The History of the Blood Services in the UK: an overview

The following abbreviations are used in this document:

BGRL	**Blood Group Reference Laboratory**
BPU	**Blood Products Unit**
BPL	**Blood Products Laboratory**
CBLA	**Central Blood Products Laboratory**
CMO	**Chief Medical Officer**
CMV	**Cytomegalovirus**
CSA	**Common Services Agency**
DHSS	**Department of Health and Social Services**
DH	**Department of Health**
HLA	**Human leukocyte antigen**
HPSS	**Health and Personal Social Service**
HSC	**Health and Social Care**
IBGRL	**International Blood Group Reference Laboratory**
JPAC	**Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee**
MRC	**Medical Research Council**
NBA	**National Blood Authority**
NBTS	**National Blood Transfusion Service**
NBTSW	**National Blood Transfusion Service Wales**
NHSBT	**NHS Blood & Transplant**
NIBSC	**National Institute for Biological Standards and Control**
NIO	**Northern Ireland Office**
NSS	**National Services Scotland**
PFC	**Protein Fractionation Centre**
PFL	**Plasma Fractionation Laboratory**
RBTO	**Regional Blood Transfusion Officer (who were later named RTDs)**
R&D	**Research and Development**

RHA	**Regional Hospital Authority**
RHB	**Regional Hospital Board**
RTC	**Regional Transfusion Centre**
RTD	**Regional Transfusion Director**
SBU	**Strategic Business Unit**
SHA	**Special Health Authority**
SHOT	**Serious Hazards of Transfusion Working Group**
SHHD	**Scottish Home and Health Department**
SNBTA	**Scottish National Blood Transfusion Association**
SNBTS	**Scottish National Blood Transfusion Service**
WBS	**Welsh Blood Services**
WHCSA	**Welsh Health Common Services Authority**

England

1. Much of the information contained within this part of the presentation comes from three sources, the article written by Dr Gunson and Helen Dodsworth entitled 'Fifty Years of Blood Transfusion' published in Transfusion Medicine in 1996 (**NHBT0000028**), the organisational rule 9 from the NHSBT authored by Dr Gail Miflin dated 19/10/2021 (**WITN0672006**) and the exhibit to that statement **WITN0672007** – the updated NHSBT family tree.

2. In 1921, Percy Lane Oliver established a civilian voluntary blood donation panel guided by the British Red Cross Society. In 1926 the Red Cross Society became fully responsible for the service. The panel arranged blood donors to a number of London hospitals to meet emergencies requiring blood transfusion. All donation was voluntary and unpaid. Other panels operated outside of London on a similar basis (**NHBT0017232** page 20).

3. At the outset of the second World War, Dr Janet Vaughan (haematologist at the Hammersmith Hospital), drawing on experiences in the Spanish Civil War, advanced a plan to supply blood for transfusion to civilians in London. This involved the creation of blood depots and in 1939 the Ministry of Health approved the establishment of four blood depots to treat London civilians. These were managed by the Medical Research Council on behalf of the Ministry of Health (**NHBT0017232** page 21). Also in 1939, an Army Blood Supply Depot, operating out of two maternity wards in Southmead Hospital in Bristol, was established by the War Office. This supplied blood to civilian hospitals in South West England, as well as meeting the requirements of the Armed Forces (**NHBT0017232** page 21).

4. In 1940, in response to a lack of provision outside London, regional blood depots were established throughout the country, close to large district hospitals in the major cities. The depots, which later became known as the Regional Transfusion Centres (RTCs), were established in Newcastle, Leeds, Nottingham, Cambridge, Birmingham, Oxford, Manchester, Liverpool, Cardiff and (later) Belfast. These RTCs were managed by the Emergency Medical Service rather than the Medical Research Council. There were regular meetings between the Regional Blood Transfusion Officers (later known as Regional Transfusion Director - RBTO or RTD – referred to in the rest of this document as RTDs) in charge of the RTCs and the Ministry of Health, to which an RTD from Scotland and Northern Ireland was invited, as well as representatives from other organisations such as the Blood Group Reference Laboratory (BGRL) (see below). The Inquiry holds minutes of such meetings from 1945. They continued until January 1989.

5. In 1943, it was agreed between the managers of the London depots, the Ministry of Health and the Medical Research Council that the blood supply system had reached such a scale that national management was required (**NHBT0017232** page 22).

6. The National Blood Transfusion Service (NBTS) for England and Wales was created by the Ministry of Health on 26 September 1946, encompassing the London depots

(which were reduced from four to two) and the Regional Transfusion Centres[1]. The RTDs met regularly with the Ministry of Health, which was responsible for managing the service. The meetings were chaired by Dr William Maycock who had been appointed Consultant Advisor on Blood Transfusion to the Chief Medical Officer of the Ministry of Health that same year. The committee comprising the RTDs and Dr Maycock had no statutory basis and so while it could formulate policy, it had no way of enforcing it. Accordingly the committee's function was to inform Dr Maycock as to how he should advise the Ministry of Health, which maintained executive authority over the NBTS (**NHBT0017232** page 23).

7. Also in 1946 a Blood Transfusion Research Unit was set up at the Hammersmith Hospital, as well as a Blood Group Research Unit and a Blood Group Reference Laboratory (BGRL), both sited at the Lister Institute, London (**NHBT0017232** page 22). These, together with a plasma drying plant, were managed by the MRC **(NHBT0000026_009** at paragraph 6).

8. On 5 July 1948, the National Health Service was established by the coming into force of the National Health Services Act 1946 ("the 1946 Act") and the National Health Service (Determination of Regional Hospital Areas) Order 1946 (SI 1946 No 2158). Pursuant to sections 11 to 14 of, and Schedule 3 to, the 1946 Act, Regional Hospital Boards (RHBs) were established within areas of England and Wales for the purpose of 'exercising functions with respect to the administration of hospital and specialist services in those areas.' The 1946 Act led to the formation in 1948 of 12 Regional Hospital Boards in England and Wales. The management of RTCs was transferred from the Ministry of Health to the RHBs (**NHBT0017232** page 24).

9. By 1953 the UK had more than 500,000 donors on its national panel (**DHSC0105487_007**). In addition to this, many hospitals had their own donor panels. These independent panels were maintained for a variety of different reasons, including because of a failure on the part of the relevant RTC to meet the demands of

[1] Initially there were 11 of these, being joined in 1955 by Brentwood and in 1964 by the Lancaster Blood Transfusion Centre and the Southampton Blood Transfusion Centre.

the hospital (see for example the letter from Dr Slater of St Thomas's Hospital to Dr Smithies about the Tooting RTC in January 1986 **(DHSC0002291_008)**), or because the hospital required products such as 'fresh warm blood' which could not be provided by the RTCs).[2]

10. RTCs were responsible for a range of services, including the collection of blood from voluntary donors, the processing and testing of blood donations, and the supply of blood to hospitals within their area. On some occasions, RTCs also supplied blood to other hospitals and bodies outside their Region (for example, to the Ministry of Defence) **(NHBT0000026_009** at paragraph 5). Moreover, not all RTC operational areas corresponded precisely with the areas of the Regional Hospital Board which managed it. By way of example, and as Dr Gunson noted: '*In the case of Wales, which did not have a regional structure, South Glamorgan Health Authority maintained and operated a Transfusion Centre in Cardiff for all the Welsh Districts save Gwynedd Health Authority and Clwyd Health Authority which were served by the Mersey RTC.*' **(NHBT0000026_009** at paragraph 5).

11. Each RTC was managed by an RTD who was medically-qualified. The RTD was appointed by, and accountable to, the RHB. The management of RTCs by RHBs from 1948-1974 meant that requests for further funding went through the RHBs, rather than coming directly from central Government funds. They were therefore subject to the usual competition with other regional priorities. An example of this can be seen in the November 1954 Regional Transfusion Directors meeting at which a programme for the expansion of the NBTS had been approved in principle by the Treasury, ostensibly in order to provide sufficient blood for the drying plant. (**NHBT0018394** page 2, para 2(b)). Each RTC was advised to make an application to their RHB in the event that funds were required for additional equipment, staff and facilities. Concern was expressed by some RTDs that "*money was not available for normal capital expansion of the service; expansion in any particular branch of work could only be carried out by economising in another branch of work.*" The suggestion made by RTDs that hospitals pay towards the cost of services received from RTCs was criticised by the

[2] The use of fresh warm blood is an issue that will be explored in later hearings

Ministry of Health as not *"administratively acceptable."* **NHBT0018394** page 3, para 3).

12. RTCs were independent from the hospitals to which they supplied blood. At times, this caused difficulties as some hospitals were reluctant to report serious transfusion reactions to RTCs as they were concerned about the implications of "reporting on colleagues". (See for example the minute of the RTD meeting in April 1953: **NHBT0017682** page 1, para 3).

13. In 1949, Dr Maycock was appointed Superintendent of the Lister Institute Laboratories. BPL was established at Elstree in 1954 (although its history goes back to 1943 - **CBLA0000005_002** paragraph 4). Plasma supplied by the RTCs was fractionated at BPL to produce blood products, as the RTCs did not have their own fractionation facilities.[3]

14. In the June 1961 RTD meeting, a DHSS representative undertook a listening exercise on behalf of the Ministry to sound out discussion of the future of the NBTS, whereupon it was noted it was *"rather isolated from the rest of the NHS"* (**NHBT0018370_001** page 3, para 7). A wide range of opinions on the optimal structure and functions of the NTBS were expressed. The focus was on, in the words of Dr Goodman, "*the problems that seem to arise from a national service being administered regionally*." (**NHBT0018370_001** page 5, para 13).

15. Regional Transfusion Directors identified a number of ways (some contradictory) in which the service could develop:

    - Central production of certain equipment and solutions, rather than contracting;
    - Decentralising procurement and functions;
    - Greater internal cohesion between centres, central laboratory and the Ministry;
    - Placing the RTC at the heart of decision making at the RHB.

[3] The activities of BPL are outwith this presentation. The Inquiry will present evidence about BPL in 2022.

(**NHBT0018370_001** page 4)

16. It was further noted that changing patterns of demand and lack of facilities meant RTCs would struggle to do R&D (research and development) work and that, while control of uses of blood was necessary, it should not be by NBTS because it was not responsible for treatment.

17. The views expressed in this meeting were not, however, unanimous. The Scottish attendee argued that central control was preferable to regional control[4]. A central committee with clinicians and RTDs was considered, as was control of RTCs by hospitals. Members noted that the most efficient and progressive foreign centres were those most closely integrated; that demand for blood and anticoagulants was likely to rise; and that an integrated national service was necessary if rare blood sera were to be fairly distributed. (**NHBT0018370_001** page 5)

18. By 1970, the service had expanded to fourteen RTCs. Each region had one RTC, save for in South London where one RTC served two regions. Each remained quasi-independent centres managed by their respective Regional Hospital Boards. (**NHBT0017232** page 24)

19. Due to the autonomy of the RTCs, divergence in practice between them continued. Dr Gunson, director of the NBTS, described how efforts were made to standardise the medical selection of donors and other functions. He noted that these efforts were only ever partially successful as there was no obligation on RTDs to adopt national policy, particularly where this came into conflict with regional policy (**NHBT0017232** page 25).

20. In 1970, the blood services were affected by the broader efforts to restructure the NHS. A special meeting was held on 16 April 1970, chaired by Dr Maycock and attended by RTDs and DHSS representatives, to consider the Green Paper on the

[4] It should be noted that at that time, the SNBTS was already more centrally managed than in England and Wales.

Future Structure of the NHS. RTDs advanced the case for a national service on the basis that the existing structure of 14 independent RTCs was leading to fragmented administration, a lack of uniform financial and staffing policies and the absence of any obligation to carry out centrally agreed policies. Three unanimous conclusions were reached at the meeting:

- Rejection of the proposal that the NBTS should be administered by Regional Councils, as these were advisory bodies that lacked executive authority to run RTCs.
- Rejection of the suitability of the Area Health Boards as administrators of the NBTS, as their focus differed substantially from the respective RTCs.
- Proposal of a centrally financed and administered blood service that would allow national planning, specialised functions and improved efficiency. It was noted that, "*Since the administration of the service had been decentralised in 1948... development of the regional centres had been uneven... many difficulties had arisen from the fact that that administration and financing of service were the responsibility of 13 different authorities.*" (**NHBT0017065** pages 2-3).

21. Members at the meeting identified two potential models for the running of a national service:
    - Direct control by the Department of Health, with or without intermediary regional offices.
    - The formation of a service run by a board and responsible to the Secretary of State.

22. No firm preference was expressed between the two models, though maintaining the regular meetings of the RTDs was unanimously supported, with consideration to be given to making this a statutory committee. There was also support for having local transfusion committees to provide links between RTCs and Regional Health Authorities. (**NHBT0017065** page 3)

23. The DHSS rejected the proposals of the RTCs as set out in the 1970 special meeting (**NHBT0017232** page 25). Rather, the DHSS opted to move management of RTCs to Regional Health Authorities accountable to the DHSS, and to form the Central Committee for the NBTS. This committee was replaced in December 1980 by the DHSS Advisory Board. (**CBLA0001207 and DHSC0002307_059**)

24. While the DHSS accepted that a degree of central coordination was '*highly desirable, if not essential*', they stated that the new, broader restructuring of the NHS would ensure that NBTS requirements were met through the greater intervention by the DHSS in the running of the NHS (**NHBT0016117** pages 4-5). Under the proposed structure, RTD meetings would be the primary venue for providing professional and technical advice on NBTS issues to the Secretary of State, with further DHSS scrutiny to be applied in respect of RTC planning (**NHBT0016117**). In addition the DHSS agreed to consider whether it would be appropriate to make some 'special administrative arrangements' to ensure co-ordination and administrative uniformity within the NBTS.

25. The NHS reorganisation took effect from the start of 1974, with the National Health Service Reorganisation Act 1973 ("the 1973 Act") replacing the Regional Hospital Boards with Regional Health Authorities. Members of the Regional Hospital Boards (including the Regional Transfusion Director) were directly appointed by the Secretary of State. (**NHS Reorganisation Act 1973, schedule 1 para 1.**)

26. As such, from 1974 the management of the RTCs was transferred away from the Regional Hospital Boards to the newly created Regional Health Authorities. As there was no national executive control of blood services policy, local management of the RTCs continued. Nevertheless, it was recognised that the NBTS continued to require some form of central coordination '*To keep under review the operation of the National Blood Transfusion Service, including the Blood Products Laboratory and Blood Group Reference Laboratory, in England and Wales and to advise the*

Department of Health and Social Security and the Welsh Office on the development of the Service' (**NHBT0000028** page 25 - 26). To that end, the DHSS:

- Appointed a Senior Administrative Officer and a Senior Medical Officer, both of whom were tasked with working exclusively with the blood services on behalf of Government.
- Created a Central Committee of the National Blood Transfusion Service in 1975 so as to coordinate the work of the RTCs (**NHBT0001635_002**).[5] The Central Committee was charged with keeping under review the operation of the NBTS, including BPL and the Blood Group Reference Laboratory in England and Wales and advising the DHSS on the development of the service. (**NHBT0017232_page_26**). Its first meeting was held on 19th June 1975 (**MRCO0000060_023**).

27. RTD meetings continued, but there were no formal arrangements for regulating the relationship between the RTD meetings and the Central Committee. It was Dr Gunson's view that this management structure did not enable the Central Committee of the NBTS to properly advise the DHSS or to best determine the means of managing national resources (**NHBT0017232** page 26).

28. In April 1974 RTDs expressed the need for guidance from the DHSS on the relationship between the RTCs and the Regional Health Authorities and in particular as to whether the RTD had the right to attend meetings of the RHA where blood transfusion was being discussed (**PRSE0002186**). In October 1974, Regional Health Authorities were still awaiting general guidance (**NHBT0016494** page 8).

29. The lack of central coordination within the blood services continued to be a concern. On 27 July 1974 an editorial in the BMJ stated (**DHSC0100024_126**):

"The problem rests on the quality of management (or lack of it) which has led to a steady decline in the British Blood Transfusion Service since the late 1950s. There has

[5] Members of the committee included some RTDs, Dr Maycock, and a range of other clinicians. Meetings were attended by members of the DHSS, the Welsh Office and the MRC.

been no effective national planning; the regional and protein fractionation centres now lack sufficient staff, accommodation, equipment and the basic organizational units to do the job. Moreover, the medical staff in the centres are often geographically and administratively isolated from the care of patients. The remedy then, is .....an urgent appraisal (for the first time) of a national policy for the procurement and eventual distribution of a national resource which, unlike oil, will be still readily available in 100 years' time"[6]

30. In May 1977, the NBTS (together with the director and the director designate of BPL, Dr Lane) submitted "The National Blood Transfusion Service: Its present Status and Proposals for Reorganisation" for consideration by the Royal Commission on the NHS. (**CBLA0000612** page 2) The submission provided as follows:

    - The NBTS had "*assumed an increasingly national role which has suffered from constraints arising from regional development, inadequate central coordination and financing and a poor integration of the activities of Regional Transfusion Centres*." (**CBLA0000612** page 3, para c).
    - Services provided by the RTCs varied considerably from region to region (**CBLA0000612** page 5, para 2).
    - The internal structure of the NBTS was described as "*a loose confederation of 14 RTCs, independently financed, each providing services which vary considerably from Region to Region, and 3 central laboratories financed by the DHSS*." (**CBLA0000612** page 5, para 2).

31. The submission outlined the four links between the blood services and the DHSS:
    - A part-time consultant advisor on Blood Transfusion to the DHSS.
    - The RTD meetings, without statutory constitution or executive function, operating as an informal mechanism for information exchange.
    - The Central Committee for the NBTS formed by the DHSS.

[6] For a later analysis of the impact on the blood service of the structural inadequacies of the NBTS see the BMJ editorial 9 August 1980 **IPSN0000260_021**

- Meetings of the Regional Donor Organisers, chaired by the Senior Administrator of the DHSS, which largely focused on reviewing publicity material for the recruiting of blood donors.

32. The submission suggested improving the national service by the allocation of central finance and management through a statutorily constituted executive committee and the appointment of a national medical coordinator (**CBLA0000612** page 3, para d).

33. Several limitations in the structure of regionally managed RTCs were identified:
    - There was no statutory or substantive provision for RTCs to have central representation.
    - The Central Committee was only advisory.
    - The DHSS was not in a position to instruct Regions on the allocation of finance to RTCs.
    - The Regional Health Authorities were not involved in national policy making for the NBTS, beyond financing regional projects.

    (**CBLA0000612** page 10, para 3).

34. The submission suggested that further concentration and specialisation of functions in different RTCs might assist, though they noted that this would be either at the expense of other services provided by the RTC for national or regional use, or regional health spending on other aspects of the Health Service (**CBLA0000612** page 11, para 2). It also proposed a strong central organisation and planning on a national level, with accompanying central funding for the NBTS and the creation of a national service for the collection of blood for issue and fractionation (**CBLA0000612** page 11, para 4 to page 12, para 2).

35. Dr Lane wrote to Dr Gunson in October 1977, noting that there was serious concern as to whether the DHSS would attempt to interfere in *"the process of Royal Commission investigation into Blood Transfusion affairs."* It is not clear whether any such interference materialised but Dr Lane continued to record his concern that the

DHSS' "long-term intentions" with respect to the NBTS appeared to be at odds with those working within the service (**CBLA0005060**).

36. In 1975 the Lister Institute took over full responsibility for BPL on behalf of the DHSS (**CBLA0000005_002** paragraph 7). Then in 1978 the DHSS took over the management of BPL and BGRL. Management was delegated to North-West Thames Regional Health Authority (**NHBT0001635_002**). On Dr Maycock's retirement in 1978, Dr Lane replaced him as the director of BPL.

37. Also in 1978 Dr Geoffrey Tovey succeeded Dr Maycock as Consultant Advisor in Blood Transfusion to the Chief Medical Officer **(CBLA0000802**).

38. Dr Tovey established three divisions comprising the RTCs in the relevant districts:

    - Eastern: North London, Brentwood, South London, Cambridge
    - Western: Oxford, Bristol, Southampton, Birmingham, Cardiff
    - Northern: Newcastle, Manchester, Sheffield, Leeds.

39. These divisions met regularly and were tasked with discussing NBTS policy ahead of RTD meetings. They were encouraged to advance policy proposals (**NHBT0017232** page 27).

40. At a March 1979 DHSS meeting to consider the long-term management of the NBTS and Central Blood Laboratories, it was agreed to recommend to ministers that the management of the laboratories would continue mostly unchanged. It was further agreed that in response to calls for a nationally managed blood service, the existing Central Committee should remain unchanged. A further ad-hoc committee to try to achieve better coordination of NBTS activities was recommended. The committee would comprise DHSS members, Scottish Home and Health Department, Welsh Office, two RTDs, the Joint Management Committee for the Central Laboratories, NHS administrators, NHS treasurers, directors of the Central Laboratories, clinical users and experts in serology. The function of the committee would be planning and

coordinating the activities of the Regional Centres and the Central Laboratories so as to ensure the NBTS was able to meet future requirements for blood products **(DHSC0002193_006).**

41. Dr Tovey drafted a report, dated 28 February 1980, titled "Proposed Plan for Reorganisation of the NBTS", in which he noted that there was broad agreement within the NBTS that increasing national demand had led the NBTS to suffer from the "*constraints arising from regional development, inadequate central coordination and financing and poor integration of the activities of Regional Transfusion Centres*". This report built on the NBTS submission to the Royal Commission three years earlier. He suggested that some progress had been made in the establishing of a Joint Management Committee for the Central Laboratories by the introduction of meetings of all consultant medical staff at the RTCs (the "Regional Group" meetings) and the new "Ad-hoc meeting" between three senior RTDs and the Director of BPL chaired by the Consultant Advisor to the DHSS. Nevertheless, he noted that there was a general appreciation within the service that the "major defects" within the service were unlikely to be overcome in the absence of a national managed authority with statutory powers. Noting that such a policy would not be implemented immediately, he made a number of interim suggestions to improve coordination amongst RTCs and for closer links with the Scottish NBTS (**DHSC0002197_089**).

42. Due to the perceived failure of the Central Committee of the NBTS to effectively pursue national policies within a system of devolved RTC governance, the DHSS in 1980 adopted a proposal from Dr Tovey to replace the Central Committee with a new Advisory Committee on the NBTS. This Committee was to be chaired by the DHSS, and be made up of three transfusion directors, Dr Lane and Dr Tovey of BPL, a Regional Administrator, a Regional Medical Officer and a Regional Treasurer. Members of the DHSS, the Welsh Office and Northern Ireland would be in attendance. The terms of reference were '*To advise the DHSS and Welsh Office on the co-ordination of the development and work of Regional Transfusion Centres, and the Central Blood Laboratories in England and Wales; and the English and Welsh Blood*

Transfusion Service with that of Scotland and Northern Ireland.' **(DHSC0002365_021** page 4). Its first meeting was on 1 December 1980 **(CBLA0001207).**

43. Prior to this development, there had been no official liaison between the English and Welsh service and the Scottish service (**NHBT0017232** page 28).

44. While the Advisory Committee on the NBTS did pursue a number of national policies within the service, the difficulty in achieving national standardisation persisted. Dr Gunson highlighted the inconsistent and inadequate supply of plasma to BPL and the difficulty in implementing HIV testing in light of a lack of national policy for decision-making as examples of this (**NHBT0017232** page 28).

45. Dr Gunson replaced Dr Tovey as the Consultant Advisor to the Chief Medical Officer in 1981.

46. In July 1982, at the DHSS' request, the Regional Transfusion Directors and Joint Liaison Committee met to discuss the supply of blood to the private sector and private donor panels. RTDs believed it was important that RTCs kept control over donor recruitment, and private hospitals were not prioritised over the NHS. (**NHBT0010079**)

47. In 1982, the Central Blood Laboratory Authority (CBLA) was established, pursuant to the Central Blood Laboratories Authority (Establishment and Constitution) Order 1982 SI No. 1515 ("CBL Order"). CBLA's functions included providing laboratories for the manufacture of blood products, preparing plasma fractions, research and development of fractionation, and the manufacture of blood grouping reagents. CBLA's remit included BPL at Elstree, the BGRL, and the Plasma Fractionation Laboratory in Oxford. Target capacity for the laboratory was set by the Policy Steering Group. (**CBLA0001448**)

48. Also in 1982 the MRC's Blood Transfusion Research Committee (formed in 1939) was disbanded, severing the last formal link between the NBTS and the MRC.

49. Between 1983 and 1985 the case for the formation of a nationally managed service was once more advanced (see for example the discussion in the Eastern Division Consultant meeting of 19 December 1984 **(NHBT0092839)**). The transfer of management from Regional Hospital Boards to Regional Health Authorities with DHSS oversight had not led to the desired change, as local pressures on regional authorities were still causing RTCs to be managed differently. RTDs further suggested that as the work of the RTCs changed over time there were more functions that required national management, including plasma supply to BPL to support the goal of self-sufficiency. (**NHBT0001635_002** page 2)

50. In February 1985, South Western RTC Director I. D. Fraser wrote to the DHSS on behalf of Dr Gunson with a document incorporating feedback from all RTCs. The document, reflecting the views of the RTCs, requested the DHSS to consider the options available for a nationally co-ordinated Transfusion Service for England and Wales. It further requested that a Working Party be established under the NBTS Advisory Committee. It stated that the advantages could include a co-ordinated national blood collection to make better use of donors, reducing duplication, allowing for uniform implementation of policies (e.g. testing), rationalisation of blood production and better co-ordination/integration with the hospital network, rather than regional boundaries. (**DHSC0002259_037**)

51. Some of the disadvantages of not having a centralised national service were identified in the July 1985 memo from Dr Alison Smithies to Dr Harris (DCMO), in which she noted that research and development were being duplicated across RTCs, BPL and the Protein Fractionation Laboratory in Scotland due to a lack of central coordination. She further noted that the introduction of heat treatment would benefit from central coordination (**PRSE0003881**).

52. At the meeting of the Advisory Committee to the NBTS on 6 November 1985 (attended by the DHSS) (**CBLA0002277**) it was decided that a working group should be convened to consider the organisation of the NBTS. At the following meeting on 12 March 1986 (**PRSE0000128**) it was agreed that a DHSS/NHS steering group would supervise the examination of the NBTS organisation.

53. By 1986, it was agreed that the DHSS Central Management Services would carry out an investigation into the organisation of the NBTS. Their report, dated October 1987 (**CBLA0002392**), identified three possible routes forward,:

- Maintain the present system (but with the introduction of reliable management information).
- Create a new Special Health Authority to manage the system centrally.
- Retain management of the RTCs by Regional Health Authorities but with formal, national coordination of their work.

(**NHBT0017232** page 29)

54. In 1986 Dr Gunson re-defined the responsibilities of the RTCs into 'Core Activities' and 'Specialist Activities' (**NHBT0000028 page 29**). Core activities were to be undertaken in all RTCs. The Core Activities were:

- Maintenance of volunteer, unpaid, donor panels
- Blood collection and blood grouping
- Testing blood donations for infectious markers
- Processing of donations into blood products:
    - Platelet concentrates
    - Plasma for clinical use
    - Cryoprecipitate
- Distribution of products to hospitals
- Supply of plasma for fractionation to BPL including normal plasma and special antibody containing plasma
- Supply of antisera to IBGRL

- Selection of donors for the national and international panels of donors of rare types.

55. The Specialist Activities were:
    - Antenatal testing
    - Reference work, both clinical and serological for transfusion problems
    - Tasks undertaken on behalf of NBTS:
        - Pyrogen testing
        - Frozen blood banking
        - Provision of antisera prepared in animals
    - Provision of tissue-typing service
    - Provision of bone marrow and HLA-typed donors
    - Provision of CMV-antibody negative donors
    - Training of medical, scientific and nursing personnel
    - Research and Development.

56. In September 1987, Dr Cash publicly described the NBTS as a "fragmented and disorganised shambles" in the British Medical Journal. Cash attributed the NTBS' structural failure as responsible for the "*concept of the "gift relationship" of the voluntary donor and the needs of the patient [having] been lost by a service which in truth is a series of tight compartments with little or no facility to work together. This system of management is wholly inappropriate for modern blood transfusion practice; it is both wasteful and dangerous*." Cash argued "*the only option that will provide the quality of service the health services in England and Wales need, and the one that will give the blood donors an assurance that their gifts are appropriately used, is the creation of an integrated National Blood Transfusion Service which is removed from direct regional health authority funding and managed by a new and separate health authority which includes the Blood Products Laboratory*." Noting that his critique was *"partly based on 'self interest'"*, he concluded that "*the continued decline of the National Blood Transfusion Service is now having a destabilising effect on the Scottish service*." (**PRSE0000598**)

57. In 1988, the DHSS decided to adopt the third recommendation made as part of the 1987 report, i.e. to continue regional executive management with further central coordination. The proposal to implement a fully nationally managed service was apparently rejected because it was considered too costly. (**NHBT0001635_002** page 2). As such, there was still to be no national management of the RTCs but further coordination of the centres was to be promoted through the formation of the new National Directorate of the NBTS. This was formed on 28 July 1988. A press release published by the Department of Health stated:

"We therefore intend that operational responsibility at the national level for the NBTS and the Central Blood Laboratories Authority (CBLA) will be exercised on behalf of the Health Ministers for England and Wales by the NHS Management Board undertaken by its Director of Operations, in consultation in respect of Wales with the Director, NHS Wales. Day to day implementation of the national strategy will be delegated to a new National Director of the NBTS and a small supporting staff."

(DHSC0004764_060)

58. This body was directly funded by the DHSS. Dr Gunson was appointed as National Director and reported to the Director of Operations of the NHS Management Board. Mr Roger Moore, a civil servant at the DHSS, was appointed deputy director.

59. The role of the National Directorate was to coordinate the work of the RTCs, formulate national blood collection policy, ensure adequate plasma standards, promote quality assurance, institute an information management system and examine cost-effectiveness. Management of the individual RTCs remained with the Regional Health Authorities (**NHBT0001635_002** page 1 and **DHSC0004764_060**).

60. The National Directorate was not granted executive authority. That authority remained with the RTCs and their Regional Health Authorities. Dr Gunson has described the National Directorate as operating via "persuasion" rather than executive power. Furthermore, where National Directorate policy proposal involved the use of additional resources by RTCs, this created difficulties as their budgets remained controlled by the Regional Health Authorities (**NHBT0017232** page 30).

61. The National Directorate aimed to replace the 'informal' arrangements by RTDs and occasional direct intervention from the DHSS (now the Department of Health 'DH'). The Directorate acted as a focal point for DH interest in the NBTS, and liaised between CBLA and NBTS, in order to try and provide safe, efficient and cost-effective supply of plasma throughout the UK (**NHBT0004014_049**).

62. Examples of the National Directorate having to work by persuasion can be seen as follows:

    - In the July 1990 letter to Dr Donald in the Quality Department at BPL Dr Gunson noted that there were different criteria at different RTCs for the repeating of anti-HIV tests. Dr Gunson stated that he was "*trying to establish a uniform system through the Service, but... still [has] some work to do.*" (**BPLL0001702**)
    - In relation to the timing of the introduction of anti-HCV screening, Dr Gunson stated, in a letter on 25 September 1990, that a universal approach across RTCs should be adopted. (**NHBT0000190_013**) He did not achieve this as Dr Lloyd of the Newcastle RTC implemented HCV testing before other RTCs.
    - Similarly, Dr Gunson wrote to the Senior Medical Officer at the Department of Health in October 1990, asking for a uniform policy for anti-HBc testing, which had been implemented by some (but not all) RTCs. He noted that this would prevent criticism for "piecemeal" introduction of testing, divergent standards of testing for HBV and reduce the risk of legal action. He further recorded that the issue had been addressed several years prior by an advisory group but that the group had not met now for several years (**NHBT0003601**).

63. On 1 December 1988 the first meeting of the National Directorate of the NBTS National Management Committee took place (**NHBT0118864_012**). This Committee was attended by the Director and Deputy Director and a number of RTDs (including from the three divisions). The terms of reference were:

- To consider matters of importance in relation to the work of the NBTS and to advise the National Director.
- To bring forward to the committee matters of national importance to the work of the NBTS.
- To receive reports from the NBTS/CBLA Liaison Committee, meetings of the Head Laboratory Scientists, Nurse, Donor Service Managers and Administrators/Managers, ad hoc RTD working parties and National Publicity Sub-committee.
- To report to the Divisions the decision reached by the National Directorate.

64. Also around this time, an NBTS/CBLA Liaison Committee was established. This held its first meeting in January 1989 at which Dr Gunson stressed the importance of RTC's and CBLA laboratories working closely together, to avoid the past misunderstandings which had occurred due to a mutual lack of knowledge of the operations of the two organisations (**NHBT0015545**). The liaison committee was occupied with cross-accounting (the process of charging NHS hospitals to recover RTC costs for processing blood) and creating a specification for fractionated plasma. They also discussed the conflicting roles of the CBLA and the RTCs. CBLA wanted access to "end users" to encourage maximum usage of products, whereas RTCs saw their role as encouraging minimum use consistent with clinical need and patient safety (**NHBT0010493_001**).

65. Despite the prevailing concern within the NBTS to promote further national coordination, the meetings of the RTDs which had occurred since the formation of the RTCs, were abolished on 18 January 1989 (**NHBT0018188**). In a memorandum of the last RTDs' meeting of 18 January 1989, R Stewart noted that *"There was no discussion of the advantages and disadvantages of dissolving the RTD meetings"* and that in *"the midst of a slightly non-plussed silence"*, the final meeting was concluded (**SBTS0000628_011**).

66. Dr Gunson suggested that the RTD meetings might change in scope and frequency, taking on the form of a regular symposium to address clinical and scientific matters (**NHBT0018188**).

67. The minutes of the last RTD meeting record that:

- Once the meetings were abolished, the only remaining formal contact between Scotland and England would be between Dr Gunson and Dr Cash.
- Following the cessation of the RTD meetings there remained three channels of communication between the DoH and the NBTS:
  - Direct contact between Dr Gunson and DHSS officials and doctors
  - Via the NHS Management Board Co-ordinating Committee
  - Via the annual report submitted by the NBTS.

(NHBT0018188)

68. In R Stewart's memo of that last RTD meeting, he noted that the RTD committee had been frustrated over a number of years. The committee saw itself as ineffective, because there was little ability for their discussion to influence policy decisions. In a comment setting out his own personal views he wrote that "*Directors may, therefore, on consideration, regret the dissolution of the RTD committee, just at the point where it could have been in a position to exercise influence*." (**SBTS0000628_011**).

69. On 24 February 1989 the new UK Advisory Committee on Transfusion Transmitted Diseases met for the first time. This was formed to advise the Department of Health on policy. The group consisted of Drs Gunson (chair), Wagstaff (deputy chair), Cash, Contreras, Follett, Mitchell and Mortimer (**NHBT0000043_002**). The Committee did not have any executive authority over RTCs, in line with the then present management structure of the NBTS, however the minutes noted that any dissent from RTDs with decisions of the Committee would require 'good reasons'.

70. The devolution of health budgets to districts, as part of the NHS and Community Care Act 1990, meant that RTCs had to recover their operating costs through

reimbursements for blood products and services. This led to RTCs relying more than ever on their relationships with local hospitals and the particular financial situations for each RTC began to diverge yet further. This led, in Dr Gunson's view, to the National Directorate being marginalised as its efforts of "persuasion" were weakened as the financial ties between RTCs and hospitals grew stronger. As such, promoting the adoption of national policy became more difficult (**NHBT0017232** page 30-31; **NHBT0001635_002**).

71. In June 1990 Dr Gunson prepared "A Proposal to The Department of Health for National Management of the Blood Transfusion Service in England and Wales". He referred to the prior decision of the DHSS not to implement a nationally managed NBTS. Reflecting on recent developments, Dr Gunson stated that changes within the broader health service had resulted in RTCs being challenged to be more financially oriented and "managerially responsible". He expressed the view that the National Directorate would not be viable beyond October 1991 "given the direction and pace of current changes" because RTCs were not financially accountable to the directorate. He proposed a fully national service with a central executive management. He argued that this would increase efficiency, supply and quality of blood products (**NHBT0001781**).

72. Discussion about the administration and organisation of the NBTS continued:
    - In October 1990 the Department of Health issued a statement, entitled "Supply of blood products: The UK view" (**PRSE0001581**), which noted the UK's long tradition of "voluntary blood donation" and the aim of self-sufficiency. The statement made clear the department's respect for clinical freedom and the ability of individual clinicians to decide on the blood products to be administered to patients, including the decision to import commercial blood products from outside the European Community. Thus self-sufficiency was described as meaning that '*the supplies of domestically sourced blood products should be sufficient, both in range and quantity, to meet the needs of all patients whose clinicians prefer these to other available products*'.

- Dr Cash, in a letter to the British Medical Journal that same year, expressed his and his colleagues' disappointment with the DH statement. He noted that the blood transfusion services required more effective integration and management, as well as further finance for research towards developing blood products from unpaid British donors. He exhorted the government to persuade the Medicines Control Authority to restrict the licensing and import of blood products derived from paid donors. He expressed criticism of the government's references to clinical freedom, noting that such an approach was frustrating efforts towards self-sufficiency. (**PRSE0002443 page 1**)

- A number of RTDs wrote in support of Dr Cash including Dr Contreras (**PRSE0002443 page 2**), Dr Ala and Dr Fraser, directors of Birmingham and Bristol RTCs respectively, who noted that the Department of Health had, five years prior, rejected a proposal to create a special health authority for the National Blood Transfusion Services. They further recorded their concerns about the limited authority of the National Directorate, which did not have the power to formulate national policy in light of the independent management of the RTCs. (**PRSE0002443 page 3**)

73. Ernst & Young conducted a structural review of the NBTS in early 1991, looking at its need for central organisation. The potential arrangements identified as best meeting the service's needs were: (i) a Central Contracting Authority (unified National Directorate and CBLA); or (ii) a Centrally Managed Service with direct line management. The report favoured the contractual model (**NHBT0001799** page 5 (internal page 3), paragraph 5).

74. The formation of a Special Health Authority as a "contracting authority" with RTCs and BPL was advanced in line with then current Government NHS policy. The proposal was for a central NBTS body to agree operating contracts with RTCs as a

means of managing the national service, with the aim of increasing central executive authority over the blood services. However, it was acknowledged that such a model would ultimately maintain the local autonomy of the RTCs in negotiating and agreeing distinct contracts with the central authority. Rejecting this proposal the Department of Health decided to form the National Blood Authority (NBA) as a central, strategic management authority. This option went out to consultation within and outside the NBTS in September 1991 (**HSOC0004153**). A special meeting of the NBTS Management Committee took place on 30 September 1991 **(NHBT0001877)** to discuss the future of the NBTS.

75. On 21 October 1991, eight RTC directors (Professor Jean-Pierre Allain, Dr Frank Boulton, Dr Marcela Contreras, Dr Colin Entwhistle, Dr Huw Lloyd, Dr Tony Napier, Ms Belinda Phipps and Dr Angela Robinson) suggested various amendments to the NBA proposal (**NHBT0001882**). They favoured a central national authority for the English and Welsh transfusion service with the aim of:
    - "Cost-effective treatment with safe and efficacious products";
    - Protection of voluntary blood donors from exploitation; and
    - National self-sufficiency.

    (**NHBT0001882** pg 5)

76. They proposed that each RTC would enter into a contract with the NBA in which costing, minimum standards, plasma production and conformity to specifications would be set out. In this way, the RTC would essentially be accountable to the NBA, but management of the RTCs would remain local. They recommended that CBLA remain the managing body of BPL (**NHBT0001882**).

77. An early critic of the contracting model was Dr Lloyd who set out many of the problems such an arrangement would create (**NHBT0074034_001** at pages 40 - 42).

78. The CBLA produced a consultation document on the NBA. They believed the NBA should be structured around two distinct units, those related directly to donors and patients (NBTS Unit), and the industrial fractionation of blood plasma (BPL Unit).

Research and Development was to be incorporated into the NBTS Unit (**NHBT0001888**).

79. On 1 April 1992, Dr Gunson wrote a report entitled 'Challenges for the 1990s' in which he set out the key issues upcoming for the NBTS including potential organisational changes. These changes would encompass the reduction in the number of RTCs, supra-regional testing, and larger managerial units (**NHBT0000488_011**).

80. The NBA's final structure was gradually determined by the National Blood Authority Technical Working Group. The group set out a criteria for considering the NBA's new structure at a meeting in April 1992 (**NHBT0000488_005**). The group considered various options for the NBA's future management structure in the following months (**NHBT0000488_006; NHBT0000488_002, NHBT0000488_001;** page 2, para 4). The Group produced a report in July 1992 entitled 'Report of the Technical Working Group on Operational Aspect of the National Blood Authority' (**SBTS0000466_008**). The recommendations made included the following:

- The NBA should be given the authority and means to achieve the national objectives for the blood supply.
- The proposed role of the NBA as a central contractor should not be pursued.
- It should operate as a strategic authority to plan and implement national strategy for the blood services.
- It should approve key aspects of the RTC's business plans and monitor their output.
- It should control the transfer of plasma to BPL.
- The RTCs and BPL should not be considered for NHS Trust status until the NBA had developed its strategy for the blood services.
- The NBA should have maximum influence over strategic capital investment in the RTCs preferably through direct control of the capital budget. The NBA should also control the maintenance capital.

81. In the article written by Dr Gunson and Helen Dodsworth entitled 'Fifty Years of Blood Transfusion' Dr Gunson stated that '*As discussions proceeded it became apparent that ..... for the NBA to contract directly with the hospitals was considered impractical. These considerations, together with the impending changes for RHAs led to the conclusion that the NBA should directly manage BPL, IBGRL and the RTCs.*' (**NHBT0000028** page 78)

82. On 27 November 1992 the Department of Health announced its intention to establish the NBA on 1 April 1993.

83. In March 1993, the NBTS decided that further consultation with RTCs about the development of the NBA was still required, at least 2-3 times per year (**NHBT0000487_003** page 4, para 4).

84. On 1st April 1993, the Department of Health established a single body with executive authority, the National Blood Authority ("NBA"), with responsibility for both the central laboratories (including BPL and the International Blood-Group Reference Laboratory (IBGRL) and the English RTCs[7]. This was achieved pursuant to the National Blood Authority (Establishment and Constitution) Order 1993 SI No 585 ("the NBA Order 1993") which established the NBA as a special health authority. Shortly after the NBA Order was made, it was significantly amended by the National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589 ("the NBA (Amendment) Order 1994).

85. According to paragraph 37 of the statement of Dr Miflin (**WITN0672006**), the aims of the new SHA were to:
    - To maintain and promote blood and blood products supply based on the outstanding system of voluntary, unpaid donors.
    - To implement a cost-effective strategy of ensuring an adequate supply of blood and blood products to meet national needs.

[7] There were by this stage 13 RTCs across 16 sites, with around 4,500 employees (**NHBT0015901_001** page 4)

- To ensure that the high standards of safety and quality in the blood supply were maintained throughout the blood service.
- To ensure that blood products met a consistent standard of safety and quality.
- To ensure the cost-efficient operations of the transfusion centres and the Bio Products Laboratory both individually and together as part of the national service.

86. Thus, 32 years after the RTDs first suggested it, the Department of Health had finally agreed that regional management of the RTCs should come to an end (**NHBT0001635_002**).

87. Pursuant to article 2 of the NBA Order 1993, the NBA's functions were prescribed as follows[8]:

    (aa) collecting, screening and processing blood and its constituents and supplying blood, plasma and other blood products for the purposes of the health service (As inserted by National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589)

    - the provision of laboratories for the manufacture of blood products and for other purposes;
    - the preparation of plasma fractions and other products for therapeutic, diagnostic and other purposes;
    - research and development in plasma protein fractionation and for other purposes;
    - the manufacture of blood grouping re-agents and other related re-agents;
    - the supply of products prepared or manufactured under sub-paragraph (b) or (d) above for the purposes of the health service;

    .....

[8] This list of functions is as amended by the NBA (Amendment) Order 1994. In particular, the following two functions were omitted and replaced with function (aa) below: "(f) the monitoring of the operation by Regional Health Authorities of the transfusion service, and the provision of advice to the Secretary of State in connection with that service" and "(g) the provision of advice to Regional Health Authorities as to the co- ordination of their respective activities in connection with the transfusion service, with a view to securing and maintaining an adequate supply of blood and plasma for the purposes of the health service".

(h) the promotion, by advertisement and otherwise, of the giving of blood and its constituents for the purposes of the health service, with a view in particular to maintaining an adequate number of persons who are willing to give blood or its constituents for those purposes; (As amended by the National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589)

88. Pursuant to article 1 of the NBA Order 1993, "the transfusion service" was defined as "the arrangements made by Regional Health Authorities with respect to the collection and supply of blood in their respective regions for the purposes of the health service." This definition was removed from the NBA Order 1993 by the NBA Amendment Order 1994. The consequence of this is set out in Dr Miflin's witness statement at paragraphs 272 - 274 (**WITN0672006**):

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On 1 April 1993 the National Blood Authority ('NBA'), the predecessor to NHSBT, was established as an SHA. At that time the NBA was responsible for BPL and the International Blood Group Reference Laboratory ***('IBGRL')****. On 1 April 1994 the NBA then became responsible for the RTCs. I understand that from that date the regional health authorities no longer managed the RTCs. The name of the RTCs was changed to blood centres (BCs).*

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Referring to the documents I have been provided, it would appear that the BCs and their functions became assimilated into the NBA as a single national service. The centres increasingly were treated as parts of the whole institution, rather than distinct institutions operating around the country. Fifty Years of Blood Transfusion indicates that there was a three Zone system with zonal administrative directors of each reporting to the executive director of the NBA (see p.83 of [NHBT0000028]). I have been provided a Department of Health briefing paper: Plans for the Future of the National Blood Service [CABO0000048_003]. This indicates various proposed changes to the BCs and the administration of the NBA.

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I understand that, once part of the NBA, over time the BCs ceased to operate as separate centres. They became places where the NBA delivered its services as a centralised SHA.

89. The Central Blood Laboratories now came within the remit of the NBA. Pursuant to the Central Blood Laboratories Authority (Revocation) Order 1993 SI No 587, the Central Blood Laboratories Authority (Establishment and Constitution) Order 1982 was revoked, and the Central Blood Laboratories Authority was accordingly abolished.

90. In November 1993, the NBA described its "overall philosophy" as running a decentralised organization with a "lean and mean" head office where direction can be given by functional specialists and a strong executive team and main board (**NHBT0015901_001** page 4, para 7).

91. 1n May 1994 Dr Angela Robinson replaced Dr Gunson as national director of the NBA and subsequently the NHSBT.

92. In September 1994, the NBA issued the "Proposals for the Future Blood Service" consultation document, a synopsis of a 777-page review (the Bain report) (**NHBT0000236_014**). The report proposed (at page 3) centralising management into a single small unit, consolidating testing facilities, and putting cost-saving proposals into effect, whilst securing the future blood supply in terms of quantity and safety.

93. The NBA received over 500 oral responses and 1300 letters from members of the public, predominantly from Liverpool, Oxford, Lancaster, Brentwood and Plymouth. The main concerns raised by consultees were travelling long distance for blood

collection, blood shortages, issues with processing and testing, and increased costs in transportation and administration (**NHBT0009877_009** pages 10-11).

94. Following the consultation:

- The NBA created three Administrative Zones (London and the South East, Midlands and the South West and Northern) with an Administrative Centre in each (North London, Bristol and Leeds).
- Amalgamated Lancaster RTC with the Manchester RTC, and the Bristol RTC with the Plymouth RTC, and Oxford RTC with Birmingham RTC.

95. A national computer system, Pulse, was introduced between 1996 – 1998. It was operated as three different systems, covering the three different zones, until a single Pulse database was created in July 2008.

96. The National Blood Authority and United Kingdom Transplant (Abolition) Order 2005 SI No 2532, which came into force on 1 October 2005, abolished the NBA.

97. The NBA was replaced by the establishment of the NHS Blood and Transplant ("NHSBT"), a special health authority in England and Wales, by the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005 SI No 2529 (**RLIT0001551**), and NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) Regulations 2005 SI No 2531 (**RLIT0001553**).

98. Pursuant to Regulation 3 of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005/2529 (**RLIT0001551**), NHSBT's functions in England and for parts of Wales (see paragraphs 116 – 119 below) included:

- collecting, screening, analysing, processing and supplying blood, blood products, plasma, stem cells and other tissues to the health service;
- the preparation of blood components and reagents;

- facilitating, providing and securing the provision of services to assist tissue and organ transplantation; and
- such other functions as the appropriate authority may direct.

99. The NHS Blood and Transplant (England) Directions 2005 (**RLIT0001545**) also apply to the NHSBT in England. These require (where relevant) the NHSBT to conduct or commission research and promote blood donations and the appropriate use of blood.

100. Pursuant to Article 5 of the Abolition Order 2005, any right that was, immediately before 1st October 2005, enforceable by or against the NBA shall, on or after that date, be enforceable by or against NHSBT.

101. On 26 July 2010, the Department of Health conducted a review of its arms-length bodies, including NHSBT. (RLIT0000721). It concluded that the Bio Products Laboratory ("BPL") should be transferred out of NHSBT into a Department of Health owned company. This was on the basis that it was considered that (at paragraph 3.48): *"Bio Products Laboratory will benefit from greater commercial freedom and closer integration with its plasma supply chain, and it will therefore be transferred into a Department of Health-owned limited company."*

102. Consequently, on the 1 January 2011, BPL was transferred out of NHSBT to a new legal entity, Bio Products Laboratory Limited ("BPLL"). BPLL was a wholly owned subsidiary of Plasma Resources UK Limited ("PRUK") that, in turn, was 100% owned and managed by the Department of Health. (NHS BT, Annual Report and Accounts 2010/11 (7 July 2011). Available online here: RLIT0000722)

103. On 17 January 2013, the Parliamentary Under Secretary of State for the Department of Health, Dr Daniel Poulter, announced that the Government had decided to seek private sector investment in the government-owned limited company, Plasma Resources UK Ltd (PRUK), through the sale of the majority or all of the

shares in the company. On 18 July 2013, Bain Capital purchased an 80% stake in PRUK.

104. The current position is that NHSBT is the blood service with responsibility for managing blood services in England. It also has responsibility for managing services (including transplantation services) in relation to stem cells, human tissue and human organs in the UK.

Wales

105. Much of the information in this section comes from the statement of Catherine O'Brien, Interim Chief Operating Officer of Velindre University NHS Trust, seconded from her post as Director of the Welsh Blood Service (WBS) (a post she has held since November 2013) **WITN6876001**, the witness statement of Dr Miflin dated 19/10/2021 **WITN0672006** and from Dr Napier's statement dated 20/10/2021 **WITN6915001**. There is less detailed information available about the history of the blood service in Wales, compared to England and Scotland, but it may be possible to gain a greater understanding of that history when Dr Napier gives oral evidence.

106. The Welsh Blood Service (WBS) was formed in 1999. Its predecessor was the NBTS (Wales)[9]. NBTS (Wales) was made up of a single Regional Transfusion Centre in Cardiff which served the hospitals in South and Mid Wales. The Director of the Cardiff Regional Transfusion Centre was Dr Napier from 1978 to 1998 (and part time as medical director of WBS from 1999 – 2002). Hospitals in North Wales, however, were served by the Regional Transfusion Centre in Liverpool, and as such formed part of the English service.

[9] Although according to Dr Napier's statement **WITN6915001** it was called the Welsh Blood Transfusion Service (WBTS).

107. Given these historic circumstances (i.e. only one RTC in NBTS (Wales), with the hospitals in North Wales being served by an English RTC) the Welsh RTD was part of the same committees, groups and decision making forums as the English RTDs. For this reason, much of what is said in the preceding section on England applies to Wales. What is set out below are the matters that apply only to Wales.

108. The RTC in Cardiff was established in 1940 during the Second World War and following the establishment of the NHS, was managed by the Welsh Regional Health Board.

109. NBTS (Wales) had representation at the Regional Transfusion Directors' meetings via its RTD from 1948. The extent to which Wales had representation on decision making or advisory forums such as meetings of the Central Committee of the NBTS is an issue to be explored at the hearings.

110. It was not until 1974 that the NBTS Wales (namely the Cardiff RTC) became the responsibility of the Welsh Office.

111. In 1982 responsibility was delegated by the Welsh Office to the South Glamorgan District Health Authority and in 1991 to the Welsh Health Common Services Authority (WHCSA). In February 1991 the Welsh Office set up a Blood Transfusion Service Committee within WHCSA, which was to include service users [**NHBT0000489_008**].

112. NBTS Wales remained within WHCSA until 1999. It did not become part of the NBA when it was formed in 1993. The hospitals in North Wales continued to be served by the Liverpool RTC after the formation of the NBA, and so formed part of that organisation.

113. Consideration as to the future management of the WBTS was set out in the report entitled 'Recommendations for Future Management Arrangements for the National Blood Transfusion Service (Wales)', circulated by NBTS (Wales) in October 1994 [**SCGV0000053_013**]. This report recommended that a dedicated special health

authority should be formed to manage NBTS (Wales). This option does not appear to have been adopted, and the service continued to be managed within WCHSA.

114. In 1999 responsibility for NBTS Wales transferred over to the Velindre NHS Trust [10] pursuant to the Velindre National Health Service Trust (Establishment) Amendment Order 1999/826. This provided that one of the functions of the Velindre NHS Trust was:

- *"to own and manage Welsh Blood Service Headquarters, Ely Valley Road, Talbot Green, Pontyclun CF72 9WB and associated premises, and there to provide and manage services relating to the collection, screening and processing of blood and its constituents and to the preparation and supply of blood, plasma and other blood products."*

115. Until 1999 and the establishment of the National Assembly for Wales, NBT (Wales) reported to the Ministry of Health/Department of Health and Social Services and then from 1965 to the Welsh Office.

116. In 2005 the NHS Blood and Transplant ("NHSBT"), a special health authority in England and Wales was established by the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005 SI No 2529 (**RLIT0001551**), and NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) Regulations 2005 SI No 2531 (**RLIT0001553**).

117. Pursuant to Regulation 3 of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005/2529 (**RLIT0001551**), NHSBT's functions in England and Wales included:

- collecting, screening, analysing, processing and supplying blood, blood products, plasma, stem cells and other tissues to the health service;

[10] Which became the Velindre University NHS Trust in 2018

- the preparation of blood components and reagents;
- facilitating, providing and securing the provision of services to assist tissue and organ transplantation; and
- such other functions as the appropriate authority may direct.

118. Crucially however, paragraph 2(2) of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Wales) Directions 2005 provides as follows:

> *In order to promote or secure the effective supply of blood, stem cells and bone marrow for the purposes of the health service,* ***the Assembly directs NHSBT in relation to the county boroughs of Anglesey, Gwynedd, Conwy, Denbighshire, Flintshire and Wrexham,***—
>
> *(a) to provide a collection, storage and delivery service for blood and stem cells;*
>
> *(b) to provide a screening, testing and processing service for the preparation of blood and stem cells;*
>
> *(c) to conduct or commission research into the uses of and development of blood and stem cells;*
>
> *(d) to provide diagnostic and other services in connection with the collection and use of blood and stem cells and treatments depending on or requiring their use (including, for example, reagent preparation and provision, patient pathology and therapeutic services, histocompatibility and immunogenetic services, platelet and granulocyte immunology);*
>
> *(e) to promote, by advertising, marketing and otherwise, the donation of blood and stem cells, with a view in particular to maintaining an adequate supply of blood and stem cells;*
>
> *(f) to prepare, store and distribute plasma fractions and other products for therapeutic, diagnostic and other purposes;*
>
> *(g) to promote, through advice and guidance, the appropriate use of blood and stem cells (having regard in particular to the need to promote the effective*

use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients; and

(h) to establish and manage a register of blood and bone marrow donors and any associated services necessary for the treatment of patients.

[Emphasis added]

119. Thus in 1995, NHSBT only took responsibility for those county boroughs in North Wales that had historically been served by the Liverpool RTC and formed part of the English service. The Velindre NHS Trust continued to be responsible for WBS. It was not until 2016 that management of the provision of hospitals in North Wales transferred from NHSBT to WBS, creating for the first time, a unified Welsh service.

Scotland

120. Much of the information from this section comes from the witness statement of Marc Turner **WITN3530007** dated 7 October 2021 (Medical Director of SNBTS, a position which he has held since April 2011), the paper authored by Dr Ronald Girdwood entitled 'Fifty Years of an Organised Blood Transfusion Service in Scotland' published by the Scottish Medical Journal in 1990 (**PRSE0003986**), and the paper 'Governance and financing of the blood supply in Scotland 1974 – 2009' by J Francis and N Billing 2011/00141) (**SBTS0002609_011**).

121. Originally, a walking blood donor panel was established in Edinburgh by Mr Jack Copland at the Edinburgh Royal Infirmary. There were initially 12 volunteers on the panel, and they would be collected and taken to the patient when blood was required.

122. Once it looked likely that there would be a war, the Department of Health set up a Transfusion Sub-Committee. This recommended that stores of blood should be made available in various centres. By the beginning of World War II there were blood banks at the Royal Infirmary in Edinburgh and Stobhill Hospital in Glasgow.

123. In 1940 the Scottish National Blood Transfusion Association (SNBTA) – a charitable body - was formed to run the blood transfusion service (hereafter referred to as the blood service). The BTS at this stage consisted of five Regional Blood Transfusion Centres, Edinburgh and South East Scotland; Glasgow and West Scotland; Dundee and East Scotland; Aberdeen and North East Scotland and Inverness and North Scotland (referred to in this document for ease of reference as Regional Transfusion Centres or RTCs). Each RTC had a RTD. In addition there was a National Organiser. Initially this was Mr Copland.

124. By 1944 the SNBTA had 57,000 donors.

125. In 1948 the National Health Service was created. Pursuant to the National Health Service (Scotland) Act 1947 (which provided that it was for the Secretary of State to

promote the establishment of a comprehensive health service which included the provision of blood for clinical use), the blood service became the responsibility of the Secretary of State for Scotland. The SNBTA continued as a charitable body which managed the blood service through its executive committee, but the Secretary of State for Scotland took over all its premises, equipment and staff.

126. Following the discovery that plasma could be dried and then reconstituted, a unit for the production of dried plasma was set up in Edinburgh at the beginning of 1943 named the Blood Products Unit (BPU) (**PRSE0003971**). The centre was expanded in 1952 to handle plasma fractionations. By 1965, planning was underway for a new centre at Liberton, Edinburgh (named PFC in 1970). Mr John Watts was appointed its first Scientific Director. The new centre at Liberton began operating in 1974/75. PFC received plasma from whole blood or plasmapheresis donated in the five Scottish Regional Blood Transfusion Services / Centres. Plasma from Northern Ireland was also processed at PFC from the early 1980s and products supplied back to Northern Ireland.

127. At the beginning of the 1970s the SHHD was considering restructuring the way that health services were run. On 3 November 1972 the SHHD issued a circular HSR(72)C2 titled 'Health Service Reorganisation Scotland: Common Services Agency' (**PRSE0001217**). This appears to be a consultation on the transfer of the blood services from being managed by the SNBTA to being managed by the Common Services Agency (CSA). The CSA was a non-departmental public body.

128. The circular provided that:

- The CSA is to be managed by a committee (with the chair and members appointed by the Secretary of State).
- The likely range of functions of the CSA will include the blood transfusion service.

- The CSA's prime role will be 'to act as agent for the health boards in providing them with important supporting services of a kind likely to be best organised centrally.'
- The broad policies and questions of broad resource allocation will be decided by the Secretary of State. Each operational division of the CSA will operate within its predetermined budget allocated by the Department to the CSA.

129. A report as to the future of the blood service was written by the SHHD[11] and discussed by RTDs and Mr Watt at a meeting on 2 February 1973 (**SCGV0000071_060**).

130. In a further circular, HSR(73)C40 dated 26 October 1973 and titled 'Common Services Agency – The Blood Transfusion Service' (**LOTH0000249_002**) the SHHD confirmed that (having had discussions with the SNBTA) the responsibility for the blood service (referred to in this document from this point onwards as SNBTS) would indeed transfer to the CSA. The circular outlined the proposed arrangements which were said to have been agreed by the SNBTA. The plan was to appoint a National Medical Director to '*co-ordinate and oversee the activities of the five regional centres and the Protein Fractionation Centre'*. The SNBTS was to be responsible to the CSA Management Committee and both the National Medical Director and the Management Committee would:

> *"obtain advice on the administration of the service from a panel appointed by the Management Committee which will include both persons with specialised interests in blood transfusion and those with wider experience in the health service. Advice on major policy matters will be obtained through a committee of the Planning Council, on the lines of the Central Consultative Committee which at present advises the Secretary of State on blood transfusion policy."*

[11] The Inquiry has not been able to locate this report

131. In a paper authored by the South East RBTS about this circular concerns were raised about the lack of detail as to how the service was to operate after 1 April 1974 (**PRSE0000790**).

> *"I disagree entirely with the view expressed in para. 8*[12] *– that the C.S.A. will decide the future function of the S.N.B.T.A. There is already an apparent lack of appreciation of the complexity and importance of blood donors as an integral component of the Service particularly at a time when it faces a confrontation with the pharmaceutical industry, which could bring the voluntary donor system in this country to an abrupt end. In my opinion the C.S.A. – from the little we know of its composition – is unlikely to be qualified to make such a decision on function."*

132. The concerns of the RTD of the South East RTC, Dr Cumming, were set out rather more frankly in a letter to Dr Wallace in a letter dated 29 November 1973 (**PRSE0004322**).

> *"What is so distressing is the suspicion which has been around that the present Executive*[13] *has become no more than a vehicle for putting into practice policies which are not in the best interests of the Service, and contrary to the stated views and advice of the Regional Directors. As a result it is in danger of losing the confidence of the professional side of the Service – if that has not already happened. When one looks at this in the context that it is the Executive Committee which will be responsible for 'handing over' the Service, the implications are alarming if not grave."*

133. In a document titled 'The Scottish National Blood Transfusion Association: A Future in the Common Services Agency?' dated December 1973, John Watt of the PFC set out some of the failings of the SNBTA (**PRSE0000373**) and in particular his surprise at the SNBTA apparently being satisfied (as recorded in HSR(73)C40) with the proposed reorganisation of the SNBTS given that there was no clear statement as to the future relationship between the donor and the Service. The paper provides:

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[12] This is not a view expressed in the copy held by the Inquiry

[13] Which is likely to be a reference to the Executive Committee of the SNBTA

"The part played by the blood donor, in recent years, in the executive function of the Scottish National Blood Transfusion Association had declined into a relatively minor role and has been replaced by a number of appointed executive members who do not represent necessarily the best interests of the donor, the recipient or the professional and executive staff employed by the Association…… there has been a lessening of confidence, by senior staff of the Association, in the functional role of the governing executive and in the manner in which that function is discharged. It can be postulated that, were there wider dissemination of information, this same diminution of confidence could become apparent in the donor population, with possibly disastrous results.

……

The wholly bureaucratic structure evidenced in HSR(73)C40 is unlikely to provide the necessary environment in which effective blood transfusion can flourish. Proof of this is already apparent in the effect of the over-structured committee system which has been functioning with seemingly increasing difficulty over the last few years. "

134. Following a meeting between the RTDs and the PFC on 9 January 1974[14] a letter was sent to N A Milne (the Secretary to the SNBTA) setting out RTDs '*unanimous opinion and constructive suggestions regarding the future arrangements for the management of the Blood Transfusion Service in Scotland'* (**PRSE0004463**). In short, they suggested holding off the transfer of the SNBTS to the CSA until urgent discussions had taken place between the RTDs, the Medical and Scientific director of PFC, the Central Consultative Committee and the SHHD. This letter was signed by amongst others, Mr Watt and Dr Cash.

135. Despite this request, in April 1974 (pursuant to section 19 of the National Health Service (Scotland) Act 1972), the blood service was reorganised and placed administratively within the newly formed Common Services Agency (CSA) of the Scottish Health Service, in a Division of the CSA called the Scottish National Blood Transfusion Service (SNBTS).[15]

[14] The minutes of which are missing

[15] Since 2004 the CSA has been known as NHS National Services Scotland)

136. The CSA was overseen by the SHHD (and its successors namely the Scottish Executive Health Department and the Scottish Government Health Department). The SHHD (and its successors) was administered prior to devolution by the Scottish Office (the department of the Secretary of State for Scotland). Since devolution in 1999 the CSA through the relevant Minister (currently called the Minister for Health and Social Care) is answerable to the Scottish Parliament.

137. The functions of the CSA were initially set out in the National Health Service (Functions of the Common Services Agency) (Scotland) Order 1974 and required the CSA to supply '*human blood for the purposes of carrying out blood transfusion and related services, including the production of blood fractions*.' Its functions also included the donor services previously administered by the SNBTA (which continued as a charitable body to represent blood donors).

138. In October 1976 the RTDs sent the SHHD a paper setting out their views on the future of the BTS titled 'Future Management of the Blood Transfusion Service of Scotland' (**PRSE0001535**). This reported that the anxiety expressed by the RTDs since the publication of HSR(73)C40 had been realised:

"The Management Committee does not have within, or available to it, such independent specialist and other advice as was available within its predecessor, the Executive Committee of SNBTA."

The document went on to argue that the BTS headquarters should move out of the CSA headquarters and into its own. '*Interposing CSA headquarters as a tier between the Directors of CSA Divisions and the Management Committee to which they are accountable has been most unfortunate.'*

139. The document concluded:

> *"After 2 ½ years experience and following careful consideration it is the view of the Transfusion Directors that BTS should be administered as a National Service and that its nature renders it unsuited to management by a committee*

composed entirely of Health Board members and officers and Officials of SHHD within the framework of CSA."

140. The SHHD's response to this was in a letter dated 2 December 1976 (**PRSE0002319**):

> *..... the SNTBS is now formally part of the NHS and can therefore only be administered in the existing health service framework. On a number of occasions General Jeffrey raised with officers of the Department the question of the SNBTS being taken outside the framework of the CSA and on each occasion it was made quite clear that there would be no question of this.*

141. The RTDs continued to press their point to the SHHD, for example they met with them on 18 May 1977 and had a frank exchange of views (**PRSE0002113).**

142. On 15 June 1977 an agreement was reached to establish an ad hoc committee '*to examine and report to the Management Committee on the management arrangements for the Blood Transfusion Service within the Common Services Agency.'*

143. It was agreed at a Special Meeting of the Management Committee of the Common Services Agency held on 26 April 1978 that a sub-committee of the Management Committee would be established known as the Blood Transfusion Sub-Committee. The members of the Committee would be six members of the Management Committee, two specialists in clinical medicine, two specialists in laboratory medicine, one medical officer from SHHD and one representative of Donor Interests. The National Medical Director of the BTS and all RTDs should receive the agenda and supporting papers and the National Medical Director had the right to attend or be represented at each meeting. It was also agreed that the National Medical Director would have a small staff in the BTS headquarters (**PRSE0000108**).

144. The terms of reference of the CSA Blood Transfusion Service Sub-Committee included (**PRSE0000501**):

(i) The review of the operational activity of the Blood Transfusion Service to ensure that the services provided are efficient and economic and within approved financial allocations.

(ii) The formulation of proposals for the development and improvement on the services given by the Blood Transfusion Service and to make recommendations by the priority and proposed programming of such developments and improvements.

(iii) Liaison with other authorities on developments in the Blood Transfusion Service and on operational matters.

145. Also agreed on 26 April 1978 were the duties and responsibilities of the National Medical Director. These included:

(i) Ascertaining the needs of clinicians for blood products and ensuring in consultation with the RTDs and the Scientific Director of the PFC that adequate supplies of plasma are made available and processed at the PFC to meet those needs.

(ii) Co-ordinating the distribution of supplies of blood products

(iii) Preparing annual estimates and reports on the operation and development of the BTS as required by the Management Committee or any sub-committee.

(iv) Ensuring that any reactions arising from the use of blood or blood products are fully investigated and followed up within the Blood Transfusion Service.

(v) Advising SHHD on national policy questions affecting the development of the BTS.

146. There were further legislative changes in 1978 which had the effect of reconstituting the CSA (pursuant to the National Health Service (Scotland) Act 1978), pursuant to which the members of the Management Committee of the CSA were appointed by the Secretary of State.

147. This structure remained largely unchanged following the appointment of Professor Cash in 1978 as the National Medical Director. The extent to which Regional Services retained autonomy throughout this period will be explored within the hearings.

148. A National Headquarters Research Laboratory, National Reagents Units and National Quality Unit were also created around this time.

149. While there was no formal liaison committee between SNBTS and NBTS until January 1989:

- The SNBTA and/or the SHHD or latterly the SNBTS usually through Dr/Professor Cash had a representative at the National RTD meetings in England.
- Dr Cash attended the Advisory Committee on the NBTS whose first meeting on 1 December 1980 made it clear that the Committee dealt with matters concerning only England and Wales [**CBLA0001207**].
- There was often an English RTD or a representative of the NBTS National Directorate at Scottish RTD meetings.

150. In 1990, a General Manager position was created (renamed National Director in 1996) and the National Medical Director became the National Medical and Scientific Director. The Regional Directors and PFC Director became managerially accountable to the General Manager / National Director and professionally accountable to the National Medical and Scientific Director. Each of the Regional Blood Transfusion Centres were renamed Regional Transfusion Centres.

151. The SNBTS Management Board at this stage comprised

- National Director (General Manager)
- National Medical and Scientific Director
- 5 Regional Transfusion Centre Directors
- Director of National Science Laboratory

- Director of PFC
- National Donor Services Manager
- Director of Human Resources
- Director of Finance
- Director of Quality (excluding PFC).

152. Following a strategic review in 1998/99, SNBTS was restructured to reflect a move away from a regional structure and towards a national functional structure. Since this time all blood donor services have been managed nationally.

- A Director of Operations was created to manage Donor Services, Manufacturing and Logistics and the number of blood processing and testing units was reduced to two.
- A National Quality Directorate was formed along with other national support services.
- Hospital blood banking and related clinical and laboratory functions remained distributed within the Regional Transfusion Centres.
- The Regional Transfusion Directors became Clinical Directors.

153. In 2002/2003 the CSA underwent a strategic review. Once again the SNBTS expressed its dissatisfaction with the CSA as being not qualified to manage the performance of the SNBTS. The report concluded that there was some justification for these concerns because of (i) the lack of a developed system of clinical governance in CSA, (ii) a lack of clarity about the role and purpose of the Board and (iii)a lack of clarity about how the CSA and its Divisions add value to each other's activities.[16]

154. Following this review the governance arrangements were strengthened, the SNBTS National Director became an Executive Director of the CSA Board and the CSA Board adopted the governance structure of other Health Boards including a Clinical Governance Committee and the centralisation of some support services.

[16] **RLIT0000720**

155. On 1 October 2008 the National Health Service (Functions of the Common Services Agency) (Scotland) Order 2008 removed the production of blood fractions from the functions of the CSA. The CSA remained responsible for the provision of supplies of human blood for transfusion and related services.

156. There was a period of wider organisational structural change in 2012/2013 which resulted in the consolidation of a number of CSA (now commonly referred to as National Services Scotland or NSS), Divisions into Strategic Business Units (SBUs) and the centralisation of support services such as Human Resources, Finance and IT with business partners being appointed to SNBTS Senior Management Team. SNBTS was considered of sufficient size and speciality to retain its own identity and dimensions. In 2013, the SNBTS 'Board' was renamed the Senior Management Group chaired by the SNBTS National Director and the Medical and Scientific Committee was renamed the Clinical Governance and Safety Group chaired by the SNBTS Medical Director. The posts of Clinical Directors were removed and SNBTS was organised into a number of national Directorates led by Associate Directors:

- Donor & Transport Services;
- Blood Manufacturing; Tissues, Cells and Advanced Therapeutics;
- Patient Services; Quality Assurance & Regulatory Compliance;
- Strategy, Planning and Performance.

157. The Operational Management Group was established and chaired by the Associate Director of Strategy, Planning & Performance. There has been no significant further change to structure since this time.

158. As for how the SNBTS was funded over the relevant period:

- All funds came from the Scottish Government's central budget (rather than from regional health budgets as was the case in England and Wales).

- Until 2002/2003 the SHHD provided the CSA with a ring fenced budget for the SNTBS.
- After this time it was left to the CSA to allocate a budget to the SNBTS as part of its internal business planning.

Northern Ireland

159. Much of the information in this section comes from the second witness statement of Karin Jackson **WITN26810026**, the CEO of the NIBTS since October 2016 and the timeline from the NIBTS web site https://nibts.hscni.net/about-us/timeline-of-service/. There is comparatively little documentation available about the NIBTS but it may be possible to gain a greater understanding about its history and structure through oral evidence in due course.

160. In 1946 the Blood Transfusion Service was established by the Ministry of Health (as set out above). In 1948 that the Northern Irish service became the responsibility of the Northern Ireland Hospitals Authority.

161. In 1953 a new headquarters was established in Belfast, which later became the Belfast RTC. Also in 1953 the service started to use a mobile donation unit – the first of its kind in the UK.

162. At this stage the blood transfusion laboratories were at the Royal Victoria Hospital. In 1961 they moved to Belfast City Hospital. In 1970 the laboratories and the blood donor organisation were brought together in one building and amalgamated into a single organisation.

163. In Northern Ireland, the NHS was merged with the broader social care system in 1973 and called the Health and Personal Social Service (HPSS) and later the Health and Social Care (HSC) system.

164. Between 1972 and 1999, the health system of Northern Ireland was managed by the UK government via the Northern Ireland Office (NIO). This meant that, until 1999 when devolution was restored in Northern Ireland, public and social policy decisions were taken at Westminster and communicated through the Secretary of State within the Northern Ireland Office, who answered directly to the UK Government. During the period of direct rule in Northern Ireland (1972 – 1999), it appears that the

default position in terms of reform and the development of policy and strategy in health and social services was to mirror English policy decisions.

165. During this time (and specifically between 1972 and 1994), the service came under the remit of the Eastern Health and Social Services Board (EHSSB).

166. On 1st June 1994 the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 came into operation. This enabled the establishment of a Special Health and Social Care Agency to which the Department of Health and Social Services could delegate its functions.

167. Also on 1st June 1994, the Northern Ireland Blood Transfusion Service (Special Agency) (Establishment and Constitution) Order (Northern Ireland) 1994 came into operation. This established the Northern Ireland Blood Transfusion Service (Special Agency) as a special health and social care agency pursuant to the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990.

168. On the same date the Functions of the Northern Ireland Blood Transfusion Service (Special Agency) (No 1) Directions (Northern Ireland) 1995 came into force (**WITN26810026**). This sets out the functions of the NIBTS as follows:

> *To ensure that all hospitals and other clinical units in Northern Ireland are provided with adequate supplies of blood and blood products and that these comply with all current national standards of safety and efficacy. In discharging this function it will require to -*
>
> *(a) assess and anticipate the needs of the health and personal social services in Northern Ireland for blood and blood products;*
>
> *(b) recruit and maintain adequate numbers of healthy, voluntary, non-remunerated donors;*

(c) ensure the health and safety of blood donors during their contact with the Blood Transfusion Service, also provide counselling to donors found to have abnormalities during routine screening;

(d) perform appropriate processing and testing of blood and blood components;

(e) ensure that an effective quality assurance programme is applied to all aspects of the production process and other areas of the Blood Transfusion Service;

(f) provide an education and advisory service on the utilisation of blood and blood products by clinicians.

169. Other functions include:

(a) provide a reference laboratory service to all hospital blood banks in Northern Ireland;

(b) provide a regional antenatal blood screening service in blood group serology, rubella, hepatitis B including the organisation of a perinatal hepatitis B immunisation programme;

(c) provide in conjunction with the British Bone Marrow and Platelet Donor Panel, a bone marrow donor service including recruitment and counselling of donors and maintenance of the local donor panel;

(d) provide advice on all aspects of transfusion medicine including certain aspects of immunohaematology and the antenatal service;

(e) provide practical and theoretical instruction in all aspects of transfusion medicine and science to appropriate health service staff;

(f) undertake relevant research and development to improve the services provided by the Blood Transfusion Service Agency; and

(g) maintain appropriate links with organisations in Great Britain and elsewhere in pursuit of these objectives.

170. In 1995, NIBTS moved to a purpose-built facility on the City Hospital site in Belfast. This remains the headquarters for NIBTS.

171. The service had one regional transfusion centre, in Belfast. The first director of the service from between 1969 and 1980 was Col. T.E. Field, followed from June 1980 to May 1994 by Dr Morris McClelland (who was also RTD of the Belfast RTC). From June 1994 and the creation of the NIBTS, Dr Morris McClelland's title became that of Chief Executive and Medical Director. He stepped down in 2009.

172. A representative of the service attended English and Welsh RTD meetings from the 1960s through to 1989 when these meetings were abolished. This was Dr M Mclelland once he was in post. The Northern Ireland Office (via a representative of the Department of Health and Social Services Northern Ireland) attended meetings of the Advisory Committee of the NBTS (see for example the first meeting 1 December 1980 at **CBLA0001207**).

173. Initially the service was having its plasma fractionated by BPL. In the early 1980s it began sending its plasma to Scotland for fractionation at PFC (**CBLA0001621**).

Committees and Working Groups[17]

174. The period of the blood services' history with which the Inquiry is primarily concerned was renowned for the proliferation of different committees. Some of them have been mentioned above (such as the meetings of the RTDs in England and Wales). In addition there were meetings of the Northern, Eastern and Western Divisions of English and Welsh RTCs, meetings of the SNBTS Directors in Scotland, as well as the meetings of the Co-ordinating Group of the Scottish National Blood Transfusion Service. In some regions there were also regular meetings between RTDs and haemophilia centre directors.

175. It is likely that during the forthcoming hearings, the Inquiry will also look at or refer to the minutes of a number of other committees. These may include the following:

- From September 1982 until January 1987, the UK Working Party on Transfusion Associated Hepatitis held meetings.
- On 4 October 1983 the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) had its first meeting (although the minutes at **MHRA0020214** note an earlier meeting in February 1983).
- Also in October 1983 the CBLA formed a Working Group on AIDS in relation to blood transfusion and the MRC formed a Working Party on AIDS.
- In November 1984 the Advisory Committee on the NBTS set up a Working Group on AIDS. It remains unclear how many times this Working Group met.
- The Expert Advisory Group on AIDS was constituted in January 1985, chaired by the Deputy Chief Medical Officer with terms of reference 'to provide advice on such matters relating to Acquired Immune Deficiency Syndrome (AIDS) as may be referred to it by the Chief Medical Officers of the Health Departments of the United Kingdom'.
- In January 1989 an NBTS/CBLA Liaison Committee was formed, chaired by Dr Gunson.

[17] For a list of some of the key committees and Groups in England see **BPLL0004826'**

- The NBTS formed the UK Advisory Committee on Transfusion Transmitted Diseases (UKACTTD). The first meeting was held on 24 February 1989 and the aim of the Committee was to consider the implication of transfusion transmitted infections on the Transfusion Services in the UK and to provide advice to the Departments of Health. The name was changed to the Advisory Committee on Transfusion Transmitted Infections in 1993.
- The UK Advisory Committee on the Virological Safety of Blood (ACVSB) was established in April 1989. Its terms of reference were 'to advise the Health Departments of the UK on measures to ensure the virological safety of blood whilst maintaining adequate supplies of appropriate quality both for immediate use and for plasma processing'.
- From June 1990 an NBTS/SNBTS Liaison Committee met, chaired by Dr Gunson.
- On 7 October 1991 the Standing Advisory Committee on the Care and Selection of Donors had its first meeting.

176. The Serious Hazards of Transfusion Working Group (SHOT) had its first meeting on 21 December 1994 **NHBT0007853_001**. At that first meeting, Dr Lorna Williamson was voted Chair, and Dr Love, Secretary. Other members of the Group at that stage were Professor Cash (Scotland), Dr Robinson (England) and Dr Napier (Wales). It was noted that Northern Ireland was not represented and the group agreed to write to Dr M Mclelland for his views on representation.

177. The remit of the group was:

> *To produce recommendations for the reporting of serious complications.*
>
> .....
>
> *To educate in the fields of hazard of transfusion in order that reporting should be as comprehensive as possible.*

178. It was agreed that the group would be independent of the NBA and would report to the Committee responsible for drafting the Red Book Guidelines for the NBTS.[18]

179. SHOT remains in existence today. Detailed information about its remit and work can be found at www.shotuk.org.

180. SHOT's purpose as described on the web site is to '*collect information on transfusion reactions and adverse events from all healthcare organisations in the United Kingdom that are involved in the process of blood transfusion'.*

181. Its mission statement is to improve patient safety in blood transfusion.

182. SHOT's aims are to:

- Improve standards of hospital transfusion practice
- Educate users on transfusion hazards and their prevention
- Aid production of clinical guidelines
- Inform policy within the UK Blood Services
- Inform national policy on transfusion safety within the UK
- Inform Europe about transfusion safety in the UK.

183. The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) carries out two functions:

> *To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services.*
>
> *To be an Advisory Committee to the United Kingdom Blood Transfusion Services, normally by reporting to the Medical Directors of the individual Services who are themselves individually accountable to the Chief Executives of the Services.*

[18] Now JPAC

184. The Joint UKBTS Professional Advisory Committee is the successor to the UKBTS/NIBSC Executive Committee.

Jenni Richards QC

Katie Scott

Silas Lee

Members of the Inquiry Team

England and Wales

REGION	DIRECTOR	TERM
Northern (Newcastle) 1940; new centre built in 1985	Dr S Murray	1951 - 1979
	Dr Anne K Collins	1979 - 1988
	Dr Huw Lloyd	1988 - 1995
Yorkshire (Leeds) 1944; new centre built in 1988	Dr L A D Tovey	1966 - 1988
	Dr Angela Robinson	1989 - 1994
Trent (Sheffield) 1940; new centre built in 1971	Dr R H Malone	1948 - 1952
	Dr C C Bowley	1953 - 1974
	Dr William "Bill" Wagstaff	1974 - 1995*
North Western (Manchester/Lancaster) 1949	Dr F Stratton	1948 - 1980
	Dr Harold Gunson	1980 - 1988
	Dr Douglas Lee	1989 - 1995*
Mersey (Liverpool) 1946; new centre built 1968	Dr Dermot Lehane	1945 - 1978
	Dr Freda Roberts	1979 - 1986
	Dr A Shepherd	1986 - 1988
	Dr Vanessa J Martlew	1988 - 1996*
Wales (Cardiff) 1946	Dr R J Drummond	1948 - 1974

	Dr G O Walters	**1974 - 1975**
	Dr B Bevan	**1975 - 1977**
	Dr J A Napier	**1978 - 1998***
West Midlands (Birmingham) 1946	**Dr G W G Bird**	**1967 - 1982**
	Dr F Ala	**1982 - 1996***
Oxford 1946	**Dr Jean Grant**	**1948 - 1975**
	Dr Harold Gunson	**1975 - 1980**
	Dr C Entwistle	**1980 - 1995***
Wessex (Southampton) 1971	**Dr D S Smith**	**1969 - 1990**
	Dr F Boulton	**1990 - 1996***
South Western (Bristol) 1946	**Dr Geoffrey H Tovey**	**1948 - 1979**
	Dr Ian Fraser	**1979 - 1992**
	Dr Tim Wallington	**1992 - 1995***
East Anglia (Cambridge) 1946	**Dr Jack Darnborough**	**1969 - 1990**
	Prof John-Pierre Allain	**1991 - 1992**
	Dr S M McDougall	**1992 - 1995**
	Dr Lorna Williamson	**1995***
North West Thames "North London" (Edgware) 1952	**Dr J D James**	**1948 - 1965**
	Dr Tom E Cleghorn	**1966 - 1980**
	Dr T D Davies	**1980 - 1983**

	Dr Marcela Contreras	**1984 - 1994***
North East Thames (Brentwood) 1955	**Dr W John Jenkins**	**1955 - 1981**
	Dr Jean Harrison	**1981 - 1995***
South London (Sutton) 1946**	**Dr R A Zeitlin**	**1947 - 1970**
	Dr Keith Rogers	**1970 - 1991**
South Thames (Tooting) 1970	**Belinda Phipps**	**1991 - 1994***
	Vacant	**1992 - 1993**
	Dr Sue Knowles	**1993 - 1996***
***Evidence indicates the Director held the position "at least until/from" the date shown.**		
****South London, based in Sutton, later moved headquarters to Tooting and renamed South Thames**		

<u>Scotland and Northern Ireland</u>

REGION	DIRECTOR	TERM
National Medical Director SNBTS 1930	**Major General H C Jeffrey**	**1971* - 1979**
	Dr John Cash	**1979 - 1996**
	Professor Ian Franklin	**1997 - present**
	Angus Macmillan Douglas	**Circa 1997**
Aberdeen and North-East 1936	**Dr H B Lewis**	**1964* - 1983**

	Dr Stan Urbaniak	**1983 - 1998***
Inverness and North 1936	**Dr I A Cook**	**1964 - 1982**
	Dr William Whitrow	**1983 - 1993**
	Dr George Galea	**1993 - 1996***
Edinburgh and South-East 1936	**Dr Robert Cumming**	**1964 - 1974***
	Dr John Cash	**1975* - 1979**
	Dr Brian L McClelland	**1979 - 1997***
Dundee and East 1936	**Dr Charles Cameron**	**1954 - 1981**
	Dr Ewa Brookes	**1981 - 1996***
	Dr George Galea	**1996 - 1999**
Glasgow and West 1936	**Dr John Wallace**	**1946 - 1978**
	Dr Ruthven Mitchell	**1978 - 1995***
Northern Ireland 1946	**Dr M C Huth**	**1967* - 1969**
	Col T E Field	**1969 - 1980**
	Dr W Morris McClelland	**1980 - 1998***

_*Evidence indicates the Director held the position "at least until or from" the date shown.