Scottish Office and SHHD Decision-Making: Presentation Note

Contents

I. INTRODUCTION

1. This presentation note relates to decision-making in the Scottish Office, primarily the Scottish Home and Health Department ("SHHD"), and focuses on the period from 1970 to the early 1990s.

2. Many of the issues covered by this presentation were investigated by the Penrose Inquiry ("Penrose"). The focus of this note is on contemporaneous documents and witness evidence. Where appropriate, however, reference is made to evidence submitted to or findings made by Penrose. While the note is detailed, it is not intended to be comprehensive, particularly in relation to witness evidence.

3. Unless specified otherwise, page references to documents are to Relativity, rather than internal, numbering.

II. STRUCTURE AND ORGANISATION

Outline of SHHD structure

4. During the course of Penrose, a document entitled "*Penrose Inquiry – SHHD Structure – 1980 to 1991*" was created [PRSE0000358]. It is a useful source for understanding the SHHD's structure in this period and for the identity of relevant officials and ministers. It has also been referred to by two witnesses to this Inquiry.[1] The following points, arising from the document, are noted:

    a. The hierarchy of administrative officials in the SHHD was headed by the SHHD Secretary and moved down to Under Secretaries, Assistant Secretaries/Senior Principals and Principals/Senior Executive Officers. The way in which the SHHD was split into different groups and divisions is explained further below.
    b. The SHHD's hierarchy of medical officials was headed by the Chief Medical Officer ("CMO"), beneath whom were Deputy Chief Medical Officers ("DCMOs"), Principal Medical Officers and Senior Medical Officers.
    c. The Penrose document includes the names of some officials who were in post earlier than 1980. These include Dr Ian Macdonald and Dr Graham Scott (both DCMOs) and Dr Archibald McIntyre (Principal Medical Officer, in post from 1977 to 1993, and whose remit included the SNBTS). They also include Dr Albert (Bert) Bell, Senior Medical Officer with responsibility for blood services until 1985. Documents referred to below suggest that Dr Bell was in post from at least 1973.
    d. The Penrose document does not include the names of Scottish Office ministers in the 1970s. The available documents and public sources are not entirely clear on which junior ministers had responsibility for health in the 1970s, but they suggest that they were: Teddy Taylor (1970-71); Hector Monro (1970-74); Robert Hughes (1974-75); Frank McElhone (1975-79[2]); and Russell Fairgrieve (1979-81).[3] The Secretaries of State for Scotland were: Gordon Campbell (1970-74); William Ross (1974-76); and Bruce Millan (1976-79).

[1] Namely, Duncan Macniven [WITN7064001] and Lord Michael Forsyth [WITN7126001].
[2] It appears that Harry Ewing may also have had some responsibility for health during this period.
[3] See the 1974-1976 Civil Service Year Books [within WITN0001020], Hansard and the UK Parliament website.

Ministerial and administrative structure

5. In his IBI written statement and oral evidence, Duncan Macniven provided further detail on the structure and organisation of the Scottish Office and SHHD during his time as Assistant Secretary (1986-1989) [WITN7064001 from p.9 and INQY1000230 from p.5]. His evidence included the following:

    a. The Scottish Office was organised in a number of functional departments, including the SHHD.
    b. Each department was headed by a Secretary, who reported to the Permanent Secretary (the most senior administrative civil servant in the Scottish Office).
    c. Departments were divided into groups of divisions, headed by an Under Secretary. Each division was headed by an Assistant Secretary or Senior Principal.
    d. Group IV was one of two groups responsible for the health service (the other being Group V). Group IV "*essentially, dealt with the running of the Health Service*" and was *"more of a managerial group*", whereas Group V "*dealt with health policy and services, which were not run by the health boards and Common Services Agency*" [INQY1000230 p.10].
    e. Mr Macniven's Division was named IVD and was one of the four Divisions in Group IV.
    f. Divisions were generally divided into branches (though the terminology changed over time). Branches were usually headed by a Principal or Senior Executive Officer.
    g. In parallel, medical and other experts had their own hierarchies.
    h. Each department reported to one or more junior ministers, and through the junior minister to the Secretary of State.
    i. The junior minister with responsibility for health could be a Parliamentary Under-Secretary or Minister of State (the latter being more senior).

6. In his Inquiry witness statement, Lord Forsyth explained that ministerial responsibilities in the Scottish Office "*were allocated by the Secretary of State who remained in charge of policy and was kept fully informed of decisions made by junior Ministers and would,*

from time to time, intervene if he wished an alternative approach" [WITN7126001 §13.1].

Medical structure

7. In a written statement to Penrose, Dr Macdonald explained that, as a Medical Officer/Senior Medical Officer between 1965 and 1973, he had responsibility for the SHHD's "*medical interest in blood transfusion*" [PRSE0004162 §8]. At that time, the Scottish National Blood Transfusion Association ("SNBTA"), was responsible for the operation of the blood transfusion service, and the SHHD's medical officer "*held a position... with the curious title of Medical Secretary*". Dr Macdonald's recollection was that he spent about a third of his time on blood transfusion matters during this period.[4] He explained that "*issues relating to blood transfusion arising within or referred to SHHD would be passed to me for medical advice or opinion*" [§10].

8. Dr Macdonald further explained that, until 1974, the SHHD had one DCMO, to whom Principal Medical Officers reported [PRSE0004162 §4]. Each Principal Medical Officer "*headed a group of perhaps 3 or 4 Senior Medical Officers and Medical Officers and each PMO*[5] *group had a defined remit*". In 1974, "*a second DCMO post was created and I was appointed to that post. Responsibilities at that level had therefore to be divided so that some PMOs reported one DCMO and some to the other*" [PRSE0004162 §4]. The PMO group with responsibility for blood transfusion did not report to Dr Macdonald, though he had "*some awareness in broad terms of major developments*". When Dr Macdonald was appointed CMO in 1985, the SHHD "*reverted to the arrangement prior to 1974 and had only one DCMO*". As CMO from 1985 to 1988, Dr Macdonald had a "*total medical staff of perhaps 20 to 25 individuals*".

9. Dr Macdonald went to on to describe two practices which were "*intended to keep the CMO and DCMO(s) aware of the work in which medical staff were engaged and of any special or difficult situations that might be arising*" [PRSE0004162 §5]. These were:

[4] Mr Macdonald added that the "*head of an administrative branch in the Department also spent a significant amount of his time on blood transfusion matters*"
[5] I.e. Principal Medical Officer.

a. A meeting "*every Monday morning chaired by the CMO, or in his absence a DCMO, and attended by the PMOs heading each of our groups. ... These were quite informal meetings and notes were not made*".

b. A monthly report written by Senior Medical Officers and Medical Officers "*indicating briefly the activities in which they had been engaged during the month. These were passed to their PMOs and by them to the CMO and DCMO(s). It was then open to CMO and DCMO(s) to ask for more information on any particular matter*". Dr Macdonald added that "*[u]nfortunately these reports cannot now be found*".

10. Dr Macdonald explained that the "*remits of the PMO groups were, as a general rule, in sufficiently broad terms to ensure that any issue likely to arise would belong to one or other of these groups. Nevertheless, CMO or a DCMO might decide to take the lead on a particular issue, with support from the relevant PMO group, because it had some unusual significance*" [PRSE0004162 §6].

11. Dr Scott, in a written statement to Penrose, noted that he was appointed DCMO around 1974 [PRSE0002943 §1]. At that time, he was one of two DCMOs, alongside Dr Ian Macdonald. He explained that it was considered appropriate to have two DCMOs because the CMO at the time, Sir John Reid, was "*often absent from the Department as he was much concerned with WHO matters*". Dr Scott stated that, when he was appointed, he "*took over responsibility for all matters relating to the SNBTS*" and sat on the CSA[6] Management Committee, but that he "*only spent around 5%*" of his time on SNBTS matters. Dr Scott described himself as "*heavily reliant*" on Dr McIntyre and Dr Forrester.[7]

12. Also in a written statement to Penrose, Dr McIntyre explained that he was a Senior Medical Officer at the SHHD between 1974 and 1977, and Principal Medical Officer from 1977 to 1993 [PRSE0000915 §4]. His recollection was that, when he became Principal Medical Officer, there were four PMO groups. His was the Public Health Group and its areas of responsibility were communicable diseases and environmental health. He explained that he reported to the DCMO, "*Dr Scott (who had responsibility*

[6] I.e. the Common Services Agency, explained further below.
[7] Dr Forrester was a Senior Medical Officer in 1985-1988 and Dr Bell's successor.

for all CSA matters) and to the CMO, who from 1985 onwards was Dr Macdonald" [§6]. He added that he "*briefed the DCMO regularly and there was also briefing among the various PMO groups*". Dr McIntyre stated that "*[b]lood transfusion was only a very small part of my job*".

Relationship between administrative and medical officials

13. Dr Macdonald, in a statement to Penrose, described medical staff as being "*related to administrative colleagues as advisers*" [PRSE0004162 §7]. His evidence was that the medical staffing structure "*matched the administrative structure fairly closely. This facilitated the development of working relationships. While the administrative staff were ultimately accountable for expenditure the advice of medical staff would be taken into account whenever appropriate*". As an example, he suggested that, if medical staff had been persuaded that surrogate testing for non-A non-B hepatitis ("NANB hepatitis") "*was a reliable procedure which would give few false results (positive or negative) and be free from adverse effects they would have advised administrators accordingly and it would have been highly likely that funding would have been provided*".

14. Dr McIntyre's evidence was that it "*tended to be that action would be taken on the "administrative" side, by which I mean that recommendations and formal advice would be generated by our administrative colleagues. We fed that process by reporting back the outcomes of meetings which we attended as medical observers and providing medical advice generally. This was usually done by internal memoranda*" [PRSE0000915 §6].[8] He commented that the SHHD's medical officers had a "*very good relationship with our administrative colleagues at all levels and kept each other up to date*" [§5].

15. Alexander (often known as Sandy) Murray was a Senior Executive Officer and Head of Branch 3 of Division IVD between December 1983 and 1987. In a written statement to Penrose, he explained that he would be involved "*in the preparation of the first draft*

[8] Dr McIntyre added that memoranda "*placed on the official file would be retained in the usual way while those in the medical officer's personal files would be discarded when he left office*" [PRSE0000915 §6].

of a Ministerial submission for putting forward to senior officers, but would be guided and advised by medical colleagues who in effect provided the substance; I provided the form" [PRSE0002440 p.2].

16. Dr Scott, in a statement on surrogate testing for NANB hepatitis, described SHHD medical officers as being "*reliant on expert advice, such as that provided by the various working parties to which SHHD were invited to send observers*" [PRSE0002609].

17. Dr Forrester suggested in a written statement to Penrose that his role mainly comprised "*gathering information at Committees and elsewhere, and transferring it to the SHHD, and the reverse, as promptly and accurately and lucidly as I could.*" [PRSE0004061]. Similarly, in oral evidence he described his role as being a "*relayer of information and the gatherer of information from the different sources it could come in*" [PRSE0006066 p.11]. In the context of questions about surrogate testing for NANB hepatitis, he suggested that he "*would have thought it above his position to take an independent view*" on whether testing should be introduced, and instead that his role was to "*find people who knew*" [p.15].

18. In oral evidence to this Inquiry, Mr Macniven agreed with a suggestion that Dr Forrester would "*independently throw himself into a topic and do reading around it and come to his own views*", and stated that Dr Forrester "*saw it, and I saw it, as important that he should do so*" [INQY1000230 p.60]. His evidence was that Dr Forrester "*certainly listened to the SNBTS views... with great attention. But he would have wanted to make his own mind up about the matter, taking into account not only the assertions of the SNBTS, but also the evidence which he was able to bring to bear*".

Relationship between ministers and officials

19. In his Inquiry statement, Mr Macniven explained that, "*[i]n practice, most decisions were taken by the officials of the* [SHHD] *without reference to the small number of ministers, with only the most difficult or politically-contentious matters being decided personally by ministers*" [WITN7064001 §11.1]. Elsewhere in his statement and in oral evidence, he described the process by which ministerial submissions were prepared and how contact with ministers took place [WITN7064001 §§12.1-13.1; INQY1000230

p.32-37]. As for deciding whether to refer an issue to minsters, his evidence was that he recalled "*no set criteria. It was a matter of judgement whether at any given time it was necessary to refer a matter to ministers. That judgement would be exercised by the responsible official at or above Assistant Secretary – in consultation if necessary with more senior officials*" [WITN7064001 §13.1].

20. Mr Murray, in the context of a Penrose statement concerning the introduction of HTLV-III screening, described the factors which would lead to a minister becoming involved in an issue as follows [PRSE0002440 p.4]:

> *"An issue like this would normally be brought to Ministers' attention in the following circumstances: to keep Ministers aware of important current developments; if something was going to appear in the media; if a decision had to be made which officials considered only Ministers could make; if an interdepartmental dispute needed to be resolved; to bring together, in an overview submission, a number of issues affecting multiple divisions within a department, or multiple Departments; or where developments in Scotland affected UK departments and vice versa. When a Department considered an issue was of such importance that the final decision required to be made by the Secretary of State, the submission would be in the form of going first to the junior Minister concerned and then to the Secretary of State."*

21. In his written Inquiry evidence, Lord Forsyth stated [WITN7126001 §9.1]:

> "*Submissions concerning routine Health policy would be sent to me by officials and, depending on importance, copied to the Secretary of State. Cabinet level or less routine matters would be directed to the Secretary of State and usually copied to me. I would respond by writing my view on the submission and, if I had any concerns or issues, I would ask my private office to arrange a meeting to discuss them. These meetings would be minuted by my private Secretary and copied to relevant officials and if appropriate to the Secretary of State"*

22. Lord Forsyth added that officials "*would be responsible for the administration of agreed policy and were expected to draw to the attention of Ministers any issues of*

concern". In oral evidence, he explained that "*in the main, I would expect things to come to ministers which needed to be drawn to their attention and needed to have a decision*" [INQY1000231 p.23].

Budgets and funding

23. In his Inquiry statement, Mr Macniven addressed the process by which the SHHD budget was set during his time as Assistant Secretary [WITN7064001 §16.1]. His recollection was that the "*budget was set by means of a 3-year forward look (the Public Expenditure Survey) followed, with regard to the year immediately ahead, by the Supply Estimates which were approved by Parliament*". This process included a request from Division IV "*to the CSA for bids covering all of its functions, including the SNBTS*". Once scrutinised, the bids were amalgamated "*into a bid covering the whole of SHHD, which was in turn incorporated in Scottish Office-wide bid approved by ministers which was the subject of discussions with the Treasury, with the final decision being taken collectively by the Cabinet*".

24. Lord Forsyth explained that the "*determination of the budget and negotiations with the Chief Secretary to the Treasury were the responsibility of the Secretary of State. Bids would be made by each department with the relevant junior Ministers, including SHHD indicating their preferences and priorities*" [WITN7126001 §19.1]. He also noted that the Barnett formula "*provided the Scottish Office automatically with approximately 10% of any increase given to equivalent departments and responsibilities in England*".

25. A number of contemporaneous documents are available on the process by which SHHD budgets were negotiated and funds allocated to the CSA and SNBTS. For example:

    a. SNBTS funding was addressed in detail at a meeting of its Co-ordinating Group in October 1980, attended by Mr Morrison for the CSA [SBTS0000223_033]. This included discussion of the introduction of cash limits as a result of the Health Service Act 1980 and the importance of ensuring that spending fell within allocations. Mr Morrison explained during the meeting that "*the CSA received one overall allocation from SHHD, and within this allocation there was a base figure for each Division*".

b. In a July 1983 minute to Mr Kernohan in the Finance Office, John Davies (SHHD Assistant Secretary), described how he proposed to approach a 2% reduction in expenditure which he had been asked to implement following a statement by the Chancellor [SCGV0000049_120 and SCGV0000049_121]. He explained that he did not think it would be reasonable to impose a 2% cut on the ambulance and blood transfusion services and suggested that they be asked for a cut of 1%. A table attached to Mr Davies' note suggests that, in 1983, spending on the blood transfusion service was the third largest item in his Division.[9]

c. After the SNBTS's allocation for 1984/85 was set, officials corresponded directly with Professor Cash in 1984 in order to discuss the preparation of the SNBTS's estimates for 1985/86 and later years (see, for example, [SBTS0000149_113, SBTS0000616_015, SBTS0000501_195, SBTS0000501_246 and SBTS0000683_131]).

26. Further documents referred to below illustrate the process by which funding was sought and obtained in the context of particular issues.

III. RELATIONSHIP WITH UK GOVERNMENT

27. The nature of the relationship between the Scottish Office and the UK Government – and more particularly between the SHHD and DHSS/DoH[10] – is an important aspect of SHHD decision-making in the period considered in this presentation note.

28. In a written statement on the introduction of HTLV-III screening, Dr Macdonald described the SHHD's relationship with the DHSS as follows [PRSE0002766 p.2]:

> *"The way in which the government's health interests were distributed in the ministerial and departmental arrangements had a bearing on how significant*

[9] Capital expenditure on Health Boards was by far the largest, and spending on the ambulance service was around twice that on the blood transfusion service. See also an October 1983 letter from Professor Cash to the CSA, explaining that he foresaw "*major difficulties*" in making a required reduction of £115,000 in SNBTS running costs [SCGV0000133_081].

[10] During the course of 1988, the Department of Health and Social Security ("DHSS") was divided into two departments, one of which was the Department of Health ("DoH").

policy issues such as those arising from the emergence of HIV/AIDS were determined. In department terms a major role fell to DHSS, but the Scottish, Welsh, and Northern Ireland Offices (sometimes described as territorial departments) each had a health department within their arrangements in Edinburgh, Cardiff, and Belfast.

It was expected that DHSS, as a Whitehall department, would take the lead and that they and the 'territorial departments' would then implement a common policy, subject only to a modest degree of adaptation by the latter departments if required by local circumstances.

Staffing implications followed from this. DHSS had significantly larger numbers of both administrative and medical staff who could give their attention to health matters than SHHD. Consequently individual members of staff in DHSS could handle in greater depth a smaller number of issues than their opposite numbers in SHHD who had to spread their attention more widely."

29. Dr Macdonald was asked again in oral evidence about the relationship between the SHHD and DHSS during his time as CMO from 1985 to 1988 [PRSE0006066 pp.80-81]. His evidence included the following: "*I think the position, as ministers would have seen it, was that the DHSS would have been expected to take a lead on major policy matters and Scottish, SHHD, and the Welsh Health Department, would have been expected to fit their policy around that. In other words, there can be a bit of variation for local circumstances, but broadly the policy would be evolved in DHSS.*" Dr Macdonald went on to describe the involvement of Scottish members in expert advisory groups, commenting: "*On the whole, I think it worked reasonably well. I think the profession in Scotland was content with it. I think they would have been less than content if DHSS involved only their English colleagues, but they were sensitive to it and I think it did work quite well*".

30. In oral evidence to Penrose, Dr Scott stated that the SHHD "*had liaison with the DHSS at all kinds of levels. I would go down and attend the policy meetings of the chief medical officer of the DHSS and I would... listen to the discussions and then come back*" [PRSE0006049 pp.130-131]. He added that there "*would also be contacts at all*

levels, going backwards and forwards, talking to each other, what we were doing, et cetera. That doesn't mean to say if DHSS decided to do something, we would necessarily do it". Dr Scott's view on the relationship between the DHSS and SHHD in the context of the introduction of HTLV-III screening is described further below.

31. In his statement to this Inquiry, Mr Macniven described responsibility for the health service in Scotland as being "*entirely devolved to the Secretary of State and through him to the SHHD. The DHSS had no oversight role*" [WITN7064001 §16.1]. He added that, as "*a matter of good administration, SHHD and DHSS will have kept each other in touch with developments in one country which might affect the other*". If any significant disputes between the departments had existed, "*they would have been resolved by senior-level discussions, or in the end by contact between the relevant ministers*".

32. In oral evidence, Mr Macniven noted that, while legislative devolution from Westminster did not take place until the creation of the Scottish Parliament, there was a "*very large measure of executive devolution to the Scottish Office*" prior to that [IBI 19 July 2022 transcript p.6]. He added that, "*as a matter of good collective government*", the DHSS and SHHD "*needed to take care that we didn't embarrass each other*", and that they had "*quite close liaison in order to avoid embarrassing our ministers*" [p.39]. Mr Macniven's evidence was there were no occasions on which the DHSS "*overstepped the mark in advising or suggesting or pressuring*" the SHHD in what it could put to its ministers, that they "*wouldn't have tried to do that*" and that it was "*just not the way that business was conducted*".

33. Lord Forsyth, in his Inquiry statement, described health policy in Scotland as being "*a matter for the Scottish Office*" [WITN7126001 §27]. He stated that "*any serious disagreements*" between the DoH and SHHD "*would be resolved by senior officials or, if necessary, at Ministerial level*", adding that there "*were occasions when the DoH did not take into account of Scottish circumstances and moved ahead without proper consultation particularly around the issue of compensation*". In oral evidence, Lord Forsyth stated that "*broadly speaking, every Secretary of State used to say that they were Scotland's person in the Cabinet, not the Cabinet's person in Scotland. And that is how we operated...*" [INQY1000231 p.38].

34. The nature of the SHHD's relationship with the DHSS is explored further below in the context of particular issues. The contemporaneous documents illustrate that contact between the two departments took place in a number of different ways, including direct correspondence and meetings, as well as through attendance at meetings with other groups. This included SHHD officials observing meetings of Regional Transfusion Directors ("RTDs") in England and Wales, which were also attended by the DHSS[11], as well as later meetings of the Central Blood Laboratories Authority ("CBLA").[12] It also included visits from officials. For example, in March 1981, Dr Scott reported on a visit by the DCMO for England, Dr Harris, to SNBTS headquarters [SCGV0000127_009].

35. The extent to which the SHHD considered that it should – or was required to – adopt the same policies as the DHSS is an issue of particular relevance to decisions around the introduction of screening for HTLV-III, NANB hepatitis (through surrogate markers) and hepatitis C. It also arose in areas of more peripheral relevance to the Inquiry. For example, in an October 1981 minute to an administrative official on the question of charging the private sector for blood, Dr Bell wrote that, while "*there may be grounds for assuming that the small private sector in Scotland will accept any decisions which have been reached in the south, this would not necessarily apply to the SNBTS or to SHHD in relation to its blood transfusion interest*" [SCGV0000132_182]. He considered that it "*should be clear that neither SHHD nor the SNBTS could be committed by policies adopted by DHSS*", and that it "*may be that we shall find it acceptable to follow a uniform UK policy but in the field of blood transfusion nothing is predictable or non-controversial*".

[11] See, for example, Dr Bell's notes of such meetings in February 1978 [SCGV0000072_021] in February 1979 [SCGV0000072_005].
[12] See, for example, a May 1983 letter nominating Dr Bell as an observer [PRSE0000201].

IV. RELATIONSHIPS WITH OTHERS

With the Common Services Agency

36. The reorganisation of the NHS in Scotland, which included the anticipated creation of the CSA, was discussed at a December 1971 meeting of the SHHD Central Consultative Committee ("CCC") [SCGV0000070_035]. The steps that were subsequently taken to establish the CSA, as well its relationship with the SHHD and Scottish blood services, have been described in other evidence heard by the Inquiry: in particular, the presentation on the history and organisation of blood services [INQY0000307 pp.39-46]. These issues were also addressed in some detail in the Penrose Inquiry Final Report [PRSE0007002 §§17.13-17.75].

37. Witness evidence provides further insight into the CSA's relationship with the SHHD. For example, Mr Macniven's Inquiry statement includes the following [WITN7064001 §9.5]:

> *"The Common Services Agency (CSA) was not part of the Scottish Office. It was a statutory body, part of the health service, akin in governance to the 15 territorial health boards. It was essentially a holding company providing a wide variety of services to the territorial health boards or directly to the public – including blood transfusion, through the Scottish National Blood Transfusion Service (SNBTS), and also (for example) the ambulance service, legal services, building services and health education. The CSA was formally responsible to the Secretary of State for Scotland, who appointed its Management Committee. It had a close relationship with SHHD and in particular with my Division, which was responsible for appointments to, and general oversight of, the CSA as well as having a specific responsibility for the oversight of the SNBTS (and the Scottish Ambulance Service). Indeed, its Management Committee included two appointees from SHHD – the Group IV Under Secretary (who was my boss) and the Deputy Chief Medical Officer."*

38. In a written statement to Penrose, Mr Murray described the CSA as a "*composite entity, comprising all its Divisions together with such core offices as the Central*

Administration and the Treasurer's Department. The Divisions, such as the SNBTS and Scottish Ambulance Service, were essentially stand alone bodies, which technically fell within the remit of the CSA's management" [PRSE0001363 §2]. He explained that the functions of Branch 3 of SHHD Division IVD included co-ordinating the "*SHHD consideration of the annual omnibus financial bid by the CSA for each of its Divisions and functions*" and "*coordinating SHHD briefings for Department Under Secretary in connection with meetings of the CSA Management Committee*" [§3].

39. Mr Murray added that his routine communication would be "*with the Central Administration of the CSA or, less frequently, with the Treasurer's Department*", though he could be in direct communication with the SNBTS in certain circumstances [§6]. He also stated that on "*occasions SHHD medical staff communicated directly with SNBTS, with no involvement of CSA Central Administration*".

With the SNBTS and PFC

Overview

40. The SHHD's contact and relationship with the SNBTS is a key part of the evidence described in this presentation.

41. In written evidence to Penrose, Dr Macdonald explained that between 1965 and 1973 he "*chaired quarterly meetings in St Andrew's House of the five Regional Directors of the SNBTA*" [PRSE0004162 §9]. As reflected in the documents described below, SHHD officials continued to attend meetings of SNBTS directors in the remainder of the 1970s and the 1980s. They were also in regular direct contact with the SNBTS, most notably through Professor Cash.

42. Contact with the SNBTS appears almost always to have occurred through SHHD officials rather than ministers, though there appear to have been occasional exceptions. For example, at the 24 June 1980 meeting of SNBTS directors, attended by Dr Bell and Mr Finnie for the SHHD, it was reported that "*Russell Fairgrieve, Minister for Health and Social Work, had a particular interest in the blood transfusion service and would be pleased to assist with donor publicity*" [SBTS0000090_036]. It was suggested that

Mr Fairgrieve "*might be invited, as a first step, to pay recess visits to the PFC and a Donor Centre*".

43. In his written Inquiry statement, Mr Macniven stated that the "*SHHD – both my Division and the CMO's staff – had a close relationship with the SNBTS, reflecting the importance to the health service of its work*" [WITN7064001 §31.1]. He explained that the SHHD Under Secretary and DCMO were members of the CSA's governing body and "*attended its formal meetings (at which SNBTS matters were discussed) and of its Blood Transfusion Service Committee*". A member of the CMO's staff also "*attended the quarterly meetings of the SNBTS directors*". As well as these formal links, Mr Macniven explained that there was frequent contact between the SHHD and SNBTS, mostly though Professor Cash. The SHHD's and CSA's relationships with the SNBTS were "*less overlapping than hierarchical: the SNBTS was part of the CSA which, like the rest of the Scottish health service, reported through SHHD to ministers*" [PRSE0002666 §5].

44. The available documents suggest that most of the SHHD's contact with the PFC took place through the wider SNTBS, though there were sometimes direct communications: see, for example, an October 1981 letter from Mr Watt to Dr Bell providing specifications for a number of blood products [CBLA0001467]. Mr Watt also appears, in 1982, to have resisted SHHD attempts to prevent or limit his direct communication with the DHSS [SBTS0000473_069].

SHHD-SNBTS tensions

45. Difficulties in the relationship between the SHHD and SNBTS – and in particular with Professor Cash – were referred to by a number of SHHD witnesses in the Penrose Inquiry. For example, Dr Scott suggested that Professor Cash, "*where possible, would be critical of SHHD, no matter what they did*" [PRSE0006049 p.136]. In a written statement on surrogate testing for NANB hepatitis, Dr Scott commented that the SNBTS "*were always keen to secure more funding, and were often disappointed. Their applications were always considered carefully, but often sought unrealistically high amounts. SNBTS appeared to highly dislike the CSA Management Committee*" [PRSE0002666 §5]. Dr Macdonald, while noting that he was not directly involved at the time, commented that he understood the relationship between the SNBTS and

SHHD around 1986-1987 to be "*a little difficult*" and that there was "*an uneasy relationship*" [PRSE0006066 p.144].

46. Mr Macniven's Inquiry statement described "*longstanding tension between the SNBTS and SHHD*" which pre-dated his time as Assistant Secretary [WITN7064001 §32.1]. He expanded on this in oral evidence, in particular in relation to Professor Cash's role [INQY1000230 p.47-61].

47. Tension in the relationship between the SHHD and SNBTS is reflected in a number of contemporaneous documents. For example, a note by Dr Harris of an April 1981 visit to Scotland described a long-standing labour dispute at the Edinburgh RTC, with which the SHHD had become involved, and stated that a "*fallout of the dispute has been the deteriorating relationship between Dr Scott and Dr Cash*" [SCGV0000001_019].[13]

48. Difficulties also appear to have arisen in 1983 in relation to Medicines Inspectorate reports on the SNBTS. Dr Bell was highly critical of a letter Professor Cash had written on this issue in a June 1983 internal SHHD minute [SCGV0000270_015 and PRSE0000830]. He described one part of the letter as "*typical of the exaggerated claims which unfortunately so often discredit Dr Cash's campaign*", suggested that another involved "*the SNBTS at its most typically arrogant*", and concluded by commenting:

> *"I dare say Dr Cash is trying to cope with the difficult problems of the transfusion service in his somewhat unenviable position, and he seems to believe that putting everything into the hands of the Medicines Inspectorate would make life easier. Possible it would if we had a bottomless pit of money and believed that the SNBTS knew best how to spend it efficiently and effectively. This not being the case we have to look to other means of helping to resolve some of the genuine problems of resource allocation and use in the SNBTS, and I imagine that Mr Wastle*[14] *would point first to the need for better financial management on the part of the CSA."*

[13] While the reasons are unclear, Professor Cash also expressed an intention to resign as the SHHD's consultant adviser in blood transfusion in April 1981 [RCPE0000391_002], before deciding later in the year to accept a continuation of his appointment [RCPE0000391_003].
[14] Mr Wastle was a Senior Executive Officer at the SHHD and Alexander Murray's predecessor.

49. Strain in the relationship between the SHHD and SNBTS appears again to have come to the fore following Dr Bell's replacement by Dr Forrester, in the context of PFC studies to validate the effectiveness of its heat-treatment programme in inactivating HTLV-III (sometimes referred to as "spiking experiments"). Professor Cash explained the background to this work in a December 1985 letter to the CSA, requesting funds to enable it to begin and explaining that a key missing element was a high risk laboratory in which the work could be carried out [SBTS0000496_163].

50. The SHHD's response to this request appears to have led Professor Cash to write to Dr McIntyre in January 1986 to express his "*grave concern at the way colleagues in SHHD have been put in a position (and appear to have accepted this position) in which they are prepared to challenge the professional competence of my senior scientific and medical staff*" [PRSE0002563]. In a further letter in February 1986, following a visit from Dr Forrester, Professor Cash wrote that this was "*the second time since I was appointed NMD and Consultant Adviser to SHHD on Blood Transfusion in 1979 that the traditional close professional liaison between SHHD and the SNBTS has abruptly and unexpectedly broken down*" [PRSE0003084].

51. This correspondence appears to have been the background to a 9 February 1986 letter from Dr Forrester to Dr Perry (PFC Scientific Director), in which he referred to correspondence from Dr McIntyre and wrote: "*I am sorry if you supposed that your scientific integrity or competence has been impugned; you will by now realise that that is not the case*" [PRSE0001098]. In an 18 March 1986 minute to Dr Macdonald on the issue, Dr McIntyre described a concern that Professor Cash might "*once again*" be adopting "*his divide and rule*" tactic in relation the SHHD's medical and administrative officials [SCGV0000215_094].[15]

52. Later in 1986, Professor Cash raised further concerns about Dr Forrester. In a 21 August 1986 letter to Hugh Morison (SHHD Under Secretary), he wrote: "*I must once again request that consideration be given by appropriate colleagues in SHHD to give Dr J M Forrester duties which do not include an interface with the Scottish Transfusion*

[15] Issues related to the PFC's validation studies continued to be considered over subsequent months, until it was agreed around April/May 1986 that, with additional measures in place, the spiking experiments could be carried out in the PFC's high security microbiology laboratory [SCGV0000215_094, PRSE0003127, SCGV0000215_003, PRSE0003172 and SCGV0000215_079].

Service" [PRSE0004596]. The letter appears to have been prompted by comments made by Dr Forrester regarding endotoxic shock/overwhelming coliform septicaemia, which Professor Cash regarded as "*bordering on insulting*" and as revealing "*a depth of scientific/medical understanding that was remarkably and disturbingly shallow*".

53. Professor Cash described this "*most recent episode*" as having "*all the hallmarks of the events which took place in late 1985 which led to a 6 month delay in the AIDS validation studies of our plasma derived blood products, a delay which would have been much longer without the intervention of yourself and the CMO*". He stated, "*with regret*", that the SNBTS directors had "*little or no confidence in the person who currently provides the vital medical link between the operational part of the Blood Transfusion Service and the SHHD*". While accepting that the fault did not lie entirely with Dr Forrester, Professor Cash suggested that the SNBTS had "*never had this type of difficulty with Dr Forrester's predecessors*".[16]

54. The SHHD response to Professor Cash's letter came from Dr Macdonald in October 1986 [PRSE0002521]. Dr Macdonald explained that he would not be arranging to replace Dr Forrester at this stage, and that the latter "*was not involved in any way in the policy considerations which led to the delay in the AIDS validation studies*". He described Dr Forrester as a "*knowledgeable and experienced doctor who applies himself with great diligence to his duties*" and stated that this was "*the first complaint about him that has come to my notice*". He added that the "*highly unfavourable conditions of service in the Medical Civil Service*" had led to the departure of some very experienced colleagues, and that the Department was "*operating four Senior Medical Officers under strength*". Dr Macdonald concluded by alluding to a history of difficulties in the relationship between the SHHD and SNBTS: "*As you recognise the BTS has never been the simplest organisation to deal with – for many, many years – and several of us have the scars to prove it*".

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[16] While the documents outlined above indicate that difficult relations between Professor Cash and SHHD medical officers pre-dated Dr Forrester's arrival, and that Dr Bell was critical of Professor Cash, there is evidence that Professor Cash was more positive about Dr Bell. See, for example, a January 1981 letter to Dr Lane, in which he suggested that Dr Bell be invited to a fractionation workshop and described him as "*pretty knowledgeable*" [CBLA0007642]. See also the minutes of the 15 May 1985 minutes of the Haemophilia and Blood Transfusion Working Group, attended by Professor Cash and chaired by Dr Macdonald of the Glasgow haemophilia centre [PRSE0003930]. Dr Bell, who was leaving the SHHD, was thanked "*for his excellent service to the SNBTS*", with the Chair acknowledging his "*considerable help and efficiency to all aspects of the Scottish Health Service but particularly the SNBTS*".

55. Strains in the SHHD-SNBTS relationship reappeared at other times. They were, for example, discussed at a meeting on 30 November 1988, described in a letter from Professor Cash to Mr Hamill (SSHD Under Secretary) on 20 December 1988 [SBTS0000187_032]. Professor Cash wrote that he had learned a number of things at the meeting, one of which was that "*it would appear that the SNBTS...has over a number of years, outrageously tormented both the good doctors Ian Macdonald and Graham Scott.*". Professor Cash further noted that comments made at this meeting confirmed his view that "*all is not well with the relationships between the Main Board and the Operational Team.*"

With haemophilia centre directors

56. The SHHD's contact with Scottish haemophilia centre directors appears primarily to have taken place through its attendance at meetings of SNBTS and haemophilia directors, which it chaired. These meetings were generally held annually but their frequency varied: for example, there were two meetings in 1977 but no meeting appears to have taken place between 1978 and 1980.[17]

V. SELF-SUFFICIENCY AND THE SUPPLY OF BLOOD PRODUCTS

57. This section addresses the SHHD's involvement in issues relating to self-sufficiency and the supply of blood products. It should be read in the context of evidence previously considered by the Inquiry: in particular, the March 2022 presentation on self-sufficiency and domestic production of blood products in Scotland and Northern Ireland ("the self-sufficiency presentation"). It seeks to set out evidence additional to that considered in the self-sufficiency presentation, focusing on SHHD decision-making.

[17] For examples of minutes to 1987, see: 1975 [CBLA0000275 and PRSE0002823]; 1976 [PRSE0000983]; 1977 [PRSE0003415 and PRSE0002273]; 1981 [PRSE0000144]; 1983 [PRSE0001736]; 1984 [PRSE0002066]; 1985 [SBTS0000829]; 1986 [PRSE0001081]; and 1987 [PRSE0002769].

Self-sufficiency and supply

Early 1970s[18]

58. In 1970, the Central Consultative Committee on Blood Transfusion ("CCC") was established. It appears to have been created to report to the SHHD and its meetings were attended by SHHD officials. The minutes of the first meeting on 2 July 1970 record that members were welcomed by Mr Elliott-Binns on behalf of the Secretary of State [SCGV0000070_059].

59. As well as attendees from the SHHD, the CCC included Scottish transfusion directors and others. The minutes of the 2 July 1970 meeting record that the CCC "*had been formed in the knowledge that the Blood Transfusion Service was expanding, and that substantial changes could be expected as a result of the Zuckerman Committee Report*". Its terms of reference were to advise the Secretary of State and the SNBTA "*on the policy and forward planning of the blood transfusion service generally including scientific and technical development, and on the staffing structure and overall production and financial policies of the Liberton Protein Fractionation Centre*". A sub-committee for the management of the PFC was established at the July 1970 meeting, with Mr Watt as an ex officio member. The CCC discussed its role in relation to PFC further at its second meeting on 22 September 1970 [SCGV0000070_053].

60. At the CCC's 16 November 1970 meeting, some concern was expressed over the timetable for building the Liberton site [SCGV0000070_048]. The meeting also discussed production levels of blood products.

61. The management structure of the PFC and Scottish blood transfusion service was discussed at the CCC's 4 February 1971 meeting, when it was recommended that a national medical director be appointed [SCGV0000070_046]. It was also agreed that "*if the PFC was temporarily unable to cope with any aspect of production, the assistance of outside commercial agencies could be sought as an interim measure*". At

[18] For material relating to the SHHD's position in the 1960s, see Dr Macdonald's written evidence to Penrose [PRSE0000304 and PRSE0004162].

the 21 April 1971 CCC meeting, it was suggested that "*submissions to the Secretary of State should be made simultaneously by the CCC and Executive Committee to enable the strongest possible case for a national medical director with consultant grading to be put to the Advisory Committee on Consultant Establishments*" [SCGV0000070_043]. The meeting also discussed different bodies' responsibility for levels of production of blood products:

> *"The Regional Directors had felt that difficulties might arise in future over priorities for production, and sought guidance on where responsibility lay in this matter. Members were of the opinion that responsibility for identifying production priorities must remain with the Directors but that the responsibility for implementation of their recommendations should lie with the CCC. In particular, any question of the introduction of material involved high risk eg, an antibody to the hepatitis antigen, would have to be referred to them. The problem lay in the fact that the Directors would be under pressure to produce substances which might or might not be effective and it was felt that they should not be placed in a situation where responsibility for taking the decision was left entirely with them."*

62. Further discussion of the timetable for the Liberton site and the management of blood services, including the role of PFC's scientific director, took place at the 28 September 1971 CCC meeting [SCGV0000070_038].

63. At its 16 May 1972 meeting, the CCC discussed the supply of factor concentrates and agreed to set up a working party to consider the production and evaluation of factor VIII and IX products [SCGV0000070_030]. It was noted that the PFC "*had recently decided to concentrate on production of super concentrates and were almost ready to release material for clinical trials.*" The minutes also recorded that "*[a]lready one American commercial firm was preparing to introduce a new Factor VIII product. Dr Wallace felt that the Service had a responsibility to the Haemophilia Societies and that Scotland already had experience, material and facilities to start on clinical trials*".

64. By the time of the CCC's 10 October 1972 meeting, the working party had reported that approximately 30,000 donations of blood per annum would be required for the

production of factor VIII concentrate, that large quantities of factor IX products should be prepared, and that there was a "*need for extended clinical trials of coagulation factors*" [SCGV0000070_028].

Arrival of commercial concentrates and Anglo-Scottish planning

65. At a March 1973 CCC meeting, it was suggested that the figure of 30,000 donations per annum for the production of factor VIII concentrate "*was probably an underestimate now*" [PRSE0003570]. The arrival of commercial products was highlighted again: it was said that the "*situation was further compounded now because a commercial super-concentrate had been licensed for sale in this country at a high price; there was to be a meeting at DHSS on 20 March to discuss the matter*". Ahead of that meeting, the SHHD wished "*to know the Scottish objective.*"

66. The minutes further record that it "*was hoped that there would be a step-up of production of Factor VIII and that in the meantime although the commercial material might require to be used it would only be in very small quantities.*" It was said that the "*situation was an evolving one and although 30,000 donations might have been the correct figure six months ago 50,000 was perhaps a more realistic figure now.*" It was suggested that the facilities at the new Liberton site "*would be more than adequate to provide all the Factor VIII products required*". The meeting agreed that "*if commercial concentrates had to be provided it should be by central purchase but that distribution should be made by the Haemophilia Centres not through BTS Centres*".

67. The licensing of imported commercial factor VIII was addressed further in a 28 March 1973 letter from Dr Macdonald to Senior Administrative Medical Officers ("SAMOs") (copied to various others including haemophilia directors) [PRSE0004351]. The letter noted that consideration was being given to likely trends in haemophilia treatment and UK production of blood products, and referred to the recent grant of licences to two firms for commercial AHG concentrate (i.e. factor VIII). Dr Macdonald did not refer to any issues relating to the viral safety of this product. Instead, the letter appears to have focused on its expense. Dr Macdonald wrote it had "*come to the notice of the Department that one of the firms is already engaged in active promotion of this expensive product. The purchase of these products could result in very significant*

expenditure". He added that "*in view of the impending availability of foreign human AHG concentrate and its very high cost you may like to let all concerned with the treatment of haemophilia in your region know what is happening*".

68. The impact of commercial concentrates and Scottish production levels were discussed again at the 27 June 1973 CCC meeting [SCGV0000070_022]. The minutes record that, since the CCC's previous meeting, "*the Factor VIII situation had been complicated by the availability of imported foreign commercial products which had received licences from the Medicines Commission*". The positions in Scotland and England and Wales were contrasted and emphasis placed on the financial implications of importing concentrates. It was said that in Scotland "*the supply of Factor VIII was fairly satisfactory but the position was not so encouraging in England where, because of lack of supply there was a significant market for the commercial products. It had been estimated that it could cost as much as £2,000,000 a year if the commercial products were provided for haemophiliacs*".

69. The minutes suggest that Scotland "*was meeting its own demands for Factor VIII and was likely to be able to do so for the next few years; England on the other hand was not self-sufficient and produced less per head of population than did Scotland*".

70. It also was noted that these issues had been discussed at the recent first meeting of the Joint Working Party on Blood Products Production ("JWP"), which had been "*set up as a result of an agreement made in 1964 between the Health Departments that there should be two centres for the production of blood products*".[19]

71. By the time of the 16 October 1973 CCC meeting, concern was being expressed at an apparent lack of progress in the JWP and different rates of progress in Scotland and England and Wales were noted [SCGV0000070_020]. A meeting due to take place on 26 October had been postponed, and this postponement "*was seen as a serious delay*". The minutes record that it had been "*clear from the discussion at the last meeting that Scotland had already reached its proportion of the intermediate of collections required to produce material for the treatment of haemophilia and the next step had to come*

[19] It had been agreed, at an 8 February 1973 meeting between the SHHD and DHSS, to establish a Joint Working Party on Blood Products to consider UK production [SCGV0000074_101].

from England". It was suggested that "*[d]efinite information about whether England wanted to increase production to meet the expected clinical demand was required. Commercial material was being used and the danger of a commercial take-over was feared*".

72. There was also discussion of whether the PFC site should be extended in order to be able to meet English needs. It was noted that the "*PFC building as it stood was more than adequate to meet the needs of the Scottish regions*" and that Treasury approval would be needed to proceed with an extension. It was agreed that the SHHD:

> *"should inform DHSS that the time scale had shortened and that information was urgently required if a financial year was not to be lost; a clear declaration of intent was needed to support an application to Treasury. If it was clear that this information was not forthcoming within a short time DHSS should be advised that the CCC recommended that the PFC plans for Scotland must go ahead immediately and that unless English support was given now there would be no guarantee that in a few years time the PFC would be able to meet England's requirements".*

73. Some of the difficulties that had emerged in the relationship between Scotland and England and Wales in the production of blood products were addressed in a 31 October 1973 minute from Dr Macdonald to Dr Bell [SCGV0000074_036]. Dr Macdonald explained that the DHSS had suggested that there was "*no point*" in holding a further meeting of the JWP (referred to here as the Joint Steering Committee) in the immediate future because "*they had not been able to resolve the questions of how much raw material would be available for processing and whether they would be willing to put an additional investment into Liberton in order to do it*". At this time, the focus of DHSS-SHHD discussions was on the production of plasma protein solution (an albumin product). However, Dr Macdonald linked that issue to the broader question of the relationship north and south of the border:

> *"... it seemed to us that the first question[s] to be answered were not the technical ones about production methods, availability of plasma etc. The first question to be answered is whether, in the United Kingdom, we are to aim at a*

comprehensive Blood Transfusion Service including a sufficient production of the full range of blood products or if we are to be dependent to a greater or lesser extent on imports of blood products. I pointed out that the importing of blood products had changed the situation dramatically and we could no longer attempt to control a "closed" situation in which the availability of any given product could be determined centrally and the usage held to that level."

74. On 6 November 1973, Dr Macdonald wrote again to SAMOs and others regarding the supply of factor VIII concentrate [PRSE0000432]. He explained that the DHSS Supply Division had negotiated the supply of commercial product from two firms to enable haemophilia centres to purchase it, and reminded SAMOs of the arrangements "*whereby the SNBTA prepares and distributes AHG and cryoglobulin precipitate for the treatment of haemophilia*". Dr Macdonald added that the SHHD, "*in close co-operation with DHSS, is considering ways of increasing NHS production of AHG concentrate*".

75. Correspondence between the DHSS and SHHD continued. For example, Dr Bell addressed PFC's capacity in a 22 November 1973 letter to Dr Waiter [DHSC0103209_107]. He explained that the PFC was "*briefed for a process capacity 1,500 litres plasma (7,500 donations) a week*", but that because of "*cuts in the brief and reallocation of storage space*", changes would be required in order for the PFC to process that amount of plasma. He went on to suggest that the PFC's capacity could be increased beyond 1,500 litres a week, either by extending working hours, or by extending the plant. Dr Waiter later provided Dr Bell with a note of a visit by the DHSS to the PFC in October 1973 [SCGV0000074_027].

76. In a 7 December 1973 minute to Miss Macdonald at the SHHD, Dr Macdonald suggested that "*the ideal solution would be… to build a second BPL in England*" [SCGV0000074_028].

77. The impact of licences being granted for commercial factor VIII was discussed further at the 31 January 1974 CCC meeting [SCGV0000070_017]. The minutes record that "*[f]ears had been expressed recently about the appearance of commercial blood products on the market and the consequent threat to the BTS. The Department were*

concerned about the developments and since the blood transfusion service in the UK was involved arrangements were being made for a high level meeting with DHSS".

Mid-1970s: uncertainty over Anglo-Scottish planning

78. Further discussion of the manufacture of blood products in Scotland and the PFC's role in UK production took place at the 14 March 1974 CCC meeting [SCGV0000070_015]. It was noted that there continued to be uncertainty on the question of whether PFC would process English plasma. The CCC "*felt that an ultimatum should now be put to DHSS and that if a decision on the English requirements from the PFC was not forthcoming soon the matter would be referred to Ministers and that this should strengthen any discussions which the CMO might have with DHSS*".

79. A report on the ongoing discussions between the SHHD and DHHS was subsequently provided at the 13 June 1974 CCC meeting [SCGV0000070_012]. The DHSS was said to be "*totally committed to the voluntary donor principle, would not wish it to be eroded and would be prepared to consider the introduction of legislation if it was in danger*". The *"aim of the two departments was to achieve self-sufficiency as soon as the necessary financial resources could be made available*".

80. Once the question of additional funding in England had been clarified, "*consideration would be given to the issue of a circular later in the year affirming the policy of self-sufficiency and the provision of resources to enable this end to be achieved. It was thought that such a statement would go some way to discouraging commercial firms from committing themselves too deeply in the blood products field*". As for the purchase of commercial products, "*[e]verything pointed to the commercial sales of Factor VIII being less than had been expected*".

81. By the time of the 10 October 1974 CCC meeting, no further JWP/JSC meeting had taken place and it was reported that "*DHSS had not yet resolved their difficulties*" [SCGV0000070_008]. The CCC also discussed production and supply in Scotland. Concern was expressed about the low stock position for various blood products during PFC's transition from the Royal Infirmary Edinburgh to the Liberton site, and it was recommended that PFC be given authority to purchase and distribute commercial

fractions. Reference was also made to "*unnecessarily emotive articles in medical journals about the Factor VIII situation.*" The CCC was reassured that "*no haemophiliacs in Scotland were going without AHG although albumin and PPS were in short supply*". However, if material was not available "*commercial sources would require to be used*".[20]

82. Concern at the apparent slow progress in commissioning the new PFC site and increasing production of factor VIII was discussed amongst SHHD officials in early 1975 [SCGV0000070_069 and SCGV0000070_070]. At the 12 March 1975 meeting of SNBTS directors, attended by Dr McIntyre and Mr Roberts, it was agreed that "*the stock held at PFC could be called upon in an emergency*".

83. DHSS and SHHD officials continued to consider the relationship between production of factor concentrates in Scotland and England and Wales in the second half of the 1970s, including as a result of direct ministerial requests. For example, a 22 January 1976 DHSS minute, copied to Dr McIntyre, recorded the Minister's[21] concern that there "*should be maximum co-operation between all concerned in Scotland and England with the production at Elstree and Liberton of AHG*" [CBLA0000334].[22]

84. Similarly, a 3 March 1976 note by Mr Roberts, following a telephone conversation with Mr Dutton of the DHSS, recorded that "*DHSS were under increasing pressure from their Minister of Health (Dr Owen) about the production etc of anti-haemophilia fraction Factor VIII*" [SCGV0000114_053]. It was agreed that an existing expert group on haemophilia would look at the issue. Mr Roberts further recorded that "*[i]t was put to Mr Dutton that we in Scotland would not necessarily be able to commit ourselves to following a line discussed in London without putting it through the existing advisory machinery*". Mr Dutton followed these issues up in a letter to Mr Roberts the following day [SCGV0000114_049].

[20] Note that the CCC appears to have been disbanded and part of its role taken over by the Scottish Health Service Planning Council Blood Transfusion Advisory Group ("BTAG") [SCGV0000079_007], though the BTAG seems to have met a limited number of times before being disbanded around 1978/79 [SCGV0000080_028, SCGV0000080_015, SCGV0000080_013 and SCGV0000080_007].
[21] I.e. David Owen.
[22] Mr McLean wrote in response to this minute on 28 January 1976 [SCGV0000114_060].

85. In a 16 March 1976 minute to Mr Roberts and Dr Scott, Dr McCreadie commented that it was important for Scotland to be represented on this expert group [SCGV0000114_046]. He noted that Scotland's production was based on targets which the expert group originally set in 1973 and commented that "*it is rather interesting that our target production is very much higher than that of England and Wales for the 410 haemophiliacs which we have in Scotland*".

86. In a minute to Dr McCreadie that same day, commenting on a paper which described the reactions of Scottish clinicians to PFC factor VIII, Dr Scott outlined his understanding of the relative risks of viral infection in Scottish and commercial concentrates [SCGV0000114_045]. He explained that he was concerned about a suggestion that the PFC product did not always produce the expected haemostasis and that the factor VIII content could be as low as 50% of the stated amount. He went on to comment: "*The only way in which our product seems better than the commercial products is in its freedom from hepatitis (at least relatively) and this arises from circumstances and has nothing to do with the PFC itself.*"

87. Dr McIntyre commented on this minute the following day [SCGV0000114_044]. The available copy is faint but it appears to suggest that the comment regarding the quality of PFC factor VIII "*had been made in the early days and was based on a single assay*". In relation to the supply of PFC factor VIII, Dr McIntyre suggested that the "*real problem*" seemed to rest with the haemophilia directors in the West of Scotland, who were said to differ from the rest of the country "*not only in their preference for cryoprecipitate but also in the number of units that they use to treat any particular patient*", which resulted in less fresh frozen plasma being sent to PFC. He added that it was "*not for us to decide what clinicians should use but an agreed policy will be required to be worked out with them*".[23]

Shift working and plasma availability

88. As explored in the self-sufficiency presentation, whether or not shift working could be introduced was a significant issue for the PFC and the possibility of Scotland processing English plasma. These issues were explored in a paper sent by the SHHD to the DHSS

[23] Dr Scott responded to Dr McIntyre on 18 March 1976 [SCGV0000114_043].

in January 1977 [SCGV0000001_195 and SCGV0000001_196]. A meeting to discuss shift working with representatives of various departments, including the Civil Service Department, subsequently took place on 25 January 1977 [DHSC0000923].

89. On 5 February 1977, an official at the Department of Employment wrote to Miss Lemond at the SHHD to inform her than an improved pay offer could not be made to enable shift working to be introduced [SCGV0000001_169]. The letter recorded that "*in spite of the public expenditure arguments which you advanced we still consider that the pay policy objections to any improvement in the existing offer are of overriding importance. The only consolation I can offer is that the Centre is not unique in representing an investment of public capital which cannot be fully utilised because staff are unable to accept the constraints of pay policy*".

90. In March 1977 the SHHD sought to persuade the Department of Employment to re-consider its position [SCGV0000001_170]. The reply the SHHD received made reference to a future review of pay policy generally, but stated that, in any case, there "*still seem to us to be objections to an improved offer at the PFC. There would inevitably be repercussions on the rest of the NHS and, more important, the Civil Service, whose rates form the basis of the current offer*" [SCGV0000001_171].

91. In a 25 April 1977 letter, Mr Roberts informed Mr Dutton that the SHHD had "*regretfully... come to the conclusion that, in the present circumstances, which do not allow a shift system to be introduced, it will not be possible to increase production at the PFC to a level which would allow the processing of plasma from England*" [DHSC0001766].

92. Nonetheless, officials continued to discuss these issues: see, for example, a 23 October 1979 meeting between the SHHD and DHSS "*to discuss mutual problems*" [SBTS0000216_163]. They also shared information: for example, in January 1980, Mr Dutton wrote to Mr Finnie at the SHHD, having previously provided a copy of the DHSS ministerial submission, to inform him of the Minister's decision on the future of BPL [DHSC0002313_020].

Early 1980s

93. As explored in the self-sufficiency presentation, the possibility of PFC fractionating plasma from England was revisited in the early 1980s. In a 24 September 1980 minute to Mr Macpherson, Dr McIntyre commented it was important "*to keep in mind that at the time the PFC was being planned our perception of the future needs for blood products was at least twice that considered necessary by DHSS*" [SCGV0000127_039]. He added that "*there was considerable opposition to the scale on which we were planning and a paranoid delusion still exists in this office that the DHSS views were partly responsible for the skimp financing of the project by Treasury. The effect of cutting cost corners is now beginning to show*".

94. Dr McIntyre suggested that, if the PFC were to fractionate any English plasma, it would do so on a contractual basis, before commenting:

> *"The PFC must not be considered as a unit of a UK scheme and subject to overall UK direction. This is not said in any political nationalistic sense but relates to the fact that blood is voluntarily donated, that we are virtually self-sufficient in blood products, that we fractionate to a level considered necessary for the Scottish situation etc."*

95. In a 9 December 1980 letter to Mr Macpherson, Mr Harley of the DHSS commented that it would "*seem sensible to plan for the PFC and BPL jointly to provide for the needs of the blood transfusion services of all four UK countries*" [DHSC0003715_088]. He recorded the view of DHSS that it was essential for a shift working experiment at PFC to be carried out without delay.

96. In a note of a meeting of the NBTS Advisory Committee on 23 February 1981, Dr Bell reported that DHSS ministers "*had gone firm on planning for a new BPL on the same site*" [SCGV0000082_041]. He explained that he had not raised "*the question of planning BPL in relation to the PFC's role UK fractionation in open committee, because of our vulnerability to adverse comment about the time taken to deal with the Medicines Inspectorate's Report and the need to follow up our inter-Departmental meeting at officer level*". He suggested that the SHHD might wish to obtain a copy of

the DHSS ministerial submission and to clarify "*the collaborative mechanism whereby development of the two major fractionation centres will be co-ordinated*".

97. Dr Bell also suggested that an "*inhibiting feature of this kind of meeting, embracing as it does a number of English health service interests, is trying to avoid embarrassing exchanges between Government Departments which can otherwise be carried out at officer level*". He further reported that a working party was being set up to advise on the need for a plasmapheresis programme in England and Wales, and that Professor Cash had expressed an interest in relation to Scotland.

98. In a 27 February 1981 response to Dr Bell, Dr McIntyre expressed concern at the suggestion that plasmapheresis was being explored and suggested that it was linked to factor VIII use, which he seems to have regarded as excessive [SCGV0000082_039]:

> *"Off and on for a number of years I have expressed concern that with regard to haemophilia and Factor VIII production the focus seems to be on only one side of the equation. The emphasis tends to be on ever increasing production of Factor VIII to meet the demand brought about by the policies, set by clinicians and others, which require larger doses partly for medical reasons and partly to allow the patient to enjoy a fuller life. While this question has been raised in discussion from time to time and is apparently appreciated by others it does not seem to affect the activities of those clinicians who have become the pacesetters. No one denies that everything possible must be done to ameliorate the lot of sufferers of haemophilia but this must be kept within reasonable bounds. This is particularly important as the increase in Factor VIII consumption seems to be out of all proportion to the additional benefits achieved. So far we have not been able to get any indication of the proportion of haemophiliacs who are "severe" and the proportion of the Factor VIII supplies they use."*

99. Dr McIntyre was concerned that moving from routine donation to plasmapheresis would deter donors. He commented that the UK was fortunate "*in having such a public spirited group of blood donors but we must be careful not to push them too far*". He also suggested that the frequency of donation suggested in a paper presented to the NBTS Advisory Committee meeting might "*lead to the slippery slope to the paid*

donor". Dr McIntyre added that, in planning for plasma collection, the SHHD should not be "*blinded by the arithmetic of how much plasma is required to meet the very heavy (? unnecessary) demands for Factor VIII being made by certain haemophilia clinicians who have no responsibility for the collection of the basic raw material*".

100. Dr Scott expressed similar views regarding plasmapheresis and factor VIII, though he appears to have believed that the amount of material used was the result of patient rather than clinician demand [SCGV0000082_040]:

> *"I think the haemophiliacs as a group contain certain elements mainly parents whose ideas are totally unrealistic and who seem to feel that we can easily move into widespread preventive use of Factor VIII on a massive scale simply to enable their offspring to lead a full and happy life. While there is no doubt we must do everything we can to ensure sufficient supplies of Factor VIII to enable them to live as full lives as possible, the definition of possible must also contain some aspects of the realities of the economic facts of life and the patience of donors. I very much agree with you that it is one thing being a donor on the usual basis and another to be asked to submit oneself to plasmapheresis 10 times a year. We may be in danger of killing the goose."*

101. Meanwhile, SHHD and DHSS discussions over UK production of blood products continued. In late March 1981, Dr Harris of the DHSS visited the SHHD, the Edinburgh RTC and the PFC. His internal DHSS note of the visit provides some insight into perceptions of the SHHD at the time [SCGV0000001_019]. Dr Harris recorded that it had not been possible to operate a 24-hour shift at PFC, but if that this problem were overcome, Mr Watt was confident was "*confident that all the present United Kingdom's plasma could be fractionated in the Centre. He is certainly willing and able to receive supplies from England and Wales even on the basis of a daytime shift system*".

102. Dr Harris added a number of general comments, including:

a. The "*professions*" (presumably the transfusionists and fractionators) were "*all in favour of an integrated United Kingdom BTS. However, I detected an underlying opposition from Drs Scott and Bell*".

b. Having "*recognised this attitude in SHHD it was still agreed that we should move towards a closer co-ordination between England, Wales and Scotland*".

c. Professor Cash and Mr Watt were described as "*very competent in their field but are strong personalities and any scheme to integrate north and south of the border would have to take account of this because of the personality of the BPL Director*".

d. The "*three experts all expressed great willingness to co-operate and assist in every way. They conveyed the view that SHHD would be the major obstacle to progress*".

103. Internal SHHD documents provide different perspectives. In a 20 August 1981 minute to Dr McIntyre, Mr Finnie described a letter from Mr Harley at the DHSS regarding the shift working trial at PFC as a "*a masterpiece of sitting on the fence*" [SCGV0000127_004]. He suggested that it showed a "*lack of enthusiasm for the project notwithstanding it is being mounted for DHSS benefit*". Mr Finnie added that he had, "*in the past, strongly supported the concept of an integrated fractionation capacity and have been prepared to overlook much of the past bickering from DHSS. The longer this goes on however the more uneasy I become about DHSS intentions. However I may be wrong*".

104. SHHD officials also expressed concerns at SNBTS estimates of factor VIII use. In an internal note of a 22 September 1981 meeting of SNBTS directors, Dr Bell recorded that he had "*pointed out, and was supported by Mr Finnie, that however well intentioned, the SNBTS assessment of future needs might not be regarded as realistic in the current economic climate, and that hence detailed work on the implementation of an ambitious programme of expansion might be inappropriate*" [SCGV0000104_121]. Dr Bell also referred to a report of an SNBTS visit to Belgium, where factor VIII was "*supplied mostly as freeze dried cryoprecipitate*". Demand estimates and Scottish trial of freeze dried cryoprecipitate were discussed further at a 4 November 1981 meeting of the Haemophilia and Blood Transfusion Working Group, attended by Drs McIntyre and Bell and Mr Finnie [PRSE0004212].

Decisions on separate fractionation

105. In early March 1982, Mr Harley informed the SHHD that the steering group on the redevelopment of BPL had decided to recommend that plans should proceed on the assumption that BPL would process all plasma for England and Wales [SCGV0000002_024]. In a 15 March 1982 response, Mr Macpherson described the SHHD as "*most disappointed*" by this development, given that "*we have now demonstrated that half of your requirements could be supplied by the Protein Fractionation Centre at Liberton if it were to be run on the basis of shift working*". He added: "*I expect you will be advising your Ministers in due course of the public expenditure implications of this decision, and I have no doubt that our Minister for Health will wish to be assured at that point that full account has been taken of the potential capacity at the PFC*" [SCGV0000002_023].

106. Mr Macpherson went on to suggest, based on "*informal soundings*", that there was reason to believe that shift working arrangements were capable of being negotiated. He commented that it seemed "*altogether undesirable to assume that difficulties over this will prevent the PFC from playing a part in the processing of English plasma*".

107. These points were reiterated and expanded upon in a 16 July 1982 letter from Mr Walker at the SHHD to Mr Cashman at the DHSS [SCGV0000002_013]. Mr Walker described the trial of shift working the previous year as successful and stated that "*we do not think the unions will refuse to reach an acceptable agreement on shift working although hard bargaining will be required*". He sought confirmation on whether English plasma could sent to PFC, noting that the "*Scottish Minister concerned has made clear to me his wish to be satisfied that the Health Departments have acted in concert in appraising the various options for meeting the UK's needs in this field*".

108. Mr Cashman's response stated that the issue was likely to be decided by how the cost of the different options compared and suggested that it would be best to wait until a draft ministerial submission had been prepared [DHSC0003725_013]. He subsequently provided a draft copy of the DHSS submission to Mr Walker in early September 1982 [WITN0771015]. As noted in the self-sufficiency presentation, Mr Walker responded on 15 September 1982, noting, "*not without some sense of relief*",

the DHSS had ruled out PFC as a source of supply for England and Wales [DHSC0002333_018]. This development was reflected in a submission to Mr Mackay on 15 October 1982 [SCGV0000147_114].

109. As described below, during the course of 1983, Mr Mackay sought information from SHHD officials on the possibility of PFC producing factor VIII for England in response to the risk of AIDS. This possibility was also raised in 1984 in correspondence from Clive Jenkins (General Secretary of the Association of Scientific, Technical and Managerial Staffs).

110. On 10 May 1984, Mr Davies provided Mr Mackay's Private Secretary with a copy of correspondence on this issue between Mr Jenkins and Lord Glenarthur, suggesting that a response to a recent letter from Mr Jenkins come from Mr Mackay [SCGV0000118_007]. Mr Davies commented that "*PFC is currently capable of coping adequately with the needs of Scotland and Northern Ireland and it has been made clear by Lord Glenarthur that there is no question of England and Wales looking there for help.*"

111. Mr Mackay subsequently sent a letter to Mr Jenkins dated 14 May 1984, in which he wrote [MACK0002271_012]:

> *"The function of the PFC is to concentrate on the needs of Scotland and Northern Ireland. It performs this role satisfactorily: we are virtually self-sufficient in Factor VIII. As Simon Glenarthur explained in his letter of 2 April, the needs of England and Wales are to be met by a new production unit being at BPL Elstree, and not by looking to any expansion of production at PFC..."*

112. In a 31 August 1984 response to Mr Mackay, Mr Jenkins wrote [SCGV0000118_012]:

> *"I think you have misunderstood my motivation for raising the issue with Lord Glenarthur and my suggestions concerning the use of the PFC in Edinburgh. Factor VIII from commercial American sources in my opinion poses a risk that is unacceptable. Factor VIII manufactured at PFC would pose a much lower*

risk of being contaminated with HTLV III the AIDS agent. Elstree cannot, at the moment, make up the English and Welsh shortfall of Factor VIII supplies and Factor VIII from commercial sources is being bought to make up the shortfall. It would seem, therefore, perfectly reasonable for supplies from Scotland to be increased until the Elstree site was in a position to supply England and Wales."

Funding for heat treatment

113. One of the issues considered by the SHHD in 1983-1984, in relation to the supply of blood products, was the provision of funding for the heat treatment of PFC factor concentrates. At a 25 May 1983 meeting of the CSA BTS Sub-Committee, attended by Dr Bell, it was agreed that funding would be sought from the SHHD for the "*pilot stage of heat treatment of factor VIII*" as a bid against Medicine Inspectorate development funds [PRSE0004117 p.7]. The CSA subsequently made the application to the SHHD on 6 June 1983 [PRSE0002685].[24] Funding for heat treatment was not approved until the summer of 1984.

114. On 20 September 1983, Mr Wastle responded to the CSA's application with a number of comments [PRSE0002772]. These included that the SHHD did "*not accept that the heat treatment of Factor VIII*" arose from the Medicines Inspectorate recommendations, but that it was "*prepared to consider this matter further*". On 22 February 1984, at a meeting attended by Dr Bell, the CSA BTS Sub-Committee "*approved a submission by the National Medical Director for the development of heat treated Factor VIII at the Protein Fractionation Centre*" [PRSE0001792]. On 14 May 1984, Mr Wooler wrote to the SHHD to request an update on the application [SBTS0000161_013].

115. Dr Bell subsequently commented on the CSA's funding request in a 23 May 1984 minute to Mr Murray [PRSE0004029]. He suggested that the paper supporting the request failed to bring out "*the policy case for proceeding with this development. The*

[24] Penrose described the reason for attempting to link heat treatment to the Medicines Inspectors recommendations as having been "*largely a pragmatic one, based on the fact that a large sum of money (circa £650,000) had already been allocated for compliance with the Medicines Inspectorate's recommendations relating to the quality of the PFC's facility*" [PRSE0007002 §23.123].

objective of this more complicated means of producing factor VIII from plasma is to reduce the risks of transmission of viral disease, particularly hepatitis".[25] Dr Bell added:

> *"The international commercial manufacturers of factor VIII are beginning to produce heat treated products and if this country is to be self-sufficient in blood products in any meaningful sense of the term we must provide a similar therapeutic product. Otherwise Health Boards will be forced into very expensive purchases of commercial product and the resources of the SNBTS will not be used to best effect. This is not a matter of product differentiation for marketing purposes but represents a genuine and important advance in therapy. The heat treated factor VIII may also prevent the transmission of AIDS, though it is too early to make such a claim with any confidence.*
>
> *It is not for me to say how this development should be financed but I can say that it is a genuine technological advance and a failure to bring it about would be very difficult to defend publicaly* [sic]*."*

116. In a 13 August 1984 letter to Mr Wooler at the CSA, Dr Perry stated that this additional funding for heat-treatment was "*becoming a matter of urgency*" [PRSE0000336], Mr Wooler responded a few days later to confirm that authorisation would be issued shortly [PRSE0001297].

117. Mr Morison provided an update on PFC heat treatment to SHHD colleagues when circulating a note of a 21 November 1984 meeting of the CSA BTS Sub-Committee [SCGV0000138_053]. He noted that heat treatment of factor VIII was "*on schedule. As an introductory step, existing stocks of Factor VIII and future stocks will be dry heated; this will destroy the AIDS virus but will not deal with hepatitis. A clinical trial is to start within the next few days; all existing stocks will be treated by January, and from the end of the year – or earlier if possible – all the Factor VIII which is used should have been treated*".[26]

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[25] This document is quoted further below in relation to the SHHD's understanding of NANB hepatitis.
[26] Further reference to the introduction of heat treatment is made in the section on the SHHD's knowledge of and response to the risk of AIDS in blood products.

118. The SHHD continued to be apprised of developments in the heat treatment of PFC factor VIII, in particular through attendance at meetings: see, for example, the 7 March 1985 meeting of SNBTS and haemophilia directors, chaired by Dr Bell attended by Dr McIntyre [SBTS0000829]. Dr Bell also provided an update on PFC's progress in heat treatment in a 13 March 1985 note for Dr Scott ahead of a meeting between the CBLA and CSA [SCGV0000052_061].

119. As explored in the self-sufficiency presentation, the heat treatment regime applied to the first iterations of PFC factor VIII was less severe than the BPL equivalent. The documents indicate that the SHHD was aware of this, though it does not appear to have sought to procure BPL factor VIII for Scottish patients. For example, Dr Forrester was present at the 10 December 1985 meeting of SNBTS directors, when further developments were reported and Dr Perry stated that the PFC's "*long term plan was to heat blood products at 80°C for 72 hours*" [PRSE0002258]. By contrast, BPL's heat-treated factor VIII product – 8Y – was already heated at 80°C for 72 hours. Dr Forrester was also present at the 19 December 1985 CBLA meeting, during which Dr Rizza reported that he had been using BPL's heat-treated product for around nine months and that "*none of his patients, including children, had become clinically ill and, therefore, the immediate signs were encouraging*" [CBLA0002287].

120. Further developments in PFC heat treatment were discussed at the 5 March 1986 meeting of SNBTS and haemophilia directors, chaired by Dr Forrester and attended by Dr McIntyre [PRSE0001081]. During the meeting, Professor Cash "*informed members that even material dry heated at 68°C for 24 hours may not be non-infective with regard to HTLV III and Non A/Non B hepatitis*", and Dr Perry explained that the PFC hoped to have a product dry heated at 80°C for 72 hours available for clinical evaluation in April and for routine clinical issue within 3 months.

121. By this stage, however, a concern among haemophilia directors about the lack of compensation or indemnity arrangements for clinical trials of PFC factor products – in existence for some time – had come to the fore.

Clinical trials and compensation/indemnity arrangements

122. Issues relating to compensation and indemnity arrangements for participants in clinical trials of blood products have been considered in evidence previously heard by the Inquiry.[27] This section focuses on additional evidence relevant to the SHHD's decision-making.

Professor Ludlam raises concern

123. Professor Ludlam's evidence to the Inquiry was that he first raised concerns about a lack of compensation arrangements for clinical trials in 1983.[28] He is recorded in the contemporaneous documentation as having done so at the 14 November 1983 meeting of the Haemophilia and Blood Transfusion Working Group [PRSE0002581]. The meeting was attended by Dr Bell, who "*outlined the insurance position of government departments in general and the particular arrangements for blood donors*". Professor Cash is recorded as having agreed to raise the matter with the CSA, "*who could take legal advice and liaise with SHHD.*" Whether any steps were taken by the SHHD to progress matters following this meeting is unclear.

124. Professor Ludlam again expressed his "*concern*" about the lack of guidance on compensation arrangements in clinical trials at the meeting of SNBTS and haemophilia directors on 2 February 1984 [PRSE0001556], a month after he had reported an adverse reaction to PFC heat-treated factor VIII in a severe haemophilia patient [SBTS0000319_010]. This meeting was attended by Dr McIntyre and chaired by Dr Bell, with the latter stating that he was "*not in a position to give directly relevant advice at present though he mentioned the arrangements which existed for blood donors throughout the UK*". It was agreed that Dr McClelland would prepare a paper on this subject, to submit initially to the BTS sub-committee of the CSA.[29]

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[27] See, in particular, the evidence of Professor Ludlam and the presentation note on self-sufficiency and domestic production of blood products in Scotland and Northern Ireland.
[28] See Professor Ludlam's oral evidence to the Inquiry, 4 December 2020, p.139 [INQY1000080].
[29] Note that but the topic does not appear to have been discussed at the BTS sub-committee meeting of 23 May 1984 [PRSE0003159].

125. Dr McClelland subsequently prepared a paper on the issue, dated 20 August 1984, which recorded that it was prepared "*following problems*" arising from a "*non SNBTS*" trial of plasma fraction which appeared to have transmitted hepatitis [PRSE0002261]. The paper made a number of suggestions, including that the "*legal office be consulted with a view to preparing guidelines, based on the ABPI*[30] *documents and modified as appropriate, which would be used in the conduct of all SNBTS trials involving both patients and volunteers...*".

126. There appears to have been little progress by 7 March 1985, when the situation was described as "*unsatisfactory*" at an SNBTS and haemophilia directors' meeting [SBTS0000829]. Professor Cash explained "*the difficulties that the SNBTS had perceived in attempting to resolve the problems through the CSA*", and Professor Ludlam "*requested that some action should be taken urgently*". Dr Bell and Dr McIntyre were present and the latter is recorded as having agreed to raise the matter within the SHHD.

127. On 15 March 1985, Dr McIntyre wrote a minute to Mr Davies on the question of "*who compensates the volunteer*", or the family of a volunteer in the case of death, in a clinical trial of an SNBTS product where "*adverse reactions occur due either to the toxicity of the product or to hypersensitivity on the part of the volunteer*" [PRSE0004468]. Dr McIntyre wrote that the "*clinicians concerned would like the legal position to be stated quite clearly and in particular to be reassured that compensation would be paid without prolonged legal wrangles*". The minute indicated "*a hint of reluctance*" on the part of clinicians to "*persuade volunteers to take part in trials without reassurance that compensation would be paid.*" Dr McIntyre commented that "*[s]hould this attitude harden considerable problems would result*".

128. In a further minute to Mr Davies on 28 March 1985, Dr McIntyre attached correspondence between Professor Cash and Professor Ludlam and wrote that there was "*a measure of urgency to this problem*" due to the "*AIDS/Factor VIII issue*" [SCGV0000217_124]. He added that "*the problem is not confined to Scotland, and Mr Smart, Chairman of the CBLA has written in similar terms to Dr Harris, DCMO and*

[30] I.e. Association of the British Pharmaceutical Industry.

DHSS". Dr McIntyre considered it "*unlikely that the clinicians will be content with anything less than an assurance that government (or the CSA) will act in a similar manner to a commercial company in similar circumstances.*"[31]

129. On 2 April 1985, Mr Calder (Chief Pharmaceutical Officer) advised Dr McIntyre that, before proceeding any further, the SHHD should obtain legal advice, "*from our own lawyers*" and also "*from the legal department of CSA*" [PRSE0001970].

130. Dr McIntyre forwarded this minute to Mr Davies on 10 April 1985, suggesting that "*perhaps we should defer further action*" until *"legal advice is available*", while noting: "*As the clinicians are much concerned about this matter I trust the legal advice will not be too long in coming*" [PRSE0004395]. A manuscript response, which appears to be from Mr Davies, suggests that he considered the issue to be one for the CSA to resolve: *"We are indeed expecting the CLO*[32] *to be consulted – this is part of an exercise to persuade the CSA to take themselves decisions properly theirs. While it would doubtless be possible to consult our Solicitor's Office in parallel, I am not persuaded it is necessary to do so. As to how long it will take, that depends on the lawyers*".

Extension of existing compensation scheme to cover hepatitis B immunisation

131. In parallel to its consideration of these issues, it seems that the SHHD obtained Treasury approval in or around April 1985 to extend a scheme which already provided compensation for injury or loss suffered by donors "*participating in the "HDN Scheme" or apheresis*" to those receiving the hepatitis B vaccine [SBTS0000244_034]. In a note to Mr Mutch (Secretary of the CSA) on 12 April 1985 to convey this approval, Mr Murray explained that "*the question of compensation should not be over-stressed in case volunteers, or the public, come to believe that the risks are greater than in fact they are*" [SCGV0000217_081]. Instead, any donor enquiring about this "*should be advised that it is the practice of the Scottish National Blood Transfusion Service to deal*

[31] A manuscript note at the bottom of the page appears to be from Mr Davies and to read: "*Mr Murray – I believe you are already looking into this – though, as far as I can recall, the CSA* [illegible] *have not written in! I find it a little strange, as surely there is also a risk of claims if non-heat treated FVIII is used, which is known to be 'riskier'?*" [SCGV0000217_124].

[32] I.e. the Central Legal Office.

promptly and generously with those who suffer as a result of giving blood", and that arrangements had been made "*for claims for compensation to be sympathetically considered by a small tribunal established by the Department for this purpose*".

Professor Cash's letter to the CSA and legal advice

132. On 11 March 1985, Professor Cash wrote to Mr Mutch at the CSA regarding compensation arrangements in cases of adverse reactions for a number of different groups, including healthy volunteers infused with SNBTS-produced blood products and patients who received newly developed BTS products "*on the understanding the exercises are experimental in nature and are not intended as treatments*" [PRSE0000888]. Professor Cash wrote that the CSA "*must attempt to resolve these anomalies as soon as possible*". The letter distinguished trials involving patients from studies involving healthy volunteers and made a number of suggestions on compensation arrangements for each category. It ended by suggesting several steps to be taken, including: clearance "*in principle*" from the SHHD, establishment of a body to consider claims and the preparation of guidelines by the legal office.

133. This letter was copied to Dr McIntyre and later was forwarded separately to Mr Davies and Mr Murray [SCGV0000217_129 and PRSE0003664]. This appears to have prompted Mr Murray to seek advice from the SHHD's Finance Division. The advice, provided by Mr Kernohan on 10 April 1985, was that if a compensation scheme was to be implemented "*along the lines of the HDN or apheresis schemes*", Treasury approval was "*obviously*" required [PRSE0001452]. Mr Murray also forwarded Professor Cash's letter to the DHSS in April 1985, noting that both departments were considering similar issues and suggesting that there seemed "*no reason why we should not reach a common conclusion on how to deal with this issue*" [PRSE0003695].

134. Also in April 1985, the CSA obtained advice from Mr Griffiths of the CLO [SBTS0000146_021]. Mr Griffiths' view was that Professor Cash was effectively proposing no fault compensation and it was "*entirely a policy matter for administration*" to decide whether such a policy should be adopted. Mr Griffiths

nevertheless raised the "*possible difficulty of establishing cause and effect*" and warned of the "*possible cost to the service of claims for compensation*".[33]

135. On 29 April 1985, Mr Murray asked that a further point be put to the CSA's legal adviser on the position of a clinician who administered a substance produced by the SNBTS, "*following which there was an unpredicted adverse reaction*" [PRSE0004546]. Mr Griffiths responded on 10 July 1985, explaining that in a negligence claim for injury resulting from the use of an SNBTS substance, the injured party could choose who to sue (depending on the negligence alleged) [PRSE0000802]. The SHHD received this advice via the CSA on 12 July 1985 [SCGV0000228_030].[34] A month later, on 12 August 1985, Mr Kernohan expressed confusion at Mr Griffiths' memorandum of 10 July because it spoke of actions in negligence, whereas Mr Kernohan had thought that the issue under discussion related to the compensation of volunteers who "*are accepting an experimental substance or treatment in the knowledge that there is an element of risk*" [SCGV0000217_105].

Impact on clinical trials of factor VIII

136. Meanwhile, and as explored in other evidence heard by the Inquiry, Professor Ludlam again emphasised his concerns about this issue. For example, in a 19 March 1985 letter to Dr Boulton, he commented that the "*commitment of either the CSA or Scottish Home and Health Department to give reasonable compensation has not been demonstrated to my satisfaction*" [PRSE0001819]. As a result, before proceeding with clinical evaluation of further batches of PFC heat-treated factor VIII, he would seek the approval of the Area Ethical Committee and required a full product description. Professor Ludlam added that he "*might be prepared to not seek ethical approval*" if he "*could be assured that there was a reasonable system for compensating patients*",

[33] The CSA conveyed this information to Dr Cash, who responded on 30 July 1985 to agree that it was "*indeed a matter of policy*" to decide whether or not to compensate volunteers in clinical trials in the event of "*adverse reactions*" and that this was reason that he had raised the matter with SHHD [SCGV0000217_103]. He agreed that a negligence claim "*might be expensive*" and reiterated his point about PFC adopting a similar manufacturing practice to industry. He ended by suggesting Mr Griffiths obtain a copy of the ABPI guidelines.

[34] On 6 August 1985, Mr Murray sent Mr Griffiths' memo of 10 July to various recipients, including Mr Calder, Dr McIntyre and Dr Forrester, commenting that "*[t]his does not seem to take us very far forward*" [SCGV0000217_108].

though he was "*becoming increasingly apprehensive about testing further batches without adequate arrangements for compensation*".

137. In a 22 March 1985 letter, copied to Dr McIntyre, Professor Cash described himself as "*most distressed and surprised*" to read this 19 March letter, and asked Professor Ludlam to reconsider his position and "*proceed with the requested clinical studies as soon as possible and without referring the matter to the Ethics Committee*" [PRSE0004298]. In his response, Professor Ludlam maintained that he needed the full product description, adding that he was "*very unhappy*" about the lack of compensation arrangements and that he had raised this issue "*a long time ago at the Department*" but had not "*perceived any change in their position or enthusiasm to take up this issue*" [PRSE0001907]. Dr Boulton subsequently indicated to Professor Cash that as soon as he received details of the product he would contact Professor Ludlam to "*thrash out a mutually acceptable protocol*" for the trial [PRSE0004240]. On 29 April 1985, Professor Ludlam wrote to Professor Cash to confirm that he had sought ethical approval and was arranging for four haemophilia patients to attend for a trial "*in the very near future*" [PRSE0002907].

138. As well as being copied into parts of this correspondence, SHHD officials continued to attend meetings in which the issue was discussed. On 15 May 1985, Dr Bell and Dr McIntyre attended the Haemophilia and Blood Transfusion Working Group meeting, during which a "*general discussion*" relating to compensation/indemnity arrangements took place [PRSE0003930]. Dr McIntyre reported that in the view of the SHHD Chief Pharmacist (i.e. Mr Calder), blood products, whether used in clinical trials or ordinary therapy, were covered by Crown indemnity but that the Solicitor's Office was considering the SHHD's position.

139. At a meeting of the CSA BTS Sub-Committee on 21 August 1985, attended by Mr Morison for the SHHD, "*after a full discussion and having noted the possible legal implications*", it was agreed that Professor Cash would "*bring forward*" the proposals contained in his letter of 11 March 1985 "*in consultation with the Central Legal Office*" [MACK0001018_015]. In a minute reporting on this meeting to Mr Davies, Mr Morison recorded that he had said that the SHHD would pursue the issue "*with DHSS, as a matter of urgency*" and that "*the question would be required to be considered in a*

GB context", although it was said that the CSA needed first "*to clarify the boundaries of their proposals*" before the SHHD took the matter forward. Mr Morison had also "*explained that the question would be required to be considered in a GB context*" [PRSE0004303].

140. Mr Murray wrote to Mr Williams of the DHSS in November 1985 to explain that the SHHD had asked the CSA to clarify its proposals and to ask about any progress the DHSS had made, as "*it would seem desirable for these questions to be considered in a GB context*" [PRSE0000484].

141. Although Professor Cash and Mr McCubbin (legal adviser to the Scottish Health Service CLO) apparently arranged to meet on 11 August 1985 to discuss the issue [SBTS0000146_025], it appears that Mr McCubbin's advice was not conveyed to the CSA until almost a year later in a letter to Mr Wooller on 17 July 1986 [SBTS0000146_033]. Mr McCubbin described himself as having been unaware "*that the matter was one of urgency*" and as having deferred detailed consideration of it while resolving other pressing matters. His view was that "*the general compensation provisions for cases of plasmapheresis*" could simply be extended "*to those cases already covered by the pharmaceutical industry guidelines*". He considered that the guidelines set out in Professor Cash's 11 March 1985 letter could appropriately be adopted by the SNBTS in relation to cases of patients "*who agree to receive newly developed BTS products on the understanding that the exercises are experimental in nature and are not intended as treatments*". Mr McCubbin agreed with Professor Cash that the question of "*healthy volunteers, including both staff and donors*" was "*a separate one*".

142. Professor Cash wrote to Mr Wooller on 6 August 1986 to ask, in light of McCubbin's advice, "*what the next moves*" were, noting that the SNBTS had a number of ongoing clinical trials [SBTS0000146_003]. At a meeting of the CSA Blood Transfusion Service Sub-Committee on 20 August 1986, attended by Dr Forrester, it was "*agreed that the General Manager should now pursue the bringing forward of firm proposals*" [PRSE0000410]. The CSA General Manager was Mr Donald at the time. Professor Cash wrote to Mr Donald the day after the meeting, apologising for "*pestering*" on the topic and suggesting that Mr Mutch "*take on the task of drafting the*

appropriate document, destined for the BTS Sub-Committee and thence to SHHD" [SBTS0000146_032]. The Inquiry has been unable to identify a response to this letter or other evidence that the CSA moved matters forward before 1987.

Wider issue of no-fault compensation

143. The SHHD appears to have been prompted to revisit these issues in late 1986 in the context of a report on no fault compensation. The documents suggest that the issues relating to such compensation, whether in the context of clinical trials or more broadly, cut across a number of different SHHD branches.

144. In a minute to Mr Morison and others on 6 November 1986, Miss Cox described a recent report from the Royal College of Physicians, which recommended that the Government "*should introduce "no fault compensation" for any health* [sic] *volunteer who suffered damage in the course of drug trials and other experiments*" [SCGV0000228_008]. Miss Cox wrote that "*further papers which have come in to Mr Calder from DHHS*" indicated that the "*discussion is widening in DHSS*" to cover no fault compensation for "*any person suffering damage in the course of medical procedures, not just for healthy volunteers*." She suggested that Division IVB of the SHHD should take the lead in receiving papers from the DHSS and keeping "*a watching brief*".

145. In a 14 November 1986 minute to Mr Morison, responding to Miss Cox, David Stevenson described no fault compensation as one of "*the stray sheep*" which had "*wandered into the Division IVB fold during the last 2 years*" [SCGV0000228_038]. He noted that Branch 2 had "*been dealing with Ministerial and other enquiries on the possibility of introducing such a scheme, and with all references to the Pearson Committee Report of 1978*". Mr Stevenson commented that, "*[u]nfortunately, like Branch 2, our opposite numbers in DHSS have had major staff changes, and our communications with them are not very good.*" He explained that "*[w]e had therefore not picked up the fact that DHSS are having a wider look at the subject; we had only seen a reference via the Chief Scientist's Office to compensation for health volunteers*". Mr Stevenson added: "*We shall now try to re-establish good lines of communication*

with DHSS to ensure that we are kept abreast of what is going on; and we shall keep the other parts of the Department informed" [SCGV0000228_038].

Professor Ludlam refuses to carry out further trials

146. Professor Ludlam again raised the lack of compensation/indemnity arrangements in an 11 December 1986 letter to Professor Cash, copied to Dr Forrester [PRSE0000696]. He explained that, before undertaking studies of the PFC product Z8, he was "*awaiting an appropriate commitment from either PFC, SHHD or DHSS concerning the question of indemnity should any of the patients materially suffer as a result of assessing the new factor VIII product*". He noted that he had "*raised this a long time ago with SHHD*" and that there was "*very great disquiet*" about the lack of formal arrangements among other haemophilia directors.

147. Professor Ludlam's position was also recorded in a 30 December 1986 handwritten SHHD note to Mr Murray [PRSE0003720]. The note recorded that this "*ongoing topic*" had again been "*brought to the fore*": Drs McIntyre and Forrester had recently seen Mr Macniven to explain with "*with some urgency*" that Professor Ludlam was "*seeking some form of compensation scheme for patients before embarking on the testing of "super-heated" Factor VIII on haemophiliacs*". The note suggested that the SHHD was still "*awaiting clarification from CSA of the boundaries of the proposals*", while recording that there was "*now great urgency*" as Professor Ludlam was declining to administer the new product unless he received "*notification of some form of compensation cover*". It was further recorded that *"[a]ttempts to contact Clive Wooller, DHSS and (at Mr Macniven's insistence) the Treasury had apparently met with failure*".

148. These developments appear to have led Mr Macniven to ask his SHHD colleagues for an assessment of the risk to volunteers in trials of SNBTS factor VIII, which was provided by Dr Forrester on 7 January 1987 [PRSE0002267]. Dr Forrester assessed that "*on the evidence, the chance of immediate ill-effect appears extremely small*" and although "*the chance of virus transmission exists*" it "*cannot be convincingly estimated on present international experience*". Dr Forrester provided a further minute on the same day, enclosing documents received from Dr McIntyre and

Professor Cash which appeared to him "*to shift the goalposts*" [SCGV0000217_087]. He wrote that a letter from Professor Ludlam referred to compensation for "*patients suffering harm in tests of a new product whether the product is given as treatment or not*" and declined "*to use new product for ordinary treatment unless it receives a Product Licence*". The letter to which he referred, dated 5 January 1987, stated that Professor Ludlam was "*unwilling to test further blood products on patients*" without "*written assurance that appropriate compensation will be available*", and not just "*verbal assurances*" [PRSE0003282].

149. Professor Cash and Professor Ludlam continued to correspond on this matter, and on 9 January 1987 the latter indicated that he would organise infusion studies "*immediately*" if provided with an appropriate written assurance from the SHHD [PRSE0002134]. He also asked that the SHHD extend the indemnity cover "*until a product licence is obtained*" as he envisaged a period after the "*results of the infusion data*" when Z8 would be available on a "*named patient basis*" prior to obtaining the product licence.

Treasury approval for compensation arrangements for factor VIII trials

150. Professor Ludlam's refusal to proceed with factor VIII trials appears to have accelerated progress in resolving this issue. On 12 January 1987, Mr Murray minuted Mr Kernohan in relation to seeking Treasury approval for compensation for clinical trials of factor VIII [PRSE0001577]. He noted that clinicians had refused to carry out the necessary trials unless compensation arrangements could be offered in line with ABPI proposals, and that a scheme therefore required to be agreed in order to maintain supplies of heat-treated factor VIII from mid-February. Mr Murray noted that "*Treasury have previously given their agreement to compensation arrangements in several similar circumstances*", and "*have agreed that the PHLS may follow the ABPI guidelines on compensation as a general rule.*" He enclosed a draft letter for Mr Kernohan to send to the Treasury, which included "*the required medical advice*". Mr Kernohan wrote to the Treasury two days later [PRSE0003888].

151. After an exchange of letters on the proposal [PRSE0001726], Treasury approval was obtained on 5 February 1987 for compensation arrangements for factor VIII trials,

"*along the lines of the ABPI guidelines*", that is, "*where the damage suffered is severe and permanent*" [DHSC0001077]. Mr Murray informed Professor Cash of this development on 6 February 1987 [PRSE0000760].

Request to extend the scheme

152. On 10 February 1987, in a minute to SHHD colleagues, Mr Macniven described this outcome as "*a satisfactory conclusion*" but asked why there was "*not some general scheme*" for all SNBTS products, as he anticipated "*the same sort of request for a compensation scheme for other new (or revised) SNBTS products*" [SCGV0000217_064].

153. Mr Macniven's prediction appears to have been accurate. The following day, Professor Cash wrote to Mr Murray to say that he was "*delighted*" with the news of Treasury approval, but that he proposed to "*take the principle of what has been achieved a stage further*" [SBTS0004103_153]. He listed all PFC products which were either undergoing clinical trials or would do so in the next 18 months, apparently requesting to extend the scheme to all PFC products, not just factor VIII.[35]

154. Mr Calder replied to Mr Macniven's minute on 11 February 1987 to say that he knew "*of no reason why there should not be a national scheme of compensation approved by the Treasury for all products manufactured by the NHS on which clinical trials are conducted on healthy volunteers*", but that as far as he was aware, "*the NHS or Health Departments have never formally proposed such an arrangement*" [SCGV0000217_062].

155. At this stage, it appears that the SHHD understood there to be two parallel questions to be considered in relation to compensation in clinical trials: first, compensation for non-therapeutic trials of all PFC blood products; second, compensation for therapeutic trials, or specifically, the second part of a clinical trial where the product is used for its therapeutic benefits as well as for trial purposes. The

[35] It seems that Professor Cash did not receive a reply to this request, as he noted in a letter to Professor Ludlam on 25 June 1987 [PRSE0000866].

SHHD seems to have considered it necessary to proceed with caution, as can be seen in a minute from Mr Murray to Mr Macniven and Mr Morison, briefing them in advance of a BTS Sub-Committee meeting on 25 February 1987 [PRSE0004718]:

> *"Dr Cash has now written to me asking if we can agree a scheme for compensation to cover all clinical trials of all PFC products. I shall pursue this with medical colleagues and DHSS as it will need to be a UK scheme. We shall need to approach Treasury with some care however, as we got approval to the Factor VIII compensation scheme on a somewhat exceptional basis ... and we would not wish our Treasury colleagues ... to feel that we had conned them into a precedent."*

156. Nevertheless, there was a recognition of the need to extend the compensation provisions. At the BTS Sub-Committee meeting of 3 March 1987, attended by Dr Forrester, the arrangements that had been agreed were noted as being "*exceedingly narrow*", and the SNBTS indicated that it was working with the CSA on a proposal for extending them [PRSE0004163].

Professor Ludlam's concern over the scope of the agreed compensation scheme

157. Around this time, Professor Ludlam sought confirmation that the compensation arrangements agreed by the Treasury applied up to the grant of a product licence. He wrote to Mr Murray about this on 23 February 1987 [PRSE0003852]. It appears that Mr Murray's letter was passed to Dr Forrester, as the latter minuted Mr Murray on the issue three days later [PRSE0004360]. Dr Forrester's view was that the SHHD was "*not yet in a position to follow the ABPI guidelines beyond the stage of where the injections begin to be given for treatment and not purely for reasons of testing.*" He also noted that he had told Professor Ludlam recently of his "*doubts whether the full product licence procedure would ever go into action*".

158. Professor Ludlam wrote to Dr Forrester about the issue again on 12 March 1987, after having received the draft minutes of the SNBTS and haemophilia directors meeting on 9 February 1987 [PRSE0000948]. He wrote that it was his "*clear understanding*" that the compensation/indemnity arrangements would apply also to the

second part of the clinical trial, which involved "*giving the new product to many patients therapeutically to ensure that it is effective*". By contrast, the minutes recorded Mr Macniven as agreeing "*to investigate the position in relation to "named patient" administration of products, which follows initial trials*" [PRSE0002769]. They recorded that "*[t]he newly secured compensation scheme does not apply to administration for therapeutic purposes*".

159. Dr Forrester met Professor Ludlam on 24 March 1987 to discuss this issue and minuted Dr McIntyre, Mr Macniven and Mr Murray about the meeting the following day [PRSE0001132]. He wrote that the "*Department's position*" was as expressed in the 6 February 1987 letter from Mr Murray to Professor Cash [PRSE0000760]: that volunteers "*participating for non-therapeutic purposes in trial of FVIII*", who "*naturally enjoy exceptional public sympathy*", were covered by the compensation arrangements, but those "*who receive FVIII for reasons of treatment as well as trial*" were not.

160. Dr Forrester added that the "*next aim*" was to "*extend the arrangements to participants in non-therapeutic trials of other PFC products*". A list of PFC products had been provided by Professor Cash who, Dr Forrester suspected, read "*it as extending the arrangements to all participants in clinical trials of FVIII, whether they receive the product as treatment or not*", which Dr Forrester described as "*just wishful thinking*". Dr Forrester ended his minute by reporting that he had told Professor Ludlam "*that the immediate prospects of extending the arrangements to participants in clinical trials in general seemed to me poor, because the issues there transcend those of SNBTS and its products*".

Deliberations about extending the compensation arrangements

161. A note of a meeting between the SHHD and SNBTS on 31 March 1987 recorded that the SHHD intended to pursue, first and as a priority, the extension of "*compensation arrangements for non-therapeutic trials*", which Dr Forrester was "*hopeful*" was achievable; and secondly, the extension of compensation arrangements "*to cover the "named patient only" period of clinical trials*" [SBTS0000178_002]. The latter was described as being "*a great deal more problematic, and would be pursued*

less urgently". Mr Murray wrote a minute about these two forms of extension of the existing compensation arrangements on 20 May 1987 [SCGV0000217_041]. On funding and extending the arrangements "*to cover the "named patient only" period of clinical trials*", he expressed the view that "*the approach to Treasury would be best dealt with as a joint approach by DHSS and* [SHHD]".

162. On 4 June 1986, Mr Murray minuted Mr Macniven to set out the "*developments and difficulties*" in the extension of compensation arrangements [SCGV0000217_034 p.3]. He explained that he was awaiting a response from Dr Moore of the DHSS to his suggestion of "*a co-ordinated approach to Treasury of all clinical trials of PFC and CBLA products*". He also noted that Dr Forrester supported the extension of compensation for the "named patient" stage of a trial, and that Mr Calder had cast "*doubts not only on the "named patient" arrangements but also on compensation for clinical trials of all blood products*".[36]

163. On 27 May 1987, Professor Cash wrote to Mr Macniven to press for a "*resolution*" to the compensation issue [SBTS0000047_026]. Dr Forrester provided comments on a draft response to Professor Cash on 11 June 1987, suggesting that the response should intimate that the focus "*for the moment*" would be on non-therapeutic trials of human blood products, "*because this is the field that will currently command public and Government sympathy*" [SCGV0000217_029].

164. On 10 June 1987 (it would seem belatedly), Mr Murray wrote to Mr Donald of the CSA to confirm Treasury approval of the compensation arrangements [PRSE0000037]. He wrote that the SHHD had "*cover for those haemophilia patients participating in clinical trials to ascertain the quality and efficacy of new batches of Factor VIII which have been subjected to the improved heat-treatment process*", and that Treasury approval had been received for a compensation scheme adhering to ABPI guidelines.[37]

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[36] Dr Forrester's views were set out in a 26 May 1987 minute to Mr Murray [SCGV0000217_040], and Mr Calder's in a minute the following day [SCGV0000217_038], both of which responded to a 20 May 1987 minute from Mr Murray [SCGV0000217_041].

[37] This letter was later described as "*seriously misleading*" by Dr Forrester in a minute to Mr Murray on 17 July 1987, because "*it implied that arrangements now cover all clinical trials, whether non-therapeutic (these are covered) or not.*" [SCGV0000217_015].

165. Professor Ludlam, as recorded in a letter to Dr Forrester on 11 June 1987, continued to believe that the SHHD had given an "*undertaking that infusions of factor VIII, including those to assess clinical efficacy, would be covered by the ABPI Guidelines*" [PRSE0003563]. Two other clinicians wrote to Dr Forrester to express similar views: Dr Forbes, director of the Glasgow Haemophilia Centre [SCGV0000217_016] and Dr Mayne, of the Northern Ireland Haemophilia Reference Centre [PRSE0003135].

166. The SHHD set out its position in a response from Mr Macniven to Professor Cash on 23 June 1987 [SCGV0000217_028]. In relation to the non-therapeutic phase of clinical trials, the letter requested "*a statement of the available evidence ... bearing on the risk of any ill effect in the volunteers*" for all products listed in Professor Cash's letter of 11 February 1987. Mr Macniven described extending the compensation arrangements to cover the therapeutic administration of products under trial as "*much more difficult*", suggesting that it should be considered later due to the potential effect of the Consumer Protection Act 1987 and related government guidance [SCGV0000217_028].[38] On 8 July 1987, Professor Cash provided information about the risks arising from the products listed in his 11 February letter [PRSE0002256].

167. Dr Forrester subsequently wrote to Professor Ludlam and Dr Forbes, emphasising a distinction between healthy volunteers and patients in clinical trials [PRSE0003573; LOTH0000010_033]. In his letter to Dr Forbes, he wrote that there was "*a world of difference*" in the Treasury's mind "*between a mishap to a volunteer who receives something he would not otherwise get, and a mishap to a patient in the course of treatment, whether with something new or not. The first commands a depth of public sympathy that the second cannot match.*" [LOTH0000010_033].

168. Notwithstanding the SHHD's reservations, compensation arrangements were subsequently approved for the therapeutic stage of clinical trials. On 26 October 1987, at a meeting between the SHHD and the SNBTS, Mr Macniven reported that

[38] Further detail on the reasoning behind this letter is contained in an 11 June 1987 minute from Mr Macniven [SCGV0000217_030].

compensation could be extended to the therapeutic stage of clinical trials of factor VIII, but that "*[a]s expected, it had not been possible to make rapid progress with extending the compensation arrangements to "a wider range of products"*" [PRSE0004722].

169. The extension of compensation arrangements to the therapeutic stage of clinical trials of heat-treated factor VIII was confirmed in a letter from Mr Macniven to Professor Cash on 9 November 1987 [LOTH0000010_040]. He noted, however, that the SHHD was "*still considering the difficult question of extension of compensation arrangements to other products, whether for therapeutic or non-therapeutic trials*", which must, the SHHD considered, "*be given product by product*".

170. While beyond the scope of this presentation note, these issues continued to be considered in relation to other blood products into 1989.[39]

VI. KNOWLEDGE OF AND RESPONSE TO RISK: HEPATITIS B

Knowledge of risk and screening

171. This section considers SHHD knowledge and decision-making in relation to hepatitis B, and in particular issues around the screening of blood donations for the virus.

1960s

172. Some evidence is available of the SHHD's understanding of hepatitis B in the late 1960s.

173. For example, in a 27 September 1968 "Dear Doctor" letter, Dr Brotherston, the CMO for Scotland, addressed hepatitis in the context of the Public Health (Infectious Diseases) (Scotland) Amendment Regulations 1968, which had the effect of making

[39] See, for example, the documents at [SBTS0000832, SBTS0000414_130, SBTS0000666_068, SBTS0000414_112, SBTS0000414_089 and SBTS0003850_010].

"*infective jaundice*" generally notifiable [SCGV0000279_165].[40] The letter appears to have been sent to "*Medical Officers of Health*" and "*General Medical Practitioners*". It described the majority of cases of infective jaundice as being likely to be due "*infective hepatitis*" (i.e. hepatitis A). It described "*serum hepatitis*" (i.e. hepatitis B) as occurring less frequently, and as "*potentially a more serious condition with a longer incubation period of usually, 60-160 days*". A "*history of blood transfusion*" was noted to be a factor which might suggest a diagnosis.

174. In a 27 February 1969 letter to Dr Macdonald at the SHHD, Dr Wallace (director of the Glasgow and West of Scotland RTC) stated that he not been informed officially of hepatitis becoming compulsorily notifiable in Scotland [PRSE0001967]. If the disease was notifiable, he wished to know "*what advice has been or is being given about recognising and reporting cases of serum hepatitis*". Dr Pendreigh responded on Dr Macdonald's behalf, enclosing a copy of the official circular and noting that it included a paragraph on serum hepatitis [PRSE0003792].

175. The notification of hepatitis cases was subsequently discussed at a 6 May 1969 meeting of Scottish transfusion directors [PRSE0004105]. The only available record of the meeting is an extract from the minutes which does not include attendees, but records of other meetings indicate that an SSHD representative was usually present. The minutes record that the "*Chairman agreed to raise the question centrally of local health authorities possibly notifying directors at regular intervals*" of: i) patients "*developing infective jaundice at a relevant period after having had blood or blood products*"; ii) household contacts who were donors; iii) cases where the patients were donors and might have given blood while infected.

Early 1970s: debate over screening

176. In the early 1970s, the SHHD was involved in debates among RTDs over the introduction of screening of blood donations for Australia antigen (i.e. hepatitis B screening).

[40] A circular of the same date, enclosing a copy of the Regulations, was also issued [SCGV0001191_181].

177. On 2 June 1970, a meeting took place to discuss a policy which might be recommended to the SNBTA on the use of Australia antigen screening of blood donations [SCGV0000279_215]. The meeting, which took place at the time of a hepatitis outbreak in Edinburgh, was attended by transfusion directors and the SHHD (including Dr Macdonald). A note of the meeting recorded that, prior to the Edinburgh outbreak, "*Scottish Directors had felt that the time was not yet ripe for screening of blood*", and that research should be conducted instead. This view had been modified and "*some degree of screening in relation to high risk patients might now be considered*", though it was noted that research should continue and that "*at best screening with Australia antigen by present techniques was no more than 40 per cent successful in eliminating hepatitis*". The meeting accepted that blood for patients on chronic dialysis should be screened, but it was suggested that "*it would not be feasible to screen large quantities of blood as a standby for emergency use*".

178. In a 25 June 1970 letter to Dr Macdonald, Dr Cumming (director of the Edinburgh and South East Scotland RTC) provided comments on this note, explaining that he was "*genuinely seriously concerned at the present trend of events*" and that he was "*more than ever convinced that national action is essential*" [SCGV0000279_098]. As for the introduction of screening, Dr Wallace explained that his note of the discussion indicated that "*whatever the opinion had been in the past the decision now was to proceed as rapidly as possible to institute measures for eventual full donor screening, if necessary by a phased programme*".

179. Screening was also discussed at CCC meetings. The minutes of its 2 July 1970 meeting record that "*a great deal of the discussion centred around the question of the Blood Transfusion Association's attitude to the screening of blood for hepatitis antibodies*" [SCGV0000070_059]. The CCC agreed that screening methods should be investigated and that "*as an initial step, all blood required for use in planned transfusions of patients on chronic dialysis and, where practicable, undergoing transplant operations should be screened. It was accepted that it would not be possible to screen large quantities of blood as a stand by for emergency use; in the occasional emergency unscreened blood would have to be used*".

180. Meanwhile, Dr Wallace continued to press for the introduction of more widespread screening. In a 16 July 1970 letter to Dr Macdonald, he explained that he had accepted an invitation to join a committee to consider the problem of hepatitis in renal units and attached a paper on serum hepatitis and the blood transfusion service [SCGV0000279_085 and SCGV0000279_086]. The paper recorded that, for "*the past thirty years homologous serum jaundice (serum hepatitis) has been recognised as a delayed complication of the transfusion of blood and of blood products*".

181. Dr Wallace reviewed steps that had been taken to date and proposed additional measures, such as further incidence surveys. He recorded that the highest incidence of serum hepatitis in recipients had been observed in recipients of plasma prepared during World War II, which was "*not surprising because it was not uncommon to prepare a plasma pool from 500 donations of blood*". He also suggested that not all cases of serum hepatitis were being notified and recorded that transfusion services had previously decided against the routine screening of donors for serum hepatitis antigen (though it had been introduced for planned transfusions in chronic dialysis units).

182. In a further 11 August 1970 letter to Dr Macdonald, Dr Wallace referred to the "*tragic recurrence of hepatitis in Edinburgh*" and proposed that "*we embark on the screening of all donors for HAA*" [SCGV0000279_072]. He commented that "*[e]ven if this mass screening only reduces the incidence of serum hepatitis by 25 per cent, it would still be a significant reduction in the incidence of what can be serious illness. In the present climate I think the S.N.B.T.A. must be seen to be doing everything possible to reduce this serious transfusion risk*".

The Maycock Advisory Group

183. By this time, the introduction of screening was also being considered by the DHSS. On 20 July 1970, Dr Macdonald attended a meeting at the DHSS, chaired by Dr Maycock, on Australia antigen and the blood transfusion services [NHBT0017062]. The meeting was called in part to provide advice "*on what the Department* [i.e. the DHSS] *could do now... to lessen the risk of transmitting hepatitis by blood and blood derivatives*". A note of the meeting recorded that it "*appeared to agree that, in the light of present knowledge of HAA* [hepatitis associated antigen]*, the Department should*

facilitate, in every way it could, the testing of blood donations for the presence of HAA and its antibody." It was said that it was "*not yet possible to possible to organize testing on a national scale*", but that testing might be started "*in a few centres... to test the feasibility of routine screening*".

184. In September 1970, further to this meeting, the Advisory Group on Testing for the Presence of Australia (Hepatitis Associated) Antigen and its Antibody ("the Maycock Advisory Group") was appointed jointly by the DHSS, SHHD and Welsh Office, chaired by Dr Maycock and with Dr Wallace as a member [CBLA0000869 §2]. Dr Wallace's invitation to join the group was recorded in a 1 October 1970 letter from Dr Macdonald, which noted that the group had been set up "*to advise the Health Departments on screening in relation to blood transfusion*" [SCGV0000279_044].

185. A 29 December 1970 note, which appears to have been prepared by the SHHD for the Advisory Group, set out the screening arrangements then in place in Scotland [DHSC0002486_031]. This recorded that the extent of screening undertaken and the method adopted differed across RTCs.[41]

186. The Maycock Advisory Group was not the only forum in which serum hepatitis/hepatitis B was being considered around this time. At a meeting of the Standing Advisory Committee on Laboratory Services ("SACLS") epidemiology sub-committee on 15 June 1971, Dr Macdonald noted that another committee, chaired by Lord Rosenheim, was looking at issues relating to serum hepatitis [SCGV0000204_158].[42]

187. The SHHD was also involved in discussions relating to hepatitis screening in other contexts. For example, Dr Macdonald and Mr Roberts attended a 16 February 1972 meeting of the SNBTA Chairman's Advisory Group [SCGV0000070_033]. The

[41] The extent of screening for HAA undertaken in Scottish RTCs was also discussed at the 22 September 1970 meeting of Scottish RTCs [SCGV0000070_053].

[42] The Rosenheim committee was set up following an outbreak of fatal hepatitis cases in an Edinburgh renal unit, as well as cases elsewhere. Its report – "*Hepatitis and the treatment of chronic renal failure. Report of the Advisory Group 1970-1972*" – was completed in March 1972 [LOTH0000111_013] and has have been referred to by Inquiry witnesses (see, for example, the transcripts of Professor Ludlam's oral evidence on 1 December 2020 p.107 [INQY1000077] and 2 December 2020 p.1-2 [INQY1000078]).

meeting focused more broadly on arrangements for virological services, including the possibility of "*establishing a national reference laboratory for hepatitis work*".

188. In May 1972, the Maycock Advisory Group published its first (revised) report [CBLA0000869]. It recommended the institution of routine testing of all blood donations for Australia antigen and its antibody.

189. It appears that, around this time, the Chairman's Advisory Group made recommendations on virological issues. The minutes of the 10 October 1972 CCC meeting, attended by Dr Macdonald and Mr Watt, record that the RTDs "*were in general agreement*" with these recommendations, but were concerned about the delay in introducing developments including "*more sensitive screening of donations for Australia Antigen and its Antibody*", as well as "*co-operation with regional reference laboratories in relation to testing for hepatitis*" [SCGV0000070_028].

Incidence and severity

190. The available documents provide some insight into the SHHD's understanding of the incidence and severity of hepatitis B in the early 1970s. For example, in April 1972, Dr Wallace provided Dr Macdonald with a report of a recent blood transfusion symposium held in Brussels [SCGV0000204_106 and SCGV0000204_108]. As well as addressing screening for Australia antigen, the report included the following in relation to severity (recording a presentation by Dr Prince of New York):

> *"600 Au + donors – 20-30% had raised enzyme levels*
> *10-12% biopsies showed – none normal, there were benign lesions but no fibrosis or serious liver damage.*
> *One-third had chronic cirrhosis i.e. 5-10% of the whole group were at risk of developing chronic liver disease."*

191. An extract from the minutes of the 18 January 1973 meeting of the SACLS epidemiology sub-committee also records some discussion of these issues [SCGV0000204_089]. Dr Macdonald, in "*response to a suggestion that too much anxiety and alarm had been spread about Australia Antigen positive groups*", is

reported to have said that this "*possibly arose from the Maycock Committee's recommendations about what the Blood Transfusion Service should do about positive findings. These had created some uncertainty about repercussions from blood donors, although in practice no information had come forward to suggest that difficulties had been created for donors and there had been no compensation cases so far*". The minutes include the following:

> *"Professor Stewart enquired if any effort was made to screen out drug addicts from amongst blood donors. In the USA there was an incidence of hepatitis in 40% of drug addicts (5% of whom had been blood donors). It was considered unlikely that in the UK's voluntary (unpaid) blood donor system this problem would arise."*

192. The incidence of hepatitis was also addressed in a 30 January 1973 letter and attachment from Dr Lewis, director of the Aberdeen RTC, to Dr Macdonald [SCGV0000204_085 and SCGV0000204_086]. Dr Lewis explained that, from 1 January 1972, "*as a matter of interest and to detect potential donors of antibody to Australia antigen*", the RTC began testing "*virtually all blood samples referred to us for both antigen and antibody*". During 1972, 43,905 samples had been tested and 20 individuals found to be positive for Australia antigen.

Debate over screening techniques

193. From 1973, the SHHD became more closely involved in discussions about the appropriateness of different screening techniques for Australia antigen.

194. In an 8 February 1973 letter to Mr Roberts at the SHHD, copied to Dr Macdonald, Dr Wallace explained that he was exploring radioimmunoassay, which appeared to be a very sensitive technique but would be too expensive for the RTC's existing budget [SCGV0000204_083]. Dr Wallace enquired about the possibility of additional funding and explained that he was seeking more information for a potential trial of the tests from Abbott Laboratories Ltd, the relevant firm.

195. Dr Wallace and the SHHD continued to correspond about this issue in March 1973. The trial would involve a comparison of the RTC's existing electrophoretic method, with Abbott loaning equipment free of charge and the RTC only required to purchase reagents [SCGV0000204_082]. In providing the SHHD's assent to the trial, Mr Roberts wrote that the "*Blood Transfusion Service has, to an extent, pioneered testing for Australia antigen and it seems right that it should be given the opportunity of looking at various alternative methods to determine which is the most successful*" [SCGV0000204_081].[43]

196. Dr Macdonald addressed some of these developments in a 6 August 1973 minute to Mr Roberts, copied to Dr Bell [SCGV0000204_068]. He described a telephone call from Dr Maycock, who had been "*visited by two representatives from Abbott Laboratories who were pressing very hard for the United Kingdom to adopt the Abbott radioimmunoassay test*" for Australia antigen. In doing so, Abbott were said to have "*relied to some extent on the investigation being undertaken by Dr Wallace*".

197. Dr Macdonald also described a conversation with Dr Wallace, who was said to be "*willing to make his results available*" but also considered that he would be "*bound to report*" to Abbott. Dr Wallace's "*tentative view*" was said that to be that there was a "*need a for more sensitive test for use in the Blood Transfusion Service but the haemagglutination test may be preferable to the radioimmunoassay one. It may be rather less sensitive but it is cheaper and simpler to perform and does not give rise to such extensive follow-up investigations*".

198. Dr Wallace provided an update on trials of different screening methods in a 9 August 1973 letter to Mr Roberts [SCGV0000204_065]. He described the haemagglutination method as a "*practical proposition as a screening procedure*", and as identifying more positive donors than the standard IEOP method, while noting that it was "*early days*" to comment on Abbott's "AusRIA" method. A meeting with Abbott in September 1973 was proposed, to which Dr Maycock was invited but chose not to attend [SCGV0000204_055, SCGV0000204_050, SCGV0000204_047, SCGV0000204_046, SCGV0000204_045 and SCGV0000204_044].

[43] See also a 14 March 1973 letter from Abbott to Dr Wallace [SCGV0000204_080], as well as his 20 March 1973 letter to the SHHD [SCGV0000204_079].

199. Dr Macdonald summarised the meeting with Abbott, which took place at Law Hospital in Glasgow, in a 10 September 1973 minute to Dr Bell, copied to Mr Roberts [SCGV0000204_032]. Transfusion service representatives at the meeting included Dr Wallace. Abbott's representatives included a senior scientist from the USA and another with responsibility for the company's activities in Europe. Dr Macdonald thought that it was "*clear to the Abbott representatives that Dr Wallace and his colleagues were by no means satisfied that this test should be brought into routine use*", but it was agreed that the next part of Dr Wallace's investigation should continue.

Notification of hepatitis cases

200. Meanwhile, the SHHD continued to be involved in discussions relating to the risk of hepatitis from blood products. Dr Bell made reference to such risks in a note to Dr Macdonald, summarising a 28 November 1973 meeting of NBTS RTDs [SCGV0000204_022]. It had been explained at the meeting that "*with recent licensing of blood products there was a requirement that adverse reactions should be notified*", and that "*[i]n the first instance the Adverse Reactions Sub-Committee*" wanted "*to know about hepatitis*". Dr Bell noted that it appeared that the sub-committee already received "*some notification about post-transfusion hepatitis in England and Wales but they may not hear of Scottish cases*". He also recorded that there had been discussion over difficulties in defining an "adverse reaction" in transfusion cases, and that he had asked Dr Maycock for an example of the form used for reporting.

201. This issue was revisited at a CCC 14 March 1974 meeting, attended by Dr Bell [SCGV0000070_015]. It was reported at the meeting that "*the Regional Directors had agreed a uniform method of reporting post-transfusion hepatitis cases to the Adverse Reactions Sub-Committee of the Committee on Safety of Medicines*".

202. The SHHD and SNBTS also discussed the notification of hepatitis cases during this period: see, for example, internal minutes and correspondence with Major General Jeffrey, SNBTS National Medical Director, in June 1974 [SCGV0000204_004 and SCGV0000204_003].

Mid 1970s: further developments in screening techniques

203. In the mid-1970s, RTCs continued to carry out trials of different screening techniques. At a 10 October 1974 meeting of the CCC, attended by Dr Bell and Mr Roberts, it was recorded that the Maycock Advisory Group "*had proposed that parallel trials of the reverse haemagglutination and radioimmunoassay techniques for the detection of HBAg be instituted*", and that the Edinburgh and South-East RTC had developed a modified technique [SCGV0000070_008]. The minutes record that trials "*would probably have to be conducted on a multi-centre basis*" and that "*[a]s it would be at least a year before trials could be evaluated interim advice would probably be issued pending final decisions*".

204. The SHHD gave further consideration to hepatitis B screening in early 1975, when a further report became available from the Maycock Advisory Group. In a 26 February 1975 minute to Mr Elliott-Binns at the SHHD, Dr Macdonald reported that the final draft of the Advisory Group's second report was available [SCGV0000205_098]. He explained that from "*a medical point of view we are perfectly content with the technical recommendations about methods of testing*", but that medical officials had concerns with draft letters appended to the report, "*which suggest disclosure of information about a positive result to general medical practitioners and to dentists*". Dr Macdonald described the difficulty as being that "*no advice is readily available to doctors or dentists on how to handle this situation. The implications of a positive result are not fully understood and it is perhaps understandable that practitioners faced with this situation may sometimes take extreme precautions even to the extent of limiting treatment*".

205. At this stage, the Maycock Group's updated report had not yet been circulated widely. Nonetheless, in a 27 February 1975 letter to Dr Scott, Major-General Jeffrey noted that the Advisory Group's revised report was likely to recommend the use of reverse passive haemagglutination for screening rather than IEOP, and provided estimate figures for the purchase of kits across RTCs [SCGV0000205_095].

206. The death of a patient from hepatitis prompted more exchanges on screening between the SHHD and SNBTS in March 1975. On 22 March 1975, Dr Wallace wrote

to Dr McIntyre, following up a conversation the previous day "*regarding a fatal case of hepatitis*" and enclosing a preliminary report on the case sent to a Dr Pauline Bailey [BNOR0000452_003 and BNOR0000117_004].[44] He suggested that the SHHD would wish to "*correlate this unfortunate case... with the recommendations of the Maycock Advisory Group*". As for his own views on screening, Dr Wallace commented as follows:

> *"For the present I am convinced that the introduction of the more sensitive methods of testing donations will prevent some cases of post-transfusion hepatitis. Unfortunately a few cases of post-transfusion-hepatitis would still occur. Even the RIA test is unlikely to detect every example of HBsAg in apparently health donors and it may well be that infective agents other virus B are responsible for some cases of post-transfusion hepatitis."*

207. Dr Wallace's report recorded that the deceased patient had been treated with blood products from 31 donors, all of whom had tested negative for hepatitis B (as had the patient) using the standard counterimmunoelectrophoresis (CIEP) technique, as well as following repeat testing with the reverse passive haemagglutination (RPHA) technique [BNOR0000117_004]. However, screening and confirmatory tests by RIA suggested that serum from the patient and one of the donors "*contained a very weak form of HbsAg*". This suggested the cause of the patient's hepatitis "*was a virus B infection and the infective agent may have been transmitted by transfusion*". Dr Wallace commented that it seemed "*surprising that if the fulminant hepatitis in the patient... was due only to virus B infection that the HBsAg in his serum was so weak*" and suggested possible reasons for this.

208. In a further 28 March 1975 letter to Dr McIntyre, Dr Wallace provided additional information regarding the patient, noting that while "*all agree that hepatitis was the cause of death there are doubts about the cause of hepatitis*" [BNOR0000452_001]. He went to comment that, while it "*would be wrong to overemphasise the significance of one case*", this particular case emphasised an important point in relation for HBsAg screening. Having noted that the Maycock

[44] Details of the patient and where they were treated have been redacted in the documents available to the Inquiry.

Advisory Group was likely to recommend that RHPA be introduced for screening donations, he recorded that there was "*no doubt that RPHA is more sensitive than the current CIEP method*", and that it could be introduced quickly without the need for expensive equipment. Dr Wallace's "*main reservations*" about it were that "*the test is subjective and that it is less sensitive than RIA*". He added that he was "*now completely convinced that if RIA is not to be used for screening donations then all presumptive positive reactions by haemagglutination must be confirmed by RIA*".

Debate over the Maycock Group's recommendations

209. Further consideration to the Maycock Advisory Group's draft report was given in April 1975. In a 23 April 1975 letter, sent to Mr Roberts at the SHHD, Dr Maycock provided members of the Advisory Group with an updated draft report [SCGV0000205_138]. In a 24 April 1975 minute to Dr McIntyre, Dr Scott suggested that the Advisory Group had "*exceeded their remit*" [SCGV0000205_087]. He described testing of specimens as being "*what they were asked to report on and which is relatively straight forward*". He was also critical of the draft report's approach to "*PH*" (passive haemagglutination), suggesting that it was commended as being "*simple, rapid, economical and highly sensitive*" in one part of the report and ignored elsewhere.

210. Mr Roberts relayed some of these comments in a 5 May 1975 letter to the DHSS, stating that the PH method had been "*ignored entirely*" in the report's recommendations, which could be interpreted as meaning that RPH and RIA were the only two acceptable methods [SCGV0000205_084]. Mr Roberts provided further alternative wording in a 12 May 1975 letter [SCGV0000205_082].

211. In a 1 May 1975 minute to Mr Roberts and Dr McIntyre, Dr Scott recorded that the NMD (i.e National Medical Director, Major-General Jeffrey) had asked whether RTDs who wished to use the RPHA method in place of CIEOP could do so in anticipation of the Maycock/Advisory Group report [SCGV0000205_085]. He commented: "*I have no qualms about anticipating the Maycock report as I wonder if we could in any case stop a RTD who wished to do RPH now or indeed RIA. It is to a great extent a clinical matter; similarly we cannot force Dr Cash and the others to adopt RPH in place of PH.*" As for financial considerations, he wrote: "*There is the*

question of money but that would be up to the NMD. However this is a matter of such importance I should have thought that the money must be found".

212. In a 13 May 1975 minute to Dr Scott, copied to Mr Roberts, Dr McIntyre wrote that there was "*no doubt*" that the Advisory Group would recommend RPH for routine screening [PRSE0000704]. Following representations from the SHHD, it was also likely that the passive agglutination test would be accepted as "*perfectly satisfactory*". Dr McIntyre suggested that Major-General Jeffrey be made aware in advance of the forthcoming SNBTS directors' meeting that "*we were agreeable in principle to the introduction of a more sensitive test*". He agreed that "*the question of money will be up to the NMD*" but felt "*sure that he will eventually come to us for additional money for this purpose*".

213. The Maycock Advisory Group's updated report – "*Second Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody*" – was dated September 1975 [CBLA0000313]. However, as outlined below, the SHHD does not appear to have circulated it widely until early 1977.

214. The report's screening recommendations were discussed at a 14 October 1975 meeting of the Blood Transfusion Advisory Group to the Scottish Health Service ("SHS") Planning Council, attended by Dr McIntyre and Mr Roberts [SCGV0000079_016]. The minutes record that "*Directors were particularly concerned that the replacement of the counterimmunoelectrophoresis method of testing by the reverse passive haemoglutination* [sic] *(RPH) method (or the passive haemoglutination inhibition method (PH) being used in the Edinburgh Blood Transfusion Centre and acceptable to the Advisory Group) should be implemented without delay*".

215. SNBTS directors discussed the Advisory Group's second report at their 17 December 1975 meeting, attended by Dr McIntyre [PRSE0002061]. Dr Wallace is recorded as having emphasised that the advice in the report "*had been drafted early in 1975*". Directors "*agreed with its main recommendations and asked Dr McIntyre if SHHD would endorse the report to confirm Scottish BTS Regions in their respective practices.*" Dr McIntyre explained "*that a general memorandum on hepatitis was being drafted by SHHD for issue to Health Boards and that the report under discussion would*

probably accompany the memorandum. Meanwhile it would be brought to the attention of SHHD's Advisory Group on Communicable Diseases".

216. The SHHD gave further consideration to the Advisory Group's report during the course of 1976. In a 24 March 1976 minute to Dr McCreadie, Dr McIntyre proposed an office meeting to discuss it, noting that "*[i]n Scotland sensitive tests for the detection of HBsAg are now being used in all five regional transfusion centres*", but that other recommendations in the Report had not yet been implemented and "*the views of the Department on these is awaited*" [SCGV0000205_043].

217. At the 1 April 1976 SNBTS directors' meeting, attended by Dr McIntyre and Mr Roberts, Dr McIntyre "*explained that the general memorandum on hepatitis to which he had referred at the last meeting would be issued before summer 1976*" [MACK0000862].

218. An SHHD office meeting was held on 15 April 1976 to discuss "*what should be said in a covering circular to the Maycock report*" [SCGV0000205_039]. It was thought that the Report "*could eventually issue under cover of a circular endorsing its terms and drawing attention*" to points including "*the need for sensitive testing*" and the "*treatment of people with antibody positive blood*".

1976: Dr Wallace and the SHHD disagree

219. By the summer of 1976, differences had emerged between the SHHD and Dr Wallace about hepatitis B screening. In a detailed, 22 June 1976 letter to Dr McIntyre, Dr Wallace wrote that, during meetings of the Maycock Advisory Group, it was acknowledged that RIA was the most sensitive available method for detecting HBsAg but that, "*in practical terms*", it (and a WHO group) recommended that RPHA "*should be introduced as the method of total screening because RPHA could be introduced much more rapidly than the more sophisticated RIA technique*" [PRSE0000964].

220. Dr Wallace noted that he had been carrying out a trial of the RIA method since August 1975 and that it was due to end in August 1976. He provided figures on the number of cases detected by different methods and recorded that "*if we have been*

relying on RPHA for total screening we would have missed, in a period of 9 months, at least 7 examples of HBsAg positive donations and perhaps as many as 12". Dr Wallace considered that there was "*substantial evidence in favour of total screening by RIA rather than RPHA*", while noting that this would require additional funding. Having referred to previous compensation claims relating to hepatitis infection, Dr Wallace concluded by commenting: "*I have not, at this stage, informed either the Scottish Legal Office or my own Defence Society of the position because I am hoping that something can still be done to maintain a sensitive method of testing donations. If by the middle of August we are obliged for financial reasons to adopt a less sensitive method of testing then clearly I will have to inform these bodies...*".

221. This letter was considered in a number of internal SHHD minutes. On 25 June 1976, Dr McCreadie brought it to the attention of Dr Scott and Dr McIntyre [SCGV0000205_037 p.2]. Having summarised Dr Wallace's suggestion that it would be "*inadvisable*" not to use the RIA test, he commented: "*This brings us back to the old question of what can we afford to achieve a marginal improvement in the goal of perfection. According to Dr Wallace the cost of RIA screening is 100% more than the cost of RPHA screening test. We have at least the backing of the Maycock Committee and WHO for the utilisation of the RPHA test*". Dr McCreadie's view was that "*in the present financial climate it would not be justified to increase our testing costs by 100% to obtain marginally improved sensitivity*".

222. In a minute to Dr Scott on 28 June 1976, Dr McIntyre highlighted Dr McCreadie's comments and commented as follows [SCGV0000205_037]:

> *"Dr Wallace has been involved in the problems of hepatitis right from the beginning and knows that the problem is complex and that hepatitis B is only the tip of the ice-berg. If we accede to his request for additional money so that he can continue RIA then we are saying that this is such a preferable method that we considered the additional expenditure is justified. This leaves us in a difficult situation as regard the other centres. It may be that we could argue that they do not have the equipment necessary and therefore further additional costs over and above the reagent would be involved. Should a case of hepatitis B arise*

in any of these of these other regions however it could be construed that by implication we were adopting in these regions a less sensitive testing method."

223. Dr McIntyre responded to Dr Wallace's letter on 30 June 1976 [SCGV0000205_036]. He described the Maycock Advisory Group as having favoured RPH after "*weighing up factors such as sensitivity and cost*". He noted that, beyond August 1976, the estimated cost of RIA testing on a commercial basis was likely to be twice that of RPH, and concluded that, in "*light of the Maycock Report which took into account the greater sensitivity of RIA, the method of testing recommended by the Advisory Group should be employed* [as] *in other transfusion centres in Scotland*".

224. This response appears to have led Dr Wallace to write to medical officers and haematologists in the West of Scotland on 26 July 1976 [SCGV0000205_032]. The letter summarised the Maycock Advisory Group's recommendations and the evaluation conducted by Dr Wallace over the previous year, before recording that the SHHD had stated that "*RPHA is the recommended method of testing and is the method which should be employed in this region after the middle of August, 1976".* Dr Wallace concluded by stating that RIA testing would be replaced by RPHA at the RTC on 14 August, and that in "*light of the evaluation it is estimated that in the course of one year from 9 to 16 donors who are chronic carriers of HBsAg detectable by RIA will not be detected by RPHA*".

225. Dr Wallace's letter led to further discussion in the SHHD. In a 29 July 1976 minute enclosing a draft letter to him, Dr McIntyre commented that the "*point at issue is not the sensitivity of the test* [i.e. RIA] – *of that there has never been any doubt – but the policy to be adopted after consideration of the other factors such as capital and recurrent costs. In my view Dr Wallace has not shown any reason why the present policy should be changed at this time*" [SCGV0000205_118 and SCGV0000205_119]. He noted that there were regions in England and Wales using RIA and left open the possibility that it would be used as a routine test in Scotland, while suggesting that "*already other allegedly more sensitive tests are on their way which might well supercede* [sic] *it in the foreseeable future*".

226. Before responding to Dr Wallace, the SHHD wrote to the Chief Administrative Medical Officers ("CAMOs") who had received Dr Wallace's 26 July 1976 letter. In a 3 August 1976 letter, Dr Macdonald set out the Maycock Group's recommendation and noted that it had been endorsed by the SHS Planning Council Blood Transfusion Advisory Group [SCGV0000205_117]. He explained that the most recent version of the report had not yet been formally circulated but that RTDs had been "*advised informally that the Department accepts the recommendations made relating to routine testing*". He added that the cost of the West of Scotland RTC continuing RIA testing on a routine basis would be approximately twice that of alternatives such as RPH, and that the SHHD accepted the Maycock Group's recommendation.

227. Dr McIntyre wrote directly to Dr Wallace the following day, enclosing his letter to CAMOs and commenting as follows [SCGV0000205_116]:

> *"I am sorry that you felt it necessary write such a letter which does not present the full facts about the situation. It might have been helpful if you had made it clear that you are a signatory to the report of the Advisory Group, that in making its recommendation the Group was aware of the additional sensitivity of RIA and that as a member of the Blood Transfusion Advisory Group you subsequently endorsed the relevant recommendations of the report without demur; also that WHO had made similar recommendations. As you know the report has not yet been accepted in its entirely and has therefore not been generally circulated. Those to whom you have written therefore are for the most part not aware of the basis on which the Advisory Group reached their recommendations and may come to conclusions which are unjustified."*

228. Dr Wallace responded to this with a series of letters on 6 August 1976. These included two letters to Dr Macdonald, one of which he described as "*formal*" and the other as "*informal*". In the short, "*formal*" letter, Dr Wallace wrote that he had "*no intention of defending either my professional opinion or my action. The former is based on recent and sound scientific evidence and would be supported in 1976 not only by all the other members of the Maycock group, but by eminent authorities throughout the world*" [SCGV0000205_026].

229. In the longer, "*informal*" letter, Dr Wallace provided a number of additional comments [SCGV0000205_027]. These included:

a. Neither the Maycock report nor the WHO report to which Dr Macdonald had referred were "*recent. Each report really states views held by experts in the second half of 1974*".

b. Both of those reports (and earlier iterations) made it "*abundantly clear that the situation is dynamic and that recommendations must, of necessity, be interim. Expert opinion today recommends either RIA or EIA as the technique of choice*".

c. Having attended meetings of the Maycock Group and received papers provided to it, the SHHD would have been aware that "*members of the Group were in a quandary by the middle of 1974 as to whether to recommend RPHA or RIA. There was a definite polarisation of members between finance and sensitivity*".

d. Since then, Dr Wallace had presented evidence to the SHHD with the results of comparative trials of RHPA, RIA and EIA.

e. As for funding, he commented: "*I have told Dr. McIntyre repeatedly that I accept the sad fact that there is no more money available for developments, but I reserve the right to inform medical colleagues in the region for which I am responsible, that I am discontinuing the use of RIA, and as a consequence I anticipate a definite number of false negative donations. What I cannot quantify is the number of cases of type B hepatitis which will result or the amount of cross contamination of products and fractions which will occur*".

f. Dr Wallace referred to previous cases of hepatitis B infection in the West of Scotland (including the fatal case) before adding: "*What is much more worrying and potentially more serious is the dissemination of these infective agents in multiple blood products. I know that this possibility is causing concern to Maycock and to Watt*".

230. Dr Wallace repeated these points in a third letter that day, addressed to Dr McIntyre [SCGV0000205_114]. He concluded by commenting: "*It is my duty as a professional in the field, to advise those who take administrative decisions of my observations and my views. This I have done and I now accept the decision of the High*

Command. I will continue to make by [sic] *observations and to keep colleagues like yourself informed*".

231. Other documents suggest that, even with the use of more sensitive screening tests, occasional hepatitis B transmission through PFC factor concentrates continued to occur. This issue was considered at a 4 October 1976 meeting of SNBTS and haemophilia directors, attended by Dr McIntyre and Mr Roberts for the SHHD [PRSE0000983]. The discussion seems to have been prompted by the investigation of two batches of PFC factor VIII. This suggested that "*there had probably been one positive donation which had been missed on the initial screening or that there might have been a number of positive donations which were just below the level of sensitivity in the test used*".

232. Further discussion of a batch of factor VIII which appeared to be "*implicated in the outbreak of hepatitis*" took place at the 24 January 1977 meeting of SNBTS and haemophilia directors, again attended by Dr McIntyre and Mr Roberts [PRSE0003415]. It was noted that, while circumstantial evidence indicated that the batch was implicated, it was negative for HBs Ag "*by the most sensitive methods of testing available*".

233. Hepatitis B screening was revisited at the 26 January 1977 SNBTS directors' meeting, attended by Dr McIntyre and Mr Roberts, and in part by Dr Moir [SBTS0000088_005]. It was noted that the SHHD had issued the Advisory Group's second report on 19 January 1977 under cover of a circular. Dr Wallace stated that "*the report represented the consensus views of the Working Party in late 1974 and was therefore already out of date in some respects*". Following discussion "*it was agreed that Dr Cash should circulate copies of a paper produced recently in his Centre. On receipt of that and the light of development towards cheaper methods of testing by RIA the matter should be considered further a future meeting*".

234. Screening was discussed again at a 9 March 1977 meeting of the SHS Planning Council Blood Transfusion Advisory Group, attended by Dr McIntyre and Mr Roberts [SCGV0000079_013]. During discussion of the Advisory Group second report, "*Dr Wallace emphasised the point he had made at the last meeting that the information contained in the Report was based on 1974 data and was now substantially out of date.*

In view of the considerable advances which had been made in the meantime he and most of the members of the Maycock Group would no longer agree with the main recommendations of the Report". The minutes further record:

> *"Rapid progress was being made in the use of various blood products with a consequent increase in the risk of the spread of hepatitis. Regional Directors were concerned at this increasing risk and would be considering the entire question in the near future. The situation whereby Reports of this kind had to be widely circulated for approval prior to publication invariably resulted in the document being somewhat dated, particularly in a developing situation. However, a suggestion that this situation could be overcome by the issue of updating information sheets was thought to have considerable merit. It would also avoid having to go over old ground again. It was intimated that the Report was initially a Report to the Health Departments for consideration of any financial implications although tests recommended in the Report had been in use for some considerable time."*

Late 1970s and early 1980s: further development of screening tests

235. Hepatitis B screening was again revisited at the 21 April 1977 meeting of SNBTS directors, attended by Dr McIntyre and Mr Roberts [SBTS0000088_067]. It was agreed at the meeting that "*the possibility of developing a low-cost RIA test was good*". It was also agreed that *"the ORPHA test merited further consideration*" and that the directors would await the results of a pilot study of this technique that was being undertaken at the SE Scotland BTS.

236. Around mid-1978, the DHSS decided to reconvene the Advisory Group, with Dr Jenkins of the North East Thames RTC as chair. Dr Fletcher set this out in a (draft) August 1978 letter to Dr Bell, recording that the Advisory Group had been asked to advise on the following points [DHSC0103342_154]:

a. The "*possible introduction of other and more sensitive techniques*" for screening blood donors for HBsAg, such as enzyme immunoassay (EIA or ELISA).

b. The "*value of tests for hepatitis B core antibody as a marker of infectivity*" with hepatitis B.

c. The "*merits of routine screening of blood donors for raised serum transaminases*".

d. Whether blood donors with "*a history of hepatitis should ever be accepted and whether donors found to be HBsAg positive should be re-examined and, if negative, then reinstated*".

e. The "*pool-size of plasma for fractionation to factor VIII concentrate and what tests should be applied to donations going into this pool*".

237. The decision to reconvene the Advisory Group was recorded at a 4 October 1978 meeting of RTDs for England and Wales, attended by Dr Bell [DHSC0002367_005]. The aim was described as being to update the existing report on hepatitis B testing "*and to consider a number of special problems associated with hepatitis B in the context of blood transfusion*".

238. Further discussion of hepatitis B screening took place at the 27 June 1979 meeting of NBTS RTDs, attended by Dr Bell, including the development of an RIA test at BPL [SCGV0000072_006]. Dr Tovey "*suggested that there ought to be uniformity of practice in the use of the test, with a change by all RTCs to RIA if this were to be agreed policy*".

239. Dr Bell attended the second meeting of the reconvened Advisory Group on hepatitis B on 2 April 1979, during which the development of different hepatitis B tests was discussed, including BPL's test and an enzyme-immunoassay test [CBLA0000931]. It was agreed at the meeting that an interim report should be submitted to the DHSS "*as it was likely that delays in making recommendations and revision of the Second Report would now be inevitable*" in light of the need to investigate various issues further.

240. Further discussion of screening took place at the 6 March 1980 meeting of the reconvened hepatitis B Advisory Group, attended by Dr Bell [CBLA0007195]. The minutes record that the Advisory Group "*strongly supported the development and distribution of the BPL RIA test*" and that the DHSS would be informed.

241. During the course of 1980, a new Advisory Group on Hepatitis was established. At its first meeting on 3 October 1980, attended by Dr Forbes for the SHHD, it was noted that the Advisory Group on hepatitis B had prepared a third report, but that it had not yet been approved and circulated [DHSC0002199_066]. Dr Jenkins summarised the report's recommendations, which included the sensitivity of screening techniques used to screen donations "*destined to contribute to protein fractionation at NHS Fractionation Centres*". The third report continued to be unavailable by the time of the 5 December 1980 meeting of the Advisory Group on Hepatitis, attended by Dr Prentice for the SHHD [DHSC0000127]. It was agreed at that meeting that it would be better to appoint small working groups on an ad hoc basis to replace the Advisory Group on hepatitis B testing.

242. Dr Bell attended the 23 February 1981 meeting of the Advisory Committee on the NBTS [CBLA0001287], and subsequently summarised the discussion of hepatitis B testing that took place at the meeting in a note to SHHD colleagues [SCGV0000082_041]. He described a "*refreshingly uninhibited discussion... concerning the decision that the BPL radioimmunoassay should only be made available to the transfusion service at a cost of 20p per test*" when its actual cost was 7p or 8p. Dr Bell commented that "*[a]lthough we in Scotland are affected to some extent this is really a DHSS/English issue and I did not think it appropriate to register an SHHD view*", adding: "*since in Scotland we have a "devolved" health service under the Secretary of State would there be anything to stop us making the RIA test for our own use?*".

243. By the time of the 11 May 1981 meeting of the Advisory Group on Hepatitis, attended by Dr Prentice for the SHHD, the third report of the Advisory Group on hepatitis B was available [DHSC0000128]. The report, which was endorsed at the meeting, summarised the background to hepatitis B screening, considered the merits of RIA, ELISA and RPHA tests, and recommended minimum sensitivity levels for tests used by RTCs [PRSE0000862]. It additionally concluded that it was "*only possible to lay down approximate guideless for the sensitivity of testing*".

244. This report was also discussed at the 22 September 1981 meeting of SNBTS directors, attended by Dr Bell and Mr Finnie [PRSE0003920]. Dr Bell "*advised that the document was not intended to provide a legal safety net but to provide guidelines on the best procedures to be adopted, and that Directors' clinical judgement and adherence to the recommendations, within the finance available, was all that could be expected of them*".

VII. KNOWLEDGE OF AND RESPONSE TO RISK: HIV/AIDS

Knowledge of risk and initial response

245. The earliest reference to AIDS in documents involving the SHHD – in the available material – would appear to be a 21 January 1983 meeting of SNBTS and haemophilia centre directors, chaired by Dr Bell and attended by Dr McIntyre and McBryde [PRSE0001736]. The minutes record that Professor Cash drew the meeting's attention "*to recent articles in the United States, and also in the Observer and the Lancet, about this problem. A MMWR extract (CDC, Atlanta) had been circulated with his paper. Dr Ludlam informed members that in the UK a letter and questionnaire had been sent out to haemophilia directors*".

246. By May 1983, the SHHD was receiving information relating to AIDS from the DHSS. A 3 May 1983 minute on the subject from Mr Parker at the DHSS to Geoffrey Finsberg's Private Office, enclosing a line to take and background note which had been prepared for the Prime Minister, was copied to John Davies, Assistant Secretary at the SHHD [DHSC0001651]. The line to take included that "*there is as yet no conclusive proof that AIDS has been transmitted from American blood products*". The note identified haemophilia patients treated with factor VIII as being at increased risk of AIDS and stated: "*As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact but the evidence is suggestive that this is likely to be the case*" [DHSC0003824_173].

247. The SHHD was also receiving information internationally. On 5 May 1983, Dr Prentice forwarded a telex from Dr Velimorovic of the WHO to various SHHD

colleagues, including Drs Scott and McIntyre [SCGV0000147_177 and SCGV0000147_180].[45] The telex recorded that a meeting regarding AIDS would be held in Denmark in November and that, as of 1 May 1983, there had been over 120 cases of AIDS in the European countries that had provided information to the WHO.

248. Both of these sources of information were reflected in a 6 May 1983 minute from Dr McIntyre to Mr Davies, which appears to have been provided for the purposes of a ministerial submission [SCGV0000147_181]. Dr McIntyre commented that the background note provided by the DHSS reflected "*the situation in England and Wales*" and that, while Scottish transfusion directors had been in touch with Dr Gunson, there had not been any formal discussions with directors in England and Wales. He noted that Dr Prentice was "*in close contact with the Communicable Disease (Scotland) Unit at Ruchill to which any case of AIDS arising in Scotland would be notified.*" Dr McIntyre recorded that no "*proven case*" had been notified to date, though he commented that the signs and symptoms of AIDS were "*somewhat vague*". He stated that "*nearly all*" blood products used in Scotland, including factor VIII, were "*produced at the PFC from blood voluntarily donated within Scotland*", and that the use of imported factor VIII was limited to a few patients. He also outlined a number of measures being considered by the SNBTS.

249. A ministerial submission, addressed to John Mackay's Private Secretary, was prepared by Mr Davies on 6 May 1983, the same day as Dr McIntyre's note [PRSE0004037]. Mr Davies noted that "*Mr Mackay may have seen comment recently in the media about AIDS*" and enclosed the DHSS material prepared for the Prime Minister. He commented that "*[w]e* [i.e. the SHHD] *agree with the general line in the briefing. There are, however, a few Scottish points to be made...*". These included that Scotland "*is virtually self-sufficient in Factor VIII. Occasional purchases of imported concentrate are made for clinical reasons: only a very few patients are involved*". Mr Davies noted that no confirmed cases of AIDS had been reported in Scotland, and that any suspected or diagnosed cases would be reported to the CDU at Ruchill. He also outlined four measures being considered by the SNBTS (reflecting those set out in Dr McIntyre's minute):

[45] A manuscript note suggests the telex was also forwarded to Mr Davies.

a. Briefing "*all front line blood bank staff to handle questions from donors*".
b. Preparing a "*neutral factual leaflet about AIDS and making this available at donor sessions – perhaps drawing attention to it as a follow-up to recent press and television publicity.*"
c. "*Informal contact with representatives of the relevant gay associations*".
d. Avoiding collection "*in high risk locations such as prisons or where there is known to be a high proportion of homosexuals or drug abusers in the population*".

250. Mr Mackay's Private Secretary responded on 9 May 1983 to record that the Minister was grateful for Mr Davies's note [SCGV0000147_175].

First AIDS donor leaflets and other steps

251. Around this time, Dr Brian McClelland of the South East Scotland RTC had begun work on an AIDS donor leaflet. The steps taken by Dr McClelland in relation to AIDS donor leaflets have been explored in evidence previously heard by the Inquiry.[46] During oral evidence, he described his contact with the SHHD while preparing a first leaflet as follows: "*...I telephoned Dr Bell, who was my medial liaison in the Department, the SHHD, and I basically told him I was going to do it, because I didn't want to ask. I felt it was a sort of "seek forgiveness not permission" situation really. I just really wanted to get on with it*" [INQY1000177 p.156].

252. At a 24 May 1983 meeting of the SNBTS Co-Ordinating Group, which was not attended by the SHHD, Dr McClelland presented a draft AIDS leaflet [PRSE0003620]. A leaflet was subsequently issued by the South East Scotland RTC in June 1983 [PRSE0004850]. It stated that AIDS was "*thought to be caused by an infectious agent, perhaps a virus*", and that "*[i]f a blood donor happened to carry the agent responsible for AIDS it is possible to transmit the disease to those not usually at risk. For example,*

[46] See, for example, the transcripts of Dr McClelland's oral evidence to the Inquiry on 27 January 2022 pp.155-162 [INQY1000177] and 28 January 2022 pp.2-44 [INQY1000178], as well Dr McClelland's written statement [WITN6666001].

factor VIII (the clotting factor extracted from plasma for treatment of Haemophilia) could have become infected and caused AIDS in a few cases of Haemophilia in USA".

253. AIDS and donor selection leaflets were discussed at a 14 June 1983 SNBTS directors' meeting, attended by Dr Bell and Mr Wastle for the SHHD [MACK0001960_001]. Part of the meeting was also attended by two RTDs from England: Dr Gunson and Dr Wagstaff. Following discussion of the approach being taken in England and Wales, the minutes record that Dr McClelland had:

> *"amended his leaflet following discussion with representatives of the Scottish Homosexual Rights Group who were issuing a press statement and who would distribute the leaflet, (which was ready for issue) within their own organisation. It was acknowledged that if the purpose of a leaflet was to deter donors it would require to be issued before they attended a donor session…".*

254. The meeting discussed "*the attitude being taken by the American Red Cross and by the Council of Europe*" and Professor Cash agreed to circulate a Council of Europe paper on the subject of AIDS. The directors further noted that "*the DHSS were closely involved in England and Wales and recommended that the SHHD should have a similar involvement in Scotland. There would also be a need for a Government Press Officer to handle enquiries*". Professor Cash undertook to liaise with the SHHD.

255. Dr Bell addressed this meeting in two minutes to Dr McIntyre and Mr Wastle the following day. In the first, he outlined the development of an AIDS leaflet in England and Wales, recording that it was being re-written by Dr Gunson and was not yet available for detailed discussion [PRSE0002473]. He commented that there was "*no doubt about the desire in the transfusion services to collaborate fully north and south of the Border*", noting that "*Dr Gunson has promised to let SNBTS have his latest version… He will also try to ensure that DHSS consult SHHD in good time before there is ministerial involvement in going public on this subject*".

256. Dr Bell described the directors as now being "*more aware of the complexity of the issues involved particularly in relation to the views of the homosexual community, the scope for misrepresentation by the press and the public, and the diplomacy required*

in presenting the AIDS issue in donor centres. For example no one is now quite sure as to whether the proposed leaflet should be for "pick-up" or "hand-out". (DHSS were for hand-out)." It was thought that two leaflets might be needed: "*one for donor centres in general and the other slanted more specifically to the homosexual community*". Having noted that the DHSS had received a significant number of PQs relating to AIDS, Dr Bell commented: "*I don't think there is any doubt that SHHD will have to involve our Minister and that we cannot rely solely on the views of the SNBTS*".

257. In his second 15 June 1983 minute, Dr Bell explained that he had been informed that the leaflet prepared by the Edinburgh RTC, in consultation with the Scottish Homosexual Rights Group ("SHRG"), had had begun circulating through the SHRG network [PRSE0004396]. Dr Bell suggested that it appeared that "*de facto, we are about to reach a situation in which there will be two slightly different leaflets*".

258. Relatively brief reference to AIDS was made by Dr Bell in a note of the 21 June 1983 first meeting of the Central Committee for Research and Development in Blood Transfusion, which he had attended at BPL as an observer [PRSE0004804]. He reported that Dr McClelland had introduced nine topics regarding AIDS for consideration, which led "*to a rather diffuse discussion in which... no firm conclusions were reached*". Dr Bell also noted that he had responded positively to a suggestion that the blood transfusion services contribute to AIDS research while making "*a particular point of the current stress on our BTS budget*".

259. By mid-1983, AIDS cases in Scotland were being reported in the press. An article in the July/August 1983 edition of *Gay Scotland*, which appears to have been published in late June or early July, reported that two cases of AIDS that were "*highly suspected, though not yet confirmed*", had been reported in Edinburgh in Tayside [PRSE0003358].

Development of DHSS/UK leaflet

260. SHHD officials continued to liaise with their DHSS counterparts over the development of an AIDS donor leaflet in late June and early July 1983. In a handwritten file note, an SHHD official recorded a conversation with Mr Winstanley of the DHSS

on 20 June 1983 [SCGV0000147_171]. Mr Winstansley was said to have a "*confirmed that a revised leaflet – based on Dr McClelland's – was being prepared. He agreed to let me have copies of the final draft and to keep me in touch developments, especially on the timing of submission to Ministers*". Dr Bell was said to have had a similar conversation with Dr Walford. In a further note, the official recorded a second conversation with Mr Winstanley on 28 June 1983. The latter "*said that progress on preparing a draft leaflet and a draft submission to Ministers was slow, but was well aware of the need to consult SHHD on the leaflet and give adequate warning on the timing of an approval to Ministers*". A further note recorded that Mr Davies had been kept informed of developments.

261. A DHSS submission on publication of an AIDS leaflet was subsequently submitted to ministers on 1 July 1983, copied to Mr Wastle at the SHHD [DHSC0002309_024]. The submission, prepared by Dr Walford, stated that "*[a]lthough there is no conclusive evidence, it seems very likely that AIDS is caused by an as yet unidentified virus*" [DHSC0002309_121]. A draft leaflet, dated 24 June 1983, stated that AIDS could "*[a]lmost certainly*" be transmitted through blood and blood products [DHSC0002309_122]. Further DHSS internal correspondence was copied to the SHHD, including a 4 July 1983 minute from Mr Parker confirming that Lord Glenarthur was content with the proposed leaflet [DHSC0002309_026].

262. These developments were soon discussed with the DHSS and within the SHHD. A 6 July 1983 handwritten note to Dr Bell described a conversation with a DHSS official [SCGV0000147_161]. This recorded that the DHSS "*Ministers had mixed reactions and it required a meeting attended by Mr Parker this morning to secure agreement from Ministers who nevertheless wish the terms of the leaflet to be toned down*". DHSS ministers had also asked for a statement to be used when publishing the leaflet to "*put the matter in perspective*" and to "*allay any impression of over-reaction*".

263. In minute prepared that same day, Dr Bell provided Dr Scott with a copy of the DHSS ministerial submission [PRSE0000049]. He explained that the submission and proposed leaflet were in line with what had been "*tentatively agreed by the English and Scottish RTDs*", though the section requesting high risk donors not to give blood was different to the version prepared by Dr Gunson (which was based substantially on Dr

McClelland's version). The SHHD had been "*informed that Mr Fowler's first reaction*" was that "*the terms of this leaflet are strong, and that DHSS may therefore be making further amendments*". Professor Cash was said to be content with the current DHSS version and strongly to favour a single UK leaflet. Dr Bell agreed that a single leaflet would be best, while noting that this would be an SNBTS leaflet with the same text as the DHSS.

264. Soon thereafter, on 11 July 1983, Mr Davies provided Mr Mackay with a minute on developments around the AIDS leaflet [SCGV0000147_157]. He attached the draft leaflet provided to the DHSS by RTDs in England [SCGV0000147_158], noting that DHSS ministers had expressed reservations over it and that DHSS officials were "*toning down the text somewhat, largely to make clear that, even in the US, only a small number of cases has been reported*". Mr Davies explained that publication and distribution of a donor leaflet would conform with a draft resolution prepared by the Council of Europe's Committee of Experts on Blood Transfusion. He informed Mr Mackay that the SHHD considered that the leaflet should be issued on a UK basis, and that officials were arranging for the text to be adjusted accordingly. The main change would be to "*alter references to the 'National' (ie English and Welsh) Blood Transfusion Service*". Mr Davies advised that "*[n]o separate Scottish announcement would be called for, but an important point for any press inquiries is that Scotland is virtually self sufficient in Factor VIII*".

265. In a response the following day, Mr Mackay's Private Secretary explained that the Minister had "*enquired whether the surplus capacity*" at the PFC "*could be used to increase UK production of Factor VIII – he believes the current English production is only some 60% of demand*" [SCGV0000147_153]. A 13 July 1983 manuscript note, which appears to have been from Mr Davies to another official, recorded a belief that proposals to process English plasma had been rejected in favour of enlarging BPL and requested the papers that would provide an explanation.

266. Alongside the SHHD's consideration of these issues, it received updates from the SNBTS. In a 19 July 1983 letter to Dr McClelland, copied to Dr Bell, Professor Cash enclosed a draft leaflet he had received (presumably from the NBTS) [SBTS0004433_052 and SBTS0004433_053]. He proposed that the SNBTS Co-

ordinating Group meeting on 30 August 1983 be updated on the position with regard to a UK leaflet and agree on a method of distribution to donors.

267. Meanwhile, the SHHD continued to be updated about the DHSS's approach to the donor selection leaflet. A 29 July 1983 DHSS submission seeking ministers' agreement to printing and distribution arrangements for the proposed AIDS leaflet was copied to Mr Davies [DHSC0002327_016]. In a file note, Mr Wastle recorded a telephone conversation in which Mr Winstanley explained that DHSS Ministers had agreed the contents of the AIDS leaflet and a draft statement [SCGV0000147_142]. The DHSS "*intended to proceed with printing immediately*", and Mr Wastle had reminded Mr Winstanley that "*it had been agreed that a single leaflet should be used throughout GB and that the print order should include sufficient for SNBTS*".

268. Mr Wastle further recorded that, when the DHSS papers arrived on 3 August 1983, "*it was apparent that the amendments agreed between Mr Davies and Mr Parker... had been overlooked. When I pointed this out to Winstansley he said that the leaflet had gone for printing and he was not inclined to withdraw it for amendment (Mr Davies subsequently agreed that the matter was not worth pursuing).*" Mr Winstanley was said to have undertaken to provide 200,000 leaflets for use in Scotland, as well as agreeing to keep Mr Wastle "*in touch with the timing of the issue of the Ministerial statement and the Press release*".

269. In a 19 August 1983 letter to Dr McClelland, Professor Cash outlined the arrangements for the distribution of the DHSS/UK leaflet, which was due to arrive the following week [PRSE0001400]. In doing so, he described his understanding of the DHSS's and SHHD's approach. Professor Cash explained that "*the "English" Minister*" would make a statement on AIDS, and that "*[i]n the first instance Ministers feel that the way the leaflets are distributed should be left to the discretion of individual RTDs*". He wrote that the "*Scottish Minister will not make a separate but the Scottish Information Office will issue a press release (based on the "English" Minister's Statement).*" He further recorded that the "*"English" Minister has instructed that NBTS RTDs do not respond to any subsequent policy questions from donors but that they should refer these questions to DHSS. SHHD feels the same approach should apply in Scotland but that the questions reach the SHHD via the HQ unit.*"

270. Around this time, Professor Cash was also providing information to the SHHD on the origin and use of blood products. In a 29 August 1983 letter to Mr Wastle, he provided annual figures on the amount of factor VIII issued as cryoprecipitate, PFC concentrate and commercial concentrate in 1978-1982 [PRSE0000798 and SCGV0000147_125]. Professor Cash explained that it "*would be safe to say that over 90% of the commercial material is derived from plasma sources that are "American in origin"*". This information may have been intended to be used in a press release or other SHHD statement. Professor Cash added: "*You may wish to include in the statement that an SNBTS heat treated factor VIII concentrate will undergo clinical trials within the next 2-3 weeks. This may be importance because if AIDS is a virus then we would anticipate the heat treated product will be safer*".

271. On 1 September 1983, the SHHD issued a press release on the publication of the UK AIDS donor leaflet [PRSE0002778]. It stated that "*[n]o cases of the disease have been confirmed in Scotland and the Scottish Home and Health Department emphasised today that there is no conclusive proof that the disease can be transmitted in blood products*". Donors were asked not to give blood "*if they think that they may have the disease or be at risk from it*". The press release added that "*Scotland is self sufficient in whole blood and virtually so in blood products. Nearly all the factor VIII issued for the treatment of haemophilia is produced from blood plasma donated to the SNBTS by blood donors in Scotland*".

Ministerial query on PFC's capacity

272. SHHD officials worked on a response to Mr Mackay's 12 July 1983 query regarding surplus PFC capacity in September and early October 1983. Mr Wastle first sought and obtained suggested amendments to a draft from Dr Bell on 6 September 1983 [SCGV0000147_117, SCGV0000147_118 and SCGV0000147_116]. He subsequently provided drafts to Mr Davies on 12 September and 3 October 1983 [SCGV0000147_112, SCGV0000147_113 and SCGV0000147_107].

273. The finalised minute, signed by Mr Davies, was provided to Mr Mackay's Private Secretary on 4 October 1983 [SCGV0000118_011]. It stated that BPL met

about 50% of the demand for factor VIII in England and Wales, the remainder being imported, with the limiting factor being plasma availability. Mr Davies noted that the redevelopment of BPL was scheduled for completion in 1986 and that the NBTS planned to increase its plasma stock. If this stock were likely to exceed BPL processing capacity, the SHHD would "*discuss with DHSS whether the PFC could process the surplus. Such a step would not be possible without some capital investment in the additional facilities for storage, filling, packaging etc at PFC, and would also result in increased running costs*".

274. Mr Davies also noted a further difficulty: production at the PFC had recently been adversely affected by works required by the Medicines Inspector that would continue into 1984. A backlog of plasma for processing had built up as a result, and temporary overtime arrangements would be needed to clear it. The backlog would be another factor in considering whether PFC could process plasma from BPL. Mr Mackay's Private Secretary relayed the Minister's gratitude for Mr Davies's note on 5 October 1983 [SCGV0000147_105].

275. In a 25 October 1983 letter to Mr Winstanley, Mr Wastle described the contents of the 4 October 1983 minute to Mr Mackay, before adding: "*We undertook to discuss with you the prospects for processing English plasma at PFC if we are approached. It is as well for you to know that, in the short term at least, we would be unlikely to be able to help!*" [SCGV0000002_002].

Late 1983: monitoring developments

276. In late 1983 and 1984, SHHD officials appear primarily to have monitored developments relating to AIDS and blood products, including proposals for further steps that might be taken in response.

277. For example, in a note of the 17 October 1983 meeting of the Advisory Committee on the NBTS, Dr Bell recorded a suggestion, made in a different group, to concentrate "*on small pools of donors, ie more intensive plasmapheresis of donors whose health status could be monitored*" [SCGV0000083_048]. The meeting minutes also record an update on AIDS from Dr Walford, who reported that "*to date of the 24*

cases of AIDS reported in the UK, two were haemophiliacs of whom one had died. Comparison with reported incidences in the UK haemophiliac population suggested that the UK could anticipate between 2-4 deaths amongst haemophiliacs from the disease" [CBLA0001763].

278. At an 18 October 1983 meeting of the Advisory Group on Hepatitis, attended by Dr Prentice for the SHHD, Dr Craske reported that the number of AIDS cases in the USA was doubling every six months "*but that there was still a very low risk of contracting the disease*" [BPLL0008168].

279. A 31 October 1983 article in the Scotsman reported a 50 per cent jump in the number of AIDS cases in Britain in September, from 16 to 24 [SCGV0000147_098]. Three of the eight new cases had died, including a haemophilia patient "*who, according to some reports, was given blood-clotting agent contaminated from an AIDS-infected American donor*". The article appears to have been placed in an SHHD file and flagged for the attention of Mr Davies, Dr McIntyre and Dr Bell. A manuscript note beside the paragraph addressing the haemophiliac death appears to read: "*We have already heard about these cases*".

280. During this period, the SHHD continued to monitor the approach taken to AIDS in England and Wales through attendance at meetings. In a note of the 7 November 1983 meeting of the CBLA Central Committee for Research and Development, Dr Bell reported that, during a discussion of the AIDS leaflet, "*some doubt was expressed as to whether the message was being got over and it was mentioned that Dr Gunson and Dr Walford intended to consider a revision before the next print*" [SCGV0000052_086]. Dr Bell believed that, with Dr McClelland on the AIDS Working Group, the SHHD could "*rely on there being consultation with Scottish interests*". Following a discussion of possible surrogate screening for AIDS, "*[s]mall pool apheresis was suggested as a potentially significant strategy, within transfusion practice, in combating AIDS*".

281. Dr Bell also attended the 14 November 1983 meeting of the Haemophilia and Blood Transfusion Working Group, during which trials of heat-treated PFC factor VIII were discussed [PRSE0002581]. Attendees at the meeting were also asked "*for their views on the effectiveness of the leaflet which had been prepared by the SNBTS and*

DHSS". The minutes record that it "*was felt generally that the leaflet had not been particularly useful although it had been put out freely at donor sessions and had been made widely available at other locations including VD clinics*".

1984: changes to the AIDS donor leaflet and other developments

282. Developments in the distribution of the AIDS donor leaflet were discussed at an 8 December 1983 meeting of SNBTS directors, attended by Dr Bell and Mr Murray [PRSE0002899]. It was noted that the leaflets had been available for some time at donor sessions and it "*was agreed that a more active approach would be acceptable now*". Attendees considered that each blood donor should receive a copy and that the health questionnaire to donors should include the question: "*Have you read and understood the leaflet on AIDS?*". Dr McClelland agreed to produce a revised version of the leaflet.

283. It is unclear whether a revised leaflet had been prepared by the time of the 2 February 1984 meeting of SNBTS and haemophilia directors, chaired by Dr Bell and attended by Dr McIntyre [PRSE0001556]. In relation to AIDS, the minutes record that there was discussion of "*reports from abroad which suggested that recipients of blood could also be at risk. The effectiveness of the leaflet addressed to blood donors was discussed. It was felt that some modifications might be made and stressed that the leaflet must in the absence of a test to screen out donors be given to all prospective donors*". The meeting also discussed haemophilia directors' treatment policies for the use of cryoprecipitate and concentrate in light of the risk of AIDS.

284. On 15 February 1984, following an SNBTS Co-ordinating Group meeting [SBTS0000615_042], Professor Cash wrote to Dr Bell regarding transfusion-associated AIDS research [PRSE0003911]. He relayed the view of SNBTS directors that there should be a "*single UK group responsible to the Departments of Health for co-ordinating research in the area covering the interface between blood transfusion and AIDS.*" He suggested that the group should have representatives of "*existing smaller groups already in existence – haematologists and haemophilia centre directors and of the SNBTS Directors*".

285. An article published on 17 February 1984 in the Daily Record reported the first death of an AIDS patient in Scotland [SCGV0000147_089]. The article, which appears to have been placed on the SHHD file and brought to the attention of Dr Bell, stated that "*until now there had been no diagnosed cases in Scotland*". The individual who died was described as having returned to Scotland "*after spending years in East Africa*", and a doctor was quoted commenting that this "*was an isolated case – a one in a million chance*".

286. In a note of the 28 February 1984 meeting of the CBLA Central Committee for Research and Development in Blood Transfusion, Dr Bell described a proposal for a study on the identification of high-risk donors for AIDS by HBc screening [SCGV0000052_073]. He "*sensed that there was not great enthusiasm in the Committee for this particular study but rather a feeling that since some steps had to be taken to identify potential transmitters of AIDS other than reliance on individuals opting out themselves, an exercise of this kind had to be undertaken and no one could produce a better protocol*".

287. Scotland's AIDS donor leaflet was considered again at a 13 March 1984 meeting of SNBTS directors, attended by Dr Bell and Mr Murray [PRSE0003405]. A draft revised leaflet had been circulated by Dr McClelland, with the Directors undertaking to send comments on the draft within two weeks. It was reported that "*Dr Alison Smithies of the DHSS would undertake revision for England and Wales*". The minute record that, while the existing leaflet "*had been mailed to all blood donors in some English Transfusion Regions, in Scotland it had been made available at donor sessions and at some STD clinics and the Scottish Directors felt their position would be strengthened by mailing to all blood donors*".

288. Other evidence suggests that SHHD officials were monitoring the contents of AIDS donor leaflets in Scotland. A leaflet containing an appeal for donors to give blood in Edinburgh in March 1984 contained the following paragraph on AIDS: "*It will not be possible to accept your blood on this occasion if you have nad* [sic] *symptoms which could suggest AIDS (Acquired Immune Deficiency Syndrome) or if you are in a group with an increased risk of AIDS. AIDS is a rare but very serious disease which may occasionally be transmitted by blood. A leaflet about AIDS is available at the Donor*

Session or by telephoning the Blood Transfusion Service" [SCGV0000147_088]. A manuscript note, which appears to have been addressed to Mr Murray and written by Mr Davies, marked up this passage and commented: "*This is stronger than anything I have seen before*".

289. The process for amending the DHSS/UK leaflet was discussed again at the 10 April 1984 meeting of the Advisory Committee on the NBTS, attended by Dr Bell [CBLA0001835]. Dr Smithies provided an update on the number of AIDS cases and deaths reported to the CDSC and reported that the 6 months trial of the AIDS leaflet was complete. The DHSS proposed to prepare a revised version for submission to ministers and, following discussion on whether a more aggressive approach to discouraging high risk donors was required, the Committee recommended that DHSS ministers consider issuing the revised leaflet with donor call up cards in all regions. In his note of the meeting, De Bell recorded that Dr Smithies had "*confirmed the arrangements, of which we were aware, for revision of the leaflet (including suggestions from the SNBTS)*" [SCGV0000083_020].

290. Alongside these DHSS/NBTS discussions, a revised leaflet was agreed at the 12 June 1984 SNBTS directors' meeting, attended by Dr Bell [PRSE0002709]. The leaflet, appended to the minutes, stated the "*cause of AIDS is unknown, but the disease, which is frequently fatal, may be transmitted by blood or blood products*". Miss Corrie, the SNBTS secretary, "*undertook to make the arrangements necessary to provide leaflets which could be used by each Transfusion Centre appropriate to the local method of preparing call-up letters*".

291. It appears that, by mid-1984, the DHSS and SHHD were liaising less frequently about the contents of AIDS donor leaflets. For example, the SHHD was not included in the distribution list for the 10 August 1984 DHSS ministerial submission on a revised AIDS leaflet [DHSC0002309_044].

Health Education Council leaflet

292. Alongside these developments, SHHD officials considered a proposed Health Education Council ("HEC") AIDS leaflet in August 1984. The draft leaflet, described

as having been prepared as part of the HEC's work on the prevention of sexually transmitted diseases, was put to DHSS ministers in a 9 August 1984 submission [DHSC0002309_043]. The submission and leaflet were copied to Mrs Craghill at the SHHD, who forwarded them to Drs Prentice and McIntyre and Mr Davies [SCGV0000147_080 and SCGV0000147_070]. Mrs Craghill commented that her inclination was "*simply to let HEC get on with it and leave SHEG to use the HEC leaflet if they wish*", noting that the SHHD could let the SHEG of its views informally, while querying whether the issue should be reported to Mr Mackay.

293. Several SHHD medical and administrative officials commented on the draft leaflet. Dr Bell noted that the SNBTS had carried out its revision to the leaflet on blood donors, so any reference to a blood donor leaflet would have to be adjusted to take into account the separate DHSS revision [SCGV0000147_077]. He suggested modifying a reference to haemophiliacs in the leaflet's list of groups who had developed AIDS to date to refer to haemophiliacs "*treated with blood products derived from infected donors*". Dr McIntyre made similar comments, as well as commenting that the SNBTS's "*original leaflet was made available in donor centres with hardly a ripple and the intention now is to include the revised leaflet in the mailings calling up donors*" [SCGV0000147_076].

294. Dr Scott, as well as suggesting revisions to the draft, commented: "*Certainly, we should not prepare our own leaflet. So far as I know we have had no cases in Scotland and I am also sure the gay (or is it homosexual) community in Scotland know more about AIDS than the leaflet will tell them*" [SCGV0000147_075]. In a 23 August 1984 minute, Mr Davies suggested to Mrs Craghill that it would be necessary to put the leaflet to the Minister:

> *"...this Division kept Mr Mackay informed about AIDS last year when the presenting issue was largely the risk of transmission through donated blood. I passed to him, under cover of my minute of 6 May 1983, material which DHSS had prepared for their Ministers and the Prime Minister. I sent you a copy at the time. We also showed him the leaflet which the Blood Transfusion Directors later produced. In the light of these precedents, I do not think you can avoid*

showing him the HEC leaflet. Even if you were minded to repress it, there would be the possibility of unfavourable repercussions."

295. By this time, Lord Glenarthur's Private Office had informed the relevant DHSS official that he was content with the approach set out in the 9 August 1984 submission [SCGV0000147_078]. The distribution list and manuscript annotations indicate that this minute was forwarded to the SHHD.

296. On 29 August 1984, Mr Davies wrote to Mr Mackay's Private Secretary to inform him of a development relating to AIDS [SCGV0000147_073]. The text of the minute is short and merits being set out in full, particularly for Mr Davies's description of the way in which the risk to Scottish haemophiliacs had previously been described:

> *"We have recently heard that a Scottish resident haemophiliac (living in Wishaw) has contacted* [sic] *AIDS. We have hitherto reported that Scotland is virtually self-sufficient in Factor VIII, the blood product used in treating haemophiliacs; and therefore that there was no risk to Scottish haemophiliacs. This case may appear to provide contrary evidence, and may possibly be so reported by the Press.*
>
> *We are informed that the patient concerned has only recently moved to Scotland. He has hitherto been treated in Newcastle where imported Factor VIII has probably been used. The disease takes some time to manifest itself, and the Scottish product is not implicated."*

297. This development was reflected in a 4 September 1984 minute from Dr Covell to Mrs Craghill, commenting on the draft HEC leaflet [SCGV0000147_071]. Dr Covell suggested that, "*[n]ow we have a definite case reported in Scotland, perhaps Mr Mackay should be informed*".

298. On 14 September 1984, Mrs Craghill provided a submission on the HEC leaflet to Mr Mackay, copied to Mr Davies and others [SCGV0000147_069]. She explained that the DHSS, with ministerial agreement, would be discussing the distribution and handling of the HEC's leaflet on AIDS, commenting that "*[g]iven its content any health*

education initiative in this area is bound to be highly sensitive and presentationally difficult". She added that the SHHD did "*not think that the preparation of a separate leaflet for Scotland is justified. It should suffice if SHEG uses any HEC leaflets as they do in some other areas of activity*".

299. Mr Mackay's Private Secretary responded to confirm that the Minister was "*content for SHEG to make use of the HEC booklet on AIDS whenever necessary*" [SCGV0000147_068]. SHHD officials discussed further amendments to an updated draft HEC leaflet in October 1984 [SCGV0000147_061 and SCGV0000147_064].

300. Alongside these developments, the SHHD was liaising with the DHSS about the membership of the Working Group on AIDS of the NBTS Advisory Committee. In a 26 September 1984 letter to Dr Abrams, Dr Bell confirmed that he would attend on behalf of the SHHD, as well as explaining that, following a conversation between Dr McIntyre and Dr Abrams about "*the implications of this Group's Work for SHHD and the SNBTS as well as DHSS and the NBTS*", the SHHD wished to nominate Dr McClelland as an expert member [PRSE0002002].

The Edinburgh cohort: discovery and response

301. In October 1984, haemophilia clinicians and the SNBTS discovered that a group of patients in Edinburgh, who had been treated with PFC factor VIII, had developed antibodies to HTLV-III. The timing of and immediate response to this discovery have been addressed in evidence already heard by the Inquiry – notably that of Professor Ludlam and Dr Brian McClelland, as well as in the self-sufficiency presentation – and are not addressed in detail here. An early chronology of events, beginning on 26 October 1984, is available in a 20 November 1984 memo from Dr McClelland to Dr Perry and Professor Cash [PRSE0000828].

SHHD Ministers informed

302. The precise date on which SHHD officials first became aware of the Edinburgh patients is unclear. On 20 November 1984, Hugh Morison (SHHD Under Secretary)

informed Mr Mackay of the development in a minute copied to the Secretary of State and others [SCGV0000147_058]. Having provided an update on the revision and distribution of Scotland's AIDS donor leaflet, Mr Morison wrote as follows:

> *"A development of particular concern in Scotland is that 16 Scottish haemophiliacs have been identified as having antibodies to the virus HTLV III, which is implicated with AIDS. The presence of the antibodies indicates that the patients have been exposed to the virus but does not mean they will necessarily develop AIDS. A batch of Factor VIII (the blood clotting agent given to haemophiliacs) produced at the Protein Fractionation Centre at Liberton appears to be implicated. As Factor VIII is produced from plasma recovered by blood donations it must be assumed as probable that the batch was contaminated by a Scottish donor. The batch has been with withdrawn and the SNBTS are taking vigorous steps to identify the source of infection. This, however, will not be an easy task since blood from many donors is used to produce a single batch of Factor VIII. In the meantime, work is urgently proceeding to introduce heat-treatment for Factor VIII in order to kill the virus, and to develop a screening test for HTLV III antibodies. No such test is, however, likely to be readily available in the immediate future.*
>
> *It would not be appropriate at this stage to issue any statement on the discovery of the antibodies in the Scottish haemophiliacs. Suitable defensive briefing has however been given to SIO."*

303. Also on 20 November 1984, Mr Morison forwarded a copy of the minute and attached briefing notes to the SIO, copied to Dr Scott, Dr Bell and Mr Macpherson [SCGV0001147_139].

304. Most of the briefing was in the form of a Q&A [SCGV0000147_058 pp.2-3]. Having described the introduction of AIDS donor leaflets, the briefing stated the following (within manuscript square brackets): "*Antibodies to HTLV III, the virus which it is believed caused AIDS, have been discovered in 16 Scottish haemophiliacs. A batch of Factor VIII produced at the Protein Fractionation Centre is implicated. <u>No statement is to be released on this at present.</u> If however there are specific enquiries*

from the media on this matter, the following material should be used." This was followed with four initial questions and answers:

a. "*Is it true that AIDS has been detected in Scottish haemophiliacs?... No. Antibodies to HTLV III, the virus connected with AIDS, have been discovered in a small number of haemophiliacs. This indicates exposure to the virus but does not mean that these individuals will necessarily develop AIDS.*"
b. "*Is it true that Scottish plasma has been contaminated with AIDS? ... There is evidence that some Scottish plasma has been contaminated and may possibly have been capable of transmitting the virus believed to be responsible for AIDS.*"
c. "*How widespread is the contamination? ... It is believed to be limited to a single batch of Factor VIII, used in the treatment of haemophiliacs.*"
d. "*What is being done about it? ... The batch of Factor VIII is being withdrawn. The SNBTS are taking vigorous steps to trace the donor whose blood may have contaminated the batch. Measures are also being taken to ensure that in the very near future all Scottish Factor VIII will be heat-treated, a process which counteracts the AIDS virus*".

305. The briefing ended with an additional Q&A, for use "*[o]nly if pressed*": "*What should Scottish haemophiliacs do? ... They should make enquiries of the consultant treating their case.*"

306. A manuscript note was subsequently added to the minute itself [SCGV0000147_058]. It would appear to be from Mr Mackay and to read: "*Thanks: While I fully appreciate that a statement would give rise to great concern among haemophiliacs – and indeed among recipients of blood generally – I do not want us to be accused of a "cover-up". If we are approached we must be perfectly open. When is heat-treatment likely to be ready?*" A 21 November 1984 response from Mr Mackay's Private Secretary recorded Mr Mackay's gratitude and included a comment and query identical to those noted in manuscript [PRSE0002945].

307. Mr Morison provided a further minute to Mr Mackay's Private Secretary on 26 November 1984 [PRSE0002376]. Having explained that trials of heat-treated SNBTS

factor VIII were beginning, Mr Morison wrote that, in the meantime, the SNBTS was "*beginning to make arrangements to withdraw existing stocks of Factor VIII from Regional Centres and individual haemophiliacs for heat-treatment*". He added that heat-treated product was expected to be available by the beginning of 1985, and commented: "*Mr Mackay will note that we are well in advance of England and Wales in regard to both heat treatment and self-sufficiency, where we are already self-sufficient in Factor VIII*".

308. As for press statements, Mr Morison wrote: "*Mr Mackay's point on publicity about antibodies is well taken. We are keeping in close touch with the Blood Transfusion Service on the matter, which has not so far been picked up by the media*".

309. A note from Mr Morison to Mr Davies, summarising issues arising at a 21 November 1984 meeting of the CSA BTS Sub-Committee, provides some further insight into the SHHD's approach to the Edinburgh discovery becoming public knowledge [SCGV0000138_053]. Mr Morison wrote:

> *"There was discussion of recent Press coverage which highlighted action being taken in England and Wales and did not refer to the self-sufficiency in Factor VIII attained in Scotland. Professor Girdwood*[47] *had written to the Agency suggesting that Dr Cash or the Chairman should write to the newspapers to set the record straight. I strongly discouraged this. Dr Cash explained that he had been taking steps to brief journalists on the Scottish situation. The Committee agreed to take no further action until the results were visible; thereafter Dr Cash and the Chairman should have discretion to take whatever action they thought best."*

310. Mr Morison went on to record that transfusion directors had agreed "*to take steps to ensure that the new leaflet is seen by all individual donors. Each donor will be questioned before donation and asked to confirm that he is not a representative of a high risk group*". He further summarised developments in HTLV-III screening and heat treatment, noting that, as "*an introductory step, existing stocks of Factor VIII and future*

[47] Chair of the SNBTA.

stocks will be dry heated: this will destroy the AIDS virus but will not deal with hepatitis."

311. On 21 November 1984, the Times published an article on AIDS and blood: "*Life-Blood, or death?*" [SCGV0000147_052]. The article proposed two policies, including that "*Strict questioning of donors and the rigorous exclusion of all practising homosexuals should be enjoined on the collectors of blood*" [SCGV0000147_052]. A manuscript note, which appears to have been written by Mr Davies, commented: "*What a load of tosh! The pallid ghost of the* [thunderer?] *waves its* [shroud?]". Another note, which seems to have been written by Mr Murray to Mr Davies, stated: "*a magisterial pronouncement!*".

312. The article also quoted Derek Ogg, co-ordinator of the AIDS Monitor and a former chair of the SHRG, as stating that there had been "*no recommendation from the blood transfusion that gays cease to donate blood. I know that because I helped re-draft their latest leaflet on the subject which they sent out to all their donors... It clearly defines the high-risk donors... and that is not the average homosexual, but those who are more permissive*".

Late November 1984 developments

313. It appears that, notwithstanding the SHHD's discouragement, Professor Girdwood suggested to the press that Scottish blood products were safe as a result of self-sufficiency having been achieved. A newspaper article published on 28 November 1984 – entitled "*'Good Scottish blood' lessens the risk of disease*" – began as follows: "*Not one person has contracted AIDS in Scotland as a result of blood transfusions or treatment with preparations made from Scottish blood*" [PRSE0003234]. Professor Girdwood was quoted as commenting: "*I think the public should be reassured – I do not think people in Scotland have anything to worry about, whether they are getting blood transfusions or other treatment with blood products*". He was also described as attributing "*this enviable position to well-organised transfusion service and community spirit. "In all regions of Scotland you find that there is community caring, a spirit which you do not get in a great impersonal city like London.'*""

314. Also on 28 November 1984, Mr Mackay answered a PQ on AIDS and steps taken by the SNBTS in response to it [SCGV0000148_082].[48] He stated that three confirmed cases of AIDS had been registered with the Scottish communicable diseases unit, and that the SNBTS had, in consultation with the SHHD, "*issued a revised leaflet on AIDS and how it concerns blood donors. Steps are being taken to ensure that this leaflet is seen by all potential donors in Scotland before they give blood. It reinforces my Department's previous advice that persons at high risk of contracting AIDS should not donate blood*". Mr Mackay's answer was reported in a newspaper article the following day [HSOC0016013_001].

315. Also on 29 November 1984, in a letter which appears to have been forwarded to Mr Davies, Professor Cash wrote to Scottish RTDs about the revised leaflet [SCGV0000147_037 and SCGV0000147_038]. Steps to be taken with respect to distribution included enclosing the leaflet in every donor call-up letter, sending a leaflet to the home address of known donors who were not normally individually called to sessions, and giving every donor a leaflet at the session. Each donor would also be asked to sign the following statement: "*I have read the SNBTS AIDS leaflet (Important Message to Blood Donors) and confirm that, to the best of my knowledge, I am not in one of the defined transfusion-related risk groups*".

316. An internal Cutter report, dated 30 November 1984 and completed following a visit to the UK on 26-27 November, provides additional insight into how the viral safety of PFC products was understood at this time [BAYP0000025_087]. The report suggested that "*AIDS has finally come to the United Kingdom with a force that has caused a virtual panic in the Department of Health*", with the DHSS described as belatedly seeking to license heat-treated commercial products in response to newspaper articles on the death of haemophiliac patients from AIDS. It then recorded the following with respect to Scottish factor VIII:

> *"In the third quarter of this year the Scottish PFC shipped 4 million units of excess factor VIII material to England. ... The Scottish PFC suggests that it is*

[48] It appears that the PQ was referred to Mr Davies, Mr Murray and Mr Morison to prepare an answer [SCGV0000033_068].

AIDS free as they do not have AIDS victims in their blood donation program. It is expected that late this year or early next year that the Scottish PFC will ship an additional 4 million units as they lower their inventories in preparation for their planned conversion to a heat-treated factor VIII program in 1995. ... (why they wish to heat-treat factor VIII if there is no AIDS danger in Scotland is unknown)."

Discussion of whether to inform patients and families

317. On 29 November 1984, the SHHD, SNBTS and haemophilia centre directors met to discuss issues related to the Edinburgh patients, as well as positive test results in haemophilia patients elsewhere in Scotland [PRSE0002066]. The meeting was chaired by Dr Bell and attended by other SHHD officials. Dr Forbes outlined findings of HTLV-III antibody sero-conversion among Glasgow patients, which were due to be published in the Lancet, and Dr Gibson described "*the anxiety felt by parents of haemophiliac children treated at RHSC Glasgow, where imported factor VIII had been used until relatively recently. Five out of 10 of these patients were HTLV III antibody positive*". The meeting note, which appears to have been prepared by the SHHD, recorded the following with respect to informing patients and their families of the test results.

"Views were exchanged on the very difficult ethical problems which had arisen. These included whether patients and patients' relatives should be informed and perhaps subjected to needless worry; whether publicity additional to that already provided should be given, and how directors should respond to direct enquiries or requests for advice. The chairman advised members that ministers had been informed and that SIO had been briefed. While a press statement would not be issued by the Department at present any enquiries would be answered. It was agreed that every effort should be made for patients to have the situation explained to them before the impending publicity."

318. Mr Mackay was provided with a further update in a 5 December 1984 minute from Mr Davies to his Private Secretary, copied to a large distribution list (including the Secretary of State) [PRSE0003032]. Mr Davies made reference to the 29 November

1984 meeting and noted that Mr Mackay had already been informed of the 16 infected Edinburgh patients, before adding:

> *"There is also a number of patients with antibodies known to have been treated with imported Factor VIII: it is only relatively recently that Scotland has become self-sufficient. There are also 2 or 3 individuals with antibodies not known to have received imported Factor VIII, though they may have, possibly outwith Scotland. An article describing a study of the position in the West of Scotland has, we understand, been accepted for publication in the Lancet. Medical advice is that it should not be embarrassing."*

319. Mr Davies added, from the available figures, that it appeared that "*out of the approximately 400 haemophiliacs in Scotland, no more than about 10% have antibodies to HTLV III. Only other countries themselves self-sufficient in Factor VIII can match these figures*". The incidence in England was understood to be "*considerably greater*", and in the USA the "*great majority*" of haemophiliacs would have HTLV III antibodies. Mr Davies wrote that the medical view was that "*probably less than 10%*" of individuals with antibodies would develop AIDS. He referred to newspapers articles, the "*general tenor"* of which was "*to give Scotland a somewhat cleaner bill of health than we now know to be justified*". Remarks attributed to Professor Cash, about which he was not "*entirely happy*", were described as having the effect of "*preparing the ground for any subsequent statement reporting the actual position that needs to be made*".

320. Mr Davies wrote that "*[n]o statement can be made at the moment until the haemophilia directors resolve the very difficult ethical problem of what action to take with regard to their patients about the matter*". As well as providing an update on heat treatment, Mr Davies wrote as follows with respect to the product that had infected the Edinburgh patients:

> *"The BTS believe that they have now identified the donor responsible for the contaminated of the batch of Factor VIII. Fractions of blood from the same individual have also been transfused into 2 individual patients. He is thought to have been sharing accommodation in Glasgow with a number of other men and*

to have given blood despite the known contra-indication. He has now moved to England. A copy of a circular to Regional Directors of the BTS in Scotland regarding the further steps to be taken in ensuring that donors are aware of their responsibilities is attached."

321. Mr Mackay's Private Secretary responded on 6 December 1984, relaying that the Minister hoped that the English BTS had been informed about the donor so that they could decline his blood if offered [SCGV0000147_033]. A manuscript note, which appears to have been written by Mr Davies to Mr Murray, recorded: "*I have told Miss Teale* [the Private Secretary] *that I believe the BTS in England told SNBTS about him*".

Heat treatment and press interest

322. The documents suggest that, around this time, SHHD officials monitored developments in PFC's introduction of heat treatment closely. On 6 December 1984, Dr Perry wrote to Scottish RTDs to inform them that the first batches of heat-treated PFC factor VIII would be delivered around 10-11 December [PRSE0002675]. A copy of the letter appears to include a manuscript note from Mr Davies to Mr Morison, dated 10 December, and which seems to read: "*To see. I* [take?] *to contain encouraging news*" [SCGV0000147_030].

323. On 10 December 1984, the Elstree meeting of haemophilia reference centre directors and others took place [CBLA0001948]. It was attended by Professors Cash and Ludlam, but not by the SHHD, and resulted in the 14 December 1984 AIDS Advisory Document [HCDO0000270_007]. The SNBTS directors' approach to the factor VIII batch which infected the Edinburgh patients was discussed at their 11 December 1984 meeting, attended by Dr Bell and Mr Murray [PRSE0001767].

324. In a 12 December 1984 minute to Mr Davies and Mr Hoy at the SIO, copied to Dr McIntyre and Mr Murray, Dr Bell explained that he had been informed by Drs McClelland, Ludlam and Cash that the Yorkshire Post was likely to publish an article regarding the Edinburgh patients the following day [PRSE0000810]. Dr Bell commented that it had to be "*presumed that this had been leaked by one of the English haemophilia directors*" involved in the recent meeting of UK reference centre directors.

325. He later updated the minute, following contact from Professor Ludlam, to explain that the journalist had agreed to postpone his report until 20 December, which would enable the haemophilia clinicians to call a meeting with their patients. In light of this, Dr Bell advised that "*SHHD should not publicise this matter before the patients themselves have been informed professionally*", adding that it "*would be important for Dr Ludlam to be able to assure the journalist as soon as possible that we do not intend to anticipate his publication*".

326. That same day, a minute from Mr Mackay's Private Secretary to Mr Davies, copied to a number of others, recorded that she had informed Mr Mackay of the Yorkshire Post's interest, and that they had "*discussed whether we should now be making any statement about the Scottish position*" [PRSE0001293]. The minute appears to have been written following a telephone call with Mr Davies that morning. It recorded the following:

> *"Mr Mackay is firmly of the opinion that we should not make any announcement at this stage, before those concerned have been told that they have been affected. He does however feel that it is now absolutely imperative that every effort should be made to inform the haemophiliacs, or their parents, as I understand that some of them are in fact children.*
>
> *Mr Hoy* [of the SIO] *tells me that, if the Yorkshire Post do decide to follow up this story, it is not likely that they will publish it before a week tomorrow. It would therefore seem obvious that every effort should be made to inform the people concerned as soon as possible and definitely by the beginning of next week.*
>
> *In the meantime Mr Mackay feels that we should respond to any press enquiries with the line that we have identified various people with the problem, that we are taking steps to inform them and that in the meantime it would be extremely distressing for these people, particularly the parents of children, to read about it in a newspaper, not forgetting that press publicity on this before the people*

have been informed could stir up a totally unnecessary scare amongst the 400 haemophiliacs in Scotland.

You may however wish, in the meantime, to discuss with SIO the possibility of issuing some sort of statement on the subject once those involved have been informed. Perhaps you could consider this in conjunction with Mr Hoy."

Press release

327. A further series of exchanges within the SHHD began a week later. On 19 December 1984, Dr Bell circulated a draft press release related to the Yorkshire Post article [PRSE0003525].[49] That same day, Mr Davies wrote to Mr Mackay's Private Secretary, attaching an updated draft and recording that a "*a meeting of Scottish haemophiliac patients is being held this evening, at which the position is to be explained to them. We now understand that 15, not as hitherto thought 16, patients with Scottish produced Factor VIII have antibodies to HTLV III*" [PRSE0002049].[50]

328. The press release, entitled "*New measures to counter AIDS*", was issued the following day [PRSE0000225]. It began by stating that the SNBTS had announced that day that all Scottish factor VIII had "*now been heat treated to counter HLTV III*", before describing the discovery of the Edinburgh patients as follows:

"This move follows the recent discovery that 15 Scottish haemophiliac patients treated with a particular batch of Factor VIII have developed antibodies to HTLV III. It is suspected that a pool of plasma used to prepare this batch of Factor VIII contained blood from a donor who had been exposed to the virus. The batch has since withdrawn.

Doctors have stressed that although some haemophilia patients treated with Factor VIII develop HLTV III antibodies this certainly does not mean that they have AIDS, or even that they will necessarily go on to get the disease. The

[49] The draft would appear to be the document at [SCGV0000147_024].
[50] The draft would appear to be the document at [SCGV0000147_022].

problem is much smaller than in most other countries, because in recent years Scotland has become virtually self-sufficient in the production of Factor VIII and has imported very little commercially produced Factor VIII which carries a greater risk of transmitting AIDS."

329. The press release did not include a line, relating to the donor who had infected the batch, which appeared in one draft version and had been struck through in another: "*every effort is being made to trace the source*" [SCGV0000147_024 and SCGV0000147_022].

330. The Yorkshire Post article – entitled "*NHS blood carries killer AIDS virus*" – was also published on 20 December 1984 [PRSE0004577]. Similar articles appeared the following day, including in the Scotsman [HSOC0016028] and the Daily Express [HSOC0015962].

331. A handwritten SHHD note suggests that such press reports were being monitored. The note, which appears to be dated 21 December and was addressed to Mr Thomson, seems to read: "*There will be press cuttings to get hold of (including, if possible, the Yorkshire Post for yesterday) and possibly also a transcript of Dr McClelland's piece on Radio Scotland this a.m. – very smoothly done, with what sounded to me like planted questions!*" [SCGV0000147_014].

332. Newspaper reports continued the following day. A 22 December 1984 article in the Scotsman commented that, with the "*benefit of hindsight, it is now possible for doctors to reflect on the inevitability of AIDS ... gaining a foothold in Scotland*" [HSOC0016029]. The article reported that the source of the donation that had infected the factor VIII batch was "*a blood donation given somewhere in the East of Scotland about 12 months ago*". It suggested that "*Government scientists are now working to trace the donor but it is by no means certain they will be successful as plasma is made up from many thousands of individual donations*". It added that newly drafted leaflets requested "*all homosexuals to refrain from donating blood... In the past, the advice has been aimed at only those homosexuals who have a large number of sexual partners*".

333. Mr Mackay also answered a PQ on this issue in early February 1985 [PRSE0001051].

Later evidence of seroconversions

334. As explored in other evidence heard by the Inquiry, heat-treated factor VIII was introduced in Scotland in December 1984. In a 24 February 1986 letter to Dr Forrester, Professor Ludlam provided information on HTLV-III seroconversion among Scottish haemophilia patients in 1985 [MACK0001399_002]. He reported that all haemophilia B patients in Scotland were negative. Three haemophilia A patients in Glasgow had developed antibodies to HTLV-III during 1985, and three patients in Edinburgh "*were first found to be seropositive in 1985 – all received the "infected" batch SNBTS VIII and could be considered late seroconversions*". He commented that this data suggested that "*seroconversions may occur up to 9 months after "presumed" exposure to HTLVIII. This information may be of interest to you in relation to the recent unfortunate publicity about the safety of heat-treated blood products*".

335. This issue was discussed at a 5 March 1986 meeting of SNBTS and haemophilia centre directors, chaired by Dr Forrester and also attended by Dr McIntyre [PRSE0001081]. Dr Forbes reported at the meeting that average time to seroconversion was 84 days but that it had been reported "*as early as 2 weeks and as late as 11 months*". Dr McClelland stated that the "*late seroconversion had all been from one batch of SNBTS VIII*" and there was "*no evidence of infectivity in any other batches*".

HTLV-III screening of blood donations

Initial consideration

336. The evidence suggests that, by the summer of 1984, the SHHD had begun considering the introduction of an HTLV-III screening test. In a 16 August 1984 minute to Mr Murray, Dr Bell wrote that he had "*information that research and development work in London is proceeding with the objective of introducing a screening test for HTLV III, the putative causal agent of AIDS*" [SCGV0000147_079]. The minute

recorded that Professor Cash had "*already indicated to Mr Davies that additional revenue costs have to be foreseen for the introduction of an AIDS screening test for blood donations*", and that Dr Bell believed that resources would probably be required in the year 1986/87.

337. Progress in the development of HTLV-III screening was discussed at an 11 September 1984 meeting of SNBTS directors [PRSE0000098]. The meeting was attended by Dr Bell, who "*advised that it was hoped to establish a UK Working Party on AIDS related to the Transfusion Service to which Scotland would be invited to nominate a representative* ".

338. Further reference to this working party was made in an 8 October 1984 letter from Professor Cash to Mr Davies [SBTS0000501_201]. Professor Cash suggested that "*[w]hilst this group should influence the rate at which all donations will be tested for AIDS you might wish to know that the latest information from the States which suggest that kits will be available for some time between the Spring and Summer of 1985.*" As for funding, he commented that "*[s]ome special reserve provision in the Development Allocations for 1985/86 would be much appreciated*".

339. Dr Bell provided a brief update on HTLV-III screening to SHHD colleagues in his note of an 8 November 1984 meeting of the Advisory Committee on the NBTS [SCGV0000083_014].

340. Developments in HTLV-III screening were discussed in more detail at a meeting of the Working Group on AIDS of the Advisory Committee on the NBTS on 27 November 1984. A note of the meeting, which Dr McClelland believes that he prepared[51], recorded that he could "*get no clear picture of when or how a serviceable assay will be provided*" [PRSE0004191]. It was recorded that it had been unanimously agreed that HTLV-III testing of donors should be introduced. As for whether donors should be told, the meeting was said to have concluded that they should be told by the BTS, but that the "*potential difficulties of this were inconclusively discussed*".

[51] See the transcript of Dr McClelland's IBI evidence, 28 January 2022, p.36.

341. Dr McClelland reported these developments at an 11 December 1984 SNBTS directors' meeting, attended by Dr Bell and Mr Murray [PRSE0001767]. These included that there had been "*unanimous agreement to test all donors once an antibody test was available. The matter of how to counsel and take care of antibody positive donors was acknowledged to be a very difficult problem*".

DHSS position and role of expert groups

342. DHSS and SHHD officials also corresponded directly about HTLV-III screening. On 17 January 1985, Alun Williams of the DHSS wrote to Mr Murray, enclosing a copy of the DHSS ministerial submission on the need to introduce HTLV-III screening, on which a decision was awaited [PRSE0000992]. He commented that he thought it was "*important we keep in touch on this issue*" and asked whether Mr Murray had any information on what was proposed for the SNBTS. The ministerial submission, dated 11 January 1985, sought approval in principle for the introduction of a screening test in the NBTS [DHSC0000562].

343. Dr Bell addressed this submission in a 21 January 1985 minute to Mr Murray [PRSE0004472]. He commented that the information in the submission was in line with what the SHHD had learned and that he believed the considerations would be familiar to the SNBTS. Dr Bell described the Abbott screening test as using a "*less convenient ELISA technique*" and as requiring dedicated equipment. He commented that he "*would hope that the SNBTS would wish to use the new UK test and that this test would be made equally available north of the Border*". Dr Bell added that the "*estimated cost of screening looks to be rather more than we have provisionally budgeted so far, but of course it is unlikely that the test will be in operation for more than 6 months of the current year*". He also referred to briefing the SHHD minister, including with respect to financial allocation, following the DHSS ministers' response. A manuscript note on the minute, addressed to Mr Davies, also referred to financial considerations and to a forthcoming meeting with Dr Smithies and Mr Williams of the DHSS.

344. By late January 1985, criticism of the Working Group on AIDS was emerging. The minutes of the 23 January 1985 meeting of NBTS RTDs, attended by Professor Cash and Dr McClelland, record that the RTDs who attended the November meeting

felt that it was "*unproductive... there being as yet no new leaflet, no finance and no positive move towards full donor screening*" [PRSE0002062].

345. Professor Cash expressed his concern directly to the SHHD in a detailed letter to Dr Bell the following day [PRSE0004386]. He described himself as "*seriously concerned by reports I have received from those who attended the meeting of the Working Group on AIDS*" to consider HTLV-III screening. The meeting, "*from the stand-point of those left with the actual responsibility of running the UK Transfusion Services, was wholly inadequate.*"

346. Professor Cash described, in February 1984, having conveyed the views of SNBTS directors that "*it would be inappropriate to 'go it alone'*" to the SHHD, and suggesting that the issues urgently needed to be taken up as a UK matter. He suggested this had not been done and that there had been "*a "secret meeting" between DHSS officials, Professor Weiss, Dr Tedder and Wellcome Diagnostics*".

347. Professor Cash also criticised the trials of commercial screening tests that he understood were underway and suggested that there "*were just no mechanisms in the UK for these crucially important topics to be discussed, openly and confidentially, and for clear, co-ordinated policies to emerge*". He described anxiety amongst NBTS directors that the "*the Scots... will unilaterally move to come in line with the American proposals*", commenting that "*[t]hey're right*" before describing steps the SNBTS had taken towards the introduction of screening. Professor Cash suggested that the DHSS was "*lost and floundering in an increasingly high profile*". He asked "*once again*" that the SHHD pursue this issue "*into the UK arena*".

SNBTS consider evaluating tests

348. By the time of this letter, Professor Cash was already corresponding with SNBTS colleagues about their evaluation of commercial tests. On 21 January 1985, Dr Mitchell (of the Glasgow and West of Scotland RTC) wrote to him to report on a visit from Abbott the previous week, which had been undertaken with a view to the RTC starting an evaluation of Abbott's ELISA system [PRSE0004372]. Professor Cash responded on 25 January 1985, in a letter which appears to have been copied to Dr Bell,

to record a conclusion that "*the WBTS should undertake, on behalf of the SNBTS, initial evaluation studies of commercial HTLV-III antibody kits, but that current pressures from commercial organisations to meet their deadlines should be resisted and priority given to SNBTS interests – particularly in terms of confidentiality and ethical clearance*" [PRSE0001075].

349. Further discussion of HTLV-III screening took place at the 29 January 1985 first meeting of the Expert Advisory Group on AIDS, attended by Dr Covell [PRSE0002734]. A sub-group, of which Dr McClelland was a member, was set up to consider the issue. Dr Covell subsequently provided a note of the meeting to his SHHD colleagues [PRSE0003641]. This included a detailed summary of the discussion relating to the introduction of HTLV-III screening.

Officials consider SHHD position

350. Following this, SHHD officials began exchanging an important series of minutes on the introduction of HTLV-III screening in Scotland. In a 7 February 1985 minute to Dr Scott, copied to Dr McIntyre, Mr Macpherson and Mr Robertson, Mr Davies reported that DHSS Ministers had agreed, "*apparently with great reluctance*"[52], that all blood donations in England and Wales should be screened for HTLV-III antibodies [PRSE0001054]. The SHHD therefore had "*to decide whether we have any alternative to advising our Minister that it is necessary to follow suit in Scotland*". Mr Davies described the risks relating to unscreened blood as follows:

> *"There are over ¼ million donations of blood in Scotland each year. As far as we are aware, only one donation to date has contained antibodies to HTLV III. We now require a signed statement from all potential donors that they are not in one of the at risk categories for contracting AIDS. Hence the number of "infected" donations, already vanishingly small, should decrease still further. The information, admittedly fragmentary, in paragraph 5 of the recent ADCP guidelines suggests that antibodies are not present in the blood of members of the general public, even those attending genito-urinary clinics. Haemophiliacs*

[52] This phrase is a manuscript addition but appears to have been added by Mr Davies.

in Scotland are now not at risk as all Factor VIII is heat treated – the situation in England is different. In any case, only a proportion of those with antibodies develop AIDS: I have seen figures ranging from 10% down to one in several hundred."

351. Mr Davies commented that, if a test were introduced, it would "*presumably be necessary to arrange follow-up for all individuals whose blood gives a positive result*". He stated that it was "*not clear whose responsibility that would be, or what the cost implications are. As any test will inevitably be imprecise, there will inevitably be a problem created by false positives, and also the knowledge that there may also be false negatives, and hence it will never be possible to be absolutely certain that the virus is not present in transfused blood*". He noted that there was a risk, as Dr Scott had previously said, of individuals who considered themselves at risk attending donor sessions in order to have their blood tested.

352. Mr Davies described the financial implications of introducing testing as "*considerable*". He noted that heat treatment had been introduced at a cost of £80,000 and that screening, "*even at the lower end of the price range, would cost £300,000 a year, set against the £50,000 which we are seeking for the purpose*". He added, however, having discussed the problem with Mr Robertson, that "*though the financial angle cannot be ignored, we are both agreed that it should not be determining factor in this case*". The financial mechanism in Scotland would be to provide the CSA with additional funds.

353. The minute concluded with the following comment:

"It seems to me that the balance of rational argument would be heavily against introducing a test on all donations. I accept, however, that there is little rationality to be seen where AIDS is concerned. We seem to have reached the point where an AIDS victim cannot even be given a public funeral, presumably in case noxious vapours emanating from the coffin strike down the congregation in the middle of the service. I would be grateful for your guidance as to what we should tell Ministers."

354. In a response the following day, Dr Scott described Mr Davis's minute as having "*clearly and succinctly the problems associated with the routine testing of all donations of blood for HTLV III*" [PRSE0003846]. He outlined his own view as follows:

> *"From a cold objective scientific viewpoint the case for the introduction of a test for HTLV III antibodies in the present statement of development and without being properly validated is not clear cut. There is no doubt, however, that there is a lot of public interest and we are liable to be carried along in the rising tide of emotion. We are in a particularly difficult situation in that DHSS Ministers have agreed, however reluctantly, to the introduction of the test. It is most unfortunate that a policy decision on this matter was not made at a UK level, though understandable given the degree of public and media hysteria."*

355. Dr Scott suggested an office meeting, to which Professor Cash might be invited as consultant adviser to the SHHD, before putting these issues to Ministers in a full submission. If Professor Cash "*strongly advocated introducing the test despite its limitations the Minister would be open to criticism if he did not agree to the introduction of the test*". If he were "*to advise unequivocally against the introduction of the test that might be another matter*".

356. A further response to Mr Davies's minute followed from Mr Macpherson on 11 February 1985, in which he commented [PRSE0002457]:

> *"I accept the validity of all you say in support of the proposition that we should not take similar action in Scotland; but I very much doubt if we can hold this line now that English blood donations are being tested. It is now more a question of public presentation than a matter of medical judgement, and the pressure on us to follow the English example will be irresistible."*

357. Mr Davies responded to Dr Scott on 12 February, describing his understanding that "*DHSS Ministers only agreed to the test being introduced in England under heavy pressure from their CMO who said that the Blood Transfusion Service would otherwise lose all credibility*" [PRSE0001925]. He suggested that there "*might have been have been other ways of achieving the same effect: I have detected recent signs that the*

heavier end of the Press is coming to accept the realities of the situation and it might have been possible to build upon this". He added that this was "*a hard task as some of the more lurid papers will probably be satisfied with nothing less than a Bill to provide for the public disembowelling of any homosexual caught trying to give blood*". Mr Davies agreed with the suggestion that Professor Cash should be invited to an office meeting.

358. As described further below, a ministerial submission on screening was provided to Mr Mackay on 21 March 1985. Before then, a number of other developments took place.

SNBTS position on evaluation of tests

359. On 12 February 1985, Professor Cash wrote to Dr Reid, the Scottish CMO, regarding the introduction of screening tests [PRSE0002659]. He described current evidence as suggesting that "*most of the emerging commercial kits for HTLV-III antibody testing may have a false-positivity which, in the context of testing all blood donations, is embarrassingly high*", and set out the reasons why he would oppose their introduction. He suggested that the "*efforts of commercial kit manufacturers*" were such that the "*demands of the market place* would *"overwhelm*" the DHSS working groups, describing formal contacts from at least four of these companies. Professor Cash strongly advised that "*serious and urgent consideration be given to persuading the Minister to make a statement*" stating that: the NHS was committed to the introduction of HTLV-III screening; that this would be "*actively discouraged until such times as the Government is advised that its introduction is in the best interests of the Transfusion Services*"; and that active steps would be taken to establish a national kit evaluation programme.

360. On 13 February 1985, DHSS officials agreed that an ad hoc working group should be set up for the evaluation of screening tests [DHSC0002259_038].

361. At the 15 February 1985 meeting of the EAGA screening test sub-group, Dr Smithies reported that the DHSS had invited companies developing test kits to take part in a Departmental evaluation, that an "*ad hoc panel of experts with DHSS officers would*

agree a protocol and arrange for a PHLS virologist to carry out the evaluation", and that this would include the British test under development [DHSC0000425].

362. The SNBTS's approach to the evaluation of screening tests was discussed again at a 19 February 1985 Co-ordinating Group meeting, which was not attended by any SHHD representatives [PRSE0003378]. The minutes record that there was "*growing concern about the number of false positives produced by the current generation of tests*" and that "*all available kits were to be evaluated, under DHSS sponsorship, by the Middlesex Hospital and PHLS in field studies and there would be RTC studies of donor incidence*". The Group agreed that "*Dr Cash's letter of 25 January to Dr Mitchell ... should not be pursued at the present time*"; i.e. that the SNBTS should not carry out its evaluation programme.

363. This conclusion was highlighted at the 27 February 1985 SNBTS directors' meeting, attended by Dr Bell and Mr Murray [PRSE0003628]. The minutes record that it had been agreed that "*no Transfusion Centre would commence HTLV-III testing unilaterally*". Dr Bell later thanked Professor Cash for informing him of "*the decision by the SNBTS directors to hold off from validation of kits until protocols have been agreed through the EAGA*", commenting that "*[t]his is to be welcomed*" [PRSE0003505].

364. On 2 March 1985, the Lancet published a letter from a number of NBTS directors, as well as Professor Cash and Dr McClelland, "*strongly*" supporting the introduction of screening, but advising that it be delayed "*until test systems have been appropriately evaluated and efforts have been made to give all members of the public access to HTLV-III antibody testing*" [PRSE0004824].

365. On 26 February 1985, Professor Cash wrote to Mr Mutch, the CSA Secretary, regarding testing facilities, enclosing a draft letter for AHBs (i.e. Area Health Boards) [SCGV0000149_025]. The letter described the SNBTS as being concerned to avoid high risk donors attempting to give blood in order to be tested, and asked AHBs to consider making tests available to the general public as soon as possible. Professor Cash noted that he had copied the letter to the SHHD in light of the "*fairly significant policy matters*" involved in his proposal. In a 28 February 1985 minute, Dr Bell drew SHHD

colleagues' attention to the letter, recording his hope that Mr Mutch would consult the Department [SCGV0000149_023]. In a letter to Professor Cash that same day, Mr Mutch noted that he would take the matter up with the SHHD [SCGV0000149_022].

366. Dr Covell commented on Professor Cash's letter in a 5 March 1985 minute to Dr Bell and other SHHD officials [SCGV0000149_020]. He noted that he understood Professor Cash's "*anxiety over a possible rush on BTS for HTLV III antibody testing by those at risk of infection*", while commenting critically on the way he had approached Mr Mutch. Dr Covell suggested that, when it did arrive, the test would be limited in supply and there was "*little doubt that the first priority should lie with the BTS*".[53]

367. Professor Cash provided Mr Davies with an update on screening in a 14 March 1985 letter [SBTS0004051_144]. He explained that, based on a price quoted by the only manufacturer licensed by the FDA, the annual cost of the screening kits would be £495,000 (in addition to other costs). Professor Cash suggested that September was a likely date for testing to begin.

Ministerial submission

368. Alongside these developments, SHHD officials began preparing a submission to Ministers on the introduction of screening. It appears that Mr Davies circulated an initial draft on 21 February 1985. Dr McIntyre responded on 26 February 1985 with suggested amendments [SCGV0000149_027 and PRSE0001082]. A further draft is dated 19 March 1985 [SCGV0000149_018]. On 21 March 1985 Mr Davies circulated an updated section on blood transfusion and screening to Mr Macpherson and other SHHD colleagues [SCGV0000149_012].

369. That same day, Mr Macpherson provided the finalised submission to Mr Mackay and the Secretary of State [PRSE0004593]. It covered two issues: whether to make AIDS a notifiable disease and the introduction of HTLV-III screening. The submission recorded that DHSS ministers had agreed in principle that screening should

[53] A manuscript note on the minute, which appears to have been written by Mr Davies and addressed to Mr Murray, commented that it "might have helped if Dr Covell had been at the meeting with Dr Cash".

be introduced in England and described the views of RTD directors, as reflected in the letter to the Lancet, on the question of timing. The submission supported these views and described them as "*sensible and responsible*". It also noted that all Scottish factor VIII was heat treated. The risk from blood transfusions was described as "*very small; as far as is known, in Scotland where 280,000 donations are collected each year, there has only been one infected donation of blood (the one which contaminated the batch of Factor VIII); there is other evidence that blood donated is "clean"; and donors are now required before giving blood to sign a statement that they are not in a group at risk of contracting AIDS*".

370. The submission further stated that the tests becoming available from US companies had "*a high rate of false positive results – maybe 4%*". The implications of this, for the individuals concerned and resources, were described as "*profound and substantial*". The tests were further said to have "*an unpredictable false negative rate*". As for financial considerations, the submission described antibody testing as "*at present expensive*", with an estimated overall annual expenditure of around £600,000. It also noted that the cost could reduce and commented: "*we should not wish to stand in the way of testing solely on financial grounds*".

371. As for individuals in high risk groups attempting to give blood in order to be tested, the submission proposed that "*testing facilities should be made available by the Health Service, possibly associated with sexually-transmitted disease (STD) clinics, prior to the introduction of general screening by the transfusion service, so that people considering themselves to be at risk to AIDS can have access to the antibody test without presenting themselves as blood donors*". The submission commented that there would "*no doubt ... be public pressure for routine screening of blood donations once it is known that commercial tests are available*".

372. The recommendation to Ministers was the adoption of a "*phased policy leading to the routine screening of blood donors, which would take into account a comparative evaluation of the tests available, the need for ready access to testing facilities outwith the transfusion service and a recognition of the considerable requirement for additional testing, monitoring and counselling of donors with positive tests*". This was on the basis of: a) the "*limitations of currently available tests*"; b) the "*disproportionate effects of a*

high rate of false positive findings": and c) the "*need to provide alternative screening facilities to divert at "at risk individuals from the Blood Transfusion Service*".

373. The following comment from Mr Mackay was relayed by his Private Secretary in a 22 March 1985 telex [PRSE0000850]:

> *"I fully appreciate the logic of this advice, especially the danger that "at risk" men may use the Transfusion Service as a screen, and as the test is not absolutely reliable some blood may enter the system which is infected. Whatever we do on the BTS, recommendation 12(c)*[54] *is essential. Also we do have to keep in line or ahead of England, otherwise we would be subject to very severe criticism."*

374. The Secretary of State's Private Secretary responded on 26 March 1985 to say that he agreed to the recommendation in Mr Macpherson's minute [PRSE0004255].

Expert group evaluation

375. Meanwhile, the SHHD continued to monitor developments at UK level. For example, on 22 March 1985 Dr Covell circulated a note of the 13 March 1985 EAGA meeting, which he had attended and had discussed HTLV-III screening, including the question of confirmatory testing [SCGV0001125_035].

376. The EAGA testing sub-group meeting on 28 March 1985 was attended by Dr Bell, who later provided a copy of his note to Dr McClelland [PRSE0000961]. This recorded agreement at the meeting that "*informed consent*" of donors for screening tests would be difficult to achieve "*because of the complexity of the situation and the time required to educate donors fully*". It also addressed issues relating to the phasing of the evaluation programme. A further update was provided by Dr Covell to SHHD colleagues in a note summarising the 22 April 1985 EAGA meeting [SCGV0001125_018].

[54] This concerned the requirement for alternative screening facilities.

377. EAGA's discussion of HTLV-III screening continued at its 29 May 1985 meeting, attended by Dr Covell [PRSE0002837]. Dr Smithies explained at the meeting that the PHLS "*had been asked to evaluate all available screening test kits*". The Chair, Dr Harris, commented that "*while it was important to introduce a reliable screening test as soon as possible, an effective evaluation of the tests was essential and should not be rushed*". By contrast, Professor Bloom is said to have "*expressed his concern at delaying the introduction of a screening test in the Blood Transfusion Service and hoped that it would be introduced as soon as possible*".[55]

378. The 20 June 1985 meeting of SNBTS directors was attended by Mr Murray and Dr Forrester (Dr Bell's successor) [PRSE0001423]. The minutes record that "*the SNBTS were awaiting the evaluation of tests arranged by the Expert Advisory Group*" and that the "*SHHD had undertaken to provide funds for testing kits once it had been agreed to commence routinely*". Dr Forrester subsequently circulated an extract from the minutes, relating to the counselling and management of patients who had tested positive, to other SHHD medical officials [SCGV0000150_002].

Timing and funding of screening

379. SHHD officials provided a further update to Mr Mackay later on that month. In a 28 June 1985 minute, Mr Davies provided Mr Mackay's Private Secretary with a DHSS press notice which had been issued in response to a report in the Guardian that a particular HLTV-III test "*had already been chosen and was about to be introduced*" [SCGV0001146_042 and DHSC0001184]. The press notice set out a reply to a PQ from Kenneth Clarke, DHSS Minister for Health, in which he stated: "*We hope to be able to introduce a test within four to five months*". In his minute, Mr Davies wrote that the "*SNBTS are taking steps to ensure that the test will be introduced in Scotland as quickly as possible once the evaluations have been completed and facilities for suitable confirmatory testing are available*", before commenting: "*We are not convinced that the DHSS timetable is achievable, but the intention is that routine testing should start*

[55] On 22 June 1985 the Lancet published a letter from Professor Bloom, Dr Forbes and Dr Rizza, in which they expressed concern at the time taken to introduce HTLV-III screening [PRSE0001917].

at the same time throughout the United Kingdom". Mr Murray subsequently circulated this minute to other SHHD officials [SCGV0000149_002].

380. On 8 July 1985, Dr Scott wrote to Scottish CAMOs, suggesting that it was probable that routine screening of blood donors would begin before the end of the year, and seeking information on how they proposed to provide alternative testing facilities [PRSE0000841].

381. Around this time, the SHHD gave further consideration to the amount of funding required for screening to be introduced. In a 12 July 1985 minute to Mr Robertson, Mr Davies suggested that costs might be in the region of £750,000 per year, while commenting that the situation was "*still far from clear*" [SCGV0001146_026].

382. On 23 July 1985 Dr McIntyre informed Mr Davies that the "*evaluation of test kits had reached the stage when the Evaluation Committee are able to recommend two tests as being superior to the others*", while noting that the SHHD did not yet know the price or the identity of the manufacturers [PRSE0004109]. In a further minute to Mr Henderson and other SHHD officials on 25 July 1985, Dr McIntyre attached a draft copy of a letter the DHSS intended to send to RHAs concerning the outcome of the evaluation [PRSE0001279 and SCGV0000150_012]. He commented that "*[n]ow that a reasonably reliable screening test has been identified it is likely that the routine testing of blood donations will commence in October*", as well as setting out the arrangements and amount required for confirmatory testing in Scotland. Mr Henderson responded to confirm that the funding for confirmatory testing would be made available [SCGV0001146_014].[56]

383. On 25 July 1985, Professor Cash wrote to Dr McIntyre, requesting his urgent assistance with putting arrangements into place for screening to commence, given that there were only "*8 weeks to go*" [PRSE0004362]. He was particularly concerned about progress in relation to alternative testing facilities.

[56] Dr Forrester provided Mr Henderson with a further update on the type and cost of confirmatory testing on 28 August 1985 [PRSE0000251], to which Mr Henderson responded on 2 September 1985 [PRSE0002418]. Also on 2 September 1985, Dr Forrester wrote to the Glasgow Health Board CAMO regarding funding for confirmatory testing [SCGV0000150_051].

Choice of screening kit and other arrangements

384. The EAGA held a further meeting on 30 July 1985, attended by Dr Covell, in which significant updates on HTLV-III screening were given [PRSE0002628]. Dr Smithies reported that two kits – Wellcozyme and Vironostika – were considered to be "*particularly suitable for use in blood transfusion centres*". These would be the "*first to be investigated in the second stage of the evaluation which was designed to investigate performance in large scale screening of blood donors*". The minutes record agreement that it would "*be tragic to expose the BTS to the risk of being the only free access testing point*" and that it was "*essential to have sufficient counselling arrangements set up by the time the tests were introduced*".

385. In a 31 July 1985 minute to SHHD colleagues, Mr Murray commented on a letter the DHSS proposed to issue on the results of the screening kit evaluation [PRSE0003443]. He suggested that the SHHD would need to issue a similar letter and that he would consult Professor Cash, who he understood had been kept "*fully in the picture on the results of the evaluation*". Mr Murray noted that the routine testing of blood donations in England and Wales was likely to begin in October-November and that he would "*take the opportunity of sounding out Dr Cash on the likely commencement date in Scotland*".

386. The final version of the DHSS letter referred to by Mr Murray would appear to be a 1 August 1985 circular to RTDs [PRSE0003215]. It explained that the first phase of the evaluation was complete and that the second one had begun in the North London and Manchester RTCs. The letter recorded that RTDs had "*agreed that routine screening of donations should be introduced simultaneously throughout the U.K.*", and that the second stage would take 2-3 months to progress to a formal report. RTDs were to use that period to make preparations to introduce routine screening, with a target date of mid-October. A short press release was issued the same day, which outlined the developments in evaluating the kits but did not suggest a likely date for screening to be introduced [DHSC0000513].

387. Professor Cash wrote a similar letter to Scottish RTDs on 2 August 1985 [PRSE0000228]. This noted that the second stage of the evaluation had started but that the full report would not be available until the end of October. In relation to timing for the introduction of screening, Professor Cash wrote that the "*commitment for the SNBTS/NBTS to start "simultaneously" still stands.*" He suggested that it would be appropriate to plan a commencement date in the first week of October 1985, but that this was subject to "*a large number of variable and complex operational problems*" being resolved.

388. Professor Cash also gave detailed advice on the introduction of the kits, including suggesting that in the latter weeks of September 1985, RTCs should be slowly introducing selected screening at a low grade of activity, before changing to full screening in early October. He described developments in donor counselling as "*perhaps inevitably... less well planned by central authorities*". He also enclosed a first draft of a letter to be sent to all donors [PRSE0001560].

389. In a 2 August 1985 letter, copied to the SHHD, Professor Cash provided the CSA with an update on estimated costs for screening, suggesting that the cost of the kits for the first six months would around £320,000 [SBTS0000617_075]. Mr Murray forwarded this letter to Mr Kernohan in the SHHD Finance Division, commenting that the figures would probably have to be accepted as the best available [SCGV0000150_030].

390. On 6 August 1985, Dr Scott wrote a short letter to CAMOs, enclosing a summary of the results of the PHLS evaluation of screening kits and providing details of the Scottish facilities for confirmatory testing [PRSE0001882]. He wrote a further, longer letter on 14 August 1985 in relation to testing facilities outside the transfusion service [LOTH0000227]. This noted that routine screening of donations was likely to begin in mid-October and that it was essential for Health Boards to have made and publicised arrangements for testing individuals other than blood donors before the end of September. Dr Scott also provided guidance on making arrangements for counselling patients.

Publicity for screening and updating ministers

391. SHHD officials began to give attention to the issue of media publicity for the introduction of screening in the second half of August 1985. In a 19 August 1985 minute, Mr Murray reported that Professor Cash was strongly of the view that there should be "*maximum media coverage*", and that this should address both the blood transfusion test and the "*diversionary test*" (i.e. alternative screening facilities) [SCGV0000150_037]. Mr Murray commented that considerable publicity could be gained for the introduction of the BTS test without too much difficulty, but suspected that putting across the message on the diversionary test effectively would be much more difficult to achieve. If it could not be achieved, "*media publicity for the BTS test alone will simply result in increased risk to the blood supply*". He stated that Ministers would need to be informed of the steps being on the introduction of the two tests, and that they would wish to know what steps were proposed on publicity, suggesting that a "*very important element here is what DHSS are planning to do*".

392. Dr Covell replied on 21 August 1985, agreeing that mention should be made of alternative screening when testing in the BTS was publicised, while recording that the specific ways in which the tests would be publicised was the responsibility of local health authorities [PRSE0000905]. He added that, while the timing for the introduction of testing and accompanying publicity in Scotland and England and Wales "*should be synchronous, the substance of any such publicity and any parallel action in the NHS may well differ in Scotland from that put out by the CMO of DHSS*".

393. A 27 August 1985 letter from Dr Mitchell to Professor Cash provides some insight into Mr Mackay's awareness of developments in the introduction of HTLV-III screening [SBTS0000169_008]. Dr Mitchell described a recent visit from the Minister, during which he "*asked specifically to see the AIDS testing area*". While Mr Mackay was told that resources had been allocated for purchasing the test kits and associated machinery, "*there were strong hints given to the Minister that staff at the correct level of competence would be a major problem*". Mr Mackay was described as "*obviously appreciative of the up-to-date information that he received*" and "*concerned about the overall cost of the new development to the Blood Transfusion Service... there was no doubt that he was also concerned about the staffing requirements*". Dr Mitchell went

on to explain that it would be "*extremely difficult if not impossible to introduce the testing without addition of staff*".[57]

394. In late August 1985, SHHD officials began preparing a ministerial submission, while giving further consideration to the question of SHHD publicity for the introduction of screening. Mr Murray and Mr Davies prepared a contribution in late August 1985 [SCGV0000150_042]. On 29 August 1985 Mr Liddle provided a handwritten minute to Mr Macpherson, enclosing a draft DHSS press release that that just arrived [SCGV0001145_150].[58] He suggested that "*[c]learly we need to consider the possibility of a statement by Mr Mackay (or perhaps go for association with any statement by DHSS?).*"

395. In a minute that same day, Dr Scott responded to say that he was "*not in favour of any rushed statements from Mr Mackay to duplicate any similar rushed statements from DHSS*". He believed that it was "*time Mr Mackay had a full statement of what is going on on the AIDS front and there is a lot!*" [SCGV0000150_047]. Mr Murray responded with his own comments on the possible contents of an SHHD press release on 30 August 1985 [SCGV0000150_048].

396. On 17 September 1985, Mr Liddle provided Dr Young and other SHHD officials with a draft ministerial submission on AIDS [SCGV0000150_057 and SCGV0000150_058]. Responses were received on 19 September 1985 from Mr Davies and Dr Young [SCGV0000150_061 and SCGV0000150_062].

397. The finalised submission was provided by Mr Liddle to Mr Mackay's Private Secretary, copied to others including the Secretary of State's Private Secretary, on 20 September 1985 [PRSE0001516]. It was described as "*an update*" on earlier submissions and addressed a number of different areas. With respect to HTLV-III screening, it described the expectation that screening of all blood donations would be in place from mid-October, as well as outlining arrangements for alternative and confirmatory testing. It explained that Health Boards would "*be expected to absorb the*

[57] For a different example of a request to Mr Mackay for additional funds for work relating to the HTLV-III screening, see a 3 September 1985 letter from the Scottish National Party [SCGV0001194_040].
[58] The draft press release would appear to be the document at [SCGV0001145_152].

cost of the screening facilities they have been asked to introduce but the 1985/86 revenue allocation for SNBTS has been increased by £322,000 to provide for the purchase of screening test kits". Brief reference was made to the kit evaluation that had already been undertaken by the PHLS. The submission stated as follows with respect to timing and publicity:

> *"The testing of blood for the detection of HTLV-III antibody, whether by the NHS or by the Blood Transfusion Service is to commence in mid-October and we have impressed on Health Boards the importance of adequate publicity being given to the facilities available outside the Blood Transfusion Service. However, there is a likelihood of a Ministerial Statement issuing from DHSS sometime before mid October and we are currently preparing a draft Statement for Mr Mackay. Should Mr Mackay wish to discuss the action being taken in Scotland officials are of course available."*

Screening announced

398. A draft press statement was shared amongst SHHD officials on 24 September 1985 [SCGV0000150_066 and SCGV0000150_065]. Dr Young and Dr Forrester provided comments on 26 September 1985 [SCGV0000150_071 and SCGV0000150_072]. That same day, Mr Hoy (of the SIO) minuted Mr Mackay's Private Secretary, informing the Minister that a DHSS press release on action being taken to counter the spread of AIDS had been issued, and attaching a draft equivalent for Scotland [SCGV0000150_074 and PRSE0004027]. The statement – entitled "*Countering the spread of AIDS in Scotland*" – announced that £400,000 was "*being made available in Scotland to prevent the spread of the disease AIDS and support research*". It added that all blood donations would be screened from mid-October, with alternative testing facilities available at the same time for those who thought they might have been exposed to infection. The statement also listed other measures taken in Scotland in relation to AIDS.

399. On 1 October 1985, Dr Reid (CMO for Scotland) wrote to CAMOs, enclosing a letter and booklet to be sent to all doctors within a Health Board's area on the

introduction of HTLV-III screening [PRSE0003208, PRSE0002654 and PRSE0004235].

400. An update on the introduction of screening at Scottish RTCs and the PFC was provided at the 2 October 1985 SNBTS directors' meeting, attended by Dr Forrester and Mr Murray [MACK0000911]. The Wellcome test appears to have been preferred by most directors. On 8 October 1985, Dr Forrester provided Dr McIntyre with the following summary, which seems to have intended for a PMO report [SCGV0000150_088]:

> *"From mid-October, all new donations will be tested for AIDS antibodies, by one or other of the approved tests, and no blood products derived from new or existing stock will be issued except those that had been similarly tested with negative results, or else heat-related. A uniform procedure has been established to investigate and confirm positive antibody tests, and all initial counselling of any donors with confirmed antibodies will be undertaken by Blood Transfusion Service staff."*

Relationship between DHSS and SHHD decisions

401. One of the issues explored in witness evidence in Penrose was the relationship between SHHD and DHSS decisions on the principle and timing of introducing HTLV-III screening.

402. Dr Scott's oral evidence was that, if the DHSS "*hadn't decided to do it, then we might well have done it. In this case DHSS were very equivocal about introducing tests and we decided that we would go ahead whatever happened*" [PRSE0006049 p.131]. He added that, with the agreement of ministers, it would have been possible that Scotland would have introduced screening ahead of England.

403. While noting that he had no direct involvement in the issue at the time, Dr Macdonald offered a different perspective [PRSE0002766 §27]:

"With regard to an issue such as HIV testing, where there is media interest and a concerned patient group, it would be very easy for one system to embarrass the other by doing different things. The suspicion would be that one system was right and one was wrong, or at least that one would be better than the other. It should also be borne in mind that at the relevant time SHHD and DHSS were simply 2 different Departments of the same Government."

Later developments

404. The SHHD was involved in further correspondence, in late October 1985, regarding stocks of donations collected before 14 October 1985. In a 25 October 1985 letter, Alun Williams informed Mr Murray that the DHSS had written to RTDs in England "*asking them to ensure that all stocks of blood donations are tested for HTLV III antibody wherever this is practicable*" [DHSC0000480]. It would appear that, following this letter, the SHHD asked Professor Cash to clarify the position in Scotland. In a 28 October 1985 letter to Dr McIntyre, he explained that "*[a]ll stocks of products held at RTCs were tested prior to 14th October 1985 deadline*" but that the position was different for factor concentrates [PRSE0004085]:

"*We have decided that it would be unreasonable to attempt to test plasma donations currently held in PFC stores. Aside from the massive operational difficulties and cost of this exercise we felt that the heat treatment programmes for factors VIII and IX concentrates... are virucidal with respect to HTLV-III.*"

405. Developments in HTLV-III screening were discussed at a 10 December 1985 meeting SNBTS directors, attended by Dr Forrester [PRSE0002258]. It was noted that "*US Armed Forces were testing new recruits*" but that the "*position of serving men or women was unknown. Meanwhile it was noted that the Transfusion Centres continued to visit US bases to collect blood and it was agreed that no change should be made meantime.*"[59]

[59] The final sentence in this quote is in bold and underlined in the minutes.

406. This issue was addressed in a 17 January 1986 letter from Dr Forrester to Professor Cash [SBTS0000094_026]. He wrote that "*US forces insist that the confirmed presence of HBsAg, HLTV III antibodies or evidence of syphilis in these donations must be reported to the local US Military Medical Authority, and the donor must consent to this disclosure before the donation is taken*". Dr Forrester commented that US forces had "*[n]o doubt*" already taken steps to ensure this, but asked that Professor Cash arrange for RTDs to be informed.

407. Professor Cash subsequently wrote to Dr Smithies at the DHSS, enclosing a US military document regarding blood donation he had received from Dr Forrester [SBTS0000671_135]. The document suggested that UK blood services were required to report all positive results for "*syphilis, hepatitis and HLTV-III antibody*" in blood donated by US military personnel. Professor Cash considered that there were "*some quite worrying operational and even perhaps legal difficulties*" with the document and believed that the matter should be referred to EAGA.[60]

408. In a 20 January 1986 DHSS minute, copied to Mr Murray, Dr Smithies reported the number of donations positive for HTLV-III between 14 October and 31 December 1985, as well as referring to a draft press release [PRSE0004555 p.12]. In a 29 January 1986 minute to Mr Murray, Dr Forrester appears to have commented on this draft press release and minute, criticising the figures set out by Dr Smithies [SCGV0000150_138].

409. An update on screening was provided by an SHHD official to Mr Morison and Mr Mackay, copied to the Secretary of State and others, on 4 February 1986 [SCGV0000150_151]. The minute recorded that screening had "*commenced throughout the UK on 14 October 1985*". The results to the end of December 1985 were available and it was proposed that the press be informed. Between 14 October and 31 December 1985, 593, 393 donations had been tested throughout the UK. 13 donors had been found to be HTLV-III positive and their donations withdrawn. Of these, 8 were in England, 4 were in Scotland one in Norther Ireland. The minute added:

[60] For further documents relating to this issue, see [SBTS0000094_022, SBTS0000094_020, SBTS0000618_085, SBTS0000671_130 and ARCH0002254].

"While these figures have no statistical significance and the total number of Scottish donors concerned is only 4 (2 in Edinburgh and 2 in Dundee) the proportion of donations found positive in Scotland (0.0059 per cent) is nearly 4 times as great as in England (0.0016 per cent)."

410. It was noted that the DHSS was proposing to issue a press release of these results on behalf of all Health Ministers, giving a UK figure without any regional breakdown. It was said this "*would have advantages since the figures of antibody positive donors are so small it would be misleading to encourage general conclusions from regional comparisons*". SHHD officials supported a single joint press release.

Schools, counselling and the wider AIDS campaign

Advice to schools

411. As well as the SHHD, other parts of the Scottish Office were involved in issues arising from the infection of haemophilia patients with HTLV-III. For example, in an October 1985 letter to directors of education and regional authorities, the Scottish Education Department gave preliminary guidance on "*the implications for schools of the fact that some children with haemophilia may have been exposed to the HTLV-III virus which has been linked to... AIDS*" [LOTH0000268_002].

412. The letter recorded that a proportion of haemophiliac children in Scotland had been exposed to the virus through blood products but that none had developed AIDS. Having explained the available evidence on transmission routes, it stated: "*All evidence is that haemophiliac children whose blood contains antibodies to HTLV-III are not at risk to other children or to teachers or other staff at schools*". Guidance was given on dealing with spillages of blood and similar scenarios, and it was said that the guidance should apply to all haemophiliac children.

Counselling

413. In March 1985, SHHD officials considered a funding application for research into counselling of haemophilia patients at risk from AIDS in Glasgow. In a 20 March

1985 minute, Dr Boyd explained that the application proposed a "*study to establish the extent of the social and psychological problems related to AIDS experienced by patients with haemophilia and their families*", commenting that it was "*disturbing that no consensus exists at present on what kind of support and information should be given*" [PRSE0004853 and PRSE0000771].

414. Dr Covell supported the application, commenting that "*[a]ppropriate counselling of those at risk from AIDS and those anxious they may be at risk*" was "*an important task*" and would become more so as tests for the virus became readily available [PRSE0001644]. Dr Bell was also generally supportive, noting the "*serious threat posed to haemophiliacs from the risk of being infected by AIDS through the use of blood products*", and commenting that "*[u]ndoubtedly haemophilia patients require skilled and sympathetic counselling and I would support any moves to give the benefit of such a service*" [SCGV0000149_005]. Dr Bell's only reservation was that the proposal appeared to have "*a profound academic orientation*", suggesting that it "*would be unfortunate if support for this research project distracted attention for the need, as of now, for on the ground practical help and support*". He also noted that, when HTLV-III screening of blood donors was introduced, there would be "*another large group of individuals... for whom counselling services*" would be required.

415. Reference was also made to counselling in answers to PQs in late 1985. In answer to a question on the total cash available in Scotland to deal with AIDS and how it was allocated, Mr Mackay explained that the cost of treating AIDS patients was met by health boards from their existing resources and outlined the items that had been funded centrally (including £322,000 for the purchase of HTLV-III screening kits and £1,500 for courses for AIDS counsellors) [MACK0000103_002]. In response to a question on funding for haemophilia centres and counselling, Mr Mackay stated: "*Both the haemophilia reference centres in Scotland are closely involved in work relating to AIDS, they are not separately funded for any of their functions. Although social work departments are not directly concerned with the work of the centres they are able to contribute their special skills in supporting the families of haemophiliacs*".

416. The provision of funding for counselling to haemophilia centres in Scotland was raised again in a May 1986 letter from David Watters of the Haemophilia Society to Mr

Mackay, contrasting the position in England and Wales [SCGV0000011_075]. Mr Mackay's response explained that funding arrangements in Scotland differed from those in England and Wales, and that in "*Scotland the Government does not allocate resources to Health Boards against specific expenditure. Instead, it is left to Health Boards to use the resources made available to them in the best interests of patient care within their respective areas*" [SCGV0000011_073]. He added that he understood that "*the interests of the major haemophilia centres in Scotland have been borne in mind by the Health Boards concerned in the allocation of resources, so that adequate counselling services can be provided for their patients*".

Stigma and wider AIDS campaign

417. During 1986, Mr Mackay faced some criticism for remarks he made in relation to AIDS. For example, in a May 1986 letter to the Minister, Mr Watters took issue with a statement he had made in the House of Commons that "*AIDS is a totally self-inflicted illness*" [SCGV0000011_077]. While noting that the remark had been made during a discussion of intravenous drug users in Scotland, Mr Watters wrote that it had "*caused a great deal of resentment among people with haemophilia and it was certainly, in my view, a sweeping condemnation of the people we represent*". He asked that Mr Mackay correct the misapprehension that AIDS was self-inflicted in the case of people with haemophilia.

418. Mr Mackay's (unsigned) response stated that his remark about AIDS being totally self-inflicted was made in the context of comments about drugs and AIDS, adding: "*Of course this is not so with regard to haemophiliacs and I did not intend to imply that it was. The sooner certain sections of society change their lifestyle the sooner we will be able to see an end to the totally undeserved side effects visited on some haemophiliacs*" [SCGV0000011_076].[61] In a reply to this letter, Mr Mackay wrote that haemophilia treatment was now "*completely safe*" and was "*not therefore totally reliant upon other people changing there* [sic] *lifestyle*" [SCGV0000011_075].

[61] Note that Mr Mackay's letter mistakenly refers to the date of Mr Watters' letter as 2 May, and the mistake was repeated in a further response from Mr Watters [SCGV0000011_075].

419. Mr Mackay was also criticised elsewhere. A 6 September 1986 newspaper article reported that the Minister was "*facing calls for his resignation after declaring in a newspaper interview that Aids "could easily be prevented" if homosexuals changed their lifestyles*" [HSOC0022113]. Mr Mackay was said to have described AIDS as a "*straightforward moral issue*", to have been "*dismissive of Government publicity campaigns stressing the need for "safe sex"*" and to have said that if the NHS "*lacked the resources to treat Aids "the other way round is for people who get it to pay themselves"*".

420. Shortly before this article, Mr Forsyth had been in correspondence with other members of the UK Government regarding the AIDS public education campaign. On 21 August 1986, Norman Fowler wrote to Viscount Whitelaw, copied to other members of the Government, proposing that an AIDS leaflet be delivered to every household in the UK, "*spelling out in simple and explicit language what they need to know*" [DHSC0003836_045]. Mr Fowler noted that he hoped to have agreement for the leaflet to be issued on a UK basis. Mr Mackay responded to this proposal in a 1 September 1986 letter to Viscount Whitelaw, noting that he was doing so in the absence of the Secretary of State, Malcolm Rifkind [HMTR0000008_003]. He suggested that the proposed leaflet dealt with the issues superficially and did not add anything to previous newspaper advertising, commenting:

> *"We therefore run the risk of being heavily criticised both for delivering sexually explicit leaflets to every household in the country whether the occupiers wish to receive it or not, and for the inadequacy of the guidance in the leaflet, while at the same time we would not achieve any advance on what has been and can be achieved by public advertising".*

421. Mr Mackay suggested that more time be taken to consider the leaflet, commenting: "*While I acknowledge that we must do more to increase public awareness of the issues relating to AIDS, we should take time to get our publicity right if it is to have the desired effect*" [HMTR0000008_003].

422. Mr Rifkind also had some involvement in decisions relating to the wider AIDS campaign around this time, attending meetings of the Sub-Committee on AIDS of the

Cabinet Home and Social Affairs Committee (see the minutes of meetings in late 1986 and early 1987 [CABO0100010, CABO0100009, CABO0100008, WITN0771171 and WITN0771160]).

VIII. KNOWLEDGE OF AND RESPONSE TO RISK: NANB HEPATITIS AND HEPATITIS C

Understanding of NANB hepatitis and surrogate screening of donations

423. This section focuses on the SHHD's understanding of the incidence and severity of NANB hepatitis and its decision-making around surrogate screening of blood donations.

Prior to 1986

424. Relatively little evidence is available on the SHHD's understanding of NANB hepatitis before the mid-1980s. Most of the available documents relate to officials' attendance at meetings of working groups and committees.

425. Evidence from the second half of the 1970s is particularly limited. However, the 30 May 1977 meeting of SNBTS and haemophilia directors, attended by Drs McIntyre and Bell and Mr Roberts, may provide some information from this period [PRSE0002273]. Dr Craske attended the meeting to discuss a proposal to "*extend his survey on the incidence of hepatitis after transfusion with Hemofil and Kryobulin to encompass Scottish centres and Factor VIII*", as well as outlining the findings of an earlier study. While the minutes do not refer explicitly to NANB hepatitis, the description of Dr Craske's work in other contexts suggest he may have discussed hepatitis cases other than hepatitis B.[62]

426. One forum in which information related to NANB hepatitis was shared in the late 1970s and early 1980s was the Medical Research Council ("MRC"). The SHHD

[62] See, for example, the description of Dr Craske's work at the 13 January 1977 meeting of UK haemophilia centre directors [PRSE0002268].

appears to have attended some but not all of its meetings. For example, unlike the DHSS, no SHHD representative attended the 12 February 1979 meeting of the MRC's ad hoc group on hepatitis, during which NANB hepatitis was discussed in detail [PRSE0001960]. By contrast, Dr Bell attended the 17 December 1979 meeting of the MRC's Blood Transfusion Research Committee, when NANB hepatitis was mentioned as a "*problem*" with factor VIII concentrates, though the incidence or severity of NANB hepatitis does not appear to have been discussed [CBLA0001040].

427. NANB hepatitis was also discussed at other meetings attended by the SHHD. For example, Dr Bell attended the meeting of the Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody on 2 April 1979 [CBLA0000931]. The minutes record that the DHSS was "*anxious to encourage research directed towards establishing the extent of the problem and the development of tests for the agent(s)*" of NANB hepatitis, and reference was made to work proposed by the MRC. Similarly, at the 3 October 1979 meeting of NBTS RTDs, attended by Dr Bell, the Chair of the Reconvened Advisory Group reported that "*the Group was concerned about the incidence of post-transfusion jaundice*" [SBTS0000290_023]. It was "*particularly anxious to receive from Regions details of patients suffering from Non-A and Non-B hepatitis*".

428. Dr Bell also attended the meeting of the Reconvened Advisory Group on 6 March 1980 [CBLA0007195]. Its minutes include the following in relation to the MRC's work on NANB hepatitis:

> *"Members were concerned about the incidence of non-A, non-B hepatitis and the possibility that new viruses were perhaps being introduced through the use of commercial blood products, namely Factor VIII and Factor IX. Professor Zuckerman reported that he knew of 2 haemophiliacs who had suffered severe non-A, non-B hepatitis after receiving commercial concentrates. In both cases the disease had a short incubation period. Members agreed that the hazard from non-A, non-B hepatitis should now be recognised and brought to the attention of the appropriate departmental bodies responsible for control of hepatitis".*

429. At the same meeting, Dr Craske presented a paper which concluded that NANB hepatitis had been associated with "*all brands of commercial and NHS VIII and IX concentrates*", and that "*the use of commercial concentrates in the past 4 years had exposed 90% of haemophiliacs to hepatitis B virus and at least 2 strains of non-A, non-B hepatitis virus*". The paper also found that "*[t]he occurrence of both B and non-B hepatitis associated with NHS factor VIII treatment meant that at least one serotype of non-A, non-B hepatitis virus was endemic in the UK but probably at a low incidence.*" Dr Craske stated that he intended to continue the study for several years, and members agreed that "*the new hepatitis committee*" should be made aware of this study and of the "*concern*" of the working party on the matter.

430. Unlike the DHSS, the SHHD did not attend meetings of the Working Party on Post-Transfusion Hepatitis in the early 1980s, which replaced the MRC's 1979 ad hoc group and was chaired by Dr Gunson. The Working Party only met twice (in 1980 and 1981) and the SNBTS (through Dr McClelland) took part in its meetings [MRCO0000029_003; NHBT0000068_049]. By 1982, it had been replaced by a new working party set up by the NBTS: the Working Party on Transfusion-Associated Hepatitis. As before, the SHHD did not take part, but the SNBTS was represented by Dr McClelland, Dr Mitchell and Dr Cuthbertson in 1982-1983 [CBLA0001625; NHBT0000023_002; NHBT0000023_003; PRSE0001299]. As explored in evidence previously heard by the Inquiry, Dr McClelland unsuccessfully proposed studies on NANB hepatitis during meetings of these working parties.[63]

431. Although it did not attend the meetings of MRC and NBTS working parties on hepatitis, the SHHD was provided with information on their work through other meetings. One example is the 23 June 1981 meeting of SNBTS directors, attended by Dr Bell [PRSE0003924]. The minutes record that Dr McClelland described a proposal for a two-centre study on the transmission of NANB hepatitis by transfusion, and it "*was agreed that similar studies might be made in Scotland*". Despite this, and Dr McClelland offering to circulate his proposal and a recent article in the New England Journal of Medicine, the minutes record that "*Scottish Directors would not proceed with liver function tests on existing donations for the time being*".

[63] See, for example, Dr McClelland's 28 January 2022 oral evidence to the Inquiry [INQY1000178].

432. Shortly thereafter, Dr Bell attended the MRC's Blood Transfusion Research Committee meeting on 25 June 1981, during which Dr Gunson described the work of the Working Party on Post-Transfusion Hepatitis [CBLA0001396]. Dr Gunson reported that research was being carried out "*into the identification of agents*" of NANB hepatitis, which was "*proving to be very complex. Results so far had shown that two, perhaps three or more different type viruses were responsible for the parenteral transmission of non-A, non-B hepatitis.*" Having described the difficulties of research into carriers of NANB hepatitis, Dr Gunson noted that "*large-pool blood products were especially likely to cause liver damage in haemophiliacs*". The minutes record agreement that there was "*at present no need to screen potential blood donors for non-A non-B hepatitis but the production of a vaccine would be waited with interest*", and that in the meantime "*it would be valuable*" for patients with raised ALT post-transfusion to be followed up.

433. Other than the 23 June 1981 meeting described above [PRSE0003924], there appears to have been little discussion of NANB hepatitis at meetings of SNBTS directors in the first half of the 1980s.[64]

434. However, some discussion of NANB hepatitis took place at meetings of SNBTS and haemophilia directors, attended by the SHHD. For example, at their 30 January 1981 meeting, attended by Dr McIntyre and Mr Finnie, it was proposed that a smaller working group be set up to consider "*the problem of hepatitis*" (likely a reference to NANB hepatitis) [PRSE0000144]. Further reference was made to NANB hepatitis in the context of heat treatment of factor concentrates. For example, at the 21 January 1983 meeting, chaired by Dr Bell and attended by Dr McIntyre and Mr McBryde, it was noted that the PFC was "*going ahead with the development of a heat-treated* [factor VIII] *product with reduced risk of transmitting hepatitis*" (i.e. NANB hepatitis) [PRSE0001736].

[64] See, for example, Professor Cash's proposal in December 1981 that a UK Working Party on Post-Transfusion Hepatitis be established [PRSE0003364], which does not appear to have been taken forward [PRSE0003465].

435. A 23 May 1984 letter from Dr Bell to Mr Murray, concerning funding for PFC's heat treatment of factor VIII, provides further insight into the SHHD's understanding of NANB hepatitis and the risks associated with factor concentrates around this time [PRSE0004029]:

> *"At present nearly all "virgin" (newly-treated) haemophiliacs become infected with non-A non-B hepatitis, though not usually of dramatic severity. About 40% show evidence of infection by hepatitis B. The longer term effects of such infection in haemophiliacs is not known with certainty because until relatively recent years haemophiliacs had little prospect of living into middle or old age. However a significant proportion of "normal" patients infected with hepatitis B go on to suffer severe liver impairment which, apart from the personal aspect, makes significant demands on health care resources".*

436. The development of heat-treated PFC factor VIII was revisited at the 29 November 1984 meeting of SNBTS and haemophilia directors, chaired by Dr Bell and attended by Mr Murray [PRSE0002066]. During the meeting, which had been called to discuss the implications of HTLV-III antibodies being discovered in Scottish haemophilia patients, Dr Perry "*explained that the PFC had for some time been developing methods of heat treating factor VIII, aimed particularly at preventing transmission of NANB hepatitis*". These developments continued to be discussed as the PFC introduced different heat-treated products from late 1984/1985. For example, at the 5 March 1986 meeting of SNBTS and haemophilia directors, chaired by Dr Forrester and attended by Dr McIntyre, Professor Cash "*informed members that even material dry heated at 68°C for 24 hours may not be non-infective with regard to HTLV III and Non A/Non B hepatitis*" [PRSE0001081].

437. From around late 1985, evidence of the SHHD's understanding of and response to NANB hepatitis becomes closely linked to the question of whether NANB surrogate screening should be introduced in Scotland. The SHHD official who had most involvement in this issue appears to have been Dr Forrester. In written evidence to Penrose, Dr McIntyre stated: "*Dr Forrester also had an interest in NANBH, in that he was involved in "research" issues. I recall that he would assess research applications before they were submitted to the Biomedical Research Committee.*" [PRSE0004764].

A 3 September 1985 letter, in which Dr Forrester suggested that Dr McClelland redirect a research proposal to investigate liver function tests in blood donors, provides an early example of his involvement in considering NANB research [SBTS0000295_014].

1986: debate on whether to introduce NANB surrogate screening

438. On 25 March 1986, Dr Forrester attended an SNBTS directors' meeting [ARCH0002254]. In response to a suggestion that NANB surrogate testing "*might soon*" be introduced by transfusion services in the USA, Dr Forrester "*said it was highly unlikely that the UK Departments of Health would fund testing based on data from the USA, but it was recalled that HBs-Ag and AIDS antibody testing had both been introduced without prior UK research.*" The minutes record that "*[c]ertain clinicians and haematologists in this country had felt that the Transfusion Services had been slow to commence AIDS antibody testing and others had similar views in relation to non-A non-B hepatitis surrogate tests.*" Dr McClelland is reported to have said that "*he would be able to provide data about raised ALT levels in blood donors by the Autumn of 1986, following a successful Ethics Committee proposal*". The minutes also record that "*the Directors agreed to give consideration to funding someone to undertake research*" on NANB surrogate testing.

439. The following day, Dr Forrester provided a note of this meeting to Dr McIntyre and Dr Scott [PRSE0003127]. Having described NANB hepatitis as "*a medley of conditions*", he reported that "*[s]ince any additional test of this kind must necessarily be non-specific and could well prove expensive*", he had "*immediately made further enquiries and discovered that the number of cases in Scotland due to blood transfusion is probably exceedingly low*". Dr Forrester referred to "*a solid body of work (a Ph.D. thesis) exploring the matter*" and recorded that he was "*securing Dr Dan Reid's opinion in writing in the near future*".

440. Dr Forrester also noted that it had been "*argued at the meeting that urgent action was called for rather than a search for reliable information and that the case was comparable with that of AIDS*". He described having challenged this comparison on the basis that "*the steps taken to deal with AIDS were taken in the face of a rapidly rising incidence*" whereas the incidence of NANB "*so far as I know is small and steady*". He

commented that there was "*no justification for panic measures*", while indicating that the SHHD "*was perfectly open to proposals for funding research in this field, if research is required to determine the true size of the problem and the likely effect of any proposed remedy*".

441. As is apparent from later documents, the PhD thesis referred to by Dr Forrester was Dr Dow's, earned at the University of Glasgow in 1985 for research into NANB hepatitis in the West of Scotland, under the supervision of Dr Mitchell and Dr Follett [PRSE0003937]. The thesis concluded that "*[t]ransfusion-association NANB is a very rare occurrence with an average of only 3 reported cases annually*" (p.7). It also reported that a "*study of haemophiliacs and renal patients*" had shown that "*there are occasional episodes of hepatitis (usually mild)*". Dr Dow had previously been involved in a 3-year study of NANB hepatitis with Dr Follett – with the research carried out between 1980 and 1983 – which found that cases of post-transfusion hepatitis were rare in the West of Scotland, although "*haemophiliacs and drug abusers do present with unexplained jaundice episodes*" [PRSE0002577].

442. On 26 March 1986, Dr Forrester requested an opinion from Dr Reid, of the Communicable Diseases Surveillance Unit, on NANB hepatitis; in particular, its likely incidence in Scotland, the "*proportion attributable to blood transfusion or administration of blood*", and "*[h]ow far any proposed test could reduce this proportion*" [PRSE0003198]. Dr Reid's response has not been found, but he appears to have responded and to have sent with his response a copy of Dr Dow's thesis. In a letter on 12 June 1986, Dr Forrester thanked Dr Reid for his "*informative letter of 4 June and for a sight of Dr Dow's excellent thesis*" [SCGV0000163_203]. As concluded by Penrose, it would appear that Dr Reid's response did not recommend surrogate testing [PRSE0007002; §27.128]: in a later note, Dr Forrester reported that Dr Reid's opinion was that NANB surrogate testing could not be justified [PRSE0000017].

443. The SHHD was also aware that RTDs in England and Wales were considering NANB surrogate screening around this time. The issue was discussed at their 25 April 1986 meeting, attended by Dr Forrester [CBLA0002307]. Under the heading "*Should the N.B.T.S. carry out a study on NANB Hepatitis*", the minutes record the following:

"The Chairman reported that this had been discussed by the Scottish Directors and that he had agreed to raise it with RTD's. Dr Gunson reminded Directors of two previous attempts, one by the MRC and one by the Transfusion Associated Hepatitis Working Party, to study this problem. After discussion it was agreed that this should not be pursued because of lack of time and resources."

444. In May 1986, Dr Dow produced a report on NANB surrogate testing [PRSE0002544]. This suggested that even if a combination of ALT and antibody to hepatitis B core antigen (anti-HBc) tests were 100% effective, "*the economics involved in conducting these tests would greatly outweigh the costs of hospitalization of the few reported NANB PTH cases*". The report concluded that surrogate testing "*would have little impact on reducing the already low level of NANB PTH cases at present reported within the West of Scotland region*". The report, which Dr Dow had been asked to prepare by Dr Mitchell, was circulated to RTDs ahead of the 25 June 1986 SNBTS directors' meeting [PRSE0003246]. It is unclear if a copy was provided to the SHHD and the report is not mentioned in the meeting minutes (attended by Dr Forrester) [PRSE0002641].

Dr Forrester's notes and discussion with SNBTS directors

445. On 12 June 1986, Dr Forrester wrote a note entitled: "*Transmission of non-A, non-B hepatitis by blood and blood products: is it practicable to reduce or prevent it by introducing ALT testing of donations?*" [PRSE0000857]. The note set out Dr Forrester's understanding of the risk posed by NANB hepatitis and the efficacy of ALT screening. It began by recording that the information it contained was mostly derived from Dr Dow's thesis. Dr Forrester wrote that transfusion-associated NANB hepatitis was "*very uncommon in the West of Scotland*", with "*no upward trend*", and that in relation to haemophiliacs, "*Dr Dow found no evidence of any substantial problem*". The note recorded that "*Dr Dow reckons that the proportion of donations infected with non-A, non-B hepatitis may be 18 per hundred thousand.*" As for the severity of NANB hepatitis, Dr Forrester wrote:

"The condition is not as a rule serious, and most of the cases detected have not even been jaundiced. There may however be a tendency for it to become chronic, and the long-term outlook is inevitably not yet known. The case fatality rate is estimated in a textbook consulted by Dr Dan Reid at less than 0.1%, except in pregnant women, who are at much greater risk (10% if they contract it during that last 3 months of pregnancy)."

446. As for surrogate testing by ALT, Dr Forrester noted that the advantage was that some donations that would transmit NANB hepatitis might be excluded. The drawbacks were said to be that there might be false negatives and false positives, with American evidence that these drawbacks were "*serious: only perhaps 38% of the genuinely infective donations are detected, some 70% of the apparently infective donations are harmless*". Dr Forrester suggested that rejection of donations "*might reach 3% - a grave loss*". He reported that Dr Dow had concluded that the cost of introducing ALT testing in Scotland "*would be extremely high and benefit minimal, especially when only a few cases of non-A, non-B post-transfusion hepatitis are reported each year*". The note concluded by recording that Dr Reid and Dr Follett did not recommend the introduction of ALT testing of Scottish blood donations.

447. Surrogate testing was subsequently considered at the SNBTS directors' meeting of 25 June 1986, attended by Dr Forrester [PRSE0002641]. It was noted that that there was "*increasing evidence*" that the USA and several European countries "*were introducing anti-HBc and/or ALT testing of blood donors in an effort to minimise the risks of NANB transmission through blood and blood products*". It was recorded that "*Dr Cash believed that the SNBTS would soon come under pressure from clinicians to introduce testing.*" There was also some discussion of further study. The minutes indicate that "*a limited study involving follow up donors with abnormal liver function tests was about to take place in Edinburgh*" and that Dr Fraser and Dr Contreras (of the Edgware Transfusion Centre) intended to set up a small group to explore the issue. It was agreed that the matter should be discussed again once "*the outcome of Dr Fraser/Dr Contreras' joint deliberations*" was known.

448. Dr Forrester commented on the discussions at this meeting in a 30 June 1986 note to Dr McIntyre and Dr Scott [PRSE0000017]. As well as suggesting that Scottish

RTDs may have been unaware that Professor Cash had just submitted a request for £800,000 to the CSA to fund surrogate testing in 1987-1988, Dr Forrester wrote as follows with respect to the suggestion that surrogate testing be introduced:

> *"There is a proposal to introduce a liver function test (and a test for the core antigen of Hepatitis B) for all donations. An able PhD thesis of last year concluded that in the West of Scotland any advantage would in no way justify the cost and the loss of donations entailed. However, in USA certain blood banks have understandably adopted these measures to restrict their legal liabilities. I have previously examined a copy of the thesis; Dr Dan Reid's opinion is that non-A, non-B hepatitis is heterogeneous and generally mild (except in pregnant women), and that a testing programme cannot be justified. Dr Smithies tells me that there is no pressure in England to institute one, and the recent Directors' meeting there would not even back research into its value."*

449. Surrogate screening was discussed again at the 9 October 1986 meeting of SNBTS directors, attended by Dr Forrester and Mr Murray as well as by two English RTDs (Dr Gunson and Dr Fraser) [PRSE0001880]. Following discussion of a proposed multi-centre study on the incidence of raised ALT and anti-HBc levels in donors, it was agreed that the UK Working Party on Transfusion Associated Hepatitis "*was the most appropriate body to pursue the issue of implementing surrogate testing in RTCs*", and that Professor Cash "*should write to Dr Gunson on behalf of SNBTS Directors formally requesting that this working party be reconvened, with a view to making proposals to Department of Health*".

SHHD concern and DHSS position

450. Around this time, concern seems to have arisen at the SHHD about the possibility of Scotland introducing NANB surrogate screening before the rest of the UK. In a 16 October 1986 minute to Dr Forrester Mr Murray, Dr Scott requested an update on the issue and commented: "*CMO DHSS is worried that if we go ahead England and Wales will have to follow suit. I think there must be consultation with DHSS before we agree to provide funds for this screening.*" [PRSE0004812].

451. Dr Forrester responded the following day, providing his June 1986 note and an article from Nature, and reporting that the American Association of Blood Banks had decided, "*without any enthusiasm*", to start screening [PRSE0002172]. He referred Dr Scott to the following paragraph in his note of the SNBTS directors' 9 October 1986 meeting:

> *"Dr Cash is pressing the English BTS to seek a start of this, apparently on the ground that UK are "lagging behind others parts of the world". The initial – and very prudent – response is likely to be a call for research. Some has already been done last year, but turned out discouraging to Dr Cash's purposes; certainly he never mentions it. Dr Gunson of English BTS believes that "external pressures" will compel a start of Surrogate testing. One may guess that this testing would cost the UK about £9m."*

452. Dr Forrester concluded by commenting: "*There seems no justification for introducing this screening without gathering further British evidence, because the American experience of frequent post-transfusion hepatitis does not seem to be duplicated here.*"

453. The UK Working Party on Transfusion-Associated Hepatitis reconvened for the first time 24 November 1986, at a meeting attended by Dr Forrester [NHBT0000023_007]. During discussion of the available data, the minutes record a view that "*[c]urrent UK data on PTH NANB was inadequate to base decisions upon, in terms of cost-effectiveness of surrogate screening, even if this had been proved to be of value for reducing PTH in the USA. No USA studies have yet proven this*". It was suggested that, in "*the absence of more data, meaningful comparisons of money spent on surrogate testing of donors vs costs of treating acute and chronic PTH NANB could not be made*". The meeting agreed that "*a full prospective study of a group of recipients of <u>all</u> transfused blood or component units... would be too expensive and inappropriate in the UK*". However, a funding application for a study to follow up recipients of elevated ALT and anti-HBc positive units had been submitted by the North London RTC, and it was agreed that consideration should be given to a study screening 3,000 donors at four RTCs for anti-HBc and ALT. This would gather "*current information on*

the prevalence of surrogate markers in different areas in the UK" and follow up "*'positive' donors prospectively*".

454. Dr Forrester reported on this meeting in a 1 December 1986 minute to Dr McIntyre and others [PRSE0003801]. He recorded that the Working Party considered that the American experience of "*frequent non-A, non-B hepatitis in recipients of blood and blood products*" was not reproduced in the UK, although "*to examine the question properly would be a long and expensive business*". Implementing surrogate screening was described as involving an "*arbitrary decision on where the draw the line*", with Dr Forrester commenting that it was "*clear that much "innocent" blood would be excluded*". As for research, Dr Forrester wrote that the meeting "*felt that a prospective study to discover the present burden of transfusion-associated non-A, non-B hepatitis was impracticable on grounds of cost and huge sample size.*" Instead, it proposed "*a study to identify in three centres (1 Scottish) donors positive for ALT or core antibodies, and search for other risk factors in them.*"

455. Dr Forrester suggested that the "*position explicitly reached at the meeting*" was "*to recommend research of no great significance or scientific interest because the prospect of research would serve to counter pressure from for example haemophiliacs and Haemophilia Directors to embark on an indirect and largely ineffective form of screening, which would also lose us a certain amount of perfectly harmless blood*". He relayed figures which he said were produced at the meeting (but are not recorded in the meeting minutes [NHBT0000023_007]) of annual NANB hepatitis cases among haemophiliacs and patients with von Willebrand's disease: "*the average UK total per year is 35 over the past 6 years…a proportion of these cases among haemophiliacs and similar patients are asymptomatic.*"

456. On 22 January 1987, Dr Forrester attended a meeting of the Transfusion-Associated Hepatitis Working Party, during which a draft protocol for an anti-HBc/ALT screening trial was discussed [PRSE0000450].

457. One of the means by which information was shared in the SHHD at this time was the preparation of a Principal Medical Officer report. Dr Forrester explained in oral evidence to Penrose that he would compile material which he would send to Dr

McIntyre (Principal Medical Officer) for the latter to use in compiling the PMO report [PRSE0006066 pp.25-26]. Dr MacDonald explained in oral evidence that these were monthly reports [PRSE0006066 p.106].

458. On 26 January 1987, Dr Forrester wrote a document entitled "*Material for PMO Report*" which included a section on NANB hepatitis [PRSE0001376]. He described NANB hepatitis as "*a residual rag-bag when Hepatitis B and Hepatitis A are excluded*", which "*is relatively benign*". He recorded that US blood banks were expected to introduce "*a combination of a liver function test and a test for the core (not the surface) antigen of Hepatitis B*" which would distinguish "*perhaps a third of blood donations which would convey non-A, non-B "Hepatitis" and allows them to be excluded*". Dr Forrester described exclusion as being "*far from complete, and besides, some 2% of "innocent" donations may also be excluded*". He noted that, in contrast to the USA, "*[h]ere, it is intended instead to enquire about the number of relevant donations and the characteristics of the donors, before taking any further step*".

459. Shortly thereafter, Dr Forrester chaired a meeting of SNBTS directors and haemophilia directors, on 9 February 1987 [PRSE0002769]. Under the heading "*Non-A, Non-B Hepatitis screening*", the minutes record that Dr Forrester reported the results of the recent Transfusion-Associated Hepatitis Working Party meeting (which had taken place on 22 January 1987): "*In the USA between 5% and 25% of transfusions lead to the recipient contracting Non-A, Non-B Hepatitis. In the UK the figure is approximately 2.5% and in Scotland, during the last decade, there have only been 1 to 5 cases per annum. Non-A, Non-B Hepatitis would appear to be relatively benign, despite some risk of cirrhosis of the liver in the long term.*"[65]

460. Dr Forrester also reported that a study involving four centres was proposed, one of which would be in Scotland, and described its aims. Professor Cash suggested that part of the study "*might lead to delay in the introduction of screening; meantime commercial products, if derived from screened plasma, might enjoy an advantage over SNBTS products derived from unscreened plasma*". However, the minutes record that

[65] Those figures are not recorded in the minutes of the Working Party meeting of 22 January 1987 [PRSE0000450], nor do the minutes mention any literature which the members would have considered at or in advance of the meeting.

the haemophilia directors present "*advised that they would not resort to commercial products for this reason.*" Dr Perry also suggested that he "*expected improved heat treatment to do more to abolish transmission of non-A, non-B Hepatitis than screening could, and Dr Ludlam considered that Scottish Factor VIII was already safer than before in this respect*".

461. On 10 February 1987, Dr Forrester wrote to Dr Moir to seek the Chief Scientist Office's ("CSO's") agreement in principle to fund the Scottish component of the study proposed by the Working Party on Transfusion-Associated Hepatitis, estimated at £20,000 [PRSE0002803].[66] He commented that such research had been proposed "*instead of blindly adopting American practice*".

SNBTS calls for surrogate screening in Scotland

462. In March 1987, the SNBTS's call for the introduction of NANB surrogate screening in Scotland became explicit.

463. The minutes of a 3 March 1987 meeting of SNBTS directors, attended by Dr Forrester, record that the Working Party on Transfusion-Associated Hepatitis was considering surrogate screening that and, after the modification of a proposal, no Scottish RTC was being asked to participate in a study related to the issue [PRSE0004163].[67] It was noted that "*some commercial plasma collectors and non-profit blood collectors in the US had begun surrogate testing in 1987 and that in Britain the Haemophilia Society may adopt a position which put pressure on BPL to ensure surrogate testing was introduced*". Following discussion, the directors agreed the following:

[66] Dr Forrester wrote to Dr Lader of the DHSS on this topic on the same date, 10 February 1987, to thank her for a letter and "*constructive comment*" [PRSE0004779].

[67] No note from Dr Forrester about this meeting has been found. The Penrose Final Report recorded the following on his actions following the meeting: "*While Dr Forrester was present at the meeting of the SNBTS Directors on 3 March 1987 at which the recommendation to introduce surrogate testing was made, the Inquiry has been unable to recover a copy of any note he sent his medical or administrative colleagues reporting on the meeting or the recommendation that surrogate testing should be introduced. In his evidence to the Inquiry, Dr Forrester had no recollection of the meeting or recommendation but did not think that he would have been the messenger for transmitting the recommendation to the SHHD and thought, instead, that it would have been transmitted formally, in writing, through a different channel, perhaps via the PES funding bid.*" [PRSE0007002 §27.184].

"To recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres. It was noted that research was being undertaken into a combined core/surface antigen test."

464. Dr McIntyre addressed this development in a minute to Dr Scott and others – including Dr Forrester, Mr Morison and Mr Macniven – on 6 April 1987 [PRSE0000618].[68] He began by summarising the background, which included that in the USA, "*largely one suspects because of the fear of litigation, there has been a great deal of pressure to introduce this indirect screening for 'Non-A, Non-B Hepatitis' and we understand this is likely to happen soon. A similar situation is said to exist in Germany*".

465. Dr McIntyre noted that the SHHD "*was asked last year to meet the expenditure of £810k annually to establish screening of all blood donations*" with the intention of reducing transmission of NANB hepatitis. He explained that approval was not given for this request "*as the research already conducted in the West of Scotland with CSO funding indicated that the impact there of transfusion-associated 'Non-A, Non-B Hepatitis' was not great; also that the indirect screening proposed would be expensive, could not in any event abolish the transmission of this 'Hepatitis' by blood and blood products, and would lead to a loss of a perceptible amount of 'innocent' blood which nevertheless failed to pass the screen. We also wished to await DHSS thinking on this subject.*"

466. Having noted that the Transfusion Associated Hepatitis Working Party proposed further research, Dr McIntyre described the position of the SNBTS directors, and his own view, as follows:

[68] On the same date Dr McIntyre wrote to Dr Forrester on Scottish participation to the UK research project on NANB hepatitis: [MACK0001209_019]

"The Directors of the SNBTS are unanimous, and are now pressing fairly strongly, that this screening should be instituted; though perfectly aware that it would be costly and could not abolish transmission completely, they could then claim to have taken all steps open to them to reduce transmission. Before embarking on such an expensive programme it would seem logical to participate in the proposed research and to delay any further action until the results of this were known."

467. Dr McIntyre suggested that "*the Edinburgh SNBTS*" be asked to prepare a detailed research proposal "*along similar lines to that of their English counterparts*".

468. In a 7 April 1987 response, Dr Scott noted that he agreed in principle with Dr McIntyre's suggested approach and commented: "*We must do whatever we can to prevent the BTS going ahead with a full scale introduction of this testing – or at least trying to blackmail us into the provision of* funds" [PRSE0002916]. He added that the Edinburgh research proposal would have to be scrutinised by the CSO and that he would "*not like to see it fail on the grounds of finance because the stakes are high*". On 9 April 1987, Mr Macniven noted that he and Mr Morison agreed with Dr Scott's comments, adding that it was "*important that the decision on whether or not to screen all blood for Non-A and Non-B Hepatitis, which will not be cheap and may not be certain, should be taken on the basis of the sort of UK research you suggest*" [PRSE0000784].

469. Dr Moir, of the CSO, responded to Dr McIntyre's minute on 23 April 1987 [PRSE0004370]. Having referred to the earlier funding applications, he highlighted the requirements the Edinburgh research proposal would have to meet in order to obtain funding from the CSO, commenting: "*I trust that when Dr McClelland submits his application to the Biomedical Research Committee he will put forward a cogently argued case for the resources he requires as otherwise they may not carry adequate priority over alternative uses of research funds*".

470. On 1 May 1987, Dr Forrester provided Mr Macniven with a copy of a letter from Dr Contreras and others of the North London RTC, which had been published in the Lancet on 18 April 1987 [SCGV0000163_171]. The letter argued against the introduction of NANB surrogate screening without further UK research. Dr Forrester

described it as reinforcing "*the arguments I have presented from the start against screening – at least until suitable research provides a genuine case*".

471. In a 14 May 1987 minute to Dr McIntyre, copied to Dr Scott and Mr Macniven, Dr Forrester commented that "*we are under pressure to spend some £800k annually on screening all blood donations in an indirect way*" [PRSE0001191]. He explained that the Scottish component of the research project on NANB hepatitis, which was to be directed by Dr Gillon of the Edinburgh BTS, had been abandoned. He suggested that the Edinburgh director, Dr McClelland, was unlikely to press this, "*since his current view is that we had better simply institute screening. I understand that he will inform Dr Gunson, so that English BTS will know*".

472. This suggestion appears to have concerned Dr Scott, who commented as follows: "*I take it that Dr McClelland will NOT introduce screening before the results of the research is known. It is not quite clear what is intentions are, from Dr Forrester's minute, of 14 May*" [PRSE0002731]. Dr Forrester responded to this on 18 May 1987, highlighting the agreement recorded in the minutes of the 3 March 1987 SNBTS directors' meeting[69], and commenting that "*this resolution was approved with Dr McClelland's agreement, in my presence and to my astonishment, although I had heard him say on other occasions that he viewed the institution of screening as inevitable*" [PRSE0001663].

Scottish involvement in study and SHHD position

473. There appears to have been a lack of clarity around this time regarding Scotland's involvement in the UK NANB hepatitis study. At the 10 June 1987 SNBTS directors' meeting, attended by Dr Forrester, it was "*confirmed that the minute of the previous meeting was incorrect and that the Edinburgh Centre*" was contributing to the UK study [PRSE0000633]. It was noted that Dr McClelland would probably apply to the CSO for a research grant. The minutes also record, in relation to NANB surrogate testing, that "*Directors noted the need for synchrony with England and Wales*".

[69] I.e. That the directors agreed to recommend to the SHHD that surrogate testing should be implemented from 1 April 1988.

474. Uncertainty around Scottish involvement in this study was reflected in a 15 June 1987 minute from Dr McIntyre to Dr Moir, copied to Mr Macniven and Mr Murray [SCGV0000163_167]. Dr McIntyre noted that there seemed to be "*some confusion about this matter. It is alleged that Dr Gunson is concerned that the Scottish component of the proposed research programme is not proceeding*". He enclosed a draft letter to Professor Cash seeking clarification on whether funding for Scottish involvement would be sought from the CSO.

475. The following month, Professor Cash and Dr McClelland made their position on the introduction of surrogate screening clear. On 4 July 1987, the Lancet published a letter they (and others) had authored, suggesting that the time for further study had passed and that the introduction of surrogate testing for NANB hepatitis was "*now virtually inescapable*" [PRSE0001444]. The letter stated that "*the decision which has to be made is when rather than whether the UK transfusion services follow the lead of the United States and other European Countries in donor screening.*"

476. This letter was described in a 21 July 1987 minute from Dr McIntyre to Mr Macniven and others, which suggested that the SNBTS might "*institute testing without further discussions as a fait accompli*" [PRSE0004562]. Dr McIntyre noted that the "*[i]n theory SNBTS would not be able to start without the necessary funds but in practice they may be able to start albeit in a limited fashion but nonetheless setting a preceding*". While Professor Cash had assured Dr Fraser (of Bristol Transfusion Centre) that he would not institute testing "*unilaterally*", "*we have however no assurance that he will not do so in the near future without specific funding and without necessarily reporting what he has done to CSA or SHHD.*" Dr McIntyre described the letter to the Lancet as having caused "*concern and dismay*" at the DHSS, which had "*interpreted this as being SHHD policy*". While the SHHD "*attempted to reassure them that it is not so*", the DHSS's concern was that if Scotland "*should commence testing unilaterally they will obliged to follow.*" The minute ended by noting that Professor Cash and his colleagues had withdrawn from the opportunity to engage in a research programme as they felt that the time for the study had passed.

477. Notwithstanding the fears expressed by the DHSS and SHHD, the SNBTS did not introduce NANB hepatitis surrogate screening without the SHHD's agreement. On 6 August 1987, Dr McClelland applied to the CSO Biomedical Research Committee for funding for the "*Scottish leg of a four-centre study*" on surrogate screening [PRSE0001233]. Dr Forrester commented on this application in a 20 August 1987 letter to Dr Lader at the DHSS, seeking information about the likely timing of the DHSS decision [PRSE0002147].

478. Dr Forrester addressed the application further in a 20 August 1987 minute to Dr Forbes of the CSO, in which he commented that the benefits of surrogate screening were "*not clearly established*", and that the "*drawbacks (beside substantial expense) include perceptible loss of "innocent" blood, and distress among donors erroneously identified as virus carriers*" [PRSE0000607]. Having set out the reasons why the SHHD did not consider Dr Dow's earlier work "*to be a sufficient guide*", Dr Forrester signalled that he or Dr McIntyre wished to attend the Committee meeting which decided the application.

479. Dr Forrester later reported, in a 1 October 1987 minute to Mr Macniven, that the CSO Committee had rejected Dr McClelland's application [PRSE0004545]. He noted that he was present when the application had been decided and agreed that the grounds for rejecting it were "*substantial*". He also described various requests he had made of Dr Forbes, who was copied into the minute, in communicating the rejection. These included ensuring that the minutes of the meeting which decided the application "*confirm that the reason for rejection is not that research is superfluous (which is what SNBTS claims is the practical proposition)*", and deferring an announcement of the decision until the CSO had co-ordinated its actions with the DHSS. Dr Forrester envisaged that the DHSS might wish to take over the research proposal by adding a fourth English centre to the study. His preference was to wait until these steps had been taken before reaching a decision on the SNBTS's request for money for screening. He also added a summary of the SHHD's position, which included that the gathering of the evidence necessary to decide whether to introduce surrogate screening, "*at least in Scotland, is obstructed by the inadequacies of the research proposal*".

480. Mr Macniven responded to Dr Forrester the following day, mostly agreeing with him but expressing concern about the anticipated timescale [PRSE0003515]. He commented that he was "*very anxious indeed for our decision (on whether or not to put resources into NANB testing) should be properly informed by research evidence*". He highlighted the "*substantial patient safety/expenditure issues which are at stake*" and asked whether the provision of feedback to the SNBTS on the CSO application could be expedited. Mr Macniven also provided the following more general comment on the SHHD's approach:

> *"If* [the research] *evidence justifies testing, then it is very important that we should be able to find the money to start it quickly. If it does not justify testing, it is equally important that we should not have allocated money to the SNBTS for the purpose, thereby sterilising it for other uses. But I think the worst of all possible worlds is that research cannot get off the ground: I fear that, in those circumstances, we would be subjected to increasingly irresistible pressure to spend the money in any case, for the sake of improving (at any price) the safety of blood and blood products."*

481. In a 7 October 1987 minute to Mr Macniven, Dr Forrester referred to an article on NANB surrogate screening by Dr Perry and others in the PFC and SNBTS, which he described as concluding that "*[m]ore information is needed before expensive surrogate testing can be justified for donations included in pools used for manufacturing plasma products*." [PRSE0003307].

482. According to a later minute by Dr Moir, Drs Gillon and McClelland were informed by letter dated 19 November 1987 that the CSO Biomedical Research Committee had rejected their application [PRSE0002392].

483. The question of NANB surrogate screening was revisited in a 17 December 1987 minute from Dr Forrester to Mr Macniven [PRSE0001159]. Dr Forrester reported that a commercial producer of blood products was "*being allowed by DHSS*" to market its product with a statement that it was derived from donations which had been ALT tested. He noted that the SNBTS had not been provided with funds to introduce NANB surrogate screening and that, as far as he knew, no research was "*being mounted in*

Scotland or England into the cost and value of the screening". Dr Forrester suggested that the *"recipients of SNBTS unscreened blood have no choice: they cannot get other blood. But the recipients of blood products do have a choice*", namely unscreened SNBTS products or products from "*partially screened donations: partially, because ALT screening is only one of the two tests proposed together to reduce transmission of non-A, non-B hepatitis*".

484. He commented that it was "*credible that the commercial products, derived from the donations of paid donors, are safer because of ALT testing than they would otherwise be. But it is not clear that a sensible clinician would prefer them to SNBTS products*." Dr Forrester suggested that it was likely that haemophilia clinicians were likely to press the SHHD to introduce surrogate testing, and that the SNBTS was "*sure to resume similar pressure*".

1988: NANB screening considered further

485. Little progress in decision-making on the introduction of NANB surrogate screening appears to have been made in 1988.

486. The minutes of the SNBTS directors' meeting of 12 April 1988, attended by Dr Forrester, suggest that directors were undertaking research on ALT testing and leaving open the possibility of introducing NANB surrogate screening in the future [PRSE0003650]. It "*was confirmed that it had been agreed not to introduce ALT testing in Scotland until it had become UK policy, but Directors wished to reserve their position on this matter in the light of reports of the commencement of ALT testing in at least one E/W RTC.*" The minutes also record Professor Cash's recommendation that the SNBTS "*should continue its current research"* and directors' agreement that the matter should be discussed again at a Co-ordinating Group meeting.

487. The multi-centre study proposed in 1987 received DHSS funding almost a year after it was initially envisaged. In a 14 April 1988 minute, copied to Dr Moir, Dr Forrester noted that the SHHD CSO had declined to fund the Scottish limb of the study, as its assessors "*evidently felt that the case at that time for introducing screening did not stand up to scrutiny, and that on the face of it, screening would offer a negligible*

contribution to health in Scotland, and be costly as well" [PRSE0004467]. However, DHSS research funds had "*very recently become available*". The SHHD could therefore "*expect, on the conclusion of this one-year project, English data on the cost and benefits of screening.*" This data would, "*in an ideal world*", enable the SHHD to "*make a rational decision on whether to introduce screening*". However, "*in the real world, our hand may be forced, especially because England is accustomed to buy a lot of commercial blood product.*" If BPL blood products were not "*cleared*" for ALT, they might be rejected by users and prove "*unmarketable*". Dr Forrester suggested that the pressure would be greater because the nature of the test would be "*incomprehensible*" to "*any outsider*", and the picture would be "*of a recalcitrant authority refusing to keep the national blood supply properly pure*".

488. On the question of whether the Scottish component of the study could be revived, Dr Forrester considered the obstacles "*insurmountable*", because even if funding were to be found and the original four-centre basis for the study restored, the "*Scottish researchers*" would not, in Dr Forrester's view, set their minds to their task, "*when they know well enough that political and commercial considerations may settle the issue, rather than scientific and sensible arguments.*" He commented that, "*[t]hus far, England have been afraid of a unilateral step by SNBTS. From now on the tables are turned*". Dr Forrester concluded that the SHHD would have to "*watch what England do*", which could mean being "*left behind*", "*but in this particular context, there may not be drawbacks*". In his written evidence to Penrose, Dr Forrester explained that what he meant by this was that "*[r]esearch done by England into the merits of testing could (with some hesitation) be assumed valid also for Scotland*" [PRSE0000269].

489. Dr Moir responded to Dr Forrester's minute on 15 April 1988 [PRSE0002392]. He wrote that Dr Forrester was wrong to suggest that the DHSS research division had released funds for the English component of the study, as it had "*reservations on whether this study could achieve its stated objectives*". Instead, the relevant DHSS policy division appeared to have "*taken the view that such considerations required to be set aside since the study would at least provide some limited information about the prevalence of some aspects of the study*".

490. Dr Moir described a telephone conversation with Dr Metters of the DHSS, who had told him that "*his DHSS colleagues with policy interests feel particularly vulnerable since they are aware that there is some Scottish data on the prevalence of this problem as a result of the study CSO funded a few years ago whereas there is no comparable data relating to England and Wales*". Dr Metters was also described as feeling "*that a substantial part of his policy colleagues' interests in funding this "research" study was that it would allow them to "play for time" in the hope that instead of ALT a more suitable screening assay could be found which would act as a marker for Non-A Non-B Hepatitis*".

491. NANB surrogate screening was revisited at the 5 May 1988 meeting of SNBTS and haemophilia directors [SBTS0000832]. Dr Forrester, who chaired the meeting, reported that "*a research project was being mounted in England and that a decision whether to introduce screening would probably wait upon its outcome*". The minutes record that Professor Cash and Dr McClelland "*considered the delay unjustifiable*". It was noted that haemophilia directors "*had not identified any case of non-A non-B hepatitis transmitted by heat-treated PFC products for haemophiliacs*".

492. From late 1988, and as explored below, the question of whether to introduce NANB surrogate screening in Scotland became interlinked with, and was eventually overtaken by, developments related to the discovery of the hepatitis C virus.

Risk of NANB hepatitis in heat-treated factor VIII

493. Around this time, the SHHD was also informed of the possibility that certain heat-treated factor concentrates might transmit NANB hepatitis. On 26 August 1988, Hamish Hamill, SHHD Under Secretary, asked the CMO, Dr Macdonald, for his views about "*a Departmental line*" on the risk of transmission of NANB hepatitis by factor VIII manufactured by Alpha Therapeutic UK [PRSE0001935], a concern raised by Mr Donald (General Manager of the CSA) in a 24 August 1988 letter [PRSE0003250].

494. Mr Hamill's request appears to have been passed down from Dr Macdonald to Dr Forrester. Manuscript comments in the margin of Mr Donald's letter, which seem to

have been made by Dr Forrester, suggested that there was "*no evidence*" that the Alpha factor VIII product transmitted NANB hepatitis [PRSE0003250].

495. Dr Forrester subsequently sent a minute to Dr Macdonald on 30 August 1988 with his views on the subject [PRSE0003962]. He made three comments on Mr Donald's concerns about the risk of transmission of NANB hepatitis by the Alpha factor VIII. First, he noted that the Alpha product was licensed while PFC factor VIII was not. Second, the Haemophilia Society viewed "*the Alpha product as third choice*" and believed "*that the PFC product is safer, but point out that the evidence is not available*". Thirdly, Dr Forrester referred to a study published in the Lancet on 23 July 1988, reporting that no NANB hepatitis had been found in recipients of a factor VIII preparation "*made without any heat treatment, but by a process "closely akin to Alpha's*." Dr Forrester added that "*the risk* [of transmission] *is certainly not clearly established*" and ended by commenting: "*we cannot prudently make much of the point but this particular hepatitis is so benign, at least in the short term, that evidence of transmission has to be specially sought, the patient not being ill at all in the ordinary sense*."

Hepatitis C screening

496. This section addresses SHHD decision-making on the question of whether, and when, to introduce screening of blood donations for hepatitis C.

May 1988: the Chiron discovery

497. On 13 May 1988, it was announced in an article in the American Association of Blood Banks magazine "Blood Bank Week" that researchers from the company Chiron had discovered the NANB hepatitis virus (later referred to as hepatitis C), and that Chiron would be submitting an ELISA screening test for FDA approval [PRSE0003126]. The test kit would be marketed by Ortho Diagnostics Systems.

498. The SHHD was made aware of this development through Dr Forrester and Mr Macdonald's[70] attendance at the SNBTS directors' meeting of 14 June 1988, when it was mentioned [PRSE0003031]. The minutes of the meeting record that Professor Cash would contact Ortho Diagnostics to enquire about the availability of the test in the UK. On 5 July 1988 he wrote to both Chiron in the USA and Ortho Diagnostics in England to enquire about the test kit [PRSE0000670 and PRSE0002363]. The reply came on 19 July 1988: Ortho would market the Chiron kit but it was not known when it would be available, with the end of 1989 a possibility [PRSE0002112].[71] The SHHD does not appear to have been involved in these early attempts to obtain the Chiron test kits.

The ACVSB and ACTTD

499. Evidence relating to the role of and relationship between different advisory committees is an important part of understanding the introduction of hepatitis C screening in Scotland and the rest of the UK: in particular, the Advisory Committee on the Virological Safety of Blood ("ACVSB") and the Advisory Committee on Transfusion Transmitted Diseases ("ACTTD"). The detail of these committees' creation, their discussions and their inter-relationship is beyond the scope of this presentation note. Instead, reference is made to them insofar as necessary to understand the development of SHHD decision-making on hepatitis C screening.

500. The SHHD and DoH corresponded about the creation of the ACVSB in late 1988. Having been provided with a copy of a draft submission to DoH ministers on the subject in October 1988 [PRSE0000216], Mr Macniven confirmed the following month that he was content that the Committee should operate on a UK basis and report to the CMOs of all four health departments [PRSE0002344]. Correspondence also took place at ministerial level. In a 13 January 1989 letter, the Parliamentary Under-Secretary of State for Health at the DoH, Roger Freeman, sought Mr Forsyth's agreement to the setting up of the ACVSB, described as a "*new advisory committee to provide advice to the Chief Medical Officers on the virological safety of blood*" [PRSE0004664]. Mr Freeman commented that it seemed "*timely that the Blood Transfusion Services and all*

[70] Mr Macdonald was an administrative official. Dr Macdonald was, at this time, CMO.
[71] In another letter on 8 August 1988 [SBTS0000435_005] Ortho Diagnostics indicated that they would contact Professor Cash when they had sufficient material to develop and market the test.

other interested parties should act in unison on this important matter". Mr Forsyth provided his agreement on 8 February 1989 [PRSE0000967]. Dr McIntyre subsequently attended the first ACVSB meeting on 4 April 1989 as an SHHD observer [NHBT0000041_003].

501. Around the same time, the SNBTS and NBTS were also considering the formation of a group to advise the health departments. At the 13 December 1988 meeting of SNBTS directors, attended by Dr Gunson and Dr Wagstaff for the NBTS, and Dr Skinner[72] and Mr Panton for the SHHD, it was agreed in the context of microbiological testing that the "*UK Blood Transfusion services should establish a group to advise the Departments of Health on policies*" [PRSE0001626].

502. In a 9 January 1989 letter to Dr Pickles at the DoH regarding the ACVSB, Dr McIntyre expressed concern regarding the proposed creation of this new group [SCGV0000210_141]:

> *"... we felt there was a measure of urgency about setting up this Advisory Committee. I now enclose, IN CONFIDENCE, an extract from an unconfirmed draft minute of a meeting of the Directors of the Scottish National Blood Transfusion Service held in Edinburgh on 13 December 1988 at which Dr H Gunson and Dr W Wagstaff were present. This extract, you will note, suggests that the UK blood transfusion services should establish a group to advise the Departments of Health on policies relating to microbiological testing. This method of approaching the problem we consider to be unsatisfactory and we suspect that the decisions reached might be influenced to a considerable extent by the views of the Transfusion Directors. As this is a matter which has policy implications and will be of considerable interest to Ministers we feel that this Advisory Committee should be set up jointly by the Departments. In Scotland we are under considerable pressure from the SNBTS to fund the introduction of additional virological testing and as this is a matter which we feel should be addressed on a UK basis, I should be grateful if you could let me know what steps your Department intends to take in this matter as we would not like to be*

[72] Dr Forrester had retired from the SHHD by the time of this meeting.

forced into a course of action which might have repercussions for the UK as a whole."

503. Nonetheless, the ACTTD was established and met for the first time on 24 February 1989 in Manchester, with Professor Cash, Dr Mitchell and Dr Follet attending [NHBT0000043_002]. The SHHD and DoH did not take part in its meetings.

UK-wide approach and early consideration of tests

504. As well as the proposed creation of a new advisory committee, the 13 December 1988 SNBTS directors' meeting included discussion of both the Chiron test and NANB surrogate screening [PRSE0001626]. It was noted that the DoH intended to carry out a study of ALT and anti-HBc testing, and that Chiron "*had agreed to test one thousand randomly selected samples from the NBTS study*". Professor Cash is said to have "*confirmed that Scottish Directors would not commence surrogate testing until the Department of Health and SHHD supported and funded the project.*"

505. At the 14 May 1989 ACTTD meeting, an update was given on hepatitis C testing of samples from the NANB surrogate screening trial in England and Wales, and Professor Cash reported that the SNBTS would be interested in taking part in evaluative trials of the Chiron test [NHBT0000088_001]. The ACVSB agreed at its second meeting on 22 May 1989, attended by Dr McIntyre as an observer, that "*NANB testing should not be introduced into the NBTS prior to the results of the UKBTS NANB trial*" [NHBT0005019]. Testing would be kept under review, and the "*use of Chiron or surrogate testing would be influenced by Chiron data once released*". NANB surrogate screening and the Chiron test were discussed further at the ACVSB's third meeting on 3 July 1989, attended by Dr McIntyre [NHBT0000072_025]. An update was given on the NBTS's ALT and anti-HBc study, and an initial report was given on the Chiron test in recipients of BPL 8Y.

506. In a letter to Dr McIntyre on 28 July 1989, Professor Cash described a telephone conversation the previous week in which Dr McIntyre was said to have "*indicated that the decision to commence routine donation testing, using the Ortho (Chiron) test, throughout the SNBTS, would be made by SHHD, and that it would not be appropriate*

at this time for senior SNBTS managers to liaise with Ortho Ltd with respect to arranging supplies of tests for routine donation testing. Such discussions should not take place until instructions are received from SHHD" [PRSE0002499].

507. Dr McIntyre replied on 2 August 1989 [NHBT0000061_034]. The letter began by highlighting the role of the ACVSB in "*considering the sensitivity and specificity of the tests available for a variety of infective agents*". Dr McIntyre added: "*If it is considered desirable to introduce a further routine screening test for blood donors I understand that this will be done simultaneously throughout the UK – as was done in the case of the current HIV test.*"

508. Professor Cash conveyed this position to his SNBTS colleagues in a letter on 3 August 1989, in which he wrote that *"[t]he decision to commence testing will be a UK one and will be made by the UK Departments of Health*" [NHBT0000188_014]. He added that the "*start date for commencing full testing*" would, as with HIV/HTLV-III, "*also be a matter for central government decision, with, of course, appropriate consultation with the UK BTS Directors*".

509. Similarly, in a letter to Dr Gunson on 28 July 1989, Professor Cash wrote: "*We will not move unilaterally unless instructed to do so by SHHD. Thus close collaboration seems certain.... I have taken a very hard line with Ortho. I have indicated that we are unable to discuss contracts for supply etc until instructed to do so by our Department of Health*" [NHBT0000188_011]. In a letter to Dr McIntyre on 4 August 1989, Professor Cash wrote that he had met Mr Savage of Ortho and advised him that the decision to introduce Chiron testing[73] would be made "*on a UK basis*", and that he had declined to discuss start dates [NHBT0000188_016]. Professor Cash also suggested a timetable for the test to be introduced in the UK which, subject to certain steps taking place, envisaged that full testing would commence on 1 June 1990[74] with "*significant funding*" made available from 1 April 1990 "*for a two month run-up period*".

[73] At this time, the test was generally referred to in correspondence as a NANB or Chiron test, though it soon became known as a test to detect hepatitis C.
[74] The letter states 1 June 1989 but this must be a typographical error, given the date of the letter and the dates referred to by Professor Cash.

510. One of Professor Cash's concerns around this time related to the availability of confirmatory tests from Ortho/Chiron. This was reflected in a letter published in the Lancet on 26 August 1989, signed by Professor Cash, Dr McClelland and others, which stated that the absence of a confirmatory test would "*cause serious problems for blood transfusion services*" and called on Ortho to make available appropriate reagents and/tests which could be used for confirmation testing "*as a matter of urgency*" [NHBT0083819].

Informing SHHD Ministers and further consideration by committees

511. Hepatitis C screening was addressed in a 23 August 1989 minute from Mr Tucker (SHHD Assistant Secretary and Mr Macniven's successor) to Mr Forsyth [PRSE0000558]. The minute was prompted by a recent article in the Guardian concerning the Chiron/Ortho test.[75] Mr Tucker wrote that other countries were also considering the Ortho test, but the SHHD understood that it was "*not in routine use in any country*" and did not have a product licence in the USA. He reported that a pilot study had been carried out on volunteer donors in Scotland and England, who had agreed to have their blood screened for NANB hepatitis and whose blood was also tested using the Ortho kit for hepatitis C. Of these, 0.5% to 1% of donors were positive. Mr Tucker wrote that "*[o]nly a minority of those infected with HPC display any symptoms either in the short or long term*" and commented that the Guardian article was "*unnecessarily alarmist*" in suggesting that 6,000 people may have received blood infected with hepatitis C in the previous year.

512. Mr Tucker also recorded that the ACVSB would be discussing the test in October 1989, that its accuracy had "*not yet been fully established*" and that it was "*felt to be essential to have confirmatory assays to eliminate the possibility of cross-reactivity with other antigens before policies for generalised screening of blood donations are implemented*". He added that the cost to the SNBTS of introducing this test in routine screening was estimated to be "*in excess of £600k per annum*". The "*line to take*" proposed in the minute included that the Ortho test was under review and that the UK health departments would examine the available data before introducing

[75] The article is available at [NHBT0000014_060].

generalised testing. It also included that "*UK blood is still considered one of the safest in the world*" and that "*the prevalence of HPC in the population in this country has not been established, nor has the role of blood in its transmission*". The minute ended by stating that the testing of blood for hepatitis C was "*a UK issue and D of H will be taking the lead but SHHD and SNBTS will represented* [sic] *in any meeting and the Minister will be consulted before any decisions are taken*."

Consideration by ACVSB and ACTTD

513. Meanwhile, the ACVSB and ACTTD continued to consider hepatitis C screening. This included the ACVSB requesting a paper from the ACTTD on the "*policy regarding Anti-HCV testing of blood donors*", with the request discussed by the ACTTD at its 9 October 1989 meeting [NHBT0000043_034].

514. An ACTTD paper subsequently appears to have been discussed at the 6 November 1989 ACVSB meeting, attended by Dr McIntyre, with the meeting considering hepatitis C screening in detail [PRSE0001071]. Dr Metters explained that the DoH had to "*bear in mind the possible litigation that could arise from a prolonged delay in the introduction of general screening*", while stating that "*more facts and figures*" were needed before screening could be supported. The discussion also explored the proportion of patients who developed chronic hepatitis.

515. The minutes record that the "*feeling of the Committee... was that the* [Chiron] *test represented a major step forward, but that that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of FDA decision, it could prove difficult if the FDA do not decide in favour of the test*". The ACVBS also felt that "*there was no case for using surrogate tests for NANB.*" However, it "*would support the general introduction of the Chiron test*" if the FDA approved it and a proposed pilot study in English RTCs showed that it was "*feasible and non-problematic*".

516. The minutes of the ACTTD meeting on 22 November 1989 record "*the ACVSB had agreed to most of the points put forward in the Committee's paper on anti-HCV testing*", that it was "*agreed that the anti-HCV test was a major step forward in*

identifying those who could potentially transmit HCV", and that it "*had noted the need for a confirmatory test either before or shortly after any routine testing of donations.*" [NHBT0000043_039]. It was also agreed that "*routine screening should not commence until the FDA had granted a licence which may be June/July, 1990*", and that a cost benefit appraisal should be conducted and discussed with the DoH.

517. At its meeting on 17 January 1990, attended by Dr McIntyre, the ACVSB considered whether the time had "*now come for the introduction of routine Hep C testing*" [PRSE0001477]. The "*general consensus of the Committee*", as summed up by the Chair, included that "*routine testing should not be introduced in advance of the FDA decision*" on whether to license the test and that "*scientifically, not enough is known yet, but there is agreement that the test does detect some people who transmit*". It was agreed that the ACVSB would discuss the matter further at its next meeting and that, "*in view of the media interest, a submission to Ministers should set out the present position and the Committee's views*".

518. While hepatitis C testing does not appear to have been directly addressed in a submission to Scottish Ministers until July 1991, Mr Tucker made reference to it in a 1 February 1990 minute to Mr Forsyth's Private Secretary concerning the Macfarlane Trust [SCGV0000230_145]:

> *"All budgets are likely to be very tight next year and the Common Services Agency Budget in particular is likely to come under severe pressure from a number of sources which were not foreseen at the time of framing bids for PES. (Eg. The prospect of a two year settlement for pay of ambulance staff and the introduction of routine blood testing for Hepatitis C which is expected to become unavoidable following expert advice that such testing should be introduced in order to prevent the risk of future claims against the Government similar to those now pending in respect of haemophiliacs with HIV.)"*

ALT screening by BPL

519. In early 1990, concern emerged in the SNBTS and SHHD at a suggestion that the NBTS would introduce ALT testing of plasmapheresis donations. This proposal

related to the development of an immunoglobulin product rather than factor concentrates. However, documents relating to the issue provide further insights into the relationship between the SHHD and DoH in a similar context, as well referring more broadly to NANB surrogate screening of donations and hepatitis C screening.

520. In January 1990, Professor Cash wrote to Dr Gunson about this issue, having heard from Dr Contreras that the NBTS was introducing routine ALT donation testing on plasmapheresis donations on 1 April 1990 [NHBT0000027_011]. He referred to the assurance the SNBTS had given that "*Scotland would not introduce any form of routine surrogate NANB donation testing, unless it was a joint UK exercise and one which, like HIV-1 donation testing, had Ministerial approval*". He expressed his concern that it appeared that the NBTS and SNBTS would "*go their separate ways in regard to quality assurance*", having believed that there would be more coming together in light "*all the emerging litigation associated with blood and blood products, particularly against the background of the new product liability laws*".

521. A manuscript note on another copy of this letter suggests that it was passed to Mr Tucker [DHSC0002541_086]. Professor Cash also followed it up with a letter to Mr McIntosh, the new General Manager of the SNBTS, on 22 January 1990, referring to the "*possible necessity for the SNBTS to introduce ALT testing of all plasmapheresis donations after 1st April 1990*" [RCPE0000331_018].

522. Dr McIntyre wrote to Dr Pickles about this issue on 5 February 1990, expressing concern that BPL appeared to be introducing a policy which went against the recommendation of the ACVSB that routine ALT screening of blood donations should not be introduced, and for which "*the science*" was in his view not "*very convincing*" [NHBT0000061_102]. He expressed his concern at the "*adoption of different 'safety' standards by the two NHS/Government fractionation centres and that these are being adopted in a manner which seems not to accord with the guidance of the ACVSB*". Dr Pickles answered on 7 February 1990, stating that the decision "*about ALT testing of material to be processed into iv gamma relates more to regulatory red-tape than to science*" but that it was necessary for a reason related to BPL product licensing [NHBT0000014_091].

523. Mr McIntosh wrote to Dr McIntyre on 12 March 1990 to ask for confirmation that "*neither we nor the English will be introducing ALT testing for the time being*" and that "*as a matter of policy, we should not have any plans to introduce ALT testing at this time*" [PRSE0000855]. He also noted that "*we all anticipate the need to start new testing procedures – probably including ALT testing – in conjunction with another/other test(s)*".

524. Dr McIntyre subsequently wrote again to Dr Pickles, on 11 April 1990, to ask whether ALT testing was "*likely to become the practice, and perhaps even the formal policy*" for all blood donations in England [NHBT0000061_123]. He suggested that BPL's practice for the immunoglobulin product would lead that a requirement that all donations be ALT tested, and that it seemed possible that in England, routine ALT testing could be introduced for all blood donations "*via the backdoor*". He added: "*If we were not to follow then we might lay ourselves open to claims for damages if a person receiving non ALT tested blood developed Non A, Non B Hepatitis. Our concern is not for the fractionated products which we consider safe but for the cellular component*".

525. Dr Pickles' reply included the following [PRSE0004330]:

> *"There is no question of backdoor routine ALT testing being introduced this way. As we have agreed, any such decision, as with hep C testing would be a UK decision on the advice of the ACVSB, on which SHHD is represented. These arrangements were established to ensure we do not find ourselves in the situation you describe with policy in one part of the UK being used in the Courts against the policy in another area."*

Developments in the ACVSB and elsewhere

526. On 24 April 1990 the ACVSB met again, with Dr McIntyre present as an observer [NHBT0000072_098]. Following a discussion of recent scientific developments, it was noted that France, Belgium and Luxembourg had introduced routine screening of blood for hepatitis C antibody, and that Italy had introduced the

test on a voluntary basis. However, the introduction of screening in the UK was not yet recommended.

527. The Chair's summary of the discussion included: "*there was insufficient scientific data to support the introduction of the Ortho test for routine screening*"; "*a confirmatory test was needed which could be used in the RTCs and not just specialised laboratories*"; "*the FDA had not yet approved the test*" and it would be reassuring if it did so; and that a prospective study involving 25-50,000 donors would generate sufficient positives for confirmatory testing. It was agreed that a sub-group would prepare a protocol for a pilot testing study, and that a note for ministers would be prepared to inform them of the outcome of the discussion. Given the absence of any minute to SHHD ministers on hepatitis C around this time, it would seem that this was a reference to DoH ministers.

528. On 23 May 1990 Dr Young (DCMO at the SHHD) wrote to Dr McIntyre and Mr Tucker to ask them to brief him on hepatitis C testing so that he could provide a position paper on the subject in advance of a meeting with the CSA management committee in June [PRSE0000982].

529. In a 6 June 1990 response, Dr McIntyre wrote that "*[t]hings are moving very fast on the Hepatitis C front.*" [PRSE0003099]. He informed Dr Young that the FDA had approved the hepatitis C antibody test and as a result the next ACVSB meeting had been brought forward to 2 July, which Dr McIntyre would attend. He wrote that he was "*in little doubt that for a variety of reasons, many of them non scientific*", the introduction of testing would be recommended.

530. He also explained his understanding that it was "*likely that 1 in 250 blood donors will be found to have Hepatitis C antibodies in their blood but that only a fraction of these will be infectious; also that for most of them it will be of no clinical significance*". Dr McIntyre further referred to the possibility of litigation, describing "*one of the problems*" in the HIV haemophilia litigation as being "*whether or not the HIV testing was introduced as early as possible.*" He commented that "*[a]lthough Hepatitis C is not such a fatal condition as HIV infection litigation would be possible if a patient was subsequently to determine that he had been transfused with Hepatitis C*

positive blood – or blood which had not been tested for Hepatitis C antibodies". He suggested that the SHHD "*delay further action until the meeting on 2 July*".

531. A manuscript note on Dr Mcintyre's minute of 6 June 1990, which would appear to be from Mr Panton (of the NHS Management Executive), asked Mr Hogg to "*continue to push for funds*" for the hepatitis C screening study and indicated that he would speak to Mr McDonald about the "*first dip*" into the contingency fund in advance of the ACVSB decision on hepatitis C screening [PRSE0003099].

532. On 18 June 1990, Mr Panton wrote to Mr Hancock (of the Scottish Office finance department) to ask him to consider a bid for an estimated £100,000 required to fund pilot hepatitis C testing in Scotland [PRSE0000744].

533. The reply from Mr Hancock came on 2 July 1990, in which he wrote that since "*around £1.2m*" had been estimated for full hepatitis C screening in the 1990-1991 PES allocations, and "*the programme is not yet up and running*", the cost of the pilot study could "*be accommodated within the provision available.*" [PRSE0000407]. A 3 July 1990 manuscript note, which appears to be from Mr Hogg and to be addressed to Mr Panton, asked: "*Do we now draft a letter to the CSA/SNBTS telling them to fund from the reserve? Is the pilot to proceed?*". A 9 July reply on the same document, which appears to be from Mr Panton, reads: "*1. Any news on testing start dates. 2. Draft to SNBTS saying no funds (sorry).*"

534. At a CSA management committee meeting on 20 June 1990, it was noted that "*[i]t was likely that up to 100,000 tests per annum would be needed at a cost of £1.3 million. Should testing be started during the current financial year, funding would have to come from the contingency fund*" because there would be no additional finance available from SHHD [PRSE0001592].

Deciding a start date for testing

535. The next ACVSB meeting took place on 2 July 1990 and was attended by Dr McIntyre [PRSE0000976]. It agreed to recommend hepatitis C screening to ministers after a pilot study to determine whether the Ortho or the Abbott test was most suitable

for use in RTCs. The estimated timescale for this study was around four months. The ACVSB also agreed that both plasma and whole blood should be tested for hepatitis C.

536. The results of the pilot study were presented at the ACVSB's 21 November 1990, attended by Dr McIntyre [NHBT0000073_018]. The minutes record that "*[t]he Committee agreed that it was important to start screening as soon as practicable as a measure which would enhance the safety of the blood supply*". There was also agreement that RTCs would decide individually whether to use the Ortho or Abbott test and on how to approach confirmatory tests. In what would again appear to be a reference to DoH ministers, the minutes record that a "*submission would go to Ministers regarding this significant policy decision and the Management Executive would consider the funding aspect*".

537. Dr McIntyre prepared a note of this meeting, which he provided to Mr Tucker (copied to the CMO, Mr Panton and Dr Skinner) on 26 November 1990 [PRSE0001481 and PRSE0000206]. This recorded that the Chairman had suggested 1 April 1991 as a start date for testing, while "*[s]ome wanted to start forthwith.*" [PRSE0000206]. Dr McIntyre noted that the Chair and Mr Canavan of the DoH had agreed to send a copy of the draft DoH submisision to Scotland, Wales and Northern Ireland within the next few days. Dr McIntyre thought it seemed unlikely that the test would be introduced in that financial year, but suggested the SHHD should await the DoH's draft submission.

538. On 27 November 1990 Professor Cash wrote to SNBTS directors to ask "*when would be the earliest date you could start routine screening and have your counselling team in place.*" [PRSE0003619]. He explained that this was part of "*an information gathering exercise designed to obtain a UK consensus for a future simultaneous start date*".

539. It appears that Mr Canavan may have sent a draft version of the DoH submission to Mr Panton on 27 November 1990 [DHSC0002498_072]. A manuscript note on the cover sheet suggests that it enclosed a draft which had been prepared before the recent ACVSB meeting and would need to be revised in light of it.

540. The submission to DoH ministers, drafted by Mr Canavan and copied to Mr Panton, was dated 21 December 1990 [PRSE0004667]. It recommended the introduction of hepatitis C screening and noted that the "*other UK Health Ministers are also being asked to approve the introduction of screening in their transfusion services*". Under the heading "*Timing of Introduction*" the submission stated that, "*[i]n view of the operational matters that need to be discussed finalised, it is unlikely that routine screening could be introduced before 1 April 1991.*"

1991: changing start date

541. On 21 January 1991 Mr Tucker wrote to Mr Panton, copying Dr McIntyre, to inform him that the "*Department of Health Ministers have given their approval to the submission on Hepatitis C testing.*" [PRSE0002817]. He noted that Mr Canavan, who had relayed this information, did "*not yet know what date for the introduction will be chosen since some laboratories will require new equipment. He is to convene a meeting with RTCs to ascertain what would be practical.*" Mr Canavan was said to agree "*that there should be a common start date for the whole of the UK*", though there appeared to be "*some concern by English Public Health Laboratories about testing*". Mr Tucker had suggested to Mr Canavan that it "*might be better to set a target of 1 April as the earliest possible date for introduction but leave it to Blood Transfusion Centres to come in line thereafter since to delay for the slowest could mean a long wait*". Mr Tucker's minute asked Mr Panton to prepare a draft submission to Mr Forsyth "*explaining briefly the background and the English decision*", and to ascertain from the SNBTS when it would be practical to introduce testing in Scotland, while indicating "*that we wish to maintain a UK approach.*"

542. In oral evidence to Penrose on 24 November 2011, in answer to the question: "*Why did you think it might be a good idea to set a specific target date?*", Mr Tucker answered: "*Well, because we wouldn't have gone to our minister without telling him when the testing was going to start. We wouldn't have said to him, "As soon as practicable", because he would have said, "What does that mean?*" [PRSE0006069 p.117].

543. Mr Tucker's minute suggested that Mr Canavan would let the SHHD know the position on timing following a meeting with RTCs. No evidence has been found to indicate that Mr Canavan did go back to Mr Tucker with the outcome of this meeting, but the DHSS's position may have been communicated to the SHHD through other channels. A 13 February 1991 handwritten SHHD note, which would appear to be from Sandra Falconer, indicates that she had spoken to Elaine Webb (at the DoH) who "*advised that officially no date has been given. ... Unofficially it is hoped to commence 1 July*" but that "*this date is confidential & DOH did not want SNBTS or anyone outwith the office informed.*" [PRSE0002364]. The note also recorded that an ACVSB meeting was scheduled for 25 February 1991 and that a date would be discussed then.

544. In the meantime, the NBTS and SNBTS were also corresponding about a start date for testing. On 24 January 1991 Professor Cash wrote to Dr Gunson to inform him that, having liaised with SNBTS RTDs, "*we are unanimous*" in advising that hepatitis C donation testing should not be commenced "*until after the Gulf conflict is over or at least until such time as we are confident our blood collection and microbiology testing teams can cope with what will be quite substantial changes and increased workloads*" [NHBT0000073_033]. Professor Cash stated that the SNBTS remained "*firmly committed to starting on the same day as our NBTS colleagues*" and commented that "*if pressed by Ministers I would suggest, in the circumstances, a May/June date should be considered*". The copy list at the bottom of Professor Cash's letter is unclear and it is uncertain whether the SHHD was aware of his correspondence with Dr Gunson.

545. The ACVSB met again on 25 February 1991, with Dr McIntyre in attendance [PRSE0002280]. The meeting included discussion of the likely availability of second generation hepatitis C tests from Ortho and Abbott and of "*operational factors which might influence the decision by RTCs as to which screening test to choose*". It was suggested that a population of 10,000 samples from a previous study be retained for "*other candidate HCV tests*" and that the Committee "*may wish to see the results from the second generation Ortho and Abbott tests*". The meeting also agreed that "*any new test should be evaluated against the full 10,000 specimens to ensure that it was at least as good as the tests already evaluated*" and that "*Ortho and Abbott 1 and 2 should in principle be available among others from 1 July for RTCs to choose*".

546. Dr McIntyre appears to have believed that the ACVSB had decided that the start date for hepatitis C screening would be 1 July 1991. The day after its meeting, 26 February 1991, he discussed the issue with Mr Bayne and Mr Panton of the SHHD. Mr Bayne's note of the discussion recorded that Dr McIntyre had informed them "*that following the UK Advisory Committee meeting, hepatitis C testing would commence on 1 July*" [PRSE0003746]. The note went on to indicate that "*the next step*" was to contact Mr McIntosh about a procurement contract. [PRSE0003746]

547. The start date of 1 July was referred to in other correspondence around this time. For example, a 12 March 1991 letter from Mr McIntosh to Dr McIntyre (copied to Dr Perry, Professor Cash and Mr Panton) made reference to "*the agreed national (UK) introduction date (1st July 1991)*" [SBTS0000301_057]. A manuscript note, which would appear to be from Ms Falconer and to be dated 19 March 1991, referred to the ACVSB meeting of 25 February and recorded: "*Date of commencement of testing 1 July 91. What about submission?*" [PRSE0002304]. An unsigned handwritten comment, which appears to have been written in reply, stated: "*Draft submission based on English one – shorter version. Other ministers have agreed.*" Mr Hogg stated in evidence to Penrose that he viewed this as an instruction from Mr Panton [PRSE0007002, §31.307].

Start date changed again

548. The minutes of the 25 March 1991 ACTTD meeting, which was not attended by the SHHD, record that "*the proposed starting date of 1st July presented difficulties since it was considered essential that the second generation test from both Orth* [sic] *and Abbott should be evaluated prior to the commencement of routine tests.*" [NHBT0000073_063]. Two days after the meeting, Professor Cash wrote to Mr McIntosh, copied to Dr McIntyre, to say that "*our NBTS colleagues are struggling, on a number of accounts to meet the 1st July deadline*" [PRSE0003692]. He believed that the "*fundamental problem is one of financial resourcing*" and reported that, at the recent ACTTD meeting, it had been agreed that Dr Gunson "*would advise DOH that the 1st July start date should be delayed until such time as evaluation of the new generation of HCV screening tests had been completed. If this is accepted it could push a start date to September.*" Professor Cash noted that he had supported this proposal.

549. A handwritten comment on Professor Cash's letter, which appears to be from Mr Panton and to be addressed to Mr Hogg, stated: "*this is worrying. Pse speak to DOH. We can't go to the minister until we know the start date*" [PRSE0003692]. A 3 April 1991 note, which appears to be from Mr Hogg to Ms Falconer, asked her to "*check with DOH if they have considered a new start date*" [PRSE0000447]. What seems to be a 4 April 1991 response from Ms Falconer to Mr Hogg stated that "*DOH are now considering new start date of 1 Sept 91. This date has not yet been finally agreed. Will BF 15/4 to check again.*" [SCGV0000163_052].

550. According to Penrose [PRSE0007002 §31.347], Ms Falconer received a draft letter from the DoH to the general manager of the NBTS by fax on 11 April 1991, with information on several topics, one of which was "*hepatitis C antibody screening*".[76] In relation to hepatitis C screening, the draft letter stated: "*No date for the introduction of routine testing has yet been fixed but this is unlikely to be before 1 September 1991. You will be informed as soon as a date has been agreed*" [PRSE0002695]. On 15 April 1991, Ms Falconer appears to have sent this letter to Mr Hogg with a note indicating that the date had "*not yet been fixed but unlikely to be before 1 Sept 1991*", before asking: "*Can we now put forward submission?*" [PRSE0001682]. The note also asked: "*If testing to commence 1 Sept what happens to balance of funding provided to cover testing from 1 Jul. 91.*"

551. The start date was discussed further at a 30 April 1881 SNBTS/NBTS liaison committee meeting, attended by Mr McIntosh and Professor Cash, but not by the SHHD [PRSE0004478]. The minutes record that it had been suggested that "*a commencement date of 1 September 1991 UK-wide would be appropriate*" but that the Newcastle RTC had commenced testing within the previous week. In view of the "*implications for the rest of the UK blood transfusion services*", Mr McIntosh "*immediately informed Scottish Home and Health Department officials*". It was noted that Dr Gunson had "*already advised Department of Health counterparts and advice was awaited*". Dr Gunson also hoped to establish a multi-centre evaluation of second-generation test kits,

[76] The fax is available at [PRSE0002874] but the date is illegible.

to which the SNBTS would contribute. The meeting agreed that a "*firm clarification of policy was urgently required from DoH/SHHD within 7-10 days*".

552. On 9 May 1991, Ms Webb of the DoH faxed Mr Panton a copy of a DoH memo entitled "*Hepatitis C Antibody Screening*" [PRSE0001017 and NHBT0000062_060]. The memo stated that the 1 July start date had been "*delayed to allow evaluation of the "second generation" test kits*", but that "*[d]espite this,* the Northern Regional Transfusion Centre had made "*a unilateral decision to start screening from late April.*" It was suggested that press interest was likely to focus on the prospect of other regions using untested blood, and might attempt to link this with the haemophilia HIV litigation and compensation claims for people infected with HIV through blood transfusion. The memo included a background note which explained that the second generation tests were being evaluated in some RTCs, and that the results of these trials would "*allow the RTCs to select the most suitable testing kit*". It was expected that these would be completed, and arrangements for supplementary tests and counselling would be in place, in time for testing to begin from 1 September 1991.

553. The fax cover page for this document included a handwritten note, which would appear to be addressed to Mr Hogg from Mr Panton, indicating that the latter had discussed the matter with Mr Tucker and suggesting that "*we should put our submission forward about the 1 sept. start date and incorporate this: - Northern jumped the gun etc. Line to take for media enquiries.*" [PRSE0001017]. As set out below, it would appear that the SHHD submission referring to the start date of 1 September 1991 was provided to the Minister approximately 2 months later, in July 1991.

554. A further ACVSB meeting took place on 21 May 1991 [NHBT0000042_080]. Dr McIntyre had sent his apologies and does not seem to have been replaced by another SHHD representative. Topics discussed at the meeting included an update on trials of second generation hepatitis C tests. The minutes also included the following: "*The Chairman voiced the concern of the Committee that Northern Region had unilaterally begun routine testing for HCV antibody. He said that the policy for a uniform starting date had been endorsed by all UK Health Ministers and despite Northern Region's action this policy remained firm*".

555. The extent to which SHHD officials considered proposing an earlier start date than 1 September 1991 to Scottish Office Ministers is unclear from the available documents. The contemporaneous documentation is also unclear on the reasons why the SHHD submission was not provided to Mr Mackay until 24 July 1991, as described below.

556. Some evidence is available of consideration being given to these issues within the SNBTS. For example, on 11 June 1991, Dr McClelland wrote to Professor Cash to request that hepatitis C testing be discussed at a forthcoming SNBTS board meeting [PRSE0001759]. He wrote that the "*the fact that some Centres are carrying out testing, albeit on a large pilot study basis, leaves us in a very exposed position*", before commenting:

> *"I would like to be reassured that we are taking the correct decision, both professionally and medical legally, to stay in line with the position of the majority of English RHA's; I think this is in fact what we are now doing rather than abiding by a Department of Health policy because it seems to me that de facto, may no longer be a Department of Health policy in this area".*

557. This issue was discussed at the SNBTS Board meeting of 11 and 12 June 1991, which was not attended by the SHHD. The minutes record, very briefly, under the heading Anti-HCV Testing: "*Agreed: Routine donation testing to begin on 1st September 1991*" [PRSE0000298].

558. SHHD notes from 25 June 1991 provide some insight into the steps being taken by officials around this time [PRSE0002245]. A note which appears to have been addressed from Ms Falconer to Mr Hogg recorded: "*Spoke to Elaine Webb who confirmed that only Northern Region has started routine testing. Some other RTCs inc Birmingham are involved in the evaluation of the second generation tests*". Another note, which seems to have been from Mr Hogg to Mr Panton, stated: "*can we discuss the submission format now...*".

559. The 1 September 1991 start date was also discussed in a 1 July 1991 letter from Dr McIntyre to Dr Metters [NHBT0000192_103]. The letter was prompted by a paper

in the BMJ by Professor Tedder and others on sexual transmission of hepatitis C. Dr McIntyre suggested that these findings would "*pose some problems for colleagues counselling donors found to be Hepatitis C positive*" and asked whether the publication of the article was "*likely to result in any changes in the policy decision to implement routine screening on 1 September*".

560. In an 11 July 1991 response, Dr Metters recorded that Professor Tedder was a member of the ACTTD, which was considering the counselling of donors [PRSE0001103]. He did not anticipate that "*advice from this Committee* [i.e. the ACTTD] *would influence the date of the introduction of routine hepatitis screening*." This response appears to have been considered to be significant by SHHD officials. A handwritten note on the letter, dated 17 July 1991 and which seems to have been from Mr Panton to Mr Hogg, stated: "*We can now proceed with the Hep C submission. We must get it up this week before Recess*."

The ministerial submission

561. The SHHD's submission on hepatitis C screening was sent by Mr Tucker to the Minister, Mr Forsyth, on 24 July 1991 [PRSE0004608]. It recommended that hepatitis C testing of blood donations be introduced from 1 September 1991 in Scotland. The submission set out arguments for and against screening. The arguments in favour of screening included that it was "*a public health measure which would reduce the incidence of post transfusion hepatitis and the spread of HCV in the community at large*", and that it "*reduces the risk of litigation from those who develop hepatitis or cirrhosis as the result of a transfusion when screening tests are available*".

562. The background section noted that screening tests had been developed since mid-1989 and stated that the "*early tests produced many false positives and for some time there was no supplementary tests to indicate whether positive cases were infective*". It recorded that routine screening had nonetheless been introduced in other countries, but that the UK was "*advised by experts not to introduce screening until the available tests had been evaluated, supplementary tests have proved satisfactory and appropriate arrangements for positive donors were in place*". Mr Tucker further noted that "*[t]he SNBTS have been in favour of introducing the test for Hepatitis C for some*

time now but on the basis that a reliable testing kit can be supplied", and that a PES bid had been made successfully in anticipation that testing would be introduced in 1991/92.

563. The submission appears to have anticipated the possibility of criticism on the timing of screening. It stated: "*No specific publicity is being given by Department of Health Ministers to the introduction of the tests in England Wales. This is probably in view of the current sensitivity surrounding blood transfusions and HIV and the need to avoid giving an opportunity for further criticism that testing should have been introduced earlier*." It continued:

> *"It is considered that an announcement may prompt questions about blood safety and that it would give rise to another pressure group seeking compensation for contracting Hepatitis C. If however the Minister considers that the balance of advantage lies in assuring the public that all possible steps are being taken in accordance with specific and medical knowledge currently available, to ensure the efficacy of blood and blood products, we shall prepare a Press Release to this effect for the Minister's approval."*

564. On 25 July 1991, Mr Panton provided Colin Morton (Scottish Office Information Directorate) with a copy of Mr Tucker's submission and a draft press release [SCGV0000163_038 pp.2-6]. In a handwritten note he added: "*Although we have advised the Minister not to issue a release we prepared the att'd just in case. I am also awaiting word from DOH as to whether or not an announcement would embarrass them*."

565. Mr Forsyth's endorsement of the recommendation in the submission was communicated to Mr Tucker on 26 July 1991 [SCGV0000163_031]. His Private Secretary also recorded that he considered a press release to be appropriate.

566. Mr Panton communicated this decision to Mr Donald at the CSA in an 8 August 1991 letter [PRSE0004513]. As for the availability of funds, he wrote: "*As the SNBTS had already been funded for the introduction of this test I should be grateful if you would make the necessary arrangements to allow testing to begin from 1 September*."

567. The Scottish Office press release was issued on 2 September 1991 [PRSE0000743]. It announced that Mr Forsyth had approved routine testing for hepatitis C and stated that "*additional funds*" would be allocated to the SNBTS to cover the annual cost of testing. Quotes from Mr Forsyth included that it was "*only very recently that appropriate technology has become available to reliably allow routine testing for Hepatitis C*", and that "*additional funding*" was being made available to the SNBTS to "*allow this testing to start today throughout Scotland*".

IX. PRISONS

568. On 1 May 1975, the CMO for England, Dr Yellowlees, wrote to regional medical officers regarding blood donation and hepatitis [PRSE0000009]. As well as providing advice on the identification of donors from countries with a high risk of hepatitis B, the letter discussed the collection of blood from prisons. It stated that there was "*a relatively high risk of hepatitis B being transmitted by the blood of prisoners*", but that the DHSS had been advised that it was "*not necessary to discontinue the collection of blood at prisons and similar institutions provided all donations are subjected to one of the more sensitive*" hepatitis B tests. A copy of this letter was received by the SHHD and SNBTS, but the documents suggest that their discussion of its contents focused on donors from high risk hepatitis areas, rather than prisons: see, for example, an 8 May 1975 minute from Dr Scott [PRSE0003803]; 16 May 1985 letter from Dr McIntyre to Major General Jeffrey [PRSE0003502]; 21 May 1975 letter from Major General Jeffrey to Mr Watt [PRSE0002286]; and minutes of the 11 June 1975 meeting of SNBTS directors [PRSE0003812].

569. As explored in other evidence heard by the Inquiry (in particular, relating to the SNBTS), blood was collected from prisons in Scotland in the 1970s and part of the 1980s. Brief reference was made to this practice in annual reports on prisons in Scotland that were presented by the SHHD to Parliament: see, for example, the reports for 1978 [PRSE0001508 p.4]; 1979 [PRSE0002834 p.4]; and 1980 [PRSE0003781 p.11].

570. The practice was also discussed at the 29 March 1983 meeting of SNBTS directors, attended by Dr Bell and Mr Wastle, with the minutes recording that the

Medicines Inspector had "*commented adversely on the practice of collecting blood in prisons and borstal institutions*", but that it was "*not possible for the Directors to agree on future policy*" [PRSE0000193]. The Medicine Inspectorate's position was also referred to in a July 1983 DHSS minute, which noted that the practice had been described as "*highly questionable because of the incidence of homosexuals and homosexual activity in prisons and the present unease about the incidence of AIDS among this group of people*" [PRSE0004345].

571. It appears that, the following month, the DHSS contacted the SHHD to discuss the issue. A handwritten SHHD note, dated 11 August 1983, recorded that Mr Winstanley of the DHSS had telephoned to enquire about the Scottish position on the collection of blood from prisons, with the SHHD official directing him to the minutes of the 29 March 1983 SNBTS directors' meeting [PRSE0003281].

572. The collection of blood from prisons and other penal institution was explored with a number of SHHD witnesses in the Penrose Inquiry. Their evidence was generally that decisions relating to it were a matter for the SNBTS. For example:

a. Dr Scott stated that he did not recall being asked to consider the risks of collecting blood from penal institutions between 1975 and 1984, and in any event he "*would not have considered it appropriate to interfere with SNBTS practices*" [PRSE0002943]. In oral evidence he described the issue as "*a matter for the SNBTS directors*" [PRSE0006011 p.134], and stated that he regarded the question of whether it would be appropriate to accept blood donations from prisoners as a matter of clinical judgement rather than policy [pp.166-167].
b. In a written statement, Dr McIntyre described the continued collection of blood from penal institutions as "*really an issue for the Regional Transfusion Directors to address*", adding: "*We could see why the practice was employed, and over time we could see that the incidence of such collections was reducing and therefore there was no need for us to intervene*" [PRSE0002702]. He did not believe there was much discussion between SHHD and SNBTS on the topic and commented: "*We knew that SNBTS were running the show and there was felt to be no need for us to interfere. SHHD did not set policy for SNBTS in this area*".

X. COMPENSATION, LITIGATION AND FINANCIAL SUPPORT

Compensation for haemophilia patients infected with HIV

1987: initial Government refusal

573. In early 1987, the SHHD became aware of calls for the Government to compensate haemophilia patients infected with HIV by blood products. This included letters from clinicians such as Professor Ludlam, who wrote to Scottish MPs asking for their support.[77]

574. At this stage, SHHD officials appeared to emphasise the importance of following the DHSS position closely. In a 9 February 1987 minute to SHHD colleagues, seeking views on a draft minute to the Minister (i.e. the Minister of State, Lord Glenarthur) and proposed replies to correspondence, Mr Lugton enclosed a copy of "*advice from DHSS to their Minister*" [SCGV0000013_082]. He also enclosed a letter from Lady Trumpington to Dr Forbes, informing the latter that there was no intention for the Government to compensate infected haemophiliacs. Mr Lugton commented: "*I do not think that we can advise the Minister of State to take a different line from Lady Trumpington*".

575. Later that day, Mr Lugton provided the finalised minute and draft letters to Lord Glenarthur's Private Secretary [SCGV0000229_232 and SCGV0000229_233]. The minute described the correspondence as part of a campaign for compensation for haemophiliacs who had been infected with HIV "*from supplies which were unwittingly provided before treatment was introduced to minimise the risk of Factor VIII containing the AIDS virus*". Mr Lugton stated that the "*cost of "no fault" compensation*" to the patients involved could be high, and that before such compensation could be "*seriously considered... it would have to be clearly established that they were a unique group who*

[77] See for example, the response from David Steel MP to Professor Ludlam on 23 February 1987 at [PJON0000072_076]

could be clearly distinguished from any other victims of drug mishaps or other medical accidents".

576. The minute also made reference to the 1978 Pearson Report, before stating: "*We and DHSS are considering the problems for people generally who are HIV positive, eg difficulties in obtaining life assurance and mortgages, but it seems very unlikely that we shall be able to recommend compensation for haemophiliacs*". Mr Lugton concluded by commenting: "*we consider that the Minister's replies should not hold out any hope of a change of the Government's policy on this matter, and the drafts attached have been prepared accordingly*".

577. Lord Glenarthur's Private Secretary responded on 13 February 1987 with comments on the draft letters [SCGV0000229_230]. The Minister was "*not entirely sure that the balance*" in the letters was right and considered that "*reference might be made to the Pearson Report and to the heat treating of blood products with an indication of how long this has been carried out*". He was also "*unsure of the reference to the full range of social security benefits being available to those who are infected with the AIDS virus*".

578. Mr Lugton sought the assistance of Mr Macniven and Mr Stevenson in responding to Lord Glenarthur's request for amendments [SCGV0000229_229]. He noted that DHSS officials had not included reference to the Pearson Report in draft replies they had prepared for Lady Trumpington, and commented that he was "*doubtful about the wisdom of referring to the Report in these replies*".

579. Mr Stevenson responded to say that he saw no particular objection to a reference to the position on no fault compensation, though he did not think "*it would be wise to refer to any reconsideration of policy on this matter*" [SCGV0000229_227]. He noted that the DHSS was "*supposed to be studying experience of such schemes in New Zealand and Sweden*", but it appeared that "*little progress*" had been made so far. He also commented: "*It is, I suspect, one of these issues which the government will only be forced to look at seriously if a major public campaign is mounted about it*".

580. Mr Murray provided a further response to Mr Lugton's minute on 18 February 1987 [SCGV0000229_228]. He advised "*the greatest caution and restraint in going into any great detail*" in the draft replies, which including a letter to Professor Ludlam. He commented that Professor Ludlam was "*closely involved in the arrangements for planning production and issue of PFC products to haemophiliac. Not only can we tell him nothing that he does not already know, but he is in the best possible position to pick us up on any detail*". Mr Murray also outlined the introduction of heat-treated PFC factor VIII and the circumstances around the infection of haemophilia patients in Edinburgh with HTLV-III, before commenting: "*The precise nature of cause and effect here may in fact soon be a matter for the courts. I understand that a test case is being brought by a Scottish haemophiliac… against the SNBTS. This underlines the fact that it would be most unwise to comment or speculate in the reply on Dr Ludlum's* [sic] *statement regarding his patients*".

581. On 17 March 1987, Mr Mackay replied in writing to a PQ on whether steps would be taken to allow patients infected with HIV from PFC blood products to claim compensation [LOTH0000009_038]. His response was that there was "*no scheme to compensate those who allegedly suffer adverse effects as a result of medical treatment*", referring to the possibility of the courts awarding compensation where negligence could be proved.

Refusal to pay compensation maintained

582. The question of compensation was considered again by the SHHD in October 1987, after Dr Lowe (director of the Glasgow Haemophilia Centre) wrote to Mr Forsyth, supporting the Haemophilia Society's campaign for compensation [SCGV0000007_054]. On 6 October 1987, Mr Lugton minuted Mr Forsyth with a draft response to Dr Lowe, explaining the line taken in January 1987 and enclosing a recent minute from the Secretary of State for Social Services to the Prime Minister which "*concluded that the previous line was right*" [SCGV0000007_051]. Mr Lugton added that any *"special arrangements for compensation would cost at least £3 million and it would be logically difficult to distinguish the claim by haemophiliacs from claims of others damaged in the course of their medical treatment*".

583. The following day, Mr Lugton provided a copy of this minute and draft letter to Mr Macniven, raising the question of which branch or division of the SHHD should take the lead in issues relating to compensation for haemophiliacs infected with HIV [SCGV0000229_195]. He recorded that, in preparing the draft response to Dr Lowe, he had drawn on a "*model reply which is to be used by DHSS in response to the stream of letters*" which could be expected as a result of the Haemophilia Society's campaign.

584. The reply from Mr Forsyth to Dr Lowe was sent on 9 October 1987 [SCGV0000007_047]. It recorded that, while the Government had "*the greatest sympathy for the individuals and families whose lives have been tragically affected in this way*", it maintained its earlier position on compensation, in particular because of "*the difficulties which we see in drawing a distinction between different individuals or groups suffering harm as a result of necessary medical treatment carried out without negligence, using the knowledge and products available at the time*".[78] A similarly worded letter was sent by Mr Rifkind, Secretary of State for Scotland, to George Younger MP on 23 October 1987 [SCGV0000007_009].[79]

585. On 13 October 1987, Mr Macniven responded to Mr Lugton's minute regarding the SHHD branch which should take the lead on compensation for haemophiliacs infected with HIV [SCGV0000229_188]. He considered that, while his branch would be "*ready to provide advice and comment for the 'blood' interest as necessary*", lead responsibility should remain with Branch 3 in Mr Lugton's Division, which dealt with communicable disease. Mr Scott (of the VB Division) responded to say that he disagreed with Mr Macniven and, "*[h]aving regard to the position that the lead in DHSS is being taken by the Blood Products Division*" and that the "*AIDS Branch*" was under very severe strain, he was "*firmly of the view that the lead responsibility would more appropriately lie*" with Mr Macniven's division than his [SCGV0000229_184].

586. As Mr Scott and Mr Macniven were unable to agree [SCGV0000229_184], they sought the views of Miss Cox and Mr Morison [SCGV0000229_173]. The latter

[78] For examples of similar letters from Mr Forsyth around this time, see [SCGV0000007_004 and SCGV0000008_082].
[79] The letter from Mr Younger to Mr Rifkind is at [SCGV0000007_122] and the letter from the Scottish Haemophilia Society to Mr Younger is at [SCGV0000007_125].

assigned responsibility to Mr Scott because "*AIDS Branch deals with AIDS issues, whatever the source of the infection*", and because "*[i]n replying to correspondence on the issue, VB have sensibly drawn not only on specific haemophilia points, but also on general AIDS points.*" [SCGV0000229_167] He added that while the DHSS had given this issue to the BTS Division, "*we do not organise ourselves in the same was as DHSS.*" Mr Lugton therefore retained the lead on the matter.

587. During this period, the SHHD continued to monitor the DHSS's position on compensation for haemophilia patients. For example, on 27 October 1987 Mr Morison met with Mr Harris, Assistant Secretary responsible for the blood transfusion service at the DHSS, who told him that "*Ministers were likely to stick to their line*", and that a suggestion by "*officials*" of a "*hardship fund*" of approximately £1 or £2 million had been "*ruled out by the Secretary of State*", and in any event could not be reintroduced since "*in the current state of the debate, the campaigners would regard it as unacceptable*" [SCGV0000268_033].

Decision to make an ex gratia payment

588. On 3 November 1987, Mr Lugton minuted a number of senior SHHD officials regarding an upcoming meeting of the Home and Social Affairs Committee ("H(A) committee") on 10 November 1987, which would consider compensation for infected haemophiliacs [SCGV0000229_180]. He noted that a 30 October DHSS minute to the Prime Minister had apparently suggested "*some softening of the Government line*", though the Prime Minister's reaction was not yet clear.

589. As explored in other evidence heard by the Inquiry, on 6 November 1987 a memo was prepared for members of the H(A) committee, indicating that Mr Moore (Secretary of State for Social Services) considered that the position against compensation was "*not sustainable*" unless concessions were made, and proposing a one-off grant of £10 million to the Haemophilia Society "*to be distributed to cases of need*" [CABO0000205].

590. That same day, Mr Lugton circulated to his SHHD colleagues a copy of the memo and a draft brief summarising its main points [SCGV0000229_176 and

SCGV0000229_177]. Miss Cox responded on 9 May 1987 with comments on the draft brief, which included that it should "*repeat the point*" that the Secretary of State for Scotland "*must make plain that the amount required to compensate Scottish haemophiliacs can not be found within the Scottish block*" [SCGV0000229_175].

591. The H(A) meeting, attended by Mr Rifkind, was held on 10 November 1987, and it was agreed that £10 million should be made available to be administered by the Haemophilia Society [CABO0100016_011].

592. The following day, Mr Lugton minuted the Private Secretaries to Mr Rifkind and Mr Forysth, as well various senior SHHD officials, regarding the outcome of this meeting [SCGV0000229_171]. In relation to the source of funding for the ex gratia payment, Mr Lugton outlined his understanding that "*the Treasury are almost certain to agree that additional money should be provided from the contingency reserve*". Mr Lugton noted that the DHSS was preparing a draft statement, which the SHHD had asked to see, but "*because events are moving rapidly, it may have to be circulated at Ministerial level without previous interdepartmental official consideration.*" On 13 November 1987, Mr Forsyth's Private Secretary relayed the Minister's suggestion that, subject to the Secretary of State's views, it would be appropriate to issue a Scottish Office press release on this issue [SCGV0000229_164].

593. Mr Lugton provided a further minute on 13 November 1987, in which he circulated a copy of a statement the Secretary of State for Social Services proposed to make on behalf of the Government [SCGV0000229_165 and SCGV0000229_166]. He noted that the details of the grant and trust fund were "*yet to be settled*" and an "*exchange of letters with the Society*" was expected. Mr Lugton wrote that the SHHD would "*ensure that letters on behalf of the Government make it clear that Scottish haemophiliacs are to receive support consistent with the support received by those who live elsewhere.*" He also referred to an enquiry from Mr Forsyth's Private Secretary as to how the grant "*would help with the problem of mortgage protection policies etc*", to which he responded:

> *"The existence of the trust fund will not of course make it easier for infected haemophiliacs to obtain life assurance cover or mortgage protection, because*

they will remain, in the view of life insurance companies, uninsurable risks; but the fund will ensure that there is some financial support for those who, because of the combination of their haemophilia and their HIV infection, find themselves in extreme financial difficulties. There may be pressure in due course for further financial support from the Government to haemophiliacs, but for the present it seems that the Haemophilia Society have gratefully accepted the not insubstantial sum which the Government are making available".

594. On 27 November 1987, Mr Lugton wrote to Mr Harris at the DHSS regarding the details of the grant, which were due to be considered with the Haemophilia Society [DHSC0003093_001]. He explained his understanding that the DHSS and the Society were "*jointly giving consideration to the setting up of a structure to ensure that the grant is efficiently administered*", before commenting as follows on the SHHD's involvement:

> *"Our main concern in this Department is to ensure that the structure which is set up, and the arrangements for making payments, are such that infected haemophiliacs in Scotland, and their families, receive an appropriate share of the money which is disbursed. One way to achieve this might be to have Scottish representation in the committee structure, and I should be grateful if you would bear this in mind; a possibility might be to invite the doctors at the haemophilia reference centres in Edinburgh and Glasgow to join one or more of the committees. There is, I am afraid, no possibility of this Department making any significant contribution to the setting up or running of the structure, but I should, as I have indicated, be glad if you would keep me in touch."*

595. From the available documentation, the SHHD appears to have had minimal involvement in the setting up the Macfarlane Trust in early 1988. Nevertheless, of the four trustees appointed by the Secretary of State, one of those put forward for appointment was from a Scottish institution: Christina Leitch, a social worker to the Glasgow Haemophilia Centre [DHSC0003422_002]. She was invited to accept the appointment by the DHSS on 11 March 1988 [DHSC0003421_012] and attended the first trustees' meeting on 29 March 1988 [DHSC0003299_006].

Additional payment to the Macfarlane Trust

596. On 23 November 1989, Kenneth Clarke announced an additional ex gratia payment of £19 million to the Macfarlane Trust [DHSC0002536_027]. According to a later minute from Mr Tucker to Mr Forsyth's Private Secretary, this decision was taken without "*any prior consultation and agreement with the other Health Departments*" [SCGV0000230_145].

597. In a letter to Norman Lamont, Chief Secretary to the Treasury, also on 23 November 1989, Mr Clarke wrote that he would "*of course be expecting Territorial Departments to make the usual contribution*" to the additional payment [DHSC0002536_027]. This letter was copied to the Secretary of State for Scotland (and others). On 28 November 1989, Mr Rushworth wrote to Mr Tucker to suggest that "*Ministers should be briefed strongly to resist Mr Clarke's attempt to secure a Scottish contribution*", as "*DH did not consult SHHD at all about this initiative*" [SCGV0000230_150].

598. On 22 December 1989, Jane Wheeler of the DoH Finance Division wrote to Mrs Beattie of the Scottish Office Finance Division to "*seek a proportionate contribution towards the overall cost of the scheme*" [SCGV0000230_060]. Ms Wheeler wrote that the Treasury had agreed for the "*full cost*" of "*£24 million*" to be advanced from the contingency reserves, of which £12 million would be "*repaid by the health departments*" from identified savings or cash limit reductions in 1990-91. The letter sought Mrs Beattie's agreement to "*a contribution from SHHD of £1.2 million based on the standard contribution for Scotland of 10 per cent of the £12 million repayable to the Reserve*".

599. On 4 January 1990, Mrs Beattie wrote to Mr Tucker, attaching a copy of this letter and proposing that the SHHD/Scottish Office refuse to contribute due to the lack of consultation before the arrangements were announced [SCGV0000230_055].[80] A manuscript note at the bottom of the page appears to read: "*PS. I gather that Northern Ireland are considering offering payment based on the number of infected*

[80] A draft response to Ms Wheeler can be found at [SCGV0000230_057] but it is not clear that this was ever sent.

haemophiliacs in the Province – apparently an extremely small number. Wales are considering doing likewise or they may decide to refuse payment altogether".

600. Negotiations between the different departments involved continued during January 1990. In an 18 January 1990 minute, copied to Mr Tucker, Mr Rushworth reported a discussion he had had with a Treasury official [SCGV0000230_056]. He recorded that, of the £12 million which was not being funded from the contingency reserve, the DoH was "*looking for territorial contributions, which in our case is 7% or £840,000*". Mr Rushworth explained that he had told the Treasury that the SHHD "*had not yet agreed the DH proposal that we pay a share*", partly because of the lack of consultation and partly because "*we simply do not have the spare cash in the current financial year*". He added: "*We would either have to persuade DH to cover our figure of £840,000, whether this year or next year, or if our Ministers decide they wished to make their contribution nonetheless we would have to find it next year.*"

601. The figure of £840,000 was explained further in a 26 January 1990 letter from Ms Wheeler to the Scottish Office Finance Division [DHSC0046951_090]. Ms Wheeler wrote that, while she was "*disappointed*" that the Scottish Office did not "*feel able to contribute to the Government grant in line with the usual arrangement*", she was "*prepared to accept in this case*" that its contribution should be determined according to the proportion of haemophiliacs infected with HIV from blood products who resided in Scotland. This proportion was estimated at 7% and 7% of £12 million was £840,000.

602. On 1 February 1990, Mr Tucker provided Mr Rushworth with a draft minute to Mr Forsyth on this topic [SCGV0000230_040]. He noted that the Northern Ireland Office and Welsh Office were not prepared to support the Scottish Office in challenging the DoH and the Treasury and commented: "*I appreciate that there are very serious difficulties in finding the money but there seems no alternative since we do have some moral obligation to Scottish haemophiliacs*".

603. In a response that same day, Mr Rushworth suggested that "*the minute should be more open-ended and give more priority to the option of declining to make any contribution at all*" [SCGV0000230_038]. Mr Gray (of the SHHD's IVA Division) also

provided his views on 1 February 1990 on the mechanism by which the funding should be allocated [SCGV0000230_042].

604. Mr Tucker's minute was provided to Mr Forsyth's Private Secretary later on 1 February 1990 [SCGV0000230_145]. It noted that the Scottish Office had not been asked for any contribution to the initial funding of £10 million for the Macfarlane Trust, *"although there were a number of haemophiliacs in Scotland with HIV"*. As the decision to make an additional payment to the Trust "*was taken without any prior consultation and agreement with the other Health Departments, it was assumed*" at the time of the announcement that the "*monies would be provided from Treasury*". Having provided further background, Mr Tucker recorded that the Treasury was seeking a payment of £840,000 from the Scottish Office. He explained that no funds were available in the current financial year and, as no prior notice had been given to the SHHD, it had not been possible to include the matter in Ministers' PES decisions in November.

605. Mr Tucker also commented that there could be "*no question of Scottish haemophiliacs with HIV not benefiting from the Trust and thus arguably we have a moral obligation to make a contribution*". If Mr Forsyth agreed that "*a payment should be made from next year's allocation as a priority then this would mean withholding funds from either Health Boards or the Common Services Agency*". While this would lead to some developments having to be curtailed and to criticism, there appeared "*to be no alternative unless Ministers*" wished to decline to contribute. It was suggested that this would "*be difficult for Ministers*", and that the Scottish Office contribution should therefore be made "*a priority for payment in the next financial year from within the existing CSA PES provision*".

606. Mr Forsyth's Private Secretary, Mr Binnie, responded to Mr Tucker on 6 February 1990 [SCGV0000230_143]. He relayed that the Minister was "*of the belief that we will clearly need to make our appropriate financial contribution*", but that he was "*somewhat surprised that this issue was not marked up for his attention, even tentatively, during PES discussion*". Mr Binnie also asked for an indication from Mr Tucker "*as to what line should adopted to the overtures (now daily) which are being received from DoH*" as to the Scottish Office's stance on the issue.

607. Mr Tucker responded on 13 February 1990, recording that officials were not aware during PES discussions that a decision to increase the Macfarlane Trust funding was to be taken and that the other territorial departments would be asked to make a contribution [SCGV0000230_122]. He also provided an update on funding allocation: he explained that, "*in the course of technical discussions*" between Finance Division and the Treasury, it had been possible to earmark resources to cover the £840,000 required from Scotland. As a result, Mr Tucker advised that, if approached by the DoH, Mr Binnie "*may wish to advise them that we have provided our share of the cover on a basis acceptable to the Treasury*".

The HIV litigation

1988-1989: first claims in Scotland and preparation of defence

608. Claims against Scottish health boards, the SNBTS and the Secretary of State for Scotland by haemophiliacs infected with HIV through blood or blood products began to be issued in 1988.[81]

609. Two of these claims were discussed in a meeting between the SHHD, CSA and SNBTS on 18 April 1988, which was recorded in a note by Mr Macdonald [SBTS0000687_089]. The meeting included discussion of the "*possibility at the time the virus was transmitted of substituting cryoprecipitate for Factor VIII.*" Professor Cash was recorded as suggesting that this "*would have been a logistic impossibility*" and referring "*to the professional view that the risk did not justify such substitution*". It was agreed that the SHHD and SNBTS would "*continue to research the background to the 2 cases independently (to maximise the chance of identifying all relevant facts).*"

[81] One example is at [DHSC0043352_156].

610. The SHHD's Branch IVD/3 was responsible for the interests of the Secretary of State as third defender in these actions.[82] It prepared a four-page note dated 17 May 1988 on the infection of haemophiliacs in Scotland with HIV [SCGV0000229_095].[83]

611. Reference was made to this note during a further meeting between the SHHD, CSA and SNBTS on 15 June 1988 [SBTS0000178_011]. It was recorded that the note had been prepared by Mr Macdonald and provided to Professor Cash, "*in the same way that Professor Cash had a copied a note of his researches following the last meeting*". It was also agreed that a meeting would be arranged by the SHHD involving "*interested parties from all 3 defenders, with legal representatives as desired*".

612. It appears that a meeting involving these parties took place on 5 September 1988. On 8 September, Mr Lindsay of the Solicitor's Office provided Mr Panton with a note containing his initial views on the broad issues in the case [SCGV0000506_097]. He recorded that it appeared that "*all defenders are of the view that the actions should be resisted*" and commented that the "*real difficulty*" was "*to determine where liability should rest*". He was also of the view that "*the main focus of attention will ultimately be that period within which the possible contamination of factor 8 was within knowledge and yet that factor 8 was still supplied*". Mr Lindsay suggested that one of the areas for investigation was "*how far the Department involved itself in policy making in respect of supplies of blood*", in particular from the time when AIDS was becoming recognised as a disease which affected haemophiliacs and "*presumably later which could be known to be transmitted by factor 8*".

613. Mr Lindsay also wrote that it appeared "*clear from what Professor Cash had to say that it was in the absence of any direction from the Secretary of State that SNBTS resolved upon a policy that it would become self-sufficient insofar as a factor 8 for Scotland. As Dr McIntyre pointed out, however, it appears that the policy or policy intention was supported financially by Central Government*". The note recorded that

[82] See, for example, a 20 September 1988 minute from Mrs Howieson (of the Solicitor's Office) to Dr Covell and Mr Lugton [SCGV0000229_064].
[83] This included a summary of discussions on AIDS risks and treatment policies at the 2 February 1984 SNTBS and haemophilia directors meeting (with detail which would seem to go beyond what is contained in the meeting minutes).

Mr Panton had "*agreed to prepare a detailed chronology showing the extent of the Department's contact and knowledge of the problem throughout*".

614. The Solicitor's Office continued to correspond with the SHHD about events relevant to the claims in the remainder of 1988.[84]

Minister updated and cost considered

615. Press reports of the litigation in early 1989 led SHHD officials to update the Minister. On 6 January 1989, the Daily Record published an article about the HIV litigation with the title "*You Gave Us AIDS!*", reporting that families of infected haemophiliacs in Scotland were forming "*an organised group for their fight through the courts*" [SCGV0000229_054]. Jane Rougvie (Assistant Private Secretary to Mr Forsyth) wrote to Mr Lugton on 18 January 1989, noting that Mr Forsyth had read the article and would welcome "*any advice you could give*" [SCGV0000229_053].

616. This advice was provided by Mr Macniven in 15 February 1989 minute [SCGV0000229_052]. He stated that "*some of the 75 haemophiliacs in Scotland who are HIV positive*" had "*raised actions in the Court of Session – alleging negligence by the NHS*". Having summarised the nature of the claims, Mr Macniven recorded that the Secretary of State had been served with summonses by 13 haemophiliacs (the number 11 was typed but crossed out and replaced with 13 in manuscript). He also noted that the SHHD was working with the Solicitor's Office to prepare defences on behalf of the Secretary of State, as well as co-ordinating with the Health Board involved and the SNBTS. Mr Binnie relayed Mr Forsyth's gratitude for the minute on 22 February 1989 [SCGV0000229_051].

617. During the course of 1989, concerns were raised about the potential cost of the litigation if the claims were successful. A 25 April 1989 letter from Mr Winter of the Scottish Health Service General Managers' Group to Mr Hamill noted that it was "*thought likely that, in cases where the court finds for the claimant, costs would be in excess of £250,000 per case; and it was noted up to approximately 60 such cases might*

[84] See, for example, Mrs Howieson's 20 September 1988 minute to Mr Lugton [SCGV0000229_064].

be raised" [SCGV0000229_048]. Mr Winter asked what arrangements had been made by the SHHD to meet these costs "*centrally*". A manuscript note addressed to Mr Macniven, and which would appear to be from Mr Panton, recorded that the SHHD had "*made no provision*" and commented: "*It is unlikely that all cases will incur such high costs as the first 'test' cases will be the expensive ones and presumably set precedents*".

618. It seems that Mr Winter's letter caused Miss Ross (of the Scottish Office Finance Department) to contact the Treasury. In an 11 August 1989 letter, Miss Mankelow of the Treasury noted that Miss Ross had "*heard from a General Manager*" concerned about 60 potential cases with awards of £250,000 each, equating to £15 million [SCGV0000229_016]. Having recorded points previously explained by another Treasury official, including that "*there is no general contingent liability*", the letter asked for further information. Miss Ross sought this further information from Mr Panton [SCGV0000229_015]. After being chased for a reply [SCGV0000229_013], the SHHD responded in a minute dated 12 October 1989 [SCGV0000229_011]. As well as suggesting an approximate timescale, this recorded that 13 cases had been received so far, with a further 35 likely to come, that the £250,000 estimated cost per case was "*only in respect of settlement costs*" and that "*any legal costs*" would have to be considered in addition.

619. At this time, the SHHD's position remained, as with the rest of the Government, that liability was not accepted and that the actions were being defended. This can be illustrated by a 27 November 1989 minute to Mr Forsyth, enclosing a Q&A brief concerning haemophiliacs who had been infected with HIV [SCGV0000230_111]. The brief stated that the Government did "*not accept any liability for the infection of haemophiliacs*", and that its earlier ex gratia payments were made on "*humanitarian grounds*".

620. The Scottish Office continued, during the course of 1990, to monitor the DoH's position on the HIV litigation and the possibility of additional payments being made. For example, in a 18 October 1990 minute to Mr Hancock – entitled "*PES 1990: Compensation for haemophiliacs*" – Mr Rushworth explained that, as far as he was aware, the DoH had not made an additional bid to the Treasury for a possible payment to haemophiliacs [SCGV0000230_007 p.2]. He and Mr Tucker had considered a

contingency PES bid but decided that it was still "*too early*" for this. Mr Rushworth asked that DoH Finance be contacted to establish how they were planning for this potential demand for resources in 1991 and to "*register with them that if DH are moving towards some sort of decision on this over the next year ... would they please keep us in touch as soon as anything changes*".

621. A 30 October 1990 SHHD note, commenting on this minute, recorded that the DoH had not made a PES bid and that officials were "*intending to seek access to the Reserve, if and when any agreement to pay compensation is reached*" [SCGV0000230_007]. While Ms Wheeler in DoH Finance had undertaken to keep the Scottish Office updated with developments, the minute commented: "*They seem to be as much in the dark as us over this issue*".

The decision to settle the HIV litigation

622. John Major replaced Margaret Thatcher as Prime Minister on 28 November 1990. It appears that, in early December, the Scottish Office came to believe that there was some possibility that a payment might be made to settle the litigation. A 7 December 1990 minute to Mr Hancock on compensation reported that the author had spoken to Ms Wheeler's replacement at the DoH, who "*confirmed that following the Prime Minister's statement that he would look again at the whole question of compensation DH were waiting for a direct steer from Ministers before approaching Treasury. He estimated that the sum involved would be in the region of £50m*" [SCGV0001029_112]. It had been explained to the DoH official (who agreed to keep the Scottish Office closely informed of progress) "*that this would have obvious consequences for Scotland*".

623. On 11 December 1990, the Prime Minister announced, in response to a PQ, that the Government had agreed in principle to proposals to settle the HIV litigation [DHSC0003654_003]. The SHHD does not appear to have had any involvement in the negotiations leading to this announcement, and the documents indicate that this resulted in difficulties for the SHHD's attempts to settle the Scottish claims.

624. Mr Tucker minuted Mr Forsyth on the day of the announcement [BNOR0000064]. He recorded that the compromise would result in the Government providing, in addition to the £34 million already paid to the Macfarlane Trust, a further sum of about £42 million, as well as paying the plaintiffs' reasonable legal costs. It was "*proposed to apply the outcome of any settlement to all parts of the United Kingdom*". Mr Tucker explained that as "*the Scottish plaintiffs were not directly involved with the proposals formulated by the English lawyers, it will be necessary to consult with the representatives of the Scottish plaintiffs in the proposals*". Mr Tucker proposed arranging a meeting with the Scottish legal representatives as soon as possible and enclosed a proposed statement for Mr Forsyth to make.

625. On 12 December 1990, Mr Rusworth wrote to Graeme Dickson at the Treasury to express the Scottish Office's concern at its lack of involvement in the negotiations leading to the settlement announcement, and to emphasise that settlement figures for Scottish haemophiliacs had to be properly taken into account [HMTR0000002_029]. He wrote that the Scottish Office "*had not been expecting*" the settlement announcement and that "*there had been no consultation with us about the details of requirements in Scotland*". Mr Rushworth noted that Mr Dickson had explained his understanding that the compensation figure was £42 million, covering seven different categories for all 1,365 haemophiliacs registered with the Macfarlane Trust, and that it would be "*a claim on the Reserve*"; there was also the possibility of a further £4-5 million being made available for legal costs. Mr Rushworth added:

> *"It would therefore seem that these sums include provision for compensation and associated costs for haemophiliacs resident in Scotland. There has not, however, been any parallel negotiation with the legal representatives of Scottish haemophiliacs and this is now being commenced by the Scottish Home and Health Department. Our legal advisers have raised a number of questions about the details of the Heads of Compromise and we are concerned that there may be difficulties here in reaching agreement with the Scottish legal representatives. In addition we are concerned that the number of possible claimants could be very much larger than the figure of 77 known cases in Scotland which is what we assume the Department of Health have taken into account."*

626. Mr Rushworth wished "*to record that Scottish haemophiliacs must of course be included in this scheme*", and that until further details were available, it was possible that the costs would be greater in respect of Scottish haemophiliacs than had been assumed.

627. Also on 12 December 1990, the Chair of the Scottish Haemophilia/HIV Litigation Group, of Balfour and Manson solicitors, wrote to the Secretary of State for Scotland (Ian Lang) to inform him that members of the Group were "*dismayed*" at the Government's announcement, given that "*not only were the Scottish lawyers excluded from the discussions with the government, they were not even advised that these discussions were taking place*" [PRSE0003064]. The letter recorded that there were "*clear and identifiable differences between the litigation in Scotland and the litigation in England*" and commented that, "*[u]ntil we know that the offer includes Scottish Haemophiliacs and until we know the contents of the offer, we are not even able to take the first steps towards advising our clients regarding acceptance or otherwise*".

Discussions over settlement terms

628. By 13 December 1990, the Solicitor's Office had obtained from the DoH a draft of the proposed terms of settlement. Mr Beaton (of the Solicitor's Office) wrote to Mr Tucker with "*preliminary (and very basic) comments*" on the draft [SCGV0000506_034]. Among other matters, he noted that a provision in the draft agreement "*purports to disapply the terms of settlement to people who have brought proceedings in Scotland or Northern Ireland*", which he presumed to mean that there would "*have to be a settlement agreement separately in relation to the Scottish cases*".

629. In a letter to Mr Dobson at the DoH that same day, Mr Tucker noted that the SHHD had been advised that "*there can be no certainty*" that the Scottish lawyers would take the same view as the English Steering Committee of counsel and solicitors

on the settlement proposals, so it was important that the structure of the trust document and terms offered were "*workable in terms of Scots law*" [DHSC0003655_046].[85]

630. In a minute to Mr Tucker the following week, Mr Henderson reported on a meeting with representatives of Balfour and Manson, in which they discussed the latest draft of proposed terms of settlement [DHSC0003655_004]. Balfour and Manson were acting "*for some 41 haemophiliac claimants*", though not all "*had commenced legal action*". Mr Henderson reported that the "*most important point*" arising from the meeting related to the question of time and funding for the lawyers to carry out further investigation, to enable them to advise their clients on the merits of the settlement. As a result of legal aid not being available, "*no worthwhile preparation could possibly have taken place*" for legally aided cases, while for private client cases preparation had not taken place because of the expense.

631. Mr Henderson advised Mr Tucker that a deadline of April 1991 proposed by the DoH in which to accept the offer could lead to a "*politic problem*", in that the SHHD would "*be seen to be attempting to steamroller a settlement through deliberately without giving an opportunity for proper investigation of the efficacy of the offer*". He suggested that Mr Tucker indicate to the DoH that anything less than six months for acceptance of the offer would be "*highly likely*" to lead to an amendment of that timeframe for the Scottish litigants.

632. Mr Tucker conveyed the substance of this advice to the Private Secretaries of Mr Forsyth and Secretary of State on 21 December [SCGV0000501_138], in response to Mr Forsyth expressing the view that the SHHD "*should move speedily towards a settlement in Scotland*" [SCGV0001029_104] and the Secretary of State requesting an indication of the timetable for settlement [SCGV0000501_142]. Mr Tucker explained that the SHHD had "*to move in step with the Department of Health who are the lead Department on this matter to ensure that the terms of settlement minimise the risk of legal challenge*", but that applying the DoH timetable in Scotland could lead to "*criticisms that the Government is attempting to steamroller a settlement*". He commented that the estimated six months required for the Scottish plaintiffs to obtain

[85] Also on 13 December 1990, Mr Rushworth minuted Mr Tucker on funding mechanisms for the compensation payment [SCGV0001029_106].

advice was "*unlikely to be acceptable*" to the DoH and that it "*may be prudent*" to allow an extension of two months instead, while noting that any extension to the time limit for acceptance of the offer would "*pose problems*" for the DoH as it "*would continue to keep the issue at the forefront of people's minds*".

633. Mr Tucker proposed that the SHHD first "*issue an offer to the Scottish Steering Group*" based on the terms of the offer made by the DoH "*as soon as it is available*" and that it review the position with the DoH before advising Ministers further. Mr Tucker also commented that it was "*clear that the terms of settlement as advanced in England and Wales*" had been "*proposed without regard to the situation of the Scottish claimants*" and there "*may well be pressure*" to amend them.[86]

634. Mr Forsyth replied through his Private Secretary to Mr Tucker's minute of 21 December 1990 a week later, commenting that he considered that the matter was "*best handled by the Secretary of State*", but that in his view, it was essential that the SHHD and DoH "*proceed at the same pace and that is as swiftly as possible if only for the sake of the families themselves*" [SCGV0001029_100].

635. Mr Gallagher, Private Secretary to Mr Lang, replied on 10 January 1991 to indicate that, in addition to official level approaches to the DoH, the Secretary of State proposed to "*write to Mr Waldegrave putting clearly on record the different Scottish situation, and the need to make sure that we and the Department of Health match timetables so far as possible*" [SCGV0000231_021]. He added that "*part of the root of this difficulty is the fact that the English offer was put together without reference to us, and there would be no harm in the letter's mentioning that*".

636. Mr Tucker provided a further minute in response on 15 January 1991, informing Ministers that most of the provisions of the settlement document in England and Wales had been completed and it was expected that the vast majority of the 1000 litigants

[86] On the same date, 21 December 1991, Mr Henderson informed Mr Tucker that he had been contacted by Mr Powell and, as he understood it, the terms of settlement had been finalised and would be put to plaintiffs in England and Wales the next day; however Mr Henderson would "*not be prepared*" to put the Scottish draft settlement terms to Balfour and Manson until he had confirmation of "*exactly what the final form of the English one*" was [SCGV0000501_140].

would accept the terms [SCGV0000231_019].[87] However, Scottish solicitors had not carried out any informal soundings of their clients "*chiefly because they have not been involved in the negotiation process at all*" and therefore did not have any "*material*" to use for that purpose, "*other than the public statements by Ministers*". Mr Tucker noted that the SHHD had been advised that "*the offer in the Scottish cases will have to take a slightly different form*". The Solicitor's Office had drawn up draft proposals for Scotland, which would be shown to the plaintiffs' solicitors "*in the next day or so*".

637. On timing, Mr Tucker explained that it seemed unlikely that the SHHD would be able to put the Scottish offer formally at the same time as the English offer. After putting the formal offer, he recommended that the Scottish solicitors be allowed three months to investigate the claims and advise their clients, with reasonable legal expenses for this work reimbursed (the funds for which would "*have to come*" from the Treasury and be "*channelled through the Department of Health*"). Mr Tucker advised that, in light of the "*special circumstances of the Scottish position*", some flexibility in the timescale for acceptance should be given, and enclosed a draft letter for the Secretary of State to send to Mr Waldegrave.[88]

638. This letter was sent by Mr Lang on 17 January 1991 [DHSC0003660_009]. It asked for flexibility in the timeframe, noting that the Scottish lawyers had not been party to the negotiations and this had "*placed the Scottish Office in a difficult position*". It also suggested that the cost of the plaintiffs' additional legal expenses be met by the Treasury. Mr Waldegrave replied on 30 January 1991, agreeing to Mr Lang's proposal to set a "*reasonable period for Scottish litigants to be advised by their lawyers on a response to the offer*", but insisting that the terms of the settlement must be the same for all "*to avoid re-opening the whole issue*" [DHSC0003660_010]. He proposed that "*size and categories of payment on offer must be common to all litigants wherever they have pursued their action*".

[87] Mr Tucker noted that there were also a number of possible medical negligence cases against health authorities, which it was hoped would be processed alongside the main settlement.
[88] Mr Forsyth's Private Secretary responded to Mr Tucker's minute on 17 January 1991 to note that the Minister was content with the proposal in the minute, while recording his concern that compensation did not apply to non-haemophiliacs who had been infected (as explored further below) [SCGV0000231_019].

639. Mr Mellor, Chief Secretary to the Treasury, wrote to Mr Lang the next day to advise that, as there was "*only a small number of litigants in Scotland*", he was content to agree with the suggestion that additional time be given to the Scottish litigants [DHSC0003657_019]. However, he believed there was a risk of "*losing the momentum of settling with the vast majority of claimants if the entire settlement were delayed*", and suggested that the DoH should "*press ahead and reach an agreement in England*" as quickly as possible. He was also unpersuaded that the legal cost of the Scottish litigants should be met by the Treasury rather than the Scottish Office.

640. Mr Tucker minuted Mr Forsyth's and the Secretary of State's Private Secretaries on 8 February 1991 in response to these letters [SCGV0000232_110]. He indicated that the SHHD could "*readily*" give an assurance that the terms of the settlement in relation to the size and categories of payment would be common to all litigants. He went on to reiterate the reasons why additional time was required for the offers to be considered in Scotland, and recommended that three months be given from the time of the formal offers. Mr Tucker also addressed the question of legal expenses, suggesting that the Treasury be "*pressed to treat the Scottish Office on the same basis as the Department of Health and reimburse the legal expenses judged to be commensurate with settling the actions raised*".

641. A further minute from Mr Tucker on 12 April 1991 indicated that, while the "*Scottish terms of settlement cannot be finalised until after the English terms have been*", the SHHD was "*anxious*" to avoid criticism about delay in settling the Scottish claims (as had already been made in England) [SCGV0000233_080]. He described the SHHD's position as being that "*final Scottish terms of settlement should be presented to the Scottish Steering Group not later than 7 days after the English Court has given its authority to the English settlement*".

Information to non-litigant haemophiliacs

642. The SHHD was also involved, alongside the DoH, in drafting a letter to extend the settlement offer to haemophiliacs who were not involved in the litigation.

643. On 22 January 1991, Mr Burrage of the DoH asked that Mr Tucker provide comments on a draft letter intended to go out "*on Government letter headed notepaper with the next Macfarlane Trust newsletter*" [SCGV0000501_082]. Mr Tucker passed this on to Mr Henderson for his comments [SCGV0000232_066].

644. Mr Henderson responded on 24 January to explain that he had redrafted the letter "*in the form of an address to the Macfarlane Trust rather than to individual haemophiliacs*" as he thought at this stage "*there should be minimal direct contact between the Secretary of State and individual haemophiliacs*" to "*minimise inquiries of legitimate expectation*" [SCGV0000501_076]. He had also amended the letter to "*make it clear that we what we are doing is discussing the terms of settlement*" and not "*that we are following on the coat tails of England and Wales*", because "*if it was too apparent from the terms of the letter that the real negotiation was being carried out in London then although everybody knows that this is the case we would expect some possibility of criticism*".

645. Mr Henderson provided additional comments on the wording of the letter, including on the confidentiality of information provided by haemophiliacs on the information slip, and on the "*minimum percentage required to sign up for the settlement before it will operate*".

646. A finalised version of the letter was sent by Mr Tucker to the Macfarlane Trust on 25 January 1991 [MACF0000083_147]. It was addressed to the Trust, rather than individual haemophiliacs, and described its principal purpose as being "*to make known to those who are neither pursuing litigation nor consulting their lawyers, the details of the payments on offer in terms of the settlement*".

Finalising the Scottish settlement agreement

647. Mr Henderson led the negotiations on the terms of the settlement agreement with the solicitors representing the Scottish litigants, regularly corresponding with Mr Tucker to update him on progress and seek his instructions on certain points (see, for example, the documents at [SCGV0000232_095, SCGV0000233_102, SCGV0000233_103, SCGV0000233_082 and SCGV0000233_087]). Mr Henderson

was also in contact with Mr Powell of the DoH, in particular on the terms of the Deed of Trust necessary for the handling of settlement payments (for example, [SCGV0000233_094 pp.3-5]).

648. On 11 April 1991, Mr Henderson wrote to Mr Tucker to indicate that there was a "*realistic possibility that we will be some time behind the English*" if the English settlement were to proceed (as had been proposed) on 1 May 1991 [SCGV0000233_082]. In the event, the Macfarlane (Special Payments) (No 2) Trust was declared on 3 May 1991 [MACF0000083_004], the agreement in England and Wales was announced on 10 June 1991 [DHSC0002451_011], and Mr Henderson (on behalf of the Secretary of State) formally offered the terms of settlement to Balfour and Manson on 24 June 1991 [DHSC0003635_065 and BNOR0000329].

649. Two days later, Mr Tucker provided an update on "*the line to take should a question be raised at PM's Question Time on the Scottish Settlement*" [SCGV0000234_033 and SCGV0000234_034[89]]. His note indicated that a formal offer of settlement had been made, that legal advisers were consulting individual claimants on the terms of the settlement, and that payments would be made through the Macfarlane Trust "*as quickly as possible after the terms have been accepted*".[90]

650. The procedure envisaged for the acceptance of offers was that litigants' representatives would send a formal acceptance letter to the Scottish Office, along with a schedule providing details of each claimant and a completed undertaking in an agreed form (as explained in Mr Henderson's offer letter of 24 June 1991 [DHSC0003635_065]). Mr Henderson started to receive these documents in respect of individual litigants shortly after his offer letter and confirmed receipt of them by letters to their solicitors (for example, on 8 July 1991 [SCGV0000504_072] and 9 July 1991 [SCGV0000234_010]). On 9 July 1991, Mr Henderson provided Mr Tucker with a list of litigants who had accepted the offer and provided the necessary documents

[89] The note was later updated to record that a small number of claimants had indicated their acceptance of the offer [SCGV0000234_023].

[90] A background note, dated 3 July 1991, for a PQ on the topic explained that "*the offer of settlement is on the same basis as that for England and Wales*" although it had been "*necessary to adjust the terms of the England and Wales settlement to accord with the requirements of the Scottish legal system*", adjustments which had been "*agreed with the Steering Committee of Scottish Solicitors acting for those affected*" [SCGV0000234_028].

[SCGV0000234_008]. He confirmed receipt of acceptance documents in respect of additional litigants in August 1991 [SCGV0000235_193].

Extension of eligibility for Category G claimants in Scotland

651. Category G claims were those, "*put broadly, by spouses, parents and children of HIV* [infected] *haemophiliacs where the claimants had not themselves contracted HIV but were at risk of so doing because of their close and regular contact with the infected haemophiliac.*" [SCGV0000235_152].

652. As reflected in the documents below, the terms of the Scottish settlement provided for payment to Category G claimants, but this was restricted to those who had issued a legal claim prior to 13 December 1990 or had lodged a legal aid application before that date. Because of differences between the litigation in England and Wales and Scotland and the way in the settlements were reached, the restriction on eligibility for Category G claimants had the effect of excluding more Category G claimants in Scotland than in England and Wales.

653. In September 1991, the Scottish Steering Group wrote to Mr Henderson to request an extension of the terms of the settlement to allow more Category G claims [SCGV0000235_162]. The letter recorded that "*only one Category G claim has, to date, been certified for settlement in Scotland*". It was said that this was "*principally because of your refusal to allow any latitude, in Scotland, in relation to the date of 13 December 1990 by which date either proceedings required to have been raised or Legal Aid Applications lodged*" for such a claim to qualify. The letter added that "*the failure to treat Category G claims in Scotland sympathetically has given rise to a great deal of anger and upset by a number of families who feel that they ought to have qualified*".

654. Upon receipt of this letter, Mr Henderson wrote to Mr Tucker on 11 September 1991 to explain the request, commenting that he suspected that there was "*a basis for Scottish Category G claimants to feel aggrieved*" [SCGV0000235_160]. He also suspected that there had been a "*realisation that in England and Wales there are many more Category G claims than there have been in Scotland*", and that this related to a time limit on joining the conjoined action in England and Wales which had not existed

in Scotland. Mr Henderson suggested a meeting to discuss the issue. A manuscript note, which appears to be from Mr Panton, asked Mr Hogg to arrange a meeting: "*the sooner the better – we don't want Mr Tyler*[91] *going to the press*".

655. Mr Powell, Mr Burrage and Mr Henderson met on 19 September 1991 to discuss the issue [DHSC0003664_015 and DHSC0003664_016]. Mr Henderson suggested during the meeting that there was an injustice in the difference between Scotland and England and proposed that the eligibility of Scottish Category G individuals be expanded. Mr Burrage and Mr Powell agreed to consult within DoH on this proposal.

656. Following the meeting, Mr Henderson wrote a note to Mr Panton, to "*set out the arguments*" for the extension of Category G eligibility in Scotland [SCGV0000235_152]. This set out the history of Category G negotiations as well as various proposals on how to extend eligibility to address the disadvantage for claimants in Scotland.

657. On 8 October 1991, Mr Tucker wrote to Mr Rushworth to explain that, following discussions with DoH officials and between Mr Henderson and the Steering Group, "*there is a possibility that we can reach agreement on redefining Category G in Scotland so that payment can be made from the Macfarlane Trust for a few more cases in this Category*" [SCGV0000235_142]. This would cover cases "*where there is some indication that the position of the Category G case was raised with and considered by a legal adviser at some point prior to 13 December 1990.*"

658. Mr Tucker wrote that "*[i]f DofH agree then there will be no necessity to involve Ministers since the position will be covered by the terms of the existing settlement for Scottish litigants.*" As for funding, there was already a possibility that the Macfarlane Trust would "*need to be topped up to meet all outstanding claims*" as the £42 million was almost exhausted, and the additional costs of the extended Category G cases would "*have only a minor effect*". Mr Tucker added that in the event of an "*overspend*" by the Trust, "*we can expect DofH to ask the territorial Departments*" for contributions "*in proportion to number* [sic] *of claimants*" but the amount "*should not be significant*".

[91] Solicitor at Balfour and Manson.

659. Mr Tucker wrote to Mr Dobson the following day to explain the proposal, which he estimated would apply to around 15 possible cases [SCGV0000235_139]. It would involve:

> *"redefining those eligible for Category G in Scotland to spouses, partners or parents who carry out nursing functions. It would exclude close relatives (such as siblings) and would be limited to those cases which have been considered legally prior to 13 December 1990 either because or other claimants were present at the consultations between the legal adviser and the haemophiliac litigant or alternatively where the haemophiliac had specifically sought legal advice about the position of his or her spouse, partner or parents in relation to his or her claim."*

660. Mr Dobson responded on 11 October 1991 to indicate that the proposition to limit the interpretation of Category G cases "*to those that had been legally considered before 13 December 1990*" was an "*acceptable way of resolving the problem with minimal risk of reopening the issue in England*" [SCGV0000235_130]. He expressed hope that the SHHD would be "*able to persuade*" the Scottish Solicitors Steering Group of the merits of the proposal. Mr Dobson ended by indicating that the DoH was "*likely to seek contributions*" from the SHHD towards the "*overrun*" of the Macfarlane Trust as a result of this extension.

661. In light of the agreement between the DoH and SHHD, it appears that that it was not necessary to finalise and submit a draft ministerial submission, prepared by Mr Tucker, on this issue [SCGV0000235_143].

662. Mr Henderson put the offer to extend Category G to the Scottish Steering Group on 14 October 1991 [SCGV0000235_127]. However, it was some time before all of the claims were settled.

663. A letter from Mr Canavan (DoH) to Mr Williams of the Macfarlane Trust on 5 February 1992 on Category G claims suggested that the "*initiative*" now rested with the plaintiffs' solicitors "*to examine their records and notify the Department of the cases*

that might be entitled to payment" [MACF0000083_106]. He noted that the SHHD was not surprised that claims had not yet been put forward as the firms involved were busy with other matters.

664. Contact between the SHHD and the solicitors involved appears to have resumed in late February 1992 and to have continued until around March 1993, when progress again paused as the SHHD sought Treasury approval for the settlement payments (see, for example, the documents at [SCGV0000235_072, SCGV0000235_071, SCGV0000236_135, SCGV0000236_175 and SCGV0000236_174]).[92]

665. On 26 July 1993, Mr Panton drafted a letter to the Treasury seeking approval for the payment of compensation to 19 Category G claimants in Scotland [SCGV0000236_166 and SCGV0000236_167]. Mr Aldridge (of the SHHD Finance Division) proposed a more concise draft on 30 July 1993 [SCGV0000236_107].

666. A minute from Mr Henderson to Mr Panton on 2 August 1993 made it clear that there had "*now been an agreement between the Department and the Steering Group*" in relation to Category G cases [SCGV0000236_104]. Mr Henderson proposed that the letter to the Treasury might be altered to reflect this, as all that was needed was to notify the Treasury that the SHHD was "*calling up an authority previously granted*" rather than seeking authority to make such payments.

667. Correspondence with the Treasury appears to have continued throughout the remainder of 1993 and early 1994, until the Treasury confirmed in on 28 February 1994 that the Category G payments could be treated as ex gratia or extra statutory (see, for example, [SCGV0000236_083, SCGV0001032_026, SCGV0000236_080, SCGV0001032_025 and SCGV0001032_022]).

668. On 3 March 1994, Mr Henderson wrote to Balfour and Manson, explaining that the Treasury had provided clearance for payments to be made to the outstanding Category G claimants and providing revised drafts of the letter of acceptance

[92] See also the summary in Mr Henderson's 3 March 1994 letter [SCGV0001032_017].

undertaking [SCGV0001032_017]. The firm responded on 10 March 1994, accepting the revised drafts [SCGV0001032_015].

669. A letter from Balfour and Manson to Mr Henderson on 28 March 1994 explained that the firm hoped "*to be in a position to forward the completed undertakings and letters of acceptance from the various claimants shortly*" and asked for minor clarifications on eligibility and legal fees [SCGV0000236_144]. Mr Henderson responded on 29 March 1994 [SCGV0000236_145].

670. In a 5 April 1994 minute to Mr Wildridge, Mr Grant (Solicitor's Office) reported his understanding that "*the claims could be settled in the next few weeks*" [SCGV0000042_174]. By 15 April 1994 Mr Wildridge was writing to Mr Henderson about the eligibility of specific cases [SCGV0000236_059] and a manuscript note on the page suggests that payment authorisation for the claims had been raised on 30 March 1994.

671. The position expressed in a letter from Lord Fraser of Carmyllie (Minister for Home Affairs and Health in the Scottish Office) to Malcolm Rifkind MP on 21 April 1994 was that officials in the SHHD were "*making arrangements for all eligible claims to be settled in the next few weeks*" [SCGV0000042_170].

Compensation for HIV infection through blood transfusion

Initial consideration

672. Around the time of the additional payment to the Macfarlane Trust in November 1989, consideration was given within the SHHD to the question of compensation for patients who had been infected with HIV through blood transfusions. An early example of the SHHD's position can be seen in a letter from Dr McIntyre to Dr Porter Boveri of the Tayside Health Board in December 1989, confirming that, while it had been decided to make a further ex gratia payment to haemophilia patients, there was "*no intention to extend the scheme to other groups*" [SCGV0000230_062].

673. This issue was revisited in the SHHD in early 1990, following a letter from Allan Stewart MP to Mr Forsyth regarding a constituent who had contracted HIV from a blood transfusion and was seeking financial support.[93] A draft response appears to have been provided by Mr Tucker to Mr Forsyth around 28 January 1990, explaining that financial support was not available [DHSC0002840_003].

674. In a 29 January 1990 minute to Mr Tucker, Mr Bearhop (Mr Forsyth's Assistant Private Secretary) explained that the Minister had seen the draft reply and had asked that consideration be given "*to the extension of the scheme to include people infected*" as a result of blood transfusion [DHSC0002840_002].

675. Mr Tucker replied on 6 February 1990 with a minute and a revised draft letter to Mr Stewart [DHSC0002840_018]. He set out two grounds on which a campaign for such financial help had been resisted in the past: that haemophiliacs differed from recipients of blood transfusions in that they already suffered from a disability affecting their employment, mortgage and insurance prospects; and that the hereditary nature of haemophilia could mean more than one member of the family was affected. Mr Tucker noted that the number of people reported to have been infected with HIV as a result of blood transfusion in Scotland was 12, and that the campaign for such patients to receive a payment seemed to be starting up again.

676. Mr Tucker also recorded that the SHHD had been in touch with the DoH and there were "*no plans to extend the remit of the Macfarlane Trust to cover non-haemophiliacs who have become HIV infected. There has never been a system of 'no fault' compensation for medical accidents under successive Governments. The Scottish Office could not adopt a policy which would undermine the stance taken by other UK Health Departments*".[94]

677. Mr Bearhop responded on 9 February 1990, relaying that Mr Forsyth felt that some of the arguments in Mr Tucker's minute – relating to the differences between haemophiliacs and other patients – should not be adopted [DHSC0002839_015]. The

[93] The letter from Mr Stewart is not available but its contents are referred to in other documents.
[94] A manuscript note at the top of this document seems likely to be Mr Forsyth's and to reflect the comments provided by Mr Bearhop on 9 February 1990.

minute added: "*His view is that if haemophiliacs are already disadvantaged vis a vis mortgages etc then people who are HIV positive following blood transfusion are more disadvantaged.*" Nonetheless, Mr Bearhop noted that the Minister had signed the response to Mr Stewart (available at [DHSC0002840_001]).

Further consideration during the HIV litigation

678. Mr Forsyth re-affirmed his view on this issue a year later, in the context of the settlement of the HIV litigation. In a minute to Mr Tucker on 17 January 1991, Mr Forsyth expressed concern, through his Private Secretary, "*that compensation does not apply to others who have been infected by HIV through deficient blood products but who are not haemophiliacs, eg people suffering from leukaemia who have received transfusions*" [SCGV0000231_017].

679. This issue returned to the SHHD in the spring of 1991. Between December 1990 and March 1991, the DoH had been involved in correspondence on the possibility of making such payments with solicitors representing patients infected with HIV through whole blood transfusions in Scotland [DHSC0003657_119, DHSC0002851_012 and DHSC0014965_087], as well as with Samuel Galbraith MP [DHSC0014966_144]. The most recent letter from the solicitors' firm was addressed to Virginia Bottomley and was dated 20 March 1991 [DHSC0014965_087].

680. When the SHHD became aware of this correspondence, it sought advice from Mr Henderson, who responded in a minute on 18 April 1991 [SCGV0000233_047]. In Mr Henderson's view, the DoH should not have commented on this matter as the claims were "*made and addressed to the Secretary of State for Scotland*". He then considered the argument, advanced by the DoH in correspondence, that a distinction should be made between haemophiliacs and people without haemophilia, and that the former had a stronger claim to compensation because their underlying condition meant that they were not in a position to insure or build up savings in order to provide for their dependants. His view was that this was "*in no way a legal argument*" and "*a moralising position relating to what people perhaps ought to have done*", which was unlikely to "*secure a sympathetic hearing from those acting on behalf of these particular claimants*".

681. Mr Henderson was also critical of an argument put forward by the DoH to the effect that it may be more difficult for patients who had received blood transfusion to establish that their infection was caused by the transfusion than it would be for infected haemophiliacs.

682. Mr Tucker subsequently asked Mr Henderson to advise on a draft minute to the Secretary of State and Mr Forsyth on this issue. Mr Henderson did so in a minute on 25 April 1991, indicating that since his 18 April minute, an article had been published in The Observer which included a comment that "*the distinction between the cases of the haemophiliacs and those infected through normal surgical procedures*" was "*such patent nonsense as it is extraordinary that it should have been seriously put forward*" [SCGV0000509_027].

683. Mr Henderson went on to address the difficulties plaintiffs would face in proving a causal connection between their transfusion and HIV infection where – as in a previous case – the Government prevented disclosure of records that would allow the donor to be identified. He commented that, if evidence were "*available by which the causal connection*" could "*clearly be shown between the infection and a transfusion*", it would be "*verging on the devious to suggest that proving the connection might be difficult and other sources of infection might be involved.*"

684. Mr Henderson further advised that arguments about whole blood victims having had opportunities not available to haemophiliacs were not "*wise*", as the victims of whole blood transfusions were "*equally economically disadvantaged as are haemophiliacs*". In his view, it was "*a strange proposition to assert that because somebody starts off in a weaker position then they are to be given protection when they are injured, even though when another person who starts in a stronger position who suffers an injury becomes equally weak*". He therefore suggested that Mr Tucker hold to "*a comparison of whole blood victims with other victims of NHS treatment*" and not a comparison with infected haemophiliacs, but warned that the SHHD "*may expect to receive escalating criticism*".

685. Mr Tucker advised the Secretary of State and Mr Forsyth of the correspondence between the DoH and the firm of Scottish solicitors in a minute dated 29 April 1991 [SCGV0000233_124]. He noted that the SHHD "*were not consulted on the terms*" of the replies from the DoH, and that it did not consider that either of the reasons advanced by the DoH had substance. On the causation issue, he wrote that "*the difficulties for the pursuer in proving the cause or link would largely be occasioned by the reluctance of Government to allow the pursuer access to blood transfusion records*". He recorded that the Courts had "*already upheld a claim on behalf of the Secretary of State for Scotland that it is not in the public interest that such records should be released*", and that this decision was "*specifically in relation to an application for recovery of those records made by a petitioner infected with HIV allegedly as a result of tainted blood transfusion*".

686. Mr Tucker further advised that the argument that haemophiliacs had a stronger claim for compensation because of their underlying condition should not be "*persisted in*" as it "*necessarily implies some moral judgement on victims who have been infected through no fault of their own*".

687. Mr Tucker also noted that, to date, damages claims from three infected individuals had been received. A medical report already produced for one of them indicated that the transfused blood "*came from an individual now known to be an HIV positive homosexual*". He reported "*increasing media interest in this matter*" and referred to the article in The Observer on 26 April 1991.

688. Mr Tucker further explained that the DoH had consulted the SHHD on a draft reply to the most recent letter from the Scottish solicitors. On the question of whether responsibility for replying should transfer from the DoH to the Scottish Office, he suggested that there "*would be consistency*" in the DoH continuing to take the lead, and advised that "*as the issue of compensation is a UK one we should not seek to take over responsibility at this time in responding to the Scottish firm of solicitors*". He noted that, while legal advice was that the Secretary of State for Scotland should take the lead, this would run "*the risk of drawing the criticism on the Scottish Office.*"

689. The Secretary of State responded, via his Private Secretary, on 1 May 1991 to say that he was "*inclined to let the Department of Health make the running on this awkward issue*" and had "*no particular desire to take over this correspondence*" [SCGV0000509_025].

690. Mr Forsyth's Private Secretary responded the following day to relay that the Minister considered this to be "*an extremely serious matter and that the Government's position is indefensible*" [SCGV0000234_198]. He commented that "*we are in danger of losing a lot of goodwill carping over a small financial obligation; our refusal to release information on records leaves us particularly vulnerable*". He hoped that the Scottish Office "*might try to change the Government's line on this matter*". The Secretary of State's Private Secretary responded further on 8 May 1991, noting that the Secretary of State agreed that this was a serious matter, but also that "*he thinks that the Department of Health should make the running for the Government as a whole*" [SCGV0000234_181].

Government position maintained

691. In the summer of 1991, the MP for Edinburgh West, Lord James Douglas-Hamilton, wrote to Mr Forsyth regarding financial compensation for people infected with HIV from blood transfusions. This appears in part to have prompted a minute from Mr Tucker to the Minister on 17 July 1991, noting that there was "*no doubt that a decision to extend compensation for those people infected with HIV through blood transfusion would be popular and would defuse political and media pressure at present on the Government*" [SCGV0000237_181]. Mr Tucker advised that an Edinburgh firm was leading a national pressure group and that changing position on this issue "*would reduce the risk of embarrassing and costly litigation and criticism for 'forcing people with a fatal infection to go to Court*". It would also bring the UK "*in line with Norway, Sweden, Denmark, Australia and Canada*".

692. Mr Tucker went on to set out a number of reasons against providing such compensation, including the following:

"However a further concession will send a message that the Government will compensate if faced with an orchestrated campaign and it would be difficult to establish a credible ring-fence to prevent further placement movement towards a general no fault scheme for medical accidents. The extension of financial help to the blood transfusion cases would make it impossible to justify withholding it from those few who have become infected with HIV through tissue or organ transplants. It would also increase public pressure for compensation for other diseases transmitted through blood and blood products. A number of haemophiliacs have hepatitis and while few haemophiliacs will die as a result of hepatitis there are some early indications that those excluded from the HIV settlement may seek to be compensated."

693. Having set out some of the difficulties relating to the cost and process involved in a compensation scheme, Mr Tucker commented that it "*would be difficult therefore to take a separate Scottish initiative if this was considered by Ministers to be advantageous*". He added that the Secretary of State for Health had "*reviewed the policy on compensation for blood transfusion recipients with HIV last month*" and it was understood that "*the current stance of resisting requests for similar treatment to haemophiliacs with HIV is being maintained*". Mr Tucker enclosed a draft reply to Lord James [SCGV0000237_182] and concluded: "*We assume the Ministers will wish to endorse the Department of Heath line*".

694. Lord James later forwarded further representations from his constituents [SCGV0000041_151]. Mr Tucker (after receiving advice from Mr Henderson on the SHHD's role in patients being warned of possible risks [SCGV0000041_130]), minuted the Minister on 22 October 1991 to advise that the SHHD had confirmed with the DoH that there were still no plans to extend the special financial help to haemophiliacs and enclosing a draft reply [SCGV0000041_120].[95]

695. By November 1991 claims had been received by the Scottish Office's Solicitor's Office for HIV infection from blood transfusion, as recorded in a meeting

[95] Mr Tucker minuted again on the next day to say that Lord James's constituent had "*now indicated that he considers the correspondence can be terminated and we would agree*" [SCGV0000041_114].

between the SHHD, SNBTS and Central Legal Office on 5 November 1991 [SCGV0000237_094]. Mr Tucker reported at the meeting that "*the Government line remained the same and that there were no signs of DOH opening up compensation to non-haemophiliacs*".

The decision to compensate people infected through blood transfusions

696. On 2 December 1991, Mr Waldegrave wrote to the Chief Secretary to recommend a change of policy, and that payment should be made to people infected with HIV from blood transfusions and their families [DHSC0002921_009]. He suggested that this could be done in two ways: first, "*by giving them the same as we have to the haemophiliacs and their families in the out of court settlement*"; and second, "*by also giving them the earlier help provided to haemophiliacs including if we can arrange it access to the original Macfarlane Trust*". He proposed the second of these options and estimated the cost to be around £12 million. Mr Waldegrave hoped "*that the other Health Departments will be able to make a contribution in respect of cases arising in their countries*", with the rest being met by the Treasury from the Reserve. The letter was copied to the Secretary of State for Scotland, Ian Lang.

697. The SHHD immediately began to consider the budgetary consequences of this proposed payment. The Chief Executive of the NHS in Scotland, Mr Cruickshank, expressed the view that funds "*should come out of HCH General*"[96] and not the CSA budget [SCGV0000237_100]. On 9 December 1991, a draft minute from Mr Tucker to the Secretary of State was circulated to the Finance Division and Solicitor's Office for their comments [SCGV0001031_070]. It indicated that the SHHD "*would have preferred that the Treasury met the whole costs*" but if necessary, "*would try to find the money within the cash-limited Health Vote*".

698. Manuscript notes on the cover page of the minute suggested that the SHHD could find the £300,000 "*from Vote 26 if needed this year*" and that it "*still had £0.3m on CSA unallocated*" [SCGV0001031_070]. However, Mr Rushworth was of the view

[96] HCH would appear to stand for Hospital and Community Health services, see [SCGV0000299_001].

that the SHHD "*should not reveal to the Treasury that we can definitely find savings in the year's Vote*" [SCGV0000237_095].

699. In an 11 December 1991 response to Mr Tucker's draft minute, Mr Henderson noted that it said nothing about the "*floodgates argument*" and that he was unsure how Mr Tucker proposed to deal with such an argument [SCGV0000112_134]. In light of the Secretary of State's position on the disclosure of blood transfusion records, he advised that it would be "*dangerous… to be too strong in justifying the extension of the HIV haemophiliac settlement to HIV whole blood victims only by reference to the difficulty in establishing causation because of the public interest immunity claims put by the Lord Advocate*". He also commented that "*[o]bviously Hepatitis C cases are in almost exactly similar position to HIV whole blood victims*", and that he expected that patients infected with hepatitis C "*and other blood transfusion injury victims*" were "*likely to seek redress from the projected settlement*".

Decision by SHHD Ministers and implementation

700. Mr Tucker's finalised minute and a proposed letter to the Chief Secretary were provided to the Secretary of State and Mr Forsyth on 11 December 1991 [SCGV0000237_089 and DHSC0002921_009]. The minute recommended that the Secretary of State agree to the proposal of compensating patients who contracted HIV from blood transfusions, as there was "*considerable public sympathy*" for them, "*the media is sympathetic*", and the arguments defending the differences between haemophiliacs and this group of patients had "*increasingly been recognised as untenable*".

701. Mr Tucker suggested that a "*settlement on the basis of that agreed for the haemophiliacs would however present a number of difficulties not least in validating who would be eligible*". The anticipated cost to Scotland of the proposal was in the region of £900,000. The SHHD "*would have preferred that Treasury met the whole costs since our contribution would divert funds from other health care priorities*", but if the Treasury insisted "*on a contribution as a prerequisite to an agreement then we will try to find the money within the cash-limited Health vote*".

702. On 13 December 1991, Mr Tucker suggested to Mr Collier (Finance Division) that, if the Treasury agreed to pay thirds of the estimated £900,000 settlement figure, he "*may have to find £300,000 from the HCH Vote*" for the following year [SCGV0000237_083].

703. On 12 February 1992, Mr Tucker informed Mr Cruickshank that the Prime Minister would be announcing the payment scheme the following day [SCGV0000237_026]. Mr Tucker was awaiting details from the DoH on the scheme's operation, and commented that "*[a]s in the past, DOH have taken the lead on this and our influence on the detail of the policy is relatively small*". He also wrote that the Treasury had refused to fund the payments from the Reserve and expected the SHHD to cover the Scottish element of the scheme. He estimated costs as between approximately £1 million and £2 million "*depending on how many cases come out of the woodwork*". The SHHD had "*made no provision for this settlement*" and would "*have to raid other budgets next year*".

704. A manuscript note on the minute recorded that the SHHD would be meeting with Mr Henderson to discuss whether there was a need for a separate expert panel to determine claims in Scotland [SCGV0000237_026]. It appears to have been decided that there was such a need, and in March 1992 the SHHD was involved in inviting experts to accept appointment to the panel [DHSC0002654_002]. It would consist of "*two medical practitioners and one legally qualified chairman*" to decide "*difficult cases where there is doubt or dispute about any aspect of the claim*".

705. On 14 February 1992, Mr Tucker provided Mr Forsyth with draft replies to a number of MPs with whom he had corresponded previously, including Gavin Strang MP, informing them of the decision to extend financial help to people infected with HIV from blood transfusions or tissue transfer [SCGV0000041_161]. A response was sent by the Minister to Mr Strang on 17 February 1992, setting out details of the scheme [SCGV0000041_087].

706. In March 1992, the SHHD liaised with the DoH to ensure that the scheme in Scotland was compatible with the equivalent in England and Wales and that the timetables for dealing with applications would coincide [SCGV0000041_072].

707. On 9 April 1992, Mr Tucker wrote to Mr Cruickshank to seek his approval of the Scottish scheme [SCGV0000239_024]. The minute set out a detailed explanation, including any differences between the English and the Scottish schemes, the procedure by which payments would be made and the undertaking that claimants would be asked to sign. According to Mr Tucker, the scheme in Scotland, unlike the English one, did not require an undertaking discharging the Secretary of State of liability for infection with hepatitis. He explained that the SHHD considered itself "*to be bound by the terms of the haemophilia settlement which did not limit an applicant's right in connection with hepatitis infection. We have had strong representation against extending the undertaking into this area*". The SHHD's "*medical and legal advisers*" had specifically advised in support of excluding references to hepatitis in the undertaking.[97]

708. The scheme was approved and signed in Scotland on 10 April 1992 [DHSC0002703_001]. It appears that the DoH were not in a position to do the same with the English equivalent on the same date, and asked on 10 April that the SHHD "*delay further action*" on the scheme "*pending approval of theirs*" [SCGV0000238_029]. Mr Henderson wrote to Mr Tucker to advise that this was "*not a course that is open to us now*" as the scheme had been "*made and is operational*". He did not recommend that the SHHD "*unmake it*" because the solicitors in the Steering Group were aware that the scheme was operational, although public notice could be delayed. Mr Henderson suspected that "*if the boot had been on the other foot the Department of Health would not have paid one blind bit of attention to us*."

709. In a minute to Mr Forsyth's Private Secretary on 15 April 1992, attaching a draft reply to a further letter from Mr Strang, Mr Tucker wrote that the SHHD expected claims to be made "*now*" and recorded that "*the intention is to give high priority to processing these and for payments to be made as soon as possible*" [SCGV0000041_046].

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[97] Further research is being carried out on this issue.