Witness Name: Professor Brian Edwards

Statement No.: **WITN7641001**

Exhibits: **WITN7641002 -**

WITN7641012

Dated: 18 January 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR BRIAN EDWARDS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 November 2022.

I, Brian Edwards, will say as follows:

Contents

Preface

1. My name is Professor Brian Edwards. My date of birth is GRO-C 1942 and my address is known to the Inquiry. I was a Regional Administrator at the Trent Regional Health Authority ('Trent RHA') between April 1981 and June 1984. In June 1984, I was appointed Regional General Manager at Trent RHA and, in June 1993 (until March 1996), moved to the West Midlands Regional Health Authority ('West Midlands RHA').

2. I provide this statement to the Inquiry in response to a Rule 9 request dated 17 November 2022 and I follow the section headings in the Inquiry's request.

Opening comments

3. I would like to begin my witness statement by making a few brief opening comments. I had no knowledge at the time of the harm that resulted from contaminated blood. I ask myself whether I ought to have known and if I had known what I would have done. With the benefit of hindsight, I would have ensured that all injured patients received the best and continuing healthcare that was available, including appropriate psychological support. My Regional Medical Officer ('RMO') colleague had the principal link with clinicians in the region. I would, I think, have asked the RMO to speak with lead clinicians to establish what the situation was and whether any action was needed at a regional or national level. I would have made myself available for discussions if that seemed appropriate or if I had my own concerns. I would not however have got involved with the questions of compensation or ex-gratia payments. I would, I think, have regarded that as a matter for ministers.

4. This was a tragedy for patients and their families and the response by the NHS could and should have been better. I hope the Inquiry report will help ensure that patients who were harmed, and their families, are properly provided for as well as offer insights and advice that will enable the NHS to deal better with any similar problems in the future.

5. I also hope that the government will reconsider its attitude to no fault compensation. I accept that this is a difficult and challenging area of public policy, particularly at a time when the balance between public and private health provision is changing. There is international experience which would help in any policy debate.

6. Finally, it is worth noting that I have been provided with limited documentation to inform my written statement and so am heavily reliant on my memory. I have also had the opportunity to consider and consult my own papers and records, although there was little of relevance to assist me in answering the Inquiry's questions. While I have prepared this statement to the best of my ability, the events referred to within the Inquiry's request took place over 25 years ago and, as such, my recollections are in some parts limited.

Section 1: Introduction

7. I have been asked to provide my employment history, including the various roles and responsibilities held throughout my career. I have set this information out, to the best of my recollection, in Table 1 below.

1958 - 1964	I worked in various junior administrative posts within the NHS in the Mersey region.
1964 - 1966	In 1964, I was selected to join the NHS National Training Scheme based at the University of Leeds.
1966 – 1968	On completion of the scheme, I became a Hospital Secretary at Keighley Victoria Hospital.
1968 – 1970	I then worked as an Assistant Group Secretary with Mansfield Hospital Management Committee.
1970 – 1972	In 1970, I became a Lecturer in Health Services Studies and a Tutor to the NHS National Training Scheme at the University of Leeds. In addition to running the training scheme, I made teaching contributions to other undergraduate and postgraduate courses, and had a research focus on the management of change.
1972 – 1973	From 1972, I worked as Deputy Group Secretary for Hull 'A' Hospital Management Committee. The committee managed acute hospital services for the city of Hull.
1973 - 1976	In 1973, I worked as District Administrator for the Area Health Authority covering Leeds Western District. I was responsible for the management of Leeds General Infirmary, community services in Leeds West as well as a mental health service based at High Royds Hospital.

1976 - 1981	I then joined the Cheshire Area Health Authority where I was the Area Administrator. I had overall responsibility for policy and planning in Cheshire and monitored the performance of five operational health districts: Chester, Halton, Warrington, Macclesfield and Crewe.
April 1981 – June 1984	In 1981, I became the Regional Administrator for Trent RHA, where I was the administrative member of the multi-disciplinary top team.
June 1984 – May 1993	Following an internal competition, I was appointed Regional General Manager of Trent RHA. My role was equivalent to Chief Executive Officer, though I chose to operate under the title 'Regional General Manager' as I felt that it reinforced my role as a member and leader of a multidisciplinary team. In c.1993, I was seconded on a part-time basis to lead the Secretary of State's Working Group on Quality and Health (see paragraph 9.d below).
June 1993 – March 1996	I was seconded to the West Midlands RHA in June 1993, following a request by the Department of Health in the wake of major policy and probity issues within the West Midlands region. My original job title was Chief Executive of West Midlands RHA. It later changed to Regional Director for NHS West Midlands, though my responsibilities remained the same. In this role, I was

	directly accountable to the Chief Executive of the NHS for all NHS services in the West Midlands. From 1994, I was also a member of the NHS Executive Board.
1996 - 2002	In 1996, I became a Professor of Healthcare Development at the University of Sheffield, where my teaching and research focused primarily on effective healthcare delivery systems. Between 1996 and 1998, I was the Dean of the School of Health and Related Research and, from 2000, Deputy Dean of the Faculty of Medicine.
2002 - 2003	Between 2002 and 2003, I was the Chairman of the Arden Cancer Network, which concerned the coordination and development of cancer services in the eastern part of the West Midlands.
2001 - 2006	From 2001 until 2006, I was the Chairman of the Nottinghamshire NHS Trust, which provided general mental health services for Nottinghamshire and managed the Rampton Secure Hospital.
2005 – 2009	I then became the Chairman and Senior Consultant for ATM Consulting Ltd, a management consulting company with specialist skills in health planning and complex human relations problems working with both public and private sector clients. In this role, I handled the selection process for many senior appointments at the Department of Health

	and a number of Strategic Health Authorities and PCTs.
2010 – Present	Since 2010, I have been a lecturer and authored numerous books relating to healthcare and the NHS.

8. I hold the following professional qualifications:

    a. Fellow of the Institute of Health Services Management (1983)

    b. Honorary Fellow of the Royal College of Pathologists (1993)

    c. Honorary Member of the Association of Clinical Pathologists (1994)

    d. Honorary Doctor of the University, Birmingham City University (1997)

    e. Emeritus Professor of Healthcare Development at the University of Sheffield (2002)

    f. Professorial Fellow of the Royal Academy of Public Health (2012)

    g. Honorary Doctor of Medicine at the University of Sheffield (2017)

    h. Former Companion of the British Institute of Management

9. I have been asked to set out my membership, past or present, of any committees, associations, parties, societies or groups, relevant to the Inquiry's Terms of Reference. I have belonged to, at various times, the following committees or groups:

    a. Chairman, NHS Regional General Managers Group (1991 – 1993)

    b. Chairman, Clinical Pathology Accreditation Limited (1991-2000)

    c. Leader, NHS Patients Charter Team (1992-1993)

d. Leader, Secretary of State's Working Group on Quality and Health (1993). The group produced a series of leaflets that guided those purchasing healthcare and those providing it on what a patient's perception might be in a range of clinical specialities. One of the leaflets was focused on haemophilia ([DHSC0002465_003). I was seconded on a part-time basis from Trent RHA to lead this group.

e. Chair, Council for regulating the professions supplementary to medicine (1997-2002)

f. President, European Healthcare Federation (2005-2008)

10. I have not given evidence nor been involved in previous inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus (HIV), and/or hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infections and/or variant Creutzfeldt-Jakob disease (vCJD) in blood or blood products.

Section 2: Roles and responsibilities at Trent RHA and West Midlands RHA

11. As set out above, I was the Regional Administrator at Trent RHA from April 1981 to June 1984. Following an internal competition, I became Regional General Manager ('RGM') in June 1984 and worked in this role until my secondment to the West Midlands RHA in June 1993. The RGM role was akin to a Chief Executive though, as set out above, I chose to operate as RGM. I left West Midlands RHA / NHS West Midlands in March 1996 following which I became Professor of Healthcare Development at the University of Sheffield.

My role and responsibilities at Trent RHA

12. I have been asked to describe my roles, functions and responsibilities while working at Trent RHA. As Regional Administrator, I was a member of the Regional Team of Officers which comprised of an Administrator (my role), an RMO, a Regional Nursing Officer, a Treasurer and a Regional Works Officer / Architect. The team was the senior management group within the RHA that advised the RHA board and carried out day-to-day management of regional operations. I acted as the team's general coordinator which included overseeing the building of new hospitals within the region and acting as the main link between District Health Authorities ('DHAs') and the RHA. The Chair of the executive board revolved amongst the Regional Team of Officers and so, for a period of about a year, I chaired general meetings. I was also Company Secretary to the (non-executive) RHA board. Shortly after my appointment as Regional General Manager, the Regional Team of Officers (including me) became members of the RHA board along with a Chairman and other non- executive directors. This reflected ministers' wishes for the board to adopt a business-like profile rather than have a public sector separation between non- executive members and officers.

13. As RGM, I oversaw the performance and development of the NHS in South Yorkshire and the East Midlands. The area was a deprived region and was benefiting from increased national investment designed to level up investment across the NHS in England. Many new hospitals were designed, built and commissioned during this time. I was responsible for managing the regional headquarters, which at that time had over 1,000 staff members, as well as

developing and executing a regional development plan.

14. In 1982, under the guidance of Norman Fowler, the Secretary of State for Health and Social Services between September 1981 and June 1987, an annual review system was introduced whereby each RHA was required to submit a statement to the Department of Health and Social Security ('DHSS') on its performance over the previous year. The Chairman and executive team would then meet with ministers (originally the Secretary of State and, in later years, junior ministers in DHSS) in London where we were challenged on Trent's performance. Issues would be debated, reviewed and, if necessary, targets imposed for the upcoming year. In my role as RGM, I oversaw this process and attended any such meetings.

15. Trent RHA also managed numerous regional services directly, including the Blood Transfusion Service ('BTS'), computing and estates divisions, South Yorkshire Ambulance Service and the supply and distribution network. Trent BTS was a regional service serving all of the clinical units in the region. As RGM, the head of BTS was accountable to me, though day-to-day liaison and medical and scientific oversight sat with the RMO. A few clinical specialities, such as cardiothoracic surgery, were also designated as regional specialities and funded by the RHA as they served a wider population than the host DHA that managed them.

16. In January 1985, the Trent RHA Regional Executive Team (otherwise referred to as the Regional Team of Officers) agreed to set up a working party to "*assess the advantages and disadvantages of running the supply function of the Blood Transfusion Service on a commercial basis by charging District Health*

Authorities for blood and blood products supplied" (WITN7641002). The decision to do so would have been stimulated by the ongoing national discussions about charging by the BPL and achieving the national self-sufficiency target. The group was made up of Regional and District Officers and Consultant Haematologists and chaired by a member of the RHA. The resulting report dated January 1986 was shared with DHSS and concluded that, "*it would be advantageous to recharge District Health Authorities with the cost of blood products but not whole blood*" (WITN7641002). It also made a number of recommendations regarding charging arrangements. The report was, I am sure, accepted by the RHA not least because the working party had been overseen by Dr Sewell who was a member of the RHA board. It was however likely overtaken by national events in this policy area, including the Steering Group on Management Services Study of the National BTS, the national working party which was set up towards the end of 1986 to look at cross- charging arrangements amongst other things. As far as I can recall I had no personal involvement in the Trent working party (or its report) other than to agree its creation in January 1985. I have also been shown a minute dated 22 May 1986 from A J Davies to Graham Hart regarding the formation of the Steering Group on Management Services Study of the National BTS including its membership (DHSC0002441_109). I can see from this minute that I relayed RGMs' concerns about the membership of the steering group and provided input on the RGMs' preferred appointments. As far as I can recall, and in line with the Trent working party, I would have had no direct involvement in the steering group following its formation.

17. My later years with Trent RHA were dominated by the development of the NHS

internal market which was established by the National Health Service and Community Care Act 1990 and designed to separate the purchasing and providing of health services. This included, amongst other things, the creation of NHS Trusts and fund-holding GP practices. The region had to develop and introduce the NHS internal market within the policy lines set out by the Department of Health ('DH'). As Regional General Manager, I was tasked with implementing the new system within the Trent region, and also joined the national team handling negotiations with the British Medical Association ('BMA') regarding these measures (and their impact on, for example, young doctors' training positions and distinction merit awards). As the NHS internal market developed, most regional services, including the BTS, were transformed into arm's-length organisations with their own boards. These boards remained ultimately accountable to the RHA and, therefore, to me as Chief Executive.

18. I had various other roles and responsibilities at this time, including:

    a. I was involved in creating the Trent Institute, which was set up to encourage the Universities and medical schools to work together. This involved regular meetings with the Vice Chancellors of various universities in the region, including the medical schools in Leicester, Nottingham and Sheffield, and targeted investment to stimulate clinical research. The Trent Institute had a primary focus of developing research skills.

    b. I was the Chair of the Regional General Managers group (originally called the Regional Administrators group), from around 1991 until June

1993. I retired as Chair on moving to West Midlands RHA. The Regional Administrators group / RGMs group met on a monthly basis and was attended by the Administrator / General Manager / Chief Executive of each region. By way of background, the Regional Administrators / RGMs usually met privately and, later the same day, would meet with the NHS Management Board and its Chief Executive / the NHS Management Executive and/or representatives from DHSS / DH. As Chair, I managed the group's interface with DHSS / DH. I attended most of these meetings from my first appointment as Regional Administrator in April 1981 until the regions closed down and I became Regional Director in March 1995. In general the types of matters that were discussed could cover a wide range of NHS business such as NHS funding, the implementation of emerging policy plans by ministers, NHS pay, industrial action, defining quality, use of locum agencies, performance indicators, closing large psychiatric and mental handicap hospitals and moving to community care, planning for the future, income generation, links with local government, efficiency targets, creating an internal market, waiting lists and policies for patient empowerment. The RGMs only rarely became involved in matters that were strictly clinical. Occasionally, the RGMs would look at clinical futures with experts with a view to understanding their potential impact, for example genetics or the implementation of the health targets set out in "*Health of a Nation – A Strategy for England*" (first published in 1992).

My role as Chair changed markedly with the creation of the NHS Management Executive in 1989. I became responsible for leading the

work with the NHS Chief Executive in the move to single centre working (i.e., the NHS Management Executive and the regions working as one unit whilst the NHS internal market was created) and organising the allocation of special interests between RGMs - each RGM was allocated a special interest area to work on with departmental colleagues. In terms of special interests, I was responsible for patient empowerment, manpower planning and acted as the link to the doctors and medicine more generally (including with the BMA and Royal Colleges). As far as I can recall, Catherine Hawkins was the RGM designated with looking after blood policy.

My responsibilities at West Midlands RHA

19. I have further been asked to describe my roles, functions and responsibilities while working at West Midlands RHA.

20. In the wake of major policy and probity problems in the West Midlands and following the departure of the former Chair and Chief Executive, in 1993 I was asked by DH to take over as Chief Executive of the West Midlands RHA.

21. I was faced with and worked through four major challenges:

    a. To give the region a new sense of purpose and direction in the new NHS internal market.

    b. To resolve the overspending problems in Birmingham, rebuild the relationship with Birmingham City Council and, at the same time, to restructure the hospital sector so that it could grow and thrive again. Birmingham DHAs had 1,000 more staff than they had the funds to pay

and were running a substantial financial deficit. The first step was to work out what cuts needed to be made, the timeframe within which these cuts needed to be made and the likely consequences. I arranged for 'bridging' money to be provided to Birmingham Health Authorities for c.2 years to allow time for them to take agreed measures to reduce overspending and, at the same time, opened dialogue with Birmingham City Council in efforts to build an amicable relationship. In the end, the staff levels at the Birmingham DHAs were largely reduced through natural attrition, and the depth of the cuts required was lessened by natural growth coming back into the system.

c. To instil a strict adherence to excellent standards of probity in the conduct of public business. As part of this process, I appointed a Head of Probity who ensured that everything was done as it should be.

d. To downsize and reinvigorate the headquarters organisation.

22. For a period, I was also accountable for the regional Blood Transfusion Service though, once again, day-to-day liaison sat with the RMO. At some point in 1994/95, although I cannot recall the exact date, the National Blood Authority took over the management of this service, following which I had no direct involvement with it.

23. From 1994, I also attended NHS Executive Board meetings following a decision that Regional Directors would become members of the board. I have provided an example of an NHS Executive Board meeting held on 6/7 July 1995 (WITN7641003). You can see from this the type of issues that were discussed, including plans for the re-organisation of the Blood Transfusion Service. In this

meeting, Regional Directors were asked to consider ways to "*assist in the integration of the National Blood Authority with the mainstream NHS through carefully planned meetings with NBA zonal managers*", and to "*encourage understanding and support locally for the changes and to discourage ill informed publicity*". I do not recall whether I took any actions in respect of the National Blood Authority following this meeting.

The organisation of Trent and West Midlands RHAs

24. I have been asked to describe the organisation of the Trent and West Midlands RHAs, including their structures, staffing, funding, remit, the regulations that they were subject to and their relationships with the Blood Products Laboratory ('BPL'), the Plasma Fractionation Centre ('PFC') and any other laboratories involved in the production of blood products or the processing of blood.

25. In respect of the structures, both Trent and West Midlands RHAs were large organisations with over 1,000 staff. Prior to my appointment as Regional General Manager, I reported to the Regional Health Authority board and my board reported directly to ministers and the NHS Chief Executive. During my tenure as RGM at Trent RHA and Chief Executive at West Midlands RHA, I was a member of the Regional Health Authority board and reported directly to the Chief Executive of the NHS.

26. As set out above, the RHAs managed a range of regional services (including, for example, the Blood Transfusion Service, computing and software development teams, and estates division) and were funded by the Department of Health from the main general allocation to that specific region.

During my time with the RHAs, the level of funding fluctuated according to government policy at the time. On the recommendation of the Resource Allocation Working Party ('RAWP'), the government had introduced a national programme of equalisation in the late 1970's which was designed to distribute funds across the NHS in a way that took account of the differing needs of the population across the country and address previous inequalities in funding distribution (WITN7641004). The intention was to level up per capita investment across England and, as particularly deprived regions, Trent and the West Midlands were major recipients of additional funding each year. As far as I can recall, the formula for calculating the allocation of funds across the country evolved in the early 1990's as the RAWP equalisation targets were largely achieved, and Trent and the West Midlands no longer received the preferential treatment that they had been afforded in the late 1970's and 80's. I have provided an extract from a Trent RHA report entitled "*A fair share for Trent*", which shows that funding targets were close to being met in 1986/87 (WITN7641005).

27. Trent RHA covered all hospitals and primary care services in Sheffield, Rotherham, Doncaster, Barnsley and Bassetlaw, Derbyshire, Nottinghamshire, Lincolnshire and Leicestershire. I understand, from a report dated 7 August 1991 prepared by the Trent Purchasing Agency, an arms-length organisation, and entitled "*Plasma and Fractionated Blood Products and associated Blood Bags*", that this coverage included six haemophilia centres including in Sheffield, Derby, Nottingham and Leicester (WITN7641006). These centres would have been managed by the relevant DHA. West Midlands RHA covered Birmingham and the Black Country, Staffordshire and Stoke, Shropshire, Warwickshire, Worcestershire and

Herefordshire. I cannot now recall how many haemophilia centres or hospitals were covered within this area.

28. As set out in further detail at paragraph 14 above, Trent and West Midlands RHAs were subject to annual reviews by ministers which were published. Annual reviews were focused on past performance (i.e. hitting targets), contemporary problem areas and future operational plans. They had a strong financial basis, and represented an important linkage between ministers, regions and DHAs. I have been shown a copy of a document dated February 1990 and entitled "*Short Term Programme 1990/91*" (WITN7641007). This type of document was produced by the regions to enable DH to "*assess the Region's plans for the coming year in order to identify any issues of serious concern and approve objectives*" and would have been discussed as part of the annual review process. Following its creation in 1989, the NHS Management Executive took over the management of these annual reviews. The Royal College of Pathology also inspected all laboratory services in the region that trained pathologists, including the Blood Transfusion Service. As far as I can recall, the Blood Transfusion Services were also inspected by the Medicines Inspectorate and voluntarily accredited by Clinical Pathology Accreditation, which would have involved laboratory inspections. I do not remember the RHAs being subject to any further form of regulation and/or review.

29. Relationships with the BPL, PFC and any other laboratories involved in the production of blood products or the processing of blood would have been managed by the Blood Transfusion Service with minimal input from the RHAs. Having said that, the RHA would have become involved as and when costs and prices became an issue, for example when the cost of producing more

plasma was greater than that paid by the BPL. I have also been referred to a letter dated 17 May 1982 from Dr Wagstaff, the Director of Trent BTS, to Mr Banham (NHBT0019158). Mr Banham was part of the Standing Working Group at Trent RHA putting together the operational plan for the upcoming year. Dr Wagstaff enclosed BTS operational planning forms and set out a number of factors that would affect the expansion at the BTS and should therefore be borne in mind when preparing the region's operational plan. It was standard practice for regional services to input into this operational plan and Dr Wagstaff's comments would likely have been fed into the plan, though I would not have been directly involved in this process. I would however have signed off on a draft of the operational plan prior to its formal submission to the RHA board.

Relationship between RHAs and corresponding DHAs

30. The Inquiry has asked me to explain the structural and financial relationships between the RHAs and their corresponding DHAs.

31. DHAs were independent statutory organisations whose members and chairs were initially appointed first by RHAs, then ministers on the advice of the Regional Chairs, and then, from 2001, by the NHS Appointments Commission, though the latter post-dated my time in Trent and the West Midlands.

32. District Administrators reported directly to their respective DHA boards and the relevant Chairs, although I acted as assessor at all appointments. I did on very rare occasions block the appointment of a candidate who I regarded as inexperienced or unsuited for the role. I also assessed the appointment of

District General Managers, who were also accountable to their DHA boards. However, in these cases, the Secretary of State's approval was also required.

33. In respect of the financial relationship, the RHAs allocated funding to DHAs in their region based on local formulae which mirrored the national Resource Allocation Working Party model. RHAs were responsible for decisions relating to the funding of Regional Transfusion Centres ('RTCs') which, as far I can recall, included the funding of appropriate testing kits for donation screening. The responsibility for procuring haemophilia treatment lay with the DHAs who managed the haemophilia centres.

34. I have been referred to an extract from the minutes of a meeting dated 29 November 1982 held by the Regional Team of Officers at Trent RHA (NHBT0019160). The minutes stated:

> "*The team agreed to support the introduction of automated plasmapheresis within the Trent Region, which would entail: -*
>
> a. *The phased introduction of plasmapheresis teams and the need to provide capital funds.*
>
> b. *The budget for the existing supply of blood products from the Blood Transfusion Service being transferred from Regionally Managed Services to Districts and all blood products to Districts in future being the subject of a recharge from the Blood Transfusion Service.*
>
> c. *The requirement for Districts eventually to cease purchasing blood products from commercial sources.*"

35. I cannot recall in any detail why we decided to devolve funding to districts,

though such a decision would have been very much in line with the creation of an internal market in every part of the NHS. To the best of my recollection, the decision to "*cease purchasing blood products from commercial sources*" was based on economic grounds in order to justify the investment in in-house services; I cannot recall any concerns being raised about the safety of commercial products.

Relationship between RHAs and the Department of Health and Social Security

36. I have been asked to comment on the frequency and nature of dealings with both the DHSS and the corresponding Secretaries of State. During my time with the RHAs, I had close and regular contact with the Regional Liaison Division of DHSS and, in particular, Andy McKeon who was a civil servant designated as the main point of contact for Trent. I do not recall who the designated civil servant contact was during my time in the West Midlands. I had a close working relationship with the Regional Liaison Division; I, or one of my colleagues, would approach the division if we had any issues and/or questions for DHSS, for example, in relation to targets. In my role as Chair of the Regional General Managers group, I also had regular contact with senior civil servants within DHSS on a similar basis to that set out directly above.

37. As set out at paragraph 28 above, the RHAs' performance was also reviewed annually by ministers. It provided an opportunity for reporting and challenge and would potentially result in the setting of new and/or revised targets.

38. During my time with Trent and West Midlands RHAs, the Secretaries of State for Health and Social Security and, later, for Health were as follows:

    a. Patrick Jenkin MP (May 1979 – September 1981)

    b. Norman Fowler MP (September 1981 – June 1987)

c. John Moore MP (June 1987 – July 1988)

d. Kenneth Clarke MP (July 1988 – November 1990)

e. William Waldegrave MP (November 1990 – April 1992)

f. Virginia Bottomley MP (April 1992 – July 1995)

39. The Secretary of State had regular meetings with the RHA Chairmen and occasional meetings with Regional General Managers / Chief Executives. As far as I can recall, meetings between the Secretary of State and the Chairs of the RHAs were held quarterly. I understand that the purpose of these meetings was to update the Secretary of State on NHS affairs and allow them to use the Chairmen as a sounding board on NHS policy. As Chair of the Regional General Managers Group, I would receive copies of all papers relevant to these meetings, including agendas and minutes, and would brief my regional Chairman in advance of meetings. On occasion, I joined the Chairmen in meetings with ministers on issues such as NHS funding. I have enclosed a copy of minutes from a meeting held on 23 September 1992 between the Secretary of State (Virginia Bottomley) and the RHA Chairmen by way of example (WITN7641008). While I did not attend this particular meeting, I can see that the proposal to introduce a National Blood Authority was discussed. I would likely have briefed my regional Chairman on this issue, including on the RGMs' reservations over the "*danger of too top heavy a bureaucracy*".

40. In July 1989, the NHS Policy Board was created to allow ministers to share policy ideas with a wider group of people, including leaders from industry and commerce (including Aerospace, British Steel and Cadbury). The membership of the board changed over the years but included the Secretary of State (who was the Chairman of the NHS Policy Board), the Chief

Executive of the NHS Management Board (Duncan Nichol), the Permanent Secretary at DH, the Chief Medical Officer, two regional Chairs and a medical consultant. I did not attend these meetings as a routine although I may have been invited to report on a particular issue such as waiting lists or quality issues.

41. Notwithstanding the above, RHAs had a substantial degree of operational freedom. We had an open relationship with the Regional Liaison Division at DHSS / DH and understood that we had to implement national policy once it was determined. Ministers did have a degree of influence and oversight on the way in which regions apportioned their basic allocations but, for the most part, this was at a very high level. For example, ministers might have challenged an RHA on the level of overall spend on mental health in the previous year, or have required an RHA to make "adequate" provision for a service, such as AIDS screening, and requested that it report on what the region had done in its next operational plan and/or annual review.

42. If an RHA had wanted to seek additional funding from DHSS / DH, it would have submitted a request via either the Regional Liaison Division or via the Regional Treasurer's link to DHSS / DH. In respect of RAWP's national programme of equalisation (as set out at paragraph 26 above), we also dealt directly with senior civil servants and ministers as it was necessary to engage in conversations to ensure that the policy was implemented at an acceptable pace.

Section 3: Relationship between Trent RHA and West Midlands RHA and corresponding RTCs

43. I am asked to describe the relationship between the Trent RHA and West Midlands RHA and their corresponding Regional Transfusion Centres.

44. As set out at paragraph 15 above, the Trent regional Blood Transfusion Service was directly managed by Trent RHA, initially via the RMO and subsequently by myself when I became RGM. I visited on occasion, but the main oversight and policy link was with the RMO. The BTS Director (Dr Wagstaff) met a small multidisciplinary business team on a regular basis and particularly as the region prepared its annual budgetary plan. The team would have comprised of one of my senior staff, the RMO (or one of his staff) and a representative of the Regional Treasurer. These meetings would have been primarily finance based though they may have also discussed personnel issues such as staff grades. The same would have been true of West Midlands RHA and the corresponding regional BTS, though I have no clear recollection of the detail.

45. As set out in the Trent Purchasing Agency report dated 7 August 1991, and around 1992, the BTS was *"put under an agency agreement at "arms length" from region and managed by its own Board made up of executive and non executive directors"*. The board was then responsible to the RHA for the management of the BTS (WITN7641006). The National Blood Authority later took over the management of the BTS, as set out in paragraph 22 above.

46. Until the BTS moved to arms-length status, Dr Wagstaff also met regularly (I believe 3 – 4 times a year) with a subcommittee of the RHA. The sub-committee

comprised of three members of the Trent RHA board and officers from disciplines that interfaced with the BTS, including admin, the RMO's office and finance. I have been shown the minutes of a meeting dated 30 July 1985 held by the RHA sub-committee (DHSC0032165_156). While I would not have been in attendance at these meetings, I expect that any important news or information would have been reported back to me, and I would have taken appropriate action, as necessary. I do not recall whether equivalent meetings were held in the West Midlands.

47. The BTS (at both Trent and West Midlands) was a regional service with a good deal of clinical autonomy and operational independence which, in my judgement, it exercised in a responsible manner. It is my understanding that the Inquiry has looked into the frequency and nature of the BTS Directors' meetings and that evidence has been given on the subject. I had no knowledge at the time of the BTS Directors' national meetings and would have expected the Directors of the relevant regional BTS' or my RMO colleague to inform me if there were any major issues with which I could help or support.

48. Funding decisions relating to regional BTSs were taken via an annual budget plan which would be approved by the relevant RHA. The relevant BTS Director would be questioned about any bid for increased funding set out in the plan, and a considered view would be taken by the corresponding RHA.

49. I have no independent recall of whether the RTCs made any further funding requests to the RHAs during my time at Trent and the West Midlands but, if they had done, I believe they would have been agreed. I have also been referred to an extract (at paragraph 79) from Dr Wagstaff's written statement

dated 11 January 2022 which supports this recollection (WITN6988001).

50. The Inquiry has asked me to explain how the RTCs funded plasma procurement and the role played by Trent and West Midlands RHAs. I have no clear independent recollection of how plasma procurement was funded but I have been referred to extracts from Dr Roger Moore's written statement at Q14 where he stated that "*...RHAs were responsible for funding RTCs from 1974 until 1993... From 1989 when cross charging was introduced, BPL paid RTCs for the plasma they supplied. This payment offset the costs incurred by RTCs in plasma procurement. and so for funding plasma procurement during the 1980's until 1989 when cross charging came in...*" and at paragraph 37.3 where he stated that "*although RHAs were expected to provide the funding for plasma procurement it was up to each RTC to seek its own allocation from them*" (WITN6919001). I agree with Dr Moore's explanation.

51. I have been asked to explain whether the RTC had targets for the amount of plasma that had to be collected by the centre. I have been referred to an extract from Dr Roger Moore's written statement at paragraph 38.2 where he stated that "*...RTC plasma targets were set on a per capita basis, so there was a correlation between funding and plasma targets at a RHA level*" (WITN6919001). I agree with this assessment though I do not recall the RHAs having any involvement in setting these targets and/or of personally being asked to give a view on plasma targets. To the best of my recollection, targets were set nationally by the BPL to match supply and demand, with input from DHSS / DH on occasion. In Trent, the BTS' funding was supplemented by the RHA to assist them in meeting these targets and to cover any gap between the cost of plasma production and income from the BPL, though I cannot now recall what was done in the West Midlands. In this respect, I have been

referred to a letter dated 10 August 1984 from J A Parker (of DHSS) to all Regional Administrators expressing concern that RHAs had, in some cases, not provided the necessary additional funding to RTCs to meet plasma targets set for 1988 (WITN7641009). I replied to Mr Parker on 6 September 1984 (WITN7641010). I wrote: "*The RHA has always provided a growth rate to the BTS based on the Regional average and in the Regionally Managed Services financial plans and cost improvement programmes for 1984/85 and 1985/86, a considerable amount is earmarked for use in moving towards the Region's procurement target.*"

52. To the best of my recollection, both Trent and West Midlands BTSs always met their plasma targets, though I don't believe that there were any penalties had they failed to do so nor were there any benefits had they exceeded targets. Having said that, I have been referred to a report of the Working Party of the Trent RHA dated January 1986 and entitled, "*National Blood Transfusion Service Recharging Policy*" (WITN764002). It stated: "*The quantity of blood products which a Region can obtain from the Blood Products Laboratory is related to the quantity of plasma it is prepared to supply.*" I think, therefore, that the region would have received more blood products from the BPL had it exceeded its targets.

53. The Inquiry has asked whether automated plasmapheresis was introduced in the Trent region and, if so, whether it helped the region to achieve self sufficiency. I have been referred to the following documents in this respect:

    a. An extract from the minutes of a meeting dated 29 November 1982 held by the Regional Team of Officers at Trent RHA (NHBT0019160). As set out at paragraph 34 above, it stated that the Regional Team of

Officers had agreed to support the introduction of automated plasmapheresis in the Trent region.

b. A report on the Regionally Managed Services Short Term Programme 1986 – 1987 prepared by Trent RHA (NHBT0019171). It stated: "*The Regional Strategic Plan reflects the need to enable Trent Regional Health Authority to contribute to National Health Service self-sufficiency in blood and blood products. This is to be achieved by a major investment in plasmapheresis and SAG-M which will permit an increasing quantity of plasma to be made available to the National Blood Products Laboratory.*"

54. To the best of my knowledge, I believe that automated plasmapheresis was introduced in the Trent region. It would have helped towards the drive for self sufficiency, though I cannot now recall any further details.

Section 4: Arrangements for obtaining and allocating factor concentrates

55. I have been asked to set out my understanding of the arrangements in place in the Trent and West Midlands regions for the purchase and holding, and the allocation to haemophilia centres within the region, of NHS factor concentrates and imported commercial factor concentrates.

56. I do not have any clear recollection of which haemophilia centres were supplied with factor concentrates by the RTC / RHA and over what period of time.

57. I have further been asked to explain how the haemophilia centres within the

region were funded and the role played by the RHA in funding. As set out at paragraph 15 above, certain clinical services were funded by the RHA as a regional speciality but run by a DHA for the entire region. The Trent and West Midlands regions had about a dozen of these specialities, including cardiothoracic and neurosurgical services. There was also a small group of specialties that were funded by the National Supra Regional Services Group at DHSS / DH (for example, paediatric cardiac services and spinal injuries). In this regard, I have been referred to a letter I wrote to Mr A Hurst dated 1 August 1985 in relation to supra-regional services and haemophilia reference centres (WITN7641011); (DHSC0002347_063). The letter enclosed a formal application requesting that the haemophilia reference centre in Sheffield be considered for supra-regional designation. The bid was made by Trent RHA on the grounds that it was one of only ten national reference centres and provided a wider service than just the Trent region. I can't recall if the bid was successful though, during my tenure, I don't think that the haemophilia centres had specialist funding and/or regional speciality status.

58. Funding for the haemophilia centres directly would therefore have been a matter for DHAs. As far as I can recall the RHA had no role in funding the haemophilia centres other than by virtue of the fact that they allocated funding to the DHAs. The funding was allocated as a block grant to the DHAs. The RHA would not specify how the DHA should distribute the funding amongst the services. There would have been discussion on funding at a review meeting as a matter of policy for example the RHA might have asked why a DHA wasn't spending as much on mental health as other DHAs. Once the internal market was in place, funding would have come from other DHAs (with cross charging) and perhaps GP Fundholders. Cross charging meant that the

BTS charged each DHA for the blood and blood products they ordered. It was at the time judged that it would induce a more careful use of a scarce resource in an internal market. Once cross charging was in place, the directors of the haemophilia centres had to negotiate with the local DHA who set the budget. The haemophilia directors had to therefore make sure there was enough in the budget to cover the blood products required.

59. The funding arrangements and the role the RHA played in funding for the West Midlands would have been very similar to funding in the Trent region.

60. I don't recall either Trent RHA or West Midlands RHA having any direct role in relation to the purchase, holding or distribution of any factor concentrates. However, as set out above, the regional BTS' were managed by and fully accountable to the corresponding RHAs. In this regard, I have been referred to a report dated 7 August 1991 prepared by Trent Purchasing Agency regarding plasma and fractionated blood products (WITN7641006) which supports my recollection. It stated: "*the funding of BTS being a regionally managed service, was provided by the RHA as part of the regionally, managed services*".

61. As far as I can recall, factor concentrates were ordered by haemophilia centre directors from the BTS (in the case of Factor VIII produced by BPL) or purchased commercially. The decision was for the haemophilia centre directors to make. At that time, clinical freedom was highly regarded. The RHA relied on the expertise of the haemophilia centre directors to make decisions about the type and quantity of products purchased, and the safety of those products.

62. I don't recall either the Trent RHA or West Midlands RHA having any

involvement with any pharmaceutical company in connection with the supply of blood or blood products.

63. From my recollection, neither Trent RHA nor the West Midlands RHA sought to exercise any influence over, or provide any advice or guidance in relation to, the decisions about the choice of product used to treat patients in haemophilia centres and/ or hospitals. As set out at paragraph 61 above, this was due to the long-standing principal of clinical freedom, which I understand was part of the deal struck between ministers and the medical profession when the NHS was first started. The one exception to this was the national and regional plans to move from commercial to BPL produced blood products. In this respect, I have been shown a report dated 7 August 1991 prepared by the Trent Purchasing Agency entitled "*Plasma and Fractionated Blood Products and associated Blood Bags*" (WITN7641006). It stated: "*Fractionated Products...This region was faced with the problem of the Directors of the Haemophilia Centres in the vanguard of saying it was their budget and they had the freedom to choose the best source of supply... Considerable persuasion had to be exercised on our clinicians by the most senior management at the RHA and myself to convince them that the best value for money deal, in all the circumstances, was to place the bulk of the business with BPL (90%) and the remainder with commercial services.*" However, as was always the case, if a clinician had good reason to continue with a particular commercial product for a particular patient, their judgment would be respected. I also do not personally recall any conversations with clinicians in either Trent or the West Midlands designed to put pressure on them to select a particular product.

64. It is correct that financial budgets were devolved to individual regional districts within the Trent RHA. I think this was from 1 April 1990. I have been referred to a letter dated 30 May 1990 from Ernie Gascoigne (from the BIO-Products Laboratory) to Mr R Soulsby (from Trent RHA) regarding the regional agreement for the purchase of BPL therapeutic products (JPAC0000198_093). This was, I think, the sort of minimal support that the Regional Supplies Department of Trent RHA provided the BTS. The letter related to concerns raised by the Trent RHA in relation to the purchase of BPL therapeutic products and sought to address those concerns. Within this context, the second paragraph of the letter stated that "*budgets have devolved to District level*" and this is in line with my recollection.

65. The decision of Trent RHA to devolve the BTS budget to hospitals is also referred to at paragraph 2 (iii) of the Trent Purchasing Agency report (WITN7641006). The report stated: "*Decision of Trent RHA to devolve the BTS budget to hospitals and BTS to recover their costs from the hospitals for the services BTS provide to them, this to be formalised under individual service agreements between BTS and the hospital provider units, including Trusts.*" Although the RHA may have made a small additional contribution to cover the costs of specialist laboratory services (this would have been for special reference laboratory work).

Commercial blood products

66. I have been referred to a letter dated 17 May 1982 from Dr Wagstaff to Mr Banham regarding operational planning of the BTS (NHBT0019158). Commercial products were used in the Trent region but, as explained at

paragraph 61 above, were purchased by the haemophilia centres directly. As far as I can recall, the RHA was not involved; it was left to the DHAs and the haemophilia centres, though I believe that other RHAs may have had contracts for commercial blood products.

67. As far as I can recall, no safety concerns about commercial products were ever raised with me, and I was not aware of any measures implemented by haemophilia centres or hospitals to reduce their reliance on commercial blood products.

68. I have also provided a copy of a minute of the Regional Chairmen's private meeting held on 22 September 1992 (WITN7641012). It stated: "*Stuart Burgess* [Chair of the Oxford region] *reassured Chairmen about the safety of imported blood products; there was now rigorous testing in the US both of the donors and of the product".* I was not in attendance at the meeting but, as Chairman of the RGMs group, I would have received copies of the minutes. My recollection is that I was aware of the assurance given.

69. Beyond the general drive towards self-sufficiency I cannot now recall, given the passage of time, whether there were any specific measures taken by Trent RHA to reduce reliance on commercial blood products.

Section 5: Reduction of Risk of Infections

Introduction of HIV testing

70. Funding and operational support was provided by both Trent RHA and West Midlands RHA to the corresponding RTCs to aid in the introduction of HIV screening on 14 October 1985. I have been provided with a document entitled

"*Notes of a Meeting of the Regional Health Authority Sub-Committee held on 30 July 1985*" (DHSC0032165_156). Dr Wagstaff updated members and officers on the current situation regarding screening for AIDS. The notes stated: *"It was anticipated that the BTS would start the screening tests at the end of September / early October and the RHA had allocated a sum of £500,000 to cover the cost."* I cannot recall any other details of any funding or operational support. I believe that we met national targets, though I do not remember any detail in respect of these national targets. I also don't have any knowledge in relation to whether this had an effect on the RTC's ability or willingness to commence testing earlier.

Introduction of anti-HCV screening

71. I have been referred to correspondence dated 11 December 1991 from Dr Ala, Director of the regional BTS under the West Midlands RHA, to Dr H Gunson, the National BTS Director, in relation to financing HCV testing (NHBT0000193_083). In the letter Dr Ala stated that: *"…The RHA in the West Midlands did (after some gnashing of teeth) provide support for the first seven months of anti-HCV screening and supplementary testing. From April 1992, however, the users will have to defray our estimated £800,000 annual costs…"*. I was not seconded to West Midlands RHA until June 1993 and so am not in a position to comment on whether there was any resistance by West Midlands RHA at the time. However, I do not believe I was made aware of any such resistance following my appointment as Chief Executive.

Counselling

72. I have been referred to correspondence dated 3 October 1985 from A J

Williams at DHSS to me (DHSC0002281_035). The letter related to additional financial resources for certain RHAs in 1985 as a contribution towards the costs of development of services in connection with the HTLV-III infection. The letter stated: "*I am now writing formally on behalf of the Secretary of State to notify you of an addition of £15,000 to your Authority's revenue cash limit for 1985-86. This is a contribution towards the development of counselling in connection with HTLV III infection, and is for use within the Haemophilia Reference Centre at The Department of Haematology, Sheffield Childrens Hospital, Western Bank, Sheffield S10 2TH and the Department of Haematology, The Hallamshire Hospital, Glossop Road, Sheffield S10 2JF.*" The additional funding would, I assume, have been passed on to Sheffield Health Authority. My recollection is that the funding was probably not sufficient to deal with the additional counselling although it would have been a welcome contribution. I am unable to recall if any extra funding was requested for HTLV-III counselling or how much was spent on this each year.

Unscreened blood

73. I have been asked to consider a letter I wrote on 28 February 1986 to Dr Moore at the DHSS (DHSC0002295_031). I stated: "…*we have decided to carry out a further check through District Medical Officers to investigate the possibility of hospital departments collecting unscreened blood donations outside the NBTS.… A suggestion has also been made that it could be the practice in some neonatal paediatric units where babies need only a small donation of blood, for fresh blood to be taken direct from staff. We are naturally treating these suggestions seriously, and have asked District Medical*

Officers to investigate these and any other possibilities very thoroughly." There was a shortage of blood donations at the time and screening was fairly expensive. My view is that the collection of unscreened blood would have been a sensible act of exploring alternatives. At the time, ideas were being sought and this was a sensible discussion about what could be done. Any ideas would have been taken seriously. I had thousands of discussions similar in approach to this over the years. I cannot specifically remember what happened as a result of the letter and so am unable to assist the Inquiry in terms of actions taken to decrease the risk of blood borne infections to blood recipients.

Section 6: HCV Look Back

74. I have been asked to confirm whether I was involved in setting up any HCV look back programmes during my time at the RHA. I was not.

Section 7: Other Matters

75. I have been provided with a copy of a Writ of Summons dated 23 January 1990 in relation to a claim against, amongst others, Sheffield Health Authority, Trent RHA and DH regarding an individual who died after receiving blood contaminated with HIV (DHSC0043021_068). I am unable to recall anything in relation to this specific legal action. At the time, the RGM lead on the subject of HIV litigation for the whole of England was Gerry Green. The lead for the Chairmen was R Martin QC (the Chair of the North West region) and Dr Richard Alderslade led for the Regional Medical Officers. For the case in question, Trent RHA was one of a number of organisations being sued and so

the litigation would have been handled by Oxley & Coward, the legal representatives for Trent RHA, and the solicitors for the other organisations. To the best of my recollection I would not have had any substantial involvement in the litigation, though would likely have been involved in issues such as the payment of legal costs on occasion.

76. I have been referred to a letter dated 17 September 1990 from Oxley & Coward Solicitors addressed to me (DHSC0043557_025). The letter refers to a statement made by Mr Justice Ognall on 26 June 1990 in which he "*invited all parties to give "anxious consideration" to the prospects of a settlement*". I have also been shown a letter dated 3 July 1990 from Dr Alderslade to Gerry Green regarding the HIV litigation in which Dr Alderslade relayed that the Regional Directors of Public Health were strongly in favour of a negotiated settlement (DHSC0042547_109). I was copied into this letter, though I do not recall having seen it. I suspect that I received a copy of this letter in my capacity as RGM because it related to litigation involving Trent RHA. As set out above, I cannot recall the specific litigation referred to and, in turn, do not remember whether settlement was reached.

Statement of Truth

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

Signed GRO-C

Dated 18 January 2023

Exhibit Table

	Description	UID
1.	Minute from Kate James to Ms Copeland dated 29 January 1993	DHSC0002465_003
2.	Report of the Working Party of the Trent RHA dated January 1986	WITN764002
3.	Memo from A Davies to Mr Hart dated 22 May 1986	DHSC0002441_109
4.	Action Note of an NHS Executive Board Meeting from 6-7 July 1995	WITN7641003
5.	Paper entitled "Resource Allocation: Weighted Capitation Formula" by the Department of Health	WITN7641004
6.	Chart entitled "The Facts: Revenue resources. Progress towards target from 1977 onwards"	WITN7641005
7.	Report by the Trent Purchasing Agency entitled "Plasma and fractionated blood products and associated blood bags"	WITN7641006
8.	Report by the Trent Regional Health Authority entitled "Short Term Programme 1990/1991"	WITN7641007
9.	Letter from Dr W Wagstaff to Mr Banham dated 17 May 1982	NHBT0019158
10.	Extract of meeting minutes of the regional team from the Trent RHA held on 29 November 1983	NHBT0019160
11.	Minutes of a meeting between the Secretary of State and the Regional Health Authority Chairmen	WITN7641008
12.	Notes of a meeting of the RHA Sub-Committee on 30 July 1985	DHSC0032165_156
13.	Written statement of Dr William Wagstaff dated 11 January 2022	WITN6988001
14.	Written statement of Dr Roger Moore dated 5 December 2021	WITN6919001

15.	Letter from J A Parker to unnamed recipient in relation to the supply of plasma to the blood products laboratory	WITN7641009
16.	Letter from B Edwards to Mr Parker in relation to the supply of plasma to the Blood Products Laboratory	WITN7641010
17.	Report on the Regionally Managed Services Short Term Programme 1986-87 by the Trent RHA	NHBT0019171
18.	Letter from Brian Edwards to Mr Hurst in relation to supra-regional services - Haemophilia Reference Centres	WITN7641011
19.	Report by Brian Edwards	DHSC0002347_063
20.	Letter from Ernie Gascoigne to R Soulsby dated 30 ay 1990	JPAC0000198_093
21.	Minutes of the Regional Charimen's Private Meeting	WITN7641012
22.	Letter from Dr F Ala to Dr H Gunson dated 11 December 1991	NHBT0000193_083
23.	Letter from A Williams to Brian Edwards dated 3 October 1985	DHSC0002281_035
24.	Letter from Brian Edwards to Dr R Moore dated 28 February 1986	DHSC0002295_031
25.	Writ of Summons issued on 23 January 1990	DHSC0043021_068
26.	Letter from Diane Hallatt to Brian Edwards dated 17 September 1990	DHSC0043557_025
27.	Letter from Richard Alderslade to G Green dated 3 July 1990	DHSC0042547_109