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Statement No.: WITN2189005

Exhibits: WITN2189006 – WITN2189065

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INFECTED BLOOD INQUIRY

EXHIBIT WITN2189047

VISIT TO EDINBURGH AND SE SCOTLAND BTS

DATES: 10-11 March 1982 and 10-12 May 1982

INSPECTORS: Mr D R S Warburton
Mr D Haythornthwaite

1. INTRODUCTION

1. This Centre has not been formally inspected before but informal visits were paid on 12 June 1981 and 21 July 1981. The latter occasion was used to discuss some of the proposals for Livingstone House.

2. Livingstone House is a separate building and is located about half a mile away from the existing Transfusion Centre. When refurbished it will house the main processing activities of the Centre. The anticipated completion date is July 1982.

3. The use of Livingstone House is assumed to be an interim measure only. The early re-establishment of the activities of Livingstone House back into the Phase 1 building must be completed no later than June 1985. As it is the Transfusion Centre will be split between 3 locations:

Existing Royal Infirmary
New Phase 1 Royal Infirmary
Livingstone House.

4. This will cause severe problems of supervision, communication and supply and should not be prolonged unnecessarily.

5. This proved to be a difficult Centre to inspect. This was caused partly by the considerable changes in progress. There is no doubt that the existing facilities for the processing and handling of blood are grossly deficient and would have been quite unacceptable. It therefore seems unreasonable to "dwell" unnecessarily on facilities which will only be used for 3-4 months. It is equally difficult to assess a building which is still in the process of being refurbished. A further inspection of Edinburgh will therefore be necessary within 6 months.

6. The Manufacturing Licence for this Centre expired on 30 June 1981 and no application has been made for renewal.

7. Different personnel responsible for Quality Control and Production have not been nominated.

8. This inspection was made easier by the more helpful attitude of staff when it came to discussing details. On the second visit in May a number of records and procedures were produced for discussion. These certainly helped to produce a more "balanced" view of the control being exercised.

9. Elsewhere it was noted that an objective attitude to the preparation of Standard Operating Procedures was apparent and housekeeping showed signs of improvement though this is difficult under the existing overcrowded conditions.

10. The conditions under which blood is taken were explored a little more closely in that a local donor centre session (at Linlithgow) was visited. The conditions themselves were adequate but the following topice in particular were discussed:

11(a) The responsibility and the consistency of decision taken over which donors to accept or reject with regard to illnesses and medicines and whether donors really read the questionnaire. Just how comprehensive is the questionnaire?

12(b) The location of bleeding and type of donor. For example, whether Prisons and Borstals were really appropriate or necessary as a source material. The possible advantages of a "mobile donor centre" (consistency of environment and increased procurement capability) were also considered.

13(c) The problems associated with blood bags (these included blunt needles, pin-holed bags, fungally contaminated outers, splits in the rubber segment of the donor tube).

14(d) The practice of pre-filling syringes from a multi-dose vial for a session.

15(e) The non-use of automatic cut-off balances and agitators during donation.

16(f) The lack of definition or control of a "slow bleed" (can lead to increased clots).

17(g) The surprising practice of retaining blood routinely at ambient temperature for up to 18 hours. Two new refrigerated vans have recently been purchased so presumably this practice can cease immediately. Certainly protocols should be established for this process.

18(h) The non-use of "segments" on the donor tube for cross-matching purposes.

19(i) The volume of blood taken. This is presently 420 mls but may be increased to 450 mls.

20(j) The ratio of 3 donors to 1 donor attendant was higher than seen elsewhere. (This has both safety and training implications and the ratio should be reduced.)

21(k) The use of a haemoglobinometer rather than the copper sulphate test.

22. The pursuit of "ever increasing" shelf lives for various products was briefly discussed. Whilst the need for this can be explained the desirability of such a policy was questioned.

23. Discussions were also held on the concept of clinical validation of processed material. In some respects there would appear to be room for the generation of more data.

24. "Out of hours" supervision could well be missing in the processing area. This should be rectified without delay.

25. Edinburgh is a Centre which appears to do a number of activities "differently" from elsewhere. The full significance and range of "differences" was not gone into due to lack of time. It is not suggested that a difference "per se" is important but they might rank as "query-able". (Examples include: storage of washed red cells for 5 days (elsewhere 12 hours); the time lag before blood is cooled; differences in centrifuge practice; repeat checks in Grouping which rely on the use of the same reagents and the same equipment; pigtail packs; lack of agitation and close temperature control of platelets.)

2. STAFF LIST (not complete)

26.

Dr B McClelland	-	Director
Dr S Urbaniak	-	Deputy Director
Dr F Boulton	-	Consultant
Mr R Wilson	-	PMLSO
Mr G Allen	-	SCMLSO (Blood Products)
Mr A McGowan	-	SCMLSO (Immunology)
Mr A Watt	-	CMLSO (Microbiology and Hepatitis)
Mr J Scott	-	SCMLSO (Donor Grouping and Blood Bank)
Mr P Braynion	-	CMLSO (Blood Bank)
Mr H Bethel	-	CMLSO (Donor Grouping)
Mrs J McDonald	-	SNO (Donors)
Dr Robertson	-	MO (Donors) (retired May 1982)
Mr A McGill	-	CMLSO (Separation)
Dr J Davidson) Dr M Greiss)	-	PT Medical Officers (Donors)
Dr A Smith	-	Consultant (in post 1 September 1982)

3. LIST OF MEDICINAL PRODUCTS

27.

Pooled fresh frozen plasma	"Open" process
Pooled time-expired plasma	" "
Cryoprecipitate (thaw syphon)	" "
Leucocyte depleted blood	" "
Red Cell Concentrates	" "
Platelet concentrates	"Closed" process - first stage "Open" process - pooling
Buffy coats	"Closed" process
Clinical fresh frozen plasma	" "

28. About 60% of donations are for components and processing, the remainder is available for transfusions as whole blood.

29. Blood taken into single packs is used mainly for plasma pooling which will be done at Livingstone House. The future nature of plasma pooling is very dependent on the PFC coming up with a functioning pack stripping machine.

4. INSPECTION

30. The Centre will shortly be located on 3 separate sites. Brief visits were paid to both the Phase 1 Royal Infirmary and Livingstone House.

31. Summaries of both these facilities follows in terms of accommodation and any major problems discussed. As both were still incomplete observations that could be usefully made were limited.

31. Phase 1 - Royal Infirmary Site

List of facilities

One one level:

Donor Centre including facilities for manual plasmapheresis, donor records, bleeding, interviewing, resting etc
Reagent production

Team preparation area
Immunoglobulin investigating laboratory
Cold rooms (A, B and C)
Equipment room
Clerical support facility
Immunology and Tissue Typing
Dark room
Immunology (White Cell Typing)
Isotope laboratory (reagents)
Hepatitis laboratory
Microbiology laboratory
Offices
Staff room
Seminar room
Wash-up (Preparation) Autoclave
Library
Teaching laboratory and lecture room
Sample reception and associated laboratory
Antenatal screening laboratory
Donor grouping laboratory.

33. On lower level:

Liquid nitrogen store
Mobile team store
Bag store.

Discussions were held on:

34. The lack of security of the Centre "out of hours". It is understood that the main entrance must remain unlocked - a most unsatisfactory situation from the security viewpoint. Priority must be given to resolving this item.

35. Some unsuitable furnishings have been provided in a few areas and it is hoped these will not delay the use of the department.

36. The hepatitis laboratory has been designed as a 3-roomed suite but access to the corridor is possible from the room containing the microbiological safety cabinet.

37. The microbiology laboratory (designated) is not satisfactorily equipped.

38. It is strongly recommended that the area presently being used as a temporary pharmacy should, when vacated, be converted for the use of the Blood Transfusion Centre into a processing and laboratory facility. This would allow the main functions of the Centre to be housed together on one floor.

39. Livingstone House

List of facilities

Ground floor:

Centrifuge room (light spin) - 6 centrifuges
Centrifuge room (hard spin) - 8 centrifuges
Change room
Clean room
1st stage platelet preparation area
Thawing of packs area (cryoprecipitate)

Rapid plasma freezing area (liquid nitrogen)
-40°C chest and upright deep freezers
Reception and despatch
+4°C refrigerators
Cloakroom facilities
Store
Office

40. Upstairs:

Domestic facilities and plant room.

Discussions were held on:

41. In the Clean Room

The design of the drain (no air break - which should be outside the clean room).

Windows installed with ledges and a rubber gasket (attracts dust).

42. Centrifuge rooms

The arrangement for extraction here using large and cumbersome hoods is not the most appropriate. In practice localised point extraction is usually more effective.

43. It may be necessary to provide additional cooling capacity in these two areas.

44. It is also recommended that thorough smoke tests are carried out under varying working conditions to establish that the centrifuge extracts do not cause an influx of unfiltered air into the clean room itself (eg by way of the hatch).

45. Activities which will be left in the "old" Royal Infirmary include:

Cross-matching and Blood Bank
Coagulation Laboratory
Frozen cell bank (and frozen platelets)
Facility for carrying out leucocyte depletion.

46. Outline plans were briefly discussed for improving the cross match, blood bank, issue area and pooling facilities.

47. The existing Cross Match Laboratory is dangerously overcrowded handling about 6,000 units a month in a very small facility.

48. The existing Issue facility is most unsatisfactory - it is overcrowded and blood may be left for up to an hour at ambient temperature.

49. The existing Pooling facility is most unsatisfactory. There are too many other activities nearby as well as draughts from opening windows. Even the proposed upgrading will not convert this into a Clean Room environment.

50. The existing Royal Infirmary Site

This is split between 2 areas:

a. Processing, donor centre, some laboratory facilities (eg hepatitis testing and microbiology) in Archibald Place.

b. Remaining laboratories, refrigerators, issue etc in the main hospital building.

4.1 51. Storage facilities

Existing storage facilities were seen to be inadequate, with goods, equipment and rubbish cluttering up corridors.

52. Insufficient refrigerator space was available so that one refrigerator designated for expired material contained "in-date" FVIII and freeze dried cryoprecipitate.

4.2 53. Blood and Blood Processing

Brief summary of existing facilities with comments

The existing processing area is located in the basement of Archibald Place, a building scheduled for demolition.

54. Entry for staff and materials is via the back door where one is confronted with an appalling mess of rubbish which is totally inadequately controlled and removed. Whilst it may be very difficult to control the cockroach and rodent infestation in old buildings of this type, the unacceptable health hazard posed by the additional material in this area must be given continuing priority attention by the hospital authorities.

55. The only concession to clean room working conditions that has been possible is to supply HEPA filtered LAF cabinets. These have been located in standard laboratories or worse, in corridors. No staff changing facilities are available. Outer surfaces of bags are not sanitised before aseptic handling.

56. Under such conditions the skill of staff, a disciplined and conscientious approach and adherence to good housekeeping practices are all of importance.

57. Without wishing to detract in any way from the efforts of staff some improvements in aseptic manipulation and the housekeeping of LAF cabinets needs to be considered. Examples of working on the edge of cabinets and with ungloved hands in a position liable to contaminate connectors were seen.

58. The whole question of training of staff would seem to need some consideration. By adopting a formalised approach improvements should occur.

59. In terms of speed of processing it is understood that donations taken by the mobile teams are normally processed the same day (except evening sessions). Blood taken in the Centre is processed up to 7.00 pm, though it is understood the Centre would like to continue processing up to 11.00 pm. This must, however, be done with adequate qualified supervision.

60. The Pigtail Pack

The Edinburgh Centre, unique in the UK, continues with the Tuta pigtail pack.

61. The defined usages for the pigtail packs are for the preparation of cryoprecipitate by thaw syphoning or for plasma pooling.

62. The use of this pack may decline should the multiple pack with SAG or SAGM increase.

63. Thaw-syphon produced cryoprecipitate (Small Pool Donor Source)

Discussions were held on the need for cryoprecipitate. The following reasons seem important:

64(a) There is a reduced risk of contracting hepatitis from a small pool donor source. It is argued by others that the risk of contracting hepatitis is substantially increased when a pool exceeds 10.

65. Edinburgh use an initial pool of 3 but this is later pooled with 4 other pools (making a total of 12 donors involved).

66. The Inspector would prefer the Centre to investigate the possibility of using accredited donors in an attempt to reduce this risk.

67(b) Cryoprecipitate produces a higher yield of F VIII from a given unit of plasma compared to freeze dried intermediate F VIII. It is only by producing 10,000 packs of cryoprecipitate per annum that the Centre can meet its needs.

68. The "gap" between needs and quantities of F VIII available from the PFC could be substantially narrowed if a national policy of distribution were adopted. That is, supply would go to the Centres with the greatest needs.

69(c) A small quantity of cryoprecipitate might still be required for its fibrinogen content or for the treatment of Von Willebrand's disease.

70. The method of preparation was briefly observed.

71. The cryoprecipitate is produced from a triple pool of plasma flash frozen to -30 to -40°C. Sixteen such pools are thawed at 2-3°C. The cryoprecipitate depleted plasma is syphoned off and the cryoprecipitate is frozen and stored for up to 6 months. (Consists of 4 by 3 donor pools.)

72. Triple pools of cryoprecipitate are of one ABO group (normally "O" or "A"). Patients requiring more than one triple pool may be given a mixed pool of group "O" and group "A" to reduce the amount of "Anti-A" present (absorbed by "Soluble A substance").

73. Increased "side effects" are a consequence of the use of cryoprecipitate but as used it does not appear to be amenable to purification.

74. Connections to bags for pooling and thaw-syphoning are carried out under LAF protection. Whether better facilities are needed was not resolved - pooled product can be stored for up to 6 months, albeit under frozen conditions, so a case could be made for a clean room facility.

75. Aliquot sampling might be more representative than the existing sacrifice of a single unit for testing purposes.

76. Red Cell Washing

The machine used, an IBM 2991, is inappropriately located in a corridor. Bags are connected to the machine without the protection of HEPA filtered air.

77. Red cells in the cryoprotected state and stored in the vapour phase of liquid nitrogen are given an indefinite shelf-life even though temperatures are inadequately monitored.

78. Neo-natal plasma units

200 mls of fresh platelet depleted plasma is split into 4 x 50 mls for infusion as single 50 ml containers.

79. No microbial data has been generated on this product. This would seem worthwhile as neonates are particularly "at risk".

80. Lab for pooling of "expired" plasma

Pooling is carried out in a LAF cabinet but the environment is unsatisfactory and the room itself also contained centrifuges. No staff change is available.

4.3 81. Quality Assurance

There is no centralised QA function and so far a distinction has not been made between a nominated person responsible for production and one for QC.

82. A number of different laboratories exist but these tend to operate independently according to their function.

83. A QC Procedures Manual is available and a summary of the "Test Summary Sheet" was requested.

Laboratory functions include:

84. Donor Grouping

Machine grouping is carried out on a Technicon machine but this has been unreliable and requires constant operator supervision.

85. Investment in modern equipment linked to a computer which could "scan" and "comprehend" labels must be a priority. The Scottish Transfusion Service as a whole is still in the process of evaluating their requirements.

86. To proceed to an even more automated system would still require staff in this section to be able to "fall back" to less sophisticated techniques should it be necessary. It is noticeable that heavy reliance is already placed on the Technicon machine. Repeat groupings are merely sent through the equipment a second time using the same reagents and paper. In other fields this would not be considered good or safe practice though it is true in the case of grouping one has a "long-stop" in the shape of the Cross Matching Laboratory. (In a real emergency Cross Matching might be by-passed and the "long-stop" no longer exists.)

87. Syphilis testing

This is carried out manually and by machine. Antipathy was expressed towards the test by Centre staff.

88. For reasons such as there are many more false positives than real ones and "cooling" of blood is said to kill the infective treponema. It would be useful to see modern data on this last point. Unfortunately the practice of holding blood at ambient at Edinburgh for up to 18 hours must preclude any possibility of dropping the test.

89. Hepatitis and Microbiology

These are located on the floors above the Public Access levels in Archibald Place.

90. The main biohazard area although segregated and entered via a change room must be considered as unsatisfactory. It has a very slight negative pressure and HEPA filters do not appear to have been fitted on the exhaust ducting.

91. The autoclave located here used for inactivating contaminated items still runs on a pressure gauge (20 lbs for 45 minutes) and has not been checked or regularly maintained.

Microbiology

92. A level of microbial testing is carried out on product and a limited environmental testing scheme is included. This latter system includes "Biotest" checks on LAF cabinets but these cannot be checked for particles or flow (by anemometer) nor are settle plates routinely used. "Biotest" results are highly variable.

93. Test methods applied are not pharmacopoeial and positive controls on media are not done. Sample sizes are often small.

4.4 Documentation and Standard Operating Procedures

94. A Working Party at the Centre is reviewing the need for and the details to be included. A useful start has been made.

95. Existing documentation and data generation is fairly substantial but it is not clear whether it is all "usable".

96. When it comes to identifying donors from a specific batch of plasma full traceability is maintained. However, tracing where other components may have gone from the same donation (eg the red cell concentrate) may not be done with absolute certainty.

97. Plasmapheresis

The Centre has a small (3 bed) manual pheresis programme going. Accurate identification of patient and red cells for re-infusion is aided by a colour band and signature system. This is probably safe for about 7 or 8 beds but certainly no more.

98. Cell Separator

This can be used to obtain single donor components for a named patient (as well as for patient treatment).

99. It is a complex piece of equipment which requires that the correct connections should be made using aseptic technique.

100. A few Comments were passed over the absence of a "use by" date on autoclaved equipment and some confusion was experienced with the use of autoclave tape as a substitute for adhesive tape.

101. Brief discussions were held over the matter of QC tests. Much reliance would seem to need to be placed on "accrediting" the donor as per WHO guidelines.

102. It was noted that an initial saline rinse through the machine is retained for testing in case of subsequent patient reaction.

4.6 103. Blood Bank/Issue/Ward refrigerators

Stock rotation of blood for issue is maintained by physically moving blood upwards on the holding racks.

104. Returned blood is held and physically examined before returning to stock. This does not provide too much of a guarantee that handling away from the Centre has been adequate.

105. It is understood that new ward refrigerators are to be provided in the near future and these will be checked daily by Centre staff. (Would have been better to have been doing this with existing unsatisfactory refrigerators.)

106. Documentation in this area appeared sufficient for tracing purposes (though "traceability" might be lost at Ward level).

107. "Compatible" labels on each pack should help eliminate transfusion errors providing they are read and understood.

5. 108. SUMMARY OF MAIN ITEMS DISCUSSED (This section relies on recipients reading all the report.)

Donor aspects and control of the main "raw material" (ie blood) (See paragraphs 10-21)

109. Unsatisfactory nature of the existing facilities and the urgent need to be established on one site.

110. The need for greater validation in terms of clinical efficacy as well as the more routine use to establish product similarity. (Some differences in practices do occur here - Paragraph 25).

111. The need to be able to call on other "expertise" (eg Medical Physics).

112. Documentation and records are being actively upgraded. If possible reconciliations and traceability should be improved.

113. The limitations of being without a computer and the contingency arrangements when one is available.

114. The lack of action in controlling the rubbish in the hospital precinct.

115. The lack of "out of hours" supervision in processing.

116. Ph 1 Royal Infirmary and Livingstone House (Section 4) and the arrangements for the existing centre and how it is to be upgraded.

117. The question of training and the role of proficiency tests. (Test sensitivity may cause "missed" reactions)

CONCLUSIONS

118. This must be considered as an interim report as so much will shortly change. Further inspections will be needed.

119. Existing facilities are quite inadequate and must rank amongst the worst seen anywhere.

120. There remains a good deal of detail which was not explored due to lack of time. Obviously this is "unsatisfactory" for both sides. It may be that the "differences" seen would be better examined by the staff themselves with the Inspector merely kept informed.