

**Witness Name: David Brian LorimerMcClelland**

**Witness Statement 5**

**Dated: 28<sup>th</sup> January 2011**

**Inquiry ref:**

**THE PENROSE INQUIRY**

**Witness Statement of Dr David Brian Lorimer McClelland**

**I, Dr David Brian Lorimer McClelland say as follows:-**

**Donor Selection: Actions to discourage donation by those who may be at higher risk of AIDS**

**Background information**

Some of the matters covered in the Schedule are addressed in a paper entitled “Actions taken by SNBTS to protect patients from AIDS”<sup>1</sup>. An SNBTS paper entitled “Donor Selection Policies and Procedures” prepared by Dr J Gillon also bears on these questions<sup>2</sup>.

**Questions in the Schedule**

**1 How did I first obtain the donor selection information from the USA?**

I had received a copy of the Morbidity and Mortality Weekly Report (MMWR) dated March 4 1983 that contained the article “Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Interagency Recommendations”<sup>3</sup> This includes the text

“As a temporary measure, members of groups at risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at

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<sup>1</sup> Actions taken by SNBTS to protect patients from AIDS Paper submitted to the Penrose Inquiry with witness statement by Dr Brian McClelland.

<sup>2</sup> Scottish National Blood Transfusion Service Donor Selection Policies and Procedures, J Gillon. This paper is yet to be submitted formally to the Penrose Inquiry by the SNBTS but will form an appendix to the response on Donor Selection Documentation requested by Gregor Mair on 30 November 2010, headed “Penrose Inquiry – Topic C1 – Hepatitis C – Unsuitable donors – Document Request”

<sup>3</sup> Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS) :Report of Interagency Recommendations MMWR March 04, 1983/32(8);101-3

little risk. Centers collecting plasma and/or blood should inform potential donors of this recommendation. ...This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available”

The groups at risk for AIDS were described as follows

“...persons who may be considered at increased risk of AIDS include those with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past abusers of intravenous drugs, patients with haemophilia and sexual partners of individuals at increased risk of AIDS”

I do not recall receiving copies of donor information leaflets from other blood collecting organisations by May 1983 when Dr Anne Smith/Dewar and I prepared what I believe to be the first draft of the SEBTS leaflet “AIDS and blood transfusion – some background to the recent publicity”. This contains the following statements:

*“Who can get the disease? ...* “homosexual men particularly those with multiple partners”

*“Whose blood could be a risk? ...* “homosexual men”

## **1.2 What lay behind my decision to draft a leaflet**

I cannot claim to recall my thought processes in early 1983 when we began work on the leaflet. I was aware of the evidence that had started to emerge in July 1982 that AIDS was transmissible by blood and was therefore more likely to be due to a transmissible infectious agent than to any of the other causes then being considered. I think it would have seemed fairly obvious then that it was important to take whatever action we could identify to reduce risk to transfusion recipients. I do recall another factor that increased our awareness of the need to take some form of preventive action against the risk of a blood recipient contracting AIDS. During 1983 one or two local newspapers took up the suggestion that Edinburgh could become the “AIDS capital of the North”, arguing (a) that AIDS mainly affected gay men and (b) that the Edinburgh International Festival would selectively attract individuals at risk of AIDS.

Since we did not know if or when there would be a reliable specific test, the challenge was to devise some form of screening procedure that might reasonably be expected to have some ability to detect individuals who might be materially more likely than the donor population as a whole to transmit AIDS to a transfusion recipient.

The most obvious approach was to follow the principles of the US Public Health Services Interagency Guidelines which made use of epidemiological data to identify subgroups within the population that appeared to have an excess incidence of AIDS. We slightly adapted these recommendations for the first version of a donor selection policy for Edinburgh because in early 1983, almost all the epidemiological information that I was aware of had been obtained in the United States. We were aware from the start that the epidemiology of AIDS might prove to be different in the UK so that the donor selection criteria might well prove to need alteration as we gained more data about the condition in the UK. We had no evidence in 1983 that changes in donor information or selection would be effective in reducing the AIDS risk to recipients of blood transfusion, although evidence did accumulate later from several sources to support the effectiveness of donor selection measures.

A second approach was to try and use one or more laboratory tests of immune function to identify individuals who might have sub clinical evidence of impairment of immune function. We referred to this approach as surrogate testing as the intention was to detect consequences rather than the cause of acquired immunodeficiency. In a paper submitted to the Inquiry <sup>4</sup> I have described what we did to explore this approach. Eventually surrogate testing for AIDS risk was not pursued into the routine practice of blood donor assessment in the UK.

A short review that I wrote during 1985 for a book edited by Dr John Cash that was published in 1986 <sup>5</sup> reflects my personal views at that time about what I felt were the important issues about AIDS in relation to transfusion safety. This account was written at a time when a specific test was available for an infective specific agent that was becoming accepted as the cause of AIDS.

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<sup>4</sup> "Actions taken by SNBTS to protect patients from AIDS" B McClelland. Paper prepared for the Penrose Inquiry. See reference 1

<sup>5</sup> McClelland DBL. LAV/HTLV-III infection and transfusion In Cash JD ed. Progress in Transfusion Medicine 1 (1986) Churchill Livingstone, ISBN0443 03261 0

**1.3 Was I aware of possible AIDS cases in Edinburgh at the time of the first draft of the leaflet?**

I am not certain whether in May 1983 I had definite knowledge of cases of AIDS in Edinburgh. I was aware that there were cases of AIDS in the UK, and the donor leaflet referred to this fact. I have responded to this question in my witness statement dated 2010 12 09 headed "AIDS and HIV" which deals mainly with sources of factor VIII. I have reproduced part of that statement here:

"I think that soon after the initial CDC reports of the new syndrome, some clinicians, especially those working in genito-urinary medicine (GUM) and caring for gay men suspected that they were seeing patients with some features that suggested this new form of immune deficiency. From May 1983 or possibly a little earlier, Dr Anne Smith and I were meeting with Dr Sandy MacMillan, a GU medicine Consultant in the Royal Infirmary of Edinburgh and Mr. Derek Ogg of the Scottish Homosexual Rights Group to work out ways of communicating to gay men the message that they should refrain from donating blood. Dr MacMillan would have been restrained by clinical confidentiality from mentioning any specific cases, but it is my recollection that he was aware that some of his male patients who were known to be gay were showing clinical features that suggested that they could be suffering from this new form of immune deficiency disorder."

**2.1 Why did I use the wording "homosexual men" rather than "sexually active homosexual or bisexual men with multiple partners"?**

I am not entirely sure which draft this question refers to. The very first draft of the SEBTS leaflet "AIDS and blood transfusion – some background to the recent publicity"<sup>6</sup> contains the following statements:

*"Who can get the disease? ...* "homosexual men particularly those with multiple partners"

*"Whose blood could be a risk? ..."*homosexual men"

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<sup>6</sup> AIDS and Blood Transfusion. Some background to the recent publicity June 1983 BMcC Personal unique ID 10193

In a second draft, also dated May 1983, the wording is the same:

*“Who can get the disease? ... “homosexual men particularly those with multiple partners”*

*“Whose blood could be a risk? ...”homosexual men”*

In the June 1983 draft the wording is:

*“Who can get the disease? “men who have multiple partners of the same sex”*

*“Whose blood could be a risk? “...we would ask people in any of the high risk groups described above to avoid giving blood until we have a reliable screening test.*

### **3 Why did the text of the leaflet change soon after May 24?**

From the number of versions of the leaflet that are still extant, it is evident that the text of the leaflet was in a state of continuing evolution over the early period of its existence. I do not now recall the specific reasons for the selection of words during this evolution. I can say with confidence that there was extensive discussion of the drafts and I feel fairly sure that the changes reflect our efforts to produce something that would be understandable by donors, would not cause undue offence and that would be practicable to apply in the situation of a blood donor session. The June 1983 version, which was the first to be put into practice, avoided the use of the words “homosexual” and “sexually active”. I think we hoped that “men who have multiple partners of the same sex” would be seen as more specific and possibly less emotive.

I cannot remember whether changes in wording that were made soon after May 24, 1983 were in response to comments made at the Directors’ meeting. I do not recall that there was any “process” for changes in the document in these very early days other than that we were endeavouring to improve it in the light of whatever new information became available, and to keep colleagues informed as we went along.

### **4 What led to the change from “Can it be transmitted by...” to “How it can be transmitted by...”?**

From the documents that I have been able to review up to now I cannot answer this

question. It may well be that this change reflects an awareness that the evidence had accumulated to the point that there was little or no doubt that AIDS could be transmitted by blood and that the message to donors should reflect that degree of certainty.

**5. Can (I) recall the debate about methods of distribution? What were the issues? How did the leaflet commence circulation through SHRG?**

*Distribution of the original SEBTS leaflet.* My recollection is that this was intentionally shared with the SHRG, despite the suggestion in SGF.001.0960 that this was a result of a misunderstanding. I recall that Dr Smith, together with one or two SHRG members, visited a number of gay clubs in Edinburgh over the summer of 1983 to distribute the leaflet and explain its rationale to individuals or small groups. I know that the various drafts were available to all the SNBTS directors. My recollection is that it was at this time still considered to be the responsibility of each director to decide on the information to be given to donors and the means by which it should be delivered.

*Distribution of donor AIDS information leaflets in the NBS.* I recall that initially the individual NBS centres chose very different approaches to distribution of the first NBS leaflet and that this was reflected in large differences in the number of leaflets that they ordered from the central supply point. Dr W Wagstaff of NBS Sheffield surveyed the distribution arrangements in NBS centres as referred to in DHF.001.5119. His letter and attachment of July 6<sup>th</sup> 1983 are attached.<sup>7</sup> and also that of January 3<sup>rd</sup> 1984<sup>8</sup>

**6. It is evident that, as at May 1983, there had been a change in written material in the West of Scotland and there was to be no leaflet in the North East of Scotland. Can (I) recall the position in the rest of Scotland?**

I do not remember any specifics of the way that the AIDS exclusion criteria were made available in the different SNBTS centres, but I recall that there were differences

<sup>7</sup> Letter from W Wagstaff to B McClelland, 06 07 1984 with attached draft AIDS leaflet.

<sup>8</sup> Letter from W Wagstaff to B McClelland, 03.01.1984

in opinion among the Scottish directors (as in England) and that some directors were very concerned about the risk of offending donors by giving too much prominence to the leaflet.

**7. We should like Dr McClelland to comment on his involvement in the donor information issue at a U.K. level – the later letter from (presumably) Dr Wagstaff (DHF.001.5119) records his involvement in the first UK leaflet. Can Dr McClelland summarise this UK involvement? What if any perception did he have of the way in which the matter was progressing in the Department of Health? There is reference to Ministers being keen on a “low key” approach. Was a similar attitude evident in those Ministers responsible for health in Scotland?**

My recollection is that in relation to AIDS, I was in quite close touch with Dr Harold Gunson of the NBS from around May 1983 onwards and that I supplied him with copies of all the early versions of the SNBTS leaflet. I think that from very early on there was a clear intention that there should be commonality in the information given to donors throughout the UK, and that the intention was to have a single donor leaflet for the whole country. I sent a proposal for a revision of the leaflet to Dr Wagstaff on 10<sup>th</sup> January 1984<sup>9,10</sup>

I was a member of the Expert Advisory group on AIDS from 1985 to 1991 and I participated in various meetings about AIDS convened by the NBS. Through these routes I was able to make a contribution to the development of policy relating to AIDS and transfusion in the UK during these early years.

It was interesting to read the Department of Health correspondence about the AIDS leaflet that was supplied with the witness statement request, as I do not have any recollection of being aware of these discussions at the time. I do not recall being aware of pressure from the SHHD about the content or distribution of the leaflet.

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<sup>9</sup> Letter from B McClelland to W Wagstaff, 10 01 1984

<sup>10</sup> Draft of leaflet on AIDS – designed to be sent to blood donors with routine call up letters during 1984

**8. When Dr McClelland agreed in December 1983 to produce a revised leaflet, (paragraph 8.64 of the Preliminary Report) was this seen as a purely Scottish leaflet and, if so, why was the Scottish service revising the leaflet rather than participating in revision at UK level? What was the particular need for revision?**

I cannot recall the detail of this redrafting. My letter to Dr Cash dated December 23<sup>rd</sup> 1983<sup>11</sup> outlines suggested changes to the donor leaflet and refers to a new donor questionnaire. I suspect that I had acquired a great deal of new information during the WHO AIDS conference in November 1983, since this was the first time I had attended any international gathering of experts on AIDS, and indeed I think it was the first large international AIDS conference to be held. This may well have been what led to the consideration of a new draft. As I had been careful to communicate with the NBS through Dr Gunson and there was a definite intention to use a common set of criteria, our intention may have been to use a new SNBTS draft to suggest changes in a UK leaflet.

As mentioned above I was also in communication with Dr Wagstaff, Chairman of the NBTS Directors' group, about the new draft in early 1984. A letter dated January 10<sup>th</sup> 1984<sup>12</sup> gives a sense of the multiplicity of groups concerned with AIDS and blood safety at that time. I explained that I was sending a reworded version of the AIDS leaflet. I stated that the changes were my personal suggestions and that they had yet to be discussed by the SNBTS regional directors, the AIDS working party of the Central Blood Laboratories Authorities subcommittee, the transfusion directors Hepatitis Working Party or any of the other numerous groups who were concerned with this problem.

I have appended Dr Jack Gillon's paper on donor selection, as this gives a sense of the rate of change in donor selection policies during 1983-1984<sup>13</sup>

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<sup>11</sup> Letter from B McClelland to Dr JD Cash, 23.12.1983

<sup>12</sup> See reference 9

<sup>13</sup> See reference 2

**9. In 1984, the leaflet was revised to change the first category of donors who were declined to “sexually active homosexual men”. What was it in particular that led to this change, given the politics of the situation that had applied the previous year?**

The reasons for these changes were put forward in my letter to Dr Cash dated 17 December 1984<sup>14</sup>.

**10. Does Dr McClelland share the view of Dr Seale as expressed to The Standard on 20 November 1984 (DHF.001.6009) that the decision was “18 months” too late?**

I do not agree. The Dr Seale quoted in the Standard article that is date stamped November 20 1984 incorrectly implies that “the Americans” started to “clamp down on homosexual blood donors almost two years before”. The US PHS first issued guidance on AIDS exclusion criteria in March 1983. The SNBTS initiated discussions with the SHRG and drafted its first AIDS exclusion during May 1983, and first introduced the leaflet into routine use in June 1983.

**11 Was the introduction of the signing by donors of a statement that they were not in a risk group in response to the discovery of “the Edinburgh Cohort”?**

I do not remember whether there was any relationship between these events, but since both happened around November 1983, they may well be related.

**12. Why did the leaflet need to be revised again at the end of 1984?**

I do not recall the specific reason. New information was accumulating rapidly

**13. What led to the flashcard?**

My recollection is that this was a first attempt to respond to the concern that donors might pick up the AIDS leaflet but not read it carefully or at all. The flashcard was a way of moving towards a more direct approach to asking donors if they belonged to any of the risk groups.

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<sup>14</sup> Letter from DBL McClelland to Dr JD Cash, 17.12.1984

**14. What is meant by the reference to “withdrawing” leaflets with effect from 31 December 1986? Which particular leaflets were those?**

I think that this would have been part of the routine document control process that required a document to be withdrawn at the time it was replaced by a new version. I cannot remember that there was any specific concern that lead to withdrawal of a particular leaflet.

**15. The document reference SNF.001.3399 includes a chronology which refers to appendices. The Inquiry wishes to see these appendices and Dr McClelland is requested to advise if he is aware of how these might be located, and to produce them if they are available.**

The page labelled SNF.001.3401 is an extension of a chronology covering May 1983 to November 30<sup>th</sup> 1983 by Mrs M Thornton that is included in the paper I have submitted to the Inquiry “Actions taken by SNBTS to protect patients from AIDS”. I have not been able to identify all of the documents referred to, and I cannot advise where they could be found. What follows is a short account of documents that I have identified that are relevant to the matters described in the chronology.

*December 17<sup>th</sup> 1984:* I wrote to Mr Derek Ogg of the Scottish Homosexual Rights Group requesting a meeting in view of statements made by SHRG that conflicted with advice given in the SNBTS and Terence Higgins Foundation leaflets<sup>15</sup>. On February 1<sup>st</sup>, 1985, Mr Ogg wrote to inform me that he was satisfied with the new draft questionnaire for donors<sup>16</sup>.

*January 16<sup>th</sup> 1985:* Dr Patricia Hewitt, deputy director of the NBTS North London Blood Transfusion Centre wrote responding to my request for information about the way in which that centre had operated that included an “opt out clause” for donors . The wording used was “If you think that you may be in a HIGH RISK GROUP as defined in the leaflet and you would still like to donate, please tick this box. In this case we shall use your blood for research purposes only.”<sup>17</sup>

<sup>15</sup> Letter from B McClelland to Mr D Ogg, 17.12.1984

<sup>16</sup> Letter from mr D Ogg to Dr McClelland, 01.02.1985

<sup>17</sup> Letter from Dr Patricia E Hewitt to B McClelland, 16.01.1985 and attachments

*January 18<sup>th</sup> 1985:* Mrs M Thornton (SEBTS donor organiser) sent me a report on the steps being taken to implement the “opt out” procedure<sup>18</sup>. Attached to this was the pilot donor questionnaire containing the added text “If you think there is any reason why your blood should NOT be used for transfusion, please tick. (If you tick the box we will take a full donation which may be used for research purposes and you will not be questioned further

*January 29<sup>th</sup> 1985:* (I suspect that there may be an error in the original dating of this memo). Sister Jean MacDonald (Head Nurse in SEBTS) sent me a memo stating that since the introduction of the (opt out) system, on December 3 1984, four donations had been withdrawn.<sup>19</sup>

*February 13<sup>th</sup> 1985:* I wrote to Mrs Thornton confirming that she should as soon as possible be sending to all donors who we do not routinely call up, and to whom it is possible, a letter enclosing the AIDS leaflet<sup>20</sup>.

*March 21<sup>st</sup> 1985:* I wrote to Mrs Thornton reporting a meeting with representatives of SHRG at which they had accepted the wording of an amended health check for donors and requesting that this be printed<sup>21</sup>. I also pointed out that we should anticipate the need for further changes in about six months and therefore should only order a six months’ supply.

*April 26<sup>th</sup> 1985:* Mrs J MacDonald informed her staff that the new health check forms would be in use at all sessions from the next week<sup>22</sup>.

*? September 1985:* An undated letter from the donor organising secretary to all donors refers to the new donor leaflet (dated “Autumn” 1985) and also contains the text “If you feel that you should not give blood, you can advise us now by returning the attached slip. The information will be treated in complete confidence and you will not

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<sup>18</sup> Memorandum from M Thornton to Dr McClelland, 18.01.1985. Donor Health Questionnaires

<sup>19</sup> Memorandum from Mrs JM MacDonald to Dr McClelland, 29.01.1985

<sup>20</sup> Memorandum from B McClelland to Mrs M Thornton, 13.02.1985

<sup>21</sup> Memorandum from B McClelland to Mrs M Thornton, 21.03.1985

<sup>22</sup> Memorandum from Mrs JM MacDonald to All Staff, 26.04.1985

be questioned further”<sup>23</sup>.

“*Autumn 1985*”: This is the dating on a new leaflet “AIDS: Information to all blood donors” that provides donors with information about the commencement of routine HTLV-III testing and informs donors that “If you do not wish to have your blood HTLV-III tested, please do not donate blood at any session”<sup>24</sup>.

**15a Dr McClelland is also requested to provide an explanation of the reference in that chronology to the abandonment of the “infected donation” policy. What was this policy and why was it abandoned?**

This was a short term measure that was introduced to ensure that before the availability of fully automated, bar code based systems, that units of blood with an initially positive screening test result for HTLVIII antibody were clearly identified for quarantining. When a different system was introduced to identify reactive units, the use of the “infected donation” label was stopped. Relevant documents are:

*November 21, 1984*: Memo from Senior Nursing Officer to All donor staff explaining the procedure with follow up memos.<sup>25</sup>

*November 29<sup>th</sup> 1984*: Letter from B McClelland to Dr Cash making suggestions related to the potential medico-legal importance of the signed donor forms<sup>26</sup>.

*December 5<sup>th</sup> 1984*: Reply from Dr Cash<sup>27</sup>.

## **Appendix 1**

### **Extract from paper by Dr J Gillon on SNBTS donor selection policies**

This first leaflet (ie the SEBTS June 1983 leaflet) was widely circulated within the UK transfusion services, but there is little surviving information on how it was used. The National Blood Transfusion Service (NBTS) Directors decided to produce their

<sup>23</sup> Letter from Donor Organising Secretary to all Donors, undated

<sup>24</sup> Leaflet for All Donors ‘AIDS: New Information for All Blood Donors’, dated Autumn 1985

<sup>25</sup> Internal Memorandum from Mrs JM MacDonald to All Donor Staff, 21.11.1984

<sup>26</sup> Letter from B McClelland to Dr JD Cash, 29.11.1984

<sup>27</sup> Letter from Dr JD Cash to B McClelland, 5.12.1984

own leaflet, "AIDS and how it concerns blood donors", issued in December 1983 and used UK-wide, thus superseding the SNBTS leaflet. The high risk groups were reduced to three: homosexual men; drug addicts, male and female, using injections; sexual contacts of people suffering from AIDS. A history of blood transfusion was not included as a risk factor, as it was considered that "... there is only the most remote chance of this happening with ordinary blood transfusions given in hospital."

Activity in transfusion centres was by now frenetic, with a remarkable increase in volume of internal memos, discussions, staff training sessions etc. Morbidity and Mortality Weekly Reports (MMWR), the official bulletin of the Centers for Disease Control in Atlanta, and the American Association of Blood Banks (AABB) Weekly Reports, as well as reports from UK infection surveillance agencies (Communicable Disease Surveillance Centre (CDSC) in Colindale and Communicable Diseases (Scotland)(CD(S)) at Ruchill Hospital, Glasgow) were scanned for the latest information on the epidemic, and the definitions of the high risk groups evolved rapidly. Early advice to Ministers was given by the ACVSB, and in 1985 (check) the Department of Health established a UK national committee called the Expert Advisory Group on AIDS (EAGA) comprising experts in all disciplines relevant to the problems being posed by the emerging epidemic, and this included SNBTS representation. It was advice from this and other national committees that determined how the definition of high risk groups would change over the coming years, taking into account the epidemiological, virological and clinical evidence appearing in published materials in the UK and in other countries. The USA was to remain at the epicentre of this process, and as a general rule the UK and other developed countries followed their lead, with account being taken of local factors as they became known. Also, just as dialogue with the Scottish homosexual community had proved vitally important, so links were established with UK organisations such as the Terence Higgins Trust.

The SNBTS leaflet was revised and issued in August 1984 as an "Important Message to Blood Donors". For the first time Africa was included as a risk factor and Haiti was reinstated, as in "residents of or visitors to certain areas such as Chad, Haiti and Zaire." As before, donors regarding themselves as belonging to any of the high risk groups were asked not to donate, but already there was concern that this approach

might be inadequate, and in November 1984 the SEBTS issued redesigned donor questionnaires which required the donor to sign a declaration that they did not belong to one of the high risk groups.

Discussions with SAMG continued, and in spite of the above measures the SHRG representatives advised in a meeting in January 1985 that there was evidence that some high risk donors could still be giving blood. The questionnaire for regular donors was amended and issued in March 1985. By May 1985 all registered donors in SE Scotland had received at least one copy of the leaflet (no record has so far been found... of the timing of its dissemination in the other regions).

**Statement of truth**

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

Signed *DBL J. C. Mend.*.....

Date *28-01-2011*.....