

### **Monitoring International Trends** July – September 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 key topics have appeared in news media, online publications, industry, and research updates and have been included in this report:

**Blood supply:** Australian researchers conducted a cross-sectional national population survey to estimate how many residents were eligible to donate, which incorporated all people eligible after the removal of deferrals for variant Creutzfeldt-Jakob disease (vCJD) was lifted.

**Product development and applications:** An Australia team is part of an international trial to determine if cold stored platelets can be used in complex heart surgeries. The first treatment under the <u>Chilled Platelet Study (CHIPS)</u> took place in August.

**Blood diseases and treatment:** An organ transplant in the US is believed to have resulted in the spread of Legionella bacteria from a donor to recipients. Two people developed Legionnaires' disease after receiving a donated lung.

**Blood practice trends and blood management:** A Nordic study has found a possible link between donors who developed spontaneous intracerebral haemorrhage and the risk of spontaneous intracerebral haemorrhage in patients who received a transfusion of blood from that donor.

<u>Blood practice trends and blood management</u>: The Patient Blood Management Guideline for adults with critical bleeding has been published on the National Blood Authority's website. This is an update to clinical guidance for health professionals providing immediate in-hospital care for adults.



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#### 1.0 Blood supply and demand

#### 1.1 Blood supply Australia

Nationwide search for O and A blood donors with rare blood type to help sick <u>mum</u>

In July Lifeblood launched a nationwide search for blood donors to help a South Australian woman with a rare blood type, with only one in 10 000 people holding the same type. Australians responded and the woman was able to receive blood in early August, including eight units from overseas donors from the United Kingdom and France.

#### <u>Blimey! UK blood and plasma donors exceed expectations after 'mad cow' rule</u> <u>change</u>

Donations from ex-UK residents have added more than 123,000 blood and plasma donations to the Australian blood supply since the deferral for possible exposure to variant Creutzfeldt-Jakob Disease (vCJD) was lifted. Lifeblood anticipated the rule change would result in 18,000 new donors, but more than 34,000 new donors registered to donate in the first 12 months.

#### Prevalence of blood donation eligibility in Australia: A population survey

Australian researchers conducted a cross-sectional national population survey to estimate how many residents were eligible to donate. The study incorporated people who were able to give blood for the time after the removal of deferrals for variant Creutzfeldt-Jakob was lifted and included Australian residents over the age of 18. Researchers estimate that around 10.5 million people in Australia are eligible to donate blood with 14.2% of those eligible at the time of survey donating blood within the previous 2 years.

<u>Defence urges public to join annual Defence Blood Drive and save lives</u> The Australian Defence Force (ADF) blood drive took place in September and

this year the ADF invited the public to get involved. The ADF aimed to raise 11,000 blood donations across the services and appealed for the public to also assist by also donating blood in support of the drive.



#### 1.2 Blood supply USA

#### Blood shortage continues, please give blood now

The American Red Cross declared a national blood shortage in September due to a critically low blood supply level that dropped by 25% from the start of August. The request for help has seen an increase in donations to the Red Cross but supplies remain low.

### What's behind the current blood shortage? Here's what you need to know about this 'often-invisible emergency'

The blood supply shortage in the United States has been caused by a range of factors including seasonally expected downturns, holiday periods and weather events. However, changes to the way in which people work may also be affecting blood donation regularity, as less contact hours in offices means that coordinated events such as blood drives are a less effective way to collect donations.

#### Supplemental findings of the 2021 National Blood Collection and Utilisation Survey

The US Department of Health and Human Services' National Blood Collection and Utilization Survey (NBCUS) estimate national blood collection in the United States. This survey was conducted in 2021 and compared with a previous survey conducted from 2013–2019. Researchers found that, blood donations increased nationally, although donations from younger people aged under 25 years and ethnic minorities declined. On average US hospitals also paid for more for blood products in 2021 than in the previous survey period.

#### **1.3** Blood supply world news

#### <u>Canadian Blood Services in dire need of more blood donors following low</u> <u>summer turnout</u>

Canadian Blood Services has made an urgent request to the public for blood donations, after lower than expected turn out across the summer.

Appointment cancellations were higher throughout the Canadian summer due to increased donor travel which reduced the pool of reliable repeat donors.



#### 2022 SHOT report details transfusion-related events in the UK

The UK Transfusion Serious Hazards of Transfusion (SHOT) annual report has been released for 2022. The report highlights delays and transfusionassociated circulatory overload (TACO) as the most common causes of transfusion-related mortality in the UK. The report also found that the pattern of reports was similar to previous years, but the number of reports increased.

#### Celebrating 25 years of New Zealand Blood Service

The New Zealand Blood Service (NZBS) celebrated its 25<sup>th</sup> anniversary on 1 July. The NZBS was established in 1998 as single, integrated blood service for New Zealand to ensure the safe and sufficient supply of blood and blood products throughout the country.

#### 2.0 Product development and applications

#### 2.1 Red blood cells

Outcomes following perioperative red blood cell transfusion in patients undergoing elective major abdominal surgery: a systematic review and metaanalysis

This study investigated the effect of perioperative blood transfusions on postoperative outcomes in elective abdominal surgery recipients. Researchers reviewed 37 studies published between January 2000 and June 2020 from across the globe to determine the effect of transfusion on complications, mortality and morbidity. They confirmed that perioperative blood transfusion in patients undergoing elective major abdominal surgery is associated with poorer postoperative outcomes.

<u>Transfused red blood cell characteristics and kidney transplant outcomes</u> <u>among patients receiving early posttransplant transfusion</u>

Red blood cell (RBC) transfusion may be required post-kidney transplant, so this study investigated the impact of red blood cell storage duration on survivability of kidney transplant recipients. Researchers reviewed the over 12,000 kidney transplant cases and found that longer RBC storage was associated with longer transplant survival among patients receiving early posttransplant transfusion.



#### 2.2 Plasma products

Early antibody treatment, inflammation, and risk of post-COVID conditions Convalescent plasma has been used to treat COVID-19 patients with severe symptoms since the beginning of the pandemic, however, studies to date have had varying conclusions regarding the impact. This multi-centre comparative study found that patients receiving early convalescent plasma treatment (≤5 days after symptom onset) compared to late convalescent plasma treatment t had statistically significant lower odds of post-COVID conditions.

#### FDA clears plasma product to help test FVIII activity in haemophilia A

The US FDA has approved the use of <u>CRYOcheck Factor VIII Deficient Plasma</u> <u>with VWF</u>, in laboratory settings to identify FVIII deficiency and aid in monitoring FVIII activity in haemophilia A patients.

#### Preclinical development and characterization of a human plasma-derived highpurity factor X concentrate for therapeutic use

Scientists at Bio Products Laboratory have developed a highly purified concentrate to treat hereditary factor X deficiency. The concentrate is manufactured from human plasma and remains stable in a freeze-dried state for at least three years.

### Increasing the time-to-freezing for clinical apheresis plasma meets quality specifications

This Australian study investigated if increasing the time to freezing plasma beyond six hours could alleviate supply issues in remote communities. The researchers suggest that clinical apheresis plasma can be frozen within 12 hours of collection, allowing collections from more remote donor centres and to limit impacts from unexpected transport delays. The findings from this study have been confirmed in a manufacturing validation, and the data has been submitted to the regulatory authority for review.



#### 2.3 Immunoglobulin

Intravenous immunoglobulin can treat myelin oligodendrocyte glycoprotein antibody-associated optic neuritis in paediatric population

In this article researchers outline the case of an eight-year old treated for optic neuritis presenting as chronic relapsing inflammatory optic neuropathy (CRION) successfully treated with intravenous immunoglobulin (IVIg) therapy.

#### Effectiveness of intravenous immunoglobulin therapy for invasive group A Streptococcus infection

This study investigated the effectiveness of intravenous immunoglobulin (IVIg) in the treatment of Invasive group A Streptococcus infection (iGAS). Researchers reviewed 481 cases of iGAS in Japan's nationwide database and found that IVIG administration had no survival benefit but stressed the need for further study to confirm these findings.

#### <u>Clinical efficacy of immunoglobulin on the treatment of severe fever with</u> <u>thrombocytopenia syndrome</u>

This study evaluated the efficacy of using intravenous immunoglobulin (IVIg) to treat severe fever with thrombocytopenia syndrome (SFTS). Researchers reviewed over 2,000 patient records and found that IVIg therapy was related to higher viral loads and reduced counts of lymphocytes, T cells, CD4+ T cells and natural killer cells in the blood. The researchers stated that IVIg did not improve patient outcomes and should be administered with caution when treating STFS.

## Effect of intravenous immunoglobulin on the outcome of children with septic shock in a PICU

Researchers investigated the impact of administering intravenous immunoglobulin (IVIg) in the paediatric intensive care unit (PICU) on patients with septic shock. Researchers found that IVIg as an adjuvant therapy didn't reduce in-hospital mortality in patients.

#### Intravenous immunoglobulin may prevent severe infections associated with anti-BCMA therapy for multiple myeloma

Researchers have found that intravenous immunoglobulin (IVIg) can reduce the risk of severe infections by 90% in patients with multiple myeloma undergoing treatment with an anti-BCMA bispecific antibody.



#### 2.4 Platelets

#### Australian first platelet trial could reduce blood loss during surgery

Current practice for platelet management in Australia is store the product at room temperature with constant agitation for no more than 7 days. The <u>Chilled</u> <u>Platelet Study (CHIPS)</u> is an international trial testing cold-stored platelets invitro to determine if they are a viable option in complex heart surgeries, with first Australian treatment taking place in August. Cold-storing platelets could improve the life span of the product from one to three weeks, and it is theorised that the process may also reduce bleeding in complex surgeries.

#### Biochemical and functional characteristics of stored (double-dose) buffy-coat platelet concentrates treated with amotosalen and a prototype UVA lightemitting diode illuminator

In this study researchers compared the in vitro quality of stored buffy-coat (BC) platelet concentrates (PCs) treated with a prototype light-emitting diode (LED) illuminator versus regular broad-spectrum UVA illumination. Researchers found that replacing the UVA lamp for photochemical treatment with LED illuminators had no impact on platelet metabolism, spontaneous activation, apoptosis or viability, or on the in vitro function of BC-PCs. These findings support improved procedures for the pathogen reduction and storage of PCs.

#### 2.5 Gene therapies

#### NICE rejection for CSL Behring gene therapy

The UK's National Institute for Health and Care Excellence (NICE) issued <u>a draft</u> <u>appraisal document in August</u> which recommend against the use of CSL Behring's Haemophilia B gene therapy, Hemgenix (etranacogene dezaparvovec). NICE, cited concerns about the drug's effectiveness relative to other therapies, long-term durability and cost-effectiveness. The single dose therapy was costed at US \$3.5 million when it received FDA approval in November 2022.



#### Delivery of gene therapy in haemophilia treatment centres in the United States: Practical aspects of preparedness and implementation

As gene therapy for the treatment of haemophilia becomes more prevalent, healthcare providers will need to adapt to provide patients with the high-level care. The authors of this review examine the effects of gene therapy on patient care and service delivery based clinical experience and an examination of current literature, noting that successful implementation of this new treatment modality will require communication and collaboration among multiple stakeholders. The authors note that while this article reflect experiences and expertise leveraged from US there may be applicability for patients across the globe. In Australia the Australian Haemophilia Centre Directors' Organisation (AHCDO), has developed the <u>Gene Therapy Roadmap</u> to provide a Clinical Implementation Plan that sets out a preferred approach to implementation of gene therapy for haemophilia in Australia.

#### 2.6 Cell therapies

#### Infections in haematology patients treated with CAR-T therapies

This study looked at reports of patients treated with CAR-T therapies to identify the instances of infection, according to their underlying haematological malignancy. Researchers found that 17% of patients experienced a serious infection after CAR-T therapy, with bacterial infections being more common than viral or fungal infections. Higher grade infections were most common in patients receiving therapy for multiple myeloma.

#### 2.7 Immunotherapy

FDA approves GSK's momelotinib for myelofibrosis patients with anaemia THE FDA has approved the use of Ojjaara (momelotinib) for the treatment of myelofibrosis in adults with anaemia. In a phase 3 trial Ojjaara was effective in terms of alleviating symptoms, improving splenic response and increasing transfusion independence.



#### 3.0 Blood diseases and treatment

#### 3.1 Haemophilia

<u>Bleeding Disorders Awareness Month - Haemophilia Foundation Australia</u> October was Bleeding Disorders Awareness Month in Australia and this year's theme was 'Working Together'. People were encouraged to get involved with <u>an official event</u> or learn more about haemophilia, von Willebrand disease and related inherited bleeding disorders.

The in vitro effect of anticoagulant agents on coagulation and fibrinolysis in the presence of emicizumab in the plasmas from patients with haemophilia A On-going studies on the effects of Hemlibra (emicizumab) are providing additional context to clinicians when considering prescribing the product. This study anticoagulants affect the coagulation and fibrinolysis potentials in plasma from PwHA spiked with emicizumab.

# Evaluation of treatment and outcome for patients with haemophilia A and haemophilia B on extended half-life (EHL) factor products

Researchers conducted a national retrospective study utilising data from the Australian Bleeding Disorders Registry (ABDR) to determine what outcomes patients with haemophilia had experience on extended half-life (EHL) factor products. Patients with haemophilia had high rates of adherence to prophylactic extended half-life (EHL) factor VIII or IX concentrates, with at least 50% of patients reporting no spontaneous bleeding events during a 1-year period.

#### 3.2 Multiple myeloma

#### FDA grants accelerated approval to Pfizer's multiple myeloma treatment

The FDA granted accelerated approval to the multiple myeloma treatment, Elrexfio (elranatamab-bcmm) in August. Elfrexfio is approved for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy.

#### Vaccine may help boost response to stem cell transplant: Phase 1 trial

This phase 1 trials tested a cell-based vaccine designed to promote immune responses against the protein survivin which helps tumor cells survive and expand. Researchers found that the treatment was safe and feasible for multiple myeloma patients when administered with an autologous stem cell transplant.



#### 3.3 Leukaemia

#### Asian patients with AML may have lower risk of VTE

Researchers have found demographic and individual characteristics may raise the risk of venous thromboembolism (VTE) in patients diagnosed with acute myeloid leukemia (AML).

#### 3.4 Thalassaemia

## Long-term clinical efficacy and safety of thalidomide in patients with transfusion-dependent beta-thalassaemia

Regular blood transfusion is the mainstay of treatment in transfusiondependent beta-thalassaemia (TDT) but transfusions culminate in an array of serious complications. This single-arm, non-randomised clinical trial was conducted in Pakistan with hydroxyurea refractory TDT patients to explore the long-term safety and efficacy of thalidomide in TDT patients, while noting the well documented risks of the treatment. The primary outcomes for efficacy were rise in haemoglobin (Hb) level and changes in transfusion frequency. Researchers found that thalidomide was an effective and well-tolerated drug that could improve Hb levels and reduce transfusion burden in hydroxyurea refractory TDT patients.

#### 3.5 Sickle cell disease

## Impact of Imatinib on reducing the painful crisis in patients with sickle cell disease

In this Iranian study researchers investigated the efficacy of using tyrosine kinase inhibitor (TKI) Imatinib mesylate (Gleevec) for reducing vaso occlusive crises (VOC) in sickle cell disease (SCD) patients resistant to current pain management treatments. Seven patients who were resistant to hydroxyurea and folic acid treatment with a minimum of four crises per year were included. Researchers found that the number of hospitalisations and duration of time in hospital reduced after treatment with requests for pain relief and nonsteroidal anti-inflammatory drugs also reduced. This suggested that Imatinib may be a suitable therapeutic option for reducing painful crises in patients with SCD.

### Mitapivat seen to increase haemoglobin for nearly half in SCD trial: 2 dose groups meet efficacy goal in Phase 2 part of RISE UP study

In this Phase 2 trial researchers found that nearly half of people participants with sickle cell disease experience significant increases in levels of haemoglobin production while taking Mitapivat.



#### 3.6 Myelodysplastic syndromes

## Luspatercept is FDA approved as first-line treatment for adults with transfusion-dependent, lower-risk MDS

In August the US FDA approved luspatercept-aamt (Reblozyl) as an anaemia treatment for erythropoiesis-stimulating agent–naive adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS).

#### 3.7 Other

### Transplanted lungs likely spread dangerous legionella infection to two recipients, study says

Organ transplants in the US resulted in the spread of legionella bacteria from a donor to recipients. Two people developed Legionnaires' disease after each received a donated lungs from a man declared brain dead after drowning. One of the patients recovered, the second died six months after the transplant surgery due to respiratory failure. The <u>CDC has reported</u> that three additional recipients who received an organ transplant from the same donor have had no evidence of legionella infection.

#### 4.0 Blood practice trends and blood management

#### 4.1 Donations

#### Relevance of haemoglobin monitoring in apheresis plasma donors

This Canadian study investigated the effect plasma donation had on haemoglobin (Hb) levels to determine if monitoring these levels pre-donation was necessary. The study reviewed the records of 9535 men and 9409 women who made two or more (up to 16) apheresis plasma donations from October 2020 to October 2022. Researchers found that both men and women maintained their Hb levels above the deferral threshold, although there was a small decrease in Hb levels, suggesting that individuals may not need to monitor as frequently when donating plasma.

#### Effects of donation frequency on US source plasma donor health

In the US compensated donations are more frequent, so researchers from plasma supplier Grifols investigated the effect of frequency of donation on the health of donors. Donors were asked to report on their health in a survey and assigned to a group depending on tier frequency of donation. Researchers found that the US FDA permitted frequency of donation was adequate to maintain donor health.



## <u>A donor safety evidence literature review of the short- and long-term effects of plasmapheresis</u>

Plasmapheresis collection is the way in which Lifeblood collect plasma from Australian plasma patients and is an effective method for collecting plasma from donors. This study looked at injury and long-term effects of plasmapheresis donation and determined that overall is generally well tolerated. The authors noted that frameworks of the type used by Lifeblood would allow US collectors to safely increase plasma collection, balancing donor health with collection efficiency.

#### 4.2 Screening and cross-matching

#### Blood donor genotyping for prediction of blood group antigens

Researchers in Denmark performed routine genotyping for selected blood groups of blood donors for period of 5 years and found allele frequencies and phenotype frequencies for 16 blood groups from a total of 31,538 genotyped blood donors.

## Association of blood donor characteristics and in vitro haemolysis of packed red blood cell concentrates during storage

This study aimed to determine if donor characteristics affected in vitro storage haemolysis of packed red blood cells (PRBCs). Whole blood donors were enrolled, and a pre-donation sample collected for haemoglobin (Hb) and serum uric acid (UA) levels. Researchers found that a significantly higher rate of haemolysis observed in packed red blood cells (PRBCs) from donors with low uric acid (UA) levels during the storage period.

#### 4.3 Patient blood management

#### Patient blood management guideline for adults with critical bleeding

The Patient blood management guideline for adults with critical bleeding has been published on the NBA's website. The guide provides updated clinical guidance for health professionals providing immediate in-hospital care for adults with critical bleeding, including the use of a major haemorrhage protocol (MHP) to guide the use of blood components, blood products and blood conservation strategies.



#### <u>Cell salvage for minimising perioperative allogeneic blood transfusion in adults</u> <u>undergoing elective surgery</u>

Cochrane Library conducted this review to determine the safety of cell salvage in elective or non-urgent surgery, incorporating 106 randomised controlled trials with over 14 000 participants across 24 different countries and across 43 years. They found that in some types of elective surgery, cell salvage may reduce the need for and volume of allogeneic transfusion.

## Exploring the potential harm of varied blood storage on patients undergoing cardiovascular surgery

Canadian researchers sought to determine if the duration of red blood cell (RBC) storage may have an adverse effect on patients undergoing cardiac surgery. The research included patient records for all adult receiving at least one allogeneic red cell transfusion while hospitalised for bypass surgery in a single service in Hamilton, Canada from 2004-2017. Researchers found no significant effect of receiving short duration stored red blood cells or fresh blood cells on patient mortality when undergoing cardiac bypass surgery.

#### <u>A randomised cross-over study of cryopreserved platelets in prophylactic</u> <u>transfusions of thrombocytopenic patients</u>

Researchers compared the safety and efficacy of using cryopreserved buffy coat-derived pooled platelets (CP) to liquid-stored platelets (LP) in the prophylactic transfusions of thrombocytopenic haematology patients. Researchers found more adverse events occurred in patients treated with CP, but noted that these adverse events were mild, both CP and LP treated patients had similar bleeding rates and no thromembolism was observed. Researchers suggested during shortages, CP could potentially supplement LP in prophylactic transfusions of thrombocytopenic patients.

#### 4.4 Inventory management

Quality improvement review of O positive blood in emergency transfusion This retrospective review of emergency transfusions was conducted in Queensland between June 2020 and June 2021, after the introduction of a policy to use O positive red cells in emergency transfusions for males over 16 years of age and females over 50 years of age. Researchers found that while there were some situations which were higher risk, the use of O positive blood for emergency transfusions improved the supply of O negative red cell units without any adverse patient outcomes.



#### 4.5 Transfusion

Correlation between mortality and blood transfusion in patients with major surgery initially admitted to intensive care unit: a retrospective analysis Chinese researchers investigated the effect of blood transfusions on the mortality rate of ICU patients after major surgery. The study included data collected from October 2020 and February 2022 at the Huanggang Central Hospital of Yangtze University. Researchers found that more severe cases were less likely to survive three months after post treatment.

#### Home transfusions are implemented using diverse approaches in Japan

Japan has the largest number of older residents in the world at 28% of the total population, which has resulted in an increased reliance on residential healthcare, including home transfusions. This review looked at the reasons for and administration of home transfusions in Japan with haematological malignancies and solid tumours accounted being the reason for 70% of required transfusions.

#### 4.6 Haemovigilance

Transfusion-associated adverse events incidence and severity after the implementation of an active haemovigilance program with 24 h follow-up This Spanish study investigated the incidence of transfusion-associated adverse events (TAAEs) within an active Haemovigilance program to determine if there was a difference in reporting of events when compared with voluntary reporting. Incidents reported under the program were 14 times higher than voluntary reporting, indicating that active haemogivilance programs are likely to result in better recognition TAAEs as well as their frequency and severity.

### Non-O blood type transfusions, higher intravenous immunoglobulin led to increased risk of haemolytic reactions

In this analysis of Canadian haemovigilance data from Ontario (2013–2021) was compared with IVIg distribution and transfusion data a blood supplier, and local transfusion registry to determine the frequency of haemolytic reactions in the Ontario region. Researchers found that the frequency of haemolytic reactions had decreased and that higher risk factors for reactions were having non-O blood and higher IVIg doses.



#### 4.7 Haemorrhage and clotting

### Intracerebral haemorrhage among blood donors and their transfusion recipients

In this study from Denmark and Sweden, researchers found a possible link between donors who developed spontaneous intracerebral haemorrhage and the risk of spontaneous intracerebral haemorrhage in patients who received a transfusion of their blood. The research included record data from over one million patients across Denmark and Sweden and suggests an agent associated with some types of spontaneous intracerebral haemorrhage could be transfusion transmissible.

# The interaction of thrombocytopenia, haemorrhage, and platelet transfusion in venoarterial extracorporeal membrane oxygenation: a multicenter observational study

Thrombocytopenia and haemorrhage are known risks associated with venoarterial extracorporeal membrane oxygenation (VA ECMO). This multicentre study investigated the prevalence of VA ECMO based complications focusing on platelets and found that 95% patients developed a thrombocytopenia, 45% of which were severe. As a result, platelet transfusions were administered in 54% of cases and 49% suffered a haemorrhagic event indicating that thrombocytopenia occurs more frequently than currently recognised.

#### 5.0 COVID-19

#### <u>Government to launch inquiry into federal, state and territory response to</u> <u>COVID-19 pandemic</u>

The Australian government has launched an inquiry into the federal response to the COVID-19 pandemic and will include a review of governance and health response measures with a focus on dealing with future pandemics.

#### Clotting proteins linked to long COVID's brain fog

Scientists have identified two proteins involved in blood clotting, fibrinogen and D-dimer that may be the cause of brain fog associated with cases of long COVID. A large US study of people hospitalised with COVID-19 early in the pandemic has identified found that people with high levels of fibrinogen and Ddimer at the time of infection were more likely to suffer on-going effects of COVID infection.



#### 6.0 Research and development

#### Vitestro begins blood-drawing device study

Medical robotics company, Vitestro has started a trial of its new autonomous blood drawing device in the Netherlands. The study is expected to include over 10,000 patients and utilises artificial intelligence I-based, ultrasound-guided 3D reconstruction to guide robotic needle insertion.

#### NHMRC Partnership Project grants awarded to UNSW researchers

A team from the UNSW Kirby Institute, led by Professor John Kaldor was awarded nearly \$1.5 million in NHMRC funding in August as part of long-term collaboration with Australian Red Cross Lifeblood aimed at improving and protecting Australia's blood supply.

#### Future prospects for the clinical transfusion of pig red blood cells

This paper discusses some recent progress in the field of xenotransfusion, in particular, pig RBCs (pRBCs) which have functional similarities to human red blood cells (hRBCs).

### The typing is on the wall: Australia's healthcare future needs a digitally capable workforce

This paper outlines the current challenges in the health care services in implementing complex digital technologies designed to improve healthcare delivery and reduce pressures on the healthcare system.

#### 7.0 NBA - National Blood Sector Research and Development Program completed projects

Concealing treatment in pregnancy anaemia randomised trials: can it be used? This seed grant from Round 3 of the NBA's grant program assessed the feasibility and acceptability of blinding/use of placebo intravenous iron infusions for patients and clinicians as well as treatment side-effects, adherence and haematological measures in women receiving IV versus oral treatment. The trial found treatment side effects were low and did not differ significantly at baseline or four weeks after treatment, however, 69% of patients correctly identified their first treatment and 87% identified their treatment four weeks post infusion. The results suggest only some effectiveness of blinding with a final paper due for publication 2024.



Are red cell transfusion requirements and patient outcomes in Aboriginal and Torres Strait Islander (First Nations) versus non- Aboriginal Torres Strait Islander people different?

This project grant from <u>Round 5</u> of the NBA's grant program studied more than 15,000 patients in the Northern Territory and South Australia to better understand the outcomes and use of blood transfusion for Aboriginal and Torres Strait Islander (First Nations) people. In patients admitted to intensive care, undergoing heart surgery and receiving pregnancy care, the study found significant differences in the frequencies of different blood groups (ABO and Rh blood groups) between First Nations and non-First Nations patients. Researchers also found that First Nations patients were more likely to form antibodies against transfused red blood cells (alloantibodies), compared to non-First Nations patients. The research highlights the need to improve shared decision-making approaches with First Nations patients. A summary of this project has been included in the NBA Annual Report 2022-2023 (page 75).

#### 8.0 Industry, supply chains and economy

#### 8.1 CSL

#### CSL Vifor lays off 85 staffers in wake of \$11.7B buyout

CSL Vifor has laid off 85 staff members following a strategic review of operations at their Redwood City location in the US.

#### <u>Australia's CSL stock down as Novo Nordisk's kidney trial success stokes</u> <u>competition concerns</u>

Shares in CSL fell to a four-year low in October following news of additional competition for CSL Vifor in treatments for kidney disease and iron deficiency.

#### 8.2 Roche

Roche claims another legal victory over Takeda in haemophilia patent case A US Court of Appeals has upheld a prior ruling in favor of Roche's Genentech, which found that the company's haemophilia A therapy Hemlibra (emicizumab) had not infringed on patent protections held by Takeda's Baxalta.



#### 8.3 Takeda

#### WHO experts recommend the use of Takeda's dengue vaccine QDENGA

The World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) has recommended the use of Takeda's QDENGA a vaccine for dengue fever. SAGE has recommended use of the vaccine in places with a high dengue burden and high transmission intensity and should be introduced to children aged six to 16 years old.

#### 8.4 Novo Nordisk

#### Inside the FDA's Form 483 findings at Novo Nordisk's North Carolina semaglutide plant

The FDA has flagged two incidents of lapsed quality control at Novo Nordisk's Clayton manufacturing facility in the US. The FDA report suggested the company failed to thoroughly investigate batch discrepancies and needed to improve microbial controls.

#### 8.5 Pfizer

#### Tornado-damaged Pfizer plant in North Carolina restarts production

A Pfizer pharmaceutical plant has restarted production 10 weeks after it was heavily damaged by a tornado with full production across the facility's three manufacturing sites expected by the end of the year.

#### 9.0 Government, policy and regulation

#### Prime Minister Anthony Albanese opens CSL's new Global Headquarters and Centre for Research & Development

CSL has opened a new Global Headquarters and Centre for Research and Development (R&D) in the Parkville biomedical precinct in Melbourne. The plant was opened by Prime Minister, Anthony Albanese in August and is the culmination of A\$2 billion infrastructure investment program in Australia undertaken by CSL over the past four years.

## Disability royal commission hands down final report with 222 recommendations for change

A report by the Royal Commission into Violence, Abuse, Neglect and Exploitation of People with Disability was tabled in parliament in September. The report contains 222 recommendations formulated from a four-year investigation into the lives of people with disability.



#### <u>An El Nino looms over Australia's stressed electricity system – and we must</u> <u>plan for the worst</u>

The Bureau of Meteorology has declared a high chance an El Niño event developing in 2023. El Niño events typically affect temperature and rainfall, with higher temperature and heatwaves expected. Higher temperatures increase the demand of electricity and increasing the risk of supply shortages in some areas.

#### **10.0** Other diseases and developments

#### 10.1 Malaria

#### Mainstay malaria drug may be beginning to fail in the horn of Africa

A report released in September has confirmed that malaria parasites in East Africa are developing an increasing resistance to artemisinins, the primary treatments for malaria.

### Scientific breakthrough harnesses mRNA technology to develop powerful malaria vaccine

A trans-Tasman research team have developed an mRNA-based vaccine designed to effectively target and stimulate protective immune cell responses against the malaria-causing parasite. Researchers plan to move to human trials in the near future.

#### 10.2 Dengue

#### Bangladesh: Nearly 1,000 people die of dengue in severe outbreak

Bangladesh is experiencing a severe dengue outbreak with nearly 1,000 people reported to have died this year. An extremely wet monsoon season have made it easier for mosquitoes that carry the dengue virus to breed and spread the disease, meaning hospitals have been critically overwhelmed.

#### Spike in dengue cases due to global warming, warns WHO

More countries are at risk of dengue with an eight-fold increase in new infections record by the WHO since the year 200. The WHO estimates that about half of the world's population is at risk, with 129 countries currently affected including Australia.



#### 10.3 Japanese encephalitis

#### Joint National Japanese Encephalitis Virus Outbreak Response Plan

The Australian Government released the Joint National Japanese Encephalitis Virus Outbreak Response Plan (JEV Outbreak Plan) in June, Australia's first response plan for Japanese encephalitis. The plan outlines a framework for a national co-operative response to managing Japanese encephalitis virus outbreaks.

#### 10.4 Cholera

#### New analysis confirms world seeing an upsurge of cholera

The WHO has confirmed that new cholera continuing to grow with cases reported to the WHO in 2022 doubling those of 2021. Forty-four countries reported infections in 2022, increasing from 35 countries in 2021.

#### 10.5 Murray Valley encephalitis

Record Murray Valley encephalitis cases in the NT sparks health warning The was an outbreak of Murray Valley encephalitis (MVE) in June and July with high number of infections of the mosquito-borne disease recorded in the Northern Territory and Western Australia.

#### 11.0 In case you missed it

Stronger together – Allied Health Professions Day 2023

The 14 October was International Allied Health Professions Day. The theme for 2023 was Stronger Together, focusing on the value of multidisciplinary care in achieving better results for patients.