

Monitoring International Trends

May 2021

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.

Highlights include:

Research and development in the health sector, and clinical trials, continue to have a strong focus on pandemic related matters, although other issues are receiving more attention than a year ago. Professional societies are holding virtual conferences and annual meetings.

Some developments in treating blood disorders (hereditary angioedema, paroxysmal nocturnal haemoglobinuria, and haemophilia) are described on page 3. Hereditary angioedema patients in the United States, the European Union and Japan now have the option of oral prophylaxis rather than injection or infusion.

Researchers reinforced the view that the use of tranexamic acid in hip and knee arthroplasties could reduce blood transfusions (page 3). Others found that intravenous immunoglobulin did not relieve the pain of idiopathic small fibre neuropathy (page 4).

Some scientists are estimating the life of antibodies in people who have had a COVID-19 infection (page 4), others are trialling the efficacy of monoclonal antibodies in treating the disease (pages 4 and 5), and there is interest in what is termed “long COVID” (page 4).

With a number of COVID-19 vaccines in large-scale use, discussion continues about their effectiveness against a variety of variants, their possible side effects, whether they should be used sequentially in the same patients, how much they permit break-through infection, whether they prevent disease transmission to others, how long the immunity they produce will last and whether boosters will be required (pages 6 to 9).

A number of countries have been dealing with surges in COVID-19 infection, and there is increasing concern that children appear to be accounting for more new cases than was previously the case, while speculation remains on differences in transmissibility between variants (pages 11 to 13).

Although the focus of public health globally is on COVID-19, other diseases with implications for the blood sector continue to attract the interest of scientists and policy makers e.g. malaria, hepatitis, HIV, influenza, dengue and cytomegalovirus (page 13).

Table of contents

1. TREATING BLOOD DISORDERS	3
2. SAFETY, PATIENT BLOOD MANAGEMENT AND BLOOD PRODUCTS	3
5. CLINICAL EXPERIENCE IN COVID-19	4
6. POTENTIAL TREATMENTS FOR COVID-19 NOT MENTIONED ELSEWHERE	4
7. DEVELOPING VACCINES FOR COVID-19	6
Approved or close to submission for approval.....	6
General comments.....	6
Astra Zeneca and Johnson & Johnson (adenovirus vaccines).....	7
Moderna, Pfizer/ BioNTech and CureVac (mRNA vaccines)	8
Novavax	10
Sinovac and Sinopharm.....	10
At an earlier stage of development.....	10
8. MANAGING THE PANDEMIC	11
Individual country experience	11
Transmission.....	12
9. MISCELLANEOUS NEWS	13
Diseases other than COVID-19	13
Other	14

1. Treating blood disorders

- BioCryst Pharmaceuticals, in marketing its oral preventive treatment for hereditary angioedema, has found that patients are pleased at the prospect of taking a pill rather than having to cope with injection or infusion¹.
- Apellis' C3 inhibitor pegcetacoplan, marketed in the US as Empaveli, is for patients with paroxysmal nocturnal haemoglobinuria (PNH). The company says new late-stage data show the treatment can help patients regardless of their treatment history².
- Catalyst Biosciences initiated its Phase I/II trial of Marzeptacog alfa (activated) in Factor VII deficiency, Glanzmann thrombasthenia and haemophilia A with inhibitor patients receiving Hemlibra prophylaxis³.
- Dr Michel Sadelain⁴ told the annual meeting of the American Society for Gene and Cell Therapy (ASGCT) that "lentiviral vectors show promise for monogenic blood disorders" and that "the future is bright for these genetically modified cell therapies"⁵.
- BioMarin Pharmaceutical updated its previously reported results from an open-label phase I/II study of valoctocogene roxaparvovec, its investigational gene therapy for adults with severe haemophilia A. The data will be presented at the International Society on Thrombosis and Haemostasis (ISTH) 2021 Virtual Congress (July 17th to 21st)⁶. BioMarin plans to submit a Marketing Authorization Application for valoctocogene roxaparvovec for haemophilia A to the European Medicines Agency in June 2021. In the US, BioMarin hopes to submit a biological licence application in the second quarter of 2022⁷.
- Takeda and Bayer have settled over the patent infringement verdict on Adynovate⁸.

2. Safety, patient blood management and blood products

- Researchers found that "tranexamic acid use in high-risk patients during total hip and total knee arthroplasties was associated with decreased odds of blood transfusion with no increased risk for complications"⁹.
- A NSW inquiry has been told that only 9 of the 38 hospitals in the State's western region carry blood¹⁰.
- Tasso's push-button collection device for blood samples has been approved for use in Europe¹¹.

¹ <https://www.fiercepharma.com/marketing/biocryst-persistence-for-patient-perspective-leads-to-new-insights-and-a-bigger-market>

² <https://www.fiercepharma.com/pharma/apellis-pnh-victory-lap-newly-fda-approved-empaveli-helped-patients-without-prior-soliris>

³ <https://pipelinereview.com/index.php/2021051878169/Proteins-and-Peptides/Catalyst-Biosciences-Announces-First-Patient-Dosed-in-Marzeptacog-Alfa-Activated-Phase-1/2-Study-in-Factor-VII-Deficiency-Glanzmann-Thrombasthenia-and-Hemophilia-A.html>

⁴ In delivering the George Stamatoyannopoulos Memorial Lecture

⁵ <https://www.scienceboard.net/index.aspx>

⁶ <https://www.streetinsider.com/dr/news.php>

⁷ <https://seekingalpha.com/news/3698183-biomarin-reports-five-year-data-from-mid-stage-gene-therapy-study-in-hemophilia-a>

⁸ <https://www.fiercepharma.com/pharma/takeda-unit-reaches-settlement-bayer-following-173m-hemophilia-patent-infringement-loss>

⁹ <https://www.healio.com/news/orthopedics/20210505/tranexamic-acid-during-tja-associated-with-fewer-blood-transfusions-minimal-complications>

¹⁰ <https://www.abc.net.au/news/2021-04-30/cobar-health-inquiry-l4l-hospitals-bloody/100107698>

¹¹ <https://www.fiercebiotech.com/medtech/tasso-s-at-home-blood-sampling-device-for-virtual-clinical-trials-snags-european-approval>

- Some researchers are questioning the continuing use of anticoagulants for stroke prevention in patients with advanced dementia¹².
- Researchers found that in patients with painful idiopathic small fibre neuropathy intravenous immunoglobulin (IVIg) did not deliver clinical pain relief¹³.
- Bolivia's National Institute of Health Laboratories (Inlasa) is developing a COVID-19 hyperimmune serum using the plasma of three donkeys¹⁴.
- The Indian Council of Medical Research dropped convalescent plasma therapy for treating mild COVID-19, but there are still some private hospitals prescribing it¹⁵.

5. Clinical experience in COVID-19

- US researchers checked antibody levels of 250 former COVID-19 patients six to twelve months after diagnosis. All of the former inpatients and 95 per cent of the outpatients still had neutralizing antibodies¹⁶.
- A study found that the majority of dialysis patients infected with COVID-19 maintained antibodies for at least six months¹⁷.
- A further study has suggested that people who have had dengue, if infected with COVID-19, are twice as likely to develop symptoms¹⁸.
- Researchers reporting on a case of COVID-19 presenting as Guillain-Barre Syndrome¹⁹ concluded that "children with an unexplained neurologic process should be tested for SARS-CoV-2."
- Australian monitoring suggests that of people who have "recovered" from severe Covid-19, two thirds have ongoing problems²⁰.

6. Potential treatments for COVID-19 not mentioned elsewhere

- Bristol Myers Squibb acquired two antibody treatments from Rockefeller University earlier this year. As it conducts Phase I trials, it is licensing Xencor's technology to extend the combination's half-life²¹.

¹² <https://www.medscape.com/viewarticle/951405> and [Anticoagulant Use for Atrial Fibrillation Among Persons With Advanced Dementia at the End of Life | Atrial Fibrillation | JAMA Internal Medicine | JAMA Network](#)

¹³ <https://www.neurologyadvisor.com/topics/neuropathy/iv-immunoglobulin-therapy-fails-to-treat-pain-of-idiopathic-small-fiber-neuropathy/>

¹⁴ <https://riotimesonline.com/brazil-news/miscellaneous/covid-19/donkey-plasma-serum-bolivias-new-bet-against-covid-19/>

¹⁵ <http://www.millenniumpost.in/delhi/experts-ponder-over-plasma-but-calls-grow-for-trials-of-all-covid-drugs-440719>

¹⁶ <https://www.medscape.com/viewarticle/950396> and [SARS-CoV-2 antibodies remain detectable 12 months after infection and antibody magnitude is associated with age and COVID-19 severity | medRxiv](#)

¹⁷ <https://www.medpagetoday.com/nephrology/esrd/92629>

¹⁸ <https://eminetra.com/previous-dengue-infection-significantly-increases-the-risk-of-symptomatological-covid-19/554674/>

¹⁹ [First case of COVID-19 presenting as Gullian- Barre syndrome \(medicaldialogues.in\)](#)

²⁰ [COVID-19 patients from Australian ICUs still reporting symptoms six months after infection - ABC News](#) and <https://www.healio.com/news/infectious-disease/20210430/covid19-long-haulers-face-substantial-burden-of-health-loss>

²¹ <https://www.fiercebiotech.com/biotech/bristol-myers-taps-xencor-s-half-life-tech-for-covid-19-antibody>

- When Humanigen's new monoclonal antibody lenzilumab was added to treatments being given to COVID-19 in-patients still able to breathe unaided, it improved their odds of not needing invasive mechanical ventilation²².
- An inhaled nanobody prevented severe COVID-19 in hamsters²³.
- Apeiron Biologics will study an inhaled formulation of its ACE2 receptor decoy APN01, in the hope that direct delivery to the lungs may prove more successful than intravenous delivery²⁴.
- Researchers²⁵ have developed two new drugs, which acted in different ways: by preventing the SARS-CoV-2 virus from entering cells and by preventing it from replicating if it does enter cells. Whether the drugs act better in combination or separately will be tested in clinical trials²⁶.
- The Action trial²⁷ found that in stable hospitalised patients, the use of therapeutic anticoagulation with rivaroxaban 20 mg once daily could increase bleeding without significant clinical outcomes²⁸.
- At the 2021 American Thoracic Society International Conference (ATS 2021) Regeneron presented detailed results from the Phase III pivotal trial showing REGEN-COV™ (casirivimab with imdevimab) significantly lowered the risk of hospitalisation or death, reduced symptom duration and decreased viral load in outpatients with COVID-19²⁹.
- South Korea's Celltrion Group confirmed that CT-P59, its anti-COVID-19 monoclonal antibody treatment candidate, demonstrated neutralising potency against emerging variants first identified in New York (B.1.526), Nigeria (B.1.525) and India (B.1.617)³⁰.
- Memo Therapeutics announced in Switzerland that its antibody MTX-COVAB, showed efficacy (in early studies) against the original SARS-CoV-2 virus as well as the UK variant. The company said developing antibodies against other variants can take less than a month³¹.
- The European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion on GSK and Vir Biotechnology's sotrovimab for treating COVID-19 under certain conditions³².

²² <https://www.medscape.com/viewarticle/950947> and [LENZILUMAB EFFICACY AND SAFETY IN NEWLY HOSPITALIZED COVID-19 SUBJECTS: RESULTS FROM THE LIVE-AIR PHASE 3 RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL | medRxiv](#)

²³ [Inhalable Nanobody \(PIN-21\) prevents and treats SARS-CoV-2 infections in Syrian hamsters at ultra-low doses | Science Advances \(sciencemag.org\)](#) and [Pitt's inhalable 'nanobody' fights off COVID-19 in hamsters at ultralow doses | FierceBiotech](#)

²⁴ <https://www.fiercepharma.com/drug-delivery/apeiron-plans-covid-19-trial-inhaled-ace2-formulation>

²⁵ at QIMR Berghofer Medical Research Institute in Queensland, senior researcher Professor Sudha

²⁶ [Coronavirus: New drugs could be one-two punch to stop COVID-19 in its tracks \(theage.com.au\)](#)

²⁷ Reported at the virtual American College of Cardiology (ACC) 2021 Scientific Sessions.

²⁸ <https://www.medscape.com/viewarticle/951475>

²⁹ <https://pipelinereview.com/index.php/2021051778148/Antibodies/Phase-3-Data-Presented-at-ATS-2021-Show-REGEN-COV-casirivimab-with-imdevimab-Reduced-Risk-of-Hospitalization-or-Death-by-70-in-Non-hospitalized-COVID-19-Patients.html> and [Monoclonal antibody cocktail cut COVID-19 hospitalization, death by 70% in outpatient setting \(healio.com\)](#)

³⁰ <https://pipelinereview.com/index.php/2021051878154/Antibodies/Celltrion-Confirms-Neutralising-Potency-Against-Emerging-SARS-CoV-2-Variants-With-Anti-COVID-19-Monoclonal-Antibody-Treatment-regdanvimab-CT-P59.html>

³¹ <https://pipelinereview.com/index.php/2021051878164/Antibodies/Memo-Therapeutics-AG-Antibodies-Against-SARS-CoV-2-Show-Efficacy-Against-British-and-South-African-Variant.html>

³² <https://pipelinereview.com/index.php/2021052178211/Antibodies/EMA-Issues-Positive-Scientific-Opinion-on-GSK-and-Vir-Biotechnologys-Sotrovimab-For-the-Early-Treatment-of-COVID-19.html>

7. Developing vaccines for COVID-19

Approved or close to submission for approval

General comments

- A Spanish study in a small sample of participants suggested that following a dose of the Pfizer vaccine with a dose of AstraZeneca boosted immunity³³.
- A study reports that mixing doses of Pfizer and AstraZeneca vaccines leads to more reports of mild and moderate side effects³⁴.
- Health officials in the UK have said that both the Pfizer/BioNTech and AstraZeneca vaccines are effective against the UK and Indian variant³⁵.
- Dr Anthony Fauci, Director of the US National Institute of Allergy and Infectious Diseases, said he expects booster vaccine shots will be required a year after first vaccination, as durability of protection is not lifelong³⁶. Pfizer's CEO said it was likely a booster would be needed between 8 and 12 months out³⁷. Some scientists think booster shots may not be necessary³⁸.
- Meanwhile, the UK is investigating whether giving a third dose of vaccine would be safe and effective in extending protection. Vaccines in the evaluation include the three which have been used in the UK – Pfizer, Moderna and AstraZeneca --and others for which it has supply deals – Novavax, CureVac, Valneva and Johnson & Johnson³⁹.
- With the Olympics close, Japan gave emergency approval for use of the AstraZeneca and Moderna vaccines⁴⁰.
- The US CDC says immunocompromised people will still need to take precautions against catching COVID-19 even after being fully vaccinated⁴¹. This has raised the question of whether immunocompromised people need a third vaccine dose⁴².
- A UK study found that a small number of frail, elderly patients are being hospitalised and sometimes dying despite their first dose of Pfizer or AstraZeneca vaccine⁴³.
- In considering patients with primary immunodeficiencies who receive immunoglobulin, the US Centers for Disease Control has said "...administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination."⁴⁴

³³ <https://www.news.com.au/national/queensland/news/combining-astrazeneca-and-pfizer-vaccines-may-boost-your-immunity-to-covid> and <https://www.medscape.com/viewarticle/951336>

³⁴ [Covid vaccines: Mixing increases reports of mild side-effects - BBC News](https://www.bbc.com/news/health-57111111)

³⁵ <https://www.axios.com/pfizer-biontech-astrazeneca-covid-variants-effective-28bc0355-e361-4b32-9c6c-328185a36036.html>

³⁶ <https://www.reuters.com/business/healthcare-pharmaceuticals/fauci-expects-covid-19-vaccines-kids-late-2021-sees-need-booster-shot-2021-05-19/>

³⁷ <https://www.dailymail.co.uk/health/article-9597791/Americans-need-dose-COVID-19-vaccine-September.html> and

<https://www.miamiherald.com/news/coronavirus/article251533118.html>

³⁸ [Top scientists question the need for COVID-19 booster shots | Reuters](https://www.reuters.com/business/healthcare-pharmaceuticals/top-scientists-question-the-need-for-covid-19-booster-shots-2021-05-19/)

³⁹ <https://www.medscape.com/viewarticle/951452>

⁴⁰ <https://www.fiercepharma.com/pharma/olympics-just-months-away-japan-issues-emergency-nod-for-astrazeneca-moderna-vaccines>

⁴¹ [COVID-19 Vaccines May Not Work As Well for Immunocompromised People | Health.com](https://www.health.com/condition/coronavirus/covid-19-vaccines-may-not-work-as-well-for-immunocompromised-people)

⁴² <https://www.medpagetoday.com/special-reports/exclusives/92698>

⁴³ <https://www.medscape.com/viewarticle/950270> and [ISARIC4C and CO-CIN: Hospitalised vaccinated patients during the second wave - update April 2021, 22 April 2021 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/isaric4c-and-co-cin-hospitalised-vaccinated-patients-during-the-second-wave-update-april-2021)

⁴⁴ [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](https://www.cdc.gov/media/releases/2021/s0511-covid-19-vaccine-considerations.html)

- Doctors say that, with thrombocytopenia always a concern with primary immunodeficiency patients, those who are on a thrombopoietin receptor may need to be checked for lowered platelets after the vaccine, in which case platelet therapy can be temporarily increased⁴⁵.
- Speculation continues on whether and when further COVID-19 vaccines could be manufactured in Australia⁴⁶.
- WHO asked countries to donate vaccines internationally before vaccinating children⁴⁷.
- UK officials said one dose of the AstraZeneca vaccine gives an 80 per cent lower risk of death⁴⁸. UK data also suggested two doses of either the Pfizer or AstraZeneca vaccine reduces the risk of becoming infected with COVID-19 by 70 per cent⁴⁹.

AstraZeneca and Johnson & Johnson (adenovirus vaccines)

- German scientists say they know why the AstraZeneca and Johnson & Johnson vaccines cause rare blood clots (related to the use of an adenovirus vector), and that they know how the problem can be fixed⁵⁰.
- The European Medicines Agency (EMA) is investigating the death of a woman in Belgium after a dose of Johnson & Johnson's vaccine and a subsequent blood clot with low platelets. Belgium has since suspended the vaccine's use in people aged 41 or less⁵¹.
- The European Medicines Agency decided the Johnson & Johnson vaccine should carry a warning of "very rare" side effects, blood clots and low platelet count⁵².
- Australia's Therapeutic Goods Administration announced on 20 May: "A possible link between Guillain-Barre Syndrome (GBS) and the AstraZeneca COVID-19 vaccine remains under investigation in Australia and internationally. As of 19 May 2021, we have received eight reports of GBS in patients vaccinated with the AstraZeneca COVID-19 vaccine".⁵³
- India said it found 26 possible cases of bleeding and clotting after 164 million doses of AstraZeneca vaccine administered⁵⁴. Commentators have pointed out the country's hospitals have been overwhelmed with COVID-19 patients.
- The US CDC reported on 13 May that it had "identified 28 cases of thrombosis with thrombocytopenia syndrome (TTS) among more than 8.7 million people given the J&J vaccine. TTS involves blood clots accompanied by a low level of platelets"⁵⁵.

⁴⁵ <https://www.specialtypharmacycontinuum.com/Online-First/Article/06-21/Primary-Immunodeficiencies-and-the-Pandemic-63568>

⁴⁶ <https://www.smh.com.au/business/companies/us-biotech-novavax-could-make-covid-vaccine-onshore-in-australia-20210520-p57tgb.html> and <https://www.msn.com/en-au/news/australia/locally-manufactured-covid-19-vaccines-will-help-enormously/ar-AAKdeIM>

⁴⁷ <https://www.fiercepharma.com/pharma/covid-19-tracker-pfizer-vaccine-data-babies-could-come-by-september-spain-s-reig-jofre-to>

⁴⁸ [One AstraZeneca vaccine dose gives 80 per cent lower COVID death risk, England Public Health says - ABC News](#)

⁴⁹ [Coronavirus Australia: Pfizer vaccine beats back COVID-19 variants as AstraZeneca receives a timely boost \(smh.com.au\)](#)

⁵⁰ <https://www.dailymail.co.uk/health/article-9622627/German-scientists-claim-figured-Covid-vaccines-cause-blood-clots.html>

⁵¹ [EU drug regulator reviewing woman's death in Belgium after getting J&J shot | Reuters](#)

⁵² <https://www.explica.co/the-ema-sees-a-possible-relationship-with-very-rare-cases-of-thrombi-but-endorses-its-use.html>

⁵³ [Probe into paralysing illness after vaccine | Daily Mercury](#)

⁵⁴ <https://www.medscape.com/viewarticle/951301>

⁵⁵ <https://www.reuters.com/business/healthcare-pharmaceuticals/us-cdc-finds-more-clotting-cases-after-jj-vaccine-sees-causal-link-2021-05-12/>

- The vaccine alliance, Gavi, is to provide over time 200 million doses of the Johnson & Johnson vaccine for the World Health Organization's COVAX program⁵⁶.

Moderna, Pfizer/ BioNTech and CureVac (mRNA vaccines)

- Pfizer has started testing its COVID-19 vaccine and 20-valent pneumococcal vaccine candidate together⁵⁷.
- Moderna is hoping to launch a single dose vaccine in India in 2022⁵⁸.
- Moderna said that “a single booster dose of its original COVID-19 vaccine — or a modified version made specifically for the variant first identified in South Africa — offered protection against two SARS-CoV-2 variants of concern” (the South African and Brazil variants)⁵⁹.
- As Moderna moves to roll out its vaccine globally, it is arranging for South Korea’s Samsung Biologics to provide large-scale fill-finish support⁶⁰.
- Moderna reported that its vaccine is effective in people aged 12 to 17⁶¹.
- In the US, sudden hearing loss has been reported as a side effect of mRNA vaccines⁶².
- In the US, the CDC's Advisory Committee on Immunization Practices said it had investigated reports that a few young vaccine recipients, predominantly males, mostly adolescents and young adults, developed myocarditis, an inflammation of the heart muscle, following vaccination with mRNA vaccines⁶³.
- A study which assessed reported cases of thrombocytopenia following mRNA vaccines reported that the number of cases did not suggest a safety concern⁶⁴.

⁵⁶ https://www.upi.com/Top_News/World-News/2021/05/21/switzerland-Gavi-vaccine-doses-COVAX-COVID-19/3151621622865/

⁵⁷ <https://www.fiercepharma.com/pharma/pfizer-begins-testing-elderly-co-administered-covid-19-booster-and-prevnar-20-vaccines> and [Pfizer Initiates Study Exploring Coadministration of Its 20-valent Pneumococcal Conjugate Vaccine Candidate Along With a Third Dose of the Pfizer-BioNTech COVID-19 Vaccine in Older Adults](https://www.fiercepharma.com/pharma/pfizer-initiates-study-exploring-coadministration-of-its-20-valent-pneumococcal-conjugate-vaccine-candidate-along-with-a-third-dose-of-the-pfizer-biontech-covid-19-vaccine-in-older-adults)

⁵⁸ <https://www.fiercepharma.com/pharma/moderna-will-launch-a-single-dose-covid-19-vaccine-next-year-india-report-says>

⁵⁹ <https://www.healio.com/news/infectious-disease/20210506/moderna-says-covid19-boosters-effective-against-variants>

⁶⁰ <https://www.fiercepharma.com/manufacturing/moderna-taps-samsung-for-fill-finish-duties-hundreds-million-covid-19-vaccine-doses> and <https://samsungbiologics.com/media/company-news-view>

⁶¹ [Moderna's Vaccine Is 100% Effective in 12- to 17-Year-Olds | PEOPLE.com](https://www.people.com/story/moderna-s-vaccine-is-100-percent-effective-in-12-to-17-year-olds/2021/05/21/) and <https://www.cbsnews.com/news/moderna-covid-19-vaccine-teens-effective/>

⁶² <https://www.medpagetoday.com/infectiousdisease/covid19vaccine/92699>

⁶³ [US investigates rare heart issues after teens and young adults receive COVID vaccines - ABC News](https://www.abcnews.com/news/2021/05/21/us-investigates-rare-heart-issues-after-teens-and-young-adults-receive-covid-vaccines/) and [US investigating handful of myocarditis cases following COVID-19 vaccination | Live Science](https://www.livescience.com/100000-covid-19-vaccines-and-myocarditis.html)

⁶⁴ <https://www.docwirenews.com/abstracts/thrombocytopenia-including-immune-thrombocytopenia-after-receipt-of-mrna-covid-19-vaccines-reported-to-the-vaccine-adverse-event-reporting-system-vaers/> and [Thrombocytopenia including immune thrombocytopenia after receipt of mRNA COVID-19 vaccines reported to the Vaccine Adverse Event Reporting System \(VAERS\) - PubMed \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/37111111/)

- The European Medicines Agency (EMA) announced on May 17 that its Committee for Medicinal Products for Human Use had, along with regulatory agencies elsewhere⁶⁵, recommended an update in the approved storage conditions for Pfizer/BioNTech's COVID-19 vaccine. This extends the approved storage period of the unopened thawed vial at 2–8 degrees Celsius from five days to 31 days⁶⁶.
- WHO says “preliminary laboratory studies of the mRNA vaccines by Pfizer and Moderna have shown decreased effectiveness against the double mutant variants discovered in India”⁶⁷. The Organization has named the Indian variant as the fourth COVID-19 variant of concern⁶⁸, saying it is also more transmissible.
- Following on its partnership with Pfizer, German company BioNTech is partnering with Fosun Pharma to manufacture and sell its mRNA vaccine in China, producing up to 1 billion doses per year⁶⁹.
- Following US FDA approval of the Pfizer/ BioNTech vaccine for adolescents aged 12 to 15⁷⁰, CDC advisers have endorsed immediate implementation⁷¹.
- Some researchers claim that both the Pfizer and Moderna vaccine are likely to be effective against the India variant⁷².
- Qatari-based researchers say the Pfizer vaccine seems about 70 per cent effective against the South African variant, and about 97 per cent effective against illness and death⁷³.
- Pfizer and BioNTech began a rolling submission of a Biologics License Application with the US FDA for approval of their mRNA vaccine. It is currently being administered under an emergency use authorisation⁷⁴.
- The EU contracted with Pfizer for a further 1.8 billion doses⁷⁵. Meanwhile, Europe's drug regulator was evaluating a number of suggested but in some cases unproven side effects of COVID-19 vaccines, including myocarditis and pericarditis following inoculation with an mRNA vaccine⁷⁶.

⁶⁵ <https://www.npr.org/sections/coronavirus-live-updates/2021/05/19/998420256/pfizer-vaccine-can-stay-longer-at-lower-temperatures-before-being-discarded>

⁶⁶ [EMA Recommends Change in Storage Conditions for Pfizer/BioNTech Vaccine](https://www.ema.europa.eu/en/news/ema-recommends-change-storage-conditions-pfizer-biontech-vaccine) ([biopharminternational.com](https://www.biopharminternational.com)). Australia's changing conditions may be followed at <https://www.tga.gov.au/>

⁶⁷ <https://www.livemint.com/news/india/pfizer-moderna-jabs-show-reduced-antibody-response-against-variant-from-india-11620819709502.html>

⁶⁸ <https://www.cidrap.umn.edu/news-perspective/2021/05/who-names-b1617-fourth-covid-19-variant-concern>

⁶⁹ <https://www.fiercepharma.com/manufacturing/biontech-fosun-pharma-eye-1b-doses-covid-19-vaccine-capacity-new-china-jv>

⁷⁰ [FDA Authorizes Pfizer-BioNTech Vaccine for Children 12 to 15 - The New York Times](https://www.nytimes.com/2021/05/17/health/pfizer-biontech-vaccine-children.html) ([nytimes.com](https://www.nytimes.com))

⁷¹ <https://thehill.com/policy/healthcare/553132-cdc-panel-recommends-pfizer-covid-vaccine-for-adolescents>

⁷² <https://www.medscape.com/viewarticle/951107> and [Infection and vaccine-induced neutralizing antibody responses to the SARS-CoV-2 B.1.617.1 variant | bioRxiv](https://www.biorxiv.org/content/10.1101/2021.05.17.444444)

⁷³ [Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants | NEJM](https://www.nejm.org/doi/full/10.1056/NEJMoa210507)

⁷⁴ <https://www.healio.com/news/infectious-disease/20210507/pfizer-biontech-begin-process-of-seeking-full-fda-approval-for-covid19-vaccine>

⁷⁵ [EU Covid Vaccine New Contract With Pfizer-BioNTech as Soon as Friday: Sources - Bloomberg](https://www.bloomberg.com/news/articles/2021-05-17-eu-covid-vaccine-new-contract-with-pfizer-biontech-as-soon-as-friday) and [EU signs deal with Pfizer for potential 1.8 billion doses of the coronavirus vaccine - ABC News](https://www.abcnews.com/news/2021-05-17/eu-signs-deal-with-pfizer-for-potential-1-8-billion-doses-of-the-coronavirus-vaccine)

⁷⁶ <https://www.fiercepharma.com/pharma/europe-s-drug-regulator-evaluates-reports-heart-inflammation-rare-nerve-disorder-covid-19> and <https://www.reuters.com/business/healthcare-pharmaceuticals/us-cdc-has-not-seen-link-between-heart-inflammation-covid-19-vaccines-2021-04-27/#>

Novavax

- Novavax is reported to be looking for an Australian manufacturer for its vaccine, with CSL said to lack the capacity to make both the AstraZeneca vaccine and the Novavax vaccine at the same time⁷⁷. In the US, Emergent BioSolutions admitted it struggled to make both the AstraZeneca and Johnson & Johnson vaccines⁷⁸.
- Novavax used ferrets and hamsters to test a combination of its flu vaccine and its COVID vaccine and reported that “the shot produced antibodies against both viruses at levels comparable to what was seen with either component vaccine alone”⁷⁹. Meanwhile, the US CDC has said that there is no reason not to give COVID vaccine along with other vaccines⁸⁰.
- Novavax is reported to have delayed applying for approval of its COVID vaccine in the US at least until July⁸¹. Australia has Novavax vaccine on order, subject to TGA approval.
- In a mid-stage trial, the Novavax vaccine showed 51 per cent efficacy against the South African variant in HIV-negative participants, 43 per cent in those who were HIV-positive⁸².
- Novavax has expanded a late-stage trial to include participants aged from 12 to 17⁸³.

Sinovac and Sinopharm

- The European Medicines Agency has begun reviewing Sinovac’s vaccine⁸⁴.
- WHO has approved Sinopharm’s vaccine for emergency use⁸⁵.

At an earlier stage of development

- Sanofi and GSK said their investigational vaccine facilitated strong immune responses across all adult age groups in its Phase II trial⁸⁶.

⁷⁷ <https://www.fiercepharma.com/manufacturing/novavax-hunts-for-australian-manufacturer-as-csl-homes-astrazeneca-vaccine-production>

⁷⁸ [Emergent was unequipped to produce both J&J and AstraZeneca COVID-19 vaccines, execs tell lawmakers | FiercePharma](#)

⁷⁹ <https://www.fiercebiotech.com/research/covid-flu-combo-vaccine-from-novavax-sparks-immune-response-to-both-viruses-animals> and [Combination Respiratory Vaccine Containing Recombinant SARS-CoV-2 Spike and Quadrivalent Seasonal Influenza Hemagglutinin Nanoparticles with Matrix-M Adjuvant | bioRxiv](#) (not yet peer reviewed).

⁸⁰ <https://edition.cnn.com/2021/05/12/health/us-coronavirus-wednesday/index.html>

⁸¹ [Novavax not expected to seek authorization for experimental coronavirus vaccine until June at the earliest - The Washington Post](#) and <https://www.fiercebiotech.com/biotech/novavax-delays-covid-19-vaccine-regulatory-submissions-again> and <https://thehill.com/policy/healthcare/552740-novavax-to-apply-for-fdas-emergency-authorization-in-2021s-third-quarter>

⁸² <https://www.fiercebiotech.com/biotech/novavax-shares-red-after-vaccine-sees-51-efficacy-against-south-african-covid-variant>

⁸³ <https://www.reuters.com/article/health-coronavirus-novavax/update-1-novavax-expands-covid-19-vaccine-study-to-include-adolescents-idUSL4N2MQ22J>

⁸⁴ <https://www.medscape.com/viewarticle/950441>

⁸⁵ <https://www.medscape.com/viewarticle/950749> and [WHO lists additional COVID-19 vaccine for emergency use and issues interim policy recommendations](#) and [WHO approves Sinopharm vaccine in potential boost to COVAX pipeline | Reuters](#)

⁸⁶ <https://pipelinereview.com/index.php/2021051778145/Vaccines/Sanofi-and-GSK-COVID-19-vaccine-candidate-demonstrates-strong-immune-responses-across-all-adult-age-groups-in-Phase-2-trial.html> and <https://www.reuters.com/business/healthcare-pharmaceuticals/sanofi-gsk-report-positive-interim-results-their-covid-19-shot-2021-05-17/>

- Medicago reported positive safety and immunogenicity data from a Phase II trial of its plant-derived vaccine which was tested in combination with GSK's adjuvant⁸⁷.
- Clover reported positive pre-clinical data for its second-generation vaccine⁸⁸.
- French company Valneva has yet to complete clinical trials of its vaccine, but it has been claimed to induce a general immune response to Sars-CoV. It has been described as "variant-proof"⁸⁹.
- GlaxoSmithKline and CureVac announced that their second generation Covid vaccine CV2CoV had induced "high levels of antigen production and strong, dose-dependent immune responses" in vaccinated rats⁹⁰.
- Inovio said a mid-stage trial in 400 adult participants showed its investigational vaccine is safe, well tolerated, and produces an immune response. The company says it will use this data in answering regulatory questions about its delivery device before it can initiate its Phase III trial⁹¹.

8. Managing the pandemic

Individual country experience

- On 10 May, India reported 366,161 new infections and 3,754 deaths. (Total known infections 22.66 million, total reported deaths 246,116). Calls continued for a national lockdown to slow transmission⁹².
- Malaysia faced a surge and locked down for the third time⁹³.
- The US Centers for Disease Control and Prevention reported that of about 101 million people nationally who had by 30 April received both doses of the Pfizer/BioNTech or Moderna vaccines or the single-shot Johnson & Johnson vaccine, more than 10,000 had later become infected. Twenty-seven per cent of these were asymptomatic⁹⁴.
- The US Government announced that if COVID vaccine booster shots are necessary they will be free of charge⁹⁵.
- A US study found that people who recovered clinically from COVID-19 but still tested positive did not seem to transmit the virus to close contacts⁹⁶.
- In the US, children are accounting for over 20 per cent of new COVID cases⁹⁷.

⁸⁷ <https://pipelinereview.com/index.php/2021051878151/Vaccines/Medicago-and-GSK-announce-positive-interim-Phase-2-results-for-adjuvanted-COVID-19-vaccine-candidate.html>

⁸⁸ <https://pipelinereview.com/index.php/2021051878166/Vaccines/Clover-Announces-Positive-Preclinical-Data-for-Second-Generation-Protein-Based-COVID-19-Vaccine-Candidate-Demonstrating-Broad-Neutralization-Against-Variants-of-Concern.html>

⁸⁹ [What's the Valneva COVID-19 vaccine, the French shot that's supposed to be 'variant-proof'? - ABC News](#) and [This French firm's more variant-proof coronavirus vaccine could help in long-term fight against Covid-19 | South China Morning Post \(scmp.com\)](#)

⁹⁰ http://www.pharmatimes.com/news/gsk_curevacs_next-gen_covid-19_jab_generates_positive_preclinical_data_1370041

⁹¹ <https://www.reuters.com/business/healthcare-pharmaceuticals/inovio-says-vaccine-candidate-safe-effective-clinical-trial-2021-05-10/>

⁹² [Calls grow for nationwide lockdown in India as new COVID-19 cases and deaths stay close to record highs - ABC News](#)

⁹³ [Malaysia locks down for a third time as coronavirus cases surge - ABC News](#)

⁹⁴ https://www.upi.com/Health_News/2021/05/25/coronavirus-fully-vaccinated-breakthrough-infection-cdc/2101621951479/ and <https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm>

⁹⁵ <https://thehill.com/policy/healthcare/552904-covid-boosters-will-be-free-biden-health-official-says>

⁹⁶ <https://www.healio.com/news/primary-care/20210426/nba-study-shows-persistent-positive-cases-do-not-transmit-covid19-after-recovery>

⁹⁷ <https://www.npr.org/sections/coronavirus-live-updates/2021/05/03/993141036/children-now-account-for-22-of-new-u-s-covid-cases-why-is-that>

- Researchers say that about 2 per cent of asymptomatic students at a Colorado college carried 90 per cent of COVID-19 viral load levels⁹⁸.
- The US announced it would donate to overseas countries 60 million doses of AstraZeneca vaccine, which is not authorized for use in the US. Now it has added a further 20 million vaccine doses, made up of products in use domestically⁹⁹.
- In the Seychelles, 62 per cent of the population have had two doses of either the Sinopharm or AstraZeneca vaccine but COVID case numbers have recently surged, with 37 per cent of new active cases and 20 per cent of hospital cases being fully vaccinated. Experts say the 62 per cent full vaccination rate may be too low a level for herd immunity in the light of the vaccines in use; that dominant variants can escape the vaccines; that the Indian variant which is spreading may be more infectious than others; or that cold-chain logistics in transporting and storing the vaccine were unsatisfactory¹⁰⁰.
- Victoria's Chief Health Officer warned that the Indian variant, responsible for the current outbreak in Victoria, is said to multiply at a rate of five¹⁰¹. (Each infected person infected an average of five other people.) Professor Sharon Lewis of the Doherty Institute said "we know the Indian variant is more infectious"¹⁰². A UK epidemiologist has said that it appears that people under 21 are more likely to be infected with this strain than with others¹⁰³.
- Researchers from Monash University and the Peter Doherty Institute have developed a five-minute screening test for COVID-19 using infrared light technology¹⁰⁴.
- Professor James McCaw, an epidemiologist and mathematical biologist with the University of Melbourne said Australia is at its highest risk of a COVID-19 outbreak since early 2020 when the pandemic began¹⁰⁵.

Transmission

- Singapore provisionally approved a one-minute breathalyser test for COVID-19¹⁰⁶.
- The US Food and Drug Administration has given emergency use authorisation to Eurofins for its at-home COVID-19 testing kit for children three years and upwards¹⁰⁷.
- Scientists have advised the UK government that the Indian variant B.1.617.2 spreads more easily than the Kent variant which had previously been dominant¹⁰⁸.
- President Biden has told the US intelligence community he expects a report on the origins of the pandemic within ninety days¹⁰⁹. This follows an intelligence report that in November 2019, some researchers from the Wuhan Institute of Virology were hospitalised.

⁹⁸ <https://www.medscape.com/viewarticle/951102>

⁹⁹ <https://www.reuters.com/business/healthcare-pharmaceuticals/biden-announce-us-will-send-20-million-vaccines-abroad-by-end-june-2021-05-17/>

¹⁰⁰ [COVID is surging in Seychelles, the world's most vaccinated country. Why? - ABC News](#)

¹⁰¹ [COVID 19-Victoria: Warning over 'highly infectious' strain loose in state \(news.com.au\)](#)

¹⁰² [Victoria: Indian variant in state cluster 'of concern', say experts \(news.com.au\)](#)

¹⁰³ <https://www.news.com.au/world/coronavirus/health/young-people-could-be-more-at-risk-of-indian-covid19-variant-expert-warns>

¹⁰⁴ <https://www.9news.com.au/national/scientists-victoria-monash-university-coronavirus-test-saliva-sample-five-minute/2f867ed5-0be0-44b4-a410-99eb57b0bd80eb57b0bd80>

¹⁰⁵ [Coronavirus: Australia at highest risk of outbreak since start of pandemic \(news.com.au\)](#)

¹⁰⁶ <https://www.fiercebiotech.com/medtech/breathonix-s-covid-19-breathalyzer-test-receives-provisional-authorization-singapore>

¹⁰⁷ <https://www.massdevice.com/eurofins-gains-eua-for-young-childrens-covid-test/>

¹⁰⁸ [Indian Covid variant: How much faster does it spread? - BBC News](#)

¹⁰⁹ [Wuhan: Biden tasks intelligence community to report on Covid origins in 90 days - CNNPolitics](#) and <https://www.news.com.au/world/coronavirus/covid19-origins-joe-biden-gives-us-intelligence-90-days-to-find-more-information-says-lab-leak-theory-is-being-considered>

- A group of scientists has declared that the theory that the pandemic was caused by a laboratory leak should not be ruled out unless proof is provided by “a rigorous data-led investigation”¹¹⁰.
- An independent panel which reviewed the global response to the current pandemic has produced a highly critical report and warned that “urgent and vital” steps are necessary to prevent another catastrophic pandemic¹¹¹.
- Researchers found that “only 54% of solid organ transplant recipients demonstrate evidence of antibody development after receiving the COVID-19 vaccine”¹¹².
- WHO and the US Centers for Disease Control and Prevention updated their advice on airborne transmission of COVID-19, leading to calls for an update on Australian guidelines on air quality¹¹³.
- The UK is investing £29.3m in its COVID-19 variant testing capabilities¹¹⁴.

9. Miscellaneous news

Diseases other than COVID-19

- Scientists say that the malaria parasite can hide undetected in the spleen¹¹⁵.
- WHO had a target to eliminate viral hepatitis globally by 2030, but concentration of health efforts on the pandemic could have delayed this achievement¹¹⁶.
- In the US Dr Anthony Fauci says the national goal of ending the HIV epidemic by 2030 is achievable¹¹⁷.
- Scientists have warned that highly pathogenic avian flu H5N8 caused many outbreaks across the world in 2020, with the death or culling of millions of birds. They emphasised the need to monitor this trend as it is a danger to human populations¹¹⁸.
- Takeda says that its two-dose dengue vaccine demonstrates continued protection after three years¹¹⁹.
- In Burkina Faso, genetically modified mosquitoes are being tested as a way to prevent the spread of malaria¹²⁰.

¹¹⁰ [COVID-19 lab leak theory cannot be ruled out, leading scientists say | Reuters](#) and [COVID-19: Leaked Chinese document reveals a sinister plan to ‘unleash’ coronaviruses \(news.com.au\)](#)

¹¹¹ [COVID-19 warnings were ignored, independent review of global response finds - ABC News](#)

¹¹² <https://www.healio.com/news/rheumatology/20210513/organ-transplant-recipients-should-not-assume-immunity-from-covid19-vaccine>

¹¹³ [Coronavirus Australia: New advice on COVID spread puts air quality in the spotlight \(theage.com.au\)](#)

¹¹⁴ http://www.pharmatimes.com/news/uk_bolsters_covid-19_variant_testing_capabilities_with_29.3m_investment_1369175

¹¹⁵ <https://www.abc.net.au/news/science/2021-05-27/malaria-is-not-only-a-blood-disease-it-also-hides-in-the-spleen> and [Hidden Biomass of Intact Malaria Parasites in the Human Spleen | NEJM](#) and [Evaluation of splenic accumulation and colocalization of immature reticulocytes and Plasmodium vivax in asymptomatic malaria: A prospective human splenectomy study \(plos.org\)](#)

¹¹⁶ <https://www.healio.com/news/gastroenterology/20210518/covid19-impacts-the-global-2030-target-to-eliminate-viral-hepatitis>

¹¹⁷ <https://www.cnbc.com/2021/05/25/covid-fauci-says-us-can-still-end-hiv-epidemic-by-2030-despite-pandemic.html>

¹¹⁸ <https://www.sciencealert.com/highly-pathogenic-h5n8-virus-outbreak-needs-to-be-stopped-scientists-warn> and [Emerging H5N8 avian influenza viruses | Science \(sciencemag.org\)](#)

¹¹⁹ [Takeda Confident As Dengue Vaccine Shows Benefits Three Years Out :: Scrip \(informa.com\)](#)

¹²⁰ <https://www.voanews.com/science-health/burkina-faso-testing-genetically-modified-mosquitoes-curb-malaria>

- The US Food and Drug Administration has granted priority review to Takeda's Maribavir for treating cytomegalovirus infection post-transplant in certain conditions¹²¹.
- Rapidly-moving syphilis outbreaks have been reported in Melbourne's outer suburbs¹²².
- Queensland has reported cases of leptospirosis have almost doubled compared with last year. The bacterial disease is carried by rodents, and the current mouse plague is blamed for the increased incidence¹²³.

Other

- Bluebird's gene therapy for adrenoleukodystrophy appears set to be approved for the European market¹²⁴.
- The Tzar Labs have developed a non-invasive diagnostic tool they say "can identify and categorise solid tumours, haematological malignancies and sarcomas according to their stage"¹²⁵.
- Results from the Phase III PROTECT study showed that a three-antigen hepatitis B virus vaccine candidate yielded higher sero-protection rates in adults than did a monovalent vaccine¹²⁶.
- Johnson & Johnson is donating up to 200,000 doses of its Ebola vaccine regimen to deal with an outbreak in Sierra Leone. The regimen was developed with Bavarian Nordic¹²⁷.

¹²¹ <https://pipelinereview.com/index.php/2021052178200/Small-Molecules/U.S.-Food-Drug-Administration-Grants-Priority-Review-of-Maribavir-for-the-Treatment-of-Post-Transplant-Recipients-With-Cytomegalovirus-Infection-in-Those-Resistant-and/or.html>

¹²² <https://www.theage.com.au/national/victoria/syphilis-epidemic-in-melbourne-suburbs-scientists-use-genomic-sequencing-to-track-std-20210511-p57qqv.html>

¹²³ <https://www.qt.com.au/news/new-disease-spreading-in-queensland/4257301/>

¹²⁴ <https://www.biopharmadive.com/news/bluebirds-next-gene-therapy-gets-backing-from-european-regulator/600603/>

¹²⁵ <https://www.medicaldevice-network.com/news/tzar-blood-test-cancer/>

¹²⁶ <https://www.healio.com/news/infectious-disease/20210428/threeantigen-hbv-vaccine-produces-high-seroprotection-rates-in-adults>

¹²⁷ <https://endpts.com/johnson-ji-xing-promises-more-than-127m-for-milestones-nasal-spray-for-rapid-heart-rate/>