

## The Quick Reference Guide: *December 2010* 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 info on the derivation of the risks refer to Blood Service clinical transfusion website:

[www.transfusion.com.au/adverse\\_events/risks/estimates](http://www.transfusion.com.au/adverse_events/risks/estimates)

Agent	Australian residual risk estimates for transfusion-transmitted infections per unit <i>HIV, HCV, HBV risks based on Australian Red Cross Blood Service data from 1/1/08 to 31/12/09 (HTLV: 1/1/04 to 31/12/09) and calculated using three mathematical models.</i>
HIV	<b>Less than 1 in 1 million</b>
Hepatitis C	<b>Less than 1 in 1 million</b>
Hepatitis B	<b>Less than 1 in 1 million</b>
HTLV 1 and 2*	<b>Less than 1 in 1 million</b>
Malaria	<b>Less than 1 in 1 million</b>
CMV#	<b>Important consideration</b> in certain patient groups (see below)
variant CJD	<b>Possible. Not yet reported in Australia (see below)</b>

- The viral risks above are very small compared to risks of everyday living (see 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 and pregnant women) and may be dependent on the patient's CMV status (past infection) – consult your transfusion service provider. 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 and refer to hospital guidelines.
- Fractionated plasma-derived products: the manufacturing process includes dedicated pathogen inactivation steps and therefore the infectious risks are much lower.

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

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

\* **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.

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.
- The most frequently reported causes of serious / fatal transfusion reactions are TRALI<sup>#</sup>, bacterial sepsis, and ABO incompatibility (the latter mostly due to preventable errors linked to patient / specimen ID).
- The following table gives estimates of risk 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).
- A national reporting system for reactions and near misses (haemovigilance) is in development and will help provide Australian risk estimates in the future.
- Remember to report all transfusion related events (including suspected and near miss events) to the transfusion service provider.
- The transfusion of autologous blood is not without risk and the same indications for the use of homologous blood apply.

## Other Serious Risks of Blood Transfusion (International Data)

Adverse Reaction		Risk per unit transfused (unless specified)
Bacterial sepsis: (Clinically apparent reactions)	Platelets	1: 75,000
	Red Cells	1: 500,000
Haemolytic reactions:	Acute – ABO incompatibility	1: 12,000 to 77,000
	Delayed	1: 2,500 to 11,000
Anaphylaxis – IgA deficiency		1: 20,000 to 50,000
Fluid overload / cardiac failure		Up to 1: 100 per transfused patient
Transfusion-related acute lung injury <sup>#</sup>		1: 5,000 to 190,000
Transfusion-associated graft versus host disease <sup>##</sup>		Rare

Above information with updates available at [www.transfusion.com.au/adverse\\_events/adverse-reactions-blood](http://www.transfusion.com.au/adverse_events/adverse-reactions-blood)

<sup>#</sup>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.

<sup>##</sup>TA-GVHD – Transfusion Associated Graft Versus Host Disease is due to viable engraftment of 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?

**Document the consent process** – as per hospital/health service policy

Give written information or use diagrams where appropriate.

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

### More Info? Ask your transfusion service provider or visit:

[www.health.sa.gov.au/bloodsafe](http://www.health.sa.gov.au/bloodsafe) or [www.transfusion.com.au](http://www.transfusion.com.au) (Blood Service clinical website)

or for interactive and free online transfusion education: [www.bloodsafelearning.org.au](http://www.bloodsafelearning.org.au)



**Government of South Australia**  
SA Health