SA Health

# Policy

## Blood Supply Stewardship for South Australia



Version 2.3

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PDS Reference No: D0412

Government of South Australia

SA Health

## 1. Name of policy

Blood Supply Stewardship for South Australia

## 2. Policy statement

The purpose of this policy is to establish the basis for blood and blood product stewardship by promoting the safe, responsible, and appropriate use of blood and blood products with a view to optimising patient outcomes. Broad stewardship expectations for the blood sector are outlined in the 2010 Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products. The National Blood Agreement also requires blood supply stewardship activities to be undertaken within jurisdictions (clause 26).

## 3. Applicability

This policy applies to all employees of SA Health services that receive blood and blood products, including, but not limited to, hospitals, health centres, SA Pathology and SA Ambulance Service.

The principles of this policy are also strongly recommenced to all non-public health care providers who interact with SA Health. Private hospital and pathology providers who utilise government funded blood and blood products should seek to adopt these measures in their own organisations.

## 4. Policy principles

SA Health's approach to blood supply stewardship is underpinned by the following principles:

- We recognise that blood and blood products are generously donated by the Australian public
- We use blood products in a clinically appropriate manner in accordance with relevant professional guidelines and standards
- We recognise that patient blood management principles are a fundamental component of blood and blood product stewardship
- We implement informed consent procedures for all patients
- We have processes, programs and facilities in place to minimise the wastage of blood products
- Our facilities are accredited with the appropriate bodies to meet all quality and safety obligations
- We collect and appropriately manage transfusion related adverse event information
- We have an ordering and receipt verification process in place which provides adequate financial accountability for blood product use
- We provide regular and timely inventory data to assist in supply and demand planning and shortage responses

## 5. Policy requirements

### 5.1 Australian Health Provider Blood and Blood Products Charter (Access to Blood and Blood Products)

- All health sites that are in receipt of blood and blood products are required to complete, sign and adhere to, the relevant charter document (hospitals; pathology providers; general practitioners/other providers).

- The charter is a national obligation that outlines and commits sites to quality and safety standards and national stewardship obligations re blood and blood products across the public and private sectors. Details on the obligations of health providers can be found on the National Blood Authority's website at: https://www.blood.gov.au/supply-system/australian-health-provider-access-blood-and-blood-products.
- As a whole-of-health approach, the Chief Executive SA Health signed the charter on behalf of all entities within SA Health, including LHNs, SA Pathology and SA Ambulance in April 2019. A copy of the signed charter can be obtained by emailing Blood, Organ and Tissue Programs at healthbot@sa.gov.au.

> All health sites that are in receipt of blood and blood products must adhere to other national policies as and when they are developed by the National Blood Authority.

### 5.2 Access to Immunoglobulin Products

> For access to immunoglobulin products *under* the National Blood Arrangements, sites must adhere to the National Blood Authority's National Policy for Access to Government Funded Immunoglobulin Products in Australia.

- This includes adherence to the Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia, as well as usage of the National Blood Authority's BloodSTAR system, which standardises and manages access to the supply of immunoglobulin products according to the criteria.
- More details on the national immunoglobulin product authorisation and management arrangements, including the national policy, clinical criteria for use, clinician and patient materials, can be found on the National Blood Authority's website at: https://www.blood.gov.au/supply-system/governance-immunoglobulin-products.

> For access to immunoglobulin products *outside of* the National Blood Arrangements (ie where the patient's indication does not meet the National Blood Authority's Criteria for Clinical Use), it is still possible to access product at the nationally negotiated price through the Jurisdictional Direct Order process.

- A request with supporting evidence must be sent to the Chair of the South Australian Immunoglobulin Therapy Group for consideration. The submission is then reviewed by sub-specialty expert members of the group. If the request is approved, notification is sent to the relevant Drug & Therapeutic Committee for their records.
- The requesting unit must pay for this treatment in full; it is not covered under the National Blood Arrangements.
- An overview of the process is attached in appendix 1.

### 5.3 Patient Blood Management, including BloodSafe

> All SA Health services that receive blood and blood products must have a process for progressing patient blood management in their relevant organisations. This must include, but not be limited to:

- Implementation of the National Blood Authority's Patient Blood Management guidelines (modules 1-6) (available at https://www.blood.gov.au/patient-blood-management-guidelines). As part of the implementation, clinical units must establish criteria that represent appropriate use for their specific area against the relevant guidelines. *Note that these guidelines are currently under review*.
- Supporting the BloodSafe Nurses and Clinical Portfolio Blood Link Nurses in patient blood management efforts as directed by the SA Blood Management Council.

- Requiring the completion of applicable BloodSafe eLearning Australia online Transfusion Practice Courses for relevant staff (see Transfusion Education section below).

### 5.4 Local Governance and Statewide Advisory Groups

> All SA Health Local Health Networks / Services must have a Transfusion and/or (Patient) Blood Management committee which oversees the operational elements of this Policy.

> All LHNs, including separate SA Pathology representation, must participate in the following state-wide advisory groups (where the relevant products are held in the LHN):

- SA Blood Management Council
- Immunoglobulin Therapies Advisory Group (immunoglobulin products)
- Haemophilia Treatment Network (bleeding disorders products)
- Other blood sector advisory groups as and when they are formed.

### 5.5 Inventory Management and Wastage (BloodMove)

> All SA Health pathology providers that receive blood and blood products must utilise BloodNet to order and receipt blood products electronically, as well as to enter local inventory levels daily.

> All pathology providers must also use the BloodNet system to record all discards of blood and blood products.

> All SA Health services that receive blood and blood products must adhere to Australian Standard AS3864: Medical refrigeration equipment – for the storage of blood and blood products – manufacturing requirements.

> All SA Health sites and pathology providers must participate in the SA Health BloodMove program and its initiatives.

- Sites must participate in the transfer of near expiry products to other sites more likely to utilise them, thus minimising wastage across all of South Australia.
- Collaboration must occur across networks and reporting of wastage rates must take into consideration sites that accept near expiry product (ie their wastage rate may be higher, but this allows the statewide rate to remain lower).

> All SA Health services, in particular clinical, retrieval services and pathology providers, must be familiar with, and implement when required, the following clinical guidelines aimed at optimising the use of blood and blood products:

- CMV (cytomegalovirus) Seronegative Blood Components for Clinical Use
- Irradiated Blood Components for Clinical Use
- Use of O negative Red Cells (under development)
- Any other clinical guidance / fact sheets / communiques promulgated by Blood, Organ and Tissue Programs and/or other statewide guidelines that contain blood and blood product components from time to time

### 5.6 Emergency Blood Management Plans

> All SA Health LHNs, SA Pathology and SAAS must develop a local emergency blood management plan to conserve inventory in times of local shortages and/or activation of the National Blood Supply Contingency Plan.

> These plans must work in with both the SA Blood Supply Contingency Plan (SA statewide plan – refer to supporting documents in section 7) and the National Blood Supply Contingency Plan (available at: https://www.blood.gov.au/supply-system/managing-blood-supply/risk-management-and-national-blood-supply-contingency-plan).

## 5.7 Transfusion Education

- All SA Health staff that are involved in the handling, storage or administration of blood and blood products must complete the BloodSafe eLearning Australia Transfusion Practice Courses relevant to their area of work:
  - Clinical Transfusion Practice and/or Clinical Transfusion Practice (Refresher) – medical staff, nurses, midwives, laboratory staff
  - Collecting Blood Specimens – specimen collectors, phlebotomists and venepuncture staff
  - Transporting Blood – hospital orderlies, couriers, porters and patient service assistants
- All medical, nursing and midwifery staff that handle blood and blood products must complete the Patient Blood Management general course.

## 5.8 Haemovigilance

- The Safety Learning System (SLS) is mandatory for reporting of adverse events and near misses related to blood and blood products. This includes not only adverse reactions, but also blood specimen collection and labelling errors, patient identification errors and inappropriate wastage.
- All clinical staff involved in the administration of blood and blood products must also notify their pathology service of any product related issues. The pathology service must notify the relevant supplier.

## 5.9 High Cost Patient Reporting (LHNs only, excluding SAAS)

- The South Australian Haemophilia Treatment Network has an endorsed reporting process for high cost care for coagulation disorders, which must be followed by all LHNs. This process is set out in appendix 2.
- Use of any other product that could result in an individual patient expenditure exceeding $10,000 in any one episode must also be reported to Blood, Organ and Tissue Programs in a timely manner (phone 08 8226 6114, 08 8226 7254 or 08 8463 7058 and/or email to healthbot@sa.gov.au or specific staff member). As Blood, Organ and Tissue Programs is responsible for the blood supply budget for the entire state, this enables the team to monitor for any potential cost overruns that might require additional approvals to be flagged ahead of time.

## 5.10 Statewide and National Reporting / Registries (LHNs only, excluding SAAS)

- All patients with bleeding disorders must be enrolled on the Australian Bleeding Disorders Register (ABDR) in order to meet the state's requirements under the National Blood Agreement, including reporting on high cost users (see point above). More information is available at https://www.blood.gov.au/clinical-guidance/bleeding-disorders/australian-bleeding-disorders-registry.
- All SA Health LHNs must contribute to the ongoing ability of the Department to collate blood usage data through the timely completion of patient episode details on the relevant hospital and SA Pathology systems, as well as the timely provision of any required data extracts directly from hospitals and/or SA Pathology.
- All LHNs must contribute any required data for the Department to fulfil its obligations to the Independent Hospital Pricing Authority. This applies particularly in relation to the implementation of national activity based funding and pricing models for Australian public hospitals.

## 6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- National Blood Agreement (in particular clause 26 which relates to the national blood supply roles of States and Territories) – available https://www.blood.gov.au/national-blood-agreement
- Australian Health Provider Blood and Blood Products Charter – available at https://www.blood.gov.au/supply-system/australian-health-provider-access-blood-and-blood-products
- Criteria for the Clinical Use of Immunoglobulin in Australia – available at https://www.blood.gov.au/supply-system/governance-immunoglobulin-products/criteria-immunoglobulin-products
- Patient Blood Management Guidelines – available at https://www.blood.gov.au/patient-blood-management-guidelines
- National Safety and Quality Health Service Standard 7 Blood Management – available at https://www.safetyandquality.gov.au/standards/nsqhs-standards/blood-management-standard
- Australian Standard AS3864: Medical refrigeration equipment – for the storage of blood and blood products – manufacturing requirements – available via https://www.lifeblood.com.au/health-professionals/products/storage-and-handling/maintenance-of-storage-devices
- National Blood Supply Contingency Plan – available at https://www.blood.gov.au/supply-system/managing-blood-supply/risk-management-and-national-blood-supply-contingency-plan#national-blood-supply-contingency-plan
- BloodSafe eLearning Australia (specific courses for different staff per policy requirement 5.7 above) – available at https://bloodsafelearning.org.au/

## 7. Supporting documents

- SA Blood Supply Contingency Plan (a copy of the most recent contingency plan can be obtained by emailing Blood, Organ and Tissue Programs at healthbot@sa.gov.au)
- SA Blood Supply Contingency Plan template for LHN local emergency blood management plans (a copy of the most recent template can be obtained by emailing Blood, Organ and Tissue Programs at healthbot@sa.gov.au)
- National Stewardship Program – available at https://www.blood.gov.au/supply-system/managing-blood-supply/national-stewardship-program
- Guidelines for the management of haemophilia in Australia – available at https://www.blood.gov.au/guidelines-management-haemophilia-australia
- National Haemovigilance Reporting – https://www.blood.gov.au/haemovigilance-reporting
- Safety Learning System Topic Guide – Transfusion of Blood Products – available (SA Health Intranet only) at https://inside.sahealth.sa.gov.au/wps/wcm/connect/non-public+content/sa+health+intranet/resources/safety+learning+system+topic+guide+on+transfusion
- CMV Seronegative Blood Components for Clinical Use Clinical Guidance – available at https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/policies/cmv+seronegative+blood+components+for+clinical+use+clinical+guideline
- Irradiated Blood Components for Clinical Use Clinical Guidance - available at https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/irradiated+blood+-+clinical+update

- Emergency Use of Group O Red Cells – available at https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/blood+organ+and+tissue/blood+management/blood+sector+policies%2c+guidelines+and+standards/emergency+use+of+group+o+red+cells

## 8. Definitions

- **BBPS** means Blood and Blood Product Stewardship, an effective approach to ensuring responsible, sustainable and appropriate use of blood and blood products with a view to optimising patient outcomes.
- **blood and blood products** means all products derived from blood, including fresh, recombinant and therapeutic immunoglobulin products, that are listed on the national supply list.
- **haemovigilance** is defined as a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow up of its recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.
- **inventory** means the total stockholding of blood and blood products held in the hospitals and / or pathology laboratory for patient use
- **SLS** means the Safety Learning System that SA Health services use to record, manage, investigate and analyse patient and worker incidents as well as consumer feedback.
- **wastage** means blood and blood products not put to therapeutic use (ie used by patients) due to incorrect handling, poor storage, time expiry or other reasons

## 9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Risk Management, Integrated Compliance and Internal Audit Policy.

Any instance of non-compliance with this policy should be reported to the Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

## 10. Document ownership

Policy owner: Executive Director Provider Commissioning and Performance as Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain

Title: Blood Supply Stewardship Policy

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Contact for enquiries: healthbot@sa.gov.au

## 11. Document history

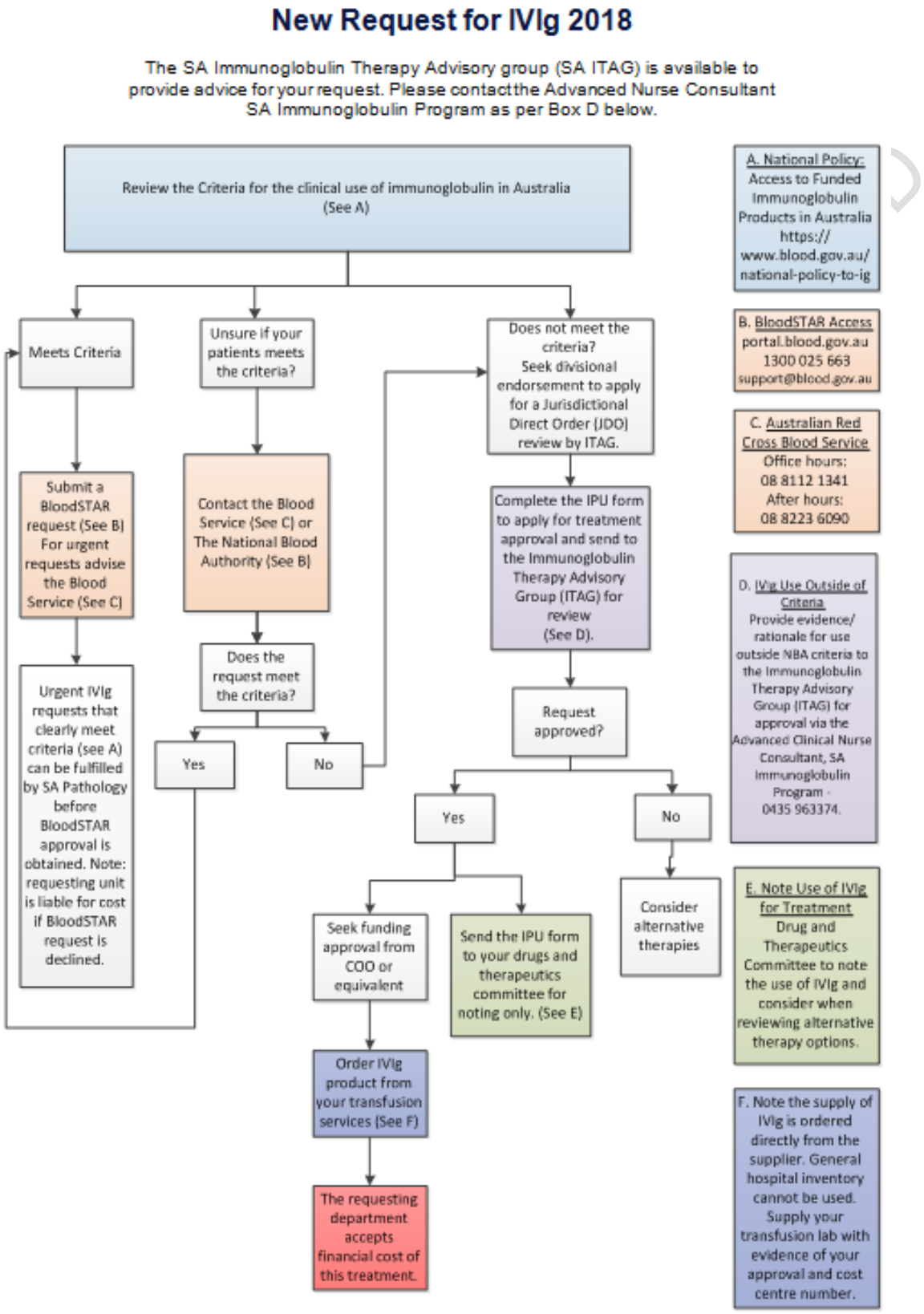
| Version | Date approved | Approved by | Amendment notes |
|---|---|---|---|
| V2.3 | | | Web links updated |
| V2.2 | 07/08/2022 | Deputy Chief Executive, Corporate and System Support Services<br>*following review by:*<br>DHW Operational Clinical Governance Committee | Translation to new template with minor changes to suit new style.<br>Addition of references to blood related clinical guidance documents published since version 2 was endorsed.<br>Formalisation of high cost reporting for products outside of haemophilia care setting. |
| V2.1 | 20/08/19 | SA Health Safety and Quality Strategic Governance Committee | Endorsed version 2 with minor change to educational requirements |
| V2.0 | 05/03/19 | SA Blood Management Council | Endorsed version 2 |
| V1.0 | 23/05/16 | Portfolio Executive | Original PE approved version |
| V1.0 | 20/04/16 | SA Health Safety and Quality Strategic Governance Committee | Endorsed version 1 |
| V1.0 | 20/04/16 | SA Blood Management Council | Endorsed version 1 |

## 12. Appendices

1. Request Flowchart for IVIG – Mandatory Instruction
2. High Cost Patient Reporting – Mandatory Instruction
3. SA Health compliance indicators - Mandatory Instruction

## Appendix 1: Request Flowchart for IVIG - Mandatory Instruction

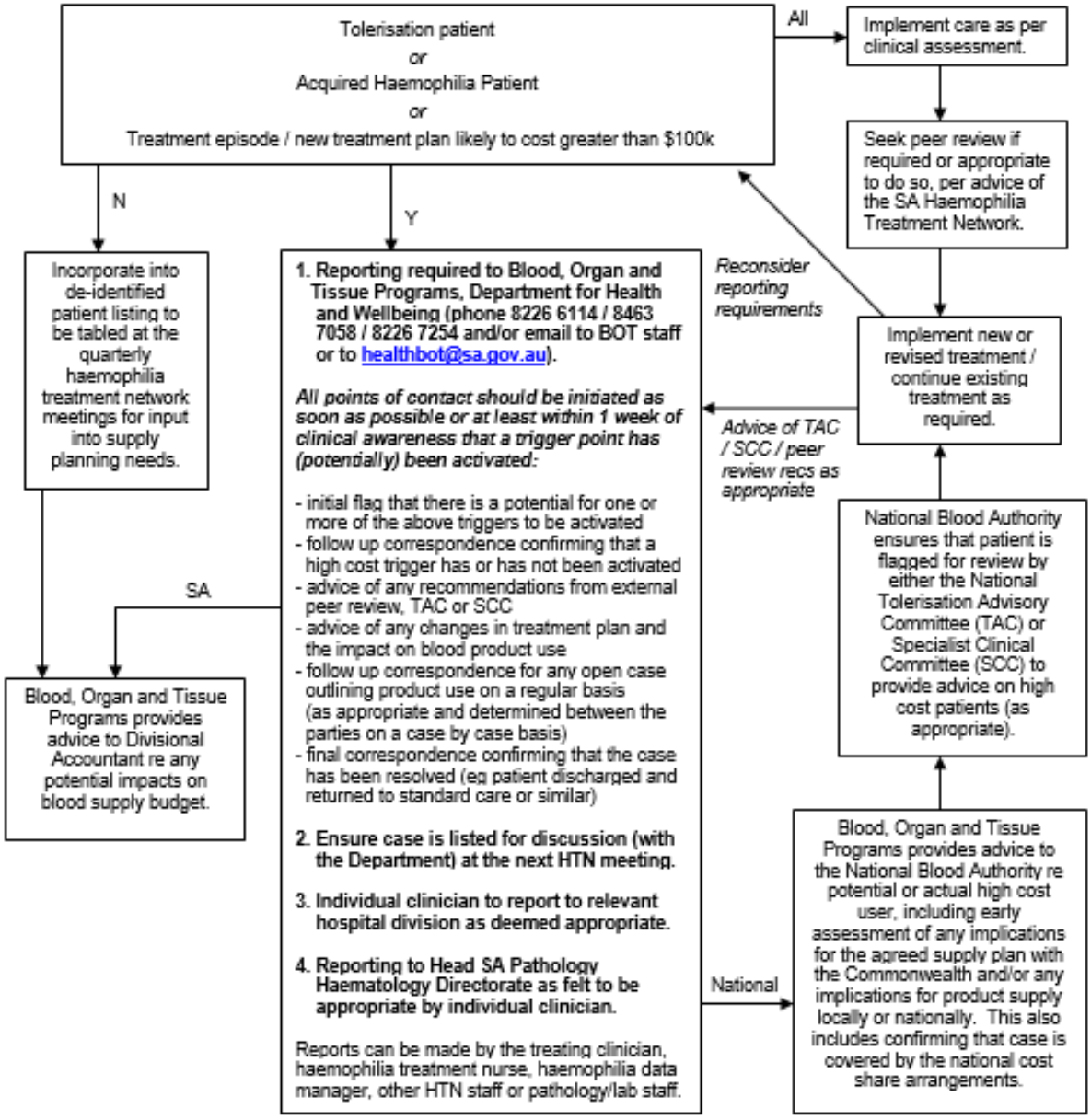
The following Instruction (process) must be complied with to meet the requirements of the *Blood Supply Stewardship Policy* per policy requirement 5.2 above.



## Appendix 2: High Cost Patient Reporting - Mandatory Instruction

The following Instruction (process) must be complied with to meet the requirements of the *Blood Supply Stewardship Policy* per policy requirement 5.9 above.

### Reporting Process for High Cost Care for Coagulation Disorders




**Reporting Detail Required (indicative – may vary case by case)**

- Treating clinician name and hospital
- Deidentified patient initials
- Basic history of / background to the clinical situation
- Summary of peer review (if relevant to particular case) and any follow up reviews by TAC / SCC (as they relate to blood product use)
- Products used to date
- Estimate of type and volume of products to be used under clinical protocol / treatment plan
- Likely timeframe for clinical protocol to continue
- Advice on any changes to the treatment plan and their projected impact on blood product use
- Regular updates on product use (as determined between the parties) and finalisation of case

# Appendix 3: SA Health compliance indicators - Mandatory Instruction

The SA Health-wide compliance indicators for this policy are set out below. These indicators are mandatory and required to be met across all SA Health services.

| Indicator | Description |
|---|---|
| Health Provider Blood and Blood Products Charter Compliance | • Per policy requirement 5.1, health services must have a signed Health Provider Blood and Blood Products Charter with the National Blood Authority.<br>• Per policy requirement 5.1, health services must have a documented plan as to how they have implemented the requirements of the Blood and Blood Products Charter. |
| Hospital Transfusion or Blood Management Committee | • Per policy requirement 5.4, health services must have a transfusion / blood management committee that meets regularly with an appointed Chair and agreed terms of reference. |
| Daily stock levels updates | • Per policy requirement 5.5, pathology providers must enter local stock levels into BloodNet on a daily basis to ensure accurate data is provided for contingency plan activation |
| Current emergency blood management plan | • Per policy requirement 5.6, health services must have a documented emergency blood management plan that articulates to the statewide and national blood contingency plans. |
| Use of statewide blood and blood product guidelines | • Per policy requirement 5.5, any adoption of alternative guidelines must involve a liaison with Blood, Organ and Tissue Programs. |
| Transfusion Education | • Per policy requirement 5.7, health services must ensure that appropriate staff have completed the required transfusion education |
| High cost patient reporting process | • Per policy requirement 5.9, health services must have in place processes to support the timely reporting of high cost patients. |