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Fresh Frozen Plasma Transfusion – Guideline for Practice

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Target Audience	All staff involved in prescribing and administering blood components

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DOCUMENT VERSION CONTROL SCHEDULE					
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2009 Version 1	Dr Kanchan Rege	May 2009	Original document		April 2009
2013 Version 2	Dr Kanchan Rege	February 2013	Review led by Hospital Transfusion Team. Re formatted into current trust procedural documents format	Quality Governance Operational Committee	27/02/2013
2015 Version 3	Dr M Sivakumaran	13/07/2016	Review led by Hospital Transfusion Team. NICE guidance on indications for use incorporated Information regarding Solvent Detergent treated FFP. Change to post thaw storage time for major haemorrhage. Advice on Hepatitis E negative components included	Quality Governance Operational Committee	12/07/2016
2019 Version 4	Dr M Sivakumaran, Kaye Bowen, Andy King Venables	14/10/2019	Information on Hepatitis E Negative components removed, as all components now screened for Hepatitis E. 1:2 unit ratio of FFP : red cell transfusion in initial resuscitation in major haemorrhage , and 1:1 in trauma with or at risk of massive haemorrhage. New NHSBT leaflet included	Quality Governance Operational Committee	10/10/2019

Key Points

- Fresh Frozen Plasma (FFP) for adult use is produced from voluntary blood donations collected in the UK.
- FFP for patients born after 1st Jan 1996 is collected from non UK donors, to reduce the risk of transmission of variant CJD. The plasma is then virally inactivated by treatment with Methylene Blue or solvent detergent, to reduce the risk of transmission of pathogens.
- The indications for the use of FFP are limited but are primarily to provide clotting factors to prevent bleeding due to coagulopathy.
- FFP is stored frozen (-30°C) and is defrosted in preparation for patient use. At least 30 minutes should be allowed from the time of request to issue to permit appropriate thawing.

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Contents

1. Introduction

FFP is leucodepleted plasma that has been obtained from whole blood donations or by apheresis from male donors. Plasma is sourced from male donors to reduce the risk of transfusion-related acute lung injury (TRALI). The plasma has been rapidly frozen to below -25°C, to maintain the integrity of labile coagulation factors, and may be stored for up to 36 months.

Individuals born after 1st January 1996 should receive either Methylene Blue treated FFP (MBFFP) or Solvent Detergent treated FFP (SDFFP), to reduce the potential risk of transmission pathogens including variant CJD .

Methylene Blue treated FFP (MBFFP) is made from non-UK sourced plasma. It is made from a single donation from a previously tested donor, either a male, or a female who has been screened for any Human Leucocyte Antigens in the last 2 years; it is leucodepleted and treated with methylene blue (MB) followed by exposure to visible light to inactivate viral pathogens.

Solvent Detergent treated FFP (SDFFP) is made from a pool of several hundred donations which are leucodepleted and treated with solvent detergent to destroy viral pathogens. Octaplas LG, a SDFFP which also includes a prion reduction step, is available in the UK.

If MBFFP or SDFFP are not available, patients should be treated with standard FFP, when indicated, in an emergency.

The indications for the use of FFP are limited but are primarily to provide clotting factors to prevent bleeding due to coagulopathy.

The risks of transmitting infection are similar to those of other blood components unless specialised pathogen reduced plasma is used. Of particular concern are allergic reactions and anaphylaxis, pulmonary complications and haemolysis from transfused antibodies to blood group antigens especially A and B.

FFP is stored frozen (-30°C) and is defrosted in preparation for patient use. At least 30 minutes should be allowed from the time of request to issue to permit appropriate thawing. Please note that FFP will only be thawed for immediate use, not on ‘standby’.

2. Purpose

The purpose of this document is to give guidance to clinical staff who may be involved in the requesting, prescription or administration of Fresh Frozen Plasma in North West Anglia NHS Foundation Trust. The guidelines aim to standardise use of FPP across the trust in line with national guidelines.

3. Scope

These guidelines apply to all members of staff involved with the prescription, handling and administration of Fresh Frozen Plasma.

4. Definitions of Terms

FFP – Fresh Frozen Plasma- Plasma produced from blood donations and stored at -30°C.

MB FFP – Fresh Frozen Plasma produced from non UK blood donations and treated with Methylene Blue to reduce the risk of transmission of pathogens.

SD FFP – Solvent detergent treated FFP.

5. Indications for use

Acute Disseminated Intravascular Coagulation (DIC) in the presence of haemorrhage and a documented coagulopathy.

Thrombotic Thrombocytopenic Purpura (TTP) usually in conjunction with plasma exchange.

Major Haemorrhage. Early infusion of FFP is recommended in a ratio of 1-unit FFP to 1-unit red cells for trauma and at least 1-unit FFP to 2 units of red cells in other major haemorrhage settings. Once bleeding is under control, FFP administration should be guided by timely tests for coagulation. The Major Haemorrhage policy must be activated if bleeding severe.

Haemorrhagic disease of the new-born; FFP 10-20ml/kg and Intravenous Vitamin K should be given.

Only consider fresh frozen plasma transfusion for patients with clinically significant bleeding but without major haemorrhage if they have abnormal coagulation test results - for example, prothrombin time (PT) ratio or activated partial thromboplastin time (APTT) ratio above 1.5.

NICE recommends that fresh frozen plasma transfusion is not offered to correct abnormal coagulation in patients who:

- Are not bleeding (unless they are having invasive procedures or surgery with a risk of clinically significant bleeding).
- Need reversal of a vitamin K antagonist.

Replacement of a single clotting factor deficiency when a virus –free fractionated product is not available.

6. Dose and group

FFP is issued according to weight at a dose of 15ml/kg,. This equates to approximately 1L (four units) of FFP for an ‘average’ 70kg patient: heavier patients may require more units (caution should be used in obese patients as

the volume suggested **may be an over estimation and may risk fluid overload**) and lighter patients fewer units.

Weight / kg	15mL/Kg	Units of FFP to be given
50	750mL	3
60	900mL	3
70	1050mL	4
80	1200mL	4
90	1350mL	5
100	1500mL	5

The prescription should ideally be made on the dedicated blood product prescription chart. For adults, FFP should be prescribed as individual units NOT as a quantity in mL. For children the prescription should be in mL

Reassess the patient's clinical condition and repeat the coagulation tests after fresh frozen plasma transfusion to ensure that they are getting an adequate dose, and give further doses if needed.

The PT and APTT should be monitored and kept below 1.5 x normal control (refer to trust policy for massive blood loss).

Patients born after 1st January 1996 should only receive virally inactivated FFP, this is Methylene blue (MB FFP) or solvent detergent treated (SD FFP) from non-UK donors.

In order to avoid the risk of ABO-associated haemolysis in recipients, ABO group identical FFP should be given whenever possible. If not possible, FFP of a different ABO group may be acceptable but only after discussion with the hospital transfusion laboratory staff or Consultant Haematologist. ABO compatibility for plasma components is different to that of red cells and **Group O FFP must only be given to Group O recipients.**

RhD (D) positive plasma may be given to RhD (D) negative females of childbearing potential. Anti D prophylaxis is not required.

FFP has no cellular content and therefore, does not need to be irradiated or to be selected as Cytomegalovirus (CMV) sero-negative

7. Methylene Blue treated FFP (MBFFP) and Solvent detergent treated FFP (SD-FFP)

Methylene Blue treated FFP (MBFFP) is made from non-UK sourced plasma. It is made from a single donation from a previously tested donor, either a male, or a female who has been screened for any Human Leucocyte Antigens in the last 2 years; it is leucodepleted and treated with methylene blue (MB) followed by exposure to visible light to inactivate viral pathogens.

Solvent Detergent treated FFP (SDFFP) is made from a pool of several hundred donations which are leucodepleted and treated with solvent detergent to destroy viral pathogens. Octaplas® LG, a SDFFP which also includes a prion reduction UK guidelines recommend imported SD-FFP for plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP).

8. Administration

FFP must be administered through a 170-200µm filter (standard blood giving set). A filter is required for the giving of FFP via a syringe for neonatal transfusion.

The FFP pack should be visually inspected for pack integrity and discolouration prior to transfusion. Check that packs do not appear grainy or more cloudy than usual. If in doubt, DO NOT TRANSFUSE and contact the transfusion laboratory for advice.

All patients receiving FFP must wear a trust ID band. The patient's identity must be checked by 2 members of staff (either a Doctor, Registered Nurse or Midwife or ODP) prior to commencement of the transfusion. The details on the tag attached to the FFP pack must be checked against the details on the patients ID band. In addition, the patient should be asked to confirm their name and date of birth, if they are able to do so.

FFP takes approximately 20- 30 minutes to thaw, and for maximum efficacy should be administered as soon as possible after thawing.

Start the transfusion as soon as the pack is received. Return unused packs to the transfusion laboratory for safe storage if transfusion is not started within 30 minutes of removal from the blood fridge. FFP that is out of the blood fridge can be accepted back if this occurs on one occasion only of less than 30 minutes.

Transfusion of FFP should be completed within 4 hours of removal from the blood fridge.

FFP packs are stored at 4ºC once thawed, and must be used within 24 hours of thawing- there will be a note to this effect on the compatibility form issued with the pack. JPAC (the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee) have approved an extension of the post-thaw expiry of FFP in accordance with clinical guidelines from 24 hours to 120 hours (5 days) when stored between 2-6°C for use in a major haemorrhage. For indications other than unexpected major haemorrhage, the component should be used within 24 hours of thawing. This change only relates to UK-sourced adult plasma and does not extend to imported MBFFP, the post-thaw expiry of which remains unchanged at 24 hours.

In adults the infusion rate is typically 10–20 mL/kg/hour (approximately 30 minutes per unit), although more rapid transfusion may be appropriate when treating coagulopathy in major haemorrhage

In paediatrics, the recommended rate of transfusion is 10-20ml/kg/hr

Inform the patient of possible complications of transfusion, and the importance of reporting any adverse effects. A number of reactions may follow FFP transfusions. They are the same as those which can occur after the transfusion of red cell concentrates including:

- Febrile Reactions.
- Urticarial Reactions.
- Anaphylactic Reactions.
- Reaction to a bacterially contaminated unit.
- Pulmonary complications. Because of the high volumes required to produce a haemostatic benefit, patients receiving FFP must have careful haemodynamic monitoring to prevent Transfusion Associated Circulatory Overload (TACO).

Follow the same baseline, 15 minute and post transfusion observation checks as for red cell transfusions.

If a reaction is suspected, STOP THE TRANSFUSION, and inform medical staff and the transfusion laboratory immediately. An adverse event and transfusion reaction form must be completed

9. Endorsement

This guideline will be approved by the Hospital Transfusion Committee and endorsed by the Quality Governance Operational Committee.

10. Distribution

This guideline will be available on the trust intranet.

11. References

British Society of Haematology (2018) Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding Available : https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.15167 [Accessed 17/06/2019]

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12. Associated documents

- Blood Transfusion Policy.
- Guideline for Management of Massive blood loss.
- Policy for Competency Assessment of Staff Handling Collecting and/or Administering Blood and Blood Components.

Appendix 1 NHS Blood and Transplant Factsheet- Fresh Frozen Plasma

NHS
Blood and Transplant

FACTSHEET

Standard Fresh Frozen Plasma (FFP), Methylene Blue treated FFP, and Solvent Detergent treated FFP

Information for Healthcare Professionals

The indications for transfusing FFP are limited and specific.
Transfusion of plasma-rich components is associated with an increased risk of adverse events compared to red blood cells.

Please transfuse appropriately.

Fresh Frozen Plasma (FFP)

FFP is leucodepleted plasma that has been obtained from whole blood donations or by apheresis from a male donor. Plasma is sourced from male donors to reduce the risk of transfusion-related acute lung injury (TRALI). The plasma has been rapidly frozen to below -25°C, to maintain the integrity of labile coagulation factors, and may be stored for up to 36 months.

Clinical indications for the use of FFP*

- **Major Haemorrhage –** Early infusion of FFP is recommended in a ratio of 1-unit FFP to 1-unit red cells for trauma and at least 1-unit FFP to 2 units of red cells in other major haemorrhage settings. Once bleeding is under control, FFP administration should be guided by timely tests for coagulation
- **PT Ratio/INR >1.5 with bleeding –** Clinically significant bleeding without major haemorrhage. FFP required if coagulopathy. Aim for a PT and APTT ratio of ≤1.5
- **PT Ratio/INR >1.5 and pre-procedure –** Prophylactic use when coagulation results are abnormal e.g. disseminated intravascular coagulation and invasive procedure is planned with risk of clinically significant bleeding
- **Liver disease with PT Ratio/INR >2 and pre-procedure –** FFP should not be routinely administered to non-bleeding patients or before invasive procedures when the PT ratio/INR is ≤2
- **Thrombotic Thrombocytopenic Purpura (TTP)/plasma exchange**
- **Replacement of single coagulation factor.**

(*National Blood Transfusion Committee Indication Codes for Transfusion, 2016.)

FFP should NEVER be used as circulating volume replacement.

Dosage of FFP

In non-bleeding patients, the recommended starting dose of FFP is 15mL per kg of body weight. This equates to approximately 1L (four units) of FFP for an 'average' 70kg patient: heavier patients may require more units (but caution should be used in obese patients) and lighter patients fewer units.

In major haemorrhage, FFP should be used as part of initial resuscitation in at least a 1 unit: 2-unit ratio with red cells, until results from coagulation monitoring are available. Once bleeding is under control, further FFP should be guided by laboratory tests (transfusion trigger of PT and/or APTT >1·5 times normal) at a dose of 15-20 mL/kg.

Methylene Blue treated FFP (MBFFP) and Solvent Detergent treated FFP (SDFFP)

MBFFP and SDFFP pathogen inactivated plasmas are made from non-UK sourced plasma. They should be used for individuals born after 1st January 1996. Patients who are likely to receive large or repeated doses of FFP should also receive pathogen reduced plasma.

MBFFP is made from a single donation from a previously tested donor, either a male, or a female who has been screened for any Human Leucocyte Antigens in the last 2 years; it is leucodepleted and treated with methylene blue (MB) followed by exposure to visible light to inactivate viral pathogens. Any residual MB is then removed.

SDFFP is made from a pool of several hundred donations which are leucodepleted and treated with solvent detergent to destroy viral pathogens; the residual levels of SD are not toxic. SDFFP is a licensed pharmaceutical product so reactions must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA), via the yellow card scheme, as well as to the Serious Adverse Blood Reactions and Events (SABRE) online scheme. Indications and shelf life of SDFFP are governed by the manufacturer.

If MBFFP or SDFFP are not available, patients should be treated with standard FFP, when indicated, in an emergency.

Practical instructions for use of FFP

Once thawed, the FFP must not be refrozen and should be transfused as soon as possible using a standard blood administration set with a 170-200 micron filter. If delay is unavoidable, standard FFP and MBFFP may be used within four hours if kept at 22°C±2°C or within 24 hours if stored at 4°C±2°C (note – different conditions apply to SDFFP).

Pre-thawed standard FFP can also be stored at 4°C±2°C for up to 120 hours for use only in patients who develop unexpected major bleeding e.g. following trauma. Note that the post thaw shelf life of MBFFP cannot be extended beyond 24 hours.

In an emergency, where pre-thawed FFP is not available, it is important to factor the thawing time of FFP into the availability of the component (usually 20-30 minutes).

The typical administration rate is 10-20mL/kg/hr, but this may vary depending on the patient's condition.

Compatibility

ABO group identical FFP should be given whenever possible; if not possible, FFP of a different ABO group may be acceptable (this must be discussed with the hospital transfusion laboratory staff or haematologist).

ABO compatibility for plasma components is different to that of red cells and **Group O FFP MUST only be given to Group O recipients**.

Group AB FFP contains no ABO antibodies and can be given to anyone, but it is in short supply and should only be used for non- AB recipients if essential. If FFP is urgently needed for bleeding adult patients with unknown blood group, Group A FFP should be used which is high titre (HT) negative for anti-B activity.

Guidance on plasma blood group selection following ABO incompatible haematopoietic stem cell transplants is available in the 2018 BSH guidelines on the spectrum of FFP and cryoprecipitate products.

Blood group selection for Standard FFP HT negative

Recipient Group	O	A	B	AB
1st Choice	O	A	B	AB
2nd Choice	A	B	A	A
3rd Choice	B	AB	AB	B
4th Choice	AB			

Blood group selection for MB FFP and HT untested/positive Standard FFP

Recipient Group	O	A	B	AB
1st Choice	O	A	B	AB
2nd Choice	A	AB	AB	A*
3rd Choice	B	B*	A*	B*
4th Choice	AB			

*Only suitable for emergency use in adults

Standard FFP units must be high-titre negative (HT-) for anti-A/anti-B.

MB FFP units are not tested for HT- for anti-A/anti-B. Group compatible MBFFP and SDFFP should be used wherever possible. Discuss possible options with your transfusion laboratory staff or haematologist.

D group

FFP **does not need to be matched for D group**. D positive plasma components may be given to D negative recipients without the need for anti-D Ig prophylaxis. The EU Blood Directive currently requires that the D group is stated on the label.

If you are unsure about the compatibility of FFP for your patient always check with your hospital transfusion laboratory staff before transfusing.

Specific requirements

FFP has no cellular content and therefore, does not need to be irradiated or to be selected as Cytomegalovirus (CMV) sero-negative.

The use of other frozen components produced by NHS Blood and Transplant is covered in a separate factsheet:

- Standard Cryoprecipitate and Methylene Blue treated Cryoprecipitate.

References:

Green, L *et al* on behalf of British Society of Haematology (2018) *Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding.* Available at: https://www.b-s-h.org.uk/guidelines/guidelines/spectrum-of-fresh-frozen-plasma-and-cryoprecipitate-products/

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Robinson, S. *et al* on behalf of the British Society for Haematology (BSH) (2017) *Administration of Blood Components.* Available at: https://www.b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/

Further supplies of this factsheet can be ordered by accessing
https://hospital.nhsbtleaflets.co.uk

For further information please consult your Hospital Blood Transfusion Policy or contact a member of your Hospital Transfusion Team.

NHS Blood and Transplant

NHS Blood and Transplant (NHSBT) saves and improves lives by providing a safe and reliable supply of blood components, organs, stem cells, tissues, and related services to the NHS and other UK health services. We manage the UK-wide voluntary donation system for blood, tissues, organs, and stem cells and turn these donations into products that can be used safely to save lives or radically improve the quality of people's lives.

We rely on thousands of members of the public who voluntarily donate their blood, organs, tissues, and stem cells. Their generosity means each year we're able to supply around 2 million units of blood to hospitals in England and 7,500 organ and tissue donations within the UK, which save or improve thousands more people's lives.

The information in this factsheet has been sourced from NHSBT transfusion experts. NHSBT Customer Services Patient Blood Management Practitioner Team does not accept any legal liability for errors or omissions.

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Quality Assurance Checklist - Version Number: 3 **Appendix: 2**

		Y/N/n/a	COMMENTS (where necessary)
1	**Title of document** Fresh Frozen Plasma Transfusion- Guideline for Practice (C0329)		
2	**Type of document (e.g. Policy, guidance)**	Guideline	
	Is it clear whether the document type is a policy, guideline, procedure?	Yes	
3	**Introduction**		
	Are reasons for the development of the document clearly stated?	Yes	
4	**Content**		
	Is there a standard front cover?	Yes	
	Are the key points identified? (Policies only)	N/A	
	Is the document in the correct format?	Yes	
	Is the purpose of the document clear?	Yes	
	Is the scope clearly stated?	Yes	
	Are the definitions clearly explained?	Yes	
	Are the roles and responsibility clearly explained? (policies only)	N/A	
5	**Evidence Base**		
	Is the type of evidence to support the document explicitly identified?	Yes	
	Are key references cited?	Yes	
	Are associated documents referenced?	Yes	
6	**Approval Route**		
	Does the document identify which committee/ group will approve it?	Yes	
7	**Process to Monitor Compliance and Effectiveness (policies only)**		
	Are there measurable standards or KPIs to support the monitoring of compliance with the effectiveness of the document?	Yes	
8	**Review date**		
	Is the review date identified?	Yes	
9	**Equality and Diversity (policies only)**		
	Is a completed Equality Impact Assessment	N/A	

If answers to any of the above questions is 'no', then this document is not ready for endorsement, it needs further review.

Compliance Team:		
1.	Date of Compliance Team approval	20/05/2019
2.	Comments to author for any amendments	
3.	Name of compliance lead	Stanley Balachander, Quality Governance and Policies Administrator

Approval Committee: Hospital Transfusion Committee			
If the committee/group is happy to approve this document would the chair please sign below and send the document and the minutes from the approval committee to the author. To aid distribution all documentation should be sent electronically wherever possible.			
Name	LMGNADUQ	**Date**	18/9/19.
Signature			

Ratifying Committee: Quality Governance Operational Committee			
If the committee/group is happy to endorse this document would the chair please sign below and send the document and the minutes from the endorsing committee to the author. To aid distribution all documentation should be sent electronically wherever possible.			
Name	Suzanne Hamilton	**Date**	10.10.19
Signature	SHamilton		