

Monitoring International Trends

August 2020

The NBA monitors international developments that may influence the management of blood and blood products in Australia. Our focus is on:

- Potential new product developments and applications;
- Global regulatory and blood practice trends;
- Events that may have an impact on global supply, demand and pricing, such as changes in company structure, capacity, organisation and ownership; and
- Other emerging risks that could put financial or other pressures on the Australian sector.

Of particular interest:

1. The US Food and Drug Administration declined to approve BioMarin's gene therapy for haemophilia A (page 3)
2. A study found that restrictive transfusion strategies are safe for extremely low birth-weight infants (page 3)
3. Experiences in using convalescent plasma to treat COVID-19 are outlined (page 15).

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1. Treating haemophilia, sickle cell disease and Kawasaki disease

- Researchers at the Wake Forest Institute for Regenerative Medicine reported that they have developed an optimized cellular platform for **delivering Factor VIII to patients with haemophilia A**.¹
- A report by **Australia's Haemophilia Federation** says that **people with bleeding disorders are living longer** than in the past, and this means new strategies are needed for ongoing care.²
- **Roche** will begin a **Phase III trial of its haemophilia A gene therapy in 2021**.³
- **Novo Nordisk** announced that the clinical trials in the concizumab Phase III programme (explorer 6, 7 and 8) are being resumed. These are investigating **subcutaneous concizumab prophylaxis treatment in haemophilia A and B patients irrespective of inhibitor status**. The trials were paused in March 2020 due to the occurrence of non-fatal thrombotic events in three patients. New safety measures and guidelines, based on analysis of all available data, have been agreed with the FDA and the clinical hold has been lifted.⁴
- The US **FDA declined to approve BioMarin's haemophilia A gene therapy**, valoctocogene roxaparvovec (Valrox) over concerns about its durability, with factor VIII levels falling after 12 to 18 months and a possible need for repeat dosing.⁵
- The [Scottish Medicines Consortium](#) has approved the use of [Xromi](#) (hydroxycarbamide)⁶ in children with **sickle cell disease**.⁷
- Researchers reported that in **Kawasaki disease** “coronary artery complications can be reduced or prevented in many severe cases with early intensification of standard treatment such as use of a combination of intravenous immunoglobulin and corticosteroids”⁸. This confirmed common practice for many clinicians.

2. Patient blood management and blood safety

- A study of Australian **patients with possible transient ischaemic attack and minor stroke** found that **fewer than 10 per cent were taking anticoagulant therapy** at the time.⁹
- Researchers in Victoria have been working towards a **novel antithrombotic agent that acts selectively on platelets to inhibit thrombosis but avoids bleeding complications**.¹⁰

¹ <https://www.news-medical.net/news/20200728/A-new-cell-based-gene-therapy-approach-to-better-treat-patients-with-hemophilia-A.aspx>

² <https://www.haemophilia.org.au/HFA/media/Documents/Ageing/HFA-Getting-older-report-full.pdf> and <https://thelimbic.com/haematology/older-age-unknown-territory-for-patients-with-bleeding-disorders/>

³ <https://endpts.com/playing-catch-up-roche-outlines-plans-for-a-phiii-hemophilia-a-program-next-year/>

⁴ <https://www.fiercebiotech.com/biotech/novo-nordisk-s-concizumab-trials-can-resume-after-safety-trial-halt>

⁵ <https://www.fiercebiotech.com/biotech/fda-gets-out-its-red-pen-again-rejecting-biomarin-s-gene-therapy-valrox-amid-durability> and

<https://www.biopharmadive.com/news/hemophilia-gene-therapy-cure-biomarin/583105/> and

<https://www.biopharmadive.com/news/fda-rejection-biomarin-gilead-roctavian-filgotinib/583776/>

⁶ a liquid form of [hydroxyurea](#)

⁷ <https://sicklecellanemianews.com/2020/08/13/sickle-cell-treatment-xromi-approved-in-scotland/>

⁸ <https://www.healio.com/news/cardiology/20200819/combo-therapy-reduces-risk-for-abnormalities-treatment-failure-in-kawasaki-disease>

⁹ <https://thelimbic.com/haematology/tia-often-follows-suboptimal-anticoagulant-therapy-study/>

¹⁰ <https://stm.sciencemag.org/content/12/553/eaar8430> and <https://thelimbic.com/haematology/novel-selective-antithrombotic-agents-may-avoid-bleeding-complications/>

- The Effects of Transfusion Thresholds on Neurocognitive Outcomes of Extremely Low-Birth-Weight Infants (ETTNO) trial concluded that **restrictive transfusion strategies are safe for extremely low birth-weight infants**.¹¹
- **AABB** has requested advice from the **US Food and Drug Administration on whether potential blood donors who have received an investigational COVID-19 vaccine are eligible to donate**.
- **Cerus has shipped 7.5 million INTERCEPT Blood Systems disposable kits** since they were launched in 2015.¹²
- The FDA issued an **emergency use authorisation to CytoSorbents for its blood purification technology**, permitting its use in COVID-19 patients 18 years of age or more, hospitalised in the intensive care unit for respiratory failure. CytoSorb reduces cytokine storm and inflammatory responses.¹³
- Tasso is developing devices which enable people to **collect their own blood** to send for testing.¹⁴

3. Clinical experience with COVID-19

Respiratory and cardiovascular concerns

- Researchers are finding six months into the pandemic that even people whose disease appeared to be mild may have **damaged cardiovascular muscles and continuing inflammation**.¹⁵
- Observational studies have not necessarily all led to the same recommendations concerning the impact of clot prevention on mortality from COVID-19, and the matter needs to be resolved through randomized controlled trials.¹⁶ Now the US National Institutes of Health has announced the [ACTIV-4 set of adaptive platform clinical trials to evaluate safety and effectiveness of varying types of antithrombotics for adult COVID-19 patients](#).
- A small observational study showed **prothrombotic autoantibodies elevated in COVID-19** and linked to development of thrombosis.¹⁷
- Researchers have said that: "Physicians should lower their threshold of suspicion for **large vessel stroke in patients with COVID-19** who present with acute neurologic symptoms".¹⁸
- A case report from the US reminds physicians that **COVID-19 can lead to fatal pulmonary fibrosis**, which is "a possibility in recovering patients recovering from COVID-19 who experience continued shortness of breath".¹⁹
- Researchers reported on a particular approach to **extracorporeal membrane oxygenation (ECMO)** in COVID-19 patients which they said had a high success rate at two tertiary medical centres in Chicago.²⁰

¹¹ <https://transfusionnews.com/2020/08/19/restrictive-transfusion-strategies-safe-for-extremely-low-birth-weight-infants/>

¹² <https://seekingalpha.com/news/3602886-cerus-announces-sales-milestone-for-intercept-system>

¹³ <https://www.fdanews.com/articles/198630-fda-authorizes-cytosorbents-blood-purification-technology-for-emergency-use>

¹⁴ <http://www.finsmes.com/2020/07/tasso-raises-17m-in-series-a-financing.html>

¹⁵ <https://newatlas.com/health-wellbeing/heart-damage-recovered-covid19-patients-coronavirus/> and <https://www.medpagetoday.com/infectiousdisease/covid19/87758>

¹⁶ <https://www.medpagetoday.com/infectiousdisease/covid19/87792>

¹⁷ <https://www.medpagetoday.com/infectiousdisease/covid19/88044>

¹⁸ <https://www.medpagetoday.org/infectiousdisease/covid19/88031and>

<https://www.ajronline.org/doi/full/10.2214/AJR.20.23847>

¹⁹ <https://www.medscape.com/viewarticle/935302>

²⁰ <https://www.medpagetoday.com/infectiousdisease/covid19/88018>

- In cases of respiratory failure as can occur with COVID-19, **breathing oxygen-enriched air may save patients' lives, but researchers say it may also damage their lungs** because of an oxygen-induced shift in the balance of bacterial species in the lung.²¹

Neurological Symptoms

- Researchers suggest that [Myasthenia gravis](#) should be added to the growing list of potential neurological consequences of COVID-19 infection.²²

COVID-19 in paediatric patients

- In the US, by 15 July there had been 342 reported cases of [multisystem inflammatory syndrome in children](#) with a disproportionate number reported in children who were Black, Hispanic or Latino.²³
- A study found that children aged less than five carry higher amounts of SARS-CoV-2 RNA in their nasopharynx compared with both older children, adolescents and adults.²⁴
- A study of almost 600 people at a Georgia camp found that the attack rate of COVID-19 was 56 per cent for staff, 51 per cent for children aged 6 to 10, 44 per cent for those aged 11 to 17, and 33 per cent for those aged 18 to 21.²⁵
- The US National Institutes of Health is offering up to \$US 20 million to selected **research proposals developing ways to identify children at high risk of developing multisystem inflammatory syndrome.**²⁶
- The US Centers for Disease Control and Prevention on 7 August published a report showing that although **hospitalisation rates for children with COVID-19 remained low, they had been increasing** and that a similar proportion of hospitalised children needed intensive care as adults.²⁷
- **Evidence of SARS-CoV-2 was found in cardiac tissue of a child who died of heart failure**, having presented with [myocarditis](#) and exhibited multisystem inflammatory syndrome (MIS-C) related to COVID-19.²⁸

Other issues in clinical management

- Autopsies have found patients who tested positive for SARS-CoV-2 in the mastoid or middle ear which suggest that **droplet precautions for healthcare professionals during ear surgery** are necessary when patients have COVID-19.²⁹

²¹ <https://www.the-scientist.com/news-opinion/disturbed-microbes-contribute-to-lung-damage-from-oxygen-treatment-67818> and <https://stm.sciencemag.org/content/12/556/eaau9959>

²² <https://www.medscape.com/viewarticle/935985>

²³ <https://www.healio.com/news/pediatrics/20200722/syndrome-linked-to-covid19-disproportionately-affects-black-hispanic-and-latino-children>

²⁴ <https://www.healio.com/news/pediatrics/20200731/young-children-potentially-important-drivers-of-sarscov2>

²⁵ <https://www.medpagetoday.com/infectiousdisease/covid19/87849>

²⁶ <https://www.nih.gov/news-events/news-releases/nih-funded-project-seeks-identify-children-risk-mis-c>

²⁷ <https://www.physiciansbriefing.com/pediatrics-15/coronavirus-1008/cdc-pediatric-hospitalizations-for-covid-19-increasing-760241.html> and <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e3.htm>

²⁸ <https://www.medscape.com/viewarticle/936244>

²⁹ <https://www.medpagetoday.com/infectiousdisease/covid19/87720>

- The US Centers for Disease Control and Prevention reported that a survey found a third of **people infected with COVID-19 said their symptoms were with them for some weeks**.³⁰
- A study in 143 **patients who had recovered from COVID-19 reported at least one persistent symptom in 90 per cent of them**.³¹
- A virtual meeting of the [International Association for Chronic Fatigue Syndrome / Myalgic Encephalomyelitis](#) (IACFS/ME), allocated its first session to research on the **extent to which COVID-19 survivors subsequently meet ME/CFS criteria**, and to examining underlying mechanisms.³²
- Researchers have said that “although **acute kidney injury** is seen in a substantial minority of patients with severe COVID-19³³, no evidence of the presence of SARS-CoV-2 was found in kidney biopsies from a small series of such patients.”³⁴
- The Alzheimer's Association announced a global study of the **impact of COVID-19 on the brain**. It will be led by researchers at the Alzheimer's Association and the University of Texas Health San Antonio.³⁵
- Researchers say **skin eruptions** could identify patients with severe COVID-19 **at risk of developing coagulopathies**.³⁶
- Scientists have suggested that the **severity of COVID-19** in individual patients may be **influenced by the complement system and coagulation dysfunction**.³⁷
- Researchers say that **embryos may be susceptible to the SARS-CoV-2 virus** if the mother becomes ill, and this could adversely affect the outcome of the pregnancy.³⁸
- **Hair loss** is being reported as an apparent consequence of some COVID-19 infections, possibly because of stress.³⁹
- The US National Institute of Biomedical Imaging and Bioengineering plans to develop **new diagnostics and machine learning algorithms** to assess the severity of an infection and estimate the patient's responses to different treatments. The Institute's Director, Bruce Tromberg, said: “This program is particularly exciting because it will give us new ways to rapidly turn scientific findings into practical imaging tools that benefit COVID-19 patients”.⁴⁰
- A systematic review and meta-analysis found that, in hospitalised patients with COVID-19, **being a modest smoker increased the chance of severe disease**.⁴¹

³⁰ <https://www.9news.com.au/world/coronavirus-news-covid-19-patients-feel-symptoms-for-weeks/86c48ae9-8091-4b13-87d4-8c1ab492629c>

³¹ <https://jamanetwork.com/journals/jama/fullarticle/2768351> and <https://www.healio.com/news/infectious-disease/20200813/almost-90-of-recovered-covid19-patients-report-persistent-symptoms>

³² <https://www.medscape.com/viewarticle/936252>

³³ <https://www.medscape.com/viewarticle/935165> and <https://link.springer.com/article/10.1007/s40620-020-00789-y>

³⁴ <https://www.medscape.com/viewarticle/934435>

³⁵ <https://www.medscape.com/viewarticle/934985>

³⁶ <https://www.medscape.com/viewarticle/935216?>

³⁷ <https://www.genengnews.com/news/covid-19-severity-linked-to-coagulation-dysfunction-and-ancient-branch-of-immune-system/>

³⁸ <https://www.labonline.com.au/content/life-scientist/news/embryos-could-be-susceptible-to-covid-19-820976829> and <https://royalsocietypublishing.org/doi/10.1098/rsob.200162>

³⁹ <https://www.medscape.com/viewarticle/934820>

⁴⁰ <https://www.fiercebiotech.com/medtech/nih-launches-imaging-ai-collaboration-for-covid-19-and-beyond>

⁴¹ <https://www.healio.com/news/primary-care/20200731/smoking-modestly-increases-risk-for-severe-covid19-research-now-shows>

- A very small single-centre study in Brooklyn found **children who tested positive for SARS-CoV-2** had no respiratory illness.⁴²
- Medical staff in Bengal report that **COVID-dengue co-infections** are challenging to deal with.⁴³
- The UK National Diabetes COVID-19 Response Group has issued **guidance on glucose management in COVID-19 patients on dexamethasone therapy**.⁴⁴
- New research⁴⁵ found rates of [thyrotoxicosis](#) to be significantly higher among patients who are critically ill with COVID-19 than among patients who are critically ill but who do not have COVID-19. Researchers suggested an atypical form of [thyroiditis](#) related to infection with the SARS-CoV-2 virus. The researchers did not find that thyroid disorders increase the risk of developing COVID-19. Angela Leung⁴⁶ said: "This study joins at least six others that have reported a **clinical presentation resembling subacute thyroiditis in critically ill patients with COVID-19**".⁴⁷

COVID-19 antibodies

- A group of researchers found that antibody levels in people with mild COVID-19 had a **half-life of about five weeks**.⁴⁸ However, some scientists say they have seen signs of **strong and lasting immunity** in people who have been infected with SARS-CoV-2.⁴⁹ Historic studies on **milder coronaviruses than SARS-CoV-2** found **human immune systems forgot them quickly**.⁵⁰
- A team at the University of Hong Kong has reported on a **33-year-old man they claim has had COVID-19 twice this year**, with symptoms the first time but not the second.⁵¹ Similar reports have come from Belgium and the Netherlands.
- Researchers reported that **patients who survived COVID-19 and those who did not** demonstrated **antibody responses against different SARS-CoV-2 proteins**.⁵² A study in 22 hospitalised patients found "antibody responses against SARS-CoV-2's spike protein were stronger among COVID-19 survivors, whereas antibody responses targeting the virus's nucleocapsid protein were elevated in patients who died".⁵³
- Interest continues in laboratory-made **monoclonal antibodies** which could neutralize SARS-CoV-2 and serve as an **alternative to a vaccine**; they could also be used to **treat COVID-19**.⁵⁴ The US Department of Justice has written to Eli Lilly,

⁴² <https://www.medscape.com/viewarticle/935398>

⁴³ <https://theprint.in/health/covid-dengue-co-infections-are-bengals-new-challenge-as-doctors-say-treatment-very-tricky/477020/>

⁴⁴ <https://www.medscape.com/viewarticle/935348>

⁴⁵ <https://www.medscape.com/viewarticle/935872>

⁴⁶ of the Division of Endocrinology, Diabetes, and Metabolism, Department of Medicine, David Geffen School of Medicine, UCLA at Los Angeles

⁴⁷ <https://www.medscape.com/viewarticle/935872>

⁴⁸ <https://www.medscape.com/viewarticle/934474>

⁴⁹ <https://www.nytimes.com/2020/08/16/world/coronavirus-covid-19.html>

⁵⁰ <https://www.the-scientist.com/news-opinion/cold-causing-coronaviruses-dont-seem-to-confer-lasting-immunity-67832>

⁵¹ <https://7news.com.au/lifestyle/health-wellbeing/hong-kong-man-tests-positive-to-coronavirus-months-after-first-diagnosis--c-1262972> and

<https://www.medscape.com/viewarticle/936216>

⁵² <https://www.genengnews.com/news/covid-19-patients-exhibit-early-antibody-signatures-potentially-predictive-of-death-or-recovery/>

⁵³ [https://www.cell.com/immunity/fulltext/S1074-7613\(20\)30327-7#%20](https://www.cell.com/immunity/fulltext/S1074-7613(20)30327-7#%20) and <https://www.the-scientist.com/news-opinion/differences-in-antibody-responses-linked-to-covid-19-outcomes-67836>

⁵⁴ <https://www.nih.gov/news-events/nih-research-matters/potent-neutralizing-antibodies-target-new-regions-coronavirus-spike> and <https://www.reuters.com/article/us-health-coronavirus-treatments-antibod/next-big-covid-19-treatment-may-be-manufactured-antibodies-idUSKBN24Z1DY>

Amgen, AbCellera Biologics, AstraZeneca, Roche Holding's Genentech unit and GlaxoSmithKline, saying that demand for monoclonal antibodies targeting COVID-19 is likely to exceed what one firm could produce on its own, and that it will not block companies from **sharing information to help scale up to manufacture antibody treatments**.⁵⁵

- Researchers at Columbia University harvested **neutralizing antibodies** from five patients with severe COVID-19, chose 19 that aggressively killed SARS-CoV-2 *in vitro*, and say their **antibody cocktail** could be powerful in treating or preventing COVID-19.⁵⁶
- Eli Lilly began a Phase III trial of antibody LY-CoV555, to see if it **prevents residents and staff of nursing homes from developing COVID-19**.⁵⁷ This antibody from Lilly's collaboration with AbCellera is a neutralizing antibody against SARS-CoV-2.⁵⁸
- **AstraZeneca began a Phase I clinical trial of its monoclonal antibody combination** against COVID-19. The company will test multiple intramuscular and intravenous doses of AZD7442, against a placebo in healthy adults.⁵⁹
- Swiss company **Memo Therapeutics AG (MTx)** and **Northway Biotechpharma**, a biopharmaceutical contract development and manufacturing organization, announced a **partnership to manufacture MTx's therapeutic COVID-19 antibody candidate** in a four-month fast-track process.⁶⁰
- **Germany's Robert Koch Institute** reported that recent blood testing of 2203 adults in Kupferzell (population 6000) showed that 7.7 per cent had antibodies for the coronavirus, while only 100 people had tested positive for the coronavirus with a swab test. The study's authors say **more people must have been exposed to SARS-CoV-2 than previously thought**.⁶¹
- **Qiagen will launch a new digital test (for COVID-19 antibodies)** that can run multiple samples simultaneously on a portable device, with results in approximately 10 minutes.⁶²

⁵⁵ <https://www.reuters.com/article/us-health-coronavirus-pharmaceuticals/u-s-clears-way-for-drugmakers-to-share-covid-antibody-capacity-idUSKCN24O30E> and <https://www.fiercepharma.com/manufacturing/az-lilly-amgen-and-more-score-justice-department-nod-for-monoclonal-antibody-scale-up>

⁵⁶ <https://www.fiercebiotech.com/research/columbia-team-identifies-potent-antibody-cocktail-for-covid-19>

⁵⁷ <https://www.fiercebiotech.com/biotech/lilly-starts-phase-3-test-covid-19-antibody-nursing-homes> and <https://www.prnewswire.com/news-releases/lilly-initiates-phase-3-trial-of-ly-cov555-for-prevention-of-covid-19-at-long-term-care-facilities-in-partnership-with-the-national-institute-of-allergy-and-infectious-diseases-niaid-301104445.html>

⁵⁸ <https://pipelinereview.com/index.php/2020080375465/Antibodies/Lilly-Initiates-Phase-3-Trial-of-LY-CoV555-for-Prevention-of-COVID-19-at-Long-Term-Care-Facilities-in-Partnership-with-the-National-Institute-of-Allergy-and-Infectious-Disease.html>

⁵⁹ <https://www.fiercebiotech.com/biotech/astrazeneca-starts-phase-1-antibodies-could-protect-against-covid-19-for-6-months> and <https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/phase-1-clinical-trial-initiated-for-monoclonal-antibody-combination-for-the-prevention-and-treatment-of-covid-19.html>

⁶⁰ <https://pipelinereview.com/index.php/2020081575577/Antibodies/Memo-Therapeutics-AG-and-Northway-Biotechpharma-Collaborate-on-the-Fast-Track-Manufacturing-of-a-SARS-CoV-2-Neutralizing-Antibody-for-the-Therapy-of-COVID-19.html>

⁶¹ <https://www.9news.com.au/world/coronavirus-world-news-uk-secures-90-million-vaccine-doses-germany-hotspot-numbers-four-times-previous-estimate/0de692b5-11e5-4af3-ae3a-cda3e10c37c4>

⁶² <https://www.fiercebiotech.com/medtech/qiagen-to-launch-digital-portable-test-for-covid-19-antibodies-preordering-900k-for-u-s>

- **Vir Biotechnology** is initiating a mid-to-late stage trial of VIR-7831 a **monoclonal antibody** that binds itself to the SARS-CoV-2 live virus and neutralizes it.⁶³
- With expensive monoclonal antibody drugs seen as a stopgap while the world awaits a COVID-19 vaccine, there are **calls for worldwide antibody access via partnerships and technologies so generic drug-makers could manufacture them.**⁶⁴

4. Developing vaccines for COVID-19

Vaccine trials

- There are currently **200 COVID-19 vaccine candidates globally**, with only **22 in clinical trials** so far.⁶⁵ WHO said researchers are making “good progress” on vaccines but their **first use** cannot be expected till **early 2021.**⁶⁶
- **Moderna** announced its contract with the US Biomedical Advanced Research and Development Authority (BARDA) had been modified with a further commitment of up to \$US 472 million to support late stage clinical development of its mRNA vaccine candidate (mRNA-1273). This includes an expanded Phase III study.⁶⁷ This COVE (Coronavirus Efficacy) study is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) and BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the US Department of Health and Human Services.⁶⁸
- Trial data for the **University of Oxford and AstraZeneca's possible coronavirus vaccine** will be provided to regulators when the project's scientists are satisfied the product is safe and effective. While that could be this year, Andrew Pollard, director of the Oxford Vaccine Group, said corners cannot be cut to speed up approval for emergency use.⁶⁹ Media reports had suggested that US authorities were looking for a possible emergency use authorization for AstraZeneca's vaccine before the November presidential election⁷⁰, but AstraZeneca says it has not been involved in those talks, and that it's too early to speculate.⁷¹
- **Pfizer and BioNTech** initially tested four versions of their vaccine candidate in humans. The version they have begun testing in a Phase III study was better tolerated than their initial choice, and they said it would better protect elderly people at most risk from COVID-19.⁷² The **Pfizer/BioNTech Phase III trial** in the US has a

⁶³ <https://www.reuters.com/article/us-health-coronavirus-vir-biotech/vir-biotech-to-begin-mid-to-late-stage-study-of-covid-19-drug-candidate-in-august-idUSKCN2572Q7>

⁶⁴ <https://www.fiercepharma.com/pharma/coronavirus-tracker-novavax-boasts-billion-plus-shot-capacity-by-2021-russia-s-world-first>

⁶⁵ <https://www.abc.net.au/news/2020-07-25/coronavirus-vaccine-development-sees-uk-australia-alliances-form/12488762>

⁶⁶ <https://www.medscape.com/viewarticle/934413>

⁶⁷ <https://pipelinereview.com/index.php/2020072775403/Vaccines/Moderna-Announces-Expansion-of-BARDA-Agreement-to-Support-Larger-Phase-3-Program-for-Vaccine-mRNA-1273-Against-COVID-19.html>

⁶⁸ <https://pipelinereview.com/index.php/2020072775411/Vaccines/Moderna-Announces-Phase-3-COVE-Study-of-mRNA-Vaccine-Against-COVID-19-mRNA-1273-Begins.html> and <https://www.biopharmadive.com/news/coronavirus-moderna-phase-3-start-vaccine-trial/582330/>

⁶⁹ <https://www.abc.net.au/news/2020-08-25/astrazeneca-oxford-vaccine-could-be-put-to-regulators-this-year/12594842>

⁷⁰ <https://www.ft.com/content/b053f55b-2a8b-436c-8154-0e93dcdb3c1a>

⁷¹ <https://www.fiercepharma.com/vaccines/astrazeneca-not-involved-covid-19-vaccine-emergency-use-authorization-talks-spokeswoman>

⁷² <https://www.biopharmadive.com/news/biontech-pfizer-start-phase-3-coronavirus-vaccine-trial/582405>

proposed cohort of 30,000. By the time 11,000 had been enrolled, Pfizer's senior vice president of vaccine clinical research and development said: "**Between Latinx and Black or African American populations, we're running at about 19 percent or so.** We're trying to push even higher than that."⁷³ These population groups have been infected with COVID-19 at more than twice the rate of white Americans, with Native Americans infected at still higher rates.

- The **University of Queensland vaccine trials** in hamsters are reported to have produced a good level of protection against the virus, and in humans have not caused adverse side effects.⁷⁴
- **Johnson & Johnson** announced that its lead vaccine candidate protected against infection with SARS-CoV-2 in pre-clinical studies⁷⁵.
- **Inovio** said that its DNA vaccine INO-4800 targeting SARS-CoV-2 was effective in protecting rhesus macaques from live virus challenge 13 weeks after the last vaccination⁷⁶. Inovio will initiate a mid-to-late stage study in September.⁷⁷
- **VBI Vaccines** has been granted \$C 56 million from the Strategic Innovation Fund of the Government of Canada towards the development of the company's COVID-19 candidate, VBI-2900, through Phase II clinical trials.⁷⁸
- **Arcturus Therapeutics** announced that all subjects in the first cohort have been dosed in the Phase I/II clinical study with its ARCT-021 investigational vaccine for COVID-19. The study is being conducted in collaboration with Duke-NUS Medical School in Singapore.⁷⁹
- **Italy** has begun human testing of a potential vaccine called GRAd-COV2, which was developed by ReiThera, based in Rome. The trial involves 90 volunteers.⁸⁰
- **PDS Biotechnology Corporation** announced preclinical data for its COVID-19 vaccine candidate, Versamune-CoV-2 (PDS0203)⁸¹.
- **Heat Biologics** reported preclinical data for its COVID-19 vaccine candidate, announcing robust T cell mediated immune response directed against the spike protein of SARS-CoV-2.⁸²

⁷³ <https://www.reuters.com/article/us-health-coronavirus-pfizer-vaccine-exc/exclusive-nearly-a-fifth-of-enrollees-in-pfizer-biontech-covid-19-vaccine-study-are-black-or-latino-idUSKBN25H2HM>

⁷⁴ <https://www.9news.com.au/national/coronavirus-vaccine-by-university-of-queensland-boost-immunity/0a79d9d8-b4d8-41de-9ba7-3c4bf9e79dcf> and <https://www.abc.net.au/news/2020-08-26/ug-covid-19-vaccine-candidate-safe-and-working-on-hamsters/12594726>

⁷⁵ <https://pipelinereview.com/index.php/2020073075445/Vaccines/Single-Dose-of-Johnson-Johnson-COVID-19-Vaccine-Candidate-Demonstrates-Robust-Protection-in-Pre-clinical-Studies.html>

⁷⁶ <https://pipelinereview.com/index.php/2020073175455/Vaccines/INOVIOS-COVID-19-DNA-Vaccine-INO-4800-Provides-Protection-with-Memory-Immune-Responses-In-Non-Human-Primates-Challenged-with-SARS-CoV-2-Virus.html>

⁷⁷ <https://in.reuters.com/article/health-coronavirus-inovio-pharma/inovio-to-begin-mid-to-late-stage-study-of-covid-19-vaccine-candidate-in-september-idINKCN25709I>

⁷⁸ [https://pipelinereview.com/index.php/2020080675501/Vaccines/VBI-Vaccines-Awarded-Up-to-CAD\\$56-Million-Contribution-from-Canadian-Government-to-Accelerate-Coronavirus-Vaccine-Development.html](https://pipelinereview.com/index.php/2020080675501/Vaccines/VBI-Vaccines-Awarded-Up-to-CAD$56-Million-Contribution-from-Canadian-Government-to-Accelerate-Coronavirus-Vaccine-Development.html)

⁷⁹ <https://pipelinereview.com/index.php/2020081175552/Vaccines/Arcturus-Therapeutics-Announces-that-it-has-Initiated-Dosing-of-its-COVID-19-STARR-mRNA-Vaccine-Candidate-LUNAR-COV19-ARCT-021-in-a-Phase-1/2-study.html>

⁸⁰ <https://www.abc.net.au/news/2020-08-25/coronavirus-updates-covid-19-who-experimental-plasma-usa-france/12590636#france>

⁸¹ <https://pipelinereview.com/index.php/2020072775416/Vaccines/PDS-Biotech-Announces-Preclinical-Data-for-PDS0203-a-T-Cell-Activating-Recombinant-Protein-Vaccine-Against-COVID-19.html>

⁸² <https://pipelinereview.com/index.php/2020072975436/Vaccines/Heat-Biologics-COVID-19-Vaccine-Demonstrates-Immunogenicity-Proof-of-Concept-in-Pre-Clinical-Studies.html> and

- **COVAX-19, developed in South Australia**, has been shown to be safe and to induce antibodies that attack SARS-CoV-2, according to lead researcher Professor Nikolai Petrovsky. He said: "We can now test the vaccine in nursing home patients and show that it's effective in inducing the right type of immune responses and hopefully, ultimately, show that it's effective in preventing them getting infected".⁸³
- **Merck's** recent purchase of Themis means it plans to start human testing of a COVID-19 vaccine in this third quarter of 2020.⁸⁴
- ImmunityBio announced positive preclinical results for its vaccine candidate containing both the spike and nucleocapsid SARS-CoV-2 proteins. The trial showed positive T cell and antibody immune responses.⁸⁵
- **ZyduS Cadila** announced that a Phase I clinical trial found its plasmid DNA vaccine to be safe and well tolerated. Phase II clinical trials began on 6 August.⁸⁶
- **Novavax** announced Phase I trial data of its vaccine with and without Matrix-M™ adjuvant. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses.⁸⁷ Novavax has partnered with **Takeda** for the development, manufacture and commercialization of the vaccine candidate in Japan. Takeda will receive funding from Japan's Ministry of Health, Labour and Welfare, and expects to manufacture at least 250 million doses annually.⁸⁸ Novavax also announced a licence agreement with the **Serum Institute of India** for the development and commercialization of its vaccine candidate, in low- and middle-income countries including India.⁸⁹ Fujifilm will manufacture clinical supply for a **Phase III trial of Novavax's vaccine** candidate.⁹⁰
- **Sinopharm** has published positive data from Phase I and Phase II trials of its vaccine.⁹¹ **CanSino Biologics** cancelled plans for a clinical trial in Canada.⁹²

<https://seekingalpha.com/news/3596617-heat-biologics-covidminus-19-vaccine-shows-encouraging-action-in-preclinical-study>

⁸³ <https://www.abc.net.au/news/2020-08-01/sa-potential-coronavirus-vaccine-passes-first-phase/12514988>

⁸⁴ <https://www.fiercebiotech.com/biotech/merck-via-its-themis-buy-to-move-first-covid-19-vaccine-into-clinical-development-q3>

⁸⁵ <https://pipelinereview.com/index.php/2020080375477/Vaccines/ImmunityBio-Study-Shows-Positive-T-Cell-and-Antibody-Immune-Responses-to-its-COVID-19-Vaccine-Candidate-that-Targets-Both-Spike-and-Nucleocapsid-Virus-Proteins.html> and [A Next Generation Bivalent Human Ad5 COVID-19 Vaccine Delivering Both Spike and Nucleocapsid Antigens Elicits Th1 Dominant CD4+, CD8+ T Cell and Neutralizing Antibody Responses](#) published without peer review on *bioRxiv*.

⁸⁶ <https://pipelinereview.com/index.php/2020080575496/Vaccines/ZyduS-Cadila-Announces-Completion-of-Dosing-in-Phase-I-Clinical-Trial-of-ZyCoV-D.html>

⁸⁷ <https://pipelinereview.com/index.php/2020080575497/Vaccines/Novavax-Announces-Positive-Phase-1-Data-for-its-COVID-19-Vaccine-Candidate.html> and

⁸⁸ <https://pipelinereview.com/index.php/2020080775525/Vaccines/Novavax-and-Takeda-Announce-Collaboration-for-Novavax-COVID-19-Vaccine-Candidate-in-Japan-Takeda.html> and

http://www.pharmatimes.com/news/novavax_covid-19_vaccine_produces Immune_response_in_early_study_1346397 and

<https://www.fiercepharma.com/vaccines/novavax-takeda-team-up-to-introduce-covid-19-vaccine-to-japan>

⁸⁹ <https://pipelinereview.com/index.php/2020080775518/Vaccines/Novavax-and-Serum-Institute-of-India-Announce-Development-and-Commercial-Collaboration.html>

⁹⁰ <https://www.fiercepharma.com/manufacturing/novavax-fujifilm-lock-up-clinical-supply-for-late-stage-covid-19-vaccine-trial>

⁹¹ <https://www.fiercebiotech.com/biotech/sinopharm-shares-phase-2-data-inactivated-covid-19-vaccine> and <https://jamanetwork.com/journals/jama/fullarticle/2769612>

⁹² <https://www.biopharmadive.com/news/cansino-biologics-canada-end-coronavirus-vaccine-deal/584237/>

- The **US National Institute of Allergy and Infectious Diseases is to develop a modified strain of SARS-CoV-2 for use in potential challenge trials.**⁹³ In challenge trials healthy people are injected with vaccine and then deliberately infected with the virus to speed up the review process—typically when a virus is no longer widely circulating.⁹⁴
- **BIOQUAL** announced publication of the non-human primate preclinical viral challenge study of a COVID-19 vaccine (mRNA-1273).⁹⁵

Vaccine research

- **MediciNova** announced an agreement with **BioComo and Mie University** (Mie prefecture, Japan) for joint development of a SARS-CoV-2 vaccine using BC-PIV, a human parainfluenza virus type 2 vector developed by BioComo and Tetsuya Nosaka, professor of the Department of Microbiology and Molecular Genetics, Mie University Graduate School of Medicine.⁹⁶
- Some scientists hope that **T cells may offer long-lasting protection** against the SARS-CoV-2 virus.⁹⁷
- Germany's Robert Koch Institute has said that while a COVID-19 vaccine may be available in the northern hemisphere autumn, this does not mean the pandemic will be under control. It warned that the **impact of the vaccine could be limited by mutations in the virus, or because the immunity provided by the first products in the market might be only short-term.**⁹⁸
- Amongst the many **vaccines under development, some use relatively new technology. If they are shown to be effective this could speed the development of other new vaccines.**⁹⁹
- **Genecure Biotechnologies**¹⁰⁰ has initiated a vaccine program¹⁰¹ for COVID-19 infection.
- **Vaxart**, which is developing oral recombinant vaccines administered by tablet rather than by injection, announced that it has filed its COVID-19 Investigational New Drug application with the US FDA.¹⁰²

⁹³ <https://www.fiercepharma.com/pharma/coronavirus-tracker-novavax-boasts-billion-plus-shot-capacity-by-2021-russia-s-world-first>

⁹⁴ <https://www.fiercepharma.com/pharma/coronavirus-tracker-novavax-boasts-billion-plus-shot-capacity-by-2021-russia-s-world-first>

⁹⁵ <https://pipelinereview.com/index.php/2020081075536/Vaccines/BIOQUAL-Announces-Publication-in-The-New-England-Journal-of-Medicine-of-Non-Human-Primate-Preclinical-Viral-Challenge-Study-of-an-mRNA-Vaccine-Against-COVID-19-mRNA-1273.html>

⁹⁶ <https://pipelinereview.com/index.php/2020072775405/Vaccines/MediciNova-Announces-SARS-CoV-2-Vaccine-Joint-Development-with-BioComo-and-Mie-University-Japan.html>

⁹⁷ <https://www.the-scientist.com/news-opinion/the-search-for-immune-responses-that-stop-covid-19-67769> and <https://www.bmj.com/content/370/bmj.m3096> and <https://www.fiercebitech.com/research/inducing-t-cell-response-outside-spike-protein-for-new-covid-19-vaccines>

⁹⁸ <https://www.medscape.com/viewarticle/935582> and <https://www.abc.net.au/news/health/2020-08-15/coronavirus-new-strains-mutation-vaccine-headlines/12519576>

⁹⁹ <https://www.vox.com/2020/8/13/21359025/coronavirus-vaccine-covid-19-moderna-oxford-mrna-adenovirus>

¹⁰⁰ www.genecure.com

¹⁰¹ www.clinicaltrials.gov; NCT04428073 and

<https://pipelinereview.com/index.php/2020081075537/Vaccines/GeneCure-Biotechnologies-launches-first-in-human-therapeutic-vaccine-to-treat-Covid-19-patients.html>

¹⁰² <https://pipelinereview.com/index.php/2020081075538/Vaccines/Vaxart-Announces-IND-Filed-for-COVID-19-Vaccine.html>

- **Intravacc and Celonic** agreed to develop and produce a vaccine.¹⁰³

Vaccine manufacture and distribution

- A patent court in the US has found in favour of Arbutus Biopharma in a patent dispute with Moderna. Whether this would affect Moderna's progress with its COVID-19 vaccine was not certain in the stock market and the company share price fell nine per cent.¹⁰⁴
- In the US, the Director of the National Institute of Allergy and Infectious Diseases, Dr Anthony Fauci, has said that it is likely that a COVID-19 **vaccine will not be “widely available” in the US until “several months” into 2021.**¹⁰⁵ Stephen Hahn, the FDA Commissioner, has re-iterated that **“all FDA decisions have been, and will continue to be, based solely on good science and data”**. He said again that any approved vaccine “would need to show that it prevents the disease or decreases its severity in at least 50 percent of people who are vaccinated”; and that “all phases of vaccine clinical development should include the people most affected thus far by COVID-19, specifically racial and ethnic minorities, elderly individuals, and people with other medical conditions”.¹⁰⁶
- The US Health Secretary announced any **US vaccine or treatment for COVID-19 would be shared with the world only after US needs had been met.**¹⁰⁷
- The **US government had, by 7 August, announced agreements with Janssen Pharmaceutical Companies (Johnson & Johnson), Sanofi and GlaxoSmithKline, Pfizer Inc., Novavax Inc., and AstraZeneca concerning large scale manufacturing of their vaccine candidates if successful. It was also providing additional funding to Moderna for the Phase III trial of its candidate mRNA-1273.**¹⁰⁸
- The US government has agreed to pay **Sanofi and GlaxoSmithKline** up to \$A2.9 billion to supply it with enough vaccine for 50 million people, with the option to buy further 500 million doses.¹⁰⁹
- Moderna has had almost \$1 billion in research funding through its COVID-19 vaccine partnership with the US Government. Now under a deal worth over \$1.5 billion, Moderna will deliver 100 million doses of its mRNA vaccine if it is approved. Considering the research and supply funding it has received, **Moderna's effective price to the government is just under \$25 per dose, while Moderna says it is charging smaller purchasers from \$US32 to \$US37 per dose.**¹¹⁰

¹⁰³ <https://pipelinereview.com/index.php/2020072975428/Vaccines/Intravacc-and-Celonic-to-Develop-and-Produce-a-Novel-COVID-19-Vaccine.html>

¹⁰⁴ <https://www.fiercebiotech.com/biotech/moderna-stock-sinks-as-patent-case-spurs-concern-for-covid-19-vaccine>

¹⁰⁵ <https://www.9news.com.au/world/usa-news-covid-19-vaccine-probably-wont-be-widely-available-until-2021/e27b37fd-3f51-475d-8051-6680eaf4766e>

¹⁰⁶ https://www.washingtonpost.com/opinions/fda-commissioner-no-matter-what-only-a-safe-effective-vaccine-will-get-our-approval/2020/08/05/e897d920-d74e-11ea-aff6-220dd3a14741_story.html

¹⁰⁷ <https://www.reuters.com/article/taiwan-usa-health-coronavirus/u-s-s-azar-says-any-u-s-vaccine-would-be-shared-once-u-s-needs-met-idUSL4N2FC1IP>

¹⁰⁸ <https://www.medicalcountermeasures.gov/newsroom/2020/moderna-phase-3/>

¹⁰⁹ <https://7news.com.au/news/health/us-deal-for-100-million-doses-of-vaccine-c-1209913> and <https://www.fiercepharma.com/pharma/sanofi-gsk-win-hefty-2-1b-operation-warp-speed-funding-for-covid-19-vaccine>

¹¹⁰ <https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s> and https://www.upi.com/Top_News/US/2020/08/05/Moderna-prices-potential-COVID-19-vaccine-at-32-37-per-dose/5081596628532/

- **Novavax says it will have the capacity in 2021 to supply millions of vaccine doses** and could easily meet US demand of 500 to 600 million doses.¹¹¹
- **The US is organising arrangements for distributing vaccines** when approved.¹¹² **The federal government will meet the cost of vaccines**, and it is dealing with private health insurers so people will not have to pay to have the vaccine administered.¹¹³
- **Pfizer and its mRNA partner BioNTech** have agreed with Japan to provide 120 million doses of their leading vaccine candidate, BNT162b2.¹¹⁴ **Japan then agreed to buy a further 120 million doses of AstraZeneca and the University of Oxford's candidate** if successful.¹¹⁵ Provided regulatory approval is forthcoming, thirty million doses are expected by March. Japanese companies will have some involvement in production. Additional trials will be conducted in Japan.
- The **Russian government** has said it will manufacture a vaccine from September and commence **mass immunisation in October**, but if and how it has been tested is not clear.¹¹⁶ **Russia, in announcing approval of a locally-developed vaccine**, named it Sputnik V, at the same time as it began Phase III trials. Western experts considered the plan to begin mass vaccination in October premature.¹¹⁷ Virologists have expressed **concern about Russia's rollout of its Sputnik-5 vaccine** before trials are completed, warning that a vaccine that is only partially effective could cause the coronavirus to mutate.¹¹⁸
- **China's drug authority expects a COVID-19 vaccine for approval to be at least more than 50 per cent more effective than placebo** and to provide at least six months of protection.¹¹⁹
- **AstraZeneca signed a licensing agreement with Chinese firm BioKangtai** to help provide its adenovirus vector-based COVID-19 vaccine candidate to China. They may also produce the vaccine for other countries.¹²⁰
- State-owned Chinese drug-maker **SinoPharm, said that 30 "special volunteers", including upper management, had "pre-tested" its vaccine** before the company received approval for its first human trial.¹²¹
- **AstraZeneca is expanding its deal with Brazil**, with \$US 360 million for a supply and licensing deal involving a further 100 million doses of vaccine.¹²²

¹¹¹ <https://www.fiercepharma.com/pharma/novavax-aims-for-billions-covid-19-vaccine-doses-2021-more-than-enough-to-supply-u-s>

¹¹² <https://www.usatoday.com/story/news/2020/08/14/texas-based-mckesson-tapped-distribute-coronavirus-vaccines/5587672002/>

¹¹³ <https://www.wsj.com/articles/covid-19-vaccines-will-not-come-with-copays-u-s-health-official-says-11597360354>

¹¹⁴ <https://www.fiercepharma.com/vaccines/pfizer-and-biontech-keep-supply-deals-rolling-120m-dose-japan-pact>

¹¹⁵ <https://www.fiercepharma.com/manufacturing/astrazeneca-taps-jcr-pharmaceuticals-daiichi-sankyo-and-other-local-pharmas-to-supply>

¹¹⁶ <https://www.bmj.com/content/370/bmj.m3096>

¹¹⁷ <https://www.fiercepharma.com/pharma/russia-skips-ahead-covid-vaccine-race-authorizing-unproven-shot> and <https://www.labonline.com.au/content/life-scientist/article/russia-approves-covid-19-vaccine-but-is-it-safe--677287859> and <https://www.medscape.com/viewarticle/935731>

¹¹⁸ <https://www.medscape.com/viewarticle/936121>

¹¹⁹ <https://www.fiercepharma.com/vaccines/chinese-regulator-guides-covid-19-vaccine-approval-criteria-how-do-they-compare-to-fda-s>

¹²⁰ <https://www.fiercepharma.com/manufacturing/astrazeneca-takes-covid-19-vaccine-to-china-biokangtai-deal-for-200m-dose-capacity-by>

¹²¹ <https://www.abc.net.au/triplej/programs/hack/covid-19-coronavirus-vaccine-race-is-struggle-global-domination/12533944>

¹²² <https://www.fiercepharma.com/manufacturing/astrazeneca-bumps-up-vaccine-deal-brazil-to-360m-more-doses-licensing-rights>

- The **European Union agreed to purchase 300 million doses of Astra Zeneca's vaccine to supply to member countries**, extending an earlier deal the company made with France, Germany, Italy and the Netherlands. The European Commission was also in talks with Johnson & Johnson and the Sanofi/ GlaxoSmithKline partnership.¹²³ **CureVac and the EU** are discussing a deal for 225 million doses of the company's mRNA-based vaccine if its trials are successful.¹²⁴
- The **Bill & Melinda Gates Foundation donated a further \$US 150 million to Gavi, the Vaccine Alliance**, which will provide funds to the **Serum Institute of India** to produce 100 million doses of vaccines from **AstraZeneca** and **Novavax for low- and middle- income countries**.¹²⁵ **India has multiple deals to produce new coronavirus vaccines** if they succeed in clinical trials.¹²⁶
- **AstraZeneca will work with Mexico and Argentina to produce between 150 million and 250 million doses of vaccine** at no profit starting in the first half of 2021. The supply will be for Latin American countries.¹²⁷

5. Potential treatments for COVID-19

Hyperimmune immunoglobulin and convalescent plasma

- **Grifols** delivered its first batch of SARS-CoV-2 **hyperimmune globulin** for clinical trials.¹²⁸
- **Researchers trialling convalescent plasma as a treatment for COVID-19 have specifically included pregnant women** in their trial protocols.¹²⁹
- Examination of a dozen studies involving a total of 800 patients concluded those who received convalescent plasma therapy were less likely to die than those who were given other treatments. The analysis has not yet been peer reviewed.¹³⁰
- In the US, the **National Heart, Lung and Blood Institute is sponsoring a trial of convalescent plasma in outpatients**, to see whether it can stop progression of COVID-19 to severe disease.¹³¹

¹²³ <https://www.biopharmadive.com/news/europe-coronavirus-vaccine-supply-astrazeneca-johnson-johnson/583547/> and

<https://www.fiercepharma.com/pharma/astrazeneca-europe-ink-covid-vaccine-supply-deal-for-400m-doses> and <https://www.fiercepharma.com/pharma/heels-u-s-deal-johnson-johnson-strikes-covid-vaccine-supply-pact-europe>

¹²⁴ <https://www.fiercepharma.com/pharma/curevac-advanced-talks-eu-to-supply-225m-coronavirus-vaccine-doses>

¹²⁵ <https://www.fiercepharma.com/pharma/coronavirus-tracker-novavax-boasts-billion-plus-shot-capacity-by-2021-russia-s-world-first>

¹²⁶ <https://www.biopharmadive.com/news/serum-institute-wockhardt-coronavirus-vaccine-manufacturing/583053/> and <https://www.fiercepharma.com/manufacturing/az-taps-indian-pharma-wockhardt-for-u-k-shot-finishing>

¹²⁷ <https://www.fiercepharma.com/manufacturing/astrazeneca-will-hand-covid-19-shot-production-rights-to-mexico-argentina-report>

¹²⁸ <https://pipelinereview.com/index.php/2020072875425/Antibodies/Grifols-delivers-first-manufactured-batches-of-its-anti-SARS-CoV-2-hyperimmune-globulin-for-clinical-trials.html>

¹²⁹ <https://www.the-scientist.com/news-opinion/two-covid-19-clinical-trials-seek-to-enroll-pregnant-women-67755>

¹³⁰ <https://www.livescience.com/convalescent-plasma-therapy-reduces-covid19-deaths.html> and <https://www.washingtonpost.com/opinions/2020/08/03/4-former-fda-commissioners-blood-plasma-might-be-covid-19-treatment-we-need>

¹³¹ <https://www.medpagetoday.com/infectiousdisease/covid19/87936>

- a. Convalescent plasma had reportedly been used in the US (under emergency use guidelines) to treat around 85,000 patients by 7 August.¹³² A preliminary analysis of data from a significant proportion of these patients **reported ten per cent fewer deaths in critically ill hospitalized COVID-19 patients given plasma with higher concentrations of antibodies compared with those who received lower concentrations.**¹³³ Receiving the plasma earlier rather than later in the course of the disease was also thought to be important.
- b. However, epidemiologist Ian Lipkin of Columbia University has said: **“Without a randomized controlled trial, it’s very difficult to be certain that what you have is meaningful.”**¹³⁴ Attempted placebo-controlled trials have had difficulty in recruiting participants.
- c. The **FDA placed on hold an emergency use authorisation for convalescent plasma** in COVID-19 while it reviewed more data.¹³⁵ **Then, quite suddenly, emergency use authorization was granted** for patients hospitalized with COVID-19, with FDA commissioner Stephen Hahn standing beside President Trump for the announcement.¹³⁶ **Alex Azar, Health and Human Services Secretary, said:** “The FDA’s emergency authorization for convalescent plasma is a milestone achievement in President Trump’s efforts to save lives from COVID-19”.¹³⁷
- d. WHO chief scientist Dr Soumya Swaminathan commented that WHO still considers convalescent plasma therapy to be experimental, requiring further evaluation, as studies to date had provided only "low-quality evidence".¹³⁸
- e. A **study in the Netherlands was stopped** after investigators saw no difference in mortality, length of hospital stay or disease severity compared with placebo.¹³⁹

¹³² Estimate from Mayo Clinic cardiologist Scott Wright,

<https://www.buzzfeednews.com/article/danvergano/convalescent-plasma-eua-fda>

¹³³ <https://www.startribune.com/mayo-s-plasma-program-shows-first-signs-of-covid-19-benefit/572021282/> and <https://www.medscape.com/viewarticle/935812>

¹³⁴ <https://www.the-scientist.com/news-opinion/doctors-forge-ahead-with-plasma-for-covid-19-benefits-uncertain-67828> and <https://www.nytimes.com/2020/08/04/health/trump-plasma.html>

¹³⁵ <https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html> and

<https://www.fiercebiotech.com/biotech/fda-halts-covid-blood-plasma-emergency-approval>

¹³⁶ <https://www.fiercepharma.com/marketing/fda-reputation-line-trump-deep-state-charge-and-ensuing-eua-for-covid-plasma-therapy> and <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>; <https://www.fiercepharma.com/pharma/fda-chief-hahn-walks-back-plasma-claims-but-experts-say-correction-wasn-t-accurate>;

<https://www.medpagetoday.com/infectiousdisease/covid19/88236>;

<https://www.biopharmadive.com/news/fda-emergency-approval-convalescent-plasma-covid-19/583998/>; and

<https://www.fiercepharma.com/pharma/fda-s-emergency-use-authorization-for-convalescent-plasma-raises-questions-whether-politics>

¹³⁷ <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

¹³⁸ <https://www.abc.net.au/news/2020-08-25/coronavirus-updates-covid-19-who-experimental-plasma-usa-france/12590636#france>

¹³⁹ <https://seekingalpha.com/news/3607063-convalescent-plasma-players-under-pressure-on-fda-hold-on-emergency-use-nod>

- f. The **US Department of Defense has signed a contract worth \$US 750,000 with Plasma Technologies** to develop scaled-up COVID-19 convalescent plasma technologies.¹⁴⁰
- Regeneron will partner with Roche to more than triple output of its **COVID-19 antibody therapy, REGN-COV2**, and to handle worldwide distribution. The licensing deal is for seven years, with Regeneron undertaking the US rollout and Roche distributing to the rest of the world.¹⁴¹
 - Hospitals in Florida are using convalescent plasma for COVID-19 patients, but supply is limited and **more recovered patients are being sought as donors**.¹⁴²
 - In the US, testing company LabCorp hopes to **boost plasma donations by offering a free antibody testing programme** for three months (using the Roche Elecsys Anti-SARS-CoV-2, authorized under an FDA emergency use authorization).¹⁴³

Remdesivir

- Discussion continues on the relationship between treatment **with remdesivir and mortality** from COVID-19.¹⁴⁴
- An ongoing randomised controlled trial is testing the safety and efficacy of the broad-spectrum antiviral **remdesivir in combination with the immunomodulator interferon beta-1a** (Rebif) for patients with COVID-19. The Adaptive COVID-19 Treatment Trial 3 (ACTT-3) is sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID). It aims to enrol more than 1000 hospitalised adults at up to 100 sites in the US and elsewhere.¹⁴⁵
- Pfizer has joined a network of more than 40 drug-makers in the U.S., Europe and Asia, who will produce Gilead's remdesivir.¹⁴⁶
- Gilead's remdesivir (Veklury) is currently available in the US under an FDA Emergency Use Authorisation for treatment of severe COVID-19 patients in hospital. Gilead has now submitted a New Drug Application to the FDA for use of the drug in patients with COVID-19.¹⁴⁷

¹⁴⁰ <https://edition.cnn.com/2020/08/17/health/convalescent-plasma-covid-19-research/index.html> and <https://www.defense.gov/Newsroom/Releases/Release/Article/2314525/dod-awards-750000-to-plasma-technologies-llc-for-manufacturing-of-convalescent/>

¹⁴¹ <https://www.fiercepharma.com/manufacturing/roche-regeneron-join-forces-to-more-than-triple-manufacturing-covid-19-antibody> and <https://investor.regeneron.com/index.php/news-releases/news-release-details/regeneron-and-roche-collaborate-significantly-increase-global>

¹⁴² <https://www.naplesnews.com/story/news/coronavirus/2020/07/30/demand-exceeds-supply-convalescent-plasma-help-covid-19-patients/5535485002/>

¹⁴³ <https://www.fiercebiotech.com/medtech/labcorp-covid-tests-free-for-three-months-to-aid-plasma-donations>

¹⁴⁴ <https://www.medscape.com/viewarticle/934894>

¹⁴⁵ <https://www.medscape.com/viewarticle/935606> and <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-testing-remdesivir-plus-interferon-beta-1a-covid-19-treatment-begins> and <https://www.the-scientist.com/news-opinion/seeking-an-early-covid-19-drug-researchers-look-to-interferons-67753>

¹⁴⁶ <https://www.fiercepharma.com/manufacturing/pfizer-signs-up-to-help-manufacture-gilead-s-covid-antiviral-remdesivir>

¹⁴⁷ <https://pipelinereview.com/index.php/2020081075535/Small-Molecules/Gilead-Submits-New-Drug-Application-to-U.S.-Food-and-Drug-Administration-for-Veklury-Remdesivir-for-the-Treatment-of-COVID-19.html>

- Suggestions have been made to Gilead Sciences, which manufactures remdesivir, that it should trial another of its products (GS-441524) in COVID-19. This has been **used to treat cats infected with a feline-specific coronavirus**.¹⁴⁸
- Researchers have suggested that **clinical trials of remdesivir did not provide sufficient representation of Black, Hispanic or Native Americans**, who are over-represented in US COVID-19 case data.¹⁴⁹

Other therapies

- Researchers reported that administering **high-dose methylprednisolone with tocilizumab** as required to COVID-19 patients experiencing a hyperinflammatory state (a cytokine storm) was associated with **faster respiratory recovery, a lower likelihood of mechanical ventilation, and reduced in-hospital mortality** compared with supportive care alone.¹⁵⁰
- A joint clinical program called I-SPY will **test Takeda’s Firazyr, Amgen’s Otezla, and AbbVie’s experimental drug cenicriviroc** to see if they can ameliorate potentially life-threatening immune overreaction seen in some serious COVID-19 patients.¹⁵¹
- **Tocilizumab (Actemra)** was the subject of a Phase III trial in hospitalised patients with severe COVID-19 associated pneumonia. Genentech reported that the trial did not meet either its primary endpoint (improved clinical status of patients) or its key secondary endpoint of reducing mortality.¹⁵²
- Observing human lung cells infected with SARS-C0V-2 in the laboratory has led to suggestions that **anti-cholesterol drugs and antihistamines** could be trialled for COVID-19.¹⁵³
- US researchers say **nasal irrigation** might ameliorate symptoms of COVID-19 and reduce transmission.¹⁵⁴
- A study has compared outcomes for COVID-19 patients dosed pre-emptively with **anti-coagulants** with those for patients who were dosed prophylactically. It concluded that **pre-emptive therapeutic dosing increased in-hospital mortality**.¹⁵⁵
- **Sarilumab** was found to be associated with faster recovery in COVID-19 patients with minor lung consolidation.¹⁵⁶
- The Alfred Hospital and Monash University are enrolling symptomatic people, within five days of diagnosis of COVID-19, in a trial of the flu drug Favipiravir to see if it hastens recovery. The trial is placebo-controlled.¹⁵⁷

¹⁴⁸ <https://www.the-scientist.com/news-opinion/gilead-urged-to-explore-remdesivir-relative-as-covid-19-drug-67811>

¹⁴⁹ <https://www.fiercebiotech.com/biotech/researchers-call-out-gilead-over-diversity-remdesivir-trials>

¹⁵⁰ <https://www.medscape.com/viewarticle/934567>

¹⁵¹ <https://www.fiercepharma.com/pharma/abbvie-amgen-and-takeda-test-anti-inflammatory-drugs-joint-covid-19-study>

¹⁵² <https://pipelinereview.com/index.php/2020072975429/Antibodies/Genentech-Provides-an-Update-on-the-Phase-III-COVACTA-Trial-of-Actemra-in-Hospitalized-Patients-With-Severe-COVID-19-Associated-Pneumonia.html>

¹⁵³ <https://www.medscape.com/viewarticle/934803>

¹⁵⁴ <https://www.medscape.com/viewarticle/934807>

¹⁵⁵ <https://www.medpagetoday.org/infectiousdisease/covid19/87909>

¹⁵⁶ <https://www.healio.com/news/rheumatology/20200804/sarilumab-safe-effective-in-severe-covid19-with-minor-lung-consolidation>

¹⁵⁷ <https://7news.com.au/lifestyle/health-wellbeing/new-vic-virus-trial-could-hasten-recovery-c-1225532>

- Miami’s Westchester General Hospital will test Ifenprodil, repurposed by Algernon Pharmaceuticals as a possible treatment for COVID-19 damage in the lungs. The pill was originally developed in the 1970s to treat blood circulation disorders.¹⁵⁸
- In a nine-patient retrospective study (not a randomised trial), patients who received icatibant (Firazyr), the bradykinin inhibitor normally used for hereditary angioedema, had less need for oxygen supplementation compared with controls.¹⁵⁹
- Researchers will test an adapted cancer treatment in COVID-19, to see if it can prevent the virus from moving into lungs and spreading to others.¹⁶⁰

6. Managing the pandemic

Individual country experience

- In **Germany**, the head of the Robert Koch Institute for infectious diseases said the rise in new coronavirus infections was ‘to do with the fact that **we have become negligent**’. He urged people to practise social distancing.¹⁶¹
- **Scientists in France have warned a second wave of COVID-19** is likely to hit in autumn and winter.¹⁶²
- The US Centers for Disease Control and Prevention has projected **the US death toll from coronavirus** to reach 182,000 by late August.¹⁶³
- A report says that **school closures** in the northern Spring “may have been associated with approximately 1.37 million fewer cases of COVID-19 in the United States over a period of 26 days and 40,600 fewer deaths from the disease over 16 days.”¹⁶⁴
- US researchers say that while **adults with diabetes and hypertension** are at high risk of ICU admission and death from COVID-19, there may be fewer patients with those co-morbidities than previously reported.¹⁶⁵
- As US **college students** began a new semester, **many contracted COVID-19**.¹⁶⁶
- Modelling suggested that if US colleges re-open **frequent testing with quick results** will be the key to avoiding campus outbreaks of COVID-19.¹⁶⁷
- US universities and healthcare institutions are hoping to use **spit tests to screen for COVID-19**.¹⁶⁸

¹⁵⁸ <https://www.miamiherald.com/news/local/community/miami-dade/article244809382.html>

¹⁵⁹ <https://www.medpagetoday.com/infectiousdisease/covid19/88076>

¹⁶⁰ <https://7news.com.au/news/health/tests-underway-for-covid-19-treatment-c-1243689>

¹⁶¹ <https://www.medscape.com/viewarticle/934703>

¹⁶² <https://www.medscape.com/viewarticle/935160>

¹⁶³ <https://www.dailymail.co.uk/news/article-8583271/CDC-projects-death-toll-coronavirus-reach-182-000-late-August.html>

¹⁶⁴ <https://www.healio.com/news/pediatrics/20200729/us-school-closures-associated-with-40k-fewer-deaths-from-covid19-study-finds> and Auger KA, et al. *JAMA*. 2020;doi:10.1001/jama.2020.14348 and Donohue JM, et al. *JAMA*. 2020;doi:10.1001/jama.2020.13092

¹⁶⁵ <https://www.healio.com/news/endocrinology/20200730/prevalence-of-diabetes-hypertension-among-covid19-patients-likely-lower-than-reported>

¹⁶⁶ <https://www.the-scientist.com/news-opinion/covid-19-outbreaks-occur-as-students-return-to-campus-67830>

¹⁶⁷ <https://www.the-scientist.com/news-opinion/study-test-college-students-for-coronavirus-every-two-days-67787>

¹⁶⁸ <https://www.the-scientist.com/news-opinion/saliva-tests-how-they-work-and-what-they-bring-to-covid-19-67720>

- In the **US**, the Infectious Diseases Society of America and the HIV Medicine Association wrote to the Vice President **requesting a federal directive that masks be made mandatory in all States**.¹⁶⁹
- Also in the US, the [Council on State and Territorial Epidemiologists \(CSTE\)](#) has said that positive **rapid antigen tests should be counted in daily case tallies**, although they could be distinguished as probable rather than confirmed.¹⁷⁰
- **A nursing home in Pennsylvania says it contained a COVID-19 outbreak** through a universal and repetitive testing strategy.¹⁷¹
- Researchers reported that in **New York City's overall mortality during its recent COVID-19 peak was higher than in the 1918 flu pandemic** there.¹⁷²
- The US FDA has authorised a **test from the Centers for Disease Control and Prevention which determines whether a patient is infected with influenza or SARS-CoV-2**.¹⁷³
- The US **FDA has approved the COVID-19 saliva test** developed for screening NBA players for use across the US.¹⁷⁴
- In the US, the **CDC has issued advice to owners whose pets test positive to SARS-CoV-2**¹⁷⁵, and to handlers of service and therapy animals.¹⁷⁶ The EPA issued guidance on managing the quality of indoor air in homes in the pandemic.¹⁷⁷
- At the end of August, in a move which might be interpreted as bowing to political pressure and reducing testing, the US Centers of Disease Control relaxed its COVID-19 testing guidelines.¹⁷⁸
- The Department of Health in the **Philippines** has warned that buying plasma from COVID-19 survivors and selling it is illegal.¹⁷⁹ Under the National Blood Service Act of 1994, blood and blood products are collected only from volunteer donors. The law precludes payment for blood donations.
- **South Korea** has been dealing with new outbreaks, the largest linked to a church. Social distancing rules have been strengthened.¹⁸⁰
- Korean researchers found that “**viral loads were similar among asymptomatic and symptomatic COVID-19 patients** and remained that way for weeks after diagnosis”.¹⁸¹

¹⁶⁹ <https://www.idsociety.org/globalassets/idsa/public-health/covid-19/whtf-letter-masks-final.pdf> and <https://www.forbes.com/sites/alisondurkee/2020/08/05/group-of-12000-infectious-disease-experts-say-federal-mask-mandate-needed-to-save-lives/> and <https://www.the-scientist.com/news-opinion/how-our-exhalations-help-spread-pathogens-such-as-sars-cov-2-67763>

¹⁷⁰ https://www.medpagetoday.com/infectiousdisease/covid19/87930?xid=nl_medpageexclusive_2020-08-07&eun=g465425d0r&utm_source

¹⁷¹ <https://www.healio.com/news/infectious-disease/20200811/universal-testing-contains-covid19-outbreak-in-nursing-home>

¹⁷² <https://www.medpagetoday.com/infectiousdisease/covid19/88048>

¹⁷³ <https://www.healthcarediver.com/news/cdc-gets-fda-nod-for-coronavirus-flu-combination-diagnostic/581070/>

¹⁷⁴ <https://www.fiercebitech.com/medtech/fda-green-lights-game-changing-covid-19-saliva-test-used-by-nba>

¹⁷⁵ <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/positive-pet.html>

¹⁷⁶ <https://www.cdc.gov/coronavirus/2019-ncov/animals/service-therapy-animals.html>

¹⁷⁷ <https://www.epa.gov/coronavirus/indoor-air-homes-and-coronavirus-covid-19>

¹⁷⁸ <https://edition.cnn.com/2020/08/26/health/cdc-guidelines-coronavirus-testing/index.html>

¹⁷⁹ <https://newsinfo.inquirer.net/1318794/doh-warns-buying-selling-of-plasma-from-recovered-covid-19-patients>

¹⁸⁰ <https://www.medscape.com/viewarticle/935822>

¹⁸¹ <https://www.medpagetoday.com/infectiousdisease/covid19/87926>

- Chinese authorities reported they had found **SARS-CoV-2 on the packaging** of imported frozen seafood.¹⁸²
- A study in Wuhan found that **28 days after** COVID-19 patients had been discharged from an isolation ward, **SARS-CoV-2 RNA could still be detected on the surfaces of pagers and in drawers.**¹⁸³
- Modelling the **effect of a Chinese wet market on COVID-19 transmission** concluded that market-to-human transmission had a lower reproduction number than human-to human transmission, and that asymptomatic and subclinical infections represented a substantial component of the morbidity burden.¹⁸⁴
- **Japan’s resurgence** of COVID-19 has been blamed in part on insufficient testing.¹⁸⁵
- A report by Médecins Sans Frontières (MSF) on responses to COVID-19 outbreaks criticised **“alarming living conditions” in Belgian and Spanish care homes.** Stephanie Goublomme, a Belgian MSF project coordinator, said: “Retirement homes were asked to operate like hospitals, but not given the protective means and necessary personnel to do so. We witnessed a true humanitarian crisis.”¹⁸⁶

Transmission

- Australian research has shown that “for speaking, a single-layer cloth face covering reduced the droplet spread but a double-layer covering performed better. For coughing and sneezing, though, a double-layer cloth face covering was significantly better at reducing the droplet spread. A **three-ply surgical mask performed best** of all for every type of respiratory emission.”¹⁸⁷
- Two New York City Health systems are collaborating with Nanowear to use clinical-grade **wearable technology to identify physiological and biomarker changes** in patients who have, or may have, COVID-19.¹⁸⁸
- Researchers found that healthy adults who appeared not to have been exposed to SARS-CoV-2 could have **T Cells in their blood that were reactive to the virus.** Researchers said they may have been developed in response to previous infections with endemic coronaviruses.¹⁸⁹
- **C. Buddy Creech** (associate professor of paediatrics and director of the Vanderbilt Vaccine Research Program at Vanderbilt University Medical Center) said: “There is **still much to learn about the kinetics of the virus in children.** For the most part, symptoms are mild in children and we do not yet know the burden of asymptomatic disease in children. Once we have more reliable antibody testing, we may be able to determine seroprevalence more precisely”.¹⁹⁰
- The **case fatality rate** is a concept being used during this pandemic, and now scientists are explaining how it should be interpreted.¹⁹¹

¹⁸² <https://health.economictimes.indiatimes.com/news/industry/coronavirus-found-on-frozen-seafood-in-china/77488087>

¹⁸³ [https://www.ijidonline.com/article/S1201-9712\(20\)30451-3/fulltext](https://www.ijidonline.com/article/S1201-9712(20)30451-3/fulltext)

¹⁸⁴ [https://www.ijidonline.com/article/S1201-9712\(20\)30398-2/fulltext](https://www.ijidonline.com/article/S1201-9712(20)30398-2/fulltext)

¹⁸⁵ <https://www.bmj.com/content/370/bmj.m3221>

¹⁸⁶ <https://www.bmj.com/content/370/bmj.m3271>

¹⁸⁷ <https://www.medpagetoday.com/infectiousdisease/covid19/87716>

¹⁸⁸ <https://www.fiercehealthcare.com/tech/hackensack-meridian-health-maimonides-medical-center-piloting-sensor-embedded-clothing-for>

¹⁸⁹ <https://7news.com.au/lifestyle/health-wellbeing/why-some-people-who-havent-had-covid-19-might-already-have-some-immunity-c-1209840>

¹⁹⁰ <https://www.healio.com/news/pediatrics/20200730/qa-are-asymptomatic-children-driving-the-spread-of-covid19>

¹⁹¹ <https://www.medscape.com/viewarticle/934641> and <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003189>

- A study suggests that **dogs may be trained to identify (by sniffing) people infected with SARS-CoV-2.**¹⁹²
- A study found that **asymptomatic COVID-19 patients are as contagious** as those who display symptoms.¹⁹³
- China's health authorities reported they had found **SARS-CoV-2 arriving with imported frozen food.**¹⁹⁴
- **While food packaging is transporting SARS-CoV-2 internationally,** some experts believe the risk of developing COVID-19 from handling the packaging is low.¹⁹⁵
- Researchers reported that disease caused by the **SARS-CoV-2 virus "is worse in colder months** and dry indoor air could encourage its spread".¹⁹⁶
- A study in Sydney suggested **dry air could aid the spread of SARS-CoV-2.**¹⁹⁷
- A small study in Turkey found that people with **asymptomatic COVID-19 infections** who had a **routine ophthalmology examination left behind environmental samples on which SARS-CoV-2 was detected,** even although chin and forehead rests were wiped down.¹⁹⁸
- Researchers at the Stanford University School of Medicine found that **"vaping" is a significant risk for COVID-19 infection.** In teens and young adults who were tested, those who had used e-cigarettes were five to seven times more likely to be infected than non-users.¹⁹⁹
- **Vaccines against some diseases are known to be less effective in obese adults** than in the general population, and this could be the case for COVID-19.²⁰⁰
- A Chinese study found the risk of **secondary infections with COVID-19** to be highest for household contacts, followed by healthcare settings and public transport. The risk for secondary transmission was correlated with the severity of index cases.²⁰¹
- **A strain of SARS-CoV-2 (D614G)** which originated in Europe and has been dominant in the US has been identified in the Philippines, Malaysia, India and China. It is now the most common strain globally. There are concerns the mutation could limit the efficacy of vaccines under development.²⁰² Paul Tambyah²⁰³ said evidence suggests the proliferation of the D614G mutation in some parts of the world has

¹⁹² <https://www.medscape.com/viewarticle/934876> and

<https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-020-05281-3>

¹⁹³ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769235> and

https://www.upi.com/Health_News/2020/08/06/Asymptomatic-COVID-19-patients-as-contagious-as-those-with-symptoms/7711596724661/

¹⁹⁴ <https://www.news.com.au/lifestyle/food/coronavirus-found-on-frozen-chicken-wings-chinese-authorities-claim/news-story/4eeb5391df884a4b97292840aeff19b3>

¹⁹⁵ <https://www.the-scientist.com/news-opinion/coronavirus-found-on-food-packaging-but-likely-of-little-concern-67825>

¹⁹⁶ <http://www.pharmatimes.com/news/covid-19-more-severe-in-colder-months-research-suggests-1345326>

¹⁹⁷ <https://www.abc.net.au/news/2020-08-25/weather-covid-19-coronavirus-and-humidity-study/12587402>

¹⁹⁸ https://www.medpagetoday.com/infectiousdisease/covid19/87880?utm_source

¹⁹⁹ <https://7news.com.au/travel/coronavirus/young-vapers-more-likely-to-get-covid-19-c-1233383> and <https://www.sciencedirect.com/science/article/pii/S1054139X20303992>

²⁰⁰ <https://www.medscape.com/viewarticle/935289>

²⁰¹ <https://www.medscape.com/viewarticle/935758> and <https://www.acpjournals.org/doi/10.7326/M20-2671>

²⁰² <https://www.medscape.com/viewarticle/935915>

²⁰³ senior consultant at the National University of Singapore and president-elect of the International Society of Infectious Diseases

coincided with a drop in death rates. He commented: “Maybe that’s a good thing to have a virus that is more infectious but less deadly”.²⁰⁴

- **Qiagen has released new tools for tracking mutations** in SARS-CoV-2.²⁰⁵
- **A US report warned that 37.7 million adults sharing a household with school aged children and 2.9 million school-teachers are at risk from COVID-19**, for while children are at low risk of severe COVID-19, they can transmit the virus.²⁰⁶

Origins of the pandemic

- Scientists reported that “the spike proteins of SARS-CoV-2 and of the closely related bat coronavirus RaTG13—while similarly structured overall—differ in their stability and affinity for binding ACE2, the receptor that SARS-CoV-2 uses to infect human cells”. They said it is therefore “likely that **SARS-CoV-2 “had been evolving in some other species**—possibly an intermediate species—before it acquired the ability to be this human pathogen”.²⁰⁷

7. Other news

Infectious diseases other than COVID-19

- Ridgeback Biotherapeutics announced the US FDA accepted the Biologics License Application and granted priority review designation for the company’s **investigational Ebola treatment, ansumimab (mAb114)**.²⁰⁸ The FDA had already granted Breakthrough Therapy Designation status to ansumimab as a treatment for Ebola in September 2019.
- Regeneron has signed an agreement with the US Biomedical Advanced Research and Development Authority (BARDA) to supply REGN-EB3, its cocktail of **three fully-human monoclonal antibodies for treating Ebola**, for the National Stockpile.²⁰⁹
- Singapore- based company [Tychan](#) announced a report in the [New England Journal of Medicine \(NEJM\)](#) demonstrating the safety and efficacy for TY014, a novel monoclonal antibody candidate treatment for **yellow fever**.²¹⁰
- SAB Biotherapeutics is developing a novel immunotherapy platform to produce fully human polyclonal antibodies without the need for human donors. The company announced that it had begun dosing participants in its Phase I clinical trial of SAB-

²⁰⁴ <https://www.reuters.com/article/us-health-coronavirus-mutation/infectious-covid-19-mutation-may-be-a-good-thing-says-disease-expert-idUSKCN25E08Y>

²⁰⁵ <https://www.fiercebiotech.com/medtech/qiagen-launches-new-tools-for-tracking-coronavirus-mutations-and-strains>

²⁰⁶ <https://www.healio.com/news/primary-care/20200824/40-million-teachers-adults-living-with-schoolchildren-at-risk-for-severe-covid19> and <https://www.healio.com/news/pediatrics/20200812/qa-pediatric-covid19-cases-increase-by-90-over-4-weeks>

²⁰⁷ <https://www.the-scientist.com/news-opinion/spike-structure-gives-insight-into-sars-cov-2-evolution-67746>

²⁰⁸ <https://pipelinereview.com/index.php/2020072975438/Antibodies/Ridgeback-Biotherapeutics-LP-Announces-Priority-Review-of-Biologics-License-Application-for-ansumimab-Ebola-Treatment.html>

²⁰⁹ <https://seekingalpha.com/news/3596564-regeneron-lands-barda-contract-for-ebola-cocktail>

²¹⁰ <https://pipelinereview.com/index.php/2020073075443/Antibodies/NEJM-Study-Demonstrates-Safety-and-Efficacy-of-First-Novel-Monoclonal-Antibody-Specifically-Developed-to-Treat-Yellow-Fever.html>

176 for the treatment of seasonal influenza. SAB-176 is a human immunoglobulin G (IgG) immunotherapy which **targets four influenza virus strains**.²¹¹

- Researchers reported that although the rate of **seasonal flu vaccination** in the US is low among high-risk groups (such as the elderly and residents of nursing homes) **those who are vaccinated “have a significantly lower risk for cardiovascular events”**.²¹²
- AstraZeneca shipped only 757,000 doses of its nasal flu vaccine in the last season but is planning to produce 8 million this year. **Flu vaccine manufacturers are hoping to deliver 200 million doses for the approaching northern hemisphere season**, to prevent co-infections with COVID-19.²¹³
- Scientists are reported to regard **influenza, coronaviruses, and Nipah virus** as the three most likely sources of a pandemic at the present time.²¹⁴
- An *in vitro* study showed some **active ingredients in mouthwash are effective against pneumonia-causing bacteria**.²¹⁵
- The Australian government is committing funding **to study a new vaccine for Q fever**.²¹⁶
- Researchers say **automatic hand dryers in public restrooms can harbor and spread bacteria**, including *Staphylococcus* and faecal matter.²¹⁷
- **H7N7 avian influenza** was detected on a free-range egg farm near Geelong.²¹⁸
- The US FDA approved Bayer’s Lampit® (nifurtimox) for use in paediatric patients for the treatment of **Chagas disease** caused by *Trypanosoma cruzi*. The medication is available in a dividable tablet and can be dispersed in water if required.²¹⁹ China has seen re-emergence of the novel bunyavirus, a viral haemorrhagic fever, in two eastern provinces, announcing 60 diagnoses and seven deaths by 7 August.²²⁰
- In the Chinese region of **Inner Mongolia** authorities sealed off a village after a resident died of **bubonic plague**.²²¹ The first death from human plague for the year occurred in New Mexico.²²²
- Researchers say that in some patients in emergency departments suspected of having **sepsis, prompt administration of antibiotics might not have been the best course**.²²³

²¹¹ <https://pipelinereview.com/index.php/2020073175456/Antibodies/SAB-Biotherapeutics-Announces-First-Participant-Dosed-in-Phase-1-Clinical-Trial-of-SAB-176-for-Seasonal-Influenza.html>

²¹² <https://www.medscape.com/viewarticle/934892>

²¹³ <https://www.fiercepharma.com/pharma/astrazeneca-after-prior-issues-flumist-ramps-up-production-response-to-pandemic>

²¹⁴ <https://www.the-scientist.com/feature/characteristics-that-give-viruses-pandemic-potential-67822>

²¹⁵ <https://www.healio.com/news/infectious-disease/20200804/mouthwash-ingredients-effective-against-pneumonia-pathogens>

²¹⁶ <https://www.abc.net.au/news/rural/2020-08-06/q-fever-research-funding-boosted-in-search-for-better-vaccine/12526106>

²¹⁷ <https://www.healio.com/news/infectious-disease/20200803/bathroom-hand-dryers-can-harbor-spread-staphylococcus-fecal-matter>

²¹⁸ <https://www.9news.com.au/national/bird-flu-outbreak-found-on-victorian-egg-farm-no-risk-to-public-say-authorities-avian-influenza/b571fa55-b149-4db3-afef-eb254f3209d5>

²¹⁹ <https://pipelinereview.com/index.php/2020080775526/Small-Molecules/U.S.-Food-and-Drug-Administration-Approves-Lampit-nifurtimox-for-the-Treatment-of-Chagas-Disease-in-Children.html>

²²⁰ <https://www.mirror.co.uk/news/world-news/china-hit-another-virus-outbreak-22486119>

²²¹ <https://www.9news.com.au/world/bubonic-plague-china-inner-mongolia-death-village-sealed-off/529ce80c-5ac6-4e5c-80e8-0975c389b546>

²²² <https://losalamosreporter.com/2020/08/07/rio-arriba-county-man-dies-from-human-plague/>

²²³ <https://www.medpagetoday.com/meetingcoverage/ats/88014>

- **Current animal vaccines for anthrax** are delivered by injection, which is time consuming in the case of livestock, and especially challenging for wildlife. **An oral vaccine has now been developed.**²²⁴
- A study in Columbia confirmed that **Zika virus disease is associated with brain and eye birth defects.**²²⁵
- Researchers at Nanyang Technological University, Singapore reported they have developed a **synthetic peptide which, when administered in combination with existing antibiotics, can render multidrug-resistant bacteria sensitive to antibiotics again.** They say the peptide can also kill bacteria that have become resistant to antibiotics.²²⁶

Alzheimer's disease

- Researchers have developed a **method for detecting changes in RNA at the single-cell level**, making it easier to study viral replication in single cells.²²⁷
- Lilly's P-tau217 **blood test has demonstrated high accuracy in diagnosing of Alzheimer's disease.**²²⁸
- UCB announced a global, exclusive licence agreement with Roche/Genentech, for the **development and commercialization of UCB0107 in Alzheimer's disease**, subject to antitrust clearance.²²⁹ The candidate is *anti-Tau antibody treatment*.
- Scientists at Macquarie University say they have demonstrated a **gene therapy approach to treating advanced forms of Alzheimer's disease** which can reverse memory loss in mice.²³⁰

Miscellaneous

- The US FDA has permitted [Cadila Healthcare](#) to begin trials of **Desidustat** in chemotherapy-induced **anaemia.**²³¹
- **Novo Nordisk's operating profit** increased by 8 per cent at constant exchange rates in the first six months of 2020.
- Researchers report that almost **a third of Australian haematologists and medical oncologists receive payments from the pharmaceutical industry:** and that this rate is three times higher than the average for specialist physicians.²³²

²²⁴ <https://www.sciencedaily.com/releases/2020/08/200811133228.htm>

²²⁵ <https://www.2minutemedicine.com/further-evidence-that-zika-virus-disease-associated-with-brain-and-eye-birth-defects/>

²²⁶ https://www.labonline.com.au/content/life-scientist/article/synthetic-peptide-takes-away-bacteria-s-drug-resistance-703029819?utm_source=Adestra&utm_medium

²²⁷ <https://www.fiercebiotech.com/research/outsmarting-covid-19-and-other-coronaviruses-by-analyzing-rna-single-cells>

²²⁸ <https://pipelinereview.com/index.php/2020072975430/More-News/Lillys-P-tau217-Blood-Test-Shows-High-Accuracy-in-Diagnosis-of-Alzheimers-Disease-in-Data-Published-in-JAMA.html> and <https://jamanetwork.com/journals/jama/fullarticle/2768841> and <https://www.medscape.com/viewarticle/934831>

²²⁹ <https://pipelinereview.com/index.php/2020072975427/Antibodies/UCB-enters-into-collaboration-with-Roche-to-develop-antibody-treatment-for-people-living-with-Alzheimers-Disease.html>

²³⁰ <https://newatlas.com/medical/world-first-gene-therapy-alzheimers-memory/>

²³¹ <https://www.moneycontrol.com/news/business/stocks/cadila-healthcare-shares-gain-after-zydus-gets-usfda-nod-for-cancer-drug-trials-5586341.html>

²³² <https://thelimbic.com/haematology/pharma-industry-payments-to-haematologists-under-the-microscope/>

- **Public Health England (PHE) is being replaced** with a new organisation, the National Institute for Health Protection (NIHP).²³³
- In the US, it is reported that some **regenerative medicine companies** offering unproven treatments are including COVID-19 in their list.²³⁴
- A study²³⁵ has **linked urinary BPA levels to overall mortality**.²³⁶

²³³http://www.pharmatimes.com/news/hancock_confirms_replacement_of_public_health_england_1347010

²³⁴<https://www.healio.com/news/rheumatology/20200821/unproven-stem-cell-therapy-claims-spread-beyond-arthritis-into-covid19>

²³⁵<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769313>

²³⁶<https://www.medscape.com/viewarticle/935809>