NATIONAL BLOOD AUTHORITY
AUSTRALIA

Monitoring International Trends

October – November 2021

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.

Some key topics that have appeared in news media, online publications, and industry and research updates have been included in this report, including:

- **Blood Supply:** Calls for blood donations continue internationally as COVID-19 affects blood supplies with extreme shortages in the United States (US). Efforts are underway to recruit more diverse donors to ensure sickle cell disease patients can find matches. An inquiry into the historical administration of infected blood is underway in the United Kingdom (UK). Changes have been made to the criteria for blood donation in Australia and the Canada.
- **Blood Disorders:** Research continues for vaccine-induced immune thrombotic thrombocytopenia (VITT), with the risk of VITT declining within weeks after initial diagnoses. Among this month's report is also news about haemophilia, anaemia, sickle cell disease, and several blood cancers.
- **Transfusion:** There are a significant amount of reports of relating to transfusion practices in paediatrics. Analysis of blood transfusion practices and blood management programs have also been common with a focus on blood product usage and how wastage can be reduced.
- **Gene Therapy**: Bio-tech company, Bluebird, has officially asked the US Food and Drug Administration (FDA) to approve their therapy for beta-thalassemia. The FDA approved a fast-tracked treatment for relapsed multiple myeloma. Gene therapy trials are also underway for haemophilia and sickle cell disease.
- **COVID-19:** The effects of the virus are being felt across the blood sector, including on blood collection and hospitalisations. As vaccination numbers increase, the focus of research and treatment options is turning to the management of the unvaccinated and immunocompromised.
- **Other items of interest:** Europe is looking to rewrite its 'pharma' legislation to promote breakthroughs in areas of unmet need. The UK has opened consultation on the scope of current regulation of medical devices.

Contents

1 Blood supply

This section contains news articles and government agency statements on blood supply, changes to donation criteria as well as a report from the UK Infected Blood inquiry.

1.1 Blood supply – North America

There was consistent reporting throughout October and November of severe blood shortages across the United States (US) with the Northern hemisphere going into winter and flu season. The American Red Cross said supply has not been this low since 2015 and has been calling for donations from healthy, eligible donors. Treatment efforts for those suffering sickle cell disease and those requiring transfusions are being hampered by shortages. Across the United States and Canada blood supply remains at decade low levels.

- US blood supply is extremely low, Red Cross encourages everyone eligible to donate
- US blood Donors Urgently Needed This Fall as COVID-19 Pandemic Continues
- American Red Cross facing blood, platelet shortage
- Blood supply critical, down to 1-day supply, donor centre says
- Blood donation shortage puts patients at risk
- US AABB weekly Group O Blood Supply Report
- Blood Centres declare critical blood supply shortage, urge donations
- Blood supply crisis calls for increased donation, awareness
- Red Cross urges donations as flu season may affect blood supply
- American Red Cross says there's an 'emergency' blood shortage
- Oh no, no type-O: National blood shortage strikes home
- Low blood supply hampers sickle cell treatment efforts
- American Red Cross Offering Incentives to Donors Amid Emergency Blood Shortage
- Local organizations see shortage of Type O blood donations
- Emergency blood shortage persists as patient needs continue over holiday season
- Red Cross announces lowest holiday blood supply in more than a decade
- Lack of O-positive blood donors in Quebec, Canada sparks surgery cancellations

1.2 Blood supply - World news

French ‘rare blood’ drive seeks to woo diverse donors

While most blood types will match by group and RhD status, e.g. B+ donor to type B+ recipient, it is possible that genetic material in a recipient’s blood can lead to complications with transfusion. After a patient suffered serious health complications as a result of this, a French ‘rare blood’ drive is seeking diverse donors with a program of events to encourage donations from members of certain ethnic groups who possess rare blood groups.

Irish appeal for blood donations as hospitals warned services down to a three-day supply

In late October, the Transfusion Service in Ireland requested the public come forward and donate if eligible, with blood supply down to a three-day supply across main blood groups.

Blood supply shortage likely in Zamboanga del Sur, Lanao provinces after Philippine Red Cross facility fire

A fire at a blood processing facility in the Philippines in early November resulted in the Philippine Red Cross (PRC) raising the alarm on temporary blood shortages for the region, with blood supply likely to run out in areas that depended on PRC for supply.

Bangladesh blood banks scramble for platelets as dengue cases rise

Bangladesh has seen a significant spike in dengue fever with 15,976 cases and 59 deaths to September this year. This created a huge rush of blood use by dengue patients leaving the region critically low in platelets.

1.3 Regulatory and donation criteria changes

Call for Action: Enhancing plasma collection through increased regulatory efficiency *and* New approaches urged to boost collection of plasma in EU

The European Commission is revising the European Union Blood, Tissue and Cells legislation, noting recent technological, scientific, epidemiolocal and societal developments. Several organisations including the Plasma Protein Therapeutics Association and several Members of the European Parliament have been publicly supportive of updates. The changes should lead to increased plasma collection in Europe, to benefit the 300,000 European patients who rely on plasma therapies to treat rare, chronic and life-threatening conditions.

Kenya to develop policy to regulate blood services

The Kenyan government is formulating policies to regulate blood services and products. The policy and regulatory framework should be in place by March 2022 – with a focus on blood and blood products safety, security and availability. The lack of regulation to date has been blamed on an absence of guidance for the sector and has led to medical services selling blood to patients at exorbitant prices.

Canadian Blood Services to recommend end to ban on donations to be more inclusive

Canadian Blood Services is seeking to end the practice of screening donors based on sexuality and instead focus on screening based on high-risk sexual behaviour. Potential donors could be asked if they have had multiple sexual partners, and about their sexual behaviour instead of their sexuality and gender.

Varadkar calls for change to blood donation rules for gay men

The Irish Tánaiste (deputy head of Government) has publicly supported changing the rules to allow gay men to donate blood.

International Forum on Gender Identification and Blood Collection

Blood collection centres across the world are being asked to allow blood donation from transgender donors. This survey identifies variation in determining the gender of a potential donor, including a policy to address transgender and non-binary identifying donors.

1.4 Blood and plasma donation: Australia and New Zealand

As lockdowns lifted in parts of Australia in November, elective surgeries recommenced and experts were concerned about a spike in road trauma. The Australian Red Cross Lifeblood called for people to donate in November as cancellations increased. Blood demand is at a 10-year high and reserves of O-negative blood are being challenged with numbers of donors down during the pandemic. Several articles reporting the issues are linked below:

- Red Cross calls for 7000 extra people to donate blood
- Thousands of blood donors needed as demand reaches 10-year high
- Lifeblood seek O Negative blood donors
- Red Cross calls for 7000 extra people to donate blood

1.5 Other items

UK contaminated blood scandal: Schoolboy survivors say they were 'injected with death'

An investigation into the administration of blood products in the UK throughout the 1970s, 80s and 90s estimates the up to 30,000 people were treated with contaminated blood, including schoolboys at a specialist haemophilia school. Questions relating to the administration of blood in Australia throughout the same period have arisen as a result of this inquiry.

Delivering blood components through drones: leaner approaches to the supply chain

Challenges identified in the supply chain related to high wastage levels, ability to predict demand for blood, low level of centralisation in developing countries, unexpected short-term changes in demand and sanitary, environmental and infrastructural risks. Improvements could include gains in delivery time, allowing a better model of distribution.

1.6 Blood donor characteristics and donation effects

Blood donors not following up quickly on Lifeblood advice

A study from the Australian Red Cross Lifeblood found only half of donors with an iron-related deferral followed advice from Lifeblood and visited their GP within 30 days of deferral.

Notifying donors when their deferral is ending: An effective donor retention strategy

A study found that sending a reminder message to donors when their deferral is coming to an end is a simple, effective and cost-effective method to retain donors.

Plasma vigilance: Source plasma joins the call to arms

This very large study demonstrates that source plasma (collected by apheresis for the sole purpose of fractionation) presents a low risk to donors, similar to blood donation. It further informs on specific donor attributes associated with increased adverse event risk, providing a foundation to explore mitigation strategies.

Willingness of blood donors in Australia to provide additional data and blood sample for health research

Donors surveyed reported a high willingness to participate in health research by completing surveys, allowing linkage to external datasets and providing a blood sample. This provides support for future longitudinal research studies with Australian blood donors.

Donation-induced iron depletion is significantly associated with low haemoglobin at subsequent donations

Blood donation is associated with a loss of haemoglobin (Hb) bound iron. Typically, Hb levels recover quickly by using stored iron. However, researchers have found repeated donations may induce iron deficiency, which corresponds to an over tenfold increased risk of having insufficiently restored Hb levels at a subsequent donation attempt.

Low ferritin levels appear to be associated with worsened health in male repeat blood donors

Frequent blood donation depletes iron stores of blood donors. Iron depletion may lead to anaemia, but the health effects of iron depletion without anaemia in healthy blood donors are not well understood. Researchers found that low iron is associated with worsened health even in non-anaemic repeat donors. However, it was noted that a more holistic health analysis of repeat donors may also link this to other lifestyle factors.

2 Blood disorders and treatments

This section includes published new media, research and industry statements on the progress of blood disorder treatments across various conditions.

2.1 Vaccine-induced immune thrombotic thrombocytopenia (VITT)

Vaccine-induced thrombotic thrombocytopenia (VITT) is caused by extreme immune system reactions to AstraZeneca, University of Oxford and Serum Institute of India COVID-19 vaccines.

'Just in time': how Australian doctors drastically reduced deaths from vaccine-linked blood clots

Australia has recorded a total of 148 cases of confirmed or probable VITT from 11.6 million AstraZeneca vaccine doses. A huge collaborative effort to quickly resolve the issue led to patients being treated with blood thinners and intravenous immunoglobulin.

Vaccine-induced immune thrombotic thrombocytopenia

A summary of the evolution of VITT and the rapid recognition and treatment. This review confirms through the few hundred cases published in literature the method of treatment and that current research efforts should focus on determining the optimal long-term management of survivors and further unravelling of mechanism.

2.2 Haemophilia

Haemophilia is caused by defective or missing clotting factors resulting in spontaneous and excessive bleeding. Treatment can involve replacement therapy that relies on frequent transfusions or the use of extended half-life products which have been developed to reduce infusion frequency.

Breakthrough Bleeds Likely for Haemophilia A Patients on Hemlibra

A study reported that the odds of bleeding episodes for patients with haemophilia A, increased by a factor of 1.029 for every one year of age, while being treated with Hemlibra (emicizumab). Hemlibra is a routine prophylaxis to prevent or reduce the frequency of bleeding episodes. The study reported that the risk of bleeding persists, with most patients on the preventative treatment experiencing spontaneous or traumatic bleeds at some point.

Haemophilia patients express gains in switch to extended half-life therapies

Patients using extended half-products often report much higher self-reported gains to their health-related quality of life. However, researchers have found that the current questionnaires used to track these perceived and actual patient benefits were developed long before these products were introduced. They note that improved self-reporting tools are needed to better track their performance and patient benefits.

Extended factor IX (FIX) preventive therapy for Haemophilia B may not ease patients' pain

Adult men with severe haemophilia B report quality of life improvements from preventative treatment with extended half-life recombinant factor IX (FIX). However, research suggests that these patients continue to experience chronic pain and reliance on pain killers after two years on this treatment. Researchers note that careful surveillance of patients using this preventative therapy is required, as well as access to multidisciplinary teams to provide the appropriate care and monitoring.

Canadian Blood Services awards Takeda Canada three-year tender for Haemophilia treatment ADYNOVATE

This is the second time Takeda has been awarded the tender to provide the drug to Canadian haemophilia A patients. Adynovate is based off of Advate, an artificially made version of factor VIII (FVIII), the blood-clotting protein that is missing or defective in haemophilia A patients. Both treatments are currently available in the Australian market.

2.3 Anaemia

Anaemia describes a deficiency in the number or quality of red blood cells in the body. A protein called haemoglobin on red blood cells carries oxygen around the body. Anaemia means the level of red blood cells or level of haemoglobin is lower than expected. Sickle cell anaemia related articles are included in the sickle cell disease section below.

Relationship between anaemia, coagulation parameters during pregnancy and postpartum haemorrhage at childbirth

From a prospective cohort study, researchers have concluded that altered blood coagulation profile in pregnant women with severe anaemia could be a risk factor for postpartum haemorrhage and requires further evaluation.

Assessment of the management of anaemia in acute care settings in the United Kingdom

A study found appropriateness of transfusion and investigation of anaemia in acute care settings required improvement. The study also demonstrates the value of Haematology Specialty Trainee Audit and Research (HaemSTAR) in facilitating time-efficient collection of high-quality data.

Preoperative intravenous iron to treat anaemia before major abdominal surgery

Research from June 2021 found no significant differences in the rates of blood transfusion or death at 30 days after operations, between anaemic patients who received intravenous iron preoperatively and those who did not.

Atypical Haemolytic Uremic Syndrome (aHUS) in 3-year-old girl likely triggered by severe COVID-19 infection

Atypical Haemolytic Uremic Syndrome (aHUS) is a rare disease characterised by haemolytic anaemia or red blood cell destruction, low platelet count and kidney failure. A group of researchers in Turkey have reported a 3-year-old girl whose aHUS appeared to be trigged by infection with COVID-19.

Anaemia in elderly patients at discharge from intensive care and hospital

Anaemia is common in the elderly and is recognised as a risk factor for adverse patient outcomes. Researchers investigated the prevalence of anaemia in elderly patients, finding a high prevalence on discharge from ICU and to a lesser degree at hospital discharge. It is noted that elderly patients may benefit from higher haemoglobin on discharge from ICU which may be achieved by reducing the length of stay and maintaining higher base levels of haemoglobin.

Positive results for GlaxoSmithKline's anaemia drug daprodustat

Positive data has been revealed from phase III studies for an investigational treatment in patients with anaemia due to chronic kidney disease. In a study of over 8000 people, the drug has been well tolerated both in non-dialysis and dialysis populations.

Regular intake of millets helps tackle anaemia: Study *and* Regular millet consumption can improve haemoglobin and combat anaemia

Millets are a group of highly variable small-seeded grasses, widely grown around the world as cereal crops or grains for fodder and human food. Research conducted across four countries found regular consumption of millets can improve haemoglobin and serum ferritin levels reducing iron deficiency anaemia.

Tackling Anaemia Through Fortified Rice: A Pilot Programme Shows Promise in Gadchiroli, India

There have been reports of fortified rice pilot programme in Gadchiroli, India with iron deficiency is the most common cause of anaemia developing. Public health and nutrition experts have reiterated a need for iron food fortification across India as critical in the anaemia battle and micronutrient malnutrition. In late November the Global Nutrition Report showed no progress had been made on anaemia in India with over half of Indian women between 15 and 49 years old are anaemic.

Reducing Anaemia in Pregnancy in India— randomized-controlled trial comparing the effectiveness of treatments of iron deficiency anaemia in pregnant women

The RAPIDIRON trial is set to provide evidence to determine if single-dose intravenous iron infusion is more effective and economically feasible in reducing iron deficiency anaemia in pregnancy than the current standard of care of oral iron supplements.

Apellis (APLS) Gets Committee for Medicinal Product for Human Use (CHMP) Nod for Rare Blood Disorder Drug

The European Medicines Agency's CHMP has recommended market authorisation for 'Aspaveli' (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria, a disorder characterised by red blood cells destruction, blood clots and impaired bone marrow function.

2.4 Sickle cell disease

The most common type of sickle cell disease is sickle cell anaemia. It results in abnormality in the oxygen-carrying protein haemoglobin found in red blood cells – leading to a rigid, crescent shape red blood cell. Symptoms that may develop include attacks of pain (known as crisis), anaemia, swelling in the hands and feet, bacterial infections and stroke.

The National Institute for Health Care Excellence (NICE) recommends first treatment in two decades for sickle cell disease

Made by Novartis, the new treatment is a drug called 'Adakveo' (crizanlizumab) administered intravenously alongside standard treatment. An initial trial showed those on treatment had a crisis 1.6 times a year on average, compared with control patients having nearly three crises a year. Clinical trials will continue with the National Institute for Health and Care Excellence (NICE) recommending use under a

special arrangement in those over 16 years old. Draft guidelines were published on 5 October 2021 with over 300 people expected to receive the treatment per year via a managed access agreement.

American Society of Haematology issues guideline on the use of haematopoietic stem cell transplantation (HSCT) for sickle cell disease

Clinical guidelines published at the end of September list eight conditional recommendations for the use of HSCT in sickle cell disease.

Screening of newborns for sickle cell disease debuts in sub-Saharan African countries

A program has launched in Africa to screen for sickle cell disease in newborns over the next five years. More than 300,000 babies are born with the disease every year in sub-Saharan Africa and between 50 and 80 per cent of these children do not live past the age of five. Research will be focused on the long-term benefits of newborn diagnosis and early clinical intervention to increase the chances of survival.

Experimental experience of triple-knockout pig red blood cells as potential sources for transfusion in alloimmunized patients with sickle cell disease

A small-scale study suggests that pigs with certain genes extracted may be an alternative source of red blood cells in an emergency, if no human cells are available for sickle cell disease transfusions.

2.5 Blood cancers

Blood cancers develop when blood cells are not formed properly in bone marrow or the lymphatic system. This hinders the body's ability to fight infection and function to full capacity. Treatment is highly variable from monitoring to chemotherapy and stem-cell transplants.

Bone marrow transplant for acute myeloid leukemia (AML): Survival rate, risks, and more

Newly published research suggests bone marrow transplant can improve survival rates for some people with AML. It does this by replacing the damaged cells with healthy ones, reducing a person's chances of bone marrow damage and AML relapse.

FDA hits the red light on an early-stage Acute myeloid leukemia (AML) study after a patient dies

The FDA has put a hold on a clinical trial of a Kura Oncology cancer drugs 'KO-539' after the death of a patient who had failed four previous treatments and was on the lower dose of the drug. AML is a type of bone marrow cancer which makes a large number of abnormal blood cells.

Researcher works to ease side effects like graft-versus-host-disease that plague bone marrow transplant patients

Bone marrow transplant is used as a treatment for leukemias, lymphomas, aplastic anaemia, immune deficiencies and some solid tumour cancers. The treatment has harmful side effects on around 70 per cent of transplant recipients. This is caused by the immune system response to introduced blood cells. The

reaction is known as graft-versus-host-disease. Research is underway investigating why some cells attack the recipient's healthy tissue and others assist in fighting cancer.

National Institute for Care and Excellence (NICE) recommends Inrebic for rare blood cancer

NICE have issued a final appraisal determination recommending the use of 'Inrebic' (fedratinib) on the NHS for the treatment of myelofibrosis, a rare blood cancer affecting the bone marrow and disrupting the body's production of blood cells. The same drug was approved for use by the FDA in the United States in August 2019.

Drug enhances bone marrow transplant outcomes for leukaemia patients

Researchers have identified that the drug 'interferon' can reduce the risk of leukaemia recurring when administered in combination with a bone marrow transplant.

Protein could help bone marrow transplants

Bone marrow transplants can be a treatment for cancers such as leukaemia, myeloma and lymphoma. New research has found that a naturally occurring protein could protect blood cancer patients from the potentially deadly side-effects of bone marrow transplants.

Risk factors for intracranial haemorrhage in adults with acute leukemia

Intracranial haemorrhage (ICH) is a rare but serious complication in patients with acute leukemia. It refers to acute bleeding inside the skull or brain. Researchers have found that older age and more proliferative disease appear to be associated with ICH.

Preventing leukemia by preventing rogue blood

Clonal haematopoiesis happens when a mutant haematopoietic stem cell, which can develop into different types of blood cells, starts making cells with the same genetic mutation and forms a distinct population. If this rogue clone acquires more mutations, it can turn to leukemia. Researchers are investigating whether these rogue populations could be picked up early to prevent potentially fatal leukemia from ever starting.

Maintenance therapy after second autologous hematopoietic cell transplantation for multiple myeloma

Maintenance therapy after high-dose chemotherapy and first autologous transplantation in multiple myeloma is well established. Researchers were able to conclude that maintenance after a second autologous haematopoietic cell transplant was associated with improved 5-year outcomes.

FDA extends review of Johnson & Johnson and Legend's cell therapy for multiple myeloma

A delay of three months is anticipated for the Food and Drug Administration approval decision on a multiple myeloma cell therapy known as 'cilta cel'. The delay is based on a need for evaluation of 'updated analytical method' for the treatment.

2.6 CAR-T therapy

T-cells are a type of immune system cell taken from a patient's blood and then modified with special receptors targeting the patient's cancer cells, called a chimeric antigen receptor (CAR) and then infused back into the body.

FDA grants orphan drug designation to dual-target CAR-T for advanced multiple myeloma

Orphan drug designation in America has been granted for 'GC012F', a novel CAR-T for relapsed or refractory multiple myeloma. Like other CAR T-cell treatment, it produces patient derived therapy within 24 hours which targets certain antigens and proteins on the surface of cancer cells. It is also currently under evaluation in China.

Priority review for Novartis CAR-T cell therapy Kymriah

The Food and Drug Administration (FDA) and European Medicines Agency (EMA) have both accepted Novartis' 'Kymriah therapy' for review as a treatment for adult patients with relapsed or refractory follicular lymphoma after two lines of prior treatment. Currently Kymriah is approved by the FDA, EMA and Australian Therapeutic Goods Administration (TGA) for the treatment of relapsed or refractory acute lymphoblastic leukaemia (ALL) and relapsed or refractory adult diffuse large B-cell lymphoma.

New findings may help widen therapeutic interventions for B-cell acute lymphoblastic leukemia

A retrospective study has found a CAR T-cell immunotherapy drug 'tisagenlecleucel' demonstrated safety and efficacy in paediatric patients with relapsed and refractory B-cell acute lymphoblastic leukemia.

Brexucabtagene Autoleucel Approved for Relapsed or Refractory B-Cell Precursor acute lymphocytic leukemia

The FDA has approved a CAR T-cell therapy 'brexucabtagene autoleucel' for treatment of adult patients with relapsed or refractory B-cell precursor acute lymphocytic leukemia. The FDA decision is based on data from a single-arm multicentre trial.

Gilead wins approval of CAR-T therapy in adult leukemia

A therapy called 'Tecartus' is now approved in America to treat adults with acute lymphoblastic leukemia. This is the treatment's second clearance by the FDA and the first for a so-called CAR-T drug in people with blood cancer who are older than 25.

CARsgen Announces CAR T-cell Product Candidate CT041 Granted Priority Medicines (PRIME) Eligibility by the European Medicines Agency (EMA)

The EMA has granted priority medicines eligibility for a CARsgen CAR T-cell product for the treatment of gastric/gastroesophageal junction cancer.

2.7 Immune system and immunotherapy

Efficacy and safety of intravenous and subcutaneous immunoglobulin therapy in idiopathic inflammatory myopathy: A systematic review and meta-analysis

Idiopathic inflammatory myopathy (IIM) and juvenile dermatomyositis (JDM) are conditions of skeletal muscle and skin inflammation. Researchers have concluded that Ig therapy improves muscle strength in patients with refractory IIM, but evidence on Ig therapy in new-onset disease and extra-muscular disease activity is uncertain.

Discovery Points to a Crucial Role Red Blood Cells Play in Our Immune Systems

A recent study has confirmed that red blood cells do more than previously thought, also playing a critical role in inflammation. Researchers agree that looking at red blood cells differently and how these findings might apply to different diseases has the potential to inform future diagnostics and therapeutics.

The promise and perils of immunotherapy

A review paper examining the fast-growing field of research with preclinical and clinical studies evaluating novel treatment strategies and therapeutic combinations of immunotherapeutic treatment. The authors highlight recent advances and discuss controversies and future direction for hematologic oncology and blood-related diseases.

Study Evaluates Intravenous Immunoglobulin (IVIg) in Treating Multisystem Inflammatory Syndrome in Children

Intravenous immunoglobulin (IVIg) has been found to target an activated type of white blood cell showing promise in treating some children with inflammation in Kawasaki disease and multisystem inflammatory syndrome (MIS). Both Kawasaki and MIS cause inflammation in blood vessels throughout the body.

Corticosteroid treatment for Primary immune thrombocytopenia (ITP)

Primary ITP is an acquired autoimmune disorder which increases patient bleeding risk typically treated with corticosteroids. However, 80% of adult patients will experience treatment failure or become dependent on them and require second line therapy. Researchers recommended trialling any of the newer medications that are continuously being developed and evaluated in randomised clinical trials over the therapies with less validation, for later use if required. Researchers also stated that the number of patients unresponsive to or dependent on corticosteroids may able to be reduced in future through more aggressive initial treatment.

The single-use, multiple-pass protein A adsorber column in immunoadsorption

Immunoadsorptions (IA) are used to remove autoantibodies from plasma, as an option to treat patients with severe autoimmune-mediated diseases as such as myasthenia gravis or stiff-person syndrome.

Researchers have looked at what impact the use of IA had on patients' blood and any resulting clinical effects.

Sutimlimab suppressed cold agglutinin disease (CAD) response in heart surgery patient

CAD is a rare autoimmune disorder characterised by the premature destruction of red blood cells. A recent case study report suggests red blood cell destruction can be prevented using the drug 'sutimlimab', along with other measures, for patients with CAD who are undergoing major surgery.

NICE approves first long-acting jab for HIV to replace daily pills

NICE has published draft guidance recommending the first long-acting injectable treatment for the blood-borne HIV-1 infection in adults. HIV-1 is the most common type of two strains of HIV, both of which remain incurable despite scientific advances. The current standard of daily multi-tablet regimens can be difficult with drug-related side effects, toxicity and other psychosocial issues. This longer acting drug offers the first alternative to the daily antiretroviral drugs with only six injections a year.

With safety a concern, Merck and Gilead pause study of HIV drugs

A clinical trial of a combination of drugs 'islatravir' and lenacapavir for HIV has stopped enrolling patients after safety signals from another combination trial they were conducting. This trial found that patients who received a combination of 'islatravir' and 'MRK-8507' had decreases in certain kinds of white blood cells. The companies said they remain optimistic about the pairing of islatravir and lenacapavir, and that participants already enrolled will keep receiving the drugs. They will also continue to be monitored per the current protocol.

2.8 Research, industry and developments

10 research funding wins in haematology: NHMRC grants announced

$36 million has been announced for a wide range of research projects in research and treatment across malignant and non-malignant haematology.

AstraZeneca to buy rare disease drug maker Caelum in small deal

Light chain amyloidosis is caused by defective plasma cells, resulting in misfolded proteins that can build up in organs and cause organ failure or death. The drug CAEL-101, developed by Caelum, is an antibody that binds to the misfolded proteins and holds promise as a new drug. AstraZeneca is intending to buy the rare disease drug maker Caelum to progress this drug.

Blood could be manufactured for transfusion within a decade after 'Rosetta Stone' moment for embryo scientists

Embryonic development from 14 to 21 days is a vital part of human development as uniform stem cells evolve into different types of cells for specialist functions. Due to a legal ban on keeping embryos in labs longer than 14 days, this development not been studied. However, observations carried out from an

aborted embryo have significantly increased understanding on the formation of red and white blood cells. This breakthrough may go a long way to enabling researchers to mimic the process and mass-produce blood resolving shortages. This kind of development is likely still a decade away.

CSL hunts for start-ups to keep local ideas, research onshore in Australia

CSL Behring is searching for start-ups to move into its new Melbourne headquarters as it launches an incubator program with the intention to keep Australian research and ideas onshore. The program is designed to help researchers learn how to bring new products to the market with CSL Behring's understanding of commercial aspects of medicine development.

FDA shakes up hepatitis C testing market by opening up 510(k) pathway

Certain hepatitis C antibody and nucleic acid testing has been reclassified by the FDA to come to market via a less-burdensome pathway for the first time. This change has been welcomed by manufacturers including the main providers. The change should increase competition without affecting safety and effectiveness.

AstraZeneca, after years of delays, opens UK hub meant to recharge drug research

AstraZeneca has officially opened a new headquarters and research hub in Cambridge, UK. The drug maker is seeking to revitalise its R&D pipeline by creating new ties with academics and small biotech as well as consolidating most of its British operations under a single roof.

New Mechanism Underlying Red Blood Cell Aging Revealed

A study has found an important biophysical mechanism underlying red blood cell aging in which deprivation in oxygen can lead to mechanical degradation of the red blood cell membrane.

Investigation of Bacterial Infections Among Patients Treated with Umbilical Cord Blood

Unapproved stem cell products can expose patients to serious risk without proven benefit. Sequencing has suggested a common source of extensive contamination, likely occurring during processing of cord blood into products.

Altered Red Blood Cell Process May Contribute to Lupus

Researchers found that Lupus may be triggered by a defective process in the development of red blood cells. The research found that a large number of patients with lupus had red blood cells with detectable levels of mitochondria, with higher levels more common in patients with severe lupus, while the control subjects had no mitochondria-containing red blood cells.

Rare Case of Myasthenia Gravis and Bone Marrow Disorders Reported

In myasthenia gravis (MG) the immune system produces self-reactive antibodies that erroneously attack neuromuscular receptors and other proteins involved in nerve-muscle communication, causing muscles to become weaker. A patient diagnosed with MG in the 1990's has recently had lab tests confirm they also have aplastic anaemia, a rare condition in which red blood cells are destroyed faster than they are made.

The patient has been safely treated and, although extremely rare to have both, it is believed the conditions could be linked in their mechanisms of action.

All American adults under 60 should get hepatitis B shots

The Advisory Committee on Immunisation Practices has unanimously approved the recommendation for all United States adults under 60 to be vaccinated against hepatitis B, as progress against the liver-damaging disease has stalled.

US Food and Drug Administration (FDA) Approves Treatment for Rare Blood Disease

The FDA has approved an injectable drug known as 'Besremi' to treat adults with polycythemia vera – a rare blood disease that causes the overproduction of red blood cells. Excess blood cells can be removed either via a procedure or medication such as this new drug. This is the first approved therapy specifically for this disease and can be taken regardless of treatment history.

Study Suggests a Better Blood Thinner Could Be Near

The benefits of blood-thinning pills have long been known to add to the risk of excess bleeding. An experimental anti-clotting drug 'milvexian' has been found effective in patients who have had knee replacement surgery, without adding to the excess risk of bleeding. The knee replacement cohort was chosen as they are known to be at high risk for blood clots after surgery which can be readily detected with x-rays of the veins of legs.

Lack of important molecule in red blood cells causes vascular damage in type 2 diabetes *and* MicroRNA in red blood cells causes vascular damage in type 2 diabetes

Patients with type 2 diabetes are known to have an increased risk of cardiovascular disease. The mechanism underlying this cardiovascular injury have been largely unknown with treatments lacking. Research in recent years has shown altered function in red blood cells may be the cause. Results from a new study in cells from mice and patients with type 2 diabetes show that this effect is caused by low levels of an important molecule in red blood cells.

3 Transfusion

This section includes published research and industry publications on transfusion procedures to improve patient outcomes and reduced wastage of blood products.

3.1 Paediatrics

Transfusion Outcomes in Very-Low-Birth Weight Infants Associated with Donor Sex and Age

Researchers in Atlanta Georgia, have evaluated very low body weight (VLBW) infants following transfusions and found significant association in donor gender, age and number of transfusions and outcomes for the infant. Larger studies are needed to confirm initial findings that red blood cells from older female donors are associated with protection from severe clinical outcomes in VLBW infants.

Red blood cell storage duration and peri-operative outcomes in paediatric cardiac surgery

Researchers found transfusing red blood cells stored for a longer duration was not associated with an increased risk of morbidity or prolonged length of stay in paediatric cardiac surgery.

Paediatric trauma: Blood product transfusion characteristics in a paediatric emergency department, a single centre experience

This study finds no significant difference in mortality between those who received massive transfusion and those who did not.

Necrotizing enterocolitis (NEC) and mortality after transfusion of ABO non-identical blood

Researchers concluded that ABO non-identical transfusion was not associated with NEC or mortality in neonates with NEC. It was associated with increased mortality in neonates without NEC.

Exchange transfusion in the management of critical pertussis in young infants: a case series

Early exchange transfusion may be a useful and rapid lifesaving treatment in children with critical pertussis (whooping cough) and severe leucocytosis before cardiopulmonary complications appear.

Association between the length of storage of transfused leukoreduced red blood cell units and hospital-acquired infections in critically ill children

Researchers investigated the use of leukoreduced red blood cell units (RBCs with donor leukocytes filtered) that had been stored for 35 days or more. Researchers found the longer storage was associated with increased hospital-acquired infection incidences in otherwise stable critically ill children.

Patterns of paediatric massive blood transfusion protocol use in trauma and non-trauma patients

Although infrequently required in children, massive blood transfusion can be a lifesaving intervention for excessive bleeding or clotting. However, there are highly variable product volumes and ratios as well as unknown optimal component ratios in the paediatric population. Researchers have found that a massive blood transfusion protocol for trauma patients can be applied to non-trauma, but standard components may not be optimal for all children. This research shows that underling patient diagnoses may be a factor when designing a protocol for the paediatric population.

3.2 Management

A comparison between liquid group A plasma and thawed group A plasma for massive transfusion activation in trauma patients

Thawed plasma (TP) has been frozen and can only be stored for five days. Liquid plasma (LP) has never been frozen and can be stored for 26 days. Researchers in this study aimed to determine if LP is of clinical benefit to patients requiring massive transfusion. Through a comparison of TP and LP, researchers did not find a difference between the two plasma states and so suggested LP should be considered an alternative to TP in trauma patients requiring immediate plasma resuscitation.

Red Blood Cell and Plasma Transfusions Decreased in the U.S. (2015-2018)

Previous research in America indicated that red blood cell transfusions started declining in 2008. Plasma transfusions have shown a similar decline, but cryoprecipitate use increased suggesting a widening recognition of hypofibrinogenemia management for patients at increased risk of haemorrhage.

A pilot randomized clinical trial of cryopreserved versus liquid-stored platelet transfusion

Platelets for transfusion have a shelf-life of 7 days, limiting availability and leading to wastage. Cryopreservation at -80°C extends shelf-life to at least 1 year. However, the safety and effectiveness of cryopreservation is uncertain. This randomised controlled trial adds to growing data supporting the safety of the use of cryopreservation of platelets for transfusion.

Two weeks' anticoagulation could replace long-term treatments

For low-risk isolated symptomatic deep vein thrombi patients, current guidelines recommend 6-12 weeks therapy in Australia and New Zealand. A prospective study has shown that just two weeks could help resolve symptoms and prevent thrombus extension.

Application of unsupervised machine learning to identify areas of blood product wastage in transfusion medicine

This paper describes the effective use of unsupervised machine learning for the purpose of investigating wastage in large blood banks, helping guide quality improvement initiatives. These machine learning techniques may be useful tools in determining complex causes of wastage and wastage-associated factors.

Demonstration of a United States nationwide reduction in transfusion in general surgery and a review of published transfusion reduction methodologies

While red blood cell transfusions in surgical procedure can be lifesaving, recent research has shown transfusions are associated with a dose-dependent increase in postoperative morbidity and mortality. The research demonstrates a 27% decrease in general surgery transfusions between 2012 and 2018, with an associated reduction in morbidity and mortality.

Comprehensive patient blood management program can reduce use of transfusions, improve patient outcomes

In the United States, a growing number of hospitals have implemented patient blood management programs to reduce unnecessary blood transfusion and costs. An observational study from 2010 to 2018 has shown such a program can not only substantially reduce transfusions, but also reduce length of hospital stay and in-hospital adverse outcomes.

3.3 Research

Preventing transfusion-transmitted malaria in France

In malaria non-endemic countries, transfusion-transmitted malaria is most often caused by *Plasmodium falcipasrum* in recipients of red blood cell components. In France, a combination of blood donor interview

and serological screening has considerably reduced the frequency of this transmission from five cases a year in 1986 to less than 0.2 cases in 2019.

The in vitro quality of X-irradiated platelet components is equivalent to gamma-irradiated components

Blood components are irradiated to inactive lymphocytes in an effort to prevent transfusion-associated graft versus host disease. Researchers examined the invitro quality of platelet components following X- or gamma-irradiation concluding that have similar effects.

Peri-transfusion quality-of-life assessment for patients with myelodysplastic syndromes

Red cell transfusions are given to many patients with myelodysplastic syndromes (conditions in which blood forming cells in bone marrow become abnormal, also known as blood cancer) for symptoms associated with anaemia with transfusions triggered by haemoglobin level. Researchers concluded that while helpful for some, transfusions may not achieve intended goal of improving quality of life.

Relationship between transfusion burden, healthcare resource utilization, and complications in patients with beta-thalassemia in Taiwan: A real-world analysis

Researchers investigated the complexities of treatment of beta-thalassemia and concluded that the clinical and healthcare resource burden of patients is closely related to transfusion burden.

Cryopreservation alters the immune characteristics of platelets

Cryopreserved platelets are being clinically evaluated as they offer improved shelf-life and potentially effectiveness to prevent bleeding. However, the effect on characteristic related to the immune function of platelets has not been examined. Recently published research has determined that cryopreservation alters the immune phenotype of platelets and may influence the likelihood of adverse events.

Effect of storage on survival of infectious Treponema pallidum (syphilis) spiked in whole blood and platelets

Blood donations are routinely tested for syphilis, which can be transfusion transmitted. It is commonly believed the bacterium causing syphilis does not survive in blood during cold storage leading to suggestions that screening may no long be needed. Researchers investigated this possibility and concluded that storage conditions cannot be relied upon to eliminate the bacteria from blood or platelets.

Cold-stored whole blood and platelet counts in severe acute injury: A comparison of four retrospective cohorts

Low-Titer Group O Whole Blood (LTOWB) is unseparated blood collected from donors with low IgM and/or IgG. The product can be stored or given fresh. LTOWB is preferred for acute trauma care as it delivers concentrated and balanced haemostatic resuscitation in a single bag. There is uncertainty on the products ability to sustain platelet counts. Recent comparison of four retrospective studies suggests to support the use of LTOWB as a platelet source.

Transfusion 2024: A five-year strategy to make transfusion care safer across NHS

This newly published report for NHS providers and other key stakeholders sets key priorities for clinical and laboratory transfusion practices for safe patient care over the next five years. Access to the full report and a podcast outlining the key objectives is here.

High B-cell activating factor levels in multi-transfused thalassemia patients

Research has indicated B-cell activating factor (BAFF) levels were elevated in multi-transfused thalassemia and the BAFF to absolute lymphocyte ratio was associated with red blood cell (RBC) immune response to foreign antigen(s) from genetically different blood.

4 Gene therapies

This section includes industry updates and research on the progress of gene therapies though regulatory bodies as well as gene therapy safety.

4.1 Blood related gene therapies

Bluebird, after delays, gets speedy FDA review for beta thalassemia gene therapy

By May 2022, the FDA will decide on Bluebird bio's gene therapy for beta thalassemia, a condition in which the production of haemoglobin is reduced. If approved, the treatment 'beta-cel' would be the third gene therapy cleared in the US for an inherited disease. The treatment consists of a patient's own stem cells, extracted and genetically modified to express a gene that is missing or dysfunctional in people with beta thalassemia.

CRISPR Therapeutics touts new results as fresh questions surround 'off-the-shelf' CAR-T

The biotech's lymphoma treatment initially seems as potent as earlier cell therapies, but its effects waned, adding to doubts about off-the-shelf CAR-T.

ALLO-605 Receives FDA Fast Track Designation for Relapsed/Refractory multiple myeloma

ALLO-605 is an allogeneic, gene-edited, BCMA-directed CAR T-cell therapy. Phase I trial evaluating safety, feasibility and recommended phase II does has begun enrolling patients with relapsed or refractory multiple melanoma.

Allogeneic CAR-T trials paused due to chromosomal abnormality detected in patient

ALLO-501a is a Stage IV transformed follicular lymphoma treatment. The FDA has placed a hold on the study after a patient who received the drug was reported to have a chromosomal abnormality that may be related to treatment.

NICE recommends gene silencing therapy for porphyria patients on NHS

The National Institute for Health and Care Excellence (NICE) have recommended the use of 'givosiran', a gene silencing therapy, on the NHS in England, as an option for the treatment of acute haptic porphyria

(AHP), a painful disease usually first seen in young women in their 20s. AHP involves the loss of heme proteins that help make red blood cells. Using a 'gene silencing' approach, researchers can now target the production of toxic compounds that have the potential to wreak havoc in the body – tackling the cause of a patient's attacks at the source.

Beam gets green light to begin first clinical test of base editing

The FDA have given the green light to proceed with the first clinical trial testing a new type of gene editing. The therapy is designed to treat sickle cell disease by reactivating a form of the oxygen-carrying protein haemoglobin that normally disappears soon after birth.

4.2 Regulatory and industry developments

Building a Bridge of Equivalence to Facilitate and Implement Rapid Process Changes in Gene Therapy Manufacturing

The gene therapy market is expanding globally at approximately 30% annually. A current challenge is that there is no clear regulatory path for establishing equivalency of gene therapy manufacturing processes, and this is limiting greater progress toward more cost-effective treatments.

Bluebird, winding down in Europe, withdraws another rare disease gene therapy

Skysona, a treatment for inherited neurological disorder called cerebral adrenoleukodystrophy, has been approved by European regulators in July 2021. A month later Bluebird announced it would shut operation in Europe to focus on the US.

Analytic Considerations in Applying a General Economic Evaluation Reference Case to Gene Therapy

Gene therapy is a novel approach that uses specific genetic material to treat or prevent disease. It has been argued that these therapies have special characteristics that pose new challenges for economic evaluation. The article provides a detailed analysis of the special characteristics of gene therapy, discusses what changes in methods may be necessary, and outlines the particular factors which analysts and decision makers (such as the NBA) should pay particular attention to.

4.3 Non-blood related

Gene therapy developer gets chance at a comeback with Pfizer deal

Pfizer has clinical stage gene therapy programs in Duchenne muscular dystrophy and haemophilia. Voyager has developed a new technology dubbed TRACER, more specific to cell and tissue than previous gene therapy attempts, and Pfizer has paid $30 million USD for a chance to licence the viral shell.

Recent Gene Therapy Deaths Raise Safety Concerns

In response to safety concerns include the death of a young boy with rare neuromuscular disease, the FDA held a two-day public meeting with external experts to discuss managing potential serious side effects associated with gene therapies.

5 COVID-19

This section contains news articles, peer reviewed papers and industry publications on the changing COVID-19 pandemic and management of the virus across the world including effects on blood and related services.

5.1 COVID-19 effect on blood, blood diseases and related services

Motivation, blood donor satisfaction and intention to return during the COVID-19 pandemic

This study describes the motives and well as donation experiences and intentions to return for further donations of German whole blood donors, who donated at the beginning of the COVID-19 pandemic.

Inflammatory micro clots in blood of individuals suffering from Long COVID

New research indicates that an overload of various inflammatory molecules become 'trapped' inside insoluble microscopic blood clots and may be the cause of lingering symptoms in individuals with long COVID-19.

Long-lasting immune abnormalities detected in recovered COVID-19 patients

Australian research, yet to be peer-reviewed or published, has found substantial dysregulation of immune cell numbers strongest at 12 weeks post infection but still evident in most cases up to six months. Further research is required to confirm these findings.

Details behind kidney transplant recipients' immune response to the virus that causes COVID-19: Recipients mount a slower IgG antibody response following infection

Findings from research indicate that the antibody response to COVID-19 infection is delayed production of IgG antibodies with IgM and IgA responses being similar in those observed in induvial who had not received a transplant.

Serum albumin independent risk factor for severe infection and mortality in COVID-19

Reduced serum albumin levels in patients hospitalised with COVID-19 appears to be an independent risk factor for severe disease and mortality.

Researchers identify COVID-19 proteins that cause blood vessel damage

Researchers have identified five of the 29 proteins of COVID-19 that are responsible for damaging blood vessels. In severe COVID-19 cases there is a high incidence of vascular disuse and blood clotting. The hope is this identification of specific proteins will assist in developing targeted drugs for COVID-19 that reduce vascular damage.

Poor overall survival in bone marrow transplant patients with COVID-19

Research has found patients who have undergone haematopoietic stem cell transplantation (HSCT) and develop COVID-19 have poor overall survival rates, underscoring the stringent surveillance and pre-emptive measures against COVID-19 in this patient group.

Effect of the first year of COVID-19 pandemic on the collection and use of blood components in Colombia monitored through the national hemovigilance system

Researchers reviewed the National database of confirmed cases of COVID-19 and the National Hemovigilance Systems and concluded that mandatory lockdowns in Colombia decreased both blood collection and usage resulting in a reduction of blood component transfused.

How Age Impacts Post-COVID Antibody Numbers

Researchers were surprised to find that antibodies produced by naturally infected individuals 50 and older provided a greater degree of protection than adults below 50 years of age.

Successful treatment of COVID-19-related acute respiratory distress syndrome with a rare blood type

People with rare blood types, or those who refuse blood transfusion, do not benefit from extracorporeal membrane oxygenation (ECMO), when being treated for COVID-19. ECMO, is a procedure where blood is pumped outside the body to a heart-lung machine that re-oxygenates blood and then returns it to body. Conservative fluid management should be considered for better oxygenation in this case.

5.2 COVID-19 news

Study Finds Gene Linked to Higher Risk of Severe Covid-19

A gene known as LZTFL1 has been associated with increased incidence of critical symptoms such as separatory failure among people infected with COVID-19.

For unvaccinated, reinfection by COVID-19 is likely

For those who are unvaccinated, strong protection following natural infection is short lived and infection reasonably possible in three months or less.

Measures against COVID-19 may have eliminated a strain of flu

A study from the University of Melbourne suggests the Yamagata strain of influenza virus type B may have disappeared or gone into a dormant state following lockdowns and COVID-19 preventative measures.

5.3 COVID-19 Policy and Industry

Australia

Australian hospitals will cope under strain of COVID-19 cases, health boss says

National Cabinet was been provided with a Doherty Institute modelling report on the demand on state and territory hospitals, as the country reopens and case numbers increase. In early October, Health Department Secretary, Prof. Brendan Murphy stated hospitals will be able to cope with increased case numbers. National Cabinet will decide if this report will be made public.

Victoria, Australia: 1000 healthcare workers to be recruited

The Victorian Government will spend $2.5 million to recruit up to 1,000 healthcare workers from overseas to help ease the pressure on hospital systems dealing with COVID-19.

North America

With federal sign-offs, all American adults now eligible for coronavirus vaccine boosters

A "booster for all policy" has made all American adults eligible for COVID-19 boosters last Friday, ending months of confusion over varying and complicated guidelines.

Moderna faces new delay in plans to bring coronavirus vaccine to American youth

The Food and Drug Administration needs more time to review Moderna's request to clear its COVID-19 shot for use in adolescents, due to risk of heart inflammation seen in rare cases. This comes just days after the FDA authorised Pfizer and BioNTech's shot for children as young as five.

Johnson & Johnson foresees end to not-for-profit sales of coronavirus vaccine

By late 2022 or early 2023, Johnson & Johnson expect to shift to for-profit sales.

Europe

European Medicines Agency supports molnupiravir prior to formal authorisation

Emergency use advice has been issued to support the early use of Merck's molnupiravir, the oral antiviral drug for the treatment of patients with COVID-19, despite the EU regulator still yet to formally authorise the drug.

Under-18s with COVID-19 in UK advised to wait 12 weeks for vaccine dose

New clinical guidance in the UK provides advice for vaccination for 12 to 17-year old's to delay the COVID-19 vaccination for 12 weeks following a positive COVID-19 test result.

Blood donation in times of crisis: Early insight into the impact of COVID-19 on blood donors and their motivation to donate across European countries

Researchers have conducted a survey aimed to provide early insight into the impact of COVID-19 on blood donors and their motivations to donate during the crisis. Suggestions from the authors include that blood collection services consider specialist campaigns that focus on the altruistic motivation of donors during crisis and a continued communication of additional safety measure in place whilst donating.

United Kingdom disposed of 600,000 Astra-Zeneca vaccine doses after they passed expiry date

The wastage of more than 600,000 doses of Astra-Zeneca is being labelled a 'absolute scandal' as doses were not donated to poorer countries with low rates of vaccinations.

Asia

Singapore will stop paying the medical bills of unvaccinated COVID-19 patients

Singapore has opted for 'user pays' for COVID-19 treatment if the person is unvaccinated.

5.4 COVID-19 Research and Treatment

ANU research finds Indigenous adults at risk of severe illness from COVID if unvaccinated

A study from the Australian National University has reinforced the need for Aboriginal and Torres Strait Islanders to remain a priority group for vaccination.

Large Study Finds Convalescent Plasma Doesn't Help Seriously Ill COVID-19 Patients

Convalescent plasma does not reduce risk of incubation or death for hospitalised COVID-19 patients. More than half a million American hospitalised with COVID-19 have been treated with plasma from COVID-19 survivors.

Coronavirus vaccines are rolling out quickly. Here's where the pipeline stands

This is a summary of COVID-19 vaccines that have made it to market globally, including efficacy and a detailed summary of each company's approach, supply targets, funding and development timeline.

FDA advisers support Pfizer's coronavirus vaccine for young children

In the USA, an expert panel this week endorsed the use of Pfizer's COVID-19 vaccine for 5- to 11-year-olds, judging the benefits to outweigh the safety risks.

FDA authorizes additional Moderna, J&J shots, broadening booster rollout

Millions more are eligible from as FDA expanded authorisations for Moderna and Johnson & Johnson booster shots.

Prescribed blood thinners can help reduce hospitalizations related to COVID-19

The National Institute for Health has reported that many with COVID-19 develop abnormal blood clots from high inflammation which can lead to compilations. A study has found that prescribing blood thinners can reduce hospitalisations.

Specific ultraviolet (UV) light wavelength could offer low-cost, safe way to curb COVID-19 spread

UV light is not only extremely effective at killing the virus but is also safer for use in public spaces, new research has found.

AstraZeneca pursues approval for COVID-19 antibody cocktail

AstraZeneca has submitted an emergency approval to drug regulators for its COVID-19 antibody cocktail, the first non-vaccine protection from the virus to be granted approval in America.

Pfizer pill for COVID-19 shows dramatic benefit in major study finding

Trial results of a new COVID-19 pill from Pfizer called Paxlovid may be the second effective oral treatment after Merck's molnupiravir. The new drug showed an 89 per cent reduction in risk for patients who received it within three days of symptoms.

Merck pill could cut COVID risk in half but won't be a 'miracle' cure for coronavirus

An antiviral pill developed by US drug maker Merck could reduce chance of mortality or hospitalisation for those most at risk of contracting severe COVID-19. Merck plans to seek US emergency use authorisation as soon as possible.

Asia-Pacific Countries Rush to Buy Merck COVID-19 Pill

Molnupiravir, the home treatment is reported to halve the risk of hospitalisation and death from the virus. The US has agreed to by enough pills for 1.7 million treatment at a cost of $1.2 billion.

Atea, Roche change plans for oral COVID-19 drug after trial setback

An experimental oral treatment failed to significantly clear viral loads compared to placebo in a mid-stage study of patients with mild or moderate COVID-19.

6 Other items of interest

This section contains general industry and regulator updates as well as developments in non-blood and non-COVID related diseases that may have flow on affects to the blood industry.

6.1 Industry and research & development news

TraumaChek: Next step in life-saving blood-assessment technology

Development is underway on a medical device to quickly assess a wounded soldier's critical clotting issues and other blood conditions on the battle field. If successful this would be the next generation of the successful ClotChip which emergency works can use to measure how well a patient's blood clots.

Europe

In bid to attract more R&D innovation, Europe looks to rewrite its pharma legislation

Europeans are looking to rewrite pharmaceutical legislation before the end of 2022. The purpose is to stimulate new breakthroughs in areas of unmet need, increase the accessibility of drugs across the continent, and make the EU pharma system more attractive.

European Union proposes delay to In Vitro Diagnostics Medical Device Regulation, citing COVID-19 backlog

The European Union is proposing a delay to the incoming medical device regulations pertaining to In Vitro Diagnostics. Originally set to come into effect in May 2022, a progressive roll out is now planned for incoming medical device regulations for products that still need assessment of a notified body.

European Union (EU) task force calls for medical device regulation legacy device surveillance requirements

An EU task force has proposed a grace period allowing products certified under the old directive to come to market after the date of application. Full details of the rules that will apply are lacking.

Australia

Consumers Shaping Health - October 2021

Submissions have recently closed on a Review of the National Medicines Policy (NMP) and of the future strategic directions for the Medical Research Future Fund (MRFF).

Application made to MSAC for Multiple Myeloma highly specialised therapy

Submitted by Janssen Australia and New Zealand, ciltacabtagene autoleucel is a chimeric antigen receptor T (CAR-T) cell therapy for the treatment of patients with multiple myeloma who are refractor or have failed more than three lines of prior therapy. The therapy involves taking the patient's own cells from peripheral blood, enriching them for T-cells (a type of white blood cell essential in the immune system) and genetically modifying them before infusing them back into the patient to treat the MM.

Application for diagnostic genetic testing for variants associated with haematological malignancies

The application has been submitted by the Royal College of Pathologist of Australasia and is targeting next generation sequencing panels focusing on specific genes for the molecular characterisation of haematological malignancies.

Australia's Therapeutic Goods Administration (TGA) mulls mandating medical device adverse event reporting by healthcare facilities

The TGA is seeking feedback on plans to expand mandatory reporting of adverse events linked to medical devices, to healthcare facilities. Currently, only manufacturers and sponsors are required to report adverse events.

Australian Medical Research and Innovation Strategy 2021-2026

The Australian Medical Research and Innovation Strategy 2021-2026 sets out the vision, aims and strategic objectives of the Medical Research Future Fund (MRFF). Published 8 November 2021.

6.2 Other diseases and developments

Causes of Death, Australia, 2020

The Australian Bureau of Statistics has released a report showing that 2020 saw a decrease in mortality, COVID-19 was the 38th leading cause of death with 898 deaths.

Vaccines in development: What we can look forward to in preventing infectious diseases

Worldwide there are more than 2,600 infectious disease vaccines under development. This link contains a summary of the top 14 infectious disease vaccination developments that will have a large impact, particularly in United States paediatrics, if they proceed to the commercial phase.

Study finds new biomarker for a disease caused by bone marrow transplant

Researchers found a consistent elevation of a specific acid molecule in the blood of patients before and during the onset of chronic graft versus host disease. This acid emerged as the single most significant metabolite associated with the disease.

Study reveals how the blood and immune systems develop in prenatal bone marrow

Researchers found that in the space of a few weeks, numerous blood and immune cell types emerge from developing bone marrow, including key white blood cells that protect against bacteria.

6.2.1 Malaria

Breakthrough malaria vaccine offers to reinvigorate the fight against the disease

The World Health Organization has endorsed the first ever vaccine to prevent malaria. Annually half a million people die from the disease or complication. GlaxoSmithKline has shown their product to have efficacy of around 50% against severe malaria in the first year with that figure dropping close to zero by the fourth year. The vaccine, trade name Mosquirx is given in four doses to children between the ages of 5 months and 17 months. The efficacy is about 40% against malaria and 30% against severe malaria.

6.2.2 Dengue and Zika

There were 1,171 dengue cases in the first six days of November after reporting only 1,200 though the whole of October. Nine deaths have been reported in this current outbreak.

- Dengue outbreak: Centre sends central teams to 9 states
- Dengue Cases Piling Up, Outbreak Worst in Several Years: Delhi Hospital
- Delhi Adds 2,570 Fresh Dengue Cases, Tally Highest Since 2015 Outbreak
- Dengue cases cross 5,000 mark, Delhi's highest since 2015 outbreak
- India battles spike in dengue cases amid COVID pandemic

Scientists successfully stop dengue spread through mosquitoes

An international research collaboration, led by a CSIRO scientist, have used a bacterium to sterilise males of the Aedes aegypti species (mosquito) which are known to spread dengue, yellow fever and Zika among other viruses. This has been tried in Queensland and Verily Life Sciences are now looking into trialling the technology in other parts of the world.

Zika cases in other districts put Noida area on alert

Over 100 Zika virus cases have been reported in Uttar Pradesh, the most populated state in India.

Secrets of antibodies: When it comes to dengue and Zika, dengue antibodies can knock out Zika—and vice versa

A longitudinal analysis of children in Nicaragua has unexpectedly revealed that antibodies from either dengue or Zika naturally protect against infections caused by either virus and remain stable for years.

6.2.3 Ebola

Democratic Republic of the Congo (DRC) reports eight Ebola cases

Health officials have confirmed eight cases in a north-eastern province of the DRC. 573 people have been exposed to the virus since its identification. Other reports have been linked below with varying numbers of cases and deaths.

- Five Months Outbreak Ended, DR Congo Again Reports 11 Ebola Virus Cases
- Democratic Republic of the Congo: Eight Cases of Ebola Confirmed in North Kivu

- Two recovered Ebola patients discharged in latest DR Congo outbreak

Johnson & Johnson's two-dose Ebola vaccine regimen is safe, well tolerated and produces a strong immune response

According to two new papers published in Lancet Infectious Diseases, the two-dose vaccine regimen from Johnson & Johnson for Ebola is safe and well tolerated for those over one year old.

University of Oxford begins Phase I trial to test Ebola vaccine

Oxford University is also developing a vaccine for Ebola which has progressed to a Phase I trial. The study will assess the immune response and safety of the new vaccine against the Zaire and Sudan species of Ebola.

6.2.4 Avian influenza outbreaks

Cases of bird flu of various strains have been rising in the last two months with outbreaks of two strains occurring in Asia (H5N6) and Europe (H5N1).

Asia

Chinese health authorities have confirmed 21 human infections with the H5N6 avian flu subtype this year. Below are several articles reporting these outbreaks:

- China confirms human case of bird flu –WHO calls for 'urgent' action to prevent outbreak
- Rise in human bird flu cases in China shows risk of fast-changing variants
- Japan reports first bird flu outbreak of season, culling 143,000 chickens

Europe

The highly contagious H5N1 bird flu has been detected in European bird populations, with no human infections detected at present. The virus spread across Europe during the late October and early November with outbreaks in several countries including France, Germany, Italy and the Netherlands and Denmark.

- Bird flu: France orders poultry 'lockdown'
- Bird flu in Scotland: H5N1 detected in flock of captive birds in Angus
- Poland reports highly pathogenic H5N1 bird flu in poultry
- Germany reports another outbreak of H5N1
- Bird flu is found at sites in Yorkshire and Lancashire

6.2.5 Other

Emerging infectious disease caused by a new nairovirus identified in Japan

A previously unknown virus that can infect humans named Yezo virus is transmitted by tick bites and causes a disease characterised by fever and reduction in blood platelets and leucocytes.