Australian and New Zealand Society of Blood Transfusion

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# GUIDELINES FOR TRANSFUSION AND IMMUNOHAEMATOLOGY LABORATORY PRACTICE

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# In memoriam

We would like to dedicate these revised guidelines to the memory of Tony Greenfield who died so tragically on 1 December 2019. Tony was a highly-valued member of the committee (and wider transfusion community) and we will miss his wisdom, humour and knowledgeable contributions to our activities.

# Guidelines for transfusion and immunohaematology laboratory practice

**1st Edition Revised**

Prepared by the:

**Transfusion Science Standing Committee**
Australian and New Zealand Society of Blood Transfusion Ltd

145 Macquarie Street

Sydney
NSW 2000

AUSTRALIA

# Transfusion Science Standing Committee

## Committee

| | |
|---|---|
| Nicole Zacher | Australian Capital Territory (Chair) |
| Simon Benson | New South Wales |
| Greg Irwin | New South Wales |
| Liz Lennox | Queensland |
| Samantha Lennard | Queensland |
| Annette Le Viellez | Western Australia |
| Helen Stathopoulos | South Australia |
| Diane Woolacott | New Zealand |

## Previous committee members (contributing to development and writing of the guidelines)

| | |
|---|---|
| James Daly | Queensland |
| Dhana Gounder | Auckland, New Zealand |
| Tony Greenfield | New South Wales (deceased) |
| Helen Haysom | Victoria |
| Pam Hudson | New South Wales |
| Friend Maviza | New South Wales |
| David Roxby | South Australia |
| Michael Sagan | Victoria |

# Foreword

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) Council is pleased to release this revision of the first edition of the ***Guidelines for transfusion and immunohaematology laboratory practice***.

These guidelines are aimed at pathology laboratories responsible for providing transfusion services and obstetric immunohaematology testing. They are intended to complement existing standards in this area and to provide more detailed guidance to assist laboratories, both in their routine day-to-day practice and in meeting accreditation requirements.

The ANZSBT's Transfusion Science Standing Committee (TSSC) once again undertook the task of revising the guidelines with energy and enthusiasm. I should note that publication does come with some sadness following the loss of Tony Greenfield in early December 2019. Tony's presence on the committee will be sorely missed.

We appreciate the feedback received since publishing the first edition; whilst we may not have incorporated every suggestion or point of view there have been a number of necessary changes or clarifications through the document to ensure it continues to represent what the TSSC believes are current best and safe practices in the pretransfusion, prenatal and postnatal settings.

Previous guidelines have been widely accepted and we are confident that this revised document will once again prove to be extremely valuable to Australasian laboratories.

**Simon Benson**
**ANZSBT President**

**January 2020**

# Contents

# Introduction

The aim of these guidelines is to provide guidance and direction for pathology laboratories responsible for providing transfusion services and undertaking immunohaematology testing, particularly in the prenatal and postnatal settings.

Adherence to standards, guidelines and documented policies and procedures is absolutely crucial to patient safety. Consequently, the laboratory must have a documented quality management system that describes the organisational structure, policies, procedures, processes and resources required to operate in accordance with safe and appropriate laboratory and clinical practice. In these settings, the provision of safe and appropriate practice requires:

- documentation and patient identification systems that minimise clerical errors and misidentification
- determination of a patient's ABO and RhD group, and performance of an antibody screen to detect clinically significant red cell antibodies
- diagnosis and management of haemolytic disease of the fetus and newborn
- adherence to the stringent requirements necessary for the use of information and communications technology
- contingency plans for use when routine systems are not available – these should include manual systems to deal with loss of automation and the laboratory information system
- suitable quality control (QC) programs for reagents, techniques, equipment and personnel
- selection and provision of clinically safe and appropriate blood and blood products
- appropriate storage and handling of blood and blood products
- appropriate investigation of adverse effects of transfusion
- appropriate retention of records, data and documentation as required by regulatory bodies.

These guidelines reflect the broader transfusion and health-care environment that encompasses the requirements of national accreditation authorities, national blood services and other regulatory bodies. The laboratory should also be aware of any current complementary standards, requirements or guidelines; for example, those published by the National Pathology Accreditation Advisory Council, the Australian and New Zealand Society of Blood Transfusion, Standards Australia, Australia's National Blood Authority, the Australian Commission on Safety and Quality in Health Care or the National Association of Testing Authorities.

## *Terminology*

These guidelines are primarily informative and reflect what the Transfusion Science Standing Committee believes is the minimum acceptable level of practice. Guidance is provided in the form of recommendations, the strength of which is indicated by the following (modal) terms:

**Must** Indicates a strongly recommended practice where compliance would be expected.

**Should** Indicates a recommended practice where compliance would be expected but alternative practices may be acceptable.

**May** Indicates a practice that is permitted within the context of the guidelines.

# Section 1
## Requests, specimens and record keeping

### 1.1 General principles

1.1.1 All requests must comply with these guidelines, although the laboratory may choose to adopt more stringent requirements.

1.1.2 Specimens used for pretransfusion testing must have been collected in accordance with these guidelines. This includes specimens originally collected for other reasons; for example, prenatal or postnatal immunohaematology, haematology or biochemistry tests.

ⓘ Cord blood specimens should not be used for pretransfusion testing.

1.1.3 The laboratory should have a policy for managing requests associated with patients transferred from other hospitals, facilities or external locations outside of their jurisdiction.

### 1.2 Electronic or 'paperless' systems

1.2.1 Electronic systems used by the laboratory must comply with all applicable guidelines and standards. This includes stand-alone systems and those interfaced with institutional systems; for example, the laboratory information system (LIS), patient admission system (PAS), hospital electronic medical record (EMR) or computerised prescriber order entry system (CPOE).

ⓘ The ANZSBT endorses the British Society for Haematology (BSH) *Guidelines for the specification, implementation and management of information technology (IT) systems in hospital transfusion laboratories* (2014)[1]

1.2.2 Electronic solutions are available that integrate the LIS, EMR and mobile devices, barcode scanners and label printers or radio-frequency identification (RFID) technology, and these can enhance safe and secure patient identification across the transfusion process.

1.2.3 All transactions within an electronic system must be securely and unambiguously recorded, with the ability to trace and attribute them to the operator performing them.

1.2.4 Where an operator is required to 'sign' or 'initial' a document or record (e.g. the declaration on a transfusion request), the use of a unique electronic or digital signature or other appropriate system-generated identifier is acceptable and has the same status as handwritten details.

1.2.5 Electronically stored information must be fully accessible for the entire regulated retention period with no changes to or loss of data and accommodating any subsequent redundancy or changes to the storage technology or media.

1.2.6 The laboratory must have contingency plans including manual systems to manage occasions when electronic systems are unavailable and it is not possible to access electronic patient or test records.

### 1.3 Patient identification

1.3.1 Failure to correctly identify the patient (e.g. at specimen collection or before transfusion), prescribing the wrong product and transfusing the wrong patient are all causes of major morbidity and mortality.

1.3.2 Patient details, for example provided on requests (see 1.4, 1.5 and 1.6), specimens (see 1.7) and in laboratory records (see 1.9) must comply with the requirements of the National Pathology

[1] https://b-s-h.org.uk/guidelines

Accreditation Advisory Council (NPAAC) *Requirements for medical pathology services:*

- **three unique** identifiers must be used for requests, compatibility reports and labels, laboratory records; and
- **two unique** identifiers must be used when labelling the specimen (although three are preferable).[2]

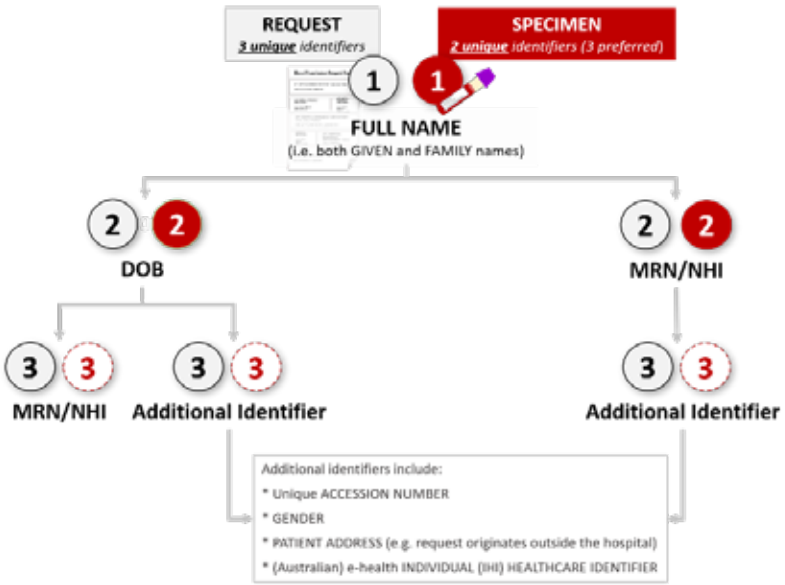
1.3.3 The patient identifiers must include the patient's FULL NAME and at least one of either DATE OF BIRTH (DOB) or a UNIQUE RECORD NUMBER such as a MEDICAL RECORD NUMBER (MRN) in Australia or NATIONAL HEALTH INDEX (NHI) number in New Zealand.

ⓘ The Australian MEDICARE NUMBER is not a unique record number and therefore not an approved identifier.

1.3.4 Other approved additional identifiers include:[3]

- Unique ACCESSION NUMBER
- GENDER
- PATIENT ADDRESS (e.g. if request originates outside the hospital)
- (in Australia) e-health INDIVIDUAL HEALTHCARE IDENTIFIER (IHI)

*Figure 1: Request and specimen identification*




1.3.5 Alternative identifiers may be used in special circumstances, such as when patients are to remain anonymous.

1.3.6 The patient identifiers recorded on the request and specimen label must agree.

1.3.7 When collecting specimens, institutional policy may permit the phlebotomist to amend patient identifiers on the request to match the **confirmed details** provided by the patient.

1.3.8 Procedures for patient identification must include management of:

- patients without an identification wristband or who are unconscious, irrational or otherwise unable to respond to direct questioning
- patients whose details change (e.g. when the true identity of an unknown patient is subsequently established), including a procedure for linking or merging the different identities.

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[2] https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-medpathserv-2018

[3] National Safety and Quality Health Service Standards: Communicating for safety standard (https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/correct-identification-and-procedure-matching/action-65)

1.3.9 If the patient's identity is not known or is unclear (e.g. in trauma situations), temporary or emergency identifiers must be used until the patient's actual identity is confirmed. In events involving multiple casualties, temporary medical record numbers should not be consecutive.

1.3.10 Temporary patient identifiers must be used for all blood product requests until the patient's actual identity is established and a new request (and a new specimen, if necessary) is received with the updated details.

1.3.11 Truncation of patient identifiers, for example by laboratory and/or hospital information systems, is a potential cause of misidentification errors. The laboratory must have a policy and procedure for handling the issues arising when long patient names (or other mandatory identifiers) are truncated or shortened.

## 1.4 Requests

1.4.1 A request must be received by the laboratory before testing or the issue of blood products can occur.

1.4.2 Requests that do not comply with the laboratory's requirements must not be accepted, except at the discretion of the laboratory director.

1.4.3 Requests may be written, verbal (see 1.6), electronic or any combination of these. For transfusion requests, a dedicated form is recommended.

ⓘ The request **is not** a prescription and in some organisations practitioners other than doctors have the authority to generate requests for transfusion.

1.4.4 The request must clearly (and legibly) identify the patient with **THREE unique identifiers** (see 1.3).

1.4.5 Requests for pretransfusion testing (including prenatal and postnatal specimens upgraded to a pretransfusion request) must contain a declaration, similar to the one shown below, that has been signed by the person collecting the specimen:

> *I certify that I collected the specimen accompanying this request from the stated patient whose details I confirmed by direct enquiry and/or examination of their ID wristband and I labelled the specimen immediately after collection in the presence of the patient.*

1.4.6 The request should also provide the following information:

*Table 1.1: Additional information required when making a request*

| All requests | Requests for which blood products are required |
|---|---|
| ▪ Patient's gender<br>▪ Patient's location<br>▪ Test(s) requested<br>▪ Signature (or other traceable identifier) and contact details of the phlebotomist<br>▪ Date and time specimen was collected<br>▪ Name and contact details of the requesting practitioner | ▪ Type of blood product(s) with number of units or dose<br>▪ Special requirements (e.g. irradiated or CMV seronegative products)<br>▪ Clinical diagnosis and indication for transfusion<br>▪ Date, time and location of transfusion<br>▪ Previous transfusions including any adverse reactions<br>▪ Relevant patient history such as red cell antibodies and obstetric history including receipt of RhD-Ig |

CMV, cytomegalovirus; RhD-Ig, RhD immunoglobulin

## 1.5 Requests for cord blood or newborn testing

1.5.1 The request must clearly identify the baby **and** include information linking the baby to its mother; for example:

SINGLE BIRTH

- [mother's] FAMILY NAME, Baby of [mother's GIVEN NAME] — for example SMITH, Baby of Jane
- baby's DOB
- baby's gender

MULTIPLE BIRTHS

- [mother's] FAMILY NAME, Baby [1, 2 etc.] of [mother's GIVEN NAME]— for example SMITH, Baby 1 of Jane
- baby's DOB
- baby's gender.

1.5.2 If the baby's MRN/NHI is available this should be included on the request.

1.5.3 The request should also include:

- signature and contact details of the phlebotomist
- date and time cord blood (or baby's venous) specimen was collected
- name and contact details of the person making the request.

## 1.6 Verbal requests for blood products

1.6.1 The patient must have a valid group and screen (where applicable).

1.6.2 Verbal requests for blood products may be made either face-to-face or by telephone, but institutional policy or other regulations may require a retrospective formal written or electronic request.

1.6.3 Verbal requests must be documented by the person receiving the request and confirmed (e.g. by repeating back the information provided).

1.6.4 The person making the request must be recorded along with the information shown in Table 1.2.

*Table 1.2: Information required when making a 'verbal' request*

| Patient information | Blood product information |
|---|---|
| ▪ Three unique identifiers (see 1.3.3):<br>○ FULL NAME<br>○ DOB and/or MRN/NHI<br>▪ Prescribing clinician's name<br>▪ Requestor's name | ▪ Product type(s) required<br>▪ Number of units or dose<br>▪ Date and time required<br>▪ Reason or clinical indication for request<br>▪ Location of intended transfusion |

DOB, date of birth; MRN, Medical Record Number; NHI, National Health Index

1.6.5 Records of verbal requests must be retained according to regulatory requirements; for example, by scanning a copy of the written note into the LIS or EMR.

## 1.7 Specimens

1.7.1 All specimens (whether pretransfusion, prenatal or postnatal) must comply with the labelling requirements in this document.

1.7.2 Procedures for specimen collection, handling and management should include unidentified patients (see 1.3.8) and unlabelled, inadequately or incorrectly labelled specimens.

1.7.3 The performance characteristics and suitability for immunohaematology testing of different specimen tube types may vary; therefore, tubes must be used in accordance with the manufacturer's instructions.

1.7.4 EDTA (plasma) or clotted (serum) specimens are both suitable for immunohaematology testing, although which is used will depend on the test and method or platform (e.g. automated versus manual methods).[4] For the purposes of these guidelines, 'plasma' will be used irrespective of specimen type unless otherwise stated.

ⓘ If using **plasma** some weak complement-binding antibodies may be missed.

ⓘ If using **serum** haemolysis can indicate a positive reaction.

1.7.5 The specimen must be clearly and legibly labelled with the patient's details. Labelling must be performed immediately after collection **and** in the presence of the patient; the patient's details must

[4] EDTA: ethylenediaminetetraacetic acid

agree with those on the request.

1.7.6 Handwritten labelling of specimens is strongly recommended in the absence of a full electronic system that securely identifies the patient and prints labels on demand at the bedside.

ⓘ Preprinted addressograph (or similar) labels are not recommended but may be accepted at the discretion of the laboratory director.

1.7.7 The specimen must be labelled with at least **TWO unique patient identifiers** (although **three** should be used if they can be accommodated; see 1.3).

1.7.8 The patient (if conscious and rational) must be asked to both state and spell their FULL NAME, state their DOB and confirm their ADDRESS if used as an identifier.

1.7.9 The specimen must also be labelled with the:

- SIGNATURE (or other traceable Identifier) of the phlebotomist, who must be the same person completing the declaration on the request.
- DATE and TIME the specimen was collected, if this is not otherwise recorded electronically and fully traceable.

1.7.10 The patient's details recorded on the specimen and request must be checked against their hospital identification wristband (for hospital inpatients).

1.7.11 If an inpatient does not have a hospital identification band, a specimen should not be collected until this situation has been remedied or the patient has otherwise been appropriately identified.

1.7.12 Specimens that are unlabelled, incorrectly labelled or about which there is doubt as to the integrity of labelling (e.g. evidence suggesting removal of a previous sticky label or a label from one patient stuck over that of another patient) must not be used for testing.

1.7.13 Correction of incorrect details, relabelling specimens or retrospective labelling of unlabelled specimens is not permitted.

## 1.8 Specimen storage

1.8.1 Specimens must be stored at a temperature that maintains their viability for the lifetime of the request. Table 1.3 shows the combination of permissible storage times and storage temperatures.

*Table 1.3: Storage temperatures for whole blood and plasma used in pretransfusion testing*

| | Storage temperature | | |
|---|---|---|---|
| **Specimen type** | **18–25 °C** | **2–8 °C** | **–20 °C** |
| Whole blood (EDTA) | Up to 48 hours | Up to 7 days | N/A |
| Separated plasma | Up to 48 hours | Up to 7 days | Up to 3 months [5] |

EDTA, ethylenediaminetetraacetic acid; N/A, not applicable;

1.8.2 Laboratories choosing to use extended storage of separated plasma must understand the risks of doing so and have a documented procedure that ensures that the integrity of patient identification and labelling of the secondary tube is maintained.

1.8.3 Pretransfusion specimens from recipients of red cells should be retained for up to 7 days after transfusion to allow investigation of possible transfusion reactions; separation and freezing of the plasma or serum during the storage period is not required.

## 1.9 Laboratory records

### *1.9.1 General principle*

1.9.1.1 Records must comply with the requirements of the national accreditation authority or regulatory body, and be retained in accordance with statutory requirements.

[5] BSH *Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories* (2012) (https://b-s-h.org.uk/guidelines)

### 1.9.2 Patient records

1.9.2.1 A record containing the information shown in Table 1.4 must be held for each patient for whom pretransfusion or other testing (e.g. prenatal or postnatal) or blood products are requested.

*Table 1.4: Information required for patient records*

| Patient information | Blood product information |
|---|---|
| ▪ Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI<br>▪ Gender<br>▪ ABO/RhD blood group<br>▪ Date and time of specimen collection (if one collected)<br>▪ Antibody screen results<br>▪ Other testing results (e.g. antibody identification, antigen typing, DAT)<br>▪ Specimen or request validity/expiry (see 2.2.6)<br>▪ Details of the person performing the testing<br>▪ Special requirements, warnings or other relevant information | ▪ Product type<br>▪ Expiry date<br>▪ Donation or batch number<br>▪ ABO/RhD blood group<br>▪ Antigen typing<br>▪ Date of compatibility testing<br>▪ Compatibility testing result<br>▪ Date and time of issue (transfusion)<br>▪ Details of the person performing the compatibility testing |

DAT, direct antiglobulin test; DOB, date of birth; ID, identification; MRN, Medical Record Number; NHI, National Health Index

### 1.9.3 Compatibility or issue report

1.9.3.1 A compatibility or issue report should be provided by the laboratory either before or with the first blood product released for the patient. The report must be placed in the patient's clinical notes or uploaded to the EMR as a record of pretransfusion testing.

1.9.3.2 The report must include the information shown in Table 1.5 and may be provided as a printed paper copy, as a removable portion of the compatibility label or electronically.

*Table 1.5: Information required for the compatibility or issue report*

| Patient information | Blood product information |
|---|---|
| ▪ Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI<br>▪ ABO/RhD (if applicable)<br>▪ Pretransfusion testing results including interpretation and clinical comments<br>▪ Special requirements, warnings or other relevant information | ▪ Product type<br>▪ ABO/RhD<br>▪ Donation or batch number<br>▪ Blood product expiry date<br>▪ Quantity issued (if applicable) |

DOB, date of birth; MRN, Medical Record Number; NHI, National Health Index

1.9.3.3 The compatibility or issue report must not be used as part of the pre-administration bedside identity check but may be used to check blood product information once the recipient's identity is established.

### 1.9.4 Compatibility or issue label

1.9.4.1 A compatibility or issue label, with the patient and product information listed in Table 1.6, must be securely attached to each blood product unit or boxed bottle or vial when the product is allocated or issued to a patient. Some elements of this information may also be presented in barcoded form.

*Table 1.6: Information required for the compatibility or issue label*

| Patient information | Blood product information |
|---|---|
| ▪ Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI<br>▪ Patient's location or ward<br>▪ ABO/RhD blood group | ▪ Donation or batch number<br>▪ ABO/RhD blood group (where applicable)<br>▪ Statement of compatibility or suitability<br>▪ Blood product expiry date and time<br>▪ Identity of the person affixing the label |

DOB, date of birth; MRN, Medical Record Number; NHI, National Health Index

1.9.4.2 Additional information may be provided on the compatibility label in accordance with local policies; for example:

- laboratory request or event number
- special patient or product requirements
- identity of the person allocating (or issuing) the product
- date and time of issue or allocation of product
- date and time of intended transfusion
- date and time after which the product must not be transfused.

### *1.9.5 Receipt of blood products*

1.9.5.1 The laboratory must keep a record of the following information for each blood product received:

- donation or batch number
- product type
- ABO/RhD group (where applicable)
- supplier
- date and time received
- expiry date and time.

1.9.5.2 The laboratory may also record the results of antigen typing, and special attributes or modifications, such as cytomegalovirus (CMV) seronegative or irradiated.

### *1.9.6 Issued or transfused blood products*

1.9.6.1 The laboratory must keep a record of the following for each blood product issued for transfusion:

- recipient's FULL NAME
- recipient's DOB; and/or recipient's MRN/NHI
- date and time of issue or transfusion
- location.

### *1.9.7 Fate of blood products*

1.9.7.1 It must be possible to trace every blood product from receipt by the laboratory to its ultimate fate, whether this is to a patient, clinical area, another facility or disposal.

1.9.7.2 The change in status or fate of each blood product must be recorded by the laboratory; for example:

- ISSUED (i.e. from the laboratory or a remote location)
- TRANSFUSED (where this is known)
- DISCARDED (e.g. expired, out of controlled storage, damaged or recalled by supplier)
- TRANSFERRED to another laboratory or institution.

1.9.7.3 Transfused blood packs, bottles or vials should not normally be returned to the laboratory except where required for further investigation (e.g. products implicated in a transfusion reaction).

# Section 2
# Pretransfusion testing

## 2.1 General principles

2.1.1 The ABO group is the most important pretransfusion test. It is therefore crucial that the sensitivity and security of the testing system is not compromised.

2.1.2 Automated systems should be used where possible to minimise opportunities for interpretation or transcription errors.

2.1.3 A **full** ABO group (see 2.5.1.1), RhD type and antibody screen (e.g. 'group and screen' or 'G&S') must be performed on all specimens submitted for pretransfusion testing. For prenatal and postnatal specimens, a blood group and antibody screen are performed as required.

2.1.4 Obtaining a current drug or treatment history is important particularly if the patient is receiving agents known to cause immune haemolysis, a positive DAT or otherwise interfere with pretransfusion testing.

## 2.2 Specimen acceptance criteria

2.2.1 Specimens must be checked on receipt to ensure that they are appropriately labelled and the patient's details are the same as those provided on the request.

2.2.2 Grossly haemolysed specimens should not normally be accepted for testing. Haemolysed specimens may be caused by inappropriate collection, storage or transport, or by the patient's underlying condition or treatment.

2.2.3 The blood group and antibody screen should be completed within 48 hours of the specimen being collected unless it is stored refrigerated (see 1.8.1).

2.2.4 When there is a delay between collection and receipt, the laboratory must ensure that transport and storage conditions maintain the specimen's viability.

2.2.5 Specimen acceptance depends on a reliable transfusion or obstetric history. It is the responsibility of the requestor to ensure that this information is documented and provided to the laboratory.

2.2.6 Appropriately stored specimens (see Table 1.3, page 6) are acceptable for pretransfusion testing as follows:

- **72 hours** from collection: if the patient has been pregnant or transfused in the previous 3 months (or if this information is not available or is unreliable).
  - ⓘ If permitted by the LIS specimen validity or expiry may be set to **3 days** (i.e. midnight of the third day following collection) rather than 72 hours.
- **7 days** from collection: if the patient has not been pregnant or transfused in the previous 3 months.
- **(Up to) 3 months** from collection: for specimens taken in advance of elective surgery; it must be confirmed at the time of collection **and again** following their subsequent admission to hospital that the patient has not been pregnant or transfused in the preceding 3 months.

2.2.7 If a patient is receiving repeated transfusions, a new specimen should normally be collected every 72 hours.

2.2.8 The laboratory may choose to extend specimen validity to 7 days in certain clinical situations – such as pregnant women with a high risk of transfusion (e.g. placenta praevia) – or for transfusion-dependent patients with no clinically significant alloantibodies.

2.2.9 If the patient is subsequently transfused a new specimen should be obtained for a group and screen as soon as possible following the transfusion.

2.2.10 For transfusion-dependent patients the decision to extend specimen expiry must be reviewed **at least annually** or if the patients subsequently develop alloantibodies.

2.2.11 The decision to extend specimen validity is at the discretion of the laboratory director and should be based on an assessment of the risk to the patient. Any extension to specimen validity must be documented in the LIS and patient's clinical record.

## 2.3 Automated immunohaematology instruments

2.3.1 Automated instruments must undergo appropriate validation and verification (see 8.8) before being introduced into routine use, with records kept in accordance with national regulatory requirements.

2.3.2 If the instrument is interfaced with the LIS, the validation must include the interface.

2.3.3 The laboratory must maintain a validated manual system to cover instrument failure and downtime.

2.3.4 After scheduled preventative maintenance or emergency repair, a documented 'return to service' procedure must be followed.

2.3.5 The laboratory should have a documented procedure for manual editing and authorisation of test results, including the designation of staff allowed to perform these tasks.

2.3.6 Editing and authorisation of results should require password-controlled access where possible.

2.3.7 The laboratory must have a written policy and procedure for data backup, archiving of data and recovery of data in the event of instrument failure.

2.3.8 Instruments should have in-built safeguards (with user notification) to detect system failures; for example:

- failure of liquid circuits or mechanical valves
- inappropriate storage conditions for reagent red cells and other fluids
- failure to dispense or aspirate samples, reagents or wash solutions
- inappropriate level of test mixture in the reaction vessel.

2.3.9 Instruments must ensure security of patient identification between the sample and testing results; the use of barcoded laboratory accession numbers is recommended.

2.3.10 Secondary barcodes on specimens (or samples) must not obscure the primary label.

2.3.11 The laboratory must have a procedure to check that secondary labels have been applied to the correct specimen (or sample).

## 2.4 Labelling of secondary samples, test tubes, cassettes

2.4.1 Sample tubes, test tubes, column agglutination technology (CAT) cassettes or other media must be labelled with sufficient details of the patient (and, where appropriate, the blood product) to ensure that test results are assigned to the correct patient or blood product.

## 2.5 Blood grouping

### *2.5.1 ABO group*

2.5.1.1 A full ABO group consists of both forward and reverse groups that must be agreed for a valid group to be recorded; that is:

**Forward group** Red cells tested with monoclonal anti-A, anti-B reagents. Anti-A,B must be used when testing newborns, but otherwise use is optional.

ⓘ If no plasma is available for the reverse group, the forward group should include a test of patient's red cells against reagent diluent or AB plasma as a control for autoagglutination.

**Reverse group** Plasma is tested against $A_1$ and B reagent red cells.

2.5.1.2 The reverse group provides an important check of the forward group, and can highlight ABO grouping anomalies; for example, due to transfusion, stem cell transplantation and other factors such as ABO subgroups, cold agglutinins or the patient's age or clinical condition.

2.5.1.3 A reverse group is not necessary for specimens from newborn infants up to the age of 4 months because any ABO antibodies are likely to be of maternal origin and are therefore unlikely to be informative.

### 2.5.2 RhD typing

2.5.2.1 RhD typing in pretransfusion testing, testing prenatal and postnatal maternal specimens and testing newborn specimens (e.g. cord blood) consists of red cells tested with a monoclonal anti-D reagent that **does not** detect RhD category VI (DVI).

2.5.2.2 A diluent control should be included where specified by the reagent manufacturer.

2.5.2.3 Further testing of apparent RhD negatives (e.g. by IAT) is not required.

### 2.5.3 Confirming the patient's ABO/RhD type

2.5.3.1 If the patient has a historical ABO/RhD type, the current typing results must match those obtained previously.

2.5.3.2 New patients must have a second, confirmatory ABO/RhD type performed on either a new aliquot from the original specimen tested with the same or different reagents or a new specimen collected independently of the original specimen:

- If confirmation is performed by **manual** methods it should, wherever possible, be performed by a second individual having no prior knowledge of the original result; or
- If confirmation is performed by **automated** methods there must be a procedure for independently verifying the patient's identity and ensuring that the correct barcode label has been applied to the specimen being tested.

### 2.5.4 ABO/RhD typing anomalies

2.5.4.1 ABO or RhD anomalies should be resolved before selection of blood products for transfusion.

2.5.4.2 If the ABO group or RhD type (or both) cannot be determined, they should be reported as indeterminate:

- group O red cells must be used until the ABO group is resolved
- RhD negative red cells should be used until the RhD type is resolved, particularly for females with childbearing potential.

2.5.4.3 In emergency situations, if the ABO/RhD type has not been or cannot be determined, selection of blood products should be in accordance with 4.1.4.

### 2.5.5 Confirming the ABO group and RhD types of donor red cell units and other types of donation

2.5.5.1 The ABO group of all donor red cell units and the RhD type of RhD negative units must be confirmed before use. RhD negative donor red cell units do not need to be tested for RhD variants.

2.5.5.2 Apparent RhD negative bone marrow, haemopoietic stem cells, granulocytes and other types of donation (e.g. directed donations) must be confirmed by testing with an RhD reagent that detects category DVI.

2.5.5.3 Group confirmation of donor units is usually performed by the laboratory undertaking pretransfusion testing. However, it is permissible for testing to be centralised; for example, at the base hospital or main laboratory of a network with 'group-confirmed' units distributed to their satellite facilities. The group confirmation results should be available (in written or electronic form) to the laboratory performing pretransfusion testing.

2.5.5.4 Group confirmation testing of donor units with subgroups of A or B (e.g. $A_x$, $A_m$, $A_{el}$ or $B_x$ units) may give results that contradict the primary blood group label by appearing to type as group O although labelled as group A or B respectively.

ⓘ ABO subgroups identified and confirmed by the blood service are printed on the unit's blood group label as a 'phenotype'. This should be considered sufficient to resolve the apparent discrepancy, allowing the unit to be accepted into the inventory and safely transfused to a

recipient ABO compatible with the unit's labelled blood group. Any unexpected discrepancies must be referred to the blood service.

### 2.5.6 Controls for ABO/RhD typing

2.5.6.1 Positive and negative controls must be regularly included during testing, when reagent lots change and when the analyser is started up.

2.5.6.2 The frequency at which controls are used depends on work patterns, methods used and the manufacturer's instructions. As a minimum, controls should be included once per day or on each day that the laboratory undertakes testing when this is not daily (as per 8.6.3).

*Table 2.1: Controls for ABO/RhD typing*

| Reagent | Positive control cells | Negative control cells |
|---|---|---|
| **Anti-A** | A | B |
| **Anti-B** | B | A |
| **Anti-D** | RhD positive | RhD negative |

## 2.6 Antibody screening

### 2.6.1 General principles

2.6.1.1 Antibody screening is performed to determine whether a patient has clinically significant red cell antibodies.

2.6.1.2 The patient's plasma is tested by an indirect antiglobulin test (IAT) method against a mini-panel of two or three reagent red cells, each of which has a known antigenic profile.

2.6.1.3 Clinically significant red cell antibodies are generally those that are reactive in a 37 °C IAT.

2.6.1.4 Anti-A, anti-B and anti-A,B must always be regarded as clinically significant.

2.6.1.5 A standard low ionic strength solution (LISS) IAT screening method must be capable of detecting at least 0.1 IU/mL anti-D; more sensitive IAT methods can detect lower concentrations.

2.6.1.6 Manual and automated methods for IAT may differ in their specificity and sensitivity, and the chosen technology or platform must be fully validated.

2.6.1.7 Other methods, such as enzyme techniques, may be used to supplement (but not replace) the IAT technique. These may be inferior to the IAT for detecting some examples of clinically significant antibodies.

2.6.1.8 The increased sensitivity of red cells with homozygous antigen expression, such as Jk(a+b-), is particularly important for preventing delayed transfusion reactions, especially those due to Kidd antibodies.

### 2.6.2 Antibody screening cells

2.6.2.1 Antibody screening cells are a complementary set of two or more group O reagent red cells (each prepared from a single donor), which between them must possess the antigens C, c, D, E, e, M, N, S, s, K, k, $Fy^a$, $Fy^b$, $Jk^a$, $Jk^b$, $Le^a$ and $Le^b$. The cells from different donors must not be pooled to achieve the desired antigen expression.

2.6.2.2 One screening cell should be $R_1R_1$ (or $R_1^WR_1$) and another $R_2R_2$.

2.6.2.3 The homozygous phenotypes Jk(a+b-), Jk(a-b+), Fy(a+b-) and Fy(a-b+) must be represented; the phenotypes SS and ss are also desirable.

### 2.6.3 Controls for antibody screening

2.6.3.1 A weak positive antibody control, such as anti-D at a concentration of at least 0.1 IU/mL (or other weak antibody specificity at a comparable concentration), should be run at least once per day, or on each

day that the laboratory undertakes testing when this is not daily, to monitor efficacy of the test procedure (as per 8.6.3).

2.6.3.2 The acceptable reaction strength for each control batch will depend on the manufacturer's specifications, technique used and scoring system (i.e. 0–4 or 0–12).

## 2.7 Antibody identification

2.7.1 The specificity of antibodies detected during screening must be identified and their clinical significance assessed (see Table 2.2, page16).

2.7.2 Laboratories that do not routinely perform antibody identification should send specimens with a positive antibody screen to an appropriately accredited laboratory (ideally within 24 hours of detecting the antibody). It may be necessary to refer specimens to a specialist reference laboratory for further investigation or confirmatory testing.

2.7.3 Patients known to have a red cell antibody must have each new specimen (as required in 2.1.3) tested to exclude formation of additional antibodies.

2.7.4 The patient's plasma should be tested by IAT against a red cell identification panel capable of identifying clinically significant antibodies. Inclusion of the patient's own cells (auto control) may be helpful in determining the presence of an autoantibody or an antibody to a high-frequency antigen.

2.7.5 The specificity of an antibody can normally be assigned when it is reactive with at least two red cells carrying the corresponding antigen and two red cells lacking that antigen.

2.7.6 The presence of anti-Jk$^{a}$, -Jk$^{b}$, -S, -s, -Fy$^{a}$ and -Fy$^{b}$ should be excluded by using red cells with homozygous expression of the corresponding antigens.

2.7.7 Using a variety of different techniques – for example, enzyme-treated cells, polyethylene glycol (PEG)-IAT, prewarmed reagents or neutralisation – may assist in confirming the presence of Rh antibodies, antibodies weakly reactive by IAT or suspected mixtures of antibodies.

2.7.8 The patient's red cells usually lack the antigen against which the antibody is directed unless it is an autoantibody. The patient's antigen typing should be confirmed using commercial antisera (if available) by the laboratory performing pretransfusion testing.

2.7.9 Where conventional serological phenotyping is inappropriate – either because the patient was recently transfused or has a positive direct antiglobulin test (DAT), or where the results are ambiguous or require confirmation; for example, due to a Fy(a-b-) and GATA mutation – then a specimen should be referred to a specialist reference laboratory for a genotype.

## 2.8 Compatibility testing (crossmatching)

2.8.1 The laboratory must have procedures to ensure compatibility between the recipient and donor.

2.8.2 Crossmatching procedures must primarily detect ABO incompatibility; suitable techniques include RT immediate-spin, IAT or electronic crossmatching.

2.8.3 For clinical procedures where the likelihood of red cell use is low only a 'group and screen' is recommended. If transfusion becomes necessary, crossmatched blood must be available in a timely manner that is consistent with local clinical needs.

2.8.4 The laboratory should avoid unnecessary holding or reserving of crossmatched red cells by only crossmatching on demand when transfusion is required or adopting a 'maximum surgical blood order schedule' (MSBOS; Appendix 1).

2.8.5 An abbreviated crossmatch (using an immediate-spin tube technique) or an electronic crossmatch (eXM; see 2.9) may be used if the patient has no clinically significant antibodies or no history of such antibodies.

2.8.6 An immediate-spin crossmatch must not be performed if the patient has weak anti-A or anti-B reactions in their reverse group.

2.8.7 If the immediate-spin technique is used, it is recommended that the donor red cells should be washed at least once to minimise the possibility of the patient's anti-A or anti-B (or both) being neutralised by soluble donor ABH substance.

2.8.8 If the patient has a clinically significant antibody (or has a history of such antibodies), then donor red

cells negative for the corresponding antigen should be selected. The selected red cells must be crossmatched by IAT.

2.8.9 The antigen types of selected donor units should be confirmed using commercial antisera (if available).

2.8.10 The antigen typing should be undertaken by the laboratory performing the pretransfusion testing, except where typed red cells are distributed between accredited facilities of a laboratory network or organisation.

2.8.11 Requests for crossmatching can be made at any time during the lifetime of the specimen (see 2.2.6). Once a transfusion episode has commenced, the crossmatch request becomes invalid at either the original expiry of the specimen, or 72 hours/midnight of the third day (as applicable) after transfusion of the first unit of red cells began, whichever occurs first.

2.8.12 Once a transfusion episode has commenced, subsequent specimens from the patient have an expiry of 72 hours until at least 3 months has elapsed since the last transfusion (see 2.2.6).

## 2.9 Electronic crossmatch

2.9.1 An eXM is permitted when:

- the laboratory has a comprehensive, validated, electronic data management system
- a valid pretransfusion specimen has been tested in accordance with the requirements given in 2.5 and 2.6
- the patient has no clinically significant antibodies or no history of such antibodies.

2.9.2 The LIS must not permit selection of ABO-incompatible red cells. When products with a different but compatible ABO/RhD type are selected (see 3.1.1.2) the LIS should generate a warning message or flag.

2.9.3 In exceptional cases (e.g. emergency transfusions; see 4.1), where a group and screen specimen is unavailable or testing is incomplete, an eXM is permissible but the LIS must only **allow group O red cells** to be issued until a **current valid** ABO group is available, irrespective of whether there is a historical record of the patient's ABO/RhD type.

2.9.4 When a patient requires a 'special' product (e.g. CMV negative or irradiated), the LIS must generate a warning message or flag. The system must not allow products to be released until the warning or flag is addressed and suitable products selected.

2.9.5 After eXM, the blood product must be labelled with a unique compatibility label. The software must check that the group of the labelled unit is compatible with the recipient's group.

2.9.6 The laboratory must have a mechanism for ensuring that the correct unit has been labelled.

2.9.7 A compatibility or issue report should be produced with the first unit issued (see 1.9.3).

## 2.10 Release or issue of blood products

2.10.1 Requests to release (or issue) blood products may be made by telephone or fax, electronically or in person (e.g. an orderly or nurse coming to the laboratory or accessing a remote blood refrigerator), or by other acceptable means.

2.10.2 The requestor must clearly identify the intended patient, providing (as a minimum) the patient's full name and DOB and/or MRN/NHI.

2.10.3 Blood products may be released directly to someone collecting them from the laboratory, delivered through a validated pneumatic tube system (PTS) or released for remote storage location (e.g. ward or theatre refrigerator, or a satellite facility).

2.10.4 The laboratory should be able to confirm if and when the blood product arrived at its intended destination.

2.10.5 The identity of the person releasing the blood product from the laboratory or removing it from a remote blood refrigerator must be recorded either electronically or in a written register kept for that purpose.

## 2.11 Electronic remote release of blood products

2.11.1 The information system for electronic remote releasing of blood products must meet the requirements specified in 2.9.

2.11.2 All users must be appropriately trained before using electronic remote release procedures, with competency reviewed regularly; also, they must have individual passwords with designated levels of access to the IT system.

2.11.3 The remote release software must have features that ensure that:

- all requirements for computer crossmatching are met
- a patient with a clinically significant antibody (or a history of such antibodies) is excluded from remote release, with the appropriate explanatory warning message or flag.

2.11.4 The parent laboratory should be notified (in **real time**, where applicable) when blood products are released or issued from remote storage to facilitate inventory management and, in particular, timely replenishment of stock.

*Table 2.2: The clinical significance of red cell alloantibodies and selecting blood for transfusion*

| Antibody specificity | Clinically significant | Selection of units* |
|---|---|---|
| Anti-$A_1$ | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-HI ($A_1$ and $A_1B$ individuals) | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-M (active at 37 °C) | Rarely | Antigen negative |
| Anti-N (active at 37 °C) | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-S, -s, -U | Yes | Antigen negative |
| Anti-P1 (Only if active at 37°C) | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-D, -C, -c, -E, -e | Yes | Antigen negative |
| Anti-$C^W$ | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-$Lu^a$ | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-$Lu^b$ | Yes | Antigen negative |
| Anti-K, -k | Yes | Antigen negative |
| Anti-$Kp^a$ | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-$Le^a$, -$Le^b$, -$Le^{a+b}$ | Rarely | IAT crossmatch compatible at 37 °C |
| Anti-$Fy^a$, -$Fy^b$ | Yes | Antigen negative |
| Anti-$Jk^a$, -$Jk^b$ | Yes | Antigen negative |
| Anti-$Co^a$ | Yes | Antigen negative |
| Anti-$Co^b$ | Sometimes | IAT crossmatch compatible at 37 °C |
| Anti-$Wr^a$ | Rarely | IAT crossmatch compatible at 37 °C |
| HTLA antibodies | Unlikely | Local policy or seek advice from reference laboratory |
| Antibodies to low- or high-frequency antigens | Depends on specificity | Local policy or seek advice from reference laboratory |
| Other antibodies active by IAT at 37 °C | Depends on specificity | Local policy or seek advice from reference laboratory |

HTLA, High-titre, low-avidity; IAT, indirect antiglobulin test; * Antigen-negative red cells should be crossmatched by IAT at 37 °C

# Section 3
# Selecting blood products for transfusion

## 3.1 Red cell products

### *3.1.1 General principles*

3.1.1.1 Procedures for selecting red cell products must cover both routine and exceptional (e.g. emergency or trauma) situations.

3.1.1.2 Red cell products should be of the same ABO/RhD type as the patient.

ⓘ Selecting products with different but compatible ABO/RhD types is permissible and may assist in reducing wastage. However, this should be balanced against creating unnaturally high usage, for example the elective use of near-expiry O RhD negative red cells for non-O RhD negative recipients.[6]

3.1.1.3 To avoid unnecessary wastage, it is preferable to maintain an appropriately representative inventory of different ABO/RhD types that reflects local usage.

3.1.1.4 Group O red cells must be selected when the patient's ABO group cannot be determined; similarly, RhD negative red cells should be used if an RhD group cannot be obtained.

3.1.1.5 Females of childbearing potential should, in addition to receiving red cells matched for ABO and RhD, also receive red cells matched for K (see 4.3).

### *3.1.2 Selecting red cells when the patient has a clinically significant antibody or has a history of such antibodies*

3.1.2.1 If the patient has a clinically significant antibody (or has a history of such antibodies), red cells negative for the corresponding antigen should be selected for crossmatching (see Table 2.2, page 16).

3.1.2.2 When transfusion is required before pretransfusion testing is complete, or is unavoidable, particularly in urgent situations, it may be necessary to select ABO/RhD compatible but otherwise serologically incompatible red cells.

3.1.2.3 The decision to transfuse must be based on consultation between the patient's clinician and a transfusion medicine specialist or the laboratory director, taking into account the clinical significance of the antibody.

3.1.2.4 For some antibodies or in complex cases, there may be a significant delay while compatible red cells are identified. The patient's clinician should be advised accordingly.

3.1.2.5 If the patient has a history of a clinically significant antibody but one that is **not currently detectable by IAT**, antigen-negative red cells are required and must be crossmatched by IAT.

### *3.1.3 Selecting red cells when the patient has a positive antibody screen due to a red cell antibody not considered clinically significant*

3.1.3.1 If the patient has an antibody not considered clinically significant but which is reactive by IAT at 37 °C – for example, anti-$A_1$, -$P_1$, -$Le^a$, -$Le^b$, -$Le^{a+b}$, -HI, autoanti-I (or other cold agglutinins) – IAT crossmatch compatible red cells should be selected for transfusion; these red cells need not be antigen negative.

3.1.3.2 If the patient has a history of an antibody with no (or doubtful) clinical significance but it is **not** currently reactive by IAT (at 37 °C) it may be permissible to issue ABO compatible red cells without

[6] Australian Red Cross Lifeblood *Use of group O RhD negative red cells* (https://transfusion.com.au/blood_products/components/red_cells/GroupO)

performing an IAT crossmatch or selecting antigen-negative red cells.

## 3.2 Plasma products

3.2.1 Plasma products (i.e. fresh frozen plasma [FFP], extended life plasma [ELP], cryoprecipitate or cryodepleted plasma [CDP]) should preferably be of the same ABO group as the patient. Where this is not possible, products that are ABO compatible with the patient's red cells should be selected to avoid haemolysis due to donor anti-A or anti-B (see Table 3.1).

*Table 3.1: Selection of plasma products*[7]

| | **Plasma product ABO group** *(in order of preference)* | | | |
|---|---|---|---|---|
| **Recipient's ABO group** | **1st choice** | **2nd choice** | **3rd choice** | **4th choice** |
| **O** | O | A | B | AB |
| **A** | A | AB | B^ | - |
| **B** | B | AB | A^ | - |
| **AB** | AB | A^ | B^ | - |
| **Unknown** | AB | A^ | - | - |

^ Plasma products that have low-titre anti-A/B pose a lower risk of haemolysis when transfusing ABO incompatible plasma.

3.2.2 Plasma products with different ABO groups must not be pooled.

3.2.3 Group AB plasma products, although suitable for patients of all ABO groups and typically used when the patient's group is unknown, are often in short supply and use may be restricted (e.g. for neonates).

**Adults** In emergencies or trauma situations when the patient's ABO group is unknown, group A plasma products may be used as an alternative to group AB (unless the product is known to have high-titre anti-B).

**Neonates** Group AB plasma products should be selected.

3.2.4 Plasma products may be selected without regard to the patient's RhD status. RhD immunoglobulin (RhD-Ig) is not required if RhD negative patients receive RhD positive plasma products.

3.2.5 Compatibility testing (or crossmatching) is not necessary before transfusing plasma products. However, the patient's ABO group should be determined before the first transfusion episode to establish a baseline record and to ensure that plasma with the appropriate ABO group is selected.

3.2.6 The patient's ABO group does not need to be retested before subsequent plasma product transfusions.

### *3.2.7 Extended life plasma (ELP)*

3.2.7.1 ELP is a separate but complementary product to thawed FFP but which in contrast has an extended shelf life of up to 5 days after thawing, when stored at 2-6°C. Labile coagulation factors V, VII and VIII are reduced in ELP but after 5 days of storage still remain at haemostatic levels (Table 3.2).

*Table 3.2: Coagulation factors (IU/mL) in FFP at thawing and after extended post thaw storage**

| **Factor** | **At thawing** | **Day 3** (post thaw) | **Day 5** (post thaw) |
|---|---|---|---|
| **Factor V** | 0.89 ± 0.14 | 0.83 ± 0.17 | 0.75 ± 0.13 |
| **Factor VII** | 1.0 ± 0.21 | 0.89 ± 0.17 | 0.85 ± 0.17 |
| **Factor VIII** | 1.08 ± 0.33 | 0.63 ± 0.18 | 0.56 ± 0.15 |

* Australian Red Cross Lifeblood data used with permission (FFP n=30 / CDP n=30)

[7] Australian Red Cross Lifeblood *Component compatibility* (https://transfusion.com.au/blood_basics/compatibility)

3.2.7.2 Where FFP is not transfused within 24 hours of thawing it may be converted to ELP as long as it has been maintained under appropriately controlled storage.

3.2.7.3 Each health service must consider whether ELP is applicable for use in its local setting. The decision to offer ELP should be made after due consideration of the advantages, contraindications and clinical risks of doing so and it may not be suitable for all patient groups or situations. Where a transfusion service provider only handles a small number of trauma or emergency cases holding an inventory of ELP is not recommended.

3.2.7.4 The hospital transfusion (or patient blood management) committee must provide guidance for the clinical indications and contraindications of plasma (including ELP). Appropriate clinical uses of plasma can be found in the *Patient Blood Management Guidelines* published by Australia's National Blood Authority.[8]

*Table 3.3: Advantages, clinical risks and contraindication for the use of ELP*

| | |
|---|---|
| **Advantages** | • reduced wastage of unused thawed plasma<br>• immediate availability of thawed plasma if required urgently, for example in trauma and massive transfusion<br>• suitability for storage and use for prehospital retrieval |
| **Clinical Risks** | • reduced levels of factors V, VII and VIII (see Table 3.2)<br>• presence of DEHP (see 3.2.7.5) |
| **Contraindications** | • not recommended for use in neonates (and FFP should be used in this patient group)<br>• not recommended for use in patients with congenital factor V or VIII deficiency if specific factor concentrates or FFP are available |

3.2.7.5 The plasticiser di(2-ethylhexyl)phthalate (DEHP) has been shown to leach into the protein and lipid rich contents of the product during storage. The consequences of transient exposure to DEHP from plasma are unclear.

3.2.7.6 The transfusion service provider must assess the risks associated with managing ELP and maintain documentation of handling, storage and requirements for use.

3.2.7.7 ELP must be clearly identifiable (and traceable) with the change in product type from FFP to ELP and updated expiry date/time being recorded in the LIS.

3.2.7.8 The laboratory must apply a label that obscures the original product name (FFP) and storage conditions and states the new product type (ELP), storage conditions and expiry (i.e. 5 days post-thaw).

ⓘ Laboratories may choose to use a printed label which includes a new product barcode. Until appropriate ISBT 128 labelling has been determined the CODABAR code A0195903B (where A0 and 3B are start and stop codes respectively) may be used.

3.2.7.9 The issue or compatibility reports must show the product type is 'Extended Life Plasma'.

## 3.3 Platelet products

3.3.1 Platelet products should preferably be the same ABO/RhD type as the recipient. This may not always be possible; for example, if there are stock constraints or where special requirements such as human leucocyte antigen (HLA) or human platelet antigen (HPA) matching take precedence.

3.3.2 Platelet units with different ABO groups must not be pooled.

3.3.3 If ABO identical platelets are not available, then ABO nonidentical platelets may be used; the decision to use such platelets should take into account the patient's age, diagnosis and available product type.

[8] http://www.blood.gov.au/pbm-guidelines

*Table 3.4: Selection of platelet products*[9]

| | **Platelet product ABO group** *(in order of preference)* | | |
|---|---|---|---|
| **Recipient's ABO group** | **1st choice** | **2nd choice** | **3rd choice** |
| **O** | O | A* | B |
| **A** | A | B# or O# | AB |
| **B** | B | A*# or O# | AB |
| **AB** | AB | A# or B# | O# |
| **Unknown** | A*# or O# | - | - |

* Group A platelets that have an $A_2$ subgroup do not express significant amounts of A antigen and are therefore more preferable for transfusion to group O and B recipients than other A platelets.

\# Apheresis platelets that have **low-titre anti-A/B** or **pooled platelets**, pose a lower risk of haemolysis when transfusing ABO incompatible products

3.3.4 Matching of platelets for RhD type is desirable but may be considered less important than ABO matching.

3.3.5 Caution should be exercised when transfusing ABO nonidentical platelets to neonatal, paediatric and small adult patients, particularly when using apheresis platelets, due to the risk of haemolysis from donor anti-A and anti-B antibodies.

3.3.6 RhD negative patients, especially females of childbearing potential (including female children), should receive RhD negative platelets wherever possible.

3.3.7 If an RhD negative patient receives RhD positive platelets, RhD-Ig should be offered in accordance with institutional policy; this will be at the discretion of the patient's clinician and will depend on the patient's gender, age and diagnosis.

3.3.8 It is not normally necessary to offer RhD-Ig to RhD negative males, postmenopausal women or those (male or female) who are heavily immunosuppressed (e.g. due to haematological malignancy).

3.3.9 If a thrombocytopenic patient requires RhD-Ig, an intravenous (IV) preparation should be considered.

## 3.4 CMV seronegative blood products

### *3.4.1 General principles*

3.4.1.1 All red cell and platelet products manufactured by the Australian and New Zealand blood services are leucodepleted.

3.4.1.2 Haemopoietic stem cells and granulocytes are not leucodepleted.

3.4.1.3 Locally collected products such as autologous blood might not be leucodepleted; if products are not leucodepleted, they should be transfused using a bedside leucodepletion filter.

3.4.1.4 Leucodepleted blood products may be considered CMV safe.

3.4.1.5 If CMV seronegative blood products are required in an emergency situation but none are available, leucodepleted blood products of unknown CMV status (i.e. CMV safe) may be used to avoid unnecessarily delaying transfusion.

### *3.4.2 Patients who require CMV seronegative cellular blood products*

3.4.2.1 CMV seronegative products should be used for the following clinical indications:

- pregnant women regardless of CMV status who require regular elective transfusions during pregnancy (but not during delivery)
- intrauterine transfusion (IUT)

[9] Australian Red Cross Lifeblood *Component compatibility* (https://transfusion.com.au/blood_basics/compatibility)

- neonates (up to 28 days post expected date of delivery)
- granulocyte transfusions for CMV negative patients.

### *3.4.3 Patients where leucodepleted blood products may safely be used*

3.4.3.1 Leucodepleted blood products are considered suitable for use (i.e. CMV safe) in the following situations, with the decision to use such products dictated by local clinical policies:

- solid organ transplants
- haemopoietic stem cell transplants (HSCT; all adult and paediatric HSCT patients)
- haematology and oncology patients
- immunodeficient patients, including those with human immunodeficiency virus (HIV).

3.4.3.2 Institutions should consider whether to introduce polymerase chain reaction (PCR) monitoring for CMV for at-risk patients to allow early detection of any possible CMV infection (whether transfusion-transmitted or otherwise acquired).

# Section 4
## Use of blood products in specific clinical situations

### 4.1 Emergency transfusion

4.1.1 In an emergency situation, a pretransfusion specimen should be obtained as soon as possible and before blood products are administered.

4.1.2 Specimens must be labelled in accordance with routine pretransfusion practice.

4.1.3 Pretransfusion testing (performed as per requirements of Section 2) must be completed as soon as possible, regardless of the fate of the patient.

4.1.4 If blood products are required before a specimen has been received, or a confirmed blood group obtained or pretransfusion testing is completed:

- red cells must be group O
- ABO/RhD compatible red cells (ideally the same group as the patient) may be issued once the patient has a confirmed ABO/RhD type (as per 2.5)
- red cells must not be issued on the basis of a historical blood group
- ABO nonidentical platelets may be given in the absence of a confirmed blood group (see Table 3.4).
- plasma products should be group AB if possible, although group A may be used (see 3.2.3).

4.1.5 If the patient has a positive antibody screen, the patient's clinician and the laboratory director or a transfusion medicine specialist must be informed that there may be a delay while the antibody is identified and compatible red cells are found:

- Where transfusion is urgently required, particularly in life-threatening situations, it may be necessary to provide ABO/RhD compatible but otherwise serologically incompatible red cells until further investigations are completed.
- Compatibility testing, including an IAT crossmatch, should be performed in accordance with 2.8 and 3.1, but the degree to which this is done will ultimately be determined by the urgency of transfusion; if necessary, testing may be performed retrospectively.

4.1.6 When stocks of RhD negative blood products are limited, the laboratory may choose to use RhD positive blood products for specific clinical situations, in accordance with local policies:

- RhD negative females with childbearing potential should only receive RhD positive products in **exceptional** circumstances
- administration of RhD-Ig should be considered if a female with childbearing potential receives RhD positive products.

4.1.7 Where a patient with an unknown blood group is receiving group O red cells, transfusion with red cells of the patient's ABO/RhD type should commence as soon as possible once a confirmed blood group is obtained.

4.1.8 Red cells issued before completion of pretransfusion testing must be clearly identified; for example, as 'Uncrossmatched blood' or 'Emergency issue – compatibility testing not completed'.

4.1.9 When uncrossmatched red cells are issued, a crossmatch segment from the unit should be retained in case retrospective testing is required.

### 4.2 Massive transfusion

4.2.1 A 'massive transfusion' is defined as either:

- transfusion (in an adult patient) of more than 1 blood volume (i.e. 10 units) in 24 hours; or
- (in acute situations) transfusion of half the blood volume (equivalent to 5 units) in 4 hours;

although other local definitions may also be acceptable.

ⓘ In contrast, 'critical bleeding' may be defined as life-threatening major haemorrhage likely to result in the need for massive transfusion.

4.2.2 The laboratory must have a written policy for managing massive transfusions (and critical bleeding), developed in consultation with clinicians having expertise in this area.

ⓘ The Australian National Blood Authority (NBA) publication *Patient blood management guidelines: Module 1 critical bleeding/massive transfusion* provides a massive transfusion protocol (MTP) template that can be adapted for local institutional use. [10]

4.2.3 Where a patient has received 10 or more red cell units in 24 hours, additional red cells can be issued without a serological crossmatch (where normally performed by the laboratory). An eXM may be used provided that the criteria in 2.9.3 are met.

4.2.4 If the patient has a clinically significant antibody, selection of red cells should be in accordance with 3.1.2. If the patient has received 10 or more red cell units in 24 hours, the laboratory director and patient's clinician may opt to transfuse appropriately antigen-negative red cells without crossmatching.

4.2.5 If a patient is receiving ABO nonidentical red cells, a return to red cells of the patient's own blood group should occur as soon as possible.

4.2.6 The monitoring of haemostasis is important for guiding the decision to transfuse other blood products. Viscoelastic tests (e.g. thromboelastometry or thromboelastography) or platelet count and coagulation parameters – for example, international normalised ratio (INR), activated partial thromboplastin time (aPTT) and fibrinogen – may be used, in which case the results should be available in the transfusion laboratory.

## 4.3 Transfusion in pregnancy

4.3.1 Prenatal and postnatal specimens must be treated the same as pretransfusion specimens in respect of patient identification, collection and labelling (in accordance with Section 2).

4.3.2 Women with clinically significant antibodies must have a valid group and screen available when they are in labour, with suitable antigen-negative red cells also available should transfusion be required (see also 4.3.5).

4.3.3 Red cells selected for transfusion in pregnancy should be matched for RhD and K in addition to the patient's ABO group.

4.3.4 K negative red cells are clinically indicated (listed in priority order) for women who:

- currently have anti-K or have a history of anti-K
- are K negative (use of K negative red cells for women who are K positive is unnecessary)
- are unable to be K typed before urgent transfusion.

4.3.5 Previously alloimmunised pregnant women typically have a greater risk of further sensitisation. It is recommended that in addition to Rh and K, red cells also matched for $Fy^a$, $Fy^b$, $Jk^a$, $Jk^b$ and Ss are selected for transfusion (see 4.4.2.1).

4.3.6 Pregnant women, irrespective of CMV status, should receive CMV seronegative blood products (see 3.4). In critical bleeding situations, transfusion should not be delayed because of the unavailability of CMV seronegative products.

## 4.4 Transfusion of the fetus and newborn

### *4.4.1 Transfusion of neonates and infants up to 4 months post delivery*

4.4.1.1 Initial pretransfusion testing in the 4 months after delivery should be performed on specimens from both the mother and infant, as follows:

[10] http://www.blood.gov.au/pbm-guidelines

| | |
|---|---|
| **Maternal sample** | ABO, RhD and antibody screen |
| **Newborn sample** | ABO, RhD and DAT<br>If maternal plasma is not available, perform an IAT antibody screen (and IAT crossmatching if required) on the infant's plasma<br>**Note:** cord samples are not suitable for pretransfusion testing. |

4.4.1.2 If the pretransfusion antibody screen and DAT are negative, no further testing is required until the infant reaches 4 months of age; red cells may be issued by eXM.

4.4.1.3 If the infant's DAT is positive due to ABO antibodies or antenatal RhD-Ig prophylaxis, electronic crossmatching is permissible.

4.4.1.4 If the maternal or infant's plasma contains a clinically significant antibody, the infant must receive red cells that lack the corresponding antigen and that are IAT crossmatch compatible with either the maternal or infant's plasma.

4.4.1.5 When maternal antibody is no longer detectable in specimens from the infant, antigen-negative red cells are not required.

4.4.1.6 Blood products selected for transfusion should be:

- the same ABO/RhD type as the infant or ABO/RhD compatible:
  - if the neonate has an unresolved or indeterminate RhD type, RhD negative red cells should be selected
  - if ABO/RhD compatible red cells (but not the same group as the infant) have been transfused, further transfusions should continue using group compatible red cells
  - red cells of the infant's blood group may be used once any passively acquired anti-A or anti-B is no longer detectable by IAT; tests for anti-A must use $A_1$ red cells.
- CMV seronegative (if preterm infant, up until 28 days post expected date of delivery)
- irradiated, if the infant:
  - is having exchange transfusion(s)
  - has received an IUT; irradiated blood products are required until 6 months of age
  - is receiving blood products donated by a direct relative
  - has a very low birth weight (< 1500 g)
  - is immunocompromised.

### *4.4.2 Intrauterine transfusion*

4.4.2.1 Red cells for IUT should be:

- 5 days old or less
- ABO compatible with both the mother and fetus; if the fetal blood group is not known, group O should be used.
  - ⓘ Whole blood plasma-reduced red cells (used in New Zealand) must have low titre IgG anti-A and anti-B
- K negative
- negative for the antigen against which the maternal antibody is directed; it may be desirable to perform an extended maternal red cell phenotype and provide matching red cells so that the mother is not exposed to other major blood group antigens she lacks
  - ⓘ In exceptional cases, it will be necessary to give O RhD positive, c negative blood, for example in HDFN because of anti-c alloimmunisation, where giving RhD negative blood would be harmful [11]
- CMV seronegative
- irradiated (must be used within 24 hours of irradiation).

[11] Royal College of Obstetricians and Gynaecologists (RCOG) *The Management of Women with Red Cell Antibodies during Pregnancy* (2014) https://ranzcog.edu.au/statements-guidelines

## 4.5 Transfusion-dependent patients

4.5.1 The institution's transfusion provider should be advised when there is a plan to start a course of transfusion therapy for a transfusion-dependent patient; for example, those with sickle cell disease, thalassaemia or haematology–oncology conditions such as myelodysplasia. In this group of patients, the risk of developing a red cell alloantibody may be considered likely, with the potential to cause difficulties for ongoing transfusion support. Measures to reduce this risk or difficulty should be considered.

ⓘ Pretransfusion testing for patients receiving anti-CD38 (e.g. daratumumab) and other similar monoclonal antibody therapies such as anti-CD47 may be complicated by the interference causes by this type of drugs and provision of blood may be delayed whilst this is resolved.

4.5.2 Patients should have a red cell phenotype (or genotype) determined before their initial transfusion. Typing may be limited to Rh and K or extended to also include $Jk^a$, $Jk^b$, $Fy^a$, $Fy^b$, S and s.

4.5.3 The decision whether to transfuse red cells matched to the patient's red cell phenotype (or genotype) either from the initial transfusion or only after antibody formation and the degree of matching (i.e. limited to Rh and K or to the extended type) will depend on local policy or availability of suitable red cells (or both).

## 4.6 Patients with warm autoimmune haemolytic anaemia

### *4.6.1 General principles*

4.6.1.1 If the patient has a warm (i.e. reactive at 37 °C) autoantibody, investigations should focus on obtaining a valid ABO/RhD type and establishing whether there is an underlying alloantibody.

4.6.1.2 The patient's drug history should be checked as a potential cause of the positive DAT, autoantibody or immune haemolysis.

4.6.1.3 The interpretation of results and the need for specialised testing such as adsorption generally requires staff with significant experience in performing these procedures. Because of the potential complexity of, or difficulties associated with, pretransfusion testing in cases of warm autoimmune haemolytic anaemia (WAIHA), it may be necessary to refer the specimen to a reference laboratory.

4.6.1.4 Before starting regular transfusions, the patient should have an extended red cell phenotype (or genotype) determined – a minimum of Rh, K, $Jk^a$, $Jk^b$, $Fy^a$, $Fy^b$, S and s is recommended.

4.6.1.5 Genotyping should be considered (see 2.7.9) if phenotyping is not possible because the patient is recently transfused, has been transfused or has a positive DAT, or if suitable typing reagents are not available.

4.6.1.6 Knowing the patient's extended phenotype (or genotype) gives an indication of which alloantibodies they could potentially form.

4.6.1.7 Transfusing phenotype (or genotype) matched red cells is recommended to reduce the risk of alloantibody formation. The degree of matching (e.g. limited to Rh and K or to the extended type) will depend on local policies or availability of suitable red cells (or both).

4.6.1.8 Prophylactic transfusion of phenotypically matched red cells should be considered.

4.6.1.9 Adsorption of the patient's plasma may be used to remove autoantibody activity and reveal the presence of a coexisting alloantibody:

**Autoadsorption** Using the patient's own red cells (if the patient has not been transfused within the preceding 3 months).

**Alloadsorption** Using phenotyped donor red cells (if the patient has been transfused in the previous 3 months or there is a limited volume of the patient's red cells).

4.6.1.10 If adsorption reveals a clinically significant alloantibody antigen-negative red cells should be selected. If an IAT crossmatch is performed use adsorbed plasma where available.

4.6.1.11 Reducing the frequency of testing (e.g. omitting regular adsorptions or serological crossmatches) may be considered if the patient is clinically stable and has formed no alloantibodies. The decision to

abbreviate testing should be made in consultation between a transfusion medicine specialist, the laboratory director and the patient's clinician.

### *4.6.2 Positive DAT with a negative antibody screen*

4.6.2.1 If the patient has not been transfused in the preceding 3 months and has no history of a clinically significant antibody, the specimen can be treated in the same way as a routine pretransfusion specimen with a negative antibody screen, and red cells can be issued using the laboratory's abbreviated crossmatch procedure.

4.6.2.2 The patient's drug history should be checked as a potential cause of the positive DAT.

4.6.2.3 If the patient has been transfused in the last 3 months:

- review laboratory results for evidence of haemolysis; for example, haemoglobin, bilirubin, lactate dehydrogenase and blood film
- check whether the patient has recently received ABO-mismatched blood products, intravenous immunoglobulin (IVIg), or a haemopoietic stem cell or solid organ transplant
- perform an elution if a delayed haemolytic transfusion reaction is suspected.

4.6.2.4 If the patient has a history of a clinically significant antibody, or if an alloantibody was detected in the eluate, red cells should be issued in accordance with 3.1.2.

4.6.2.5 If the patient has no history of a clinically significant antibody, or if no alloantibody was detected in the eluate (or elution was not indicated), the specimen can be treated as if for routine pretransfusion testing.

### *4.6.3 Historically positive DAT (with or without an autoantibody) now resolved*

4.6.3.1 If the patient has a negative antibody screen and no history of a clinically significant antibody, and the DAT is currently negative, then the specimen can be treated in the same way as a routine pretransfusion specimen with a negative antibody screen, and red cells can be issued using the laboratory's abbreviated crossmatch procedure.

## 4.7 Allogeneic haemopoietic stem cell transplant

4.7.1 Patients with allogeneic HSCT often present with an unusual immunohaematological picture. The transplant may result in the appearance of a new ABO antigen (major mismatch) or an ABO antibody (minor mismatch), or both.

4.7.2 The transfusion laboratory supporting the transplant centre should have clear protocols for the selection of blood products with respect to ABO/RhD types of the recipient and donor. These protocols must be provided to the transfusion laboratory of the institution where the patient may be transferred after the transplant.

4.7.3 Red cells and platelets must be irradiated to prevent transfusion-associated graft versus host disease (TA-GVHD).

4.7.4 The decision on whether to use CMV seronegative products should be in accordance with local clinical policy (see 3.4).

## 4.8 ABO-mismatched renal transplants

4.8.1 During the transplantation period, recipients of a kidney from an ABO-mismatched donor should be transfused with blood products, and in particular plasma products, where the ABO antibodies are compatible with the ABO group of graft.

4.8.2 Irradiated or CMV seronegative red cells and platelets are generally not indicated for recipients of ABO-mismatched renal transplants.

4.8.3 In choosing to transfuse, the following factors should also be considered:

- 'passenger lymphocyte syndrome' is a rare but significant occurrence
- platelets that are ABO-incompatible with the recipient's plasma may have shortened survival and their use should be avoided if possible.

4.8.4 Renal transplant patients should remain on their transplant transfusion protocol indefinitely, with specific product requirements determined in consultation with their renal physician.

## 4.9 Autologous transfusion

4.9.1 Autologous blood donation is only recommended for exceptional circumstances where compatible donors are rare or difficult to find (e.g. in patients with rare blood groups or multiple red cell antibodies).

4.9.2 Pretransfusion procedures for autologous transfusions should generally be the same as those for allogeneic transfusions.

4.9.3 Autologous units should be clearly labelled to distinguish them from allogeneic (homologous) units, and stored in a separate designated area. Systems must be in place to prevent autologous units being issued to patients other than the donor.

4.9.4 A compatibility label must be attached to autologous units before release.

5

# Section 5
# Storage and transport of blood products

## 5.1 Inventory management

5.1.1 Blood and blood products will normally only be supplied by the blood service to appropriately accredited pathology providers or approved health facilities, in accordance with national regulations. Direct supply of labile components (red cells, platelets and plasma) to non-approved facilities e.g. remote healthcare facilities without onsite or local pathology providers is only permissible in exceptional circumstances and only then under pathology provider and/or health department guidance with assurance of appropriate storage and handling, record keeping and traceability.

5.1.2 Laboratories must have written policies that ensure proper and efficient inventory management, ensure traceability, and minimise wastage of blood and blood products.

5.1.3 Laboratories must have processes to ensure the timely return to stock of unused patient-assigned blood products as determined by sample validity and blood product expiry.

5.1.4 The laboratory must (where possible) participate in a national electronic blood management and inventory tracking program.

5.1.5 Inventory practices should be reviewed at least annually, and wastage monitored against national benchmarks to ensure that appropriate inventory levels are set and wastage is minimised.

## 5.2 Temperature-controlled storage

5.2.1 Blood products must be stored at the relevant temperature (see Table 5.1, page 31) in appropriately monitored temperature-controlled equipment or facilities, in accordance with the requirements of the manufacturer or supplier.

ⓘ Although not recommended practice it is recognised that equipment used for storing blood products is also used to store (for example) donor or patient specimens, reagents, plasma derivatives, tissues and other medicines. The decision to do so must be based on a risk assessment and items must be appropriately segregated.[12]

5.2.2 The organisation that owns or manages equipment or facilities used to store or transport blood products is responsible for ensuring compliance with AS3864 and all other regulatory requirements.

5.2.3 **All** refrigerators, cool rooms and freezers used to store labile products i.e. red cells and plasma must comply with Part 1 (Manufacturing requirements) and Part 2 (User-related requirements for care, maintenance, performance verification and calibration) of Australian Standard AS 3864 *Medical refrigeration equipment – for the storage of blood and blood products*.

ⓘ Although **platelet agitators** or **incubators** are not included in the standard, applicable requirements from Part 2 should be followed. Equipment should have alarms for motion failure, open door (where relevant) and power failure. High and low temperature alarm points should be set at 23.5 °C and 20.5 °C respectively. Where platelets are not stored in a platelet incubator the laboratory must be able to demonstrate that the required room temperature is maintained.

5.2.4 Products issued by the laboratory to another location e.g. ward, theatres, those sent with patients transferred from locations or facilities outside the jurisdiction of the receiving laboratory or products accompanying emergency retrieval teams (e.g. in a helicopter or ambulance) are considered to be in **storage**.

5.2.5 If the transfusion laboratory issues blood products to a location where the laboratory is not responsible for the storage equipment or facilities, staff must be satisfied that the storage arrangements are safe and appropriate, and comply with all regulatory requirements.

[12] New Zealand Blood Service (NZBS) *Refrigeration guidelines* (June 2019) (https://www.nzblood.co.nz/clinical-information/transfusion-medicine/refrigeration-guidelines)

5.2.6 To check compliance, the issuing laboratory must obtain copies of temperature monitoring, maintenance and spatial checking records from the organisation responsible for the equipment or facility.

5.2.7 Under the following circumstances affected blood products must not be transfused (except at the discretion of the laboratory director):

a) Storage at temperatures outside the specified limits; or

b) Storage in nonconforming equipment; or

c) Where there is any doubt regarding storage temperatures or conditions.

5.2.8 Any deviations from the required storage temperatures or conditions must be clearly documented and the products quarantined until their fate is decided.

5.2.9 Policies for managing affected blood products, including the decision to return to the inventory or for subsequent transfusion, must be based on a risk assessment.

## 5.3 Removal from and return to temperature-controlled storage

### *5.3.1 General principles*

5.3.1.1 Time out of controlled storage should be minimised.

5.3.1.2 If a short delay occurs (or is anticipated) before starting a transfusion, the product may be held at ambient temperature at the patient's bedside, provided the transfusion can be completed within the total allowable duration (normally four hours; see ANZSBT *Guidelines for the administration of blood products)*.[13]

5.3.1.3 In some instances, it may be necessary to issue products (e.g. recently thawed FFP or irradiated red cells) that have not cooled to the required temperature before distribution and may still be warm on receipt. Specified temperature limits are not applicable in these instances.

ⓘ When issuing or shipping warm products these should be segregated from refrigerated products issued at the same time, using a separate shipper if necessary.

5.3.1.4 Products issued by the laboratory to another location (see 5.2.4) must be placed either into a monitored temperature-controlled device or kept in a validated shipping container able to maintain the appropriate storage temperature (see Table 5.1 page 31).

### *5.3.2 Red cells*

5.3.2.1 Under normal circumstances, if red cells are taken for transfusion but then returned, the time out of controlled storage (2-6 °C) should not exceed 30 minutes.

ⓘ Recent studies suggest that red cells can safely remain out of controlled storage for up to 60 minutes without any detrimental effects on red cell quality or bacterial proliferation. The laboratory director may therefore, in exceptional circumstances, permit extension of the time allowed out of controlled storage from 30 to 60 minutes provided the unit is quarantined, by placing in a secure refrigerator for at least 6 hours, to allow the unit to return to 2-6°C prior to reissue. The laboratory must be able to identify these units so that extended periods outside of controlled storage (i.e. between 30 and 60 minutes) occur on no more than three occasions.[14, 15]

5.3.2.2 If a product has been out of controlled storage (2-6°C) for longer than the maximum allowable time, and there is no prospect of imminent transfusion, it should be returned to the laboratory for disposal, or placed in quarantine at the remote location and the laboratory contacted to determine the fate of the product.

[13] https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines

[14] Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) *Guidelines for the Blood Transfusion Services* (https://www.transfusionguidelines.org/red-book/chapter-7-specifications-for-blood-components)

[15] BSH *Guidelines for the administration of blood components* (2017) (https://b-s-h.org.uk/guidelines)

### 5.3.3 Fresh frozen plasma

5.3.3.1 Thawed FFP can be accepted back into inventory if it has been out of controlled storage (2-6 °C) for 30 minutes or less on no more than one occasion.

### 5.3.4 Platelets and cryoprecipitate

5.3.4.1 Refer to Table 5.1 page 31.

## 5.4 Transporting blood products

### 5.4.1 General principles

5.4.1.1 **Transport** is the process of shipping blood products from the supplier e.g. blood service to the hospital laboratory, from the base hospital to its satellite laboratories or between laboratories in a network.

5.4.1.2 Blood products must be transported using appropriately validated transport containers and packing configurations, in accordance with the requirements of the manufacturer or supplier and the receiving laboratory.

5.4.1.3 Products must be maintained within the specified temperature range for the duration of transport, irrespective of mode of delivery (see Table 5.2, page 31).

5.4.1.4 Acceptance of blood products by the receiving transfusion laboratory is conditional on evidence of suitable storage and handling while in transit from the issuing facility.

5.4.1.5 Blood products where the temperature during transport was outside the specified limits, transported in nonconforming equipment or where there is doubt regarding the transport condition must not be transfused (except at the discretion of the laboratory director). Any deviations must be clearly documented with the products quarantined until their fate is decided.

### 5.4.2 Pneumatic tube system (PTS)

5.4.2.1 The PTS must be appropriately validated for the transport of blood products (see 8.8).

5.4.2.2 The PTS must not expose blood products to physical forces or environmental factors (including temperature) that could result in adverse changes to the quality of the product.

5.4.2.3 The laboratory must have procedures for dealing with blockages in the PTS or for decontamination following blood product breakages or leaks during passage through the system. The procedures should include system access points and canister dumping stations.

5.4.2.4 The laboratory should ensure that the clinical area requesting the blood products is alerted to expect delivery through the PTS.

5.4.2.5 The receiving area should have a procedure for notifying the laboratory as to receipt of the blood product and its removal from the PTS (or failure of the blood product to arrive as expected).

*Table 5.1: Blood product storage temperatures*

| Product | Storage temperature | Maximum storage duration |
|---|---|---|
| Red cells | 2 °C to 6 °C | 42 days |
| Paediatric red cells | 2 °C to 6 °C | 35 days |
| Washed red cells | 2 °C to 6 °C | 28 days |
| Irradiated red cells | 2 °C to 6 °C | 14 days post irradiation<br>24 hours post irradiation for IUT or exchange transfusion<br>48 hours for neonatal or infant small volume transfusions |
| Frozen red cells | -60 °C to -80 °C or below | 30 years[16] |
| Thawed red cells | 2 °C to 6 °C | 24 hours post thawing |
| Platelets | 20 °C to 24 °C<br>In a room at ambient temperature or platelet incubator with continuous gentle agitation, preferably on a flatbed agitator | 5 days |
| Frozen plasma (FFP, CDP, cryoprecipitate) | –25 °C or below | 12 months<br>If storage temperature is between –18 °C and –25 °C expiry should be reduced to 3 months |
| Thawed plasma (FFP, CDP) | 2 °C to 6 °C | 24 hours |
| Extended life plasma (ELP) | 2 °C to 6 °C | 5 days |
| Thawed cryoprecipitate | 20 °C to 24 °C | 6 hours |
| Plasma derivatives and recombinant products | As per manufacturer's or suppliers' instructions | |

CDP, cryodepleted plasma; ELP, extended life plasma; FFP, fresh frozen plasma; IUT, intrauterine transfusion

*Table 5.2: Blood product transport temperatures*

| Product | Transport temperature |
|---|---|
| Red cells | 2 °C to 10 °C |
| Frozen plasma (FFP, CDP, cryoprecipitate) | –25 °C or below<br>If transport temperature is between –18 °C and –25 °C expiry should be reduced to 3 months |
| Thawed plasma (FFP, CDP), ELP | 2 °C to 10 °C |
| Thawed cryoprecipitate | 20 °C to 24 °C |
| Platelets | 20 °C to 24 °C<br>Time without agitation should not exceed a total of 24 hours |
| Plasma derivatives and recombinant products | As per manufacturer's or supplier's specifications |

CDP, cryodepleted plasma; FFP, fresh frozen plasma; ELP, extended life plasma

[16] European Directorate for the Quality of Medicines & Healthcare of the Council of Europe (EDQM). Guide to the preparation, use and quality assurance of blood components. 19th edn. Strasbourg: EQQM Publications, 2017 (https://www.edqm.eu/en/blood-guide)

# Section 6
# Management of transfusion reactions

## 6.1 Notification of transfusion reactions

6.1.1 The transfusing institution must have systems and procedures to identify, manage and investigate transfusion reactions or other transfusion-related adverse events.

6.1.2 Serious events should be discussed with a suitably experienced pathologist (e.g. laboratory director, haematologist or transfusion medicine specialist) to ensure appropriate management of the patient, particularly as regards ongoing or future transfusions.

6.1.3 Serious events – in particular, suspected cases of transfusion-transmitted bacterial, viral or parasitic infections or transfusion-related acute lung injury (TRALI) – should be reported to the blood product manufacturer or supplier and, where necessary, to the relevant regulatory authority.

6.1.4 Events with product safety, quality or donor implications should be reported as soon as possible because immediate follow-up action may be required; for example, recalling potentially bacterially contaminated products prepared from the same donation or where further patient or donor investigations are necessary (e.g. suspected TRALI).

## 6.2 Investigation of transfusion reactions

6.2.1 Serious transfusion reactions must be appropriately investigated before any further transfusions.

6.2.2 The patient's identification and product compatibility labels must be rechecked at the bedside to rule out clerical or administration errors, or ABO incompatibility.

6.2.3 The following items must be sent to the laboratory as soon as possible after the reaction:

- a 'transfusion reaction investigation request' providing details of the clinical signs and symptoms of the reaction
- EDTA, clotted and other specimens, as necessary, collected immediately post-reaction and from a site opposite to the infusion site (e.g. opposite arm)
- a sample of the first urine produced post-transfusion
- remnants of the blood product being transfused when the reaction occurred and its administration set
- empty bags or bottles from blood products transfused before the implicated unit (if available).

  ⓘ When returning used or empty blood products to the laboratory, local occupational health and safety policies (in particular, those for handling clinical waste) must be observed.

6.2.4 The following clerical checks must be performed:

- patient's identity on the request form(s), pretransfusion and post-transfusion specimen(s), compatibility label(s) and the pretransfusion testing records
- the blood product donation or batch number(s)
- the ABO/RhD types of the patient and products.

6.2.5 The laboratory investigations shown in Table 6.1 should be performed.

*Table 6.1: Transfusion laboratory investigations following transfusion reactions*

| Patient or product | Investigations |
|---|---|
| **Patient** | • Visual examination of the post-transfusion plasma for haemoglobinaemia and haemolysis<br>• ABO/RhD type, antibody screen and DAT on pretransfusion and post-transfusion specimens<br>**Note:** a negative post-transfusion DAT does not exclude a severe haemolytic transfusion reaction |
| **Red cells** | • Determination of the ABO/RhD type of the unit being transfused at the time of the reaction, and any previously transfused units, where available<br>• IAT crossmatch of the patient's pretransfusion and post-transfusion specimens against the red cell unit being transfused at the time of the reaction and any previously transfused units (where available)<br>• Inspection of the contents and XM segments of the implicated red cell unit and any previously transfused units for evidence of clots, haemolysis or discolouration |
| **Platelets or plasma** | • Reverse ABO group of the transfused unit(s) |

DAT, direct antiglobulin test; IAT, indirect antiglobulin test; XM, crossmatch

## 6.3 Additional laboratory testing

6.3.1 Distinguishing haemolytic or simple febrile nonhaemolytic transfusion reactions from suspected bacterial contamination may be difficult; if testing is inconclusive, the following may be informative:

- plasma haemoglobin, serum bilirubin and haptoglobin levels
- urinary haemoglobin and urobilinogen
- gram stain and blood culture of the unit being transfused at the time of the reaction and any previously transfused units or administration sets
- patient blood cultures.

6.3.2 Additional patient or donor investigations may be indicated or considered for specific reactions, as shown in Table 6.2.

*Table 6.2: Additional laboratory investigations associated with transfusion reactions*

| Suspected reaction | Tests |
|---|---|
| **FNHTR** | HLA, HPA and HNA antibodies |
| **TRALI** | HLA and HNA typing and antibodies |
| **TACO** | BNP or N-terminal pro-BNP may be useful for distinguishing TACO from TRALI |
| **Anaphylaxis** | IgA levels or anti-IgA (other plasma proteins if indicated), tryptase |

BNP, brain natriuretic peptide; FNHTR, febrile nonhaemolytic transfusion reaction; HLA, human leucocyte antigen; HNA, human neutrophil antigen; HPA, human platelet antigen; IgA, immunoglobulin A; TACO, transfusion-related circulatory volume overload; TRALI, transfusion-related acute lung injury

## 6.4 Other transfusion-related adverse events and reactions

6.4.1 Inappropriate transfusion (e.g. avoidable, delayed or under-transfusion), or transfusion of blood products intended for another patient or products that do not meet special requirements (e.g. not CMV seronegative or irradiated) are all examples of transfusion-related adverse events, which reflect failures in the transfusion process.

6.4.2 It is important that these types of transfusion-related adverse events are recognised and reported even though the patient may not experience (or show) any adverse effects.

6.4.3 The nature of these transfusion-related adverse events means that the reporting requirements will vary according to local, state or national policies and, in particular, whether they are considered quality incidents or patient safety incidents. Events may, for example, be reported to one or more of the following: transfusion laboratory, hospital transfusion (or patient blood management) committee, incident management system, or relevant state or national haemovigilance program.

## 6.5 Final reporting of transfusion reactions

6.5.1 The transfusion laboratory should provide a report of the findings from investigation of the adverse reaction (or adverse event) to the patient's clinician, with a copy placed in the patient's clinical notes.

6.5.2 The report should include details of the event and recommendations for managing future transfusion requirements.

6.5.3 A report should be sent to the state/territory or national haemovigilance programme in accordance with jurisdictional requirements.

# Section 7
# Testing during pregnancy and at delivery

## 7.1 General principles

7.1.1 The rationale for testing during pregnancy and at delivery is to prevent haemolytic disease of the fetus and newborn (HDFN) as well as providing appropriate transfusion support (if required) to the mother, fetus or infant. See Table 7.3 (page 41) for the scope and timing of routine prenatal testing.

ⓘ Recommendations in this section are based on the BSH *Guidelines for blood grouping and antibody testing in pregnancy* (2016) and the associated clinical guidance from the RCOG *The Management of Women with Red Cell Antibodies during Pregnancy* (2014) which are referenced on the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) website[17, 18]

7.1.2 Close communication between the laboratory and patient's clinician will facilitate the diagnosis and appropriate management of HDFN, and ensure prompt referral to a specialist fetal medicine unit when necessary.

7.1.3 Patient identification, requests, specimens and testing should be treated in the same way as those in the pretransfusion setting (see Sections 1 and 2).

7.1.4 Diagnosis and management of HDFN is aided by laboratory testing, the key elements of which are:

- RhD typing to identify RhD negative women who should be offered prophylactic RhD-Ig
- antibody screening to identify women with clinically significant red cell alloantibodies
- monitoring of the level of maternal antibodies, either by titration or quantitation, to identify at-risk pregnancies and those fetuses or newborns likely to require treatment for HDFN
- detecting and quantifying of fetomaternal haemorrhage (FMH) using the Kleihauer-Betke test or flow cytometry to determine the required dose of RhD-Ig or identifying fetuses at risk due to blood loss.

7.1.5 Routine RhD typing by IAT to detect RhD variants should **not** be performed.

7.1.6 Weak (≤ 2 [0–4 scale] or ≤ 8 [0–12 scale]) or inconclusive RhD typing results should be treated as RhD negative until the RhD status is confirmed by a reference laboratory.

7.1.7 Women with RhD variants known to produce anti-D may require RhD-Ig prophylaxis, depending on the specific RhD variant. Conversely, women with an RhD variant not known to produce anti-D can be treated as RhD positive and do not require RhD-Ig.

7.1.8 In cases of suspected HDFN where the maternal plasma appears to lack clinically significant antibodies, or testing was not possible, other immunological causes for the infant's clinical condition should be excluded; for example:

- ABO incompatibility between mother and child
- maternal antibody to a low frequency (paternally derived) antigen.

7.1.9 For RhD negative women, specimens must be collected prior to giving RhD-Ig. If RhD-Ig has been given for a prior sensitising event, an antibody screen must still be performed. To assist with the interpretation of results, the date RhD-Ig was given should be provided on the request.

7.1.10 It is acceptable for RhD-Ig to be given immediately after taking the blood specimen, before antibody screen results are available.

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[17] https://b-s-h.org.uk/guidelines

[18] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg65 and https://ranzcog.edu.au/statements-guidelines

7.1.11 Determining if the fetus carries the relevant red cell antigen may be clinically appropriate where a clinically significant maternal antibody is identified, or where the mother has a history of HDFN and the father is heterozygous for the relevant antigen (or a paternal phenotype is unavailable).

7.1.12 Paternal phenotyping or genotyping can assist in predicting the likelihood of fetal inheritance of the particular red cell antigen, and therefore the risk of HDFN.

## 7.2 Routine prenatal testing

7.2.1 An ABO/RhD type and IAT antibody screen should be performed as early as possible during each pregnancy, preferably at the first prenatal visit (typically 8–12 weeks gestation) or early in the first trimester. The maternal ABO type may be useful for identifying cases of ABO HDFN.

7.2.2 All women irrespective of RhD type should also have an ABO/RhD type and IAT antibody screen performed at 28 weeks. For RhD negative women, the specimen should be collected before giving prophylactic RhD-Ig.

7.2.3 When a red cell antibody is detected, its specificity must be identified, clinical significance determined and risk of HDFN assessed. If the antibody is clinically significant, the level should be measured by titration or quantitation.

7.2.4 Clinical assessment should include reviewing the patient's obstetric and transfusion history, and determining whether RhD-Ig has recently been given. A paternal phenotype may also be informative.

## 7.3 Alloimmunisation in pregnancy

7.3.1 To ensure appropriate patient management it is imperative that all relevant information and history is available, such as:

- previous history – for example, transfusion, pregnancies and RhD-Ig prophylaxis
- previously affected pregnancies – for example, IUT, neonatal exchange transfusion and jaundice
- paternal blood group and Rh phenotype.

7.3.2 The clinical significance of antibodies detected during routine prenatal testing should be assessed (see Table 7.4, page 42). Antibody prevalence can vary between countries or regions, reflecting geographical or racial variations in gene frequencies and blood bank or transfusion practices.

7.3.3 Antibodies that cause HDFN are immunoglobulin G (IgG) and reactive by IAT. Anti-D, anti-c and anti-K are most commonly implicated in causing haemolytic disease severe enough to warrant prenatal intervention. If there is evidence of fetal anaemia, an IUT may be necessary.

7.3.4 Women with a history of significant HDFN or IUT should be referred to a specialist fetal medicine unit, preferably before 20 weeks gestation, **irrespective of the antibody specificity and level**.

7.3.5 At-risk pregnancies should be monitored by Doppler ultrasound assessment of the fetal middle cerebral artery peak systolic velocities (MCA PSV); this technique is noninvasive and more appropriate than serial amniocentesis and spectrophotometric $OD_{450}$ measurement.

## 7.4 Fetal genotyping

7.4.1 Fetal RhD genotyping using non-invasive prenatal testing may be considered for high risk pregnancies in accordance with national guidelines. Genotyping for other red cell antigens may also be indicated where this testing is available.

ⓘ Non-invasive testing of fetal DNA from maternal plasma provides a safer alternative to using DNA obtained by amniocentesis or chorionic villus sampling, both of which carry risks of further antibody stimulation or spontaneous miscarriage.

## 7.5 Women with anti-D

### *7.5.1 Distinguishing between passive and immune anti-D*

7.5.1.1 When anti-D is detected, it is important for the management of the patient to ensure that an immune antibody is not misinterpreted as residual RhD-Ig, and further prophylaxis withheld. The laboratory

should discuss with the patient's clinician whether the anti-D is believed to be immune or the result of RhD-Ig prophylaxis.

7.5.1.2 At present, passively acquired anti-D (due to RhD-Ig) cannot be serologically differentiated from immune anti-D otherwise stimulated by pregnancy or transfusion, and differentiation based on the reaction strengths from antibody screening is not reliable.

7.5.1.3 If the anti-D is no longer detectable by IAT and the quantified level is falling, it is probably RhD-Ig; conversely, a stable or rising antibody level suggests alloimmune anti-D.

7.5.1.4 The post-prophylaxis concentration of RhD-Ig would not be expected to exceed 0.1 IU/mL (following a standard 625 IU intramuscular dose) or 0.4 IU/mL (following a 1500 IU IV dose) unless multiple doses were given.

7.5.1.5 RhD-Ig prophylaxis should continue unless it is unequivocally confirmed that the anti-D is alloimmune.

7.5.1.6 Anti-D should be considered immune if there is no record, or it is not known whether RhD-Ig has been given. The patient should be treated as sensitised with antibody levels monitored (as per 7.4.2). Further RhD-Ig prophylaxis is not required if it has been unequivocally confirmed that the anti-D is immune.

7.5.1.7 Further testing after 28 weeks is not necessary if anti-D is not detectable in a specimen taken before giving RhD-Ig, or if RhD-Ig has recently been given (in the previous 8–12 weeks) or the anti-D concentration is < 0.1 IU/mL.

7.5.1.8 Anti-D may be considered residual RhD-Ig if it is **confirmed** that RhD-Ig was given in the previous 8–12 weeks with the patient treated as unsensitised, and further prophylaxis may be offered as indicated.

### *7.5.2 Women with immune anti-D*

7.5.2.1 A baseline antibody level should be determined either by titration or quantitation (against the international anti-D standard) when the anti-D is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter.

7.5.2.2 Each specimen should be tested in parallel with the previous specimen.

7.5.2.3 Laboratories should provide guidance on the test method used and the significance of the results.

7.5.2.4 The patient should be referred to a specialist fetal medicine unit for assessment and monitoring if they have an anti-D level ≥ 4 IU/mL or titre ≥ 32 (or a significant rise in titre).

*Table 7.1: Clinical significance of anti-D concentrations*

| Anti-D concentration (IU/mL) | Risk of HDFN |
|---|---|
| < 4 | Unlikely; continue to monitor |
| 4–15 | Moderate risk; refer to a specialist fetal medicine unit |
| > 15 | High risk; refer to a specialist fetal medicine unit |

HDFN, haemolytic disease of the fetus and newborn; IU, international units

7.5.2.5 If a specimen with anti-D is referred for routine antibody screening or pretransfusion testing, a selected panel of RhD negative cells (an 'RhD negative set') that possesses all other relevant red cell antigens should be used to detect (or exclude) the formation of other antibody specificities.

7.5.2.6 An antibody detected using the 'RhD negative set' should be fully investigated as per 7.2.3.

7.5.2.7 Once the patient has been referred to a specialist fetal medicine unit the value of continued monitoring of antibody levels (whether by titration or quantitation) is doubtful, although testing a specimen at 28 weeks to exclude formation of additional antibodies is still important.

### *7.5.3 Clinical interpretation and reporting of anti-D*

7.5.3.1 Laboratory results should be reviewed in conjunction with the patient's clinical history including potential sensitising events and recent (i.e. in the previous 8–12 weeks) administration of RhD-Ig.

7.5.3.2 Reports to the patient's clinician should interpret the results in the context of the patient's clinical history and offer an assessment as to whether the antibody is presumed to be residual RhD-Ig or alloimmune in origin.

## 7.6 Women with anti-c

7.6.1 A baseline antibody level should be obtained either by titration or quantitation (against the international anti-c standard) at the time the anti-c is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter.

7.6.2 Each specimen should be tested in parallel with the previous specimen.

7.6.3 Laboratories should provide guidance on the test method used and the significance of the results.

7.6.4 The patient should be referred to a specialist fetal medicine unit for assessment and monitoring if they have an anti-c level ≥ 7.5 IU/mL, or titre ≥ 32 (or significant rise in titre).

*Table 7.2: Clinical significance of anti-c concentrations*

| Anti-c concentration (IU/mL) | Risk of HDFN |
|---|---|
| < 7.5 | Unlikely; continue to monitor |
| 7.5–20 | Moderate risk; refer to a specialist fetal medicine unit |
| > 20 | High risk; refer to a specialist fetal medicine unit |

HDFN, haemolytic disease of the fetus and newborn; IU, international units

7.6.5 Once the patient has been referred to a specialist fetal medicine unit, the value of continued monitoring of antibody levels (whether by titration or quantitation) is doubtful; however, testing a specimen at 28 weeks to exclude formation of additional antibodies is still important.

## 7.7 Women with apparent anti-C+D (possible anti-G)

7.7.1 Some examples of apparent anti-C+D antibodies may actually be anti-G (or anti-C+G).

7.7.2 It is important that the correct antibody specificity is assigned in cases of apparent anti-C+D because women with anti-G (or anti-C+G) but not anti-D may form immune anti-D and are therefore eligible for both prophylactic and post-delivery RhD-Ig.

7.7.3 Confirming the presence of anti-G requires specialist techniques, and specimens may need to be referred to a reference laboratory.

## 7.8 Women with anti-K (or other Kell system antibodies)

7.8.1 If anti-K (or other Kell blood group system antibodies) are detected, referral to a specialist fetal medicine unit should occur as soon as the antibody is detected **regardless of the antibody titre**.

7.8.2 Anti-K impairs haematopoiesis as well as causing haemolysis and peripheral sequestration. Previous obstetric history is not predictive of the likely severity of disease related to anti-K antibodies.

7.8.3 A baseline antibody titre should be obtained at the time the antibody is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter. Anti-K titres do not correlate with clinical severity.

7.8.4 Once the patient has been referred to a specialist fetal medicine unit, the value of continued monitoring of antibody levels (whether by titration or quantitation) is doubtful; however, testing a specimen at 28 weeks to exclude formation of additional antibodies is still important.

7.8.5 Paternal K antigen status should be checked. If the paternal phenotype is K positive or unknown, fetal genotyping may be indicated. If the fetus is K negative, the mother should be treated as for an unaffected pregnancy.

## 7.9 Women with other red cell antibodies

7.9.1 Antibodies that cross the placenta and potentially cause HDFN are IgG and are reactive by the IAT. Women with antibodies not implicated in HDFN do not need to be monitored.

7.9.2 If clinically significant antibodies other than anti-D, anti-c and anti-K are detected during prenatal testing prior to 28 weeks gestation, an antibody titre should be obtained at the time the antibody is first detected (for the baseline level) and repeated during routine screening at 28 weeks gestation. If the titre is ≥ 32 (or other critical titre defined by the laboratory), the patient should be referred to a specialist fetal medicine unit for further assessment and testing.

7.9.3 In the absence of a prior history of HDFN, performing regular titres beyond 28 weeks gestation in women with titres ≥ 32 is unlikely to be informative. Although rare, cases of significant anaemia are likely to be detected by subsequent regular Doppler MCA monitoring.

## 7.10 Testing at delivery

### *7.10.1 Testing of the mother*

7.10.1.1 If the maternal ABO/RhD type is not known, a pre- or post-delivery specimen should be tested to determine if the mother is RhD negative and therefore offered RhD-Ig.

7.10.1.2 The decision to request a group and screen before delivery should be based on the risk of maternal bleeding and of factors that may delay transfusion, such as availability of emergency blood products or presence of clinically significant antibodies.

7.10.1.3 If the newborn shows clinical evidence of HDFN (e.g. a positive DAT) but the maternal antibody screen is negative and there is no fetomaternal ABO incompatibility, an antibody in the maternal serum to a low incidence antigen should be considered. A crossmatch between maternal plasma and paternal red cells (if ABO compatible) may be informative.

### *7.10.2 Testing of the newborn*

7.10.2.1 If the mother is RhD negative and/or has a clinically significant antibody or was not tested during pregnancy, a cord specimen should be collected and ABO/RhD typing, DAT, haemoglobin and bilirubin performed. In other instances, routine ABO/RhD typing, DAT, haemoglobin and bilirubin testing of all newborns is not necessary.

7.10.2.2 Cord blood specimens not needed for testing may be stored (as per Table 1.3, page 6) in case testing in the perinatal period is required.

7.10.2.3 A DAT is indicated when there are clinical signs of jaundice or anaemia in the infant, and where the mother is known to have a clinically significant antibody.

7.10.2.4 A positive DAT indicates that the infant's cells are coated with antibody but does not predict severity of haemolysis. An elution should be performed to confirm the identity of the antibody coating the cord red cells.

7.10.2.5 In ABO HDFN, the DAT may be negative. In some cases, although the causative ABO antibody is not detectable by DAT, it may be demonstrable by elution.

7.10.2.6 Newborns of RhD negative mothers should be tested by a technique that detects **clinically significant RhD variants** to ensure that RhD-Ig is offered to the mother when indicated. Most significant RhD variants should be detected by monoclonal anti-D typing reagents.

7.10.2.7 It is unlikely that newborns with the DVI antigen will cause maternal sensitisation; therefore, it is not necessary to type the newborns with reagents specifically capable of detecting DVI.

## 7.11 Testing for fetomaternal haemorrhage (FMH) to determine the need for RhD-Ig

7.11.1 FMH can occur at any time during pregnancy or at delivery, potentially leading to alloimmunisation of the mother, with sensitisation of RhD negative mothers by RhD positive infants being of primary interest.

7.11.2 It is important to estimate the volume of FMH following delivery (or other potential sensitising events) to ensure that the appropriate and timely (i.e. within 72 hours) dose of RhD-Ig is given to prevent RhD sensitisation.

7.11.3 Tests for FMH should be done in the following situations:

- RhD negative women delivering an RhD positive infant; or
- RhD negative women experiencing a potentially sensitising event at >20 weeks of gestation; for example:
  - amniocentesis, chorionic villus sampling or other in-utero therapeutic intervention or surgery (e.g. IUT or shunting)
  - ectopic pregnancy
  - antepartum haemorrhage
  - external cephalic version
  - maternal abdominal trauma
  - intrauterine death or stillbirth
  - spontaneous abortion
  - termination of pregnancy.

ⓘ Before 20 weeks, the fetomaternal blood volume is sufficiently small to be covered by the standard dose of RhD-Ig; therefore, quantitation of FMH volume is unnecessary.

7.11.4 A test for FMH is not required in women who have pre-formed immune anti-D.

7.11.5 The two assays used for detection and quantitation of FMH are the Kleihauer-Betke test (acid elution) and flow cytometry. Flow cytometry is considered more precise and reproducible.

7.11.6 All RhD negative women without evidence of immune anti-D experiencing a sensitising event or delivering an RhD positive baby should have a test for FMH as soon as practical. It is recommended that a specimen is collected 30-45 minutes following the sensitising event and ideally within 2 hours.

7.11.7 A single 625 IU dose of RhD-Ig will protect against an FMH of up to 6 mL of fetal red cells; for FMH > 6 mL, a dose of 100 IU/mL is recommended. Depending on the estimated volume of FMH, more than one dose of RhD-Ig may be necessary.

ⓘ Calculations for determining the volume of FMH can be found in the ANZSBT *Guidelines for laboratory assessment of fetomaternal haemorrhage.*[19]

7.11.8 If large doses of RhD-Ig are indicated or intramuscular injections are inappropriate or unsuitable an IV RhD-Ig preparation should be considered.

[19] https://anzsbt.org.au/pages/anzsbt-guidelines.html

*Table 7.3: Routine prenatal testing*

| Test | Circumstances | Timing |
|---|---|---|
| Blood group (ABO/RhD) | All pregnant women | Initial prenatal visit<br>28 weeks |
| | Pretransfusion testing | As required |
| Antibody screen | All pregnant women | Initial prenatal visit<br>28 weeks<br>Collect blood specimen before administration of RhD-Ig |
| | RhD negative females receiving RhD-Ig following a sensitising event | As required; collect blood specimen prior to administration of RhD-Ig |
| | Pretransfusion testing | As required |
| Antibody identification | Positive antibody screen | Following initial detection of antibody and repeated as necessary |
| Antibody levels (by titration or quantitation) | All women with a prior history of significant HDFN or IUT **irrespective of antibody specificity and level** | Refer to a specialist fetal medicine unit, preferably before 20 weeks gestation |
| | Anti-D, anti-c or anti-K | Every 4 weeks until 28 weeks gestation, then every 2 weeks until delivery<br>Refer to a specialist fetal medicine unit for further management |
| | Other antibodies likely to cause HDFN detected during routine prenatal testing | Initial prenatal visit or 28 weeks<br>For titres ≥ 32 (or other critical titre defined by the laboratory) refer to a specialist fetal medicine unit |
| Testing for FMH | RhD negative women following a potentially sensitising event (> 20 weeks gestation) | As required |
| | RhD negative women delivering an RhD positive infant | As required |
| Fetal RhD genotyping using non-invasive prenatal testing | High risk pregnancy | As per national guidelines - performed ≥ 12 weeks gestation |
| Fetal genotyping (other than RhD) | At-risk pregnancy:<br>• With no history of HDFN but elevated titre of clinically significant red cell antibody; or<br>• Previous pregnancy complicated by HDFN with unknown or heterozygous paternal blood type; or<br>• Paternal K positive or unknown phenotype | As required (depending on availability of testing) |

FMH, fetomaternal haemorrhage; HDFN, haemolytic disease of the fetus and newborn; IUT, intrauterine transfusion; RhD-Ig, RhD immunoglobulin

*Table 7.4: Red cell antibodies and the risk of haemolytic disease of the fetus and newborn*

| | | HDFN | |
|---|---|---|---|
| **Antibody specificity** | **IgG** | **Likelihood** | **Severity** |
| ABO | Some | Yes | No to moderate (rarely severe) |
| M | Most | Rare | No to severe |
| N | Some | No | |
| S, s, U | Most | Rare | No to severe |
| $P_1$ | Rare | No | |
| Rh | Most | Yes | Mild to severe |
| Lutheran | Most | Rare | Mild |
| Kell | Most | Yes | Mild to severe |
| Lewis | Some | No | |
| Duffy | Most | Rare | Mild to severe |
| Kidd | Most | Rare | Mild to moderate (rarely severe) |
| Diego | Most | Rare | Mild to severe |
| Yt | Most | No | |
| Xg | Most | No | |
| Scianna | Most | Yes | Mild to severe (only anti-Sc3, anti-Rd) |
| Dombrock | Most | No | |
| Colton | Most | Rare | Mild to severe |
| LW | Most | No | |
| Chido/Rogers | Most | No | |
| H | Some | Rare | No to severe |
| Gerbich | Most | Yes | Mild to severe (only anti-Ge3) |
| Cromer | Most | No | |
| Knops | Most | No | |
| Indian | Most | No | |
| JMH | Most | No | |
| I | Rare | No | |
| Vel | Yes | Rare | Severe |
| HLA | No | | |
| Other antibodies active by IAT at 37 °C (including antibodies to low or high frequency antigens) | | Depends on specificity; May need to seek advice from reference laboratory | |

HDFN, haemolytic disease of the fetus and newborn; HLA, human leucocyte antigen; IAT, indirect antiglobulin test; IgG, immunoglobulin G

# Section 8
# Quality management

## 8.1 Quality system

8.1.1 The laboratory must have a quality management system in accordance with national accreditation and regulatory requirements.

8.1.2 All policies, procedures and methods must be clearly documented in a quality manual, which must be readily accessible within the laboratory.

8.1.3 The quality manual should be periodically reviewed (e.g. annually) to ensure that it remains current. Electronic document control systems facilitate continual review of documents and timely updates.

## 8.2 Accreditation of medical testing laboratories

8.2.1 Medical testing laboratories are accredited in Australia by the National Association of Testing Authorities/Royal College of Pathologists of Australasia (NATA/RCPA) and in New Zealand by International Accreditation New Zealand (IANZ) against the respective national standard: AS ISO 15189 *Medical laboratories – Particular requirements for quality and competence* or NZS/ISO 15189 *Medical laboratories – for quality and competence.* [20, 21, 22]

8.2.2 In New Zealand, accreditation of transfusion medicine laboratories is further supported by the New Zealand Blood Service *District Health Board Clinical Oversight Programme*, which provides formal clinical and technical oversight of blood banks through a combination of site visits, clinical audits and regional blood bank meetings.

## 8.3 Governance of hospital transfusion activities

8.3.1 Health service organisations must have governance and systems in place for the safe and appropriate prescribing and clinical use of blood products, in accordance with the Australian National Safety and Quality Health Service (NSQHS) Standards *Blood Management Standard*, or a similar quality and safety framework.

8.3.2 In many organisations, a hospital transfusion committee (HTC) or patient blood management committee (PBMC) provides governance and oversight of patient blood management and transfusion-related activities.

8.3.3 The HTC or PBMC brings together a cross-functional or multidisciplinary group of health professionals, and plays a critical role in ensuring that blood products are used appropriately, safely and efficiently. In some locations, particularly small health service organisations, this function may be incorporated into other committees or roles that oversee medicines or broader clinical practice.

8.3.4 The HTC/PBMC is responsible for ensuring that transfusion-related activities comply with relevant local and national guidelines and standards; for example, in:

- disseminating national or local guidelines within the institution
- developing local policies and protocols for blood use and collection
- auditing use and wastage, and developing related performance indicators
- risk management
- communication with internal and external bodies about quality assurance matters.

[20] www.nata.com.au

[21] www.rcpa.edu.au

[22] www.ianz.govt.nz

8.3.5 The HTC/PBMC provides support to haematologists and transfusion laboratory staff in enforcing policies relating to non-laboratory aspects of transfusion practice; for example:

- informed consent
- documentation of transfusion
- identification of patients
- collection of pretransfusion specimens
- correct prescribing of blood products.

## 8.4 Internal quality control

8.4.1 The laboratory must regularly assess the performance of its test system(s) including staff proficiency, by including 'control' specimens and comparing the results with those previously obtained.

8.4.2 Controls must be specific and sensitive, reflect the patient population being tested and monitor critical points in the test procedure.

8.4.3 In automated systems, controls should detect unexpected dilution of the testing environment (and therefore loss of ionic strength); for example, due to leaks, backflow contamination (e.g. valve leaks) within the fluidic system or sample carryover.

8.4.4 Controls for antibody screening should be chosen so that both positive and negative results are obtained for each reagent screening cell.

8.4.5 The intervals at which controls are included should be set so as to provide timely detection of deteriorating performance or failure of the test system, and should be based on a documented risk assessment of the consequences of this occurring. The frequency will be influenced by a variety of factors; for example:

- the number of patient specimens tested
- the work flow of the laboratory
- the scope of testing (in particular, whether crossmatching is performed)
- the storage requirements and the usage patterns of reagents.

8.4.6 Laboratories that primarily provide blood grouping and antibody screening and are not associated with an acute care facility may choose to run controls only once per day because the consequence of test failure may simply be repeating the testing of all affected specimens.

8.4.7 Control specimens containing weak antibodies (e.g. anti-$Fy^a$ or anti-$Jk^a$) should be regularly included to monitor both the sensitivity of the test system and the stability of red cell antigens on reagent red cells. Obtaining weaker than expected reaction strengths will help in detecting deteriorating test performance and, in particular, changes in antigen expression.

ⓘ Inclusion of controls with mixed cell populations or a weak positive DAT is also recommended.

8.4.8 Controls should be validated under the laboratory's normal testing conditions. New controls should be tested in parallel with the current controls using the same reagent red cells in order to establish new QC limits.

8.4.9 Weak IgG-coated red cells should be used to control the washing phase of tube or microplate IAT methods. These are added to all negative IAT results with a positive result indicating a valid test. A negative result suggests incomplete washing and the test run is invalid.

8.4.10 Control failures require documented corrective action as well as the repeat of all patient tests performed since the control material last returned expected results.

8.4.11 Internal QC results must be regularly reviewed by a senior staff member with outcome of the review documented.

## 8.5 External quality assurance

8.5.1 The laboratory must participate in an accredited external quality assurance program (QAP) appropriate to the range of immunohaematology testing undertaken and which should, if appropriate, include extended phenotyping, titration and FMH estimation.

8.5.2 All staff must ideally undertake at least two exercises per year. Where a large number of staff precludes regular individual participation in the chosen QAP, the laboratory must provide a replicate testing program to supplement QAP participation.

8.5.3 The laboratory should choose QAPs accredited to ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing.

## 8.6 Quality control

### *8.6.1 General principles*

8.6.1 All equipment (instruments, reference materials, consumables, reagents and analytical systems) must be subjected to regular maintenance and calibration programs to ensure reliability.

8.6.2 Equipment performance must be monitored at regular intervals in accordance with the manufacturer's recommendations and relevant national accreditation guidelines.

8.6.1.1 The manufacturer's instructions must be followed although more stringent testing may be performed where this is felt to be beneficial.

8.6.1.2 Records must be maintained of all QC performed by the laboratory in accordance with national regulatory requirements.

8.6.1.3 The laboratory should record all batch numbers and expiry dates of reagents, and the time period during which they were used. It should be possible to link each test to the reagents used.

### *8.6.2 Acceptance testing of reagents*

8.6.2.1 The laboratory must have documented procedures for assessing the suitability of reagents before they are introduced into routine use.

8.6.2.2 Acceptance testing must specify criteria against which reagents are assessed and the action required if these criteria are not met. Any item failing the acceptance criteria should not be used in testing.

8.6.2.3 When defining acceptance criteria, it is recommended that laboratories use expected reaction strengths of red cells (against antisera of known concentration or titre) or expected titres of antisera (against standard indicator red cells).

8.6.2.4 Acceptance testing provides a baseline against which ongoing performance of reagents can be assessed.

8.6.2.5 A base laboratory may choose to perform centralised acceptance testing of the reagents it distributes to satellite or regional laboratories for use.

8.6.2.6 The decision to omit further acceptance testing at the secondary laboratories will be based on an assessment of potential risks to reagent performance that include:

- transit time
- reagent stability at ambient temperatures
- potential damage during transit
- suitable control or monitoring of transport conditions (e.g. use of temperature data loggers).

### *8.6.3 Frequency of reagent quality control*

8.6.3.1 The performance of reagents must be checked on a regular basis against the manufacturer's specifications or performance criteria set by the laboratory (or both).

8.6.3.2 In general, reagent QC checks should be performed at least **once per day** (of use), although longer intervals between testing may be acceptable if mandated by the manufacturer or if the laboratory can show that the extended interval has been appropriately validated.

## 8.7 Maintenance and calibration

8.7.1 Table 8.1 (page 48) shows the recommended maintenance or calibration intervals for equipment. These are only guidelines and are intended for use where requirements have not been set by the

supplier, or where the supplier's requirements are less stringent than those required by regulatory standards.

8.7.2 Equipment calibration must be checked following repair or a significant change in location.

## 8.8 Validation, verification and changes

### *8.8.1 Validation*

8.8.1.1 All critical processes, equipment, facilities or systems must undergo appropriate validation before use, with records held in accordance with national regulatory requirements.

8.8.1.2 Automated equipment must be shown to:

- be capable of achieving the required performance
- comply with the specifications associated with the tests performed, transport or storage
- comply with the laboratory's requirements
- comply with regulatory requirements.

8.8.1.3 Where a laboratory is associated with other laboratories in a network that are, for example, using the same processes, equipment and reagents, a single validation performed at one of the sites may be acceptable. Each laboratory should have a mechanism for ensuring that its test results are comparable to the other sites in the network.

8.8.1.4 All validation failures or nonconformances must be fully investigated to determine the root cause and to resolve the problem. Investigation and subsequent corrective or remedial action must be fully documented, and records retained according to accreditation requirements. Any subsequent variation to a manufacturer's recommended solutions must be validated by the user.

### *8.8.2 Verification*

8.8.2.1 Performance of automated equipment must be regularly checked (verified) by testing a suitable combination of the following, chosen to challenge the expected range of sensitivity and specificity:

- specifically formulated QC material
- previously analysed samples
- commercial controls
- reference material.

8.8.2.2 All verification failures or nonconformances must be fully investigated to determine the root cause. All findings, including resolution of the problem, must be documented.

### *8.8.3 Modifications and upgrades*

8.8.3.1 A risk assessment must be undertaken before equipment is modified or upgraded (or changes are made to the operating software) to identify critical control points and areas where failure could cause harm to a patient.

8.8.3.2 All changes to critical processes, equipment, facilities or systems must be validated before the system is brought back into use.

8.8.3.3 Following modifications or upgrades to the equipment or changes to operating software, operators should receive relevant retraining, and performance must be verified to show that any change has not had an adverse effect.

### *8.8.4 Software validation*

8.8.4.1 Software used by the laboratory must undergo a documented validation in accordance with 8.8.1. The following information must be recorded and kept in accordance with regulatory requirements:

- software version
- date of validation
- identity of the person performing the validation

- evidence of an independent check of all the validation documentation by a senior member of the laboratory staff.

8.8.4.2 Validation must ensure that software performs as expected and required (irrespective of the source and manufacturer's prior testing), and should include both destructive testing of individual modules (to test their robustness) and integrated testing of the complete system and logic paths using correct and incorrect data.

8.8.4.3 A validation checklist should be prepared that provides a series of challenges to the software to ensure that the appropriate responses are generated and in particular to demonstrate the following:

- ABO-incompatible units cannot be issued
- expired blood products cannot be issued
- unambiguous warning flags or messages (that cannot be inappropriately overridden) highlight special transfusion requirements or other locally applied protocols
- the software correctly and appropriately handles all expected donor and recipient ABO and RhD type combinations when determining compatibility (or incompatibility) of each blood product.

### *8.8.5 Software modifications or upgrades*

8.8.5.1 Before undertaking modifications or upgrades to software, a risk assessment must be performed to identify critical control points and areas where failure could cause harm to a patient.

8.8.5.2 All software modifications or upgrades must be fully documented and records kept.

8.8.5.3 Modified or upgraded software must be fully validated (unless the changes are considered minor) to show that any changes have not had an adverse effect. Even minor changes to software may affect the functionality or operation of the system; therefore, extra vigilance is required to ensure the system is operating as expected.

8.8.5.4 Electronic release of blood products or computer crossmatching is prohibited until any validation is completed.

8.8.5.5 Operators should receive appropriate retraining following any software modifications or upgrades.

*Table 8.1: Maintenance and calibration schedules*

| Device | Requirement | Interval |
|---|---|---|
| Thermometers – digital | Calibration (check against reference device at temperature of use or ice point) | 6 months |
| | Calibration check | 2 years |
| Temperature measuring devices<br>Liquid in glass – reference | Calibration check (check ice point) | 6 months |
| | Calibration | 5 years |
| Temperature measuring devices<br>Liquid in glass – working | Calibration check (check at ice point or against reference thermometer at one point in working range) | 6 months |
| | Calibration | 5 years |
| Centrifuges | Calibration | Annually |
| Timers | Timer accuracy | 6 months |
| Refrigeration equipment | Temperature check (both digital and chart recorders) | Daily |
| | Chart recorder change | Weekly |
| | Alarm backup battery check | Monthly |
| | Cleaning (as required) | Monthly |
| | Temperature monitoring and alarm system accuracy | 6 months |
| | High/low temperature | 6 months |
| | Power failure alarm | 6 months |
| | Mechanical inspection | 6 months |
| | Temperature monitoring and alarm system calibration | Annually |
| | Alarm reactivation test | Annually |
| | Spatial temperature check | On receipt, following move of equipment or significant repair |
| | Defrosting | As required |
| | Download electronic monitoring data | As required |
| Platelet rotator/agitator | Temperature check | Daily |
| | Calibration | Annually |
| | Spatial temperature check | On receipt, following move of equipment or significant repair |
| | Rotation rate or agitation frequency (as per manufacturers' specifications) | On receipt, following move of equipment or significant repair |
| | Alarm checks | 6 months |
| Thawing equipment | Temperature check | Daily |
| | Cleaning | Weekly |
| Heat blocks, water baths, incubators | Temperature check | Daily |
| | Calibration | Annually |
| | Spatial temperature check | 3 years |
| Pipettes | Dispensed volume (requirements for calibration and/or checking based on criticality and/or reproducibility of dispensing volume | According to local policy |

# Abbreviations

| | |
|---|---|
| AABB | American Association of Blood Banks |
| ACSQHC | Australian Commission on Safety and Quality in Health Care |
| ANZSBT | Australian and New Zealand Society of Blood Transfusion |
| aPTT | activated partial thromboplastin time |
| AS | Australian Standard |
| BMI | body mass index |
| BNP | brain natriuretic peptide |
| BSH | British Society for Haematology |
| CAT | column agglutination technology |
| CDP | cryodepleted plasma |
| CMV | cytomegalovirus |
| CPOE | computerised prescriber order entry |
| C:T | crossmatch to transfusion (ratio) |
| DAT | direct antiglobulin test |
| DOB | date of birth |
| DVI | RhD category VI |
| EDTA | ethylenediaminetetraacetic acid |
| ELP | extended life plasma |
| EMR | electronic medical record |
| eXM | electronic crossmatch |
| FFP | fresh frozen plasma |
| FMH | fetomaternal haemorrhage |
| FNHTR | febrile nonhaemolytic transfusion reaction |
| G&S | group and screen |
| GVHD | graft versus host disease |
| HDFN | haemolytic disease of the fetus and newborn |
| HIV | human immunodeficiency virus |
| HLA | human leucocyte antigen |
| HPA | human platelet antigen |
| HSCT | haemopoietic stem cell transplant |
| HTC | hospital transfusion committee |
| HTLA | high titre, low avidity |
| IAT | indirect antiglobulin test |
| IgA | immunoglobulin A |
| IgG | immunoglobulin G |
| IHI | Individual Healthcare Identifier |

| | |
|---|---|
| INR | international normalised ratio |
| ISO | International Organization for Standardisation |
| IT | information technology |
| IU | international units |
| IUT | intrauterine transfusion |
| IV | intravenous |
| IVIg | Intravenous immunoglobulin |
| LIS | laboratory information system |
| LISS | low ionic strength solution |
| MCA | middle cerebral artery |
| MDS | myelodysplastic syndrome |
| MRN | medical record number |
| MSBOS | maximum surgical blood order schedule |
| NATA | National Association of Testing Authorities |
| NBA | National Blood Authority |
| NPAAC | National Pathology Accreditation Advisory Council |
| NHI | national health index |
| NZS | New Zealand standard |
| PBMC | patient blood management committee |
| PCR | polymerase chain reaction |
| PEG | polyethylene glycol |
| PT | prothrombin time |
| PTS | pneumatic tube system |
| RCPA | Royal College of Pathologists of Australasia |
| RhD-Ig | RhD immunoglobulin |
| QAP | quality assurance program |
| QC | quality control |
| RFID | radio-frequency identification |
| SaBTO | Advisory Committee on the Safety of Blood, Tissues and Organs |
| TACO | transfusion-associated circulatory overload |
| TA-GVHD | transfusion-associated graft versus host disease |
| TRALI | transfusion-related acute lung injury |
| WAIHA | warm autoimmune haemolytic anaemia |

# Glossary

| | |
|---|---|
| Australian Standard (AS) | Precedes document number of standards issued by Standards Australia |
| Blood components | Red cells, platelets, fresh frozen plasma, cryoprecipitate and white cells derived from human blood |
| Blood product | To assist in the clarity of these guidelines, the term **blood product** has been used generically to describe blood components, plasma derivatives and recombinant products |
| Blood Service | Australian Red Cross Lifeblood or New Zealand Blood Service |
| Brain natriuretic peptide (BNP) | Test for BNP levels used to distinguish TACO from TRALI |
| Child bearing potential (reproductive age) | Defined by the World Health Organisation as all females aged 15-49 |
| Daratumumab | Human monoclonal antibody with anti-CD38 specificity used to treat myeloma |
| Destructive testing | Destructive software testing attempts to cause a piece of software to fail in an uncontrolled manner, in order to test its robustness |
| Ethylenediaminetetraacetic acid (EDTA) | Anticoagulant, chelating agent |
| Extended life plasma (ELP) | Thawed plasma with a 5-day post-thaw shelf life |
| GATA mutation | A mutation in the promoter region of the FYB gene that disrupts a binding site for the erythroid transcription factor GATA-1, resulting in the loss of FY expression on red cells. Found in individuals of African descent with a Fy(a-b-) phenotype. The presence of FYB means these individuals do not produce anti-$Fy^b$, making it easier to find antigen-matched blood. |
| Group and screen (G&S) | A shorthand description for pretransfusion blood group (ABO/RhD typing) and antibody screening of the recipient |
| Hospital | The hospital, health-care facility or other organisation under whose direction requests for pretransfusion testing are made |
| IgA, IgD, IgE, IgG, IgM | The five classes of immunoglobulin; glycoprotein molecules that are produced by plasma cells in response to an immunogen and which function as antibodies |
| Individual Healthcare Identifier (IHI) | A nationally unique 16-digit number allocated to all individuals enrolled in Medicare, or who hold a Department of Veterans' Affairs treatment card and others who seek health care in Australia |
| International Accreditation New Zealand (IANZ) | New Zealand's national authority for accreditation which includes accreditation of medical testing laboratories |
| International Organization for Standardisation (ISO) | International standard-setting body composed of representatives from national standards bodies |
| Kleihauer-Betke test | Test used to detect and quantify fetomaternal haemorrhage |
| Laboratory | The blood bank or pathology laboratory responsible for performing pretransfusion testing on behalf of the hospital |

| | |
|---|---|
| Laboratory director[23] | The pathologist, transfusion medicine specialist, medical officer or Clinical Scientist with responsibility and authority for the clinical and scientific oversight of the laboratory.[24] |
| National Association of Testing Authorities (NATA) | Australia's national laboratory accreditation authority |
| Neonate | Newborn infant aged under 1 month |
| National Pathology Accreditation Advisory Council (NPAAC) | Australian body that advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories. NPAAC has a key role in ensuring the quality of Australian pathology services and responsible for the development and maintenance of standards and guidelines for pathology practices. |
| National Health Index (NHI) | A unique identifier that is assigned to every person who uses health and disability support services in New Zealand |
| New Zealand standard (NZS) | Precedes document number of standards issued by Standards New Zealand |
| Plasma derivatives | Plasma proteins fractionated from large pools of human plasma under pharmaceutical conditions (e.g. coagulation factors, albumin and immunoglobulins) |
| Recombinant product | Nonhuman-derived replacement for specific clotting factor deficiency |
| Remote release of blood | Issuing blood products directly from a satellite refrigerator at a physically distinct location from the supplying laboratory, such as a ward or other clinical area or facility |
| RhD variant | RhD antigen with fewer antigen sites or missing epitopes leading to weak(er) or absent reactions with anti-D sera |
| Radio-frequency identification (RFID) | The process of using an electrical transponder that stores information that can be used to identify the item to which the transponder is attached |
| Transfusion dependent | Any patient with a long-term hereditary or incurable condition (with expected survival > 12 months) who requires regular and ongoing transfusion support |

[23] AS ISO 15189 *Medical laboratories – requirements for quality and competence (2013)*

[24] NPAAC *Requirements for supervision in the clinical governance of medical pathology (2018)*

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# Appendix 1
## Maximum surgical blood order schedule

The maximum surgical blood order schedule (MSBOS) provided below is intended as a guide only; local jurisdictional policy requirements may be different. Consideration should be given to the availability of onsite pathology services, and alternative quantities may be required for regional facilities without onsite pathology. When establishing additional surgical services or contemplating unusual or complex surgery, a local risk assessment should be considered that takes into account:

- availability of transfusion support (location, inventory level and time for resupply)
- presence of red cell alloantibodies or autoantibodies that may delay availability of blood
- complexity of surgery
- distance from tertiary support services, availability of evacuation or retrieval services and associated blood product inventory.

The laboratory, together with the relevant surgeons and anaesthetists, should assess the usual red cell requirements for each procedure in the hospital(s) that they serve.

The crossmatch (C) to transfusion (T) ratio (C:T ratio) is a useful measure for the appropriateness of crossmatch requirements; procedures with a C:T ratio > 1.8 can normally be considered suitable for a group and screen (G&S) only.

Following risk assessment laboratories may opt to only provide blood on demand following a G&S, to minimise unnecessary crossmatching. A G&S policy is preferable when there is a 24/7 onsite transfusion laboratory at the transfusing institution.

Specialised surgical procedures (e.g. cardiac, hepatic and neurosurgery) usually employ standard protocols developed in consultation with the laboratory.

*Table A1: Maximum surgical blood order schedule*

| Clinical specialty | Procedure | Requirements |
|---|---|---|
| **General surgery** | Abdomino-perineal resection | G&S |
| | Amputation (below or above knee) | G&S |
| | Anterior resection | G&S |
| | Appendectomy | Nil |
| | Apronectomy (mini-abdominoplasty) | G&S |
| | Bowel resection | G&S |
| | Breast surgery (lumpectomy) | G&S |
| | Burns debridement | Individual assessment |
| | Cholecystectomy (open) | G&S |
| | Cholecystectomy (laparoscopic) | G&S |
| | Colectomy (formation or closure) | G&S |
| | Ethmoidectomy | Nil |
| | Gastrectomy | 2 |
| | Gastric stapling | G&S |
| | Haemorrhoidectomy | Nil |
| | Hiatus hernia repair (abdominal) | G&S |
| | Hiatus hernia repair (transthoracic) | G&S |
| | Incisional hernia repair | Nil |
| | Laparotomy | G&S |
| | Lipectomy | G&S |
| | Lumbar sympathectomy | G&S |
| | Mastectomy (simple) | G&S |
| | Mastectomy (radical) | G&S |
| | Mastoidectomy | Nil |
| | Pancreatectomy | G&S |
| | Parotidectomy | G&S |
| | Rhinoplasty | G&S |
| | Splenectomy | 2 |
| | Thyroidectomy | G&S |
| | Tonsillectomy | Nil |
| | Tracheostomy | G&S |
| | Vagotomy and drainage | G&S |
| | Varicose veins stripping | Nil |

| Clinical specialty | Procedure | Requirements |
|---|---|---|
| **Gynaecological surgery** | Caesarean section | Nil |
| | Colposuspension | Nil |
| | Cone biopsy | Nil |
| | D&C | Nil |
| | Ectopic pregnancy | G&S |
| | Hysterectomy | G&S |
| | Laparoscopy | Nil |
| | Myomectomy | G&S |
| | Ovarian cystectomy | G&S |
| | Termination of pregnancy | Nil |
| | Tubal ligation | Nil |
| | Vaginal repair | Nil |
| | Vulvectomy | Nil |
| **Orthopaedic surgery** | Arthroscopy | Nil |
| | Arthrotomy | Nil |
| | Femoral nail removal | Nil |
| | Fractured femur | G&S |
| | Harrington's rods | 4 |
| | Hip replacement | G&S |
| | Hip replacement – redo | G&S |
| | Knee replacement | G&S |
| | Laminectomy | G&S |
| | Menisectomy | Nil |
| | Putti-Platt | Nil |
| | Spinal fusion | G&S |
| | Synovectomy (knee) | Nil |
| **Thoracic surgery** | Lobectomy | G&S |
| | Pleurectomy | G&S |
| | Pneumonectomy | G&S |
| | Thymectomy | G&S |
| **Urological surgery** | Cystectomy | G&S |
| | Cystoscopy or cystotomy (vesicotomy) | Nil |
| | Nephrectomy | G&S |
| | Nephrolithotomy | G&S |
| | Prostatectomy (open) | G&S |

| Clinical specialty | Procedure | Requirements |
|---|---|---|
| **Urological surgery** *continued* | Prostatectomy (transurethral resection; TURP) | Nil |
| | Pyelolithotomy | G&S |
| | Ureterolithotomy | G&S |
| **Vascular surgery** | Aortic aneurysm (elective) | 2 |
| | Aorto-femoral bypass graft | G&S |
| | Aorto-iliac bypass graft | G&S |
| | AV shunt | Nil |
| | Carotid endarterectomy | G&S |
| | Femoro-popliteal bypass graft | G&S |
| | Ilio-femoral bypass graft | G&S |
| | Sympathectomy lumbar | G&S |

AV, arteriovenous; D&C, dilation and curettage; G&S, group and screen; TURP, transurethral resection of the prostate

# Appendix 2
## Summary of changes from the original first edition

Changes from the original first edition are tabulated below. It is recommended that readers review the document in its entirety to ensure that their policies and procedures are valid and consistent with what is recommended.

*Table A2: Summary of changes from the original first edition*

| Section | Change details | Original | New |
|---|---|---|---|
| **All** | Footer: "*Guidelines for transfusion and immunohaematology laboratory practice (1st edition revised January 2020)*" | X | Footer |
| **Section 1** | 1.2.1: Informatory bullet point updated to reflect name change to "British Society for Haematology (BSH)" | 1.2.1 | 1.2.1 |
| | 1.2.4: Wording in brackets changed to "(e.g. a declaration on a transfusion request)" | 1.2.4 | 1.2.4 |
| | Footnote: "https://b-s-h.org.uk/guidelines" | X | Footnote 1 |
| | New 1.3.2: "Patient details, for example provided on requests (see 1.4, 1.5 and 1.6), specimens (see 1.7) and in laboratory records (see 1.9) must comply with the requirements of the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for medical pathology services:*<br>• three unique identifiers must be used for requests, compatibility reports and labels, laboratory records; and<br>• two unique identifiers must be used when labelling the specimen (although three are preferable)" | X | 1.3.2 |
| | Footnote: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-medpathserv-2018" | X | Footnote 2 |
| | New 1.3.3: "The patient identifiers must include the patient's FULL NAME and at least one of either DATE OF BIRTH (DOB) or a UNIQUE RECORD NUMBER such as a MEDICAL RECORD NUMBER (MRN) in Australia or NATIONAL HEALTH INDEX (NHI) number in New Zealand.<br>ⓘ The Australian MEDICARE NUMBER is not unique and therefore not an approved identifier." | X | 1.3.3 |
| | New 1.3.4: "Other approved additional identifiers include:<br>• Unique ACCESSION NUMBER<br>• GENDER<br>• PATIENT ADDRESS (e.g. if request originates outside the hospital)<br>• (in Australia) e-health INDIVIDUAL HEALTHCARE IDENTIFIER (IHI) | X | 1.3.4 |
| | New figure: "Figure 1: Request and specimen identification" | X | Figure 1 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 1** *continued* | Footnote: "National Safety and Quality Health Service Standards: Communicating for safety standard (https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/correct-identification-and-procedure-matching/action-65)" | X | Footnote 3 |
| | New 1.3.5: "Alternative identifiers may be used in special circumstances, such as when patients are to remain anonymous" | X | 1.3.5 |
| | New 1.3.6: previously 1.3.2 reworded by removing "both" from the sentence | 1.3.2 | 1.3.6 |
| | Renumbering to reflect insertion of new steps | 1.3.3 – 1.3.6 | 1.3.7 – 1.3.10 |
| | New 1.3.11: "Truncation of patient identifiers, for example by laboratory and/or hospital information systems, is a potential cause of misidentification errors. The laboratory must have a policy and procedure for handling the issues arising when long patient names (or other mandatory identifiers) are truncated or shortened. | X | 1.3.11 |
| | 1.4.4: reworded, and bullet points deleted, in line with changes to 1.3 "The request must clearly (and legibly) identify the patient with **THREE unique identifiers** (see 1.3)" | 1.4.4 | 1.4.4 |
| | 1.4.5 and 1.4.6 deleted | 1.4.5, 1.4.6 | X |
| | New 1.4.5: previous 1.4.7 reworded "Requests for pretransfusion testing (including prenatal and postnatal specimens upgraded to a pretransfusion request) must contain a declaration, similar to the one shown below, that has been signed by the person collecting the specimen: | 1.4.7 | 1.4.5 |
| | Renumbered step | 1.4.8 | 1.4.6 |
| | Table 1.1: table description reworded by addition of "Additional" at beginning of sentence | Table 1.1 | Table 1.1 |
| | Table 1.1: reworded fourth bullet point of first column "Signature (or other traceable identifier) and contact details of the phlebotomist" | Table 1.1 | Table 1.1 |
| | Table 1.2: column headings renamed "Patient information" and "Blood product information" respectively | Table 1.2 | Table 1.2 |
| | Table 1.2: wording of required patient identifiers in left column changed to "Three unique identifiers (see 1.3.3):<br>○ FULL NAME<br>○ DOB and/or MRN/NHI" | Table 1.2 | Table 1.2 |
| | 1.7.2: reworded "Procedures for specimen collection, handling and management should include unidentified patients (see 1.3.8) and unlabelled, inadequately or incorrectly labelled specimens" | 1.7.2 | 1.7.2 |
| | 1.7.4: reworded with "Ethylenediaminetetraacetic acid (EDTA; plasma)" replaced by "EDTA (plasma)" | 1.7.4 | 1.7.4 |
| | Footnote: "EDTA: ethylenediaminetetraacetic acid" | X | Footnote 4 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 1** *continued* | 1.7.7: bullet points deleted and "see 1.3" added to end of sentence | 1.7.7 | 1.7.7 |
| | 1.7.9: reworded "The specimen must also be labelled with the:<br>• SIGNATURE (or other traceable Identifier) of the phlebotomist, who must be the same person completing the declaration on the request.<br>• DATE and TIME the specimen was collected, if this is not otherwise recorded electronically and fully traceable. | 1.7.9 | 1.7.9 |
| | Table 1.3: reference to BSH guidelines moved to footnote "BSH *Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories* (2012) (https://b-s-h.org.uk/guidelines)" | Table 1.3 | Footnote 5 |
| | Table 1.4: column headings renamed "Patient information" and "Blood product information" respectively | Table 1.4 | Table 1.4 |
| | Table 1.4: left column bullet points reworded "<br>• Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI<br>• Gender<br>• ABO/RhD blood group<br>• Date and time of specimen collection (if one collected)<br>• Antibody screen results<br>• Other testing results (e.g. antibody identification, antigen typing, DAT)<br>• Specimen or request validity/expiry (see 2.2.6)<br>• Details of the person performing the testing<br>• Special requirements, warnings or other relevant information" | Table 1.4 | Table 1.4 |
| | Table 1.5: column headings renamed "Patient information" and "Blood product" information respectively | Table 1.5 | Table 1.5 |
| | Table 1.5: wording of required patient identifiers in the left column changed to: "<br>• Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI" | Table 1.5 | Table 1.5 |
| | Table 1.6: column headings renamed "Patient information" and "Blood product information" respectively | Table 1.6 | Table 1.6 |
| | Table 1.6: wording of required patient identifiers in the left column changed to: "<br>• Three unique identifiers (see 1.3.3):<br>  ○ FULL NAME<br>  ○ DOB and/or MRN/NHI" | Table 1.6 | Table 1.6 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 1** *continued* | Table 1.6: in right column, addition of a new final bullet point and (original final) now penultimate bullet point reworded "<br>• Blood product expiry date and time<br>• Identity of the person affixing the label" | Table 1.6 | Table 1.6 |
| | 1.9.4.2: final bullet point reworded "date and time after which the product must not be transfused" | 1.9.4.2 | 1.9.4.2 |
| **Section 2** | 2.1.3: rewording of "(e.g. 'group and screen')" to "e.g. 'group and screen' or 'G&S'" | 2.1.3 | 2.1.3 |
| | New 2.1.4: "Obtaining a current drug or treatment history is important particularly if the patient is receiving agents known to cause immune haemolysis, a positive DAT or otherwise interfere with pretransfusion testing. | X | 2.1.4 |
| | 2.2.6: typo corrected in informatory bullet point associated with first bullet point, with "the" following "specimen" removed | 2.2.6 | 2.2.6 |
| | 2.2.6: third bullet point reworded "**(Up to) 3 months** from collection: for specimens taken in advance of elective surgery; it must be confirmed at the time of collection **and again** following their subsequent admission to hospital that the patient has not been pregnant or transfused in the preceding 3 months" | 2.2.6 | 2.2.6 |
| | 2.5.1.1: second paragraph of "Reverse group" moved to "Forward group" and reworded as an informatory bullet point "If no plasma is available for the reverse group, the forward group should include a test of patient's red cells against reagent diluent or AB plasma as a control for autoagglutination" | 2.5.1.1 | 2.5.1.1 |
| | 2.5.2.1: reworded "RhD typing in pretransfusion testing, testing prenatal and postnatal maternal specimens and testing newborn specimens (e.g. cord blood) consists of red cells tested with a monoclonal anti-D reagent that **does not** detect RhD category VI (DVI)" | 2.5.2.1 | 2.5.2.1 |
| | 2.5.2.3: reworded "Further testing of apparent RhD negatives (e.g. by IAT) is not required" | 2.5.2.3 | 2.5.2.3 |
| | 2.5.2.4: deleted | 2.5.2.4 | X |
| | 2.5.3.2: reworded by incorporating original bullet points into the original statement | 2.5.3.2 | 2.5.3.2 |
| | 2.5.3.3: changed to a first bullet point (for 2.5.3.2) and reworded "If confirmation is performed by manual methods it should, wherever possible, be performed by a second individual having no prior knowledge of the original result; or" | 2.5.3.3 | 2.5.3.2 |
| | 2.5.3.4: changed to a second bullet point (for 2.5.3.2) with original final sentence deleted | 2.5.3.4 | 2.5.3.2 |
| | 2.5.5: subsection heading reworded with addition of "and other types of donation" at end of sentence | 2.5.5 | 2.5.5 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 2** *continued* | 2.5.5.2: reworded "Apparent RhD negative bone marrow, haemopoietic stem cells, granulocytes and other types of donation (e.g. directed donations) must be confirmed by testing with an RhD reagent that detects category DVI" | 2.5.5.2 | 2.5.5.2 |
| | 2.6.1.7: deletion of "or Polybrene®" in first sentence and "alternative methods" from the second sentence | 2.6.1.7 | 2.6.1.7 |
| | 2.6.3.1: reworded "A weak positive antibody control, such as anti-D at a concentration of at least 0.1 IU/mL (or other weak antibody specificity at a comparable concentration), should be run at least once per day, or on each day that the laboratory undertakes testing when this is not daily, to monitor efficacy of the test procedure (as per 8.6.3)" | 2.6.3.1 | 2.6.3.1 |
| | 2.8.11: reworded "Requests for crossmatching can be made at any time during the lifetime of the specimen (see 2.2.6). Once a transfusion episode has commenced, the crossmatch request becomes invalid at either the original expiry of the specimen, or 72 hours/midnight of the third day (as applicable) after transfusion of the first unit of red cells began, whichever occurs first" | 2.8.11 | 2.8.11 |
| | 2.9.4: Wording "(or appropriately overridden)" deleted | 2.9.4 | 2.9.4 |
| | Table 2.2: Wording "(active at 37 °C)" added to "Anti-P1" | Table 2.2 | Table 2.2 |
| **Section 3** | 3.1.1.2: reworded second sentence of informatory bullet point "However, this should be balanced against creating unnaturally high usage, for example the elective use of near-expiry O RhD negative red cells for non-O RhD negative recipients" | 3.1.1.2 | 3.1.1.2 |
| | Footnote: "Australian Red Cross Lifeblood *Use of group O RhD negative red cells* (https://transfusion.com.au/blood_products/components/red_cells/GroupO)" | X | Footnote 6 |
| | 3.1.1.3: reworded "To avoid unnecessary wastage, it is preferable to maintain an appropriately representative inventory of different ABO/RhD types that reflects local usage" | 3.1.1.3 | 3.1.1.3 |
| | Table 3.1: First row heading second word changed to "product" and table revised based on additional information provided by Australian Red Cross Lifeblood including an additional row for "unknown products" and an explanatory note "Plasma products that have low-titre anti-A/B pose a lower risk of haemolysis when transfusing ABO incompatible plasma" | Table 3.1 | Table 3.1 |
| | Footnote: "Australian Red Cross Lifeblood *Component compatibility* (https://transfusion.com.au/blood_basics/compatibility)" | X | Footnote 7 |
| | New 3.2.7: new sub-subsection "Extended life plasma (ELP)" adapted from the ANZSBT guidelines "Extended Life Plasma: A Framework for Preparation, Storage and Use" | X | 3.2.7 |
| | New table: "Table 3.4: Selection of platelet products" added to 3.3.3 based on information from Australian Red Cross Lifeblood | X | Table 3.4 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 3** *continued* | Footnote: "Australian Red Cross Lifeblood *Component compatibility* (https://transfusion.com.au/blood_basics/compatibility)" | X | Footnote 9 |
| | 3.3.5: reworded by removal of "high titre" from sentence | 3.3.5 | 3.3.5 |
| **Section 4** | 4.1.4: fourth bullet point reworded with "(ideally pooled platelets)" deleted from sentence and "(see Table 3.4) added | 4.1.4 | 4.1.4 |
| | Footnote (in informatory bullet of 4.2.2) renumbered and reworded "(http://www.blood.gov.au/pbm-guidelines)" | Footnote 1 | Footnote 10 |
| | 4.1.5: original 4.1.6 and 4.1.7 changed to explanatory bullet points | 4.1.6, 4.1.7 | 4.1.5 |
| | 4.1.8: renumbering to reflect changes to 4.1.6 and 4.1.7 | 4.1.8 – 4.1.11 | 4.1.6 – 4.1.9 |
| | 4.2.3: reworded first sentence "Where a patient has received 10 or more red cell units in 24 hours, additional red cells can be issued without an immediate-spin crossmatch (where normally performed by the laboratory)." | 4.2.3 | 4.2.3 |
| | 4.3.5: reworded "Previously alloimmunised pregnant women typically have a greater risk of further sensitisation. It is recommended that in addition to Rh and K, red cells also matched for $Fy^a$, $Fy^b$, $Jk^a$, $Jk^b$ and Ss are selected for transfusion (see 4.4.2.1)" | 4.3.5 | 4.3.5 |
| | 4.4.1.6: new first sub bullet point "if the neonate has an unresolved or indeterminate RhD type, RhD negative red cells should be selected" | X | 4.4.1.6 |
| | 4.4.2.1: reworded second bullet point "ABO compatible with both the mother and fetus; if the fetal blood group is not known, group O should be used" and addition of informatory sub-bullet "Whole blood plasma-reduced red cells (used in New Zealand) must have low titre IgG anti-A and anti-B"; and informatory sub-bullet point added to fourth bullet point "In exceptional cases, it will be necessary to give O RhD positive, c negative blood, for example in HDFN because of anti-c alloimmunisation, where giving RhD negative blood would be harmful" | 4.4.2.1 | 4.4.2.1 |
| | Footnote: Royal College of Obstetricians and Gynaecologists (RCOG) *The Management of Women with Red Cell Antibodies during Pregnancy* (2014) https://ranzcog.edu.au/statements-guidelines | X | Footnote 11 |
| | 4.5.1: In first sentence insertion of "such as myelodysplasia" after "… or haematology-oncology conditions" and addition of informatory bullet point "Pretransfusion testing for patients receiving anti-CD38 (e.g. daratumumab) and other similar monoclonal antibody therapies such as anti-CD47 may be complicated by the interference causes by this type of drugs and provision of blood may be delayed whilst this is resolved" | 4.5.1 | 4.5.1 |
| | 4.5.2: reworded "Patients should have a red cell phenotype (or genotype) determined before their initial transfusion. Typing may be limited to Rh and K or extended to also include $Jk^a$, $Jk^b$, $Fy^a$, $Fy^b$, S and s" | 4.5.2 | 4.5.2 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 4** *continued* | 4.6.1.2: reworded "The patient's drug history should be checked as a potential cause of the positive DAT, autoantibody or immune haemolysis. | 4.6.1.2 | 4.6.1.2 |
| | 4.6.1.9: in first sentence "necessary" changed to "used" | X | 4.6.1.9 |
| | 4.6.1.10: original sentence split into two sentences after "selected" with second sentence worded "If an IAT crossmatch is performed use adsorbed plasma where available" | X | 4.6.1.9 |
| | 4.6.2.3: end of first bullet point changed to "… and blood film"; final bullet point reworded "perform an elution if a delayed haemolytic transfusion reaction is suspected" | 4.6.2.3 | 4.6.2.3 |
| | 4.8.1: reworded "During the transplantation period, recipients of a kidney from an ABO-mismatched donor should be transfused with blood products, and in particular plasma products, where the ABO antibodies are compatible with the ABO group of graft" | 4.8.1 | 4.8.1 |
| | 4.8.2: rewording "blood products" to "red cells and platelets" | 4.8.2 | 4.8.2 |
| | 4.8.3: reworded with addition of "also" after "should" and first bullet point deleted | 4.8.3 | 4.8.3 |
| **Section 5** | New 5.1.1: "Blood and blood products will normally only be supplied by the blood service to appropriately accredited pathology providers or approved health facilities, in accordance with national regulations. Direct supply of labile components (red cells, platelets and plasma) to non-approved facilities e.g. remote healthcare facilities without onsite or local pathology providers is only permissible in exceptional circumstances and only then under pathology provider and/or health department guidance with assurance of appropriate storage and handling, record keeping and traceability" | X | 5.1.1 |
| | Renumbered step | 5.1.1 | 5.1.2 |
| | New 5.1.3: "Laboratories must have processes to ensure the timely return to stock of unused patient-assigned blood products as determined by sample validity and blood product expiry" | X | 5.1.3 |
| | Renumbering to reflect new 5.1.1 and 5.1.3 | 5.1.2 - 5.1.3 | 5.1.4 - 5.1.5 |
| | 5.2.1: insertion of informatory bullet point "Although not recommended practice it is recognised that equipment used for storing blood products is also used to store (for example) donor or patient specimens, reagents, plasma derivatives, tissues and other medicines. The decision to do so must be based on a risk assessment and items must be appropriately segregated" | 5.2.1 | 5.2.1 |
| | Footnote: reference to "New Zealand Blood Service (NZBS) *Refrigeration guidelines* (https://www.nzblood.co.nz/clinical-information/transfusion-medicine/refrigeration-guidelines)" | X | Footnote 12 |
| | New 5.2.2: original 5.2.4 | 5.2.4 | 5.2.2 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 5** *continued* | 5.2.3: reworded first sentence with "blood products" changed to "labile products i.e. red cells and plasma" and in informatory bullet point, comma after "20.5 °C" removed and new final sentence "Where platelets are not stored in a platelet incubator the laboratory must be able to demonstrate that the required room temperature is maintained" | 5.2.3 | 5.2.3 |
| | New 5.2.4: original 5.2.2 | 5.2.2 | 5.2.4 |
| | 5.2.6: word "issuing" inserted before "laboratory" | 5.2.6 | 5.2.6 |
| | 5.2.7: reworded "Under the following circumstances affected blood products must not be transfused (except at the discretion of the laboratory director):<br>a) Storage at temperatures outside the specified limits; or<br>b) Storage in nonconforming equipment; or<br>c) Where there is any doubt regarding storage temperatures or conditions" | 5.2.7 | 5.2.7 |
| | New 5.2.8: reworded second sentence from original 5.2.7 "Any deviations from the required storage temperatures or conditions must be clearly documented and the products quarantined until their fate is decided" | X | 5.2.8 |
| | New 5.2.9: "Policies for managing affected blood products, including the decision to return to the inventory or for subsequent transfusion, must be based on a risk assessment" | X | 5.2.9 |
| | New subsection 5.3: "Removal from and return to temperature-controlled storage" | X | 5.3 |
| | Renumbered subsection 5.4 | 5.3 | 5.4 |
| | Renumbered 5.4.2: addition of abbreviation "(PTS)" to subsection heading | 5.3.2 | 5.4.2 |
| | Table 5.1: red cell product names revised | Table 5.1 | Table 5.1 |
| | Table 5.1: removal of "if suspended in additive solution" from "Washed red cells" | Table 5.1 | Table 5.1 |
| | Table 5.1: for 'Irradiated red cells" addition of "post irradiation" to expiry time for "IUT or exchange transfusion" and new statement "48 hours for neonatal or infant small volume transfusions" | Table 5.1 | Table 5.1 |
| | Table 5.1: revised entry for "Frozen red cells" to distinguish from "Thawed red cells" | Table 5.1 | Table 5.1 |
| | Table 5.1: for "Platelets" removal of "with continuous gentle agitation, preferably on a flatbed agitator" from third column and incorporation into explanatory note in second column | Table 5.1 | Table 5.1 |
| | Table 5.1: in first column of "Frozen plasma [etc.] "or" removed and explanatory note in third column reworded "(If storage temperature is between –18 °C and –25 °C expiry should be reduced to 3 months)" | Table 5.1 | Table 5.1 |
| | Table 5.1: for "Thawed plasma [etc.] "ELP" removed and "CDP" added in first column and "(FFP); 5 days (ELP)" deleted in second column | Table 5.1 | Table 5.1 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 5** *continued* | Table 5.1: new row "Extended Life Plasma (ELP)" added | Table 5.1 | Table 5.1 |
| | Table 5.1: in second column of "Plasma derivatives [etc.]" "or suppliers" inserted after "manufacturer's" | Table 5.1 | Table 5.1 |
| | Footnote: reference to European Directorate for the Quality of Medicines & Healthcare of the Council of Europe (EDQM). Guide to the preparation, use and quality assurance of blood components. 19th edn. Strasbourg: EQQM Publications, 2017 (https://www.edqm.eu/en/blood-guide) | X | Footnote 16 |
| | Table 5.2: removal or "blood" from "red blood cells" | Table 5.2 | Table 5.2 |
| | Table 5.2: in first column of "Frozen plasma [etc.] "or" removed | Table 5.2 | Table 5.2 |
| | Table 5.2: deletion of "or cryoprecipitate" and "Extended life plasma" from first column of "Thawed plasma [etc.]" with "ELP" added, and in second column explanatory sentence deleted | Table 5.2 | Table 5.2 |
| | Table 5.2: new row "Thawed cryoprecipitate" | Table 5.2 | Table 5.2 |
| | Table 5.2: final row "Manufactured products" changed to "Plasma derivative and recombinant products" | Table 5.2 | Table 5.2 |
| **Section 6** | Table 6.2: "tryptase" added to testing for anaphylaxis | X | Table 5.2 |
| | New 6.5.3: "A report should be sent to the state/territory or national haemovigilance programme in accordance with jurisdictional requirements" | X | 6.5.3 |
| **Section 7** | 7.1.1: addition of informatory bullet point "Recommendations in this section are based on the BSH Guidelines for blood grouping and antibody testing in pregnancy (2016) and the associated clinical guidance from the RCOG The Management of Women with Red Cell Antibodies during Pregnancy (2014) which is referenced on the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) website | X | 7.1.1 |
| | Footnote: "BSH *Guidelines for blood grouping and antibody testing in pregnancy* (2016) (https://b-s-h.org.uk/guidelines)" | X | Footnote 17 |
| | Footnote: "RCOG *The Management of Women with Red Cell Antibodies during Pregnancy* (2014) https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg65 (and https://ranzcog.edu.au/statements-guidelines)" | X | Footnote 18 |
| | 7.1.6: removal of "+" from scoring schema | 7.1.6 | 7.1.6 |
| | New 7.1.9: reworded 7.1.12 "For RhD negative women, specimens must be collected prior to giving RhD-Ig. If RhD-Ig has been given for a prior sensitising event, an antibody screen must still be performed. To assist with the interpretation of results, the date RhD-Ig was given should be provided on the request" | 7.1.12 | 7.1.9 |
| | New 7.1.10: original 7.1.13 | 7.1.13 | 7.1.10 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 7** *continued* | New 7.1.11: original 7.1.10 | 7.1.10 | 7.1.11 |
| | New 7.1.12: original 7.1.9 with addition of "or genotyping" | 7.1.9 | 7.1.12 |
| | 7.2.3: reworded in second sentence first "level" changed to "antibody" and after second one "of antibody" deleted | 7.2.3 | 7.2.3 |
| | New subsection 7.4: "Fetal genotyping" | X | 7.4 |
| | New 7.4.1: "Fetal RhD genotyping using non-invasive prenatal testing may be considered for high risk pregnancies in accordance with national guidelines. Genotyping for other red cell antigens may also be indicated where this testing is available" with addition of reworded 7.1.11 as informatory ballet point "Non-invasive testing of fetal DNA from maternal plasma provides a safer alternative to using DNA obtained by amniocentesis or chorionic villus sampling, both of which carry risks of further antibody stimulation or spontaneous miscarriage. | X | 7.4.1 |
| | Renumbered subsection 7.5 | 7.4 | 7.5 |
| | New 7.5.1.2: original 7.4.1.2 final portion of sentence reworded "... the reaction strengths from antibody screening is not reliable" | 7.4.1.2 | 7.5.1.2 |
| | Renumbering of steps 7.5.1.3 to 7.5.1.8 | 7.4.1.3 - 7.4.1.8 | 7.5.1.3 - 7.5.1.8 |
| | New 7.5.2.1: original 7.4.2.1 reworded "A baseline antibody level should be determined either by titration or quantitation (against the international anti-D standard) when the anti-D is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter" | 7.4.2.1 | 7.5.2.1 |
| | New 7.5.2.3: reworded previous 7.4.2.4 "Laboratories should provide guidance on the test method used and the significance of the results" | 7.4.2.4 | 7.5.2.3 |
| | Renumbering of 7.4.2.5 | 7.4.2.5 | 7.5.2.4 |
| | Table 7.1: columns swapped around and deleted reference to "BSH *Guidelines for blood grouping and antibody testing in pregnancy* (2016)" | Table 7.1 | Table 7.1 |
| | Renumbering to reflect new subsection 7.5 and deletion of original 7.4.2.3 | 7.4.2.6<br>7.4.2.7 | 7.4.2.5<br>7.4.2.6 |
| | New 7.5.2.7: renumbered 7.4.2.8 with final sentence deleted | 7.4.2.8 | 7.5.2.7 |
| | Renumbered subsection 7.6 | 7.5 | 7.6 |
| | New 7.6.1: original deleted and replaced by reworded previous 7.5.2 "A baseline antibody level should be obtained either by titration or quantitation (against the international anti-c standard) at the time the anti-c is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter" | 7.5.2 | 7.5.1 |
| | New 7.6.2: original 7.5.3 deleted and step renumbered | 7.5.3 | 7.6.2 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 7** *continued* | New 7.6.3: original 7.5.4 deleted and replaced with reworded previous 7.5.5 "Laboratories should provide guidance on the test method used and the significance of the results" | 7.5.5 | 7.6.3 |
| | New 7.6.4: original 7.5.6, reworded by replacing "if the person has" with "if they have" | 7.5.6 | 7.6.4 |
| | Table 7.2: columns swapped around and deleted reference to "BSH *Guidelines for blood grouping and antibody testing in pregnancy* (2016)" | Table 7.2 | Table 7.2 |
| | New 7.6.5: original 7.5.7 reworded by removal of final sentence | 7.5.7 | 7.6.5 |
| | Renumbered subsection 7.7 | 7.6 | 7.7 |
| | Renumbered subsection 7.8 | 7.7 | 7.8 |
| | New 7.8.4: original 7.7.4 reworded by removal of final sentence | 7.7.4 | 7.8.4 |
| | New 7.8.5: original 7.7.5 reworded "Paternal K antigen status should be checked. If the paternal phenotype is K positive or unknown, fetal genotyping may be indicated. If the fetus is K negative, the mother should be treated as for an unaffected pregnancy. | 7.7.5 | 7.8.5 |
| | Renumbered subsection 7.9 | 7.8 | 7.9 |
| | New 7.9.2: original 7.8.2 reworded "If clinically significant antibodies other than anti-D, anti-c and anti-K are detected during prenatal testing prior to 28 weeks gestation, an antibody titre should be obtained at the time the antibody is first detected (for the baseline level) and repeated during routine screening at 28 weeks gestation. If the titre is ≥ 32 (or other critical titre defined by the laboratory), the patient should be referred to a specialist fetal medicine unit for further assessment and testing" | 7.8.2 | 7.9.2 |
| | New 7.9.3: original 7.8.3 reworded "In the absence of a prior history of HDFN, performing regular titres beyond 28 weeks gestation in women with titres ≥ 32 is unlikely to be informative. Rare cases of significant anaemia are likely to be detected by subsequent Doppler MCA monitoring repeated at appropriate intervals" | 7.8.3 | 7.9.3 |
| | Renumbered subsection 7.10 | 7.9 | 7.10 |
| | New 7.10.1.1: original 7.9.1.1 reworded "If the maternal ABO/RhD type is not known, a pre- or post-delivery specimen should be tested to determine if the mother is RhD negative and should therefore be offered RhD-Ig. | 7.9.1.1 | 7.10.1.1 |
| | New 7.10.1.2: original 7.9.1.2 reworded: "The decision to request a group and screen before delivery should be based on the risk of maternal bleeding and of factors that may delay transfusion, such as availability of emergency blood products or presence of clinically significant antibodies" | 7.9.1.2 | 7.10.1.2 |
| | New 7.10.2.6: original 7.9.2.6 with wording "high affinity" replaced with "monoclonal" in final sentence | 7.9.2.6 | 7.10.2.6 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 7** *continued* | Renumbered subsection 7.11 with wording: "(FMH) to determine the need for RhD-Ig" added to end | 7.10 | 7.11 |
| | New 7.11.2: original 7.10.2 with "and timely (i.e. within 72 hours)" added | 7.10.2 | 7.10.2 |
| | New 7.11.5: original 7.10.5 and 7.10.6 merged and reworded "The two assays used for detection and quantitation of FMH are the Kleihauer-Betke test (acid elution) and flow cytometry. Flow cytometry is considered more precise and reproducible" | 7.10.5<br>7.10.6 | 7.11.5 |
| | New 7.11.6: reworded 7.10.7 "All RhD negative women without evidence of immune anti-D experiencing a sensitising event or delivering an RhD positive baby should have a test for FMH as soon as practical. It is recommended that a specimen is collected 30-45 minutes following the sensitising event and ideally within 2 hours. | 7.10.7 | 7.11.6 |
| | New 7.11.7: reworded 7.10.8 with "of fetal red cells" added after "of up to 6 mL" and addition of informatory bullet point "Calculations for determining the volume of FMH can be found in the ANZSBT Guidelines for laboratory assessment of fetomaternal haemorrhage" | 7.10.8 | 7.11.7 |
| | New 7.11.8: reworded 7.10.9 with "for example, in women with a high body mass index (BMI)" removed | 7.10.9 | 7.11.8 |
| | Footnote: https://anzsbt.org.au/pages/anzsbt-guidelines.html | X | Footnote 19 |
| | Table 7.3: in the "Anti-D, anti-c or anti-K" row of "Antibody levels [etc.]" insertion of "fetal medicine" after "specialist" in the second paragraph of "Timing" column | Table 7.3 | Table 7.3 |
| | Table 7.3: in the "RhD negative women following a potentially sensitising event [etc.]" row of "Testing for FMH" change "≥ 20 weeks" to "> 20 weeks" | Table 7.3 | Table 7.3 |
| | Table 7.3: New penultimate row "Fetal RhD genotyping using non-invasive prenatal testing" with "High risk" in the "Circumstances" column and "As per national guidelines – performed ≥ 12 weeks gestation" in the "Timing" column | Table 7.3 | Table 7.3 |
| | Table 7.3: New final row "Fetal genotyping (other than RhD) with "At risk pregnancy" and bullet points "With no history of HDFN but elevated titre of clinically significant red cell antibody: or", "Previous pregnancy complicated by HDFN with unknown or heterozygous paternal blood type; or" and "Paternal K positive or unknown phenotype" in "Circumstances" column and "As required (depending on availability of testing)" in "Timing" column | Table 7.3 | Table 7.3 |
| **Section 8** | 8.3.1: Update of Australian National Safety and Quality Health Service (NSQHS) Standard 7 to "*Blood management standard*" | 8.3.1 | 8.3.1 |
| | Footnote renumbered | Footnote 2 | Footnote 20 |
| | Footnote renumbered | Footnote 3 | Footnote 21 |
| | Footnote: " www.ianz.govt.nz" | Footnote 22 | Footnote 22 |

| Section | Change details | Original | New |
|---|---|---|---|
| **Section 8** *continued* | Table 8.1: clarifying "Requirement" versus "Interval" | Table 8.1 | Table 8.1 |
| | Table 8.1: for platelet rotator/agitator "Temperature checking" interval simplified to "daily" | Table 8.1 | Table 8.1 |
| | Table 8.1: for platelet rotator/agitator addition "Spatial temperature checks" interval changed to "On receipt, following move of equipment or significant repair" | Table 8.1 | Table 8.1 |
| | Table 8.1: addition of "as per manufacturer's specifications" to requirements for platelet rotator/agitator "Rotation rate or agitation frequency" requirement and interval changed to "On receipt, following move of equipment or significant repair" | Table 8.1 | Table 8.1 |
| **Abbreviations** | Section renamed | Abbreviations and acronym | Abbreviations |
| | Addition of "AABB (American Association of Blood banks)" | X | Abbreviations |
| | Deletion of "BCSH (British Committee for Standards in Haematology (BCSH)" | X | Abbreviations |
| | Add "BSH (British Society for Haematology)" | X | Abbreviations |
| | Deletion of "PPH" | X | Abbreviations |
| **Glossary** | Deletion of "British Committee for Standards in Haematology (BCSH)" | Glossary | X |
| | Addition of "child bearing potential (reproductive age)" | X | Glossary |
| | Addition of "International Accreditation New Zealand (IANZ)" | X | Glossary |
| | Reworded definition of "Laboratory Director" | Glossary | Glossary |
| | Footnote: AS ISO 15189 *Medical laboratories – requirements for quality and competence (2013)* | X | Footnote 23 |
| | Footnote: NPAAC *Requirements for supervision in the clinical governance of medical pathology (2018)* | X | Footnote 24 |
| **Appendix** | Section moved and renamed | Appendix | X |
| **Bibliography** | Section renamed | X | Bibliography |
| | Versions and hyperlinks updated | X | Bibliography |
| | Revision of references reflecting renamed "American Association of Blood Banks" and "BCSH" | X | Bibliography |
| | Reference to "Australian Red Cross Blood Service" updated to "Australian Red Cross Lifeblood" | X | Bibliography |
| | New reference: Daniels G. Variants of RhD – current testing and clinical consequences. British Journal of Hematology 2013; 161 (4): 461-470 | X | Bibliography |
| | New reference: Janssen. Considerations for pre-transfusion immunohaematology testing in patients receiving anti CD-38 monoclonal antibody therapy. Janssen-Cilag Pty 2018 | X | Bibliography |
| | New reference: New Zealand Blood Service (NZBS): Refrigeration guidelines. NZBS 8th edition June 2019 | X | Bibliography |

| Section | Change details | Original | New |
|---|---|---|---|
| **Bibliography** *continued* | New reference: Quach H, Benson S, Haysom H et al. Position Paper: Considerations for pre-transfusion immunohaematology testing in patients receiving the anti-CD38 monoclonal antibody daratumumab for the treatment of multiple myeloma. Internal Medicine Journal 2017; 48: 210-220 | X | Bibliography |
| **Appendix 1** | New "Appendix 1: Maximum surgical blood order schedule" | Appendix | Appendix 1 |
| **Appendix 2** | New "Appendix 2: Summary of changes from the original first edition" | Appendix | Appendix 2 |