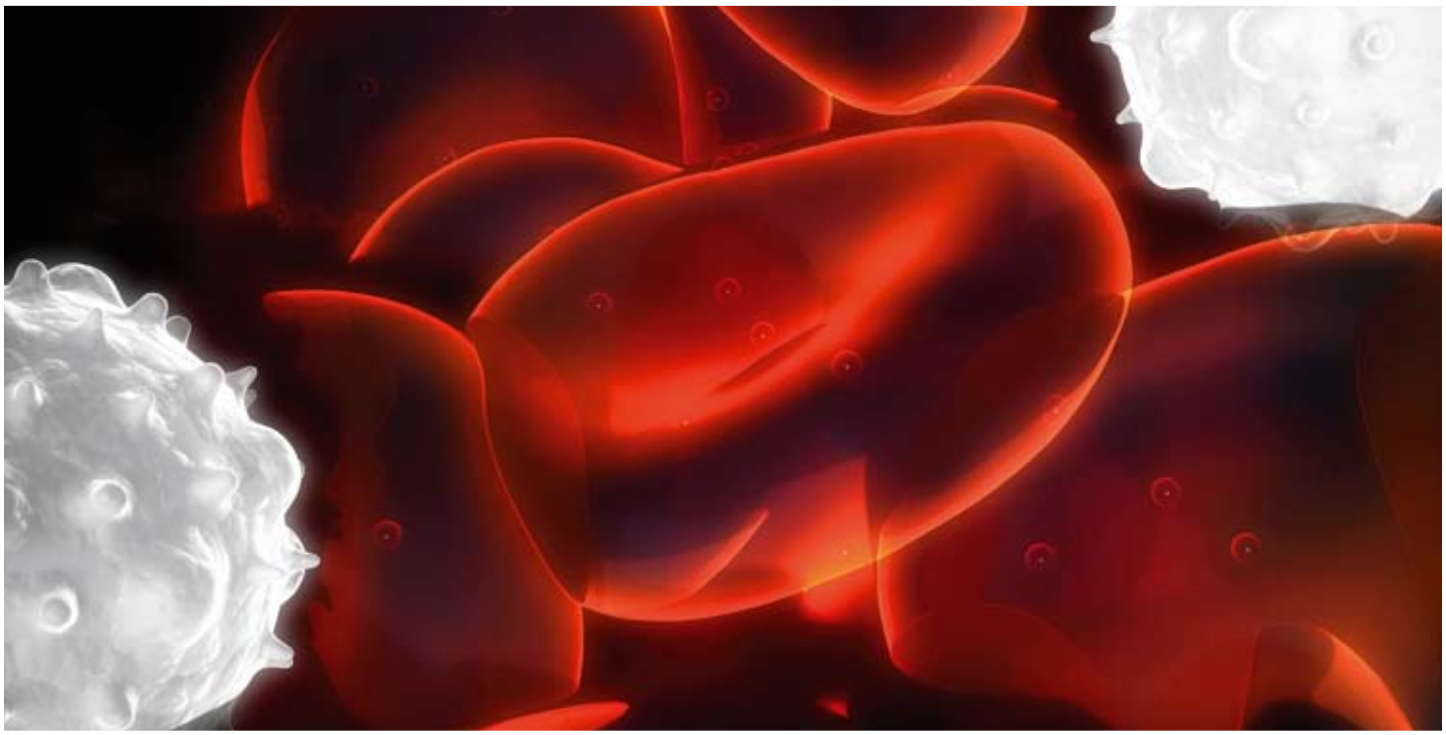
National Blood Authority Australia

Australian Red Cross BLOOD SERVICE



Blood Measures

A Guide to the Set of Standard Measures for the use of Fresh Blood Components in Australia

Consultative draft for comment and use

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Message

from
the General Manager and CEO of the National Blood Authority (NBA) and the CEO of the Australian Red Cross Blood Service (ARCBS)

The Blood Measures Project is a collaborative project between the NBA and the ARCBS. It has a national focus and has involved extensive consultation with jurisdictions and other stakeholders via a National Working Group of voluntary participants. These included both clinical experts and government representatives. The Project is consistent with the mutual goal of our two organisations: to foster good clinical practice and standards of care and the collection of quality data.

The aim of the Project is to develop national data standards to encourage consistent reporting on fresh blood component usage. Over time, this will enable comparable and more comprehensive analysis of blood usage data, which in turn will assist in fostering best practice planning and management systems. Specifically, the project aims to achieve the widespread use by those involved in the collection of blood usage data of:

- a set of standard measures and data collection points which can be included in any investigation of fresh blood component use; and
- a set of standard parameters related to the standard measures which can be used to determine appropriate use of blood.

The *Guide* is the first step in this direction and you will be interested to learn that it is the first attempt to establish a nationally recognised set of standard measures of blood components anywhere in the world.

We would like to acknowledge the hard work of members of the National Working Group (listed in the Appendix) who have given generously of their time to bring the *Guide* to this point.

Now we urge investigators of blood component usage from every part of the health sector to try out the measures contained in this consultative draft of the *Guide*. We welcome feedback on how the measures work in "real life", so that we can make improvements and publish a revised version of the document in 2010. Advice on how to give us your comments and suggestions is given on the next page.

We hope you find the *Guide* useful and look forward to your comments.

Yours Sincerely

Alison Turner
General Manager and CEO
National Blood Authority

Jennifer Williams
CEO
Australian Red Cross Blood Service

How to Comment

This Consultative Draft of the *Guide* is available for comment and use for six months, after which the material will be revised and published as a booklet, as well as being available on the NBA website.

A dedicated email address has been established to receive feedback:

blood.measures@nba.gov.au

The process for handling comments will be as follows:

1. Comments are invited on all aspects of the material – the measures and their definitions, explanatory information, format and style, ease of use
2. Comments should be submitted by email to the address given above, and include:
    a. Name and contact details; we are requesting this information so that NBA staff can contact you to obtain clarification of any issues raised
    b. The measure number(s), or chapter or page number(s) on which comments are being made
    c. Detailed comments, both positive (what worked) and negative (e.g. what was unclear, inaccurate or irrelevant, suggestions for new measures, comments on the prioritisation of measures)
3. All submissions will be acknowledged
4. The deadline for receipt of comments will be 30 June 2010
5. All of the feedback will be collated and considered by the National Working Group for the Blood Measures Project
6. In 2010 the Guide will be revised and published as a booklet; it will also continue to be available electronically

Contents

Foreword

The principal aim of the blood measures project is to focus on the patient end of the blood supply chain and collect reliable data as to where the fresh blood components are being used and for what indications. Surprisingly there has been minimal national and international data available in relationship to the usage of blood components. Until better data is available at the demand end of the blood supply chain it is difficult to realistically manage blood supply. Governments, blood services and the health care industry have a responsibility to ensure that adequate supplies of blood components are available to patients and are used in an appropriate and cost effective manner.

Blood component therapy has a central therapeutic role in clinical medicine. Demand for blood components continues to increase, despite greater attention to the appropriateness of blood transfusion. This is driven by a greater burden of chronic disease due to ageing of the population, a wider range of clinical indications for some blood components, increasing severity of illness with better life-support technology and newer blood-intensive surgical procedures. However, the extent to which this increase is driven by inappropriate use is unknown.

When prescribing blood component therapy, it is important that the clinical problem and patient's needs are accurately identified and clearly understood. In most circumstances therapy is required for haematological deficiencies until the underlying disease process can be corrected (eg surgical control for acute haemorrhage, or support for bone marrow suppression until the marrow recovers).

In recent years the role of blood transfusion in the management of a wide range of clinical settings is being reassessed, especially the use of the labile blood components, including red cells, platelets, fresh frozen plasma and cryoprecipitate. The majority of anaemias can be diagnosed and appropriately managed without red cell transfusion, and careful risk assessment with the use of blood conservation techniques could minimise or eliminate blood transfusion for most elective surgical procedures.

Of greater concern than the uncertainty about the indications and benefits of allogeneic blood transfusion is the accumulating evidence that blood transfusion is an independent risk factor for poorer clinical outcomes. This is not to deny that many of the transfusions are indicated and potentially lifesaving, but there is now a greater focus on alternatives to transfusion, techniques to minimise exposure and closer attention to the quality and immediate efficacy of blood components.

Transfusion tends to be regarded as the "default" decision when there is clinical uncertainty. The benefits of transfusion have been assumed in most clinical circumstances and it is a sobering thought to consider that when there is no evidence to support the benefit of transfusion a patient is unnecessarily exposed to potential morbidity or possibly mortality. The decision-making process for blood component therapy can be difficult and much debate continues in relation to the indications for the use of various blood components. However, there are good reasons to adopt a non-transfusion default position when there is no evidence for potential benefit. Clearly, if allogeneic blood component therapy can be avoided the potential hazards need not be considered.

Evidence based transfusion medicine should regard a patient's own blood as a valuable and unique natural resource that should be conserved and managed appropriately. There should be acknowledgement that altruistically donated blood is a valuable, unique and costly resource that is held in trust that it will be used as therapy when there is evidence for potential benefit and potential harm will be minimised.

Blood component therapy thus continues to have a central therapeutic role in clinical medicine, but the blood sector and transfusion medicine has tended to focus on the blood component supply rather than the demand/patient perspective. The clinical focus should naturally be on "what is best for the patient?" not, "what is best for the blood supply?" This is not to deny the importance of the multiple issues and challenges facing the provision of an adequate and safe blood supply.

James Isbister

Abbreviations and Acronyms

ADP	Adenosine diphosphate
ARCBS	Australian Red Cross Blood Service
APTT	Activated partial thromboplastin time
BP	Blood pressure
DDAVP	Desmopressin
DRG	Diagnostic related group
FFP	Fresh frozen plasma
FVIII	Factor eight — a plasma by-product, a clotting factor that as a concentrate is used to treat haemophilia A
Hb	Haemoglobin
Hct	Haemocrit
HDU	High dependency unit
ICD-10-AM	International Classification of Diseases (10th Revision) (Australian Modification). An internationally recognised list of known diseases and syndromes published periodically by the World Health Organization
ICU	Intensive care unit
INR	International normalised ratio
ISI	International Sensitivity Index
LOS	Length of stay
MAP	Mean arterial pressure
NBA	National Blood Authority
PAD	Pre-operative autologous donation
PT	Prothrombin time
RBC	Red blood cells
TGA	Therapeutic Goods Administration
TTP	Thrombotic thrombocytopenic purpura

Introduction

Background

This *Guide to the Set of Standard Measures for the Use of Fresh Blood Components* (the *Guide*) has been developed as the result of a collaborative project between the National Blood Authority (NBA) and the Australian Red Cross Blood Service (ARCBS).

To fulfil the primary function of the NBA under the *National Blood Agreement*, which is to meet current blood supply needs, an understanding of how and when fresh blood components are used will enable accurate forecasting to ensure adequate supply of this valuable resource.

The ARCBS is a partner with the NBA in needing to understand the parameters that influence the use of fresh blood components. Both organisations appreciate the value which can be gained from establishing a set of national measures of fresh blood components.

There are currently no agreed national approaches to how fresh blood component use is measured. Although there have been a range of initiatives around investigating the use of fresh blood components, comparison between the outcomes from these projects is not possible owing to the differences in data types, definitions and methodologies. A national set of standard data definitions and parameters could allow results from independent studies/audits/projects to be compared in a meaningful way. The *Guide* is also intended to be a useful resource for staff working in the hospital environment who are undertaking audits and assessments of their own Transfusion Practice.

The first phase in identifying the measures in this *Guide* involved a desktop research project undertaken by the Department of Epidemiology & Preventive Medicine at Monash University, in which a review of a range of indicators of blood and blood product use both in Australia and internationally was conducted.

This *Guide* was developed from the findings of the desktop research and after wide consultation with stakeholders, including clinical experts, transfusion scientists, transfusion nurses, government representatives and other relevant stakeholders. Careful consideration has been given to the potential usefulness of the measures in the Australian context, and also their epidemiological soundness, particularly the primary measures. The measures will complement the various Clinical Practice Guidelines which support the prescription of fresh blood components.

Purpose of the *Guide*

The *Guide* is designed to be an easy reference booklet for clinicians, transfusion practitioners, auditors and researchers and it is anticipated that the set of standard measures could be used in audits, quality assurance activities, clinical registries, research projects, clinical trials, and surveys of usage. The use of the set of endorsed measures will help to standardise the information reported on the use of fresh blood components.

This version of the *Guide* is a draft only. Although it is the product of extensive discussion and deliberation by our national working group, it is our view that only as the *Guide* is used will it be possible to assess how useful it is - which measures work well, which need further refinement, which are irrelevant, and which are missing! This first edition is therefore freely available on the NBA website, for people to download and use. **Comments and suggestions are keenly sought.** After a reasonable trial period we intend to revise the document in the light of practical experience and feedback from users, and publish it as a user-friendly booklet; it will also continue to be available electronically.

It should be emphasised that the *Guide* is **not** intended to be prescriptive and that users should select only those measures that are appropriate for their particular project and the resources available to them. However, it is recommended that for the measures selected, the definitions contained in this *Guide* be used. The intention is not to provide specific guidance on the establishment of audits, clinical trials, registries, or other clinical data collections. The *Guide* is analogous to a toolbar in a software program; users can customise the toolbar to meet their particular requirements. The measures chosen from the *Guide* will depend on the intent and purpose of the clinical data collection, how data is captured within the institution and the resources available for the project.

Content

The *Guide* contains data measures which could be collected about the patient and measures specific to the use of red blood cells, platelets, fresh frozen platelets (FFP) and cryoprecipitate. The measures are divided into primary and supplementary measures.

The intent is that the designers of data collections would generally include primary measures (a minimal data set), augmented by supplementary measures appropriate to their specific clinical data collection.

The Measures

Primary Measures (P)

A menu of measures that are ideally collected in all studies of fresh blood components, containing a minimal set of measures to collect about the use of fresh blood components in order to provide meaningful, critical and, wherever possible, epidemiologically sound information. An example of where these measures could be used would be when you wanted to add some additional questions about blood components to existing or proposed clinical data collections (e.g. a clinical study or registry) but had only limited scope in terms of the number of data points you could collect. These measures could also be used when designing an audit, again where you wish to capture a limited number of data points but still ensure meaningful information.

Supplementary Measures (S)

This menu of measures could be collected, in addition to the primary measures, where more information about fresh blood components is needed. This set of measures, together with the primary measures, would enable a comprehensive picture of the use of fresh blood components. One example of where these measures could be used would be to provide more information in a clinical audit by answering the specific questions the auditor is interested in. Another example would be in a detailed clinical research study investigating the transfusion triggers associated with, or the efficacy of, fresh blood components. It is anticipated that only the measures relevant to a specific question or project would be selected.

Epidemiologically sound principles

Wherever possible, epidemiologically sound measures should be used. This will be critical for some studies.

Definition:

An epidemiologically sound measure is something which is readily available and can be measured objectively and in a standard way, anywhere and in any circumstances and which can be collected by non-experts.

Epidemiologically sound means:

Routinely collected
Routinely accessible
Consistent interpretation

Consistent interpretation means that the definition is never in doubt, i.e. the data is collected in a relatively standardised fashion and is confined to accepted definitions.

The fundamental hallmark of epidemiologically sound data is that it is reproducible – i.e. no matter who collects the data, the results will be accurate and identical.

An example of an epidemiologically sound measure would be the age of the patient at the time of hospital admission. An example of a measure which is not epidemiologically sound would be "significant blood loss". This measure is not epidemiologically sound because what is considered significant to one person or in some circumstances may not be considered significant to another person or in other circumstances. Therefore, if two people record that they have observed significant blood loss, you cannot be sure that their observations are comparable when conducting a retrospective study.

Clinical judgement is usually not needed to collect epidemiologically sound data because this will inevitably introduce variability. It may be collected by non-clinicians who need to use common sense but not necessarily professional judgement.

Wherever possible, the *Guide* has suggested measures which are epidemiologically sound. However, there is some information which is important to collect in order to drive improvement in the safety and quality of transfusion care but for which epidemiologically sound measures are not possible. For example, in some studies/audits it may be important to know if the patient was actively bleeding at the time of transfusion. It is not possible to define "active bleeding" in an epidemiologically sound manner. Significant measures which are not epidemiologically sound are still included in the *Guide*.

Other principles

This *Guide* does not address other principles which are relevant to the design, methodology and conduct of clinical data collections. However, because of the sensitivity of patient clinical information, users should ensure that privacy, confidentiality, ethics and other appropriate laws, regulations and principles are observed.

Notes on usage of terms and symbols that can be used interchangeably

Throughout the *Guide*, there are a number of terms and symbols which to all intents and purposes are interchangeable, but are preferred by different groups of practitioners according to their established practice. Some of these terms are used interchangeably in the *Guide*, while for others we have fixed on one term to the exclusion of other alternatives. Each of the terms listed below has at least one synonym or can be used interchangeably with another term:

Red cells and *red blood cells* – the *Guide* uses *red blood cells*, or the abbreviation *RBC*, throughout.

Bags and *units* – these terms are used interchangeably throughout the *Guide*.

Homologous and *allogeneic* – there are several possibly antonyms of autologous.
The *Guide* uses *allogeneic* throughout.

Leuco-depleted and *leucocyte-depleted* – the *Guide* uses *leucocyte-depleted* throughout.

L and *l* (international symbol for litre) – the Guide uses *L* throughout to avoid possible confusion with the upper case of the letter i. Note, however, that *ml* is used throughout to denote millilitres.

Organisation of the *Guide*

The information is contained in six chapters which describe measures recommended in relation to demographic and pre-transfusion data about the patient, the component transfused - red blood cells (RBC), platelets, fresh frozen plasma (FFP) and cryoprecipitate - and the outcomes of the transfusion.

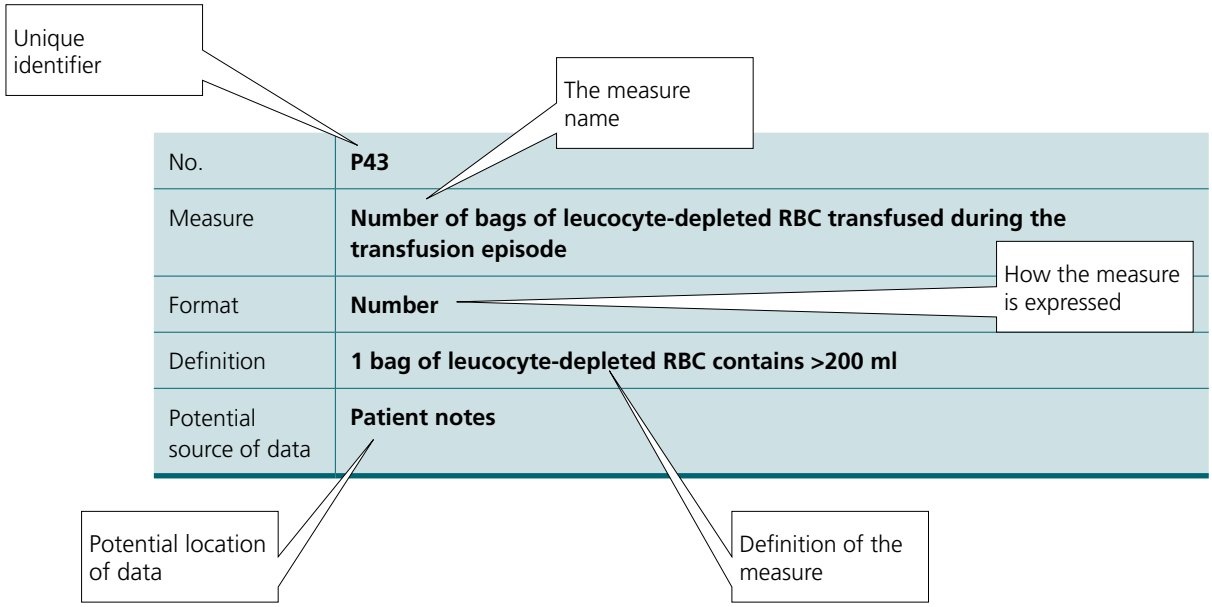
How the Measures are arranged

The measures have been grouped to provide information about the following:

- Basic demographic data
- Reasons for transfusion
- Transfusion episode
- Post-transfusion data

Chapter One contains measures describing basic demographic information about the patient. Chapter Two contains measures relating to pre-transfusion clinical details of the patient, irrespective of the blood component transfused. Chapters Three to Six then provide definitions of measures relevant to red blood cells, platelets, FFP and cryoprecipitate, respectively. Within each chapter, the measures are grouped into primary and supplementary measures, and explanatory information is sometimes provided.

In order to simplify use of the *Guide*, for each measure there is a small box containing the measure, the format and its definition; for example:



Where relevant, the measures are followed by text which offers further relevant explanatory information and/or discussion.

Over-Arching Principles or Definitions

There are some principles or definitions which apply across all aspects of the *Guide*.

Definition of Blood Component

The Therapeutic Goods Administration (TGA) defines *Blood Components* as "therapeutic components of blood (red blood cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration and freezing" (Therapeutic Goods Order No.81 refers). The term *Blood Product* is used generally to refer to plasma fractionation derivatives.

For this reason, the term *blood components* is used throughout the *Guide*.

Definition of 'Transfusion Episode'

The data collected in chapters Three to Six relate to a single transfusion episode, which is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of this fresh blood component to that patient.

A new transfusion episode starts with a new assessment and a new prescription. Transfusion episodes are typically characterised in terms of only one blood or blood component type. In other words, an episode will commence each time the participating blood bank issues one or more therapeutic doses of one blood component to a patient.

If patients receive more than one blood component, the *Guide* is structured such that each administration of an individual component is considered a separate transfusion episode, recognising that within a clinical setting, this may be considered one total episode of care.

If a clinical data collection involves collecting data on more than one transfusion episode then the measures collected for the first transfusion episode would need to be repeated for subsequent episodes. With this approach individual transfusion episodes may overlap as multiple blood components can be administered simultaneously e.g. during a massive transfusion. It will therefore be important to identify if more than one blood component is transfused, and relevant measures selected for each from the appropriate chapters.

Primary triggers

In developing the *Guide,* significant time has been spent in considering what triggers the decision to transfuse. It is clear that the final decision to transfuse depends on a combination of factors.

The *Guide* attempts to identify discrete triggers for each blood component, sometimes involving decision trees. However, for red blood cells (RBC) the triggers are often multiple and complex and there are several issues associated with asking for a "primary" trigger for RBC:

- In clinical decision-making it is generally not possible to identify ONE isolated trigger for transfusion;
- It would be impossible to list ALL of the conditions which might be co-triggers for transfusion; and
- It would not be unusual for all conditions to influence the final clinical decision to transfuse.

There are also other issues which are relevant to the documentation in medical notes of the decision to transfuse and which might be important in studies of blood usage:

- The multi-factorial information is often inadequately documented in Patient Notes or other sources, if at all, and would therefore be more difficult to audit or capture in a study; and
- The data would therefore not be epidemiologically sound

However, there are a number of measures already contained within the *Guide* which may currently encapsulate the reason or main clinical context for transfusing red blood cells. These may serve as "primary triggers":

P06	Patient condition/procedure	ICD-10-AM code
S21	Active bleeding	Y/N
S22	Massive blood loss	Y/N
S23	Relevant co-morbidities, medical and other risk factors	ICD-10-AM code(s)
P41	Pre-transfusion Hb level	Hb g/L
S42	Pre-operative Hb level	Hb g/L

After deliberation, we are of the view that the combination of the above measures may constitute sufficient reason or explanation for the transfusion of red blood cells, and that these data could then be supplemented by the other measures as appropriate.

You may find it useful to apply this approach in studies involving fresh blood components other than red blood cells.

There will of course be some exceptional circumstances where this schema will not apply.

Adverse Events

Collection of measures relating to adverse events is not included in the *Guide* as this would duplicate work being undertaken in the National Haemovigilance Program and the standardised definitions and guidelines being developed there. It is recommended that those interested in capturing adverse events refer to the Initial Australian Haemovigilance Report, available on the NBA website, www.nba.gov.au.

Chapter One: Demographic and general information about the patient

Overview

For any investigation of transfusions involving fresh blood components, some information will need to be collected about the patient, regardless of the blood component being transfused. It may be possible to capture this information from existing hospital administration systems or databases. Details of any transfusion, age, gender and reason for admission are considered to be a minimum data set necessary and are therefore listed as primary measures. Further details such as weight, and length of stay are suggested as supplementary measures.

No.	Primary measures (P)	Supplementary measures (M)
01	Transfusion occurred	
02	Component transfused	
03		Location of transfusion
04	Age	
05	Gender	
06	Patient condition/procedure	
07		Weight
08		Length of stay

Transfusion episode

A transfusion episode is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of these blood components to that patient.

P

No.	**P01**
Measure	**Transfusion occurred**
Format	**Y/N**
Definition	**A transfusion is defined as the administration of any fresh blood component**
Potential source of data	**Patient notes**

P

No.	**P02**
Measure	**Fresh blood component transfused**
Format	**RBC** **Platelets** **FFP** **Cryoprecipitate**
Definition	**Fresh blood component(s) transfused**
Potential source of data	**Patient notes**

A transfusion episode is typically characterised in terms of one fresh blood component type.

Further information about multiple transfusion episodes

In some studies it might be valuable to collect data relating to multiple transfusion episodes within one hospital admission. This might be useful, for example, if data on massive transfusion events are needed, or for studies examining the administration of more than one fresh blood component during one hospital admission.

No measure has been developed to collect this data, as there may be considerable variation in what is needed for particular studies. However, you could consider including the following:

- The number of transfusion episodes (as defined above) during one hospital admission;
- The fresh blood components administered;
- Dates and times of administration; and then
- Relevant measures selected for each fresh blood component

Information on the timing of the transfusions may be relevant for some studies. Please note that the information captured on the time of transfusion should be clearly defined. For example, time of issue may be captured as long as it is understood that this is only a surrogate measure for the actual time of transfusion and that it will vary for each patient.

S

Location of transfusion

No.	**S03**
Measure	**Location of transfusion**
Format	**Specify, for example:** • **ICU** • **Ward** • **Operating theatre** • **Recovery ward** • **Emergency Department** • **Other**
Definition	**The place where the transfusion was administered**
Potential source of data	**Patient notes**

P

Age

No.	**P04**
Measure	**Age**
Format	**Year or years and months**
Definition	**Age of the patient at the time of transfusion, calculated from the date of birth**
Potential source of data	**Hospital administrative systems**

The date of birth is generally available in hospital administration systems. Age, or Age in years and months, which may be relevant for the paediatric population, can be obtained by calculating from the date of birth.

P

Gender

No.	**P05**
Measure	**Gender**
Format	**Male** **Female** **Indeterminate**
Definition	**Sex at the time of transfusion**
Potential source of data	**Hospital administrative systems**

'Indeterminate' refers to a person who because of a genetic condition, was born with reproductive organs or sex chromosomes that are not exclusively male or female or whose sex has not yet been determined for whatever reason. This selection can only be assigned for infants aged less than 90 days.

P

Patient condition/procedure

No.	**P06**
Measure	**Patient condition/procedure**
Format	**ICD-10-AM code**
Definition	**For medical patients it is the *primary condition* that leads to medical intervention.** **For surgical patients it is the *surgical intervention* that leads to the procedure.**
Potential source of data	**Hospital administrative systems; discharge summary**

This information identifies the Principal Diagnosis which leads to medical or surgical intervention. It provides a standard way of capturing why the patient required intervention, for example, as a surgical patient to have a hip replacement, or as a medical patient to treat bone marrow suppression. The measure acknowledges that patients will not necessarily be admitted, e.g. when having day surgery.

The ICD code is usually assigned at discharge. Please note that this measure is NOT the measure which captures the primary reason for transfusion.

This measure does not identify all factors influencing the decision to transfuse or details of co-morbidities. These data can be captured in the following additional measures:

Chapter 2: General clinical data:	S21, S22, S23
Chapter 3: Red Blood Cells:	P41, S42
Chapter 4: Platelets:	P61, P62, S63
Chapter 5: FFP:	P82, P83, S84
Chapter 6: Cryoprecipitate:	P101, P102, S103

S

Weight

No.	**S07**
Measure	**Weight**
Format	**kgs**
Definition	**Most recent weight of the patient in kilograms prior to transfusion episode**
Potential source of data	**Hospital administrative systems; patient notes**

This measure would not be relevant to all fresh blood components, nor would the data always be available.

S

Length of stay

No.	**S08**
Measure	**Length of stay**
Format	**Number of days**
Definition	**The duration of time spent in hospital measured from admission to discharge dates**
Potential source of data	**Hospital administrative systems**

Although influenced by many factors, length of stay (LOS) is a fundamental measure and is often a Key Performance Indicator for hospitals. This information is generally available in hospital administration systems.

Chapter Two: General Clinical Data

Overview

This chapter describes measures which contain basic information about the patient which are of a more clinical nature but are not specific to a particular blood component. It may be possible to capture this information from existing hospital administration systems or databases.

No.	Primary measures (P)	Supplementary measures (S)
21		Active bleeding
22		Massive blood loss
23		Relevant co-morbidities, medical history, or other risk factors
24		Specialised blood conservation measures
25		Pharmacological agents administered

S

Active bleeding

No.	**S21**
Measure	**Active bleeding**
Format	**Y/N**
Definition	**Evidence of ongoing blood loss, accompanied by a decrease in the haemoglobin concentration of 30 g/L in the preceding 12 hours, or a requirement for at least 3 units of red blood cells during the same period. Note that this is not an epidemiologically sound measure.**
Potential source of data	**Patient notes**

The need for replacement of fresh blood components lost through active bleeding is a consideration in all fresh blood components, and the presence of active bleeding will inform data on the volumes and thresholds of fresh blood components administered.

S

Massive blood loss

No.	**S22**
Measure	**Massive blood loss**
Format	**Y/N**
Definition	**Replacement of patient's total blood volume or transfusion of >10 units of blood within 24 hours; OR Replacement of 50% of patient's total blood volume in <3 hours.**
Potential source of data	**Patient notes**

S

Relevant co-morbidities, medical history, or other risk factors

No.	**S23**
Measure	**Relevant co-morbidities, medical history, or other risk factors**
Format	**ICD-10-AM code(s)**
Definition	**Clinical condition(s) influencing the decision to transfuse**
Potential source of data	**Patient notes**

This measure indicates whether or not there are other clinical features which might influence the decision to transfuse a fresh blood component. For example, acute coronary syndromes and chronic renal failure are examples of co-morbidities which may have a significant influence on the transfusion threshold for red blood cells.

S

Specialised blood conservation measures or other relevant treatments used

No.	**S24**
Measure	**Specialised blood conservation measures**
Format	**Specify:** • **Pre-operative autologous donation (PAD)** • **Cell salvage** • **Peri-operative haemodilution** • **Return of residual pump-circuit volumes** • **Retrograde autologous priming** • **Mini-Cardiopulmonary bypass system** • **Controlled hypotension** • **Minimisation of laboratory sampling** • **Post-operative re-infusion** • **Others** • **Not performed**
Definition	**Technical, mechanical or autologous methods of blood conservation that reduce the need for transfusion**
Potential source of data	**Patient notes**

Note that this list is not comprehensive. If this measure is selected, procedures relevant for the specific purpose of the study may be selected.

S

Pharmacological agents administered

No.	**S25**
Measure	**Pharmacological agents administered**
Format	**Pharmacological agents used:** • **Erythropoietin** • **Haematinics: iron, vitamin B12, folate supplements** • **Anti-fibrinolytic agents (e.g. ε-Aminocaproic acid, Tranexamic acid)** • **Desmopressin (DDAVP)** • **Topical medications (e.g. Fibrin glues)**
Definition	**Administration of pharmacological agents to stimulate erythropoiesis and/or promote haemostasis**
Potential source of data	**Patient notes**

Chapter Three: Red Blood Cells

Overview

This chapter focuses on red blood cell (RBC) transfusion data. The measures are grouped as follows:

- Reasons for transfusion
- The transfusion episode
- Post-transfusion data

No.	Primary measures (P)	Supplementary measures (S)
Reasons for transfusion		
41	Pre-transfusion Hb level	
42		Pre-operative Hb level
Transfusion episode		
43	Number of bags of leucocyte-depleted red blood cells transfused during transfusion episode	
44	Volume of leucocyte-depleted red blood cells transfused during transfusion episode	
45		Type of transfusion (autologous/allogeneic)
Post-transfusion data		
46	Post-transfusion Hb level	
47		Discharge Hb level

Reasons for transfusion

Haemoglobin Levels

In relation to collecting Haemoglobin levels, either or both of Pre-operative or Pre-transfusion measures could be used. This choice would be determined by the project purpose and information available.

P

Pre-transfusion Hb level

No.	**P41**
Measure	**Pre-transfusion Hb level**
Format	**Hb g/L**
Definition	**The Hb level obtained closest to the time before the transfusion episode**
Potential source of data	**Pathology reports, patient notes for blood gas analyser or haemocue® results**

S

Pre-operative Hb level

No.	**S42**
Measure	**Pre-operative Hb level**
Format	**Hb g/L**
Definition	**The Hb level obtained closest to the time before surgery within 24 hours and before the infusion of fluids**
Potential source of data	**Pathology reports, patient notes for blood gas analyser or haemocue® results**

Primary trigger for RBC transfusion

While it seems possible to identify more discrete triggers for other blood components, for red blood cells the triggers are often multiple and complex. Several issues arise when identifying and defining a "primary trigger":

- In clinical decision-making it is generally not possible to identify ONE isolated trigger for transfusion;
- It would be impossible to list ALL of the conditions which might be co-triggers for transfusion;
- It would not be unusual for all conditions to influence the final clinical decision to transfuse.

There are also other issues which are relevant to the documentation in medical notes of the decision to transfuse:

- The multi-factorial information is often inadequately documented in Patient Notes or other sources, if at all, and would therefore be more difficult to audit or capture in a study; and
- The data would therefore not be epidemiologically sound

However, there are a number of measures already contained within the *Guide* which currently encapsulate the reason or main clinical context for transfusing red blood cells. These may serve as "primary triggers"

P06	Patient condition/procedure	ICD-10-AM code
S21	Active bleeding	Y/N
S22	Massive blood loss	Y/N
S23	Relevant co-morbidities, medical and other risk factors	ICD-10-AM code(s)
P41	Pre-transfusion Hb level	Hb g/L
S42	Pre-operative Hb level	Hb g/L

After deliberation, we are of the view that the combination of the above measures constitute sufficient reason or explanation for the transfusion, and that these data could then be supplemented by the other measures as appropriate.

There will of course be some exceptional circumstances where this schema will not apply.

Transfusion episode

A single transfusion episode is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of this fresh blood component to that patient.

A new transfusion episode starts with a new assessment and a new prescription. Transfusion episodes are typically characterised in terms of only one fresh blood component type.

P

Number of Leucocyte-depleted RBC Units transfused

No.	**P43**
Measure	**Number of bags of leucocyte-depleted RBC transfused during the transfusion episode**
Format	**Number**
Definition	**One bag of leucocyte-depleted RBC contains >200 ml**
Potential source of data	**Patient notes**

Dosage of RBC is usually expressed in terms of number of bags (see ARCBS Transfusion Medicine Services Blood Component Information, available on-line, for further details). Details about the total volume of red blood cells administered are contained in the measure P44 below.

P

Volume of red blood cells transfused

No.	**P44**
Measure	**Volume of leucocyte-depleted RBC transfused**
Format	**ml**
Definition	**Recorded volumes of completely transfused bags of leucocyte-depleted red blood cells plus an estimate of the volume transfused from partially consumed bags (if any). One bag of leucocyte-depleted RBC contains >200ml. Paediatric packs have a volume of 25-100ml**
Potential source of data	**Pathology reports, patient notes**

If the transfused volume of partially consumed bags is estimated (rather than measured) this measure will not be epidemiologically sound.

S

Type of transfusion

No.	**S45**
Measure	**Type of transfusion**
Format	**Autologous/Allogeneic**
Definition	**Autologous: derived from the recipient of the transfusion** **Allogeneic: not derived from the recipient of the transfusion**
Potential source of data	**Pathology reports**

Data relating to the type of transfusion, e.g. pre-operative autologous donation, may also be obtained from measure S24 (specialised blood conservation measures).

Post-transfusion data

Haemoglobin Levels

Once again, either or both of Post-transfusion or Discharge Hb measures could be used. This choice would be determined by the project purpose and information available.

P

Post transfusion Hb level

No.	**P46**
Measure	**Post transfusion Hb level**
Format	**Hb g/L**
Definition	**The Hb level taken closest after the completion of the transfusion episode**
Potential source of data	**Pathology reports**

S

Discharge Hb level

No.	**S47**
Measure	**Discharge Hb level**
Format	**Hb g/L**
Definition	**The last Hb level taken before patient discharge**
Potential source of data	**Pathology reports**

Note that the discharge Hb level may not always be collected on the day of discharge.

Chapter Four: Platelets

Overview

This chapter focuses on platelet transfusion data. The measures are grouped as follows:

- Reasons for transfusion
- The transfusion episode
- Post-transfusion data

No.	Primary measures (P)	Supplementary measures (S)
Reasons for transfusion		
61	Pre-transfusion platelet count	
62	Primary trigger for transfusion of platelets	
63		Administration of anti-platelet drugs prior to transfusion
Transfusion episode		
64	Number of bags of leucocyte-depleted platelets transfused during the transfusion episode	
65	Volume of leucocyte-depleted platelets transfused during the transfusion episode	
66		Type of platelet transfused
Post-transfusion data		
67	Post-transfusion platelet count	

Reasons for transfusion

Platelet function is not routinely tested. In order therefore to obtain an indication for platelet transfusion, either or both of the following measures (P61 or P62) may be relevant.

P

Pre-transfusion platelet count

No.	**P61**
Measure	**Pre-transfusion platelet count**
Format	**x 10^9/L**
Definition	**The pre-transfusion platelet count taken closest to the time, and within 24 hours, before transfusion**
Potential source of data	**Pathology reports**

The pre-transfusion platelet count is the primary measure in initiating a transfusion episode. If more than one platelet count has been undertaken, the one closest to the time of transfusion, and within 24 hours, should be used as the standard.

P

Primary trigger for transfusion of platelets

No.	**P62**
Measure	**Primary trigger for transfusion of platelets**
Format	**Specify:** **1. Platelet count low and:** • **active bleeding, or** • **prior to or during an invasive procedure, or** • **prophylaxis post chemotherapy or bone marrow transplant** **2. Known or suspected disorder (acquired or inherited) affecting platelet function and:** • **active bleeding, or** • **prior to or during an invasive procedure**
Definition	**Decision tree leading to an indication of platelets**
Potential source of data	**Pathology reports, patient notes**

S

Anti-platelet therapies administered in the five days prior to transfusion

No.	**S63**
Measure	**Anti-platelet therapy administered in the 5 days prior to transfusion**
Format	**Specify:** • **COX inhibitors, e.g. Aspirin and other non-steroidal anti-inflammatory drugs, e.g. ibuprofen** • **ADP inhibitors, e.g. Clopidogrel, Ticlopidine, Dipyridamole** • **Platelet receptor antagonists, e.g. Abciximab, Tirofiban, Eptifibatide, Xemilofiban, Sibrafiban, Lotrafiban** • **Other medications affecting platelet function**
Definition	**Pharmacological anti-platelet therapies administered in the five days before transfusion which are relevant to the decision to transfuse**
Potential source of data	**Patient notes**

Transfusion episode

A single transfusion episode is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of this fresh blood component to that patient.

A new transfusion episode starts with a new assessment and a new prescription. Transfusion episodes are typically characterised in terms of only one fresh blood component type. If more than one blood component is transfused within a single transfusion episode, relevant measures may be selected for each.

P

Number of bags or pools transfused

No.	**P64**
Measure	**Number of bags/pools of leucocyte-depleted platelets transfused during the transfusion episode**
Format	**Number**
Definition	**An adult dose of leucocyte-depleted platelets is comprised of a single apheresis donation (volume 100–400 ml), or a pooled bag containing four single contributions combined from whole blood donation (volume >160 ml)**
Potential source of data	**Pathology reports**

Refer to ARCBS Transfusion Medicine Services Blood Component Information, available on-line, for further details.

P

Volume of leucocyte-depleted platelets transfused

No.	**P65**
Measure	**Volume of leucocyte-depleted platelets transfused**
Format	**ml**
Definition	**Recorded volumes of completely transfused bags or pools of leucocyte-depleted platelets plus an estimate of the volume transfused from partially consumed bags/pools (if any). An adult bag of leucocyte-depleted platelets is comprised of a single apheresis donation (volume 100-400ml), or a pooled bag containing four single contributions combined from whole blood donation (volume >160ml). Paediatric bags are derived from a single leucocyte-depleted apheresis donation (volume 40-60ml).**
Potential source of data	**Pathology reports**

If the transfused volume of partially consumed bags or pools is estimated (rather than measured) this measure will not be epidemiologically sound.

S

Type of platelet transfused

No.	**S66**
Measure	**Type of platelet transfused**
Format	**Specify:** • **Apheresis** • **Pooled**
Definition	**An adult bag of leucocyte-depleted platelets is comprised of a single apheresis donation (volume >100–400 ml), or a pool containing four single contributions combined from whole blood donation (volume >160 ml)**
Potential source of data	**Pathology reports**

Other non-blood therapies administered

If information is required about the administration of therapies other than blood, the measures S24 (Specialised blood conservation measures) and S25 (Pharmacological agents administered) may be used.

Post-transfusion data

P

Post transfusion platelet count

No.	**P67**
Measure	**Post transfusion platelet count**
Format	**x 10^9/L**
Definition	**Platelet count taken closest to the completion of the transfusion but within 24 hours**
Potential source of data	**Pathology reports**

Chapter Five: Fresh Frozen Plasma

Overview

This chapter focuses on data for transfusion of Fresh Frozen Plasma (FFP). The measures are grouped as follows:

- Reasons for transfusion
- The transfusion episode
- Post-transfusion data

No.	Primary measures (P)	Supplementary measures (S)
Reasons for transfusion		
81	Pre-transfusion laboratory assessment of coagulation performed	
82	Pre-transfusion assessment of coagulation	
83	Primary trigger for transfusion of FFP	
84		Relevant medication
85		Details of relevant medication
Transfusion episode		
86	Number of units of FFP transfused during transfusion episode	
87	Volume of FFP transfused	
Post-transfusion data		
88	Post-transfusion laboratory assessment of coagulation performed	
89	Post-transfusion assessment of coagulation	

In investigations of the use of FFP, the following standard measures may be considered:

Reasons for transfusion

P

Pre-transfusion assessment of coagulation

No.	**P81**
Measure	**Pre-transfusion laboratory assessment of coagulation performed**
Format	**Y/N**
Definition	**Whether a pre-transfusion laboratory assessment was or was not undertaken (see P82).**
Potential source of data	**Pathology reports**

The use of FFP may be indicated for the replacement of coagulation factors and hence the assessment of coagulation is central to the decision to transfuse FFP. Because the absolute values of the available tests vary when tested in different laboratories, guidelines are usually expressed in terms of difference from normal.

P

No.	**P82**
Measure	**Pre-transfusion assessment of coagulation**
Format	**Specify:** • **APTT in seconds** • **PT in seconds/INR**
Definition	**PT:** • **clotting time of plasma recalcified in the presence of excess tissue thromboplastin** • **used to monitor integrity of the extrinsic clotting pathway** • **expressed in seconds** **INR:** • **based on the prothrombin time. Ratio of the patient's prothrombin time to that of a local control (prothrombin ratio), then corrected by a calibrator (I.S.I.)** • **used especially to monitor warfarin therapy** **APTT:** • **clotting time of plasma, recalcified in the presence of a specific phospholipid reagent** • **used to monitor unfractionated heparin therapy** • **used to test for integrity of the intrinsic system** • **may be prolonged in patients with inherited or acquired deficiencies of intrinsic clotting pathway factors** • **expressed in seconds**
Potential source of data	**Pathology reports**

For comparative purposes the same method should be used pre-transfusion and post-transfusion (i.e. primary measures P82 and P89).

P

Primary trigger for transfusion of FFP

No.	**P83**
Measure	**Primary trigger for transfusion of FFP**
Format	**Select:** **1. Haemostatic support during massive blood loss episode** **2. Warfarin reversal** **3. Thrombotic thrombocytopenic purpura (TTP)** **4. Active bleeding, prior to or during an invasive procedure and/or:** • **Disseminated intravascular coagulation** • **Coagulopathy of liver failure** • **Where there is a deficiency of a specific clotting factor, but a specific clotting factor concentrate is not available** **5. Other specialised condition — specify**
Definition	**Decision tree leading to indication for transfusion of FFP**
Potential source of data	**Pathology reports, patient notes**

If further information about the reasons for transfusion of FFP is needed, the measure P101 (Pre-transfusion fibrinogen level) could also be used.

S

Relevant medication

Further details of any relevant medication may be obtained as a supplementary measure where it may be important to know whether there are any recent medications which are relevant; this can be a common feature.

No.	**S84**
Measure	**Relevant medication**
Format	**Y/N**
Definition	**Recent history of medication which could affect coagulation and the effects of which could be reversible when treated with FFP**
Potential source of data	**Patient notes**

No.	**S85**
Measure	**Details of relevant medication**
Format	**Specify**
Definition	**Generic name of medications**
Potential source of data	**Patient notes**

Transfusion episode

A single transfusion episode is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of this fresh blood component to that patient.

A new transfusion episode starts with a new assessment and a new prescription. Transfusion episodes are typically characterised in terms of only one fresh blood component type. If more than one fresh blood component is transfused within a single transfusion episode, relevant measures may be selected for each.

P

Number of units/bags

No.	**P86**
Measure	**Number of units or bags of FFP transfused during transfusion episode**
Format	**Number**
Definition	**A unit of FFP is the plasma derived from one normal collection of whole blood. A bag of FFP is obtained by apheresis (volume of both 250–334 ml)**
Potential source of data	**Patient notes**

Refer to ARCBS Transfusion Medicine Services Blood Component Information, available on-line, for further details.

P

Volume of FFP transfused

No.	**P87**
Measure	**Volume of FFP transfused**
Format	**ml**
Definition	**Number of mls of FFP transfused. Recorded volumes of completely transfused units of fresh frozen plasma plus an estimate of the volume transfused from partially consumed units (if any)**
Potential source of data	**Product bag label, patient notes**

If the transfused volume of partially consumed units is estimated (rather than measured) this measure will not be epidemiologically sound.

Post-transfusion data

P

Post-transfusion assessment of coagulation

No.	**A88**
Measure	**Post-transfusion laboratory assessment of coagulation**
Format	**Y/N**
Definition	**Whether a laboratory assessment of coagulation was undertaken after transfusion**
Potential source of data	**Pathology reports**

P

No.	**P89**
Measure	**Post-transfusion assessment of coagulation**
Format	**Specify:** • **APTT in seconds** • **PT in seconds/INR**
Definition	**PT:** • **clotting time of plasma recalcified in the presence of excess tissue thromboplastin** • **used to monitor integrity of the extrinsic clotting pathway** • **expressed in seconds** **INR:** • **based on the prothrombin time. Ratio of the patient's prothrombin time to that of a local control (prothrombin ratio), then corrected by a calibrator (I.S.I.)** • **used especially to monitor warfarin therapy** **APTT:** • **clotting time of plasma, recalcified in the presence of a specific phospholipid reagent** • **used to monitor unfractionated heparin therapy** • **used to test for integrity of the intrinsic system** • **may be prolonged in patients with inherited deficiencies of intrinsic clotting pathway factors** • **expressed in seconds**
Potential source of data	**Pathology reports**

In order to be able to make meaningful comparisons with the pre-transfusion level, the same standard measure of coagulation capacity should be used.

Chapter Six: Cryoprecipitate

Overview

This chapter focuses on cryoprecipitate transfusion data. The measures are grouped as follows:

- Reasons for transfusion
- The transfusion episode
- Post-transfusion data

No.	Primary measures (P)	Supplementary measures (S)
Reasons for transfusion of cryoprecipitate		
101	Pre-transfusion fibrinogen level	
102	Primary trigger for transfusion of Cryoprecipitate	
103		Relevant co-morbidities, medical history or other risk factors
Transfusion episode		
104	Number of units of cryoprecipitate transfused during transfusion episode	
105	Volume of cryoprecipitate transfused	
Post-transfusion data		
106	Post-transfusion fibrinogen level	

In investigations of the use of cryoprecipitate, the following standard measures may be considered:

Reasons for transfusion

P

Pre-transfusion fibrinogen level

Fibrinogen, also called Factor I, is a blood plasma protein produced by the liver that plays an important role in blood coagulation. Assessment of fibrinogen deficiency is made through a fibrinogen level blood test, which measures the concentration of fibrinogen in the blood in g/L. Transfusion of cryoprecipitate may be indicated for the replacement of fibrinogen where this has been depleted by dilution in massive blood loss settings, by fibrinolysis, or by reduced synthesis as in fulminant hepatic failure.

No.	**P101**
Measure	**Pre-transfusion fibrinogen level**
Format	**g/L**
Definition	**The fibrinogen level tested closest prior to the transfusion episode**
Potential source of data	**Pathology reports**

If more than one test has been performed, the one closest to the transfusion episode should be used. The date and time when the test was performed could also be recorded if considered.

P

Primary trigger for transfusion of cryoprecipitate

No.	**P102**
Measure	**Primary trigger for transfusion of cryoprecipitate**
Format	**Specify:** **1. Haemostatic support during massive blood loss episode** **2. Low fibrinogen and** • **active bleeding, or** • **prior to or during an invasive procedure** **3. Dysfibrinogenaemia and** • **active bleeding, or** • **prior to or during an invasive procedure**
Definition	**Potential clinical indications leading to the decision to transfuse Cryoprecipitate**
Potential source of data	**Pathology reports, patient notes**

S

Relevant co-morbidities, medical history, or other risk factors

No.	**S103**
Measure	**Relevant co-morbidities, medical history, or other risk factors**
Format	**ICD-10-AM code(s)**
Definition	**Clinical condition(s) influencing the decision to transfuse Cryoprecipitate**
Potential source of data	**Pathology reports, patient notes**

This measure indicates that there are other clinical features which might influence the decision to transfuse cryoprecipitate. This is often the case with this fresh blood component.

Transfusion episode

A single transfusion episode is defined as:

The interval in patient care from the time of the prescription of a defined number of units of one fresh blood component type for a patient and the time of completion of administration of this fresh blood component to that patient.

A new transfusion episode starts with a new assessment and a new prescription. Transfusion episodes are typically characterised in terms of only one fresh blood component type. If more than one blood component is transfused within a single transfusion episode, relevant measures may be selected for each.

P

Number of units/bags

No.	**P104**
Measure	**Number of units/bags of cryoprecipitate transfused during the transfusion episode**
Format	**Number**
Definition	**A unit of cryoprecipitate is derived from the FFP of a normal blood donation (volume 30–40 ml). There is also an apheresis bag (volume 60 ml +/– 10%).**
Potential source of data	**Patient notes**

Refer to ARCBS Transfusion Medicine Services Blood Component Information, available on-line, for further details.

P

Volume of cryoprecipitate transfused

No.	**P105**
Measure	**Volume of cryoprecipitate transfused**
Format	**ml**
Definition	**Recorded volumes of completely transfused units of cryoprecipitate plus an estimate of the volume transfused from partially consumed units (if any). Derived from the FFP of a normal blood donation (volume 30-40 ml). There is also an apheresis bag (volume 60 ml+/- 10%). A paediatric unit is has a volume of 20 – 30 ml.**
Potential source of data	**Pathology reports, patient notes**

Post-transfusion data

P

Post transfusion fibrinogen level

No.	**P106**
Measure	**Post transfusion fibrinogen level**
Format	**g/L**
Definition	**Level of fibrinogen tested after transfusion of cryoprecipitate**
Potential source of data	**Pathology reports**

Appendix: Development of the Guide

The Blood Measures Project was designed and developed as a collaboration between the National Blood Authority (NBA) and the Australian Red Cross Blood Service (ARCBS) in response to the need for a set of national data collection points which could be used in investigations of fresh blood component use.

A Steering Committee, Chaired by Dr James Isbister, was formed and included representatives from the NBA (Alison Turner and Annie Woodhouse) and the ARCBS (Nirdosh Puri and Stuart Behncken).

The Steering Committee commissioned a desk top review of existing measures of blood product use. This included a literature review of both national and international publications and product Guidelines and was conducted by Dr Louise Phillips, Senior Research Fellow, Transfusion Outcomes Research Collaborative in the Department of Epidemiology and Preventive Medicine at Monash University.

The Steering Committee then convened a National Working Group made up of individuals from a variety of backgrounds. The National Working Group comprised volunteers with relevant clinical expertise (from disciplines including anaesthetics, orthopaedics, haematology, cardiothoracic surgery, trauma, intensive medicine) and other relevant stakeholders, such as nursing, transfusion scientists, epidemiologists and hospital administrators.

At the inaugural meeting of the National Working Group, Dr Phillips presented her review, *A Report on National and International Experience in assessing Appropriateness of Use of Blood and Blood Products*. Members then considered a range of scenarios to develop an initial list of potential measures.

The measures were refined and developed by an interactive process with the NWG over a period of time. Individual members provided information and advice on specific issues and small working parties were convened to assist in reviewing later versions. The NBA and the ARCBS would like to acknowledge and thank the members of the National Working Group who contributed to the development of the Guide:

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