# Standard 7

Blood and Blood Products

Safety and Quality Improvement Guide

# $\bullet \bullet \bullet$

October 2012

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE



ISBN: Print: 978-1-921983-39-9 Electronic: 978-1-921983-40-5

Suggested citation: Australian Commission on Safety and Quality in Health Care. Safety and Quality Improvement Guide Standard 7: Blood and Blood Products (October 2012). Sydney. ACSQHC, 2012.

© Commonwealth of Australia 2012

This work is copyright. It may be reproduced in whole or in part for study or training purposes subject to the inclusion of an acknowledgement of the source. Requests and inquiries concerning reproduction and rights for purposes other than those indicated above requires the written permission of the Australian Commission on Safety and Quality in Health Care:

#### Australian Commission on Safety and Quality in Health Care

GPO Box 5480 Sydney NSW 2001 Email: mail@safetyandquality.gov.au

www.safetyandquality.gov.au

#### Acknowledgements

This document was prepared by the National Blood Authority in collaboration with the Australian Commission on Safety and Quality in Health Care.

## Table of Contents

The National Safety and Quality Health Service Standards	2
Terms and definitions	5
Standard 7: Blood and Blood Products	6
Criterion: Governance and systems for blood and blood product prescribing and clinical use	8
Criterion: Documenting patient information	19
Criterion: Managing blood and blood product safety	25
Criterion: Communicating with patients and carers	30
References	35
Appendix: Links to resources	36



## The National Safety and Quality Health Service Standards

The National Safety and Quality Health Service (NSQHS) Standards<sup>1</sup> were developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in consultation and collaboration with jurisdictions, technical experts and a wide range of other organisations and individuals, including health professionals and patients.

The primary aims of the *NSQHS Standards* are to protect the public from harm and to improve the quality of care provided by health service organisations. These Standards provide:

- a **quality assurance** mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met
- a **quality improvement** mechanism that allows health service organisations to realise developmental goals.

### Safety and Quality Improvement Guides

The Commission has developed Safety and Quality Improvement Guides (the Guides) for each of the 10 *NSQHS Standards*. These Guides are designed to assist health service organisations to align their quality improvement programs using the framework of the *NSQHS Standards*.

The Guides are primarily intended for use by people who are responsible for a part or whole of a health service organisation. The structure of the Guides includes:

- introductory information about what is required to achieve each criterion of the Standard
- tables describing each action required and listing:
  - key tasks
  - implementation strategies
  - examples of the outputs of improvement processes
- additional supporting resources (with links to Australian and international resources and tools, where relevant).

Direct links to these and other useful resources are available on the Commission's web site:

#### www.safetyandquality.gov.au

The Guides present **suggestions** for meeting the criteria of the Standards, which should not be interpreted as being mandatory. The examples of suggested strategies and outputs of improvement processes are **examples only**. In other words, health service organisations can choose improvement actions that are specific to their local context in order to achieve the criteria. The extent to which improvement is required in your organisation will heavily influence the actions, processes and projects you undertake.

You may choose to demonstrate how you meet the criteria in the Standards using the example outputs of improvement processes, or alternative examples that are more relevant to your own quality improvement processes.

### Additional resources

The Commission has developed a range of resources to assist health service organisations to implement the *NSQHS Standards*. These include:

- a list of available resources for each of the NSQHS Standards
- an Accreditation Workbook for Hospitals and an Accreditation Workbook for Day Procedure Services
- A Guide for Dental Practices (relevant only to Standards 1–6)
- a series of fact sheets on the NSQHS Standards
- frequently asked questions
- a list of approved accrediting agencies
- slide presentations on the NSQHS Standards.



### Overarching NSQHS Standards

Standard 1: Governance for Safety and Quality in Health Service Organisations, and Standard 2: Partnering with Consumers set the overarching requirements for the effective application of the other eight NSQHS Standards which address specific clinical areas of patient care.

**Standard 1** outlines the broad criteria to achieve the creation of an integrated governance system to maintain and improve the reliability and quality of patient care, and improve patient outcomes.

**Standard 2** requires leaders of a health service organisation to implement systems to support partnering with patients, carers and other consumers to improve the safety and quality of care. Patients, carers, consumers, clinicians and other members of the workforce should use the systems for partnering with consumers.

# Core and developmental actions

The NSQHS Standards apply to a wide variety of health service organisations. Due to the variable size, structure and complexity of health service delivery models, a degree of flexibility is required in the application of the standards.

To achieve this flexibility, each action within a Standard is designated as either:

#### CORE

- considered fundamental to safe practice

OR

#### DEVELOPMENTAL

 areas where health service organisations can focus activities or investments that improve patient safety and quality.

Information about which actions have been designated as core or developmental is available on the Commission's web site.

# Quality improvement approaches in health care

Approaches to improving healthcare quality and safety are well documented and firmly established. Examples of common approaches include Clinical Practice Improvement or Continuous Quality Improvement. The Guides are designed for use in the context of an overall organisational approach to quality improvement, but are not aligned to any particular approach.

Further information on adopting an appropriate quality improvement methodology can be found in the:

NSW Health Easy Guide to Clinical Practice Improvement<sup>2</sup>

CEC Enhancing Project Spread and Sustainability<sup>3</sup>

Institute for Healthcare Improvement (US)<sup>4</sup>

## The National Safety and Quality Health Service Standards (continued)

# Roles for safety and quality in health care

A range of participants are involved in ensuring the safe and effective delivery of healthcare services. These include the following:

- **Patients and carers**, in partnership with health service organisations and their healthcare providers, are involved in:
  - making decisions for service planning
  - developing models of care
  - measuring service and evaluating systems of care.

They should participate in making decisions about their own health care. They need to know and exercise their healthcare rights, be engaged in their healthcare, and participate in treatment decisions.

- Patients and carers need to have access to information about options and agreed treatment plans. Health care can be improved when patients and carers share (with their healthcare provider) issues that may have an impact on their ability to comply with treatment plans.
- The role of **clinicians** is essential. Improvements to the system can be achieved when clinicians actively participate in organisational processes, safety systems, and improvement initiatives. Clinicians should be trained in the roles and services for which they are accountable. Clinicians make health systems safer and more effective if they:
  - have a broad understanding of their responsibility for safety and quality in healthcare
  - follow safety and quality procedures
  - supervise and educate other members of the workforce
  - participate in the review of performance procedures individually, or as part of a team.

When clinicians form partnerships with patients and carers, not only can a patient's experience of care be improved, but the design and planning of organisational processes, safety systems, quality initiatives and training can also be more effective.

- The role of the non-clinical workforce is important to the delivery of quality health care. This group may include administrative, clerical, cleaning, catering and other critical clinical support staff or volunteers. By actively participating in organisational processes – including the development and implementation of safety systems, improvement initiatives and related training – this group can help to identify and address the limitations of safety systems. A key role for the non-clinical workforce is to notify clinicians when they have concerns about a patient's condition.
- The role of managers in health service organisations is to implement and maintain systems, resources, education and training to ensure that clinicians deliver safe, effective and reliable health care. They should support the establishment of partnerships with patients and carers when designing, implementing and maintaining systems. Managing performance and facilitating compliance across the organisation is a key role. This includes oversight of individual areas with responsibility for the governance of safety and quality systems. Managers should be leaders who can model behaviours that optimise safe and high quality care. Safer systems can be achieved when managers in health service organisations consider safety and quality implications in their decision making processes.
- The role of **health service senior executives and owners** is to plan and review integrated governance systems that promote patient safety and quality, and to clearly articulate organisational and individual safety and quality roles and responsibilities throughout the organisation. Explicit support for the principles of consumer centred care is key to ensuring the establishment of effective partnerships between consumer, managers, and clinicians. As organisational leaders, health service executives and owners should model the behaviours that are necessary to implement safe and high quality healthcare systems.

## **Terms and definitions**

**BloodNet:** Australia's national blood ICT system enabling online ordering, receipting, fating and inventory management of blood and blood products.

Flexible standardisation: Flexible standardisation recognises the importance of standardisation of processes to improve patient safety across a variety of contexts. The standardisation of any process and related data sets must be designed and integrated to fit the context of health service organisations, including varying patient and staffing profiles. These vary widely as health service organisations have differing functions, size, locations, structure and service delivery modes. Tools, processes and protocols should be based on best available evidence and the requirements of jurisdictions, external policy and legislation and adapted to the local context.

Governance: The set of relationships and responsibilities established by a health service organisation between its senior executive, workforce and stakeholders (including consumers). Governance incorporates the set of processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure through which organisations can set the corporate objectives (social, fiscal, legal, human resources) and provide the means by which the objectives are to be achieved. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help in aligning the roles, interests and actions of different participants in the organisation to achieve the organisation's objectives. Governance includes both corporate and clinical governance.

Haemovigilance: Defined by the International Haemovigilance Network as, 'a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of 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'. See also the Australian Haemovigilance Report 2010.<sup>5</sup>

**Outputs:** The results of your safety and quality improvement actions and processes. Examples of outputs are provided in this guide. They are examples only and should not be read as being checklists of evidence required to demonstrate achievement of the criterion. Outputs will be specific to the actions, processes and projects undertaken in your context which will be influenced by your existing level of attainment against the criterion and extent to which improvement has been required.

**Patient blood management:** The management and preservation of patients' own blood to reduce or avoid the need for a blood transfusion.

Stewardship Statement: The Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products http://www.nba.gov.au/policy/stewardshipstatement.html.<sup>6</sup>

**Transfusion:** In this Safety and Quality Improvement Guide this terms is intended to cover the administration of all blood and blood products regardless of their route of administration.

**Transfusion Governance Group:** The group responsible for overseeing the Transfusion Quality Improvement System.

#### Transfusion Quality Improvement System:

A cycle of activities to review current practice relating to transfusion practice, assess risks, identify opportunities for improvement, implement practice improvement and measure the results.

### 

#### **Standard 7: Blood and Blood Products**

### Standard 7: Blood and Blood Products

### Clinical leaders and senior managers of a health service organisation implement systems to ensure the safe, appropriate, efficient and effective use of blood and blood products. Clinicians and other members of the workforce use the blood and blood product safety systems.

The intention of this Standard is to:

Ensure that the patients who receive blood and blood products do so appropriately and safely.

#### **Context:**

It is expected that Standard 7 and this accompanying Guide will be used in conjunction with the other Standards and their associated Safety and Quality Improvement Guides including:

Standard 1: Governance for Safety and Quality in Health Service Organisations

Standard 2: Partnering with Consumers

Standard 5: Patient Identification and Procedure Matching.

#### Introduction

Blood and blood products are a vital resource, sourced from the Australian and International donor community, and from commercial manufacture. While the use of blood and blood products can be lifesaving, there are also risks associated with their administration. This Safety and Quality Improvement Guide is designed to help health service organisations who use blood and blood products, to improve safety and quality and achieve accreditation under Standard 7. The Guide identifies implementation strategies, and proposes ways in which evidence can be produced and used in the quality improvement cycle to demonstrate compliance with Standard 7.

#### Scope

The scope of Standard 7 covers all elements in the clinical transfusion process including the principles of patient blood management, which includes avoiding unnecessary exposure to blood components through appropriate management of the patient and the use of other non-blood treatments. This consideration of other treatment options should be covered in the organisation's policies, protocols and procedures (7.1)

and in communication with patients regarding treatment options and their care plan (7.9). However, much of the Standard focuses on safety and quality activities **after** a decision to transfuse has been made, or on the management of blood and blood products.

The use of the term 'transfusion' in this Guide is intended to cover the administration of all blood and blood products regardless of their route of administration. The blood and blood products governed under this Standard include:

- Fresh blood components
  - red blood cells
  - platelets
  - clinical fresh frozen plasma
  - cryoprecipitate
  - cryodepleted plasma
- Plasma-derivatives and recombinant products
  - albumin
  - immunoglobulins, including immunoglobulin replacement therapy (e.g. IVIg) and hyperimmune globulins
  - clotting factors.

# Implementing systems to ensure safe use of blood and blood products

Expectations of health service providers with regard to the responsible, sustainable and appropriate use of blood and blood products have been communicated by Health Ministers in the *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products (The Stewardship Statement)*.<sup>6</sup> Standard 7 builds on these expectations, and outlines the safety and quality expectations of health service organisations in the management of blood and blood products.

Standard 7 aims to ensure that patients (and carers) are engaged in the decisions about their management and if they receive blood and blood products, they do so appropriately and safely.

Given the specific risks relating to the use of blood and blood products, it is recommended you develop a local Transfusion Quality Improvement System. This system will consist of a cycle of activities to review current practice, assess risks, identify opportunities for improvement, implement practice improvement and measure the results. In small organisations, the Transfusion Quality Improvement System may form part of a broader quality improvement program. It is also recommended you identify or establish a governance group to oversee implementation of the Transfusion Quality Improvement System. For the purpose of consistency, throughout this Guide this group will be referred to as the 'Transfusion Governance Group' but may have a different title in your organisation. This governance group may have other roles in relation to blood or broader clinical practice, particularly in small health service organisations.

Where any component of health service management of the provision of blood and blood product is outsourced, you remain responsible for ensuring the safety and quality of those components that relate to your health service organisation. You should have a procedure in place to confirm and monitor the activities of the third party, and receive reports from the third party that would satisfy the requirements under this Standard. A comprehensive Transfusion Quality Improvement System will have mechanisms in place to address each of the following areas fully:

- Use and management of blood and blood products in accordance with national evidence-based guidelines.
- 2. Risk mitigation, education and safety and quality improvement programs for the management and use of blood and blood products.
- 3. Reporting and feedback mechanisms into risk management processes for adverse events, incidents and near misses relating to transfusion practice.
- 4. Policies, procedures and protocols for documenting transfusion details in the patient clinical record.
- 5. Appropriate management of blood and blood products.
- 6. Informed consent is documented for transfusions.

Standard 7 requires clinician leaders and senior managers of a health service organisation to implement systems to ensure the safe, appropriate, efficient and effective use of blood and blood products. Clinicians and other members of the workforce should use the blood and blood product safety systems.

#### Criteria to achieve the Blood and Blood Products Standard:

Governance and systems for blood and blood products prescribing and clinical use

Health service organisations have systems in place for the safe and appropriate prescribing and clinical use of blood and blood products.

#### **Documenting patient information**

The clinical workforce accurately records a patient's blood and blood product transfusion history and indications for use of blood and blood products.

#### Managing blood and blood product safety

Health service organisations have systems in place to receive, store, transport and monitor wastage of blood and blood products safely and efficiently.

#### **Communicating with patients and carers**

Patients and carers are informed about the risks and benefits of using blood and blood products, and the available alternatives when a plan for treatment is developed.

For the purposes of accreditation, please check the Commission's web site regarding actions within these criteria that have been designated as core or developmental.

Standard 7



### Criterion: Governance and systems for blood and blood product prescribing and clinical use

Health service organisations have systems in place for the safe and appropriate prescribing and clinical use of blood and blood products

This criterion aligns closely with *Standard 1: Governance for Safety and Quality in Health Service Organisations.* Quality and safety governance arrangements for blood and blood products may be embedded within, or managed as an adjunct to, broader quality and safety governance arrangements. Regardless of the approach, quality and safety governance arrangements for blood and blood products are required. The Stewardship Statement<sup>6</sup> lists a number of principles, including that 'all blood and blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards.'

This Criterion and each of the actions should be considered in relation to Standard 1: Governance for Safety and Quality in Health Service Organisations.

7.1 Developing governance systems for safe and appropriate prescription, administration and management of blood and blood products

**7.1.1** Blood and blood product policies, procedures and/or protocols are consistent with national evidencebased guidelines for pre-transfusion practices, prescribing and clinical use of blood and blood products

#### Key task:

#### Identify, adopt and/or develop policies, procedures and/or protocols which are consistent with national evidence-based guidelines

Patient blood management aims to improve clinical outcomes by avoiding unnecessary exposure to blood and blood products. Decisions on whether to transfuse should be carefully considered, taking into account the full range of available therapies, and balancing the evidence for efficacy and improved clinical outcome against the potential risks.<sup>7</sup>

#### Suggested strategies:

You should ensure policies, procedures and/or protocols are in place that accord with national evidence-based guidelines for:

- pre-transfusion practice strategies to optimise the patient's own blood (as relevant to fresh blood products), as well as pre-transfusion blood sampling and testing
- prescribing practice and clinical use of blood and blood products decisions to use blood and blood products including any specific requirements e.g. irradiated products
- administration of blood and blood products including venous access, the use of equipment, concurrent fluids and medications, pre-administration identity check of patient and blood product, infusion rates, and observations and monitoring<sup>8</sup>
- management of blood and blood products including receipt, storage, collection and transport.

Where there are no national evidence-based guidelines, you may choose to develop a local policy, process or procedure that communicates the appropriate practices, or rely on clinical judgement.

Improvement of consistency of policies, procedures and protocols with evidence-based guidelines should be part of your Transfusion Quality Improvement System (refer to Action 7.4.1). This includes actions such as developing and/or reviewing policies, procedures and protocols to ensure alignment with national evidence-based guidelines, and amending such documents as required.

#### Additional information:

A number of references and resources are available.

- National Blood Authority Australia **nba.gov.au** to access the following National Health and Medical Research Council (NHRMC) approved clinical practice guidelines
  - Patient Blood Management Guidelines Module 1: Critical Bleeding Massive Transfusion<sup>7</sup>
  - Patient Blood Management Guidelines Module 2: Perioperative<sup>9</sup>
  - Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics<sup>10</sup>
- Other National Health and Medical Research Council approved guidelines: www.nhmrc.gov.au/guidelines
  - Factor VIII and FIX Guidelines<sup>11</sup>
  - Criteria for the Clinical Use of Intravenous Immunoglobulin<sup>12</sup>
  - Warfarin reversal: consensus guidelines on behalf of the Australasian Society of Thrombosis and Haemostasis<sup>13</sup>

7.1 Developing governance systems for safe and appropriate prescription, administration and management of blood and blood products

(continued)

#### (continued)

**7.1.1** Blood and blood product policies, procedures and/or protocols are consistent with national evidencebased guidelines for pre-transfusion practices, prescribing and clinical use of blood and blood products

- Australian and New Zealand Society of Blood Transfusion (ANZSBT) publications web site: www.anzsbt.org.au/publications/
- National Blood Authority Australia www.nba.gov.au/appropriate use
- Australian Standard for Medical Refrigeration Equipment For the Storage of Blood and Blood Products (AS3864)<sup>14</sup>
- Australian Red Cross Blood Service Blood Component Information Circular<sup>15</sup>
- ANZSBT Guidelines for the Administration of Blood Products<sup>8</sup>
- ANZSBT Guidelines for Pre-Transfusion Laboratory Practice<sup>16</sup>
- National Pathology Accreditation Advisory Council (NPAAC) Requirements for Transfusion Laboratory Practice<sup>17</sup>
- The Australian Red Cross Blood Service Blood Components and Products web site www.transfusion.com.au/blood\_products
- The Australian Red Cross Blood Service Patient web site www.mytransfusion.com.au
- BloodSafe eLearning Australia module on Transporting Blood www.bloodsafelearning.org.au/node/54
- National Blood Authority Australia
   www.nba.gov.au
- NBA BloodNet Web site www.nba.gov.au/bloodnet

- policies, procedures and/or protocols which reference national evidence-based guidelines across the broad range of transfusion practice
- documentation from a patient blood management program
- documentation of assessment of iron status prior to surgery
- communiqués providing national evidence-based guidelines
- tools to support transfusion decision
- orientation and/or training for the clinicians based on national evidence-based guidelines
- prescription forms that align with clinical practice guidelines
- documentation on consultation processes in the development and review of policies, procedures and/or protocols.

7.1 Developing governance systems for safe and appropriate prescription, administration and management of blood and blood products

(continued)

**7.1.2** The use of policies, procedures and/or protocols is regularly monitored

#### Key task:

 Monitor the use of policies, procedures and protocols, and amend them as appropriate

#### Suggested strategies:

You are required to monitor the use of the policies, procedures and/or protocols which were identified or developed in Action 7.1.1. You should ensure these policies, procedures and protocols are readily available to the workforce. Members of the workforce should be trained in the use of such documents and procedures, where appropriate.

This action requires **monitoring** of compliance, rather than requiring compliance. Clinicians are ultimately responsible for decisions regarding patient care and treatment. It is recommended that health service organisations require that where clinical decisions result in a deviation from a protocol, the deviation, and the justification for the deviation then this is recorded. Deviations would routinely be reviewed by the Transfusion Governance Group (refer to Action 7.4.1) to identify outliers. This will assist in identifying where changes in clinical behaviour are appropriate, and where refinement of the policy, procedure and/or protocol may be required to reflect best practice. Further, where adverse patient outcomes are identified through incident monitoring (Action 7.3.1), the Transfusion Governance Group would normally assess whether these incidents could be reduced by improvements to policies, protocols and procedures.

Investigations audit and/or assessment of practices against national evidence-based guidelines: For example, to assess compliance with clinical practice guidelines, a comparison of the use of products by unit/clinician or surgeon per procedure could be undertaken to identify and analyse outliers.

#### Additional information:

See the National Blood Authority Australia web site: www.nba.gov.au/appropriate use

- agendas, meeting minutes and/or reports of relevant committees that detail monitoring of the use of policies, procedures and/or protocols
- reports from audits of compliance with policies, procedures and/or protocols on the prescription and administration of blood or blood products.

7.1 Developing governance systems for safe and appropriate prescription, administration and management of blood and blood products

(continued)

**7.1.3** Action is taken to increase the safety and appropriateness of prescribing and clinically using blood and blood products

#### Key task:

• Implement actions to improve consistency of policies, procedures and protocols identified at Action 7.1.1 with national evidence-based guidelines, as well as compliance with these policies, procedures and protocols, as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)

Action 7.1.2 requires health service organisations to monitor the use of policies, procedures and protocols as well as their consistency with national evidence-based guidelines. Gaps and deviations identified through implementing Action 7.1.2 will determine the actions you will need to undertake to increase the safety and appropriateness of prescribing and using blood and blood products.

#### Suggested strategies:

As part of the Transfusion Quality Improvement System (refer to Action 7.4.1) you should identify and implement changes that will address non-compliance by:

- providing feedback to clinicians on results of clinical audits against guidelines
- amending of policies, procedures and/or protocols where appropriate
- educating, training, and distributing communications and information resources that actively address quality and safety deficits in appropriate prescribing and clinical use of blood and blood products.

- Documentation developed under Action 7.4.1 specifically relating to compliance with the use of policies, procedures and protocols across the range of transfusion practices:
  - pre-transfusion practice
  - prescribing practice and clinical use of blood and blood products
  - administration of blood and blood products
  - management of blood and blood products, including receipt, storage, collection and transport.

7.2 Undertaking a regular, comprehensive assessment of blood and blood product systems to identify risks to patient safety and taking action to reduce risks

**7.2.1** The risks associated with transfusion practices and clinical use of blood and blood products are regularly assessed

#### Key task:

· Regularly review system risks relevant to blood and blood products

The Australian Haemovigilance Report 2010<sup>5</sup> notes that transfusion risks generally fall into two main categories:

- 1 procedural errors such as patient mis-identification and blood sampling errors, and transfusing the wrong blood component
- 2 reactions such as acute transfusion reactions (for example, fever and chills).

#### Suggested strategies:

The administration of blood products involves a number of processes undertaken by multiple clinicians across different disciplines. For this reason, there is increased risk of human or system error. You should identify risks associated with transfusion, particularly risks relating to procedural errors, and the re-design of the system to reduce the potential for patient harm. You are required to regularly and comprehensively review systems for effective and appropriate prescribing, sample collection, cross-matching, transport and storage, and product administration to identify and address weaknesses that create the potential for error and patient harm.

To identify system weaknesses, you could:

- regularly assess risks relating to the systems you have in place for transfusion practice and clinical use of blood and blood products
- use horizon scanning for emerging risks (e.g. new products requiring different procedures or equipment to administer the product)
- regularly assess blood related incident reports, including near misses and root causes (as developed under Action 7.3.1)
- develop and monitor transfusion related key performance indicators to ensure that blood related risks are identified and addressed.

It is also important to remember that risks associated with the administration of blood products may be reduced by avoiding the transfusion altogether, and assessing the benefits of alternative treatments. However the risks of those treatments must themselves be assessed.

Action 1.5.1 requires the use and monitoring of an organisation-wide risk register. Assessment of the impact and likelihood of risks relating to transfusion will assist you make decisions about which, if any, transfusion related risks should be included in the organisation-wide risk register.

#### Additional information:

AS/NZS ISO 31000:2009, Risk management – Principles and guidelines<sup>19</sup>

7.2 Undertaking a regular, comprehensive assessment of blood and blood product systems to identify risks to patient safety and taking action to reduce risks (continued)

<i>(continued)</i> <b>7.2.1</b> The risks associated with transfusion practices and clinical use of blood and blood products are regularly assessed	<ul> <li>Outputs of improvement processes may include:</li> <li>risk assessment policy and procedure that includes assessment of blood-related risks</li> <li>a risk register or log</li> <li>other risk assessment documentation</li> <li>incident management system reports of blood-related incidents and associated root cause analyses if required</li> <li>horizon scanning reports relating to risks associated with blood and blood products</li> <li>minutes and/or reports of relevant governance committees confirming that risks are regularly reviewed and actioned</li> <li>examples of data capture and analysis to identify risks associated with prescribing, handling and/or administration of blood and blood products</li> <li>data collected pre and post interventions, analysed and tabled for review at governance meetings</li> <li>key performance indicators relating to blood related risks</li> <li>management strategies that help minimise the likelihood of transfusion (including any patient blood management programs).</li> </ul>
<b>7.2.2</b> Action is taken to reduce the risks associated with transfusion practices and the clinical use of blood and blood products	<ul> <li>Key task:</li> <li>Implement actions to reduce systems risks relevant to blood and blood products identified at Action 7.2.1 as part of your Transfusion Quality Improvement System (Action 7.4.1)</li> <li>Suggested strategies:</li> <li>As part of the Transfusion Quality Improvement System (Action 7.4.1) it is expected that actions are taken to mitigate system-related transfusion risks based on the assessment of likelihood and impact of the risk. Specific actions to address risks identified at Action 7.2.1 should include activities such as communicating issues to the workforce educating clinicians on appropriate practice and implementing change processes to improve clinical practice.</li> <li>Action 1.5.2. requires that actions are taken to minimise risks to patient safety and quality of care. The actions undertaken with relation to transfusion contribute toward the risk minimisation strategies identified in Action 1.5.2.</li> <li>Additional information:</li> <li>Blood safe learning resources available at: www.bloodsafelearning.org.au</li> <li>Institute for Healthcare Improvement web site: www.IHI.org</li> <li>AS/NZS ISO 31000:2009, <i>Risk management – Principles and guidelines</i><sup>19</sup></li> <li>Outputs of improvement processes may include:</li> <li>documentation developed under Action 7.4.1 specifically relating to mitigation of system-related risks</li> </ul>

7.3 Ensuring blood and blood product adverse events are included in the incidents management and investigation system

**7.3.1** Reporting on blood and blood product incidents is included in regular incident reports

#### Key task:

 Capture blood related incidents in your incident management system and provide reports from this system to the Transfusion Governance Group to inform activities in the Transfusion Quality Improvement System (refer to Action 7.4.1)

An incident is an adverse event, adverse reaction, or near miss, where the patient experienced actual or potential harm. Adverse reactions, adverse events and near misses relating to blood and blood products often go unrecognised and unreported.<sup>5,19</sup>

#### Suggested strategies:

It is expected that transfusion related incidents, including near misses, are captured in your incident management system (see Action 1.14). This system would normally include a category for incidents relating to blood and blood products. This information would routinely be reported to the Transfusion Governance Group (refer to Action 7.4.1) for analysis. This analysis will feed into the assessment of risks (as described at Action 7.2.1) and implementation of risk mitigation strategies (as described at Action 7.4.1).

We recommend that your local incident reporting aligns with state and national haemovigilance requirements, including classification of incidents under Action 7.3.3.

#### Additional information:

Blood Component Information (BCI)<sup>15</sup>

NBA Haemovigilance Reports 2008<sup>5,19</sup>

National Haemovigilance Data Dictionary<sup>20</sup>

Australian Bleeding Disorders Registry web page: www.nba.gov.au/abdr/

Blood Matters – Serious Transfusion Incident Reporting<sup>21</sup>

BloodSafe - Flippin' Blood<sup>22</sup>

- policies, procedures and/or protocols for reporting and managing incidents including adverse reactions and near misses relating to use of blood and blood products
- a report from your incident management system identifying incidents relating to blood and blood products
- minutes of the Transfusion Governance Group meeting that documents the review of the incident report
- record of clinical workforce attending education on recognition, documentation and reporting of adverse reactions, incidents and events
- review of incidents by the hospital Transfusion Governance Group to verify and align with state and national reporting requirements.

7.3 Ensuring blood and blood product adverse events are included in the incidents management and investigation system (continued)

<b>7.3.2</b> Adverse blood and blood product incidents are reported to and reviewed by the highest level of governance in the health service organisation	Key task:
	<ul> <li>Provide a summary analysis of blood and blood product related incidents to the highest level of governance in your health service organisation, for review and action</li> </ul>
	Suggested strategies:
	Action 1.14.5 requires incidents and analysis of incidents to be reviewed at the highest governance level of the organisation. To do this you will need to develop high level summary and analysis of the incidents reported under Action 7.3.1, and provide it to the highest level of governance for review.
	The highest governance level of a health service organisation has a critical role in monitoring the actions of groups within your health service organisation, and ensuring the accountability of the actions of these groups. They also have a role in allocation of resources to improve patient outcomes.
	Outputs of improvement processes may include:
	<ul> <li>a summary and analysis report relating to blood and blood product related incidents which were provided to your highest level of governance</li> </ul>
	<ul> <li>minutes of a meeting of your highest level of governance documenting discussion of incidents relating to blood and blood products, including actions as appropriate.</li> </ul>
<b>7.3.3</b> Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at state or national level	<ul> <li>Key task:</li> <li>Identify and implement local processes for participation in state and/or national haemovigilance programs</li> </ul>
	Suggested strategies:
	In addition to haemovigilance at a local level (as required under Action 7.3.1), it is recommended that you also participate in either state or national haemovigilance. National data collection contributes to the understanding of transfusion related errors, and allows for identification of safety and quality measures to deliver better transfusion outcomes. In many cases, a state or territory government will generate information about blood related incidents from the organisation-wide incident management system. In other cases, you may need to submit the information.
	While information collected about incidents related to the administration of blood and blood products varies between states and territories, all states and territories have agreed to align the information they collect about transfusion to allow very specific transfusion related information to be collected and provided for the purpose of national reporting. You can find definitions and types of adverse events that should be reported, as well as a national data set and data definitions, in the <i>National Haemovigilance Data Dictionary</i> . <sup>20</sup>

#### **Implementation strategies Actions required**

7.3 Ensuring blood and blood product adverse events are included in the incidents management and investigation system (continued)

(continued)	Additional information:
<b>7.3.3</b> Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at state or national level	National Haemovigilance Reports <sup>5,19</sup>
	National Haemovigilance Data Dictionary <sup>20</sup>
	Jurisdictional blood programs:
	<ul> <li>New South Wales – Blood Watch www.cec.health.nsw.gov.au/programs/blood-watch</li> </ul>
	<ul> <li>Queensland – Queensland Incidents in Transfusion www.health.qld.gov.au/qhcss/qbmp/qiit.asp</li> </ul>
	<ul> <li>South Australia – BloodSafe www.health.sa.gov.au/bloodsafe/</li> </ul>
	<ul> <li>Victoria – Serious Transfusion Incident Reporting www.health.vic.gov.au/bloodmatters/tools/stir.htm</li> </ul>
	Outputs of improvement processes may include:
	<ul> <li>policies, procedures and/or protocols identifying your haemovigilance reporting obligations</li> </ul>
	• reports which you have provided to state or national haemovigilance reporting systems.
7.4 Undertaking qu	ality improvement activities to improve the safe management of blood

and blood products

#### **7.4.1** Quality improvement activities are undertaken to reduce the risks of patient harm from transfusion practices and the clinical use of blood and blood products

#### Key tasks:

- Develop and implement a Transfusion Quality Improvement System which identifies and implements actions to improve the quality of practice across the range of activities relating to blood and blood products
- Identify or develop a Transfusion Governance Group to oversee the Transfusion • Quality Improvement System

Standard 7 requires monitoring of practices and identified risks to patients relating to transfusion of blood and blood products.

#### Suggested strategies:

In order to achieve practice improvement, you are required to have in place a Transfusion Quality Improvement System which assesses risks and implements actions to reduce such risks. This Transfusion Quality Improvement System brings together all identified risks and actions across the full range of transfusion practices described in Standard 7, as follows:

- Action 7.1.3, which aims to improve consistency of policies, protocols and procedures with national evidence-based guidelines and compliance with such policies, protocols and procedures
- Action 7.2.2, which aims to reduce system risks
- actions to reduce risks identified through analysis of incidents including adverse events and near misses identified through Action 7.3.1.
- Action 7.5.3, which aims to increase compliance with comprehensive documentation of transfusion in the patient clinical record

7.4 Undertaking quality improvement activities to improve the safe management of blood and blood products (continued)

#### (continued)

**7.4.1** Quality improvement activities are undertaken to reduce the risks of patient harm from transfusion practices and the clinical use of blood and blood products

- Action 7.6.2, which aims to reduce risks to individual patients from administration of blood or blood products
- Action 7.7.2, which aims to reduce risks associated with receipt, storage, collection and transport of blood and blood products
- Action 7.8.2, which aims to reduce wastage of blood and blood products
- Actions to improve compliance with informed consent policies identified in Actions 7.10.1 and 7.11.1.

The Transfusion Governance Group develops and oversees the Transfusion Quality Improvement System. This system identifies and coordinates actions to improve the quality of practice across the range of activities relating to blood and blood products. The Transfusion Quality Improvement System should consist of activities to:

- assess all risks identified by reviewing reports provided to the Transfusion Governance Group
- identify recurring issues or patterns in incidents
- conduct a root case analysis of incidents, where appropriate
- identify specific actions to address risks identified the level of action should be commensurate with the gap between current practice and best practice
- identify outcome measures to gauge the success of those actions
- evaluate effectiveness against outcome measures
- identify further actions required.

In small health service organisations, the roles and responsibilities of the Transfusion Governance Group may be much broader than blood and blood product management.

- documentation relating to the Transfusion Quality Improvement System across the full spectrum of activities identified under this Standard
- terms of reference for a Transfusion Governance Group responsible for overseeing the Transfusion Quality Improvement System
- position descriptions identifying roles, responsibilities and accountabilities for the management of the Transfusion Quality Improvement System
- agenda papers, meeting minutes and/or reports of the Transfusion Governance Group that detail improvement actions
- examples of improvement activities that have been implemented and evaluated
- · documentation relating to evaluation, audit and feedback processes
- benchmarking data, including relating to the use of blood and blood products for particular indications or interventions, and documentation that this data was available to and reviewed by the clinical community
- a risk register or log which identifies and assesses risks across the full spectrum of activities identified under this Standard
- an action plan addressing risks, based on the risk assessment, as well as other quality improvement activities
- attendance records and/or the results of competency-based training of the workforce (proportion of the workforce trained)
- communication to the workforce identifying risks and outlining the roles and responsibilities in mitigating risks and implementing performance improvement.



### Standard 7 Criterion: Documenting patient information

The clinical workforce accurately records a patient's blood and blood product transfusion history and indications for use of blood and blood products

Accurately recording a patient's blood and blood product transfusion history including any previous reactions and specific indications for use in the patient clinical record (written or electronic) is essential to facilitate easy and accurate review of records. Blood and blood products can be implicated in recalls or lookback processes by the Australian Red Cross Blood Service (Blood Service) and/or other commercial suppliers. A list of these suppliers may be found on the NBA web site www.nba.gov.au. It is important for the health service organisation to be able to locate the fate of all blood and blood products to allow for recall where possible and treatment, testing and/or counselling of the recipient as required. This can only be achieved through the availability of wellmaintained records regarding the fate of all blood and blood products.

Review of transfusion history is also an important component of the pre-transfusion process. It can allow for identification of any red cell antibodies, transfusion reactions or special requirements of the patient.<sup>23</sup> Thorough review of a patient's transfusion history can improve the safety of transfusions by reducing the risk of an adverse transfusion reaction.

In addition, the recording of detailed information around transfusion is important to allow for audit of the patient clinical record. For example, documenting the indication for transfusion is essential to allow audit of transfusions against guidelines (as identified as an implementation strategy under Action 7.1.3).

7.5 As part of patient treatment plan, clinical workforce accurately documenting:

- relevant medical conditions
- indications for transfusion
- any special product or transfusion requirements
- known patient transfusion history
- type and volume of product transfusion
- patient response to transfusion

**7.5.1** A best possible history of blood product usage and relevant clinical and product information is documented in the patient clinical record

#### Key task:

 Document comprehensive information regarding transfusion of blood and/or blood products in the patient clinical record

#### Suggested strategies:

The integrated patient clinical record required under Action 1.9.1 is expected to include a record of the administration of blood components. The following information should routinely be documented in the patient clinical record:

- patient consent or refusal, including documentation of the provision of information, as per Actions 7.10.1 and 7.11.1
- relevant medical conditions
- indications for transfusion or administration of the blood product
- any special product or transfusion requirements e.g. irradiated products
- known patient transfusion history
- blood or blood product identification to ensure traceability such as the blood pack donation numbers (or the product ID and batch number for plasma and recombinant blood products)
- blood transfusion compatibility label, or where used, the report form if applicable (this includes a statement of compatibility)
- type and volume of product transfused or administered
- date and time of both commencement and completion of transfusion
- evidence of observations documented on an appropriate form chart
- patient response to administration of blood products, including occurrence and management of any adverse reactions.

Transfusion details should also routinely appear in discharge documentation. If the patient becomes unwell after receiving blood, their transfusion history is important for the treating doctor.<sup>23</sup>

You should consider developing local protocols for recording transfusions in the patient clinical record. Further guidance regarding the administration of a blood transfusion, as well as documentation of the transfusion, is in the *Guidelines for the Administration of Blood Products*.<sup>8</sup> All clinicians involved in the clinical administration or prescription of blood or blood products are expected to receive orientation or training on patient record taking.

- examples of training attendance on patient record taking by clinicians who administer or prescribe blood products
- evidence of protocols relating to documentation of transfusion in the patient medical record
- a form or IT solution in the patient clinical record that prompts the inputting of all required information.

**7.5.2** The patient clinical records of transfused patients are periodically reviewed to assess the proportion of records completed

#### (continued)

#### Key task:

• Undertake an audit of the contents of the patient clinical record to assess compliance with the requirements of Action 7.5.1

#### Suggested strategies:

Action 1.9.2 requires the patient clinical record to be designed so as to allow for systematic audit of the contents against the requirements of these Standards. You should undertake an audit of the contents of the patient clinical record to assess compliance with the requirements of Action 7.5.1. Details of this audit should be included in the organisation's audit plan. The audit should reveal the level of compliance with documentation against the requirements of Action 7.5.1 and/or the protocol for documentation relating to transfusion (if developed to support implementation of Action 7.5.1).

While compliance with the specific requirements under Action 7.5.1 may be achieved through audit of the patient clinical record alone, you will also need to establish a process for identifying the proportion of patient clinical records which do not document transfusion. This could be achieved by auditing the fate of the product as recommended under Action 7.8.1 against completed patient records.

#### Outputs of improvement processes may include:

- your organisation-wide audit plan which includes a regular audit of the patient clinical record
- a report from an audit of the patient clinical record referred to in Action 1.9.2 and required under 7.5.2 confirms that all required information on the administration of blood components is included in the patient record
- sample analysis of fate of product against the patient clinical record to estimate the proportion of patient clinical records that do not identify a transfusion has occurred.

#### Key task:

• Take action to improve compliance with documentation of transfusion in the patient clinical record required under Action 7.5.1 as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)

#### Suggested strategies:

The activities implemented under this action should be developed based on the level of compliance recording in patient clinical records (Actions 7.5.1 and 7.5.2). The Transfusion Governance Group should routinely identify recurring issues, and monitor any incidents associated with incomplete patient records, as well as implement improvement strategies as part of the Transfusion Quality Improvement System to improve compliance with Action 7.5.1. These strategies may include:

- ensuring members of the clinical workforce are trained on documentation requirements relating to transfusion
- developing an action plan to improve compliance, and monitoring implementation of the action plan
- increasing circulation and/or developing new communiqués for clinicians involved in administration or prescription of blood and blood products addressing the risks identified.

#### Outputs of improvement processes may include:

 documentation developed under Action 7.4.1 specifically relating to increasing the proportion of patient clinical records of transfused patients with a complete patient clinical record.

**7.5.3** Action is taken to increase the proportion of patient clinical records of transfused patients with a complete patient clinical record

7.6 The clinical workforce documenting any adverse reactions to blood or blood products

**7.6.1** Adverse reactions to blood or blood products are documented in the patient clinical record

#### Key task:

• Train the workforce to recognise and respond to adverse transfusion reactions, and document adverse reactions in the patient clinical record

#### Suggested strategies:

Transfusion related adverse events can be associated with significant rates of morbidity or mortality.<sup>8</sup> One of the processes that can reduce the risk of an adverse event from a transfusion is to assess the patient for a history of red cell antibodies, transfusion reactions, or any other special transfusion requirements.<sup>23</sup> To enable this checking, it is important that adverse reactions to blood or blood products are documented in the patient clinical record. As Action 7.5.1 already requires the documentation of transfusion reactions in the patient clinical record, strategies implemented under Action 7.5.1 are sufficient to meet this component of this action.

To enable documentation of adverse reactions, members of the clinical workforce will require orientation and training in the recognition, response and reporting of suspected transfusion reactions. The *Guidelines for the Administration of Blood Products*<sup>8</sup> identifies the importance of recognising, reacting and reporting suspected transfusion events.

#### Additional information:

Useful information can be found at:

- Queensland Incidents in Transfusion web site www.health.qld.gov.au/qhcss/qbmp/qiit.asp
- Flippin' Blood www.transfusion.com.au/resources/flippin-blood/index.html

- training protocols which refer to recognition of transfusion reactions
- attendance records and/or results of competency-based training on the reporting of adverse transfusion reactions
- supporting evidence will include that generated through Action 7.5.1.

#### Implementation strategies

7.6 The clinical workforce documenting any adverse reactions to blood or blood products (continued)

**7.6.2** Action is taken to reduce the risk of adverse events from administering blood or blood products

#### Key task:

 Implement practices to identify at-risk patients and reduce transfusion related risks as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)

While Action 7.2.2 describes strategies you should undertake to reduce the risks associated with the administration of blood or blood products, this action relates to risks of transfusion specific to individual patients.

As identified in Action 7.6.1 one reason for documenting adverse events following administering blood or blood products is to enable identification of previous adverse reactions or special transfusion requirements.

#### Suggested strategies:

You are required to review patient clinical records and discuss with the patient previous and current transfusion risks prior to transfusion to identify at-risk patients. Action 1.8.2 requires you to undertake early action to reduce the risks for at-risk patients. This may involve:

- prescribing and ordering special products to suit the transfusion need of the patient
- amending administration practices such as infusion rate
- monitoring the patient more closely during a transfusion
- undertaking bedside checks pre-transfusion
- matching patient and intended treatment as per Action 5.5.3.

A checklist for blood product checking is included in the *ANZSBT Guidelines*<sup>8</sup> and organisational blood and blood product management policies, procedures and/or protocols should be consistent with this guideline.

- pre-transfusion protocol (identified at Action 7.1.1) which requires review of patient transfusion history
- education resources and records of attendance at training by the workforce on the requirement to review patient transfusion history is critical prior to transfusion
- administration protocols (identified at Action 7.1.1) which include a checklist for blood product checking at the patient bedside to reduce risk of incorrect administration of a blood or blood product.

**Actions required** 

#### Implementation strategies

**7.6.3** Adverse events are reported internally to the appropriate governance level and externally to the pathology service provider, blood service or product manufacturer whenever appropriate

#### Key task:

 Report adverse events in accordance with regulator and supplier requirements, as well as local policies and procedures

Action 7.3.1 requires adverse events to be recorded in the organisation's incident reports, Action 7.3.2 requires review by the highest governance in the organisation, and Action 7.3.3 recommends reporting to state or national haemovigilance committees. This action requires you to also report adverse events to the pathology service provider, Blood Service, or the product manufacturer. You may also be required to report the adverse event to the Therapeutic Goods Administration. Reporting to these organisations is important as adverse transfusion events may assist in the identification of other patients at risk because of patient identity error (e.g. ABO-incompatible transfusion to a second patient), because other blood components collected from the implicated donor may also be affected (e.g. in cases of bacterially contaminated blood components)<sup>8</sup>, or because it may assist in monitoring safety and quality of a product (e.g. allergic reactions). The *Blood Component Information Booklet*<sup>15</sup> describes adverse reactions, and identifies which reactions must be reported to the Blood Service. For commercial products you will need to check with the manufacturer to identify their adverse event reporting requirements. Links to the suppliers can be found by accessing the NBA web site www.nba.gov.au.

#### Suggested strategies:

Given the complexity and multifaceted reporting requirements for transfusion related adverse events it is recommended you have a policy, procedure or protocol in place which identifies the classes of transfusion related adverse event which must be externally reported, that includes the timeframe for reporting.

- policies, procedures and/or protocols identifying your haemovigilance reporting obligations
- reports which you have provided to the pathology service provider, Blood Service or product manufacturer.



### Standard 7 Criterion: Managing blood and blood product safety

### Health service organisations have systems to receive, store, transport and monitor wastage of blood and blood products safely and efficiently

The Stewardship Statement states that health service organisations should have processes, programs and systems in place that ensure the safe and efficient receipt, storage and transport of blood and blood products and that minimise wastage of these products and that national blood product planning, management and governance are supported by:

- health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and
- inventory data is provided on a regular and timely basis to assist in supply and demand planning requirements especially in times of national shortages.

Many of the risks associated with receipt, storage, collection and transport of blood and blood products can be avoided. Systems and processes can be designed to reduce these risks. Systems for cold chain integrity, sample collection, cross-matching, product collection, and inventory management including storage, handling and transport should be monitored to identify and address weak spots that increase the risk of human error and handling and any subsequent patient harm or wastage. As described in Action 7.1.1, these should align with better practice standards and guidelines. There are a number of publications and resources that deal with the safe handling of blood and blood products. These include:

- Australian Standard for Medical Refrigeration Equipment – For the Storage of Blood and Blood Products (AS3864)<sup>14</sup>
- Australian Red Cross Blood Service Blood Component Information Circular<sup>15</sup>
- ANZSBT Guidelines for the Administration of Blood Products<sup>8</sup>
- ANZSBT Guidelines for Pre-Transfusion Laboratory Practice<sup>16</sup>
- National Pathology Accreditation Advisory Council NPAAC Requirements for Transfusion Laboratory Practice<sup>17</sup>
- The Australian Red Cross Blood Service Blood Components and Products web site www.transfusion.com.au/blood\_products
- BloodSafe eLearning Australia module on Transporting Blood www.bloodsafelearning.org.au/node/54
- NBA BloodNet web site www.nba.gov.au/bloodnet/

7.7 Ensuring the receipt, storage, collection and transport of blood and blood products within the organisation are consistent with best practice and/or guidelines

**7.7.1** Regular review of the risks associated with receipt, storage, collection and transport of blood and blood products is undertaken

#### Key task:

 Review processes and policies for addressing risks identified with receipt, collection, storage, handling and transport of blood and blood products, and review reports from your inventory management systems

There are defined storage and handling requirements for blood and blood products. You are required to ensure these requirements are met. Failure to meet the requirements may result in degradation in product quality, and can result in risk of patient morbidity or mortality.

As identified in Action 7.1.1, you should have policies, procedures and/or protocols relating to the management of blood and blood products, including receipt, storage, collection and transport of blood and blood products. These should cover how products are ordered, receipted, stored, handled and transported in the facility, including refrigeration protocols, inventory management process and cold chain integrity.

#### Suggested strategies:

To identify the potential risks in systems, you should:

- assess compliance with policies, procedures and/or protocols relating to the management of blood and blood products, including receipt, storage, collection and transport of blood and blood products (as required in Action 7.1.2)
- regularly review reports on receipting, collection, storage and transport of blood and blood products within the facility
- monitor incidents relating to receipt, storage, collection and transport of blood and blood products and identify recurring issues
- monitor inventory levels to ensure product availability to meet clinical demand
- monitor wastage of blood and blood products (as required under Action 7.8.1)
- review the risks identified against the reports from the blood and blood product management systems, such as refrigeration temperature reports and temperature loggers.

Health service organisations are encouraged to use electronic systems (e.g. BloodNet) to monitor receipt, transfer and fate (including wastage) of blood and blood products.

Where blood management within a facility is outsourced, contracts with providers would need to include requirements to both address the strategies identified, and to provide the health service organisation with sufficient information to confirm they are implemented. You need to monitor compliance of their blood management provider with these strategies.

- reports of audits of the use of policies, procedures and protocols for the receipt, transportation, handling and storage of blood and blood products
- a register of blood and blood products which is appropriately maintained and reviewed
- audits of documentation accompanying blood and blood products, delegation records, maintenance records and performance testing of refrigerators and freezers used for storing blood and blood products
- observational audit of the use of checking processes for labels and dates when blood or blood products are handled
- other accreditation processes where these strategies are assessed (as relevant to the laboratory).

Actions required

#### Implementation strategies

7.7 Ensuring the receipt, storage, collection and transport of blood and blood products within the organisation are consistent with best practice and/or guidelines (continued)

Key task:
<ul> <li>Implement actions to reduce risks associated with receipt, storage, collection and transport of blood and blood products, as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)</li> </ul>
Suggested strategies:
The activities implemented under this action should be based on the risk assessment conducted at Action 7.7.1.
These strategies will be implemented as part of the Transfusion Quality Improvement System (refer to Action 7.4.1) to reduce risks identified at Action 7.7.1. These strategies may include:
<ul> <li>ensuring workforce are trained in receipt, storage, collection and transport of blood and blood products</li> </ul>
<ul> <li>increasing circulation and/or development of new communiqués for clinicians involved in management of blood and blood products addressing the risks identified.</li> </ul>
Outputs of improvement processes may include:
<ul> <li>documentation developed under Action 7.4.1 specifically relating to reduce the risk of incidents arising from the receipt, storage, collection and transport of blood and blood products.</li> </ul>

#### 7.8 Minimising unnecessary wastage of blood and blood products

**7.8.1** Blood and blood product wastage is regularly monitored

#### Key task:

#### · Record wastage in a system and monitor wastage reports

The Stewardship Statement for the Supply of Blood and Blood Products communicates the expectation from Health Ministers that health service organisations have processes, programs and facilities in place to minimise the wastage of blood products.

Wastage can be defined as loss resulting from carelessness, inefficiencies or even inappropriate use. Product discard is an important component of wastage. Note that due to the short shelf life of some products (particularly fresh blood products), health service organisations may have some policies in place to ensure enough product is available to meet clinical need and these policies may present limits to the complete elimination of wastage. The goal is to minimise discard while still ensuring product availability. For the purpose of this Action, you should monitor and report all discards.

#### Suggested strategies:

You should ensure documented processes and systems are in place to record fate of product by type. Health service organisations are encouraged to use electronic systems (e.g. BloodNet) to record discard as part of the fate of product. These processes clearly outline:

- what is to be reported and how
- the format in which it is to be reported
- to whom it should be reported, including the Transfusion Governance Group.

Where blood management within a health service is outsourced, contracts with providers would routinely include the requirements identified above, and provide the health service with sufficient information to confirm the routine monitoring of blood and blood product wastage. This requires a system to monitor compliance of their blood and blood products provider(s) with these strategies.

- policies, procedures and/or protocols on the minimisation of wastage of blood or blood products
- reconciled wastage reports from pathology laboratories
- audit of compliance of usage and disposal of blood and blood products against policy and procedures
- review of audit results by relevant committees
- use of an electronic wastage monitoring system such as BloodNet Fate Module
- reports on usage and wastage which were provided to the Transfusion Governance Group to monitor performance and make necessary changes to procedures
- comparison with state and national data.

#### **Implementation strategies**

#### 7.8 Minimising unnecessary wastage of blood and blood products

**7.8.2** Action is taken to minimise wastage of blood and blood products

#### Key task:

• Develop and implement an action plan to improve compliance with and minimise wastage rates identified in Action 7.8.1 as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)

#### Suggested strategies:

The activities implemented under this action will be developed based on risk assessment conducted at Action 7.8.1.

These strategies will be implemented as part of the Transfusion Quality Improvement System (refer to 7.4.1) to reduce the risks identified at Action 7.8.1. These strategies may include:

- identifying a target for wastage, based on targets communicated at a state or national level (note: the level of wastage will be product specific, and will also depend on the range of services provided by the facility)
- identifying appropriate inventory levels that ensure appropriate blood and blood products are available to meet clinical demand while minimising wastage
- identifying appropriate inventory management strategies or practices e.g. first-in-first-out (FIFO)
- communicating wastage targets to the workforce, making sure that you also communicate that meeting the target is not a goal in itself – that is, where product is available but is not clinically indicated, you should not encourage use of the product to reduce wastage
- benchmarking against your current wastage level, and against other similar health service organisations
- identifying strategies to ensure products remain within specifications so that they do not need to be disposed of, including maintaining temperature requirements, reduction in unnecessary handling, and appropriate storage.

- documentation developed under Action 7.4.1 specifically relating to reduced wastage of blood and blood products
- records of compliance with appropriate policies, procedures and protocols on the minimisation of wastage of blood or blood products
- documentation of your wastage target
- documentation of appropriate inventory levels
- communication to the workforce on wastage targets
- comparative performance data.



### Standard 7 Criterion: Communicating with patients and carers

Patients and carers are informed about the risks and benefits of using blood and blood products and about the available alternatives when a plan for treatment is developed

The Stewardship Statement www.nba.gov.au/policy/ stewardship-statement.html states that informed patient consent procedures should be implemented for all patients receiving blood. Informed consent is a legal procedure undertaken to ensure that a patient understands the risks involved with a transfusion. The elements of informed consent include informing the patient of the nature of the treatment, possible alternative treatments, and the potential risks and benefits of the treatment. In order to enable patients to be informed about the risks and benefits of a blood transfusion, and possible alternatives, the development and dissemination of information for patients relating to blood and blood products is required. Health service organisations should develop and/or identify information relating to transfusion. This information should be easy to understand by a patient, and as such a range of information of differing complexities may need to be developed.

All health service organisations are required to document informed consent. Development or identification of a protocol is required to facilitate consistency of the implementation of the informed consent procedure.

#### **Actions required**

#### Implementation strategies

7.9 The clinical workforce informing patients and carers about blood and blood product treatment options, and the associated risks and benefits

#### 7.9.1 Patient

information relating to blood and blood products, including risks, benefits and alternatives, is available for distribution by the clinical workforce

#### Key task:

 Develop and/or identify appropriate resources for patients relating to blood and blood products, including risks, benefits and alternatives. Ensure these resources are readily available to clinicians for distribution to patients

#### Suggested strategies:

You may need to develop or identify information which can be provided to patients about blood and blood products including alternatives, risks and benefits.

Information should be at a level that can be understood by the general public. It may be appropriate to identify or develop both simpler and more complex information resources, so that clinicians have access to the most appropriate information for an individual patient. Written information and diagrams may be appropriate in certain circumstances to aid understanding. Patient information may be available through web site links where the clinical team considers this to be an appropriate communication method for that individual. Health service organisations are responsible for ensuring the information provided to patients is current.

Where local information or resources are developed, it is expected that patients and/or carers will be involved in its development (as per Action 2.4).

Examples of information which can be locally adapted include:

- NHMRC Blood Components A guide for patients<sup>24</sup>
- NHMRC Blood Who Needs It? consumer brochure<sup>25</sup>
- Australian Red Cross Blood Service Patient web site www.mytransfuion.com.au
- supplier consumer medicine information.

Jurisdictional blood programs:

- New South Wales BloodWatch www.cec.health.nsw.gov.au/programs/blood-watch
- Queensland Patient Blood Management www.health.qld.gov.au/qhcss/qbmp/default.asp
- South Australia BloodSafe www.health.sa.gov.au/bloodsafe/
- Victoria Blood Matters www.health.vic.gov.au/bloodmatters/
- Western Australia Patient Blood Management www.health.wa.gov.au/bloodmanagement/home/

Information would normally be readily available to clinicians, as printed material or as information on an intranet or internet.

- information which is available for provision to patients, which meets the criteria identified in the implementation strategy. Evidence may include information relating to transfusion of varying complexity, and in one or more languages and be age appropriate
- documentation of the process of review of information identified to ensure its currency
- documentation or advice on how this information can be accessed by clinicians.

7.9 The clinical workforce informing patients and carers about blood and blood product treatment options, and the associated risks and benefits

(continued)

**7.9.2** Plans for care that include the use of blood and blood products are developed in partnership with patients and carers

#### Key task:

• Develop a plan for care relating to blood and blood products in partnership with the patient and their carer

#### Suggested strategy:

Plans for the care of a patient should identify the patient blood management strategy, including identification of when and why transfusion of blood and/or blood products may be required, and any treatment alternatives. The plan for care would routinely be developed in partnership with patients and carers. Plans for care that relate to the administration of blood products may be specific for an individual patient, or may be in accordance with policies, procedures and/or protocols (as per Action 7.1.1). The plan for care developed should be based on the communication with the patient undertaken at Action 7.10.1, including provision of information relating to blood and blood products, including risks, benefits and alternatives.

This action has been designated as developmental. The requirement to involve patients and carers as partners in the planning for their treatment is a core action at Action 1.18.1.

#### Outputs of improvement processes may include:

- patient records which include a care plan that includes patient blood management strategies
- documentation confirming consultation with the patient occurred in development of their plan for care. This could be through a patient signature on the care plan
- audit report from an audit of patient records of a group of patients (e.g. those attending surgery) to identify the level of compliance with the inclusion of blood and/ or blood products in the care plan, and identify the level of compliance with patient consultation in the development of the plan.

7.10 Providing information to patients about blood and blood product use and possible alternatives in a format that can be understood by patients and carers

**7.10.1** Information on blood and blood products is provided to patients and their carers in a format that is understood and meaningful

#### Key tasks:

- Provide information to patients and their carers about blood and blood product use and possible alternatives, in a format and of a level appropriate for the patient
- Seek feedback on resources provided to patients, and revise resources as required

#### Suggested strategies:

Clinical areas are well placed to identify opportunities to improve communication between clinicians and patients, families and carers about possible requirements for transfusion. The development of a communication strategy that ensures distribution of appropriate resources supports Action 7.9.1 to provide information to patients and carers.

The developmental aspect of this action relates to ensuring it is meaningful and understood. By seeking feedback from patients on the information provided, changes can be made to ensure it is understood and meaningful. You could seek feedback through patient surveys, or more informal discussions with patients and carers.

Where communication with the patient may not be possible, due to the acuteness of their condition, a process to manage situations will also be required. If the patient is unable to speak or understand English, you may need to involve an interpreter.

7.10 Providing information to patients about blood and blood product use and possible alternatives in a format that can be understood by patients and carers (continued)

#### (continued)

**7.10.1** Information on blood and blood products is provided to patients and their carers in a format that is understood and meaningful Documenting the information provided in the patient clinical record (as required under Action 7.5.1), will provide evidence that the informed component of informed consent was being addressed.

It is expected that reports on patient feedback are routinely provided to the Transfusion Governance Group (refer to Action 7.4.1) to assist them in determining the effectiveness of their informed consent procedures. Compliance with provision of this information is monitored through Action 7.11.1.

#### Outputs of improvement processes may include:

- documentation developed under Action 7.4.1 specifically relating to provision of information on blood and blood products to patients and carers
- documentation of the process for communication about blood and blood products
- documentation of evaluation, audit and feedback processes around compliance with the communication protocol
- patient surveys designed to assess whether the resources available achieved patient understanding of blood and blood products
- audit of patients' clinical records that show patients were provided with patient-specific information relating to the risks, benefits of, and alternatives to, blood and blood products.

7.11 Implementing an informed consent process for all blood and blood product use

**7.11.1** Informed consent is undertaken and documented for all transfusions of blood or blood products in accordance with the informed consent policy of the health service organisation

#### Key task:

• Develop and implement an informed patient consent protocol relating to blood and/or blood product transfusion and monitor compliance with the protocol as part of your Transfusion Quality Improvement System (refer to Action 7.4.1)

Action 7.10.1 covers the information provided to patients to inform as part of the informed consent process. This Action relates to the processes of documenting that informed consent. While informed consent is considered an essential part of patient care, this Action has been designated as developmental as it may not be realistic to require 'all' transfusions in a health service to have documented consent. Health service organisations are nonetheless required to have and implement an informed consent process for transfusions.

#### Suggested strategies:

A written protocol for consent, which specifically refers to consent relating to transfusions, should include:

- a requirement for consent to be documented in the patient clinical record (as per Action 7.5.1)
- any forms that may have been developed
- whether the consent can be documented by the clinician, or whether the patient signature is required
- whether the consent is specifically for the transfusion of the blood and/or blood product or is a more general consent

7.11 Implementing an informed consent process for all blood and blood product use (continued)

#### (continued)

**7.11.1** Informed consent is undertaken and documented for all transfusions of blood or blood products in accordance with the informed consent policy of the health service organisation

- the timeframe for the consent, i.e. whether it is to be sought at each transfusion or admission or whether a perpetual consent can be granted
- a process that seeks to assess patient understanding, including a requirement for the clinician to provide documentation identified at Action 7.10.1 and allow the patient sufficient time to ask questions arising from the information
- a process for when consent is unable to be gained (such as emergencies).

Some states and territories have developed consent templates or have identified appropriate consent strategies for use in their jurisdiction. Where these are available, they can be adopted or adapted and applied. Where such policies and/or templates are not available, you should develop a local protocol.

#### Additional information:

Examples of informed consent processes include:

- Queensland Government Effective Blood Use Framework Module 10 www.health.qld.gov.au/qhcss/qbmp/ebu/ebu\_home.asp
- Western Australia Patient Blood Management program www.health.wa.gov.au/bloodmanagement/home/
- Victorian Blood Matters program www.health.vic.gov.au/bloodmatters/
- The South Australia BloodSafe program www.health.sa.gov.au/bloodsafe/

As required under Action 1.18.2 mechanisms must be in place to monitor and improve documentation of informed consent. This should form part of your Transfusion Quality Improvement System (refer to Action 7.4.1).

- documentation developed under Action 7.4.1 specifically relating to implementation and documentation of informed consent or refusal for all transfusions of blood and blood products
- your local informed consent protocol
- documentation of audits of the patient clinical record identifying compliance with documentation of consent (it should include documentation of follow up when the informed consent process was not achieved according to the protocol, and actions to improve compliance with the protocol)
- documentation of patient surveys assessing the quality of the local informed consent protocol.

- 1. Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Health Service Standards*. Sydney. ACSQHC, 2011.
- 2. NSW Department of Health. *Easy Guide to Clinical Practice Improvement: A Guide for Healthcare Professionals.* Sydney, 2002.
- Clinical Excellence Commission (CEC). Enhancing Project Spead and Sustainability – A companion to the 'Easy Guide to Clinical Practice Improvement'. CEC. Sydney, 2008.
- How to Improve. Institute for Healthcare Improvement (US), 2012. (Accessed 3 September 2012, at http://www.ihi.org/knowledge/ Pages/HowtoImprove/default.aspx)
- 5. National Blood Authority Haemovigilance Advisory Committee. *The Australian Haemovigilance Report*. National Blood Authority, 2010.
- 6. The Australian Health Ministers' Conference. Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products. National Blood Authority, 2010.
- 7. National Blood Authority. *Patient Blood Management Guidelines: Module 1 Critical Bleeding Massive Transfusion*. NBA, 2011.
- 8. Australian and New Zealand Society of Blood Transfusion Ltd and Royal College of Nursing Australia. *Guidelines For the Administration of Blood Components*, 2nd Edition. Australian and New Zealand Society of Blood Transfusion Ltd, Sydney, 2011.
- 9. National Blood Authority. *Patient Blood Management Guidelines: Module 2 Perioperative*. NBA, 2012.
- 10. National Blood Authority. *Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics.* NBA, 2003.
- 11. Australian Health Ministers Advisory Council. Evidence-based clinical practice guidelines for the use of recombinant and plasma-derived FVIII and FIX products. 2006.
- 12. The Australian Health Ministers' Conference. Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia. 2007.

- Baker RI, Coughlin PB, Gallus AS, Harper PL, Salem HH, Wood EM. Warfarin reversal: consensus guidelines on behalf of the Australasian Society of Thrombosis and Haemostasis. *Medical Journal of Australia* 2004;181(9):492-497.
- 14. Standards Australia. *AS 3864-1997 Medical* refrigeration equipment – For the storage of blood and blood products. Sydney. Standards Australia, 1997.
- 15. Australian Red Cross Blood Service. Blood Component Information. Melbourne. Australian Red Cross Blood Service, 2012.
- Australian and New Zealand Society of Blood Transfusion Ltd. *Guidelines for Pretransfusion Laboratory Practice, 5th Edition.* Sydney. The Australian and New Zealand Society of Blood Transfusion Ltd, 2007.
- 17. National Pathology Accreditation Advisory Council. *Requirements for Transfusion Laboratory Practice*. Canberra. Australian Government Department of Health and Ageing, 2008.
- Standards Australia/Standards New Zealand. AS/NZS ISO 31000:2009 Risk Management – Principles and guidelines. Standards Australia, 2009.
- 19. National Blood Authority Haemovigilance Project Working Group. *Initial Australian Haemovigilance Report 2008.* National Blood Authority, 2008.
- 20. National Blood Authority Haemovigilance Advisory Committee. *The National Haemovigilance Data Dictionary: Version 3*. Canberra. National Blood Authority, 2010.
- 21. Victorian Department of Health. Serious Transfusion Incident Reporting (STIR) guide. 2011.
- 22. South Australian Department of Health. *Flippin Blood. BloodSafe Program.* 2006.
- BloodSafe Home Welcome to BloodSafe eLearning Australia. 2012. (Accessed 31 May 2012, at www.bloodsafelearning.org.au/node/9)
- 24. National Health and Medical Research Council and Australasian Society of Blood Transfusion. *Blood Components: A Guide for Patients.* Canberra. National Health and Medical Research Council, 2002.
- National Health and Medical Research Council. Blood: Who needs it? Consumer Brochure. Canberra. National Health and Medical Research Council, 2001.

#### Australian Commission on Safety and Quality in Health Care www.safetyandquality.gov.au

#### National Blood Authority

Home page www.nba.gov.au Appropriate Use www.nba.gov.au/appropriate use Australian Bleeding Disorders Registry Homepage www.nba.gov.au/abdr/ BloodNet www.nba.gov.au/bloodnet/

National Health and Medical Research Council Guidelines and Publications www.nhmrc.gov.au/guidelines

Australian and New Zealand Society of Blood Transfusion Publications www.anzsbt.org.au/publications

The Australian Red Cross Blood Service Home page www.transfusion.com.au/ Blood Components and Products web site www.transfusion.com.au/blood\_products Patients web site www.mytransfusion.com.au Flippin' Blood Guide www.transfusion.com.au/ resources/flippin-blood/index.html

#### BloodSafe eLearning Australia

Home page www.bloodsafelearning.org.au/ Transporting Blood www.bloodsafelearning.org.au/node/54

## Institute for Healthcare Improvement web site www.IHI.org

#### Jurisdictional Blood Management Programs

- New South Wales BloodWatch www.cec.health.nsw.gov.au/programs/blood-watch
- Queensland Patient Blood Management Homepage www.health.qld.gov.au/ qhcss/qbmp/default.asp Queensland Incidents In Transfusion www.health.qld.gov.au/qhcss/qbmp/qiit.asp Effective Blood Use Framework www.health.qld.gov.au/qhcss/ qbmp/ebu/ebu\_home.asp
- South Australia BloodSafe www.health.sa.gov.au/bloodsafe/
- Victoria Blood Matters Home page www.health.vic.gov.au/bloodmatters/
- Serious Transfusion Incident Reporting www.health.vic.gov.au/bloodmatters/tools/stir.htm
- Western Australia Patient Blood Management www.health.wa.gov.au/bloodmanagement/home/



#### Australian Commission on Safety and Quality in Health Care

Level 7, 1 Oxford Street, Darlinghurst NSW 2010 GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600 (international +61 2 9126 3600) Fax: (02) 9126 3613 (international + 61 2 9126 3613) Email: mail@safetyandquality.gov.au www.safetyandquality.gov.au