

18.5.99

BCSH
Transfusion Task
Force



MEMORANDUM

TO: Dr Chitra Bharucha
Dr Virge James
Dr Lorna Williamson

FROM: Dr Angela Robinson

CC:

DATE: 17 May 1999

RE: Statement on FFP

Please find attached a copy of a statement which I received via the Northern Zone on 10 May. This will be discussed at the forthcoming Clinical Directors' Meeting on 19 May.

GRO-C

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STATEMENT RE FUTURE PROVISION OF FRESH FROZEN PLASMA (FFP) IN ENGLAND AND WALES

On 14th January 1999, 14 Consultant Clinical Haematologists met in Central London to discuss informally how fresh frozen plasma or its equivalent should be provided. The meeting was underfunded by Octapharma, who made a brief presentation and then left. Twenty senior clinical Haematologists were invited by SJM because of their previous known interest in the subject and to represent a wide geographical area including teaching and District General Hospitals. No consultants from the National Blood Transfusion Service were present. In particular, the consensus views were discussed in detail and the overall opinions expressed were as follows:

1. Although the cost issue is important, it was decided not to specifically discuss this as the aim of the meeting was to recommend the ideal and safest preparation.
2. There was a unanimous decision that a virally inactivated product should be used at all times and that it was probably impossible to completely remove the risk of viral transmission taking the present degree of scientific technology available and level of knowledge about transmission of viruses and other agents at the present time.
3. Because of doubts expressed about the transmission of new variant CJD, it was also agreed that in view of other decisions taken by Government and the transfusion services that, in the short term, British Plasma should not be used for the provision of FFP.
4. There was general agreement that a single unit product rather than a pooled product is the most desirable approach.
5. At the present time, the only single unit product available (in Scotland only at present) is Methylene Blue treated plasma. However, doubts were expressed about this method for three reasons:
 - a. there has apparently been one reported case of transmission of hepatitis C and possibly other viruses using this technique;
 - b. the potential toxicity, particularly to neonates, of patients exposed to Methylene Blue in the final product, especially if a large number of units were to be transfused, is unclear.
 - c. Each individual unit cannot be validated for the inactivation procedure.
6. The other alternative, which is a licensed product, was a solvent detergent treated pooled product which has the unquantifiable risk that because its a pooled product, it may transmit some unknown virus or transmissible agent. In addition, concern was expressed about the potential to transmit parvovirus, and to a lesser extent hepatitis A, despite the fact that neutralising parvovirus antibody is likely to be present in each pooled batch.

All these facts were generally agreed and it was also commented on that the National Blood Authority and the Government have been slow to make a decision and have not taken sufficient advice from Consultant Haematologists in charge of hospital Blood Transfusion Services about the provision of fresh frozen plasma at the hospital level. It was important that a virally inactivated product should replace standard FFP as soon as possible. Suitable clinical trials should be carried out to try and address the problems listed above and that until such data was available, the solvent detergent pooled product was the best alternative available. Concern was also expressed about the potential overall high cost per viral transmission prevented compared to the other problems of transfusion practise highlighted in the annual SHOT reports where safety issues need to be improved nationally.

THE FOLLOWING CONSULTANT CLINICAL HAEMATOLOGISTS ATTENDED AND APPROVED THIS STATEMENT. NONE OF THE CONSULTANTS HAD ANY CONFLICT OF INTEREST OF FINANCIAL SUPPORT FROM ANY COMMERCIAL COMPANY CONCERNED WITH PROVISION OF A FFP PRODUCT IN THE UK:

NAME	TITLE	HOSPITAL
MACHIN S J	Professor of Haematology	UCLH
HAMILTON P J	Consultant Haematologist	Newcastle
HAMPTON K K	Consultant Haematologist	Sheffield
KELSEY, P R	Consultant Haematologist	Blackpool
DUGUID J	Consultant Haematologist	Wrexham
CUMMINS D	Consultant Haematologist	Harefield
COSTELLO C E M	Consultant Haematologist	Chelsea & Westminster
COHEN H	Consultant Haematologist	UCLH
LEE C A	Professor of Haemophilia	Royal Free
BOLTON-MAGGS P H B	Consultant Haematologist	Alderhey
HAMBLEY H	Consultant Haematologist	Welsh BTS
ARYA R	Consultant Haematologist	King's
GORDON-SMITH E C	Professor of Haematology	St George's
WILDE J T	Consultant Haematologist	QE