Policy

- The Blood Service will minimise blood product wastage through best inventory management practice and the promotion of appropriate clinical use strategies.
- The Blood Service will determine the optimal age of red cells at issue in accordance with current medical and scientific evidence.
- The Blood Service will implement strategies to optimise the age of red cells at issue.

It is recognised that the age at which blood components are transfused is dependent upon the age at which they are supplied by the Blood Service as well as hospital and laboratory inventory management practices. Avoidance of blood product wastage through appropriate clinical use and best inventory practice are actively supported by the Blood Service.

Overview

It is well documented that red cells undergo numerous, complex physical and chemical changes during refrigerated storage which impact on their function and survival, known as the "red cell storage lesion". The clinical relevance of these changes is not clear, prompting significant research and debate in this area.

There are a number of clinical studies which have attempted to answer whether the transfusion of older blood is associated with poorer outcomes for patients, compared with the transfusion of fresher blood. Overall these studies to date have provided inconclusive results and all have a number of study design limitations. There are a number of clinical trials currently underway which have been specifically designed to see whether the age of red cells at transfusion does affect the outcome of patients. It is expected the results from these trials will be available after 2012. It should also be noted there is literature which outlines the potential risks of "fresher" blood.

The international clinical consensus is that it is not prudent to alter local transfusion practice and guidelines regarding red cell storage and age at transfusion. Until these studies are completed, the Blood Service needs to ensure distribution of fresh product and encourage laboratory inventory management and clinical practice to optimise red cell age at transfusion.

Blood Service strategies

Supporting the clinicians and transfusion laboratories:

- 1. Supporting the optimisation of inventory management practices within hospitals and transfusion laboratories. This includes balancing our supply to clinical demand against avoidable wastage in the hospital laboratories.
- 2. Recognising that the optimal inventory age profile is not yet determined
- 3. Promoting the appropriate use of blood components.
- 4. Supporting and contributing to related research.
- 5. Actively engaging with the broader clinical community on this issue.
- 6. For select patient groups, such as neonates, red cells are issued at lower age in accordance with established clinical practice.

Adapting our inventory practices:

- 7. Implementation of 'patient focused' supply planning (i.e. "aligning supply with demand").
- 8. Regular review of red cell issue policies and procedures to ensure emerging evidence that particular patients may benefit from the provision of fresher red cells is taken into consideration.
- 9. Statistical supply forecasting to enable timely adjustment of collection and production activities in response to fluctuations in clinical demand.

- 10. Use of planning strategies to align inventory blood group mix with patient need.
- 11. Use of a national inventory framework and the setting of appropriate upper and lower limits for red cell inventory by ABO and Rh (D) blood group (i.e. inventory sufficiency bands). This drives the average age at issue which has been between 7 to 8 days within last 12 months. Issue of "fresher" blood allows greater flexibility in transfusion laboratory inventory management to help reduce wastage.
- 12. Optimisation of Blood Service inventory management practices.
- 13. Deployment of temporary strategies during periods of high inventory levels. Such as:
 - selective use of a "last-in-first-out" (LIFO) issue policy for particular blood groups e.g. B and AB when red cell age at issue exceeds 10 days
 - quarantining of red cells greater than 28 days old
 - changes to the age mix of red cells supplied to transfusion laboratories

Adapting our product:

14. Introduction of measures to ameliorate the storage lesion. Strategies to date include implementation of leucodepletion of all red cells and platelets, evaluation of alternative blood storage bags and options for blood components transport and storage.

Background information^{1,2}

The key question in the debate about the "age of red cells" is: What is the optimal age of a red cell at transfusion? The answer is not known and may differ according to patient group. There are several threads of information which need consideration in order to answer this question:

Red cell storage physiology

Currently red cells are licensed for storage for up to 42 days following collection and internationally the maximum red cell shelf life is up to 49 days.

It is well documented that red cells undergo numerous complex morphological and metabolic changes during storage which impact on their function and survival³. The clinical relevance of these changes, or the "red cell storage lesion", is still not well understood and has prompted significant research and debate.

Clinical research

A number of clinical studies suggest transfusion of older stored red cells is associated with poorer outcomes for patients, in particular trauma and cardiac patients, when compared with recipients of 'fresh' red cells^{4,5}. These are retrospective, observational studies, many of which were not designed to address the question of age of red cells. Differences in timeframes for analysis, manufacturing approaches and component quality are confounding variables in many studies. Other studies have not supported these findings and there is currently no consensus in the literature as to whether transfusion of older red cells results in increased morbidity and/or mortality.

In focussing on 'older' red cells it may be overlooked that transfusion of 'fresh' blood is not entirely without potential risks including Graft-Versus-Host-Disease (GVHD) and microchimerism^{6,7,8,9}.

With the current uncertainties around the safety and efficacy of transfusion a state of clinical equipoise exists which further research seeks to resolve. The impact of age of red cells at transfusion is currently a significant research focus, and is further detailed in attachment A: Research on "Age of blood" as a confounding factor in patient outcomes following transfusion.

Blood Service inventory practice

Maintaining an optimal red cell inventory requires a clear understanding of the factors affecting supply and demand. There is need for a balance between having sufficient red cells to meet demand and not having too many such that the age profile of the inventory increases.^{10,11}

The Blood Service will use strengthened statistical forecasting tools to better analyse supply trends. This should enable:

- more timely adjustment of collection and production plans; and
- improved control over red cell age as determined by defined upper and lower limits for its red cell inventory ("inventory sufficiency bands")

In addition, the Blood Service is modelling the impact of reducing the red cell shelf life from 42 days to determine the impact to the overall blood supply, should the current research support any change in the age of red cells at transfusion. In broad terms modelling of a reduction in red cell shelf life to 35 days suggests that it would likely have minimal affect on the overall blood supply and age of blood at issue from the Blood Service.¹² However there may be a significant impact on regional or remote users and further information is being gathered. There may be an impact on the inventory management of rare red cells by reducing shelf-life.

Summary

The Blood Service will continue to closely monitor the discussions and debate on the age of red cells at transfusion, and is actively engaged with the broader clinical community on this issue.

The Blood Service also supports the need for further data, including carefully designed, prospective controlled trials, to determine whether there are any patient groups that may benefit from the provision of fresher red cells. This position appears to be shared by the broader transfusion community within Australia.

Prior to implementing any changes, the Blood Service will consult with stakeholders and perform modelling and feasibility studies on the potential impact of provision of younger red cells and/or implementing a shorter red cell shelf life.

The Blood Service is moving to ensure that its inventory management practices and introduction of consistent organisational service standards will provide national equity of access to red cell components in accordance with clinical requirements. There are however no plans to reduce the shelf-life of standard red cell components until evidence is available to support such a move.

Endorsed by the Blood Service Strategic Blood and Blood Products Committee 10 December 2010

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