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30 September 1999

Dr Jonathan Wilde
Consultant Haematologist
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston

Dear Jonathan

I have provisionally organised the next meeting of the Hospital Transfusion Committee for Tuesday 19 October at 5.00 pm in the Undergraduate Centre at Selly Oak Hospital. I will circulate a full agenda and the minutes of the last meeting nearer the time.

I enclose three documents for your information. The first are the Terms of Reference for the Transfusion Committee and these are based upon the RCP recommendations for blood transfusion medicine. Secondly, there is a policy for the administration of blood and blood components which has been drawn up by Dr Heidi Doughty and Rachael Rowe and thirdly there is a discussion document drafted by Dr Heidi Doughty concerning the use of standard and virucidally treated fresh frozen plasma. Currently, virucidally treated plasma is being heavily marketed by the manufacturers of Octaplas and I am going to give all your names to the representative of this company and ask him to supply you with literature and off print relevant to this commercial product. However, Heidi's document summarises the situation well.

I will contact you before the meeting to discuss matters further. If you have any problems with this date, please let my secretary know at the earliest opportunity.

Kind regards.

GRO-C

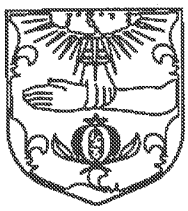
Yours sincerely

GRO-C

Allen Edwards MCh FRCS
Consultant Surgeon

Selly Oak Hospital
Raddlebarn Road, Birmingham B29 6JD Tel: 0121 627 1627
Chairman: Mr. John Charlton Chief Executive: Dr. Jonathan Michael

Terms of Reference



RCP Publications

Heidi Douglas
Jonathan Wilde
Mar Mayji
Rachel Rowe

Steve Foster
Benjamin Wright
Andy Reza

AUDIT MEASURES FOR GOOD PRACTICE IN

Blood transfusion medicine

Proforma questionnaires for

- Institutional audit of blood transfusion practice
- Audit of blood transfusion documentation
- Monitoring of acute blood transfusion reactions
- Audit of anaemic patients transfused with red blood cells
- Audit of long-term blood transfusion therapy
- Audit of the management of transfusion in acute (non-surgical) haemorrhage
- Audit of acute plasma volume replacement
- Audit of the management of patients presenting with an acute haemorrhagic diathesis
- Audit of the use of blood components in the newborn

Published by the
RESEARCH UNIT OF THE ROYAL COLLEGE OF PHYSICIANS
November 1995

Royal College of Physicians of London
11 St Andrews Place, London NW1 4LE

Registered Charity No 210508

ISBN 1 86016 027 1

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Audit measures for good practice in transfusion medicine

Introduction

by Anthony Hopkins, Director, Research Unit, Royal College of Physicians and Alan Waters, former Chairman, British Committee for Standards in Haematology.

In the quality assurance of blood transfusion, little attention has been paid to the clinical interface of blood transfusion. Laboratory performance is monitored by the National External Quality Assessment Scheme (NEQAS) for Blood Group Serology, and the British Committee for Standards in Haematology (BCSH), a subcommittee of the British Society for Haematology, makes recommendations for good transfusion practice through its Blood Transfusion Task Force. However, there is no systematic audit of the quality of the clinical transfusion process. To address this, the Research Unit of the Royal College of Physicians and the BCSH convened a Workshop to develop audit proformas to promote good practice in transfusion medicine. Membership of the Workshop also included representatives of the British Society for Haematology, the British Blood Transfusion Society, and the Royal College of Pathologists. At the time at which the workshop was held, maximum surgical blood ordering schedules had already been introduced for elective surgery and these provided an objective basis for the effective audit of blood use in surgery. The aim of the Workshop was to consider areas of transfusion practice that could be peer-reviewed and to produce audit proformas that might be used.

Examples of audit proformas are provided. The format of the review process and the criteria used should be developed by the local Hospital Transfusion Committee (see Appendix A), but guidelines for using the proformas will be found on page 5. Procedures should be reviewed and revised on a regular basis.

The background papers on which the proformas are based may be obtained from the College*, price £10.00.

* Publications Department, Royal College of Physicians, 11 St. Andrews Place, Regent's Park, London NW1 4LE

Acknowledgements

We are grateful to all those who prepared background papers for the Workshop from which these audit proformas were developed, and to Dr Marcela Contreras for piloting them. We are also grateful to the other participants for constructive discussion during their development.

The Research Unit of the Royal College of Physicians is supported by grants from the Wolfson and Welton Foundations, by other charitable donations, and by the NHS Executive.

We are grateful to Nicholas Hopkins and Jonathan Gurr for laying out the audit proformas.

The Research Unit of the Royal College of Physicians, the Royal College of Pathologists, the British Society for Haematology and the British Blood Transfusion Society

Development of audit measures for good practice in transfusion medicine

List of members of the original workshop

** Indicates authors of papers prepared for the workshop and available on request from the Publications Department of the Royal College of Physicians*

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Guidelines for using blood transfusion audit proformas

1.1 What is clinical audit?

Clinical audit is a method of improving the quality of care. It is becoming increasingly popular. It enables staff to look objectively at the work they do, and to set targets for improvement. Clinical audit involves collecting and analysing data but, for audit to be successful, talking with colleagues and working as a team are just as important. Most people enjoy examining the quality of their work and participating in clinical audit. It soon becomes an accepted part of delivering high quality care.

1.2 Audit proformas included in this pack (see page 14)

1. A proforma for institutional audit.
2. A proforma for the documentation of blood transfusion.
3. A proforma for the monitoring of acute blood transfusion reactions.
4. A proforma for anaemic patients transfused with red blood cells.
5. A proforma for long-term blood transfusion therapy.
6. A proforma for the management of transfusion in acute (non-surgical) haemorrhage.
7. A proforma for acute plasma volume replacement.
8. A proforma for the management of patients presenting with an acute haemorrhagic diathesis.
9. A proforma for the use of blood components in the newborn.

1.3 Photocopying

The booklet has been bound so that it opens flat for easy photocopying. The forms are free of copyright in the United Kingdom.

1.4 Implementing audit

The format of the review process and the criteria used should be developed by the Hospital Transfusion Committee (see Appendix A).

Ideally, everyone in the team concerned with blood transfusion practice should be involved in the audit. Each person should be made aware of his or her role in the scheme and the objectives of audit.

A selection of audit appropriate for any individual aspect of care can be made from amongst the nine accompanying proformas. It is a mistake to try and do too much at once. A careful audit of one particular aspect of transfusion practice is likely to cast more light upon the practice in an institution as a whole than a scrappy audit across the whole range of blood transfusion practice. It would be helpful to assign some sort of realistic timetable for the audit, and to allocate appropriate tasks. This will usually mean appointing one of the team to act as facilitator and to be responsible for seeing the audit to a satisfactory conclusion.

1.5 Analysing the results of audit

The first purpose of audit is to improve care within an individual institution. It will seldom be possible to make direct comparison of the results between different institutions because of variations in the case mix between them. The purpose of audit is to encourage the delivery of the best possible care to the institution under review. Nonetheless, informal comparisons between institutions may be informative, and, as experience grows, it may be possible to make more robust comparisons between the institutions.

1.6 Implementing change

However good existing practice, it is likely that audit will show up areas in which practice can be further improved. Sometimes it would be necessary to improve systems of work, and hospital management may need to be included in any plans for developing the service. It is therefore sensible to let hospital managers know at an early stage that an audit is planned, so that if the results of audit show that further resources are required to ensure a safe and efficient service, then they feel that they have been involved with the audit from the beginning.

Having completed an audit on one particular topic, and decided what needs to be changed, it would be necessary to set a date for re-auditing the same topic in order that it can be seen that the change has been successfully achieved.

1.7 The patient's perspective

The audit proformas that follow (page 14) are technical in nature. Remember that the patient's perspective of the services should also be considered, and informal enquiry of a few patients will often reveal strengths and weaknesses of a blood transfusion service in a more informative way than structured questionnaires.

Note

The audit proformas were piloted by Dr Marcela Contreras, whose help is gratefully acknowledged. However, anybody who has developed proformas of this sort is aware that weaknesses in their design often only become apparent when they are released more widely. The Research Unit of the Royal College of Physicians would therefore be pleased to hear of any ambiguities or suggestions for improvement of the proformas so that they can be updated in due course.

APPENDIX A

The role of the hospital transfusion committee in clinical audit

The main objective of the Hospital Transfusion Committee (HTC) is to promote the highest standard of transfusion practice through peer review. This follows the practice widely used in the United States (1). In this way, the HTC has an essential role to play in developing medical audit as described by the NHS Review White Paper (2).

Terms of reference

The HTC should be charged with the review of:

a) Clinical transfusion practice;

b) Performance of the hospital transfusion service;

c) Performance of the local Blood Transfusion Centre (BTC) as provider.

d) Legal implications of transfusion practice

The cost of blood and blood products is a related issue. A sub-committee of the HTC could be set up to monitor the blood supply budget and advise on appropriate economies based on good clinical practice.

The HTC should carry out reviews at regular intervals with appropriate documentation of the proceedings. The committee should be serviced by the hospital central administration and the promotion of high standards of transfusion practice should feature prominently in the hospital quality assurance statement.

The HTC should report to:

a) the hospital Clinical Audit Committee. An audit assistant should be available to the HTC to help with the audit of blood transfusion practice.

b) the hospital Clinical Policy Group. Authority should be delegated to the HTC to enable it to correct the abuse of blood and blood products.

Functions

Specific functions of the HTC relate to the terms of reference set out above. The HTC should function in association with the hospital Clinical Audit Committee.

a) The role of the HTC in clinical transfusion practice

1. To make recommendations to the medical staff concerning the proper use of blood, its components and derivatives. This advice should be based on national guidelines (3,4,5) and adapted for local conditions as appropriate.
2. To review the appropriateness of transfusions of blood, its components and derivatives based on locally agreed guidelines.
3. To review surgical blood ordering schedules regularly to detect changes in local practice and identify persistent over-ordering (3b).
4. To recommend corrective action in transfusion practice when indicated. Follow-up assessment of corrective action is required to complete the audit cycle.
5. To ensure adequate procedures for patient and sample identification and documentation of all blood transfused or disposed of (3a).
6. To review ward/theatre procedures for blood transfusion on a regular basis.
7. To review transfusion reactions and make recommendations to improve transfusion practice based on the investigation of such reactions.
8. To review post-transfusion infections in conjunction with the local BTC to trace the donors implicated.
9. To promote continuing education in transfusion medicine for all relevant members of the hospital staff.

b) The role of the HTC in monitoring performance of the hospital transfusion service

1. To review the operational aspects of the service including:
   - response to urgent requests for blood;
   - out-of-hours service;
   - the amount of blood, components and derivatives wasted and to identify the causes of such wastage;
   - cross-match to transfusion ratios for different surgical procedures and for individual consultants.

   This will identify areas requiring clinical audit.

2. To review quality assurance measures including:
   - Internal Quality Control (reagents, equipment) and regular assessment of technical competence of staff;
   - National External Quality Assessment Scheme (NEQAS for Blood Group Serology);

- Accreditation (Clinical Pathology Accreditation)
- Value for money service (Audit Commission).

c) The role of the HTC in monitoring the performance of the local Blood Transfusion Centre as provider

To audit the quality of the service provided by the local Blood Transfusion Centre regarding:

- adequate and timely provision of blood, components and derivatives;
- provision of reference laboratory services;
- consultancy services;
- out-of-hours services.

d) The role of the HTC with regard to legal implications of transfusion practice

To consider legal aspects of:

- documentation;
- consumer protection;
- product liability;
- informed consent, if required by the institution (the introduction of a legal requirement for informed consent specifically for blood transfusion is currently being considered).

Composition

The Chairman should be appointed by the hospital clinical policy group or similar body.

(S)he should have a good understanding and general experience of blood transfusion practice. The consultant in charge of the hospital Blood Transfusion Unit is an important member of the HTC. However, (s)he may be perceived as having a vested interest and should not normally be the Chairman of the HTC, but could be the Convenor. Other members could be nominated through the Directorate structure.

The following membership is suggested:

- Consultant microbiologist
- Haematologist in charge of blood transfusion
- Senior blood transfusion scientist

- Representatives of major clinical users
- Local Blood Transfusion Centre consultant (ex officio)
- Nursing officer
- Administrative representative
- Representative of junior medical staff
- Representatives may be co-opted as required from:
- Pharmacy; Infection Control; Medical Records.

It is recommended that the replacement of Committee members is staggered to maintain continuity. The chairman should be appointed for not less than two years and not more than four years.

References

1) Grindon AJ, Tomasulo PS, Bergin JJ, Klein HG, Miller JD, Mintz PD. The hospital transfusion committee. Guidelines for improving practice. *JAMA* 1985; 253: 540–543.
2) Department of Health NHS Review: *Working for patients — Working Paper 6 Medical Audit.* HMSO, London 1989.
3) British Committee for Standards in Haematology. *Standard Haematology Practice* (Ed. Roberts B). Blackwell Scientific Publications, Oxford 1991. a) pp128–138; b) pp189–197.
4) Department of Health. *Handbook of Transfusion Medicine* (Ed. McClelland DBL). HMSO, London 1989.
5) Stehling L, Luban NLC, Anderson KC, Sayers MH, Long A, Attar S, Leitman SF, Gould SA, Kruskall MS, Goodnough LT, Hines DM. Guidelines for blood utilization review. *Transfusion* 1994; 34: 438–448.

APPENDIX B
Background papers

The role of the hospital transfusion committee in medical audit

Alan H Waters, PhD, FRCP, FRCPath
Professor of Haematology
St. Bartholomew's Hospital and Medical College
London EC1A 7BE

Acute haemorrhage in the newborn

Brenda E S Gibson, MB, ChB, FRCP, FRCPath, DFM
Consultant Haematologist
Royal Hospital for Sick Children
Yorkhill
Glasgow G3 8SJ

Acute medical haemorrhage

J Keith Wood, FRCP, FRCPE, FRCPath
Consultant Haematologist
Royal Infirmary
Leicester LE1 5WW

Adverse reactions to blood transfusion

Marcela Contreras, MD, MRCPath, FRCP (Edin)
Director
Mahes de Silva, MB, BS, FRCPath
Consultant Haematologist
North London Blood Transfusion Centre
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London NW9 5BG

Guidelines for acute plasma volume replacement

Michael Murphy, MD, FRCP, MRCPath
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St. Bartholomew's Hospital and Medical College
London EC1A 7BE

Acute haemorrhagic diathesis

Michael Greaves, MD, FRCP, MRCPath
Reader and Consultant in Haematology
Honorary Consultant Haematologist and Physician
Royal Hallamshire Hospital
Glossop Road
Sheffield S10 2JF

Transfusion therapy for patients presenting with anaemia

Paul Kelsey, MB, BS, MRCP, MRCPath
Consultant Haematologist
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Lancs FY3 8NR

Long-term transfusion of red blood cells

Sally C Davies, MB, MSc, FRCP, MRCPath
Consultant Haematologist
Central Middlesex Hospital
Acton Lane
London NW10 7NS

Blood transfusion documentation

Sally C Davies, MB, MSc, FRCP, MRCPath
Consultant Haematologist
Central Middlesex Hospital
Acton Lane
London NW10 7NS

APPENDIX C
Audit proforma questionnaires

KEY:

RU43A	Institutional audit proforma for blood transfusion practice
RU43B	Audit proforma for blood transfusion documentation
RU43C1/C2	Audit proforma for monitoring acute blood transfusion reactions
RU43D	Audit proforma for anaemic patients transfused with red blood cells
RU43E	Audit proforma for long-term blood transfusion therapy
RU43F	Audit proforma for the management of transfusion in acute (non-surgical) haemorrhage
RU43G	Audit proforma for acute plasma volume replacement
RU43H	Audit proforma for the management of patients presenting with an acute haemorrhagic diathesis
RU43I	Audit proforma for the use of blood components in the newborn

INSTITUTIONAL AUDIT PROFORMA FOR BLOOD TRANSFUSION PRACTICE

RU43 A

Hospital:	Location:

1	**Are there written policies for the following?**	
	a) The taking of samples for blood grouping and cross-matching	Y N
	If yes, are the staff who take these samples:	
	i) Given a copy of the procedure?	Y N
	ii) Given training in the procedure?	Y N
	b) The transfusion of blood on the wards	Y N
	If yes,	
	i) Are copies of the policy available on all wards?	Y N
	ii) Are the staff involved in blood transfusion given training in the procedure?	Y N
	iii) Does the policy include guidance on monitoring transfusions, e.g. taking temperature blood pressure, and pulse?	Y N
	iv) Does the policy include advice about what to do if a transfusion reaction occurs?	Y N
	v) When was the most recent training session on the ward?	month [ ] year [ ]
2	**Does the hospital have a Transfusion Committee?**	Y N
	If yes, has the Committee carried out audits of transfusion practice?	Y N
	If yes, were recommendations made, based on the results of the audits?	Y N
3	**Does the hospital have a maximum surgical blood ordering schedule?**	Y N
	If yes, is it reviewed at regular, [at least yearly], intervals?	Y N
4	**Does the hospital provide a pre-deposit autologous transfusion service?**	Y N
	If yes, are patients informed of the service?	Y N
5	**Does the hospital require informed patient consent for blood transfusion?**	Y N

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1st Edition 12th October 1995

AUDIT PROFORMA FOR BLOOD TRANSFUSION DOCUMENTATION

RU43 B

Hospital:	Patient ID:
Location:	Ward:

1 Where was the compatibility report at the time of transfusion?

- a) In the patient's notes ☐
- b) Attached to the patient's prescription chart ☐
- c) On its own, at the bedside ☐
- d) Elsewhere (specify) ☐
- e) Not available ☐

2 Were the nursing observations of the transfusion filed in the patient's notes? Y ☐ N ☐

3 Were the following nursing observations recorded before the transfusion?

- a) Temperature ☐
- b) Pulse ☐
- c) Blood pressure ☐

4 Were the following observations recorded during the transfusion?

- a) Temperature following commencement of transfusion Y ☐ N ☐
  - If yes, how many minutes after commencement of transfusion? ☐
- b) Pulse following commencement of transfusion Y ☐ N ☐
  - If yes, how many minutes after commencement of transfusion? ☐
- c) Blood pressure after commencement of transfusion Y ☐ N ☐
  - If yes, how many minutes after commencement of transfusion? ☐
- d) Temperature at hourly intervals thereafter Y ☐ N ☐
- e) Pulse at hourly intervals thereafter Y ☐ N ☐
- f) Blood pressure at hourly intervals thereafter Y ☐ N ☐
- g) Urine output Y ☐ N ☐

5 Was the compatibility report filed in the patient's notes? Y ☐ N ☐

If yes, were the following recorded for each unit transfused?

a) Transfusion date:
- For all of the units ☐
- For some of the units ☐
- For none of the units ☐

b) Signature of 2 responsible officers who did ID checks:
- For all of the units ☐
- For some of the units ☐
- For none of the units ☐

6 Was the following information available in the case notes?

- a) The indication for the transfusion ☐
- b) The date that the transfusion was given ☐
- c) The number of units transfused ☐
- d) Pre-transfusion haemoglobin ☐
- e) Post-transfusion haemoglobin ☐
- f) Whether the transfusion caused an adverse effect ☐
  - If yes, where was it recorded?
  - i) Nursing notes ☐
  - ii) Medical notes ☐

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1st Edition 18th October 1995

AUDIT PROFORMA FOR MONITORING ACUTE BLOOD TRANSFUSION REACTIONS

RU43 C1

Hospital:	Patient ID:
Location:	Ward:

1 Diagnosis: _____

_____

_____

_____

2 What blood components were given?

a) Red blood cells ☐
b) Platelets ☐
c) Fresh frozen plasma ☐

3 If red cells were given, did request for cross-match provide information, on the following?

a) History of previous pregnancies Y ☐ N ☐
b) History of previous transfusions Y ☐ N ☐
c) History of previous transfusion reactions Y ☐ N ☐

4 Check of patient and donation identity before transfusion:

a) Was first signature legible? Y ☐ N ☐
b) Was second signature legible? Y ☐ N ☐

5 Where was the transfusion started?

a) Accident & Emergency department Y ☐ N ☐
b) Intensive Care unit Y ☐ N ☐
c) Operating theatre Y ☐ N ☐
d) Ward Y ☐ N ☐
e) Day ward Y ☐ N ☐

6 Were the date & time of the start of the transfusion recorded for the following?

a) First unit Y ☐ N ☐
b) Supposedly implicated unit Y ☐ N ☐

7 Was the time of reaction recorded? Y ☐ N ☐

8 Were donation numbers of all units given on that day recorded? Y ☐ N ☐

9 Was the donation number of the implicated unit identified? Y ☐ N ☐

10 Indicate symptoms / signs of transfusion reaction:

a) Fever [rise >1°C] ☐
b) Chills ☐
c) Rigors ☐
d) Itching / rash ☐
e) Back pain ☐
f) Chest pain / discomfort ☐
g) Dyspnoea / difficult breathing ☐
h) Dark urine ☐
i) Restlessness ☐

11 Were the following observations recorded during the transfusion?

a) Pulse Y ☐ N ☐
b) Blood pressure Y ☐ N ☐
c) Temperature Y ☐ N ☐

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1st Edition 18th October 1995

AUDIT PROFORMA FOR MONITORING ACUTE BLOOD TRANSFUSION REACTIONS (cont)

RU43 C2

Hospital:	Patient ID:
Location:	Ward:

12 How often were the observations recorded?

a) Before the reaction

b) After the reaction

13 Was a doctor informed? Y N

If yes, how soon after the reaction? hrs mins

14 Did the doctor see the patient? Y N

If yes, how soon after s/he was informed? hrs mins

If no, was advice given by telephone? Y N

What type of advice was given?

a) Continue as before

b) Slow drip rate

c) Stop and observe

d) Discontinue transfusion

e) Other

15 Was any medication prescribed? Y N

a) Paracetamol

b) Antihistamine

c) Diuretic

d) Hydrocortisone

e) Adrenaline

f) Other

16 Was the doctor who gave the advice a haematologist? Y N

If no, did s/he inform a haematologist? Y N

If yes, how soon after the reaction? hrs mins

17 Was transfusion of a unit of blood abandoned? Y N

If yes, what volume of the unit had been transfused? ml

18 Was a subsequent unit given? Y N

If yes, how soon after the previous unit was abandoned? hrs mins

Was the subsequent unit tolerated well? Y N

TO BE COMPLETED IF TRANSFUSION WAS ABANDONED AND NO SUBSEQUENT UNITS WERE GIVEN

19 Were blood samples taken? Y N

If yes, how soon after the reaction? hrs mins

20 Was a urine sample collected? Y N

If yes, how soon after the reaction? hrs mins

21 Was the unit returned to the transfusion lab? Y N

If yes, how soon after the transfusion of the unit was abandoned? hrs mins

22 Presumed cause of reaction:

23 Was the reaction reported to any of the following? Y N

a) Hospital blood transfusion lab Y N

b) Hospital Transfusion Committee Y N

c) Transfusion Centre Y N

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1st Edition 18th October 1995

AUDIT PROFORMA FOR ANAEMIC PATIENTS TRANSFUSED WITH RED BLOOD CELLS

RU43 D

Hospital: | Patient ID:

Location: | Ward:

1 Under which of the following categories was the patient admitted?

a) General medicine
b) Medical subspecialties
c) Haematology
d) General surgery
e) Orthopaedics
f) Gynaecology
g) Other (please specify)

2 Haemoglobin concentration before transfusion: g/dl

3 Symptoms & signs before transfusion:

a) Tiredness
b) Angina at rest
c) Angina on exertion
d) Dyspnoea at rest
e) Dyspnoea on exertion
f) Confusion of recent onset
g) Impaired consciousness
h) Pulmonary oedema
i) Peripheral oedema
j) Cardiac arrhythmia
k) Other (please specify)

4 Was the cause of anaemia known prior to transfusion? Y N

If yes, what was/were the cause(s)?

a) Acute blood loss
b) Chronic blood loss
c) Other iron deficiency
d) Malignant blood disorder
e) Megaloblastic anaemia
f) Autoimmune haemolytic anaemia
g) Other (please specify)

5 Was the anaemia of more than 4 weeks duration? Y N

6 Specify the type of blood product transfused:

a) Whole blood
b) Red cell concentrate

7 Specify the number of units transfused:

8 Duration of transfusion of 1 unit:

a) <1hour
b) 1-2hours
c) 2-3hours
d) 3-4hours
e) >4hours

9 Was haemoglobin measured after transfusion? Y N

If yes, specify haemoglobin concentration after transfusion: g/dl

10 Was diuretic given? Y N

Developed by the Research Unit of the Royal College of Physicians
in collaboration with the British Blood Transfusion Society, the British Society for Haematology, and the Royal College of Pathologists
1st Edition 18th October 1995

AUDIT PROFORMA FOR LONG-TERM BLOOD TRANSFUSION THERAPY

RU43 E

Hospital: | Patient ID:

Location: | Ward:

1 **Is the cause of anaemia known?** Y N

If yes, what is/are the cause(s)?

a) Acute blood loss
b) Chronic blood loss
c) Other iron deficiency
d) Malignant blood disorder
e) Megaloblastic anaemia
f) Autoimmune haemolytic anaemia
g) Other (please specify)

2 **Please indicate which of the following symptoms the patient had before transfusion:**

a) Tiredness
b) Angina at rest
c) Angina on exertion
d) Dyspnoea at rest
e) Dyspnoea on exertion
f) Confusion of recent onset
g) Impaired consciousness
h) Pulmonary oedema
i) Peripheral oedema
j) Cardiac arrhythmia
k) Other (please specify)

3 **In the case of a child, was growth velocity reduced over at least 6 months?** Y N

4 **Was pre-transfusion haemoglobin recorded?** Y N

If yes, specify haemoglobin concentration: g/dl .

5 **Is the patient's red cell phenotype recorded?** Y N

6 **Is the hepatitis B status (HBs Ag) recorded?** Y N

7 **If there was no evidence of previous hepatitis B infection, was the patient immunised?** Y N

8 **Is the hepatitis C status (HCV antibody) recorded?** Y N

9 **Are liver function tests checked every 3 months?** Y N

10 **Has any transfusion been associated with a fever [rise >1°C] and/or rigors?** Y N

11 **Is white cell depleted blood available?** Y N

12 **Is the haemoglobin maintained within an agreed range? [10.5-14.5 g/dl]** Y N

13 **Is the annual blood consumption recorded? [ml/kg]** Y N

14 **Have the serum ferritin levels been checked before transfusion and recorded clearly?** Y N

a) For each transfusion Y N
b) Every 3 months Y N

15 **Is the serum ferritin >600ng/l?** Y N

If yes,

a) Has desferrioxamine been started? Y N
b) Has there been an audiological review? Y N
c) Has there been an opthalmological review? Y N

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AUDIT PROFORMA FOR THE MANAGEMENT OF TRANSFUSION IN ACUTE (NON-SURGICAL) HAEMORRHAGE

RU43 F

Hospital: Patient ID:

Location: Ward:

1 **Was the patient admitted because of acute haemorrhage?** Y N

2 **Was the patient in hospital when the haemorrhage occurred?** Y N

3 **Were the following noted in the history taking and/or examination?**
- a) Pallor Y N
- b) Sweating Y N
- c) Pulse Y N
- d) Blood pressure Y N

4 **Were the following laboratory investigations requested?**
- a) Full blood count Y N
- b) Coagulation screen Y N
- c) Group and save serum Y N
- d) Baseline biochemistry Y N

5 **Was cross-matched blood ordered?** Y N

6 **Was the blood loss estimated?** Y N
If yes, state estimated loss in litres: litres

7 **Was a presumed cause of the bleeding recorded?** Y N

8 **Was a central venous pressure line placed during the admission?** Y N

9 **Were the following fluids given during resuscitation?**
- a) Crystalloids (e.g. saline, Ringer's lactate) Y N
- b) Colloids (e.g. Haemaccel, Gelofusine) Y N
- c) Human albumin solution Y N

10 **Was a blood transfusion given?** Y N

11 **Were blood components given to treat lesions in the coagulation pathway?** Y N

a) Fresh frozen plasma Y N
Was International Normalised Ratio (INR) >2? Y N

b) Platelet concentrates Y N
Was the platelet count >50 x 10^9/litre? Y N
Was the platelet count <50 x 10^9/litre? Y N

12 **Were the effects of the transfusion followed by INR and/or platelet counts?**
- a) During the episode Y N
- b) After the episode Y N

13 **Was emergency endoscopy (within 24 hours) carried out if bleeding from the GI tract?** Y N

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AUDIT PROFORMA FOR ACUTE PLASMA VOLUME REPLACEMENT

RU43 G

Hospital:	Patient ID:
Location:	Ward:

1 Were the following recorded in the patient's notes as part of the initial assessment of the patient?

	Y	N
a) Mental state	☐	☐
b) Pulse	☐	☐
c) Blood pressure	☐	☐
d) Central venous pressure &/or pulmonary artery wedge pressure	☐	☐
e) Urine output	☐	☐
f) Skin temperature	☐	☐

2 How frequently were the observations made, (in minutes)?

	<15	15-30	>30
a) Mental state	☐	☐	☐
b) Pulse	☐	☐	☐
c) Blood pressure	☐	☐	☐
d) Central venous pressure &/or pulmonary artery wedge pressure	☐	☐	☐
e) Urine output	☐	☐	☐
f) Skin temperature	☐	☐	☐

3 Do the patient's notes indicate that a provisional diagnosis of the cause of shock was made? Y ☐ N ☐

4 Were crystalloids (e.g. normal saline, Ringer's lactate) used for volume replacement? Y ☐ N ☐

If yes,

a) What volume (in litres) was given during the first 24 hours? litres ☐☐

b) Were crystalloids used before any other fluid for volume replacement? Y ☐ N ☐

5 Were synthetic colloids (e.g. Haemaccel, Gelofusine) used for volume replacement? Y ☐ N ☐

If yes, what volume (in litres) was given during the first 24 hours? litres ☐☐

6 Was human albumin solution used for volume replacement? Y ☐ N ☐

If yes,

a) Was the serum albumin measured before the use of albumin? Y ☐ N ☐

i) If yes, what was the serum albumin level? g/dl ☐☐.☐

b) Was a reason for the use of albumin stated in the patient's notes? Y ☐ N ☐

c) What volume was given in the first 24 hours? litres ☐☐

7 Was a blood transfusion given? Y ☐ N ☐

If yes,

a) What was the haemoglobin level before the transfusion of red cells? g/dl ☐☐.☐

b) How many units of red cell concentrates were given in the first 24 hours? units ☐☐

c) What was the haemoglobin level after the transfusion of red cells? g/dl ☐☐.☐

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AUDIT PROFORMA FOR THE MANAGEMENT OF PATIENTS PRESENTING WITH AN ACUTE HAEMORRHAGIC DIATHESIS

RU43 H

Hospital:	Patient ID:
Location:	Ward:

1 Is there a record that the patient was asked about recent bleeding from the following?

a) Oral mucosa Y N
b) Nasal mucosa Y N
c) Wounds / puncture sites Y N
d) Skin (bruising / purpura) Y N
e) Optic fundi Y N

2 Are the following recorded in the past medical history?

a) Dental history Y N
b) General surgical history Y N
c) For women; the obstetric history Y N
d) Any history of unusual bleeding Y N
If yes, please specify:

e) Family history of bleeding Y N

3 Does the drug history include information about the following?

a) Aspirin intake Y N
b) Non-steroidal anti-inflamatory drugs Y N
c) Other drugs Y N
d) Duration of treatment with each drug Y N

4 Where a diagnosis of disseminated intravascular coagulation has been made, are the following recorded?

a) The likely trigger (underlying causes) Y N
b) Results of coagulation tests Y N
c) Results of platelet counts Y N
d) Results of a blood film Y N
e) Whether above tests were repeated after treatment of the underlying cause Y N

5 Where replacement therapy with blood products has been given:

a) If cryoprecipitate was given, was the plasma fibrinogen level before transfusion <1g/litre? Y N
b) If platelets were given, was the platelet count before transfusion <50x10^9/litre Y N
c) Was the response to treatment monitored by laboratory testing? Y N

6 If heparin was given, was it either: Standard ☐ or: LMW ☐

a) Was a vaso-occlusive complication identified and recorded? Y N
b) Was therapy monitored by laboratory testing (KCCT)? Y N

7 In severe thrombocytopenia due to marrow failure:

a) Were haemorrhagic manifestations recorded daily? Y N
b) Was indication for platelet transfusion documented on each occasion? Y N
c) Was the platelet count before transfusion <10x10^9/litre? Y N
If no, was fever [>39°C] an indication for platelet transfusion? Y N
d) Was the haematocrit maintained at >0.30 during the period of severe thrombocytopenia? Y N
e) Were white cell depleted blood components used? Y N
If yes: i) Was this because of previous febrile transfusion reactions? Y N
ii) Was this the standard procedure? Y N

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1st Edition 18th October 1995

AUDIT PROFORMA FOR THE USE OF BLOOD COMPONENTS IN THE NEWBORN

RU43 | 1

Hospital:	Patient ID:
Location:	Ward:

1 Where fresh frozen plasma was transfused to a neonate, were the following documented?

a) Discussion with a haematologist
b) Coagulation screen
c) The reason for transfusion
d) Dose
e) The time for start and completion of the transfusion
f) Clinical response
g) Repeat coagulation screen

2 Where platelets were transfused to a neonate, were the following documented?

a) Platelet count before transfusion
b) The reason for transfusion
c) Dose
d) Clinical response
e) Post-transfusion platelet count
f) Were the platelets from:
   i) Random donors
   ii) Platelet group-specific donors

3 Where cryoprecipitate was transfused to a neonate, were the following documented?

a) Discussion with a haematologist
b) Coagulation screen
c) Fibrinogen level
d) The reason for transfusion
e) Dose
f) Clinical response
g) Repeat coagulation screen
h) Repeat fibrinogen level

4 Where a pedi-pack was requested, were the following documented?

a) That satellite pack came from a unit dedicated to the recipient
b) The reason for transfusion
c) The reason the infant was likely to require multiple transfusions
d) Volume of blood transfused
e) Haemoglobin before transfusion
f) Haemoglobin after transfusion

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1st Edition 16th October 1995
BLOODTRA.FRP

University Hospital Birmingham
NHS TRUST

POLICY FOR THE ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS

JUNE 1999

DATE FOR REVIEW: JUNE 2000

DRAFT 2 ONLY (11 June 99)

CONTENTS

POLICY FOR THE ADMINISTRATION OF BLOOD & BLOOD PRODUCTS

PURPOSE OF THE POLICY

The Department of Health directive, "A Better Blood Service" requires all NHS Trusts to have policies and guidelines on the administration of blood and blood products. This is an important aspect of patient care and because of the complexity poses a significant clinical risk. This policy has been produced in order to manage the risk and improve the quality of care to patients.

The risk incident system will be used as one mechanism to improve the standards associated with the process of blood transfusion. It is therefore vital that any near misses or errors at any stage of the process are reported so that lessons can be learnt.

ACCOUNTABILITY

Medical Staff, Nursing Staff, Operating Department Practitioners and other Professionals Allied to Medicine

All medical staff, nursing staff, Operating Department Practitioners and other professionals allied to medicine are responsible for ensuring that they read and understand the policy, that they implement and adhere to the policy and report any difficulties to their manager.

Portering Staff

All portering staff involved in the collection and delivery of blood products are responsible for ensuring that they read and understand the policy, that they implement and adhere to that policy and report any difficulties to their manager.

Laboratory Staff

All laboratory staff are responsible for ensuring that they read and understand the clinical policy and are aware of their responsibility to provide appropriate and timely advice as required.

Ward Managers and Consultants

To ensure the blood transfusion policy is implemented and adhered to, and standards of care are monitored.

Divisional Directors, Divisional Heads of Nursing and Clinical Practice Managers

To ensure that staff are aware of the Blood Transfusion Policy and assist staff to implement

Hospital Transfusion Committee

To support and advise on the Blood Transfusion Policy
To monitor compliance
To ensure the policy is regulated, updated, and complies with Local, regional and National requirements

DEFINITION OF A BLOOD TRANSFUSION

A blood transfusion is the administration of whole blood or a blood component directly into a vein

1 PRESCRIBING BLOOD

1.1 Positive identification of the patient is essential, based on -:

- Questioning the patient by asking their surname, first name and date of birth in the case of patients who are judged capable of giving an accurate, reliable response.
Checking that the details on the patient's identification wristband match those on the request form and the answers to the questions above.
All patients *including unconscious patients* must have a patient identification number and identification wristband including this number and the gender of the patient as minimum patient identifiers. When additional identification details become available, the hospital blood bank must be informed.
Accurate and complete labelling of the blood sample and blood transfusion request form are vital for the safety of patients.

The 4 key things to include are:

- **A&E/Hospital Number.**
- **Surname**
- **First Name**
- **Date of birth**

1.2 The sample tube must be labelled immediately after the blood has been taken by the person taking the sample and signed by that person. Pre printed labels should not be used as these are more likely to result in inadequate patient identification.

1.3 Where the patient's identity is unknown the request form should state *Unknown Male/Female* and the A&E / Admissions Unit number must be entered. **It is also imperative that the number used is able to follow the patient and be recognisable later by other staff in other clinical areas.**

1.4 Vacutainer tube guides are available in every clinical area to inform staff about the correct sample bottles to be used.

1.5 The request must specify the clinical indication for the transfusion, the type and quantity of blood product required, and the time and date that products are needed. The request form must be signed by the requesting practitioner.

1.6 One person within the ward/dept. should communicate with the laboratory about the urgency of the blood. The laboratory will inform the ward/dept when it is ready for collection.

1.7 The blood transfusion must be prescribed by the doctor on an intravenous infusion chart. In an emergency situation, the prescription chart must be completed as soon as possible when the emergency is under control.

2 OBTAINING A UNIT OF BLOOD FROM THE BLOOD BANK

2.1 **Blood Banks are situated:**

At Selly Oak Hospital in S block, between Intensive Care and Theatres

At the Queen Elizabeth Hospital in the East side basement .

Designated blood fridges for departmental use are situated in liver ITU, Cardiac ITU

2.2 The person collecting the blood must have a trust blood collection form (appendix 1) with the patient's registration details to ensure they pick up the correct unit. If a telephone request is given to a porter to collect blood, the porter must be given the patient identification details so that he/she can write these onto a blood collection slip, and in addition should be given the location of the patient and the degree of urgency that the blood or blood component is required.

2.3 On collection, the blood bank register must be completed with their name, date and time of collection (registers are kept by the blood banks).

2.4 Only one unit of blood should be taken out at any time (except for Theatres or in an emergency, e.g. Accident & Emergency Unit.)

2.5 On arrival in the clinical area the person collecting the blood must ensure that a trained member of the nursing staff is informed that the blood has been delivered to the ward. Blood must not be left on wards without the nursing staff being made aware that it has arrived.

2.6 Blood may be returned to the fridges but must be accompanied by a completed trust blood collection form. The lower half of this form requires details regarding how long the blood has been out of the fridge. All unused blood should be returned so that it can be accounted for. A unit of blood can only be returned to the Blood Bank stock and reissued if no more than 30 minutes had elapsed since it was
signed out.

2.7 Blood must only be stored in blood transfusion refrigerators and not in ward or domestic refrigerators.

2.8 Blue boxes are sometimes used for storing blood and their use is determined by the laboratory staff. The box usually has a coolpack in it, which means a unit of blood can be stored there fore 4 hours. If there is no coolpack, blood can only be stored in the box for a maximum of 1 hour.

2.9 The first unit of blood to be infused must have a Transfusion Report form with it from the Blood Bank. This form details each unit number for that transfusion. (appendix 2)

3) PATIENT INFORMATION

3.1 Blood transfusion must be treated like any other prescription, i.e. patients should be informed of the indication for blood transfusion, its risks and benefits and have the right to refuse it. However, signed consent is not required at the time of writing the policy.

3.2 It is helpful to provide patients with an information sheet outlining the risks and benefits of blood transfusion. National Blood Service have produced a leaflet which should be kept on wards. Further supplies can be obtained from the Haematology Office at QEH on extn 2479

3.3 **Refusal of blood on religious grounds**

Adult patient's wishes must be respected. A summary of the information given and outcome of the consultation should be documented in the clinical notes.

4 CHECKING PROCEDURE PRIOR TO ADMINISTRATION

4.1 Documentation:

- Patient's Notes (which may contain a blood group result form)
- I.V. Prescription chart.
- Transfusion Compatability Form
- Unit of blood - front label (original, printed label) and back label (generated by blood bank).
- Patient's identification wristband

The following must be checked:

- The patient's hospital number, surname, forename and date of birth.
- The patient's blood group (ABO)
- The blood group of the unit to be transfused.
- The serial number of the unit to be transfused
- The expiry date of the unit to be transfused
- Inspect the unit for evidence of leaks in the bag or an unusual colour of the blood.

4.2 The checking procedure should be carried out by a registered nurse, operating department practitioner, professional allied to medicine, or doctor who takes full responsibility for the correct administration of the blood/blood product to the patient. This process may be checked by another registered nurse, doctor, operating department practitioner, professional allied to medicine, student nurse or medical student on request.

4.3 **This is a three way checking process involving the blood product, the compatability form and the patients identification band. The check should take place next to the patient prior to commencing the transfusion.**

4.4 The persons who have carried out these checks must sign the Blood Transfusion Report form and the prescription chart.
NB: **Usually the patient's blood group and that of the unit will be the same. Occasionally, the following variations might be seen:**

i) A unit of Group O for a patient of any ABO group

ii) A unit of Group A or B for a patient of Group AB

iii) A unit of Rh neg for a patient who is Rh pos.

4.5 If any discrepancies not covered by a comment on the blood transfusion compatability form are found during the bedside checking procedure, the unit of blood or blood component must not be transfused. Advice on the suitability of a unit of blood should be sought from blood bank.

4.6 If the wrong unit has been collected it must be returned to blood bank as soon as possible, the correct unit should be collected, and the incident reported via risk management using an incident reporting form.

5 EQUIPMENT

5.1 Infusion Device

A peripheral or central line may be used to administer blood using an aseptic technique. Drugs should not be administered through the giving set of a blood transfusion - a separate line must be used.

5.2 Pumps

Electronic infusion pumps may damage blood cells, and should not be used for the administration of red cells unless they have been verified as safe to use for this purpose according to the manufacturers instructions. All companies recommend using specified, numbered administration sets which can be found in their product manuals.

5.3 Giving Sets/Filters

A blood giving set must be used to administer blood and blood products. These contain a 170 micro mesh filter which is suitable for most transfusions. Platelets should not be transfused through giving sets which have been used for blood. Special paediatric giving sets should be used for transfusions to infants, or a screen filter used if the transfusion is administered by syringe. Separate white cell blood filters are no longer necessary as all blood is leucodepleted at source.

Microaggregate filters may be used as clinically indicated.

Before transfusing blood, the giving set should be primed with intravenous sodium chloride 0.9% to prevent wasting blood if air gets in the line on priming (except in paediatrics). Blood must not be transfused through a giving set that has contained other solutions. Dextrose 5% may cause haemolysis. Calcium containing solutions may cause coagulation. The sets must be changed every 12 hours to avoid bacterial growth.

5.4 Blood Warmers

The routine warming of blood and blood products is not recommended, as it is of limited benefit and is potentially dangerous. The use of blood warmers should only be used in certain circumstances when prescribed (e.g. Accident and Emergency, massive transfusion). They should be in working order and checked regularly by medical engineers.

6 OBSERVATIONS

6.1. Any patient receiving a blood transfusion must be able to access their nurse call system if their condition allows An explanation should be given to the patient to call for help should they feel different or unwell. A patient information leaflet may be given if appropriate. A base line set of temperature, pulse, and blood pressure should be recorded before starting the transfusion.

6.2 For the first ≤15 minutes of each unit transfused, the patient should be observed closely for evidence of a severe transfusion reaction see 6.6.

6.3 Temperature, pulse and blood pressure recordings should be made after 15 minutes and documented. Subsequent observations should be recorded at intervals, depending on the clinical condition of the patient and the reason for the transfusion.
These must be recorded on the observation chart.

6.4 A fluid balance record should be used if there is a clinical indication.

6.5 Minor reactions are common and include unexplained small rises in temperature (to 37°), urticaria, rashes and headaches. The transfusion rate should be slowed, the doctor informed and the patient monitored more closely. Anti-pyretic or anti-histamine drugs may be prescribed. For patients having repeat transfusions, any reactions should be clearly documented. The medical staff should decide whether further investigation is required.

6.6 Serious Hazards of Transfusion (SHOT) should be reported using a SHOT form and the Trust Report Form (appendix 2). Both forms give good information about the identification and management of serious transfusion reactions. Both forms should be sent to either the haematology laboratory or the addressee. In the event of a suspected haemolytic transfusion reaction e.g. pain at the site of infusion, loin pain, chest pain, breathing difficulties, restlessness/anxiety, collapse, the transfusion must be stopped and the doctor called immediately. The laboratory should be informed about any adverse events and may give advice over the telephone which should be documented and followed.

7 DOCUMENTATION

7.1 Documentation permits investigation of practice and identification of patients who have received certain blood components

7.2 The blood transfusion compatability form must be readily available during the transfusion.

7.3 A permanent record of the transfusion of blood and blood components and the administration of blood products must be kept in the medical notes including-:

- **The blood transfusion compatability form**
- **The sheet used for nursing observations during the transfusion**
- **An entry in the case notes, describing the indication for the use of blood or blood components, the date, the number and type used, whether or not it achieved the desired effect and the occurrence and management of any adverse effects.**

8 DISPOSAL

8.1 A unit of blood should be started within 30 minutes of removal from the 'fridge and be completed within 5 hours of removal from the 'fridge (because of the increased risk of bacterial growth when kept at room temperature).

8.2 Blood bags should be disposed of in a yellow clinical waste bag and retained for a full 24 hours before leaving the ward. This delay will facilitate finding and the returning of a bag should a delayed problem occur.

8.3 All the giving set and sharp ends should be disposed of in the sharps box.

9 UNUSED BLOOD - TRANSFER OR RECEIPT

9.1 Blood or blood components may accompany patients during inter hospital transfer. If blood is received from outside the Trust the Blood Transfusion Laboratory must be contacted immediately to confirm they are aware of the transfer. Blood should be stored in the nearest blood fridge as soon as possible. New blood samples should be taken from the patient and sent to the transfusion lab as soon as possible. Further blood will be provided from the Trust laboratories and the transfer blood should be returned to the blood bank. The transfer blood may be used while waiting for blood from the Trust.

10 LIFE-THREATENING EMERGENCY

10.1 In a life-threatening emergency, uncrossmatched blood that is ABO compatible can be obtained from the laboratory within 5 minutes of receiving the patient's sample. If this delay is too long, 2 units of emergency O negative blood are available in two places:

i) Blood Bank Selly Oak

ii) Blood Bank Queen Elizabeth Hospital

NB: Use of this uncrossmatched blood is a medical decision made by the most senior Doctor present. It is of paramount importance that the laboratory is informed when this blood is used, because:

i) The stock will need replacing.

ii) A record will be made of who the blood was used for.

iii) The laboratory staff will know that an emergency cross-match will be arriving.

11 SPECIFIC BLOOD PRODUCTS INFORMATION

11.1 **Platelets**
The shelf life of platelets is only 5 days therefore platelets are ordered for the hospital on a named patient basis. A small emergency stock is maintained in the Blood bank on the Queen Elizabeth site. Platelets are issued directly from the laboratory and should be used soon after arrival on the ward. Platelets must be maintained at room temperature to function, therefore do not refrigerate.

11.2 **Fresh Frozen Plasma and Cryoprecipitate**

The blood group of the patient should be known before ordering. The laboratory staff will select the best matched product.

Both need to be thawed before use. Allow 20 minutes when requesting from the laboratory. Use immediately on arrival on the ward - preferably within 2 hours and must be used within 4 hours of thawing.

11.3 **Thawing Fresh Frozen Plasma**

In cases where FFP is defrosted at ward level, this may be done either in a water bath or a clean clinical bowl. The water temperature should be below 37c to avoid denaturing proteins. The protective cardboard can be removed to speed up thawing, however the outer plastic cover should not be removed to preserve legibility of the labels and reduce bacterial contamination. The double wrapped pack should be clipped to the side of the bowl when defrosting. Patient washbowls and ward sinks should not be used as these have been shown to harbour micro organisms .

11.4 **Emergency use of FFP**
Group AB FFP may be used in an emergency in patients before their blood group is available

12 LOCAL VARIATIONS IN PRACTICE

Some areas will have specific variations to the guidelines outlines above. These should be clearly documented for all staff to understand and should relate to this document. The regular review of local information should be the responsibility of one person.

These guidelines are supported by "The Handbook of Transfusion Medicine, 2nd Edition" 1996, HMSO, and the "Guidelines for the Administration of Blood and Blood Components and the Management of Transfused Patients", British Committee for Standards in Haematology, 1999.

13 AUDIT

In collaboration with the clinical areas the Hospital transfusion Committee will collate information pertaining to adherence to the Trust policy on the administration of blood and blood components. Reports will be circulated to clinical areas.

14 REFERENCES

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Acknowledgements

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Considerations concerning the use of Standard and Virucidally treated Fresh Frozen Plasma

Prepared for Dr Jonathon Michael, Chief Executive,
University Hospital Birmingham NHS Trust

By Dr Heidi Doughty, Consultant Haematologist
University Hospital Birmingham NHS Trust

17 December 1998

Contents

Abbreviations

FFP	Fresh frozen plasma
HIV	Human immunodeficiency virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HTLV-1	Human t cell lymphotropic virus 1
NAT	Nucleic acid testing
TTI	Transfusion transmitted infection

Background

Fresh frozen plasma (FFP) is a blood component used to treat bleeding by providing clotting factors. In 1997-1998 year, 12,650 bags were used in the Trust at a total cost of £317,200 (unit price £25). All blood transfusion including FFP is associated with risks, which include infection, and immune risks. The area of risk highlighted by the media is infection. The blood service has been required to introduce new technology to further reduce the potential risks due to infection. All blood will be filtered to remove white cells (leucodepletion) and pcr based technology is being introduced to test for Hepatitis C virus (HCV). The costs resulting from the new operations will be devolved to users mainly through red cell charges. At the same time, the unit cost of standard FFP will be reduced to £18.00. The trust is one of the largest users of blood components in the country with a present spending on all blood components of £2.3 million per annum. The projected cost pressure for the Trust, which reflects the revised pricing, is £1.3 million. In addition the Trust may need to consider whether virucidally treated FFP should be bought which will increase the costs by a further £626k but potentially reduce risks for patients. Commercial companies are presently actively targeting key members of clinical staff to highlight the option of treated plasma. The aim of this paper is to identify some of the factors, which should be considered concerning the future purchase of plasma.

Storage, supply and pre-patient handling

FFP is stored within -30°C freezers. The freezers are situated within the Haematology areas of the trust, Selly Oak and Queen Elizabeth Hospitals.

Stock control and issue are supported by the pathology IT system, Telepath. The procedure permits an audit trail by linking the patient with the individual blood components issued. In turn, each component is linked to the individual blood donor at the Regional blood centre. If a blood donor is later found to have a viral marker than the recipient patient can be identified, counselled, tested and treated.

Standard and treated FFP must be thawed under controlled conditions to minimise the risks of bacterial contamination from water baths and to minimise the loss of labile clotting factors. A recent survey within the Trust of 38 clinical areas has identified that non-laboratory staff throughout the Selly Oak site defrosts FFP. The areas have been screened by the microbiology environmental monitoring staff and the temperature of the water recorded. The implications of the survey are being analysed in order to draw up FFP handling guidelines for the Trust.

Risks

Infection In the UK, donors are tested for HIV, HCV, HBV and syphilis. The numbers of patients in the Trust potentially infected by these transfusion transmitted infections (TTI) from FFP a year may be calculated using the Number of transfusions and estimated risk figures (HMSO, 1996). Note that a molecular based technology to detect HCV will be introduced during the next few months called NAT (nucleic acid testing). The impact of this testing is shown in the table. The number of units of FFP transfused in the Trust

during the financial year 1997-1998 was 12,651. The estimated risk for different TTIs from UK donors are shown below. The figures can be used to estimate that the Trust will see a new case of HBV due to transfusion of FFP on average once every 19 years.

Virus	Estimated risk	Number of years required for 1 TTI in this category
HCV (Present)	1:200,000	15.9
HCV (Post NAT)	? near zero	?
HBV	1:200,000	15.9
HIV	1: 2,000,000	159
Wrong blood to wrong patient	1:30,000 (50,000 transfusion episodes - all components)	0.6

Other viruses may be transmitted by FFP, which could adversely affect patients. These include HTLV-1 which is inactivated by solvent detergent (SD) treatment. Viruses such as Hepatitis A virus (HAV) and parvovirus B19 are not inactivated by any of the viral inactivation systems but these may be neutralised by the immune neutralisation in pooled products.

Universal leucodepletion will be achieved by February 1999. Leucodepletion was introduced in view of the theoretical risk of nvCJD in Europe and the UK. All whole blood will pass through a white cell filter before separation and storage; i.e. all FFP will be filtered. Leucodepletion has many benefits including the reduction of cytomegalovirus and HTLV-1.

The risks of infection appear very low. The risks associated with receiving the wrong blood are much greater. Risk management must be directed appropriately. When considering the risks from infection, it should be remembered that 50% of patients who have received a transfusion will be dead within the year due to their underlying illness. The significance of any infection may be considered proportional to the life expectancy, e.g. children and young adults with potentially treatable diseases.

Non-infectious complications FFP is thought to be associated with adverse reactions in 1% of transfusions with serious reactions in 0.1%. The effects are in part due to cellular debris, which will be removed by filtration in UK standard products and imported plasma. Residual effects will still include;

- Circulatory overload
- Anaphylaxis associated with plasma proteins. An example is due to antibodies against IgA in IgA deficient patients.
- Transfusion related acute lung injury (TRALI)

Alternative preparations

Solvent Detergent preparations. A commercially available source of pooled, filtered, solvent detergent treated plasma is now available in the UK. The product is advertised as Octaplas produced by Octapharma Ltd. The product is issued as frozen plasma in 200ml packs with batch to batch standardisation. The unit cost is quoted as 44. The plasma source is Austrian and German donors who meet European selection criteria. If the SD process fails then the risks associated with a pooled product are considerably greater than that from a single donor product. The pooled product should confer the advantages of immune neutralisation which is important for viruses such as the Parvovirus B19. However, the manufacturers do not claim to prevent Parvovirus transmission, which may cause bone marrow suppression in some recipients and severe fetal anaemia if given to pregnant women. Octoplas claims to have a lower risk of cell-mediated or antibody-mediated adverse reactions than untreated FFP or methylene blue FFP. Plasma proteins are affected but this does not seem to affect efficacy. Assessment for liver patients has taken place within the trust as a part of a multi-centre trial. The trial has demonstrated clinical efficacy with no adverse side effects. The company literature indicates that the total clinical experience with Octoplas is equivalent to 10 years use of FFP in the UK.

Methylene Blue treated FFP. Baxter, Fenwal division has marketed a system of virucidal inactivation based on methylene blue combined with ultra-violet light. The oxygen free radicals produced cause viral DNA and RNA destruction. The system is designed to treat single units of FFP, i.e. from one donor. The product will reflect the variability of the donor in terms of content and volume, however the product will meet the present specifications for FFP (enclosed). The plasma is filtered for leukocytes before the viral inactivation process. Transfused plasma will contain methylene blue however, statements concerning product safety for neonates, pregnancy and other vulnerable patient groups have been provided by the company. Clinical experience has involved more than 2.2 million units in Europe via the German and Swiss Red Cross. Baxter has indicated that it will introduce plasma treated using this system from next year. The unit costs were not available at the time of writing but it is anticipated that these will not be greater than Octoplas.

Cost considerations for the Trust

The present blood component expenditure is £2.3 million. The cost pressure based on present blood component usage due to the new national pricing for 1999/2000 is estimated to be £1.3349 million. Approximately 60% of cost will be due to red cells. The use and abuse of red cells in the Trust is unknown.

Standard plasma costs will fall from £25 to £18. A solvent detergent treated plasma is available now at £44. The additional cost pressure if we decided to switch all plasma from standard virucidally inactivated plasma is estimated to be £626.1k. The figure acknowledges the difference in bag size (200ml c.f. average 300ml).

Available strategies for the use of FFP

- Minimise transfusion overall risk by good clinical practice. Use by clinicians must be supported by evidence based indications. National guidelines are available for the use of FFP (attached). The present practice in the Trust is unknown. Previous surveys have shown that FFP use can be safely reduced by up to 50% (Dr S Knowles, personal communication). All patients receiving regular blood transfusions should be vaccinated against Hepatitis B.

- Continue with standard single donor FFP which will be leucodepleted by January and NAT tested by spring 1999 reducing the residual risks associated with UK plasma.

- Use solvent detergent virucidally treated FFP, which is pooled from many donors and is a standardised product. The treated plasma inactivates many but not enveloped viruses. A whole plasma pool may become contaminated by a single donation containing HAV or Parvoviris B19.

- Wait for a single donor MB/light treated product next year.

- Use of treated plasma of either type could be Universal throughout the whole trust or on Named patient basis. Both of these measures will be undermined if patients are transferred from other health providers who have a different policy.

Conclusions

The Trust is faced with unavoidable significant cost pressures related to red cell transfusion products for 1999/2000. The pressure might be reduced by clinical audit and education. Treated plasma will be a further cost pressure but will provide a degree of risk reduction. The risk for viruses has been quantified and appears low but must be assessed in terms of potential litigation costs. The risk may be considered important for selected patient groups but must be supported by all health care providers to maintain the benefits for the individual patient.

Recommendations

1. The trust should decide on the approach to the use of treated plasma after wide consultation.
2. Consultation should include clinical and patient user groups and legal advice.
3. The present use of FFP in the Trust should be determined by each of the user groups involved.
4. The trust should introduce a framework, which regularly reviews transfusion issues and examines approaches to reduce unnecessary transfusion costs.
5. Any body considering transfusion issues will need to work closely with the Drugs and Therapeutic committee.
6. Guidelines for the use of standard and treated plasma should be established for future local use and audited.

Statement

The author is an employee of both the Trust and the National Blood Service. The views expressed in the document are the author's own and do not represent a formal statement by the National Blood Service.

Attachments

Guidelines for the use of FFP
Pricing structure for 1999/2000
Blood expenditure for Trust 1997/1998
Review article on Virus Inactivation of fresh Plasma by H Mohr, State of art paper given at the 1998 ISBT meeting.
Commercial literature for Octaplas and PathInact MB Plasma.