0070

SUMMARY OF PROPOSALS ON PLASMA QUALITY MONITORING AND IMPROVEMENT

1. QUALITY MONITORING

1.1 In future, all centres must participate in the quality monitoring programme. At present, 2 centres participate on an occasional basis.

1.2 All sampling must conform to a precise uniform standard laid down in a National SOP (to be drafted). This will ensure that each centre's reports on plasma quality can be compared.

1.3 National monitoring of the performance of HBsAg and HIV testing must be reinstated.

1.4 Quality monitoring data to be returned to PFC for collation (not to Law BTS as at present).

1.5 Data will be provided for each category of plasma.

ie. FA recovered
FA machine plasma pheresis
FB
Platelet supernatants

1.6 SNBTS FVIII plasma QA exercises to continue as at present.

2. PLASMA STORAGE AND TRANSPORT

2.1 Each RTC should instal dedicated -40°C freezers capable of holding plasma in transport cages.

2.2 PFC drivers will only collect plasma in loaded cages. PFC drivers will not:-

a) Assist in loading cages.
b) Be responsible for checking inventory

2.3 Dummy packs will be established at each RTC to include temperature probes which can be connected to recording system on PFC van.

2.4 Plasma will only be collected from one site at each Centre.

2.5 Each plasma delivery must be fully temperature monitored.

3. DOCUMENTATION

3.1 National SOP's will be generated for key activities of sampling and testing.

3.2 Different plasma categories will be established for different plasma types, eg.

FA = recovered plasma
FC = plasmapheresis plasma
FD = platelet supernatant plasma

3.3 A uniform plasma delivery note will be developed for use by all RTC's (At present, 2 RTC's use locally generated documentation).

3.4 Ensure that each delivery note is correctly signed to indicate that HBsAg and HIV testing has been carried out.

3.5 Extend plasma accreditation process to indicate that all features of the plasma specification have been complied with.

4. REVISION OF PLASMA SPECIFICATION

4.1 Consider setting minimum plasma volume per pack at ≥ 200mls. (This may mean pooling two donations).

4.2 Develop plasma collection programme to increase target plasma VIII content to a mean of 0.9 iu/ml.

Current performance (1990)

BELFAST	:	0.94	(n = 7)
GLASGOW	:	0.77	(n = 7)
EDINBURGH	:	0.89	(n = 7)
INVERNESS	:	1.08	(n = 7)
ABERDEEN	:	1.23	(n = 3)
DUNDEE	:	Not Known.	

However, standardising sample taking may influence the above data.

5. AUDITING

5.1 A full programme of audits must be carried out in 1991 by PFC staff. This will have the following components:

a) Pre audit briefing
b) Audit
c) Post audit debrief
d) Generation of report
e) RTC to indicate intended action and itemise any factual error in report
f) Follow up as necessary

5.2 A programme of self-inspection audits to be developed by RTC/SNBTS QA personnel:- format to be agreed with PFC personnel.

6. DATA FOLLOW UP

6.1 We must not ignore failures to meet specifications. Remedial action must be taken in all cases.

6.2 SNBTS action teams may have to be established to take action on intractable problems, eg. low plasma FVIII activity.

7. FURTHER REPORT

A further expanded report will be generated within 4 weeks providing further details on the above proposals together with a compilation of existing data.

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