The Quick Reference Guide: ***December 2015***

Obtaining Informed Consent for Blood and Blood Products

In terms of transfusion-transmitted infectious risks Australia has one of the safest blood supplies in the world:

- **Every blood donor:** is a volunteer (unpaid), must meet strict selection criteria, answers a comprehensive questionnaire about their health and lifestyle, undergoes a personal interview by trained staff and signs a declaration.
- **Every blood donation:** is screened for syphilis, hepatitis B (HBV), hepatitis C (HCV), HIV and HTLV*. In addition to antibody (or HBsAg) testing, nucleic acid testing (NAT) that detects viral material directly is used for HBV, HCV and HIV-1. Only blood that is negative for all these tests is released for use.
- **All platelets:** are tested for the presence of bacteria (estimated risk overleaf). If the screening test becomes positive after release from Australian Red Cross Blood Service, the transfusion laboratory is notified immediately (if transfused, the recipient can then be followed up/managed).

Current risks of transfusion-transmitted infection in Australia:

For updates and more information on the derivation of the risks refer to the Australian Red Cross Blood Service clinical transfusion website: www.transfusion.com.au/adverse_events/risks/estimates

Agent (Testing)	Australian estimate of residual risk 'per unit'
HIV (antibody/p24Ag + NAT)	**Less than 1 in 1 million**
Hepatitis C (antibody + NAT)	**Less than 1 in 1 million**
Hepatitis B (HBsAg + NAT)	**Approximately 1 in 557,000**
HTLV 1 & 2* (antibody)	**Less than 1 in 1 million**
Malaria (antibody)	**Less than 1 in 1 million**
CMV**	**Important consideration** in certain patient groups - see below[#]
variant CJD (no testing)	**Possible**, not yet reported in Australia - see below

HIV, HCV, HTLV risk estimates based on Australian Red Cross Blood Service data from 1/1/13 to 31/12/14 & calculated using mathematical model(s).
Occult HBV infection risk estimated on data from 1/1/14 to 16/4/15.
*HTLV: Human T-cell lymphotropic virus – an uncommon virus, which may in a small % of cases cause blood or nervous system problems.
**CMV: Cytomegalovirus – a common virus typically carried by leucocytes.

- The viral risks above are very small compared to risks of everyday living (see CALMAN chart below).
- Variant Creutzfeldt-Jacob disease (vCJD): To date there have been no reported cases of vCJD in Australia. In the UK there have been a small number of reported cases of putative/possible transfusion transmission since 2004. In Australia, as a precaution, people who have spent > 6 months in the UK between 1/1/80 and 31/12/96 and/or had a transfusion in the UK since 1/1/80 are not able to donate.
- Transfusion-transmitted CMV infection[#] may lead to severe or fatal disease in immunocompromised patients. CMV seronegative units are indicated for certain patient groups (including neonates & antenatal transfusion in pregnant women) – consult your transfusion service provider & hospital guidelines. If CMV seronegative units are not available, leucocyte depleted components are considered to offer a high level of safety in preventing CMV transmission, but are not universally believed to be equivalent to CMV seronegative components – consult your transfusion service provider & refer to hospital guidelines. For further information / updates see www.transfusion.com.au
- Fractionated plasma-derived products: the manufacturing process includes dedicated pathogen inactivation/reduction steps and therefore the infectious risks are much lower.

The CALMAN Chart (Calman 1996) for explaining risk (UK risk per 1 year):

Negligible	< 1:1,000,000 e.g. death from a lightning strike
Minimal	1:100,000 – 1:1,000,000 e.g. death from a train accident
Very low	1:10,000 – 1:100,000 e.g. death from an accident at work
Low	1:1,000 – 1:10,000 e.g. death from a road accident
Moderate	1:100 – 1:1,000 e.g. death from smoking 10 cigarettes per day
High	> 1:100 e.g. transmission of chickenpox to susceptible household contacts

See table over leaf for other serious risks of transfusion

Non-viral risks associated with blood and blood products

- The most common non-serious reactions include headache, mild fever, itching/hives.
- **Mild allergic (urticarial) reactions occur in 1 to 3%** & **febrile non-haemolytic reactions in 0.1 to 1%** of transfusions.
- The most frequently reported causes of serious/fatal transfusion reactions are TRALI[#], bacterial sepsis, TACO & ABO incompatibility (latter mostly due to preventable errors linked to patient ID).
- The following table gives estimates of risk for serious acute (<24 hours) and some serious delayed reactions based on reports from a number of countries and are subject to the problem of under-estimation due to lack of reporting and recognition of transfusion reactions (hence the broad ranges). For further information and updates refer to www.transfusion.com.au
- **Other delayed reactions include: alloimmunisation to red cell antigens (1 in 100 per unit) & HLA antigens (1 in 10 per unit)**, **iron overload** in patients with ongoing transfusion requirements (may occur after 10 to 20 units) & **transfusion-related immune modulation** (incidence is not known).
- Report all transfusion related events (suspected & near miss) to the transfusion service provider.

NOTE: The *routine* use of Preoperative Autologous Donation (PAD) is not recommended because although it reduces the risk of allogeneic red blood cell transfusion, it increases the risk of receiving any transfusion, allogeneic and autologous (Reference: National Patient Blood Management Guidelines: Module 2 - Perioperative, National Blood Authority 2012. See below for website).

Other Serious Risks of Blood Transfusion: (*Includes overseas data)

Adverse Reaction		Risk per unit transfused* (unless specified)
Septic Reaction (clinically apparent)	Platelets	At least 1 in 75,000
	Red Cells	At least 1 in 500,000
Haemolytic ABO/Rh mismatch		1 in 40,000
Acute haemolytic reaction		1 in 76,000
Fatal haemolytic reaction		1 in 1.8 million
Delayed haemolytic reaction		1 in 2,500 to 1 in 11,000
Severe allergic reactions (anaphylaxis)		1 in 20,000 to 1 in 50,000
Transfusion-associated circulatory overload (TACO)		Less than 1% of patients
Transfusion-related acute lung injury[#]		1 in 1,200 to 1 in 190,000
Transfusion-associated graft versus host disease[##]		Rare
Post-transfusion purpura		Rare

Above information with updates available at www.transfusion.com.au/adverse_transfusion_reactions/classification_and_incidence

[#]TRALI – Transfusion Related Acute Lung Injury is characterised by acute respiratory distress (within hours of transfusion) with non-cardiogenic pulmonary oedema – full recovery in 48 hours is usual if the patient is well resuscitated/ supported. TRALI is likely to be significantly under reported.

[##]TA-GVHD – Transfusion Associated Graft Versus Host Disease is due to engraftment of viable T lymphocytes and usually affects severely immunocompromised patients or recipients that share an HLA haplotype with a specific donor. Irradiation of blood products for specific at risk groups of patients (refer to hospital guidelines) prevents this rare but usually fatal event.

Checklist for Consent – Blood and Blood Products:

Consent is a process – not a piece of paper

- ☐ Explain:
  - Cause/likelihood of bleeding/low blood count (including any uncertainty)?
  - Nature of the proposed transfusion therapy – what is involved?
  - Benefits expected?
  - Risks – common and rare but serious?
  - Alternatives – including the risk of doing nothing?
- ☐ Ask:
  - Is there anything else you would like to know?
  - Is there anything you do not understand?
- ☐ Give written information and use diagrams where appropriate.
- ☐ Document the consent process as per hospital/health service policy.

Use a competent interpreter when the patient is not fluent in English.

More information? Ask your transfusion service provider or visit:

www.sahealth.sa.gov.au/bloodsafe or www.transfusion.com.au (Blood Service clinical website)
For interactive and free online transfusion education see www.bloodsafelearning.org.au/
For info on transfusion practice see national Patient Blood Management Guidelines www.blood.gov.au/pbm-guidelines
For a consumer information website see www.mytransfusion.com.au

Australian Red Cross BLOOD SERVICE

Government of South Australia
SA Health