Scottish National Blood Transfusion Service

Hepatitis C Inquiry: Crown Office and Procurator Fiscal Service

In the Deputy Crown Agent's letter of June 21, 2005 a number of specific questions are raised.

Question 1: Identification of any relevant blood product.

Question 2: "The way that the emerging science in relation to a test for HCV was considered between the time of identification of the virus in its known form (1989) and the introduction of the common testing procedures across the united Kingdom in September 1991, comparison with other countries and, in particular, reasons for any difference in the pace of introduction of testing procedures"

Question 3 "An estimate of the prevalence of the virus in donated blood in the UK until such time as a screening test was successfully introduced in 1991, information regarding the process of selection of donors to minimise any such risk".

Question 4 "The way that risk to patients was assessed generally, and in individual cases, in the light of the answer to the preceding questions and how any such risk was communicated to the patient."

Question 5 "Information as to the nature of the hepatitis C virus, particularly its seemingly ubiquitous characteristic in the population at large and the extent to which the level of infectivity may have increased in recent years."

Question 6 "The potential impact of publicity arising from any inquiry on public knowledge as to the virus which may assist efforts to stem its spread or which may adversely affect the level of donated blood".

The responses following are arranged in the order of the original questions:-

Question 1: Identification of any relevant blood product.

The notes following are based on the extracted information supplied to us by Leanne Cross of COPFS with her letter of 11 08 2005. Further information about case 3 was provided by SNBTS Glasgow and about case 4 by SNBTS Aberdeen.

Patient 1 [redacted]

[redacted]

Patient 2 [redacted]

[redacted]

[redacted]

Patient 3 [redacted]

[redacted]

Patient 4 [redacted]

[redacted]

Question 2: "The way that the emerging science in relation to a test for HCV was considered between the time of identification of the virus in its known form (1989) and the introduction of the common testing procedures across the United Kingdom in September 1991, comparison with other countries and, in particular, reasons for any difference in the pace of introduction of testing procedures".

This question has several components and the response has therefore been divided into sections, as listed below:

2a General issues relevant to transfusion safety

Some general principles affect safety of all blood products with respect to the transmission of infections. The choice of country or geographical area from which donations are obtained may be influenced by the epidemiological patterns of infection in the populations of different areas. The procedures for recruiting donors should be designed to attract those

less likely to have blood transmissable infections. The selection process for donors who attend is intended to identify possible risk factors and also to avoid taking a donation from anyone whose health could be adversely affected by giving blood.

A sample of each blood donation that is tested to detect infective agents using a system that ensures that no blood can be released for use unless all test results are satisfactory. All such tests represent a compromise between sensitivity and specificity, and all yield some false positive results (that is a positive result in the initial screening test that cannot be confirmed by subsequent more detailed testing). Because of the serious implications of a positive hepatitis or AIDS test result for a donor, it is necessary to have suitable confirmatory tests to ensure the correct interpretation of each positive screening test.

Processing of the freshly collected blood into blood components now also includes steps such as filtration, chemical or physical treatment to further reduce any infection risk. These technologies have been introduced as they have become available for implementation.

In the case of plasma derivatives such as factor VIII, all the above principles should apply. In addition there may need to be consideration of the so called "pool size" ie the number of donations, and the number of donors that are represented in each manufacturing batch. The manufacturing process should be designed and controlled to ensure that any infectious agent that has for any reason not been detected by the testing process will nevertheless be rendered non - infective or removed from the final product.

Blood products are no different from other potent therapeutic agents in that they are not and will never be completely free of risk. It is self evident that if a transfusion is not likely to offer real benefit to the patient, the risks will tend to outweigh the advantages. However there are many situations in which there may be genuine clinical uncertainty about whether blood should be given.

2b Timeline of events in the introduction of Hepatitis testing of blood donations world wide.

2c How decisions about testing were arrived at in the UK

(i) Structure and Governance of the Blood Transfusion Services in Scotland and England 1989-

(ii) Advice to the UK Governments on transfusion related hepatitis.

(iii) Sequence of events leading up to the start of hepatitis C testing of blood donations in the UK.

(iv) Implementation of hepatitis C testing in Scotland

2 c Timeline of the emerging science and events in the introduction of Hepatitis testing of blood donations world-wide.

The relevant information is extensively described in the Judgement of Mr Justice Burton in the case entitled A and others and the National Blood Authority (26 March 2001) and in

other documents such as the report of the Krever Commission in Canada. In preparing the following sections the records of the relevant meetings of UK advisory bodies have been consulted where these are available.

Prior to the discovery of Hepatitis C, it had been recognised that hepatitis occurred in some recipients of blood components and in many patients who received regular treatment with plasma derivatives. The introduction of tests for hepatitis B in 1970 reduced but did not remove this problem. In the United States, the greatest single reduction in post transfusion hepatitis due to transfusion of blood components was achieved by moving to a policy of non- remunerated voluntary blood donation. During the 1970's and 1980's, researchers in both the US and Europe tried unsuccessfully to develop a specific test that would reliably detect blood that could transmit non non-B hepatitis. It was the researchers in Chiron laboratories who eventually achieved this goal. Some of the key dates are given below

1987 November. Patent filed for putative NANBH agent identified by molecular cloning (HCV).

1988 May. Discovery of a virus associated with non-A non-B hepatitis, and named Hepatitis C Virus by the discoverers. Announced by the Chiron Company in a press release.

1988. NIH (USA) announced that the Chiron test had correctly identified NANBH infected and uninfected samples.

1989 November: Export License granted by US Food and Drugs Administration for Ortho Company which had developed, using the Chiron patented discovery, a hepatitis C antibody tests for testing blood donor samples

1989 November or December. Test introduced in Japan

1990 February. Test introduced in Australia.

1990 March. Test introduced in France.

1990 April. Test introduced in Finland

1990 May. Approval granted by the US FDA for the test to be used in the USA. Test introduced in USA and Austria.

1990 June. Test introduced in Canada and Germany.

1990 July. Test introduced in Belgium.

1990 August. Test introduced in Switzerland.

1990 September. Test introduced in Luxembourg

1990 October. Test introduced in Spain.

1991 January. Test introduced in Norway and Sweden

1991 March Test introduced in Portugal, Cyprus, Greece, Iceland, Hungary, Malta.

1991 June Test introduced in Netherlands.

1991 August Test introduced in Italy.

1991 September Test introduced in UK

1991 October Test introduced in Ireland.

1992 August Test Introduced in New Zealand.

2dc How decisions about testing were arrived at in the UK

(i) Structure and Governance of the Blood Transfusion Services in Scotland and England 1989-1991

The SNBTS consisted of 5 Regional Transfusion Services. In 1974, SNBTS became a division of the newly established Common Services Agency for the Scottish Health Service (CSA). The CSA later set up its BTS Sub-committee which was responsible to the CSA Board for the finances and management of the SNBTS. The Regional Transfusion Directors (RTD's) were not members of the BTS Subcommittee but were invited to attend as observers. The head of SNBTS was the National Medical Director until a General Manager was appointed in 1990. The Scottish Home and Heath Department was represented on the CSA BTS Subcommittee by the Deputy Chief Medical Officer.

In England, the National Blood Transfusion Service (NBTS) was made up of 14 Regional Transfusion Services each funded by and accountable to one of the Regional Health Authorities (RHA's). Steps were however being taken to move to a nationally managed service and during the early 1990's a National Directorate was established. The first National Director supported by a senior administrator seconded from the Department of Health. During 1989-91 however, funding of the NBTS was still through the RHA's.

Donation testing for antibody to the AIDS virus (now called HIV, then called HTLVIII/LAV) was started on the same date in 1985 throughout the UK.

(ii) Advice to the UK Governments on transfusion related hepatitis.

A number of groups played a part in advising the Government on blood safety with respect to hepatitis infections over the period 1989 -1991. In 1989, the DHSS established the Advisory Committee on the Viral Safety of Blood (ACVSB). It was chaired by the Deputy Chief Medical Officer in the DHSS and following his retirement by his successor. Its members were drawn from organisations in the UK that had expertise in fields including virology, haematology, transfusion and plasma fractionation. There were observers from the Department of Health, The Welsh Office, the DHSS (NI) and the Scottish Home and Health Department. Its Terms of Reference were given as follows in paper ACVSB 1:

"To advise the Health Departments of the UK on measures to ensure the virological safety of blood whilst maintaining adequate supplies of appropriate quality both for immediate use and for processing".

The paper goes on to provide the following guidance for the new Committee:

"Note remit is UK wide (sic). Our concern is matters of major policy, not the detailed implementation of policy. The intention is that any proposed changes in requirements or practices of one of the main groups (transfusion service, fractionators, regulators) that has major implications for the others are brought to this group first for discussion. Whilst our specific remit is with blood donors our advice will also be made available to others within the Department who have policy responsibility for tissue and organ donors".

The ACVSB was the formal route of advice to Ministers, and in later minutes cited below there are several clear references to this. The role of the ACVSB in advising the Scottish Home and Health Department was restated in a letter to the Medical Director of SNBTS from the Deputy Chief Medical Officer, SHHD, and its observer on ACVSB), dated 2 August 1989.

"Thank you for your letter of 28 July concerning the introduction of additional screening tests on blood donations: in particular you referred to the CHIRON test for Non A Non B Hepatitis, the HIV1 + 2 test and the HIV 2 test. As you are aware, there is a UK Advisory Committee on the Virological Safety of Blood which is meeting regularly and considering the sensitivity and specificity of the tests available for a variety of infectious agents including those named above. If it is considered desirable to introduce a further routine screening test for blood donors, I understand that this will be done simultaneously throughout the UK – as was done in the case of the current HIV test. I am sending a copy of this letter to Deputy Chief Medical Officer at the Department of Health and to administrative colleagues here in SHHD".

In the papers for the first meeting of the ACSVB, other relevant groups and their terms of reference or roles are listed as follows:

"Committee on Safety of Medicines: Gives advice to the Licensing Authority on the quality safety and efficacy of medicinal products).

National Transfusion Directorate (England): Implements the national strategy for the transfusion services and co-ordinates the activities of the BTS and the CBLA (Central Blood Laboratories Authority). England and Wales only, although frequent consultation with Scotland. Concerned with the safety and welfare of donors, supply of safe fresh blood and blood components for patients as well as fractionators: subject to resource constraints.

UK Advisory Committee for Transfusion Transmitted Diseases (ACTTD): This new group will be considering many of the same issues as the present committee, but only from a transfusion point of view".

The UK Advisory Committee for Transfusion Transmitted Diseases (ACTTD): was an initiative of the National Transfusion Directorate. Its remit is given in paper TTD2/89 as follows:

"1. To consider the epidemiological, clinical and laboratory aspects of diseases which may be transmitted by the transfusion of blood and blood products.
2. To determine the appropriate policy which should be implemented by the UK Blood Transfusion Services for the control of transfusion transmitted diseases.
3. To advise the Departments of Health accordingly".

Section 2d (iii) Sequence of events leading up to the start of hepatitis C testing of blood donations in the UK: work of the Advisory Committee on the Virological Safety of Blood.

1989 April. NBTS (England) met with Ortho Clinical Diagnostics (business partner of Chiron) to discuss assay (for antibody to HCV) for screening blood donors.

April 4 1989: Advisory Committee on Viral Safety of Blood (ACVSB) Meeting 1: The meeting addressed CJD and HTLV1. Hepatitis was proposed as a possible topic for the next meeting.

May 15 1989: ACVSB Meeting 2: paper ACVSB 2/7 (Prepared by the secretariat?) stated "At present there does not appear to be any urgent need to introduce routine surrogate testing for NANB hepatitis. The position should be reconsidered by this committee when the results of the UKBTS NANB donor study are available. The Chiron test may also make surrogate testing obsolete provided the UK and other studies confirm the promising results already reported and assuming that the cost benefit analysis is satisfactory." (Minutes of meeting 2 not in file).

1989 May 19 UKACTTD Second meeting.

1989 July. Ortho test discussed at meeting of UK Advisory Committee on the Virological Safety of Blood (ACVSB).

July 3 1989: ACVSB Meeting 3 minuted its support for the view expressed in a Council of Europe document that stated that

"anti HCV testing alone was not sufficient to eradicate post transfusion hepatitis" One virologist member of ACVSB reported on a recent conference where data had been presented that made "a persuasive case that the Chiron Test results were reliable".

1989 October 9 UKCTTD Third meeting.

30 October 1989: ACVSB Meeting 4. From the chairman's summing up of the meeting:

"the feeling of the committee was that the (Chiron) test represented a major step forward but that the committee would need to know a great deal more ... the UK would not want to go in advance of an FDA decision ... pilot studies should go on in Birmingham, Sheffield and Brentwood to show the feasibility of the test in routine practice. The committee's feeling was that there was no case for using surrogate tests for NANB. ACVSB would support the general introduction of the Chiron test if the FDA approves it... the committee should be developing an economic case (ie % of NANB that would be prevented) for the Department to fund the routine use of the test".

1989 November 22. UKACTTD Fourth meeting.

1989 November. SNBTS informed by Ortho of prototype confirmatory test (RIBA).

17 January 1990: ACVSB Meeting 5. The committee agreed that the results from the additional pilot studies were satisfactory. Cost of assay for the UK blood services estimated to be from £5M- £7M per annum. There was wide ranging discussion of Non A

Non B hepatitis – reported in 24 paragraphs of minute. One of the virologist members stated that he would not express an opinion as to whether the Chiron test should be introduced as he needed better scientific evidence. The minute does not record a clear conclusion other than that a briefing should be prepared for ministers *"setting out the present position and the committee's views".*

1990 March16. UKACTTD Fifth meeting.

1990 April. ACVSB discussed proposed confirmatory assay (RIBA). One expert thought it not good enough. It was noted that another assay for HCV (by Abbott) was under development and that the Ortho assay had not yet been approved by FDA. Agreed to establish a sub-group to prepare a protocol for a substantial pilot study.

24 April 1990: ACVSB Meeting 6. Much of the minute deals with NANB hepatitis. Reports were given by committee members who had attended two meetings recently held by the two manufacturers supplying hepatitis C tests (Abbott Laboratories and Ortho – who were by now marketing the Chiron test) While concerns were expressed about lack of specificity of the test and the lack of a suitable confirmatory test, it was also minuted that in a paper submitted by a virologist on the committee), that data presented from the USA TTV (Transfusion Transmitted Virus) study "showed the predictive level of anti HCV positivity for infection to be about 77%" The committee papers appear to have included a joint statement dated February 8 1990 of the American Association of Blood Banks, American Red Cross and Council of Community Blood Banks which states

" based on the available information that indicates a strong correlation between anti HCV in blood donors and the transmission of non A non B hepatitis to recipients ....all blood components should be tested for hepatitis C virus antibody (anti HCV) .This recommendation should be implemented as soon as feasible".

Paper ACVSB6/6 and paper 5/6 from the previous meetings discuss the need for an economic analysis but no decision was minuted about taking this forward. The chairman's summing up of the discussion includes the following:

"there was inadequate scientific data to support the introduction of the Ortho test for routine screening. The FDA had not yet approved the test and it would be reassuring if the regulatory authority in the country of origin had done so ... a prospective study involving 25,00-50,000 donors would generate sufficient positives for confirmatory testing".

A subcommittee was to be set up to plan the proposed pilot study. It was minuted that

"a note would be prepared for Ministers telling them the outcome of the discussion".

1990 May. FDA licence granted (2 May) and NBTS advised by Ortho that a confirmatory test (RIBA) was available.

July 2 1990: ACVSB Meeting 7 was largely devoted to Hepatitis C testing. A Department of Health medical officer reported

"the FDA decision to approve hepatitis C screening and that America had already introduced screening and that other countries were following. It was now felt that a study was no longer viable and the meeting had been brought forward so that a decision on the introduction of UK hepatitis C screening could be reached".

The minute (paragraph) 8 states

"After further discussion the Committee concluded that they should recommend to Ministers that Hepatitis C testing should be introduced, but that first a pilot study using the Ortho and Abbot tests was necessary to decide which was the better test for the Regional Transfusion Centres" A submission to this effect was to be put to Ministers and "consideration would be given to the funding".

November 21 1990: ACVSB Meeting 8. Reports on the performance of the two screening tests were received. *"Overall there seemed little to choose between the two screening kits"*. One virology expert repeated concerns about the fact that the two tests produced discordant results. The chairman's summing up was as follows

"there was agreement that the UK should introduce hepatitis C testing as soon as practicable. RTC's would decide individually whether to use the Ortho or Abbot test. A submission would go to Ministers regarding this significant policy decision and the Management Executive would consider the funding aspect".

1991 January. UKACTTD Sixth meeting.

Jan 21 1991: UK Ministerial approval given

January 22 1991: In a memo to all UK Transfusion Directors, the national Director of NBS announced that

"The Department of health have agreed that routine testing of all blood donations for anti HCV can be put into operation". "I have been asked to try and ensure that testing starts simultaneously in RTC's in England and Wales and that it is coordinated with commencement of testing in Scotland. Will you please advise me what you consider the earliest date that you would commence testing. Financial arrangements to cover routine screening have still to be concluded and I will advise of these at a later date"

January 25 1991: ACVSB Meeting 9. The satisfactory results of the UK BTS pilot study of hepatitis C antibody screening of donations were reported. The committee discussed the likely availability of the second generation tests and *"members agreed that it was important for proper evaluation of the Ortho and Abbot 1 and 2 tests to be carried out before RTC's decided which test to adopt"*.

The minute does not indicate what if any advice was to be passed to Ministers.

January 28 1991: National Director NBTS wrote *"It was not intended to pressurise RTC's to start testing in the immediate future which I agree is entirely impractical. For England and Wales, as you know, there is a matter of financial provision for this testing to be sorted out"*.

1991 February ACVSB decided that second generation assays should be considered because of obvious improvements over first generation assays.

March 21 1991: The NHS Procurement Directive in a letter to the National Director of NBTS, notified authorisation of

"a 'second round' comparative evaluation of hepatitis C kits at Newcastle, North London and Glasgow Regional Transfusion Centres".

1991 March UK Advisory Committee on Transfusion Transmitted Diseases (ACTTD) decides to postpone introduction of test until second generation tests had been evaluated. Following this meeting a letter from the National Director of NBTS to the regional transfusion directors included the following: *"At a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases in Manchester on Monday last, the following was agreed (a) NBTS National Director would advise DOH that the 1st July start date should be delayed until such time as the evaluation of the new generation of HCV tests has been completed. If this is accepted it would push the start date to September".*

April 3 1991 The NBTS National Director wrote to all RTD's: *"It is undoubtedly in our interest that this evaluation takes place. However to complete this study and become operational by 1st July is too tight a schedule. It is difficult to state precisely a revised date, but I think we should aim to commence routine screening for anti HCV by 1st September 1991".*

May 2 1991 The Newcastle RTC Director announces that his centre would start routine hepatitis C screening of donations so tha, by July 1, all its stock would have been tested.

May 9 1991 National Director NBTS wrote of this decision: *"This is in conflict with the Department of Health's (DH) agreed starting date for anti HCV testing of about 1st September".*

May 9 1991 National Director NBTS wrote: *I have agreed with the department of health that in view of the events that have taken place at the Northern RTC, there should be an extension of the trial of anti-HCV testing of blood donations beyond that proposed" this was to involve the RTCs of Leeds and Liverpool and Glasgow and the results from Newcastle would also be included*

May 21 1991: AVCVSB Meeting 10. The committee agreed with the framework for a protocol outlined in ACVSB10/1 and that Northern RTC's were to be included in the main trial. The Chair told the Committee that *"there were restrictions in the Department's evaluation budget that would have to be taken into account in considering this recommendation".*

1991 June 10 UKACTTD Eighth meeting.

1991 August 13 UKACTTD Ninth meeting.

1991 September 13. Special meeting of UK Advisory Committee for Transfusion Transmitted Diseases (ACTTD) Paper TTD32/91). Summarises decisions concerning hepatitis C testing taken by that committee during 1989 – 1991.

2 d (iv) Implementation of hepatitis C testing in Scotland

1988 July. SNBTS contact Ortho Diagnostic Systems (business partner of Chiron) to enquire about the availability of the Chiron test for NANBH. Advised that a test "may be available toward the end of 1989

1989 July. SNBTS approached by Ortho to introduce test for screening blood donations.

1989 August. SNBTS notified by SHHD that the topic would be addressed by ACVSB and that if a new test were to be introduced this would be done simultaneously throughout the UK.

1989 October. SNBTS evaluation of the Ortho assay completed and concluded that the test was reliable and 'user friendly' but concerned over absence of confirmatory test.

1989 November 8. A detailed briefing paper on post transfusion viral hepatitis was presented to the Blood Transfusion Subcommittee of the Common Services Agency for the Scottish Health Services by the National Director of SNBTS. The committee *"noted with interest the circulated paper containing a review of the strategy adopted by SNBTS aimed at eliminating post transfusion hepatitis. It appeared likely that screening (for hepatitis C) would be introduced in mid 1990"*

Revenue costs for SNBTS were estimated to be of the order of £600, 000 per annum.

1990 July (?). SNBTS submits revenue bid of £1.2M to finance testing (Public Expenditure Survey, bid number PES90 1.2.a.i).

26 July 1991: Draft press release for announcement by Mr Michael Forsyth MP, Minister of State at the Scottish Office with responsibility for health. Approval of routine testing for antibody to Hepatitis C: Funds in the region of £1.2 million to be allocated to SNBTS to cover this.

August 9, 1991: SHHD letter notifying CSA of decision and timing for Scotland.

HCV testing of all donors had started in Glasgow BTS from early July 1991 as part of the national evaluation programme and other SNBTS centres had, under the guise of "familiarisation" also commenced screening well before the September 1 official start date.

Question 3
"An estimate of the prevalence of the virus in donated blood in the UK until such times as a screening test was successfully introduced in 1991 ... information regarding the process of selection of donors to minimise any such risk".

Prevalence of HCV in donated blood before the start of HCV testing

The first four months of hepatitis C testing of blood donations in Scotland (September to December 1991) provides the best estimate of the prevalence in blood donors immediately before the start of testing. In that period 109,581 donations were tested and 99 were confirmed to be HCV positive. This is a prevalence of 90.34 per 100,000 (or 0.09%).

HCV infection in the Scottish population

A detailed paper by Health Protection Scotland states that by December 2003 there had been 18,109 individuals in Scotland reported to have HCV antibody. There was risk factor information available for 12,166 of these persons and of these almost 90% were reported to have injected drugs. The paper states that 5% of the 12,166 were reported to have received a transfusion 5%, and a further 5% to have had tattooing, piercing or an

occupational needle stick. The authors further estimate that by 2004, around 50,000 persons in Scotland had been infected with HCV of whom 88% (33,000) were estimated to be injecting drug users.

Blood donor selection procedures

Blood donor selection procedures have become progressively more stringent over the years in the light of information about known or possible risks. In the period 1989-91, the selection criteria used by BTS and the other UK Blood services were laid down in the Guidelines for the Blood Transfusion Services in the United Kingdom (1989). These required that all donors be questioned about risk factors for HIV which are relevant to other transfusion transmissable agents including HCV (IV drug use, sexual behaviour, residence in high prevalence areas etc).

Question 4 "The way that risk to patients was assessed generally, and in individual cases, in the light of the answer to the preceding questions and how any such risk was communicated to the patient."

Responsibility for informing the patient about treatment, including an assessment of the benefits and risks was and remains the responsibility of the clinician in charge of the patient's management. Suppliers of blood products are responsibility for informing clinicians about blood products, including the risks. Before and during the period in question, published articles, book chapters and clinical guidance documents identified and emphasised the risks of transfusion. Teaching for medical students and staff and nursing staff emphasised the need to use transfusion only when it was believed to be essential for the patient's care. For example, the first UK Handbook of Transfusion Medicine (published 1986) which was widely distributed free of charge to hospital staff and students, includes the following passages.

"Whole blood ...Infection risk: Not sterilised so capable of transmitting any agent that has not been detected by routine donor screening, including hepatitis B, hepatitis Non A Non B, HIV-1 and other viruses"

"Adverse effects of transfusion: As with all forms of therapy the risk of transfusion must be weighed up against the benefit which each individual will obtain when deciding to prescribe blood products".

"Hepatitis Non A non B: No serological screening test is yet available to detect the responsible viruses although this may be introduced in the foreseeable future...studies to detect asymptomatic hepatitis in blood component recipients suggest a frequency of 1-2.5% in the UK Netherlands and Sweden. Most patients who have received non heat treated coagulation factor concentrates have evidence of Non A Non B hepatitis".

Question 5 "Information as to the nature of the hepatitis C virus, particularly its seemingly ubiquitous characteristic in the population at large and the extent to which the level of infectivity may have increased in recent years."

In the decade before 1989, researchers around the world had been striving to develop a test that would specifically identify the cause of Non A Non B hepatitis and that could be used as a safety screen for blood donations. There is an extensive scientific literature describing

unsuccessful research that attests to the difficulty of this task. The causative virus was identified only in the late 1980's when new techniques of molecular biology could be applied. In fact the virus itself has not yet been seen by any researcher: what had been identified, and form the basis of all the tests, are the virus's genetic material (RNA), proteins produced by the virus, and antibodies that are produced by the immune system in infected individuals.

The first blood screening test to be introduced for HCV detected antibodies to the virus. This test, in improved form, is still used to check every donation. However, because antibodies may take some time to develop after a person is exposed to the infection an additional test was introduced, when it later became available, that detects the virus's RNA. This test becomes positive rather earlier in the course of a new infection and can pick up a tiny number of additional infectious donations.

Infection with hepatitis C virus is prevalent around the world. For example in the United States, there are at least 4 million infected people: the prevalence of HCV infection is reported as 1.8% overall. In 2004 there were estimated to be 170 million infected people worldwide. Most will be unaware of their infection. Chronic liver disease results from persisting hepatitis C infection in a substantial proportion of those exposed, and some patients develop liver cancer as a consequence.

In Scotland, the great majority of persons infected with Hepatitis C virus have contracted it as a result of intravenous drug misuse. Other forms of injection or procedures such as tattooing or acupuncture - if they pass blood from one person to another – can also transmit the virus. In contrast to HIV, Hepatitis C is infrequently transmitted by sexual intercourse.

The origins of the virus have been studied (using genetic analysis to identify the many sub – families that have evolved). This research shows that hepatitis C has been widely spread round the globe for a long period of time.

It is well established that among the main subtypes of the virus there are differences in virulence and in the way that established infections respond to treatment with antiviral agents. It is likely that the virus has been disseminated much more widely in recent decades as a result of the increase in the availability and use of medical injections, and the world wide problem of the improper reuse of disposable needles, syringes and other medical devices for injecting and infusing substances.

Question 6 "The potential impact of publicity arising from any inquiry on public knowledge as to the virus which may assist efforts to stem its spread or which may adversely affect the level of donated blood"

Effect on spread of hepatitis C infection

The epidemiological data summarised above shows that, before the commencement of hepatitis C screening of blood donations, transfusion contributed a small proportion of all hepatitis C infections in the community. It is well established in a number of countries that a well-controlled testing programme virtually excludes transmission of hepatitis C by blood components. Therefore there appears to be little scope for publicity arising from an inquiry to further reduce transmission by this route. The major risk of new hepatitis C infections continues to be from unsafe injections by drug users and this danger has received extensive publicity.

Effect on the level of donated blood

Necessary safety measures have made it progressively more difficult to be accepted to give a blood donation. In the current year, 30% of first time prospective donors, and almost 17% of re-attending donors are deferred ie their donation is refused. This is discouraging to potential donors. Additional precautionary safety measures over recent years have sent negative messages about transfusion to both donors and the wider public. The use of UK donor plasma for fractionation had to be stopped in 1998 as a precautionary measure against possible risk of variant Creutzfeldt Jacob Disease (vCJD) being transmitted: as a result many regular donors of plasma were informed that they could no longer donate. More recently it has been necessary to defer from donating anyone who has in the past received a blood transfusion, again sending a very negative message.

Further precautionary measures have required that some patients who are recipients of plasma derivatives, or have received the blood of certain donors, be notified that they could have been exposed to vCJD. New changes in donor acceptance criteria will be introduced in November 2005 to comply with the UK Blood Safety and Quality Regulations (2005) and these will lead to some further increases in the deferral rate for donors. A further prospect is the availability of a test suitable for screening donated blood for vCJD. It is clearly possible that a test with such grave implications may discourage some further individuals from volunteering to donate.

There is now real concern about the possibility of a blood shortage resulting from an emergency such as an epidemic or a terrorist attack. This, together with the chronic shortage of volunteer donors has lead to the recent announcement by the Scottish Executive Health Department of an integrated emergency blood shortage plan. To ensure that, as far as possible, blood remains available to those for whom it is an essential life saving requirement, the plan will require that elective surgery is cancelled, followed by progressive restriction to the issue of blood for other categories of patient. Each hospital is required to develop its own emergency blood management arrangements.

It is not possible to quantify the cumulative impact of these successive changes on the future availability of blood. However it must be a possibility that extensive publicity arising from any inquiry could add further to the difficulty of maintaining an adequate blood supply.