SIT TO ABERDEEN AND NORTH EAST SCOTLAND BLOOD TRANSFUSION SERVICE

TE: 24 March 1982

SPECTORS: Mr K J Ayling
Mr D Haythornthwaite

RSONNEL SEEN: Dr B Lewis - Director
Dr C Camm - Medical Adviser to Building Division of the CSA
Dr A D Farr - SCMLSO

INTRODUCTION

1. Previous informal visits were paid on 9 June 1981 and 2 May 1977.

2. The Centre takes in about 35,000 donations per annum. It also supplies blood to the Orkney and Shetland Islands. About 30% of donations are taken at the Centre.

3. This report concentrates on certain limited activities taking place at the Transfusion Centre. A more comprehensive report would require up to a further two weeks based at the Centre.

4. Part of the time available was spent discussing the plans for upgrading which would allow the Centre to expand onto the second floor recently vacated by the Pharmacy.

5. There remain a number of very unsatisfactory features about the upgrading plans. In any case this upgrading is seen only as an interim solution and serious consideration must be given to a new Centre by June 1987.

SUMMARY OF UNSATISFACTORY FEATURES WITH REGARD TO THE PLANS FOR UPGRADING

6. Ground floor central corridor, off which the main manufacturing and processing room is situated, is the main thoroughfare with unrestricted access.

7. The presence of a Medical Physics facility within the boundaries of the Transfusion Centre.

8. The location of the Hepatitis Testing Laboratory in close proximity to a Medical Physics Department.

9. The proposed aseptic laboratory "falls short" of acceptable standards in a number of ways:

It is too small.

It has an inadequate change facility.

There are no air locks or hatches for material transfer.

Segregation of activities will be difficult.

It lacks security.

Full specifications were not available for detailed discussion.

10. Personnel with separate responsibilities for QC and Production have not been nominated, but it is hoped that this can be resolved without difficulty.

2. STAFF LIST

11. See Appendix 1 for Organisation Chart, page 1.

Dr B Lewis	-	Director
Dr Grove	-	Associate Specialist
Dr Doss	-	Associate Specialist
Dr Farr	-	SCMLSO, responsible for all MCSO staff supervision with special responsibility for supervising the MLSO engaged on hepatitis testing
Mr Wilson	-	CMLSO donation testing and plasma processing
Miss Patterson	-	SMLSO " " " " "
Mr Main	-	CMSCO special red cell serology and ante-natal testing
Mr Clark	-	SMLSO " " " " " " "
Mr McKenzie	-	CMLSO crossmatching
Mr Wood	-	SMLSO "
Mr Shewan	-	CMLSO tissue typing and histocompatibility test
Mr Campbell	-	SMLSO " " " " "
Mrs Russell	-	MLSO hepatitis testing

3. LIST OF MEDICINAL PRODUCTS

12. Cryoprecipitate and cryosupernatant have been diccontinued at this Centre.

13. Details of the preparations produced over the last 6 years are listed in Appendix 1 page 2.

14. Details of plasma fractions issued are listed in Appendix 1 page 4. These are obtained from the PFC but not necessarily pro rata.

15. Small quantities of plasma (65.5 kg in 1981) are collected by plasmapheresis for specific immunoglobulins. All donations are taken into CPD except a few taken int EDTA solution for processing at PFC.

LIST OF PRODUCTS SENT TO THE PFC

16. Fresh frozen plasma
EDTA plasma
Specific immunoglobulin
Plasma from outdated blood

FOR LOCAL USE (blood taken into CPD)

17. Fresh frozen plasma
Platelet concentrate, platelet rich plasma
Red cell concentrate
Washed red cells
Whole blood

4. INSPECTION

4.1 STORAGE FACILITIES

18. This Centre suffers from a chronic shortage of storage space, hence one of the needs for a new facility.

+4°C room refrigerator (charted and alarmed) walk-in

19. Access to this is via the Grouping Laboratory. It is hopelessly overcrowded. Erroneous issue from this store has resulted in hepatitis positive blood being transfused on one occasion, yet it is still not possible to physically segregate between quarantined and cleared stock and there is a danger of HBs Ag positive blood being issued.

List of products

20. Blood in bags (quarantined)
Blood in bags (cleared)
F VIIIc (cleared)

-30°C deep freeze (charted and alarmed) walk-in

21. This cold store was absolutely full to the door with no further storage possible. This is undesirable for a number of reasons including an inability to rotate stock, difficulty in ensuring an even low temperature, and the impossibility of removing heavy ice build-up. Whether -30°C or -40°C is a more appropriate storage temperature when fresh frozen plasma is held for a month seems to be an open question at the moment. (Temporary storage has been made available locally as an interim measure.)

22. Materials stored here included fresh frozen and time-expired plasma, and blood grouping reagents.

Theatre blood store refrigerators (not seen)

23. It is understood that these are checked daily by Centre drivers who would remove any blood which had gone 48 hours past the quoted required date. Blood is frequently reissued. Refrigerators are monitored and alarmed but it is not possible to know with certainty that blood has not been mishandled from these units.

Other storage facilities available

24. A number of other small and crowded rooms, cupboards or corridors are used for storing miscellaneous items including such diverse items as plasma pooling bags, chemical reagents, patient records, stationery, and the materials used by the "mobile team".

4.2 RECEIPT OF BLOOD AND COMPONENTS

25. 30% of blood is currently taken at the Transfusion Centre. The other 70% is acquired using a single mobile van with its team.

26. Small quantities of plasma are obtained via a plasmapheresis programme. (Appendix 1, page 5).

27. Stock levels are determined according to a predetermined schedule amended as required.

28. The donor van itself contains two +4°C hold-over refrigerators which are plugged in whilst at the donor centre. A thermometer is used to keep a check on the temperature during transport back to the Transfusion Centre.

29. Blood is transferred to the +4°C room refrigerator on trolleys where it is held until cleared; then it is transferred to shelves. Some presumptive labelling is done at the point of blood donation.

PROCEDURES FOR TAKING BLOOD AT THE CENTRE

30. After answering a questionnaire on the state of their health a blood sample is taken from the ear. Two different strengths of copper sulphate solution are used for haemoglobin determination (depending on whether male or female).

31. Numbers are issued and a written record made.

32. One donor attendant is used per 2 beds. The Fenwal balance (said to be repeatable to 5-6 gms) automatically "cuts off" the blood supply at the pre-set weight. Regular attention to these balances is important.

33. Double packs are predominantly used.

34. Two pilot tubes are used, one for the clotted samples, the other into ACD. Seven sealed segments are produced from the donor line for matching purposes.

LABELLING OF BLOOD PACKS (not seen)

4.3 BLOOD AND BLOOD PRODUCT PROCESSING

Separation of fresh frozen plasma (closed process using double packs)

35. This is carried out in a domestically clean laboratory housing the centrifuge, separators and ethanol/dry ice freezer.

36. A constant 200 mls is separated using a Fenwal balance with cut-off. A Damon centrifuge is used for spinning down the red cells. Dry weights are available for balancing purposes.

37. About 85% of the blood processed for fresh frozen plasma is processed within 6 hours; the rest within 12 hours.

38. Blood collected at the Centre is processed within 2 hours.

39. Red cells concentrates are stored at +4°C. On clearance they are transferred to the Blood Bank with a shelf life of up to 14 days. After this they may be incinerated or sluiced.

40. This Centre sends fresh frozen plasma to the PFC as individual frozen 200 ml packs.

The "Asentic" facility

41. This is used for:

Pooling of outdated plasma
Supernatant platelet pooling
EDTA plasma pooling
Preparation of washed red cells.

42. A vertical LAF cabinet is housed in a partitioned room but the area is unsatisfactory for a number of reasons:

Vertical blinds at the opening windows
Absence of a change facility (ie uncontrolled entry)
Absence of hatch/air lock
Some surface damage to walls, and coving appears to be "coming away"

Ledges and other dust traps are present (eg hanging light fitting)
Ventilation is not HEPA filtered or terminally filtered
Soft chairs are inappropriate
No manometers are present to indicate pressure differentials.

4.4 QUALITY ASSURANCE

43. The varying laboratory functions are summarised in Appendix 1, page 1.

Grouping

44. This is done manually and by machine for new donors. By machine (Technicon BG15) for existing donors. Spent material from the Technicon drops into a chloros solution.

45. Reagents are routinely obtained from their own donors with ABO anti-sera coming from the Blood Group Reference Laboratory who are, in turn, supplied with "raw materials" on a pro rata basis.

46. It was noticeable that the Technicon BG15 equipment was very noisy and is a prime candidate for replacement.

47. There is now a double check in the grouping laboratory before details are issued for blood by labelling following an error which was not discovered until the final matching stage.

48. Donor reference samples are not retained (lack of space).

Syphilis testing

49. This is carried out at the far end of the grouping laboratory, manually, and on the Technicon machine. New donors are tested manual and machine. False positives are more frequent than true positives (very infrequent).

Label printing

50. This is done in the vicinity of the syphilis testing area. It would be better located in its own area.

Hepatitis B testing

51. This facility is poorly provided for. Opening windows with strip blinds allow a constant stream of air to blow through the laboratory into the corridor. Within the room there are no means of containment either by use of fume cupboards or safety cabinets. No air lock system or staff changing facility are available. Contaminated material is incinerated. The Centre does not have an autoclave for inactivation of contaminated material.

52. Patients known to be HBs Ag positive cannot be matched in a suitable dedicated laboratory. The hepatitis testing technician would carry out such tests in a separate laboratory (next to the Director's office). This Centre uses Ausria II for hepatitis testing.

53. Any positives (donations) are repeated with an embargo on the containers until shown to be negative. Repeat tests are carried out on a segment taken from the suspect bag.

54. Aberdeen "showed up well" on the PHLS periodic "blind" test.

The concept of Quality Assurance

55. The impressions gained is that there is "ground" to be made up here in terms of both appreciating and implementing Quality Assurance. Centre staff and the Inspector were unable to resolve this issue satisfactorily.

Other testing needed

56. Increased confidence might be gained as well as improving product effectiveness by introducing certain testing procedures and encouraging "clinical feedback". Examples include:

Microbial data on products (eg expired products)
Environmental monitoring
Meaningful reports from Service Contractors
Platelet counting
Haematocrits
pH
Random weight checks on blood bags
Pharmacopoeial tests (where appropriate).

4.5 DOCUMENTATION AND STANDARD OPERATING PROCEDURES

57. A start has been made on this topic though many more details remain to be written up and procedurised. SOPs have been prepared for products in Section 3 (Appendix 2 - on file; not part of Report).

4.6 TRAINING

58. This would appear to need to be made more formal though it is accepted that staff do rotate through laboratories to learn in the different areas.

59. It appears that for a Science Graduate to become a State Registered MLSO there is an oral examination.
(This is generally applicable throughout the UK and is not specific to Aberdeen.)

60. Proficiency tests are conducted about 6-monthly.

5. SUMMARY OF ITEMS REQUIRING ATTENTION NOTED DURING THE VISIT

61. Lack of adequate storage facilities for both ambient and refrigerated storage.

62. Inadequate processing facilities for aseptic work and some laboratory areas need improving. Much more space is needed so that adequate segregation can be practised.

63. Insufficient plasmapheresis facilities.

64. Some equipment needs improving (such as the noisy Technicon grouping machine) which would be best replaced by automated grouping equipment linked to a computer control system.

65. Inadequate hepatitis testing facility.

66. Staff training was not formalised.

67. The concept of quality assurance needs to be developed. Initially personnel responsible for QC and Production should be defined and a brief given to them.

68. Documentation, specifications and standard operating procedures need progressing.

CONCLUSIONS

69. This Centre needs more and improved storage space and facilities.

70. The Centre has competent staff but lacks comprehensive QC data to substantiate its activities.

RECOMMENDATIONS

1. Improved facilities and storage space should be provided no later than 11 June 1984.

2. Comprehensive and formal staff training should be implemented no later than 11 December 1982.

3. Full SOPs should be available no later than 11 March 1983.

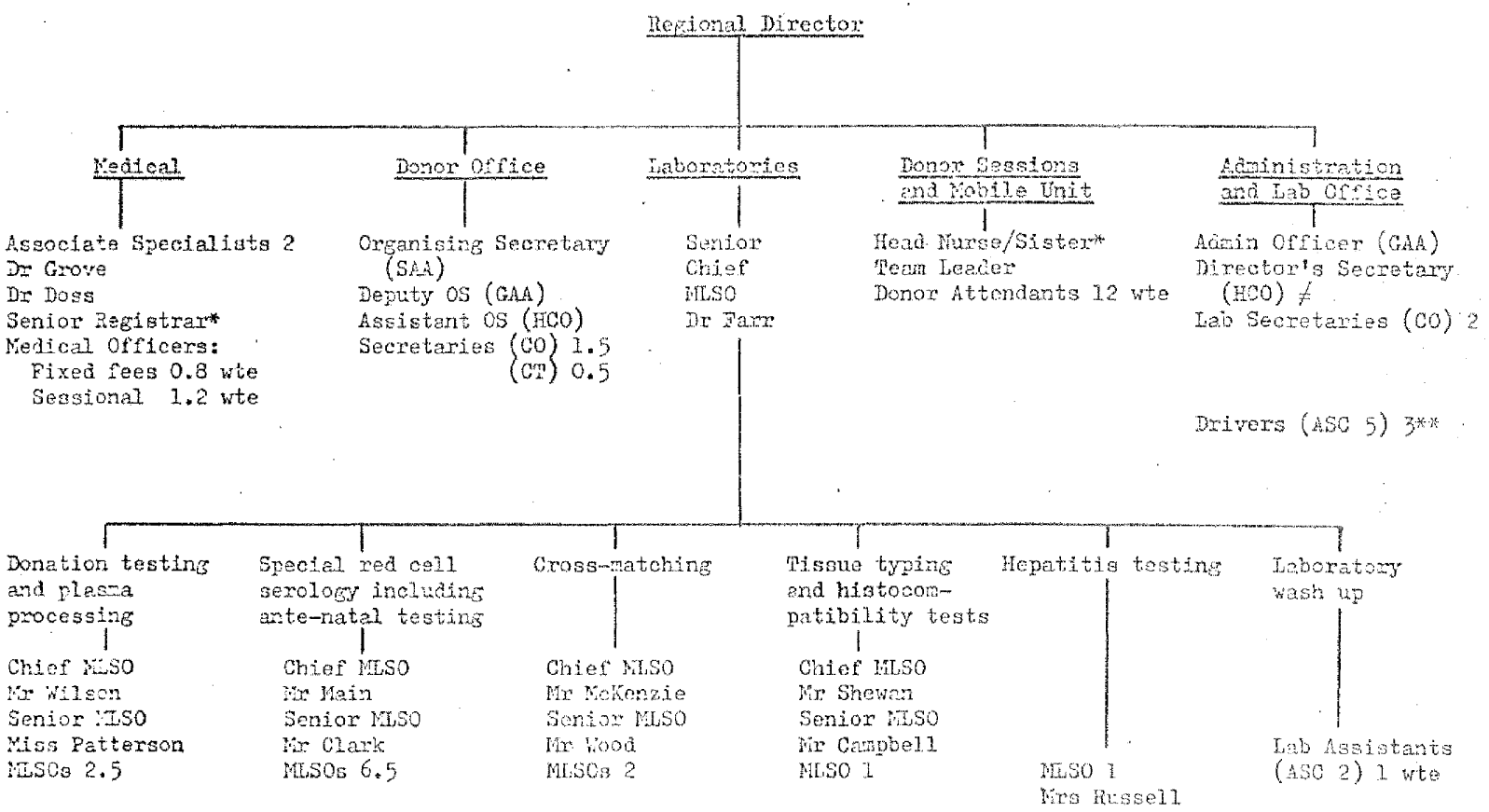
4. Quality Control procedures should be introduced on an on-going basis.

5. Restrictions must be placed on the activities carried out in the Components Laboratory (such as no Open Processes) until an appropriate Aseptic Laboratory has been provided.

6. Consideration must be given to a new purpose-built Centre within 5 years.

Aberdeen and North-East of Scotland Blood Transfusion Service

STAFF ORGANISATION



* Post vacant
** One post vacant
≠ Directly responsible to Regional Director but deputises for Administrative Offic

PRE-CLINICAL SERVICES 1975/76 to 1980/81

	75/76	76/77	77/78	78/79	79/80	80/81	
Donors attending	28,044	29,835	30,707	31,570	33,309	34,592	
Donors bled	27,125	29,039	29,841	30,565	32,225	33,434	
Full donations obtained	25,612	27,419	28,363	28,919	30,725	31,792	
Units transfused (donations):							
– whole blood	8,753	8,210	8,766	7,683	8,369	8,157	
– red cell concentrate	3,125	3,666	4,587	5,892	7,298	7,396	
– platelets	519	272	954	767	857	1,741	
– cryoprecipitate	1,825	1,005	1,228	1,320	1,987	1,585	Discontinued
– fresh frozen plasma	20	46	78	159	284	458	
Plasma sent to PFC (kg)							
– fresh	43	129	654	1,188	1,831	1,587	
– cryosupernatant	254	295	556	536	786	390	Discontinued
– out-dated – 1st class	2,121	2,743	2,478	2,158	1,826	2,131	
– 2nd class	344	148	0	0	139	62	
– EDTA	0	0	0	45	2	68	
– for specific immuno-globulins	6	10	31	30	21	57	
– total plasma	2,768	3,325	3,719	3,957	4,605	4,295	

PARA-CLINICAL SERVICES 1975/76 to 1980/81

	75/76	76/77	77/78	78/79	79/80	80/81
Patients grouped and matched	10,492	10,258	10,591	11,285	12,307	11,909
Units (donations) matched	30,973	31,824	31,753	33,440	37,029	35,935
Patients grouped (only)	402	529	530	620	698	716
Samples relating to pregnancy	12,865	13,078	13,197	14,262	14,582	15,248
Samples investigated for AIHA:						
– from Drug Monitoring Unit	8	6	31	19	20	17
– from other sources	127	220	84	134	214	201
Sera screened for HLA antibodies:						
– from ante-natal patients	8,420	9,320	9,360	9,291	9,297	9,030
– from renal patients	0	524	560	416	458	578
Patients (and others) tissue typed	29	220	105	118	223	257
Histocompatibility tests	10	13	7	16	15	17
Samples from patients tested for HBsAg	22,637	21,549	22,976	24,351	27,139	25,965
Emergency service:						
– No. of calls	2,097	2,151	2,238	2,672	2,652	2,657
– No. of samples	3,547	3,617	3,681	4,546	4,974	5,094

ISSUES OF DRIED PLASMA AND PLASMA FRACTIONS
1975/76 to 1980/81

	75/76	76/77	77/78	78/79	79/80	80/81
Dried plasma (400 ml)	744	823	12	3	155	91
Plasma protein solution (400 ml)	239	325	2,177	3,173	3,850	4,740
Albumin – 45 g	50	45	180	117	122	122
– 1 g	0	10	0	10	11	0
Coagulation factors:						
– Intermediate factor VIII (vials)	219	475	510	524	548	724
– Fibrinogen (2g)	4	26	14	10	20	4
– Factors II, VII, IX, X (vials)	5	43	10	8	14	0
– Factors II, IX, X (vials)	0	10	4	2	4	20
Immunoglobulins:						
– Normal - 750 mg	131	141	248	187	234	319
- 15 mg	0	0	1	5	13	8
– Anti-D - 50 ug	228	249	269	272	352	399
- 100 ug	620	587	653	711	768	813
- 1000 ug	6	6	4	4	11	3
– Anti-vaccinia (2000 iu)	0	2	2	5	0	0
– Anti-tetanus - 250 iu	12	9	0	114	327	370
- treatment pack	0	1	0	0	0	0
– Anti-HBs (500 mg)	21	13	49	39	119	76
– Anti-varicella/zoster (500 mg)	0	0	6	10	35	40
– Anti-rubella (750 mg)	0	0	0	5	7	1