

Monitoring International Trends

September 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.

Some items of interest are reported below. They include updates on the use of convalescent plasma to treat COVID-19, trials of manufactured antibodies to treat COVID-19, and research reports on the use of anti-coagulants in hospitalised COVID-19 patients.

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1. Treating blood disorders

- In the US, the Institute for Clinical and Economic Review said the price range estimate for BioMarin's haemophilia A therapy (\$US 2 million to \$US 3 million) could in particular circumstances be cost effective for the health sector. It commented its assessment was "highly preliminary" as the FDA had declined to approve the treatment.¹
- Sanofi's haemophilia drug BIVV001 in a small study yielded results which suggested it could be administered at weekly intervals.²
- A third edition of the World Federation of Hemophilia guidelines for management of the disorder has been released.³ New treatments such as emicizumab are featured, although many people around the world with haemophilia do not currently have access to it.
- The European Medicines Agency awarded Vertex Pharmaceuticals and CRISPR Therapeutics a Priority Medicines (PRIME) designation from for their CRISPR/Cas9 gene therapy, CTX001. This is being trialled as a treatment for patients with transfusion-dependent beta thalassemia or severe sickle cell disease.⁴
- Sanofi is financially supporting a documentary focussed on mental health issues in patients with blood disorders.⁵
- Roche's subsidiary Genentech has created mini documentaries to encourage career goals and the development of professional skills in people living with bleeding disorders.⁶

2. Patient blood management

- The IMPACT-Afib study of 50,000 people aimed to increase anticoagulation use in atrial fibrillation by mailing a one-time reminder. It did not improve compliance.⁷
- A West Australian study found that screening elective surgery patients for anaemia and low iron stores before surgery significantly reduced blood transfusion requirements.⁸
- Researchers reported that mice treated after a stroke with blood from healthy donor mice experienced less brain tissue death than control mice.⁹

¹ <https://www.biopharmadive.com/news/biomarins-hemophilia-gene-therapy-could-have-warranted-a-record-price-tag/584342/>

² https://www.nejm.org/doi/full/10.1056/NEJMoa2002699?query=featured_home and <https://www.biopharmadive.com/news/sanofi-hemophilia-drug-bivv001-nejm/585000/>

³ <https://onlinelibrary.wiley.com/doi/10.1111/hae.14046> and <https://thelimbic.com/haematology/new-haemophilia-guidelines-emphasise-outcomes-with-newer-agents>

⁴ http://www.pharmatimes.com/news/vertex_crispr_therapeutics_sickle_cell_gene_therapy_wins_prime_designation_1351077

⁵ <https://www.fiercepharma.com/marketing/sanofi-genzyme-backs-mental-health-mission-documentary-let-s-talk-focused-blood-disease>

⁶ <https://www.fiercepharma.com/marketing/sharp-knives-and-hemophilia-no-problem-roche-s-genentech-mini-series-about-worklife-and>

⁷ <https://www.medpagetoday.com/meetingcoverage/esc/88387>

⁸ <https://pipelinereview.com/index.php/2020090475772/Vaccines/Johnson-Johnson-Announces-that-Janssens-COVID-19-Investigational-Vaccine-Candidate-Prevents-Severe-Clinical-Disease-in-Pre-clinical-Studies.html>

⁹ <https://www.nature.com/articles/s41467-020-17930-x> and <https://www.the-scientist.com/news-opinion/blood-replacement-rescues-mice-from-stroke-damage-67896>

- The [REALITY trial](#) reported that “a stricter limit on red blood cell transfusion did not hurt heart attack patients with anaemia”.¹⁰
- The AABB Journal Club uses Twitter to discuss peer-reviewed, scientific journal articles on important topics in transfusion medicine and biotherapies. On September 17 and 18 the topic was *Development and performance characteristics of Platelet Virtual Crossmatch (PLT VXM), a software application for the evaluation and management of platelet transfusion-refractory platelets*.¹¹
- The US FDA granted clearance for a device which its manufacturer, Alydia Health, says “rapidly controls and treats postpartum hemorrhage and abnormal postpartum uterine bleeding”. The Jada system’s safety and efficacy were evaluated in a multicentre, prospective, single-arm treatment trial.¹²
- Philips has launched a single-use device for clearing clots from peripheral blood vessels.¹³
- Abnormal coagulation is a well-established feature of COVID-19, and prophylaxis is a regular hospital treatment.¹⁴ A new study suggests that the amount of Factor V in a patient’s blood may be linked to worse outcomes in COVID-19.¹⁵
- Experience in New York City with anticoagulants in hospitalised COVID-19 patients has been analysed in two studies examining risks, benefits and possible regimens.¹⁶
- The US National Institutes of Health has launched late stage clinical trials to test safety and efficacy of different types of blood thinners in adult COVID-19 patients.¹⁷
- South Korean researchers have suggested anaemia as a possible marker for early detection of Crohn’s disease.¹⁸

3. Plasma Products

- A new documentary says UK officials were warned about the risk of using blood products imported from the US, around the time many haemophiliacs contracted HIV and/or hepatitis from their treatments.¹⁹
- Takeda is working with drug delivery specialist Elektrofi to investigate whether that company’s microparticle formulation technology could simplify delivery of plasma-derived therapies.²⁰
- Biotest announced the completion of a Phase III study trialling IgG Next Generation in patients with primary immunodeficiency disease. Its study report is yet to be finalised.²¹

¹⁰ <https://www.medpagetoday.com/meetingcoverage/esc/88391>

¹¹ For details see <http://www.aabb.org/development/Pages/aabb-on-twitter.aspx>

¹² <https://www.healio.com/news/primary-care/20200910/fda-clears-device-for-postpartum-bleeding> and <https://www.businesswire.com/news/home/20200909006092/en/Alydia-Health-Announces-FDA-Clearance-Publication-Pivotal>

¹³ <https://www.fiercebiotech.com/medtech/philips-launches-small-push-button-blood-clot-removal-system>

¹⁴ <https://www.medscape.com/viewarticle/937559>

¹⁵ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/elevated-blood-clotting-factor-linked-to-worse-covid-19-outcomes-761202.html>

¹⁶ <https://www.onlinejacc.org/content/76/1/122> and <https://link.springer.com/article/10.1007/s12028-020-01077-0> and <https://www.medscape.com/viewarticle/936601>

¹⁷ <https://www.reuters.com/article/healthcoronavirus-usa-bloodthinners/nih-launches-two-trials-to-test-blood-thinners-in-covid-19-patients-idUSL4N2G73ON>

¹⁸ <https://www.medpagetoday.com/gastroenterology/inflammatoryboweldisease/88564>

¹⁹ <https://www.independent.co.uk/news/health/haemophilia-hiv-hepatitis-infected-blood-factor-eight-documentary-itv-warning-b580040.html>

²⁰ <https://www.fiercepharma.com/drug-delivery/takeda-taps-elektrofi-s-microparticle-platform-for-potential-plasma-pairing>

4. Use of convalescent plasma in COVID-19

- A study found a cheap and easy-to-use test that accurately measures COVID-19 antibody levels in potential donors of convalescent plasma.²²
- Although the US FDA granted convalescent plasma an emergency use authorization, the US National Institutes of Health said that such plasma "should not be considered" standard of care for treating COVID-19 patients as there are "currently no data from well-controlled, adequately powered randomized clinical trials that demonstrate the efficacy and safety" of the treatment.²³
- Michael Joyner, principal investigator for the Expanded Access Program at the Mayo Clinic says: "the largest study to date on convalescent plasma provides robust evidence that transfusion is safe in hospitalized patients with COVID-19".²⁴
- Two randomized, placebo-controlled clinical trials funded by the US National Institutes of Health are further evaluating convalescent plasma as a treatment for hospitalised patients with COVID-19. Results are expected before the end of the year.²⁵
- Medstar and Johns Hopkins University are recruiting for two new studies examining the use of convalescent plasma to treat and prevent COVID-19. David Sullivan of Johns Hopkins said: "The early treatment trial is measuring the impact of plasma on the progression of the disease and hospitalization of patients as well as viral levels. For the infection prevention trial, investigators are looking at whether plasma reduces the number of patients who test positive or become symptomatic for coronavirus after being exposed to the disease".²⁶
- Indian researchers reported that a randomized control trial²⁷ of convalescent plasma therapy in severe COVID-19 demonstrated a reduction in hypoxia compared with standard therapy. Their findings also suggested that convalescent plasma had an anti-inflammatory effect.²⁸
- The CoVlg Plasma Alliance (Takeda, Biotest, CSL Behring, and Octapharma) is working on a hyperimmune globulin therapy derived from convalescent plasma. A study sponsored by the US National Institute of Allergy and Infectious Diseases in the US is recruiting 500 participants from four countries.²⁹

²¹ <https://pipelinereview.com/index.php/2020090175723/Antibodies/Biotest-achieves-another-important-clinical-milestone-for-IgG-Next-Generation.html>

²² https://www.upi.com/Health_News/2020/09/10/New-COVID-19-antibody-test-provides-fast-cheap-way-to-identify-donors/1221599746630/

²³ <https://www.fiercepharma.com/pharma/rebuking-fda-nih-experts-say-no-data-support-plasma-as-a-covid-19-treatment> and <https://www.covid19treatmentguidelines.nih.gov/statement-on-convalescent-plasma-eua/> and <https://www.medscape.com/viewarticle/936767> and <https://www.bmj.com/content/370/bmj.m3400>

²⁴ https://mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp_ft95_6_8.pd and <https://www.medpagetoday.com/infectiousdisease/covid19/88863>

²⁵ <https://www.nih.gov/news-events/news-releases/nih-expands-clinical-trials-test-convalescent-plasma-against-covid-19>

²⁶ <https://www.washingtontimes.com/news/2020/sep/24/medstar-johns-hopkins-recruiting-plasma-covid-19/>

²⁷ By the Centre of Scientific & Industrial Research (CSIR) and the Bengal government

²⁸ <https://timesofindia.indiatimes.com/city/kolkata/plasma-therapy-can-check-hypoxia-in-covid-patients-study/articleshow/78305911.cms>

²⁹ <https://www.reuters.com/article/us-health-coronavirus-takeda-pharma-plas/takeda-led-covid-19-plasma-product-to-begin-trial-this-month-idUSKBN2681CD>

5. Other blood sector news

- Grifols will pay \$US 146 million to acquire the remaining equity in Alkahest, founded on research into the therapeutic use of plasma proteins in the diseases of aging. Grifols expects that Alkahest's focus on understanding the human plasma proteome will lead to new therapeutics and diagnostics and new indications for currently approved plasma products.³⁰
- The role of plasma proteins on the human disease phenome was the subject of a report in *Nature Genetics*.³¹
- Liminal BioSciences, through its US subsidiary Prometic Biotherapeutics, has filed a resubmission of the Biologics License Application for Ryplazim® (plasminogen) with the US Food and Drug Administration (FDA) for the treatment of congenital plasminogen deficiency.³²

6. Clinical experience in COVID-19

- Researchers reported that the lung damage displayed by most COVID-19 patients six weeks after leaving hospital had improved in some at twelve weeks.³³
- Researchers in the UK found gastrointestinal symptoms to be common in children with COVID-19, and they recommended that if these symptoms appear children should be tested for SARS-CoV-2.³⁴
- A study found that multisystem inflammatory syndrome in children is distinct from both Kawasaki disease and severe adult cases of COVID-19.³⁵
- Researchers have identified mechanisms that result in functional deterioration of the immune system in response to severe viral infections, including COVID-19.³⁶
- A study found that invasive fungal disease is common in critically ill COVID-19 patients.³⁷
- A US study reported that people with substance use disorders are at more risk from COVID-19 and its complications.³⁸
- Siew C Ng³⁹ reported that researchers had “found active and prolonged SARS-CoV-2 infection in the stool of patients with COVID-19, even after recovery, suggesting that

³⁰ <https://pipelinereview.com/index.php/2020090775784/More-News/Grifols-to-acquire-Alkahest-to-enhance-discovery-research-and-development-to-identify-innovative-therapies-for-age-related-diseases-based-upon-an-understanding-of-the-human-pla.html>

³¹ <https://www.nature.com/articles/s41588-020-0682-6> and <https://www.genomeweb.com/scan/nature-papers-role-plasma-proteins-crystal-structure-cas9-ortholog#.X2ANfC0mKhA>

³² <https://pipelinereview.com/index.php/2020090875792/Proteins-and-Peptides/Liminal-BioSciences-Announces-Resubmission-of-Biologics-License-Application-to-U.S.-Food-and-Drug-Administration-for-Ryplazim-plasminogen.html>

³³ <https://www.medscape.com/viewarticle/937263>

³⁴ <https://www.bmj.com/content/370/bmj.m3484>

³⁵ <https://www.the-scientist.com/news-opinion/kids-severe-covid-19-reaction-bears-unique-immune-signature-67996>

³⁶ <https://www.labonline.com.au/content/life-scientist/news/immune-cells-exhausted-by-severe-viral-infection-1310835980>

³⁷ <https://www.healio.com/news/infectious-disease/20200904/invasive-fungal-disease-common-among-critically-ill-covid19-patients-study-finds>

³⁸ <https://www.nih.gov/news-events/news-releases/substance-use-disorders-linked-covid-19-susceptibility>

³⁹ Associate Director of the Centre for Gut Microbiota Research at the Chinese University of Hong Kong (CUHK).

coronavirus could remain in the gut of asymptomatic carriers". He said: "due to the potential threat of faecal-oral transmission, it is important to maintain long-term coronavirus and health surveillance".⁴⁰

- Harvard researchers found that when young adults are hospitalised with COVID-19, twenty per cent will be admitted to ICU and many need ongoing medical care after discharge.⁴¹
- A study found that prolonged fever after the onset of COVID-19 can predict adverse outcomes.⁴²
- Some scientists have questioned whether a cytokine storm is the real challenge in severe COVID-19, making a case for a new mechanism, bradykinin storm, and another group says the concepts are not necessarily mutually exclusive.⁴³
- The COVID Human Genetic Effort is a project covering more than 50 sequencing hubs and many more hospitals. Its first results show that "more than 10 per cent of healthy people who develop severe COVID-19 have misguided antibodies that attack the patient's own immune system, rather than the invading virus". Furthermore, there are "at least another 3.5 per cent carrying genetic mutations that impair their immune response to the virus".⁴⁴
- Some researchers suggest that how long COVID-19 antibodies are protective depends on their concentration in the blood, and that this in turn depends on how severely the person concerned had the disease in the first place.⁴⁵
- A study in Iceland found antibodies to combat SARS-CoV-2 infection "peaked in the two months following a positive diagnosis before plateauing for a further two months in more than 90 percent of recovered patients".⁴⁶
- Two studies have found that a large proportion of asymptomatic people with COVID-19 go on to develop symptoms.⁴⁷
- Brian Garibaldi⁴⁸ and colleagues have developed the [COVID-19 Inpatient Risk Calculator](#) with 24 variables associated with COVID-19 severity, including symptom severity at the time of admission, underlying conditions, vital signs, age, and body mass index.⁴⁹
- A new study suggests that severe COVID-19 may damage bone marrow cells.⁵⁰
- A US study in 10,000 veterans testing positive for SARS-CoV-2 found that some risk factors reported by earlier researchers were not significantly associated with mortality in this group, "including obesity, Black race, Hispanic ethnicity, chronic obstructive pulmonary disease (COPD), hypertension, and smoking".⁵¹

⁴⁰https://www.medscape.com/viewarticle/937256?nlid=137292_5404&src=wnl_dne_200914_mscpedit&uac=239431PV&implID=2563490&faf=1

⁴¹ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/covid-hits-young-adults-harder-than-thought-study-761170.html>

⁴² <https://www.healio.com/news/infectious-disease/20200908/prolonged-fever-identifies-patients-at-risk-for-adverse-covid19-outcomes>

⁴³ <https://www.medpagetoday.com/infectiousdisease/covid19/88560>

⁴⁴ <https://labonline.com.au/content/life-scientist/article/the-missing-link-behind-severe-cases-of-covid-19--217276414>

⁴⁵<https://www.medscape.com/viewarticle/936574>

⁴⁶ <https://www.the-scientist.com/news-opinion/covid-19-antibodies-last-for-at-least-four-months-after-recovery-67907>

⁴⁷<https://www.medscape.com/viewarticle/938195> and <https://journals.plos.org/plosmedicine/article> and <https://thorax.bmj.com/content/early/2020/08/28/thoraxjnl-2020-215042>

⁴⁸ Associate Professor of Medicine at the Johns Hopkins University School of Medicine in Baltimore

⁴⁹<https://www.medscape.com/viewarticle/938201>

⁵⁰<https://www.medscape.com/viewarticle/937856> and

<https://immunology.sciencemag.org/content/5/51/eabd6197>

⁵¹ <https://www.medpagetoday.com/infectiousdisease/covid19/88776>

- A study has compared the difference between the different immune response in adults from that in children, and suggested that in the latter “a branch of the immune system that evolved to protect against unfamiliar pathogens rapidly destroys the coronavirus before it wreaks damage on their bodies”.⁵²
- Researchers reported that stroke may be the presenting symptom of COVID-19 in patients under the age of 50.⁵³
- A study has shown “the spectrum of cardiac manifestations among paediatric patients during the SARS-CoV2 pandemic, allowing for better detection and preparation for treatment in clinical settings”.⁵⁴

7. Developing vaccines for COVID-19

Vaccine trials and research

- WHO identified 33 vaccines against SARS-CoV-2, currently being tested in humans, with another 143 candidates in preclinical testing.⁵⁵ WHO said widespread vaccination cannot be expected until mid-2021.⁵⁶
- Johnson & Johnson said investigational vaccine candidate, Ad26.COV2.S, prevented severe clinical disease in Syrian golden hamsters when challenged with the SARS-CoV-2 virus.⁵⁷ The company began enrolling US participants in a phase III trial. Its vaccine (JNJ-78436725) has a single dose regimen. Globally, 60,000 participants are expected to be enrolled.⁵⁸
- Sinovac will now trial its vaccine in children and adolescents.⁵⁹ The company said⁶⁰ its vaccine’s Phase I/II trial showed it to be safe in older patients, but there was a weaker immune response in that group than in younger people.
- AstraZeneca was permitted by the UK’s Medicines Health Regulatory Authority to restart its Phase III trial of AZD1222 after a pause over a safety concern.⁶¹ The trial

⁵² <https://www.theage.com.au/world/north-america/research-shines-light-on-how-children-fight-off-the-coronavirus-20200928-p55zsd.html>

⁵³ <https://www.medscape.com/viewarticle/938344> and <https://n.neurology.org/content/early/2020/09/15/WNL.000000000010851>

⁵⁴ <https://www.2minutemedicine.com/covid-19-associated-with-a-wide-range-of-cardiac-manifestations-in-pediatric-patients/>

⁵⁵ <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> and <https://www.medscape.com/viewarticle/936910>

⁵⁶ <https://www.reuters.com/article/us-health-coronavirus-who-briefing/widespread-covid-19-vaccinations-not-expected-until-mid-2021-who-says-idUSKBN25V1B0>

⁵⁷ <https://www.nature.com/articles/s41591-020-1070-6> and <https://www.jnj.com/single-dose-of-johnson-johnson-covid-19-vaccine-candidate-demonstrates-robust-protection-in-pre-clinical-studies>

and <https://pipelinereview.com/index.php/2020090475772/Vaccines/Johnson-Johnson-Announces-that-Janssens-COVID-19-Investigational-Vaccine-Candidate-Prevents-Severe-Clinical-Disease-in-Pre-clinical-Studies.html>

⁵⁸ <https://www.nih.gov/news-events/news-releases/fourth-large-scale-covid-19-vaccine-trial-begins-united-states> and <https://www.reuters.com/article/us-health-coronavirus-johnson-johnson/jj-kicks-off-final-study-of-single-shot-covid-19-vaccine-in-60000-volunteers-idUSKCN26E1QX> and <https://www.biopharmadive.com/news/johnson-johnson-coronavirus-vaccine-first-data/585910/>

⁵⁹ <https://www.reuters.com/article/us-health-coronavirus-sinovac-trial/chinas-sinovac-to-test-coronavirus-vaccine-candidate-in-teenagers-children-idUSKBN2680CI>

⁶⁰ <https://www.reuters.com/article/us-health-coronavirus-vaccine-sinovac/chinas-sinovac-coronavirus-vaccine-candidate-appears-safe-slightly-weaker-in-elderly-idUSKBN25Y1QM>

⁶¹ <https://www.fiercebiotech.com/biotech/astrazeneca-oxford-re-start-stalled-covid-test-as-pfizer-ramps-up-trial-numbers-for-its-vax> and <https://www.smh.com.au/business/companies/astrazeneca-puts-covid-19-vaccine-trial-on-hold-over-safety-concern-20200909-p55ts0.html>

in Japan was then permitted to restart, but the US FDA broadened its investigation to look at data from earlier trials of similar vaccines developed by the same researchers.⁶² The US National Institutes of Health was also reportedly concerned about the adverse event that caused Astra Zeneca to pause the trial.⁶³ Also in the US, Jesse Goodman, formerly the FDA's lead vaccine regulator, said "that it is currently impossible to understand what the diagnosis was or why the safety monitoring board had the confidence to support the resumption of dosing".

- Pfizer and BioNTech now want to boost their Phase II/ III trial for one of their five mRNA vaccines, BNT162b2, from around 30,000 to 44,000. They asked the US FDA for the extra participants so they could include a broader patient population. They plan to include adolescents as young as 16 and people with chronic, stable HIV, hepatitis C or hepatitis B infection.⁶⁴
- Some data relating to Russia's COVID-19 vaccine have been published, but scientists have criticised it, drawing attention to strange patterns. Enrico Bucci⁶⁵ said: "the presentation of the data raises several concerns which require access to the original data to fully investigate".⁶⁶
- Moderna and Pfizer have released details of how they are evaluating their vaccines.⁶⁷
- Moderna says it expects to know by November if its vaccine works, probably after Pfizer/BioNTech.⁶⁸ A Phase 1 trial in 40 adults over the age of 55 suggested that Moderna's vaccine elicits an immune system response that's equal to that seen in younger recipients. Researchers said vaccine side effects "were predominantly mild or moderate in severity" and included fatigue, chills, headache or ache or discomfort at the injection site.⁶⁹ A study in adults over 75 would perhaps be of more interest, given the concentration of COVID-19 deaths in that age group.
- Novavax began a Phase III trial of its vaccine in the UK.⁷⁰
- While some companies have vaccines in Phase III trials, and are agreeing marketing contracts for potential vaccines, others are at a much earlier stage in research and development. At 24 September, ClinicalTrials.gov listed 103 COVID-19 vaccine studies as "recruiting, not yet recruiting or available".⁷¹

⁶² <https://www.biopharmadive.com/news/astrazeneca-resumes-japan-vaccine-trial-fda-delay/586299/> and <https://www.reuters.com/article/us-health-coronavirus-astrazeneca-us-exc/exclusive-astrazeneca-covid-19-vaccine-trial-in-u-s-on-hold-until-at-least-midweek-sources-idUSKBN26536Y> and <https://www.reuters.com/article/us-health-coronavirus-vaccine-astrazenec/exclusive-fda-widens-u-s-safety-inquiry-into-astrazeneca-coronavirus-vaccine-sources-idUSKBN26L3TA>

⁶³ <https://www.fiercebiotech.com/biotech/astrazeneca-s-covid-19-vaccine-adverse-event-has-nih-very-concerned>

⁶⁴ <https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-propose-expansion-pivotal-covid-19-vaccine>

⁶⁵ a systems biologist and bioethicist at Temple University

⁶⁶ <https://www.the-scientist.com/news-opinion/scientists-voice-concerns-over-russian-covid-19-vaccine-study-67926>

⁶⁷ <https://www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html>

⁶⁸ <https://www.fiercepharma.com/vaccines/moderna-expects-to-see-covid-19-vaccine-efficacy-data-november-report>

⁶⁹ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/early-results-show-moderna-s-covid-vaccine-safe-effective-in-older-people-761713.html> and <https://www.healio.com/news/infectious-disease/20200929/earllystage-covid19-vaccine-data-provides-good-news-for-older-adults> and

<https://www.nih.gov/news-events/news-releases/investigational-covid-19-vaccine-well-tolerated-generates-immune-response-older-adults>

⁷⁰ <https://www.fiercebiotech.com/biotech/novavax-kickstarts-u-k-phase-3-covid-vaccine-u-k-as-cases-surge-across-country>

⁷¹ <https://clinicaltrials.gov/search?recr=open&cond=covid-19&intr=vaccine>

- The US FDA delayed late-stage testing of Inovio's experimental COVID-19 vaccine, as awaits answers on some queries. Delivery of INO-4800 requires small electrical pulses to open pores in cell walls large enough to permit passage of the DNA plasmid which encodes production of the coronavirus' characteristic "spike" protein'.⁷²
- Vaxart announced positive results of its oral vaccine in preclinical studies.⁷³ It received clearance for its investigational new drug application to the FDA for a Phase I clinical trial.⁷⁴
- Ufovax has adopted the patented vaccine design and manufacturing platform invented by Jiang Zhu, of Scripps Research⁷⁵. The company is approaching Phase I clinical trials of its SARS-CoV-2 candidate⁷⁶.
- Merck began Phase I/II testing of a COVID-19 vaccine, after acquiring Themis and partnering with IAVI.⁷⁷ It is a live attenuated vaccine that could be given orally, and it is hoped it will be a one-dose vaccine.⁷⁸
- The Serum Institute of India and SpyBiotech began a Phase I/II trial.⁷⁹
- Vaxil announced positive results in mice.⁸⁰
- Axon announce positive preclinical results.⁸¹
- AnGes and Brickell Biotech announced collaboration.⁸²
- Companies at earlier stages of vaccine development include Aegis Life⁸³, HDT Bio Corp⁸⁴, Elixirgen Therapeutics⁸⁵, Sanofi/GSK⁸⁶, Arcturus Therapeutics⁸⁷.

⁷² <https://www.biopharmadive.com/news/inovio-coronavirus-vaccine-fda-hold/585990/>

⁷³ <https://pipelinereview.com/index.php/2020090875801/Vaccines/Vaxarts-Oral-COVID-19-Vaccine-Candidate-Induces-Potent-Systemic-and-Mucosal-Immune-Responses-in-Preclinical-Studies.html>

⁷⁴ <https://pipelinereview.com/index.php/2020091475868/Vaccines/Vaxart-Announces-FDA-Clearance-of-IND-Application-for-Oral-COVID-19-Vaccine-and-Provides-Update-on-COVID-19-Program.html> and <https://investors.vaxart.com/news-releases/news-release-details/vaxart-announces-fda-clearance-ind-application-oral-covid-19>

⁷⁵ One-component Self-Assembling protein NanoParticle® (1c-SAPNP®)

⁷⁶ <https://pipelinereview.com/index.php/2020091875911/Vaccines/Ufovax-Announces-Its-Self-Assembling-NanoParticles-as-the-Next-Generation-Vaccine-Solution-for-COVID-19.html> and <https://www.biorxiv.org/content/10.1101/2020.09.14.296715v1>

⁷⁷ International AIDS Vaccine Initiative

⁷⁸ <https://www.fiercepharma.com/pharma/merck-advancing-single-dose-and-oral-coronavirus-vaccines-could-still-make-warp-speed>

⁷⁹ <https://pipelinereview.com/index.php/2020090875790/Vaccines/SpyBiotech-and-Serum-Institute-of-India-announce-that-the-first-subjects-have-been-dosed-in-a-Phase-I/II-trial-of-a-novel-virus-like-particle-vaccine-targeting-COVID-19.html>

⁸⁰ <https://pipelinereview.com/index.php/2020090875800/Vaccines/Vaxil-Announces-Positive-Results-on-CorVax-in-vivo-Study.html>

⁸¹ <https://pipelinereview.com/index.php/2020091075828/Vaccines/Axon-Announces-Positive-Pre-Clinical-Results-for-its-Peptide-Vaccine-ACvac1-Against-Novel-Coronavirus.html>

⁸² <https://pipelinereview.com/index.php/2020090875803/Vaccines/AnGes-and-Brickell-Biotech-Announce-a-Collaboration-Agreement-for-the-Development-of-a-Novel-DNA-Vaccine-Candidate-for-COVID-19-in-the-U.S.html>

⁸³ <https://pipelinereview.com/index.php/2020090175738/Vaccines/Aegis-Life-Inc.-Launches-to-Fight-COVID-19-via-DNA-Vaccines-and-Therapeutics-Enabled-by-Proprietary-Fusogenix-Delivery-Technology.html>

⁸⁴ <https://pipelinereview.com/index.php/2020090175739/Vaccines/HDT-BIO-Receives-NIH-Contract-to-Advance-Novel-RNALION-COVID-19-Vaccine-Into-Clinical-Trials.html>

⁸⁵ <https://pipelinereview.com/index.php/2020090175744/Vaccines/Elixirgen-Therapeutics-planning-to-begin-Phase-I/II-Clinical-Trials-of-its-COVID-19-Vaccine-Candidate-EXG-5003-at-Fujita-Health-University.html>

⁸⁶ <https://pipelinereview.com/index.php/2020090375764/Vaccines/Sanofi-and-GSK-initiate-Phase-1/2-clinical-trial-of-COVID-19-adjuvanted-recombinant-protein-based-vaccine-candidate.html>

⁸⁷ <https://pipelinereview.com/index.php/2020090575781/Vaccines/Arcturus-Therapeutics-Announces-Preclinical-Publication-of-its-COVID-19-Vaccine-Candidate.html>

- Adenovirus vectors are being used in some potential vaccines but researchers ask whether pre-existing immunity from common colds will target the vaccines and make them ineffective.⁸⁸
- Some researchers think that antibodies made to the measles, mumps and rubella (MMR) vaccine might also fight SARS-CoV-2. A trial will test whether it can help healthcare workers to resist infection.⁸⁹
- Scientists have explained that it is possible for a vaccine to produce a better immune response than a natural infection.⁹⁰

Vaccine approval, manufacture and distribution

- The Australian Government arranged to have 84 million doses of vaccine to administer in 2021, if the Astra Zeneca/ University of Oxford and the University of Queensland Phase III trials are both successful.⁹¹ Astra Zeneca has begun a Phase III trial with 30,000 participants in the US for its candidate AZD 1222.⁹²
- CSL signed two separate heads of agreement for COVID-19 vaccines for use in Australia, conditional upon successful clinical trials. One is with the Australian Government for the supply of 51 million doses of the University of Queensland vaccine candidate V451 and the other is with AstraZeneca to manufacture the University of Oxford candidate AZD1222.⁹³
- There have been calls for the Australian Government to release information on how it will prioritise delivery of COVID-19 vaccines.⁹⁴
- In the US, the National Academies of Sciences, Engineering, and Medicine issued draft guidelines for an equitable allocation of a future COVID-19 vaccine, recommending it go first to front-line health workers, first responders and people at serious risk for infection.⁹⁵
- US FDA Commissioner Stephen Hahn in August said on Twitter that his agency would review coronavirus vaccines before the November presidential election.⁹⁶ Apparently in response to this, and the FDA's emergency use authorisation for convalescent plasma (mentioned above), some biotech CEOs (associated with the

⁸⁸ <https://www.the-scientist.com/news-opinion/vector-based-vaccines-come-to-the-fore-in-the-covid-19-pandemic-67915> and <https://www.fiercebiotech.com/research/using-crispr-to-make-better-viral-vectors-for-gene-therapy>

⁸⁹ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/could-the-mmr-vaccine-help-prevent-covid-19-new-trial-may-tell-761000.html>

⁹⁰ <https://www.abc.net.au/news/2020-09-16/why-coronavirus-vaccine-better-immunity-infection-covid-19/12668050>

⁹¹ <https://www.abc.net.au/news/2020-09-06/free-coronavirus-vaccine-to-be-made-available-throughout-2021/12635174> and <https://www.abc.net.au/news/2020-09-07/how-realistic-are-the-covid-19-vaccine-timelines/12636164>

⁹² <https://www.fiercebiotech.com/biotech/astrazeneca-starts-30-000-subject-u-s-phase-3-covid-19-vaccine-trial>

⁹³ <https://www.labonline.com.au/content/life-scientist/article/csl-agrees-to-manufacture-covid-19-vaccines-for-australia-902518131>

⁹⁴ <https://www.abc.net.au/news/2020-09-18/covid-19-vaccine-supply-in-australia-who-gets-it-first/12664888>

⁹⁵ <https://www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-see-public-comment> and <https://thehill.com/policy/healthcare/514670-federal-panel-lays-out-initial-priorities-for-covid-vaccine-distribution>

⁹⁶ <https://www.fiercepharma.com/pharma/pfizer-could-score-fast-covid-vaccine-approval-as-fda-s-hahn-promises-october-review-analyst>

Biotechnology Innovation Organization) have asked “all parties” involved in the FDA’s decision-making process to “adhere to high scientific standards”.⁹⁷

- The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer and Sanofi have signed a joint pledge to file for US FDA approval only after demonstrating safety and efficacy in Phase III trials.⁹⁸ This came amid the reports that the Trump Administration wanted a vaccine approved before the presidential election. Moderna has said it does not expect to file in the US for emergency use authorization for its vaccine until late November.⁹⁹
- AstraZeneca will pay Oxford Biomedica an \$US 20 million in the first instance to reserve 1,000 litres of production capacity for its vaccine, AZD1222, for at least 18 months.¹⁰⁰
- The Pfizer/BioNTech partnership negotiated to supply up to 300 million doses of its vaccine to the EU.¹⁰¹
- Valneva signed a \$US 1.6 billion deal with the UK government which could supply 190 million doses by 2025.¹⁰²
- DHL, with analysis from McKinsey and Company, has published a white paper which includes a discussion of logistics for delivering large volumes of vaccines.¹⁰³
- Sanofi and GlaxoSmithKline have undertaken to provide the European Commission with up to 300 million doses of their potential COVID-19 vaccine candidate. This is based on recombinant protein-based technology and uses GSK’s established adjuvant technology. The vaccine is at present the subject of a Phase I/II clinical trial, with a Phase III trial expected to begin before the end of this year. The EU will support financially the scale-up of the companies’ manufacturing capabilities in Europe.¹⁰⁴
- Sanofi and GlaxoSmithKline have agreed with the Canadian Government to supply up to 72 million doses of their adjuvant COVID-19 vaccine, starting in 2021.¹⁰⁵

⁹⁷ <https://www.fiercepharma.com/pharma/amid-election-frenzy-and-reputation-crisis-at-fda-biotech-ceos-lay-out-guiding-principles> and <https://www.fiercepharma.com/pharma/amid-election-frenzy-and-reputation-crisis-at-fda-biotech-ceos-lay-out-guiding-principles>

⁹⁸ <https://www.businesswire.com/news/home/20200908005282/en/Biopharma-Leaders-Unite-Stand-Science> and <https://www.fiercebiotech.com/biotech/covid-19-vaccine-ceos-vow-to-wait-for-phase-3-data-before-filing-for-approval>

⁹⁹ <https://www.fiercepharma.com/pharma/moderna-s-coronavirus-vaccine-won-t-be-ready-for-before-late-november-ceo-says-ft>

¹⁰⁰ <https://www.oxb.com/news-media/press-release/oxford-biomedica-signs-supply-agreement-astrazeneca-expand-manufacturing> and <https://www.fiercepharma.com/manufacturing/astrazeneca-shells-out-up-to-60m-to-reserve-covid-19-vaccine-capacity-oxford>

¹⁰¹ <https://www.biopharmadive.com/news/pfizer-biontech-coronavirus-vaccine-EU-supply-talks/584910/>

¹⁰² <https://www.fiercepharma.com/manufacturing/uk-signs-1-6b-supply-development-agreement-for-valneva-s-covid-19-vaccine-hopeful>

¹⁰³ <https://www.labonline.com.au/content/lab-business/news/logistics-requirements-for-a-covid-19-vaccine-1317133345>

¹⁰⁴ http://www.pharmatimes.com/news/sanofi_gsk_ink_deal_with_eu_for_300_million_covid-19_vaccine_doses_1351087 and <https://www.fiercepharma.com/manufacturing/sanofi-gsk-score-eu-vaccine-supply-deal-for-300m-doses-covid-19-shot>

¹⁰⁵ <https://medicaldialogues.in/news/industry/pharma/gsk-sanofi-ink-covid-19-vaccine-supply-deal-with-canada-69916>

8. Potential treatments for COVID-19

Antibodies and T cells

- Celltrion announced positive results from a Phase I trial of its monoclonal antibody treatment.¹⁰⁶ The company is beginning production of its drug, planning to produce a million doses before approval.¹⁰⁷
- Vir Biotechnology and GSK have begun a Phase II/III trial of their COVID-19 antibody therapy.¹⁰⁸
- Twist Bioscience announced data demonstrating the potent neutralizing effects of multiple potential therapeutic antibodies.¹⁰⁹
- Totient and Ginkgo Bioworks announced partnership to identify neutralizing antibodies.¹¹⁰
- Researchers say that some COVID-19 patients lack germinal centres which during infections produce long-lived antibody-generating cells.¹¹¹
- The UK will run a Phase III study of Regeneron's antibody cocktail, REGN-COV2, in hospitalized COVID-19 patients.¹¹²
- Initial data for Regeneron's COVID-19 antibody cocktail shows that the highest dose reduced virus levels and relieved symptoms more quickly than did placebo in patients infected with COVID-19 but not hospitalised.¹¹³
- Eli Lilly and Amgen are partnering to produce future antibody cocktails, including Lilly's LY-CoV-55, which in August began a Phase III trial for treating COVID-19.¹¹⁴ Eli Lilly said LY-CoV555 significantly reduced the risk of hospitalisation.¹¹⁵

¹⁰⁶ <https://pipelinereview.com/index.php/2020091275839/Antibodies/Celltrion-Announces-Positive-Interim-Results-From-Phase-I-Trial-of-CT-P59-an-Anti-COVID-19-Monoclonal-Antibody-Treatment-Candidate.html> and <https://www.fiercebiotech.com/biotech/celltrion-passes-early-safety-trial-for-anti-covid-antibody-as-key-tests-await>

¹⁰⁷ <https://www.reuters.com/article/us-health-coronavirus-southkorea-celltri/south-koreas-celltrion-to-begin-commercial-production-of-covid-19-antibody-drug-idUSKBN25Z1EZ?rpc=401&>

¹⁰⁸ <https://pipelinereview.com/index.php/2020090175716/Antibodies/Vir-Biotechnology-and-GSK-start-phase-2/3-study-of-COVID-19-antibody-treatment.html>

¹⁰⁹ <https://pipelinereview.com/index.php/2020090275757/Antibodies/Twist-Bioscience-Announces-Potent-SARS-CoV-2-Neutralizing-Data-from-COVID-19-Therapeutic-Antibody-Program.html>

¹¹⁰ <https://pipelinereview.com/index.php/2020091075829/Antibodies/Totient-Partners-with-Ginkgo-Bioworks-to-Apply-Unique-Discovery-Platform-to-COVID-19-Antibody-Efforts.html>

¹¹¹ <https://www.the-scientist.com/news-opinion/some-covid-19-patients-lack-key-structures-for-antibody-creation-67868>

¹¹² <https://investor.regeneron.com/news-releases/news-release-details/recovery-covid-19-phase-3-trial-evaluate-regenerons-regn-cov2>

¹¹³ <https://www.fiercebiotech.com/biotech/regeneron-s-covid-19-antibody-cocktail-curbs-virus-speeds-recovery-early-data> and <https://www.biopharmadive.com/news/regeneron-antibody-coronavirus-study-results/586105/>

¹¹⁴ <https://www.fiercepharma.com/manufacturing/eli-lilly-amgen-join-forces-to-scale-production-covid-19-antibody-cocktails> and <https://www.statnews.com/2020/09/16/lilly-covid-19-antibody-helps-patients-rid-their-systems-of-virus-sooner/> and <https://www.medscape.com/viewarticle/937501> and <https://www.biopharmadive.com/news/lilly-coronavirus-antibody-drug-data/585312/>

¹¹⁵ <https://www.the-scientist.com/news-opinion/antibody-based-drug-may-reduce-covid-19-hospitalizations-study-67942>

- Neutralizing monoclonal antibodies are promising against COVID-19, but they typically must be administered by intravenous infusion because of their size. Some researchers are working on an antibody component which is much smaller and might even be deliverable through inhalation.¹¹⁶
- Researchers have found SARS-CoV-1 reactive T cells in SARS patients 17 years after infection. They wrote: “our findings also raise the possibility that long-lasting T cells generated after infection with related viruses may be able to protect against, or modify the pathology caused by, infection with SARS-CoV-2”.¹¹⁷

Remdesivir

- Researchers in Texas have developed a dry powder formulation of Gilead's remdesivir that patients with less-severe COVID-19 might be able to take at home.¹¹⁸ The drug Gilead currently supplies is delivered intravenously.
- In a trial conducted by the US National Institute of Allergy and Infectious Diseases, Eli Lilly's rheumatoid arthritis drug Olumiant combined with Gilead's antiviral remdesivir helped patients recover faster than remdesivir alone by about one day. Eli Lilly plans to seek an emergency use authorization from the FDA.¹¹⁹
- Gilead became directly responsible for seeing remdesivir is distributed to US hospitals, ending a five-month period when the US Department of Health and Human services was responsible for allocating it.¹²⁰

Other therapies

- Data from four recently published studies suggests that treatment with corticosteroids improves the survival odds for people critically ill with COVID-19.¹²¹
- Researchers reported that high-dose methylprednisolone, followed by the monoclonal antibody tocilizumab if required, “may speed up respiratory recovery, decrease hospital mortality and prevent ventilation in patients with COVID-19-related cytokine storm syndrome”.¹²²
- Biovista has suggested a number of currently available drugs which might be useful in treating symptoms of COVID-19.¹²³

¹¹⁶ <https://www.fiercebiotech.com/research/small-sized-biologic-against-covid-19-shows-promise-animal-models>

¹¹⁷ <https://www.bmj.com/content/370/bmj.m3563>

¹¹⁸ <https://www.fiercepharma.com/drug-delivery/using-inhaled-remdesivir-and-a-repurposed-tapeworm-med-to-hit-covid-19-where-it>

¹¹⁹ <https://www.fiercepharma.com/pharma/eli-lilly-to-discuss-olumiant-emergency-authorization-fda-after-positive-covid-data> and <https://www.reuters.com/article/us-health-coronavirus-lilly/eli-lillys-rheumatoid-arthritis-drug-accelerates-recovery-in-covid-19-patients-idUSKBN2651KW> and <https://pipelinereview.com/index.php/2020091475865/Small-Molecules/Baricitinib-in-Combination-with-Remdesivir-Reduces-Time-to-Recovery-in-Hospitalized-Patients-with-COVID-19-in-NIAID-Sponsored-ACTT-2-Trial.html>

¹²⁰ <https://www.fiercepharma.com/pharma/gilead-takes-back-remdesivir-distribution-after-drop-demand-confusing-government-allocation>

¹²¹ <https://www.healio.com/news/primary-care/20200902/trials-provide-definitive-data-that-corticosteroids-successful-in-treating-covid19> and <https://www.medscape.com/viewarticle/936813> and <https://www.the-scientist.com/news-opinion/steroid-drugs-are-an-effective-treatment-for-severe-covid-19-who-67910> and <https://www.abc.net.au/news/2020-09-06/coronavirus-steroid-trials-treatment-medics-hope/12631988>

¹²² <https://www.healio.com/news/rheumatology/20200903/glucocorticoids-tocilizumab-may-reduce-complications-in-covid19related-cytokine-storm>

¹²³ <https://www.medscape.com/viewarticle/936912>

- Sanofi discontinued its study of its rheumatoid arthritis drug Kevzara in COVID-19.¹²⁴
- Clinicians have published a case study on their use of regulatory T cell therapy in two patients with acute respiratory distress syndrome arising from COVID-19.¹²⁵
- Cartesian Therapeutics has begun a Phase I/II clinical trial of its RNA-engineered cell therapy as a possible treatment for COVID-19 and acute respiratory distress syndrome.¹²⁶
- Verona is conducting a pilot study of a possible inhaler for COVID-19.¹²⁷
- The European Medicines Agency (EMA) has reviewed¹²⁸ the RECOVERY study by its Committee for Medicinal Products for Human Use. It endorsed the use of dexamethasone in patients with COVID-19 on oxygen or mechanical ventilation.¹²⁹ Dexamethasone has the advantage of being able to be administered orally, by injection, or by infusion.
- Russia has approved R-Pharm's Coronavir to treat outpatients with mild to moderate COVID-19. This follows approval of Avifavir in May. Both are based on the Japanese-developed antiviral favipiravir.¹³⁰
- Fujifilm says a Phase III study of its flu drug Avigan in 156 COVID-19 patients with non-severe pneumonia reduced time to recovery.¹³¹
- The FDA has cleared Ampio Pharmaceuticals to trial an inhalation therapy for respiratory distress in COVID-19.¹³²
- Behnood Bikdeli¹³³ said in late September: "As of now there are more than 20 ongoing or registered randomized studies to address the questions of optimal anticoagulation in various subgroups of patients with COVID-19 – from outpatients to inpatients or critically-ill patients".¹³⁴
- Humanigen, in seeking an Emergency Use Authorization from the US FDA for the use of lenzilumab in COVID-19, will collaborate with Thermo Fisher Scientific to increase manufacturing capacity.¹³⁵
- A patient in the UK has been treated in a new COVID-19 trial investigating the use of GlaxoSmithKline's experimental rheumatoid arthritis drug, otilimab, for severe lung disease.¹³⁶

¹²⁴ <https://www.biopharmadive.com/news/sanofi-kevezara-covid-19-end-research/584504/> and <https://pipelinereview.com/index.php/2020090175735/Antibodies/Sanofi-provides-update-on-Kevzara-sarilumab-Phase-3-trial-in-severe-and-critically-ill-COVID-19-patients-outside-the-U.S.html>

¹²⁵ <https://www.healio.com/news/hematology-oncology/20200908/regulatory-tcell-therapy-shows-promise-for-covid19related-respiratory-distress>

¹²⁶ <https://pipelinereview.com/index.php/2020090175743/DNA-RNA-and-Cells/Cartesian-Therapeutics-Initiates-Clinical-Trial-of-First-RNA-Engineered-Cell-Therapy-for-Acute-Respiratory-Distress-Syndrome-and-COVID-19.html>

¹²⁷ http://www.pharmatimes.com/news/inhaled_ensifentrine_will_be_assessed_in_hospitalised_patient_s_1348967

¹²⁸ <https://www.ema.europa.eu/en/news/ema-starts-review-dexamethasone-treating-adults-covid-19-requiring-respiratory-support> and <https://www.nejm.org/doi/full/10.1056/NEJMoa2021436>

¹²⁹ <https://www.medscape.com/viewarticle/937709> and <https://www.ema.europa.eu/en/news/ema-endorses-use-dexamethasone-covid-19-patients-oxygen-mechanical-ventilation>

¹³⁰ <https://www.medscape.com/viewarticle/937649>

¹³¹ <https://www.fiercepharma.com/pharma/fujifilm-s-flu-drug-avigan-improves-covid-19-recovery-time-setting-up-filing-japan>

¹³² <https://seekingalpha.com/news/3615701-ampio-pharma-on-go-inhaled-ampion-study-in-covidminus-19>

¹³³ Of Brigham and Women's Hospital and Harvard

¹³⁴ <https://www.medpagetoday.com/infectiousdisease/covid19/88825>

¹³⁵ <https://seekingalpha.com/news/3616446-humanigen-inks-manufacturing-deal-thermo-fisher-for-lenzilumab>

¹³⁶ http://www.pharmatimes.com/news/first_uk_patient_given_gsks_experimental_arthritis_drug_in_covid-19_trial_1351634

- Researchers have designed “miniproteins” which in the laboratory bound tightly to the SARS-CoV-2 spike protein so the virus could not infect human cells.¹³⁷

9. Managing the pandemic

Individual country experience

- The US Centers for Disease Control and Prevention reported that more hospital workers may have been infected with COVID-19 than previously recognised, as their cases went undiagnosed.¹³⁸
- In the US, one third of colleges and universities re-opened completely in August, but some soon closed because of campus outbreaks of COVID-19.¹³⁹
- Researchers at the US Centers for Disease Control and Prevention say that restaurants contribute significantly to the spread of COVID-19.¹⁴⁰
- The US media reported that the Department of Health and Human Services is expecting to spend \$US 250 million on advertising to “defeat despair and inspire hope” in relation to the COVID-19 pandemic.¹⁴¹
- A South Korean study found that children with COVID-19 may shed the virus for up to three weeks, even if they are asymptomatic.¹⁴²
- Sweden’s Prime Minister said in late September that the country’s resurgence of COVID-19 was “because many people seem to have set aside months of caution in favour of full-on social life once again”.¹⁴³

Transmission

- A study found that transmission of SARS-CoV-2 via breast milk is unlikely.¹⁴⁴
- Researchers who assessed in-flight transmission of SARS-CoV-2 on a ten-hour commercial flight found that “seating proximity was strongly associated with increased infection risk”. They “found no strong evidence supporting alternative transmission scenarios”. They recommended that “guidelines for preventing SARS-CoV-2 infection among air passengers should consider individual passengers’ risk for infection, the number of passengers traveling, and flight duration”.¹⁴⁵
- US scientists reporting on a study of more than 5,000 genetic sequences of the Sars-CoV-2 virus confirmed that the virus is continually mutating.¹⁴⁶

¹³⁷ <https://www.nih.gov/news-events/nih-research-matters/computer-designed-proteins-may-protect-against-coronavirus>

¹³⁸ <https://www.fiercehealthcare.com/hospitals/covid-19-often-undetected-workers-hospital-frontlines-cdc-says> and <https://www.cdc.gov/mmwr/volumes/69/wr/mm6935e2.htm>

¹³⁹ <https://www.bmj.com/content/370/bmj.m3365>

¹⁴⁰ <https://www.medscape.com/viewarticle/937430>

¹⁴¹ <https://www.politico.com/news/2020/08/31/hhs-contract-coronavirus-despair-hope-406361> and <https://www.fiercepharma.com/marketing/hhs-solicits-bids-for-massive-250-million-advertising-campaign-to-inspire-hope-around>

¹⁴² <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2770150> and <https://www.medpagetoday.com/infectiousdisease/covid19/88319>

¹⁴³ <https://www.medscape.com/viewarticle/937984>

¹⁴⁴ <https://www.healio.com/news/pediatrics/20200903/sarscov2-transmission-via-breast-milk-unlikely-study-finds>

¹⁴⁵ https://wwwnc.cdc.gov/eid/article/26/11/20-3299_article

¹⁴⁶ <https://www.washingtonpost.com/health/2020/09/23/houston-coronavirus-mutations/?arc404=true>

Testing

- Researchers have said that COVID-19 screening tests used in public places are “not particularly effective” and that their findings “point to the need for greater emphasis on other ways that may prevent transmission such as face coverings, physical distancing, quarantine, and adequate personal protective equipment for frontline workers”.¹⁴⁷
- The US FDA has approved a COVID-19 antibody test designed for use at point-of-care.¹⁴⁸
- Doctors from the Royal College of Pathologists of Australasia warned a new rapid coronavirus test, approved by the Therapeutic Goods Administration, “detects the signs of the coronavirus in between 50 and 94 per cent of cases” and is therefore not reliable.¹⁴⁹
- From 15 October United Airlines will offer COVID-19 tests to passengers flying from San Francisco International Airport to Hawaii.¹⁵⁰
- The Infectious Diseases Society of America (IDSA) has issued new guidelines in the journal *Clinical Infectious Diseases* on when to test for COVID-19 antibodies. The Society says that “antibodies to the novel coronavirus do not show up in the blood for quite a while after someone becomes infected, so serology tests are unreliable for diagnosing COVID-19 unless a patient has been sick for weeks”.¹⁵¹
- The US FDA has approved a “rinse and spit” test for COVID-19.¹⁵²
- The World Health Organisation hopes to make available to low-income countries 120 million rapid diagnostic tests for the SARS-CoV-2 virus.¹⁵³
- Roche is planning to make 40 million rapid antigen tests available per month.¹⁵⁴
- Beroni has received a CE mark for its SARS-CoV-2 antibody test kit that can deliver results within 10 minutes. The assay relies on qualitative detection of IgG and IgM antibodies to identify COVID-19 positive patients.¹⁵⁵
- Thermo Fisher Scientific is investing more than \$US140 million to expand its manufacturing of laboratory plastics disposables for COVID-19 testing, and for development and manufacturing of COVID-19 therapies and vaccines.¹⁵⁶

Masks

- Researchers have suggested that universal masking may lead to a higher proportion of asymptomatic cases of COVID-19.¹⁵⁷

¹⁴⁷ <https://www.medscape.com/viewarticle/93752> and <https://www.bmj.com/content/370/bmj.m3619>

¹⁴⁸ <https://www.fiercebiotech.com/medtech/fda-green-lights-its-first-coronavirus-antibody-blood-test-for-point-care>

¹⁴⁹ <https://www.abc.net.au/news/2020-10-02/coronavirus-australia-live-blog-queensland-pubs-clubs/12723430>

¹⁵⁰ <https://www.fiercehealthcare.com/tech/united-airlines-teams-up-color-to-make-covid-19-tests-available-to-passengers>

¹⁵¹ <https://www.medscape.com/viewarticle/938164> and <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1343/5904785>

¹⁵² <https://www.fiercebiotech.com/medtech/fda-authorizes-oral-rinse-and-spit-test-for-covid-19>

¹⁵³ <https://www.abc.net.au/news/2020-09-29/who-unveils-rapid-diagnostic-testing-in-lower-income-countries/12712462>

¹⁵⁴ <https://www.fiercebiotech.com/medtech/roche-to-launch-40m-rapid-coronavirus-antigen-tests-per-month-starting-europe>

¹⁵⁵ <https://www.fdanews.com/articles/198938-beronis-covid-19-antibody-test-kit-obtains-ce-mark>

¹⁵⁶ <https://www.medicaldesignandoutsourcing.com/thermo-fisher-ups-global-lab-plastics-production-for-covid-19/>

¹⁵⁷ <https://www.medpagetoday.com/infectiousdisease/covid19/88692>

- CSIRO has launched a surgical mask testing facility in Melbourne. It is accredited by the National Association of Testing Authorities.¹⁵⁸
- Researchers at Flinders University have tested commonly available fabric face masks. They “found they significantly reduce the number of aerosolised viruses a wearer could be exposed to, with even the poorest-performing mask filtering at least 50 per cent viruses.”¹⁵⁹

10. Miscellaneous news

Infectious diseases other than COVID-19

- Researchers have found that in pregnant women the Zika virus can invade the placenta, increasing its odds of reaching the foetus.¹⁶⁰
- A study of Nicaraguan children has linked earlier Zika virus infection with severe dengue fever symptoms.¹⁶¹ Zika can be transmitted by blood transfusion.
- Researchers found that dual infections with Zika and chikungunya viruses may trigger a stroke.¹⁶²
- Q fever has been identified in Far North Queensland, and residents who work with animals are being urged to seek vaccination.¹⁶³ A recent Australian study in blood donors found that Q fever had infected more people in rural communities than previously thought.
- The US National Institute of Allergy and Infectious Diseases awarded the University of California, Davis, [School of Veterinary Medicine](#) \$US 8 million over five years to lead the activities of a new research center, the EpiCenter for Emerging Infectious Disease Intelligence. This will focus on the Amazon and Congo Basin forests to advance understanding of how viruses emerge and jump from wildlife to people.¹⁶⁴
- Valneva has begun a Phase III clinical trial of its chikungunya vaccine candidate.¹⁶⁵
- A new model has reinforced the view that “urbanization and rising global temperatures will expand the range of the mosquito species, *Aedes aegypti*, responsible for spreading a number of debilitating diseases, including yellow fever, Zika, chikungunya and dengue fever”.¹⁶⁶
- Researchers at the UC Berkeley School of Public Health were awarded a \$US 7.78 million grant over five years to launch an arboviral disease research center.¹⁶⁷

¹⁵⁸ <https://www.labonline.com.au/content/lab-business/news/inside-australia-s-first-accredited-face-mask-testing-facility-545076648>

¹⁵⁹ <https://labonline.com.au/content/consumables/news/fabric-masks-prove-effective-at-virus-filtration-1195773820> and <https://www.mdpi.com/2076-0817/9/9/762>

¹⁶⁰ <https://consumer.healthday.com/diseases-and-conditions-information-37/zika-1007/study-zeroes-in-on-how-zika-virus-is-passed-from-mom-to-fetus-760757.html>

¹⁶¹ <https://www.the-scientist.com/news-opinion/zika-infection-increases-risk-of-severe-dengue-fever-67883>

¹⁶² <https://www.genengnews.com/news/stroke-linked-to-dual-infection-from-mosquito-borne-viruses/>

¹⁶³ <https://www.newsport.com.au/>

¹⁶⁴ <https://www.ucdavis.edu/news/amazon-and-congo-basin-focus-new-emerging-infectious-disease-research-center/>

¹⁶⁵ <https://pipelinereview.com/index.php/2020090875787/Vaccines/Valneva-Initiates-Phase-3-Clinical-Study-for-its-Chikungunya-Vaccine-Candidate-VLA1553.html>

¹⁶⁶ https://www.upi.com/Science_News/2020/09/09/Study-predicts-increase-in-mosquito-borne-diseases-as-planet-warms/3541599681843/

¹⁶⁷ <https://www.dailycal.org/2020/09/07/uc-berkeley-researchers-receive-grant-to-study-mosquito-borne-viruses/>

- Scientists found that aquatic environments can act as reservoirs for bird flu pathogens.¹⁶⁸
- In the US, the National Institute of Allergy and Infectious Diseases has established the Centers for Research in Emerging Infectious Diseases Network (CREID). US labs will collaborate with their counterparts elsewhere to investigate how viruses spill over from wildlife into humans. They will investigate known pathogens, such as Zika, Ebola, and lesser-known infectious agents, to discover how new diseases develop and spread.¹⁶⁹
- Around 15 per cent of pig farmers in China are reported to have tested positive for antibodies to a new strain of Influenza A that they caught from their swine, and was said by one commentator to have “all the attributes to cause a pandemic”.¹⁷⁰
- Virologists at the University of Wisconsin at Madison have outlined a T-cell-based vaccine strategy that was effective against multiple strains of influenza virus in mice. It is administered through the nose.¹⁷¹
- Scientists have newly identified two antibodies that protect against strains of influenza B. The findings may assist in the development of a broad-spectrum influenza drug.¹⁷²

Other

- An analysis found that “exposure to the [endocrine-disrupting chemical](#) bisphenol A was significantly and positively associated with all-cause mortality in US adults”.¹⁷³ BPA in blood bags has been a matter for discussion historically.
- Researchers at MIT have developed a double-barrelled syringe to facilitate subcutaneous injections of viscous biologics rather than infusions.¹⁷⁴
- The results of a preliminary study presented at the European Society of Cardiology Congress suggested that it was feasible to use a saliva-based rapid cardiac troponin I test to diagnose heart attacks.¹⁷⁵
- UK correspondents to *Nature* have written that UK departure from EU research “will be catastrophic for COVID-19 and other research”.¹⁷⁶
- The US FDA has approved GlaxoSmithKline’s biologic drug Nucala to treat hypereosinophilic syndrome (HES). The syndrome is caused by overproduction of a type of white blood cell.¹⁷⁷

¹⁶⁸ <https://www.the-scientist.com/news-opinion/bird-flu-viruses-can-remain-infectious-for-months-in-us-wetlands-67918>

¹⁶⁹ <https://www.medpagetoday.com/infectiousdisease/generalinfectiousdisease/88580>

¹⁷⁰ <https://www.medscape.com/viewarticle/937422>

¹⁷¹ <https://www.genengnews.com/news/t-cell-based-vaccine-effective-against-multiple-influenza-virus-strains/> and [https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791\(20\)30121-X](https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(20)30121-X)

¹⁷² <https://www.techexplorist.com/two-antibodies-protect-against-influenza-b-virus-strains/35469/>

¹⁷³ <https://www.healio.com/news/endocrinology/20200827/high-bpa-exposure-may-increase-allcause-mortality>

¹⁷⁴ <https://www.fiercepharma.com/drug-delivery/mit-researchers-develop-double-barreled-syringe-for-breezy-biologics-injections-0>

¹⁷⁵ <https://www.healio.com/news/cardiology/20200829/salivabased-rapid-test-for-heart-attack-feasible>

¹⁷⁶ <https://www.medscape.com/viewarticle/938053>

¹⁷⁷ <https://www.fiercepharma.com/pharma/glaxosmithkline-s-nucala-earns-fda-nod-for-rare-white-blood-cell-disease-shot-to-rival>