

TOPIC B1

The efforts made to discourage 'higher risk' donors from giving blood (by the dissemination of information, including leaflets); whether these efforts went far enough and began early enough.

Basis for discouraging high risk donors through the dissemination of information by way of leaflets

- 1. The nature and extent of the responsibility of the Scottish National Blood Transfusion Service and the government in Scotland for the determination of donor screening policy and the implementation of mechanisms to protect patients from AIDS.**

and

- 2. The nature and extent of the involvement of the Scottish National Blood Transfusion Service and the government in Scotland in the implementation of mechanisms to discourage high risk donors from donating blood.**

Donor selection was within the province of the SHHD only to the extent that the relevant minister was ultimately responsible for the health service,¹ and this was something that was dealt with by the SNBTS directors.² In the 1970s and 1980s it was considered that each director should have a high degree of autonomy for many issues, including donor selection.³ The National Transfusion Services had defined administrative structures but in relation to professional matters the regional transfusion centres were largely autonomous entities and local policies were determined by the directors and their consultant colleagues. Consequently, although there was discussion between regional transfusion centres at a national level, consensus was not always reached. Furthermore, every donor session was overseen by a doctor who had the final say on all matters of donor selection.⁴

¹ Transcript 24/03/11 (Day 11): 138(5-10) (Dr Scott)

² Transcript 24/03/11 (Day 11): 138(5-10) (Dr Scott)

³ Transcript 25/12/11 (Day 12): 33(17) to 34(17) (Dr McClelland)

⁴ [SNB.014.3125] at 3130

In relation to the steps taken to implementation of a mechanism to deter high risk donors from donating blood, the Inquiry heard evidence to the effect that this was done without detailed involvement of the SHHD.⁵

3. The reasons why steps were taken in early 1983 to discourage high risk donors from donating blood.

In early 1983 Dr Brian McClelland, the regional director of the Edinburgh and South East Scotland Blood Transfusion Service, took steps to discourage high risk donors in his region from donating blood by preparing a leaflet containing information about the groups known to be at high risk of AIDS. He was aware of evidence that had started to emerge in July 1982 which showed that AIDS was transmissible by blood. Two local papers had suggested that AIDS could become a problem in Edinburgh. He decided that it was important to take action to reduce the risk to transfusion recipients.⁶ His leaflet was tabled at a meeting of the SNBTS co-ordinating group on 24 May 1983.

At the time different approaches were being taken by directors in other regions. In this regard Dr Mitchell (SNBTS Glasgow) had introduced into the health questionnaire a question inviting those who were worried about AIDS to consult the doctor at the session while Dr Urbaniak (SNBTS Aberdeen) had decided to do nothing locally as he was of the view that once a donor entered the session it was too late to do anything.⁷

4. The reasons why a mechanism of self-exclusion by blood donors was selected.

and

5. The extent to which mechanisms other than self-exclusion were considered and whether they could have been implemented.

It would appear that a mechanism of self-exclusion was chosen in part because of an attitude of deference towards donors that prevailed at the time. There was a concern that embarrassing intrusions into the donors' private lives to identify in individuals who might have an increased

⁵ Transcript 25/03/11(Day 12): 45(19) to 46(5); 64(17) to 65(9); 103(3) to 104(3) (Dr McClelland);

⁶ Transcript 25/03/11(Day 12): 2(3) to 10(16); 28(25) to 29(4) (Dr McClelland); [WIT.003.0036] at [WIT.003.0037] – Statement of Dr McClelland

⁷ [SNB.003.7116] at [SNB.003.7120]

risk of carrying a transfusion transmitted disease, might deter people from donating.⁸ The option of questioning donors was suggested but rejected.⁹

There is evidence before the Inquiry that an alternative mechanism that was considered for the exclusion of donors at high risk of AIDS was the use of surrogate testing. This would have involved using one or more laboratory tests of immune function to identify individuals who might have sub-clinical evidence of impaired immune function. The intention would have been to detect the consequences rather than the cause of AIDS.¹⁰ What was also considered was the use of a screening test for antibody to the hepatitis B virus core antigen (anti HBc), which was thought might act as a marker that an individual had been exposed to an infection other than HIV, known to be transmitted by blood or other body fluids. The SNBTS investigated the use of such tests and made proposals to the Central Blood Laboratories Authority Research Committee (England and Wales) for studies in the UK but the proposals to evaluate surrogate tests were not taken up¹¹ and surrogate testing for AIDS risk was not pursued into the routine practice of blood donor assessment in the UK.¹² The issue of surrogate testing in relation to HIV is not something that has been considered during the oral hearings and it is consequently not possible to make submissions in relation to whether or not these mechanisms could have been implemented.

6. The reasons why a leaflet was selected as the basis for self-exclusion.

and

7. The extent to which mechanisms other than a leaflet were considered and whether they could have been implemented.

Dr McClelland had received a copy of the Morbidity and Mortality Weekly Report (MMWR), dated 4 March 1983, which contained an article¹³ from the Centres for Disease Control (CDC) in Atlanta. This referred to a recommendation by the US Public Health Service that as a temporary measure, members of groups at risk for AIDS should refrain from donating plasma and/or blood, even though many individuals are at little risk of AIDS, and included a description

⁸ Transcript 25/03/11 (Day 12) 23(7) to 25(17) (Dr McClelland); [SNB.014.3125] at [SNB.014.3131]

⁹ SNB.014.3125] at [SNB.014.3131]

¹⁰ [WIT.003.0036] at [WIT.003.0038] – Statement of Dr McClelland

¹¹ [SNB.014.3070] at [SNB.014.3079]

¹² [WIT.003.0036] at [WIT.003.0038] – Statement of Dr McClelland

¹³ [LIT.001.0568]

of groups at risk.¹⁴ He decided that the obvious approach for reducing the risk of transmission of AIDS to recipients was to follow the principles of the US Public Health Services Interagency Guidelines, with slightly amended recommendations for Edinburgh. He consequently prepared a draft leaflet which was tabled at a meeting of the SNBTS co-ordinating group on 24 May 1983.¹⁵ Dr McClelland's leaflet was subsequently amended to accommodate concerns raised by the Scottish Homosexual Rights Group (SHGR). The amended leaflet was distributed in the South East of Scotland in June 1983.¹⁶ Although this leaflet was made available to other regional transfusion centres, it is not clear whether or not they actually distributed it.¹⁷ At a national level the DHHS, with input from Dr McClelland, published a leaflet which was available for distribution throughout the UK by 1 September 1983.¹⁸

It is apparent that there were concerns from the beginning that simply having a leaflet available, irrespective of how it was distributed, would not guarantee that donors would read it or understand it or that it would influence their actions.¹⁹ Despite these concerns it does not appear that other methods were considered, or at least introduced, until sometime later. In this regard, towards the end of 1984, following the discovery of the infection of the Edinburgh Cohort, a more pro-active approach was taken. This included the introduction of a health questionnaire that donors were required to sign, confirming that they were not in a high risk group.²⁰ Furthermore, a flash card system was introduced in August 1986 in an attempt to address the concern that donors might pick up the leaflet but not read it carefully or at all. This was administered when the donor was face-to-face with the member of the donor selection staff. A donor would be asked questions about whether he had read the leaflet and whether he belonged to any of the high risk groups.²¹ Subsequently personal interviews were introduced for new donors and donors who had not attended for more than two years, and from January 1992 this included direct oral questioning about risk activity rather than simply asking if they had read and understood the information provided.²² Furthermore, in 1989 a pilot study had been carried out on the use of an impersonal interview using computer software, which was a more effective

¹⁴ Transcript 25/03/11(Day 12): 2(22) to 5(19) (Dr McClelland)

¹⁵ Transcript 25/03/11(Day 12): 2(3) to 10(24) (Dr McClelland); Preliminary Report, Chapter 8, paragraph 8.28

¹⁶ Transcript 25/03/11(Day 12): 69(20-24) (Dr McClelland)

¹⁷ Transcript 25/03/11(Day 12): 87(24) to 89(7) (Dr McClelland)

¹⁸ Transcript 25/03/11(Day 12): 48(11) to 51(13) (Dr McClelland); [SGH.002.6675]

¹⁹ Transcript 25/03/11 (Day 12): 15(24) to 16(12); 74(10-14) (Dr McClelland)

²⁰ Transcript 25/03/11 (Day 12): 70(18) to 71(3) (Dr McClelland)

²¹ [WIT.003.0036] at [WIT.003.0044]; Transcript 25/03/11 (Day 12): 74(10-21) (Dr McClelland)

²² [SNB.014.3125] at [SNB.014.3136]

method than direct oral questioning, but the project was abandoned after an unsuccessful funding application.²³

In our submission, given the concerns about the adequacy of simply having a leaflet, additional steps could and should have been implemented earlier to ensure both that donors had read and understood the information contained in the leaflets and that they did not fall into one of the high risk groups.

Effectiveness of self-exclusion based upon information contained in a leaflet as a mechanism to protect patients from AIDS

8. The nature and extent of the information contained in donor leaflets and whether it was sufficient to discourage higher risk donors from donating blood.

The draft leaflet of 24 May 1983 was the product of a number of successive drafts that had been prepared in an attempt to produce a leaflet that would exclude from donation any groups of people already identified as being at high risk, while at the same time have wording that was not more offensive than it needed to be and was as unambiguous as possible. Successive drafts were also prepared in an attempt to include areas that had not been adequately identified in the first version, as well as any new information that was becoming available. In order to satisfy these goals a degree of compromise had been reached in the wording of the draft leaflet.²⁴ As a result of opposition from the Scottish Homosexual Rights Group (SHRG) to any suggestion that homosexual men should not be able to give blood, the leaflet was amended in consultation with the SHRG to include wording that they were able to endorse,²⁵ and was available for distribution in June 1983.²⁶ This leaflet was subsequently withdrawn following the introduction of the UK leaflet in September 1983.²⁷ By December 1983 Dr McClelland recognised that there was a problem with the wording of the UK leaflet in that it was too reassuring, and in early 1984 the

²³ [SNB.014.3125] at [SNB.014.3136]

²⁴ Transcript 25/02/11 (Day 12): 13(9) to 15(5)

²⁵ Transcript 25/03/12 (Day 12) 18(19) to 23(23) (Dr McClelland)

²⁶ Transcript 25/03/12 (Day 12): 69(20-25) (Dr McClelland)

²⁷ Transcript 25/03/12 (Day 12): 114(3-10) (Dr McClelland)

DHSS also recognised this problem. Dr McClelland redrafted the leaflet and the revised version was available for distribution in August 1984. In December 1984 Dr McClelland suggested a further revision including that the words “sexually active homosexual men” should be changed to “homosexual or bisexual men”. Dr McClelland explained that the reason for this proposed change was probably because the phrasing relating to gay men had become a bit diluted and they were trying to tighten it up.²⁸

9. The extent to which self-exclusion based upon information contained in a leaflet was effective in discouraging higher risk donors from donating blood.

and

10. Whether the effectiveness of self-exclusion based upon information contained in a leaflet, as a mechanism to protect patients from AIDS, was undermined by differences across Scotland in terms of the content of the information contained in and the methods of distribution of leaflets.

In our submission it is evident that use of a leaflet alone was of limited effect in discouraging higher risk donors from donating blood. By November 1983 it was recognised that the leaflet that had been prepared by the SNBTS had not been particularly useful and that there was still a problem about how to screen out those in high risk groups who might present as donors despite the leaflet.²⁹ This is a problem that could not be addressed simply by changing the wording of the leaflet and additional mechanisms were necessary.

Furthermore, the effectiveness of the leaflet was undermined by an inconsistent approach that was taken to its distribution. In this regard, although the June 1983 version of the leaflet prepared by Dr McClelland was made available to other regional transfusion centres, it is not clear whether or not they actually distributed it.³⁰ When the UK leaflet was issued in September 1983 its method of distribution was left up to the regional transfusion directors³¹ and consequently different approaches were taken by the various regional transfusion centres in Scotland. In the North they were put on display with other publicity leaflets at the donor session

²⁸ Transcript 25/03/12 (Day 12): 55(17) to 68(10)(Dr McClelland)

²⁹ [snb.001.51988]; Transcript 25/03/11 (Day 12): 54(12) to 55(14)

³⁰ Transcript 25/03/11(Day 12): 87(24) to 89(7) (Dr McClelland)

³¹ [PEN.002.0005]

and in the plasmapheresis room. In the North East they were available at all mobile and fixed site sessions. In the East they were put on display and anyone requesting information was referred to the Medical Officer on duty. In the West Dr Mitchell had incorporated into his health notice the question “Have you ever heard about AIDS? If you wish to know more you may ask the Medical Officer at the session in confidence or your General Practitioner or write to the Transfusion Director” and the leaflets were available on request at sessions.³²

At a meeting on 8 December 1983 the SNBTS directors agreed that every donor should receive the leaflet and that the health questionnaire should include the question “Have you read and understood the leaflet on AIDS?”, but a decision was not taken on the best method of distribution.³³ At a meeting of the SNBTS directors on 2 February 1984 the effectiveness of the leaflet was discussed. It was stressed that the leaflet must be given to all prospective donors.³⁴ At a meeting on 13 March 1984 it was agreed by the SNBTS directors that the leaflet should be sent once to each donor as an enclosure to the call up letter.³⁵ In November 1984, following the infection of the Edinburgh Cohort, a decision was taken by the SNBTS directors about distribution of the donor leaflet, which was to be enclosed in every donor call-up letter, sent to the address of known donors who were not normally called to sessions, given to every donor at the session, distributed in advance of a sessions to which donors do not receive a personal call-up letter and enclosed in the registration book sent to new donors.³⁶

In our submission the effectiveness of the leaflet as a mechanism for deterring high risk donors from giving blood was undermined by the inconsistent approach taken to the distribution of the leaflet in Scotland. In this regard, given the nature of the fractionation process at the PFC, blood from different centres would have been pooled to produce factor concentrates. In our submission a robust uniform approach, similar to that proposed in November 1984, should have been taken earlier to enhance the effectiveness of the donor leaflet as a mechanism for discouraging higher risk donors from giving blood. Moreover, given the concerns about donors not internalising the information contained in the donor leaflets, the more direct methods that were introduced subsequently, ought to have been introduced at a far earlier stage.

³² [SNF.001.0072] at [SNF.001.0074] to [SNF.001.0075]

³³ [SNF.001.0178] at [SNF.001.0179]

³⁴ [SNF.001.5252] at [SNF.001.5254]

³⁵ [SNB.001.0484] at [SNB.001.0485]

³⁶ [SGF.001.0908]; Transcript 25/12/11 (Day 12): 70(18) to 71(2) (Dr McClelland)

Balancing the interests of donors and patients

11. The management of public opposition to the exclusion of higher risk donors and the extent to which this affected the implementation of measures to protect patients from AIDS.

and

12. The extent to which greater consideration was given to the interests of donors than to the interests of patients in implementing mechanisms to protect patients from AIDS.

In response to news that the SHRG was opposed to any suggestion that people who were homosexual should not be able to give blood it was felt that it would be better to try to work with them to create a leaflet with wording that they could endorse rather than to produce a leaflet which would be completely rejected by the gay community. The process did not result in an inordinate delay as the amended version was available for distribution the following month. However, it did require a compromise in the wording which resulted in the removal of the word “homosexual” which was seen as being offensive. The wording of the amended leaflet was less clear than the original. However, this collaboration appears to have secured co-operation in the distribution of the leaflet throughout the gay community in Edinburgh, which was important in terms of raising awareness.³⁷

There is also evidence before the Inquiry which indicates that this opposition from the SHRG was one of the reasons why a more robust approach of eliciting information from donors was not taken initially. The other was the fact that there was an indication that donor session staff, knowing that homosexual men were considered to be high risk donors, were using subjective and unsubstantiated criteria to identify potential high risk donors. Consequently a letter was issued to Sessional Medical Officers pointing out that they were not in a position to defer anyone from donating blood if they were in good health and asking them to adhere to the guidelines even if they did not agree with them.³⁸

³⁷ [SNB.014.3125] at [SNB.013.3133]; Transcript 25/03/11 (Day 12): 36(1-4) (McClelland)

³⁸ [PEN.014.0098]; [SNB.014.3125] at [SNB.013.3132]; Transcript 25/03/11 (Day 12): 37(8) to 39(9) (Dr McClelland)

13. The reasons why and the extent to which different information about the risk of AIDS was given to donors when compared to information given to patients.

The leaflet that was prepared by Dr McClelland in May 1983, and amended in June 1983³⁹ referred to haemophiliacs as being at high risk of AIDS, whereas a letter from Dr Bloom, Chairman of the Haemophilia Centre Directors, which was distributed by the Haemophilia Centre in May 1983⁴⁰ was more reassuring. Dr McClelland indicated that the advice given by Mr Bloom had been inappropriately reassuring and suggested that there might have been two reasons for this, the first being a general wish to avoid alarm among the public and the second being the concern for haemophilia patients and those treating them that the implication of accepting that AIDS could be transmitted by factor concentrates threatened the continued security of treatment.⁴¹ He pointed out that even if he had been aware of this or other statements like it at the time he would not have modified the text of his leaflet because their priority was to minimise the risk to patients.⁴²

14. The efficiency of the decision making process in relation to the approach to be taken to the exclusion of high risk donors.

In our submission, having a system in place, in which regional transfusion centres were autonomous and local policies were determined by the regional transfusion directors, meant that there was no effective way of enabling a decision to be taken about the approach that should be adopted to the exclusion of high risk donors, or of ensuring that any system of exclusion was implemented in a uniform way. This was illustrated by the different approaches taken by regional transfusion centres to the exclusion of high risk donors in May 1983 and by the delay in implementing a uniform system of distribution of the donor leaflet.

By contrast, there is evidence before the Inquiry regarding the system that was in place in Finland in which the Finnish Red Cross Blood Transfusion Service (FRC BTS) had an organisational structure that was a combination of centralisation and decentralisation. In this regard the FRC BTS had its headquarters, laboratory and plasma fractionation centre in Helsinki. The blood collection centres had no medical director but were managed by a local head nurse, with the guidance of a part-time consultant doctor, under the supervision of the

³⁹ [SNF.001.3397]

⁴⁰ [DHF.001.4474]

⁴¹ Transcript 25/03/11 (Day 25): 94(4) to 95(5) (Dr McClelland)

⁴² Transcript 25/03/11 (Day 25): 29(19) to 31(9) (Dr McClelland)

medical staff in Helsinki. This organisational system meant that it was relatively easy to implement a national policy once a decision had been made centrally.⁴³

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⁴³ [WIT.003.001] at [WIT.001.002] – Statement of Professor Leikola