NZBS POLICY ON THE PROVISION OF CMV ANTIBODY NEGATIVE BLOOD COMPONENTS

REASON FOR ISSUE: Change in name of Progesa to e-Traceline. Clarification of provision of CMV antibody negative blood for neonatal use.

1. SCOPE

This Policy relates to NZBS Manufacturing sites and all Hospital Blood Banks in New Zealand.

2. DEFINITIONS

The term CMV antibody negative blood component refers to a component derived from a donation that has been tested for and found to be negative for the presence of antibody to Cytomegalovirus.

The term neonate is defined as age up to 4 months after delivery.

3. BACKGROUND

Cytomegalovirus (CMV) is a ubiquitous herpes virus. In immunocompetent individuals primary infection is often asymptomatic. The frequency of infection, defined by the presence of antibody, increases with age. Approximately 60% of previously untested donors in New Zealand are positive for the antibody. CMV infection can be life threatening in susceptible immunocompromised individuals. This includes transplant recipients, patients with severe immunodeficiency disorders, the foetus and low weight premature neonates and pregnant women. Routine monitoring for CMV by PCR post transplant with the early initiation of specific anti-viral therapy has significantly reduced morbidity and mortality in this setting.

CMV is readily transmitted by transfusion of cellular components from infected donors. CMV is a cell-associated virus. Efforts should be made to reduce the likelihood of transmission by transfusion in susceptible individuals. This primarily involves CMV antibody negative patients and transplants involving CMV antibody negative donor and recipient pairs. Reactivation of CMV can occur in immunosuppressed CMV antibody positive patients and grafts from CMV antibody transplant donors can also lead to infection.

Blood Services can reduce the risk of transmission of CMV by blood components in two ways;

1. The use of CMV antibody negative components. Overall, this strategy appears to be associated with a more than 90% reduction in the risk of transfusion transmitted CMV in high-risk recipients. However it fails to prevent a low residual rate of transmission of approximately 1.2-1.5%, likely to be due to donation during the “window” period following infection, before the development of a detectable antibody response.

2. The removal of white cells from components. This is most effective when pre-storage leucodepletion is undertaken in controlled settings. As with CMV antibody testing, leucodepletion appears to result in a greater than 90% reduction in the risk of transfusion transmitted CMV in high risk recipients but it fails to prevent a low residual rate of transmission of approximately 2.1-2.5%, probably mediated by persistent or recurrent plasma viraemia in the donor, allowing infective virus to traverse the filter.

The Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components identifies that neither method nor the combination can completely avoid transmission from the occasional case of CMV viraemia in the early stage of acute infection. There is no consensus on the requirement for ongoing CMV antibody screening in blood services, such as NZBS, that undertake universal leucodepletion of blood components. While some services, especially those in areas that have a high prevalence of CMV have ceased testing, others believe that the combination approach may confer some additional safety.

NZBS POLICY ON THE PROVISION OF CMV ANTIBODY NEGATIVE BLOOD COMPONENTS

4. POLICY

NZBS will adopt the following approach to avoidance of transfusion transmitted CMV infection:

1. Standard blood components that have undergone pre-storage leucodepletion offer a high level of safety for all immune competent recipients.

2. Haemopoeitic stem cell and organ transplant recipients will routinely be provided with standard pre-storage leucodepleted blood components. These provide a high level of safety with respect to avoidance of transfusion transmitted CMV infection.

3. Pregnant women, regardless of their CMV antibody status, will routinely be provided with standard pre-storage leucodepleted blood components. These provide a high level of safety with respect to avoidance of transfusion transmitted CMV infection.

4. Blood components manufactured for intra-uterine use will continue to be CMV antibody negative. This recognises the particular vulnerability of these group and the difficulty of undertaking routine CMV surveillance in these settings.

5. Blood components manufactured and labelled for neonatal use will continue to be CMV negative. However, ,availability of these component types for all neonatal transfusions may not be possible in which case standard leucodepleted blood components will be issued.

6. CMV antibody negative components will continue to be provided for individual patients following discussion and agreement between the specialist responsible for the patient's care and a member of the NZBS Medical team. This will require the addition of a specific protocol within the NZBS Blood Management System (eTraceline). Such requests should be made in sufficient time to ensure that adequate numbers of suitable components are easily available.

This approach is consistent with policy developed by the American Association of Blood Banks and by the Joint UKBTS/NIBSC Professional Advisory Committee.

This policy will be reviewed in the future if compelling new evidence becomes available from clinical trials addressing this issue.