



# Monitoring International Trends

## June-July 2021

The NBA monitors international developments that may influence the management of blood and blood products in Australia. This includes:

- Potential new product developments and applications;
- Global regulatory and blood practice trends;
- Events that may have an impact on global supply, demand and pricing; and
- Emerging risks and relevant issues.

Highlights include:

- Roche has released its final analysis from a Phase III trial confirming that its haemophilia A drug Hemlibra has a “favourable” safety profile. The company said the study reinforced that Hemlibra is “associated with a low incidence of anti-drug antibody development” (Page 3).
- Biomarin says its Marketing Authorisation Application (MAA) for Valoctocogene Roxaparvec, for the treatment of severe haemophilia A, was validated by the European Medicines Agency; and an opinion from Committee for Medicinal Products for Human Use (CHMP) is expected in the first half 2022 (Page 4).
- Progress continues on gene therapy for sickle cell disease and beta thalassemia (Page 4).
- At the Congress of the International Society on Thrombosis and Haemostasis
  - Takeda announced the results of a Phase III trial investigating the efficacy and safety of recombinant von Willebrand factor prophylaxis, emphasising its benefits to patients (Page 3).
  - Researchers reported that the availability of direct oral anticoagulants (DOACs), listed by Pharmaceutical Benefits Scheme in 2013 in Australia, has changed the landscape of venous thromboembolism (VTE) management (Page 5).
  - Researchers said they had examined a small sample of total hip or knee arthroplasties and found aspirin resistance in more than half of them (Page 5).
- Researchers concluded that “pathogen reduction with methylene blue or with amotosalen provides the greater likelihood of preserving the immunological properties of the COVID-19 convalescent plasma compared to riboflavin” (Page 5).
- Scientists concluded that platelet-rich plasma injections for patients suffering from chronic midportion Achilles’ tendinopathy do not reduce tendon dysfunction (Page 6).
- Blood shortages continue in the US and Canada and a number of other countries are experiencing blood shortages or red cell shortages (Page 6).
- A meta-analysis found that death can result from severe bleeding due to use of direct oral anticoagulants, even when reversal agents are administered (Page 7).
- A randomised controlled trial found that administering hyperimmune globulin to pregnant women who tested positive for cytomegalovirus (CMV) did not reduce CMV infections or deaths among their foetuses or newborns (Page 7).
- The nature and extent of Long COVID continues to occupy researchers (Page 8).
- Experimentation with possible COVID-19 treatments continues. The antiviral, remdesivir has been used for many months but there is still not universal agreement on its merits (Page 8).
- COVID-19 vaccine issues at the moment include how long immunity lasts after vaccination, whether booster shots are needed, whether vaccinating children should be a priority and whether vaccines can be mixed (Pages 10 to 13).



- It is becoming clear that COVID-19 vaccination can reduce the risk of hospitalisation. The majority of serious cases and mortality are occurring in unvaccinated people. Vaccinated people can, however, still become infected and there are suggestions they can also spread the disease. The Delta variant is the focus of pandemic management in many countries. It appears more easily transmitted than previous strains and patients more quickly become severely ill (Pages 13 to 16).
- The advances in mRNA technology in response to the COVID-19 pandemic are being applied to development of other vaccines including malaria, influenza, melanoma, and a combination of coronaviruses. Progress is also reported on vaccines against hepatitis C, HIV, chikungunya and melioidosis (Pages 16 to 18).



## Contents

1. Treating blood disorders .....	4
2. Safety, patient blood management and blood products .....	6
3. Clinical experience of COVID-19 .....	9
4. Treatments for COVID-19 .....	10
5. Developing vaccines for COVID-19 .....	11
General comments .....	11
Astra Zeneca and Johnson & Johnson (adenovirus vaccines) .....	12
Moderna, Pfizer/ BioNTech and CureVac (mRNA vaccines).....	12
Novavax .....	13
Sinovac and Sinopharm .....	13
6. Managing the pandemic.....	14
Individual country experience .....	14
Transmission.....	16
7. Miscellaneous news .....	17
Diseases other than COVID-19 .....	17
Other.....	18



## 1. Treating blood disorders

- Roche has released its final analysis from a Phase III trial confirming that its haemophilia A drug, Hemlibra, has a “favourable” safety profile<sup>1</sup>. The study included 193 patients who received Hemlibra once a week for up to two years. It did not identify any new cases of thrombotic microangiopathy or serious thrombotic events. Adverse events experienced by 10 per cent or more of participants were joint pain (17.1 per cent), common cold symptoms (15.5 per cent), headache (15 per cent), injection site reaction (11.4 per cent) and fever (10 per cent). The company said the study reinforced that Hemlibra is “associated with a low incidence of anti-drug antibody development”.
- A Canadian study<sup>2</sup> has found that haemophilia A patients (n=82) who participated preferred subcutaneous therapy to intravenous treatment.
- Sigilon Therapeutics' encapsulated cell therapy for haemophilia A has had its Phase I/II trial stopped by the US FDA after a patient developed a serious side effect<sup>3</sup>. SIG-001 is designed to restore patients' capacity to make the clotting factor they are missing. It consists of cells that produce factor VIII. The cells are encapsulated to protect them from the patients' immune systems, being effectively sealed off from the body. Sigilon announced<sup>4</sup> that of the three patients who have so far been treated, the patient who received the highest dose developed inhibitors to factor VIII.
- At the Congress of the International Society on Thrombosis and Haemostasis<sup>5</sup>, Takeda announced<sup>6</sup> the results of a Phase III trial investigating the efficacy and safety of recombinant von Willebrand (vWF) factor prophylaxis, emphasising its benefits to patients.
- Researchers confirmed<sup>7</sup> that von Willebrand Factor aggregates “vary significantly with age, emphasising the importance of developing age-specific reference ranges, to correctly diagnose neonates and children with haematological complications”. The authors said “Our findings highlight that age-specific differences that exist physiologically are not detected using less sensitive measures that, in this case, do not account for the specific forms of the VWF multimers. Our findings are different to previously published work, potentially related to differences in neonatal subjects (gestation and health status) or methodological differences. Further studies are required to establish a gold standard for vWF multimer testing”.
- Sinocelltech Group Ltd. was given market approval from China's National Medical Products Administration for SCT-800, a B-domain deleted recombinant human coagulation factor VIII, for the prophylactic treatment of severe haemophilia A in adolescent and adult patients<sup>8</sup>.
- Biomarin says its Marketing Authorisation Application for Valoctocogene Roxaparvovec, for the treatment of severe haemophilia A, was validated by the European Medicines Agency; and an opinion from CHMP<sup>9</sup> is expected in the first half 2022<sup>10</sup>.
- The US Food and Drug Administration has allowed CSL Behring to supplement its Biological Licence Application for its Coagulation Factor IX (Recombinant), Albumin Fusion Protein<sup>11</sup>.

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<sup>1</sup>[http://www.pharmatimes.com/news/roche\\_reveals\\_new\\_safety\\_data\\_for\\_haemophilia\\_treatment\\_hemlibra\\_1373331](http://www.pharmatimes.com/news/roche_reveals_new_safety_data_for_haemophilia_treatment_hemlibra_1373331)

<sup>2</sup> [Preferences and Health-Related Quality-of-Life Related to Disease and | PPA \(dovepress.com\)](https://finance.yahoo.com/news/broadstreet-heor-sprout-health-solutions-123600171.html) and <https://finance.yahoo.com/news/broadstreet-heor-sprout-health-solutions-123600171.html>

<sup>3</sup> <https://www.fiercebitech.com/biotech/fda-puts-sigilon-s-hemophilia-cell-therapy-trial-hold-thanks-to-safety-concerns>

<sup>4</sup> [Sigilon Therapeutics Announces Clinical Hold on SIG-001 Phase 1/2 Study in Hemophilia A – Sigilon Therapeutics, Inc.](https://www.fiercebitech.com/biotech/fda-puts-sigilon-s-hemophilia-cell-therapy-trial-hold-thanks-to-safety-concerns)

<sup>5</sup> Philadelphia, 17-21 July 2021

<sup>6</sup> [Takeda Data at ISTH 2021 Highlight the Benefits of Prophylaxis for Patients with Rare Bleeding Disorders](https://abstracts.isth.org/abstract/age-specific-changes-in-von-willebrand-factor-multimers-in-healthy-children-and-adults/)

<sup>7</sup> <https://abstracts.isth.org/abstract/age-specific-changes-in-von-willebrand-factor-multimers-in-healthy-children-and-adults/>

<sup>8</sup> <https://www.bioworld.com/articles/509724-sinocelltechs-sct-800-wins-nmpa-approval-first-homegrown-drug-for-hemophilia-a>

<sup>9</sup> The committee that prepares its opinions on human medicines

<sup>10</sup> [BioMarin Announces Second Quarter 2021 Financial Results and Corporate Updates \(prnewswire.com\)](https://www.biomarin.com/news/2021/07/biomarin-announces-second-quarter-2021-financial-results-and-corporate-updates)

<sup>11</sup> [Approval Letter for IDELVION July 23 2021 \(fda.gov\)](https://www.fda.gov/oc/2021/07/23/fda-approves-csl-behring-biological-license-application-for-idelvion)



- Collaborative research between Jasper Therapeutics and Aruvant Sciences will evaluate the use of JSP191, Jasper’s monoclonal antibody, as a conditioning agent for ARU-1801, Aruvant’s experimental gene therapy for sickle cell disease<sup>12</sup>.
- There are currently seven clinical trials of potential gene therapies for sickle cell disease/ beta thalassemia, with Bluebird bio’s lentiglobin the most advanced<sup>13</sup>. Bluebird bio’s treatment has had a five-month marketing pause. Zynteglo (lentiglobin) was subject to safety concerns<sup>14</sup>, but the EU’s Pharmacovigilance Risk Assessment Committee (PRAC) has now determined<sup>15</sup> the drug’s benefits outweigh its risks.
- Scientists at the Hudson Institute have a new gene therapy strategy for dealing with beta thalassemia. In a process where therapeutic genes are delivered into blood stem cells by a virus, they can both deliver the therapeutic beta globin gene and simultaneously limit the production of surplus alpha globin<sup>16</sup>.
- Dr Lewis Hsu, Chief Medical Officer for the Sickle Cell Association of America, has spoken about the improved treatments available now or expected soon. These include not only cures to correct the causal genetic error, but also new medicines “approved by the FDA with different ways of working that could actually be used together and give more preventive, disease-modifying types of approaches rather than just waiting for the bad complications to occur”. One of these is an intravenous drug administered monthly, Adakveo (crizanlizumab), which prevents severe pain crises and hospitalisation, and reduces the volume of blood transfusions required<sup>17</sup>.
- Alexion’s Ultomiris, designated successor to the company’s paroxysmal nocturnal haemoglobinuria drug Soliris, had sales of \$US 701 million in the first half of 2021, a 48 per cent increase on the same period in 2020. Soliris still had half-year sales of \$US 2.1 billion<sup>18</sup>.

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<sup>12</sup> <https://sicklecellanemianews.com/2021/07/13/study-jsp191-conditioning-regimen-aru-1801-sickle-cell-gene-therapy/>

<sup>13</sup> <https://www.biopharmadive.com/news/gene-therapy-sickle-cell-pipeline/603041/>

<sup>14</sup> [Bluebird Bio hits pause on rollout for ill-fated gene therapy Zynteglo as trial flags 2 cancer cases | FiercePharma](https://www.fiercepharma.com/pharma/after-5-month-hiatus-bluebird-bio-s-zynteglo-bounces-back-europe-all-clear-from-safety-group) and <https://www.fiercepharma.com/pharma/after-5-month-hiatus-bluebird-bio-s-zynteglo-bounces-back-europe-all-clear-from-safety-group>

<sup>15</sup> [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 5-8 July 2021 | European Medicines Agency \(europa.eu\)](https://www.european-council.europa.eu/media/e3000000/1/attachment_data/attachment_data/file/1131222/Meeting_highlights_from_the_Pharmacovigilance_Risk_Assessment_Committee_(PRAC)_5-8_July_2021.pdf)

<sup>16</sup> <https://www.miragenews.com/researchers-develop-viral-gene-therapy-to-treat-594030/> and [Coordinated  \$\beta\$ -globin expression and  \$\alpha\$ 2-globin reduction in a multiplex lentiviral gene therapy vector for  \$\beta\$ -thalassemia: Molecular Therapy \(cell.com\)](https://www.cell.com/molecular-therapy/fulltext/S1099-0347(21)00000-0)

<sup>17</sup> <https://consumer.healthday.com/6-18-sickle-cell-plagues-many-black-americans-but-is-there-hope-for-better-treatments-2653207995.html>

<sup>18</sup> <https://www.fiercepharma.com/pharma/alexion-s-ultomiris-track-for-another-blockbuster-year-as-39b-astrazeneca-deal-looms>



## 2. Safety, patient blood management and blood products

- At the Congress of the International Society on Thrombosis and Haemostasis<sup>19</sup>
  - Researchers reported<sup>20</sup> that “the availability of direct oral anticoagulants (DOACs), listed by Pharmaceutical Benefits Scheme in 2013 in Australia, has changed the landscape of VTE management”.
  - Scientists discussed<sup>21</sup> a study which demonstrates that diabetic patients “have a more hypercoagulable profile on global coagulation assays, particularly in T2DM patients as well as patients with known diabetic complications”. They said: “Further studies with longer term follow-up are ongoing to evaluate the utility of global coagulation assays in predicting patient outcomes”.
  - Researchers examined<sup>22</sup> a small sample of total hip or knee arthroplasties and found aspirin resistance in more than half of them. They said: “aspirin may not be an appropriate agent for VTE prophylaxis for patients who are obese, have diabetes or are elderly. Further research is required to confirm the clinical implications of aspirin resistance in this cohort”.
- A prospective, double-blind, randomized controlled trial found that postoperative dalteparin bridging did not protect patients with atrial fibrillation or mechanical heart valves from major thromboembolisms or bleeding events<sup>23</sup>.
- Researchers concluded that “pathogen reduction with methylene blue or with amotosalen provides the greater likelihood of preserving the immunological properties of the COVID-19 convalescent plasma compared to riboflavin”.
- Scientists studying commercial immunoglobulin products have noted that they can contain detectable levels of factor XIa, and that spiking brings those levels into a range where they can be measured. They say: “Accurate measurement is important to inform on ‘safe’ levels of FXIa in these products and allow future safety guidelines to be set”<sup>24</sup>.
- A US study<sup>25</sup> found that “universal irradiation of blood products does not seem to impact chronic transfusion management in patients with sickle cell disease.
- The UK-based Association of Anaesthetists has released new guidelines on peri-operative management of patients with sickle cell disease<sup>26</sup>. The recommendations have been published in *Anaesthesia*<sup>27</sup>.
- Researchers have reviewed the question of albumin infusion in critically ill COVID-19 patients<sup>28</sup>.

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<sup>19</sup> Philadelphia, 17-21 July 2021

<sup>20</sup> <https://abstracts.isth.org/abstract/a-real-world-experience-of-venous-thromboembolism-vte-management-in-australia/>

<sup>21</sup> <https://abstracts.isth.org/abstract/global-coagulation-assays-and-endothelial-biomarkers-in-patients-with-diabetes-mellitus/>

<sup>22</sup> <https://abstracts.isth.org/abstract/aspirin-resistance-after-total-hip-or-knee-arthroplasties/>

<sup>23</sup> [Postoperative low molecular weight heparin bridging treatment for patients at high risk of arterial thromboembolism \(PERIOP2\): double blind randomised controlled trial | The BMJ](https://www.thecardiologysadvisor.com/home/topics/arrhythmia/no-benefit-with-postoperative-dalteparin-bridging-for-atrial-fibrillation-or-mechanical-heart-valves/) and <https://www.thecardiologysadvisor.com/home/topics/arrhythmia/no-benefit-with-postoperative-dalteparin-bridging-for-atrial-fibrillation-or-mechanical-heart-valves/>

<sup>24</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/vox.13046>

<sup>25</sup> <https://www.hcplive.com/view/universal-red-blood-cell-irradiation-appears-safe-sickle-cell-patients>

<sup>26</sup> <https://medicaldialogues.in/anesthesia/guidelines/guidelines-on-peri-operative-management-of-patients-with-sickle-cell-disease-a-consensus-statement-79928>

<sup>27</sup> [Guideline on the peri-operative management of patients with sickle cell disease - Walker - 2021 - Anaesthesia - Wiley Online Library](https://onlinelibrary.wiley.com/doi/10.1111/ana.14700)

<sup>28</sup> <https://www.docwirenews.com/vte-knowledge-hub/albumin-infusion-in-critically-ill-covid-19-patients-hemodilution-and-anticoagulation-2/> and [Albumin Infusion in Critically Ill COVID-19 Patients: Hemodilution and Anticoagulation - PubMed \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/35811111/)



- Transfusion News published
  - a report suggesting<sup>29</sup> that plasma exchange may be useful in treating refractory vaccine-induced immune thrombotic thrombocytopenia.
  - a clinical report<sup>30</sup> from Philadelphia on reducing red cell use in sickle cell patients during the pandemic.
  - a US analysis<sup>31</sup> of blood components used in victims of gunshot wounds.
  - a report<sup>32</sup> from Poland tracking HIV drug resistance and HIV mutations in blood donations, which described this as “an effective tool for monitoring newly emerging HIV subtypes”.
  - a research report<sup>33</sup> that concluded that platelet-rich plasma injections for patients suffering from chronic midportion Achilles tendinopathy do not reduce tendon dysfunction.
- Blood shortages continue in the US and Canada<sup>34</sup> and a number of other countries are experiencing blood shortages or red cell shortages<sup>35</sup>.
- GSK said its anaemia drug for patients with kidney disease was successful in late-stage trials<sup>36</sup>.
- A Phase II study<sup>37</sup> in patients undergoing total knee arthroplasty compared the efficacy and safety of postoperative abelacimab with the efficacy and safety of enoxaparin. Researchers found a single intravenous dose of abelacimab after total knee arthroplasty was effective in the prevention of venous thromboembolism.
- One of Manitoba’s regional health authorities, Southern Health-Santé Sud, has been named the first health region in Canada to receive national Using Blood Wisely Designation. Each transfusing facility within the health region has met or exceeded the national benchmark of appropriate red blood cell use in Canada<sup>38</sup>.
- Researchers say “that there is support to investigate the efficacy of plasma for the treatment of volume-depleted shock, with the aim to preserve endothelial and epithelial barrier integrity, improve intravascular volume, and ultimately oxygen delivery to reduce cellular and organ injury”<sup>39</sup>.
- Researchers are studying the use of cold platelets in trauma patients<sup>40</sup>.

<sup>29</sup> <https://transfusionnews.com/2021/07/14/plasma-exchange-for-refractory-vaccine-induced-immune-thrombotic-thrombocytopenia/>

<sup>30</sup> <https://transfusionnews.com/2021/06/30/reducing-red-cell-use-for-patients-with-sickle-cell-disease-during-a-pandemic/>

<sup>31</sup> <https://transfusionnews.com/2021/07/06/gunshot-wounds-cause-significant-mortality-blood-utilization-and-health-care-costs-in-the-u-s/>

<sup>32</sup> <https://transfusionnews.com/2021/06/22/tracking-hiv-drug-resistance-and-subtypes-in-blood-donors/>

<sup>33</sup> <https://transfusionnews.com/2021/07/21/platelet-rich-plasma-injections-do-not-reduce-tendon-dysfunction-in-patients-with-chronic-midportion-achilles-tendinopathy/>

<sup>34</sup> <https://illinoisnewstoday.com/blood-centers-in-need-of-volunteers-available-blood-supply-less-than-a-week/295866/> and

<https://news.yahoo.com/u-blood-banks-warn-less-111845735.html> and

<https://abc13.com/md-anderson-cancer-center-blood-donations-needed-patients-type-o/10899497/> and

<https://www.chattanooga.com/2021/7/20/431593/Blood-Assurance-In-Critical-Need-Of.aspx> and

<https://www.buckscountycouriertimes.com/story/news/2021/07/20/red-cross-bucks-county-blood-donation-severe-shortage-covid-amazon-vacation/7965661002/> and

<https://www.ckdr.net/2021/07/19/local-donors-urged-to-give-the-gift-of-life/>

<sup>35</sup> E.g. <https://www.localdvm.com/news/maryland/american-red-cross-seeks-extra-donations-amid-national-blood-shortage/> and

<https://abc11.com/american-red-cross-blood-shortage-donations/10869073/> and <https://www.irishmirror.ie/news/irish-news/irish-people-urged-give-blood-24431496>

<sup>36</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/gsk-drug-shows-promise-treating-anaemia-kidney-disease-patients-2021-07-16/>

<sup>37</sup> <https://www.hcplive.com/view/abelacimab-effective-prevention-vte-including-low-bleeding-risk>

<sup>38</sup> [When Every Drop Counts – Using Blood Wisely Designations in Manitoba - Shared Health \(sharedhealthmb.ca\)](https://www.sharedhealth.mb.ca/when-every-drop-counts-using-blood-wisely-designations-in-manitoba)

<sup>39</sup> <https://onlinelibrary.wiley.com/doi/10.1111/trf.16462>

<sup>40</sup> <https://onlinemadison.com/stories/ummc-taking-part-in-study-that-explores-use-of-cold-platelets-in-trauma-patients,34581>



- The European Medicines Agency's CHMP issued a positive opinion for Astellas Pharma and FibroGen's use of Evrenzo, or roxadustat, as a treatment for adults with chronic kidney disease-related symptomatic anaemia<sup>41</sup>. If roxadustat gains the European Commission's approval it could become the first hypoxia-inducible factor prolyl hydroxylase inhibitor administered orally to be available in Europe.
- The US Food and Drug Administration approved its first direct oral anticoagulant for the treatment of children with VTE<sup>42</sup>. The approval says dabigatran (Pradaxa) may be given to children after they have received a blood thinner injection for at least 5 days. Approval was also given for Pradaxa to be used to prevent recurrent clots in children who have completed treatment for their first venous thromboembolism.
- A meta-analysis found that death can result from severe bleeding due to use of direct oral anticoagulants, even when reversal agents are administered<sup>43</sup>.
- A randomised controlled trial found that administering hyperimmune globulin to pregnant women who tested positive for cytomegalovirus (CMV) did not reduce CMV infections or deaths among their foetuses or newborns<sup>44</sup>.
- The US FDA has approved Octapharma USA's Octagam 10% Immune Globulin Intravenous (Human), for treating adult dermatomyositis, an immune-mediated inflammatory disease<sup>45</sup>. Approval was based on outcomes of a randomized clinical trial<sup>46</sup>, the first to evaluate the long-term efficacy and safety of intravenous immunoglobulin for adults with dermatomyositis. The prospective, double-blind, placebo-controlled Phase III clinical trial involved 95 patients at 36 sites. Rohit Aggarwal, Medical Director of the Arthritis and Autoimmunity Center at the University of Pittsburgh School of Medicine and a member of the ProDERM study Steering Committee, said the study "will have a significant impact on clinical practice because IVIg is likely to become an important treatment option for patients with dermatomyositis. The study gives clinicians much more confidence in the efficacy and safety of intravenous immunoglobulin and provides valuable information about what type of patient is best suited for the treatment".

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<sup>41</sup> [EU Green Light for Roxadustat in Anemia of Kidney Disease \(medscape.com\)](https://www.medscape.com)

<sup>42</sup> <https://www.medpagetoday.com/cardiology/prevention/93208> and [FDA Approves First Oral Blood Thinning Medication for Children | FDA](https://www.fda.gov)

<sup>43</sup> <https://www.medpagetoday.com/cardiology/prevention/93096> and <https://thelimbic.com/haematology/doac-reversal-agents-work-but-what-comes-next-needs-more-data/>

<sup>44</sup> [A Trial of Hyperimmune Globulin to Prevent Congenital Cytomegalovirus Infection | NEJM](https://www.nejm.org) and <https://www.medscape.com/viewarticle/955577>

<sup>45</sup> <https://www.businesswire.com/news/home/20210720005999/en/FDA-Approves-Octapharma%E2%80%99s-Octagam%C2%AE-10-for-Adult-Dermatomyositis>

<sup>46</sup> [ProDERM](https://clinicaltrials.gov) (ClinicalTrials.gov Identifier: NCT02728752)





### 3. Clinical experience of COVID-19

- Brain scientists from Imperial College, London, found that people who have recovered from COVID-19 are more likely to receive low scores on intelligence tests<sup>47</sup>.
- Researchers have reported with some optimism on longitudinal cardiac and immunologic outcomes in some North American children hospitalised with multisystem inflammatory syndrome<sup>48</sup>.
- A US study in hospitalised veterans is reported<sup>49</sup> to have demonstrated that remdesivir “did not significantly improve survival”.
- UK researchers say that a diagnostic test for “long COVID” could be available in a few months. The blood test detects rogue antibodies<sup>50</sup>.
- A study has confirmed the link between anaemia and rehospitalisation after clearance of COVID-19 infection<sup>51</sup>.
- An elderly Belgian woman who was not vaccinated died after being infected simultaneously by both the UK and South African COVID-19 variant<sup>52</sup>.
- A study found that about one person in six amongst those infected with SARS-CoV-2 experiences an irregular heartbeat for more than four months<sup>53</sup>.

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<sup>47</sup> [Long Covid: Coronavirus can harm IQ Imperial College London study finds \(news.com.au\)](https://www.news.com.au/health/long-covid/coronavirus-can-harm-iq-imperial-college-london-study-finds/news-story/2021-07-07)

<sup>48</sup> [Longitudinal Outcomes for Multisystem Inflammatory Syndrome in Children | American Academy of Pediatrics \(aappublications.org\)](https://aappublications.org/) and <https://www.medscape.com/viewarticle/955002>

<sup>49</sup> [Association of Remdesivir Treatment With Survival and Length of Hospital Stay Among US Veterans Hospitalized With COVID-19 | Critical Care Medicine | JAMA Network Open | JAMA Network](https://www.medscape.com/viewarticle/954888) and <https://www.medscape.com/viewarticle/954888>

<sup>50</sup> <https://inews.co.uk/news/long-covid-tests-diagnostic-available-uk-within-six-months-1099361>

<sup>51</sup> <http://homenewshere.com/content/tncms/live/> and [Anemia during SARS-CoV-2 infection is associated with rehospitalisation after viral clearance - ScienceDirect](https://www.sciencedirect.com/science/article/abs/pii/S0950268821000500)

<sup>52</sup> [A woman who died from COVID-19 was the first recorded case of contracting 2 variants of coronavirus at the same time, researchers say | Business Insider](https://www.businessinsider.com/2021-07-07/a-woman-who-died-from-covid-19-was-the-first-recorded-case-of-contracting-2-variants-of-coronavirus-at-the-same-time-researchers-say)

<sup>53</sup> [https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781687](https://www.jamanetwork.com/journals/jamanetworkopen/fullarticle/2781687) and [https://www.upi.com/Health\\_News/2021/07/07/coronavirus-heart-rate-study/6091625664332/](https://www.upi.com/Health_News/2021/07/07/coronavirus-heart-rate-study/6091625664332/)



## 4. Treatments for COVID-19

- The US Food and Drug Administration (FDA) revised the Emergency Use Authorization (EUA) for baricitinib (brand name Olumiant). The FDA has now authorised baricitinib alone for the treatment of COVID-19 in hospitalised adults and paediatric patients two years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Baricitinib is no longer required to be administered with remdesivir<sup>54</sup>.
- The antiviral remdesivir has been used for many months to treat COVID-19 but there is still not universal agreement on its merits<sup>55</sup>.
- Working *in vitro*, Melbourne scientists<sup>56</sup> used "molecular scissors" to stop the SARS-CoV-2 virus replicating in infected human cells<sup>57</sup>. The treatment could be quickly adapted to combat new strains of the virus. The team will conduct animal studies before it can begin human clinical trials<sup>58</sup>.
- In the UK, the regulator accepted Humanigen's lenzilumab for rolling review<sup>59</sup>.
- In India, Hetero Labs has requested emergency use approval for Merck's oral drug molnupiravir, to decrease hospitalisations and hasten recovery<sup>60</sup>.
- The European Commission selected four antibody treatments and a repurposed rheumatoid arthritis drug by Eli Lilly for an initial portfolio of preferred drugs to treat COVID-19<sup>61</sup>.
- Researchers say antivirals for hepatitis C may be effective against SARS-CoV-2<sup>62</sup>.
- The World Health Organisation recommended using arthritis drugs Actemra from Roche and Kevzara from Sanofi with corticosteroids after data from some 11,000 COVID-19 patients showed they decreased the risk of death<sup>63</sup>.
- A retrospective cohort study in the US found that "patients with haematologic cancers who were hospitalized for COVID-19 had improved survival odds if they underwent convalescent plasma therapy"<sup>64</sup>. Researchers wrote: "This cohort study adds to the accumulating evidence supporting the efficacy of convalescent plasma treatment in patients with primary or secondary immunodeficiency, including those subjected to profound immunosuppression in the setting of hematopoietic stem cell transplantation."

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<sup>54</sup> [Questions and Answers Olumiant EUA Amendment \(fda.gov\)](https://www.fda.gov/oc/questions-and-answers-olumiant-eua-amendment)

<sup>55</sup> [World Health Organization says remdesivir does not help coronavirus patients - ABC News](https://www.abcnews.com/news/health/remdesivir-covid-19) [Research shows remdesivir treatment for COVID-19 has little impact on survival, increases hospital stay | Carver College of Medicine \(uiowa.edu\)](https://www.abcnews.com/news/health/remdesivir-covid-19)

<sup>56</sup> from the Doherty Institute and the Peter MacCallum Cancer Centre

<sup>57</sup> The research team used a gene editing tool (CRISPR-Cas13b) to target the blueprint of the virus and its variants.

<sup>58</sup> [Cancer treatment developed by Victorian scientists stops coronavirus replicating in cells - ABC News](https://www.abcnews.com/news/health/cancer-treatment-covid-19)

<sup>59</sup> [U.K. regulator accepts Humanigen's COVID drug for speedy review, as analysts spell out reasons to be hopeful for FDA nod | FierceBiotech](https://www.fda.gov/oc/questions-and-answers-humanigen-covid-19)

<sup>60</sup> [India's Hetero seeks emergency use nod for Merck's COVID-19 drug | Reuters](https://www.reuters.com/healthcare/india-hetero-seeks-emergency-use-approval-merck-covid-19-drug-2020-12-11/)

<sup>61</sup> [EU Picks Antibody Treatments, Arthritis Drug as Preferred COVID-19 Therapies \(medscape.com\)](https://www.medscape.com/viewarticle/954282)

<sup>62</sup> [Hepatitis C Antivirals May Fight SARS-CoV-2 \(medscape.com\)](https://www.medscape.com/viewarticle/954282)

<sup>63</sup> <https://www.medscape.com/viewarticle/954282>

<sup>64</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/93161> and [Association of Convalescent Plasma Therapy With Survival in Patients With Hematologic Cancers and COVID-19 | Hematology | JAMA Oncology | JAMA Network](https://www.jama.com/association-of-convalescent-plasma-therapy-with-survival-in-patients-with-hematologic-cancers-and-covid-19)



## 5. Developing vaccines for COVID-19

### General comments

- Research results on a study of mixing vaccines have now been published in *Nature Medicine*<sup>65</sup>. In the Australian context, the findings mean that an initial dose of Astra Zeneca followed nine to twelve weeks later by a dose of the Pfizer/BioNTech vaccine would give a good result<sup>66</sup>.
- In a real-world study<sup>67</sup> involving over a million participants, researchers assessed the incidence rates of blood clotting disorders of thromboembolism and thrombocytopenia, including the very rare thrombosis with thrombocytopenia (TTS) following vaccination with an mRNA vaccine or the AstraZeneca vaccine, and compared them with expected rates in a general population and in people with COVID-19. The researchers said the safety profiles were similar and overall, favourable. Very rare clotting disorders were observed with both<sup>68</sup>.
- A study found that people who had received two doses of either the Pfizer/BioNTech or AstraZeneca should have significant protection against the Delta variant<sup>69</sup>.
- Public Health England reported that both the Pfizer/BioNTech and AstraZeneca vaccines are effective in high-risk groups<sup>70</sup>.
- In the US, the Centers for Disease Control and the Food and Drug Administration say that Americans don't need a booster shot of vaccine yet<sup>71</sup>. The World Health Organisation said more data are needed to decide if a booster will be necessary<sup>72</sup>. The UK is planning for booster shots from September<sup>73</sup>. Pfizer/ BioNTech announced they are preparing a booster shot to target the Delta variant (first identified in India), saying immunity from their mRNA dose could wane after the second dose<sup>74</sup>. They have been trialling a third dose<sup>75</sup>.
- The German Standing Committee on Vaccination (STIKO) said that people who receive a first dose of the Oxford-AstraZeneca vaccine "should get an mRNA vaccine as their second dose, regardless of their age<sup>76</sup>."

<sup>65</sup> [Immunogenicity and reactogenicity of heterologous ChAdOx1 nCoV-19/mRNA vaccination | Nature Medicine](#)

<sup>66</sup> [Research results on mix-and-match vaccinations published \(medicalxpress.com\)](#)

<sup>67</sup> [Thromboembolic Events and Thrombosis With Thrombocytopenia After COVID-19 Infection and Vaccination in Catalonia, Spain by Edward Burn, Elena Roel, Andrea Pistillo, Sergio Fernandez-Bertolín, Maria Aragón, Carlen Reyes, Katia Verhamme, Peter Rijnbeek, Xintong Li, Victoria Strauss, Daniel Prieto-Alhambra, Talita Duarte-Salles: SSRN](#). Published as a pre-print on *The Lancet* server.

<sup>68</sup> <https://pipelinereview.com/index.php/2021072878820/Vaccines/Vaxzevria-and-mRNA-COVID-19-vaccines-showed-similar-and-favourable-safety-profiles-in-a-population-based-cohort-study-of-over-a-million-people.html> and [http://www.pmlive.com/pharma\\_news/az\\_publishes\\_new\\_real-world\\_safety\\_data\\_for\\_covid-19\\_vaccine\\_vaxzevria\\_1373754](http://www.pmlive.com/pharma_news/az_publishes_new_real-world_safety_data_for_covid-19_vaccine_vaxzevria_1373754)

<sup>69</sup> [https://www.washingtonpost.com/health/delta-variant-vaccines/2021/07/08/05b1bc5e-df75-11eb-ae31-6b7c5c34f0d6\\_story.html](https://www.washingtonpost.com/health/delta-variant-vaccines/2021/07/08/05b1bc5e-df75-11eb-ae31-6b7c5c34f0d6_story.html) and [Reduced sensitivity of SARS-CoV-2 variant Delta to antibody neutralization | Nature](#) and [Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants | NEJM](#)

<sup>70</sup> <https://www.medscape.com/viewarticle/954517> and [RCGP VE riskgroups paper \(khub.net\)](#) and [COVID-19 vaccines highly effective in most people in clinical risk groups - GOV.UK \(www.gov.uk\)](#)

<sup>71</sup> <https://www.reuters.com/article/health-coronavirus-usa-pfizer-vaccine/fda-cdc-say-fully-vaccinated-americans-dont-need-booster-shot-at-this-time-idUSFWN2OK0M1> and <https://www.fiercepharma.com/pharma/staying-vigilant-pfizer-and-biontech-plot-delta-busting-covid-19-booster-shot>

<sup>72</sup> [Question open on need for COVID booster shot, data awaited, WHO says | Reuters](#)

<sup>73</sup> [Britain Starts Planning for Vaccine Booster Shots From September \(medscape.com\)](#)

<sup>74</sup> <https://www.medscape.com/viewarticle/954357>

<sup>75</sup> [Delta Variant Study Press Statement Final 7.8.21.pdf \(pfizer.com\)](#)

<sup>76</sup> [Germany issues world's strongest recommendation for mixing Covid-19 vaccines \(9news.com.au\)](#)



- Researchers at the Duke Human Vaccine Institute have developed a pan-coronavirus vaccine that may protect against multiple coronaviruses in the SARS family. The vaccine candidate has been found to protect rhesus monkeys from the current coronavirus of concern (including its variants), as well as SARS and other SARS-related viruses circulating in bats but not yet in people<sup>77</sup>.

### **Astra Zeneca and Johnson & Johnson (adenovirus vaccines)**

- Scientists at New York University report that the Johnson & Johnson vaccine is more effective against the original strain of SARS-CoV-2 than against the Delta and Lambda variants<sup>78</sup>.
- AstraZeneca and Johnson & Johnson are researching whether modifications of their COVID-19 vaccines could reduce or eliminate the risk of rare but serious blood clots associated with the vaccines<sup>79</sup>.
- The US Food and Drug Administration is adding a new safety warning for Johnson & Johnson's vaccine after reports of very rare cases of a neurological condition called Guillain-Barré syndrome following immunization<sup>80</sup>.

### **Moderna, Pfizer/ BioNTech and CureVac (mRNA vaccines)**

- The US FDA has asked Moderna and Pfizer to trial their vaccines in more children, to “assess whether a rare inflammation of the heart muscle that has been seen in young adults shortly after vaccination is more common in younger age groups”<sup>81</sup>.
- In the US, Pfizer continues to press its case for booster shots<sup>82</sup>.
- A large real world study has shown that the Pfizer/BioNTech and Moderna mRNA vaccines are over 95 percent effective in preventing confirmed infection<sup>83</sup>.
- Pfizer/BioNTech are developing an updated version of their vaccine that targets the full spike of the Delta variant<sup>84</sup>.
- Researchers say that patients with myocarditis after their second dose of mRNA vaccine “invariably” present with chest pain approximately 2-3 days after their shot<sup>85</sup>.
- Israeli scientists reported the Pfizer vaccine is less effective in people over 50, and less effective against the Delta variant<sup>86</sup>.
- The US FDA has granted priority review for the Pfizer/BioNTech vaccine as the companies seek full approval<sup>87</sup>. So far it has had emergency use authorisation.
- The UK announced that vulnerable children aged 12-15 will be eligible for Pfizer vaccine<sup>88</sup>.

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<sup>77</sup> <https://www.businessinsider.com.au/pan-coronavirus-vaccine-variants-future-pandemics-2021-5> and [Neutralizing antibody vaccine for pandemic and pre-emergent coronaviruses | Nature](#)

<sup>78</sup> <https://www.fdanews.com/articles/203663-study-claims-ji-vaccine-much-less-effective-against-delta-lambda-variants>

<sup>79</sup> <https://www.wsj.com/articles/j-j-astrazeneca-explore-covid-19-vaccine-modification-in-response-to-rare-blood-clots-11626173015>

<sup>80</sup> <https://www.biopharmadive.com/news/fda-warning-johnson-johnson-coronavirus-vaccine-guillain-barre/603186/>

<sup>81</sup> [FDA asks Pfizer, Moderna to test their vaccines in more children to help rule out safety issues - The Washington Post](#)

<sup>82</sup> <https://www.biopharmadive.com/news/pfizer-coronavirus-vaccine-booster-plan-delta/604063/>

<sup>83</sup> [SARS-CoV-2 Vaccine Effectiveness in a High-Risk National Population in a Real-World Setting | Annals of Internal Medicine \(acpjournals.org\)](#) and <https://www.medscape.com/viewarticle/955162>

<sup>84</sup> [Delta Variant Study Press Statement Final 7.8.21.pdf \(pfizer.com\)](#) and <https://www.baynews9.com/fl/tampa/news/2021/07/21/delta-variant-booster>

<sup>85</sup> <https://www.medpagetoday.com/infectiousdisease/covid19vaccine/93662>

<sup>86</sup> <https://www.theaustralian.com.au/world/coronavirus-pfizer-less-effective-in-over50s-and-against-delta-find-israeli-researchers/news-story/b0de7db6becf35863fb789b3920750c4>

<sup>87</sup> <https://edition.cnn.com/2021/07/16/health/pfizer-covid-19-vaccine-fda-priority-review/index.html>

<sup>88</sup> <https://www.bmj.com/content/374/bmj.n1841>



- Australia's Therapeutic Goods Administration has approved the Pfizer/BioNTech COVID-19 vaccine for use in children aged 12 to 15<sup>89</sup>.
- The European Union's drug regulator is reviewing a small number of cases of an auto-immune disorder following shots of Moderna's mRNA vaccine<sup>90</sup>. Immune thrombocytopenia is characterised by low platelet levels that can lead to bruising and bleeding, the European Medicines Agency (EMA) said a link between Moderna's shot and the cases has not yet been established.
- The EU's regulator has followed the US FDA in requiring myocarditis and pericarditis to be listed as rare side effects of the Pfizer and Moderna mRNA vaccines<sup>91</sup>.
- New data suggest that protection given by mRNA-based COVID-19 vaccines from Moderna and from Pfizer/BioNTech could last for years. Scientists found high activity among the germinal centre B cells and antibody-secreting plasmablasts for at least three months after receipt of the second vaccine dose, which lead study author Ali Ellebedy said is "a good sign for how durable our immunity is from this vaccine"<sup>92</sup>.
- German company CureVac found its mRNA vaccine disappointing in a trial with 40,000 participants. Preliminary data showed the two-dose vaccine to be only 47 per cent effective at preventing disease<sup>93</sup>.
- A UK study found that increasing the interval between first and second doses of the Pfizer vaccine to twelve weeks (rather than three) increases the antibody response in people over 80 by three and a half times<sup>94</sup>.
- Moderna is expanding its production capacity so it can manufacture booster doses<sup>95</sup>.

### Novavax

- Most of the 51 million doses of the Novavax vaccine due to arrive in Australia during the second half of 2021 will not arrive till 2022. This vaccine was originally expected to serve as a primary vaccine, but it is now expected to serve as a booster<sup>96</sup>.

### Sinovac and Sinopharm

- A laboratory study showed that antibodies triggered by Sinovac's vaccine decline below a key threshold from around six months after a second dose for most recipients, although a booster shot might improve that<sup>97</sup>.
- At an earlier stage of development, researchers are continuing to work on next-generation vaccines<sup>98</sup>.
- As Sanofi and GSK conduct a global Phase III trial for their vaccine candidate, The European Medicines Agency began a rolling review<sup>99</sup>.

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<sup>89</sup> <https://www.abc.net.au/news/2021-07-23/tga-approves-covid-vaccine-children-teenagers/100316758>

<sup>90</sup> [06 Public Safety Update SPIKEVAX 14 July 2021 \(europa.eu\)](https://www.europa.eu/press-room/media/30606/public-safety-update-spikevax-14-july-2021)

<sup>91</sup> [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 5-8 July 2021 | European Medicines Agency \(europa.eu\)](https://www.europa.eu/press-room/media/30606/meeting-highlights-from-the-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021) and [New Details of Myocarditis Linked to COVID Vaccines \(medscape.com\)](https://www.medscape.com/viewarticle/955375)

<sup>92</sup> [Pfizer and Moderna Vaccines Likely to Produce Lasting Immunity, Study Finds - The New York Times \(nytimes.com\)](https://www.nytimes.com/2021/07/23/health/covid-19-vaccine-moderna.html)

<sup>93</sup> <https://www.nature.com/articles/d41586-021-01661-0>

<sup>94</sup> [https://m.economictimes.com/news/science/delay-in-second-shot-of-pfizer-vaccine-boosts-immunity-in-elderly-by-over-3-times-study/articleshow/82829648.cms](https://www.economictimes.com/news/science/delay-in-second-shot-of-pfizer-vaccine-boosts-immunity-in-elderly-by-over-3-times-study/articleshow/82829648.cms)

<sup>95</sup> <https://www.wsj.com/articles/moderna-plans-to-expand-production-to-make-covid-19-vaccine-boosters-supply-more-countries-11624273200>

<sup>96</sup> [Major delay in Australian government's Novavax deal, with 51m doses not expected until 2022 | Australian politics | The Guardian](https://www.theguardian.com/australia-news/2021/jul/23/major-delay-in-australian-government-s-novavax-deal-with-51m-doses-not-expected-until-2022)

<sup>97</sup> <https://www.medscape.com/viewarticle/955375>

<sup>98</sup> [Australian COVID-19 vaccine researchers critical in global search to find booster shots and 'next generation' jabs - ABC News](https://www.abc.net.au/news/2021-07-23/australian-covid-19-vaccine-researchers-critical-in-global-search-to-find-booster-shots-and-next-generation-jabs/100316758)

<sup>99</sup> <https://www.fiercebiotech.com/biotech/sanofi-gsk-s-covid-19-vaccine-enters-eu-rolling-review-as-companies-work-phase-3-trial> and

<https://www.ema.europa.eu/en/news/ema-starts-rolling-review-covid-19-vaccine-vidprevtyn>



## 6. Managing the pandemic

### Individual country experience

- In Australia, a teenager and young adults were amongst the sixteen people in ICU in NSW by 10 July<sup>100</sup>. Infectious disease experts have warned the country could find itself in “a situation like India” if the Delta variant is allowed to “run rampant” in Sydney<sup>101</sup>.
- The G7 Summit in Cornwall is said to have been a super-spreading event with local and regional case numbers rising dramatically after the event<sup>102</sup>.
- Public Health England says the Delta variant accounts for almost all the UK’s cases<sup>103</sup>.
- A researcher in Scotland<sup>104</sup> reported that allowing for age and comorbidities, the Delta variant roughly doubled the risk of hospitalisation, but vaccines reduced risk<sup>105</sup>.
- The US Centres for Disease Control revised its guidance on mask wearing saying even vaccinated Americans should wear them indoors in areas with high coronavirus transmission, and that in K-12 schools everyone should wear masks indoors regardless of vaccination status<sup>106</sup>. A general question raised in the US has been whether children could and should be asked to wear masks to limit infection<sup>107</sup>. When students had returned to school, the CDC had emphasised the need for masks to protect children too young to be vaccinated<sup>108</sup>.
- In the US, a deputy director of the CDC has questioned whether a third (booster) shot may risk more severe side effects.<sup>109</sup> Whether boosters are necessary remains a question for discussion round the world<sup>110</sup>. However, a CDC advisory panel is considering a third (booster) shot for people who are immunocompromised<sup>111</sup>.
- The majority of recent cases of serious illness and death in the US have been in unvaccinated people<sup>112</sup>.

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<sup>100</sup> [NSW teenager sent to ICU after positive Covid-19 diagnosis \(news.com.au\)](#) and [NSW covid: Sydney patient in 20s on ventilator as cases worsen \(news.com.au\)](#)

<sup>101</sup> [Sydney Covid: Raina Macintyre warns Delta outbreak could lead to ‘India’ situation \(news.com.au\)](#)

<sup>102</sup> <https://inews.co.uk/news/g7-summit-was-super-spreading-event-for-cornwall-as-cases-rocket-2450-after-johnson-and-biden-visit-1060710>

<sup>103</sup> [COVID-19: Almost all of UK's coronavirus cases are Delta as variant infections rise by more than 33,000 in a week | UK News | Sky News](#)

<sup>104</sup> Chris Robertson, Professor of Public Health Epidemiology, University of Strathclyde

<sup>105</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/delta-variant-doubles-risk-covid-hospitalisation-scottish-study-2021-06-14/>

<sup>106</sup> <https://www.healio.com/news/primary-care/20210727/cdc-alters-mask-guidance-says-even-vaccinated-americans-need-them-in-some-places>

<sup>107</sup> [Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Healthy Children: A Randomized Clinical Trial | Pediatrics | JAMA Pediatrics | JAMA Network](#) and <https://www.medpagetoday.com/opinion/vinay-prasad/93453>

<sup>108</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/93505>

<sup>109</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-official-says-covid-19-boosters-could-risk-more-serious-side-effects-2021-07-13/>

<sup>110</sup> <https://www.medpagetoday.com/opinion/vinay-prasad/93565> and [EU regulator weighing mixing COVID-19 vaccines, booster doses | Reuters](#)

<sup>111</sup> <https://thehill.com/policy/healthcare/563317-cdc-advisory-panel-to-consider-third-covid-19-shot-for-immunocompromised> and <https://www.cnbc.com/2021/07/15/some-portion-of-the-us-population-will-get-booster-shots-dr-scott-gottlieb-says.html>

<sup>112</sup> [https://www.upi.com/Health\\_News/2021/07/14/coronavirus-delta-long-haul-outlook-experts/2681626283411/](https://www.upi.com/Health_News/2021/07/14/coronavirus-delta-long-haul-outlook-experts/2681626283411/)



- Also from the US:
  - 11 per cent of people have missed a second COVID-19 vaccine dose<sup>113</sup>.
  - A National Institutes of Health study associates COVID-19 surges with mortality increases for patients<sup>114</sup>.
  - Dr Anthony Fauci said areas in the US could expect surges in case numbers when vaccination slows and the Delta variant spreads<sup>115</sup>. On 8 July, US officials said case numbers were up about 11 per cent<sup>116</sup>.
  - Surgeon General Dr. Vivek Murthy has said that people who received the single-dose Johnson & Johnson COVID-19 vaccine could be protected against the delta variant based on data so far. He said: "While we are still awaiting direct studies of Johnson & Johnson and the Delta variant, we have reasons to be hopeful, because the Johnson & Johnson vaccine has proven to be quite effective against preventing hospitalizations and deaths, with all the variants that we've seen to date<sup>117</sup>."
  - Christopher Murray, the director of the Institute for Health Metrics and Evaluation, suggested that vaccinated people are spreading the Delta variant<sup>118</sup>. The Centers for Disease Control recommends against testing vaccinated people unless they are symptomatic<sup>119</sup>.
  - A screening study funded by the National Institutes of Health supports frequent testing for COVID-19 antigens<sup>120</sup>.
  - A new study supported by the National Institutes of Health suggests high humidity associated with mask-wearing may delay/ reduce infection<sup>121</sup>
  - Singapore found it needed to restore its COVID-19 restrictions shortly after relaxing them<sup>122</sup>, because of a sudden spike in cases.
  - In Indonesia, there have been high infection rates with the Delta variant in children. Half the children who have died have been under five years old<sup>123</sup>.
  - In Indonesia, over 350 vaccinated medical workers have been hospitalised with the disease. Almost all had received the Sinovac vaccine. The Delta variant appears responsible for the surge in cases<sup>124</sup>.
  - India said it had detected a new variant it called "Delta plus", which it said demonstrated increased transmissibility<sup>125</sup>.
  - New Zealand's Medsafe provisionally approved the Pfizer vaccine for use in children aged 12 to 15.<sup>126</sup>

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<sup>113</sup> <https://www.healio.com/news/infectious-disease/20210706/in-us-11-of-people-have-missed-second-covid19-vaccine-dose>

<sup>114</sup> <https://www.nih.gov/news-events/news-releases/nih-study-associates-covid-19-surges-mortality-increases-patients>

<sup>115</sup> <https://www.cnn.com/2021/07/06/dr-fauci-where-to-expect-covid-surges-in-the-us-and-safety-tips.html>

<sup>116</sup> <https://www.reuters.com/world/us/us-covid-19-cases-rising-mostly-among-unvaccinated-officials-2021-07-08/>

<sup>117</sup> [U.S. surgeon general: Johnson & Johnson Covid vaccine may protect people against the delta variant \(cnn.com\)](https://www.cnn.com/2021/07/06/health/surgeon-general-covid-19-vaccine-protect-against-delta-variant/index.html)

<sup>118</sup> [A leading US disease expert says there's 'no doubt in my mind' that vaccinated people are helping spread Delta | Business Insider](https://www.bbc.com/news/health-57484848)

<sup>119</sup> [Interim Public Health Recommendations for Fully Vaccinated People | CDC](https://www.cdc.gov/media/releases/2021/s0706-covid-19-vaccine-fully-vaccinated.html)

<sup>120</sup> <https://www.nih.gov/news-events/news-releases/nih-funded-screening-study-builds-case-frequent-covid-19-antigen-testing>

<sup>121</sup> <https://magazine.medlineplus.gov/article/new-study-finds-another-good-reason-to-wear-a-mask>

<sup>122</sup> <https://www.news.com.au/world/coronavirus/global/singapore-reintroduces-covid-19-restrictions-days-after-relaxing-rules/news-story/d9ec0e764ce24e0279a2bf7c2fba1d45>

<sup>123</sup> [Indonesia grapples with high COVID rates among children as health experts urge people to protect their kids - ABC News](https://www.abc.net.au/news/2021-07-06/indonesia-grapples-with-high-covid-rates-among-children-as-health-experts-urge-people-to-protect-their-kids/10128444)

<sup>124</sup> <https://www.medscape.com/viewarticle/953367>

<sup>125</sup> [India raises alarm over 'Delta plus' COVID-19 variant as vaccine drive struggles - ABC News](https://www.abc.net.au/news/2021-07-06/india-raises-alarm-over-delta-plus-covid-19-variant-as-vaccine-drive-struggles/10128444)

<sup>126</sup> <https://www.rnz.co.nz/news/political/445213/medsafe-gives-pfizer-vaccine-provisional-approval-for-ages-12>





## Transmission

- Experience with the Delta variant has not accorded with all previous experience of COVID-19<sup>127</sup>. Scientists have warned that the symptoms of the Delta variant are different from those of earlier strains, and that patients can become severely ill in a shorter space of time<sup>128</sup>.
- Scientists say vaccines may be limiting new mutations<sup>129</sup>.
- Emerging coronavirus variants are being tracked round the world, with genomic sequencing in developing countries being assisted by scientists based elsewhere<sup>130</sup>.
- A new study found that an influenza vaccination might provide some protection against the severe effects of COVID-19<sup>131</sup>.
- The world is on alert for the Lambda variant, first identified in Peru<sup>132</sup>.
- The World Health Organisation says the delta variant is the “fastest and fittest” COVID variant and will “pick off” the most vulnerable people<sup>133</sup>.
- Researchers have offered new insights into how stem cells protect against RNA viruses<sup>134</sup>.
- Scientists have found surges in COVID-19 case numbers to be associated with deletions in the SARS-CoV-2 genome in an antigenic site of the spike protein<sup>135</sup>.
- Australian researchers have developed a biosensor to detect SARS-CoV-2 and its variants on human breath within sixty seconds<sup>136</sup>.

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<sup>127</sup><https://www.medscape.com/viewarticle/955399>

<sup>128</sup> [How Delta variant symptoms differ from other Covid-19 strains \(news.com.au\)](#)

<sup>129</sup><https://www.medscape.com/viewarticle/954621> and [COVID-19 vaccines dampen genomic diversity of SARS-CoV-2: Unvaccinated patients exhibit more antigenic mutational variance | medRxiv](#)

<sup>130</sup> [New Coronavirus Variants Are Urgently Being Tracked around the World - Scientific American](#)

<sup>131</sup> <https://consumer.healthday.com/7-12-flu-shot-might-help-ward-off-severe-covid-too-2653727606.html>

<sup>132</sup> [https://www.medpagetoday.com/special-reports/exclusives/93458?utm\\_source=Sailthru&utm\\_medium=email&utm\\_campaign=Weekly%20Review%202021-07-11&utm\\_term=NL\\_DHE\\_Weekly\\_Active](https://www.medpagetoday.com/special-reports/exclusives/93458?utm_source=Sailthru&utm_medium=email&utm_campaign=Weekly%20Review%202021-07-11&utm_term=NL_DHE_Weekly_Active)

<sup>133</sup> [Covid delta: WHO says variant is the fastest and fittest and will 'pick off' most vulnerable \(cnbc.com\)](#)

<sup>134</sup> <https://www.fiercebiotech.com/research/stem-cells-show-promise-protecting-themselves-from-rna-viruses-like-sars-cov-2>

<sup>135</sup> <https://www.the-scientist.com/news-opinion/spike-protein-deletions-linked-to-covid-19-surges-preprint-68892>

<sup>136</sup> <https://www.hospimedica.com/>





## 7. Miscellaneous news

### Diseases other than COVID-19

- In France, five public research institutions imposed a three-month moratorium on the study of prions<sup>137</sup> after a retired lab worker who had handled prions in the past was diagnosed with Creutzfeldt-Jakob disease<sup>138</sup>.
- BioNTech is working with the World Health Organisation to develop an mRNA malaria vaccine, beginning human clinical trials sometime in 2022<sup>139</sup>.
- Researchers at the University of Alberta are developing an adjuvanted recombinant hepatitis C vaccine which they say may be available in five years<sup>140</sup>.
- The US FDA announced the availability of draft guidance on the development of rabies anti-virus monoclonal antibody cocktails<sup>141</sup>.
- Europe's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Otsuka's 25 mg dispersible tablet formulation of Delytba for the treatment of pulmonary multidrug resistant tuberculosis (MDR-TB) in children<sup>142</sup>.
- Hong Kong health authorities have been monitoring human cases of avian flu (H5N6) on the mainland<sup>143</sup>.
- A Brazilian study<sup>144</sup> reported that pregnant women infected with Zika virus were not at increased risk of giving birth to a baby with microcephaly if they had previously been infected with dengue virus.
- Scientists are claiming a breakthrough on the road to a vaccine against melioidosis, linked to contact with contaminated soil and water, and found in northern Australia<sup>145</sup>.
- Researchers have developed an mRNA vaccine which protected mice against a variety of coronaviruses. They combined parts of spike proteins from different coronaviruses<sup>146</sup>.
- Genentech (the Roche Group) was granted Breakthrough Therapy Designation by the FDA for the treatment of adult patients with previously untreated intermediate, high- and very high-risk myelodysplastic syndromes with its product Venclexta (venetoclax) in combination with azacytidine. Myelodysplastic syndromes (MDS) are blood cancers that reduce the ability of the bone marrow to produce normal blood cells, resulting in anaemia, weakness and fatigue, and frequent infections. MDS can progress to acute myeloid leukemia<sup>147</sup>.
- A postdoctoral scholarship has been awarded by the US National Institutes of Health for further research on prion disease<sup>148</sup>.
- The US FDA awarded Valneva's chikungunya vaccine breakthrough therapy status<sup>149</sup>.

<sup>137</sup> misfolding, infectious proteins that cause fatal brain diseases

<sup>138</sup> <https://www.sciencemag.org/news/2021/07/france-issues-moratorium-prion-research-after-fatal-brain-disease-strikes-two-lab>

<sup>139</sup> <https://newatlas.com/health-wellbeing/mrna-malaria-vaccine-biontech-who-africa/>

<sup>140</sup> <https://www.healio.com/news/primary-care/20210726/hepatitis-c-vaccine-could-be-ready-in-5-years-nobel-prize-winner-says>

<sup>141</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rabies-developing-monoclonal-antibody-cocktails-passive-immunization-component-post-exposure>

<sup>142</sup> <https://www.fiercepharma.com/drug-delivery/chmp-supports-approval-otsuka-s-dispersible-tb-drug-for-kids>

<sup>143</sup> <http://outbreaknewstoday.com/h5n6-avian-influenza-in-china-3-additional-cases-reported-one-death-94324/>

<sup>144</sup> L. Damasceno et al. Why do different regions of Brazil have different ZIKV perinatal outcomes? Exploratory study of two cohorts, *Virus* (2021). DOI: 10.3390 / v13050736 and <https://floridanewstimes.com/studies-refute-the-suspicion-that-dengue-fever-increases-the-risk-of-microcephaly-associated-with-zika-fever/308807/>

<sup>145</sup> [Hope for vaccine amid fears disease found in suburban gardens could be a biological weapon - ABC News](#)

<sup>146</sup> [www.nih.gov/news-events/nih-research-matters/experimental-vaccine-protects-against-multiple-coronaviruses](http://www.nih.gov/news-events/nih-research-matters/experimental-vaccine-protects-against-multiple-coronaviruses)

<sup>147</sup> [FDA Grants Breakthrough Therapy Designation for Venclexta in Combination With Azacitidine for the Treatment of Patients With Myelodysplastic Syndromes | National Business | joplinglobe.com](#)

<sup>148</sup> [Postdoc Earns Prestigious NIH Fellowship to Expand Prion Disease Research | Newsroom \(ucmerced.edu\)](#)

<sup>149</sup> [Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate | Seeking Alpha](#)



- Researchers say that in the US the mortality gap between the general population and patients with HIV narrowed between 1999 and 2017<sup>150</sup>.
- University of Oxford scientists have launched a Phase I trial of a new HIV vaccine<sup>151</sup>.
- Moderna is trialling an mRNA -based influenza vaccine<sup>152</sup>.
- A new clinical trial of an mRNA melanoma vaccine has dosed its first patient<sup>153</sup>.

## Other

- National Resilience and Bluebird Bio announced<sup>154</sup> an alliance to speed research, development and delivery of next-gen cell therapies. National Resilience will pay Bluebird \$US110 million upfront to acquire a commercial suspension lentiviral vector manufacturing site in North Carolina.
- Sri Lanka has a nationally co-ordinated blood transfusion service, but recent discussion has drawn attention to a perceived need for a disaster management plan and emergency preparedness protocols. The need for ensuring transport facilities and co-ordination was mentioned as a critical aspect of that<sup>155</sup>.

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<sup>150</sup> <https://www.healio.com/news/primary-care/20210706/mortality-gap-narrows-between-patients-with-hiv-general-population>

<sup>151</sup> [http://www.pharmatimes.com/news/oxford\\_researchers\\_launch\\_hiv\\_vaccine\\_trial\\_1372739](http://www.pharmatimes.com/news/oxford_researchers_launch_hiv_vaccine_trial_1372739)

<sup>152</sup> [mRNA vaccine technology moves to flu: Moderna says trial has begun | Ars Technica](#)

<sup>153</sup> [First Cancer Patient Receives mRNA Melanoma Vaccine In New Clinical Trial | IFLScience](#)

<sup>154</sup> [Bluebird Bio and Resilience Announce Strategic Alliance to Develop Next Generation Cell Therapies | Business Wire](#)

<sup>155</sup> <https://nation.lk/online/national-plan-required-for-blood-transfusion-amidst-increased-demand-103386.html>