Schedule

Issue in respect of which a statement is sought

AIDS/HIV

The use of commercial products in Scotland, including the continuation of such use after:

(a) international realisation that these carried a risk of AIDS;

I cannot recall any dated chronology of events as this realisation unravelled

(b) the proposal by Dr Galbraith of the Public Health Laboratory Service in May 1983 that use in the UK should be stopped; and

I cannot recall this precise proposal

(c) significant progress towards self-sufficiency in the manufacture of blood products by the NHS in Scotland had been made.

My recollection is that Scotland had become largely self-sufficient by the early 1980's but some commercial product was still being used in Edinburgh and possibly more so in Glasgow. This near self-sufficiency was achieved by collecting enough donations of whole blood to collect the plasma from which the clotting factors could be extracted, but did result in a significant discard of red cells. The occasional patients with inhibitors, who were thereby 'resistant' to conventional doses of clotting factor could present a sudden demand in excess of supply, so absolute self-sufficiency would have been difficult to obtain

Sections of Preliminary Report which may assist when preparing statement

Chapter 8, "HIV and AIDS".

Matters to be included in the statement

SNAPSHOTS and LANDMARKS

1. The first point at which the topic can really be focussed is at the beginning of 1983, when there was a meeting at St Andrew's House of the Directors of SNBTS and the Haemophilia Directors (see paragraph 8.17 of Preliminary Report and copy minutes attached).
By this point, in relation to increasing awareness of AIDS, there are three specific references in the Preliminary Report:
I have no records of this meeting

i) The MMWR of 16 July 1982, in which an editorial note commented in relation to 3 cases of AIDS in heterosexual haemophiliac patients (see paragraph 8.12 and copy article attached):
".. the occurrence among the three hemophiliac cases suggests the possible transmission of an agent through blood products ..."
This is a 'classic' reference well known to historians of HIV
ii) the reference to these cases at the congress in Budapest in August 1982, which Dr Foster attended. He subsequently prepared a report, which we do not have in full (see paragraph 8.14).
I don't think I ever saw a copy of this report but I probably became aware of at least some of its contents subsequently, but I do not know what.
iii) the meeting of UK Haemophilia Centre Directors (UKHCDO) in Manchester on 13 September 1982, at which the condition was mentioned along with a reference to the possibility of involvement of commercial blood products (see paragraph 8.16).

In the minutes of the joint meeting on 21 January 1983 is recorded the following passage:

> "6 (a) Acquired Immune Deficiency Syndrome (AIDS)
> Dr Cash drew members' attention to recent articles in the United States, and also in the Observer and the Lancet, about this problem. An MMWR extract (CDC,

Atlanta) had been circulated with his paper. Dr Ludlam informed members that in the UK a letter and questionnaire had been sent out to haemophilia directors."

Again, I have no copy of the proceedings of this meeting

In relation to the continuing use of commercial products, the previous joint meeting of the Directors of SNBTS and the Haemophilia Directors on 30 January 1981 (copy of minutes attached) had discussed the use of commercial products. There had been reference to a Council of Europe recommendation that member states should be self – sufficient.

Page 5 of the minutes of the meeting of UKHCDO on 13 September 1982 refers to an "encouraging rise" in the amount of NHS factor used in the figures for 1981, but there had been no change in commercial use.

There was continuing use of commercial products in Scotland in the face of approaching self-sufficiency (achieved in 1983 – see attached copy memo of 18 November 1983). By the beginning of 1983, was there any recognition that the arrival of AIDS, and its possible connection with (US) commercial blood products, required a re-assessment of the risks/benefits associated with the use of commercial rather than NHS product? Why was there no discussion about the possible connection between AIDS and commercial blood products?

I cannot help on this point

2. The further developments which had taken place since the meeting of 21 January (all referred to in the preliminary report) included:

i) the meeting at Heathrow Airport on 24 January 1983, at which there was discussion of AIDS (see paragraphs 8.18 and 8.19). By this time there were said to have been 10 cases in patients with haemophilia in the USA.

ii) the article in the New Scientist in February 1983, again linking AIDS and blood products (see paragraph 8.20 and copy article attached).

iii) articles in the Lancet of 29 January (see paragraph 8.21) and 2 April 1983 (see paragraph 8.23 and copy articles attached).

iv) the UKHCDO meeting of 13 May 1983 at which it was, in effect, recognised that some restriction of the use of concentrates was warranted (see paragraph 8.26). It is noteworthy that there appears to have been no Scottish representation at this meeting. Glasgow and Edinburgh were supposedly reference centres by this time – should they not have been invited? Was there in fact a reluctance to involve them (see comments in letter dated 8 August 1985 referred to in paragraph 8.36, footnote 55 regarding their status)?

v) the meeting of the SNBTS co-ordinating group on 24 May 1983, at which precautionary steps were again discussed (see paragraph 8.28).

vi) Dr Galbraith of the Public Health Laboratory Service specifically recommended on 9 May 1983 that blood products from the USA should cease to be used (see paragraph 8.24). In his letter to the DHSS he said:

"I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified. Appended is a paper in which I set out my reasons for making this proposal."

There must have been knowledge in Scotland of this recommendation from Dr Galbraith. It was referred to at the English Directors' meeting of 18 May 1983, which was attended by Dr Ruthven Mitchell. He prepared a note of the meeting (see copy attached) which must have been circulated within SNBTS. Presumably it was sent to Dr Cash, whose apologies were tendered at the meeting? Moreover, Dr Gunson attended the next Scottish Directors' meeting on 14 June (see paragraph 8.33) and

must have known of the proposal, albeit he had not been present at the English meeting. Was there ever any thinking along these lines in Scotland?

There were meetings of the Directors on 14 June and the Factor VIII Safety sub-committee on 15 June (see paragraph 8.34). AIDS was discussed at both, in terms which imply an acceptance that a blood borne infectious agent was involved. Was there any recognition that cessation of use of products from the USA would eliminate the risk from that source? If not, why not?

Again, I cannot help

vii) On 24 June, Professor Bloom and Dr Rizza wrote to Dr Ludlam with recommendations (see paragraph 8.36). In essence, these prioritised the protection of mildly affected haemophiliacs and children. Did Dr Ludlam disseminate this advice round the haemophilia centres in Scotland? Was there any gathering of Scottish haemophilia clinicians to discuss the situation? Was there any different advice issued in Scotland? What, specifically, was the practice in relation to the treatment of children in Scotland? Is it the case that large amounts of commercial concentrate were used at Yorkhill?

In retrospect, it is probably the case that the risk of infection correlated with the amount of concentrate received. Was any attempt made to formulate strategies for reducing the amount of concentrate, particularly commercial concentrate, used by moderately or severely affected haemophiliacs? What use was made in Scotland of DDAVP?

I do remember at one stage in the Edinburgh Centre we attempted to reduce 'donor exposure' to haemophilics by restricting batch numbers of PFC fVIII concentrate to specified patients (in other words, once a 'new batch; of fVIII had been administered to one patient, further treatments came from the same batch until that batch was exhausted). This was Dr Ludlam's suggestion and was administered, as far as I can recall, reasonably well by the staff of the blood product issuing department of the Edinburgh and SE Scotland BTS, based in the Royal Infirmary. I cannot date the start of

this policy. I cannot comment on how much DDAVP was used, but assume that it was prescribed for certain patients on at least some occasions when appropriate

viii) Which Scottish haemophilia clinicians attended the WFH & ISTH meeting in Karolinska between 27 and 29 June 1983 (see paragraph 8.37)? Was Dr Foster's report of the meeting distributed beyond PFC?

I cannot help on this point

ix) Dr Galbraith's paper was discussed at the Biologicals sub-committee of the Committee on the Safety of Medicines in London on 13 July 1983 (see paragraph 8.41). Was there any Scottish representation at this meeting? Were its proceedings notified to anyone in Scotland?

I do not know

3. In the second half of 1983, there was the first WHO Europe conference on AIDS, entitled "AIDS in Europe, Status Quo 1983" in Aarhus, Denmark, between 19 and 21 October (see paragraph 8.57 and copy note of meeting). There was also a meeting of UK Haemophilia Centre Directors (UKHCDO) in Manchester on 17 October 1983 (see paragraph 8.61) and the WHO Conference in Geneva, 22 – 25 November 1983 (see paragraph 8.65).

i) Who attended the Aarhus conference from Scotland?

Not me

ii) Was information from the Geneva conference in 1983 disseminated beyond SNBTS?

I cannot say for certain

iii) In relation to the UKHCDO meeting and various communications from or relating to the Haemophilia Society around this time, the emphasis appears to have been strongly on maintaining the use of commercial concentrates. Is this an accurate impression? Did haemophilia clinicians from Scotland agree that patients should not be encouraged to revert to cryoprecipitate for home therapy?

I cannot recall

iv) Did haemophilia clinicians in Scotland follow the advice from the Geneva conference to avoid non-essential use of blood or blood products?

I cannot recall

v) More generally, was there an awareness of Scottish patients with AIDS? We are aware of a comment from an unnamed GU specialist to the effect that in 1983, patients were arriving in his/her clinic with symptoms of AIDS (copy of part of thesis by Bennett/Pettigrew attached). From the BMJ article dated 11 February 1984, it appears that the first Scottish AIDS death was December 1982 (copy of article attached).

I cannot say

4. By the early part of 1984, there appears to have been caution in Scotland in relation to the use of commercial products from abroad. But "small amounts" of commercial products were still purchased. Why was this necessary?

I cannot recall but see my above remarks about patients with inhibitors

We also need to ascertain what happened in practice re the use of heat treated concentrates in Scotland in 1984. When were physicians able to begin using heat treated commercial concentrate?

I cannot recall the dates

Documents Annexed

1. Copy minutes of the meeting of Directors of SNBTS and Haemophilia Directors on 21 January 1983.
2. Copy of article in MMWR dated 16 July 1982.
3. Copy minutes of the meeting of Directors of SNBTS and Haemophilia Directors on 30 January 1981.
4. Copy memo dated 18 November 1983.
5. Copy article from the New Scientist dated 3 February 1983.

6. Copy article from the Lancet dated 29 January 1983.

7. Copy article from the Lancet dated 2 April 1983.

8. Copy minutes of the meeting of the English BTS Directors on 18 May 1983.

9. Copy note of meeting of WHO Europe conference on AIDS, between 19 and 21 October 1983.

10. Copy of part of Bennett/Pettigrew thesis.

11. Copy of article from the BMJ dated 11 February 1984.

Final Comment, I recall that the clinicians at the Glasgow and W of Scotland Haemophilia Centre who cared for adult patients were general physicians who were not part of the haematology departments and had no direct responsibility for running the GRI Blood Bank. This may have added an extra layer to the chain of communication; but I cannot say more as I was not directly involved. I cannot recall who were clinically responsible at that time for prescribing the fVIII or fIX materials for the boys under paediatric care in W of Scotland.