Witness Name: Colin Entwistle

Statement No.: WITN6917001

Exhibits: WITN6917002

Dated:25/10/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF COLIN CARRUTHERS ENTWISTLE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 April 2021.

I, Colin Carruthers Entwistle, will say as follows:

Section 1: Introduction

1.

Dr Colin Carruthers Entwistle

Address: GRO-C

Date of birth: GRO-C 1935

Professional qualifications: MA Oxon; MB,ChB; FRCPath

2.

a. House Physician, Southmead Hospital, Bristol. August 1958 to January 1959
b. House Surgeon, Southmead Hospital, Bristol. January 1959 to July 1959
c. Senior House Officer in Pathology, Southmead Hospital, Bristol. August 1959 to July 1961

Learning all aspects of pathology

d. Registrar in Pathology, Chester Hospitals, August 1961 to May 1962

   Further experience in all aspects of pathology

e. Assistant in Pathology, Welsh National School of Medicine, May 1962 to October 1963

   More detailed experience in morbid anatomy, and histology, together with on-call duties including provision of cross-matched blood for transfusion

f. Lecturer in Pathology, Welsh National School of Medicine October 1963 to May 1068

   Special responsibility for running the routine 24hour blood transfusion service for the WNSM, sharing duties in haematology, and also giving lectures as required, and teaching blood transfusion to Cardiff University students

g. Consultant Haematologist, Deputy Director Blood Transfusion Centre, Cambridge, May 1968 January 1974.

   For details see paras 7-9 below. Particular responsibility for blood donors, including donor sessions. The laboratory aspects of running the Centre were the prime responsibility of the Director, except of course when he was on leave or otherwise unavailable when I was responsible. There was a limited opportunity for personal research.

   Also took part in on-call rotas dealing with management of out-of-hours provision of blood and blood products to hospitals in the East Anglian region.

h. Consultant Deputy Director National Tissue Typing and Research Laboratory, Bristol. January 1974 to May 1980

   Routine responsibility for the running of the National Tissue Typing Reference laboratory in identifying sera suitable for use to establish

tissue types of both patients and donor tissue for transplantation, throughout the UK. This led to participation with other laboratories internationally and including being among the group which set up the 7th International Workshop in Tissue Typing which was held in Oxford.

A second responsibility involved overseeing the section managing the national waiting list of patients for kidney transplantation, and communication 24/24 with transplantation hospitals as necessary

i. Consultant Director, Blood Transfusion Centre, Oxford May 1980 to September 1995

The Oxford Regional Health Authority gave me overall responsibility for all aspects of the operation of the Oxford Blood Transfusion centre, with delegation to senior staff as appropriate. Collaboration with other Transfusion Centre Directors and their staff, and with the Blood Products Laboratory, and liaison with hospital haematology consultants and staff throughout the region

3. I was a member of the British Medical Association, 1960's to about 1993

British Society for Immunology and about 1965 to 1995

British Society for Histocompatibility and Immunogenetics 1991 to 1996

Western Division of Blood Transfusion doctor, 1980 to 1995

British Blood Transfusion Society, of which I was founder member, till 1995

RTC Directors' meetings, 1980 to 1988

National Directorate of NBTS from 1991 to 1992

RTC/BPL Liaison Committee from 1991 to 1994

NBA Executive 1993 to 1995

4. A considerable time was spent in reading scientific papers, journals particularly the British Medical Journal, British Journal of Haematology and Vox Sanguinis.

I also attended meetings nationally of British Society for Immunology, and more recently the British Blood Transfusion Society of which I was a founder member. I also had the good fortune to attend a number of meetings of the American Blood Transfusion Society which afforded opportunities to liaise with international colleagues and to learn of developments elsewhere.

5. In 1994, I was asked to review evidence for a legal case involving the Wessex Health Authority. In response to your request, I have looked again at the document provided **[NHBT0044631]**. While in the absence of any other explanation, the evidence presented suggests a possibility of transfusion transmitted infection, particularly considering the timing of reported events; however, there was no positive proof to confirm this, and I conclude that transfusion transmission remains likely but unproven.
6. I have not been involved in any other inquiries relating to Hepatitis B, hepatitis C, human immunodeficiency virus or Creutzfeld-Jacob disease.

Section 2: Role at the East Anglian Regional Blood Transfusion Service

7. The Consultant Director – Dr J. Darnborough and I, his deputy, were both responsible to the East Anglian Health Authority. I naturally respected the Director's position.
8.
    a. Within the Cambridge centre, the Director and I agreed that he would retain prime responsibility for the laboratory aspects of running the Centre, except of course if he was on leave or otherwise unavailable when I was responsible. My main role concerned practical organisation of blood donor sessions, including the training of session doctors (including conducting many donor sessions myself), helping the Head Nurse with recruiting and training of donor attendants, dealing with donors who had medical problems (mostly actual or suspected anaemia), and responding as well as possible to any complaints received. I also took part in on-call rotas dealing with management of

out-of-hours provision of blood and blood products to hospitals in the East Anglian hospitals.

Although my time was devoted largely to routine matters as above, there was limited opportunity for personal research. In this, I devised detection methods for specific antibodies against tetanus and chickenpox. Later I devised a screening test for Hepatitis B antigen in donors, which I used personally on many thousands of donors over about six months before it was adopted for all incoming donations to EARTC.

b. The EARTC was funded entirely by the EARHA throughout my time there.
c. The EARTC served hospitals throughout the E Anglian region, including Cambridge, Peterborough, Kings Lynn, Norwich, Ipswich, Bury St. Edmunds and Papworth.
d. The EARTC like all other RTCs was answerable to its Regional Health Authority. Nonetheless, there were links to other RTCs initially through the Advisor to the Minister of Health and the Directors' meetings until 1988, then via the National Directorate until 1993. Responsibility of RTCs was then transferred to the newly formed National Blood Authority. This sequence is well described in Dr Gunson's statement **[NHBT0000026_009]** with which I agree.
e. The basic principle of all RTCs acting in the same way had never been fulfilled, and there were different practices in place, Nonetheless, there was communication between centres, such that practices did have a lot in common, not least to treat blood donors in much the same way everywhere, and to undertake screening again in similar ways. One exception to this was that as new screening tests were emerging, they were not always adopted at the same time in all RTCs.
f. There was no regulation as such to enforce commonality between centres.

g. The Blood Products laboratory was responsible for processing plasma submitted by each RTC to generate products such as clotting Factor VIII; initially this was on the basis of returning product at cost to each RTC in proportion to plasma submitted. However, as time went by, it became obvious that because of variations in the number of patients being treated in each region this system did not work well and other arrangements were made.

h. As far as I can remember, the EARTC used to collect approximately 65,000 donations each year

9. Blood collection by EARTC were organised on the basis of collection teams. Each team comprised a Team Leader and up to eight Donor attendants, a clerk from the Donor Registry department, and two drivers. A doctor attended session independently. The teams went out from Mondays to Fridays. Teams would travel to prearranged venues throughout the region, where the RTC Donor Organiser had recruited volunteer local donor organisers and had secured suitable premises and publicity. Teams under the control of a senior (more experienced) donor attendant set up usually eight beds for actual blood collection and a comparable number of couches for donors to rest after donation. The clerk was responsible for implementing questioning of incoming donors and one of the drivers undertook the donors' simple copper sulphate-based finger-prick blood tests for possible anaemia. The doctor performed all venepunctures and managed any medical problems (such as donors fainting, etc). As part of this pattern, donor sessions were usually held in a Cambridge venue on Monday mornings to provide fresh blood to be sent to the Papworth hospital for heart operations.

Section 3: Role in Oxford RTC

10.

a. I was in overall charge of the Oxford transfusion centre and all its staff totalling about 120. I was accountable to the Oxford Regional Health Authority. I was assisted by senior staff who initially included three

Associate Specialist medical assistants, a business manager, laboratory manager, donor organiser, head nurse. The senior team would meet regularly at least once a month.

About 1992, after identification of some poorer practices which had crept in over time, the management structure was changed to focus duties onto a smaller number of (more efficient) individuals. (See 12 below). The new management team included one of the Medical assistants who was assigned responsibility for laboratory work, the recently appointed Business manager, a new Blood Donor organiser, and for a couple of years a Quality Control manager.

b. Funding was initially from the Regional Health Authority, until the newly formed National Blood Authority took effect for all RTCs, I believe in April 1993.
c. The geographical area covered included Oxfordshire, much of Buckinghamshire, Berkshire Northamptonshire and Wiltshire, serving hospitals in Oxford, Swindon, Banbury, Northampton, Kettering, Aylesbury, Reading and Slough. There were also a small number of private hospitals which we also supplied.
d. ORTC was one of the 14 transfusion Centres which served the whole of England. The Director of ORTC, like the other Directors attended regular meetings, together with the initially the Government Adviser on transfusion, later with Dr Harold Gunson as the head of the National Directorate for Blood Transfusion. I was answerable to the National Blood Authority after it was formed in April 1994.
e. ORTC was loosely linked with other RTCs as described above, the purpose being to try to ensure that the best current practices were likely to be in place in all centres.
f. There were no unifying regulations as such governing the RTCs at least until the formation of the National Blood Authority.
g. ORTC was not linked directly with the BPL, or the PFC laboratories. However, those laboratories did set plasma collection targets for all

RTCs, initially on the basis of producing processed blood products roughly in proportion to the needs of patients in each region.

h. About 100,000 blood donations were collected annually as whole blood; increasingly, blood collected was separated into red cell concentrates, releasing plasma for fractionation. Separately, plasma was also collected by plasmapheresis but only on a very limited scale , in the order of 10 litres a week.

Section 4: Blood collection at ORTC

12. Initially, the system in place was very similar to that outlined above (see my answer to question 9). However, as time went by, with the increasing demand for plasma for fractionation, whole blood collections were increasingly separated at the RTC into red cell concentrates and recovered plasma. Further plasma collections were instituted at the RTC by recruiting plasmapheresis donors though it was felt that this procedure would not be justifiable on a large scale at ORTC until such time as the centre was unable to produce enough recovered plasma from separated whole blood.For this limited use of plasmapheresis, the centre had an increasing panel of about 400 donors contributing donations this way by the time I retired. Though pheresis served mainly as a way of collecting fresh plasma, this practice was also used to collect specific plasmas with high levels of anti- Rhesus D and sometimes other antibodies, both of which were needed for therapeutic purposes.

13. The management of donor recruiting, donor sessions and associated clerical work was initially delegated to the Donor Organiser. After her retirement, the new Donor Manager was instrumental in continuing this but also initiated a number of improvements.

a. b. and c.

The system already in place using local volunteer organisers was extended to include use of reminder letters to ensure donors of

blood group O both Rhesus positive and negative were encouraged to attend donor sessions if at all possible, as blood of these groups is more versatile than others. Appointments for donations were not offered at that time.

d. As management, the functions described fell within the remit of the Donor Organiser to whom they had been delegated, I was not usually involved unless I was made aware of particular problems.

14. During my time at the Oxford RTC, no blood was collected from Prisons, Borstals or similar institutions. This practice had ceased before 1980.

15.

a. Staffing arrangements at donor sessions changed little over my time in Oxford. The teams were usually of about eight donor attendants under a senior attendant, a clerk from donor registry, and drivers together with a doctor at all sessions.

b. Sessions took place in locations (wherever possible) previously ascertained as suitable, be they village halls, commercial premises etc. Almost all will have been used before and the experience gained put to good use (to determine adequate parking, lighting, ventilation, space, etc).

c. Donations were collected usually twice a year, and after not less than four months apart. Although consideration had been given, as proposed by Eastern Division [**NHBT0000191_144**] to reduce the time intervals between conventional donations from male donors, no national policy on that had been agreed by the time I retired.

d. Recruitment of new donors was encouraged by local publicity with posters etc. It was known that there is always a 'wastage' often in the order of around 10% of donors from aging, illness, people moving away, and because of these concerns, taking good care of the donors who do come is recognised as extremely helpful in facilitating 'word-of-mouth' recruitment.

e. Following review in August 1989, particular attention was instituted to send postal reminders to known donors of blood groups O rhesus negative and positive. Though not easy to quantify, there was the feeling that this proved helpful. I was not aware of donors being telephoned to invite attendance.

16. Donation collections were organised based on previous session performances, which overall showed remarkable consistency. There were few occasions, particularly round long bank holidays e.g. over Christmas/New Year periods and August bank holidays when there were short lived spells with less-than-sufficient collections. These did not cause serious problems, except for very fresh products, particularly platelet concentrates. In anticipation of these events, extra small in-house collections were arranged, to address that specific need.

Section 5: Plasma procurement and production at ORTC

17.

a. Plasma was separated from whole blood collections in the blood processing section of the ORTC laboratory. Plasma derived from apheresis was collected in the Donor Clinic of ORTC

b. and c. Initially, most FFP for fractionation was so-called recovered plasma derived from a proportion of whole blood donations. As plasma targets were increased, more whole blood was separated into recovered plasma and red cell concentrates; plasma collected for fractionation was increasingly supplemented by pheresis.

d. As the hospitals had clinical need of whole blood as well as red cell concentrates, I think it is likely that further increases in plasma for fractionation would have to be met by extending production by pheresis, as had been carried out in some other RTCs.

18. In the early 1980s, funding for plasma procurement at ORTC was from the Regional Health Authority, a situation which continued until the implementation of the newly formed NBA in April 1994

19. I had appraised Dr Lane of my concerns in this regard in June 1981 and indicated that I would approach the ORHA to allow funds accordingly. I have no evidence available how successful that may have been.
20. Supplies to the hospitals were entirely based on responding to demand. I was not aware of ORTC sending supplies of FFP to the Haemophilia centre.
21.
    a. The plasma target had been given initially by BPL, later by the Directorate. I had no information how this process was applied to other RTCs.
    b. The purpose of the targets was to endeavour to provide adequate amounts of plasma from each RTC to be available for fractionation roughly in proportion to meeting that region's need for processed blood products
    c. Apart from attempting to match supplies of plasma for fractionation to product being returned to each region, I cannot comment further. I suggest Information on this should be sought from sources in the Directorate. I was not privy to the details.
    d. I have no information on frequency of review; again, sources in the Directorate might have this information.

22. Target setting gave the RTCs including ORTC specific requirements for blood collections, and also for determining how much whole blood to separate into red cell concentrates and plasma.
23. Failure to reach plasma targets would jeopardise the return of blood products to the region. Any shortfall then would have to be met by BPLfrom their reserves.
24. Exceeding given targets gave no appreciable benefits to the RTC with the former arrangement. After cross-charging was implemented in 1989 there could have been possible financial benefit with increased return from BPL.

25. I was given to understand that cross-charging did help to rationalise some of the previous discrepancies matching plasma collections to the needs and supply of blood products in a region.

Plasmapheresis.

26.

a. Throughout my time at Oxford RTC, plasmapheresis was known about. Initially it had to be carried out by a rather cumbersome procedure, and this was kept to a small scale as there did not appear to be an overwhelming need for ORTC to expand on this system. Later when the automated Haemonetics system became available, it was more practicable, more popular with both donors and staff, and was used to a greater extent.

b. I was aware that plasmapheresis-derived plasma is more expensive to produce, and that the Haemonetics machines themselves add a considerable extra cost. As regards relative cost, I do not know who may have carried out a cost/benefit analysis; however, I do recall that at some time, BPL was reimbursing RTCs at about twice the price for pheresis derived as compared to whole blood derived plasma.

c. The capacity to use plasmapheresis was very limited, with initially only two then later three machines being available. Staffing both of doctors and nurses/donor attendants could be arranged around as required. However, pheresis producing about 10 litres of plasma per week would have not made a very significant difference to procurement of plasma for fractionation. To have made a substantial difference, the provision of machines and corresponding staffing would have been very considerable; it also would have been indefensible until no further plasma from separated whole blood was available.

27.

Large scale plasmapheresis was considered but only as a last resort. It was only practised on a limited scale at ORTC (see a). above).

a. This situation did not change appreciably during my time, as ORTC was actually reaching its plasma target
b. I was not aware of the extent plasmapheresis may have been used elsewhere.

Use of plasma reduced blood and red cell concentrates

28. The hospitals were encouraged through their Haematologists to promote the use of red cell concentrates. This was very largely successful, to the extent that the use of concentrates became a routine option for transfusion and indeed were preferable for non-urgent transfusion.

Section 6. Arrangements for obtaining and allocating blood products at ORTC

29. Supplies of blood products to the haemophilia centre at Oxford were entirely provided directly from BPL/PFL and not the RTC.
    a. The only Haemophilia centre in the Oxford region was that at the Churchill Hospital, though as mentioned before, processed blood products were sent directly to the Haemophilia centre, and not to ORTC. Any imported blood products used by the Haemophilia centre were acquired by them totally independently of ORTC
    b. ORTC, funded initially by the ORHA, was charged to supply fresh plasma for fractionation at PFL in Oxford in proportion to the patients served in the Oxford Haemophilia centre. Targets for plasma supply were set by PFL/BPL and over time it became obvious that there were imbalances in what PFL could process, and what patients were being treated at the Haemophilia centre with a number of more severe cases coming to Oxford from other regions. Ultimately this distortion was recognised after plasma fractionation was centralised at BPL. The fractionation facility came under the new CBLA from April 1994.

30. Because of the situation described in 29, above, there were no meetings involving ORTC with the Oxford RHA and PFL/BPL

31.

a. This situation was in place before I was appointed to ORTC, and I do not know when it was introduced.
b. The rationale for this was to simplify the whole process, leaving less room for avoidable errors or misunderstandings.
c. This arrangement simplified the role of ORTC by plasmas collection targets being set without being specifically linked to products used

32.

a. Plasma was sent to PFL for historical reasons.
b. The rationale was on the basis that Oxford region plasma would be returned as products to the Oxford region
c. Potentially this arrangement could lead to problems if there were a processing batch failure leaving Oxford patients to be provided from a national reserve pool of products
d. Added to this, as the quantity of Oxford plasma supplied increased, PFL could no longer cope, and the facility at Elstree would have to be used anyway.

33.

a. As I recall it, BPL wanted to bring Oxford and Wessex "into line" with other centres to promote simplicity of operations and greater security for Oxford and Wessex in the unlikely event of a processing failure. This seemed logical to me, since BPL would have a more streamlined and uniform system of processing and delivery of products would be achieved.
b. Supplies to the Oxford Haemophilia centre would continue to receive what was needed as normal.
c.

i. Dr Lane's opinion seemed to have merit. I also thought that the change was a largely internal rearrangement of the fractionation facility.

ii. I was not aware there had been a problem up to that time.

34. As far as I was aware, the arrangements for purchase of blood products was similar in other regions except for provision sent directly to the Oxford centre (see 29 above).

35.

a. Emphasis was needed on accuracy of documentation; but initially, as I recall, little further was done. At a much later date (in the early 1990s) ORTC instituted a specific quality control section which established standard operating procedures for (almost) everything, which greatly improved the situation, such that ORTC was the first RTC to comply with newly EU-imposed regulations.

b. I have no recollection of that.

36. At no time was either I or anyone on ORTC involved in purchasing or importing blood products from abroad.

37. There was no impact on ORTC of shortfalls in product from BPL.

38.

a. I cannot comment on how often plasma collection exceeded or fell short of the set targets. There was inevitably variation.

b. ORTC requested increased supplies of PPF and salt-poor albumin to meet current demand from hospitals. As far as I know, this request was granted.

c. I do not know. I have little doubt there were imbalances of demand/supply from time to time not only at Oxford but in other RTCs too.

39. ORTC was not involved in the choice of product for haemophilia centres

40. No.

41. As I was never involved in the possible use of imported blood products, I am not in a position to offer any useful comment.

42. My own personal view is that clinicians should have the discretion to use whichever product they feel is appropriate based on knowledge of those products, the relative risks attached to each, and availability of possible (maybe less expensive) alternatives.

43. I was not aware of how imported blood products might have been promoted by commercial companies in the Oxford region. I have no comment on this.

Section 7: Production of cryoprecipitate at ORTC

44 to 49. I understand that cryoprecipitates were made at the old transfusion centre at the Churchill Hospital during my predecessor's time. But coinciding with the move to the new centre at the John Radcliffe Hospital, and with the provision of Factor VIII from The Plasma Fractionation Laboratory it had been decided to cease production of cryoprecipitates at ORTC

Section 8: Self sufficiency

50. As applied to the ORTC, there were two main demands made on the centre: hospitals' need for blood and blood products to be met as expeditiously and adequately as possible at all times. ORTC should not have to depend on other centres to 'bail out' in times of shortage. The other main demand related to plasma procurement, see a) below. As a caveat to this, ORTC routinely supplied blood to the North West Thames centre in consideration of their on-going particular need, and the fact that ORTC had the benefit of collecting blood donations in the Slough area

51.

a. plasma procurement thus had to be matched as far as possible to the targets set

b. Please see 44 to 49.

c. ORTC was not involved at any time with purchase of commercial blood products.

d.Self-sufficiency meant that the funding from ORHA should at least meet the needs of operating ORTC for the benefit of the regions' hospitals without having to seek supplementation from other RTCs

52. It did not seem to me that the demand for products would ever be totally met by UK self-sufficiency – hence the purchases of other, commercial products made by some organisations to meet the seemingly ever-increasing clinical need

53. I believe that many of my peers were of similar opinion

54. ORTC did provide blood and blood products on a very limited scale to private hospitals in the region. The impact on self-sufficiency for ORTC was not significantly affected.

Section 9: Services for donors at ORTC

55. Documents at donor sessions did indicate that appropriate disease screening of blood donated was routine. That included screening for HBV, HIV and HCV once testing became available for each.

56. Donors who may have been found positive for hepatitis B were referred to a consultant hepatologist at the John Radcliffe hospital. ORTC were not involved directly in counselling. As regards HIV, I saw only one donor who tested positive for HIV. Initially, I dealt with that personally, and also referred her to the haematologist in GRO-A (where she lived) for further management and counselling as seemed appropriate. I do not know what other arrangements may have been made. Any other HIV positive donors were dealt with by an Associate Specialist on the ORTC staff.

57. I am unable to give a satisfactory answer to this, other than to say I was not made aware that the questionnaire appeared to have caused problems.

58. ORTC was not involved in counselling or providing psychological advice to any recipients of infected donations if those were identified.

59. For the few patients identified involved referrals were made on an ad hoc basis, not least because of geographical spread. The system inevitably evolved with time.

Section 10: Meetings of various committees

Meetings of Regional Transfusion Directors

60. In view of the fact that there was no regulatory enforcement of practices across all RTCs, it was agreed that collaboration between centres was highly desirable towards standardisation of practices across the whole country. The sensible start in this direction was for the RTC directors to meet to discuss mutual problems, and assess the way forward because so many people were involved and there was considerable expense, especially where changes to practices were to be adopted.

61. Decisions were usually arrived at by consensus after full discussion, and weighing up pros and cons of whatever was proposed. Conclusions would then be passed on by the directors to their staff.

62. To a large extent these meetings did fulfil the purpose for which they existed, but with reservations.

63. It was realised there were too many difficulties arising out of the system, particularly relating to supply of plasma to BPL and return of products to the regions which led to other arrangements being set up: in particular the National Directorate and later the National Blood Authority. These changes were designed to achieve greater harmonisation of practices across the whole NBTS, through a central body having executive authority covering all aspects of RTCs.

64. The RTD meetings were discontinued in their previous form.

65. It was however recognised that collaboration especially on scientific matters was to be encouraged, and this provided a huge impetus towards the formation in the 1980s of the British Blood Transfusion Society which gave an excellent forum, with input not only from RTDs but also from other transfusion centre staff who could and did attend those meetings.

NBTS/CBLA Liaison Committee

66. I attended meetings of the CBLA/NBTS Liaison committee as an RTC member.

67.

a. As I recall, to the National Directorate, I think about two or three times a year

b. It was advisory

c. It was a useful forum for discussion of mutual interests

National Directorate of NBTS

68.

a. My role was very similar to that in RTDs meetings.

b. The Directorate was little better than the RTDs meetings in that it was advisory only

c. It was felt that the committee had served its purpose, but was limited by not having executive authority. To this end, discussions were taking place towards the establishment of the National Blood Authority.

Meetings of the NBA/Executive committee

69.

a. I was a member of the National Directorate Management Committee as a Western Division representative.

b. This committee was still only advisory.

c. Because of b) above, and persistent co-ordination difficulties within the NBTS. The Directorate was eventually superseded by the establishment of the National Blood Authority.

Western Division of BTS Consultants

70.

a. The purposes of these meetings were to discuss issues affecting the centres concerned, with input from their other consultants, not just the Directors.

b. As I recall, about three or four times a year

c. Conclusions would be taken forward as appropriate to Directors' and Directorate meetings

Section 11: Information handling by and information sharing between RTCs

71. Blood donation records in the earlier years of my time in Oxford were on the standard group- coloured cards that had been in use from the beginning of the BTS. They were kept in the care of the Donor Registry section of the ORTC, and may be amended by clerical or laboratory staff as necessary. Cards appropriate to each donor session were taken to those sessions and were updated as necessary by the session staff. The cards were not concealed from the donors themselves. Within the RTC, these cards were available as necessary to Donor Registry staff, to laboratory and Medical staff. After computerisation, the same information was also accessible to the staff of that department.

In my last few years at Oxford, starting around 2005, computerisation of donor and laboratory information progressed and the donor record cards became obsolete.

72. The donor record cards were retained indefinitely as I recall. Primary computer records involving donor identity, blood groups and screening record were also retained indefinitely up to the time I retired, though there was a perceived potential problem in that there was an in-built limit to the capacity of the system in use.

73. Discussions at the National Directorate had suggested possibly a 30year period for record keeping, and would aim to liaise with the pharmaceutical industry.

    a. Space limitations for storage of card records was not seen as a major problem since most activities were being progressively computerised. However, changes in computer methodology such that records could in the long term become indecipherable was perceived as a potential difficulty.

    b. Although long term storage of records was perceived as a potential problem, I do not recall particular problems being actually specified, let alone steps needed to address them.

    c. The principle of keeping records for as long as possible is viewed as rather idealistic. More practical alternatives suggested include arbitrary periods such as five, ten years or some other period, and even donors' likely lifetime. My personal view is that an agreed arbitrary time is probably the best solution.

    d. While it was suggested that the BTS might remain 'in line' with the pharmaceutical industry, I was not aware of there being an overriding obligation to do so?

74. Both card and computerised records had steadily accumulated while I remained in Oxford. I am not aware of the specific policy having been devised to address this issue.

75. Donors confirmed to be virus positive were withdrawn and asked NOT to donate again. Indeterminate positives were retested after six months and, depending on laboratory confirmation, either reinstated as donors or withdrawn. Records were held on the ORTC computer indefinitely. In due course, a time limit may have to be devised according to computing capacity.

76. As far as I am aware, each centre had its own policy.

77. Yes.

78. ORTC kept records of deliveries to hospitals' blood banks. I do not recall there being any regular routine feedback of information about the products used

79. My colleague Dr Angela Dike was responsible for sending annual reports of HBsAg positive donors to Dr Barbara, as well as ensuring record of them would be retained on the ORTC computer system which was in place by 1988. I do not know if CDSC was informed.

80.

a. I do not now know exactly what data was submitted to CDSC.

b. I was aware that CDSC were collecting data on HIV positive donors from the introduction of donor anti-HIV screening in October 1985

c. I do not know

d. I cannot be certain but I think it is likely that they did.

e. ORTC held comprehensive computer records of all donors including any HIV positive donors of course so that they could be excluded if they should return uninvited

f. I cannot answer this other than to indicate that my colleague Dr Dike may have done

81. I had no knowledge of the 'J' system during my time in Oxford.

a. I do not know.

b. It seems it was being proposed within the Manchester RTC.

c. Whilst the system may well have been used in RTC Manchester I do not know if it was used in other centres.

d. Although I attended the RTD meetings, I do not recall this specific subject being raised.

e. I have no idea whether this idea was submitted to other RTDs.

f. as I now understand it, it may have been intended to collect information on possibly dangerous donors, for that information to be conveyed to other RTCs in case those donors turned up there.

g. I do not know the answers to g), h), or i)

82. I don't think ORTC specifically sent information on screen positive donors to other RTCs, neither was I aware of receiving such data from other centres.

83. I agree with Dr Gunson's comments (NHBT0000026_009) that at that time there was no central executive authority to impose standardisation of operations in all RTCs. The question of transmission of data on screen-positive donors is another example of this disparity.

Despite the situation concerning transfers of information about infected possible donors to other RTCs, my understanding is that should a "positive" donor turn up elsewhere, because of universally applied screening there should be substantially minimal risk.

Section 12: Knowledge of risk of infections while at ORTC

HIV/AIDS

84. I was well aware from early in 1982 of the existence of HIV and of AIDS from the media, and the obvious corollary of the likely impact of a positive donor turning up.

85. I was aware right from my early tenure on the subject that blood transmission was a feature of HIV particularly from so-called 'high risk' potential donors and therefore was serious potential problem for the BTS

86. I was keen that HIV screening should be introduced as soon as possible. HIV screening in ORTC started, as I recall at some time around 1985-6. It was not long after that when a young lady who I am almost certain now was a new donor, attended a session and tested HIV positive. As I had previously attended an AIDS counselling course at St Mary's hospital, Paddington, I

interviewed her, and discussed with her how she most probably got infected. I referred the young lady to her GP and to the local Haematologist near where she lived with a view to her receiving what treatment might be available. In her case, there was no look-back to be undertaken. I did not personally experience other HIV infected donors. Any that were found were managed by an Associate Specialist, but in the same way.

Hepatitis

87. I had been aware since the 1970's after the identification of hepatitis B that there was a condition given the title 'Non-A, Non-B' (for want of a better name). I was also aware that throughout most of my time at Oxford, there were no specific tests for it. It was acknowledged that this condition posed a risk of blood transmission. There was an on-going controversy about the possibility and justification of so-called surrogate testing which was of course non-specific, and was not really helpful. Later, early tests for what later came to be called Hepatitis C were being produced, though the earlier products were sadly subject to lots of both false positives and negatives which is why it took so long to establish reasonably reliable and satisfactory screening and confirmatory tests which the Transfusion Service could be recommended to adopt. This whole issue had not been fully resolved by the time I retired.

88. I cannot say for certain, but probably sometime in the 1980's.

89. The question of hepatitis transmission was a particular issue of interest for my consultant colleague Dr Angela Dike. She liaised with a consultant hepatologist Dr Roger Chapman at the John Radcliffe hospital.

90. My understanding was that hepatitis B was the most aggressive infection, but that the other forms including hepatitis-C could nonetheless lead to chronic liver disease possibly with ultimately fatal consequences in some cases.

91. I was not specifically aware of this publication.

92. I have no further comment beyond Qu.90, above.

General

93. I do not think the possibility of these conditions made a significant impact on the selection of donors for a long time. Questioning donors about previous episodes of 'jaundice' (practised by the NBTS for many years) was known to be not particularly helpful since there are other causes of jaundice, and an unknown proportion of hepatitis carriers can be asymptomatic.

94. Nothing further than that blood transfusion has always been known to be a form of treatment carrying risks, just like any other medical treatment. Transfusion therefore should only ever be given after a balanced judgement of risks has been made.

95. I am not aware that any specific guidance had been given.

e. I was concerned that aggressive questioning could not only lead to misinformation being obtained, but that there was the potential for disruptive reactions at donor sessions which could only be counterproductive.

Section 13: Reduction of risks of infections while at ORTC

Donor selection

96. Initially ORTC adopted donor selection policies in line with National guidelines from DHSS.

a. Following the emergence of AIDS/HIV all RTCs including ORTC addressed the new difficulties with various approaches to 'high-risk' donors. Leaflets were devised to give donors an opportunity to 'own up' as it were to possible risks, though it was recognised that there was always the risk information could be concealed. Such leaflets were

added to donor call-up invitations, inapplicable of course to new walk-in donors and were displayed at reception in donor sessions.

b. There were more difficulties with NANB and HCV because of the impossibility to screen accurately for these conditions. That situation had not been resolved by the time I retired.

c. Hepatitis B had been known since the 1970s and donor screening tests were already established and continued throughout my time at ORTC

97. ORTC followed such guidelines as there were, recognising that these were not entirely satisfactory, and were of course evolving.

98. Definition of 'high risk' donors was necessarily dependent on donors volunteering their status. ORTC could have no practical other way to identify them.

99. I was not aware of any particular difficulties.

100.

a. and b. There had been proposals to ask donors to self-identify if they were in at-risk groups. However, I and others felt there was the possibility some might conceal information making such an approach partially invalid. That was quite apart from possible disquiet and potential social consequences of answers to an 'aggressive' approach perhaps being overheard by other donors.

c. No

d. It was an impression I had that some at risk donors MIGHT conceal out of embarrassment or other reasons. I did not have positive proof of this.

e. I was concerned that aggressive questioning could not only lead to misinformation being obtained, but that there was the potential for disruptive reactions at donor sessions which could only be counterproductive.

f.

i. There was public disquiet and rumour about AIDS and HIV and it seemed to me that it would be appropriate to proceed more cautiously.

ii. Non-disclosure of possible risk was the most important information that could be missed. Donors could also be put off from answering routine questions about the various other conditions which may be relevant.

iii. My views on this did not change drastically. It seemed to me that the whole problem of HIV for RTCs was put into perspective with the introduction of donor screening, with a more balanced public knowledge of the problem, and later with the introduction of specific treatment for HIV.

g. I was not keen at first for an AIDS leaflet to be given to every donor because I felt that could cause unwarranted distress to some, and also could lead to routine donor questions being not answered. In the event, I was completely satisfied to go along with nationally agreed guidelines

101. ORTC used leaflets following nationally produced guidelines. ORTC had every reason not to deviate from them.

102. I cannot remember how often. Content was decided in the light of agreed guidance from RTDs meetings/ National Directorate /NBA.

103. I am not aware of other information being given to donors.

104. I think that leaflets given to donors was the only realistic measure RTCs could adopt in practice, even if not totally satisfactory.

105. ORTC had no specific role in pushing for viral inactivation. I may well have had discussions on this at Directors' meetings. My feeling was that viral inactivation if possible and practical would be an obviously desirable goal, this was something which was outside my remit.

106. I do not think that ORTC was in any position to have pushed for introduction of virally inactivated products, even if they were achievable.

Provision of diagnostic screening kits

107. ORTC used commercial screening kits which had been approved by PHLS. Where more than one was available, preference was given to using tests which gave least false positive results in confirmation retesting by an outside body.

108. I personally had no part in the acquisition of screening kits. I have no doubt that a member of my staff would have attended one of the demonstrations offered by Ortho to every RTC of their kit; this was at a time when various commercial kits were being developed, though no kits established as being ideal. My understanding is that contracts for the best kit available would have been arranged nationally, but I have no proof of that.

109. ORTC chose to use those test kits which had been shown to be of sufficient accuracy and reliability, having due regard to cost considerations for obvious reasons.

110. Test kits were monitored by outside laboratories including the PHLS, before being offered to RTCs for in house evaluation. Ultimate decision before RTC purchase rested on satisfactory performance, with acceptable sensitivity and least false positives before consideration of cost.

111.

a. It was not uncommon for companies to offer test kits for trial. Several reputable companies including Organon and Ortho were all striving to devise suitable and hopefully better test kits, but needed them to be part of trials somewhere, and I understand that many RTCs like ORTC were invited to take up offers.

b. approaches were either made directly by a company representative, or on occasion by the National Directorate agreeing to a multicentre trial.

c. ORTC only switched test kits used on very few occasions, mainly because of concerns of there being an unacceptable proportion of false positive results.

112. I understood that the BPL test kit was much cheaper than the Burroughs Welcome kit. But there were commercial challenges to the price BPL charged. ORTC was happy with the BPL kit and wished to continue using it, but had to accept a higher cost for commercial reasons.

113. As far as I am aware, no commercial company exerted more than proper advice on how their screening kits should be used in practice to achieve the best results.

Introduction of HBV screening

114. I cannot remember when the BPL-RIA test was first used.

115. I may be wrong, but I think there were concerns over the number of false positive results.

116. Again, I cannot remember this technical detail.

117.

a. a significant drop of even 5% would be of concern.

b. ORTC only switched test kits used on very few occasions, mainly because of concerns of there being an unacceptable proportion of false positive results.

Introduction of HBV screening

118.

a. the delay in implementing a suitable test occurred because earlier kits were insufficiently reliable. It could not be readily foreseen how long a delay would be required.

b. It was obvious that roll-out should be a soon as was practicable once evaluations were completed. Immediate roll-out was considered unscientific with false positives (which could have caused great alarm) and false negatives which did nobody any good.

English centres were aware of results from other countries, which did not necessarily compare.

119. ORTC did start HIV screening in the autumn which may well have been in the October, as planned.

120.

a. Initial plans were to possibly extend the laboratory into part of the adjacent store.

b. and c. In the end there was a radical rearrangement of the laboratory which allowed screening to begin on schedule at the same time as in other centres.

121. I felt it was most undesirable for individual centres to start in piecemeal fashion. This would lead to serious and possibly legal questions of unfairness in those areas where screening had not started

122.

a. Initially donors would see the approved literature at sessions telling them about screening for HIV (this was a very 'hot' topic at the time). The usual donor samples taken with the donations were tested in the laboratory in much the same way as screening was already being done for syphilis and hepatitis B.

b. Donations testing positive would be removed until further confirmatory tests were completed. If confirmed, the donation was destroyed. If

there was a false positive, then the donor would be approached for a further sample

c. Blood already collected prior to screening being started was issued in the usual way
d. Every effort was made to ensure that plasma being sent to BPL after implementation of screening was in fact screened
e. For blood found to be genuine HIV positive, the donation itself would be destroyed. The donor would be approached by either myself or one of the ORTC Associate Specialists, the situation explained, and counselling them to undergo possible further investigation through their GP or appropriate clinic, with a view to whatever treatment was available to them. No information about the donor's HIV status was given to outside parties without their consent.
f. Possibly surprisingly, there didn't seem to be any serious concern among the staff. The blood involved had of course been destroyed. Nonetheless it certainly was appreciated that HIV was a blood-transmissible disease and due care had to be exercised in how blood was handled.

123. ORTC was not involved in so-called 'batch dedication' of blood products.

Surrogate testing

124.

a. There was no surrogate testing for HIV.
b. Surrogate testing for NANB and HCV remained for most of my time in Oxford a very controversial subject, and there were no agreed specific tests available. Trials of ALT testing had been carried out elsewhere with very variable results. NBTS authorities were not in a position to recommend generalised testing until 1991.

   ORTC did however introduce ALT testing on plasmapheresis donors because they attended much more frequently (approximately monthly.

125. I was aware of that Working Groups report and agreed with, not least because I had seen other reports which underlined the uncertainty.
126. Although it could be (and was) argued that maximum safety was a desirable goal, the considerable uncertainties around surrogate tests together with the extra financial burden suggested at that time that a practical compromise had to be adopted, and to refrain from adopting those tests at all RTCs
127. I agreed with the conclusions reached, not least because they came from people more familiar with the problem than me.
128. This was an arrangement made by my then Associate Specialist colleague, Dr Angela Dike, who was in charge of the ORTC plasmapheresis program

    a. I was not actively involved in the details of this arrangement.
    b. An increased reimbursement for ALT tested pheresis plasma was justified by the consideration of safety through possible though UNPROVEN reduced risk
    c. This continued at least until I retired, as far as I know
    d. The increased sum offered for FFP was a bonus on top of the possible benefit of having plasma with a perceived lesser but unproved risk being sent for fractionation

129.

    a. There was a lot of activity elsewhere towards the possibility of some form of surrogate testing to address the known small risk from NANB hepatitis coming from asymptomatic donors It was obvious that something was likely to be found and recommended for routine use before long.
    b. Surrogate testing would also help to detect and provide supportive evidence for HCV when testing for that was introduced.
    c. I remained sceptical of the true value of surrogate tests knowing something of their inaccuracy and non-specificity

130. At no time was routine ALT testing of donors introduced at ORTC in my time, with the exception referred above, (please see 128)

131. Routine surrogate, non-specific testing of donors for HCV was not undertaken at all

132. As far as I can recall, some time in autumn 1991, at the same time as other RTCs

133. I agreed there should be a delay to look closely at anti-HCV testing evaluation to ensure the most appropriate test would be used giving best accuracy and fewest false positive (or negative) results, while at the same time not forgetting financial implications

134. I felt strongly there should be a uniform start date for HCV testing for the same reasons as given for HIV screening, (please see reply to Qu. 121 above).

135.

a. I was under the impression that all RTCs should start a new routine screen test from an agreed start date, otherwise I considered that an RTC 'breaking ranks' could only be regarded as conducting a trial
b. If one or some RTCs did NOT start at the same time as the rest, I am not a lawyer, but questioned their possible position under Product Liability legislation
c. I have not investigated this question further, but still hold the same view.

136.

a. Once routine screening was introduced, collected donations were screened for HCV in similar way to the screening carried out for other infections.
b. Those testing negative for HCV would be available for issue (pending all other tests). Those screen testing positive would be quarantined pending being retested with an independent confirmatory test (usually more expensive, hence not used for screening), being released for issue if then negative, or withdrawn if positive.
c. Blood collected before HCV testing was introduced was available for issue in the hitherto normal way.

d. For those donations considered to be HCV positive, the donor would be approached for further assessment and possible referral to a hepatologist with their consent.

   Previous donations from that donor and any recipients involved would also qualify for look back. I understood that my colleague Dr Angela Dike had undertaken investigations in regard to some HCV positive donors. I am not familiar with her results.

e. I was not in a position to quantify the risk of HCV transmission after screening was introduced.

137.

a. The study was intended to clarify testing methods for HCV, to assess the likely incidence of genuine positives, to assess acceptance or not of false positives. By using more than one centre the robustness of the tests used could be more likely to be assessed.
b. I have no idea now what those difficulties were or how they might have been resolved.

138.

a. False positive screen results are always very unwelcome. They make for uncertainty about how to treat the donor concerned, how to deal with the donation at risk of being wasted; and how to cope with extra confirmatory tests and their expense.
b. I do not know if Ortho offered free replacement kits for the false positives. That was a technical detail of which I was not aware.
c. It seemed the best policy at the time to use ORTHO for screening in spite of possible false positives while keeping the extra cost of Murex tests and PHLS referral for confirmation.

139.

a. DHA funding seemed appropriate to cover the local ORTC studies of possible HCV in plasmapheresis donors. I consider total routine HCV donor screening when implemented should be funded centrally.
b. Funds were obtained centrally to provide for total donor screening

c. Screening for HCV began as far as I can recall in the autumn of 1991.

140. The funds available were insufficient at that time for look-back of donations from those donors confirmed HCV positive which I believe was started later after I retired. As it was, I did not think that ORTC would be able to commence screening any earlier pending establishment of a recommended suitable test.

Recall practice and procedure at ORTC

141. Recall when needed was very much done on an ad hoc basis. This was not formalised properly until the institution of the development of the Quality Assurance department and SOPs (Standard Operating procedures).
142. I do not remember any specific formal recall procedures.
143. I cannot comment.
144. The most significant improvement was the institution of the Quality Assurance department, and the development of standard operating procedures for all departments. This led to ORTC being the first RTC to achieve the recently prescribed EU quality assurance certification. Training of all staff from the donor attendants at sessions to laboratory workers and all staff handling blood products was of course essential.
145. Blood safety was viewed throughout ORTC as a prime consideration, particularly with regard to all the laboratory practices.
146. ORTC did experience laboratory staffing difficulties in 1988, resulting in restriction of some procedures. While there were delays in performance of some screening tests, there was no impact on the safety of donations issued.

    The 'hepatest' was a very satisfactory test. The letter referred to in the question related to a time of staff shortage, when use of this test on antenatal samples only could be delayed. When that occurred over a weekend it could lead to no results. Blood donations continued to be screened and were not affected by the reported restrictions.

146. RTCs having consensus agreement ensured that only screen tests of reliable and confirmed accuracy would be routinely used in all centres to assure best chance of achieving safety.

147. ORTC was naturally very dependent on and respected the guidance given by NBTS outside bodies, based on experience over the years by all NBTS institutions, both local and central, and to some extent on experience in other countries.

The only conflict I had was with regard to introduction of new screening tests (see reply to qu. 121, above).

148. I personally had no reason to believe that the NBTS had changed its focus to a 'safety at any cost' philosophy. No RTC or central NBTS body could escape the practical reality of funding, as well as coping with the uncertainties engendered by unestablished procedures. At the same time, due consideration had to be given to the requirements of product licensing where applicable, and possible legal considerations.

Although some people may have encouraged the 'safety at any cost' attitude, I was not convinced that the NBTS as a whole had.

149.

a. See answer to q.148, above, I do not think that the NBTS had made this change.
b. As far as I was aware, the original policy was based on long years of experience.
c. Changes in product liability, in NBTS loss of crown immunity, the evolving process of regular audit were all leading towards a possible rethink.
d. I think one cannot divorce a philosophy of cost-benefit (a feature of practical reality) from the 'safety at all costs' approach. Both have to be taken into proper account.
e. In my view, the principles mentioned in answer in d) above, have to be applied to all blood transmissible infections.

Section 14: Look back programs at ORTC

HIV

150. I was not involved in any national look-back programs. Locally, at that time any HIV look-back was considered on an ad hoc basis.

151. Any ORTC HIV look back was agreed to be carried out by the Director or an Associate Specialist, involving face to face meeting with the infected donor, and preliminary counselling; this to be followed by notifying the nearest hospital Haematologist for further investigation. I was personally involved with only one HIV positive donor. The history in her case was very clear cut in identifying the time of infection, and I considered no look-back was indicated. Any other HIV positive donors would have been managed by an ORTC Associate Specialist, with look-back as necessary.

152.

a. In the context of this letter, I now interpret it to have meant any donor who might have been involved
b. I cannot say why the period of six years was chosen, or who chose it. I suspect now that it was an arbitrary figure on the basis that HIV had then only been recognised in the UK for about that time.
c. I personally had only experienced one HIV positive donor, (see answer to Qu. 151 above). No look back was conducted on that donor.
d. A formal system of look back remained to be drawn up.

HCV

153. I was aware that lookback for HCV was needed, but the precise scale of investigation required was uncertain. While limited investigations were being carried out, starting with the panel of plasmapheresis donors, laboratory and staffing resources were required for full implementation. A National program of HCV look-back was instituted by the NBA just before I retired; however, although diagnostic tests for HCV had improved significantly by that time, there was no specific anti-viral treatment to treat any recipient infected patients that might be identified. I understand that after I retired, interferon-alpha had become available offering hope to infected patients, and an ORTC look-back proceeded, but I do not know with what results.

154. I agree that look back of donations transfused from donors later found HCV positive should be pursued, though the scale of the problem, the clinical treatment and counselling needed had to be addressed.
155. I do not know the outcome of the reports quoted.
156. In my last year, there was one patient who it was thought might have been bacteriologically infected with transfused blood. I was in communication with the Haematologist concerned at the Swindon hospital where this happened. I had no contact with the patient or family involved. I was not informed of any possible proof of the source of the reported infection. The issue remained unresolved by the time I retired.
157. I think in general it is right to inform patients who might have been given infected blood, in the same way they should be informed of possible drug or other treatments that might have gone wrong. There are however serious considerations which should be taken into account relating to how much that patient might understand. It has to be remembered that ANY treatment given may produce reactions or have other unfortunate consequences. Blood transfusions is no different, which is why it should only be given as part of a balanced clinical judgement, giving due consideration to possible risks.
158. The only ORTC lookback programs in place before I retired involved the pheresis donors. The question of look-back for the ORTC donor population remained a subject to be fully resourced and implemented.

Section 15: Your relationship with commercial organisations

159.

a. No.
b. No.
c. No.
d. No.
e. No.
f. No.

160. In view of answers given to qu.159 such guidelines or regulations as may have been in place did not apply.

161. No.

162. No.

163. I never received funding from pharmaceutical companies for research

164. I had read about the possible transmissibility of Creutzfeld Jacob Disease (vCJD), but had no involvement in its practical implication for ORTC before I retired.

165. There were several publications, for which I was sole or co-author, two abstracts only available; these could be relevant to the Enquiry: They are as follows **[NHBT0042805_064].**

a. CMV Free Panel

C.C. Entwistle

Proc. Fifth Annual Fenwal Symposium. May 1983

b. Comparative trial of Six Methods for the Detection of CMV Antibody in Blood Donors

A.F. Hunt, D.L. Allen, R.L. Brown, B.A. Robb,

A.Y. Puckett, C.C. Entwistle

J. Clin. Path. 37: 95-97. 1984

c. The Problems of CMV in Transfusion and how to avoid it.

C.C. Entwistle

Invited Lecture to Belgian Red Cross Transfusion Service

Edmond Picardstraat 16, 1060 Brussels. Oct. 1984

d. Transfusion Transmitted CMV Infections: Clinical Importance and Means of Prevention

J.O'H Tobin and C.C. Entwistle

Invited Contribution to International Forum

Vox Sanguinis. 1984

e. Post transfusion septicaemia 1980-1989: importance of donor arm cleansing **[WITN6917002].**

A Puckett[1], G Davison, C C Entwistle, J A Barbara, Journal of Clinical Pathology 1992: 45: pp155-157

166. To my knowledge the UK was self-sufficient for red cells most of the time, although there were occasional periods of stringency (especially around and after bank holidays)

167 I am not aware of any patients being given blood imported from the USA or anywhere abroad.

168 It is now over 26 years since I retired, and I retained no records from my time in work. It must be clearly understood and will come as no surprise that to the best of my memory I am unable to provide satisfactory answers to a number of the questions asked. Some of these relate to technical matters properly within the purview of staff to whom those functions had been delegated. With this in mind, I have tried to get in contact with former staff members for assistance, but to minimal material benefit. It also should be understood that ORTC was very much a routine establishment with very limited research facilities or staffing, unlike some other RTCs. That is why I considered ORTC was obliged to introduce only those tests or procedures which had been established as sufficiently reliable and which NBTS outside authorities had pronounced as recommended for routine use in all RTCs, and starting only from agreed starting dates.

NOT RELEVANT

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 25th October 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
xx/xx/1992	Post transfusion septicaemia 1980-1989: Importance of donor arm cleansing	WITN6917002