiatives. Inspite of enormous collaboration and support from govt. departments, office of PSA to PM office has not shown any sign of development w.r.t vaccine development.

http://www.biotechexpressmag.com/editorial-why-indian-bioscience-response-is-not-enough-to-curb-global-covid19-biological-pandemic-what-are-we-missing/

The most demanding thing in this world now is vaccine against novel CoV, many countries have launched their candidates but thanks to the politics of Indian sciences we have not registered even a single candidate vaccine on global platforms.

Recently, ICMR launched COVAXIN but soon was surrounded by controversies on risk criteria and timeline. Though ICMR was criticized, we cannot ignore two facts, that such announcement were also made by other regulatory organizations in past few months and several drugs were approved for emergency use authorization and secondly, at least ICMR either independently or in collaboration with industry player(s) has come up with a candidate.

Coming back to PSA, I(we) are curious to know that how he is planning to use these precious 100 crore of public donation that he received for vaccine development and what are the activities done till now in this regard. As we have seen no innovation from PSA office, is it correct to ask whether our 100 crore will be utilized or will be wasted.

To know more about vaccine development, we communicated questions posed by Sumit Kumar to Dr Vijayraghavan but despite several attempts we could not get any response from PSA to PMO, Dr K Vijayraghavan.

Analysis

Fake, Misleading And Controversial News Surrounding Covid19 Pandemic

By Kamal Pratap Singh

Fake news is travelling much faster than the coronavirus. The world is struggling with the deluge of misinformation about the evolving pandemic. The fake news surrounding the origin of the virus, its subsequent spread and threats it poses have nearly engulfed every nation, although with varied intensity.

India is not an exception to the virus of fake news. Even before the country reported its first case on 30 January, social media was rife with fake posts, wild rumours, conspiracy theories, doctored videos about the disease's origin, its subsequent spread and possible remedies. Once the country started reporting more cases, a torrent of fake messages began populating all major social media platforms, particularly Facebook, WhatsApp, Twitter, TikTok and so on. According to a recent report by the fact checking website BOOM, COVID-19 related fake news which began climbing in the third week of March took a massive spike in early April and then.

These misleading news and statement by leaders and general public have made huge stress and panic and some of them even resulted in serious injury, for example several people were hospitalized after they consumed household disinfectant when U.S. President Donald Trump suggested scientists should investigate inserting the cleaning agent into the body as a way to cure COVID-19.

Here we are discussing some noted examples of news/comments that are/were subjected got attention for controversial matters, they are subdivided in categories. In the end, we will see through a poster how the news can be interpreted as right or wrong based on individual's assessment.

Questionable/controversial news surrounding COVID19 pandemic

There are various things that are under scrutiny or have been disregarded after thorough investigation in COVID-19 pandemics. We are categorizing these news items under various heading and will see some examples of each category.

Diagnosis

India's Coronavirus Testing Controversy Points at US Start-Up With No Track Record

On March 19, Gujarat-based CoSara Diagnostics Pvt. Ltd, a 50-50 joint venture between Utah-based Co-Diagnostics Inc. (CODX) and Synbiotics India Ltd, said it would begin manufacturing COVID-19 diagnostic tests for the Indian market after, the company's own press release stated. The local *Ahmedabad Mirror* carried the news on the same day, adding that the senior officials "helped in expediting the process for the license after inspecting the file themselves." For now, CoSARA is still awaiting final approval before it can begin making the test in India.

Congress alleges scam in COVID kits supply, asks Centre to show purchase details

Alleging that rapid test kits for COVID-19 were being sold at around 150 per cent profits to the government. Congress chief spokesperson Randeep Surjewala also said it was "shameful and inhuman" that people were supplying test kits bought for ₹225 at ₹ 600 to the state exchequer. The matter came to light in a petition before the Delhi High Court by a company supplying such equipment.

TABLE: Some of the misleading content related to COVID-19 pandemic reported by website BOOM

Source: https://www.boomlive.in/fake-news/

S.No	Rumour	Date	Source	Conclusion
1.	7 Things The Coronavirus Fears? Thai Paper Publishes Misleading Report, The 'evil things' listed include UV light, chlorine and high temperatures; claiming to kill the COVID-19.	22 March 2020	Komchadluek, A Thai News-paper	Partially false
2.	A us patent on the novel coronavirus? Conspiracy theories brew online	4 April 2020	Youtube, Facebook And Instagram	False
3.	False posts in sri lanka claim poultry infected with corona-virus	17 March 2020	Facebook	False
4.	Ancient Medicinal Herb Drink To Treat Coronavirus? A factcheck	March 13, 2020	Facebook	False
5.	Can bathing in hot water prevent covid-19?	February 18, 2020	Facebook	Misleading, urges peo-ple to buy product
6.	Can Bitter Gourd Help Cure Coronavirus Within Two Hours? Indian authorities have dismissed the claim and have called it false	8 March 2020	Facebook	False
7.	Children in senegal did not die after receiving 'coronavirus vaccine'	April 7 2020	Facebook	Fake
8.	Colour coded soaps & handkerchiefs to prevent coronavi-rus? Not really	March 16, 2020	Facebook	False
9.	Consuming Silver Particles Does Not Prevent Or Treat COVID-19 US regulators warn against posts claiming collo-dial silver can prevent or treat the novel Coronavirus.	February 18, 2020	Facebook	Misleading
10.	'Contagion' film scene shared as mass burial of coronavi-rus victims	February 25, 2020	Facebook	Misleading
11.	Corona outbreak: did an alcohol-based disinfectant cause an explosion?	March 18, 2020	Facebook And Twitter	Fake
12.	Facemask video ad claims stock image personnel as virus infected family	April 5, 2020	Facebook	Misleading, Money mak-ing
13.	Did Sulphur Dioxide Levels Rise In Wuhan Post Coronavi-rus Outbreak? The map being shared is a forecast based on past data, not real-time satellite readings.	February 9, 2020.	Facebook, Twitter, You-tube, Mailon-line, China Press; The Epoch Times	Misleading

TABLE: Some of the misleading content reported by website BOOM (continued)
Source: https://www.boomlive.in/fake-news/

14.	Cambodian pm hospitalised after contracting coronavirus	February 26, 2020	Facebook, Twitter, And On Line Messenger Messaging App Line	Misleading
15.	Report claims water ablution ritual kills the novel coronavirus	January 27, 2020	Gosulsel.Com	Misleading
16.	Nurse gives misleading information about masks in viral video	May 17, 2020	Facebook	Misleading
17.	Salt or vinegar warm water gargle eliminates the coronavirus	March 14, 2020	Facebook	Misleading
18.	Video shows covid-19 victim's bodies removed from iran hospital	February 27, 2020	Facebook and Twitter	Misleading, August 2019 video of funeral procession for Hajj pilgrimage to Saudi Arabia
19.	Message claims anti-malaria drug cures coronavirus	March 5, 2020	Whatsapp	Misleading
20.	Covid-19 testing is done to implant gates-funded microchips	June 7, 2020	Facebook	Fake
21.	Neem leaves cannot treat the novel coronavirus, Malaysia's Minsitry of Health has labelled the claim as a myth	March 22, 2020	Facebook	Misleading
22.	The britain's queen test positive for covid-19	March 28	Facebook	Fake
23.	Old video edited to show Jack Ma praising china's response to covid-19	March 16, 2020	Facebook	Misleading
24.	School Textbook Lists Cure For Coronavirus? A factcheck	March 22, 2020	Facebook	Misleading
25.	Still from grey's anatomy shared as medical staff dead in italy	March 24, 2020	Facebook	Misleading
26.	Video falsely shared as wuhan residents collecting death certificates	March 3, 2020	Twitter	Misleading
27.	Video from iran shared as body bags of coronavirus victims in italy	March 12, 2020	Facebook	Misleading
28.	Wearing shoes indoors spiked covid-19 cases in italy?	March 30, 2020	Messaging App - Line	Misleading
29.	Volcanic ash kill novel coronavirus	February 29, 2020	Facebook	Fake

https://m.dailyhunt.in/news/india/english/the+federal+english-epaper-thefeden/cong+alleges+scam+in+covid+kits+-supply+asks+centre+to+show+purchase+details-news-id-n180947302

Clinical Trials

Lancet, NEJM retract controversial COVID-19 studies based on Surgisphere data

The Lancet paper, "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis," which relied on data from a private company called Surgisphere and had concluded that hydroxychloroquine was linked to a higher risk of death among some COVID-19 patients, has been dogged by questions since its publication in late May. The publication of the study had prompted the World Health Organization (WHO) to halt a study of hydroxychloroquine, but the WHO resumed that trial once the expression of concern appeared.

A convicted felon wants people to enroll in a COVID-19 clinical trial. What could go wrong?

April 25, 2020

Richard Fleming, a felon convicted of health care fraud who has been debarred by the US Food and Drug Administration, would like to invite you to participate in a clinical trial. Fleming has registered a study on ClinicalTrials.gov to evaluate what he calls the "Fleming Method for Tissue and Vascular Differentiation and Metabolism" — a method he claims can help physicians assess pneumonia resulting from Covid-19. Fleming states he wants to enroll 500 patients who will receive various purported treatments for Covid-19, including, of course, hydroxychloroquine and azithromycin but also remdesivir.

Some Covid-19 trial sponsors never posted other study results in an EU database. Will they hide data again?

June 17, 2020

Amid a wave of research into potential Covid-19 therapies, a new analysis warns that some trials are being run by universities and companies in Europe that either have no track record filing any trial results with a European database or have failed to do so in the past. As a result, there is a risk that past performance might undermine the ongoing search for safe and effective treatments, according to the advocacy group that conducted the analysis. Researchers maintain that without access to specific data, trial results cannot be easily duplicated, which inhibits greater understanding of how medicines might work. And they argue this, in turn, can adversely affect treatment decisions and health care costs, an issue that takes on even greater urgency amid the Covid-19 pandemic and the rush to conduct studies on drugs, old and new.

Research methodology

Authors to correct influential Imperial College COVID-19 report after learning it cited a withdrawn preprint

April 26, 2020 | A March paper by researchers at Imperial College London that, in the words of the *Washington Post*, "helped upend U.S. and U.K. coronavirus strategies," cited a preprint that had been withdrawn. Azra Ghani, co-corresponding author of the *Lancet Infectious Diseases* paper, thanked Retraction Watch for bringing the withdrawal to her attention, and said she and her colleagues would ask the journal for a correction but that they are "confident that the results would still hold."

Journal temporarily withdraws COVID-19 "labor cage" study

June 25, 2020 | A study whose title suggested an "effective" way to give birth during the coronavirus pandemic has been temporarily retracted because the publisher says the word "effective" was included in the title by accident. The method (pictured above) involved an enclosed, transparent chamber walling off the mother's upper half from the rest of the world. It wasn't very well received, according to an Essential Baby article that cited Twitter users referring to the "delivery table shield" as a "labor cage" and "greenhouse."

How Did This Pass Peer Review? Thoughts on the Lancet and NEJM COVID-19 Retractions

June 15, 2020 | On June 4, two of our most prestigious medical journals *(The New England Journal of Medicine* and *The Lancet)* retracted two papers based on «data» from a previously little-known healthcare analytics company called Surgisphere. The short version of the story is that this tiny company claimed to house a system of fully integrated data from the electronic health records of at least 671 hospitals across six continents. However, it seems unlikely that the data exist as advertised. In the aftermath, some may wonder why peer review did not identify the articles as questionable, being that peer review is the main quality-control system for the integrity of the medical literature. How did the reviewers miss what, in retrospect, seems obvious?

Research Publications

The preprint problem: Unvetted science is fueling COVID-19 misinformation

5/6/2020

Not every biomedical scientist is convinced about the rise of pre-

prints in biomedical research (and in the interests of disclosure, I'm one of them). For some, their opposition has been due to policies at some journals that forbid any promotion of a research paper before it appears on their printed pages (or online at the journal's website, at any rate). Other scientists have voiced concerns that posting their work to a preprint server could allow rivals to race them to publication or beat them to the market. And others—and this is my particular fear—worry about unpolished or even inaccurate work ending up in the hands of readers ill-equipped to evaluate it. MIT Press and the Berkeley School of Public Health are launching a new COVID-19 journal, one that will peer review preprint articles getting a lot of attention -- elevating the good research and debunking the bad. (https://arstechnica.com/science/2020/05/a-lot-of-covid-19-papers-havent-been-peer-reviewed-reader-beware/)

Controversy on COVID-19 mask study spotlights messiness of science during a pandemic

June 24, 2020

The group of scientists, many from Stanford and Johns Hopkins universitiy, posted a letter that they had sent to the *Proceedings of National Academy of Sciences* (*PNAS*) requesting the retraction **of a study published the week before that purportedly showed mask use was the most effective intervention in slowing the spread of COVID-19 in New York City. «While masks are almost certainly an effective public health measure for preventing and slowing the spread of SARS-CoV-2, the claims presented in this study are dangerously misleading and lack any basis in evidence,» they wrote in a letter to the** *PNAS* editorial board, requesting retraction.https://www.cidrap.umn.edu/news-perspective/2020/06/controversy-covid-19-mask-study-spotlights-messiness-science-during

Rush to Publish Risks Undermining COVID-19 Research

June 8, 2020

"Good science is hard to do, and in an outbreak there's this tendency to say some science is better than none," said Alex John London, the Clara L. West Professor of Ethics and Philosophy at Carnegie Mellon University, who coauthored a May 1 article in *Science*, "Against pandemic research exceptionalism," that argued for a need for scientists to collaborate to effect more rigorous study design. "That is not always true. Some science can be worse than no science. Some data, some evidence can be worse than no evidence or no data if it's misleading in important ways."

https://www.insidehighered.com/news/2020/06/08/fast-pace-scientific-publishing-covid-comes-problems

Statistics on Pandemic

China's Wuhan Raises COVID-19 Death Toll By 50%, Admits To Missed Cases

China's coronavirus ground-zero city of Wuhan on Friday abruptly raised its death toll by 50 percent, saying many fatal cases were "mistakenly reported" or missed entirely in an admission that comes amid growing global doubts about Chinese transparency. The city government said in a social media posting that it had added 1,290 deaths to the tally in Wuhan. China has come under increasing pressure over the coronavirus pandemic from Western powers led by the United States, which has raised doubts about Chinese transparency and is probing whether the virus actually originated in a Wuhan laboratory.

Police Case Against Ganga Ram, Top Delhi Hospital, For COVID-19 Violation

According to the complaint, while the government had made it mandatory for registering coronavirus tests on an official software programme, authorities at the Sir Ganga Ram Hospital (SGRH) were not doing so. It was found that the RT-PCR app, developed by the central government, was not being used even on June 3 at the Sir Ganga Ram Hospital, the complaint alleged. Source: NDTV

Delhi COVID-19 Controversy: MCDs Claim Death Toll Twice Higher Than Kejriwal Govt

June **11, 2020**

According to the latest figures by the Municipal Corporation Departments (MCDs) of Delhi, at least 2,098 coronavirus patients lost their lives, as opposed to the Kejriwal government's figures of 984. Source: NDTV

Treatments

France's president fueling the hype over an unproven coronavirus treatment?

April 9, 2020

The highly politicized debate about the use of chloroquine and hydroxychloroquine, two antimalarial drugs, to treat COVID-19 has reached an extreme in France, where two small trials purporting to show potential benefit were done. French physicians have come under enormous pressure from desperate patients to prescribe hydroxychloroquine, despite scant evidence that it works.The French Ministry of Health has been "incredibly rigid" and has "diabolized" hydroxychloroquine, Perronne tells *Science*Insider.

COVAXIN controversy: Bharat Biotech-ICMR readying a COVID-19 vaccine in 45 days baffles reason, ignores safety concerns, says bioethicist

Jul 4, 2020

Dr Anant Bhan, a researcher in global health, bioethics and health policy and former president of International Association of Bioethics, spoke to Firstpost about the 'extreme urgency' shown by ICMR in developing India's COVID-19 vaccine, COVAXIN, by 15 August

FIR against Baba Ramdev, others on COVID-19 cure claim

Jun 28, 2020

Police have registered a First Information Report against yoga guru Ramdev and four others for allegedly conspiring to sell a fake Ayurveda medicine with the **misleading claim to cure COVID-19 following clinical trials** on some patients. The FIR said the claim had been made without getting the Union AYUSH Ministry›s approval.

ICMR Says Biocon's Drug Trial Not Good Enough to Prove Mortality Reduction

July 15, 2020

Indian Council of Medical Research (ICMR) director-general Balram Bhargava has acknowledged that there is no evidence from clinical trials that the drugs Itolizumab and Tocilizumab, approved for emergency use in India last month, reduce mortality in COVID-19 patients, *The Hindu* reported. ICMR director-general Bhargava appears to be the first senior government member to openly contest these claims. The other drug whose efficacy Bhargava has called into question – Tocilizumab – also intends to achieve the same outcome as Itolizumab: to reduce the mortality of COVID-19 patients by reducing the risk of a cytokine storm.

50 Ads for 'COVID Cures' by Ayurvedic, Homeopathic Drug Makers Flagged in April

25/06/2020

The Advertising Standards Council of India (ASCI) said it found 50 campaigns by Ayurvedic and homeopathic drug makers offering cure for COVID-19 in April alone, and had flagged them to the Union government for action. The disclosure from ASCI for April comes a day after the government issued a gag order against Baba Ramdev's company Patanjali Ayurved from advertising a drug as COVID-19 cure within hours of him launching it. ASCI investigated complaints against 533 advertisements, of which 115 advertisements were promptly withdrawn while evaluation of the remaining 418 advertisements led to complaints against 377 being upheld

Accusations of Money making

A Tale of Two Drugs: Money vs. Medical Wisdom on remdesivir

May 7, 2020

At the Presidential Briefing on Apr 30, Dr. Anthony Fauci announced early results, prior to peer-review, of one clinical trial using remdesivir, an intravenous (IV) *experimental antiviral medicine* in patients hospitalized with COVID-19. At the "warp speed" currently in vogue for the Fauci-led push to a new vaccine, the *very next day* the FDA issued an Emergency Use Authorization (EAU) for remdesivir to be used in seriously ill hospitalized patients. To announce the emergency approval, President Trump met with the CEO of the drug's manufacturer, Gilead Sciences, in the Oval Office.

Such rapid authorization is quite unusual with the FDA. Unlike the experimental remdesivir with *no prior FDA approval*, hydroxychloroquine (HCQ) required *two months* from reports of successful use in China and South Korea to get the Mar 28 FDA EUA for use in hospitalized COVID-19 patients.

Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - Hypochlorous Skin Spray

The FDA has observed that your website https://www.curativabay.com offers Advanced Hypochlorous Skin Spray, a topical hypochlorous acid-containing product, for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Based on our review, this product is an unapproved new drug sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

Behind the Scenes of Moderna - COVID-19 Vaccine mRNA-1273

Jul 02, 2020

Moderna has always been an odd and secretive company. Currently all eyes are on the company because it is the furthest along in developing a vaccine against COVID-19. Company shares have rocketed 200% this year. But it's worth noting it's a company that does not have a single marketed product. Investors have often been intrigued by the company, driving up its pre-IPO value despite there being no commercial products. And in December 2018, the company's initial public offering dramatically exceeded expectations, and raising $604.3 million, giving the company at that time a market value of about $7.5 billion, a record at the time.

Covid-19 protection equipment scam in Punjab, Himachal & liquor scam in Haryana in India

The small hill state Himachal Pradesh was rocked by two lockdown purchase scams. In one case, the state secretariat bosses allegedly purchased coronavirus protection equipment and consumables like sanitisers and hand wash bottles at inflated prices. Health Department director Dr AK Gupta was arrested after an audio clip in which he allegedly demanded a bribe of Rs 5 lakh from Renuka, a Sirmaur-based supplier to clear an equipment purchase. The state vigilance and anti-corruption bureau has also registered a case against the rogue firm titled M/s Lalit Kumar after the Chief Minister had ordered a probe. There are allegations that the price tags of the sanitiser bottles were tempered with and the supplies were made on inflated rates. The supplier was not even licenced under the Drugs and Cosmetics Act.

Govt Actions

Response to the COVID-19 Pandemic: Catastrophic Failures of the Science-Policy Interface

The world now recognizes that we are at war with the novel coronavirus, SARS-COV-2, which causes the disease COVID-19. The initial missteps have been costly as top government leaders downplayed or covered up the crisis in the beginning. Well documented are failures by (i) the Chinese government to alert the world early and quickly supply diagnostic data, infection statistics, and World Health Organization (WHO) access and (ii) the United States government to take timely mitigation action and employ early testing. Mistakes in early action occurred elsewhere as well, including in the United Kingdom, several countries in the European Union, and at WHO. Misinformation campaigns by some government leaders and actors on social media created public confusion and delayed action. If all governments had acted early and in unison, the public health and economic impacts would have been far less. (https://www.sciencediplomacy.org/editorial/2020/response-covid-19-pandemic-catastrophic-failures-science-policy-interface)

Indians Forced into Quarantine are Dying in Lockdown—but Not From Coronavirus

India is witnessing a threefold crisis: health crisis due to the epidemic, economic due to the lockdown and humanitarian because the government either didn't realize how a large part of the population survives or knowingly is choosing to ignore their situation," Reetika Khera, a development economist at the Indian Institute of Management, told VICE News.

Media Bias

When a News Article Vanishes, We Have More Than Just a Pandemic to Worry About

14/May/2020

The New Indian Express, one of India's major English newspapers, pulled down an article that was heavily critical of the Centre's response to the COVID-19 outbreak. The article, entitled 'Centre's COVID-19 Communication Plan: hold back data, gag agencies and scientists', discussed the government's reluctance to share outbreak-related data and attempts to muzzle scientists.

The article was published on *The New Indian Express*'s website at 7:09 pm on May 8, and it disappeared from its link within a day without any explanation. It raised following questions:

Question 1 – In a press release dated May 10, ICMR said it had developed a COVID-19 antibody-testing kit that would be mass produced by the Gujarat-based company Zydus Cadila. Why was Zydus Cadila chosen for this task over other medical diagnostic firms?

Question 2 – Why has ICMR made no attempt to alter its flawed March 22 advisory suggesting hydroxychloroquine as prophylaxis for COVID-19, given newer evidence has shown the drug is not efficacious?

Question 3: How many cases of influenza-like illnesses (ILI) have there been in India in the last few years, and is this number rising in atypical fashion in some districts this year?

Western media biased on India's handling of Covid-19' crisis

May 16, 2020

Despite struggling to control the Covid-19 outbreak in their own countries, an analysis of western media reports on India's handling of the Covid-19 crisis suggests an ingrained prejudice against the country. the western media is not sparing any chance to paint a picture as if the country has lost the war against Covid-19. For example, the BBC ran a story that Indians are dying with corona cases going unreported. The story was based on quotes of two unnamed doctors. Another report carried by Reuters said that Prime Minister Narendra Modi's Hindu nationalist party has advocated the use of cow urine as medicine and cure for cancer, "as if the whole country is banking cow urine therapy for Covid-19 and the Indian government is out on a picnic". (https://www.sundayguardianlive.com/news/western-media-biased-indias-handling-covid-19-crisis)

Politically extreme sources publish more COVID-19 news than scientifically-grounded outlets, study finds

JUNE 30, 2020

In an initial study conducted at the University of Notre Dame, researchers found that least-biased news sources and scientific-based news sources published less than a quarter of all stories currently available about COVID-19. Sources evaluated as right-leaning, left-leaning or less factual (those that cite questionable sources or share conspiratorial-pseudoscientific information) account for more than 75 percent of all COVID-19 related news stories.

https://techxplore.com/news/2020-06-politically-extreme-sources-publish-covid-.html

Media bias is politicising the coronavirus pandemic coverage

March 17, 2020

The *BBC* has used irrelevant images from Turkey in its coverage of the crisis for two consecutive days despite criticism from the Turkish authorities. In the first instance, the *BBC*, the *New York Times* and *CNN International* all decided to use images related to Turkey and Istanbul with their news stories about the outbreak of the virus in France. Later, the *BBC* used an image showing Turkish football fans wearing the Turkish flags and putting on masks. Surprisingly, the story was headlined "Trudeau and wife isolate after she tests positive". The New York Times used images of Istanbul's most famous mosques to report US President Donald Trump's travel restrictions to and from the EU due to the virus outbreak.

https://www.middleeastmonitor.com/20200317-media-bias-is-politicising-the-coronavirus-pandemic-coverage/

Propaganda Campaign

China and Russia are spreading misinformation about coronavirus, EU says

The EU's findings on China and Russia are based on a separate study by the commission's foreign and diplomatic wing, which said it had evidence of a "coordinated push" by official Chinese sources to deflect blame for the coronavirus pandemic and promote its response to the virus.

Note: This article does not necessarily reflect the opinion of the editorial board of Biotech Express and its owners.

HOW TO SPOT FAKE NEWS

COVID-19 Edition

CONSIDER THE SOURCE

Is there an author? Check out their credentials on relevant issues.

READ BEYOND

Headlines can be outrageous in an effort to get clicks. What's the whole story?

SUPPORTING SOURCES?

Click on links or check with official sources. Do they support the story?

DO OTHERS AGREE?

Are any other sites reporting this? What sources are they citing?

IS IT A JOKE?

If it is too outlandish, it might be satire. Research the source to be sure.

CHECK YOUR BIASES

Consider if your own beliefs or concerns could affect your judgement.

ASK THE EXPERTS

Ask a librarian, or consult a fact-checking site, official source like the WHO.

LOOK BEFORE YOU SHARE

Don't share posts or stories that you haven't checked out first!

International Federation of Library Associations and Institutions

With thanks to www.FactCheck.org

IFLA.org

Call for BRSI Annual Awards Nominations for 2019 and Fellows for 2020

1. Life-Time Achievement Award: Members of BRSI above the age of 55 years as on 31st December 2019 involved in Biotech R&D for life time contribution to the field of Biotechnology would be eligible. Award carries certificate, citation and Rs 50,000 cash.

2. Young Scientist Award: Members of BRSIof 35 years or below as on 31st December 2019 involved in Biotech R&D for outstanding contributions would be eligible. Award carries certificate, citation and Rs 25,000 cash.

3. Woman Scientist Award: Women members of BRSI below the age of 45 years as on 31st December 2019 involved in Biotech R&D for outstanding contributions would be eligible. Award carries certificate, citation and Rs 25,000 cash.

4. Industrial Medal Award: Members of BRSI involved in Biotech R&D for outstanding contribution, which has resulted in commercialization of a product/process. Award carries certificate, citation and Rs 25,000 cash.

5. Fellow of BRSI: Eminent members of BRSI above the age of 45 years as on 31st December 2019 having long-standing and significant contribution to the field working in various areas of biotechnology shall be considered to be elected as Fellow of BRSI (*FBRS*).

6. Honorary Fellow of BRSI: Eminent persons above the age of 45 years as on 31st December 2019 who have rendered distinguished service to the nation in Biotechnology shall be considered to be conferred as Honorary Fellow of BRSI. Award carries a citation and a memento. Nomination can be made by the members of the Board of BRSI. For this, the nominee may or may not be member of BRSI.

7. AU-CBT Excellence Awards for Research Scholars (Two awards): Members of BRSI registered for PhD studies in any Indian university/institute below the age of 30 years as on 31st December 2019 involved in Biotech R&D for outstanding performance. Award carries a citation and Rs. 5000 cash for each.

8. Malaviya Memorial Awards for Teaching Faculties (Two awards – one for Young Faculty below the age of 40 years and one for the Senior Faculty above the age of 40 years as on 31st December 2019): Members of BRSI working as teachers involved in Biotech R&D for outstanding contribution. Award carries certificate, citation and Rs 10,000 and Rs 15,000 cash, respectively.

9. SBC-MKU Genomics Award: Members of BRSI below the age of 40 years as on 31st December 2019 involved in R&D in the area of Molecular Biology/Genomics/Metabolic Engineering/ Genetics/Genetic Engineering for outstanding contribution. Award carries certificate, citation and Rs 10,000 cash.

10. Prof SB Chincholkar Memorial Award: Members of BRSI above the age of 40 years as on 31st December 2019 involved in R&D in the area of Food/Agriculture Biotechnology/Bioenergy for outstanding contribution. Award carries certificate, citation and Rs 25,000 cash.

11. BHU Centennial Award (Two awards): Members of BRSI above the age of 50 years as on 31st December 2019 involved in Biotech R&D for outstanding contributions. Award carries certificate, citation and Rs 25,000 cash.

Terms and Conditions

The evaluation sheet must be filled properly and for each point, numbered and flagged documentary support must be provided, failing with that would not be considered. Nomination form can be obtained from the homepage of the Society at www.brsi.inLast date to receive the nominations by email is **July 25, 2020** and by post **July 31, 2020; 5.00 pm.**

Incomplete applications will be rejected without any communication to the nominee**.**

Award winners will be notified in last week of September/first week of October 2020**.**

Application complete in all respects should be sent (i) by email as a single PDF file + a separate file with score sheet to brsi.india@gmail.com on or before 25th July 2020, and (ii) one printed copy should be sent to Dr P Binod, Central Office-BRSI, CSIR-National Institute for Interdisciplinary Science and Technology, Industrial Estate PO, Trivandrum-695 019 on or before 31st July 2020; 5.00 pm.

Incomplete applications or those without supporting documents as mentioned in the Score Sheet and those without numbered flags in hard copy would be rejected without any further notice.

Featured News

Moderna Phase- 1 results show COVID19 vaccine safe, improve immune response

JULY 15, 2020 | Biotech Express News Bureau

Moderna Inc's experimental vaccine for COVID-19 showed it was safe and provoked immune responses in all 45 healthy volunteers in an ongoing early-stage study, U.S. researchers reported on Tuesday.

Volunteers who got two doses of the vaccine had high levels of virus-killing antibodies that exceeded the average levels seen in people who had recovered from COVID-19, the team reported in the New England Journal of Medicine.

No study volunteers experienced a serious side effect, but more than half reported mild or moderate reactions such as fatigue, headache, chills, muscle aches or pain at the injection site. These were more likely to occur after the second dose and in people who got the highest dose.

Moderna was the first to start human testing of a vaccine for the novel coronavirus on March 16, 66 days after the genetic sequence of the virus was released.

Moderna, the biotech company ranked among a select group of companies to receive significant funding as part of Operation Warp Speed, the U.S. government program created to accelerate COVID-19 vaccine development. The U.S. government is supporting Moderna's vaccine with nearly half a billion dollars.

Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), whose researchers developed Moderna's vaccine candidate, called the results "good news," noting that the study found no serious adverse events and the vaccine produced "reasonably high" levels of virus-killing or neutralizing antibodies.

Moderna's mRNA-1273 is an mRNA vaccine against SARS-CoV-2 encoding for a prefusion stabilized form of the Spike (S) protein that mimic the outer surface of the coronavirus, which the body recognizes as a foreign invader, and mounts an immune response against. It was selected by Moderna in collaboration with investigators from Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH.

On May 6, the U.S. Food and Drug Administration (FDA) completed its review of the Company's Investigational New Drug (IND) application for mRNA-1273 allowing it to proceed to a Phase 2 study, On May 12, the FDA granted mRNA-1273 Fast Track designation.

Zydus COVID-19 vaccine got approval from DCGI to starts human dosing of its vaccine 'ZyCoV-D'

JULY 16, 2020 | Biotech Express News Bureau

India's second possible vaccine against COVID-19, ZyCoV-D, is all set to start its human trial this month, the company said. The trials will be conducted on 1,000 volunteers across multiple sites in the country. Last week, Zydus Cadila group received approval from Drug Controller General of India (DGCI) to initiate phase 1 and phase 2 human clinical trials of possible COVID-19 vaccine in India.

Speaking on the development, Chairman, Zydus Cadila, Mr. Pankaj R. Patel said, "This is an all important step in our fight against COVID-19. We acknowledge the support of National Biopharma Mission, BIRAC, Department of Biotechnology, Govt. of India and regulatory agencies ICMR and DCGI in the development of ZyCoV-D vaccine candidate. We look forward to the Adaptive Phase I/IIclinical studies and gathering important data on ZyCoV-D in the months ahead."

Dr Harsh Vardhan tweeted " ZyCoV-D, the plasmid DNA vaccine designed & developed by @ZydusUniverse & partially funded by @DBTIndia has initiated Phase I/ II clinical trials in healthy subjects, making it the first indigenously developed vaccine for #COVID19 to be administered in humans in India. @IndiaDST

In the pre-clinical phase, the vaccine was found to elicit a strong immune response in multiple animal species like mice, rats, guinea pigs and rabbits. The antibodies produced by the vaccine were able to neutralize the wild type virus in virus neutralization assay indicating the protective potential of the vaccine candidate. No safety concerns were observed for the vaccine candidate in repeat dose toxicology studies by both intramuscular and intradermal routes of administration. In rabbits, up to three times the intended human dose was found to be safe, well tolerated and immunogenic.

Another possible vaccine against COVID-19, Covaxin, will soon start human trial on over 1,100 people in two phases, according to a report. Bharat Biotech, an unlisted Indian vaccine maker, received regulatory approval to start human clinical trials for its experimental shot. The phase 1 trial of Covaxine is scheduled to start next week. The company has planned to enroll 375 people in the first phase of clinical trials, an Indian Council for Medical Research (ICMR) spokesperson told.

Though the vaccine involve govt. labs but both the vaccines have been designed and developed by private players and no govt. or publicly funded institution's scientist(s) have contributed to the design and development or science of vaccine, as per the press releases of ICMR and DBT. For Covaxin, ICMR just shared the starting material and for ZyCoV-D, DBT just provided the funding support under National Biopharma Mission.

Biocon Itolizumab attract criticsm for its COVID-19 drug

JULY 15, 2020 | Biotech Express News Bureau

The drug has recently gathered criticism regarding phase 2 clinical trial that enrolled 31 patients only. Director-General of the ICMR Balram Bhargava said at a Health Ministry press briefing on July 14, that "There is yet no evidence from trials that itolizumab and tocilizumab, two drugs, one of which itolizumab has been developed by Bengaluru-based Biocon Biologics, reduce death in severely ill coronavirus (COVID-19)patients", according to The Hindu newspaper.

On July 11, Biocon Limited announced that the Drugs Controller General of India approved its drug Itolizumab "for emergency use in India for the treatment of cytokine release syndrome (CRS) in moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19.

The drug is priced at ₹32,000 for a treatment course and ₹8000/vial.

Itolizumab is an anti-CD6 IgG1 monoclonal antibody developed by Biocon[1] and the Center of Molecular Immunology (CIM), Havana and introduced in India in 2013 under the brand name ALZUMAb to treat chronic plaque psoriasis.

Itolizumab's acts via immunomodulation. It binds to the CD6 receptor and blocks the activation of T lymphocytes, in turn suppressing the pro-inflammatory cytokines and decreasing the cytokine storm and inflammatory response.

Dr Jammi Nagaraj Rao, a public health physician, independent researcher and epidemiologist in the UK, wrote for The Wire Science:

[Biocon's] trial is seriously deficient in its design. Its defects – particularly the extremely small sample size – largely invalidate the claims made in the press release from Biocon … The researchers have also not published data that would allow independent experts to assess their claim in the press release, that "Itolizumab demonstrated statistically significant advantage over the control arm, in one month mortality rate". With such data and without further larger trials, it is difficult to see how the company can fulfil its ambition to "take this therapy to other parts of the world impacted by the pandemic". … The irony is that Itolizumab may well be a breakthrough. If it is and if its real effects can be shown conclusively in a large trial, then Biocon would be able to boast of an unbeatable product. As things stand, it is unlikely to make that breakthrough without much greater rigour in the science of clinical trials.

Brazil's President Bolsonaro tests positive but is fine now after HCQ dose

JULY 09, 2020 | Biotech Express News Bureau

Brazilian President Jair Bolsonaro said on July 8, he was "doing very well" after contracting the coronavirus, and credited an unproven drug for his mild symptoms. Bolsonaro tested positive for COVID-19 on July 8, joining a small list of world leaders who have caught the disease.

On Tuesday evening, Bolsonaro said he was already feeling much better as he took what he described as his third dose of hydroxychloroquine.

There is little scientific evidence supporting the efficacy of the anti-malarial to treat COVID-19 but Bolsonaro, like U.S. counterpart Donald Trump, has trumpeted it as a potential cure.

"To those who root against hydroxychloroquine but don't present alternatives, I hate to say I'm doing very well using it and, thank God, I will still live much longer," Bolsonaro wrote in a Twitter post on Wednesday.

Bolsonaro's handling of the crisis has drawn criticism from public health experts as he fought state and city efforts to impose social distancing, arguing that the economic damage would be worse than the disease itself.

He has fired two health ministers during the pandemic, both trained doctors, and replaced them with an active-duty army general on an interim basis.

Dexamethasone approved for COVID-19 use in India

JULY 01, 2020 | Biotech Express News Bureau

The Central government has approved the use of low-cost steroid medicine dexamethasone for the treatment of COVID-19 patients in India.

This drug will be used only to treat patients with severe symptoms. British clinical trials had earlier found Dexamethasone to be effective against severely ill COVID-19 patients.

The World Health Organisation (WHO) has already called for an increase in the production of Dexamethasone. The WHO has, however, also warned that the drug should be used under strict medical supervision and only to treat severe patients.

Dexamethasone is used to treat conditions such as arthritis, blood/hormone/immune system disorders, allergic reactions, certain skin and eye conditions, breathing problems, certain bowel disorders, and certain cancers. It is also used as a test for an adrenal gland disorder (Cushing's syndrome).

This medication is a corticosteroid hormone (glucocorticoid). It decreases your body's natural defensive response and reduces symptoms such as swelling and allergic-type reactions

CORONIL: Magical medicine from self proclaimed ayurveda doctor

JULY 09, 2020 | Biotech Express News Bureau

On July 02, the Uttarakhand High Court issued notices to yoga guru Ramdev's Patanjali, Union and state governments, seeking a reply within a week on the firm's Coronil drug. Hearing a PIL challenging Ramdev's claims regarding the medicine, a division bench of Chief Justice Ramesh Ranganathan and Justice R C Khulbe issued the notices. It also seek response from Patanjali; the director of the AYUSh department in Uttarakhand; ICMR and Rajasthan's NIMS University.

The PIL filed by advocate Mani Kumar has sought a ban on the drug, accusing the yoga guru of misleading people by launching Coronil as a medicine to cure coronavirus.

Patanjali Ayurved on July 02 said it never claimed that its newly-tested medicine could cure Covid-19, and that clinical trials of its newly tested medicines indicated that "coronavirus patients got cured after consuming them".

Ministry of Ayush said Patanjali Ayurved will not be allowed to sell its medicines with claims of curing Covid-19, though the company can sell its Divya Coronil tablets as an immunity booster and gave it the licenses to make all its three medicines, namely Divya Coronil, Divya Swasari-Vati and Divya AnuTaila. The Ministry also said in a letter addressed to Patanjali that the packaging and labelling displayed on the medicines cannot claim cure of Covid-19.

Maharashtra FDA Minister Rajendra Shingne on July 03 said that action will be taken against Patanjali if the company created confusion or misled people that Coronil can cure Covid-19.

On June 23 yoga guru Ramdev came out with a medicine for Covid-19. The kit products made of phytochemicals derived from ashwagandha, tulsi and giloy comes with a price tag of Rs 545.

Just hours after yoga guru Baba Ramdev claimed that Patanjali has discovered a medicine to 'beat' the novel coronavirus, the Ayush Ministry of Uttarakhand clarified that the licence issued was not to find a cure for coronavirus. The license was issued only for the production of immunity booster kits and fever medicine.

After the controversy had erupted, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) responded to the news with a stern statement, urging that Patanjali stop advertising their product till its claims were verified by the ministry, and the product given approval.

"If you've seen the trial report that Patanjali has sent out, it excludes everybody below 10 years and above 59 years, people with diabetes, hypertension, respiratory diseases, cancer," says Dr Om Srivastava, Visiting Professor (Infectious Diseases) and Director of the Infectious Diseases Department at Jaslok Hospital, Mumbai. "To people who are asymptomatic in the mild form of the disease, the recovery rate is between 95 and 97 percent already. So what are you really achieving?"

According to Ramdev, "Trials were conducted on 100 patients at NIMS, Jaipur and 69 per cent of them were cured in three days, while 100 per cent were cured in seven days," Ramdev claimed. The question of whether Coronil should have been propagated as an immunity booster or cure should be asked from Patanjali. We had informed the Rajasthan health department on 2 June, BS Tomar said.

The Rajasthan Police lodged an FIR against Ramdev for launching the drug without regulatory approval, PTI, reported. Four others, including the MD of Ramdev-promoted Patanjali Ayurved Acharya Balkrishna, director of National Institute of Medical Sciences and Research (NIMS), Jaipur, BS Tomar, his son Anurag Tomar and senior scientist Anurag Varshney have also been named in the FIR, as per the report. The five have been booked under Section 420 (cheating) of the Indian Penal Code (IPC), and the Drugs and Magic Remedies (Objectionable Advertisements) Act, according to police.

Another criminal complaint was filed in a Bihar court against yoga guru Ramdev and Patanjali Ayurved MD Acharya Balkrishna, alleging that they have misled and put at risk the lives of lakhs of people by claiming to have developed medicine to treat Covid-19. The court posted the matter for hearing on June 30. The complainant has sought registration of a case under IPC sections 420 (cheating and dishonesty inducing delivery of property), 120B (criminal conspiracy) and 270 (malignant act likely to spread infection of disease dangerous to life), among others.

Suryakant Dhasmana alleged that Swami Ramdev and Balkrishna had violated the norms and regulations of the National Disaster Management Act (NDMA), 2005 and Drugs and Cosmetics Act by making unverified claims of finding a cure for Covid-19 disease. He said the duo violated the circular issued on April 1 by Centre's AYUSH department prohibiting advertising of any medicine as cure for Covid-19, citing the NDMA.

In a new twist to the controversy surrounding Baba Ramdev's claims of a coronavirus 'cure', Jaipur's National Institute of Medical Sciences which had collaborated on this has now distanced itself from the controversial ayurvedic drug and stated that no clinical trials of it were conducted at the hospital. NIMS Chairman, Dr. B.S. Tomar said, "there was no clinical trial in our hospital of the drug. There was no serious case in the patients we admitted. Only 100 asymptomatic patients were given few Ayurvedic medicines under the sponsorship of Patanjali. But we did not prepare any medicine nor did we know its name. Dr. Tomar claims that he had the CTRI permission for five ayurvedic medicines to be tested on coronavirus patients. "We had not asked for medicine to cure coronavirus but only these ayurvdic immunity boosters.

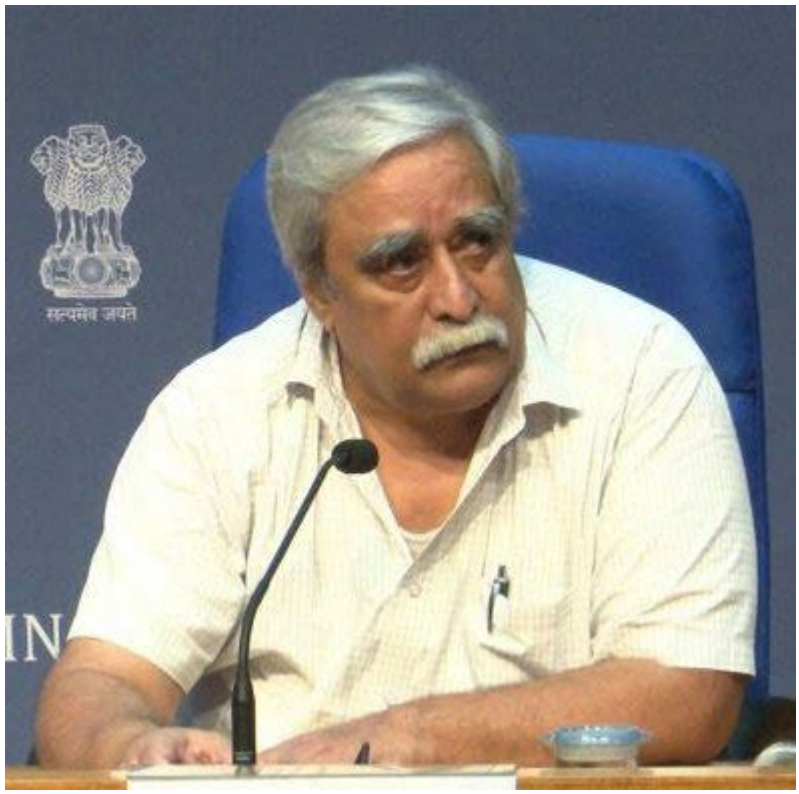
References:

1. https://www.newindianexpress.com/nation/2020/jun/27/jaipurs-nims-makes-u-turn-on-coronil-collab-with-baba-ramdev-says-no-clinical-trials-conducted-2161932.html

2. https://thewire.in/the-sciences/patanjali-baba-ramdev-covid-19-cure

No reason to say that Indian CoV strain is less virulent: Dr Raman Gangakhedkar

JULY 07, 2020 | Biotech Express News Bureau



In a 60-minute interview to Karan Thapar for The Wire, Dr Raman Gangakhedkar, retired Head of Epidemiology at the Indian Council of Medical Research spoke about issues related to coronavirus pandemic. Until June 30, he was "Man behind COVID-19 communication of ICMR in India".

First, he has disprove the health minister Harsh Vardhan's claim (made on May 23, 2020) that the virus is "not that virulent" in India.

He also spoke about two issues Prime Minister Narendra Modi has frequently mentioned to claim India is doing better than other countries. On the mortality rate, he agreed with points earlier made to The Wire by Prof. Ashish Jha of Harvard – that you cannot compare inter-country mortality rates because they do not take into account the different age demographics of each country. On the issue of recovery rate, another point frequently mentioned by the prime minister, Dr. Gangakhedkar agreed with Prof. Jha that eventually "all countries will have a recovery rate close to 99%".

On the recent controversy created by the ICMR Director General's letter stating that India would "launch a vaccine for public health use by August 15 after completion of all clinical trials", Dr. Gangakhedkar said that this would not "have a long lasting impact" on the ICMR's image.

Dr. Gangakhedkar also explained why he retired in the middle of a pandemic which is steadily getting worse. He said the ICMR "wanted to keep me". However, he explained he wanted to go back to his family after living alone for two years.

The wire wrote, Dr. Gangakhedkar is the first official connected with the ICMR who has spoken at such length and willingly addressed all the issues and concerns about India's handling of COVID-19.

It is to note that Dr Gagandeep kang has given the same reason after leaving Director's position from DBT-THSTI.

Gagandeep Kang resigned from director's position of DBT- THSTI amid COVAXIN turmoil

JULY 06, 2020 | Biotech Express News Bureau

Professor Gagandeep Kang has resigned from her executive director's position at the Translational Health Science and Technology Institute DBT-THSTI, Faridabad.

"Yes, I am leaving THSTI as Director, but hope to continue my association with the faculty and the science. The reason is to return to my family and to CMC (Christian Medical College) Vellore as I was on sabbatical from there," Kang said in an email response to PTI.

The news of her resignation, especially at a time when India's scientific community and research institutions are engaged in fighting COVID-19, has raised concerns about the events preceding her decision to quit the organisation. In April, Kang was heading a national task force on COVID-19 vaccines and drug research set up by the ICMR. However, subsequently, the task of overseeing indigenous vaccine research in the country was handed over to the department of biotechnology, headed by Dr. Renu Swarup.

Unlike every other scientist and administrator, she is the first Indian woman to have been elected Fellow of the Royal Society of London. Her research was instrumental in the development of Rotavac alongwith Dr M K Bhan, the first vaccine to be made from scratch in India. Her studies have contributed to the understanding of diarrhoeal diseases, rotavirus epidemiology and vaccinology.

Kang also holds the position of vice chair, Coalition for Epidemic Preparedness (CEPI), a global non-profit enabling vaccine development in the current pandemic.

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News of Focus

BioNTech, Pfizer COVID-19 Vaccine Candidates

Jul 13, 2020

The U.S. Food and Drug Administration (FDA) granted Fast Track designation to COVID-19 vaccine candidates under development by Pfizer and Germany's BioNTech. The designation will provide for an expedited pathway for regulatory review of the preventative medication, which could come later this year.

The FDA designation covers two of the companies' four investigational vaccine programs under development against the novel coronavirus, BNT162b1 and BNT162b2. Those two programs are the most advanced candidates under development by the two companies and are currently in an ongoing Phase I/II study.

BNT162b1 and BNT162b2 are both nucleoside-modified RNAs, formulated in lipid nanoparticles. BNT162b1 encodes an optimized SARS-CoV-2 receptor-binding domain (RBD) antigen, while BNT162b2 encodes an optimized SARS-CoV-2 full-length spike protein antigen.

Biopharma Giants Launch AMR Fund of $1 Billion

Jul 13, 2020

A collective of pharmaceutical companies, including Pfizer, Merck, GlaxoSmithKline and Johnson & Johnson, has pledged financial support of approximately $1 billion to support the Antimicrobial Resistance Action Fund. Pfizer and J&J both pledged $100 million to support the Fund, the same day the fund formally launched. The AMR Action Fund is a ground-breaking collaboration of more than 20 biopharmaceutical companies who have a goal to bring two to four new antibiotics to patients by 2030 through collaboration

AMR action fund

Bridging the gap between science and patients

between pharmaceutical companies, philanthropies, development banks, and multilateral organizations to reinvigorate and accelerate antibiotic development.

The fund will be used to address the growing need for new antibiotics due to the rapid rise of antibiotic-resistant infections due in part to the broad use of antibiotics currently available. Approximately 700,000 people die annually from infections that have become resistant to antibiotics. That number is expected to escalate dramatically due to the lack of new antibiotic development. By 2050, it is estimated that antimicrobial resistance could claim as many as 10 million lives per year.

Paul Stoffels, the chief scientific officer for J&J, said antimicrobial resistance (AMR) has the potential to render diseases that are relatively easy to treat today virtually incurable.

The AMR Fund will be guided by an advisory board that will select the most promising novel and differentiated antibiotic programs in clinical development, Holland said. The board will recommend which products to consider for funding.

Investments will be based on a priority list of pathogens developed by the World Health Organization and the CDC, with a goal of addressing major unmet needs with hope of the greatest impact on public health. The advisory board should begin making recommendations for financial support by the end of the year.

International leaders who got sick of SARS-CoV2

July 7, 2020

BRITAIN
Prime Minister Boris Johnson spent two weeks recovering from a bout of COVID-19 at Chequers, his country residence, before returning to Downing Street on April 26.

Johnson, 56, had spent three nights in intensive care in a London hospital with the illness. Leaving St Thomas' hospital on April 12, he thanked staff for saving his life.

RUSSIA
Kremlin spokesman Dmitry Peskov said in May he had tested positive and received treatment in hospital, before recovering. Other high-profile Russians to have suffered from the virus include Prime Minister Mikhail Mishustin and three other cabinet ministers.

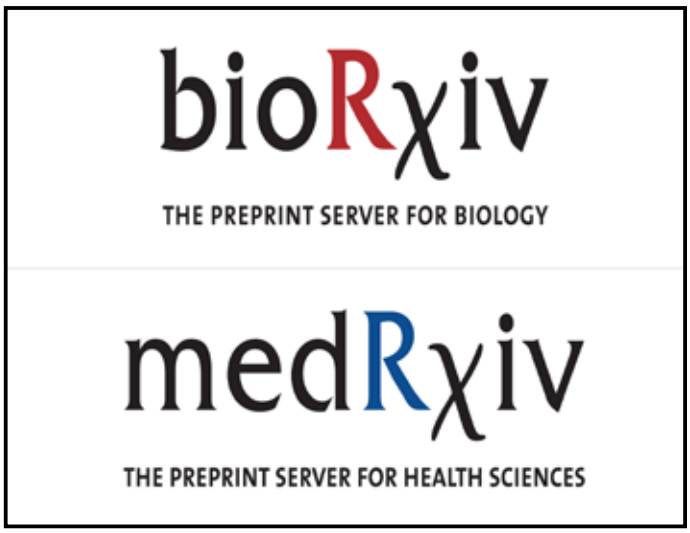
UNITED STATES
Several White House aides, staff members of Trump's re-election campaign and Secret Service agents have tested positive for the coronavirus, as has his personal valet and Kimberly Guilfoyle, his son Donald Jr.'s girlfriend who serves as a top fund-raising official for his campaign.

CANADA
Prime Minister Justin Trudeau, 48, went into quarantine in March after his wife was diagnosed with the coronavirus. He held daily news conferences in the front garden of his residence, with reporters lobbing questions at him from a distance.

New journal launched to scrutinize Covid-19 preprints papers

JULY 1, 2020

The wild, wild west of Covid-19 preprints is about to get a new sheriff. On Monday, the MIT Press is announcing the launch of an open access journal that will publish reviews of preprints related to Covid-19, in an effort to quickly and authoritatively call out misinformation as well as highlight important, credible research.



"Preprints have been a tremendous boon for scientific communication, but they come with some dangers, as we've seen with some that have been based on faulty methods," said Nick Lindsay, director of journals at the MIT Press, which will publish Rapid Reviews: Covid-19. "We want to debunk research that's poor and elevate research that's good."

The Covid-19 pandemic has produced a fire hose of preprints (papers posted to servers such as bioRxiv and medRxiv without peer review), many of questionable validity. The poster child for that is a bioRxiv preprint that suggested the new coronavirus had somehow been engineered from HIV; it was quickly withdrawn. But many other preprints, while not clearly wrong, used weak methodology, such as small numbers of patients or inadequate controls, as in an experiment concluding that a commercially available immunoglobulin might protect against the disease.

The editor-in-chief of Rapid Reviews: Covid-19, Stefano Bertozzi of the University of California, Berkeley, thinks this project has a secret sauce that similar efforts do not. It will use an artificial intelligence system developed at Lawrence Berkeley National Laboratory to categorize new preprints by discipline (such as epidemiology or clinical care) and degree of novelty.

Rapid Reviews: Covid-19 plans to tap a pool of 1,600 potential reviewers from hundreds of institutions, and will analyze papers on the economics and anthropology of the pandemic as well as biomedicine. If it lives up to its founders' hopes, it would be the largest formal effort to ride herd on Covid-19 preprints. It also plans to publish original research from areas of the world that have been underrepresented in Western journals.

Regeneron Launches Phase III COVID-19 Prevention Trial with Antibody Cocktail

Jul 06, 2020

Regeneron Pharmaceuticals, with the U.S. National Institute of Allergy and Infectious Diseases (NIAID), is launching Phase III trials of REGN-COV2, the

company's two-antibody cocktail for the treatment and prevention of COVID-19.

There are specifically two trials. A Phase III trial will study if REGN-COV2 can prevent infection in uninfected people who have had close exposure to a COVID-19 patient.

The drug has also been advanced into the Phase II/III portion of two adaptive Phase I/II/III trials evaluating the cocktail in treating hospitalized and non-hospitalized patients with COVID-19.

A Phase I trial in 30 hospitalized and non-hospitalized patients with COVID-19 received a positive review from the Independent Data Monitoring Committee.

The Phase III prevention study will be run at about 100 locations and enroll about 2,000 people in the U.S. The Phase II/III treatment trials in hospitalized patients will evaluate about 1,850 hospitalized patients and 1,050 non-hospitalized patients, and is planned for about 150 sites in the U.S., Brazil, Mexico, and Chile. It will study virologic and clinical endpoints. Preliminary data is expected later this summer.

Sanofi and Regeneron's Kevzara fails in Phase III Covid-19 trial

3 JULY 2020

KEVZARA® (sarilumab)

Sanofi and Regeneron Pharmaceuticals have reported that a Phase III clinical trial of rheumatoid arthritis drug Kevzara (sarilumab) failed to meet its primary and key secondary endpoints in Covid-19 patients who required mechanical ventilation in the US.

The study compared 400mg dose of the drug plus best supportive care to best supportive care alone.

In the primary analysis arm, adverse events were reported in 80% of patients treated with Kevzara and 77% of those on placebo.

Serious adverse events in at least 3% of patients, more frequent among Kevzara patients, were multi-organ dysfunction syndrome and hypotension.

Based on the data, the companies have halted this US-based trial, including a second cohort of patients who were on a higher 800mg dose of the drug.

The primary analysis involved 194 patients who were critically ill and were on mechanical ventilation at the time of enrolment.

NIAID Creates Clinical Trials Network COVPN to Focus on COVID-19 Vaccines, MAbs

Jul 09, 2020

The National Institute of Allergy & Infectious Diseases (NIAID) has founded a new clinical trials network focused on enrolling volunteers in clinical trials for COVID-19 vaccines and monoclonal antibodies.

The COVID-19 Prevention Trials Network (COVPN), the new network, merged four existing NIAID-funded clinical trials networks. They are the HIV Vaccine Trials Network (HVTN), which is located in Seattle; the HIV Prevention Trials Network (HPTN), based in Durham, North Carolina; the Infectious Diseases Clinical Research Consortium (IDCRC), headquartered in Atlanta; and the AIDS Clinical Trials Group, based in Los Angeles.

The new network's vaccine testing will be led by Larry Corey of the Fred Hutchinson Cancer Research Center in Seattle and Kathleen M. Neuzil of the University of Maryland School of Medicine.

Myron S. Cohen of the University of North Carolina, Chapel Hill and David S. Stephens of Emory University in Atlanta will head the network's monoclonal antibody clinical testing.

The HVTN is located at the Fred Hutchinson Cancer Research Center and will act as the new COVPN's operational center. COVPN is "functional unit" of Operation Warp Speed, which is President Trump's program to speed efforts to have a usable and safe vaccine against COVID-19 by January 2021. The network will rely on a harmonized vaccine protocol developed by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership. This protocol allows researcher to analyze data from multiple vaccine trials. It is expected to run more than 100 clinical trial locations across the U.S. and internationally.

The first Phase III trial that COVPN is expected to run is for Moderna and NIAID's mRNA-1273 vaccine, which is generally viewed as the leader in vaccine development for COVID-19. On June 11, Moderna indicated it had finalized the Phase III clinical trial structure for mRNA-1273 with plans to begin the trial in 30,000 participants in July. On July 2, there were indications that Moderna was making changes to the trial structure with the start date being pushed back.

Novavax Secures $1.6 Billion from U.S. Government for COVID-19 Vaccine Program

Jul 07, 2020

Novavax received $1.6 billion in federal funding to support the clinical development of the company's vaccine candidate, NVX-CoV2373.

Gaithersburg, Md.-based Novavax said the funding will allow the company to participate in Operation Warp Speed, the government's program that has a goal of supporting the development of hundreds of millions of vaccine doses by 2021. The funding granted to Novavax will support the late-stage clinical development of the vaccine candidate, including a pivotal Phase III study. Additionally, the funds will be used to establish large-scale manufacturing in order to deliver 100 million doses of NVX-CoV2373 by the end of the year.

Stanley C. Erck, president and chief executive officer of Novavax, said the company was honored to partner with Operation Warp Speed, a program that is supporting multiple shots on goal against COVID-19 by backing multiple vaccine projects, including Moderna's mRNA program and AstraZeneca's vaccine candidate.

In preclinical trials, NVX-CoV2373 demonstrated the indication of antibodies that block the binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. The company initiated a Phase I/II trial in May, with preliminary immunogenicity and safety results expected at the end of July. The Phase II portion of the trial, which will assess immunity, safety, and COVID-19 disease reduction is expected to begin thereafter. The $1.6 billion agreement with the U.S. government will fund the late-stage clinical studies necessary to determine the safety and efficacy of NVX-CoV2373, including a pivotal Phase III clinical trial with up to 30,000 subjects beginning in the fall of 2020.

The Phase I/II clinical trial is being supported by an up-to $388 million funding arrangement with the Coalition for Epidemic Preparedness Innovations (CEPI). The company's vaccine development program also received $60 million from the U.S. Department of Defense.

Sanofi Goes Big on $2 Billion-Plus Vaccine Partnership with Translate Bio

Jun 23, 2020

Sanofi Pasteur, the vaccines business unit of Paris-based Sanofi, and Lexington, Massachusetts-based Translate Bio announced the expansion of an existing collaboration to develop mRNA vaccines for infectious diseases. The original deal was entered in 2018.

Under the new deal expansion, Sanofi will pay Translate Bio $425 million up front, with $300 million in cash and $125 million a private placement common stock investment at $25.59 per share, a 50% premium on the 20-day moving average share price before signing.

Translate Bio will be eligible for possible milestones and other payments up to $1.9 billion, which includes $450 million that fell under the 2018 agreement.

Of the possible milestones, about $360 million are expected over the next few years, including COVID-19 vaccine development milestones. Also, Translate Bio is up for tiered royalties based on global sales of any developed vaccines.

The deal will give Sanofi about a 7.2% stake in Translate Bio in addition to the broad rights to vaccines. Sanofi expects its mRNA COVID-19 vaccine candidate to enter the clinic by the end of the year, and if everything goes well, could be up for regulatory approval in the second half of 2021.

Other companies, notably Moderna, and a Pfizer and BioNTech collaboration, are utilizing mRNA technology to develop their vaccines.

WHO justified statement of 'unknown Pneumonia' in Kazakhstan by China

Issuing statement on the 'unknown virus' found in Kazakhstan, WHO has said that it might be the novel Coronavirus, citing that there was a big surge of COVID cases in the country recently.

WHO official Michael Ryan issued the statement after the Chinese Embassy in Kazakhstan warned about the unknown virus. Ryan added that the WHO is working with authorities in Kazakhstan to investigate the potential of the virus and to identify it.

This comes after Kazakhstan's Ministry of Healthcare on July 10 dismissed a report of the Chinese Embassy about an 'unknown pneumonia'.

The Ministry of Healthcare of the Republic of Kazakhstan emphasizes that the reports of the Chinese media are not consistent with reality.

Medical practitioners and family members of victims in Kazakhstan told the BBC's Abdujalil Abdurasulov they believed the increased numbers of pneumonia cases were connected to the coronavirus but were going undetected because of low-quality testing or no testing at all.

Venera Zhanalina, whose father died three days after being admitted to hospital with coronavirus-like symptoms, told the BBC: "In the death certificate, it said pneumonia as the cause. But we don't even know if they tested him on coronavirus."

Meerut hospital in India sealed, licence revoked for providing fake COVID-19 negative report for Rs 2,500

JULY 7, 2020

The Meerut administration in Uttar Pradesh has suspended the licence of a private hospital after a video showing an employee offering negative coronavirus reports for money went viral. The facility was identified as the New Meerut Hospital on Hapur Road. However, the newspaper said the document submitted to the Uttar Pradesh Chief Minister's Office bore the stamp of the government-run Pyarelal District Hospital.

The video also shows "clients" giving Rs 2,000 to the staff member and promising to pay Rs 500 when they get the results of the coronavirus test. "From the video, it has emerged that the hospital's manager, Shah Alam, is promising people a fake Covid-19 negative report in exchange for money".

Meerut District Magistrate Anil Dhingra said the licence of the hospital has been suspended, and the place has been sealed. Anil Nausran, secretary of the Indian Medical Association's Meerut unit, said the government should close hospitals and nursing homes in the district being run by persons with no medical degree.

Alam claimed innocence. "The video is fake and has been released to malign my image and give the hospital a bad name," he said. "I am innocent and the inquiry will prove that."

COVAXIN Developed by Bharat Biotech gets DCGI approval for Phase-I and II HumanClinical Trials

JULY 4, 2020

Bharat Biotech has successfully developed COVAXIN™, India's 1st vaccine candidate for COVID-19, in collaboration with the Indian Council of Medical Research (ICMR) – National Institute of Virology (NIV). The SARS-CoV-2 strain was isolated in NIV, Pune and transferred to Bharat Biotech. The indigenous, inactivated vaccine developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) High Containment facility located in Genome Valley, Hyderabad, India.

The Drug Controller General of India – CDSCO, Ministry of Health & Family Welfare granted permission to initiate Phase I & II human clinical trials after the company submitted results generated from preclinical studies, demonstrating safety and immune response. Human clinical trials are scheduled to start across India in July 2020.

Four days after Bharat Biotech announced that it has successfully developed COVAXIN, a vaccine candidate for COVID-19, ICMR said that it wanted to "launch the vaccine for public health use latest by 15 August".

A letter, issued by the Director General of ICMR Dr Balram Bhargava, said, "This is the first indigenous vaccine being developed by India and is one of the top priority projects which is being monitored at the topmost level of the government.

The vaccine is derived from a strain of SARS-CoV-2 isolated by ICMR-National Institute of Virology, Pune.

ICMR and BBIL are jointly working for the preclinical as well as clinical development of this vaccine. It is envisaged to launch the vaccine for public health use latest by 15 August, 2020, after completion of all clinical trials.

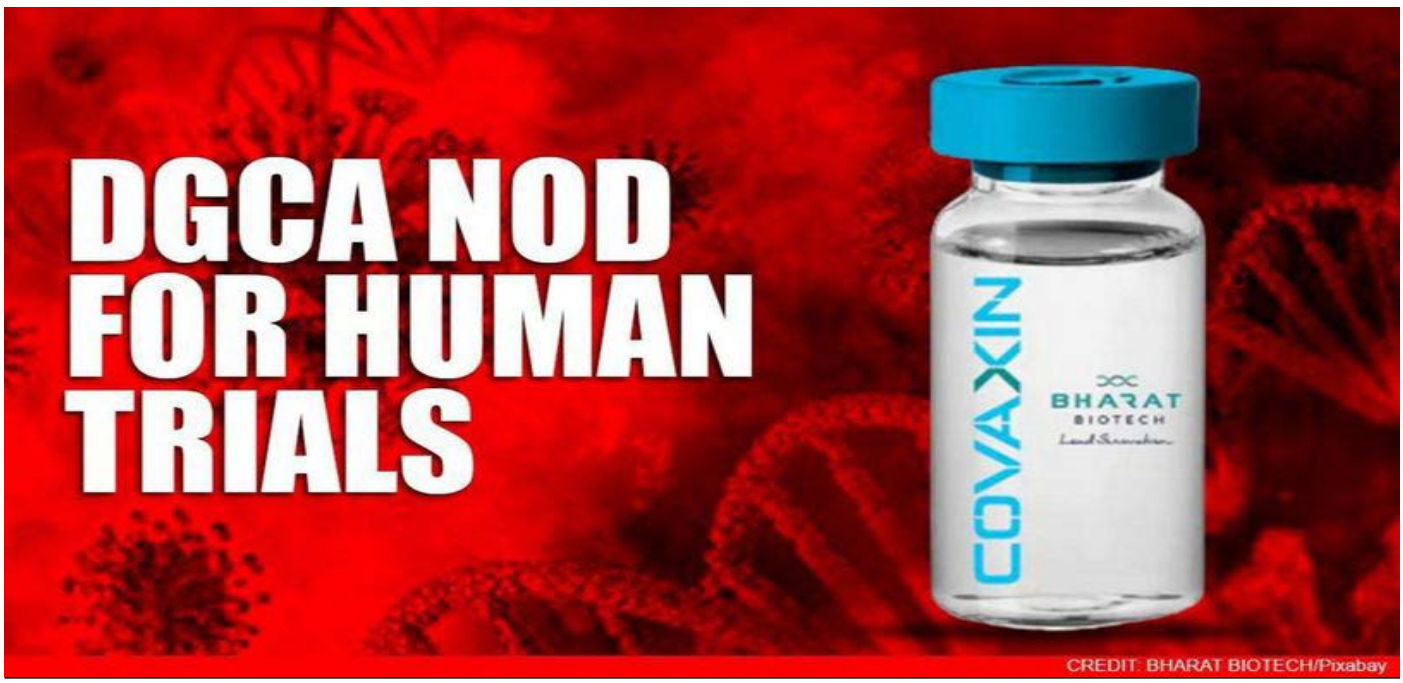
BBIL is working expeditiously to meet the target, however, final outcome will depend on the cooperation of all clinical trial sites involved in this project."

The plan was disclosed in a letter by the Indian Council of Medical Research to 12 institutes where human trials are to be held for the vaccine, Covaxin, ordering them to secure necessary approvals from internal committees by July 7 with a warning that "non-compliance will be viewed very seriously".

Dr Anant Bhan, a researcher in global health, bioethics and health policy, spoke to Firstpost about the extreme urgency of the situation. "It's understandable for a pandemic of this scale. But we can't compromise on the safety and the efficacy aspects. Minimum standards around safety, efficacy and quality need to be followed. Collapsing the entire process to just 45 days is unlikely, and almost impossible," he said. The expected duration of the trial, according to the government's official clinical trial registry, is one year and three months.

Criticised for setting an unreasonable deadline that would affect safety, efficacy and quality, ICMR later suggested that it was only making an effort to put out trial data by August 15. "Request has been made to fast track the vaccine trials," said Dr Rajnikant Srivastava, spokesperson, ICMR, in a text message. No order was issued.

ICMR's position also surprised experts because data about the vaccine's preclinical performance has not been made public yet.



WHO acknowledges 'evidence emerging' of airborne spread of COVID-19

JULY 7, 2020

The World Health Organization on Tuesday acknowledged "evidence emerging" of the airborne spread of the novel coronavirus, after a group of scientists urged the global body to update its guidance on how the respiratory disease passes between people.

"We have been talking about the possibility of airborne transmission and aerosol transmission as one of the modes of transmission of COVID-19," Maria Van Kerkhove, technical lead on the COVID-19 pandemic at the WHO, told a news briefing.

The WHO has previously said the virus that causes the COVID-19 respiratory disease spreads primarily through small droplets expelled from the nose and mouth of an infected person that quickly sink to the ground.

But in an open letter to the Geneva-based agency, published on Monday in the Clinical Infectious Diseases journal, 239 scientists in 32 countries outlined evidence that they say shows floating virus particles can infect people who breathe them in.

Cipla and Hetro revealed Prices of their Generic Remdesivir

JULY 8, 2020

Cipla Ltd has priced its generic version of remdesivir, Cipremi, at 4,000 rupees ($53.34) per 100 mg vial, the Indian drugmaker said on Wednesday, making it among the lowest priced versions of the COVID-19 treatment available so far globally. Cipla had earlier said pricing would not exceed 5,000 rupees. On Tuesday, Sovereign Pharma, which is manufacturing and packaging the drug for Cipla, said it had dispatched the first batch.

Hetero Pharma starts supplying generic version of Remdesivir. Indian generic pharmaceutical giant Hetero announced that it was all set to deliver as many as 20,000 vials of 'Covifor' which costs 5,400 rupees per

vial while Mylan prices Desrem at 4,800 rupees.

Meanwhile, Indian biotech firm Panacea Biotec Ltd said on Wednesday it remains on schedule to produce first production quantities of COVID-19 vaccine candidate by January 2021. It has set production targets of 500 million doses for 2021 and one billion doses in 2022 for its COVID-19 vaccine candidate.

As first, India's Bharat Biotech and Zydus Cadila, listed as Cadila Healthcare Ltd, have received regulatory approvals to test their vaccine candidates in humans.

On May 29, Sun Pharmaceutical Industries has announced that it has received approval from the Drugs Controller General of India (DCGI) to initiate a clinical trial with Nafamostat Mesilate in COVID-19 patients. Nafamostat is approved in Japan for the improvement of acute symptoms of pancreatitis and treatment of Disseminated Intravascular Coagulation (DIC). Dilip Shanghvi, Managing Director, Sun Pharma said, "Sun Pharma is constantly evaluating potential targets that can be explored for treating Covid-19 patients. Nafamostat has shown promising data against SARS-CoV-2 virus in in-vitro studies conducted by three independent groups of scientists in Europe, Japan and South Korea. We believe it holds promise in the treatment of COVID-19 patients."

Remdesivir's developer, Gilead Sciences Inc , has priced the original version at $390 per 100 mg vial for wealthier nations while signing licensing deals with generic producers to make the treatment widely available. It was not immediately clear how many vials would be required for a full treatment course. Gilead has said a patient would typically need six vials of remdesivir for a five-day course.

Tesla to Build Mobile RNA Microfactories for CureVac's COVID-19 Vaccine

JULY 3, 2020

Tesla, the electric car company founded and run by Elon Musk, is building mobile molecular printers to assist Germany's CureVac in manufacturing its experimental COVID-19 vaccine.

Musk tweeted the information on Wednesday, July 1. The "printers" are portable, automated messenger RNA (mRNA) production units, which Musk referred to as "RNA microfactories."

CureVac's approach to a COVID-19 vaccine is built on mRNA technology, similar to what is being used by Moderna, Pfizer and BioNTech. It takes a small piece of messenger RNA that codes for a specific molecule on the virus's surface. When injected into the body, it causes cells to churn out that molecule, which will train the immune system to identify the virus and neutralize it before it can replicate. No mRNA products have been approved for use yet.

The printers are being built at Tesla Grohmann Automation in Germany. Tesla acquired the company in 2016, which develops automated manufacturing systems for batteries and fuel cells.

On June 17, CureVac announced that it had the go-

ahead to begin the Phase I clinical trial of its COVID-19 vaccine in Germany and Belgium. The first patients will be vaccinated at the Institute for Tropical Medicine in Tubingen, Germany and the Ghent University Hospital in Belgium, the Tropical Institute of the University Hospital Munich, LMU, and the Hannover Medical School, also in Germany.

CureVac has funding for its COVID-19 vaccine programs from the Coalition for Epidemic Preparedness Innovations (CEPI), which includes support from the Bill & Melinda Gates Foundation.

A month after Surgisphere paper retraction, Lancet retracts, replaces hydroxychloroquine editorial

July 10, 2020

In early June, as controversy swirled over a high-profile study of hydroxychloroquine and COVID-19, Christian Funck-Brentano started receiving aggressive emails, texts and tweets.

Funck-Brentano, professor of medicine and clinical pharmacology at Sorbonne Université and Pitié-Salpêtrière University Hospital in Paris, and a colleague had published an editorial in The Lancet alongside the study — purportedly based on data from a company called Surgisphere — citing the results and sounding an alarm about the cardiac risks of hydroxychloroquine. Within days, that paper was retracted, along with a paper in The New England Journal of Medicine about different medications also allegedly based on Surgisphere data.

Funck-Brentano remained convinced that the risks of hydroxychloroquine in those with well-studied reasons to take it — lupus and malaria, for example — are quite low, but that they are much higher in patients with COVID-19.

As questions swirled around the paper, Stuart Spencer, an editor at The Lancet, told Funck-Brentano to wait for the audit — which turned out to be impossible because Surgisphere would not cooperate.

The journal's ethical review committee then contacted Funck-Brentano, letting him know that the paper would be retracted and that the commentary would have to be, too.

The journal — which, along with the JAMA journals has been using the "retract and replace" approach — agreed to that. Funck-Brentano and his colleague, along with a new co-author, wrote a new version, and it was accepted a few weeks ago.

Figure "anomalies" prompt Harvard group to retract Nature paper

June 18, 2020

A group of researchers based at Harvard Medical School have retracted their 2019 paper in Nature after

a data sleuth detected evidence of suspect images in the article.

The move comes ten months after the journal first heard from the sleuth, Elisabeth Bik.

The paper, "Fatty acids and cancer-amplified ZDHHC19 promote STAT3 activation through S-palmitoylation," came from the lab of Xu Wu, of the Cutaneous Biology Research Center at Massachusetts General Hospital, and his colleagues.

It appeared last August — and immediately caught the attention of Rune Linding, who flagged it for Bik, who in turn noticed several regions of concerning duplications in a few of the Western blots that appeared in the paper.

In those ten months, the paper has been cited five times, according to Clarivate Analytics' Web of Science. Here's the retraction notice:

We, the authors, are retracting this Letter owing to anomalies in Figs. 2j, 3a and 3d.

We and the Nature editors reviewed the data and found that these anomalies were present in the digital scans of the original western blot films, which could not be located for further examination.

Although repeat experiments at the time of writing the paper have reproduced the data, the anomalies undermine confidence in the published Letter. We therefore believe that the most appropriate course of action is to retract this Letter in its entirety.

We thank the readers who brought the issues to our attention, and apologize to the scientific community. We remain confident that the key findings of the Letter are valid and reproducible. All authors agree with the Retraction.

Law firm sues OSU cancer researcher for $900,000 in unpaid fees following failed libel suit

June 26, 2020

Last month, Croce lost a defamation suit he filed against David Sanders, a Purdue researcher who was quoted in a 2017 New York Times story about allegations regarding Croce's work. Croce had already lost an appeal of a related suit against the Times.

It turns out that Croce had not paid his attorneys —

Kegler Brown Hill + Ritter, of Columbus, Ohio — in a number of those cases, to the tune of $923,445.51, according to a lawsuit filed against Croce last week in Franklin County Court.

The firm had been trying to compel Croce to pay their fees since June 2018, according to the complaint. In August 2018, according to the filing, Croce — a noted art collector — said he would obtain a credit line from Sotheby's to cover the payment. Later that month, Kegler Brown withdrew as Croce's attorneys.

Croce, who has had 10 papers retracted, has also sued The Ohio State University — also unsuccessfully — to force them to restore him as chair of the Department of Cancer Biology and Genetics.

Neither Croce nor Charles Cooper, the attorney representing Kegler Brown, immediately responded to requests for comment.

Major indexing service sounds alarm on self-citations by nearly 50 journals

More than 70% of the citations in one journal were to other papers in that journal. Another published a single paper that cited nearly 200 other articles in the journal.

Now, Clarivate, the company behind the Impact Factor, is taking steps to fight such behavior, suppressing 33 journals from their indexing service and subjecting 15 more to expressions of concern — all for apparent self-citation that boosted the journals' rankings.

The list includes some of publishing's biggest players: Nine journals published by Elsevier, seven by Springer Nature, six by Taylor & Francis, and five by Wiley.

Given many universities' reliance on journal rankings to judge researchers' work as part of tenure and promotion decisions, Clarivate's suppression of a journal — meaning denying it an Impact Factor — can have far-reaching effects. Impact Factors are based on average citations to articles in a journal over a particular period of time. Many, including us, have argued that Impact Factor is not the best way to judge research — for reasons including relative ease of gaming such metrics.

Clarivate's Web of Science indexes 21,000 journals, but only 12,000 are included in the annual Journal Citation Report (JCR) and receive Impact Factors. There are currently two reasons for suppression from the JCR: journal self-citation and "citation-stacking," behavior which is sometimes referred to as taking part in "citation cartels" or "citation rings." None of the suppressions or expressions of concern this year were for citation stacking. When the company suppresses a journal from the JCR, it continues to count its citations, but does not assign it an Impact Factor.

The company has changed the way it considers self-citation and revised its methodology, Web of Science editor in chief Nandita Quaderi said, in response to patterns it's observed in the past few years.

This year, Clarivate also subjected 15 journals to editorial expressions of concern. Such journals had small numbers of articles with very high levels of citation to articles in the same journal that can have a significant effect on Impact Factor and rankings. Looking only at overall journal levels of self-citation would miss such patterns, Quaderi said, because it would not take directly into account how these citations are "concentrated" in particular articles or time periods.

Nothing changes for JCR journals subject to such flags, but they are monitored closely for re-evaluation and may lose their Impact Factors in succeeding years, or be removed from indexing altogether.

This move marks only the second time that Clarivate has issued expressions of concern. In 2018, they did so for five journals in the bone field, four of which went on to be suppressed the following year. All five are now reinstated in the JCR, Quaderi told Retraction Watch.

COVID19 Research

A new Study shows 'classic' symptoms of COVID-19

June 24, 2020

The researchers -- from five universities including the University of Leeds in the UK -- combined data from 148 separate studies to identify the common symptoms experienced by more than 24,000 patients from nine countries, including the UK, China and the US.

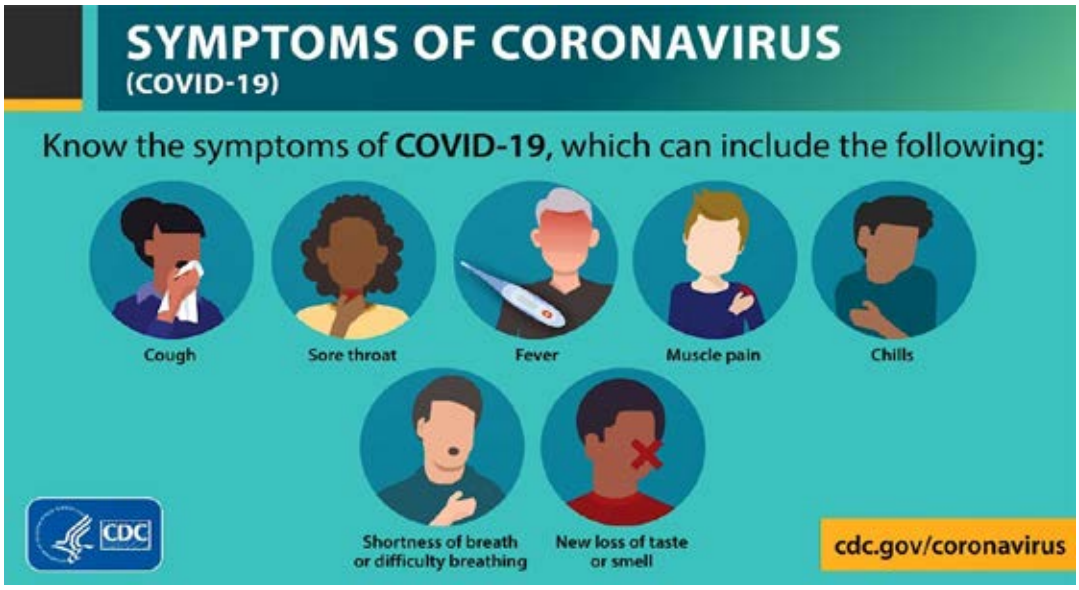
The study -- published in the online journal PLoS ONE -- is one of the biggest reviews ever conducted into COVID-19 symptoms. The researchers also acknowledge there is likely to be a large proportion of people who had the virus but did not display symptoms .

Of the 24,410 cases, the study found: 78 percent had a fever. Although this tended to vary across countries: with 72 percent of fever reported by patients in Singapore and 32 percent in Korea. 57 percent reported a cough. Again, this varied across countries, with 76 percent of patients reporting a cough in the Netherlands compared to 18 percent in Korea. 31 percent said they had suffered fatigue. 25 percent lost the ability to smell. 23 percent reported difficulty breathing. The researchers believe the variation in the prevalence of symptoms between countries is due, in part, to the way data was collected.

Of those patients who needed hospital treatment, 17 percent needed non-invasive help with their breathing; 19 percent had to be looked after in an intensive care unit, nine percent required invasive ventilation and two percent needed extra-corporeal membrane oxygenation, an artificial lung.

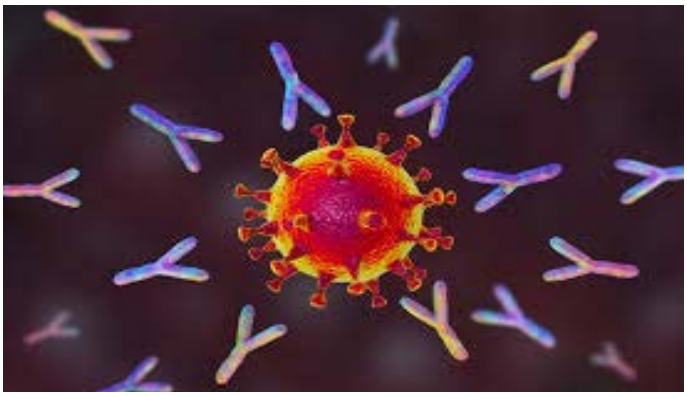
Journal Reference:

Michael C. Grant, Luke Geoghegan, Marc Arbyn, Zakaria Mohammed, Luke McGuinness, Emily L. Clarke, Ryckie G. Wade. The prevalence of symptoms in 24,410 adults infected by the novel coronavirus (SARS-CoV-2; COVID-19): A systematic review and meta-analysis of 148 studies from 9 countries. PLOS ONE, 2020; 15 (6): e0234765 DOI: 10.1371/journal.pone.0234765



Researchers identify potent antibody cocktail to treat COVID-19

June 16, 2020



Researchers at the University of Maryland School of Medicine (UMSOM) evaluated several human antibodies to determine the most potent combination to be mixed in a cocktail and used as a promising anti-viral therapy against the virus that causes COVID-19. Their research, conducted in collaboration with scientists at Regeneron Pharmaceuticals, was published in the journal Science. The study demonstrates the rapid process of isolating, testing and mass-producing antibody therapies against any infectious disease by using both genetically engineered mice and plasma from recovered COVID-19 patients.

Dr. Frieman and his UMSOM colleagues evaluated four of the most potent antibodies for to determine the potential of each one to neutralize the SARS-CoV-2 virus. They identified the two that would form the most powerful mix when used in combination.

The cocktail containing the two antibodies is now being tested in a new clinical trial sponsored by Regeneron that will investigate whether the therapy can improve the outcomes of COVID-19 patients (both those who are hospitalized and those who are not). It will also be tested as a preventive therapy in those who are healthy but at high risk of getting sick because they work in a healthcare setting or have been exposed to an infected person.

Researchers identify multiple molecules that shut down SARS-Cov-2 polymerase reaction

June 30, 2020

Researchers at Columbia Engineering and the University of Wisconsin-Madison have identified a library of molecules that shut down the SARS-CoV-2 polymerase reaction, a key step that establishes the potential of these molecules as lead compounds to be further modified for the development of COVID-19 therapeutics. Five of these molecules are already FDA-approved for use in the treatment of other viral infections including HIV/AIDS, cytomegalovirus, and hepatitis B. The new study was published on June 18, 2020, in Antiviral Research.

The Columbia team initially reasoned that the active triphosphate of the hepatitis C drug sofosbuvir and its derivative could act as a potential inhibitor of the SARS-CoV-2 polymerase based on the analysis of their molecular properties and the replication requirements of both the hepatitis C virus and coronaviruses. Led by Jingyue Ju, Samuel Ruben-Peter G. Viele Professor of Engineering, professor of chemical engineering and pharmacology, and director of the Center for Genome Technology & Biomolecular Engineering at Columbia University, they then collaborated with Robert N. Kirchdoerfer, assistant professor of biochemistry and an expert in the study of coronavirus polymerases at University of Wisconsin-Madison's Institute for Molecular Virology and the department of biochemistry.

In an earlier set of experiments testing the properties of the polymerase of the coronavirus that causes SARS, the researchers found that the triphosphate of sofosbuvir was able to terminate the virus polymerase reaction. They then demonstrated that sofosbuvir and four other nucleotide analogues (the active triphosphate forms of the HIV inhibitors Alovudine, Zidovudine, Tenofovir alafenamide, and Emtricitabine) also

inhibited the SARS-CoV-2 polymerase with different levels of efficiency.

Using the molecular insight gained in these investigations, the team devised a strategy to select 11 nucleotide analogue molecules with a variety of structural and chemical features as potential inhibitors of the polymerases of SARS-CoV and SARS-CoV-2. While all 11 molecules tested displayed incorporation, six exhibited immediate termination of the polymerase reaction, two showed delayed termination, and three did not terminate the polymerase reaction.

Prodrug medications of five of these nucleotide analogues (Cidofovir, Abacavir, Valganciclovir/Ganciclovir, Stavudine, and Entecavir) that terminate the SARS-CoV-2 polymerase reaction are FDA-approved for the treatment of other viral infections and their safety profiles are well established. Once the potency of the drugs to inhibit viral replication in cell culture is demonstrated in future investigations, then the candidate molecules and their modified forms may be evaluated for the development of potential COVID-19 therapies.

Journal Reference:

Steffen Jockusch, Chuanjuan Tao, Xiaoxu Li, Thomas K. Anderson, Minchen Chien, Shiv Kumar, James J. Russo, Robert N. Kirchdoerfer, Jingyue Ju. A library of nucleotide analogues terminate RNA synthesis catalyzed by polymerases of coronaviruses that cause SARS and COVID-19. Antiviral Research, 2020; 180: 104857 DOI: 10.1016/j.antiviral.2020.104857

New research confirms higher rates of new coronavirus in Latinx populations

June 23, 2020

In a new analysis of SARS-CoV-2, the virus that causes COVID-19, test results for nearly 38,000 people has found a positivity rate among Latinx populations about three times higher than for any other racial and ethnic group. The findings, published June 18 in the Journal of the American Medical Association (JAMA), add to evidence that there are much higher COVID-19 infection rates among U.S. minorities, particularly in Latinx communities.

Out of 37,727 adults and children tested, 6,162 tests came back positive. Of those tests, the positivity rate for Latinx was 42.6%, significantly higher than those who identified as Black (17.6%); Other (17.2%); or white (8.8%). Overall, about half of those Latinx who tested positive were women and half were men, and most (61.5%) were between the ages of 18 and 44.

The study also found that the number of positive cases in each group peaked at different times: Latinx patient cases peaked later in the study period, on May 10 at 53.4%, compared with Black patients, among whom cases peaked on April 19 (29.6%), and white patients, on April 16 (16.1%). Researchers say that as testing volume in Maryland increased for all racial and ethnic groups, positivity rates declined.

Among those who tested positive, 2,212 were admitted to a Johns Hopkins Health System hospital. The study data show that Latinx patients were less likely to be admitted to the hospital (29.1%) compared with Black (41.7%) and white (40.1%) patients. Of the patients who were hospitalized, Latinx patients

were younger (18 to 44 years); more likely to be male (64.9%); and had much lower rates of comorbidities, such as hypertension (44.8%), congestive heart failure (41.1%), pulmonary disease (20.7%) and chronic obstructive pulmonary disease (COPD) (19.2%) than Black or white patients. Eighty-two percent of Black patients and 70.4% of white patients had hypertension; 56.1% of Black patients and 56.6% of white patients had congestive heart failure; 32.9% of Black patients and 33.9% of white patients had pulmonary disease; and 27.9% of Black patients and 30% of white patients had COPD. However, more Black patients had diabetes (52.8%), compared with Latinx (32.8%) and white (29.6%) patients.

Journal Reference:
Diego A. Martinez, Jeremiah S. Hinson, Eili Y. Klein, Nathan A. Irvin, Mustapha Saheed, Kathleen R. Page, Scott R. Levin. SARS-CoV-2 Positivity Rate for Latinos in the Baltimore-Washington, DC Region. JAMA, 2020; DOI: 10.1001/jama.2020.11374

Light drinking may protect brain function

June 30, 2020

The study examined the link between alcohol consumption and changes in cognitive function over time among middle-aged and older adults in the U.S.

Regular, moderate alcohol consumption has been shown to promote heart health and some research points to a similar protective benefit for brain health. However, many of these studies were not designed to isolate the effects of alcohol on cognition or did not measure effects over time.

During the study, a total of 19,887 participants completed surveys every two years about their health and lifestyle, including questions on drinking habits. Light to moderate drinking is defined as fewer than eight drinks per week for women and 15 drinks or fewer per week among men.

These participants also had their cognitive function measured in a series of tests looking at their overall mental status, word recall and vocabulary. Their test results were combined to form a total cognitive score.

Zhang and his colleagues looked at how participants performed on these cognitive tests over the course of the study and categorized their performance as high or low trajectories, meaning their cognitive function remained high over time or began to decline.

Compared to nondrinkers, they found that those who had a drink or two a day tended to perform better on cognitive tests over time.

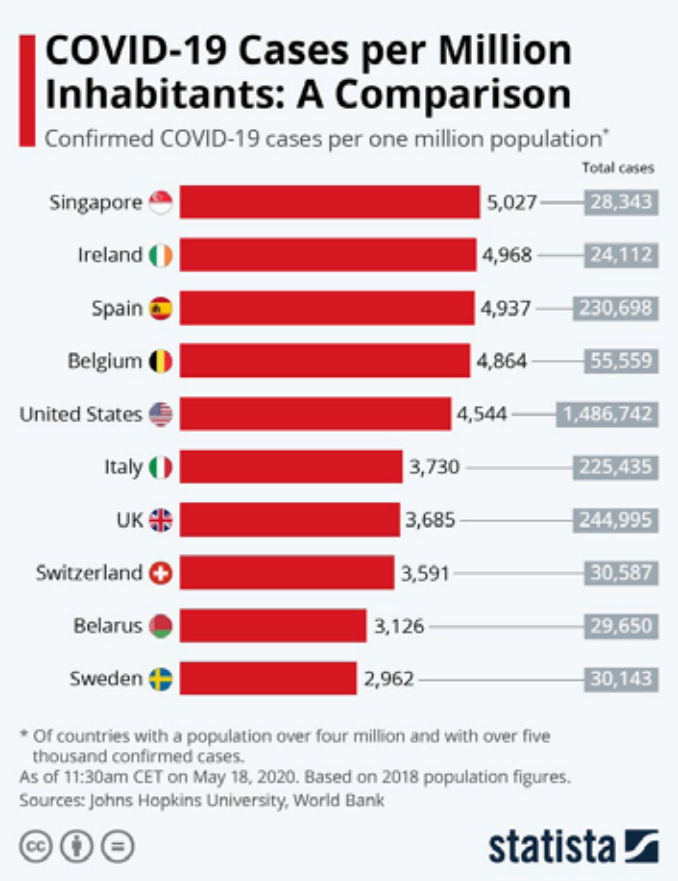
Even when other important factors known to impact cognition such as age, smoking or education level were controlled for, they saw a pattern of light drinking associated with high cognitive trajectories.

The optimal amount of drinks per week was between 10 and 14 drinks. But that doesn't mean those who drink less should start indulging more, says Zhang.

Journal Reference:
Ruiyuan Zhang, Luqi Shen, Toni Miles, Ye Shen, Jose Cordero, Yanling Qi, Lirong Liang, Changwei Li. Association of Low to Moderate Alcohol Drinking With Cognitive Functions From Middle to Older Age Among US Adults. JAMA Network Open, 2020; 3 (6): e207922 DOI: 10.1001/jamanetworkopen.2020.7922

Higher rates of severe COVID-19 found in BAME populations

June 19, 2020



The findings, published in the Journal of Public Health, suggest that the relationship between COVID-19 infection and ethnicity is complex, and requires more dedicated research to explain the factors driving these patterns.

Investigators from Queen Mary, in collaboration with the Medical Research Council Lifecourse Epidemiology Unit at the University of Southampton, used the comprehensive and unique UK Biobank cohort of over half a million people to investigate the role of a range of socioeconomic, biological, and behavioural factors in determining the ethnicity pattern of severe COVID-19. The dataset included 4,510 UK Biobank participants who were tested for COVID-19 in a hospital setting, of whom 1,326 had a positive test result.

The results demonstrate that BAME ethnicity, male sex, higher body mass index, greater material deprivation, and household overcrowding are independent risk factors for COVID-19. The higher rates of severe COVID-19 in BAME populations was not adequately explained by variations in cardiovascular disease risk, vitamin D levels, socio-economic, or behavioural factors, suggesting that other factors not included in the analysis might underlie these differences.

Journal Reference:

Steffen E Petersen, Nicholas C Harvey, Patricia B Munroe, Mark J Caulfield, Cyrus Cooper, Jackie Cooper, Mae S Bethell, Celeste McCracken, Zahra Raisi-Estabragh. Greater risk of severe COVID-19 in Black, Asian and Minority Ethnic populations is not explained by cardiometabolic, socioeconomic or behavioural factors, or by 25(OH)-vitamin D status: study of 1326 cases from the UK Biobank. Journal of Public Health, 2020; DOI: 10.1093/pubmed/fdaa095

Hamsters develop protective immunity to COVID-19 and are protected by convalescent sera

June 22, 2020

In an animal model for COVID-19 that shares important features of human disease, scientists at the University of Wisconsin-Madison, the University of Tokyo and the Icahn School of Medicine at Mount Sinai show that prior infection with the SARS-CoV-2 virus provides protection against reinfection, and treatment with convalescent serum limits virus replication in their lungs.

A study led by scientists at the University of Hong Kong, published in late March, also showed Syrian hamsters to be a good model for COVID-19-related

research. In that study, the hamsters lost weight, became lethargic, and developed other outward signs of illness.

Kawaoka's group extended this work further, demonstrating that both low and high doses of the virus, from patient samples collected in the U.S. and Japan, replicate well in the airways of juvenile hamsters (1 month old) and adults (7 to 8 months old). The virus can also infect both the upper and lower respiratory tracts.

The research team also showed that SARS-CoV-2 causes severe disease in the lungs of infected animals. This includes lesions and the kind of "ground glass" appearance often found in lung scans in human patients. Scans also revealed a region of gas in the cavity surrounding the hamster's lungs, indicating severe lung damage. Researchers observed the most severe effects within eight days after infection, and improvement by 10 days.

Overall, the researchers were able to detect virus in all of the respiratory organs of the infected hamsters within six days of infection, and also from samples collected from their brains, though these also contained portions of the olfactory bulb, which is involved in smell and may have been the source of virus in these samples. The initial dose of the virus did not affect how much of the virus researchers ultimately found in the hamster's organs.

To determine whether hamsters developed antibodies against SARS-CoV-2 that protected them from reinfection, the researchers administered another round of the virus to a number of the same animals about three weeks following initial infection and were unable to detect virus in their respiratory tracts. They did find virus in the airways of control animals not previously infected.

"The animals all possessed antibodies and did not get sick again, which suggests they developed protective immunity," says Pete Halfmann, a research professor in Kawaoka's U.S. lab. "But we still can't say how long this protection lasts."

Kawaoka's team extracted convalescent sera from previously sick hamsters and then pooled it together. They infected new hamsters with SARS-CoV-2 and then gave them this antibody-laden sera either one day or two days following infection.

The hamsters that received treatment within a day of infection had much lower amounts of infectious virus in their nasal passages and lungs than those given a mock treatment. Those that received sera on day two showed a less appreciable benefit, though they still had lower levels of virus in their respiratory organs compared to control animals.

Journal References:

1. Masaki Imai, Kiyoko Iwatsuki-Horimoto, Masato Hatta, Samantha Loeber, Peter J. Halfmann, Noriko Nakajima, Tokiko Watanabe, Michiko Ujie, Kenta Takahashi, Mutsumi Ito, Shinya Yamada, Shufang Fan, Shiho Chiba, Makoto Kuroda, Lizheng Guan, Kosuke Takada, Tammy Armbrust, Aaron Balogh, Yuri Furusawa, Moe Okuda, Hiroshi Ueki, Atsuhiro Yasuhara, Yuko Sakai-Tagawa, Tiago J. S. Lopes, Maki Kiso, Seiya Yamayoshi, Noriko Kinoshita, Norio Ohmagari, Shin-ichiro Hattori, Makoto Takeda, Hiroaki Mitsuya, Florian Krammer, Tadaki Suzuki, Yoshihiro Kawaoka. Syrian hamsters as a small animal model for SARS-CoV-2 infection and countermeasure development. Proceedings of the National Academy of Sciences, June 22, 2020; DOI: 10.1073/pnas.2009799117

2. Thomas F. Rogers, Fangzhu Zhao, Deli Huang, Nathan Beutler, Alison Burns, Wan-ting He, Oliver Limbo, Chloe Smith, Ge Song, Jordan Woehl, Linlin Yang, Robert K. Abbott, Sean Callaghan, Elijah Garcia, Jonathan Hurtado, Mara Parren, Linghang Peng, Sydney Ramirez, James Ricketts, Michael J. Ricciardi, Stephen A. Rawlings, Nicholas C. Wu, Meng Yuan, Davey M. Smith, David Nemazee, John R. Teijaro, James E. Voss, Ian A. Wilson, Raiees Andrabi, Bryan Briney, Elise Landais, Devin Sok, Joseph G. Jardine, Dennis R. Burton. Isolation of potent SARS-CoV-2 neutralizing antibodies and protection from disease in a small animal model. Science, 2020; eabc7520 DOI: 10.1126/science.abc7520

Cell 'membrane on a chip' could speed up screening of drug candidates for COVID-19

July 6, 2020

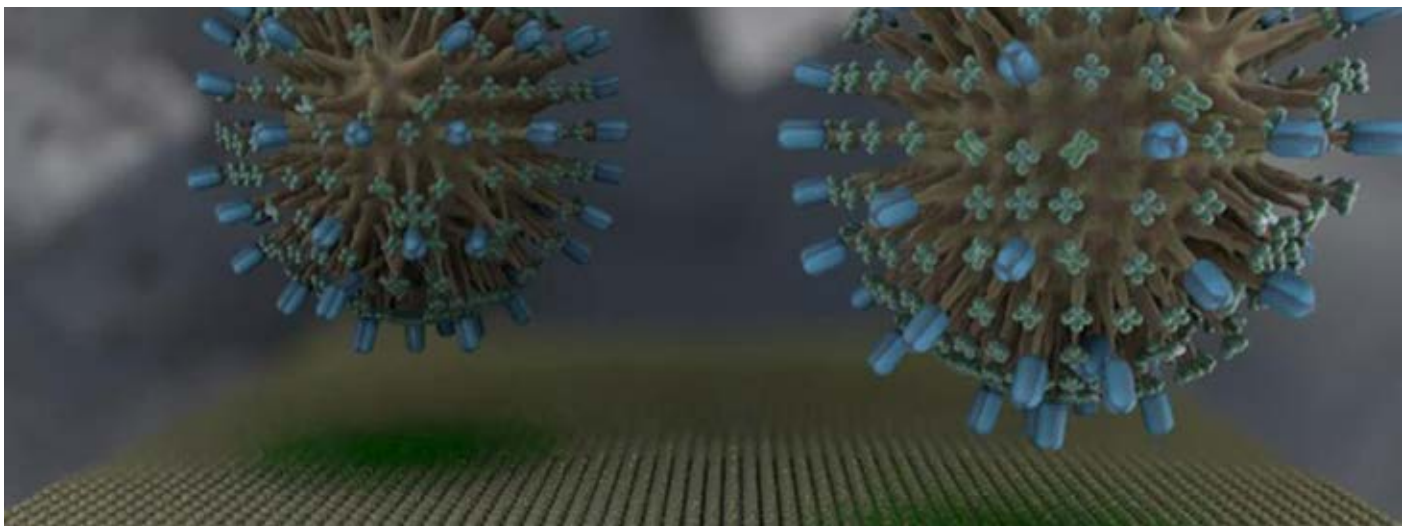
The researchers, from the University of Cambridge, Cornell University and Stanford University, say their device could mimic any cell type -- bacterial, human or even the tough cells walls of plants. Their research recently pivoted to how COVID-19 attacks human cell membranes and, more importantly, how it can be blocked.

The devices have been formed on chips while preserving the orientation and functionality of the cell membrane and have been successfully used to monitor the activity of ion channels, a class of protein in human cells which are the target of more than 60% of approved pharmaceuticals. The results are published in two recent papers in Langmuir and ACS Nano.

The device uses an electronic chip to measure any changes in an overlying membrane extracted from a cell, enabling the scientists to safely and easily understand how the cell interacts with the outside world.

The device integrates cell membranes with conducting polymer electrodes and transistors. To generate the on-chip membranes, the Cornell team first optimised a process to produce membranes from live cells and then, working with the Cambridge team, coaxed them onto polymeric electrodes in a way that preserved all of their functionality. The hydrated conducting polymers provide a more 'natural' environment for cell membranes and allows robust monitoring of membrane function.

The Stanford team optimised the polymeric electrodes for monitoring changes in the membranes. The device no longer relies on live cells that are often technically challenging to keep alive and require significant attention, and measurements can last over an extended time period.



Journal References:
Han-Yuan Liu, Anna-Maria Pappa, Aimie Pavia, Charalampos Pitsalidis, Quentin Thiburce, Alberto Salleo, Róisín M. Owens, Susan Daniel. Self-Assembly of Mammalian-Cell Membranes on Bioelectronic Devices with Functional Transmembrane Proteins. Langmuir, 2020; DOI: 10.1021/acs.langmuir.0c00804
Anna-Maria Pappa, Han-Yuan Liu, Walther Traberg-Christensen, Quentin Thiburce, Achilleas Savva, Aimie Pavia, Alberto Salleo, Susan Daniel, Róisín M. Owens. Optical and Electronic Ion Channel Monitoring from Native Human Membranes. ACS Nano, 2020; DOI: 10.1021/acsnano.0c01330

About half of health care workers positive for COVID-19 by serology have no symptoms, study finds

July 9, 2020

Among 249 front-line health care workers who cared for COVID-19 patients during the first month of the pandemic in Tennessee, 8% tested positive for COVID-19 antibodies by serology testing, suggesting they had contracted COVID-19 in the first several weeks of taking care of COVID-19 patients.

Among these health care workers with positive serology results, 42% reported no symptoms of a respiratory illness in the prior two months. This suggests that front-line health care workers are at high risk for COVID-19 and that many health care workers with the virus may not have typical symptoms of a respiratory infection.

These results were published in the journal Clinical Infectious Diseases on July 6.

In a separate study, the IVY investigators studied 350 patients across 11 medical centers in the U.S. who tested positive for COVID-19; 54% of these patients reported no close contact with another person known to have COVID-19 in the two weeks before getting sick.

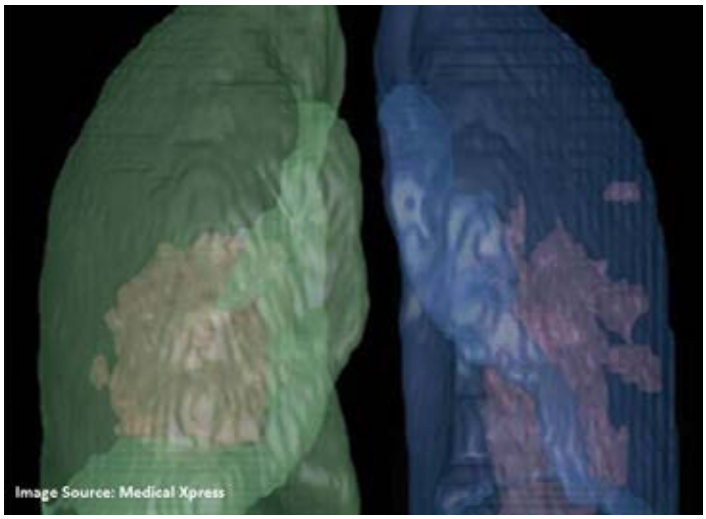
"With over half of COVID-19 patients not identifying a clear source of their infection, this study reinforces the need for practical measures to reduce the spread of the virus, such as social distancing and the use of face coverings when out in public," Self said.

Additionally, 40% of COVID-19 patients in the study remained symptomatic two weeks after a positive COVID-19 test, showing that patients with COVID-19 tend to remain ill longer than with other respiratory infections, such as influenza. The results were published by the journal Morbidity and Mortality Weekly Report on June 30.

Journal Reference:
Wesley H Self, Manish M Patel, Todd W Rice, Carlos G Grijalva, Natasha Halasa, Adrienne Baughman, Christopher J Lindsell, Michael J Ward, Ian D Jones, Natalie J Thornburg, Brandi Freeman, Sandra N Lester, Lisa Mills, Mohammed Ata Ur Rasheed, Mark W Tenforde, Leora Feldstein, H Keipp Talbot, William B Stubblefield. Seroprevalence of SARS-CoV-2 Among Frontline Healthcare Personnel During the First Month of Caring for COVID-19 Patients — Nashville, Tennessee. Clinical Infectious Diseases, 2020; DOI: 10.1093/cid/ciaa936

CT of coronavirus disease (COVID-19) versus CT of influenza virus pneumonia

July 9, 2020



A new article investigating the differences in CT findings between coronavirus disease (COVID-19) pneumonia and influenza virus pneumonia found that most lesions from COVID-19 were located in the peripheral zone and close to the pleura, whereas influenza virus was more prone to show mucoid impaction and pleural effusion. The more important role of CT during the present pandemic is in finding lesions and evaluating the effects of treatment.

A total of 97 patients (49 women, 48 men) were enrolled in this study. Of them, 52 patients (29 men, 23 women; age range, 21-73 years) had COVID-19 pneumonia; 45 patients (26 women, 19 men; age range, 15-76 years) had influenza virus pneumonia (28, influenza A; 17, influenza B). All patients had positive nucleic acid testing results for the respective viruses, as well as complete clinical data and CT images.

According to Lin and colleagues: "Between the group of patients with COVID-19 pneumonia and the group of patients with influenza virus pneumonia, the largest lesion close to the pleura (i.e., no pulmonary parenchyma between the lesion and the pleura), mucoid impaction, presence of pleural effusion, and axial distribution showed statistical difference ($p < 0.05$)."

Meanwhile, Lin et al. noted that the properties of the largest lesion, presence of ground-glass opacities, consolidation, mosaic attenuation, bronchial wall thickening, centrilobular nodules, interlobular septal thickening, crazy paving pattern, air bronchogram, unilateral or bilateral distribution, and longitudinal distribution did not show significant differences ($p > 0.05$).

Additionally, the authors observed no significant difference ($p > 0.05$) in CT score, length of the largest lesion, mean density, volume, or mass of the lesions between the two groups. Because the CT manifestations of COVID-19 and influenza virus so often overlap, "even with the characteristics evaluated using AI software," Lin et al. wrote, "no significant differences were detected."

Journal Reference:

Liaoyi Lin, Gangze Fu, Shuangli Chen, Jiejie Tao, Andan Qian, Yunjun Yang, Meihao Wang. CT Manifestations of Coronavirus Disease (COVID-19) Pneumonia and Influenza Virus Pneumonia: A Comparative Study. American Journal of Roentgenology, 2020; 1 DOI: 10.2214/AJR.20.23304

Global COVID-19 registry finds strokes associated with COVID-19 are more severe,

July 10, 2020

In "Characteristics and Outcomes in Patients with COVID-19 and Acute Ischemic Stroke: The Global COVID-19 Stroke Registry," researchers analyzed data on patients with COVID-19 and AIS treated at

28 health care centers in 16 countries this year and compared them to patients without COVID-19 from the Acute Stroke Registry and Analysis of Lausanne (ASTRAL) Registry, from 2003 to 2019. Researchers sought to determine the clinical characteristics and outcomes of patients with COVID-19 and AIS.

Between January 27, 2020 to May 19, 2020, there were 174 patients hospitalized with COVID-19 and AIS. Each COVID-19 patient with AIS was matched and compared to a non-COVID-19 AIS patient based on a set of pre-specified factors including age, gender and stroke risk factors (hypertension, diabetes, atrial fibrillation, coronary artery disease, heart failure, cancer, previous stroke, smoking, obesity and dyslipidemia). The final analysis included 330 patients total.

In both patient groups, stroke severity was estimated with the National Institute of Health Stroke Scale (NIHSS), and stroke outcome was assessed by the modified Rankin score (mRS). When AIS patients with COVID-19 were compared to non-COVID-19 patients:

COVID-19 patients had more severe strokes (median NIHSS score of 10 vs. 6, respectively); COVID-19 patients had higher risk for severe disability following stroke (median mRS score 4 vs. 2, respectively); and COVID-19 patients were more likely to die of AIS. The researchers noted there are several potential explanations for the relationship between COVID-19-associated strokes and increased stroke severity: "The increased stroke severity at admission in COVID-19-associated stroke patients compared to the non-COVID-19 cohort may explain the worse outcomes. The broad, multi-system complications of COVID-19, including acute respiratory distress syndrome, cardiac arrhythmias, acute cardiac injury, shock, pulmonary embolism, cytokine release syndrome and secondary infection, probably contribute further to the worse outcomes including higher mortality in these patients. ... The association highlights the urgent need for studies aiming to uncover the underlying mechanisms and is relevant for prehospital stroke awareness and in-hospital acute stroke pathways during the current and future pandemics."

Journal Reference:

George Ntaios, Patrik Michel, Georgios Georgiopoulos, Yutao Guo, Wencheng Li, Jing Xiong, Patricia Calleja, Fernando Ostos, Guillermo González-Ortega, Blanca Fuentes, María Alonso de Leciñana, Exuperio Díez-Tejedor, Sebastian García-Madrona, Jaime Masjuan, Alicia DeFelipe, Guillaume Turc, Bruno Gonçalves, Valerie Domigo, Gheorghe-Andrei Dan, Roxana Vezeteu, Hanne Christensen, Louisa Marguerite Christensen, Per Meden, Lejla Hajdarevic, Angela Rodriguez-Lopez, Fernando Díaz-Otero, Andrés García-Pastor, Antonio Gil-Nuñez, Errikos Maslias, Davide Strambo, David J. Werring, Arvind Chandratheva, Laura Benjamin, Robert Simister, Richard Perry, Rahma Beyrouti, Pascal Jabbour, Ahmad Sweid, Stavropoula Tjoumakaris, Elisa Cuadrado-Godia, Ana Rodríguez Campello, Jaume Roquer, Tiago Moreira, Michael V. Mazya, Fabio Bandini, Karl Matz, Helle K. Iversen, Alejandra González-Duarte, Cristina Tiu, Julia Ferrari, Milan R. Vosko, Helmut J.F. Salzer, Bernd Lamprecht, Martin W. Dünser, Carlo W. Cereda, Ángel Basilio Corredor Quintero, Eleni Korompoki, Eduardo Soriano-Navarro, Luis Enrique Soto-Ramírez, Paulo F. Castañeda-Méndez, Daniela Bay-Sansores, Antonio Arauz, Vanessa Cano-Nigenda, Espen Saxhaug Kristoffersen, Marjaana Tiainen, Daniel Strbian, Jukka Putaala, Gregory Y.H. Lip. Characteristics and Outcomes in Patients With COVID-19 and Acute Ischemic Stroke. Stroke, 2020; DOI: 10.1161/STROKEAHA.120.031208

One more new study supports remdesivir as COVID-19 treatment

July 9, 2020

This week researchers at Vanderbilt University Medical Center (VUMC), the University of North Carolina at Chapel Hill and Gilead Sciences reported that remdesivir potently inhibited SARS-CoV-2, the virus which causes COVID-19, in human lung cell cultures and that it improved lung function in mice infected with the virus.

They were the first to perform detailed studies to demonstrate that the drug, which was developed by Gilead Sciences to combat hepatitis C and respiratory syncytial virus, and later the Ebola virus, also showed broad and highly potent activity against coronaviruses in laboratory tests.

The current findings, reported this week in the journal Cell Reports, provide "the first rigorous demonstration of potent inhibition of SARS-CoV-2 in continuous and primary human lung cultures." The study is also the first to suggest that remdesivir can block the virus in a mouse model.

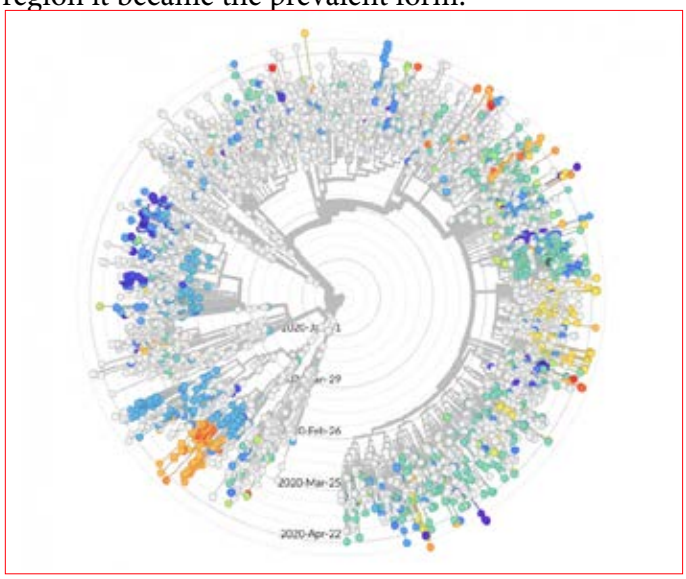
Ongoing clinical trials will determine precisely how much it benefits patients in different stages of COVID-19 disease.

Journal Reference:
Andrea J. Pruijssers, Amelia S. George, Alexandra Schäfer, Sarah R. Leist, Lisa E. Gralinksi, Kenneth H. Dinnon, Boyd L. Yount, Maria L. Agostini, Laura J. Stevens, James D. Chappell, Xiaotao Lu, Tia M. Hughes, Kendra Gully, David R. Martinez, Ariane J. Brown, Rachel L. Graham, Jason K. Perry, Venice Du Pont, Jared Pitts, Bin Ma, Darius Babusis, Eisuke Murakami, Joy Y. Feng, John P. Bilello, Danielle P. Porter, Tomas Cihlar, Ralph S. Baric, Mark R. Denison, Timothy P. Sheahan. Remdesivir inhibits SARS-CoV-2 in human lung cells and chimeric SARS-CoV expressing the SARS-CoV-2 RNA polymerase in mice.. Cell Reports, 2020; 107940 DOI: 10.1016/j.celrep.2020.107940

Variant of COVID-19-causing virus

July 2, 2020

Bette Korber, a theoretical biologist at Los Alamos National Laboratory and lead author of the study, noted, "The D614G variant first came to our attention in early April, as we had observed a strikingly repetitive pattern. All over the world, even when local epidemics had many cases of the original form circulating, soon after the D614G variant was introduced into a region it became the prevalent form."



Geographic information from samples from the GISAID COVID-19 viral sequence database enabled tracking of this highly recurrent pattern, a shift in the viral population from the original form to the D614G variant. This occurred at every geographic level: country, subcountry, county, and city.

Two independent lines of experimental evidence that support these initial results are included in today's paper. These additional experiments, led by Professor Erica Ollmann Saphire, Ph.D., at the La Jolla Institute,

and by Professor David Montefiori, Ph.D., at Duke University, showed that the D614G change increases the virus's infectivity in the laboratory. These new experiments, as well as more extensive sequence and clinical data and improved statistical models, are presented in the Cell paper. More in vivo work remains to be done to determine the full implications of the change.

The SARS-CoV-2 virus has a low mutation rate overall (much lower than the viruses that cause influenza and HIV-AIDS). The D614G variant appears as part of a set of four linked mutations that appear to have arisen once and then moved together around the world as a consistent set of variations.

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Physicians give first comprehensive review of COVID-19's effects outside the lung

July 10, 2020

"Physicians need to think of COVID-19 as a multisystem disease," Gupta says. "There's a lot of news about clotting but it's also important to understand that a substantial proportion of these patients suffer kidney, heart, and brain damage, and physicians need to treat those conditions along with the respiratory disease."

"In just the first few weeks of the pandemic, we were seeing a lot of thrombotic complications, more than what we would have anticipated from experience with other viral illnesses," says Sehgal, "and they can have profound consequences on the patient."

Scientists think these clotting complications may stem from the virus's attack on cells that line the blood vessels. When the virus attacks blood vessel cells, inflammation increases, and blood begins to form clots, big and small. These blood clots can travel all over the body and wreak havoc on organs, perpetuating a vicious cycle of thromboinflammation.

To combat clotting and its damaging effects, clinicians at Columbia, many of whom are co-authors on this review, are conducting a randomized clinical trial to investigate the optimal dose and timing of anticoagulation drugs in critically ill patients with COVID-19.

The untempered inflammation can also overstimulate the immune system, and though doctors initially shied away from using steroids to globally suppress the immune system, a recent clinical trial has found that at least one steroid, dexamethasone, reduced deaths in ventilated patients by one-third. Randomized clinical trials are underway to target specific components of thromboinflammation and the immune system, such as interleukin-6 signaling.

Clots can cause heart attacks, but the virus attacks the heart in other ways, one author says.

Another surprising finding was the high proportion of COVID-19 patients in the ICU with acute kidney damage.

Neurological symptoms, including headache, dizziness, fatigue, and loss of smell, may occur in about a third of patients.

More concerning, strokes caused by blood clots occur in up to 6% of severe cases and delirium in 8% to 9%.

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Researchers find rise in broken heart syndrome during COVID-19 pandemic

July 9, 2020

Cleveland Clinic researchers have found a significant increase in patients experiencing stress cardiomyopathy, also known as broken heart syndrome, during the COVID-19 pandemic.

Stress cardiomyopathy occurs in response to physical or emotional distress and causes dysfunction or failure in the heart muscle.

Patients typically experience symptoms similar to a heart attack, such as chest pain and shortness of breath, but usually do not have acutely blocked coronary arteries. The left ventricle of the heart, however, may show enlargement.

Other symptoms include irregular heartbeat, fainting, low blood pressure and cardiogenic shock (an inability of the heart to pump enough blood to meet the body's demands due to the impact of stress hormones on the cells of the heart).

The causes of stress cardiomyopathy, also known as Takotsubo cardiomyopathy, are not fully understood. However, physicians believe that a person's reaction to physically or emotionally stressful events causes a release of stress hormones that temporarily reduce the heart's ability to pump -- causing it to contract less efficiently or irregularly instead of in a steady, normal pattern.

For the study, cardiologists looked at 258 patients coming into Cleveland Clinic and Cleveland Clinic Akron General with heart symptoms known as acute coronary syndrome (ACS) between March 1 and April 30th and compared them with four control groups of ACS patients prior to the pandemic.

They found a significant increase in patients diagnosed with stress cardiomyopathy, reaching 7.8% compared with pre-pandemic incidence of 1.7%.

Patients with stress cardiomyopathy during the COVID-19 pandemic had a longer length of hospital stay compared with those hospitalized in the pre-pandemic period; however, there was no significant difference in mortality between the groups. All of the patients diagnosed with stress cardiomyopathy tested negative for COVID-19.

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