PATIENT INTEREST CORE PARTICIPANTS - SUBMISSIONS FOR THE B4 TOPIC

Ambit of the topic

B4) The decision not to use kits from the United States of America for testing donated blood for the virus as soon as they became available but, instead, to follow a process of evaluation of the kit before any such use

Submissions

1. Whose responsibility was it to introduce screening for HTLV-III in Scotland?

Public health matters in Scotland, such as the safety of blood collection and transfusion, were the responsibility of the Scottish Home and Health Department ("SHHD"), a department of the Scottish Office. The administration of blood collection was the responsibility of the Scottish National Blood Transfusion Service ("SNBTS"). The head of this service was Professor John Cash, the national medical director, who also had responsibility over the period with which this topic is concerned for providing advice to the SHHD about matters relating to blood transfusion in Scotland, including the issue of testing blood for the presence of antibodies to HIV, the virus which caused AIDS and which had been isolated in the USA in 1984. In one contemporaneous memo, it is clear that his advice on these matters was expected to be received by the SHHD "in his role as consultant advisor".[1] As will be discussed in more detail below, it does not appear that his advice on this issue (in particular regarding the possibility of conducting an evaluation of test kits in Scotland) was followed. Funding for blood transfusion initiatives in Scotland was controlled through the Scottish Home and Health Department. It is noticeable that the head of the SNBTS made the point in his statement on this issue that it was not clear at this time who had the duty of care to ensure that blood and plasma was

[1] SGH.002.7292 (12 February 1985)

safe in Scotland.[2] Such a viewpoint highlights the lack of any clear lines of responsibility at the relevant time.

In the autumn of 1984, it was discovered that a group of haemophilia patients in Edinburgh had contracted HTLV III (HIV) infection through their use of blood products. These infections had been discovered by the diagnostic testing of blood samples using systems which were not suitable for routine use by the blood transfusion system. Given that investigations showed that these patients had been infected by Scottish factor concentrates (in November 1984), this was an unequivocal confirmation that HIV had entered the donor population in Scotland. Even amongst the transfusion directors, there was little confidence that the existing donor exclusion measures would prevent infections. This was why Dr McClelland described testing as the "cornerstone of safeguarding the blood supply".[3] Against this background, routine anti-HTLV III screening was not introduced in Scotland until October 1985. This was despite the feeling amongst senior transfusionists that, notwithstanding the practical problems including issues with the reliability of the test kits, there was a need to move as quickly as possible.[4]

It was clear from an early stage in the process of contemplating the introduction of the tests that matters were being handled on a national level through the DHSS. This was despite the separate structures and responsibilities in Scotland, as outlined above. At a meeting of the haemophilia reference centre directors on 10 December 1984, Professor Cash expressed the concern that there was no central body organising the introduction of routine anti-HTLV III testing. This concern was echoed at that meeting by Dr Richard Tedder, who had a central role in the development of tests and diagnostic testing at that stage. There was also concern expressed about the extent to which funding would be made available from the DHSS for the testing programme.[5] That meeting was attended by Dr Alison Smithies of the DHSS who reported back to the department on matters raised.[6] The meeting was not attended by anyone from the SHHD.[7]

[2] PEN.017.1038
[3] Transcript for 29/09/11 (day 50); 8 (8 to 16) (Dr McClelland)
[4] Transcript for 29/09/11 (day 50); 8 (23) to 10 (1) (Dr McClelland)
[5] SNF.001.3850 @ 3852
[6] SNF.001.3850 @ 3851
[7] SNF.001.3850

Many of the issues regarding the routine introduction of anti-HIV testing were identified by this point in time. At the meeting on 10 December 1984 the issues of (a) cost (b) necessary equipment and (c) counselling were recognised.[8] Further, the issues of counselling, false positivity, the possibility of members of high risk groups attending donor sessions for diagnostic purposes were also recognised at a department of health meeting on 14 January 1985.[9] On the latter point it was noted that the views of the expert advisory group (which had not yet met) would be particularly useful.[10]

In April 1984 it was announced by Gallo that the virus had been isolated. However, the Expert Advisory Group on AIDS ("EAGA"), set up to give advice to the government of AIDS related matters including the possibility of routine testing for anti-HIV, did not meet for the first time until 29 January 1985.[11] AIDS had been known about since 1982. Its connection with blood transfusion had been accepted by most by the spring of 1983, at the latest. Its sexual transmissibility and hence its ability to grow from one infection into a wider public health problem was well understood from an early stage as was the likelihood that it would kill its victims (see our submission in the B2 section on the developing knowledge about the disease). The severity of the disease, the lack of treatment and the public health angle were all well understood by 1985.[12] When EAGA did have its first meeting, it was noted that the CMO (who had invited the membership of the group) wished unequivocal advice about the introduction of a screening test to the NBTS.[13] Even then, there was no apparent reference to the timing of that advice or urgency with which it was required.

The apparent lack of a proper national structure for these important matters to be handled was confirmed by Professor Cash in his letter to Dr Bell at the SHHD dated 24 January 1984. The extent of his dissatisfaction about the way in which the AIDS crisis (including decision making about routine testing) was being handled on a national level is clear.[14] He identified the fear in England at this time that Scotland would move unilaterally on routine testing. In Scotland, moves had been made towards getting routine testing introduced by this time including (a) efforts to obtain test kits from US companies (b) technical staff investigating how the tests could be implemented in existing

[8] SNF.001.3850 @ 3851
[9] DHF.002.8776
[10] DHF.002.8776 @ 8777
[11] SNB.001.0002
[12] DHF.002.2250 @ 2251
[13] SNB.001.0002
[14] SNB.005.7304

establishments (c) the ability to conduct the western blot confirmatory tests (d) discussions with communicable diseases experts about care for positive donors (counselling and treatment) and (e) financial planning to accommodate this had been undertaken.[15] This had all been done against a background where Professor Cash did not want to move unilaterally unless it proved necessary.[16] As is discussed in more detail below, it appears that despite (a) these concerns about progress at a national level and (b) steps taken to make progress to counter these problems in Scotland, the SNBTS were required by the SHHD to follow the processes being undertaken in England.

In November 1984, the NBTS Advisory Committee's Working Group on AIDS had advised that routine testing throughout English blood transfusion centres should be introduced as soon as possible.[17] By January 1985, the US test kits were available. The theoretical advice of the Working Group required to be put into practice. The evaluation process started on the same date as the first EAGA meeting (see the letter to the pharmaceutical companies referred to below). That group therefore had no opportunity to give advice on whether an evaluation needed to be done at all. No strategy had been put in place to deal with the kids of matters which the government had already identified as potentially problematic aspects of the routine testing programme. By this time, countries such as Norway had already set up a system for offering diagnostic tests to individuals on a confidential basis.[18] In our submission, the earlier setting up of this expert advisory group would have enabled expert advice to be rendered, decisions taken and strategies formulated which would have enabled the evaluation and introduction process to progress more smoothly and quickly once the US kits became available. The failure to do so resulted in the consideration of the issue of AIDS testing being considered in a piecemeal fashion in 1984 with little real preparation or co-ordination being achieved. Groups which considered AIDS included the UKHCDO, the CBLA, the English and Scottish Blood Transfusion Services (the former of which had a Working Group on AIDS), the Medical Research Council, the Advisory Committee on Dangerous Pathogens and the Communicable Disease Surveillance Centre (“CDSC”). This was a startlingly diverse and unstructured collection.

The priority given to the possibility of a British kit being made available, even over this early period, is discussed below.

[15] SNB.005.7304 @ 7305
[16] SNB.005.7304 @ 7306
[17] DHF.002.2250 @ 2251
[18] SNB.001.0162

2. What was the justification for carrying out an evaluation of the US test kits?

It is apparent from the documentation available to the Inquiry that the DoH did not, in fact, have any statutory authority at this time to insist that US companies have their tests undergo a local evaluation at all. The approach which was devised within the Department was to encourage them to participate with the carrot that their involvement may result in their kits being recommended by the DoH and hence become more attractive to the lucrative UK market. It does appear, however, that the local evaluation was not a formal legal requirement from a licensing perspective.[19]

Test kits from the USA became available in the UK in January 1985. They were subjected to a lengthy UK-wide evaluation process. The kits had been approved and licensed for export by the Food and Drugs Administration ("FDA") in America. From an early stage, it was envisaged that, despite this FDA licensing and the fact that the US kits would have required to undergo assessment there to be licensed, the UK evaluation would be in 2 stages. The initial evaluation would be into the accuracy of the kits as tests and the second stage would involve field trials of the kits in order to ascertain their usability in UK centres.[20] The first stage of the UK evaluation took a significant time to complete and was the main cause of the delay in introducing routine anti- HTLV III testing in the UK until October 1985 (see below). Greater reliance could and should have been placed on the test kit evaluation process which had been undertaken by the FDA on the very kits which underwent such a lengthy UK evaluation. This would have resulted in a significantly earlier introduction of routine anti-HTLV III testing in the UK. Dr Robert Perry was a member of the Advisory Committee on the Virological Safety of Blood later in the 1980s whish advised the UK government on matters including the introduction of testing for the presence of antibodies to hepatitis C. In his evidence to the Inquiry he stated that the UK and other European countries relied on the FDA licensing of tests to give "a high degree of comfort that it had been through a rigorous regulatory process."[21] We take from this that far greater comfort should have been taken from the FDA licensing of the anti-HTLV III kits and that the lengthy first stage evaluation process in the UK was unnecessary.

[19] DHF.002.7016 (a note emanating from the Department of Health dated 30 January 1985)
[20] DHF.002.7016
[21] Transcript for 23/11/11 (day 68); 43 (8 to 12) (Dr Perry)

The main issue with the kits at around the time of their arrival in the UK was with false positivity (low specificity). It was feared that this would give rise to the problems of many donors testing positive on the antibody test who, in fact, were not infected with HIV and would not develop AIDS. This would cause unnecessary concern to them.[22] There do not seem to have been many concerns at this time about false negativity (low sensitivity) meaning that the concern did not seem to be that positive donations would still get through the system, despite the test kits being used.[23] We note that the letter published by the blood transfusion directors in the Lancet in March 1985 expressing these concerns about false positivity (a) gives little detail about the basis on which these concerns about "likely" false positivity with the US kits are based and (b) appears on the same page as an article by US authors who suggest that their research has shown that the use of an ELISA with a confirmatory test should not cause too many false positivity issues.[24]

The requirement of evaluation in the locality where the tests were to be used therefore became the principal concern of transfusionists in January 1985. Dr Perry gave evidence to the Inquiry to the effect that local evaluation of testing kits was needed as there required to be consideration of the possibility of there being a difference in local epidemiology, compared to the kits' place of origin. However, he accepted that local evaluation would be deemed to be overkill now. It does not justify an unlimited delay, especially against a background that there was no testing system in place at all to prevent transmission of a lethal disease.[25] It must be remembered that blood used for transfusions in Scotland and human plasma-derived, non-concentrate bleeding disorder therapies such as cryoprecipitate had no heating regime applied to prevent HIV transmission in 1985. Against this background, there was a very real risk that the disease could be transmitted via these routes. In light of this, we submit that the introduction of routine testing required to be treated as a matter of the utmost urgency. Whilst we accept that some limited form of local evaluation of the US test kits was probably necessary, we submit that this could and should have been done much more quickly, in particular taking account of the data already available about the kits from the FDA. It seems likely that this could have been achieved through local evaluations done by transfusion centres such as the team in the west of Scotland. Though the fact of FDA approval seems to have been a factor which was taken into account in the UK evaluation of the kits, the extensive evaluations repeated here were, in our submission, excessive and did not take sufficient account of the details of the existing

[22] SNB.001.0162 @ 0163 and SNF.001.3355 @ 3357 - 3358
[23] SNB.001.0162 @ 0163
[24] SNF.001.3355 @ 3357 (2 March 1985)
[25] Transcript for 23/11/11 (day 68); 119 (7 to 14) (Dr Perry)

FDA data. Indeed, as is considered in some further detail below, we submit that the evaluation process (against this background) could have been undertaken substantially after the formal start of testing.

3. Could a Scottish evaluation of US test kits independent of the UK wide evaluation have been carried out in late 1984/early 1985?

By December 1984, domestically produced heat inactivated factor VIII concentrate started to be made available by the SNBTS. That step forward for the safety of blood products was achieved before it was in other countries, including England, who did not have a domestically produced factor VIII concentrate at that time. The SNBTS operated independently from the BTS in England and Wales, as is demonstrated by the earlier advances with the heat treatment of factor VIII concentrate so as to inactivate HIV at the PFC. By this time, the risk of HIV transmission through blood transfusion was well known. We would refer to our submission in the B2 section, in particular, on the emergence of the details of the infection of a baby in San Francisco, which was reported in the MMWR in December 1982. Further details of the risks from blood transfusion, in particular the risk to infants due to their unsophisticated immune systems, were known by 1984.[26]

Against this background, the priority turned within Scotland to the introduction of the routine testing of blood for the presence anti-HTLV III. Professor Cash gave evidence to the effect that he was happy that an evaluation of US test kits could and should be undertaken in Scotland in order to facilitate as early an implementation of routine testing in Scotland as possible. Arrangements for access to test kits had been arranged by the time Professor Cash wrote to Dr Bell at the SHHD on the subject of routine testing on 24 January 1985.[27] Professor Cash pointed out that the team in the west of Scotland were "quite outstanding by international standards" when it came to the evaluation of kits.[28] Dr McClelland confirmed that the Glasgow centre was very experienced in this kind of work.[29] There seems little doubt that the Glasgow team could have carried out this evaluation to a high standard and so there was no need for Scotland to await the outcome of the

[26] See LIT.001.0446 - Lancet article dated 22/29 December 1984, in particular the reference to the reports of the infection of 4 infants with HIV in Australia from blood
[27] SNB.005.7304 @ 7305
[28] Transcript for 01/12/11 (day 72); 116 (24 to 25) (Professor Cash)
[29] Transcript for 29/09/11 (day 50); 7 (9 to 10) (Dr McClelland)

evaluation being done in England. Scotland had carried out its own evaluations of the RIA HBsAg test kits and had introduced such a testing regime unilaterally.[30] On 21 January 1985, it was indicated that the Abbott kits were already being evaluated in the west of Scotland.[31]

In our submission, there is no doubt that Scotland, in particular the west of Scotland team, had the experience and materials available to carry out its own evaluation of the US test kits in early 1985.

4. Would such an evaluation process have resulted in HTLV III screening of blood donations coming into force earlier than it did in Scotland?

Professor Cash gave evidence on this to the effect that Scotland having control of its own evaluation would have meant that routine testing could have been introduced in Scotland more quickly as the evaluation would have been completed earlier. He took the view that it could have been achieved in Scotland by the same time as it was achieved in other countries, like Australia and the Netherlands, it would appear by April/May 1985.[32] Professor Cash was of this view even in light of the various practical steps which would have required to have been taken to organise confirmatory testing, counselling etc. In our submission, this claim seems justifiable , especially given that the time of his letter to Dr Bell on 24 January 1985, significant steps had been taken towards the introduction (unilaterally if necessary) of routine testing in Scotland (see above) and the apparently extensive experience within Scotland of carrying out such evaluations for large scale testing.[33]

5. The circumstances surrounding the decision not to proceed with a Scottish evaluation

Professor Cash gave evidence of having communicated to the SHHD that it was his intention to undertake a Scottish evaluation of the test kits. It was his position in evidence that he was told by Dr Archie McIntyre within the SHHD that he was not allowed to do so. In a statement provided to the

[30] SNB.005.7304 @ 7306
[31] SGH.002.7301

[32] Transcript for 27/09/11 (day 48); 185 (7) to 187 (15) (Professor Cash)
[33] SNB.005.7304 @ 7305

Inquiry on this matter, Dr McIntyre refuted this version of events. In his recollection, the decision to await the results of the UK wide evaluation was made by the transfusion directors and not by him.[34] Professor Cash pointed out that the valuation which he had proposed be done by the west of Scotland team was "banned" by Dr McIntyre who ordered that it all be centrally controlled.[35] He also expressed the view in his statement that this topic had been accorded an apparently low priority within SHHD, given that the individual nominated to act as liaison between the SHHD and the DoH on the issue had no experience of transfusion matters at all.[36] He expressed the view that matters such as this had been devolved by SHHD to the DHSS which is why his suggestion that Scotland carry out a separate evaluation of the kits was stopped.[37] As noted above, Professor Cash pointed out that the team in the west of Scotland were "quite outstanding by international standards" when it came to the evaluation of kits.[38]

In our submission, the contemporaneous documents appear consistent with Professor Cash's version of events. We consider the issue of the personalities involved to be largely irrelevant to the determination of which body took responsibility for the failure to proceed with a Scottish evaluation. The important point is that Scotland had made preparations for the evaluation of test kits by the time Professor Cash wrote to Dr Bell on 24 January 1985.[39] Scotland had previously tested the RIA HBsAg kits and had introduced testing unilaterally, as well as having its own donor leaflets in 1984 to exclude high risk donors for AIDS and had developed its own HIV-safe factor VIII concentrate.[40] The next day, Dr Mitchell was instructed to undertake testing of commercial kits by Professor Cash.[41] The SHHD were in discussions with the DHSS at time of this letter at which time the need to co-ordinate with England and the DoH was noted.[42] At the SNBTS directors meeting on 19 February, the plan which had been set out by Professor Cash in his letter to Dr Mitchell was departed from and it was agreed that the UK wide evaluation would be followed.[43] By 21 February 1985 (after the SHHD representatives had met with the DoH ones at the beginning of the month, as referred to in the 21 January memo), it suggested that Scotland should avoid the early introduction of testing.[44] In our

[34] PEN.017.0552 @ 0556-0557
[35] Transcript for 01/12/11 (day 72); 114 (18 to 22) (Professor Cash) and PEN.017.1038 @ 1040 (para 2.08)
[36] PEN.017.1038 @ 1040
[37] Transcript for 01/12/11 (day 72); 116 (1) (Professor Cash)
[38] Transcript for 01/12/11 (day 72); 116 (24 to 25) (Professor Cash)
[39] SNB.005.7304 @ 7305
[40] SNB.005.7304 @ 7306
[41] SNB.005.9713
[42] SGH.002.7301 (21 January 1985)
[43] SNB.003.9171 @ 9177
[44] SGH.002.7282 @ 7284

submission, there appears to have been at this time (a) an inclination on the part of the Scottish transfusion directors to undertake a Scottish evaluation (as they had done before) and (b) a tendency for the SHHD to follow the English plans. Given that the SHHD had the ultimate control over these matters, we can see no reason to doubt that it was made clear to SNBTS that Scotland would be expected to follow the UK wide programme.

It is interesting to note that, at the time when a Scottish kit evaluation as being considered, Dr Perry had mentioned the possibility of en evaluation of evaluating the test kits which had been developed by the Institut Pasteur.[45] It seems that one of the results of the decision not to proceed with a Scottish test kit evaluation was the loss of an opportunity to consider a test from the French cell line. This may have been of interest, given that the different source of that test may have meant that it did not have the same problems as the US test kits developed from the Gallo cell line. Of course, it subsequently transpired that the Gallo cell line was responsible for a degree of false positivity in the tests developed from it, as was explained in evidence by Professor Robin Weiss.[46]

Further, in our submission, the interaction between the officials within SHHD and those within SNBTS (in particular Professor Cash) surrounding the issue of anti-HIV testing caused cracks to develop which widened over the subsequent years. In his own statement on this topic, Professor Cash made it clear that the lack of a clear structure as to the responsibilities of the SNBTS and SHHD which became apparent over this issue was the cause of "significant operational difficulties" which lasted well beyond the period covered by this topic.[47] He also identified the cause of these problems as a "lack of clarity and reluctance on the part of SHHD to engage in dialogue directed towards resolution".[48] This working relationship deteriorated further subsequently, in our submission to the detriment of the safety of patients in receipt of blood and blood products in Scotland. The lack of clear lines of responsibility between the SNBTS and SHHD within the management structure of these two organisations was a matter on which the Inquiry heard evidence in the C4 section from Mr David Macintosh, who was appointed to the post of general manager of the SNBTS in 1990. He recognised this structural deficiency and acted to try to improve it at that time. We submit that the lack of clear lines of responsibility and the deteriorating communication and relationships between these two key

[45] SNB.007.4920 @ 4921 (8 February 1985)
[46] Transcript for 27/09/11 (day 48); 165 (24) to 167 (8) (Professor Weiss)
[47] PEN.017.1038
[48] PEN.017.1038

organisations made a significant contribution to the failure in clear decision making in connection with the evaluation of US test kits in Scotland in 1985 and also in connection with subsequent key events. Instead of learning from these experiences, it is clear from the testimony of Professor Cash that the problems manifested by examination of this topic were not resolved for many years, if at all.

6. Could evaluation have been run in parallel with the introduction of testing?

In a letter from DHSS to regional transfusion directors dated 15 March 1985, it was pointed out that the intention was to carry out (a) an initial evaluation at the PHL and then (b) tests in the field.[49] In the letter, the DoH pointed out that it was keen that screening tests should not be used until the evaluation process was completed. The fact that this is stated seems to make it clear that it would have been possible for testing to start before the evaluation at the PHLS had been done. Dr McClelland was of the view that the failure to start testing from the early months of 1985 (when kits became available) with the evaluation running in parallel may well have been one of the reasons for the overall delay.[50] As pointed out above, the DoH had no legal power to insist that the evaluation take place. Further, Professor Leikola made it clear in his evidence in the C4 section that starting routine testing with one test would not preclude switching to a better one once it became available.[51]

Whilst there may have been a need for evaluation of test kits to be undertaken, we submit that the evaluation could have substantially taken place after the routine commencement of testing. In the absence of other effective measures to exclude positive donations, we submit that such an approach would have been appropriate.

7. What were the reasons for the delay in completion of the UK wide test kit evaluation?

[49] DHF.001.9430
[50] PEN.017.1337 @ 1349
[51] PEN.017.1957 @ 1959

In the first place, it is necessary to recognise that Professor Cash gave evidence in this section concerning serious delays which occurred even before the US test kits became available for evaluation. As is noted below, there was a clear preference in 1984 for an RIA test to be developed in the UK, despite the fact that the ELISA technology in this area was known to be further advanced. Professor Cash clarified in his statement that time had been wasted by this approach which had led to "internal civil service wrangles" in 1984, causing delay when the evaluation of the US assays (already under the scrutiny of the FDA) could have been underway.[52]

The decision having been taken that Scotland would not perform an independent evaluation of the US test kits available in early 1985, the safety of Scottish blood became dependent on the efficient running of the UK wide evaluation being done in England. Letters were sent out to companies which might produce the tests by the Department of Health on 21 January 1985.[53] It is clear from this letter that the process would be controlled by the Department of Health who would make recommendations to the NHS about which tests should be used. The need to avoid unnecessary delay is emphasised. It was not observed.

UK commercial interests

In our submission, the evidence available to the Inquiry discloses that the efficient progress of the UK wide evaluation was seriously compromised by the priority given in decision making to maximising the chances that a UK produced kit would be used for the routine testing of UK donated blood for anti-HTLV III.

Dr Alison Smithies discussed the test kit evaluation in an internal DoH memo dated 21 January 1985.[54] She considered the issue of whether the US test kits would require to be approved by the FDA for consideration in the evaluation of test kits. It was stated that such a stipulation would not be "in Wellcome's best interests in the short term". Professor Cash made it clear in his evidence that he thought that a different emphasis was placed on the significance of FDA approval in connection with

[52] PEN.017.1038 @ 1039
[53] DHF.001.9140
[54] DHF.002.7101

the evaluation of the US anti HTLV III kits than there was later during the evaluation of kits for routine anti-HCV testing. This was based on the fact that the government were controlling the rules to suit the interests of the Wellcome assay being available for consideration in 1985.[55] In our submission, this memo makes it clear that the whole genesis of test kit evaluation was clearly bound up with the desire to maximise the interests of Wellcome and the UK produced kit. This was confirmed by Professor Cash, who stated that the policy at this time appeared to be designed around "allowing Wellcome Diagnostics to catch up".[56] In fact, the very first matter mentioned at the first meeting of EAGA in connection with routine testing was an update from Professor Weiss on the progress with the Wellcome test.[57]

From early on in 1985 it appears that the need to get US companies to agree to be involved in a test kit evaluation (despite the lack of authority to insist upon it) and the need that the evaluation be appraised at a site which had no connection with UK commercial interests in order to maximise the chances of US participation were recognised within the DoH.[58] The "necessity" for there to be a British test was minuted at a meeting of the CBLA on 1 February 1985. Dr Gunson was of the view that it was necessary as the introduction of routine testing with a US enzyme-based test (ELISA) would "pose serious problems for the continuation of RIA testing" in the UK.[59] Patient safety does not seem to have featured in this technical discussion. The Wellcome test which was eventually developed was an ELISA in any event. In an internal DoH memo dated 30 May 1985, it was clearly indicated that it would not be preferable for a timetable to be issued for the availability of the Abbott kit (which by that time was in routine use in the US) as it would be preferable that a British test would progress to the second stage of the evaluation process.[60]

By the time of the meeting of the screening test sub-group of EAGA on 10 June 1985, there was discussion of the possibility of letting the 3 commercial kits due to have been evaluated by the end of June proceed to the field test stage. However, the view that it was better to allow PHLS Colindale to evaluate more tests (including the Wellcome test) appears to have prevailed.[61] An opportunity to

[55] Transcript for 01/12/11 (day 72); 133 (14) to 134 (6) (Professor Cash)
[56] PEN.017.1038 @ 1040
[57] SNB.001.0002 @ 0005
[58] DHF.002.7016 (30 January 1985)
[59] DHF.003.0219 @ 0224
[60] DHF.002.2283
[61] DHF.002.7538 @ 7539

make progress was presented and it was not taken due to the need for more evaluation of the UK test.

In our submission, commercial pressures compromised safety. As Professor Cash had recognised when he made moved to undertake a Scottish evaluation, speed was of the essence to minimise the chances of transmission of what was known to be a fatal disease which could be spread through blood and blood products. The US tests were the first to become available. The quickest route to getting routine testing started was to get the evaluation of those kits underway. Patient safety might be otherwise be compromised.

Concerns about alternative testing venues

The introduction of routine anti-HTLV III testing was clearly delayed due to concerns about the risk that donor sessions would become a place where members of high risk groups would come for a diagnostic test. It was realised that this might be an issue at a department of health meeting on 14 January 1985.[62] In our submission, not enough was done to ensure that alternative diagnostic testing venues would be in place to minimise the chances that such high risk donors would come to donor sessions. This required to be done locally within Scotland. As is noted below, such systems were put in place in other countries (such as Norway) very early in this period.

The results of the tests and the extent to which the testing process was conducted as quickly as it could have been

It also appears clear to us that the first stage of the evaluation was not conducted with an appropriate degree of urgency. This is perhaps best summed up by the fact that on 27 June 1985, Kenneth Clarke (who had been briefed by the CMO[63]) told the House of Commons that routine testing would be introduced "within a few months" and that evaluation was ongoing at the PHL.[64]

[62] DHF.002.8776
[63] DHF.001.7376
[64] SGH.002.6798

This announcement was made in the same week as the public call for an immediate introduction of testing by three senior haemophilia clinicians in the BMJ (see below). As was pointed out by Professor Cash in the C4 section, there is a need in these matters to resist the suggestion that there might be a "holy grail" of the perfect test. Professor Cash acknowledged in his evidence that false positivity was an issue with every test but that it was one which just required to be handled.[65] That the introduction of the tests was left at the mercy of the detailed scientific evaluations going on within the laboratory at the PHL was not a recipe for the speedy, and safe, introduction of testing. What was needed was applied research related to getting the testing up and running and not merely biological research, according to Professor Cash.[66] At this point in time, the evaluation was being done by individuals with no experience of large scale donation testing, according to Professor Cash, which caused the evaluation to take significantly longer than it should have done.[67] Further, there must be serious doubts as to the value which the phase 1 study actually added the fact that it was making large scale assumptions based on studying only a limited number of donations.[68]

Confirmatory testing and simultaneous introduction throughout the UK

Whilst the availability of confirmatory tests and the need for simultaneous introduction of routine testing seem to have played a significant part in delaying the introduction of anti-HCV testing, these factors do not seem to have caused great concern in connection with anti-HIV testing. A Department of Health Memo (a) indicates that confirmatory testing using the western blot technique would be relatively easy to achieve using existing techniques in the PHLS laboratories (the availability of western blot technology was also noted by Professor Cash in his 24 January 1985 letter to Dr Bell) and (b) anticipates the possibility of introducing routine testing in certain "high risk" areas before others.[69] By the time of the meeting of screening test sub-group of EAGA on 10 June 1985, a venue appears to have been decided upon for confirmatory testing.[70] One assumes that this was due to the fact that it was likely that would be relatively few positives for confirmation compared to HCV. In our submission, these factors do not appear to have been legitimate reasons for any significant delay in the introduction of routine anti-HIV testing.

[65] Transcript for 27/09/11 (day 48); 78 (25) to 79 (4) (Professor Cash)
[66] Transcript for 27/09/11 (day 48); 29 (10) to 30 (2) (Professor Cash)
[67] PEN.017.1038 @ 1041 (para 2.09)
[68] PEN.017.1038 @ 1049
[69] DHF.002.0119 (31 May 1985)
[70] DHF.002.7538 @ 7539

8. Did the warnings of haemophilia doctors in 1985 about the delay in introducing of anti-HTLV III testing reduce further delay?

In 1985, haemophilia directors (in Scotland and elsewhere in the UK) lived with the reality of HIV infection amongst their patients. As Dr Mark Winter stated in his evidence, he was called upon to be the nominated AIDS doctor for his region. This was due to his first hand experience with the disease.

In a letter from Professor Bloom (then Chairman of the UKHCDO) to the DoH dated 31 May 1985, he recommended that routine anti-HIV testing be introduced immediately.[71] He stated that his fear about testing not coming in quickly enough (which he appeared to have anyway) had been compounded by the fact that there was a recent article about the increasing prevalence of HTLV III infection in London. He expressed the fear that haemophiliacs using cryoprecipitate, those with leukaemia and those have open heart surgery may be at a real risk of infection. He recommended that one or more of the FDA approved tests should be introduced immediately. By this time, the PHL stage 1 evaluation had not been completed. There seems, in our submission, to be little difference between the position in May 1985 and in January 1985 when the test kits became available in terms of the advancement in knowledge about them. This would suggest that the tests could have been introduced far earlier in the year and that Professor Bloom was not overly concerned about the results of the UK evaluation against a background of FDA approval. He makes it clear that retesting, confirmatory testing and donor counselling could be dealt with later after the donation had been discarded after an initial positive result. This approach seems to balance the urgency of the situation as far as the protection of recipients is concerned whilst also recognising that donors need to be considered too. He pointed out, correctly in our view, that donors would be happy with that arrangement as they were potential recipients of the blood too.

These views were expressed in the BMJ of 22 June 1985 by Professor Bloom and others, including Professor Forbes.[72] The article points out the dangers from cryoprecipitate use and also the fact that there was no heat treated factor IX by this time. The authors indicated that they no longer

[71] DHF.002.5510
[72] LIT.001.0333

considered cryoprecipitate to be safe due to the increasing numbers of infected persons who may be donors. They rated the current risk for blood transfusion patients exposed to blood, cryoprecipitate, red cells, platelets etc at around 1 in 20 (as they may be exposed to around 50 donors). They were of the view that the small risk of false positives was not enough to prevent the immediate introduction of testing with one of the 3 approved FDA test kits. The risk of false positivity is also addressed. It was not considered big enough to justify the non-introduction of tests. Further, this could be dealt with by confirmatory testing and counselling being implemented at a later stage. This was clearly a question of the balance between the needs of recipients and the risks of false positivity and the interests of donors. This balance is addressed in more detail elsewhere in our submissions. However, at this point, those who required to look after at least some of the recipients (those with bleeding disorders) felt strongly enough that the balance was not being struck appropriately that they expressed their view in this public way.

However, this plea for urgency was not taken on board by the by the DoH. The dangers of infection from blood which were hardly really news anyway. This had been known for some considerable time within the DoH.[73] One might have expected, however, that the identity of those who were expressing these views might have had a significant impact on the Department's attitude. It took 5 months after Professor Bloom's letter for routine testing to be introduced in the UK. The response within the DoH suggested that they required to wait for the PHL evaluation as it was not clear whether the supplier would be able to produce tests on a large scale and which would still be reliable.[74] As noted above, Professor Cash was of the view that the PHL evaluation on a limited number of donations appeared unlikely to give very satisfactory answers about this large scale issue in any event. These were the same test kits already in use in the US and elsewhere. It is interesting to note that this memo takes no issue with the proposition that false positives would cause only "a relatively small quantity of blood" to be wasted.

This attitude of the DoH in response to these very genuine concerns caused a delay which put patients at risk.

[73] SGH.002.7304 @ 7305
[74] DHF.002.0455 (10 June 1985) and DHF.002.3864 (8 July 1985)

9. Were the decisions (1) not to use test kits from the US as soon as they became available and (2) to abandon SNBTS evaluations in the best interests of patients?

By 1 March 1985, an FDA had licensed the Abbot test kit. By April 1985, routine anti-HIV testing had been introduced in the USA using the Abbott kits. It had been introduced in Australia[75] and Finland[76] by May 1985. Professor van Aken gave evidence to the Inquiry that in Holland testing was started at "the beginning of 1985".[77] In our submission, unnecessary delay was caused by (a) the decision to conduct an evaluation of test kits in the UK prior to the introduction of testing (b) the failure to proceed with a Scottish evaluation of the test kits and (c) the way in which the UK evaluation was conducted. The way in which the routine introduction of anti-HIV testing was handled was not, in our submission, in the best interests of the recipients of blood and blood products.

As part of the evidence heard from patients in the B6 section, the Inquiry heard oral testimony from "Amy". Her son was infected with HIV as a result of a which was the blood transfusion which he received as a baby in summer of 1985.[78] In our submission, an earlier introduction of testing measures may have resulted in infections like that of her son being avoided. Further, the Inquiry also heard evidence from "David". His case is analysed in our B2 submission. However, he was a haemophilia B patient who was in receipt of factor IX when he was infected in 1985. As is noted above, his likelihood of his infection may well have been decreased, had the plasma which had been used to make the products he was using been subjected to routine anti-HIV testing. Further (as our analysis of the statistical information available to the Inquiry in our B2 submission demonstrates) the other haemophilia B patient is also likely to have been infected in 1985 or 1986. It appears likely that the chances of his infection would also have been decreased materially had routine screening been introduced earlier in 1985.

Further, the Inquiry has heard evidence that the risk of HIV infection from cryoprecipitate was a reason why a previously a untreated patient might be given a factor VIII concentrate as opposed to cryoprecipitate which carried a much lesser chance of infecting the patient with NANB hepatitis (see

[75] DHF.001.7239
[76] DHF.001.7323 @ 7325
[77] Transcript for 15/09/11 (day 47); 82 (2 to 12) (Professor van Aken)
[78] WIT.004.0001 and WIT.004.0150 relating to the period after Amy's sons birth

our submission in the C3A topic). The earlier introduction of routine anti-HTLV III testing would have made the use of cryoprecipitate a more attractive alternative and may have reduced the incidence of hepatitis C infection in minimally treated patients with bleeding disorders.

JTD