Royal Hospital for Women (RHW)
BUSINESS RULE
COVER SHEET

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SUMMARY	The appropriate screening and management of all women who are unable to receive blood products or have complex red cell antibodies
Key Words	Blood products, alternatives, screening, acceptability

Blood Products – Management of Pregnant Woman unable to use Blood Products

RHW CLIN108

This Clinical Business Rule (CBR) is developed to guide safe clinical practice at the Royal Hospital for Women (RHW). Individual patient circumstances may mean that practice diverges from this Clinical Business Rule. Using this document outside RHW or its reproduction in whole or part, is subject to acknowledgement that it is the property of RHW and is valid and applicable for use at the time of publication. RHW is not responsible for consequences that may develop from the use of this document outside RHW.

Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.

1 BACKGROUND

The aim of this CBR is the appropriate assessment and management of a woman who is unable to use blood products during pregnancy, intrapartum and/or the postpartum period.

Reasons a woman cannot have a transfusion of blood products in pregnancy, intrapartum or postnatally may include[3]:

- Religious beliefs (e.g. Jehovah's Witness (JW))
- Personal grounds
- Complex red cell antibodies and/or rare blood group

2 RESPONSIBILITIES

2.1 Medical staff will:

- Identify woman who may decline or are unable to receive blood products
- Assess, counsel, explore and arrange alternative management options where appropriate
- Reduce risk of requiring blood products antenatally, intrapartum and postnatally by optimising woman's status and preventing blood loss
- Refer to and involve other consulting teams, including Anaesthetics and Haematology, as required

2.2 Midwifery and nursing staff

- Identify woman who may decline or are unable to receive blood products
- Reduce risk of requiring blood products antenatally, intrapartum and postnatally by optimising woman's status and preventing blood loss
- Refer to Obstetric team

3 PROCEDURE

3.1 Clinical Practice

Antenatal

- Identify woman who cannot receive blood products:
  - Declined by woman, OR
  - With complex red cell antibodies and/or rare blood group
- Identify and document any risk factors that may indicate need for blood products:
  - Identify deficiencies (full blood count (FBC), ferritin, B12 and folate) at first antenatal visit
  - Assess for bleeding risk including:
    - known obstetric risk factors
    - use of anticoagulant and anti-platelet medications and supplements
    - personal history of an inherited or acquired bleeding disorder
    - family history of bleeding disorder
- Identify blood group and antibody status
- Complete relevant documentation as per Refusal of Blood and/or Blood Product consent form (see appendix 1) and give woman Blood and Blood Products and Procedures/Treatments Patient information sheet (see appendix 2)
- Book woman to obstetric clinic for initial consultation after first visit, and again in third trimester to:
  - Counsel woman at increased risk of haemorrhage and possible significant morbidity/mortality
  - Advise appropriate place of birth
  - Recommend active management of the third stage of labour
  - Discuss potential treatments, including interventional radiology and postpartum hysterectomy in the case of a major/life threatening haemorrhage
  - Obtain consent and document what treatments the woman accepts if she were unconscious/unable to communicate including in the case of life-threatening haemorrhage
- Consider referral to haematologist/haematology clinic. Early Haematology referral if complex red cell antibodies and/or rare blood group.
- Optimise blood levels antenatally:
  - Perform FBC and ferritin regularly, minimum booking, 28, and 36 weeks gestation
  - Identify and treat deficiency i.e. iron, B12, folate
  - Recommend oral iron supplement (100-200mg elemental iron/day, see oral iron treatment in pregnancy factsheet for more details) and oral folate (0.5mg/day) with a target ferritin > 100ug/L
  - Recommend intravenous (IV) iron therapy if oral therapy ineffective or not tolerated
  - Reduce iatrogenic blood loss with a restrictive phlebotomy approach

  - Erythropoiesis stimulating agents (ESA) e.g. erythropoietin, darbepoietin alfa, have limited data. Consult with haematology
- Discuss recommendations to minimise blood loss at birth
  - active third stage with appropriate uterotonics +/- tranexamic acid
  - early repair of perineal trauma
  - early consideration of transfer to operating theatre
- Consider review by interventional radiologist in conditions with high risk of blood loss e.g. placenta praevia
- Ensure collaboration with haematologist and/or Australian Red Cross Blood Service (ARCBS) for woman with complex red cell antibodies and/or rare blood group
- Consider whether anticoagulant/antiplatelet medication can be withheld throughout pregnancy and prior to birth
- Consideration in the instance of refusal of blood products:
  - Advanced Care Directive (ACD), this is a legal document – ensure a copy is in the woman's medical record. Jehovah's Witness have a specific ACD which should:
    - indicate which products would and would not be acceptable to the woman. This may include preferences on:
      - Red Blood Cells (RBC), platelets, fresh frozen plasma (FFP) / Extended life plasma (ELP)
      - Minor blood fractions e.g. albumin, clotting factors, immunoglobulins, Anti-D Immunoglobulin
      - Recombinant products e.g. Eprex®
      - Procedures, involving her own blood e.g. intraoperative blood cell salvage, haemodialysis, epidural blood patch
  - Document acceptable blood products[5,6]
- Refer to anaesthetic clinic in antenatal period for consultation
- Document a clear and comprehensive intrapartum and postpartum care plan

Intrapartum

- Review the ACD and multidisciplinary care plan for birth
- Discuss intrapartum and postpartum plan with woman, including strategies to avoid prolonged labour, and active management of third stage, early repair of perineal trauma, early consideration of transfer to operating theatre
- Site 16g IV cannula, collect FBC, Antibody screen, Group and Hold and/or cross match
- Inform obstetrician, anaesthetist and haematologist that woman has been admitted
- Inform blood bank if a woman with complex red cell antibodies and/or rare blood group has been admitted

Postpartum

- Ensure regular monitoring postpartum of maternal observations, fundal height, and blood loss (including accurate documentation of cumulative blood loss)
- Manage active haemorrhage promptly as per Postpartum Haemorrhage – Prevention and Management CBR, involve obstetrician, anaesthetist and haematologist early
- Achieve haemostasis urgently - consider operating theatre (OT) early, as early procedural (e.g. intrauterine balloon tamponade, B-Lynch suture) or definitive (e.g. hysterectomy) management may be life saving[4]
- Consider cell salvage intraoperatively

Management of Postpartum Anaemia

- Identify and treat haematinic deficiency (Iron, B12, Folate)
- Restrict phlebotomy, and consider paediatric sample tubes where possible
- Additional individualised management options, in consultation with haematology include:
  - Administration of fractions (e.g. cryoprecipitate, prothrombinex) if there is ongoing bleeding and the woman consents to its use
  - Use of ESA and hyperbaric oxygen therapy
- Advise woman to return promptly to hospital if she has any concerns about bleeding during the postpartum period on discharge

3.2 Documentation

- Antenatal card
- Medical Record
- Advanced care directive
- Refusal of Blood and/or Blood Products SMR020.010

3.3 Education Notes

- There is a 45-65 times greater maternal mortality risk in those who refuse blood transfusions compared to the general obstetric population[3]
- The competent woman's choice must be respected, both ethically and legally. The competent woman has the right to refuse any form of life-sustaining treatment[3]
- Maternal autonomy before fetal beneficence upholds the law in New South Wales[3]
- Health professionals have a continuing duty to provide care and may only refuse to provide care if this decision does not adversely impact upon the woman's health, and an alternative caregiver has agreed to accept responsibility for ongoing care[3]
- Erythropoietin/darbepoietin:
  - requires haematologist review
  - is not subsidised for this indication on the pharmaceutical benefits scheme (PBS) and is restricted on SESLHD Formulary
  - Erythropoietin is ineffective in patients with iron, B12, or folate deficiency
  - Lacks good evidence for benefit
- Jehovah's Witnesses can obtain an advanced care directive from their own organisation

- The following generally apply to a woman who is Jehovah's Witness[7]:
  - Unacceptable products include:
    - major blood components (e.g. red blood cells, platelets, fresh frozen plasma)
    - autologous blood transfusion
  - Woman's personal decision include:
    - blood fractions e.g. cryoprecipitate, albumin, prothrombinex, fibrinogen concentrate
    - Anti-D immunoglobulin
    - intraoperative techniques e.g. blood salvage, acute normovolaemic haemodilution
  - Usually acceptable products include:
    - Recombinant products
- Offer employee assistance program (EAP) counselling to either groups or individual clinicians involved in traumatic cases

3.4 Implementation, communication and education plan

This revised CBR will be distributed to all medical, nursing and midwifery staff via @health email. The CBR will be discussed at ward meetings, education and patient quality and safety meetings. Education will occur through in-services, open forum and local ward implementation strategies to address changes to practice. The staff are asked to respond to an email or sign an audit sheet in their clinical area to acknowledge they have read and understood the revised CBR. The CBR will be uploaded to the CBR tab on the intranet and staff are informed how to access

3.5 Related Policies/procedures

- Postpartum Haemorrhage – Prevention and Management
- Blood component management and administration – POWH/SSEH CLIN013
- Women who choose to refuse recommended monitoring and treatment in Maternity Services in SESLHD SESLHDPR/482
- Advanced Care Planning SESLHDGL/077
- Blood Management PD2024_024

3.6 References

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4. National Blood Authority. Patient Blood Management Guidelines: Module 5 – Obstetrics and Maternity. National Blood Authority (NBA). Canberra, Australia, 2015.
5. NSW Ministry of Health. Consent to Medical and Healthcare Treatment Manual. NSW Ministry of Health. Sydney, 2020.
6. Australian Commission on Safety and Quality in Health Care (ACSQHC). Safety and Quality Improvement Guide Standard 7: Blood and Blood Products. ACSQHC. Sydney, 2012.
7. Crowe, E., & DeSimone, R. (2021). When blood transfusion is not an option owing to religious beliefs. Annals Of Blood, 7. doi:10.21037/aob-21-58

4 ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION

- Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.
- When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman or family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal Liaison Officers, health workers or other culturally specific services

5 CULTURAL SUPPORT

- For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours
- If the woman is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017_044-Interpreters Standard Procedures for Working with Health Care Interpreters.

6 NATIONAL STANDARDS

- Standard 2 – Partnering with Consumers
- Standard 5 - Comprehensive Care
- Standard 6 – Communicating for Safety
- Standard 7 – Blood Management
- Standard 8 – Recognising and responding to Acute Deterioration

7 REVISION AND APPROVAL HISTORY

Date	Revision No.	Approval
16/12/2024	6	RHW BRGC
29/10/2024		Maternity CBR Committee
Reviewed and endorsed Maternity Services LOPs June 2020 Approved Quality & Patient Care Committee 16/2/17 Reviewed and endorsed Maternity Services LOPs January 2017 Previously titled Blood Products Refusal in Pregnancy Approved Quality & Patient Safety Committee 19/8/10 Obstetrics Clinical Guidelines Group August 2010		

Appendix 1

NSW Health

Facility:

REFUSAL OF BLOOD AND/OR BLOOD PRODUCTS

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. ____/____/____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

SMR020010

This form is only to be used for an adult patient with capacity, who is refusing any blood and/or blood products. If there is any doubt about the capacity of the patient or if the patient is a minor, escalate to a more senior colleague **or an Executive staff member.**

For more information refer to the NSW Health Consent to Medical and Healthcare Treatment Manual.

If the patient is accepting ALL blood and/or blood products use the appropriate NSW Health Consent to Medical Treatment form:

- **SMR020.001 Consent for Medical Procedure/Treatment Adult (NH606006)**
- **SMR020.002 Consent Substitute Consent For Medical Procedure/Treatment (NH606007)**
- **SMR020.003 Consent for Medical Procedure/Treatment Minors (NH606008)**

There should be early identification of any blood products the patient will not consent to. This form is a part of the patient's comprehensive blood management plan. In addition to completing this form, the discussion with the patient as to whether or not any surgery, procedure or treatment should proceed must be carefully documented in the health care record.

Instructions for use of this form:

- This form must be completed by the most senior doctor available. This should be at the level of Registrar or above.
- The doctor must complete page 2 of this form indicating the blood and blood products and procedures / treatments that are acceptable or refused by the patient.
- This form only relates to the treatment of the disease, condition or the operation specified below.

Holes Punched as per AS2828.1: 2019 BINDING MARGIN - NO WRITING

Doctor to complete

I, Dr _____ have discussed with the patient, that transfusion of blood or blood products may be necessary

for _____
Name of disease or condition being treated or proposed operation

I have informed the patient that refusal of blood or blood products and/or other procedures / treatments related to transfusion may result in serious adverse consequences. These may include organ or tissue damage, disability, permanent injury or death. I have advised the patient that some blood management procedures/treatments may not be available at all health facilities.

The information sheet, titled "Blood and Blood Products and Procedures / Treatments - Patient Information" has been given to the patient.

I have clarified the patient's wishes in relation to the transfusion of blood and blood products for the treatment of the disease, condition or the operation above and these wishes are documented on page 2.

_____ ____/____/20____
Signature of senior medical practitioner — Date

Interpreter _____ _____ ____/____/20____ _____:_____ _____
Print Name — Signature — Date — Time — Emp ID/Prov No.

Patient to complete

Dr _____ has discussed with me the medical risks, benefits and alternatives related to my decision to refuse the transfusion of blood and blood products and procedures / treatments, as indicated on page 2 of this form.

- I accept or refuse blood, blood products and procedures / treatments as indicated on page 2 of this form.
- I understand and accept the risks and possible consequences including organ and tissue damage, disability, permanent injury or death, that may result from my decisions.
- I understand that if I wish to change my decision, I must advise my treating doctor/s immediately.
- I understand that elective treatments may be cancelled if my treating doctor/s believe that refusal of blood and blood products would present risks that outweigh the benefits of the treatment.
- I understand that my decision will not affect the relationship with my health care team.
- I understand that not all blood management procedures/treatments are available at all facilities.

This form clarifies my wishes and I understand that if I sign this form, and if I have an Advance Care Directive, that this form supersedes any Advance Care Directive in relation to the blood products or procedures / treatments involving blood in the treatment of the disease, condition or the operation above.

_____ _____ ____/____/20____
Name of patient — Signature of patient — Date

Withdrawal of this decision

This decision can be withdrawn or changed by the patient, at any time, either verbally or in writing. If the patient changes their mind, then this must be documented in the patient's health record; a new form must be completed and this form must be struck through with a diagonal line, on both sides. Print and sign your name and date on the line.

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REFUSAL OF BLOOD AND/OR BLOOD PRODUCTS SMR020.010

NO WRITING

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NSW Health

Facility:

REFUSAL OF BLOOD AND/OR BLOOD PRODUCTS

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION / WARD	

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

I, _____ accept or refuse blood, blood products and procedures / treatments
patient name

as indicated below.

I understand that not all of these blood products and procedures / treatments may be applicable, or available to me at all facilities.
A tick box must be checked for every item, even where the blood products or procedures / treatments are not available at the facility.

1. Donated Blood Products		
Red Blood Cells (RBC)	☐ I accept	☐ I refuse
Platelets	☐ I accept	☐ I refuse
Fresh Frozen Plasma (FFP) and Extended Life Plasma (ELP)	☐ I accept	☐ I refuse
Cryoprecipitate	☐ I accept	☐ I refuse
Cryodepleted Plasma	☐ I accept	☐ I refuse
Prothrombin Complex Concentrate	☐ I accept	☐ I refuse
Albumin	☐ I accept	☐ I refuse
Fibrinogen Concentrate	☐ I accept	☐ I refuse
Topical Thrombin and/or Fibrinogen	☐ I accept	☐ I refuse
Immunoglobulins	☐ I accept	☐ I refuse
Other plasma derived clotting factors	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
2. Laboratory Manufactured Clotting Factors		
Recombinant clotting factors	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
3. Laboratory Manufactured Animal-Derived Sealing Agents		
Bioglue	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
4. Blood Management Related Procedures / Treatments		
Peri-operative Cell Salvage	☐ I accept	☐ I refuse
Normovolaemic haemodilution	☐ I accept	☐ I refuse
Heart (Cardiac) Bypass/ECMO (Extra Corporeal Membrane Oxygenation)	☐ I accept	☐ I refuse
Plasma Exchange/Plasmapheresis	☐ I accept	☐ I refuse
Haemodialysis	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse
Other – Specify _____	☐ I accept	☐ I refuse

NO WRITING

Appendix 2

NSW Health

Blood and Blood Products and Procedures / Treatments

Patient Information

Introduction

There are many reasons why we use transfusions of blood and/or blood products for patients. Some common situations that may require transfusion include bleeding from surgery, child birth, anaemia (not enough red blood cells) and cancer.

Transfusion of blood products may be recommended for you if certain parts of your blood e.g., red cells, platelets, clotting factors or plasma, have low levels or are not working properly.

In life-threatening circumstances, despite all of our best efforts to minimise blood loss and re-utilise your own blood, there may be no substitute for donated blood products to save your life.

This information sheet is to be kept by the patient and is not to be filed in the health care record.

Donated Blood Products

Red Blood Cells (RBC)
- Carry oxygen from the lungs to the rest of the body and return carbon dioxide from the body to the lungs.
- Are used to treat severe anaemia (not enough red blood cells) or severe blood loss.

Platelets
- Help blood to clot and are given to prevent or stop bleeding.

Fresh Frozen Plasma (FFP) and Extended Life Plasma (ELP)
- The liquid part of blood after cellular components i.e. red blood cells, white blood cells and platelets, have been removed.
- Contain albumin, clotting factors and other proteins.
- Are given if a person does not have enough plasma or clotting factors.

Cryoprecipitate (sometimes known as "cryo")
- Contains important clotting factors such as fibrinogen and is given to people with certain clotting problems or low fibrinogen levels, to help blood clot.
- Is used to treat some very specific disorders.

Cryodepleted Plasma (not the same as "cryo")
- Is what is left after some blood clotting factors (cryoprecipitate) have been removed from fresh frozen plasma.
- Is used to treat some very specific disorders.

Prothrombin Complex Concentrate (PCC)
- Is collected from human plasma.
- Contains clotting factors, which help blood to clot.
- Is given to prevent or treat bleeding and reverse the effect of anticoagulants.

Albumin
- Is a protein in human plasma.
- Is given when a person's albumin is low, or when there is low blood volume in the body, which can occur with fluid loss.
- Other uses include haemodialysis and plasma exchange (blood filtering).

Fibrinogen concentrate
- Is a clotting factor collected from human plasma which helps blood to clot.
- Is given when a person's fibrinogen is low, which can occur with massive bleeding, infection or liver disease.

Topical Thrombin and/or Fibrinogen
- Is a clotting factor gel applied directly to a site of bleeding to minimise blood loss during surgical procedures.
- Are haemostatic agents used with standard surgical techniques.

Immunoglobulins
- Are human plasma proteins with broad antibody activity.
- Contain antibodies to help defend against infection.
- Are given to treat and support a range of immune deficiencies and autoimmune conditions.

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Laboratory Manufactured Clotting Factors
Recombinant Clotting Factors • Are synthetic clotting factors made in a laboratory, for example NovoSeven®. • Help blood to clot. • Are given when a person does not have enough clotting factors, such as with inherited bleeding disorders.
Laboratory Manufactured Animal-Derived Sealing Agent
Bioglue • Is a surgical adhesive made from purified animal serum albumin. • Is applied directly to a site of bleeding.
Blood Management Related Procedures / Treatments
Peri-operative Cell Salvage • Where your own blood lost during surgery is collected and then returned to you. • This can happen during or after surgery. • This can be a "continuous/closed circuit". Normovolaemic Haemodilution • Where some of your blood is removed at the start of surgery and replaced with a fluid. • The collected blood is given back to you during or after your surgery. **Heart (Cardiac) Bypass / ECMO (Extra Corporeal Membrane Oxygenation)** • Both Heart (Cardiac) Bypass & ECMO involve large tubes being placed into blood vessels, and the blood being pumped through a machine before returning to your body. • They both help provide the body with oxygen and remove carbon dioxide. • Heart (Cardiac) Bypass is usually used during heart lung surgery. • ECMO is usually used as a means of life support over a longer period. • Both are "continuous/closed circuits". **Plasma Exchange / Plasmapheresis** • Is a process in which your blood is removed and separated into red blood cells and plasma. • Your healthy red blood cells are then returned to you in a "continuous/closed circuit" and the plasma is discarded. • You will be given a transfusion of donated plasma or albumin. Haemodialysis • Is a procedure that is carried out for patients with advanced kidney failure where the waste, salts and fluid from blood are filtered through a machine to clean the blood. • This is a "continuous circuit".
More information about blood products, procedures or treatments
• Please visit *lifeblood.com.au*. • Preoperative Autologous or Directed Donations - are generally not available except for very specific medical indications. For more information refer to https://anzsbt.org.au/wp-content/uploads/2018/06/ANZSBTPADstatementApr2015.pdf • Ask your doctor or nurse.

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Position Statement