



Australian Government

Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND
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AND THE GOVERNMENT OF NEW ZEALAND

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.**

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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):

- | | |
|---|--|
| <input type="checkbox"/> Yet to emerge
<input type="checkbox"/> Experimental
<input checked="" type="checkbox"/> Investigational
<input type="checkbox"/> Nearly established | <input type="checkbox"/> Established
<input type="checkbox"/> Established <i>but</i> changed indication or modification of technique
<input type="checkbox"/> Should be taken out of use |
|---|--|

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|--|
| <input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | ARTG number
<input type="checkbox"/> Not applicable |
|--|--|

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
South Africa		✓	
Multi centred, USA, Canada, Europe	✓		
USA, Phase III trials	✓		
USA, RCT	✓		

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:

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SEARCH CRITERIA TO BE USED:

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