VISIT TO INVERNESS AND NORTH SCOTLAND BTS

DATE: 5 May 1982

INSPECTOR: D Haythornthwaite

1. INTRODUCTION

1. A previous informal visit was paid to this Centre on 16 June 1981.

2. Insufficient time was available for an examination of all activities.

3. The Centre takes about 14,000 donations a year.

4. The Centre is an important source of 'Anti-D' immunoglobulin obtained by a plasampheresis programme of boosted male donors. The proposed shut-down of the PFC for 4 months in 1983 has already been recognised as a 'difficult' period and methods of overcoming possible shortages are being considered.

5. Personnel with separate responsibilities for QC and Production have not been nominated.

6. Proportionately the Centre itself takes few donations. Some advantage might be obtained by increasing these donations and using a suitably equipped van. Some measures might be of importance to overcome short term shortages caused by adverse weather conditions.

7. The central corridor through the Centre appears to be used by people other than Centre staff. This poses some security problems and should be changed.

2. STAFF LIST

8. See Appendix 1.

3. LIST OF MEDICINAL PRODUCTS

9. Whole blood.

Plasma reduced blood (= Red cell concentrates).

Leucocyte poor blood (Dextran sedimentation now but may be filtered in the future).

Frozen "blood" for renal unit (to be discontinued).

Heparinised blood for neonates.

Platelets.

Fresh frozen plasma - patient use
- PFC processing
Plasma for Immunoglobulin - PFC processing (Mainly derived from plasmapheresis).

10. Cryoprecipitate as a source of F VIII has ceased. A stock of 12 packs kept frozen as a source of fibrinogen has been retained for emergency use.

INSPECTION

4.1 STORAGE FACILITIES

+4°C QUARANTINE REFRIGERATOR (Charted and alarmed)

11. Blood received from donor sessions arrives in crates. The blood bags are not presumptively labelled.

12. Bags are labelled before the results of hepatitis are known but they are returned to the quarantine refrigerator. A definite communication is received regarding the results of hepatitis testing. At this stage whole blood and red cell concentrates available for transfusion are transferred to the "blood for issue" refrigerator.

DISCUSSIONS included the following items:

13. The wide range of other items present. These included materials which could be issued (eg F VIII; immunoglobulins) as well as various reagents including those used in hepatitis testing, tissue typing and the VDRL carbon antigen.

14. It is recommended that additional small refrigerators are obtained so that in particular reagents can be stored in their appropriate laboratory.

15. Some blood bags are set aside for further investigation. It is recommended that these remain without their grouping label until the investigations are complete in order to help prevent any possibility of erroneous issue.

16. Refrigerators can and are independently monitored for temperature.

- 40° DEEP FREEZE

17. Access to this is gained via the +4°C quarantine room. This store is mainly used for FFP for the PFC. With the monthly collection schedule this refrigerator gets very full. This means that increased plasma procurement is impossible and it is recommended that the frequency of plasma collection is increased.

+4°C ISSUE REFRIGERATOR (Charted and alarmed)

18. This is located with an entrance into the Cross Matching Lab.

19. A particular 'Split' is maintained between concentrated red cells and whole blood. Particular shortages are normally remedied by bringing in specific donors as required.

20. Returned blood after cross matching may be reissued. Some confidence exists as the staff from the BTS carry out regular checks of hospital blood banks. Whether one can ever be absolutely certain that blood has not been mishandled is another matter. Centre staff do carry out reconciliations of blood issued, used and returned.

OTHER STORAGE AREAS (Not seen)

4.2 RECEIPT OF BLOOD AND COMPONENTS (Not seen)

4.3 BLOOD AND BLOOD PRODUCT PROCESSING

21. Component processing is carried out in a single room in which plasma/red cell centrifugation and subsequent separation is done. At this Centre plasma is separated by a syphoning (as opposed to a pressure pad technique). A constant weight of plasma (200 gms) is removed to produce red cell concentrates in the form of plasma depleted blood.

22. It should be noted that activities requiring a small aseptic facility and in which some 'open' processing may be involved are also carried out under a Bassaire horizontal LAF cabinet.

23. It is recommended that:

24. A small aseptic processing laboratory should be made available.

25. Centrifuges should be segregated off in a separate room. Centrifuges were also located in the former 'cryo' store room as well as the corridor indicating the need for more space.

26. The present room with its opening windows, lack of change room and incompatible activities is unsatisfactory. A small clean room facility would allow safe processing of platelet and time expired plasma pooling (2 litre pools) as well as recovering red cells from cryo protective agents. It would also be available for those occasionally needed preparations should it be necessary (eg cryo precipitate).

27. Brief discussions were held on the techniques involved in platelet pooling. This involves piercing the inlet port on 6 separate blood bags in order to transfer the contents to a single bag. In particular the preparations of the LAF unit (eg it is used almost immediately it is switched on) and the lack of clean room clothing and sterile gloves were mentioned.

28. It was also felt to be desirable practice to use a filter on material given to donors if this was feasible.

29. In view of the geographical difficulties of this region it is remarkable that two-thirds of the fresh frozen plasma processed is 'under 6 hour' material. Only a third is delayed for up to 18 hours.

30. The vacated liquid nitrogen room needs some attention (eg floor tiles are cracked and the wall damaged in places where services have been removed). The preparation room contains benches with their surfaces lifting and these should be repaired.

4.4 QUALITY ASSURANCE

31. A limited quality control testing programme is run. The details might be more accessible and high-lighted if summarised in their own manual. Individual operating procesures refer to some tests. Platelets for example, are routinely counted before administration and an interesting data bank has been established on this product.

32. Requirements for the length of maintenance of records can vary. However, the addition of a micro-filming of micro-fiche facility for this purpose would have advantages and allow the disposal of original records.

33. Laboratory facilities include:

GROUPING (Not inspected).

34. All grouping is done manually using micro plates. It was observed in passing that some reagents were "well past their expiry date".

CROSS MATCHING

35. This is done in a small laboratory which is short of working space. Under periods of pressure samples for matching 'back up' in a potentially hazardous manner. Plans have been proposed for overcoming this deficiency but have not been implemented.

36. An Apple II micro processor has been installed for storing information, printing labels, retrieving data, and in helping with the 'Group and Retain' patient screening service. This particular scheme helps in reducing pressure on the cross matching laboratory and allows a much faster supply of compatible blood.

37. However, it is recommended that the Apple II is taken to the next stage of sophistication which would enable it to be used for scanning label details and checking compatibilities automatically.

"OUTSIDE" LABORATORY FACILITIES

38. A limited "in numbers" service is provided by the hospital bacteriology department who carry out 4 microbiological tests per week.

39. The testing carried out exceeds the requirements of the Pharmacopoeia and may be a contributory factor in the number of tests possible.

40. It is recommended that the possibility of Centre staff carrying out their own microbiological work is investigated if the other department is unable to increase the testing.

41. The hospital biochemistry department supplies a service in screening plasmapheresis donors bled at the Centre.

HEPATITIS TESTING (Not inspected)

42. This was briefly visited only. The BPLRIA test is used. A low percentage of positives is recorded, (3 in 14,000 in 1981). A Bassaire safety cabinet is available for containment purposes. (Formaldehyde treated every fortnight).

43. The high incidence of false positives was discussed (about 3%) and the action followed should a positive be indicated.

SYPHILIS TESTING (Not inspected)

44. This is done manually.

4.5 DOCUMENTATION AND STANDARD OPERATING PROCEDURES

45. Centre staff have available a comprehensive manual detailing most of the activities of the Centre. The Director has also given added guidance on donor selection which eliminates the "guesswork" seen at other Centres with regard to whether blood should be processed or not.

46. A few activities remain to be 'written up'. A most useful addition would be a document summarising the QC tests carried out.

4.6 PLANNED PREVENTATIVE MAINTENANCE

47. Some items of equipment are on 'service schedules' but problems are apparent for the Centre for some equipment. Presumably encouragement is needed for greater 'internal capabilities' to be developed.

5. SUMMARY OF ITEMS DISCUSSED

48. Centre should try and exclude 'other' personnel. (Restricted access needed).

49. More space is required (eg Cross matching) and certain modifications are needed to provide improved clean room facilities.

50. Some activities need segregation (eg centrifuges) and improved conditions.

51. More refrigeration space is required (to enable increased plasma procurement and to enable more appropriate storage of reagents).

52. Documentation seen was considered as very good. A few more details require completion.

53. Consideration needs to be given to the question of QC checks and the possible future increase in their own increased microbiological testing capability.

54. Some minor practices were discussed and felt to be capable of improvement.

55. Some minor repair work was noted for attention (eg Preparation area and the Liquid Nitrogen room).

CONCLUSION

56. The centre is a well run unit staffed by competent people.

57. More appropriate facilities need to be provided in the future.

58. A number of 'differences' in procedures occur at this Centre compared to other Scottish Centres. Such differences may be only applicable to smaller throughput Centres. These differences are unlikely to adversely affect the product.

RECOMMENDATIONS

1. A small aseptic facility and segregated Centrifuge space should be provided no later than 11 December 1983.

2. The Cross Match Lab should be modified no later than 11 December 1983.

3. Minor repair work (eg bench surfaces, floors and wall surfaces in the Preparation Room and the Liquid Nitrogen, and the question of access) should be completed no later than 11 June 1983.

4. Further refrigerators should be provided by 11 June 1983.

5. All other items may be completed on an on-going basis.