

VISIT TO EAST OF SCOTLAND BLOOD TRANSFUSION CENTRE, DUNDEE (Nine Wells)

DATE: 25 March 1982

INSPECTORS: Mr K J Ayling
Mr D Haythornthwaite

1. INTRODUCTION

1. A previous informal visit was paid on 10 June 1981.
2. The Centre takes about 33,000 donations per annum. It also cross matches 70% of the Region's requirements.
3. Although a comparatively new hospital several surgical specialities are split between the new hospital and the "old" Royal Infirmary. All cross matching is at Nine Wells.
4. Within the Transfusion Centre itself donors are bled on level 8 and the processing, storage and testing facilities are found on level 6.
5. Personnel with separate responsibilities for production and quality control have not been nominated.
6. Licences held by the Centre expired on 30 June 1981 and have not been renewed.
7. Brief discussions were held on aspects of "Clinical Validation". For instance, it had been learned that "Platelet Rich Plasma" was clinically more effective than "Platelet Concentrates" which in turn might be attributable to the method of preparation.
8. This particular example shows the importance of not accepting without further evidence the recommendations of suppliers (in this case centrifuge suppliers). Presumably their instructions can only be treated as guidance.
9. A further "lesson" that might be drawn from such examples is the data that a Quality Control section could provide. By defining specifications and amassing information on preparations as well as arranging for "clinical feedback" the most effective preparations should be capable of being made.
10. Brief discussions were also held on sources of donated blood. At the time of this visit the Inspectorate had not visited donor sessions with "Mobile Teams". However, it would seem most unlikely that we could continue to endorse the continued collection of blood from such places as Prisons and Borstals.
11. This recommendation is based on the following:
 - 12.(a) Prison Medical Officers are often not involved in assessing the suitability of donors.
 - 13.(b) The increased risk of infection associated with prison populations and the increased risk of transmitting disease through such donations.

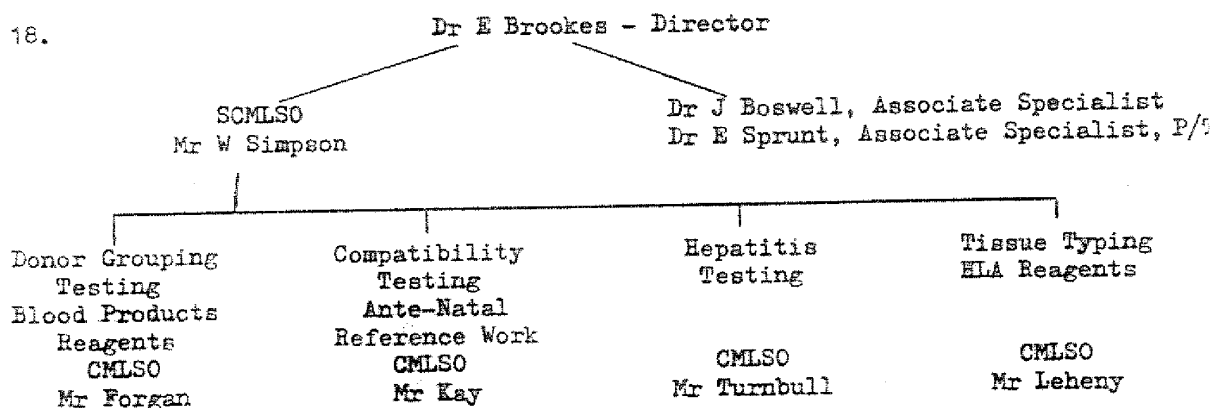
14.(c) The unreliable answers to the pre-donation questionnaire that can occur in such environments as well as the motivation of some of the donors.

15. Whilst it is understood that the questionnaire used for donors is a fairly standard one its interpretation appears not always to be consistent. It is also not entirely clear just where the responsibility rests as to whether blood should be used. For example precise advice as to which medicines are "acceptable" is needed rather than the somewhat arbitrary procedure presently used.

16. The practice of filling syringes from a multi-dose container with local anaesthetic for a donor session is not a good one. Other more satisfactory arrangements are needed (and could probably be provided by the PFC if the appropriate investment were made).

17. 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.

2. STAFF LIST AND ORGANISATION CHART



Total MLSO Establishment : 4 Senior MLSO
11 Basic and Junior

These members of staff are rotated through each Laboratory.

3. LIST OF MEDICINAL PRODUCTS PREPARED

19. Fresh frozen plasma (within 8 hours) (PFC)
 Fresh frozen plasma (8-18 hours) (PFC)
 Cytoprecipitate may be offered if fibrinogen is requested
 Platelet concentrates and Platelet rich plasma
 Washed red cells
 Concentrated red cells and plasma reduced cells
 Fresh frozen plasma for local use
 Plasma containing Anti D, zoster, rabies, rubella, measles, mumps,
 Hbs antibody (for PFC)
 Outdated plasma
 Buffy coats and leucocyte-poor red cells
 A small manual plasmapheresis programme exists (about 5-11 donations a week/mainly for specific immunoglobulin s and AB plasma

20. There would appear to be a demand for greater platelet preparations to satisfy certain Medical Specialities at Dundee (eg oncology). There is also scope for processing more fresh frozen plasma but this would probably require some 'out of hours' working. The Centre already supplies fresh frozen plasma as single packs rather than pooled.

21. 60 per cent of donations are taken into double packs. 40 per cent into singles. In the near future it is proposed to introduce the triple packs with the new platelet bag with increased storage.

4. INSPECTION

Storage Facilities

+4°C Main Blood Bank (Alarmed and charted)

22. This refrigerator is used to store a wide range of products:

Whole Blood - both cleared and quarantined (segregated on trolleys)
 (quarantine = untested)
 Time expired blood (red cells are discarded) awaiting separation
 Albumin (Liquid)
 FV111C (Dried)
 Gamma globulin
 Packed cells for issue

23. It is understood stock rotation is practised. Some stock was seen 'on the floor' which is undesirable and certain packs with labels peeling off were understood to be representative of a problem since resolved.

24. Returned blood would be recycled if it had remained within the hospital.

-30°C Deep Freeze (Charted and alarmed)

25. This was very full and iced up though it has been improved since the last visit by the addition of a plastic strip and a heated door seal.

26. Such heavy usage of refrigeration can cause stock rotation problems and control of ice becomes very difficult.

General Equipment Room - Containing Chest Deep Freezer

27. This is used to store plasma on a temporary basis. It was neither charted nor alarmed. The top was damaged.

28. There is also a -80°C tissue typing reagent refrigerator.

Corridor Storage

29. Corridors were being used to store material as diverse as:

Product eg stable plasma protein solution

Materials potentially contaminated with hepatitis

Fresh frozen plasma on a temporary basis awaiting collection by the PFC van

Other Ambient Temperature Stores

30. Secure stores, very full, were used for storage of items as diverse as chemicals, gas heaters, small centrifuges, blood bags, freeze dried plasma and orange drink.

Other +4°C Blood Banks

31. Free standing modules are available which are charted and alarmed. (For cross matched blood or being cross matched).

ACTION RECOMMENDED

32. New storage areas must be provided across the whole range of storage conditions.

33. Certain practices should be reviewed. These include:

The manner of storing contaminated material awaiting collection.

The handling of fresh frozen plasma awaiting collections by PFC.

The storage of product such as SPPS and water for injections (actually mislabelled "distilled water - pyrogen free") in an insecure manner in the corridor.

The need for more frequent collections by the PFC (though this may merely transfer the problem).

4.2 Receipt of Blood and ComponentsLabelling of Blood Bags

34. This is carried out in a separate room (formerly the clean room) and at room temperature. Bags are laid out in numerical order and are put through a triple check in the labelling process.

35. At this stage blood has been tested and cleared unless further checks are required. The decision as to the "suitability" of certain bags is also made at this stage by the CMLSO. Bags identified for further testing are not labelled with a grouping label.

4.3 Blood and Blood Product Processing (Mr A Forgan)

36. Products processed include:

Cryoprecipitate preparation and pooling
Washed red cells
Platelet concentration and Pooling
Pooling of time expired plasma (3 and 5 litre packs)
Single frozen units of fresh frozen plasma
(Constant 200 gms removed)

37. Some of these processes would be appropriately done in an aseptic facility others in a clean room and others in a domestically clean laboratory.

38. At Dundee, two Envair balanced down flow units are used for all the above activities. They are housed in an area where a number of other activities take place which are not conducive to "clean" processing. These include several centrifuges and a liquid nitrogen freezing unit. Centrifuges are noisy and generate aerosol contaminants. The liquid nitrogen freezing process requires plenty of ventilation to prevent potential staff suffocation. As a result external windows are left open which could cause contamination of products.

39. No separate change area is available for staff though operators do gown up and wear gloves for aseptic processing.

ACTION REQUIRED

40. The above activities must be segregated into separate and defined areas.

41. A purpose built aseptic processing room must be provided.

AUTOCLAVE AREA

42. An old, manually operated Drayton Castle autoclave is used for sterilising dressing packs for the mobile teams. Autoclave tape and spore strips are routinely used as "indicators" but the last thermocouple check was in 1980 and routine maintenance and checks as per HTM 10 are not done. The area is provided with very inadequate ventilation and this not only makes for uncomfortable working conditions but adversely affects the plaster finishes.

43. Spore strips should not be routinely used - reliance should be placed on physical measurements.

44. The room also houses a Barnstead still (water used for laboratory use only) and washing equipment. No change room is available.

4.4 QUALITY ASSURANCE

45. The laboratory functions include:

Grouping

46. This is carried out on a modified Technicon BC9 (converted to 15 channels).

47. Every donor is checked on the Technicon with new donors being checked additionally by a manual process. This means all donations are checked twice (known donors are checked against existing records).

48. Spent material from the Technicon machine is passed untreated to the drain.

49. Chlorox flushing is applied should EBsAg blood be detected.

50. Anti-sera is largely own donor source material processed by the Blood Group Reference Laboratory. Other sera is partially commercially sourced.

Syphilis Testing

51. This is done manually by carbon antigen. The number of false positives associated with the test are significantly higher than real positives.

Hepatitis Testing

52. This is carried out in an ante-room and L-shaped inner room. The inner room contains a Bassaire Safety Cabinet. The second room is used for "counting". The outer ante room is used for changing purposes.

53. The Centre now uses the Wellcome Hepatube technique said to be sensitive to 0.3 nanogram(?) (But this may be somewhat meaningless).

54. The printer used does NOT highlight positive results - an advantage should the number printed fail to register properly. Provision of a new printer is recommended.

IMPROVEMENTS SHOULD BE MADE IN THE FOLLOWING

55. Blood is cleared daily by a negative clearance, this must be changed to a positive system.

56. Provision of an adequate change facility.

57. Opening windows in the suite are needed for temperature control but this introduces a slight hazard in terms of containment.

58. Contaminated material and packs is autoclaved outside the Transfusion Centre (in bacteriology or in the laundry). Provision of a suitable steriliser in the Centre would be much more sensible (the "pressure cooker" used for inactivating samples is hardly adequate).

59. The follow-up of the very infrequent donors showing positive to HBsAg may be insufficient. (In particular follow-up of the previous donations if taken within 6 months and apparently found to be negative.)

OTHER TESTS

60. Platelet numbers are not checked (lack of equipment)

61. Settle plates are exposed monthly. This would be better increased to each session the LAF cabinets are used.

62. Microbial data has been built up on expired material.

63. 1981 results were

NO SAMPLES	CONTAMINATED	PRODUCT
131	0	Whole blood
103	0	Concentrated red cells
224	0	Platelets

64. These are obviously excellent results but may be thrown into doubt by the fact that non pharmacopoeial sample sizes and test methods are used.

65. A recent platelet rich plasma which might have been contaminated with *S aureus* had been followed up to the extent that no apparent patient reaction had occurred following transfusion.

66. CSA have done one test on the LAF cabinets but a report appears not to be issued.

4.5 DOCUMENTATION AND STANDARD OPERATING PROCEDURES

67. SOPs are still required in many areas though a basic "Laboratory Techniques" Manual has been compiled.

68. Attention needs paying to the production of specifications for reagents, raw materials and products.

4.6 TRAINING

69. In practice a real effort seems to be made at Dundee to steer staff through a reasonable well defined programme. This might be improved by making it more formal.

PLANNED PREVENTATIVE MAINTENANCE

70. This is carried out for some items of equipment but not all. It could be usefully extended.

5. SUMMARY OF ITEMS REQUIRING ATTENTION NOTED DURING THE VISIT

71. The need for more storage areas, both ambient temperature and refrigerated.

72. The need for defined, segregated and appropriate processing areas to include an aseptic and clean room facility, a centrifuge area, a liquid nitrogen freezing area, and an autoclave area.

73. Responsible staff should be nominated as being responsible for quality control and production.

74. Hepatitis testing could be improved by doing the following:

- (a) Improved changing room
- (b) Improved ventilation provision
- (c) Better handling of contaminated material
- (d) Instigating a positive clearance procedure
- (e) Following-up what happened to a previous donation should a regular donor be positive to HBsAg (particularly if the previous donation occurred within 6 months.

75. A number of practices were commented on including:

- (a) The use of IV bottles for non IV contents
- (b) The use of meaningful labels stating accurately the nature of things.
- (c) The risks of using an excessive number of posters
- (d) The transfer arrangements for FFP intended for the PFC.

76. The need for a comprehensive Procedures Manual (SOPs).

77. Implementation of a more comprehensive Quality Control system to include more routine laboratory tests [examples would be Platelet counts, pH checks, potassium levels].

6. CONCLUSIONS

78. This Centre, located in a comparatively new hospital, already needs to be provided with more and suitable facilities.

79. Since the first informal visit staff had made changes in response to Inspectorate comments.

80. It was felt by the Inspector that this was a well run Centre staffed by competent people.

RECOMMENDATIONS

1. Comprehensive improvements to the facilities should be provided no later than 11 June 1984 (71, 72 and 74).

2. A comprehensive procedures manual should be available no later than 11 March 1983 (76).

3. All other items for attention are for either immediate action or for ongoing action.

IMMEDIATE ACTION

Examples include: 69 (Training)
 74 (c), (d), (e)
 75 (a), (b), (c), (d)

Ongoing Action 7, 73, 74, 77