ISSUES PROPOSED BY COUNSEL FOR

THE HAEMOPHILIA SOCIETY, PATIENTS AND RELATIVES

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.

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.

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

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

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

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

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

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

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

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

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

11. 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.

Balancing the interests of donors and patients

12. 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.

13. 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.

14. 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.

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

Recommendations for the future

16. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry"s consideration of topic B1.

L-AvdW

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.**

The diagnosis and classification of bleeding disorders

1. How were patients diagnosed with bleeding disorders in the late 1970s/1980s?

2. How was the severity of their condition classified in the late 1970s/1980s?

3. Whether the system of diagnosis and classification was fit for the purpose of maximising the chance that patients would receive the best and most appropriate treatment available.

Infection routes

4. How the patients with bleeding disorders in Scotland who were infected with HIV through blood products were infected.

Knowledge of the risks of viral infection and, in particular, HIV infection for patients with bleeding disorders

5. Knowledge of the risks of viral transmission from blood products at the start of the 1980s.

6. The point at which it was and the point at which it should have been known that AIDS was a serious disease which could kill those infected with HIV.

7. The point at which it was and the point at which it should have been known that there was a real risk that AIDS was caused by a virus which was transmissible by blood and blood products.

8. The point at which it was and the point at which it should have been known that there was a real risk that the virus which caused AIDS had entered the donor population in Scotland, including knowledge about the extent of protection offered to recipients of blood products by the Scottish system of self exclusion of blood donors.

9. Communication of and access to current information and opinions on the risks of viral transmission from blood products for those treating patients with bleeding disorders in the first half of the 1980s.

Risks associated with particular blood products

10. The state of knowledge amongst those responsible for the treatment of bleeding disorders in Scotland as to the relative risks associated with the various blood products in the first half of the 1980s.

Communication of information and guidance

11. The accuracy of information and guidance emanating from the UKHCDO regarding the risk of AIDS from blood products in the first half of the 1980s, including the views expressed by Professor Bloom in the Haemophilia Society letter of May 1983.

12. The accuracy and appropriateness of information and guidance emanating from the government on the risks of AIDS associated with blood products in the first half of the 1980s.

The decision making process about product use in the first half of the 1980s

13. The nature and extent of the responsibility of (a) the Scottish National Blood Transfusion Service (b) the government in Scotland and (c) doctors in the production, selection,

procurement and distribution of products for the treatment of patients with bleeding disorders in Scotland in the first half of the 1980s.

14. The appropriateness of the decision not to convene an expert advisory group on AIDS until 1985 and the effect of that decision.

15. The way in which the procurement of blood products was funded in Scotland in the first half of the 1980s and the extent to which that arrangement affected the procurement of blood products.

16. The role of pharmaceutical companies in influencing product selection in the first half of the 1980s.

Response to knowledge about the emerging risk of AIDS

17. Whether and when, in light of international and domestic knowledge about the severity of AIDS and the risks it posed to patients with bleeding disorders, further steps should have been taken to minimise the exposure of such patients to blood products and by whom such steps should have been taken.

Practical considerations

18. The way in which projections were made for the estimated amount of blood products which would be needed for the treatment within Scotland of patients with bleeding disorders in the first half of the 1980s, the accuracy of that system and whether the system gave rise to any unnecessary exposure of patients to the risk of infection with HIV.

19. Whether it would have been feasible, in the first half of the 1980s, to switch patients receiving treatment with factor concentrates to treatment with products made from smaller donor pools, like cryoprecipitate, including whether such a change was (or should have been) contemplated.

Home treatment with factor concentrates

20. The number of patients with bleeding disorders in Scotland on home treatment with factor concentrates in the first half of the 1980s.

21. The extent to which the advantages of home treatment, if any, outweighed the risks of contracting HIV infection from the concentrates being used at home in the first half of the 1980s.

Prophylactic treatment with factor concentrates

22. The number of patients with bleeding disorders in Scotland on prophylactic treatment with factor concentrates in the first half of the 1980s.

23. The extent to which the advantages of prophylactic treatment, if any, outweighed the risks of contracting HIV infection from the concentrates in the first half of the 1980s.

Patient involvement in the decision making process as regards product use

24. The extent to which the opinions of patients with bleeding disorders were or should have been taken into account in making decisions about their treatment with blood products in the first half of the 1980s.

The continued use of imported blood products in Scotland in the first half of the 1980s

25. Whether Scotland could and should have been self sufficient in blood products in the first half of the 1980s and, if so, when.

26. Who was responsible for achieving self sufficiency in blood products in Scotland in the first half of the 1980s?

27. The reasons why imported products continued to be used in Scotland in the first half of the 1980s.

Regional variations in the types of products used in the treatment of patients with bleeding disorders in Scotland

28. The reasons why different blood products were used in different parts of Scotland and the consequences of such a divergence on the number of patients infected with HIV in the various regions of Scotland.

29. Whether a centralised system for the selection and procurement of blood products in Scotland over this period could and should have been instituted.

The impact of a more cautious approach to product use

30. Whether infections of patients with bleeding disorders in Scotland with HIV could and should have been avoided.

31. Whether the way in which NHS treatment was managed over this period was in the best interests of patients with bleeding disorders in Scotland.

Recommendations for the future

32. What lessons can be learned from and what recommendations for the future arise out of the Inquiry's consideration of the evidence in the B2 section?

JTD

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. Research and development priorities at the PFC prior to December 1984 and the extent to which consideration was given to viral inactivation of blood products.

2. Progress made by the PFC in the development of viral inactivation techniques prior to December 1984.

3. When and to what extent it was considered that viral inactivation of blood products would need to eliminate the risk of AIDS in addition to the risk of NANBH.

4. Whether and to what extent the heat treatment program at the PFC could have been accelerated or changed prior to December 1984 in order to eliminate the risk of AIDS.

5. The nature and extent of the communications between the SNBTS/PFC and the BPL/PFL in relation to viral inactivation of blood products prior to December 1984.

6. Heat treatment of Factor IX and why HTLV-III inactivated Factor IX was only available for issue in August 1985.

7. The extent to which haemophilia clinicians were aware of developments at the PFC in relation to heat treatment of Factor IX.

8. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry"s consideration of topic B3.

L-AvdW

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. Whose responsibility was it to introduce screening for HTLVIII in Scotland?

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

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

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

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

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

8. Did the warnings of Haemophilia Doctors in 1985 about the delay in introducing anti-HTLVIII testing reduce further delay

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

SdR

TOPIC B5a

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

1. The amount and content of information given to patients (or their parents) concerning the risk of AIDS as result of receiving blood products.

2. The amount and content of information given to patients (or their parents) of the risk of AIDS as a result of receiving a blood transfusion.

3. Whether patients (or their parents) were given sufficient information to be able to make an informed choice relative to the treatment they received.

4. The nature and extent of information made available by the manufacturers of blood and blood products about the risk of infection with HIV from their products.

5. The amount and content of the information given to patients (or their parents) about studies taking place involving samples of blood taken from them.

SdR

TOPIC B5b

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

1. The amount and content of information given to patients (or their parents) about the diagnostic tests being carried out upon samples provided by them.

2. Whether informed consent for such tests was obtained and the content of information given to patients concerning the results of such tests.

3. 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 HTLVIII virus.

4. 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 HTLVIII virus.

5. Efforts made to trace patients infected with HIV through blood transfusion.

SdR

TOPIC B5c

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

1. The amount, content and timing of information and counselling given to patients (and their families) found to be infected with the AIDS virus.

2. The amount, content and timing of information given to patients (and their families) exposed to the AIDS virus but were not infected.

3. The methods of communicating such information to patients (and their families).

4. The ineffectiveness of communication between health service professionals and patients (and their families).

5. The difficulties created by ineffective communication between health service professionals and patients (and their families).

6. Recommendations designed to increase the effectiveness of communication between health service professionals and patients (and their families).

SdR

TOPIC B5d

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. How did the Edinburgh Cohort come to be identified as a significant group worthy of study?

2. The information given to “members” of the Edinburgh Cohort about its existence as a significant group worthy of study?

3. How did the members of the Edinburgh Cohort become infected?

4. The amount content and timing of information given to the members of the Edinburgh Cohort and their families concerning infection with HIV and the consequences of such infection.

5. The ineffectiveness of communication.

6. The difficulties created by ineffective communication.

7. Recommendations designed to increase the effectiveness of communication.

SdR

TOPIC B6

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

1. The physical and mental effects of HIV infection on patients.

2. The physical and mental effects of treatment for HIV.

3. The personal and social consequences of HIV for patients and the stigma associated with it.

4. The personal and social consequences of HIV for patients" families and the stigma associated with it.

5. The financial consequences of HIV infection and treatment for patients and their families.

6. The effects of co-infection with HIV and Hepatitis C.

7. The level of information, support and counselling previously and currently available to patients infected with HIV through blood and blood products, and their families and the differences between centres.

8. The effect that the level of information, support and counselling has had on the ability of patients and their families to cope with HIV infection and its consequences.

SdR

TOPIC C1

The acceptance of blood from 'higher risk' donors, in particular:

C1a) prisoners; and

C1b) donors who had 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. Whether and to what extent SNBTS considered the risk from continuing to accept donations of blood from prisoners or other „higher risk" donors in the late 1970s and early 1980s.

2. Whether a decision to continue to collect blood from prisons was taken and by whom.

3. The role of the SHHD in the decision making process during the relevant period.

4. When, by whom and the reasons for any decision to cease collecting blood from prisons.

5. Whether the risks to patients were properly taken into account.

6. The decision making process relative to acceptance of donors with a history of jaundice and whether the decisions were taken in the best interests of patients.

SdR

TOPIC C2

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

Decision making systems in Scotland regarding surrogate testing for NANB hepatitis

1. The responsibility of (a) the Scottish National Blood Transfusion Service and (b) the government in Scotland for the decision making process in connection with the introduction of routine surrogate testing for markers for NANB hepatitis in Scotland.

Knowledge about NANB hepatitis and surrogate testing

2. Awareness of the potential severity of NANB hepatitis from 1985 to the point at which anti HCV testing was introduced in Scotland in 1991.

3. Whether account was taken of (a) knowledge and experience of hepatitis B and (b) knowledge and experience of the HIV crisis in assessing the public health risk posed by NANB hepatitis and in decisions concerning the introduction of surrogate testing.

4. Whether sufficient account was taken of the fact of and opinions about the introduction of surrogate testing in other countries.

Research into the prevalence of NANB hepatitis and the potential effectiveness of surrogate testing

5. The reasons why a large scale prospective study involving both donors and recipients into (a) the prevalence of HCV in the donor population and (b) the likely effectiveness of surrogate testing in reducing the transmission of Hepatitis C was never undertaken in Scotland or the UK.

6. The reasons behind and the likely usefulness of the research proposed by the Working Party on Transfusion Associated Hepatitis in November 1986 in assessing the likely effectiveness of surrogate testing in reducing the transmission of Hepatitis C.

SNBTS and surrogate testing

7. Why the SNBTS directors recommended in March 1987 that surrogate testing for markers for NANB hepatitis should be introduced in Scotland and whether such a recommendation should have been made earlier.

8. The extent to which (a) current understanding of the potential severity of Hepatitis C and (b) the reasoning for the attractiveness of introducing surrogate testing for NANB hepatitis was communicated effectively by the SNBTS to the decision makers within SHHD.

9. Why no testing algorithm (similar to that developed by SNBTS in connection with the introduction of anti HTLV III testing) was developed for NANB surrogate testing by the SNBTS.

10. Whether the SNBTS would have been able to cope with the loss of blood to the transfusion system resulting from the introduction of surrogate testing.

The accuracy of the testing mechanisms

11. The likely sensitivity and specificity of surrogate tests (a) as tests in their own right and (b) as markers for NANB hepatitis and the appropriateness of the weight accorded to these factors.

12. Whether deferral of donors with raised ALT levels for a limited time period was considered and if not should have been considered.

The role of the government in Scotland in the failure to introduce routine surrogate testing

13. The factors influencing the decision making process within SHHD relating to the proposal to introduce surrogate testing for NANB hepatitis in Scotland.

14. The reasons for the decision of administrative staff in the SHHD not to refer the specific question of surrogate testing for the consideration of the appropriate minister within SHHD.

15. The balancing exercise carried out between the rights of donors and the rights of recipients of blood and blood products in decision making about surrogate testing.

16. Whether the SNBTS gave sufficient clear advice on practical arrangements relating to surrogate testing to SHHD and whether any lack of such advice affected SHHD thinking regarding the introduction of surrogate testing.

17. When surrogate testing for NANB hepatitis in Scotland could practically have been introduced.

18. Whether consideration was, or should have been, given to the introduction of surrogate testing after the isolation and identification of the Hepatitis C virus.

19. The significance of the obligations owed by SNBTS to consumers of its products under the Consumer Protection Act 1987 both before and after its enactment and the extent to which proper cognisance was taken by the government/the NHS in Scotland of information and guidance on the nature and extent of those obligations in reaching decisions about surrogate testing.

The consequences of the failure to introduce surrogate testing

20. The number of infections with Hepatitis C in Scotland which are likely to have been avoided, had surrogate testing for NANB hepatitis been introduced.

Conclusions

21. Whether and when routine surrogate testing for markers for NANB hepatitis in Scotland should have been introduced.

22. Whether the failure to introduce routine surrogate testing for markers for NANB hepatitis in Scotland was in the best interests of the recipients of blood and blood products.

23. What lessons can be learned from and what recommendations for the future arise out of the Inquiry's consideration of the evidence in the C2 section?

JTD

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. Approach taken and progress made by the PFC between December 1984 and December 1985 in relation to eliminating of the risk of NANBH from Factor VIII.

2. Progress made by the PFC between December 1985 and April 1987 in relation to heat treatment of Factor VIII in order to eliminate the risk of NANBH.

3. The nature and extent of the communications between the SNBTS/PFC and the BPL/PFL in relation to viral inactivation of blood products between December 1984 and April 1987.

4. Reasons for the delay between the availability of Z8 for clinical trial and its issue for clinical use.

5. Whether and to what extent the development of virally inactivated factor concentrates by the PFC was affected by availability of resources.

6. The extent to which decisions taken at the PFC in relation to the development of virally inactivated factor concentrates were influenced by haemophilia clinicians.

7. The extent to which haemophilia clinicians were aware of developments at the PFC in relation to the development of NANBH/Hepatitis C inactivated Factor VIII.

8. Whether the PFC could have taken other steps that might have resulted in a NANHB/Hepatitis C inactivated Factor VIII product being available earlier in Scotland.

9. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry's consideration of topic C3.

L-AvdW

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.

The identification of patients as suffering from a bleeding disorder

1. How were previously untreated patients identified as suffering from haemophilia or some other bleeding disorder over this period?

The background knowledge of the risks of infection with NANB hepatitis over this period

2. What was known about the risk of contracting NANB hepatitis from the administration of factor concentrates (in particular factor VIII concentrate) or other blood products over this period?

3. What was known about the potential consequences of contracting NANB hepatitis over this period?

4. Access for those treating patients with bleeding disorders to current information and opinions on (a) the risks of transmission of NANB hepatitis from blood products and (b) the potential severity of NANB hepatitis over this period

5. The factors which should have influenced the choice of product to be used in the treatment of virgin and minimally treated patients with bleeding disorders over this period.

The systems in place in Scotland for managing the risks of patients with bleeding disorders contracting NANB hepatitis over this period

6. The extent to which patients presenting for treatment for bleeding disorders in Scotland were treated in a way which minimised the risk of them being infected with NANB hepatitis including (a) the systems in place at the point of first presentation of such patients and (b) the systems in place for others responsible for treating bleeding incidents.

7. The effectiveness of systems for ensuring that all reasonable steps were taken for the proper assessment of such patients and the avoidance, where possible, of them being exposed to SNBTS factor concentrates.

8. The information given to untreated and minimally treated patients with bleeding disorders of the particular risks to them of contracting NANB hepatitis during this period and the involvement of such patients in treatment decisions.

Guidance made available to hospitals involved in the treatment of patients with bleeding disorders over this period

9. The guidance in place for hospitals around Scotland as to the recommended treatments for patients with bleeding disorders and, in particular, as to the appropriate treatment for virgin or minimally treated patients including the quality and currency of that guidance (including the roles played by the UKHCDO and the government in providing guidance).

Action after May 1986

10. Steps taken by the NHS and/or the government in Scotland to minimise the risks of a virgin or minimally treated patient contracting NANB hepatitis in the aftermath of the infection of a virgin patient in Edinburgh in May 1986 or any earlier such infections within the relevant period of which the Inquiry is aware (other than the procurement of a supply of the English 8Y product).

The possibility of alternative concentrate products being made available for Scottish patients over this period

11. The advantages in this period of the English 8Y concentrate over the available SNBTS factor VIII concentrate and the effectiveness of information exchange between England and Scotland on this issue.

12. The action taken in Scotland in light of that state of affairs, including the reasons why action was or was not taken.

13. Whether, when, how, in what quantities and on what conditions a supply of English 8Y for treatment of previously untreated and/or minimally treated patients in Scotland could practically have been made available and whether, when and by whom efforts should have been made to secure such a supply.

14. The systems in place for the procurement of blood products (including the projection of demand), in particular for virgin and minimally treated patients, over this period and the effectiveness of those systems.

15. Consideration given in Scotland to the possibility of swapping a quantity of SNBTS factor VIII concentrate for a supply of 8Y.

16. The reasons why a supply of 8Y was made available to Scotland in the summer of 1986.

17. Steps taken to disseminate throughout Scotland the fact of its availability and the appropriate circumstances for its use and the extent to which those steps were appropriate in the interests of patient safety

18. What the supply of 8Y which was made available to Scotland in the summer of 1986 was actually used for.

The effects of actions and decisions taken over this period

19. The numbers of patients with bleeding disorders likely to have been infected with Hepatitis C through blood products in Scotland over this period and how they came to be so infected.

Conclusion

20. Whether the way in which the risk of contracting NANB hepatitis from NHS treatment was managed over this period was in the best interests of patients with bleeding disorders in Scotland.

Recommendations for the future

21. What lessons can be learned from and what recommendations for the future arise out of the Inquiry's consideration of the evidence in the C3A section?

JTD

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.

Division of responsibility in connection with decision making about anti-HCV testing

1. The responsibility of (a) the Scottish National Blood Transfusion Service and (b) the government in Scotland for the introduction of routine anti-HCV testing in Scotland and, in particular, for any delay.

2. The role of advisory committees in the decision making process surrounding the introduction of anti-HCV testing in Scotland.

Knowledge about hepatitis C

3. Awareness of the prevalence and potential severity of hepatitis C from the isolation of the virus to the point at which routine anti-HCV testing was introduced in Scotland in 1991.

The introduction of routine anti-HCV testing in Scotland

4. The reasons why anti-HCV testing started in certain parts of Scotland before others.

5. When anti-HCV testing could practically have been introduced throughout Scotland.

6. The effectiveness of the management structure and the decision making processes within SNBTS and the SHHD relating to the introduction of anti-HCV testing.

7. The account taken of the fact of and opinions about the introduction of routine anti-HCV testing in other countries.

8. The reasons for, effect and appropriateness of the emphasis placed by SNBTS and SHHD on synchronisation with introduction in England in delaying the introduction of routine anti-HCV testing in Scotland until September 1991.

9. The reasons for and appropriateness of concerns about (a) confirmatory testing and (b) the accuracy and usability of test kits and the effect of decisions taken regarding these matters in delaying the introduction of routine anti-HCV testing in Scotland until September 1991.

10. The reasons for and appropriateness of the decision to instigate testing on second generation kits and the effect of that decision in delaying the introduction of routine anti-HCV testing in Scotland until September 1991.

11. The balancing of the rights of donors and the rights of recipients of blood and blood products in connection with the introduction of anti-HCV testing in Scotland.

12. The impact of funding considerations on the decision making process as to when to introduce routine anti-HCV screening in Scotland.

13. The involvement of and the advice given to the appropriate minister within SHHD in the decision making process in connection with the introduction of anti-HCV testing in Scotland.

14. The significance of the obligations owed by SNBTS to consumers of its products under the Consumer Protection Act 1987 from its introduction 1 March 1988 and the extent to which proper cognisance was taken by the government/the NHS in Scotland of information and guidance on the nature and extent of those obligations in reaching decisions about the introduction of anti-HCV testing.

Consequences of the timing of the introduction of routine anti-HCV testing in Scotland

15. The number of infections with Hepatitis C in Scotland which are likely to have been avoided, had anti-HCV testing been introduced in Scotland earlier, in particular in accordance with timing achieved in other countries.

Conclusions

16. When routine anti-HCV testing in Scotland should have been introduced.

17. Whether the fact that it took until September 1991 for routine anti-HCV testing to be introduced in Scotland was in the best interests of the recipients of blood and blood products.

Recommendations for the future

18. What lessons can be learned from and what recommendations for the future arise out of the Inquiry's consideration of the evidence in the C4 section?

JTD

TOPIC 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.

1. The nature and extent of the information provided to patients (or their parents) about the risk of acquiring NANBH/Hepatitis C through blood and blood products.

2. The nature and extent of the information provided to patients (or their parents) about the possible consequences of NANBH/Hepatitis C infection.

3. The manner in which information was provided to patients (or their parents) about the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection.

4. The absence of systems, guidelines and monitoring to ensure that all patients (or their parents) treated by the NHS in Scotland were given adequate and uniform information about the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection.

5. The extent to which patients were aware of the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection, and whether communication of such information to patients was effective.

6. The extent to which patients (or their parents) were afforded the opportunity to be involved in or to make informed decisions about their treatment with blood and blood products.

7. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry"s consideration of topic C5a.

L-AvdW

TOPIC C5b

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

Information about testing and consent to testing

1. The nature and extent of the information given to patients about Hepatitis C and the possible consequences of infection prior to testing.

2. The extent to which consent was sought and obtained from patients prior to testing.

3. The extent to which lessons learned from the HIV experience ought to have informed the approach to Hepatitis C testing.

Steps taken to trace individuals who might have been exposed

4. Whether sufficient efforts were made to trace haemophilia patients in Scotland who had been infected with Hepatitis C through blood products.

5. Why the look-back exercise was not initiated as soon as a screening test for anti-HCV became available.

6. The extent of the look-back exercise and its restriction to repeat donors.

7. The effectiveness of the look-back exercise in identifying patients infected with Hepatitis C through blood in Scotland.

8. The number of patients infected with Hepatitis C through blood in Scotland who might not yet have been traced through the look-back exercise.

9. Whether adequate measures have been taken to identify patients infected with Hepatitis C through blood in Scotland who might not yet have been traced through the look-back exercise.

10. The number of patients and/or families of patients infected with Hepatitis C through blood

in Scotland who have never been advised of their diagnosis and/or the source of infection.

Recommendations for the future

11. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry's consideration of topic C5b.

L-AvdW

TOPIC C5c

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

1. The manner in which positive tests results were communicated to patients (or their parents).

2. When patients (or their parents) were advised of positive test results.

3. The nature, extent and accuracy of the information provided to patients (or their parents) about the possible consequences of their Hepatitis C infection.

4. The manner in which information was provided to patients (or their parents) about the possible consequences of their Hepatitis C infection.

5. The extent to which patients (or their parents) understood the possible consequences of their Hepatitis C infection and whether communication of this information was adequate and effective.

6. The nature and extent of the information provided to patients and their families about the risks of transmission of Hepatitis C and the precautions that should be taken to prevent transmission.

7. The extent to which family members of patients with Hepatitis C were offered testing.

8. The nature and extent of the counselling and support offered to patients infected with Hepatitis C through blood and blood products, and to their families.

9. Differences between patients and doctors in terms of their understanding of the term “counselling”.

10. The extent to which patients are satisfied with the information currently available to them regarding their Hepatitis C infection and its consequences.

11. The nature and extent of the information provided to patients about the circumstances of their infection with Hepatitis C.

12. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry's consideration of topic C5c.

L-AvdW

TOPIC C6

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

1. The physical and mental effects of Hepatitis C infection on patients.

2. The physical and mental effects of treatment with Interferon and/or Ribavirin on patients.

3. The personal and social consequences of Hepatitis C infection for patients and the stigma associated with Hepatitis C infection.

4. The personal and social consequences of treatment with Interferon and/or Ribavirin for patients.

5. The personal and social consequences of Hepatitis C infection for patients" families.

6. The personal and social consequences of treatment with Interferon and/or Ribavirin for patients" families.

7. The financial consequences of Hepatitis C infection, treatment with Interferon and/or Ribavirin, and liver failure and transplantation for patients and their families.

8. The effectiveness of Interferon and/or Ribavirin in the treatment of Hepatitis C infection.

9. The effects of exposure to multiple strains of Hepatitis C.

10. The level of information, support and counselling previously and currently available to patients infected with Hepatitis C through blood and blood products, and their families and the differences between centres.

11. The effect that the level of information, support and counselling has had on the ability of patients and their families to cope with Hepatitis C infection and its consequences.

12. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry"s consideration of topic C6.

L-AvdW

STATISTICS

HIV infections amongst people with bleeding disorders

1. How many people with bleeding disorders were infected with HIV by blood products in Scotland?

2. What proportion of the total number of people with bleeding disorders in Scotland were so infected before the introduction of factor concentrates heat treated so as to inactivate HIV?

3. What proportion of people with haemophilia so infected fall into the categories of mild, moderate and severe haemophiliacs?

4. What proportion of people with haemophilia so infected is comprised of those suffering from haemophilia A and those suffering from haemophilia B?

5. When, where and how is it likely that the patients with bleeding disorders in this group were infected with HIV?

6. How many people with bleeding disorders in Scotland who were infected with HIV by blood products were also so infected with Hepatitis C?

Hepatitis C infections amongst people with bleeding disorders

7. How many people with bleeding disorders were infected with Hepatitis C by blood products in Scotland?

8. What proportion of the total number of people with bleeding disorders in Scotland were so infected before the introduction of factor concentrates heat treated so as to inactivate Hepatitis C?

9. What proportion of people with haemophilia so infected fall into the categories of mild, moderate and severe haemophiliacs?

10. What proportion of people with haemophilia so infected is comprised of those suffering from haemophilia A and those suffering from haemophilia B?

11. When, where and how is it likely that the patients with bleeding disorders in this group were infected with Hepatitis C?

12. The prevalence of the different genotypes of Hepatitis C amongst those with bleeding disorders infected by blood products in Scotland.

HIV infections amongst the recipients of blood transfusions

13. How many people were infected with HIV through blood transfusions in Scotland?

14. When, where and how is it likely that the patients in this group were infected with HIV?

15. The desirability of an HIV Lookback exercise.

Hepatitis C infections amongst the recipients of blood transfusions

16. How many people were infected with Hepatitis C through blood transfusions in Scotland?

17. When, where and how is it likely that the patients in this group were infected with Hepatitis C?

18. The accuracy and adequacy of the efforts made by the government in Scotland to identify patients infected with Hepatitis C through blood transfusions in Scotland and the desirability of further such efforts.

HIV - the progression of the infection to AIDS

19. What proportion of those infected with HIV through blood or blood products in Scotland go on to develop AIDS?

Hepatitis C - the progression of the disease

20. The proportion of those infected with the Hepatitis C virus through blood or blood products in Scotland who clear the disease spontaneously and the proportion who progress to the various stages of the disease (including the effect of co-infection with HIV on these proportions).

21. The number of people who have contracted Hepatitis C through blood or blood products in Scotland who are still alive and have not yet suffered symptoms but are likely to do so in the future.

Mortality statistics

22. How many people who contracted HIV through blood or blood products in Scotland have died?

23. For how many people who contracted HIV through blood or blood products in Scotland who have died did AIDS make a material contribution to their death?

24. How many people who contracted Hepatitis C through blood or blood products in Scotland have died?

25. For how many people who contracted Hepatitis C through blood or blood products in Scotland who have died did their Hepatitis C infection make a material contribution to their death?

26. The accuracy of the reporting of Hepatitis C/HIV as a cause of death amongst those infected with Hepatitis C and/or HIV through blood or blood products in Scotland.

Statistics relating to the use of blood products in Scotland

27. How have the amounts of the different types of blood products used in the treatment of people with bleeding disorders in Scotland varied over the Inquiry's reference period across the country?

General - the maintenance of public statistical information

28. The relative responsibilities of different bodies in Scotland for the compilation and maintenance of statistical information relating to those infected with HIV and/or Hepatitis C as a result of treatment with blood or blood products in Scotland and its accuracy.

Recommendations for the future

29. What recommendations for the future should the Inquiry make arising out of the material considered in this topic?

JTD