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Bacterial contamination screening of platelets

From 28 April 2008, all ARCBS platelet components will be screened for bacterial contamination.

Worldwide, bacterial contamination of platelet components is recognised as the most significant residual infectious risk of blood transfusion in developed countries. As a cause of death from transfusion, bacterial sepsis is second only to ABO incompatibility.

Available international data from microbiological culture studies of platelet units suggest that the overall incidence of bacterial contamination ranges from approximately 1 in 3000 to 1 in 1000 units of apheresis platelets and 1 in every 600 to 1 in every 200 units of pooled platelets (pool of 4).

Quality control surveillance of platelet components at ARCBS since July 2005 and preparatory studies for the implementation of 100% platelet bacterial contamination screening suggest that detected contamination rates will be in the order of 0.2%.

Each platelet component will be sampled at 24 hours after collection. The samples will then be screened on the bioMerieux BacT/ALERT Automated Microbial Detection System utilising both aerobic and anaerobic culture bottles. After sampling, platelets will be available for issue from ARCBS as 'negative to date' with respect to their bacterial contamination screening status. However, the cultures will continue to be incubated over the full shelf life of the components.

If a culture becomes positive it will be automatically flagged by the screening equipment. This is termed an "initial machine positive" (IMP). It is important to note that the IMP is not conclusive evidence that the component is contaminated and many will eventually be found to be false positives. As a sample could potentially flag as positive at any time during the day, ARCBS will be setting

up technology to allow for remote monitoring of the testing system 24 hours a day 7 days a week (24/7), as well as incorporating the ability to have 24/7 recall in conjunction with a new National Recall Office.

If the platelets and/or their associated components (i.e. red cell or clinical plasma) have already been issued by ARCBS at the time of the IMP, the National Recall Office will notify the relevant transfusion laboratory so that recall of the platelet unit and any associated component can be arranged.

If the platelet or associated component has been transfused, this will allow the transfusion laboratory to contact the treating clinician enabling them to manage the patient with the knowledge of the preliminary result.

All IMPs will be sent by ARCBS to an external laboratory to have a Gram stain and culture performed. All organisms seen at microscopy in the Gram stain will be notified to the relevant transfusion laboratory. Negative Gram stain results will not be notified as they are a poor predictor of the absence of contamination and are unlikely to change the management of the patient. Gram stain results will generally be available several hours after the IMP is obtained.

As relevant additional information becomes available, ARCBS will forward a progress report to the transfusion laboratory, for example donor information that might assist therapeutic management of the patient or further information from the culture including bacterial identification.

In all cases where components have been transfused, a final report will be forwarded to the transfusion laboratory when all laboratory



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investigations are complete. Every attempt will be made to provide the identification of cultured bacteria. Where possible, antibiotic sensitivity testing will also be performed.

ARCBS believes the addition of this testing will be a significant step in further improving the safety of the blood supply. The removal of potentially bacterially contaminated components from the blood supply prior to transfusion will help avoid adverse outcomes. Additionally, knowledge of potential bacterial contamination should enable early clinical review and consideration of antibiotic intervention in situations where components have already been transfused.

The implementation of bacterial screening has been carefully planned so that there will be minimal impact on platelet inventory. Inventory levels will be closely monitored prior to and following implementation.

Criteria for the clinical use of Intravenous Immunoglobulin (IVIg) in Australia effective from 3 March 2008

The *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia* (the Criteria) has been developed to assist clinicians and transfusion medicine professionals to identify the conditions and circumstances for which the use of intravenous immunoglobulin (IVIg) is appropriate and funded under the National Blood Agreement.

The Criteria supersedes the Australian Health Ministers' Advisory Council (AHMAC) IVIg Guidelines published in 2000. A six month transition period from March has been allowed for full adoption of the Criteria.

The information and recommendations provided in the Criteria represent informed opinion based, where possible, upon systematic review of the evidence. In the absence of published evidence, recommendations are based on clinical advice provided to the parties involved in developing this document (i.e. the Jurisdictional Blood Committee IVIg Working Party and its clinical advisers and consultants, the Jurisdictional Blood Committee, and the Commonwealth of Australia).

The Criteria groups conditions into four chapters;

- Chapter 5: Conditions for which IVIg has an established therapeutic role;
- Chapter 6: Conditions for which IVIg has an emerging therapeutic role;
- Chapter 7: Conditions for which IVIg has a therapeutic role in exceptional circumstances only; and
- Chapter 8: Conditions for which IVIg use is not indicated.

In accordance with the funding policy, IVIg is available under the National Blood Arrangements for Australians whose conditions fall within Chapters 5, 6 or 7. The Criteria provides a comprehensive description of the diagnostic, qualifying, exclusion and review criteria to determine patient eligibility for access to this product under the National Blood Arrangements.

Patients who do not fulfil the Criteria will not be eligible to receive IVIg under the National Blood Arrangements. In these circumstances, individual jurisdictions or hospitals may elect to make IVIg available to clinicians and patients through the state-based funding arrangements commonly known as Jurisdictional Direct Orders (JDO).

A small number of patients currently receiving IVIg therapy may no longer qualify for access to ongoing IVIg therapy funded under the National Blood Arrangements following the implementation of the new Criteria. These patients may be able to seek access to IVIg funded under the state system or, alternatively, may need to be transitioned to alternative treatment regimes under the guidance of their treating doctor.

Current state and territory arrangements for authorisation, ordering and recording of IVIg treatment remain the same.

To further assist with the implementation process, a time-limited National IVIg Criteria Reference Group, comprising experts involved in the development of the Criteria, key users and approvers from each jurisdiction, will be established to assist with standardising interpretation of the Criteria.

Brisbane relocation

The Brisbane-based ARCBS team, including the TMS team and Chief Medical Officer, Dr Joanne Pink, are moving to new, purpose-built premises in the Kelvin Grove Urban Village on 22 February.

Phone, fax and delivery details for all staff and operation functions will change as a result of the relocation, and the TMS team will be contacting you with their new numbers, but the main details to remember are:

Main TMS numbers:

Phone: (07) 3838 9234

Fax: (07) 3838 9421

Street address:

44 Musk Street,
Kelvin Grove QLD 4059.

Existing phone and fax numbers will divert for a period after the changeover to ensure TMS, Inventory and Distribution and any other ARCBS staff you may need to contact are accessible.

The new premises allow for most of the Brisbane-based ARCBS staff to work together at one site, with more a functional, comfortable and modern environment and increased processing, storage and distribution area and generally improved functionality and capacity.

The Brisbane City Donor Centre will continue to operate from its current location on the upper ground floor, 288 Edward Street, Brisbane

The Criteria is now available at www.nba.gov.au.

A Quick Reference Guide and Frequently Asked Questions have been developed to accompany the Criteria.

Copies of the Criteria and the Quick Reference Guide will be distributed to hospitals, professional colleges, governments and contributors on 3 March.

Further free copies can be obtained from 3 March by completing a form that will be available at www.nba.gov.au.

Sign up for Med e-News

Med e-News is TMS's monthly electronic newsletter, providing you with the latest updates on news, research and product information.

If you would like to receive Med e-News in addition to Medilink please email your details to Ireid@arcbs.redcross.org.au



2006 UK SHOT report released

The 2006 Serious Hazards of Transfusion (SHOT) report summarises haemovigilance data from hospitals within the United Kingdom.

The data presented from 2006 updates previous annual reports from the group, and include valuable information on:

- Adverse transfusion reactions;
- “Wrong blood to patient” incidents, where the incorrect blood component was transfused to a patient;
- “Right blood to right patient” incidents, where, despite a serious breach of protocol, the patient received appropriate product;
- “Near misses”, which may have resulted in adverse events but were identified and prevented prior to transfusion.

Of the 531 reported events for 2006, approximately 75% were “incorrect blood component transfused” (IBCT) episodes. These are classified as episodes where a patient was transfused with a blood component or plasma product which did not meet the appropriate requirements or which was intended for another patient.

There were two deaths as a result of IBCT. These were not caused by errors in blood administration, but were due to incorrect prescribing, in both cases involving junior doctors. The first case was due to a lack of care and accuracy in paediatric prescribing which resulted in over-transfusion of platelets. The second resulted from a faulty blood sampling technique and a wrong decision to transfuse. In both instances, the deaths were not due to a single error, but rather a complex set of circumstances in which the process of evaluation and decision making, communication with colleagues, competency and knowledge level contributed. On further analysis, a total of 125 cases of IBCT were found to be due to errors made by junior medical staff.

There were no deaths related to ABO incompatible transfusion, but 2 patients suffered serious morbidity following ABO incompatible red cells.

Other events included acute transfusion reactions (16%), haemolytic transfusion reactions (6%), transfusion-related acute lung injury (TRALI) (1.9%) and two cases of transfusion-transmitted infection, both of which were due to bacterial contamination of platelets. There were no reported cases of post-transfusion purpura (PTP) or transfusion-associated graft versus host disease (TA-GvHD).

Many of the lessons and recommendations provided by the SHOT report are intuitive. For example, the learning points following the two fatal IBCT outlined were that prescriptions must be written by a doctor with a volume and rate of infusion clearly stated, medical and nursing staff should not work beyond their competence or expertise, all results – especially if highly abnormal – must be reviewed in the context of the patient’s recent history and current clinical condition, and large volumes of blood components must not be given without ongoing clinical and laboratory review.

This year’s key recommendations focus on the need for integration of transfusion medicine into the teaching and training curricula for junior hospital doctors, nursing and scientific staff involved in transfusion.

On an optimistic note, awareness of serious issues, along with product improvements seem to have impacted favourably on some types of severe reactions over the years since SHOT started its work of data collection, reporting and education.

Reports of ABO incompatible red cell transfusions and the highest risk errors (where a patient received a blood component intended for a different patient or of the incorrect group) have fallen compared with previous years.

There was a reduction in the number of reported cases of TRALI, with 2006 having the lowest reported mortality due to TRALI since SHOT began reporting in 1996.

This was attributed to the preferential use of male-donor plasma. Universal leucodepletion appears to be reducing complications such as PTP and possibly TA-GvHD. Robust haemovigilance data, and dissemination of findings in an educational context, certainly provide all involved in the transfusion process with valuable information to improve quality systems and institute policies and practices for transfusion safety.

Four UK transfusion-related deaths were reported:

- Two deaths due to incorrect prescribing;
 - A sick 12 month old preterm infant was scheduled for elective surgery. There was a written order for platelets that did not specify the volume to be transfused. A junior doctor gave a verbal instruction which was misheard by the nursing staff. The infant was over-transfused and suffered a cardio-respiratory arrest; and
 - An 80 year old woman had a post-operative Hb of 39g/L on a blood sample diluted by an intravenous infusion. A junior doctor diagnosed hypovolaemia and prescribed 6 units of red cells, all of which were administered over a 16 hour period. The post-transfusion Hb was 182g/L and the patient subsequently died of cardiac failure.
- One death from transfusion of platelets contaminated with *Klebsiella pneumoniae*.
- One death probably due to TRALI.



The Australian Red Cross Blood Service is delighted to present Transfusion Update 2008.

Invited speakers include Marc Maegele, University of Witten-Herdecke, Germany; Claire McLintock, Auckland, New Zealand and Simon Stanworth, Oxford, United Kingdom.

Presentations on issues surrounding:

- platelets
- critical bleeding and massive transfusions
- controversies within the fields of obstetrics and paediatrics

The conference also includes a Welcome Reception at the Crown Conference Centre and a Gala Dinner at Melbourne's prestigious Arts Centre.

Corporate Registration and Day Delegate rates are available. Save with an early bird booking before 7 March.

To register for the conference or receive further information contact:

Rebekah Cowie
02 9333 3210
rcowie@arcbs.redcross.org.au

View the current program and faculty:
www.transfusion.com.au



Residual Risk Estimates for Transfusion-Transmitted Infections

Agent and testing standard	Window period (days)	Estimate of residual risk 'per unit' ^a
HIV (antibody + RNA)	9	Less than 1 in 10 million
HCV (antibody + RNA)	5.4	Less than 1 in 10 million
HBV (HBsAg)	38	Approximately 1 in 660,000
HTLV I & II (antibody)	51	Less than 1 in 10 million
CMV (antibody negative)	46	Approximately 1 in 127,000
CMV (untested /WBC filtered)	N/A	Risk of recipient infection approximately 2.5% ^b
Variant Creutzfeldt-Jakob Disease (vCJD) [No testing]		Possible. Not yet reported in Australia. See section below.
Malaria (antibody)	N/A	1 in 4.9 million to 1 in 10.2 million

^a HIV, HCV, HBV risk estimates are based on ARCBS data from 1 January 2005 to 31 December 2006. HTLV risk estimate based on data from 1 January 2004 to 31 December 2006. For other agents refer below.

^b Average risk of infection in recipients of WBC-reduced components, taken from Vamvakas, E. *Transfusion Medicine Reviews* 2005; 19(3): 181-199.

Viral estimates: Seed, CR, Kiely P and Keller AJ. *Residual Risk of Transfusion Transmitted Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and Human T Lymphotropic Virus*. *Intern Medicine Journal* 2005; 35(10): 592-8.

Malaria: Seed, CR. *Residual Risk Estimates for Transfusion Transmitted Malaria (TTM)*. ARCBS DPARC; November 9/10 2005 meeting.

CMV: Seed CR. *Risk Estimate – Transmission of CMV by 'Seronegative' Blood*. ARCBS DPARC; August 14/15 2007 meeting.

There have been no reported cases of transmission by transfusion of classical Creutzfeldt-Jakob Disease (cCJD), and retrospective studies suggest that the possibility of such transmission of cCJD is remote.

To date, no Australian has been infected with vCJD. In the UK, there have been a small number of reported cases of putative transfusion transmission since 2004. In Australia, as a precaution, people who have spent a cumulative period of six months in the UK between 1 January 1980 and 31 December 1996 and/or had a transfusion in the UK between 1 January 1980 and the present time are not accepted as blood donors.