National Horizon Scanning Unit
Horizon scanning prioritising summary

Volume 1, Number 5:

Polyheme® and hemopure®, blood substitute products: For the provision of emergency, short-term transfusion to trauma patients.

November 2003
PRIORITISING SUMMARY

REGISTER ID: 0000007

NAME OF TECHNOLOGY: POLYHEME® AND HEMOPURE®, BLOOD SUBSTITUTE PRODUCTS

PURPOSE AND TARGET GROUP: PROVISION OF EMERGENCY, SHORT-TERM TRANSFUSION TO TRAUMA PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐ Yet to emerge
☐ Experimental
☒ Investigational
☐ Nearly established

☐ Established
☐ Established but changed indication or modification of technique
☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐ Yes
☒ No
☐ Not applicable

ARTG number

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
<th>Trials Underway or Completed</th>
<th>Limited Use</th>
<th>Widely Diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi centred, USA, Canada, Europe</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA, Phase III trials</td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>USA, RCT</td>
<td>✓</td>
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</tbody>
</table>

IMPACT SUMMARY:

Northfield Laboratories Inc and Biopure Corporation provides Polyheme® and Hemopure® respectively with the aim of reducing or delaying the need for allogenic red blood cell transfusion. Hemopure® is made from stabilised bovine haemoglobin in a balanced salt solution. Polyheme® is a chemically modified haemoglobin solution derived and purified from human blood. Both products have been modified to prevent the deleterious effects of mismatching during transfusion and purified to remove infectious agents. Hemopure® can be stored at room temperature, has a shelf life of 36 months and has universal compatibility. Human red blood cells (RBC) need to be refrigerated, have a shelf life of 42 days and are type-specific. Hemopure® and Polyheme® focus primarily on the delivery of oxygen at up to 3 times the efficiency of RBC, to tissues during times of emergency and traumatic blood loss and have no nutrient delivery value. Once transfused the products have a short life span of 12-24 hours, compared to up to 50 days for RBC transfusions.

There are concerns in respect of the availability and safety of allogenic blood supplies, particularly during mass trauma events. Australia, like many countries, are experiencing increasing volunteer blood donation shortages due to the increase of infectious diseases in the community (HIV, Hepatitis B and C). In addition, Australia has banned individuals from...
donating blood who have spent a cumulative period of six months or more in the United Kingdom, between 1 January 1980 and 31 December 1996, due to the unsubstantiated and unknown risk of transmission of Variant Creutzfeldt-Jakob Disease (vCJD), commonly known as Mad Cow Disease. Australian bloodstocks are regularly low or at times critical for many of the eight blood groups.

An RCT of patients undergoing cardiac surgery who required transfusion (Levy et al 2002) reported patients who received Hemopure® received a mean of 1.72 subsequent units of RBC and patients who received RBC alone required 2.19 subsequent units (p=0.05).

Hemopure® has been approved for use in South Africa for patients with chronic anaemia but as yet has not been given FDA approval in the United States.

Both Hemopure® and Polyheme® would not be suitable for transfusion use in patients of the Jehovah Witness religion, as both these products are derived from either animal or human blood sources.

CONCLUSION:
There is limited Level II evidence, Phase III trials, however there is a growing need for safe and effective blood products in the Australian health system.

HEALTHPACT ACTION:
Therefore it is recommended that this technology be referred to the Jurisdictional Blood Committee.

SOURCES OF FURTHER INFORMATION:
Khan, A. K., Jahr, J. S. et al (2003). 'Does lead interfere with hemoglobin-based oxygen carrier (HBOC) function? A pilot study of lead concentrations in three approved or tested HBOCs and oxyhemoglobin dissociation with HBOCs and/or bovine blood with varying lead concentrations', Anesth Analg, 96 (6), 1813-1820, table of contents.


**SEARCH CRITERIA TO BE USED:**

Blood Substitutes
Blood Substitutes/pharmacology/*therapeutic use
Clinical Trials
Hemoglobins/adverse effects/chemistry/pharmacokinetics/therapeutic use
Hemoglobins/*administration & dosage/metabolism
Human
Cardiac Surgical Procedures/*adverse effects
Oxygen Consumption/drug effects/*physiology
Oxygen/*blood
Oxyhemoglobins/*metabolism
Anemia/*therapy