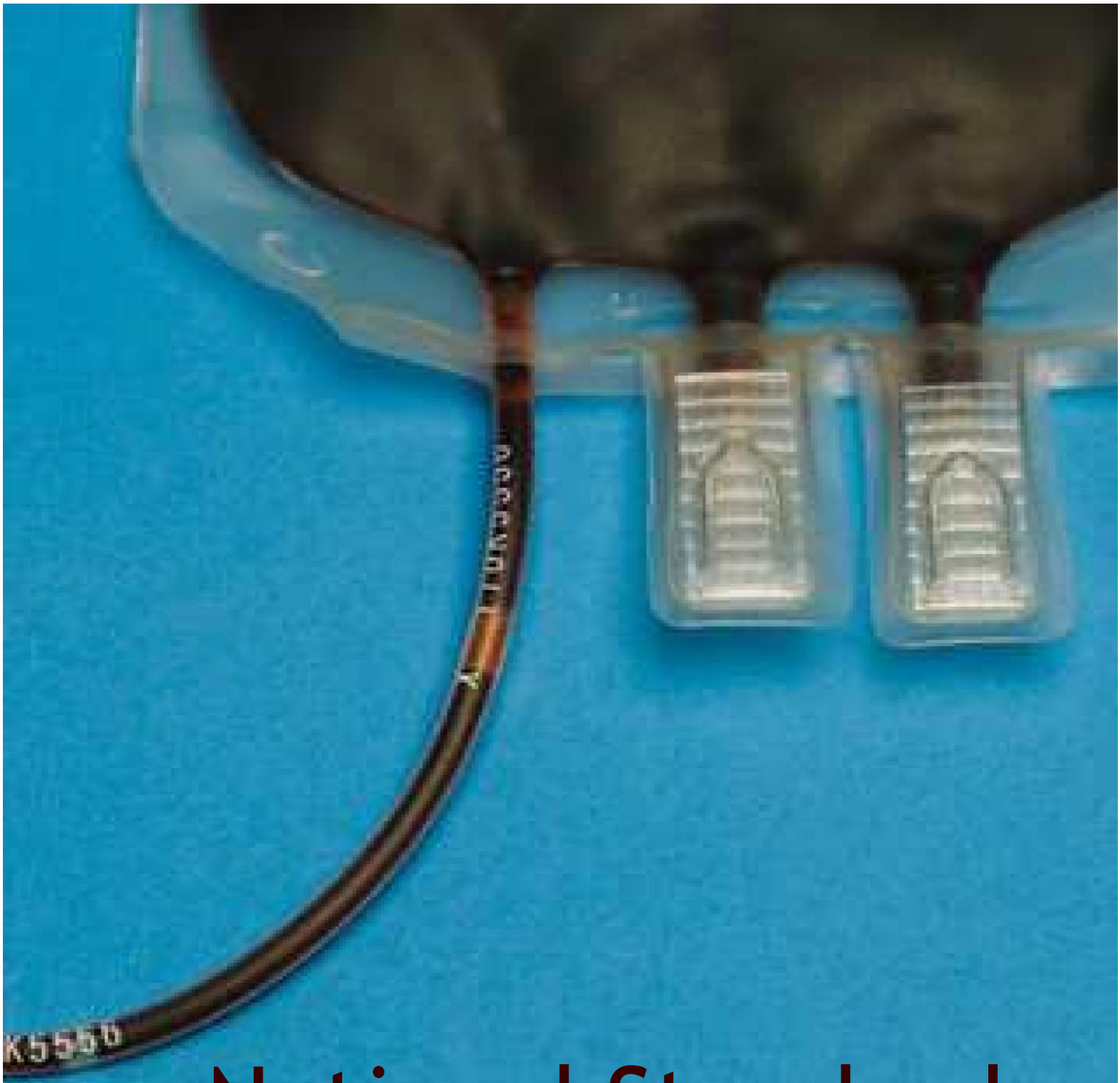

National Standards for Blood Transfusion

SUPERINTENDENCE OF PUBLIC HEALTH

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NATIONAL STANDARDS FOR BLOOD TRANSFUSION

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FOREWORD

The Department of Health has for a long time been responsible for maintaining the standards of health care for our people. This role has been further enhanced last year when the roles of the Chief Medical Officer and the Superintendent of Public Health were legally split. This is in line with Government's policy to separate the service provider function from the regulatory function.

The Superintendence of Public Health has been effectively functioning separately from the service provider for the past four years. It was previously referred to as the Department for Public Health Regulation. However it is to be made clear that the main mission of the department is to safeguard public health; regulation is one of the means to achieve that end.

Another vehicle to safeguard public health and ensure quality in the provision of care to patients is the setting of standards. Standards are a set of criteria which should guide all those involved in the provision of health care so that they ensure that the care they are providing the patient is of good quality. Standards also safeguard patient safety as if they are followed they provide a safety net against clinical errors.

In establishing standards, the department involves experts in the relative field and carries out widespread consultation with all the stakeholders. All standards set are evidence based and their impact on the service as well as on the patient are carefully evaluated prior to their adoption.

These National Standards on Blood Transfusion are the first in a series of standards that the Superintendence will be publishing. Their aim is to provide an equitable high quality level of safe care for all people receiving a blood transfusion irrespective of the health care setting in which the transfusion is provided. They also ensure a uniform system for record keeping and reporting which will facilitate both internal as well as external monitoring and evaluation.

I would like to thank the working group for their commitment and hard work in the development of these standards as well all those who have contributed to their finalisation. I hope that all involved in patient care will find these standards useful and use them to ensure the best quality and safe care for our patients.

Dr. R. Busuttil
Superintendent of Public Health

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INTRODUCTION

1. Background

Blood and blood components are a precious resource given on a voluntary basis by a small percentage of the population of Malta. Used judiciously, blood and blood components may be life saving and their use permits clinicians to perform treatment that would otherwise be impossible. Blood may also, however, cause substantial morbidity and even mortality through associated severe adverse events and reactions. Errors committed throughout the transfusion chain should be eliminated as far as possible and patients should not be exposed to transfusions unless they are really necessary. The scope of these standards is to ensure that blood is used appropriately and effectively for the ultimate benefit of all patients.

In Malta and Gozo, the number of units distributed in 2017 was 15,535 units of red cells, 2,200 therapeutic doses of platelets and 15,335 units of fresh frozen plasma. Blood components are transfused in surgery, in trauma, in chronic anaemia and in a number of other circumstances.

The National Blood Transfusion Service is responsible for collecting, processing, storing and distributing all blood components to hospital blood banks in Malta and Gozo.

Hospital blood banks are responsible for ordering and managing their supplies in a safe and effective manner, and for performing compatibility testing and issuing blood components for transfusion in health care establishments and for domiciliary transfusion.

Domiciliary blood transfusions (defined as occurring in the patient's residence) can be a convenient, beneficial and cost-effective alternative to hospitalisation for many patients. Home health care has several advantages and these same benefits can be applied to support the practice of administering blood transfusions in the home. Inpatient hospitalisation is expensive, and the demand for out-of-hospital services is partially fueled by efforts to contain costs. Patients who are frail, chronically ill or terminally ill may be considerably more comfortable, both physically and psychologically, when receiving home care. A rapidly expanding population of homebound patients, elderly individuals, patients infected with the human immunodeficiency virus and others may benefit from domiciliary blood transfusions.

2. Scope

These standards cover blood transfusion practice in all adult, paediatric and neonatal settings, for example primary care, acute care and in all hospice and home care settings. Blood derivatives that are classified as medicines are not within the scope of these standards.

3. Applicability

These standards apply to:

3.1 all service providers irrespective of whether they are public, private or both,

3.2 all health care establishments,

3.3 all health care professionals, who prescribe and/or transfuse blood components to patients within their respective service and according to their specialisation, irrespective of:

- their role, job description or area of practice,
- the way they are engaged to work (full time, part time, secondment, detailed, contractual),
- where they are practicing including in domiciliary settings.

3.4 These standards also apply to:

- health care students performing transfusion related procedures under direct supervision of qualified health care professionals and following appropriate training.
- health care workers who may be in one way or another involved in the process leading to transfusion.

The transfusion of blood components shall be in line with the code of professional and institutional ethics for the respective profession.

4. Relevant Documentation

National legislation

- Human Blood and Transplants Act (Act IV of 2006) http://www.doi.gov.mt/EN/parliamentacts/2006/ACT%20IV.pdf
- Blood (Quality and Safety) Regulations, 2006 (L.N. 272 of 2006) http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf
- Traceability Requirements and Notification of Serious Adverse Reactions and Events

Regulations, 2006 (L.N. 273 of 2006)
http://www.doi.gov.mt/EN/legalnotices/2006/11/LN273.pdf

EU directives

- Directive 2002/98/EC - setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood components
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:033:0030:0040:EN:PDF

- Directive 2005/61/EC - implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0032:0040:EN:PDF

5. Responsibilities

Decision to transfuse: The responsibility to transfuse shall rest with the doctor responsible for the patient's care.

Prescribing: Only medical doctors are allowed to prescribe blood components.

Blood component administration/transfusion: Only qualified health care professionals who are trained in transfusion, such as medical doctors and nurses, may transfuse blood components. In a domiciliary setting, the person transfusing is responsible to ensure that all necessary equipment is available. It is the responsibility of the health care professional to adhere to infection control and waste management procedures.

Health care establishment: The health care establishment shall ensure that the premises and facilities available shall be suitable for the management of the transfusion processes including that of acute adverse reactions. It is good practice that each health care establishment is responsible for developing local policy based on the standards within this document and nothing precludes the setting from adopting more stringent criteria. The health care establishment is encouraged to provide continuing education on the transfusion of blood components and can institute measures to certify competence.

Domiciliary setting: The responsibility of the risk assessment of the premises and facilities

available for the management of the transfusion processes, including that of acute adverse reactions, lies with the prescriber.

6. Aim and Objectives

The provision of a safe and effective transfusion process for the ultimate benefit of the patient.

STANDARDS

STANDARD 1: CORE PRINCIPLE – POSITIVE PATIENT IDENTIFICATION

Standard Statement 1a: Positive patient identification

There must be a robust system in place to establish positive patient identification and this must be maintained at every stage of the blood transfusion process in all settings.

Rationale

Incorrect patient identification increases the risk of patients receiving the wrong blood component. Patients who cannot confirm their identity are at particular risk. Attention to correct identification of the patient at all stages of the transfusion process is essential.

Essential Criteria

1a.1 The minimum mandatory patient core identifiers are used at every stage of the clinical transfusion process to positively identify the patient. These core identifiers are:

A. surname

B. forename

C. gender

D. unique identification number (identity card number/passport number/hospital number)

E. patient's date of birth (desirable when it is available)

1a.2 All patients requiring transfusion must be identifiable at all times by wearing a clearly legible identification bracelet. If the bracelet is not available for any reason, an alternative, risk-assessed form of identification must be adopted immediately, such as a photo ID.

1a.3 The health care professional shall, whenever possible, ask the patient to state his/her full name and unique identification number to positively identify him/herself. The information given by the patient must be identical to that on the patient's identity bracelet or identity document.

1a.4 In the case of patients who are unable to identify themselves, such as patients who are confused, unconscious or under general anaesthesia, in children or in patients where there is a language barrier, verification of the patient's identity should be sought from the identity bracelet if it is already in place. Otherwise if this is not possible, identification should be sought from a

parent, relative or carer (if present), other staff members, or from an identity document.

1a.5 For patients whose identity is still unknown (e.g. unidentified individuals in A&E), a minimum of gender and one unique identification number (identity card number/passport number/hospital number) is essential for positive patient identification.

1a.6 All paperwork relating to the patient must include, and be identical in every detail, to the minimum patient core identifiers contained on the patient's identification band or equivalent (see 1a.5).

1a.7 Special attention must be given where patients with the same name require a transfusion.

STANDARD 2: PRE-TRANSFUSION – DECISION TO TRANSFUSE

Standard Statement 2a: Patient information, consent to transfusion and pre-transfusion documentation

The decision to transfuse is made following consideration of the potential risks and benefits of, and alternatives to, transfusion. Whenever the possibility of transfusion arises, this should always be discussed between the medical doctor and the patient (or their legal guardian) in advance of transfusion, and all relevant information should be made available before gaining consent. This should always be documented. The responsibility to transfuse shall rest with the doctor responsible for the patient's care.

Rationale

Documented informed consent to treatment is an absolute requirement in all forms of health care.

Essential Criteria

2a.1 The prescriber should explain in a timely and understandable manner the proposed transfusion therapy, including the risks and benefits of, alternatives to transfusion and the option to refuse, the transfusion procedure, and the monitoring required. This information giving should always be documented.

2a.2 The explanation shall ideally be supported by written information such as a blood transfusion information leaflet explaining the procedure, the risks and benefits of, and alternatives to transfusion. These leaflets shall be readily available for patients who may require to be, or have been transfused.

2a.3 Informed consent should be obtained in line with the procedures adopted by the health care establishment where the transfusion is taking place and in line with any national requirements.

2a.4 A consent form is recommended for domiciliary transfusions, in view of the additional risks incurred by being at a distance from acute medical care.

2a.5 Where pre-transfusion discussion is not possible (e.g. in an emergency) the best interest of the patient should guide practice, however the health care establishment should develop guidelines that ensure action in accordance with the patient's treatment preferences where possible (e.g. refusal of transfusion).

2a.6 When a pre-transfusion discussion has not taken place, the reasons for transfusion (based on risks and benefits) shall be discussed with the patient retrospectively.

Standard Statement 2b: Blood component prescription

All blood components (red cell concentrates, platelets and FFP) for transfusion must be prescribed by a medical doctor.

Rationale

The responsibility for the transfusion rests with the doctor responsible for the patient's care, by ensuring that what is prescribed is in line with the patient's clinical needs.

Essential Criteria

2b.1 When the doctor responsible for the patient's care decides that the patient requires transfusion of a blood component, the following information must be entered in the medical records:

A. patient surname and forename (refer 1c.4)

B. patient gender

C. patient unique identification number (identity card number/passport number/hospital number)

D. reason for transfusion

~~D.~~E. pre-transfusion haemoglobin levels (in the case of red blood cells)

~~E.~~F.

~~F.~~G. actual blood component to be transfused

~~G.~~H. number of units or volume to be transfused

~~H.~~I. rate and duration of transfusion

~~I.~~J. any special requirements, such as cytomegalo-virus (CMV) negative or irradiated blood

~~J.~~K. any special instructions, such as the need for pre-medication/concomitant medicines required and/or blood warmer

~~K.~~L. any adverse reactions to previous transfusions

~~L.~~M. date of prescription/transfusion

~~M.~~N. legible medical doctor's name, signature and registration number

Standard Statement 2c: Domiciliary Transfusions

The patient circumstances for considering domiciliary transfusion should be determined by the criteria outlined below and by professional discretion. The home setting requirements must be met prior to initiating transfusions in a domiciliary setting.

Rationale

Domiciliary transfusions are often considered for patients who are debilitated, chronically ill individuals who may require more frequent transfusions over longer periods of time than many hospitalised patients who require transfusions. Eligible patients should include those patients for whom the burden of inpatient transfusion would present a hardship. Potential transfusion recipients must be carefully selected based on the criteria outlined below and not solely on convenience for the patient. The transfusion risk to benefit ratio in a domiciliary setting versus a health care establishment should be considered.

Domiciliary blood transfusion can be carried out in the patient's home. The home setting causes concern with reference to blood transfusions because of the limited care that can be provided if a severe, adverse reaction occurs. A home transfusion programme should have adequate safeguards to ensure that patient safety is not jeopardised.

Domiciliary blood transfusions incur additional risks due to the distance from emergency medical services. Careful assessment should minimise these risks. In domiciliary transfusion, apart from the home environment being suitable for the procedure, equipment and medication should be available for the immediate emergency management of potential adverse reactions and events associated with the transfusion.

Essential criteria

2c.1 Domiciliary transfusion may be considered in situations when:

A. the person is home-bound

B. the person is reasonably cooperative

C. the person has a stable cardiopulmonary status

D. the person has venous access which ensures smooth uninterrupted flow

E. the person does not have a history of a serious adverse reaction to a previous transfusion

F. the home setting is considered suitable for transfusion by the doctor responsible for the patient's care

G. there is adequate social support by relative/carer post-transfusion

H. equipment for the management of adverse reactions is available

I. there is adequate support and supervision by a health care professional on site throughout the transfusion, to ensure that the monitoring requirements established by these standards are met and managing of adverse reactions can be done

J. there is adequate access to emergency medical care

2c.2 The decision to transfuse a patient at home rests with the doctor responsible for the patient's care, who will ensure that the criteria for domiciliary transfusion have been met. The risk assessment of the premises and facilities available for the management of the transfusion processes should include that of acute adverse events. This assessment shall be documented in a checklist (vide **Annex 1: National Checklist for Domiciliary Transfusion**).

2c.3 The hospital blood bank shall ensure that the checklist is completely filled in before issuing the blood, and shall retain a copy of the said checklist. The hospital blood bank shall have no responsibility to verify the facts stated in the checklist, but shall retain the right to withhold issuing the blood if they are not satisfied with the contents of the checklist.

2c.4 Only red blood cells and platelets can be transfused in the home.

STANDARD 3: BLOOD SAMPLING AND REQUESTS FOR COMPATIBILITY TESTING

Standard 3a: Requests for transfusion

The doctor responsible for the patient's care is responsible for the completion of the request form with the essential information for blood component transfusion requirements.

Rationale

The appropriate completion of a request form for blood components is critical to safe blood transfusion.

Essential Criteria

3a.1 The minimum information required on the request form (vide **Annex 2: National Blood Transfusion Request Form**) is:

A. patient surname and forename (refer to 1c.4)

B. patient gender

C. patient unique identification number (identity card number/passport number/hospital number)

D. patient date of birth (desirable)

E. clinical details/current diagnosis

F. patient history (e.g. previous pregnancy, previous transfusion, previous adverse reactions to transfusion, history of anaphylaxis)/any relevant significant co-morbidity,

G. haemoglobin levels if appropriate/a clear unambiguous reason for request

H. blood component needed

I. volume/number of units required

J. special requirements (e.g. CMV negative or irradiated)

K. date when blood component is required

L. location of patient, ward (in health care establishment) and address (in the case of domiciliary transfusions)

M. date when specimen is taken

N. the requesting health care professional's name, surname, signature and medical registration number

O. consultant/firm (if applicable)

P. laboratory procedure required/pre-transfusion testing (e.g. type and screen, blood group)

Standard Statement 3b: Blood samples for pre-transfusion testing and specimen transport

Positive patient identification at the time of sampling and the use of the minimum patient core identifiers (refer to standard 1) on samples and request forms is essential for pre-transfusion testing and blood component requests.

Rationale

Most transfusion errors relate to failure to correctly identify patients. Correct identification is essential for patient safety.

Essential Criteria

3b.1 Ensure that the patient is positively identified (refer to standard 1).

3b.2 Blood samples for type and screen purposes are obtained and labelled in accordance with local protocols for blood sampling.

3b.3 The collection of the blood sample from the patient into the sample tubes and the sample labelling should be performed as one continuous, uninterrupted event, involving one patient and one health care worker only.

3b.4 Pre-labelling of sample tubes is extremely dangerous and must be avoided.

3b.5 The sample should be labelled immediately after the blood has been taken at the patient's bedside area.

3b.6 Patient details must be legible on the sample tubes and all requested information should be filled in. The sample must be labelled with the following minimum information:

A. patient surname and forename (refer to 1c.4)

B. patient unique identification number (identity card number/passport number/hospital number)

C. patient date of birth (desirable)

3b.7 Requests for compatibility testing should be refused when either the request form or the sample is inadequately labelled or signed.

3b.8 Transport of specimens for transfusion should follow protocols established by the hospital

blood bank. Samples should be submitted without delay.

STANDARD 4: BLOOD COMPONENT COLLECTION AND DELIVERY

Standard Statement 4a: Collection and delivery of blood components from the hospital blood bank and/or blood refrigerator to the clinical area

Positive patient identification is performed against the blood component label and any accompanying documentation at every stage of the blood transfusion process.

Rationale

Failure to correctly identify the patient is still the most common problem leading to transfusion error.

Essential Criteria

4a.1 Before the blood component is collected from the hospital blood bank or blood refrigerator, the health care professional attending the patient shall ensure that the patient has patent venous access and is ready to start the transfusion.

4a.2 When collecting the blood component from the hospital blood bank or blood refrigerator, a health care worker should take the required documentation (e.g. Blood Issue Form) containing the patient's core identifiers and should check these with the label on the blood component. These details should also be counterchecked by the person issuing the blood component.

4a.3 Core patient identifiers, date and time of collection and the identification details of the staff collecting the blood component must be recorded at the hospital blood bank.

4a.4 Once the blood component is collected, it should be safely delivered in an appropriate transport box without delay to the health care establishment or domiciliary setting and handed over to the respective responsible health care professional, together with the appropriate documentation.

4a.5 Checks should be repeated at every stage of handing over blood components from the responsibility of a health care worker to another.

Standard Statement 4b: Blood component storage and transport

The blood components should be transported in the specified blood transport containers designated and validated for such purpose under the proper conditions.

Rationale

Appropriate transport and storage of blood components until time of use is essential, otherwise the component safety and characteristics are compromised.

Essential Criteria

4b.1 For appropriate transport and storage:

A. **Red cell concentrates** should be maintained at a temperature between 2-6°C. Red cell concentrates should not be kept outside these conditions for more than 30 minutes prior to being transfused.

B. **Platelets** should be maintained at a temperature between 20-24°C and transfused immediately. This component must not be stored outside the hospital blood bank.

C. **Thawed Fresh Frozen Plasma** should be maintained at a temperature between 2-6°C and must be transfused within the time specified by the hospital blood bank.

4b.2 The infusion of all blood components should be commenced as soon as possible following issue from the hospital blood bank.

4b.3 If the above conditions are not adhered to, the blood component should be returned to the hospital blood bank.

4b.4 All blood component bags that are not transfused must be sent back to the hospital blood bank with the relevant traceability forms (vide **Annex 3: National Blood Traceability Form**) – refer to standard 7.

STANDARD 5: TRANSFUSION OF BLOOD COMPONENTS

Standard Statement 5a: Pre-transfusion identification of the patient

All patients receiving a transfusion must be positively identified at the bedside (refer to standard 1a.).

Rationale

Failure to correctly identify the patient is the most common problem leading to transfusion error. The formal patient identity check in accordance with local guidelines immediately before clinical transfusion is the final opportunity to prevent this occurrence.

Essential Criteria

5a.1 All patient core identifiers on the patient's identification wristband (or risk assessed equivalent as described in criteria 1a.2) must match the details on the compatibility label attached to the blood bag and any accompanying documentation, including the Compatibility Testing Report.

5a.2 Compliance with any special patient requirements (e.g. irradiated blood, CMV negative blood and blood warmer) must be ensured.

5a.3 Patient identification checks should always be performed by the health care professional transfusing the blood component. This should be done at the patient's bedside or wherever the patient is going to be transfused and should never be done remotely.

Standard Statement 5b: Pre-transfusion inspection of the blood bag

Before starting a transfusion, it is essential that inspection of the blood bag is done at the patient's bedside or wherever the patient is going to be transfused.

Rationale

Inspection of the blood bag is carried out to ensure the integrity of the blood component prior to transfusion and to return any blood bags that show any visible deterioration.

Essential Criteria

5b.1 Inspection of the blood components prior to administration should include checking:

A. the expiry date

B. the integrity of the pack for any leaks

C. the content for unusual discolouration or haemolysis

D. platelet packs to ensure that they do not show clumps or appear unusually cloudy

5b.2 The blood groups printed on both labels of the blood bag should be compatible. The blood component unit number on both labels on the blood bag and the Compatibility Testing Report should match.

5b.3 The health care professional checking the blood component shall document in the patient's record that the identification process has occurred appropriately.

5b.4 If any discrepancy during the bedside identity check and/or inspection of the blood bag is found, the blood component(s) must not be transfused. The hospital blood bank should be informed and the bag(s) returned with the supporting documentation.

Standard Statement 5c: Administration/transfusion of blood components and documentation

The administration of the blood component should only occur once the standards and criteria in 5a and 5b are met.

Blood components should be administered through the appropriate blood administration set with an integral mesh filter (170-200 µm pore size) to reduce particulate matter and microaggregates in infusions of blood components.

Transfusion can only be performed by health care professionals who are trained in blood transfusion.

Throughout the transfusion, it is imperative to ensure that the criteria of monitoring outlined in standard 6 of these standards can be readily observed. Overnight transfusions should thus, as far as possible, be avoided unless clinically essential.

Rationale

This transfusion step together with patient sampling holds the highest risk for errors. Therefore, it is imperative that any potential detectable transfusion errors that may have occurred throughout the process so far are identified before infusing the patient with the blood component.

Essential Criteria

5c.1 Blood transfusion should ideally be commenced within 30 minutes of the blood component being collected from the hospital blood bank.

5c.2 Blood components should be gently mixed.

5c.3 Cannula size depends on vein size and the rate of infusion required.

5c.4 All blood components should be administered using a CE-marked blood administration set with an integral mesh filter (170-200 µm pore size), that should only be primed with the blood component or 0.9% sterile normal saline, fully wetting the filter. The administration set should be changed at least every 12 hours. Red blood cells and plasma may be transfused using the same administration set. A new administration set should be used to transfuse platelets or if another infusion is to continue after the transfusion. When blood is being administered to paediatric patients via syringe, the appropriate paediatric blood administration set should be used.

5c.5 The duration of transfusion for one unit of:

A. **Red Cell Concentrate** transfusion should not exceed 4 hours from the removal of the unit from a temperature-controlled environment. For routine administration, there is extensive experience of safely administering a RCC in 90-120 minutes.

B. **Plasma** transfusion is typically administered at a rate of 10-20 ml/kg/hr.

C. **Platelet** transfusions are typically transfused over 30-60 minutes per adult therapeutic dose.

5c.6 The Compatibility Testing Report must be readily available during the transfusion.

5c.7 The health care professional administering the blood component must document on the patient's record when each transfused unit is commenced and ended (including date and time). This entry must be signed on the appropriate form.

5c.8 A blood warmer should be used when indicated. Blood must not be warmed by any other method.

5c.9 Electronic infusion pumps may be used for the administration of red cells, if they have been verified as safe to use for this purpose according to the manufacturer's instructions. External compression devices must be used according to the manufacturer instructions only when clinically indicated, such as in massive haemorrhage.

5c.10 No medicines or any other IV fluids should be added or infused with the blood component under any circumstance.

5c.11 The administration set should never be flushed after the transfusion has finished.

5c.12 Transfusions should only be administered in areas where the patient can be readily observed by the health care professional.

5c.13 The health care professional shall ensure that all transfusion documentation is complete at every stage of the transfusion process.

5c.14 At the end of the transfusion episode the blood administration set and bag are removed and disposed of according to local infection control and waste management procedures.

Standards 5a, 5b and 5c should be observed for every blood component unit transfused.

STANDARD 6: MONITORING OF THE PATIENT

Standard Statement 6a: Monitoring of the patient prior to commencing, during and after transfusion

Patients must be monitored for any adverse reactions. This is the responsibility of health care professionals administering the transfusion. Vital signs are measured and documented at baseline, during and after the blood transfusion process. The monitoring criteria apply to both the domiciliary and the health care establishment.

Rationale

Patient monitoring ensures that transfusion reactions can be detected swiftly and remedial action taken promptly to safeguard the patient.

Essential Criteria

6a.1 The health care professional shall monitor the patient according to the criteria established below and shall advise the patient to report any symptoms.

6a.2 Vital signs (pulse, blood pressure, temperature and respiratory rate) must be monitored and documented as follows:

A. ≤ 60 minutes prior to starting the transfusion

B. 15 minutes through the transfusion

C. at the end of the transfusion (not later than 60 minutes after the transfusion has ended)

D. more frequently if the patient's clinical status so requires

The patient should be observed throughout the transfusion.

6a.3 If any untoward events (including suspected adverse reactions) occur, the patient should be managed appropriately according to the clinical situation.

6a.4 The appropriate samples, blood bag and duly filled out adverse reaction reporting form (vide **Annex 4: National Blood Serious Adverse Reaction (SAR) Report Form**) should be promptly sent to the hospital blood bank – refer to standard 8. Patient events and/or reactions occurring during or after transfusion must be reported to the issuing hospital blood bank for further investigation, irrespective of the setting where the transfusion has taken place. It is the responsibility of the issuing hospital blood bank to maintain all appropriate documentation.

6a.5 Vital signs related to the transfusion should be documented in the patient's file separately from routine observations and clearly dated to enable the information to be retrieved later, if necessary.

STANDARD 7: TRACEABILITY

Standard Statement 7a: Traceability

A system shall be in place in every health care establishment so that every blood component unit issued by the hospital blood bank can be unmistakably traced to its recipient or to its final fate if not transfused.

Rationale

Legal Notice 273 of 2006 transposing EU directive (2002–/98/EC) requires hospitals to have systems in place which ensure that every blood component unit received into the hospital blood bank can be traced to the individual recipient or to its final fate if not transfused.

Essential Criteria

7a.1 It is the responsibility of the health care professional administering the transfusion to ensure that the traceability form (vide **Annex 3: National Blood Traceability Form**), is filled out appropriately and sent to the issuing hospital blood bank. The traceability form is to be filled in

for any blood component collected from the blood bank, irrespective whether it has been transfused, discarded or returned to the blood bank.

7a.2 The issuing hospital blood bank shall ensure that the data on such forms is appropriately stored for a minimum of 30 years and should be accessible when required.

STANDARD 8: REPORTING OF TRANSFUSION ADVERSE REACTIONS AND EVENTS

Standard Statement 8a: Reporting of transfusion errors and adverse events
All transfusion adverse reactions and events shall be reported to the issuing hospital blood bank which in turn shall investigate and report accordingly to the licensing authority.

Rationale

Legal Notice 273 of 2006 transposing EU directive (2002/98/EC) requires hospitals to report all serious adverse events and reactions associated with transfusion.
Reporting of adverse events or reactions helps identify problems in order to put in place preventive and corrective actions where necessary.

Essential criteria

8a.1 It is the responsibility of the health care professional administering the transfusion to report serious adverse events and reactions to the issuing hospital blood bank by filling in the front page of the adverse reaction reporting form (vide **Annex 4: National Blood Serious Adverse Reaction (SAR) Report Form**).

8a.2 The hospital blood bank is in turn responsible for reporting the adverse events and reactions to the licensing authority by filling in the back page of the adverse reaction reporting form (vide **Annex 4: National Blood Serious Adverse Reaction (SAR) Report Form**).

8a.3 It is highly recommended to report near miss incidents, in order to introduce preventive and corrective measures where necessary.

STANDARD 9: GOVERNANCE WITHIN HEALTH CARE ESTABLISHMENTS

Standard Statement 9a: Governance

Health care establishments shall have systems in place supporting clinical governance to ensure safe, effective and appropriate blood transfusion.

Rationale

Safe, effective and appropriate transfusion requires the support of an adequately resourced local multidisciplinary team, such as a Hospital Transfusion Committee. This will contribute to optimising the use of blood, minimising wastage, and enhancing clinical outcome.

Essential Criteria

9a.1 There must be an established, active, multidisciplinary team that has defined responsibilities and is accountable to top management.

9a.2 The multidisciplinary team has roles and responsibilities such as those specified hereunder:

A. involvement in multi-professional audits

B. education, training and the provision of advice on the improvement of transfusion practice

C. development and modification of guidelines and protocols e.g. guidelines on the use of blood components

D. involvement of stakeholders

E. the implementation of requirements and recommendations of national standards

F. reviewing all reports of adverse events and near miss incidents relating to blood transfusion and, in response, implementing changes in practice where necessary

9a.3 The multidisciplinary team should ensure that protocols are in place, and these should include but not be limited to:

A. the maximum surgical blood ordering schedule (MSBOS)

B. massive blood loss

C. emergency blood management arrangements

GLOSSARY

Audit – The measuring and evaluation of care against agreed standards with a view to improving practice and care delivery.

Blood administration set – A sterile blood administration set with an integral mesh filter (170−200 µm pore size).

Blood – Whole blood collected from a donor and processed either for transfusion or for further manufacturing.

Blood component – A therapeutic constituent of blood (red cells, white cells, platelets, plasma).

Blood refrigerator – A refrigerator for the appropriate storage of blood components at 4°C (+/- 2°C) which has continuous charted temperature monitoring.

Blood product – Any therapeutic product derived from human whole blood and plasma that is not classified as a medicine.

Blood transport containers – Transport boxes that are designated and validated for transport of blood components.

CMV negative – Blood that is tested and found to be seronegative for Cytomegalovirus (CMV). CMV is transmitted in leucocytes. All blood components other than granulocytes are now leucocyte depleted which is an effective alternative.

Compatibility testing – The test performed to ensure that blood for transfusion is appropriately matched with the patient.

Compatibility Testing Report – A report issued by the Hospital Blood Bank showing the results of the testing performed to ensure that the blood component being issued for transfusion are compatible with the named patient.

Consent (informed consent) – Agreement by a patient to undergo the transfusion process after the patient understands the benefits and risks involved.

Domiciliary transfusion – Transfusion occurring in the patient's residence, which includes homes for the elderly.

FFP (Fresh Frozen Plasma) – Plasma obtained from donated whole blood or collected by apheresis, which is then frozen and stored in the frozen state until thawed for transfusion.

Granulocytes – These are a category of white blood cells characterised by the presence of granules in their cytoplasm. They are also called polymorphonuclear leucocytes (PMN or PML) because of the varying shapes of the nucleus, which is usually lobed into three segments.

Health care professionals – All health care professionals who are registered with their respective professional regulatory council as established under the Health Care Professions Act (CAP 464 of 2003).

Health care setting – A place where a health care service is provided to patients and may include a licensed health care establishment or a domiciliary setting.

Health care establishment – A health care setting that is licensed by the relevant Competent Authority to provide a healthcare service such as hospitals or clinics.

Hospital blood bank (HBB) – A hospital unit which stores, distributes and may perform compatibility tests on patients requiring blood components exclusively for use within hospital facilities, including hospital based transfusion activities, clinics and domiciliary transfusion setups.

Hospital Transfusion Committee (HTC) – A hospital committee responsible for promoting education and training for all staff involved in the transfusion process as well as promoting best practice (through clinical governance) and leading multi-professional audits. The HTC is a committee in each hospital consisting of blood users (representatives from surgical disciplines, physicians, anaesthetists and haematologist) and representatives from administration, nursing staff and blood transfusion specialists. It promotes better blood management practice including the use of alternatives to transfusion and the avoidance of unnecessary transfusions.

Identification – The documented confirmation of personal (donor/patient) demographic data as belonging to the respective individual.

Irradiated blood – When a cellular blood component is exposed to 25 gray (Gy) gamma irradiation to inactivate lymphocytes that could cause transfusion associated graft-versus host disease in a recipient.

Issue – The provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient.

Leucocytes – Also called white blood cells, these are cells of the immune system involved in defending the body against both infectious disease and foreign materials. Five different and diverse types of leucocytes exist, but they are all produced and derived from a multipotent cell in the bone marrow known as a hematopoietic stem cell.

Medical record – Can be any form of record including electronic, where patients' medical information is documented.

Near miss/near miss event – Any event which, if undetected, could result in the determination of a wrong blood group, or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognised before transfusion took place.

Plasma – The liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh frozen plasma.

Platelets – Also known as thrombocytes, these are small anuclear discoid cell fragments that are derived from the fragmentation of precursor megakaryocytes. Their maturation time is 4 to 5 days, they have a circulating life span of 9 to 10 days and are found in the plasma. Platelets play a fundamental role in haemostasis and are a natural source of growth factors.

Positive patient identification – A process whereby a patient is actively asked to give her/his details in order to ensure correct identification and subsequent administration of the right blood component. If a patient is unable to identify him/herself, the identity should be sought from a parent or carer, another staff member, and/or the identity bracelet or identity document. If the patient identity cannot be confirmed a minimum data set of gender and one unique identification number is essential.

Prescription – The direction for the administration of blood components specifying the quantity

to be given, the duration of infusion and any other special precautions that need to be taken. This is normally the responsibility of the doctor responsible for the patient's care.

Protocol – A documented plan for the delivery of a particular aspect of care.

Prescriber – Medical doctor.

Rationale – The explanation behind the standard; an explanation of why a given task is to be performed; the logical basis of a procedure.

Request form – A form used to request blood components.

Serious adverse events – Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse reactions – An unintended response in a donor or a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Traceability – This is the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa.

Transfusion – A process of receiving blood or blood components into one's circulation intravenously.

Transfusion process – The series of events comprising the requesting of blood components for transfusion, taking pre-transfusion blood samples, laboratory practices, collection and administration of blood components, monitoring the transfused patient, managing an adverse event and documenting the transfusion events.

Type and screen – A number of immunohematological tests that are carried out at the Hospital Blood Bank to determine the ABO and Rh D group of a patient, and to screen the serum for the presence of atypical red cell antibodies that may cause reduced survival of transfused red cells.

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Further useful websites:

www.betterblood.org.uk

www.learnbloodtransfusion.org.uk

www.shotuk.org

ANNEX 1 – NATIONAL CHECKLIST FOR DOMICILIARY TRANSFUSION

NATIONAL CHECKLIST FOR DOMICILIARY TRANSFUSION

PATIENT DETAILS	
Unique identification number	
Name and Surname	
Date of birth	____/ ____/ _____
Gender	MALE / FEMALE
Clinical details / Reason for domiciliary transfusion	
Haemoglobin level (*if relevant*)	_____g/dL
Platelet count (*if relevant*)	_____x 10^9/L
Date of domiciliary transfusion	____/ ____/ _____
Product to be transfused	RCC / PLATELETS

CHECKLIST			
Patient factors:		**YES**	**NO**
1	Consent obtained?		
2	Homebound?		
3	Reasonably cooperative?		
4	Stable cardiopulmonary status? Pulse = _____ bpm Blood pressure = _____ mmHg Temperature = _____℃ Respiratory Rate =_____ /minute		
5	Adequate venous access?		
6	History of serious adverse reaction to a previous transfusion?		
Domiciliary setting:			
7	Suitable home setting?		
8	Adequate social support post-transfusion?		

Medical support:		**YES**	**NO**
9	Is equipment available to manage adverse events? Essential drug list: 1. Crystalloid 2. Antipyretic 3. Antihistamine 4. Adrenalin minijet 5. Others (please specify):		
10	Is there adequate supervision by a healthcare professional throughout the transfusion?		
11	Is there adequate access to emergency medical care?		

CARING PHYSICIAN	
Medical registration number	
Name and Surname	
Contact number	
Signature	

ISSUING OF BLOOD FROM THE HOSPITAL BLOOD BANK	
Domiciliary checklist completely filled in?	YES / NO
Blood to be issued?	YES / NO
Name and Surname of health care professional at the HBB	
Signature	

CONTACT NUMBERS	
Emergency	112
Issuing Hospital Blood Bank	

ANNEX 2: NATIONAL BLOOD TRANSFUSION REQUEST FORM

Hospital Blood Bank

ID/Hospital Number	DOB	Sex	Clinical Details
Surname		Ward	
Name		Hospital	
Locality		Date of Request	
Requesting Doctor/Signature/Pager/Registration Number		Consultant/Firm	For Laboratory Use Only
Previous Blood Group (If Known)		Laboratory Number of Previous Blood Group Test (If Known)	

Investigations				Special Requirements	
Blood Group	[ ]	Antenatal Screen	[ ]	CMV Negative	[ ]
DAT	[ ]	Neonatal Screen	[ ]	Irradiated	[ ]

Blood/Blood Product Request		Units/Volume Required	Date Required		
Type & Screen	[ ]		DD	MM	YY
Platelets	[ ]		DD	MM	YY
FFP	[ ]		DD	MM	YY
Cryoprecipitate	[ ]		DD	MM	YY

Patient History	
Previous Transfusion?	Y – N
Date of Last Transfusion	
Previous Transfusion Reaction?	Y – N
Previous Antibodies?	Y – N
Previous Pregnancy?	Y – N
Prophylactic Anti-D?	Y – N
Date of Last Anti-D Dose	

ANNEX 3: NATIONAL BLOOD TRACEABILITY FORM

Hospital Blood Bank – National Blood Traceability Form
(Name of Hospital)
(Contact Number)

ID Number: _____ Ward/Dept.: _____
Surname:____ Name: _____ Consultant: _____

Sex: _____ DOB: _/_/_____

Specimen Number: _____
Received: __/__/_____:_____ Required: __/__/_____:_____

Reason for Request:

Specimen Comment:

Unit Number	Blood Component Transfused? Yes / No	Full Name & Signature	Date & Time Transfused

THIS FORM MUST BE FILLED OUT COMPLETELY AND SENT BACK TO THE HOSPITAL BLOOD BANK AS SOON AS POSSIBLE.

ANNEX 4: NATIONAL BLOOD SERIOUS ADVERSE REACTION (SAR) REPORT FORM

NATIONAL BLOOD SERIOUS ADVERSE REACTION (SAR) REPORT FORM

PATIENT DETAILS			
Name & Surname:	**ID number:**	**DOB:** *dd / mm / yyyy*	**Gender:** MALE / FEMALE
Date of Reaction: *dd / mm / yyyy*	**Ward:**	**Firm/Physician:**	**Diagnosis:**

Type of blood / blood component *(Please tick accordingly)*	**Batch number of blood / blood component**
☐ Whole blood	
☐ Red Blood Cells	
☐ Platelets (aphareseis)	
☐ Platelets (pooled)	
☐ Plasma	
☐ Cryoprecipitate	
☐ Other *(please specify)*	

DETAILS OF SERIOUS ADVERSE REACTION (SAR)	
Date of Transfusion: *dd / mm / yyyy*	**Time of Transfusion:** *a.m. / p.m.*
Date of SAR: *dd / mm / yyyy*	**Time of SAR:** *a.m. / p.m.*
Amount transfused:_____ml	*(please tick accordingly)* ☐ <¼ ☐ <½ ☐ <¾ ☐ >¾

CLINICAL DETAILS			
Baseline observations prior to reaction	Temperature: _____°C	Pulse: _____/min	BP: _____/_____mmHg
Parameters during / after the reaction	Temperature peak: _____°C	Pulse peak or trough: _____/min	BP peak or trough: _____/_____mmHg

CLINICAL SIGNS OF REACTION					
Fever	☐	Urticaria/itching/rash	☐	Haemorrhage	☐
Hypothermia	☐	Haemoglobinuria	☐	Tachycardia/arrhythmia	☐
Nausea/vomiting	☐	Jaundice	☐	Bradycardia	☐
Chest pain	☐	Loin pain	☐	High blood pressure	☐
Dyspnoea	☐	Kidney failure/falling urine output	☐	Hypotension (low blood pressure)	☐
Stridor/wheeze	☐	Fits/seizures	☐	Shock	☐
Hypoxia (falling pO_2)	☐	Jugular Venous Distention	☐	Death	☐
Pulmonary oedema	☐	Purpura	☐	Other symptoms/Signs	☐

BRIEF DESCRIPTION OF REACTION / COMMENTS	

SAMPLES REQUIRED		
ALL	1 EDTA Sample + Return unit giving adverse reaction to HBB	
Respiratory Symptoms	1 **Extra** EDTA Sample	
Hypotension/Shock/Increase in Temperature by >2°C	Patient Blood Cultures	
Doctor's Signature	**Full Name**	**Registration Number**

All data collected is processed in accordance with the Human Blood and Transplants Act 2006 (Act IV 2006) and the GDPR and Data Protection Act 2018. Data is required for administrative purposes in the interest of Public Health.

REPORT IDENTIFICATION NUMBER (given by reporting establishment)**:** _____

CONFIRMATION OF REACTION			
Date of confirmation of reaction: *dd / mm / yyyy*			
Type of SAR *(please tick accordingly)***:**		**Type of SAR** *(please tick accordingly)***:**	
Immunological haemolysis due to ABO incompatibility	☐	Transfusion-transmitted parasitical infection (Malaria)	☐
Immunological haemolysis due to other allo-antibody (Acute)	☐	Transfusion-transmitted parasitical infection, Other *(please specify)*	☐
Immunological haemolysis due to other allo-antibody (Delayed > 24 hours)	☐	Graft versus host disease	☐
Non-immunological haemolysis	☐	Febrile non-haemolytic transfusion reactions (FNHTR)	☐
Post-transfusion bacterial infection	☐	Post-transfusion Purpura (PTP)	☐
Transfusion-transmitted viral infection (HBV)	☐	Transfusion Related Acute Lung Injury (TRALI)	☐
Transfusion-transmitted viral infection (HCV)	☐	Transfusion Associated Circulatory Overload (TACO)	☐
Transfusion-transmitted viral infection (HIV-1/2)	☐	Transfusion Associated Dyspnoea (TAD)	☐
Transfusion-transmitted viral infection, Other *(please specify)*	☐	Hypotensive transfusion reaction	☐
Other SARs (please specify)			☐

IMPUTABILITY OF SERIOUS ADVERSE REACTION	Excluded – 0 ☐	Unlikely – 0 ☐	Possible – 1 ☐
	Likely/Probable – 2 ☐	Certain – 3 ☐	Not assessable – NA ☐

SEVERITY GRADING / PATIENT OUTCOME		
0	No morbidity; no symptoms; reaction detected only through laboratory investigation	☐
1	Minor morbidity; not life threatening	☐
2	Moderate to serious morbidity; may or may not be life threatening; illness or hospitalisation is prolonged and/or results in chronic invalidity or impairment	☐
3	Serious morbidity with immediate threat to life	☐
4	Death as outcome	☐

REPORTING ESTABLISHMENT
Type *(please circle)***:** hospital blood bank, blood establishment, hospital, clinic, manufacturer, bio-medical research institution
Report made by (name)**:**
Address:
Telephone / Mobile:
E-mail address:

Signature: **Date of Report:** *dd / mm / yyyy*

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