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Inquiry Witness Statement (Topic B4) John Cash

Background Notes

1.00 Introduction

1.01 It has always been my view that the overall management of the UK's blood transfusion services' responses to HIV/AIDS was a matter of some concern and this was made known to SHHD [SNB.005.7304] [SNB.013.2233] [SNB.011.2362] [SGH.002.7524]. The areas of most concern were (a) a lack of effort to ascertain whether there were some safer options with regard to the purchase of commercial coagulation factor concentrates (b) delays in the generation of new guidelines on donor selection (c) delays in assessments of HIV donation screening kits (d) insufficient effort to examine the efficacy of HIV confirmatory tests and (e) insufficient effort to develop alternative donation testing sites for non blood donors.

1.02 Before responding to the specific B4 questions/points supplied by Ms Lovell, I believe it would be helpful to provide some further general background information on topics c-e above, as seen from my perspective. As these points are considered it is evident that throughout the1980s the answer to the question: **who had the duty of care with regard to the safety of blood and blood /plasma products in the UK?** was unclear. This lack of clarity and reluctance by SHHD to engage in dialogue directed towards resolution was a cause of significant operational difficulties which extended well beyond the period covered by topic B4.

2.00 **Donation Screening Test Kit Evaluations**

2.01 In February 1984 the SNBTS Directors advised SHHD that there was an urgent need for the UK Departments of Health to work together to ensure that appropriate steps were taken to expedite effective responses that would ensure, as much as possible, the safety of blood/blood products in the face of the new threat of HIV/AIDS [SNB.004.8639].

2.02 Some time later in early 1984 I found myself visiting Professor Robin Weiss's laboratory at the Chester Beatty Institute, London. The purpose of this visit was to explore whether Weiss's team could supply the SNBTS with aliquots of HIV to enable PFC to undertake in vitro virus inactivation validation studies [SNB.007.5427 and SNB.007.4920]. However, I also noted that the Weiss team had developed a RIA to anti-HIV. At that time I was only aware of the developing commercial ELISA programmes in the US.

2.03 It seemed to me that the Chester Beatty Institute's HIV cultures and assay were important potential developments and I called Dr Gunson to brief him and discuss how best the UK BTS might respond. I discovered that Dr Gunson was already aware of the Weiss team's assay and was strongly in favour of it being commercially developed as a RIA and marketed by BPL. In the face of the advanced position of the more attractive ELISA technology in this field, I did not share his enthusiasm for a RIA approach nor BPL's involvement. Never the less we agreed that Dr Gunson would forward a proposal to DHSS that the UK BTS should establish an assessment of the Chester Beatty Institute assay alongside those ELISA assays being commercially developed. I was to discover that, after consultation with others, Dr Gunson wrote to DHSS in July 1984 advising that a NBTS (not UK BTS) technical team should assess the Chester Beatty assay as soon as possible [SNB.006.5978]. I was disappointed that Dr Gunson did not mention including an assessment of available US ELISA assays in the proposed evaluation programme, excluded any SNBTS involvement and did not copy his letter to me!

2.04 Dr McClelland kindly sent me a copy of Dr Gunson's July letter to DHSS and throughout the late summer/autumn of 1984 I made repeated efforts to ascertain whether he had received a response from DHSS. It soon became apparent that there were difficulties. It appeared that both his passion for a RIA technical option and that the kits be manufactured in BPL had been challenged. Indeed, I had the impression that much precious time had been wasted in 1984 with internal civil service wrangles on this topic rather than pressing ahead with assessing available commercial HIV donation screening kits which were already under scrutiny by the FDA. As I recall, by December 1984 we knew Dr Gunson had lost the battle: the Chester Beatty assay project had been handed by Ministers to Wellcome Diagnostics Ltd and they (Wellcome) had (I believed wisely) rejected RIA in favour of ELISA.

2.05 By late December 1984 there was deep concern among the SNBTS Directors. Almost 12 months had gone by since they had advised SHHD to promote urgent inter-Departmental action directed to ensuring the safety (with regard

to HIV) of the UK blood supply. Moreover, we had evidence that the FDA was now well advanced in its assessment of HIV donation screening kits, which was later published [PEN.017.0651]. As far as we could judge there was no evidence that our pleas for interdepartmental collaboration was occurring. We were also concerned that the official selected by SHHD to liaise with DHSS in this area was a medical officer with no knowledge of blood transfusion matters, no past or present operational contact with the SNBTS and, as far as we were aware, no line management links with Dr Bert Bell or Dr Archie McIntyre (SHHD).

Finally, there was concern that the policy development priority in this area for the next 6 months might not be the assessment of existing commercial kits and expediting the introduction of UK wide donation screening, but actions directed towards enabling Wellcome Diagnostics to catch up. The extent of the catch up required, as of 1 January 1985, seemed substantial [SNB.005.9501].

2.06 There was no doubt that in December 1984 a priority for the SNBTS was the evaluation of developed and developing commercial HIV donation screening kits. In this regard we believed this evaluation should be done by UK BTS technical staff who had extensive experience of large scale donation screening and that the key information urgently required was specificity. We also believed, for the sake of our donors and our donor support staff, more technical effort was needed in the area of confirmatory testing [PEN.017.0649].

2.07 An analysis of the state of play, as seen by the SNBTS Directors at January 1985, was conveyed to SHHD on 24 January [SNB.005.7304]. In the earlier weeks of January the Directors had met and decided to abandon the notion of a joint UK approach and instead mount an independent SNBTS evaluation of the commercial HIV donation screening kits as soon as possible. This decision was consolidated and conveyed to colleagues and SHHD on the 25 January [SNB.005.9713]. I recall we had made it clear to manufacturers that if they wished their kits and associated equipment to be evaluated by the SNBTS then they would have to be supplied free of charge. As I recall, this they readily agreed to. Thus the only significant cost for this evaluation would be modest overtime payments for our technical staff. Once again our primary first duty of care at this time was to acquire local data on the specificity of the screening kits, as the current information (some verbal) from the US on this issue had been confused, with reports of screen positive rates in low risk blood donor like populations ranging from 1 - 10% [LIT.001.0374 at page 523] and [SNB.004.9195].

2.08 Some days after 25 January I was invited to discuss the situation with Dr McIntyre (SHHD). Dr McIntyre made it clear that SHHD was strongly opposed to the prospect of SNBTS undertaking its own kit evaluation. He further advised that SHHD had given an assurance to DHSS that they were content with the proposition that HIV kit evaluations in the UK would be managed by DHSS, and that the commencement of routine HIV donation testing in Scotland would be determined by Ministers, on the advice of DHSS, and that this date would apply across the UK. I recall that Dr McIntyre also advised that these views would be transmitted to the CSA. As I recall, I thereafter consulted with Dr Mitchell and Dr McClelland and we agreed that, in view of the hostile reaction of SHHD, this SNBTS initiative should be

stood down. This proposal was later conveyed to and supported by the SNBTS Directors. This position may have given rise to my letter to the CMO Scotland on 12 February 1985 [SNB.013.2233].

2.09 Some time after January 1985 it emerged that DHSS were moving to establish an HIV donation screening test kit evaluation programme. In the subsequent months, largely through access to EAGA meetings, I came to the conclusion that this long delayed DHSS managed evaluation programme was less than satisfactory. My concerns can be summarised as follows: (a) UK BTS scientific/technical experts, including the DHSS and SHHD consultant advisers in blood transfusion, were excluded from the design of the programme. (b) The design was undertaken by invited (by DHSS) virologists with no experience in, or responsibility for, large scale donation screening. (Of further concern was that one of these virologists was heading the Wellcome Diagnostics's HIV ELISA programme and that this was known to all planning team participants). (c) The expert virologists, with DHSS support, insisted that there was to be an independent (of UK BTS) preliminary scoping study, undertaken in PHLS laboratories and supervised by them. This phase 1 study had first to be completed before UK BTS teams could commence their evaluation. I believed that much of this preliminary study, which took nearly 6 months to complete, was unnecessary and those elements of interest to the UK BTS could have been done as well and in much less time by a UK BTS team and more certainly by a SNBTS team, as proposed in January 1985. (d) Because the DHSS invited virologists had no experience in large scale donation screening, the design of this early scoping work was less than satisfactory in terms of UK BTS requirements [SNB.001.0432] and some of the work had to be repeated, giving rise to further delays. (e) It was of interest that the preliminary scoping study (phase 1) took almost 6 months and the field evaluation (phase 2, done by UK BTS teams) 6 weeks. (f) We were later to discover that this whole programme appeared to be dogged by lack of financial support from certain DHSS budget holders [SNB.005.0191]. It was also dogged by what seemed to be an extra-ordinary laissez faire attitude among senior DHSS managers; one (the Chairman at the May 1985 EAGA meeting) declared that the preliminary evaluation study (which began in March and involved only 220 blood donor sera) should 'not be rushed' [SNB.001.0365 at 5.2]. Professor Arthur Bloom attended this meeting and rightly conveyed both at the meeting and in a letter to the Chairman (Dr EL Harris) his concern at the lack of urgency in clearing obstacles to the introduction of full routine HIV donation testing in the UK [DHF.002.5510]. Professor Bloom subsequently joined forces with the HCDs of Glasgow and Oxford to put this view into the public domain [LIT.001.0333]. I am not aware whether Professor Forbes discussed this with his SHS HCDs colleagues and conveyed these concerns to SHHD. Certainly I have no recollection of him discussing his concerns with me. (g) Finally, there were no provisions in this DHSS sponsored evaluation for studies on confirmation testing.

2.10 To the best of my recollection, the orderly and leisurely progress of the 1985 HIV kit evaluations in the UK abruptly changed with the publication of concern at its slow rate of progress [LIT.001.0333]. As a consequence appropriate UK BTS evaluations were not undertaken. Indeed the only evidence I have that some form of RTC evaluation was done appears in a NBTS/RTD's Meeting Minute

of January 1986 [SNB.011.2327 at item 9]. It still is my view that HIV donation screening was introduced in the UK without the most appropriate consideration of the welfare of blood donors.

2.11 There were frequent occasions in late 1984 and the whole of 1985 when it was embarrassingly clear that DHSS had major problems in agreeing the funding of both the evaluation and implementation of HIV blood donation screening. It is not known whether SHHD were required to make a financial contribution to the PHLS phase 1 study. But there seemed no doubt that SHHD had agreed in advance that ring fenced funding for routine HIV donation screening in Scotland would be available when required. That said SHHD used this position to ensure that it retained (through the CSA's Finance Branch) control of the start date [SNB.005.7915]. As far as I could judge, the main burden of the financial difficulties south of the border impacted most severely on confirmatory testing and the quality of the donor counselling programme. They commenced routine testing without an agreed strategy for confirmatory testing [PEN.017.0653].

3.00 Confirmatory Testing

3.01 Unlike their English counterparts, SHHD recognised that there was a need to invest in specialist confirmatory testing and donor care services. This proved to be a most significant policy decision and in due course led to the establishment of the SNBTS Microbiological Reference Centre in 1989. This development gave much value to our contract (to do no harm) to Scottish blood donors. This did not take place south of the border and became a particularly embarrassing issue when HCV donation testing emerged.

4.00 Alternative HIV Testing Sites

4.01 I recall it was in February 1985 that the FDA expressed its concern that there was a danger to the blood supply if individuals, who believed they were at risk of HIV infection but were not blood donors, took advantage of the HIV screening of donations soon to be instituted in the US simply to ascertain their HIV status. The danger was seen primarily at that time in the context that there was insufficient information on test sensitivity, but later it became apparent that a 'window period' (anti-body negative but viraemic) existed for all who became infected. The FDA therefore advised that in every locality easy access to alternative HIV testing sites should be established before routine blood donation screening was commenced. Through the good offices of Dr Ian Fraser (Chair NBTS Directors Committee) SNBTS Directors persuaded their NBTS counterparts to join with them in exhorting the UK Health Departments to instruct Regional Health Authorities to establish alternative testing sites [LIT.001.0374 at page 524]. More direct contact on this topic from the SNBTS was made to DHSS through EAGA [SNB.001.0430]. I do not recollect a response from SHHD on this issue, but am aware that in July and December 1987 communications were sent to the CMO, Scotland in which concern was expressed that alternatives sites in Scotland had either not been established or

were not working effectively [SNB.013.2889] and [SNB.013.2892]. I do not recall, and have no record, whether a response was received from the CMO to these communications.

Responses to questions/points made by Ms Lovell

SNBTS evaluations

11. In a letter to Dr A E Bell dated 24 January 1985 [SNB.005.7304], Dr Cash noted:

> "The biggest anxiety of the NBTS Directors with regard to this problem is the Scots: that they will unilaterally move to come in line with American proposals. They're right: we are in detailed discussion with commercial (kit) companies, our technical staff are already looking at ways of introducing the technology within existing staff establishments, we have the Western Blot technique (HQ and SE Labs), we are already liaising with local (Communicable Disease) physicians with a view to securing care for our positive donors and we are currently arranging our financial planning accordingly..."

> **Comment: As I recall the primary purpose of this communication of 24 January 1985 was to clarify the policy position of SHHD, to signal to DHSS (via SHHD) that we were gravely concerned with the lack of action with regard to the evaluation of available HIV donation screening kits and to put down a marker that the SNBTS Directors believed they had a professional duty of care and contribution to make in this area.**

12. On 25 January 1985, Dr Cash wrote to Dr Ruthven Mitchell (SNBTS Director Glasgow) [SNB.005.9713]. Dr Cash advised that WBTS should undertake, on

behalf of the SNBTS, initial evaluation studies of commercial HTLV-III antibody kits.

(a) What particular steps had the SNBTS taken with regard to the introduction of HTLV-III screening in Scotland as at 24 January 1985? (b) When the SNBTS was considering its own evaluation, would this have occurred at the same time as the introduction of a commercial test or would a test have been introduced only after the evaluation had been completed?

Response Most of the answers to these question can be found in the Background Notes, above. These can be briefly summarised as follows:

(a) The communication of February 1984 to SHHD [SNB.004.8639], and the interactions with Professor Weiss and Dr Gunson.

(b) If the SNBTS had been allowed to 'go it alone' with regard to the introduction of routine donation screening Directors would have insisted that, in discharging their duty of care to the wider community, this should not take place until local data on specificity had been generated and examined.

13. At the SNBTS Co-ordinating Group meeting on 19 February 1985 [SNB.003.9171] it was decided that Dr Cash's letter should not be pursued at the present time.

(a) Did the SNBTS abandon its own evaluations altogether and await the DHSS evaluations and, if so, why? (b) Was the decision to await the results of the DHSS evaluations made by the SNBTS or the SHHD? (c) What discussions took place between the SNBTS and SHHD regarding this matter?

Response The answers to all these questions can be found in the Background Notes (item 2.08). In brief (a) Yes (b) SHHD (c) the discussions were substantial.

Preference for the introduction of a "British test" into the NBTS

14. At the meeting of the EAGA on 29 January 1985, the preference for a radioimmunoassay was discussed [SNB.001.0002]. The minutes state (paragraph 21) "on the type of test to be used, Dr Gunson said that there was an overwhelming preference for the use of a radioimmunoassay test in the NBTS whilst Professor Zuckerman stressed the need, first, for evaluation of other tests, including the ELISA test".

Comment: Had the SNBTS Directors and their teams been canvassed, I doubt they would have been as enthusiastic for the radioimmunoassay approach, as Dr Gunson believed his NBTS colleagues were. I would also imagine they would have been uncomfortable with the notion that the ELISA technology was somehow 'the property' of American industry. I'm certain they would have welcomed competition from the UK into the market, but doubt whether they would have been enthusiastic that any kit was developed and marketed by BPL. I imagine they would have been of the view that the public interest would have been best served if BPL concentrated on improving its performance with regard to delivering sufficient and fully licensed therapeutic products. Specific words of caution would have come from the WBTS. Much to the consternation of HM Treasury the WBTS had previously criticised the quality of a BPL manufactured HbsAg RIA kit. Finally, SNBTS Directors would have been aware that major lobbying of DHSS officials and Ministers had occurred in 1980, by commercial interests objecting that a public sector facility (BPL) had entered the donation testing kit market [DHF.001.0465 at item 6]. I recall being convinced that the chance of Dr Gunson's proposition being accepted by Ministers in 1984/5 was remote.

15. The subject was also discussed at the 16th meeting of the Central Blood Authority on 1 February 1985 [DHF.003.0219]. The minutes record "the

Chairman stressed that revenue sparing was as important as saving. [X] emphasised that the enzyme assay was a US test and if the UK needed to be converted for enzyme testing it would pose a serious problem for the continuance of RIA testing. It was therefore considered vital that a British test be developed".

(a) Why was there an "overwhelming preference" for the use of the radioimmunoassay test in the NBTS?
(b) Was this preference shared by the SNBTS?
(c) Why did Professor Zuckerman want other tests, including the ELISA tests, evaluated?

Response: Much of the response to these questions can be found in the Background Notes above. In summary, (a) My contact with one of the senior NBTS Directors at the time led me to conclude that the reported 'overwhelming preference' was not based on the outcome of extensive consultations with the NBTS experts or RTDs. (b) There was never any evidence that this RIA preference existed in Scotland but, to be fair, I don't recall it was formally sought (c) I am unable to second guess Professor Zuckerman's reasoning but would imagine, as a recognised world authority on HBV, he was aware that arguably one of the best performing HBsAg donation screening kits was manufactured and marketed by Abbott Laboratories Inc. The technology used for their most advanced HBsAg screening kit was an RIA and, worldwide, it had a large market share. Professor Zuckerman must have believed that a move by Abbott from RIA to ELISA technology for HIV was significant and carefully considered by teams familiar with the donation screening market. He may also have been aware that Abbott were at an advanced planning stage to replace their HBsAg RIA with an ELISA assay [SNB.011.2630] and similar developments were believed to be underway in another major company [SNB.013.0724]. It follows that because of Abbott's sustained outstanding track record then any UK HIV kit evaluation programme should have included ELISA technology. To the

best of my recollection this view was shared by the SNBTS Directors - and, more certainly, by Wellcome Diagnostics Ltd.

16. We know that by July 1985 (when the first stage of the DHSS evaluation programme was completed) that Wellcome had switched from a radioimmunoassay to an ELISA test.

(a) Does Professor Cash know when the switch occurred and/or why? (b) What implications, if any, did the switch have for the NBTS and SNBTS? (c) What, if anything, had changed between January/February 1985 and the date of the switch which made it acceptable for an ELISA test to be used within the blood transfusion services when it had not been acceptable beforehand?

Response: (a) No, but I would hazard a guess that it took place some time in December 1984. However, if required, the Inquiry Team could obtain accurate information from Professor Richard Tedder and/or members of the DHSS civil service team (which I believe included Dr Diana Walford) who managed the liaison with Wellcome Diagnostics. (b) The switch proved to be highly significant. The remarkable delays in the evaluation exercise enabled Wellcome Diagnostics to 'catch up' and to such an extent that, by July 1985, it was claimed they had a sound ELISA HIV donation screening kit which later dominated the UK market. (c) Nothing.

Secret Meeting

17. In the letter to Dr Bell dated 24 January 1985 [SNB.005.7304], Dr Cash notes that Richard Lane had advised him that the CBLA had recently written to the DHSS conveying its serious disquiet about being deliberately excluded from a "secret meeting" between DHSS officials, Professor Weiss, Dr Tedder and Wellcome Diagnostics. The Inquiry does not have a record of the CBLA letter.

(a) What was the "secret meeting"? (b) When did it take place? (c) Who was in attendance?

Response **(a) I regret I have no helpful information. No doubt this information could be supplied by Professor Richard Tedder, DHSS or Wellcome**

The Introduction of HTLV-III screening in Scotland

18. On 11 July 1985, the working party of the Regional Transfusion Directors' Committee produced a report, 'Screening of blood donations for anti HTLV-III in regional blood transfusion centres' [SNB.004.9046]. The report stated that routine screening tests should not be introduced until the proposed evaluation in the NBTS of different tests had enabled satisfactory system(s) to be selected.

Comment: **(1) I believe it would be helpful to the Inquiry Team if there was an understanding of the several technical issues regarding the introduction of any form of donation screening. It is my belief that while there seems to be more than sufficient understanding of the importance of test specificity and sensitivity it may not be appreciated that there is a lot of associated and dedicated/specific equipment which comes with use of the kits.**

(2) I am unsure that the substantial challenges of data pick up and handling have yet been fully appreciated by the Inquiry Team. I make these comments because Ms Lovell has rightly referred to satisfactory 'systems'. I am least qualified to comment further on this topic, and if further expertise is required then Dr Brian Dow and/or Mr Archie Barr would be of much assistance. But I think I can advise that a particular kit manufacturer might have an excellent assay in terms of specificity and sensitivity but the associated instruments/devices and

data handling systems were less than optimal - examples of which were published [PEN.017.0653].

(3) It is also noteworthy that the expert virology team by the end of their Phase 1 studies believed that they were able to give sound judgements on specificity, based on studying only 220 donations! There was no evidence that they sought statistical advice on this [PEN.017.0653].

19. A revised corrigendum [DHF.001.7532] altered this: the evaluation should take place but urgency precluded the completion of the NBTS evaluation prior to arrangements being taken for the introduction of routine screening. Directors were advised to make arrangements for the introduction of screening whilst the NBTS evaluation was being undertaken. The selection of kits should be made on the recommendations of the PHLS study.

Comment: I recall from discussions with Dr Gunson, that DHSS saw the UK BTS component of their evaluation programme as a low priority in the steps towards full donation screening. Officials anticipated that kit selection by the UK BTS, when routine testing commenced, would be primarily influenced by the DHSS expert virology team. Of no less importance is that by July 1985 Ministers must have been aware of mounting public concern at the delay in the introduction of full HIV donation screening. I have no doubt they had been briefed following the publication of Professor Bloom's concerns in June 1985 [LIT.001.0333] and this may have given rise to a measure of alarm and perhaps even panic in some political circles.

20. Both the report and the corrigendum stated that the other steps necessary before the commencement of screening were: that reference centres had been established to carry out confirmatory tests on sera giving positive results, and that alternative venues for non blood donors to obtain testing had been established.

Comment: **(1) It is important to stress that much preparative work was required by others in a RTC before routine testing could be introduced – the programme for the care/counselling of screen positive donors, and the handling of large quantities of new information, for instance.**

(2) I don't believe it is correct to conclude that in the Report or Corrigendum the authors state that Reference Centres and Alternative Testing Venues had been established. These were perceived as conditions for the commencement of routine screening and by 14 October had often not been met. Indeed, when the phase 1 report was published on 19 October 1985 the DHSS phase 1 team declared that confirmatory testing arrangements were not in place [PEN.017.0653]. This did not apply to Scotland: full confirmatory testing was in place as was the critically important associated donor counselling and care programmes. The position with regard to alternative testing venues was, and remained, unclear (see Background Notes above) across the UK. Certainly in Scotland I had not seen copies of relevant letters to Regional Health Boards and concern about this issue was still evident up until late 1987 (see Background Notes).

21. The first stage of the evaluation was completed on 30 July 1985.

22. HTLV-III screening of blood donors was introduced in Scotland (and the rest of the UK) on 14 October 1985.

(a) Why did the working party amend the report and recommend that screening tests be introduced prior to the completion of the second stage of the evaluation?

(b) Why was HTLV-III screening not introduced in Scotland until 14 October 1985 given that the first stage of the evaluation was completed on 30 July 1985?

(c) How long did it take to make arrangements for alternative testing venues in Scotland for non blood donors to obtain testing? Who was responsible for arranging alternative testing?

Response: (a) I would suggest this is not an entirely correct interpretation of the Report. My understanding is/was that the authors were signalling that such was the concern of Ministers at the delays that there was now an urgent political imperative to commence detailed planning for implementation in October 1985, in advance, if necessary, of the completion of Phase 2 of the DHSS study. This must have been broadly welcomed by the UK BTS but I suspect there was some anxiety regarding kit selection in the context of specificity – hence the recommended advice on the avoidance of long term contracts. Whilst problems of poor specificity did not subsequently emerge, the absence of a proper Phase 2 study may have been a problem for several kit manufacturers who were excluded from the UK market on the flimsy scientific grounds generated by the phase 1 study team.

(b) The SNBTS was committed by Scottish Ministers to a policy which ensured it complied with arrangements that suited the NBTS (see Background Notes 2.08). The date selected by the NBTS was 14 October 1985.

(c) See Background Notes 4.01

23. The corrigendum recommended that long term contracts be avoided until the results of the NBTS evaluation were available. The minutes of the SNBTS Directors meeting on 2 October 1985 [SGH.001.6412] note that the South East and North regions had only purchased a 3 month supply.

With this in mind, could a short term supply contract have been entered into at an earlier date (ie. whilst the first stage of the evaluation was being undertaken)?

Response: Yes, given that we were permitted to satisfy ourselves that kits available had acceptable specificity and that Scottish Ministers would allow the SNBTS to 'go it alone'. Both were denied (see Background Notes 2.08).

24. The Inquiry team is aware that by the time that HIV screening commenced in the UK (14 October 1985), Ruchill Hospital (Glasgow) and the Clinical Virology Laboratory (Edinburgh) had been established as reference centres to carry out confirmatory testing.

When exactly were these centres established and able to start carrying out confirmatory testing? Who was responsible for establishing them?

Response: I was responsible for approaching Drs Follet (Glasgow) and Peutherer (Edinburgh) to become the first SNBTS reference laboratories. I regret I have no information on timing but clearly recollect that they were up and running by 14 October 1985. This advantageous state of affairs was a cause of some concern to many colleagues south of the border.

25. The minutes of the SNBTS Directors meeting on 2 October 1985 record that the East, South East, North and North East regions had all chosen the Wellcome test by that date.

Which test was chosen for the West?

Response: To the best of my recollection it was the Wellcome test, but this can be confirmed, or otherwise, by contact with Dr Brian Dow and/or Dr Mitchell.

Consideration given to the idea of introducing commercial tests as an interim measure

26. On 21 February 1985, Dr Cash and others from the SNBTS and NBTS sent a letter to The Lancet [SNF.001.3361]. The letter stated "we the undersigned believe that the likely incidence of false positive HTLV-III antibody tests using the current generation of commercial kits in our voluntary blood donor populations will be high".

Comment: After so many years, I'm reluctant to comment on behalf of my SNBTS/NBTS colleagues. But there was no doubt in my mind, after consulting with several US colleagues, that the position in February 1985 with regard to the specificity of the available HIV donation screening kits seemed a little uncertain and somewhat confused. Whilst an early claim that some of the kits had a high screen positive rate [PEN.017.0658] , I was advised by US colleagues that there had been significant improvements, such that by late 1984/early 1985 figures of less than 10% screen positives were quoted [LIT.001.0374 at page 523]. The US team reporting this figure, which was based on the study of over 1000 donations, claimed it would be acceptable provided the donors who were screen positive but confirmatory test negative were reinstated and not excluded from future donating. As I recall this false positive re-instatement approach was considered and rejected by UK BTS as there was at that time lack of confidence with regard to the efficacy of confirmatory tests. It followed that we might be faced with a loss of up to 10% of our donor panel. On the other hand, I recall, from contacts with FDA colleagues, I think in late 1984 that the kits they had recently looked at had screen positive rates of only 1% in a low risk population which would have much in common with our donors [SNB.004.9195].

27. By comparison, Professor Bloom was anxious that one of the FDA licensed kits should be introduced immediately and wrote to the DHSS on 31 May 1985 to convey that view [DHF.002.5510]. With others (Charles Rizza and

Charles Forbes), he wrote to the BMJ to similar effect, his letter being published on 22 June 1985 [LIT.001.0333].

Comment; I must confess to being a little surprised that Professor Bloom's concerns (which I strongly supported) were later put into the public domain. That said, I recall believing that had not Professor Bloom and his colleagues 'gone public' then the UK HIV donations screening programme might have commenced even later than 14 October 1985.

28. It appears that the SNBTS/NBTS were concerned that the effect on donors would lead to a sizeable drop in the supply of blood and blood products.

(a) *What was the SNBTS/NBTS "belief" that the current generation of commercial tests were likely to give a high rate of false positive results based on?*

(b) *What was considered a "high rate"?*

(c) *What, if anything, did the SNBTS/NBTS do to attempt to obtain information from larger blood transfusion services abroad in relation to the operation of the commercial tests?*

(d) *What consideration, if any, did the SNBTS/NBTS give to how the effect on donors/transfusion recipients could be lessened, for example, by introducing testing without any public announcement or by deferring the giving of positive test results until the results had been confirmed by a reliable test method?*

Responses:

(a) I can only comment on my own recollections and these have been summarised above (item 26). The references cited above were all in due course published. But I was privileged to enjoy many other contacts which permitted a flow of information across the Atlantic (see below).

(b) I don't recall this was defined but I'm quite certain that a figure of a 10% loss in our donor panel would have been a cause of concern. It could, for instance, have meant a significant loss of low risk PFC VIII concentrate which may have been replaced by the high risk commercial products - because at that time the introduction of Optimal Additive Solutions (OAS) and plasmapheresis programmes had not enjoyed SHHD support.

(c) I regret that most of my correspondence from the early 1980s was destroyed. But to the best of my recollection, I was in variable contact with David Aronson and Anne Hoppe (FDA), Bill Bayer (Director, Kansas City Blood Bank) Aaron Kelner (Director New York Blood Bank), Alfred Prince (New York Blood Bank) Tom Zuck (Director, US Army Blood Services), Lew Barker (CEO, American Red Cross Blood Services) and Dr Herbert Perkins (Medical Director, Irwin Memorial Blood Bank, San Francisco). I was also in close touch with all the Directors of the Australasian Red Cross Blood Services, partly as a result of our pigtail blood bag development and shared interest in OAS. I was in regular touch with colleagues in the Netherlands (Pim Van Aken and Cess Smit-Sibinga, Directors, Red Cross Blood Services), Finland (Jusi Liekola, Director Red Cross Blood Services), Switzerland (Alfred Hassig, Director, Swiss Red Cross Blood Sevices), France (J-P Soulier, (CEO) and Brachman Habbibi and Doris Demache, Directors CNTS) and Germany (Sigfried Siedl, CEO German Red Cross Blood Services).

(d) The controlling position of DHSS ensured that these options were not considered (See Background Notes 2.08), and in any event I suspect the SNBTS's management team would have regarded such a development as an unacceptably high risk one, with regard to damaging our policy of transparency and position of trust between the Service and its donor panel.

29. In a letter dated 8 January 1985 from Dr McClelland to Mr Madden (Wellcome Foundation) [SNB.005.9501], Dr McClelland states:

"I would emphasise that in my own centre at least, we would be very prepared to use, in the interim, some form of test procedure which might be considered less than satisfactory for a large scale, long term screening programme".

What was envisaged here? Was any consideration given to the idea of introducing one of the US commercial tests as an interim measure at Dr McClelland's centre or more widely throughout the SNBTS?

Response Dr Mc Clelland would be better placed to respond to the first question. The answer to the second is – no (see Background Notes 2.08)

John Cash
08 September 2011