Thank you for the opportunity to contribute to the Australian Commission on Safety and Quality in Health Care’s Regulatory Impact Statement. The NBA commends extensive consultation undertaken by the Commission and the significant progress the Commission has made in shaping a model to allow information to be generated on a set of national quality and safety measures in key areas that pose risks to patient safety.

The NBA has structured the response to the draft RIS around two sections: General Comments and Specific Comments. The General Comments section relate more to NBA’s request to change the emphasis of the Blood and Blood Product Standard (and documentation referring to it including this RIS) to focus more on the risks of concern that lie within the control of institutions and their laboratories that undertake transfusion procedures. To assist the Commission to do this, explicit examples and references are provided. The specific comments address the Commission’s questions about the RIS.

1. General Comments

- In general terms, the National Blood Authority (NBA) would like to see less emphases on product quality and product availability in both the Regulatory Impact Statement document and the National Standard for Blood and Blood Products as advised in our submission on this standard.

While hospitals have some role in product safety (e.g. storing products at the right temperature and the use of appropriate aseptic techniques when administering blood to avoid infection), they have little control over the wider national blood supply, donor selection strategies, product testing and manufacturing techniques to avoid transfusion transmitted infections such as HIV, Hepatitis B and C and vCJD and other product safety and quality issues.

As such, the Blood and Blood Product Standard and any documentation relating to it such as the RIS, should focus on those areas of potential patient harm that can be addressed directly by institutions that prescribe and administer blood and blood products to patients. Table 1 below shows that the greatest risk to patients, comes from avoidable administrative and clinical procedure errors and reactions that are unrelated to product quality. These serious acute and delayed reactions may be due to an immunological response yet to be fully studied and understood. Emerging data suggests that avoidance of transfusions results in reduced morbidity and mortality, reduced length of hospital and ICU stays and reduced infections. It is therefore important to avoid transfusions wherever the patient’s own blood can be optimised without transfusion. Transfusions can be avoided if what is known as Patient Blood Management practices are adopted. Patient Blood Management reduces the likelihood of transfusion by:

- optimising the patient’s red cell mass, often prior to hospitalization using non-transfusion techniques and pharmaceuticals (e.g. treating iron deficiency anaemia with iron therapy).
conservation of the patient’s own red cell mass (e.g. meticulous surgical technique, salvaging and returning the patients own red blood cells during or after surgery and avoiding or reducing the amount of blood taken for blood tests), and
tolerating anaemia (e.g. after surgery during which blood was lost, allow the patient who is non-symptomatic to build their own iron stores and haemoglobin levels over time in preference to transfusion.)

Table 1. Where do the risks lie in Transfusion?

<table>
<thead>
<tr>
<th>Risk</th>
<th>Chance of the risk eventuating</th>
<th>Who is responsible for mitigating the risk?</th>
<th>Include in Blood Standard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply to the hospital or local blood blank is threatened.</td>
<td>Small</td>
<td>Australian Red Cross Blood Service (the Blood Service), the NBA and the JBC under the National Blood Agreement with Australian Health Ministers. Local institutions should have (and be ready to activate) a local Blood Supply Contingency Plan that articulates with the National Blood Supply Contingency Plan.</td>
<td>The only element that should be included in the Standard is the requirement for institutions to have a local Blood Supply Contingency Plan that articulates with the National Blood Supply Contingency Plan.</td>
</tr>
<tr>
<td>Product contains an infectious agent</td>
<td>Negligible</td>
<td>Therapeutic Goods Administration. The Blood Service.</td>
<td>No</td>
</tr>
<tr>
<td>Product is damaged prior to delivery to the hospital or local blood bank (e.g. inappropriate storage, handling, transport)</td>
<td>Negligible</td>
<td>Therapeutic Goods Administration. The Blood Service.</td>
<td>No</td>
</tr>
<tr>
<td>Prescribing appropriately (e.g. transfusion not necessary, wrong product, or wrong amount)</td>
<td>High variation in prescribing of fresh blood components¹</td>
<td>Individual doctor with monitoring by institution</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion Associated Circulatory Overload. (patient's blood volume is overloaded – can be fatal particularly in the elderly or very young with compromised cardiopulmonary function). (Included in the national haemovigilance data dictionary (NHDD))</td>
<td>Up to 1 in 100 transfusions(^2). It is under-reported and can cause death.</td>
<td>Individual nurse or doctor with monitoring by institution</td>
<td>Yes</td>
</tr>
<tr>
<td>Transfusion Related Acute Lung Injury (included in the NHDD)</td>
<td>The incidence of TRALI is unknown, because a standard definition(^3) has not been available until recently. Early reports quoted an incidence of 1 per 5000 transfused blood components(^4), with subsequent reports ranging from 1 per 432 pooled whole-blood-derived platelets to 1 per 557 000 RBCs(^5). Data from the FDA for 2005 and 2006 TRALI accounted for 56% of transfusion related deaths.</td>
<td>Individual nurse or doctor with monitoring by institution</td>
<td>Yes</td>
</tr>
<tr>
<td>Recipient receives incorrect blood or blood product/</td>
<td>There are a large number of near misses that could</td>
<td>Whoever handles samples for cross matching and blood</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Component (Included in NHDD)</th>
<th>Result in this risk eventuating that are picked up. This is a significant and potentially fatal error.</th>
<th>Or blood products (individual nurse, doctor, laboratory staff member, porter) with monitoring by the institution.</th>
<th>The product is not stored at the right temperature AFTER delivery to the hospital or local blood bank.</th>
<th>Level of risk is unknown.</th>
<th>Individuals responsible for moving and storing blood within the institution with oversight from the institution.</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is not enough stock in the hospital blood bank due to poor inventory management or poor (or lack of) contingency planning</td>
<td>Low-moderate risk</td>
<td>Laboratory staff in consultation with the Blood Service and clinicians.</td>
<td>Yes</td>
<td>Blood or blood products are wasted.</td>
<td>Unknown risk as it is not reported.</td>
<td>All staff prescribing, handling and administering blood and blood products.</td>
</tr>
</tbody>
</table>

With the above in mind, it is critical that of transfusion safety in hospitals has a strong focus on:

- reducing inappropriate prescribing. This can be effectively achieved through the introduction of Patient Blood Management principles which are described above and which form the basis of the Patient Blood Management Guideline (currently under development) by the National Blood Authority in collaboration with relevant Colleges and Societies and the NHMRC. The Guideline comprises six modules that will be released sequentially in the areas of Critical Bleeding/Massive Transfusion, Perioperative, Critical Care, Medical, Paediatrics/Neonatal and Obstetrics.
- Improving transfusion related quality and safety at the bedside (e.g. making sure the sample of blood taken from the recipient for cross matching is taken from the right patient and labeled with that person’s name, double checking that the ‘right’ product is given to the ‘right’ patient and in the ‘right’ way.
- Improvements to monitoring, early recognition and reporting of adverse events known to cause patient harm (e.g. Transfusion Associated Circulatory Overload, Transfusion Related Acute Lung Injury, Incorrect Blood Component Transfused)
- Improving the safety and efficiency of how blood is managed and handled within the hospital (but not before it gets to the hospital.)

In this standard which is intended for organisations that administer blood and blood products, is essential to shift the emphasis away from product quality and national supply issues that are outside the scope of this Standard.
To facilitate this change in emphasis it is recommended that the reference to the risk of HIV be removed from the table on page 11. It would be more appropriate to include any of the following.

| Haemolytic Reactions: | Acute 1: 12,000 to 77,000  
|                       | Delayed 1: 4,000 to 9,000  |
| TACO: Fluid overload/cardiac failure | Up to 1% of patients receiving transfusions |
| TRALI                  | 1: 5,000 to 190,000          |

2. Specific comments in relation to the reforms outlined in the RIS paper.

1. Which option do you believe would be the most effective way of improving safety and quality for patients?

The National Blood Authority agrees that Option 2 would enable the Standards to be introduced in a nationally consistent manner. Stronger articulation of the anticipated role of agencies such as the National Blood Authority is required. The term ‘regulators’ appears to be more relevant to jurisdictions.

2. What do you believe are the cost, benefits and other impacts of this option, for your organisation, for consumers and/or for the health system? Please include any information or analysis to quantify and support your position.

Costs to the NBA:
- staff time in the development and review of the national standards and provision of advice to the Commission and Ministers to ensure articulation between the Standard and sector developments;
- Production of Guidelines (such as the Patient Blood Management guideline, FVIII and FIX guidelines, Criteria for the Clinical Use of Intravenous Immunoglobulin) which provide the basis for appropriate prescribing of blood and blood products;
- Maintenance of a National Haemovigilance Dataset and definitions;
- Production of Australian Haemovigilance Reports that would incorporate information about the national Blood and Blood Product Standard;
- NBA would also anticipate that time and costs would be associated with bringing together the Haemovigilance Advisory Committee to review the results of the Blood Standard published by the Commission.

Costs to others:
- Accrediting Agencies
  - Training of surveyors in the use of the Standards (will likely be passed on to users of the service)
  - Adaption of assessment systems to comply with the Commission requirements (will likely be passed on to users of the service)
  - Increased costs associated with reporting results of Standards to ACSQHC. (will likely be passed on to users of the service)
  - Costs associated with becoming ‘approved’
  - Costs associated with reviewing Standards with the Commission (4 year cycle).
- Health Services that are already
  - Cost of meeting the Standards associated with implementing safety and quality
accredited

- new equipment such as fridges to keep blood stored at the right temperature
- improvements to incident reporting systems and reporting processes
- introduction and maintenance of new governance arrangements (e.g. transfusion committee)
- cost of audits and training materials
- cost of increased resources in transfusion (e.g. Patient Blood Management Coordinator or Transfusion Consultant Nurse)
- development of support materials and clinical pathways (e.g. development of protocols and referral processes to ensure anaemia is treated before patients arrive for surgery)
- Cost of training staff
- Increased costs of participating in accreditation due to costs passed on by accrediting agencies.

Health Services not yet accredited

- As above.

Consumers

- Potential for some increase in service costs associated with:
  - newly accredited services passing on additional costs
  - passing on increased costs of accreditation process

System

- Standards development costs, initially met from the Commission’s operating budget.
- Standards implementation costs which accrediting agencies may require the Commission to support.
- Costs associated with reporting on performance against the Standards (e.g. establishment of a web-page and reporting processes, resources, database development etc)
- Costs associated with reviewing Standards on a 4 yearly cycle. This will require input from experts and associated meeting and travel costs.
- Investment in time by experts, health services and other stakeholders in the development and maintenance of Standards.

Benefits:

Assuming that the Commission agrees to amend the Blood and Blood Product Standard to align more closely with Patient Blood Management principles as requested in the NBA’s submission on 8th October, 2010 and also in this submission, significant benefits should be derived across the health care system. The NBA anticipates that the implementation of Patient Blood Management practices coupled with comprehensive haemovigilance as supported through Option 2 will result in:

- Better uptake of guidelines including Patient Blood Management practices. This should lead to reduced exposure to blood and blood products which should translate to a reduction in patient harm and improved patient outcomes including reduced morbidity: ICU and hospital LOS and rates of infections\(^6\) while simultaneously reducing blood product consumption;
- Increased local and national haemovigilance reporting. This will lead to an increase in knowledge and actions in relation to the cause of errors that lead to serious adverse reactions and incidents;
- Better information to focus quality improvement initiatives at both the local and hospital levels which should translate to more efficient use of funding for these initiatives;
- Better organisation of care around the patient\(^7\) as promoted through the recent Health Care Reforms;
- Reduced inventory pressures and costs associated with transfusion\(^8,9\):

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\(^6\) Taylor RW, O’Brien UJ, Trottier S et al. 2006 Critical Care 34(9)

• Optimum use of a precious donated product;
• More efficient and safer handling of blood and blood products; and
• Reduced wastage of blood and blood products.

Option 2 will result in improved access to standardised information by patients, health care organisations and professionals, policy developers and regulators alike.

The above benefits should outweigh the costs associated with implementing a quality and safety program using the implementation strategy proposed in Option 2, assuming that the quality and safety program is based on the principles of Patient Blood Management.

3. Are there other standards that could be more cost or clinically effective and still meet Health Ministers requirements of a national safety and quality standards?

The NBA encourages the retention and continuation of the EQuIP 5 standards for blood, developed by the Australian Council on Healthcare Standards. These standards have been evolving for a long period of time and organisations have been progressively developing their systems to meet these standards. The NBA understands that Option 2 allows for the national Standards to be appended to the existing standards utilised by the institution. The NBA understands that the EQuIP 5 standards may need to be refined to avoid duplication of accreditation requirements. The NBA supports this approach.

The Commission is recommending Option 2:

4. Please quantify any likely direct one off and/or recurrent cost impact of this option on your organisation?

Review of the standard for Blood and Blood Products will require an investment of staff time.

5. Please quantify any likely indirect costs or other impacts for staff or other resources from the implementation of this option.

The Blood Standard is based on the availability of evidence based guidelines. Option 2 will be mandatory for organisations that are likely to use blood and blood products. Under the National Blood Agreement, Health Ministers, the Jurisdictional Blood Committee and the NBA are responsible for quality and safety in relation to blood and blood products including ensuring the availability of guidelines and data to inform and support best practice. As there is a tight link between the Blood Standard and the National Blood Agreement, the following indirect costs relate to achieving the goals of both the National Blood Agreement and the implementation of Option 2.

Guideline development: includes staffing, systematic review, committee management, consultancy costs, design and promulgation (well in excess of $500,000 per year) dependent on the number of guidelines under development/review.

Haemovigilance – management of the national database, production of biannual reports and costs associated with the Haemovigilance Advisory Committee (in excess of $200,000 per year).

Development of jurisdictional haemovigilance systems (costs vary depending on the maturity of the system.

The National Blood Authority and the Jurisdictional Blood Committee have committed funds to support these quality and safety endeavors.

6. Are there changes to the options you believe are necessary for more effective implementation?

Stronger clarity and articulation of the role of agencies such as the NBA is required to ensure that future development of the standards aligns with emerging best practice. The expertise and knowledge about this practice resides in the experts who are immersed in literature pertaining to the topic. It is hoped that the Commission’s future processes will continue to facilitate strong consultation that affords stakeholders a genuine capacity to influence the drafting these standards.

7. Do you have any comments in relation to the proposal to implement the Standards?

The Standards should be designed in such a way to complement existing evidence based initiatives. This should be the case for the Blood and Blood Products Standard which is supported by a number of initiatives including guideline development, a national Patient Blood Management initiative and a National Haemovigilance program. Further work is also being undertaken in Data-linkage to support performance monitoring and feedback in select jurisdictions.

Option 2 provides for the inclusion of the private sector in a standardised reporting framework which is strongly supported by the NBA.

The NBA would like to see clearer articulation of how and when the information derived from implementing these standards will be reported back to governments including organisations such as the NBA, hospitals and the general public.

Transparency and timely feedback of information is critical to improving quality and safety.