PENROSE INQUIRY

LIST OF ISSUES PROPOSED BY INQUIRY COUNSEL

10 February 2012

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.

1. Should steps have been taken in Scotland earlier than May/June 1983 to alert blood donors to the risks of transmitting AIDS via donated blood and to prevent higher risk donors from giving blood?

2. Were there other measures which should have been adopted but were not?

TOPIC B2

The use of blood product concentrates in Scotland, including any perceived disadvantages of such products, from their introduction in or around 1974; the continuation of the use of commercial concentrates in particular after:

- **international realisation that these carried a risk of AIDS;**
- **the proposal by Dr Galbraith of the Public Health Laboratory Service in May 1983 that use in the UK should be stopped; and**
- **significant progress towards self-sufficiency in the manufacture of blood products by the NHS in Scotland had been made.**

1. Following the first reports of AIDS in patients who had received treatment with blood or blood products, by what point should clinicians responsible for the care of haemophilia patients in Scotland have recognised a possible connection between AIDS and factor concentrates?

2. After the point identified in response to question 1 what, if any, steps should have been taken by haemophilia clinicians in Scotland to reduce or restrict the use of factor concentrates?

3. When should any such step or steps have been taken?

4. Would any such steps have prevented any person acquiring AIDS from treatment with blood products in Scotland?

5. Are the answers to questions 1 – 4 affected by focusing exclusively on concentrates produced by the NHS?

6. Why were more commercial concentrates used at Yorkhill in the early 1980s than at any other haemophilia centre in Scotland?

7. Should there have been an initiative to restrict the use of commercial concentrates in Scotland similar to the proposal of Dr Galbraith of the Public Health Laboratory Service and, if so, when and by whom should it have been taken?

8. If such an initiative could and should have been taken, would it have prevented any person acquiring AIDS from treatment with blood products in Scotland?

9. The quality of information and advice concerning the relationship between AIDS and blood products available to those with haemophilia and those responsible for their treatment in Scotland from

a) UKHCDO;
b) Government Ministers and officials and
c) The Haemophilia Society

in the period 1982 to 1985.

TOPIC B3

The implementation of heat treatment against LAV/HTLV-III by the Protein Fractionation Centre in Scotland in December 1984, and the technological background to such implementation, including the history and exploration of methods of heat inactivation by the Scottish National Blood Transfusion Service.

1. Was the approach taken to viral inactivation of clotting factor concentrates at PFC in the period 1980 to 1984 reasonable?

2. Was the degree of priority accorded to viral inactivation during this period reasonable?

3. When, and how far, was it appreciated that it was likely that there would be a need for the heat treatment programme to deal with the threat of AIDS?

4. Whether there could have been acceleration of the heat treatment programme around May 1983 in response to the AIDS problem. If so, should the programme have been accelerated?

5. Should there have been a change to dry heat treatment either in the summer of 1983 or at the beginning of 1984?

6. The nature and extent of liaison between the fractionation services in Scotland and England over the period 1980 to 1984 in relation to viral inactivation.

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 kits before any such use.

1. Whether it was necessary to conduct evaluation of the kits before introducing them into screening of donated blood in Scotland.

2. Why was it not considered necessary for the kits to have the approval of the US Food and Drugs Administration for use in the United States of America before introducing them for screening of blood in Scotland?

3. Whether an evaluation exercise in Scotland, such as that proposed by Professor Cash, would have led to the introduction of screening earlier than October 1985.

4. If so, why did such an evaluation not take place?

TOPIC B5

B5a) The information given to patients (or their parents) about the risk of AIDS before their treatment with blood or blood products;

B5b) the tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products; and

B5c) the information given to patients who might have been infected, or who were found to be infected, and their families,

B5d) in particular, the circumstances in which those patients known collectively as the Edinburgh Cohort became infected with HIV, the testing of such patients for HIV and the information given to them about their infection.

1. The practice of obtaining blood samples from patients with haemophilia to monitor immunological abnormalities

2. The steps taken by SNBTS to warn patients of the possible transmission of the HTLV III virus by their blood products.

3. The steps taken by haemophilia clinicians in Scotland to warn patients of the possible transmission of the HTLV III virus by blood products.

4. The response on the part of haemophilia clinicians in Glasgow and Edinburgh in the Autumn of 1984 to the results of tests showing that some of their patients had tested positive for the antibody to the HTLV III virus.

5. The response on the part of SNBTS in the Autumn of 1984 to the information that patients who had been treated exclusively with SNBTS factor concentrates had tested positive for the antibody to the HTLV III virus.

6. The way in which information about infection with the HTLV III (HIV) virus and prognosis was communicated by haemophilia clinicians to patients in the period 1985-90.

7. The response on the part of SNBTS in the period 1985-90 to the introduction of testing for the HTLV III virus which allowed a targeted look-back of patients who had received blood components made from donations given by donors who had tested positive for the HTLV III virus

TOPIC B6

The effects of infection with HIV, including the effects of treatment, on patients and their families.

1. What were the effects of infection with HIV, including the effects of treatment, on patients and their families?

TOPIC C1

The acceptance of blood from "higher risk" donors, in particular:
(a) prisoners; and
(b) donors with a history of jaundice, and who were negative for Hepatitis B when the existence of Non-A Non-B Hepatitis was known and its presence could not be excluded

1. What evidence, if any, was there during the 1970s and early 1980s that prisoners in Scotland were "higher risk" donors i.e. that their blood carried a greater risk of transmitting infectious disease, in particular NANBH, when compared with donors who were not prisoners?

2. What, if anything, ought to have been done, by whom and when, as a result of that evidence?

3. Should the collection of blood from Scottish prisons have stopped earlier and, if so, when and why?

4. If blood had not been collected from prisons in Scotland in the 1970s and early 1980s, (1) could a sufficient blood supply have been maintained and (2) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have been reduced?

5. What evidence, if any, was there during the 1970s and 1980s that donors with a history of jaundice were "higher risk" donors i.e. that their blood carried a higher risk of transmitting infectious disease, in particular, NANBH, than donors with no history of jaundice?

6. What, if anything, ought to have been done, by whom and when, as a result of that evidence?

7. During the 1970s and 1980s should the SNBTS have refused to accept blood from donors with any history of jaundice (rather than simply refusing donors with a history of jaundice in the 12 months prior to donation) and, if so, why?

8. If, in the 1970s and 1980s, the SNBTS had rejected blood from donors with a history of jaundice, (1) could a sufficient blood supply have been maintained and (2) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have been reduced?

TOPIC C2

The non-introduction in Scotland of surrogate testing for Non-A, Non-B Hepatitis

1. Why was surrogate testing not introduced in Scotland in the second half of the 1980's, in particular, after the SNBTS Directors recommended at their meeting on 3 March 1987 that such testing should be introduced from 1 April 1988?

2. Should surrogate testing have been introduced in Scotland in the second half of the 1980's?

3. What was the state of medical and scientific knowledge regarding post-transfusion NANBH in the second half of the 1980's, in particular, in respect of its' clinical significance and likely prevalence in Scotland? To what extent did that state of knowledge influence, or ought to have influenced, the consideration of whether surrogate testing should be introduced?

4. To what extent did the strict liability provisions of the Consumer Protection Act 1987 influence, or ought to have influenced, whether surrogate testing was introduced?

5. If surrogate testing had been introduced in Scotland in the late 1980s, (1) could donor counselling have been satisfactorily addressed, (2) could a sufficient blood supply have been maintained and (3) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have reduced?

TOPIC C3

The implementation of heat treatment sufficient to inactivate hepatitis C in blood products by the Protein Fractionation Centre in Scotland in 1987, and the technological background to such implementation, including the achievement of this objective by the National Blood Transfusion Service in England and Wales in 1985

1. Until the end of 1985, was it reasonable for PFC to continue with the NYU R&D project rather than to prioritise the development of an intermediate, albeit increased, purity FVIII concentrate that could be severely dry heated i.e. Z8?
2. Once a decision had been taken to prioritise the development of Z8, why did it take until April 1987 until Z8 was issued to patients?
3. To what extent, if at all, did concerns regarding the lack of compensation arrangements for the trial and use of Z8 cause or materially contribute to any delay in the issue of Z8 to patients?
4. Were any alternative options reasonably open to PFC during 1985 and 1986 that had a realistic prospect of resulting in the earlier availability of a FVIII concentrate that had been sufficiently treated to inactivate NANBH/hepatitis C, including seeking to severely dry heat the existing NY intermediate FVIII product or seeking to copy PFL/BPL's 8Y process?

TOPIC C3A

The use of blood product concentrates in Scotland in the period between the introduction of NHS heat treated products in 1984 and the supply of NHS products sufficiently treated to inactivate Hepatitis C.

1. Given that, with effect from Autumn 1985, the Factor VIII concentrate 8Y, produced in England, was more severely heated than the Scottish product, could a supply of 8Y have been obtained to be held for the treatment of any Scottish patients with haemophilia who had received little or no previous exposure to concentrates and who required treatment before the equivalent Scottish product was available?

2. If the answer to question 1 is in the affirmative, should such a supply have been obtained (other than the small *ad hoc* supply procured by Dr Perry in the summer of 1986)?

3. If the answer to question 1 is in the affirmative, when and by whom should such a supply have been obtained?

4. In the absence of a supply of 8Y to treat patients with little or no previous exposure to concentrates, were the general approaches to blood product therapy for haemophilia in Scotland in the period 1985 to 1987 reasonable?

5. Were the arrangements for dissemination of general guidance to clinicians regarding haemophilia treatment during this period satisfactory?

TOPIC C4

The interval between the availability of tests for the Hepatitis C virus in 1989 and the introduction of screening of donated blood for the virus in the United Kingdom in September 1991.

1. When it became apparent in 1988 that tests for the hepatitis C virus were shortly to become available, was there a satisfactory mechanism for determining whether these tests should be introduced for the screening of donated blood in Scotland?

2. When it became apparent that the introduction of screening for hepatitis C might be recommended, was there a satisfactory mechanism for determining when and how the introduction of screening in Scotland would be effected?

3. Whether the existence of two groups with similar remits (ACVSB and ACTTD) impeded decision-making.

4. The factors which contributed to there being no decision to recommend to Ministers that screening should start as soon as practicable until November 1990.

5. Why was there a delay of almost ten months between the decision by ACVSB on 21 November 1990 to recommend the introduction of screening as soon as practicable and the introduction of screening in Scotland on 1 September 1991?

6. Whether, during this period, the involvement of the Health Minister earlier than July 1991 would have led to earlier introduction of screening.

7. The formulation of policy regarding the co-ordination of the starting date for the introduction of screening in Scotland with the starting date for England and Wales, the flexibility of such policy and whether such policy as existed resulted in delay in the introduction of screening in Scotland.

8. The relevance to the decision-making process of the Consumer Protection Act 1987, and the relevance for the consideration of this Inquiry of the decision in A v National Blood Authority [2001] 3 All E R 289.

TOPIC C5

C5a) The information given to patients (or their parents) about the risk of non A non B Hepatitis *and the severity of the condition* before their treatment with blood or blood products;

C5b) the tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products; and

C5c) the information given to patients who might have been infected, or who were found to be infected, and their families.

1. The steps taken by SNBTS to warn patients of the possible transmission of NANB hepatitis and Hepatitis C virus by their blood products.

2. The steps taken by haemophilia clinicians in Scotland to warn patients of the possible transmission of NANB hepatitis and Hepatitis C virus by blood products.

3. The testing of blood samples, including stored samples, from patients with haemophilia for the HCV virus in 1989 - 92

4. The response on the part of haemophilia clinicians to the results of tests showing that some of their patients had tested positive for the HCV virus.

5. The way in which information about infection with the HCV virus and prognosis was communicated by haemophilia clinicians and hepatologists to patients in the period 1989-95

6. The response on the part of SNBTS in the period 1991-95 to the introduction of testing for HCV which allowed a targeted look-back of patients who had received blood components made from donations given by donors who had tested positive for HCV.

7. The response on the part of SHHD in the period 1991-95 to the introduction of testing for HCV which allowed a targeted look-back of patients who had received blood components made from donations given by donors who had tested positive for HCV.

TOPIC C6

The effects of infection with Hepatitis C, including the effects of treatment, on patients and their families.

1. What were the effects of infection with Hepatitis C, including the effects of treatment, on patients and their families?