**International Trends for the Blood Sector**

**April – June 2023**

The NBA monitors international developments that may influence the management of blood and blood products in Australia including but not limited to:

* potential new product developments and applications
* global regulatory and blood practice trends
* events that may have an impact on global supply, demand and pricing
* emerging risks and relevant issues.

The following highlights have appeared in news media, online publications, industry, and research updates:

**Blood supply:** Changes to blood donation rules in Australia and the United States have the potential to increase the overall pool of donors. In Australia people who have had tattoos can now donate a week after getting the tattoo. In the US, the FDA has updated its policies relating to sexual activity of donors. The FDA has removed the deferral for men who have sex with men and will now ask all potential donors about the recent sexual history to determine qualifications for donation.

**Product Development and Applications:** The US FDA has approved the first gene therapy to treat the genetic bleeding disorder haemophilia A. The treatment, Roctavian is a one-time infusion Adeno-associated Virus that delivers a working copy of the gene that makes the blood-clotting protein absent in haemophilia A patients.

**Product Development and Applications:** The Australasian Society of Clinical Immunology and Allergy (ASCIA) IVIg Infusion Guidelines were updated in April to provide details about new treatments and replacement therapies.

**Blood diseases and treatments:** A breakthrough treatment for removing blood clots in pulmonary embolism has been successfully trialled in New Zealand. The new treatment was used for the first time to successfully help a patient in Auckland City Hospital, after she went into cardiac arrest and was diagnosed with a pulmonary embolism.

**COVID-19**: In May, the WHO Emergency Committee met for the 15th time and recommended that the Director-General (DG) declare an end to the public health emergency of international concern. On the Emergency Committee’s advice, the DG has decided to use a provision in the International Health Regulations to establish a Review Committee to develop long-term, standing recommendations for countries on how to manage COVID-19 on an ongoing basis.

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# Blood supply and demand

## Blood supply Australia

[Tatts no longer a barrier to blood donation under new rule change](https://www.lifeblood.com.au/news-and-stories/media-centre/media-releases/tatts-no-longer-barrier-blood-donation-under-new-rule-change)

Australians with tattoos can now donate blood a week after getting their tattoo. The policy change which came into effect in June, applies only to people who received tattoos in licensed Australian tattoo parlors or cosmetic clinics. People who received tattoos in unlicensed or overseas premises will still need to wait four months before they can donate.

[Don’t rule yourself out: 40% unsure they can donate blood or plasma](https://www.lifeblood.com.au/news-and-stories/media-centre/media-releases/dont-rule-yourself-out-40-percent-unsure-they-can-donate-blood-or-plasma)

Australians are ruling themselves out of blood and plasma donation when they may be eligible. A Lifeblood survey has found people don’t donate for a variety of reasons, however, with only 3.7 per cent of Australians maintaining the blood and plasma supply for a population of 26 million, Lifeblood has urged people to learn more about their eligibility so they can donate.

[When will Australia lift its 'gay blood ban'?](https://www.sbs.com.au/news/article/the-us-has-become-the-latest-nation-to-remove-its-gay-blood-ban-will-australia-follow/cpcpgutsa)

The ‘Let Us Give’ campaign are advocating for the removal of deferral periods for men who have sex with men, after US changed to a risk-based strategy for all potential donors. Lifeblood has made a [submission to the Therapeutic Goods Administration (TGA) to remove sexual activity rules](https://www.lifeblood.com.au/blood/eligibility/sexual-activity) from plasma donations, which has been approved. Blood supply United States

[FDA relaxes blood donation guidelines for men who have sex with men](https://www.pbs.org/newshour/health/fda-relaxes-blood-donation-guidelines-for-men-who-have-sex-with-men)

Gay and bisexual men in monogamous relationships can donate blood in the US without abstaining from sex, under a federal policy finalised in May by the FDA. The policy change means that all potential donors will be screened with a new questionnaire that evaluates their individual risks for HIV based on sexual behavior, recent partners and other factors.

[Take action: Type O negative blood donors needed for emergencies](https://www.reflector.com/enterprise/features/local/take-action-type-o-negative-blood-donors-needed-for-emergencies/article_cb14a0bf-afd7-5cf7-9454-de5856c0a99b.html)

The American Red Cross requested donations of blood or platelets during Trauma Awareness Month in May to ensure hospitals are prepared for all transfusion needs.

[AABB: Tell Congress to support strengthening the resilience of the blood supply](https://aabb.quorum.us/campaign/PAHPAreauth/)

The Association for the Advancement of Blood and Biotherapies (AABB) is advocating for policymakers to prioritise blood supply in preparedness and response policies. Over the past few years, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has made [recommendations](https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/recommendations/2020-09-25/index.html), and the Department of Health and Human Services issued a [report to the US Congress](https://www.hhs.gov/sites/default/files/hhs-adequacy-national-blood-supply-report-congress-2020.pdf) highlighting opportunities to improve the resilience of the blood supply.

## Blood supply world news

[Canadian Blood Services launches campaign looking for plasma, blood donations](https://lethbridgenewsnow.com/2023/05/18/canadian-blood-services-launches-campaign-looking-for-plasma-blood-donations/)

Canadian Blood Services (CBS) has launched its ‘Shine a Light campaign’, aimed at reaching Canadian audiences who have not previously donated blood or plasma. The campaign comes after Canadian Blood Services reported donor participation rates dropped from around four per cent of the eligible population to under two per cent.

# Product development and applications

## Red blood cells

[Better cryoprotection for red blood cells](https://www.nanowerk.com/nanotechnology-news2/newsid%3D62903.php)

This paper, published by a team of researchers in the German Chemical Society journal [*Angewandte Chemie*](https://onlinelibrary.wiley.com/doi/10.1002/anie.202217374)  presents a new option to increase red blood cell (RBC) cryopreservation efficiency.

## Immunoglobulin

[Updated ASCIA IVIg Infusion Guidelines - Australasian Society of Clinical Immunology and Allergy](https://www.allergy.org.au/about-ascia/info-updates/updated-ascia-ivig-infusion-guidelines)

The Australasian Society of Clinical Immunology and Allergy (ASCIA) IVIg Infusion Guidelines were updated in April to provide details about new treatments and replacement therapies.

[Takeda, Canadian Blood Services ink pact for immunodeficiency disease drugs](https://seekingalpha.com/news/3958151-takeda-canadian-blood-services-ink-pact-immunodeficiency-disease-drugs)

Takeda Canada announced the signing of a three-year agreement with Canadian Blood Services (CBS) for immunoglobulin therapies to treat primary and secondary immunodeficiency diseases.

[The therapeutic window of intravenous immunoglobulin (IVIg) and its correlation with clinical outcomes in Kawasaki Disease: a systematic review and meta-analysis](https://ijponline.biomedcentral.com/articles/10.1186/s13052-023-01451-6)

This study has found that intravenous immunoglobulin IVIg treatment within 7 days of Kawaski Disease (KD) illness appears to reduce the risk of coronary artery lesions and cardiac sequelae in KD patients. The study also found that early IVIg treatment within 4 days could result in IVIg resistance, but the authors noted that further trials were required to support this finding.

[Adverse reactions associated with intravenous immunoglobulin in the treatment of neurological disease: A systematic review](https://www.karger.com/Article/FullText/529110)

This review found that IVIg in the treatment of neurological disease were associated with adverse reactions in 25-34% cases. However, researchers found that the general safety profile of IVIg is favourable when compared to the adverse reaction rates of the alternative treatment options for neuroimmunological disease.

## Platelets

[Association between platelet transfusion and delirium in critically ill children](https://www.mdpi.com/2227-9067/10/5/825)

This single centre study demonstrated a significant positive association between platelet transfusion and development of next day delirium or coma in critically ill children. The authors suggest minimising platelet transfusions as much as clinically feasible may decrease delirium risk in critically ill children.

## Gene therapies

[Vertex, CRISPR Therapeutics submit BLAs to FDA for exa-cel](https://www.pharmaceutical-technology.com/news/vertex-crispr-therapeutics-exa-cel/)

Vertex Pharmaceuticals and CRISPR Therapeutics completed a rolling submission of Biologics License Application (BLA) to the US FDA for exagamglogene autotemcel (exa-cel) to treat sickle cell disease and transfusion-dependent beta thalassemia (TDT).

[Positive early results seen for CAR T-cell therapy for myeloma](https://myelomaresearchnews.com/news/positive-early-results-seen-car-t-cell-therapy-myeloma-trial/)

A clinical trial in Israel of NXC-201 (Nexcella) has yielded a positive response from most patients with hard-to-treat multiple myeloma out of a cohort of 50 people. Nexcella plan to file an investigational drug application with the US FDA requesting expansion of clinical testing to the US, as well as submit a biologics license application (BLA).

[Kite’s CAR-T therapies recommended by NICE for certain blood cancers](https://www.pmlive.com/pharma_news/kites_car-t_therapies_recommended_by_nice_for_certain_blood_cancers_1491159)

Kite's Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel) have been recommended as treatment options for aggressive blood cancers by the UK’s National Institute for Health and Care Excellence (NICE). Yescarta is recommended for use in patients with diffuse large B‑cell lymphoma (DLBCL) that returns within a year or, is resistant to first line chemoimmunotherapy. Tecartus (brexucabtagene autoleucel) as an additional treatment for patients aged 26 years and older with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

[BioMarin’s haemophilia A gene therapy Roctavian wins FDA approval after delay and rejection](https://endpts.com/biomarins-hemophilia-a-gene-therapy-roctavian-wins-fda-approval-after-delay-and-rejection/)

The US FDA approved the first gene therapy to treat the genetic bleeding disorder haemophilia A in June. Roctavian is a one-time infusion that uses an engineered virus to deliver a working copy of the gene that makes the blood-clotting protein absent in haemophilia A patients.

[FDA grants RMAT designation to Intellia's NTLA-2002 – the third of such designations.](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fhaei.org%2Ffda-grants-rmat-designation-to-intellias-ntla-2002%2F&data=05%7C01%7Chorizon.scanning%40blood.gov.au%7C7610bcd00c67490ff32208db356b5655%7C9c23305707384b4091b23798ceb38ebf%7C0%7C0%7C638162507359826170%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=DTJYj6jt4gvPbn4bgqNiuwNcm1QASLOznc%2FSi6vT3vM%3D&reserved=0)

In-vivo CRISPR-based investigational therapy, Kallikrein B1 (KLKB1) has been given Regenerative Medicine Advanced Therapy Designation (RMAT) designation to expedite the development and review of the treatment. KLKB1 is a treatment designed to prevent life-threatening swelling attacks in people with Hereditary Angioedema.

[Bluebird bio submits Biologics License Application (BLA) for sickle cell disease gene therapy](https://pipelinereview.com/index.php/2023042583119/DNA-RNA-and-Cells/bluebird-bio-Submits-Biologics-License-Application-BLA-to-FDA-for-lovotibeglogene-autotemcel-lovo-cel-for-Patients-with-Sickle-Cell-Disease-SCD-12-years-and-Older-with.html)

Bluebird bio has submitted a Biologics License Agreement (BLA) to the FDA for lovotibeglogene (lovo-cel) gene therapy for sickle cell disease patients aged 12 years and older, who have a history of vaso-occlusive events (VOEs). The FDA had previously placed an ongoing [partial clinical hold](https://www.fiercepharma.com/pharma/bluebird-bio-hits-fda-clinical-hold-again-for-gene-therapy-blood-disorder) on lovo-cel following a case of persistent, non-transfusion-dependent anaemia.

## Cell therapies

[Roche’s CAR-T cell therapy for relapsed or refractory forms of large B-cell lymphoma is approved in Canada](https://www.biopharma-reporter.com/Article/2023/03/30/Roche-s-bispecific-antibody-treatment-for-blood-cancer-nabs-first-approval-in-Canada?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)

Roche’s CAR-T cell therapy ‘Columvi’ received approval from Health Canada in March 2023 for the treatment of relapsed or refractory forms of the blood cancer diffuse large B-cell lymphoma (DLBCL). Subsequent to approval in Canada the [US FDA provided accelerated approval in June 2023](https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-glofitamab-gxbm-selected-relapsed-or-refractory-large-b-cell).

[FDA grants fast track designation to IMPT-314 for relapsed, refractory B-cell lymphoma](https://www.onclive.com/view/fda-grants-fast-track-designation-to-impt-314-for-relapsed-refractory-b-cell-lymphoma)

The US FDA has granted a fast-track designation to the CAR T-cell therapy IMPT-314 for the treatment of patients with B-cell–mediated malignancies.

[CAR T-cell therapy: Is Australia ready, willing and able?](https://evohealth.com.au/insights/car-t-cell-therapy-is-australia-ready-willing-and-able/)

This paper looks at the future of CAR T-cell therapy, suggesting that it has the potential to replace stem cell transplants (particularly for multiple myeloma) within the next five years. The authors claim that the introduction of CAR T-cell therapy for multiple myeloma could quadruple the number of patients seeking access to care compared to current levels.

## Immunotherapy

[InProTher announces €6M seed funding for cancer immunotherapy drug](https://www.biopharma-reporter.com/Article/2023/05/25/inprother-announces-6m-seed-funding-for-cancer-immunotherapy-drug?utm_source=newsletter_daily&utm_medium=email&utm_campaign=25-May-2023&cid=DM1078074&bid=120577536)

Danish early-stage biotech company InProTher has raised 6 million euros seed funding to advance its IPT001, an immunotherapy against solid tumours into clinical development.

# Blood diseases and treatment

## Haemophilia

[Concizumab prophylaxis significantly reduces bleeding events for people with haemophilia](https://www.healio.com/news/hematology-oncology/20230628/concizumab-prophylaxis-significantly-reduces-bleeding-events-for-people-with-hemophilia)

This trial evaluated the efficacy and safety of Concizumab as a prophylactic treatment for 148 patients with haemophilia A or B without inhibitors. Researchers found that it reduced the number of bleeding events in patients without inhibitors for haemophilia A by 86% and haemophilia B by 79%.

[Haemophilia B therapy concizumab to be sold in Canada as Alhemo](https://hemophilianewstoday.com/news/hemophilia-b-therapy-concizumab-be-sold-canada-alhemo/)

Concizumab has been approved as a preventive treatment in Canada for [haemophilia B](https://hemophilianewstoday.com/hemophilia-type-b/) patients aged 12 and older who are positive for factor IX inhibitors and need a routine prophylactic to prevent bleeds or reduce their frequency. This is the first approval for the daily under-the-skin injectable therapy, which will now be marketed by Novo Nordisk under the brand name Alhemo.

[Pfizer’s haemophilia B gene therapy inches closer to regulatory approval](https://www.biopharmadive.com/news/pfizer-hemophilia-b-gene-therapy-fda-review/653990/)

The US FDA has accepted an application for the treatment Haemophilia B therapy, ‘fidanacogene elaparvovec’. Pfizer submitted its application based on study results that showed a single dose of the therapy lowered participants’ yearly bleeding rates by an average of 71% compared to the study’s start.

[Haemophilia B treatment SerpinPC granted fast track status by FDA](https://hemophilianewstoday.com/news/fda-grants-fast-track-status-hemophilia-b-treatment-serpinpc/)

The US FDA has granted fast track designation to SerpinPC, an investigational treatment for people with haemophilia B. The treatment is designed to suppress protein C, allowing for greater production of the blood-clotting protein thrombin.

[Monthly injections of Fitusiran reduces bleeds in patients with haemophilia A and B](https://www.eurekalert.org/news-releases/984171)

Two international, Phase 3, controlled trials with Fitusiran have shown that monthly subcutaneous injections were effective at reducing bleeds in patients when used with haemophilia A or B.

## Multiple myeloma

[Janssen seeks European Commission approval of a new indication for earlier treatment of myeloma](https://www.globenewswire.com/news-release/2023/05/25/2675919/0/en/Janssen-Seeks-European-Commission-Approval-of-a-New-Indication-for-CARVYKTI-ciltacabtagene-autoleucel-cilta-cel-for-the-Earlier-Treatment-of-Patients-with-Relapsed-and-Refractory-M.html)

The European Medicines Agency (EMA) has received an application for approval of a new indication for CARVYKTI (ciltacabtagene autoleucel; cilta-cel, a CAR-T cell product) for the treatment of adult patients with relapsed and lenalomide-refractory multiple myeloma.

[CellCentric receives FDA Fast Track designation for inobrodib for the treatment of patients with relapsed, refractory multiple myeloma](https://www.cellcentric.com/press-release/cellcentric-receives-fda-fast-track-designation-for-inobrodib-for-the-treatment-of-patients-with-relapsed-refractory-multiple-myeloma/)

The US FDA has granted ‘Inobrodib’ Fast Track designation for the treatment of patients with relapsed or refractory multiple myeloma. The treatment is designed to be delivered as an oral capsule and can be taken without requiring intensive monitoring.

[FDA grants Orphan Drug Designation to OM-301 in multiple myeloma](https://www.onclive.com/view/fda-grants-orphan-drug-designation-to-om-301-in-multiple-myeloma)

The FDA has granted Orphan Drug Designation (ODD) to OM-301 for treatment of patients with multiple myeloma. OM-301 is an investigational fusion peptide that binds to the surface of the cancer cell and kills it. The treatment has also received an ODD for the treatment of patients with acute myeloid leukemia.

[Dramatic gains in survival seen in myeloma since early 2000s](https://myelomaresearchnews.com/news/dramatic-gains-in-survival-seen-in-myeloma-since-early-2000s-analysis/?cn-reloaded=1)

Survival outcomes for people with multiple myeloma have improved substantially over the last two decades, likely due to the availability of new, more effective treatments, according to [a population-based study from Germany](https://bmccancer.biomedcentral.com/articles/10.1186/s12885-023-10787-5). While there is no cure for myeloma, new treatments have substantially improved outcomes for patients in the last 20 years.

## Leukaemia

[New targeted drug OK'd for acute myeloid leukemia](https://www.medpagetoday.com/hematologyoncology/leukemia/105592)

The FDA has approved quizartinib (Vanflyta) for use in patients with internal tandem duplication (ITD)-positive acute myeloid leukemia (AML)

[Quality of life, physical functioning, and psychological distress of older adults undergoing haematopoietic stem cell transplantation](https://www.astctjournal.org/article/S2666-6367%2823%2901176-4/fulltext#:~:text=Older%20adults%20experienced%20a%20sharp,in%20post%2DHSCT%20QOL%20trajectory.)

This study found that older patients with haematologic malignancies experienced declines in quality of life and physical functioning following haematopoietic stem cell transplantation, suggesting a need to implement supportive care interventions to improve patient outcomes.

[Gamida Cell wins long-awaited FDA approval for Omisirge](https://www.fiercepharma.com/pharma/after-going-all-blood-cancer-therapy-gamida-cell-scores-big-win)

The US FDA has approved ‘Omisirge’, an allogenic cell therapy, to reduce the risk of infection in blood cancer patients. Omisirge works by speeding the recovery of neutrophils that combat infections.

[State of the Nation: Blood Cancers in Australia](https://www.leukaemia.org.au/how-we-can-help/advocacy-and-policy/state-of-the-nation/#:~:text=In%202022%2C%20the%20Blood%20Cancer,due%20for%20release%20in%202023.)

In February, the Leukaemia Foundation of Australia released a report “State of the Nation: Blood Cancers in Australia Report 2023” which stated that the incidence of blood cancer has increased 47% in the past 10 years in Australia. There are around 135,000 people living with a blood cancer or blood disorder in Australia today a number expected to increase to 275,000 by 2035.

[Servier receives marketing approval for leukemia drug](https://www.biopharma-reporter.com/Article/2023/05/11/servier-receives-marketing-approval-for-leukemia-drug?utm_source=newsletter_daily&utm_medium=email&utm_campaign=11-May-2023&cid=DM1075344&bid=110001584)

The European Commission (EC) has approved the use of Tibosovo (ivosidenib) to treat isocitrate dehydrogenase-1 (IDH1)-mutated acute myeloid leukaemia (AML) and IDH1-mutated cholangiocarcinoma. Tibsovo is designed to treat adult patients with at least one prior line of systemic therapy.

## Sickle Cell Disease (SCD)

[Hydroxyurea may help to prevent malaria infection in children with sickle cell anaemia](https://www.hematologyadvisor.com/home/topics/anemia/hydroxyurea-prevent-malaria-infection-children-sub-sahara-africa-risk/)

Children living in sub-Saharan Africa with sickle cell anaemia (SCA) who received the maximum tolerated dose of hydroxyurea appear to be at a decreased risk of infection with malaria. [The authors of the article in Blood journal](https://ashpublications.org/blood/article-abstract/141/12/1402/487110/Hydroxyurea-treatment-is-associated-with-lower?redirectedFrom=fulltext) state that because malaria is documented to cause frequent and severe anaemia in children with SCA, understanding the clinically significant association between hydroxyurea and lower malaria incidence represents an important research goal while expanding hydroxyurea treatment across Africa.

[Factor XII linked to complications, including thrombosis, in sickle cell disease](https://www.hematologyadvisor.com/home/topics/anemia/sickle-cell-disease-factor-xii-linked-complications-thrombosis-treatment-risk/)

A [new study](https://ashpublications.org/blood/article-abstract/141/15/1871/494268/Factor-XII-contributes-to-thrombotic-complications?redirectedFrom=fulltext) involving patients with sickle cell disease (SCD) indicated an elevated level of factor XII (FXII)-mediated contact pathway activation was present in these patients and may have a role in complications, including thrombosis.

## Thrombocytopaenia

[Platelet transfusion before CVC placement in patients with thrombocytopenia](https://www.nejm.org/doi/full/10.1056/NEJMoa2214322)

This trial aimed to review the platelet-count thresholds required by differing care providers before the placement of a central venous catheter (CVC) and recruited patients with severe thrombocytopenia who were being treated in a haematology ward or intensive care unit. They found that withholding of prophylactic platelet transfusion before CVC placement in patients with a platelet count of 10,000 to 50,000 per cubic millimeter resulted in more CVC-related bleeding events than prophylactic platelet transfusion.

[SYK inhibitor promising in early trial of Primary ITP](https://www.thelancet.com/pdfs/journals/lanhae/PIIS2352-3026%2823%2900034-0.pdf)

A small, randomised, Phase I/II trial carried out in China and published in the Lancet investigated the safety, tolerability, and effectiveness of spleen tyrosine kinase (SYK) inhibitor, Sovleplenib, as a treatment option for primary immune thrombocytopenia. Researchers found that the treatment was well tolerated, with the recommended phase 2 dose showing a promising durable response.

## Lymphoma

[Epkinly approved for relapsed, refractory diffuse large B-cell lymphoma](https://www.empr.com/home/news/epkinly-approved-for-relapsed-refractory-diffuse-large-b-cell-lymphoma/)

The US FDA has granted accelerated approval to Epkinly (epcoritamab-bysp) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

[FDA approves Polivy regimen for previously untreated diffuse large B-cell lymphoma](https://www.healio.com/news/hematology-oncology/20230419/fda-approves-polivy-regimen-for-previously-untreated-diffuse-large-bcell-lymphoma)

The FDA has approved polatuzumab vedotin-piiq (Polivy), in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, as first-line therapy for patients with certain types of B-cell lymphoma.

[B cell lymphoma drug (liso-cel; Breyanzi) recommended for EU approval](https://www.onclive.com/view/liso-cel-receives-european-approval-recommendation-for-relapsed-refractory-lbcl)

The European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of lisocabtagene maraleucel (liso-cel; Breyanzi) for the treatment of select patients with diffuse large B-cell lymphoma (LBCL).

## Other

[Despite access barriers, physicians prefer CAR-T for treatment of advanced B-cell lymphoma.](https://www.healio.com/news/hematology-oncology/20230412/despite-access-barriers-physicians-prefer-cart-for-treatment-of-advanced-bcell-lymphoma)

From a survey of 75 US-based physicians carried out by Alkemi Health, 94.7% of respondents indicated they had prescribed CAR-T cells for third-line treatment of refractory or relapsed B-cell lymphoma. However, nearly one-third of patients (30.1%) prescribed or referred for CAR-T never received treatment. Common factors cited for not receiving CAR-T included a lack of willingness to travel for treatment (49.3%), post-referral ineligibility (48%) and patient preference for alternative treatment (37.3%).

['Breakthrough' blood clot treatment used for first time in NZ](https://www.1news.co.nz/2023/03/05/breakthrough-blood-clot-treatment-used-for-first-time-in-nz/)

Doctors have successfully trialed a new treatment for removing blood clots in pulmonary embolism. The treatment involves a catheter directed thrombectomy which connects to a computer and allows doctors to pump a clot out of the arteries with minimal blood loss. The new treatment was used for the first time to successfully treat a British tourist in Auckland City Hospital, after she went into cardiac arrest and was diagnosed with a pulmonary embolism.

# Blood practice trends and patient blood management

## Donations

[Next generation sequencing to identify iron status and individualise blood donors' experience](https://pubmed.ncbi.nlm.nih.gov/37146293/#full-view-affiliation-1)

First-time blood donors to Lifeblood tend to be younger, however, these donors have a higher risk of iron deficiency anaemia when compared to older adults and non-donors. This study demonstrates sequencing methods may be used to tailor donation frequency based on genetic markers of iron homeostasis.

[Kuwait introduces new blood transfusion fees for expatriates](https://gulfnews.com/world/gulf/kuwait/kuwait-introduces-new-blood-transfusion-fees-for-expatriates-1.1683453683993)

Expatriates residing in Kuwait will now be charged per bag of blood used for their treatment in non-emergency situations. The Kuwaiti Health Ministry has stated that charging expatriates to access blood products will help to ensure blood supplies are maintained. Patients who provide their own before a procedure will be exempt from charges.

## Screening and cross-matching

[Impact of a post-donation haemoglobin testing strategy on efficiency and safety of whole blood donation in England: A modeling study](https://pubmed.ncbi.nlm.nih.gov/36794597/#:~:text=Discussion%3A%20Personalized%20inter%2Ddonation%20intervals,%2C%20inappropriate%20bleeds%2C%20and%20costs.)

This study investigated the utility of using large datasets to develop a usable model for predicting peak donation safety for people with low haemoglobin levels. They found that the model’s personalised strategy, minimised adverse events (low haemoglobin deferrals and inappropriate bleeds) in both sexes and costs in women.

[World-first NHS test to curb transfusion side-effects for thousands with inherited blood disorders](https://www.england.nhs.uk/2023/05/world-first-nhs-test-to-curb-transfusion-side-effects-for-thousands-with-inherited-blood-disorders/)

The UK NHS will become the first healthcare system in the world to provide blood group genotyping – a detailed DNA analysis of each patient’s blood group – to match more accurately those in need of transfusions to donated blood. Lifeblood currently undertake [phenotyping](https://www.lifeblood.com.au/health-professionals/products/blood-components/modifications/phenotyped), which is designed to prevent alloimmunisation and ensure compatible red cells a provided for transfusion in patients with clinically significant antibodies.

## Inventory management

[Evaluation of two temperature storage conditions for full blood count samples from Lifeblood's donors](https://onlinelibrary.wiley.com/doi/full/10.1111/tme.12962)

This study aimed to compare full blood count results under two temperature conditions to determine if the current practice for refrigerated (2–8°C) storage for testing could be replaced room temperature (20–24°C) storage and what efficiencies might occur in blood donor centres. Statistically significant differences for most full blood count parameters results were observed when comparing the two temperature conditions, however the authors stated that the clinical significance of the small numerical differences in results was minimal, and the number of blood films required remained similar under either temperature condition.

## Transfusion

[Sex of red blood cell donor has no significant impact on transfusion recipient mortality](https://www.healio.com/news/hematology-oncology/20230413/sex-of-red-blood-cell-donor-has-no-significant-impact-on-transfusion-recipient-mortality)

This Canadian trial assessed the impact of donor sex on recipient mortality among 8,719 hospital patients. The study reviewed previous research which suggested a benefit from a male donor strategy but found that limited differences in outcomes on patient mortality rates in this trial.

[The interaction effect of transfusion history and previous stroke history on the risk of venous thromboembolism in stroke patients: a prospective cohort study](https://thrombosisjournal.biomedcentral.com/articles/10.1186/s12959-023-00487-2)

Researchers have found there is a potential for increased risk of venous thromboembolism (VTE) in stroke patients if they have a history of blood transfusion, with severe strokes also increasing this risk. The study showed that the combination of a transfusion history plus previous stroke history, may yield a positive multiplicative and supra-additive effect on the risk of VTE.

[Transfusion related TRALI: a retrospective review of reported cases in Queensland over 20 years](https://www.bloodtransfusion.it/bt/article/view/303)

This report reviewed the 91 cases of transfusion-related acute lung injury (TRALI) referred for investigation within Queensland over a 20-year period. Researchers found 30 confirmed cases of TRALI and another possible 18, affecting patients of all ages. Most patients had underlying haematological malignancies (25%), surgery (15%) or liver disease (13%). Red cells were transfused in 32 cases, platelets in 18 and plasma products in 21, with 16 cases involving multiple products.

[Safe transfusion in Asian-type DEL](https://ashpublications.org/blood/article/141/17/2044/495435/Safe-transfusion-in-Asian-type-DEL)

The study suggests that individuals with Asian-type DEL express small amounts of the wild-type protein that protect them from alloimmunisation and that RhD antigen-positive RBCs can be administered without causing alloimmunisation.

[Understanding intraoperative transfusion decision-making variability: A qualitative study](https://www.sciencedirect.com/science/article/abs/pii/S0887796323000160)

This study explored the influences on intraoperative red blood cell (RBC) transfusion by anaesthesiologists and surgeons. The study identified a range of factors underlying intraoperative transfusion decision-making and partly explain the variability in transfusion behaviour including: knowledge, social/professional role and identity, beliefs about consequences, environmental context/resources and social influences.

[Current evidence and rationale to guide perioperative management, including transfusion decisions, in patients with sickle cell disease (SCD)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10171288/)

Preoperative transfusion is recommended for all patients with SCD who are undergoing surgery that either requires general anesthesia or any moderate anesthesia lasting >1 hour. This evidence-based recommendation is aimed mainly at reducing the high-mortality post-procedure risk of acute chest syndrome (ACS). The authors of this study suggest that preoperative transfusion should be done on an individualised basis: the patient’s SCD genotype and disease severity, history of antibodies and/or transfusion reactions, risk of surgery, and baseline haemoglobin levels should all be considered.

[Association of prehospital transfusion with mortality in paediatric trauma](https://jamanetwork.com/journals/jamapediatrics/article-abstract/2805185)

In this retrospective cohort study of children (0-17 years of age) in Pennsylvania (2009-2019), prehospital transfusion was associated with lower rates of mortality compared with transfusion on arrival to the emergency department, suggesting bleeding paediatric patients may benefit from early haemostatic resuscitation.

## Haemovigilance

[Injectable synthetic blood clots stop internal bleeding to save lives](https://newatlas.com/medical/injectable-synthetic-blood-clots-internal-bleeding/)

A team of scientists at Massachusetts Institute of Technology (MIT) have published a new [paper](https://onlinelibrary.wiley.com/doi/full/10.1002/adhm.202202756) on a two-pronged synthetic system that can be injected by first responders to stem internal bleeding. The system has two components, firstly nano particles that recruit platelets, and secondly a polymer that mimics fibrinogen. The platelets form a plug at the wound site followed by coagulation or the cascade of enzymatic reactions that ultimately results in conversion of fibrinogen to fibrin monomers.

[First donor haemovigilance system at a national level in China: Establishment and improvement](https://onlinelibrary.wiley.com/doi/full/10.1111/vox.13421?campaign=woletoc)

The first donor haemovigilance (DHV) system at national level in China has been established to monitor adverse reactions, starting with a pilot phase from 2019-2021. While other countries such as the United States, Britain and Italy have relatively mature DHV systems, a HV organisation was not established in China until 2017 and was managed entirely at the local level before 2019.

# COVID-19

[$50 million for research in to long COVID](https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/50-million-for-research-in-to-long-covid?language=en)

The Australian Government has promised a further $50 million from the Medical Research Future Fund (MRFF) for research into post-acute sequelae of COVID-19, commonly known as Long COVID. The new funding aims to improve knowledge of Long COVID, inform policy and clinical guidance, improve health outcomes, and increase awareness of the condition in the community.

[WHO declares COVID-19 over as a global health emergency](https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing---5-may-2023)

In May, the WHO Emergency Committee met for the 15th time and recommended that the Director-General (DG) declare an end to the public health emergency of international concern. On the Emergency Committee’s advice, the DG has decided to use a provision in the International Health Regulations that has never been used before, to establish a Review Committee to develop long-term, standing recommendations for countries on how to manage COVID-19 on an ongoing basis.

[Cryopreserved Allogeneic Hematopoietic Cell Grafts Did Not Impact OS During COVID-19 Pandemic](https://www.hematologyadvisor.com/home/topics/general-hematology/covid19-cryopreserverd-allogeneic-hematopoietic-cell-grafts-overall-survival/)

At the onset of the COVID-19 pandemic, the National Marrow Donor Program in the US mandated the cryopreservation of haematopoietic cell grafts from volunteer unrelated donors due to numerous patient and donor safety concerns and logistical hurdles. [A study](https://ashpublications.org/bloodadvances/article/doi/10.1182/bloodadvances.2023009786/495268/Clinical-Impact-of-Cryopreservation-of-Allogeneic) of the clinical impact of this practice has been undertaken by the Center for International Blood and Marrow Transplant to assess the impact of cryopreserved allografts on patients receiving haematopoietic cell transplantation (HCT) at US transplant centres.

[Long COVID now looks like a neurological disease, helping Doctors to focus treatments](https://www.scientificamerican.com/article/long-covid-now-looks-like-a-neurological-disease-helping-doctors-to-focus-treatments/)

Researchers have found that the most common, persistent, and disabling symptoms of long COVID are neurological. Some are easily recognised as brain- or nerve-related: many people experience cognitive dysfunction in the form of difficulty with memory, attention, sleep, and mood. One study found that in people with neurological COVID symptoms, the immune system seems to be activated specifically in the central nervous system, creating inflammation.

# Blood sector research and development

[Blueprint developed for research priorities of ultra-rare bleeding disorders](https://www.hematologyadvisor.com/home/topics/bleeding-disorders/bleeding-disorder-blueprint-developed-research-priorities-ultra-rare-treatment/)

The National Haemophilia Foundation (NHF) and the American Thrombosis and Haemostasis Network (ATHN) have published a [national research blueprint](https://www.tandfonline.com/doi/full/10.1080/17474086.2023.2175661) with recommendations for future research opportunities to address the priorities of patients with ultra-rare bleeding disorders. In this paper, a group of ultra-rare bleeding disorder experts, including doctors, researchers, regulators, patient advocates, and patients, identify the research that could best improve the lives of people with these disorders.

[Moderna partners with IBM to explore quantum computing and generative AI](https://www.biopharma-reporter.com/Article/2023/04/24/Moderna-partners-with-IBM-to-explore-quantum-computing-and-generative-AI?utm_source=newsletter_daily&utm_medium=email&utm_campaign=24-Apr-2023&cid=DM1071606&bid=96623144)

Computing company IBM will partner with Moderna to advance and accelerate mRNA with access to quantum computing systems. IBM will also assist with computing expertise to help Moderna in exploring use cases powered by quantum technology.

[BD explores plastic blood tube recycling](https://www.medicaldesignandoutsourcing.com/bd-plastic-blood-tube-recycling-pilot-program-sustainability/)

Medical device manufacturer Becton Dickinson and Co. are exploring blood tube recycling in a sustainability pilot program. Plastic blood collection tubes are incinerated after use instead of being recycled.

# Industry, supply chains and economy

[New $50M Venture Capital fund to focus solely on blood and cell therapies](https://www.fiercebiotech.com/biotech/nybc-ventures-launches-50m-blood-and-cell-therapies)

NYBC Ventures was [unveiled](https://www.businesswire.com/news/home/20230511005010/en/NYBC-Ventures-Launches-50M-Fund-to-Accelerate-Innovations-in-Blood-and-Cellular-Therapies) as one of the first venture funds to focus solely on advancing new blood and cell-based therapies, with $50 million in hand from the New York Blood Center. The fund will invest in new therapeutics, devices and tech that tackle challenges in haematology, transfusion medicine and infectious disease.

[Intravenous immunoglobulin market demand analysis 2023](https://market.us/report/intravenous-immunoglobulin-market/)

In 2022, the Global Intravenous Immunoglobulin Market was valued at US$ 12.6 Billion. By 2023 and 2032, this market is projected to experience a compound annual CAGR growth of 7.0%. IVIg preparations have been developed largely in response to this increasing incidence of immunodeficiency disorder patients. IVIg therapy is becoming more commonplace as the best and most efficient treatment option for acquired and primary immunodeficiency diseases.

[In pandemic’s wake, only 57% of doctors would choose medicine again](https://www.ama-assn.org/practice-management/physician-health/pandemic-s-wake-only-57-doctors-would-choose-medicine-again?utm_source=BulletinHealthCare&utm_medium=email&utm_term=052123&utm_content=physicians&utm_campaign=article_alert-morning_rounds_editors_edition&utm_effort=DAMR01)

Doctor burnout rates rose to an all-time high 63% in 2021. In a survey conducted by Stanford University, the Mayo Clinic and the University of Colorado, found that professional fulfilment scores fell, dropping to 40% in 2020 to 22.4% in 2021.

# Government, policy and regulation

[Health Portfolio Budget Statements – Budget 2023–24](https://www.health.gov.au/resources/publications/health-portfolio-budget-statements-budget-2023-24?language=en)

The 2023 Australian Government budget was released in May, with minimal change in funding levels. Associated initiatives in the health sector include:

* Several measures to boost primary health care (such as boosting bulk billing incentives and increasing Medicare rebates)
* a range of measures to increase the medical workforce
* a stronger focus on preventative health (particularly tackling smoking and vaping)
* establish an interim Australian Centre for Disease Control and replenish the National Medical Stockpile.

# Other diseases and developments

## Malaria

[Ghana first to approve Oxford’s malaria vaccine](https://www.bbc.com/news/health-65252511)

Ghana is the first country to approve a new malaria vaccine, R21, which appears to be more effective than previous ventures. The World Health Organisation is also assessing the vaccine for approval.

[Four reasons disease-carrying mosquitoes could be spreading to a car tyre near you](https://www.gavi.org/vaccineswork/four-reasons-disease-carrying-mosquitoes-could-be-spreading-car-tyre-near-you)

The incidence of dengue and chikungunya has grown dramatically in recent years. Just over 500,000 dengue cases were reported annually in 2000. By 2019, this had risen to 5.2 million, [with one in two people worldwide are now at risk of the disease](https://www.gavi.org/vaccineswork/global-warming-means-one-two-us-are-now-risk-dengue)

## Dengue

[Brazil: Nearly 83K probable cases of dengue reported in Espírito Santo through April](http://outbreaknewstoday.com/brazil-nearly-83k-probable-cases-of-dengue-reported-in-espirito-santo-through-april-24175/)

Dengue cases have spiked in Brazil up to 82,254 from 2,844 cases the previous year. Other arboviruses have also increased in prevalence, including chikungunya and Zika.

[Unique dengue disease outbreak heads North](https://www.vaxbeforetravel.com/unique-dengue-disease-outbreak-heads-north)

In Costa Rica, all four types of Dengue have been detected simultaneously, with more than 580 Dengue cases reported up to May 2023.

[Special teams deployed to control spread of dengue](https://www.adaderana.lk/news/90356/special-teams-deployed-to-control-spread-of-dengue-health-authorities)

The Sri Lankan Ministry of Health has sent a special team to the Gampaha district to control the spread of dengue. Furthermore, 15 districts have been identified to be at dengue high-risk, according to the Health Entomology Officers’ Association.

## Leptospirosis

[Philippines: Leptospirosis cases more than double last years, Deaths top 100](http://outbreaknewstoday.com/philippines-leptospirosis-cases-more-than-double-last-years-deaths-top-100/)

Health officials in the Philippines reports a 135 percent increase in leptospirosis cases year to date, according to the latest data from the Epidemiology Bureau. From 1 January to 8 April, 1,152 leptospirosis cases have been reported nationally, up from 490 cases during the same period last year.

## Japanese encephalitis

[Risk of ongoing Japanese encephalitis outbreaks in Australia](https://insightplus.mja.com.au/2023/12/dangerous-mosquitoes-infest-northern-victoria/)

This article by Dr Sarah Allen and colleagues based at the Women’s and Children’s Hospital in Adelaide states that the virus is likely to persist in mainland Australia. JEV will remain dormant in temperate regions and cause seasonal summer–autumn outbreaks.

## Monkeypox

[Monkeypox outbreak in 2022: implications for blood component and donor human milk safety in Australia](https://www.mja.com.au/journal/2023/218/5/mpox-outbreak-2022-implications-blood-component-and-donor-human-milk-safety)

Monkeypox was recorded (in relatively small numbers) in Australia for the first time during the 2022 outbreak in historically non-endemic countries. Monkeypox transmission via transfusion or breastfeeding has not been reported and the risk is reduced as the blood phase is relatively brief and low level and accompanied by leucodepletion.

[CDC warns about potential risk of monkeypox ahead of summer gatherings](https://abcnews.go.com/Health/cdc-warns-potential-risk-mpox-ahead-summer-gatherings/story?id=99339609)

The Centers for Disease Control and Prevention [alerted doctors](https://emergency.cdc.gov/han/2023/han00490.asp) across the country Monday about the potential risk of new monkeypox, warning that summer gatherings could lead to a "resurgence." The new CDC warning comes on the heels of a cluster of cases in Chicago, where health officials say there have been 12 confirmed cases and one probable case from April 17 to May 5.

## Bird Flu

[Moscow imposes quarantine in multiple districts over bird flu outbreak](https://www.themoscowtimes.com/2023/05/18/bird-flu-outbreak-prompts-moscow-mayor-to-introduce-quarantine-in-multiple-districts-a81195)

Moscow Mayor Sergei Sobyanin on Thursday [ordered](https://ria.ru/20230518/karantin-1872659395.html) a quarantine for multiple districts in Russia’s capital due to an outbreak of highly pathogenic avian influenza, commonly known as bird flu. The order introduces a quarantine for 11 of Moscow's 125 districts that have been assessed to be most at risk for spreading influenza.