

# Monitoring International Trends

## February 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.

The healthcare sector, including its research and development arm, remained heavily focussed on the COVID-19 pandemic. Of note: regulatory approvals for vaccines against COVID-19 increased and progress was made in vaccination programs across a number of countries, primarily in the developed world; emerging mutant strains of SARS-CoV-2 are causing considerable concern worldwide and there is increasing evidence that they are evolving to evade the body's natural immune response, and to evade monoclonal antibody treatments (page 9); mutant strains of the virus also appear to be significantly more contagious and likely to increase the possibility of reinfection (pages 8,9); it appears that the Astra Zeneca vaccine is more effective if the second dose is given after 2-3 months rather than after 4 weeks (page 16); and the World Health Organization (WHO) is formally recognising the lingering symptoms of COVID-19, known as long-COVID (page 11).

In other news, unrelated to COVID-19, the US Food and Drug Administration (FDA) has granted fast track designation to efanesoctocog alfa, an investigational factor VIII replacement therapy for treating haemophilia A (page 5); and US scientists have developed a new gene therapy vector for sickle cell disease and beta thalassemia (page 6).

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## 1. Treating blood disorders

### Haemophilia

- In 2020, the US FDA approved supplemental biologics license applications for two recombinant factor IX products: Wyeth Pharmaceuticals' BeneFIX and Aptevo BioTherapeutics' Ixinity. Both products were granted new indications for routine prophylaxis in adults and children with haemophilia B to reduce the frequency of bleeding episodes. On 17 February 2021, the FDA admitted that it had erred in approving the paediatric patient cohort in the prophylaxis indications because that was covered under the seven years of orphan drug exclusivity awarded to Baxalta's recombinant factor IX product Rixubis<sup>1</sup>. They subsequently rescinded the 2020 approval for the paediatric cohort.
- Sanofi announced that the US FDA has granted fast track designation to efanesoctocog alfa, an investigational factor VIII replacement therapy for treating haemophilia A<sup>2</sup>.
- Sanofi has revised the dosing schedule of fitusiran for haemophilia in its phase 3 trial to reduce the risk of thrombotic incidents<sup>3</sup>.
- Spark Therapeutics announced encouraging preliminary data<sup>4</sup> from part one of the ongoing phase 1 /2 open-label, non-randomized, dose-finding study of *SPK-8016* in haemophilia A. Part one was designed to evaluate safety and efficacy in men with severe haemophilia A and no measurable inhibitor against factor VIII<sup>5</sup>. There were four participants. Spark's Chief Medical Officer described "stable and durable FVIII activity with a safety profile supporting further evaluation at a very low vector dose".
- A European study reported that Kovaltry (octocog alfa) is safe and effective for prophylaxis in children with haemophilia A<sup>6</sup>.
- UK researchers have said that the combination of rfactor VIII and emicizumab may be helpful for haemophilia A patients requiring surgery<sup>7</sup>.
- Researchers told the Virtual Congress of the European Association for Haemophilia and Allied Disorders that further haemostatic options for severe haemophilia A are needed because patients have spontaneous breakthrough joint bleeding and impaired physical functioning despite high adherence with exogenous factor VIII<sup>8</sup>. They reported on a multinational study of 294 patients with severe haemophilia A (FVIII  $\leq$  1 IU/dL) receiving prophylactic factor VIII who were followed for up to one year. Quality of life scores were low for physical functioning, treatment concern and consequences of bleeding. Arthralgia was reported by 5.8 per cent of participants,

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<sup>1</sup> <https://www.raps.org/news-and-articles/news-articles/2021/2/fda-partially-rescinds-two-approvals-after-orphan>

<sup>2</sup> <https://hemophilianewstoday.com/2021/02/19/fda-fast-track-designation-efanesoctocog-alfa-hemophilia-a-treatment/>

<sup>3</sup> <https://www.fiercebiotech.com/biotech/sanofi-revises-fitusiran-dosing-to-cut-risk-thrombotic-events-hemophilia-phase-3>

<sup>4</sup> Data were presented at the European Association for Haemophilia and Allied Disorders 2021 Virtual Congress by investigator Spencer Sullivan, M.D., Mississippi Center for Advanced Medicine.

<sup>5</sup> <https://pipelinereview.com/index.php/2021/02/06/77366/DNA-RNA-and-Cells/Spark-Therapeutics-Announces-Preliminary-Data-from-Phase-1/2-Clinical-Trial-of-SPK-8016-in-Hemophilia-A-at-EAHAD-2021-Virtual-Congress.html>

<sup>6</sup> <https://hemophilianewstoday.com/2021/02/03/kovaltry-safe-effective-children-hemophilia-a-real-world-study/>

<sup>7</sup> [Abstract - 2021 - Haemophilia - Wiley Online Library](#)

<sup>8</sup> 3-5 February 2021

and haemophilic arthropathy by 2.0 per cent of participants. Serious adverse events were reported by 4.8 per cent of participants<sup>9</sup>.

## Sickle cell disease and thalassemia

- Bluebird bio suspended two clinical trials of its sickle cell disease gene therapy<sup>10</sup> after two participants developed cancer (acute myeloid leukemia or myelodysplastic syndrome). The company said it would evaluate whether the BB305 lentiviral vector was linked to the cases of AML and MDS.<sup>11</sup> Bluebird executives later reported they believed factors other than gene therapy were responsible for one of the cases, and that the other may not be a conclusive diagnosis<sup>12</sup>.
- Bluebird also paused selling its gene therapy Zynteglo (betibeglogene autotemcel) in Europe for beta-thalassemia, even though the cancer cases emerged in its trial for sickle disease<sup>13</sup>.
- Bluebird bio's Zynteglo was not recommended by the UK's National Institute of Health and Care Excellence for use on the NHS. The treatment was developed for transfusion-dependent beta-thalassaemia in people aged 12 years and older who do not have a beta0/beta0 genotype. It is indicated when haematopoietic stem cell transplantation is appropriate but a donor is unavailable. Criticisms by NICE included the smallness of the trial and the high cost of the product<sup>14</sup>.
- Novartis announced that the Bill & Melinda Gates Foundation will provide support funding for the discovery and development of a single-administration, *in vivo* gene therapy to cure sickle cell disease<sup>15</sup> which is to be accessible to people in poorer countries.<sup>16</sup>
- US scientists have developed a new gene therapy vector for sickle cell disease and beta thalassemia. A preclinical study suggests it could avoid genome toxicity.<sup>17</sup>

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<sup>9</sup> including haemophilic arthropathy; haematuria; haematoma; and haemorrhoidal, oesophageal, and muscle haemorrhage.

<sup>10</sup> [bluebird bio Announces Temporary Suspension on Phase 1/2 and Phase 3 Studies of LentiGlobin Gene Therapy for Sickle Cell Disease \(bb1111\) | Business Wire](#)

<sup>11</sup> <https://www.fiercebiotech.com/biotech/bluebird-stops-gene-therapy-trials-after-2-sickle-cell-patients-develop-cancer> and <https://www.biopharmadive.com/news/bluebird-pause-gene-therapy-study-leukemia-myelodysplastic/595112/>

<sup>12</sup> <https://www.biopharmadive.com/news/bluebird-reveals-new-details-on-cancer-cases-in-gene-therapy-trial/595787/>

<sup>13</sup> <https://www.fiercepharma.com/marketing/bluebird-s-zynteglo-safety-snap-may-have-broader-implications-for-gene-therapy-analysts>

<sup>14</sup> [http://www.pharmatimes.com/news/bluebird\\_bios\\_beta-thalassaemia\\_gene\\_therapy\\_rejected\\_by\\_nice\\_1363220](http://www.pharmatimes.com/news/bluebird_bios_beta-thalassaemia_gene_therapy_rejected_by_nice_1363220)

<sup>15</sup> <https://pipelinereview.com/index.php/2021021777453/More-News/Novartis-and-the-Bill-Melinda-Gates-Foundation-collaborate-to-discover-and-develop-an-accessible-in-vivo-gene-therapy-for-sickle-cell-disease.html>

<sup>16</sup> <https://www.biopharmadive.com/news/gates-foundation-backs-novartis-search-for-a-sickle-cell-cure/595203> and

[http://www.pmlive.com/pharma\\_news/novartis\\_partners\\_with\\_bill\\_and\\_melinda\\_gates\\_foundation\\_on\\_accessible\\_sickle\\_cell\\_gene\\_therapy\\_1363582](http://www.pmlive.com/pharma_news/novartis_partners_with_bill_and_melinda_gates_foundation_on_accessible_sickle_cell_gene_therapy_1363582)

<sup>17</sup> [https://www.cell.com/molecular-therapy-family/molecular-therapy/fulltext/S1525-0016\(20\)30729-2](https://www.cell.com/molecular-therapy-family/molecular-therapy/fulltext/S1525-0016(20)30729-2) and <https://www.ajmc.com/view/preclinical-study-of-gene-therapy-vector-for-scd-beta-thalassaemia-shows-promise>

## Other blood disorders

- At the 2021 American Academy of Allergy Asthma & Immunology (AAAAI) Virtual Annual Meeting in late February, Pharvaris reported clinical data supporting the pharmacokinetic and pharmacodynamic profiles of PHA121 (PHA-022121) for the treatment of hereditary angioedema.<sup>18</sup>
- An analysis of UK data suggested men with iron overload from hereditary haemochromatosis have a higher risk of developing dementia.<sup>19</sup>
- A randomised trial has found that high doses of oxytocin are no more effective than standard doses at reducing the rates of caesarean births.<sup>20</sup>
- The US National Institutes of Health's National Heart, Lung and Blood Institute will provide financial support to the [Versiti Blood Research Institute](#) in Wauwatosa, Wisconsin to develop an understanding of cell surface sugars in regulating blood cell production in health and disease<sup>21</sup>.

## 2. Safety and Patient blood management

- A point-of-care test is being recommended in the UK for detecting direct oral anticoagulants in urine.<sup>22</sup> The [DOASENSE DOAC Dipstick](#) is non-invasive; whereas, standard laboratory tests involve collection of a blood sample.
- The UK has approved Bayer's anticoagulant Xarelto as an oral suspension to treat venous thromboembolism in children.<sup>23</sup>
- The US FDA's Center for Biologics Evaluation and Research (CBER) released a list of draft and final guidances which it plans to issue in 2021<sup>24</sup>. Several of the guidances appearing on the list for 2021 have already been issued, including an update to the agency's guidance on investigational COVID-19 convalescent plasma, manufacturing considerations for licensed and investigational cell and gene therapies during COVID-19, and draft guidance on gene therapies for neurodegenerative diseases. The four guidances appearing on the list for the first time fall under the tissues and advanced therapies, and the blood and blood components categories.

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<sup>18</sup> <https://pipelinereview.com/index.php/2021022077478/Small-Molecules/Pharvaris-Presents-Pharmacodynamic-Activity-of-Oral-PHA121-Under-Development-for-the-Treatment-of-HAE-at-the-AAAAI-Annual-Meeting.html> and <https://pipelinereview.com/index.php/2021012877271/Small-Molecules/Pharvaris-Announces-Phase-1-Clinical-Data-of-PHA121-an-Oral-B2-Receptor-Antagonist-Under-Development-for-the-Treatment-of-Hereditary-Angioedema.html>

<sup>19</sup> <https://www.medscape.com/viewarticle/945393>

<sup>20</sup> <https://www.medpagetoday.com/meetingcoverage/smf/91014>

<sup>21</sup> <https://biztimes.com/versiti-blood-research-institute-awarded-12-million-research-grant/>

<sup>22</sup> [Overview | DOAC Dipstick for detecting direct oral anticoagulants | Advice | NICE](#) and <https://thelimbic.com/haematology/in-brief-pbs-restrictions-for-blood-cancer-therapies-severe-haemophilia-a-doac-dipstick-test>

<sup>23</sup> <https://www.fiercepharma.com/drug-delivery/u-k-approves-pediatric-oral-suspension-form-bayer-s-xarelto>

<sup>24</sup> [CBER Plots New Draft Guidance in 2020 on Genome Editing, CAR-T Therapies | RAPS](#) and <https://www.raps.org/news-and-articles/news-articles/2021/2/cber-lays-out-scaled-down-guidance-agenda-for-2021> and [FDA offers first thoughts on neurodegenerative disease gene therapies | RAPS](#) and [FDA explains convalescent plasma donor eligibility for COVID vaccine recipients | RAPS](#) and [FDA guides on COVID considerations in cell and gene therapy | RAPS](#)

### 3. Antibodies, T cells and COVID-19

- GSK, reporting Phase 2 results for its investigational monoclonal antibody otilimab in hospitalised COVID-19 patients, said it showed potential in older patients.<sup>25</sup>
- Adagio has begun dosing in a phase 1 trial of its monoclonal antibody candidate for preventing and treating COVID-19.<sup>26</sup> It hopes the antibody will be effective against variants.<sup>27</sup>
- Celltrion announced that its monoclonal antibody treatment candidate CT-P59 has neutralising capability against mutant strains.<sup>28</sup>
- Research scientists are interested in how the SARS-CoV-2 spike protein changes shape in response to COVID-19 antibodies; knowledge that should be useful in developing vaccines and drugs.<sup>29</sup>
- An international randomized controlled phase 3 clinical trial began evaluating the safety and efficacy of AZD7442, an investigational long-acting antibody combination developed by AstraZeneca. It is being trialled in hospitalised patients, as part of ACTIV-3, sponsored by the US National Institute of Allergy and Infectious Diseases.<sup>30</sup>
- Abpro reported positive phase 1 data indicating a good safety and pharmacokinetic profile for its antibody therapeutic, ABP 300.<sup>31</sup>
- Eli Lilly, Vir Biotechnology, and GlaxoSmithKline announced their collaboration to evaluate a combination of two COVID-19 therapies in low-risk patients with mild to moderate COVID-19. Lilly has expanded its continuing BLAZE-4 trial of two neutralising antibodies that bind to different epitopes of the SARS-CoV-2 spike protein: bamlanivimab (LY-CoV555) 700mg and VIR-7831 (also known as GSK4182136) 500mg.<sup>32</sup>
- Bristol Myers Squibb has acquired world rights to two early-stage antibodies discovered by Rockefeller University.<sup>33</sup>
- Regeneron announced that its own scientists, along with researchers at Columbia University, have independently confirmed that its antibody cocktail REGEN-COV™ (casirivimab and imdevimab) successfully neutralizes the circulating SARS-CoV-2

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<sup>25</sup> <http://www.pharmatimes.com/news/gsk/covid-19-antibody-shows-potential-in-older-patients-1364224>

<sup>26</sup> <https://pipelinereview.com/index.php/2021021677447/Antibodies/Adagio-Therapeutics-Announces-Dosing-of-First-Patient-in-Phase-1-Trial-of-ADG20-its-Lead-Monoclonal-Antibody-Candidate-for-the-Treatment-and-Prevention-of-COVID-19.html>

<sup>27</sup> <https://www.fiercebiotech.com/biotech/eying-variants-adagio-starts-phase-1-trial-covid-19-antibody>

<sup>28</sup> <https://pipelinereview.com/index.php/2021021177415/Antibodies/Celltrion-Develops-Tailored-Neutralising-Antibody-Cocktail-Treatment-with-CT-P59-to-Tackle-COVID-19-Variant-Spread-Using-Its-Antibody-Development-Platform.html>

<sup>29</sup> [Real-Time Conformational Dynamics of SARS-CoV-2 Spikes on Virus Particles: Cell Host & Microbe](https://www.fiercebiotech.com/research/insights-into-how-coronavirus-changes-shape-could-aid-development-covid-19-vaccines-drugs) and <https://www.fiercebiotech.com/research/insights-into-how-coronavirus-changes-shape-could-aid-development-covid-19-vaccines-drugs>

<sup>30</sup> <https://www.nih.gov/news-events/news-releases/clinical-trial-hospitalized-covid-19-patients-evaluates-long-acting-antibody-therapy>

<sup>31</sup> <https://pipelinereview.com/index.php/2021020277325/Antibodies/Abpro-Announces-Positive-Phase-1-Results-Demonstrating-A-Favorable-Safety-and-Pharmacokinetic-Profile-of-ABP-300-A-Neutralizing-Antibody-Therapeutic-for-the-Treatment-of-COVID.html>

<sup>32</sup> <https://pipelinereview.com/index.php/2021012777262/Antibodies/Lilly-Vir-Biotechnology-and-GSK-announce-first-patient-dosed-in-expanded-BLAZE-4-trial-evaluating-bamlanivimab-LY-CoV555-with-VIR-7831-GSK4182136-for-COVID-19.html>

<sup>33</sup> [Bristol Myers makes late play for COVID-19 antibody space, picking up 2 early-phase molecules from Rockefeller | FierceBiotech](https://www.fiercebiotech.com/news/bristol-myers-squibb-acquires-world-rights-to-two-early-stage-antibodies-discovered-by-rockefeller-university)

variants identified in the UK (B.1.1.7) and in South Africa (B.1.351).<sup>34</sup> The European Medicines Agency has begun a rolling review of Regeneron's antibody.<sup>35</sup>

- A report<sup>36</sup> (not yet peer reviewed) suggests that a mutant strain of the virus, SARS-CoV-2 501Y.V2, escapes neutralisation by three classes of therapeutically relevant monoclonal antibodies and from neutralising antibodies in COVID-19 convalescent plasma from South African donors.<sup>37</sup>
- Achilles Vaccines, based in Italy, announced the development of a novel monoclonal antibody to treat COVID-19.<sup>38</sup>

#### 4. Variant strains of COVID-19

- The European Union (EU) is reportedly adding clauses to vaccine contracts requiring vaccine makers to supply doses that protect against emerging variants.<sup>39</sup> In preparation for the next generation of vaccines that might be required, the EU has also begun a study of mutations in the SARS-CoV-2 virus.<sup>40</sup> The EU's medical regulator plans to speed up assessments of any COVID-19 vaccines modified to deal with variant strains.<sup>41</sup>
- Both the Pfizer and Moderna vaccines have been shown to be less potent against variant viruses, and booster shots are being discussed as a way to prevent "breakthrough cases"<sup>42</sup>.
- A Cambridge immunologist Sarah Caddy, in a discussion about the possible redesign of vaccines to deal with emerging strains, said of mRNA vaccines: "They are using chemically synthesized mRNA. There's no cells needed, so it is so much quicker to make and then purify."<sup>43</sup>
- Worldwide, there is recognition that the emergence of mutant strains is increasing the possibility of reinfection.<sup>44</sup>
- Experience in Brazil has shown that a severe first wave of the pandemic did not provide herd immunity to withstand a second wave, probably caused by a variant.<sup>45</sup>

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<sup>34</sup> [Increased Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7 to Antibody Neutralization | bioRxiv](https://www.biorxiv.org/content/10.1101/2021.01.18.427166v1.full) and <https://pipelinereview.com/index.php/2021012777263/Antibodies/REGEN-COV-Antibody-Cocktail-Is-Active-Against-SARS-CoV-2-Variants-First-Identified-in-the-UK-and-South-Africa.html>

<sup>35</sup> <https://www.medscape.com/viewarticle/945021>

<sup>36</sup> <https://www.biorxiv.org/content/10.1101/2021.01.18.427166v1.full>

<sup>37</sup> <https://www.theguardian.com/world/2021/feb/02/monoclonal-antibodies-great-hope-in-covid-treatments-fails-against-variants>

<sup>38</sup> <https://pipelinereview.com/index.php/2021012577245/Antibodies/AchilleS-Vaccines-Completes-Industrial-Development-of-Promising-Treatment-Against-SARS-CoV-2.html>

<sup>39</sup> <https://www.medscape.com/viewarticle/945864>

<sup>40</sup> <https://www.medscape.com/viewarticle/945847>

<sup>41</sup> <https://www.reuters.com/article/us-health-coronavirus-eu-vaccines-exclus/exclusive-eu-drugs-regulator-plans-to-fast-track-variant-modified-covid-vaccines-idUSKBN2AC27T>

<sup>42</sup> <https://www.fiercepharma.com/pharma/bring-boosters-studies-show-pfizer-moderna-covid-vaccines-are-less-protective-against-south> and <https://blogs.bmj.com/bmj/2021/02/16/what-makes-new-variants-of-sars-cov-2-concerning-is-not-where-they-come-from-but-the-mutations-they-contain> and <https://www.fiercepharma.com/pharma/moderna-aims-to-produce-up-to-1b-doses-vaccine-doses-2021-targets-1-4b-for-2022>

<sup>43</sup> <https://www.the-scientist.com/news-opinion/vaccines-versus-the-mutants-68430> and <https://www.medpagetoday.com/infectiousdisease/covid19/91122>

<sup>44</sup> <https://www.healio.com/news/primary-care/20210215/qa-sarscov2-reinfection-rate-likely-higher-than-previously-thought>

<sup>45</sup> [Covid-19: Is Manaus the final nail in the coffin for natural herd immunity? | The BMJ](https://www.bmj.com/news/covid-19-is-manauas-the-final-nail-in-the-coffin-for-natural-herd-immunity)

Brazil's health minister said a variant strain found in the Amazon was three times more contagious than the first strain experienced in the country.<sup>46</sup>

- Sinovac's Brazilian partner said the Sinovac vaccine is effective against both the UK and South African variants.<sup>47</sup>
- A small study in the UK found that the UK variant is not causing more severe disease in children.<sup>48</sup>
- The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) said it "had moderate confidence" the B.1.1.7 (UK) variant is substantially more infectious than other variants, and that there is "a realistic possibility" that infection with the variant "is associated with an increased risk of death"<sup>49</sup>. The E484 mutation which was first identified in the South African variant is now identified in the UK variant, raising concerns it too could become resistant to vaccines<sup>50</sup>. To date, over 4000 COVID-19 variants have been identified<sup>51</sup>.
- Public Health England reported cases of a new variant B.1.525, which has the E484K spike protein mutation, also present in the South African variant. The B.1.525 variant has also been detected in Nigeria, Denmark and Canada. Simon Clarke<sup>52</sup> told *The Guardian*: "We don't yet know how well this [new] variant will spread, but if it is successful it can be presumed that immunity from any vaccine or previous infection will be blunted."<sup>53</sup>
- The UK mutation was said to have evolved further, gaining a change identified in the South African mutation.<sup>54</sup>
- Japan identified a new variant in a cluster at a Tokyo immigration centre. This new variant has the E484K mutation on the spike protein which has been found in other variants.<sup>55</sup>
- The (WHO) says recovered COVID-19 patients have been reinfected with new strains.<sup>56</sup>
- The US FDA said it was developing expedited review processes for COVID-19 vaccine makers who need to update vaccines to deal with variant strains.<sup>57</sup>
- A US blueprint for dealing with variant strains was published on 17 February.<sup>58</sup>

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<sup>46</sup> <https://www.medscape.com/viewarticle/945738>

<sup>47</sup> <https://www.medscape.com/viewarticle/945971>

<sup>48</sup> <https://www.medscape.com/viewarticle/946002>

<sup>49</sup> [UK, South African, Brazilian: a virologist explains each COVID variant and what they mean for the pandemic - ABC News](#)

<sup>50</sup> [Covid-19: The E484K mutation and the risks it poses | The BMJ](#) and <https://www.nature.com/articles/d41586-021-00299-2>

<sup>51</sup> <https://www.medscape.com/viewarticle/945268> and <https://www.medscape.com/viewarticle/945315> and [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00298-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00298-1/fulltext) and <https://www.the-scientist.com/multimedia/side-by-side-comparisons-of-important-sars-cov-2-variants-68388>

<sup>52</sup> Associate Professor of cellular microbiology at the University of Reading

<sup>53</sup> [New COVID variant found in UK may reduce effectiveness of vaccines, government says - ABC News](#) and [Covid-19: The E484K mutation and the risks it poses | The BMJ](#)

<sup>54</sup> [A highly infectious new coronavirus mutation just got a little bit scarier – BGR](#)

<sup>55</sup> [New COVID-19 virus strain found in Japan as infection cluster is found in Tokyo immigration centre - ABC News](#)

<sup>56</sup> <https://www.cnbc.com/2021/02/12/recovered-covid-patients-have-been-reinfected-with-new-virus-strains-who-says.html>

<sup>57</sup> <https://www.fiercepharma.com/pharma/no-need-to-start-at-square-one-fda-mulls-over-speedy-path-for-covid-vaccines-drugs-against> and <https://www.raps.org/news-and-articles/news-articles/2021/2/woodcock-fda-plans-guidance-to-address-new-covid-1>

<sup>58</sup> <https://jamanetwork.com/journals/jama/fullarticle/2776739> and <https://www.medscape.com/viewarticle/946100>

- Two research teams in New York found a new variant carrying mutations to help it to sidestep the body's natural immune response, and also ignore monoclonal antibody treatments.<sup>59</sup>
- A study found that seven coronavirus variants similar to the UK strain are circulating in the US.<sup>60</sup>
- Researchers at the University of Pittsburgh School of Medicine discovered that SARS-CoV-2 evolves over time to evade the immune response to the virus<sup>61</sup>. It deletes part of the genetic code for the spike protein on its surface, which stops some antibodies from attaching to and neutralizing the virus. The spike protein has been a prime target for treatments and vaccines.
- Arnaud Fontanet and colleagues, commenting in *The Lancet*, wrote that "the end of the pandemic is only possible when vaccines that are effective against circulating variants are distributed equitably across the world. As high-income countries race to immunise their populations within months<sup>62</sup>, they leave themselves vulnerable to SARS-CoV-2 evolving in other countries to a new lineage that vaccines might not protect against. Repeatedly formulating new vaccines may be needed to control some new SARS-CoV-2 variants. With the increase in basic reproduction number of more transmissible SARS-CoV-2 variants, higher vaccine coverage will be required to achieve herd immunity, and vaccinating children might also be necessary to reach this coverage."<sup>63</sup>

## 5. Clinical experience in COVID-19

- A report from the US said there had been a surge in paediatric cases of multisystem inflammatory syndrome following the winter increase in COVID-19, but that diagnosis and treatment had improved since the previous surge.<sup>64</sup>
- A US study found the majority of US hospitalisations with COVID-19 were associated with four pre-existing cardio-metabolic conditions: obesity, diabetes, hypertension and heart failure.<sup>65</sup>
- A study by the US Centers for Disease Control and Prevention (CDC) found that some nursing home residents who appeared to have recovered from COVID-19 succumbed to a worse case, suggesting that asymptomatic or mild cases may not provide a lot of protection against becoming reinfected with COVID-19.<sup>66</sup>
- A US transplant recipient died after being given lungs infected with COVID-19.<sup>67</sup>

<sup>59</sup> [New York's new coronavirus variant is worrying researchers - CNN](#)

<sup>60</sup> [Emergence in late 2020 of multiple lineages of SARS-CoV-2 Spike protein variants affecting amino acid position 677 | medRxiv](#) and [Covid-19: The U.S. Has Its Own New Worrisome Variants - The New York Times \(nytimes.com\)](#) and [Coronavirus: Seven new mutations identified in US \(news.com.au\)](#)

<sup>61</sup> [Recurrent deletions in the SARS-CoV-2 spike glycoprotein drive antibody escape | Science \(sciencemag.org\)](#) and <https://www.fiercebiotech.com/research/pitt-team-sheds-light-how-covid-19-escapes-immune-destruction> and <https://www.the-scientist.com/news-opinion/sars-cov-2-with-genomic-deletions-escapes-an-antibody-68453>

<sup>62</sup> <https://www.medscape.com/viewarticle/945374> and <https://www.medscape.com/viewarticle/945375>

<sup>63</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00370-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00370-6/fulltext) and <https://www.nih.gov/news-events/news-releases/nih-experts-discuss-sars-cov-2-viral-variants>

<sup>64</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91368>

<sup>65</sup> <https://www.medscape.com/viewarticle/946488> ; see also <https://www.healio.com/news/endocrinology/20210217/metabolic-syndrome-better-prognostic-indicator-for-severe-covid19-outcomes>

<sup>66</sup> <https://www.cdc.gov/mmwr/volumes/70/wr/mm7008a3.htm> and <https://www.cnbc.com/2021/02/25/cdc-study-finds-nursing-home-residents-were-reinfected-with-worse-case-of-covid.html>

<sup>67</sup> [Transplant Recipient Dies After Receiving COVID-19-Infected Lungs - Consumer Health News | HealthDay](#)

- The WHO will create a clinical description for the lingering symptoms, known as long-COVID, which some people suffer after being cleared of their initial illness.<sup>68</sup>
- At a recent White House briefing, Dr Anthony Fauci said that so-called long COVID-19 is actually “post-acute sequelae of SARS-CoV-2 infection, which we're now referring to as 'PASC' or P-A-S-C.”<sup>69</sup>
- Researchers have identified myocardial injury in a large proportion of patients who were hospitalised with severe COVID-19 a few months earlier<sup>70</sup>.
- Mortality in blood cancer patients who become infected with COVID-19 was found to be higher than in patients with other cancers<sup>71</sup>.
- A small Italian study suggests one-third of COVID-19 survivors may come out of it with post-traumatic stress disorder<sup>72</sup>.
- A large study in the UK found children were less likely to report fever, persistent cough, and loss of appetite.<sup>73</sup>
- Researchers reported in *The Lancet Rheumatology* that interleukin-1 inhibitors are associated with decreased mortality among patients hospitalised with COVID-19, respiratory insufficiency and hyperinflammation.<sup>74</sup>
- The UK will be the first nation to conduct a COVID-19 human challenge study.<sup>75</sup>
- A study suggested that starting heparin prophylaxis within 24 hours of hospital admission offered a 27 per cent lower risk of 30-day mortality.<sup>76</sup>
- Interim results of three trials suggest that therapeutic coagulation is beneficial in patients with moderate disease, but it may do harm in those with severe disease.<sup>77</sup>
- UK research says there are four further symptoms now associated with coronavirus: chills, appetite loss, headaches and muscle aches.<sup>78</sup>
- Verily is collaborating with Johnson & Johnson's Janssen division for an at-home study to observe the body's earliest immune responses to COVID-19 infection<sup>79</sup>.

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<sup>68</sup> [Fatigue, headaches and chest pain: Medical experts try to establish 'long Covid' diagnosis for patients with lasting symptoms \(cnbc.com\)](#) and <https://www.beckershospitalreview.com/public-health/who-to-develop-agreed-clinical-description-for-long-covid-19-diagnosis.html> and <https://www.medpagetoday.com/infectiousdisease/covid19/91270>

<sup>69</sup> <https://www.medscape.com/viewarticle/946419>

<sup>70</sup> <https://www.healio.com/news/cardiology/20210218/myocardial-injury-common-in-patients-with-severe-covid19-months-after-discharge>

<sup>71</sup> <https://www.the-scientist.com/news-opinion/covid-19-more-deadly-with-blood-than-solid-cancer-study-68459> and [CD8 T cells compensate for impaired humoral immunity in COVID-19 patients with hematologic cancer | Research Square](#)

<sup>72</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91255>

<sup>73</sup> [Covid-19: Children less likely to report fever, persistent cough, or appetite loss, large UK study finds | The BMJ](#)

<sup>74</sup> <https://www.healio.com/news/rheumatology/20210223/il1-inhibitors-linked-to-significant-reduction-in-covid19-mortality>

<sup>75</sup> [World's first coronavirus Human Challenge study receives ethics approval in the UK - GOV.UK \(www.gov.uk\)](#) and <https://www.medscape.com/viewarticle/945959>

<sup>76</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91166> and [Early initiation of prophylactic anticoagulation for prevention of coronavirus disease 2019 mortality in patients admitted to hospital in the United States: cohort study | The BMJ](#) and <https://www.medscape.com/viewarticle/945902>

<sup>77</sup> <https://thelimbic.com/haematology/refining-the-anticoagulation-approach-in-covid-19-interim-results-of-three-trials/>

<sup>78</sup> <https://www.9news.com.au/world/new-coronavirus-symptoms-revealed-following-uk-imperial-college-london-study/d31f016c-1336-404d-ae4f-d6072b460149>

<sup>79</sup> <https://www.fiercebiotech.com/medtech/verily-links-janssen-for-at-home-covid-immune-system-study>

- Researchers report that severely frail patients with COVID-19 are three times more likely to die than those who were not frail, even taking into account their age.<sup>80</sup>
- Scientists say a recent study suggests SARS-CoV-2 can cause the body to attack itself<sup>81</sup>.
- Analysis shows that people with severe COVID-19 may develop a form of diabetes.<sup>82</sup>
- A new negative pressure ventilator has been developed which could provide an additional treatment option for conscious patients with COVID-19.<sup>83</sup>

## 6. Potential treatments for COVID-19 not mentioned elsewhere

- The US FDA limited the authorised use of convalescent COVID-19 plasma to high-titre plasma for hospitalised patients early in the disease, and “those with impaired humoral immunity who cannot produce an adequate endogenous antibody response”<sup>84</sup>.
- The US National Institutes of Health is funding an evaluation of remdesivir as a COVID-19 treatment in pregnant women<sup>85</sup>.
- The Pharmacovigilance Risk Assessment Committee of the European Medicines Agency has concluded (following a safety review) that remdesivir is not associated with acute kidney injury.<sup>86</sup>
- The American College of Physicians updated its guidance on the use of remdesivir confirming that in its view “5- and 10-day courses of remdesivir provide a net benefit vs. placebo or standard care in hospitalized, nonpregnant adults with COVID-19”.<sup>87</sup>
- Researchers say their study found that the diabetes drug metformin did not affect susceptibility to COVID-19 infection, nor death from it.<sup>88</sup>
- A Phase 2 clinical trial of GlaxoSmithKline’s otlimab in hospitalised patients missed its primary endpoint. However, analysis of response by older patients found signs of efficacy, which are being explored.<sup>89</sup>
- Potential therapies included in the US National Institutes of Health phase 2 /3ACTIV-2 trial are an inhalable beta interferon delivered by nebulizer; a long-acting monoclonal antibody combination that will be studied as both an infusion and an intramuscular injection; and an orally administered serine protease inhibitor that may block SARS-CoV-2 from entering cells.<sup>90</sup>

<sup>80</sup> <https://www.birmingham.ac.uk/research/inflammation-ageing/news/2021/02/severely-frail-covid.aspx>

<sup>81</sup> <https://www.medscape.com/viewarticle/945130>

<sup>82</sup> <https://www.washingtonpost.com/health/2021/02/01/covid-new-onset-diabetes/>

<sup>83</sup> [New negative pressure ventilator requiring fewer staffing resources developed in fight against COVID-19 | EurekAlert! Science News](#) and <https://www.healio.com/news/pulmonology/20210203/new-negativepressure-ventilatory-support-device-shows-promise-in-small-study> A study on invasively ventilated patients and their outcomes is available at

[https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30459-8/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30459-8/fulltext)

<sup>84</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91071>

<sup>85</sup> <https://www.nih.gov/news-events/news-releases/nih-funds-study-evaluate-remdesivir-covid-19-pregnancy>

<sup>86</sup> <https://www.medscape.com/viewarticle/945888> and [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 8-11 February 2021 | European Medicines Agency \(europa.eu\)](#)

<sup>87</sup> <https://www.healio.com/news/primary-care/20210210/acp-updates-guidance-on-remdesivir-as-covid19-treatment>

<sup>88</sup> <https://www.medscape.com/viewarticle/945941>

<sup>89</sup> <https://www.fiercebiotech.com/biotech/gsk-fails-covid-19-phase-2-subgroup-finding-fuels-further-work>

<sup>90</sup> <https://www.nih.gov/news-events/news-releases/four-potential-covid-19-therapeutics-enter-phase-2-3-testing-nih-activ-2-trial> and [http://www.pharmatimes.com/news/synairgens\\_inhaled\\_covid-](http://www.pharmatimes.com/news/synairgens_inhaled_covid-)

- On 9 February, the US FDA issued an emergency use authorisation for monoclonal antibodies bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and paediatric patients (12 years of age or more and weighing at least 40 kilograms) who test positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19. The authorisations include treatment for those who are over 65 years of age, or who have specified chronic medical conditions.<sup>91</sup>
- A study of the anti-inflammatory drug colchicine missed a primary endpoint.<sup>92</sup>
- Tiziana reported data from a small trial of a nasally administered antibody suggesting it could improve outcomes.<sup>93</sup>
- The US FDA has asked for more data from Merck on the experimental COVID-19 drug MK-7110 which it acquired from its buyout of Oncolmmune. The drug was initially developed for allogeneic hematopoietic stem-cell transplant patients.<sup>94</sup>

## 7. Developing vaccines for COVID-19

### Approved or close to submission for approval

#### General comments

- New trials are addressing vaccine safety and efficacy in pregnant women.<sup>95</sup>
- A case study has suggested that giving pregnant women COVID-19 vaccine may protect newborns.<sup>96</sup>
- Studies show that people who have already had COVID-19 should still be vaccinated to boost antibodies and hopefully fight variants.<sup>97</sup>
- France's health authority Haute Autorite de Sante recommended only a single shot of vaccine was required for people who had been previously infected<sup>98</sup>.
- Researchers have suggested that anyone who has had COVID-19 might require only one dose of an mRNA vaccine.<sup>99</sup>

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<sup>91</sup> <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0> and <https://www.drugdiscoverytrends.com/fda-authorizes-eli-lillys-monoclonal-antibody-treatment-for-covid-19>

<sup>92</sup> <https://www.medscape.com/viewarticle/945464>

<sup>93</sup> <https://www.fiercepharma.com/drug-delivery/tiziana-posts-clinical-covid-19-data-nasal-antibody-delivery>

<sup>94</sup> <https://www.fiercebiotech.com/biotech/fda-tells-merck-told-to-show-more-data-for-its-oncoimmune-covid-drug-as-eua-pushed-back>

<sup>95</sup> <https://www.the-scientist.com/news-opinion/qa-new-trials-tackle-covid-19-vaccines-in-pregnancy-68494> and

<https://www.empr.com/home/news/drugs-in-the-pipeline/pfizer-biotech-coronavirus-disease-2019-covid-19-bmt162b2/>

<sup>96</sup> <https://www.the-scientist.com/news-opinion/covid-19-vaccines-for-pregnant-moms-may-protect-newborns-68465> and

<https://www.nih.gov/news-events/news-releases/nih-calls-greater-inclusion-pregnant-lactating-people-covid-19-vaccine-research>

<sup>97</sup> [Studies Suggest People Who Had Covid-19 Should Get Single Vaccine Dose - The New York Times \(nytimes.com\)](#) and [Severe reinfection with South African SARS-CoV-2 variant 501Y.V2: A case report | Clinical Infectious Diseases | Oxford Academic \(oup.com\)](#)

<sup>98</sup> [French Authority Recommends Single COVID-19 Shot for Those Previously Infected \(medscape.com\)](#)

<sup>99</sup> [Covid-19: People who have had infection might only need one dose of mRNA vaccine | The BMJ](#)

- There continues to be pressure to delay second doses of vaccine in order to deliver first doses to more people.<sup>100</sup> Not all scientists agree.<sup>101</sup>
- Vaccine trials so far have not, for the most part, been directed at detecting their ability to prevent asymptomatic cases, which have an important role in spreading the disease. Efficacy statistics have instead emphasised their capacity to prevent people from becoming significantly ill.<sup>102</sup> However, Moderna says its vaccine may prevent asymptomatic infection,<sup>103</sup> while the Pfizer/ BioNTech vaccine was said in Israel to be 92 per cent effective at preventing infection (with or without symptoms) after the second dose<sup>104</sup> (see more on the Pfizer vaccine below). New data on the Johnson & Johnson vaccine suggests it can reduce transmission risk.<sup>105</sup> Researchers from the University of Oxford published results of a study suggesting that the Astra Zeneca vaccine “may have a substantial impact on transmission” of SARS-CoV-2<sup>106</sup>.
- Scientists writing in *The Lancet Infectious Diseases*<sup>107</sup> say that phase 3 studies of both the Pfizer/ BioNTech and Moderna vaccines “demonstrate an imbalance of cases of Bell’s palsy in the vaccine groups compared with the placebo groups”.
- To address questions of optimum time interval between vaccine doses, and interchangeability of vaccines, the Oxford Vaccine Group is conducting the COVID-19 Heterologous Prime Boost study<sup>108</sup> (the [Com-Cov study](#)). Antibody titres will be measured in more than 800 people aged 50 as the primary outcome.<sup>109</sup>
- Reporting on experience between 9 December 2020 and 24 January 2021, the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) said the first safety data related to COVID-19 vaccines was “reassuring, with most side effects reported being mild and in line with those seen with other types of vaccine”.<sup>110</sup>
- A recent report suggested the AstraZeneca vaccine would see the largest number of doses produced in 2021, followed by Pfizer/BioNTech, Johnson & Johnson, Sinovac, Sinopharm, Gamelaya Centre (Russia), NovaVax, Moderna and CureVac<sup>111</sup>.

## Astra Zeneca

- AstraZeneca’s vaccine was granted Emergency Use Listing by the WHO for active immunisation to prevent COVID-19 in people 18 years of age and older, including those over 65.<sup>112</sup>

<sup>100</sup> <https://www.medpagetoday.com/blogs/marty-makary/91029> and <https://www.medscape.com/viewarticle/946102>

<sup>101</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91288>

<sup>102</sup> <https://www.medpagetoday.com/special-reports/exclusives/91342>

<sup>103</sup> [Moderna says its COVID-19 vaccine may prevent asymptomatic infection | Reuters](#)

<sup>104</sup> [Does Pfizer's COVID Vaccine Protect Against Asymptomatic Infection? | MedPage Today](#)

<sup>105</sup> <https://www.medscape.com/viewarticle/946401>

<sup>106</sup> [Single Dose Administration, And The Influence Of The Timing Of The Booster Dose On Immunogenicity and Efficacy Of ChAdOx1 nCoV-19 \(AZD1222\) Vaccine by Merryn Voysey, Sue Ann Costa Clemens, et al. and Do COVID-19 vaccines prevent transmission of coronavirus — and how much does that matter? - ABC News](#)

<sup>107</sup> [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00076-1/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00076-1/fulltext)

<sup>108</sup> Supported by the National Institute for Health Research (NIHR)

<sup>109</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91105> and [Oxford University to launch trial alternating coronavirus vaccines from AstraZeneca and Pfizer-BioNTech - ABC News](#) and <https://www.medscape.com/viewarticle/945254>

<sup>110</sup> [Covid-19: First UK vaccine safety data are “reassuring,” says regulator | The BMJ](#)

<sup>111</sup> <https://www.pharmaceuticalprocessingworld.com/which-companies-will-likely-produce-the-most-covid-19-vaccine-in-2021/>

<sup>112</sup> <https://pipelinereview.com/index.php/2021021677439/Vaccines/AstraZeneca-COVID-19-vaccine-authorized-for-emergency-use-by-the-World-Health-Organization.html> and <http://www.pharmatimes.com/news/who-panel-recommends-azoxfords-covid-19-vaccine-1363139>

- Oxford University has initiated a COVID-19 vaccine trial in people aged between 6 and 17.<sup>113</sup>
- A US analyst suggested the FDA could decline to approve AstraZeneca's vaccine on both efficacy and manufacturing grounds.<sup>114</sup>
- The Therapeutic Goods Administration has approved the use of the Astra Zeneca vaccine in Australian adults, including in people over 65.<sup>115</sup>
- The team behind the Oxford-AstraZeneca vaccine has initiated research into developing it into a pill, which would permit faster and cheaper inoculation. Professor Sarah Gilbert said developing the vaccine into a pill form or a nasal spray would take time: "As you know all the vaccines have been given at the moment as intramuscular injections. That is not necessarily the best way to provide protection against a respiratory virus infection, where we want the immune system to be active in the upper respiratory tract and then in the lower respiratory tract, which is where the virus is causing the infection. And we have flu vaccines that are given by nasal spray"<sup>116</sup>.
- Oxford scientists found that the Astra Zeneca vaccine was 76 per cent effective at preventing symptomatic infection after the first dose, and efficacy rose with a longer interval than originally suggested before the second dose, about 90 days<sup>117</sup>. AstraZeneca confirmed that primary analysis of phase 3 trials for its vaccine showed 100 per cent protection against severe disease, hospitalisation and death<sup>118</sup>.
- AstraZeneca is collaborating with German firm IDT Biologika to hasten vaccine output in the EU.<sup>119</sup> The company may also be able to provide supplies of its vaccine to Europe from the Serum Institute of India.<sup>120</sup>
- South Africa suspended rollout of the AstraZeneca vaccine after trial data showed it offered limited protection against the South African variant.<sup>121</sup>
- At the end of January, AstraZeneca's vaccine was recommended for conditional marketing authorisation in the EU for active immunisation to prevent COVID-19 in people aged 18 or more<sup>122</sup>. The label allows the second dose to be administered

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and [World Health Organization scientists recommend Oxford/AstraZeneca vaccine for all age groups - ABC News](#)

<sup>113</sup> <https://www.medscape.com/viewarticle/945891>

<sup>114</sup> <https://www.fiercepharma.com/pharma/fda-could-reject-astra-zeneca-s-covid-vaccine-efficacy-and-manufacturing-shortfalls-analyst>

<sup>115</sup> [Coronavirus Australia: AstraZeneca COVID vaccine approved by TGA \(smh.com.au\)](https://www.smh.com.au/health/2021/02/03/coronavirus-australia-astrazeneca-covid-vaccine-approved-by-tga/)

<sup>116</sup> [Coronavirus vaccine pill: Johnson & Johnson, Oxford AstraZeneca developing new product \(news.com.au\)](https://www.news.com.au/health/2021/02/03/coronavirus-vaccine-pill-johnson-johnson-oxford-astrazeneca-developing-new-product/)

<sup>117</sup> <https://www.cnn.com/2021/02/03/delaying-second-astrazeneca-vaccine-dose-does-work-study-shows.html> and <https://www.medpagetoday.com/special-reports/exclusives/91056>

<sup>118</sup> <https://pipelinereview.com/index.php/2021020377330/Vaccines/COVID-19-Vaccine-AstraZeneca-confirms-100-protection-against-severe-disease-hospitalisation-and-death-in-the-primary-analysis-of-Phase-III-trials.html>

<sup>119</sup> <https://www.fiercepharma.com/manufacturing/astrazeneca-taps-german-cdmo-idt-biologika-to-pave-way-for-europe-s-future-vaccine>

<sup>120</sup> [U.K. inspects AstraZeneca vaccine partner's India manufacturing, setting stage for supply boost | FiercePharma](https://www.fiercepharma.com/pharma/uk-inspects-astrazeneca-vaccine-partners-india-manufacturing-setting-stage-for-supply-boost/)

<sup>121</sup> [AstraZeneca says its coronavirus vaccine can stop severe disease despite 'limited' success against South African variant - ABC News](https://www.abc.net.au/news/2021-02-08/south-africa-will-suspend-use-of-the-astrazeneca-vaccine/13131142) and

<https://www.abc.net.au/news/2021-02-08/south-africa-will-suspend-use-of-the-astrazeneca-vaccine/13131142> and [Coronavirus Australia news: Oxford-AstraZeneca vaccine may be less effective against South African variant - ABC News](https://www.fiercepharma.com/pharma/astrazeneca-oxford-race-to-update-covid-19-vaccine-as-study-flags-weak-action-against) and <https://www.fiercepharma.com/pharma/astrazeneca-oxford-race-to-update-covid-19-vaccine-as-study-flags-weak-action-against>

<sup>122</sup> <https://pipelinereview.com/index.php/2021012977291/Vaccines/COVID-19-Vaccine-AstraZeneca-recommended-for-use-in-the-EU.html>

between four and twelve weeks after the first.<sup>123</sup> Andrew Pollard, director of the University of Oxford's vaccine group, has said that in the AstraZeneca/Oxford vaccine trials, the immune response was about three times greater when the second dose was given at 2-3 months versus 4 weeks.<sup>124</sup>

## CureVac

- CureVac announced the initiation of a rolling review for its mRNA-based vaccine, CVnCoV with the European Medicines Agency.<sup>125</sup>
- GlaxoSmithKline and Bayer will support manufacturing of CureVac's vaccine.<sup>126, 127</sup>
- CureVac, in collaboration with GlaxoSmithKline, will develop next generation mRNA vaccines for COVID-19, and may take a multi-valent approach to accommodate multiple emerging variants in a single vaccine<sup>128</sup>. CureVac and the UK Vaccines Taskforce will study multiple variants of the Sars-CoV-2 virus and develop vaccine candidates against selected variants.<sup>129</sup>

## Johnson & Johnson

- Johnson & Johnson reported that the single-shot Janssen COVID-19 vaccine candidate met the primary endpoints in an interim analysis of its phase 3 ENSEMBLE trial. The level of protection against moderate to severe COVID-19 infection was 72 per cent in the US, 66 per cent in Latin America and 57 per cent in South Africa, 28 days post-vaccination.<sup>130</sup>
- On 26 February a US FDA advisory panel voted unanimously to recommend authorising the single-shot COVID-19 vaccine for emergency use in the US.<sup>131</sup> Johnson & Johnson had also submitted a conditional marketing authorisation application to the European Medicines Agency<sup>132</sup> and an emergency use listing application to the WHO.<sup>133</sup>

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<sup>123</sup> <https://www.fiercepharma.com/vaccines/amid-supply-shortfall-new-data-show-az-s-covid-19-vaccine-works-for-3-months-after-first>

<sup>124</sup> <https://www.medpagetoday.com/blogs/marty-makary/91029> and [Covid-19 vaccination: What's the evidence for extending the dosing interval? | The BMJ](#)

<sup>125</sup> [http://www.pharmatimes.com/news/curevac\\_s\\_covid-19\\_vaccine\\_begins\\_rolling\\_review\\_with\\_ema\\_1363316](http://www.pharmatimes.com/news/curevac_s_covid-19_vaccine_begins_rolling_review_with_ema_1363316)

<sup>126</sup> [GSK and CureVac to develop next generation mRNA COVID-19 vaccines | GSK and https://www.biopharmadive.com/news/gsk-curevac-coronavirus-vaccine-partnership/594449/](https://www.biopharmadive.com/news/gsk-curevac-coronavirus-vaccine-partnership/594449/)

<sup>127</sup> <https://www.fiercepharma.com/manufacturing/vaccine-manufacturing-greenhorn-bayer-to-make-160m-doses-curevac-s-covid-19-mrna-shot>

<sup>128</sup> <https://pipelinereview.com/index.php/2021020377332/Vaccines/GSK-and-CureVac-to-develop-next-generation-mRNA-COVID-19-vaccines.html>

<sup>129</sup> [U.K. government taps CureVac to target COVID-19 variants with new vaccines | FierceBiotech](#)

<sup>130</sup> <https://pipelinereview.com/index.php/2021012977295/Vaccines/Johnson-Johnson-Announces-Single-Shot-Janssen-COVID-19-Vaccine-Candidate-Met-Primary-Endpoints-in-Interim-Analysis-of-its-Phase-3-ENSEMBLE-Trial.html>

<sup>131</sup> <https://www.healio.com/news/infectious-disease/20210226/another-huge-milestone-fda-panel-endorses-oneshot-jj-vaccine> and <https://www.fiercebiotech.com/biotech/fda-arranges-feb-26-adcomm-to-discuss-j-j-covid-19-vaccine-eua>

<sup>132</sup> <https://pipelinereview.com/index.php/2021021777452/Vaccines/Johnson-Johnson-Announces-Submission-of-European-Conditional-Marketing-Authorisation-Application-to-the-EMA-for-its-Investigational-Single-Shot-Janssen-COVID-19-Vaccine-Candidat.html>

<sup>133</sup> <https://pipelinereview.com/index.php/2021021977474/Vaccines/Johnson-Johnson-Announces-Submission-to-World-Health-Organization-for-Emergency-Use-Listing-of-Investigational-Single-Shot-Janssen-COVID-19-Vaccine-Candidate.html>

- The US government said it was encouraging early production of Johnson & Johnson's vaccine.<sup>134</sup>
- South Africa's Health Products Regulatory Authority approved an implementation study of Johnson & Johnson's COVID-19 vaccine, allowing the first inoculations of frontline health workers.<sup>135</sup>

## Moderna

- The US is permitting Moderna to put 14 doses in each vile instead of ten.<sup>136</sup>
- Moderna has contracts for its vaccine in Japan and South Korea and is planning a factory in the region.<sup>137</sup>
- Moderna announced that *in vitro* neutralization studies of sera from people vaccinated with Moderna COVID-19 vaccine showed activity against UK and South African strains of SARS-CoV-2.<sup>138</sup> Moderna will test a three-shot regimen of its vaccine, after laboratory studies demonstrated the immune response stimulated by its shot is weaker against the South African variant. The third shot would be given six months to a year after the second. Moderna is also preparing a booster shot directed at the South African variant, which could constitute the second injection of a two-dose regimen.<sup>139</sup>

## Novavax

- Novavax said its COVID-19 vaccine demonstrated 89.3 per cent efficacy in a phase 3I UK trial. A phase 2Ib trial in South Africa did not match this.<sup>140</sup> Europe has begun a rolling review of the Novavax vaccine.<sup>141</sup>

## Pfizer/ BioNTech

- Pfizer/ BioNTech is testing whether a third (booster) vaccine dose can better fight new variants.<sup>142</sup>
- Pfizer has fully enrolled a paediatric vaccine trial with over 2,000 children.<sup>143</sup>

<sup>134</sup> <https://www.reuters.com/article/us-health-coronavirus-whitehouse/white-house-says-it-is-working-to-speed-early-production-of-jj-covid-19-vaccine-idUSKBN2A52DC>

<sup>135</sup> <https://www.medscape.com/viewarticle/945823>

<sup>136</sup> <https://www.nytimes.com/2021/02/12/us/politics/moderna-coronavirus-vaccine-supply.html>

<sup>137</sup> <https://www.fiercepharma.com/manufacturing/moderna-sets-sights-200m-vaccine-factory-seoul-report>

<sup>138</sup> <https://pipelinereview.com/index.php/2021012577244/Vaccines/Moderna-COVID-19-Vaccine-Retains-Neutralizing-Activity-Against-Emerging-Variants-First-Identified-in-the-U.K.-and-the-Republic-of-South-Africa.html> and [COVID-19 vaccines, and what the new coronavirus variants mean for them - ABC News](#)

<sup>139</sup> [Moderna to study vaccine booster aimed at coronavirus variant | BioPharma Dive](#)

<sup>140</sup> <https://pipelinereview.com/index.php/2021012977284/Vaccines/Novavax-COVID-19-Vaccine-Demonstrates-89.3-Efficacy-in-UK-Phase-3-Trial.html> and <https://www.medscape.com/viewarticle/944964> and <https://www.medscape.com/viewarticle/944999>

<sup>141</sup> [EMA starts rolling review of Novavax's COVID-19 vaccine \(NVX-CoV2373\) | European Medicines Agency \(europa.eu\)](#)

<sup>142</sup> [Pfizer and BioNTech Initiate a Study as Part of Broad Development Plan to Evaluate COVID-19 Booster and New Vaccine Variants | Pfizer](#) and <https://www.fiercepharma.com/pharma/three-shots-pfizer-and-biontech-rolls-third-dose-vaccine-trial-as-real-world-data-verifies>

<sup>143</sup> <https://www.healio.com/news/primary-care/20210128/pfizer-fully-enrolls-pediatric-covid19-vaccine-trial-with-more-than-2k-kids>

- Pfizer/ BioNTech asked the US FDA to relax the temperature requirements for their vaccine, as they believe it can remain stable at higher temperatures than first thought.<sup>144</sup> The US FDA is allowing Pfizer and BioNTech's COVID-19 vaccine to be stored and transported at standard pharmaceutical freezer temperatures for up to a fortnight, so long as the vials are undiluted and remain frozen. Previously, the vials needed to be stored and transported at between minus 112 degrees and minus 76 degrees Fahrenheit.<sup>145</sup>
- An Israeli healthcare provider declared the Pfizer vaccine 95 per cent effective.<sup>146</sup>
- Israeli scientists say the first shot of the Pfizer vaccine may lead to lower viral loads,<sup>147</sup> making it harder to transmit COVID-19 if the person becomes infected. Another study in Israel found that amongst 600,000 people who had received two doses of the vaccine, there was a very significant drop in symptomatic infections, and those who were infected were much less likely to suffer severe illness.<sup>148</sup>
- Pfizer/BioNTech say they could soon cut the production time for a batch of their vaccine from 110 days to 60 days.<sup>149</sup>
- New Zealand's Medsafe provisionally approved the use of the Pfizer COVID-19 vaccine.<sup>150</sup>
- A British study suggested that the Pfizer/BioNTech vaccine may be less able to protect against the South African variant than against those for which it was originally developed.<sup>151</sup>
- Novartis is assisting Pfizer/BioNTech with vaccine production.<sup>152</sup>
- Pfizer/ BioNTech released data from a laboratory study of their vaccine's response to the South African variant,<sup>153</sup> which the companies said had only a minor impact on its potency. However, laboratory studies are not perfect predictors of how vaccines will perform in people.
- Australia's Therapeutic Goods Administration found Pfizer coronavirus vaccine poses no 'specific' risk to elderly patients.<sup>154</sup>

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<sup>144</sup> <https://www.biopharmadive.com/news/pfizer-biontech-coronavirus-vaccine-normal-freezer-storage/595376/>

<sup>145</sup> [Coronavirus \(COVID-19\) Update: FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine | FDA](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer-biontech-covid-19-vaccine) and <https://www.fiercepharma.com/pharma/pfizer-s-covid-19-vaccine-rollout-could-heat-up-after-fda-clears-warmer-storage-requirements> and <https://www.medscape.com/viewarticle/946133>

<sup>146</sup> <https://www.medscape.com/viewarticle/945962>

<sup>147</sup> [Decreased SARS-CoV-2 viral load following vaccination \(medrxiv.org\)](https://www.medrxiv.org/content/10.1101/2020.07.27.20164339v1) and <https://www.the-scientist.com/news-opinion/pfizers-covid-19-vaccine-reduces-viral-load-study--68439>

<sup>148</sup> [Pfizer's COVID-19 vaccine may curb transmission, decrease symptomatic coronavirus cases, Israeli research shows - ABC News](https://www.abcnews.com/news/50120400/pfizer-covid-19-vaccine-may-curb-transmission-decrease-symptomatic-coronavirus-cases-israeli-research-shows)

<sup>149</sup> <https://www.fiercepharma.com/manufacturing/pfizer-to-nearly-halve-covid-19-vaccine-production-timeline-sterile-injectables-vp>

<sup>150</sup> [New Zealand provisionally approves use of Pfizer coronavirus vaccine - ABC News](https://www.abcnews.com/news/50120400/new-zealand-provisionally-approves-use-of-pfizer-coronavirus-vaccine)

<sup>151</sup> [POST-SUBMISSION vaccine-DCv2-2.pdf \(cam.ac.uk\)](https://www.cam.ac.uk/news/post-submission-vaccine-dc2-2) and <https://www.medscape.com/viewarticle/945099>

<sup>152</sup> <https://www.fiercepharma.com/pharma/novartis-signs-up-to-help-produce-pfizer-biontech-covid-19-vaccine>

<sup>153</sup> [Neutralization of SARS-CoV-2 spike 69/70 deletion, E484K, and N501Y variants by BNT162b2 vaccine-elicited sera | bioRxiv](https://www.biorxiv.org/content/10.1101/2020.08.11.291111v1)

<sup>154</sup> [TGA finds Pfizer coronavirus vaccine poses no 'specific' risk to elderly patients - ABC News](https://www.abcnews.com/news/50120400/tga-finds-pfizer-coronavirus-vaccine-poses-no-specific-risk-to-elderly-patients)

## Sinovac

- Sinovac announced phase 3 results for its vaccine, CoronaVac.<sup>155</sup>

## Sputnik V

- Russian vaccine Sputnik V is reported to have shown 91.6 per cent efficacy in a phase 3 trial.<sup>156</sup>

## At an earlier stage of development

- Altimune received US FDA clearance for a phase 1 clinical trial of its single-dose, intranasal COVID-19 vaccine candidate.<sup>157</sup>
- Sanofi and GlaxoSmithKline have begun a phase 2 clinical trial of a new version of their adjuvanted recombinant protein-based COVID-19 vaccine candidate.<sup>158</sup>
- Zydus Cadila has more orders for its plasmid DNA-based vaccine AyCoVD than it could produce; and expects to have increased commercial production capacity after April 2022, which fits its timeline. It has just received approval to begin phase 3 trials in India., if it receives regulatory approval, its competitors in India will include two products which already have emergency approval: Covishield under licence from AstraZeneca and Covaxin from Bharat Biotech.<sup>159</sup>
- Covaxx initiated phase 2 trials in Taiwan of its vaccine, UB-612.<sup>160</sup>
- Elicio Therapeutics announced that its vaccine demonstrates high T cell responses.<sup>161</sup>
- Vaxart announced encouraging preliminary data from its phase 1 trial of its oral tablet vaccine candidate.<sup>162</sup>

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<sup>155</sup> <https://pipelinereview.com/index.php/2021020677363/Vaccines/Sinovac-Announces-Phase-III-Results-of-Its-COVID-19-Vaccine.html>

<sup>156</sup> [Covid-19: Russian vaccine efficacy is 91.6%, show phase III trial results | The BMJ](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00191-4/fulltext) and <https://www.medscape.com/viewarticle/945141> and [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00191-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00191-4/fulltext)

<sup>157</sup> <https://pipelinereview.com/index.php/2021021777462/Vaccines/Altimune-Announces-FDA-Clearance-of-AdCOVID-IND-Application.html>

<sup>158</sup> [Sanofi and GSK initiate new Phase 2 study of their adjuvanted recombinant protein-based COVID-19 vaccine candidate Paris Stock Exchange:SAN \(globenewswire.com\)](https://www.fiercebiontech.com/biotech/after-setback-sanofi-gsk-take-tweaked-covid-19-vaccine-into-phase-2) and <https://www.fiercebiontech.com/biotech/after-setback-sanofi-gsk-take-tweaked-covid-19-vaccine-into-phase-2>

<sup>159</sup> <https://www.fiercepharma.com/manufacturing/india-s-cadila-hit-more-covid-19-vaccine-orders-than-it-can-fill>

<sup>160</sup> [COVAXX Announces Initiation of Phase 2 Clinical Trials in Taiwan of UB-612 Vaccine Candidate against COVID-19 | Vaccines | News Channels \(pipelinereview.com\)](https://pipelinereview.com/index.php/2021020377340/Vaccines/Vaxart-Announces-Positive-Preliminary-Data-from-Phase-1-Clinical-Trial-Evaluating-Its-Oral-COVID-19-Tablet-Vaccine-Candidate.html)

<sup>161</sup> [A lymph node-targeted Amphiphile vaccine induces potent cellular and humoral immunity to SARS-CoV-2 | Science Advances \(sciencemag.org\)](https://pipelinereview.com/index.php/2021020677364/Vaccines/Science-Advances-Elicio-Therapeutics-SARS-CoV-2-Vaccine-Demonstrates-T-Cell-Responses-25-Fold-Higher-Than-Benchmark-Vaccines.html) and <https://pipelinereview.com/index.php/2021020677364/Vaccines/Science-Advances-Elicio-Therapeutics-SARS-CoV-2-Vaccine-Demonstrates-T-Cell-Responses-25-Fold-Higher-Than-Benchmark-Vaccines.html>

<sup>162</sup> <https://pipelinereview.com/index.php/2021020377340/Vaccines/Vaxart-Announces-Positive-Preliminary-Data-from-Phase-1-Clinical-Trial-Evaluating-Its-Oral-COVID-19-Tablet-Vaccine-Candidate.html>

- Gritstone Oncology will test coronavirus shots in humans that it expects to stimulate a stronger response from virus-fighting T cells, offering broader protection against multiple types of coronaviruses.<sup>163</sup>
- Providence Therapeutics began dosing volunteers in clinical trials of PTX-COVID19-B. This is a messenger RNA vaccine made in Canada.<sup>164</sup>
- Two experimental vaccines developed with gene-therapy technology drew strong immune responses in mouse and nonhuman primate models.<sup>165</sup> The research team was awarded a grant from the Bill & Melinda Gates Foundation to further develop the technology, called AAVCOVID. The vaccines remain stable at room temperature. They use an adeno-associated virus vector to deliver genetic sequences of SARS-CoV-2 that generate antigens against the virus's signature spike protein, prompting an immune response. A single injection of either of the AAVCOVID vaccines induced neutralizing antibodies in one mouse model of obesity and another of aging—two conditions that have been linked with poor COVID-19 outcomes. The response lasted for at least three months, while in the monkey models, the immune response lasted for five months.<sup>166</sup>
- In Taiwan, the first participant was dosed in a phase 2 clinical trial of Medigen Vaccine Biologics COVID-19 Vaccine Adjuvanted with Dynavax's CpG 1018.<sup>167</sup>

## 8. Managing the pandemic

### Individual country experience

- Australia's Chief Medical Officer says the South African and UK strains are becoming dominant here.<sup>168</sup>
- Nancy Baxter, who is the head of the School of Population and Global Health at the University of Melbourne, said: "It does make me feel very nervous about continuing the [hotel quarantine] program at the current levels before these workers are vaccinated."<sup>169</sup>
- In the US, CDC Director Rochelle Walensky on 1 February urged states against lifting coronavirus restrictions. She acknowledged lower case counts overall,<sup>170</sup> but said contagious variants were on the rise.<sup>171</sup> On 25 February, the data update from

<sup>163</sup> [Cancer-focused biotech turns its tools to building a 2nd-generation coronavirus vaccine | BioPharma Dive](#)

<sup>164</sup> <https://pipelinereview.com/index.php/2021012677255/Vaccines/Providence-Therapeutics-announces-first-subject-has-been-dosed-in-COVID-19-vaccine-trial.html>

<sup>165</sup> [Immunogenicity of an AAV-based, room-temperature stable, single dose COVID-19 vaccine in mice and non-human primates | bioRxiv](#)

<sup>166</sup> <https://www.fiercebiotech.com/research/one-dose-covid-vaccine-candidate-can-be-stored-at-room-temperature-prompts-immunity>

<sup>167</sup> <https://pipelinereview.com/index.php/2021012677250/Vaccines/Medigen-Vaccine-Biologics-COVID-19-Vaccine-Adjuvanted-with-Dynavax-CpG-1018-Announces-First-Participant-Dosed-in-Phase-2-Clinical-Trial-in-Taiwan.html>

<sup>168</sup> [Chief Medical Officer Paul Kelly says the South African and UK coronavirus strains are becoming dominant. What does this mean for Australia? - ABC News](#)

<sup>169</sup> [Coronavirus infections in hotel quarantine workers makes it 'wrong time' to increase international arrivals, epidemiologist warns - ABC News](#)

<sup>170</sup> <https://www.reuters.com/article/us-health-coronavirus-usa-trends/u-s-covid-19-cases-and-hospitalizations-log-biggest-weekly-drops-since-pandemic-started-idUSKBN2A8286> and <https://edition.cnn.com/2021/02/07/health/us-coronavirus-sunday/index.html>

<sup>171</sup> <https://thehill.com/homenews/state-watch/537824-cdc-warns-states-against-lifting-restrictions-amid-threat-of-virus> and

Johns Hopkins University showed a continuing decrease in new cases daily, but the death toll of 3,200 the previous day was the highest since 10 February.<sup>172</sup>

- In the US the CDC said that by 10 February 65.9 million vaccine doses had been distributed and 44.7 million had been administered.<sup>173</sup> The CDC said fully vaccinated people do not have to quarantine after COVID exposure.<sup>174</sup>
- The CDC said on 1 February that of the 13 million people vaccinated in the US between 14 December and 14 January, 5 per cent had been black (proportion in the population 13 per cent); 12 per cent had been Hispanic (proportion in the population 19 per cent). The CDC said black and Hispanic people have been twice as likely to be infected with COVID-19 as white people, and four times as likely to require hospital care.<sup>175</sup>
- The US Food and Drug Administration's Acting Commissioner said the FDA has been "actively working with medical product sponsors and international partners to evaluate the impact new COVID-19 variants have on authorised medical products".<sup>176</sup>
- The US Department of Defense awarded a \$A 302 million contract to Queensland firm Ellume to increase production of its COVID-19 home test kits. The contract includes building a facility in Maryland.<sup>177</sup>
- A report suggests that the US has had three times as many COVID-19 cases as have been counted.<sup>178</sup>
- The CDC found that teachers can be infected with COVID-19 at school, and they can transmit it.<sup>179</sup>
- On 18 February a joint statement was issued by the US FDA, the US Department of Agriculture and the CDC . which emphasised that "there is no credible evidence of food or food packaging associated with, or as a likely source of, viral transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus causing COVID-19"<sup>180</sup>.
- In the US, researchers found differences between neighbourhoods in preterm birth outcomes indicated differences in regional severity of COVID-19. According to researchers, fundamental to both is community healthcare access. COVID-19 severity by postcode was also positively correlated with the proportion of residents

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<https://edition.cnn.com/2021/02/04/health/us-coronavirus-thursday/index.html> and

<https://thehill.com/policy/healthcare/537741-uk-strain-doubling-every-10-days-in-us-study>

<sup>172</sup> [https://www.upi.com/Top\\_News/US/2021/02/25/covid-cases-deaths-united-states/4181614252681/](https://www.upi.com/Top_News/US/2021/02/25/covid-cases-deaths-united-states/4181614252681/) and <https://www.reuters.com/article/us-health-coronavirus-usa-trends/new-covid-19-cases-in-u-s-fall-for-fifth-week-in-a-row-idUSKBN2AG2FX>

<sup>173</sup> [65.9 million doses of COVID-19 vaccines delivered, 44.7 million administered: U.S. CDC | Reuters](https://www.reuters.com/article/us-health-coronavirus-usa-trends/new-covid-19-cases-in-u-s-fall-for-fifth-week-in-a-row-idUSKBN2AG2FX)

<sup>174</sup> <https://www.healio.com/news/infectious-disease/20210210/cdc-fully-vaccinated-people-do-not-have-to-quarantine-after-covid19-exposure>

<sup>175</sup> [https://www.upi.com/Health\\_News/2021/02/01/CDC-Black-people-make-up-just-5-of-those-vaccinated-against-COVID-19/7121612203443/](https://www.upi.com/Health_News/2021/02/01/CDC-Black-people-make-up-just-5-of-those-vaccinated-against-COVID-19/7121612203443/)

<sup>176</sup> [Woodcock: FDA plans guidance to address new COVID-19 variants | RAPS](https://www.fda.gov/news-events/press-announcements/woodcock-fda-plans-guidance-address-new-covid-19-variants)

<sup>177</sup> [US grants \\$302 million contract to Brisbane bio-tech firm Ellume to produce at-home COVID tests - ABC News](https://www.abcnews.com/news/2021-02-18/us-grants-302-million-contract-to-brisbane-bio-tech-firm-ellume-to-produce-at-home-covid-19-tests-831788743) and <https://www.labonline.com.au/content/research-development/news/aus-biotech-company-supplies-at-home-covid-19-tests-to-us-831788743> and [What are at-home COVID-19 tests and why are they in such high demand overseas? - ABC News](https://www.abcnews.com/news/2021-02-18/what-are-at-home-covid-19-tests-and-why-are-they-in-such-high-demand-overseas-831788743) and

<https://www.fiercebiotech.com/medtech/ellume-nets-232m-government-contract-to-produce-covid-19-home-tests-u-s>

<sup>178</sup> <https://www.medscape.com/viewarticle/945596>

<sup>179</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91304> and [Clusters of SARS-CoV-2 Infection Among Elementary School Educators and Students in One School District — Georgia, December 2020–January 2021 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/6001a1.htm)

<sup>180</sup> <https://www.foodbusinessnews.net/articles/18033-us-affirms-no-transmission-of-covid-19-through-food-or-packaging> and <https://www.medscape.com/viewarticle/946116>

below the poverty line, but inversely correlated with median household income and educational achievement.<sup>181</sup>

- The US CDC made the wearing of masks on public transport mandatory.<sup>182</sup>
- A US study found that SARS-CoV-2 transmission is being sustained primarily by people in the 20-49 age group.<sup>183</sup>
- Dr Anthony Fauci, Director of the US National Institute of Allergy and Infectious Diseases, urged Americans to be vaccinated as quickly as possible to prevent more mutations from emerging,<sup>184</sup> as “viruses cannot mutate if they don’t replicate”.
- Israel reported that new infections were falling significantly following vaccination with the Pfizer/BioNTech vaccine.<sup>185</sup>
- Statistics from Israel and Italy indicate that more young children are being infected by new variants.<sup>186</sup>
- The Netherlands is introducing rapid COVID-19 breath tests.<sup>187</sup>
- Chinese researchers report that a growing proportion of COVID-19 infections are asymptomatic.<sup>188</sup>
- South Korea’s Seegene Inc says it has produced the world’s first COVID-19 diagnostic test that can identify multiple mutant variants of the virus in a single reaction.<sup>189</sup>
- A UK study found high levels of antibodies in people who had received two doses of the Pfizer vaccine, regardless of age.<sup>190</sup>
- A UK study found that 87.8 per cent of people who tested positive for SARS-CoV-2 remained seropositive for at least six months.<sup>191</sup>
- UK researchers report that “social distancing measures alone do not provide adequate protection from the virus (SARS-CoV-2)”, and they stress “the vital importance of ventilation and face masks in order to slow the spread of COVID-19.”<sup>192</sup>
- A study funded by the UK National Institute for Health Research (and not yet peer-reviewed) found that the risk of SARS-CoV-2 aerosolisation could be high in areas of hospitals outside ICU – such as emergency departments and general wards where people were coughing. Although face masks were generally used, personal protective equipment might be more appropriate.<sup>193</sup>
- Tanzania has refused COVID-19 vaccines.<sup>194</sup>

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<sup>181</sup> <https://www.medpagetoday.com/meetingcoverage/smf/90990>

<sup>182</sup> <https://www.healio.com/news/infectious-disease/20210201/cdc-mandates-masks-on-public-transit-extends-eviction-moratorium-to-slow-covid19>

<sup>183</sup> <https://science.sciencemag.org/content/early/2021/02/01/science.abe8372.full> and [https://www.upi.com/Health\\_News/2021/02/02/Younger-adults-fuel-COVID-19-spread-in-US-study-finds/9491612284129/](https://www.upi.com/Health_News/2021/02/02/Younger-adults-fuel-COVID-19-spread-in-US-study-finds/9491612284129/)

<sup>184</sup> <https://edition.cnn.com/2021/02/01/health/us-coronavirus-monday/index.html>

<sup>185</sup> <https://www.bmj.com/content/372/bmj.n338>

<sup>186</sup> [Covid-19: More young children are being infected in Israel and Italy, emerging data suggest | The BMJ](#)

<sup>187</sup> <https://www.medscape.com/viewarticle/945178>

<sup>188</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/91004>

<sup>189</sup> <https://www.reuters.com/article/us-health-coronavirus-southkorea-seegene/s-koreas-seegene-develops-first-covid-19-test-kit-that-can-detect-multiple-variants-idUSKBN2A11HK>

<sup>190</sup> <https://www.medscape.com/viewarticle/946450>

<sup>191</sup> <https://www.medscape.com/viewarticle/945169>

<sup>192</sup> <https://www.labonline.com.au/content/lab-design-fit-out-services/news/the-role-of-ventilation-in-covid-19-transmission-948281677>

<sup>193</sup> [Covid-19: Risk of aerosol transmission to staff outside of intensive care is likely to be higher than predicted | The BMJ](#)

<sup>194</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00362-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00362-7/fulltext)

- In Australia, COVID-19 vaccination details for individuals will be recorded on the Australian Immunisation Register.<sup>195</sup>
- New figures from Russia suggest it might have had the third highest death toll in 2020, after the US and Brazil.<sup>196</sup>
- A report on 27 February on vaccine acceptance in Europe said Germany had by then administered only 187,000 of the 1.5 million doses of the AstraZeneca vaccine in its possession.<sup>197</sup>

## Transmission

- Scientists have suggested COVID-19 will become endemic, with its potency decreasing over time.<sup>198</sup>
- Some experts say it will take six years before enough of the world's population are vaccinated to reduce the threat from COVID-19.<sup>199</sup>
- A study suggested that "respiratory droplets evaporate faster on porous surfaces than on impermeable surfaces, a contributing factor behind why SARS-CoV-2 does not live long on surfaces like cloth and paper".<sup>200</sup>
- WHO investigators have ended research into whether COVID-19 leaked from a Wuhan lab.<sup>201</sup> The Australian member of the WHO team sent to investigate the origins of the pandemic reported "a lot of pressure" in their meetings with their hosts. He reported that the "preliminary findings had failed to conclude anything clear about how the pandemic started"<sup>202</sup>.
- Experts advised that when a person positive for COVID-19 uses a nebuliser he or she would be "releasing up to 10,000 times more aerosol particles than if they were breathing normally"<sup>203</sup>.
- Monash University researchers found that people who have had COVID-19 have an immune memory that lasts at least eight months.<sup>204</sup>
- Natascha Tuznik, an infectious disease specialist at the University of California Davis, said of a study of Sars-CoV-2 transmission on a long-haul flight, that it "reinforces that if you're going to be taking a long flight, you have to consider that your chance of being exposed is going to go up".<sup>205</sup>

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<sup>195</sup> [The COVID vaccine is here. Who will be able to see if you've had it? - ABC News](#)

<sup>196</sup> <https://www.medscape.com/viewarticle/945481>

<sup>197</sup> <https://www.dailymail.co.uk/news/article-9305945/Germany-losing-vaccine-war-EU-pay-price-says-GUY-ADAMS.html>

<sup>198</sup> [Covid-19 will become endemic but with decreased potency over time, scientists believe | The BMJ](#)

<sup>199</sup> [Coronavirus: Worldwide COVID-19 vaccinations will take six years, experts say \(theage.com.au\)](#)

<sup>200</sup> <https://www.healio.com/news/primary-care/20210209/researchers-identify-reason-behind-shorter-coronavirus-life-on-porous-surfaces>

<sup>201</sup> [WHO to end research into unlikely theory COVID started in Wuhan lab \(usatoday.com\)](#)

<sup>202</sup> [Australian WHO investigator sent to probe origins of coronavirus says there were 'tense moments' with China - ABC News and Coronavirus Australia news: WHO COVID-19 investigation team identifies animal transmission as starting point for further investigation - ABC News and China refused to provide WHO with raw data on COVID cases, says Australian investigator - ABC News and Coronavirus's origins may remain a mystery as the WHO leaves China with more questions than answers - ABC News](#)

<sup>203</sup> [How a nebuliser can give coronavirus millions more droplets to 'hitch a ride on' - ABC News](#)

<sup>204</sup> <https://www.studyfinds.org/covid-immunity-lasts-8-months>

<sup>205</sup> <https://www.medscape.com/viewarticle/945437>

## Other

- The WHO has warned against “vaccine nationalism”, which it said would risk further mutations in the SARS-CoV-2 virus.<sup>206</sup>
- Europol warned of potential illicit trade in false negative COVID-19 test certificates.<sup>207</sup>
- Researchers say they have developed a rapid and accurate test to detect coronavirus antibodies.<sup>208</sup>
- People infected with the UK variant are reported as more likely to suffer from sore throat, exhaustion and muscle aches than those with the original strain.<sup>209</sup>

## 9. Miscellaneous news

### Diseases other than COVID-19

- Dynavax received European Commission marketing authorisation for its two-dose adjuvanted hepatitis B vaccine.<sup>210</sup>
- During the wet summer just ended, Ross River virus in Australia has surged. While insect spraying has increased, one of the sprayers said "It is really bringing a knife to a gunfight"<sup>211</sup>. The Southern New South Wales Local Health District has been warning of Ross River Fever and Barmah Forest Virus outbreaks.<sup>212</sup> Victoria has also had cases<sup>213</sup>.
- A randomized, placebo-controlled phase 1 clinical trial of two monoclonal antibodies directed against the coronavirus that causes Middle East respiratory syndrome found them to be well tolerated and generally safe when administered simultaneously to healthy adults. REGN3048 and REGN3051 target the MERS CoV spike protein used by the virus to attach to and infect target cells.<sup>214</sup>
- A Zika vaccine is reported to have demonstrated promise in early trials.<sup>215</sup>
- Scientists using CRISPR gene-editing technology developed mosquitoes which cannot replicate the Zika virus.<sup>216</sup>

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<sup>206</sup> [Covid-19: WHO warns against “vaccine nationalism” or face further virus mutations | The BMJ](#)

<sup>207</sup> <https://www.europol.europa.eu/newsroom/news/europol-warning-illicit-sale-of-false-negative-covid-19-test-certificates>

<sup>208</sup> <https://innovationorigins.com/results-in-twelve-minutes-new-rapid-test-to-detect-coronavirus-antibodies/>

<sup>209</sup> [Covid-19: Sore throat, fatigue, and myalgia are more common with new UK variant | The BMJ](#)

<sup>210</sup> <https://pipelinereview.com/index.php/2021022077475/Vaccines/Dynavax-Announces-European-Commission-Marketing-Authorization-for-HEPLISAV-B-a-2-Dose-Adult-Hepatitis-B-Adjuvanted-Vaccine.html>

<sup>211</sup> [Ross River virus cases are surging in La Niña conditions and mosquito control needs a silver bullet - ABC News](#)

<sup>212</sup> <https://the-riotact.com/suspected-outbreak-of-ross-river-fever-and-barmah-forest-virus-in-southern-nsw/439983> and [Ross River virus infections reach record levels in NSW - ABC News](#)

<sup>213</sup> <https://www.gippslandtimes.com.au/story/7117228/at-least-10-ross-river-virus-cases-this-year-so-far/> and <https://www.news.com.au/lifestyle/health/health-problems/health-officials-issue-alert-following-outbreak-of-ross-river-virus-cases-in-victoria>

<sup>214</sup> <https://www.nih.gov/news-events/news-releases/monoclonal-antibodies-against-mers-coronavirus-show-promise-phase-1-nih-sponsored-trial>

<sup>215</sup> [https://www.upi.com/Health\\_News/2021/02/15/Zika-vaccine-shows-promise-in-early-trials/4561613418623/](https://www.upi.com/Health_News/2021/02/15/Zika-vaccine-shows-promise-in-early-trials/4561613418623/) and [A Double-Blind, Randomized, Placebo-Controlled Phase 1 Study of Ad26.ZIKV.001, an Ad26-Vectored Anti-Zika Virus Vaccine | Annals of Internal Medicine \(acpjournals.org\)](#)

<sup>216</sup> <https://www.labonline.com.au/content/life-scientist/news/mosquitoes-genetically-modified-to-be-resistant-to-zika-908186178>

- The WHO asked six African countries to be alert for possible Ebola infections, as Guinea and the Democratic Republic of Congo reported new cases.<sup>217</sup> The US FDA approved Ridgeback Biotherapeutics' Ebanga for the treatment of Ebola.<sup>218</sup>
- Scientists have warned that the next pandemic could be a brain-swelling disease much more deadly than COVID-19.<sup>219</sup>
- African swine fever has mutated, one suggestion being that this could have happened through the use of an illegal vaccine.<sup>220</sup>
- Zydus Cadila announced that its antimalarial compound ZY19489 (MMV253) in development with Swiss-based product development partnership Medicines for Malaria Venture (MMV) had completed a phase 1 clinical evaluation.<sup>221</sup>
- A bat on the Gold Coast has been found to be infected with bat lyssavirus.<sup>222</sup>
- Anthrax has been confirmed in New South Wales and producers urged to vaccinate livestock.<sup>223</sup>
- Merck, Novartis and the Bill and Melinda Gates Foundation have contributed \$US 300 million into a new fund launched by investment firm Adjuvant Capital to focus on public health challenges that are "historically overlooked"<sup>224</sup>.
- GlaxoSmithKline is expanding its collaboration with Vir Biotechnology from research on coronavirus therapies to treatments for influenza and other respiratory viruses.<sup>225</sup>
- An intranasal flu vaccine elicited a strong immune response in a phase 1 trial<sup>226</sup>.
- Takeda has reported on a successful phase 3 trial of maribavir in transplant recipients with refractory cytomegalovirus infection.<sup>227</sup>
- Gilead Sciences and Gritstone are collaborating on an HIV cure.<sup>228</sup>
- IAVI and Scripps Research announced that a phase 1 trial of a novel vaccine approach to prevent HIV had produced promising results.<sup>229</sup>
- Brisbane hospitals will trial a new "wet-etching" metal treatment on surfaces which is set to reduce hospital infection rates.<sup>230</sup>

<sup>217</sup> <https://www.medscape.com/viewarticle/945866> and [Guinea declares new Ebola outbreak after death of three people - ABC News](https://www.abc.net.au/news/2020-09-04/guinea-declares-new-ebola-outbreak-after-death-of-three-people) and [https://www.reuters.com/article/health-ebola-congo-who/ebola- and vaccination-campaign-begins-in-democratic-republic-of-congo-idUSL8N2KL36C](https://www.reuters.com/article/health-ebola-congo-who/ebola-and-vaccination-campaign-begins-in-democratic-republic-of-congo-idUSL8N2KL36C) and [Congo working to stop new Ebola outbreak in country's east amid COVID-19 resurgence - ABC News](https://www.abc.net.au/news/2020-09-04/congo-working-to-stop-new-ebola-outbreak-in-country-s-east-amid-covid-19-resurgence)

<sup>218</sup> <http://outbreaknewstoday.com/fda-approves-ebanga-for-the-treatment-of-ebola-56371/>

<sup>219</sup> [Nipah virus 75 times more deadly than Covid may be next pandemic \(news.com.au\)](https://www.news.com.au/health/2020-09-04/nipah-virus-75-times-more-deadly-than-covid-may-be-next-pandemic)

<sup>220</sup> [African swine fever mutates, heightened biosecurity measures set to be put in place - ABC News](https://www.abc.net.au/news/2020-09-04/african-swine-fever-mutates-heightened-biosecurity-measures-set-to-be-put-in-place)

<sup>221</sup> [ACTRN12619000127101](https://www.actrn.gov.au/actrn/view/ACTRN12619000127101) and [ACTRN12619001215112](https://www.actrn.gov.au/actrn/view/ACTRN12619001215112) and

<https://pipelinereview.com/index.php/2021020477345/Small-Molecules/Zydus-announces-completion-of-Phase-I-trials-of-ZY19489%E2%80%94A-single-dose-cure-for-Malaria-in-collaboration-with-MMV.html>

<sup>222</sup> [https://www.mycg.com.au/locals-warned-after-infectious-bat-picked-up-on-the-gold-coast/>](https://www.mycg.com.au/locals-warned-after-infectious-bat-picked-up-on-the-gold-coast/)

<sup>223</sup> <https://www.beefcentral.com/production/anthrax-outbreak-spurs-nsw-vaccination-warning/>

<sup>224</sup> [Adjuvant Capital Announces \\$300 Million Venture Fund Designed to Improve Global Public Health \(prnewswire.com\)](https://www.prnewswire.com/news-releases/adjuvant-capital-announces-300-million-venture-fund-designed-to-improve-global-public-health) and <https://www.biopharmadive.com/news/adjuvant-capital-merck-novartis-overlooked-diseases/595301>

<sup>225</sup> <https://www.biopharmadive.com/news/gsk-vir-expand-deal-influenza-respiratory-viruses/595208/>

<sup>226</sup> <https://www.nih.gov/news-events/news-releases/intranasal-influenza-vaccine-spurs-strong-immune-response-phase-1-study> and [JCI - A replication competent adenovirus-vectored influenza vaccine induces durable systemic and mucosal immunity](https://www.jci.org/articles/view/125000)

<sup>227</sup> <https://www.fiercebitech.com/biotech/takeda-s-maribavir-clears-cytomegalovirus-infections-phase-3>

<sup>228</sup> [Gilead Sciences and Gritstone Announce Collaboration Utilizing Gritstone's Vaccine Platform Technology for HIV Cure | More News | News Channels \(pipelinereview.com\)](https://www.pipelinereview.com/news/gilead-sciences-and-gritstone-announce-collaboration-utilizing-gritstone-s-vaccine-platform-technology-for-hiv-cure)

<sup>229</sup> <https://pipelinereview.com/index.php/2021020577359/Vaccines/First-in-human-clinical-trial-confirms-novel-HIV-vaccine-approach-developed-by-IAVI-and-Scripps-Research.html>

<sup>230</sup> [Virus-neutralising, roughened metal surfaces to be trialled on Brisbane hospital equipment - ABC News](https://www.abc.net.au/news/2020-09-04/virus-neutralising-roughened-metal-surfaces-to-be-trialled-on-brisbane-hospital-equipment)

## Other

- Seventh Sense Biosystems has gained Conformité Européenne (CE) mark certification for its push-button blood collector.<sup>231</sup> Patients place the device on their upper arm and push a button to start blood collection which takes two to three minutes.
- Figures recently published show that globally from January to May 2020 there was a 60 per cent reduction in new oncology trials.<sup>232</sup>
- A commercial report says that the emergence of variant strains of SARS-CoV-2 with the potential to reduce the efficacy of vaccination have slowed the resumption of clinical trials not related to the pandemic.<sup>233</sup>

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<sup>231</sup> <https://www.fdanews.com/articles/201307-seventh-sense-biosystems-gets-ce-mark-for-push-button-blood-collector>

<sup>232</sup> <https://www.fiercebiotech.com/cro/cancer-trials-a-major-victim-pandemic-as-global-studies-dropped-by-60-jama-study>

<sup>233</sup> <https://www.fiercebiotech.com/cro/new-covid-mutations-putting-a-strain-trial-resumptions-report>