

**Agenda Item 2**  
**18 April 2006**

**HC/S2/06/09/03**

**LETTERS FROM MINISTER FOR HEALTH AND COMMUNITY CARE**

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31 January 2006

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Dear Roseanna

**HEPATITIS C: TRACEABILITY**

Following this afternoon's evidence session, I have made further urgent enquiries about the traceability issue in the light of the concerns expressed by the Committee.

May I first comment that I do not believe that the issues raised represent new information or evidence, or that they are relevant to the question of whether there should or should not be a public inquiry.

I can confirm that once screening of blood donations for Hepatitis C was put in place in 1991, there was a look back exercise undertaken by UK blood services in 1995. If any blood donor was identified as having Hepatitis C then archived samples were retrieved and tested. Any patient who could be traced and might have been infected as a result of receiving blood products from the infected donor was informed.

This exercise detected 379 infected donors in Scotland, and involved 2,142 transfusions. 858 patients were identified as possibly being exposed to the virus. Of those, 223 were tested and counselled, 515 were deceased and 120 were lost to follow-up. This approach was not capable of identifying everyone infected by blood products. This is because some infected donors who gave blood prior to the introduction of screening will not have come forward again and will not therefore have been picked up by the screening process.

As indicated to the Committee, I will now urgently review further whether any further steps on traceability would be feasible and would offer benefits in terms of information and reassurance for patients.

I hope this is helpful.  
**ANDY KERR**

**SCOTTISH EXECUTIVE**

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20 February 2006

Dear Roseanna

This letter follows my letter of 31 January in relation to traceability for those infected with Hepatitis C through blood transfusion. I now enclose a paper which sets out fully our response to the issues raised during the Committee discussion.

I hope this is helpful.

*Yours  
Andy*

**ANDY KERR**



## HEPATITIS C: NHS TREATMENT WITH BLOOD AND BLOOD PRODUCTS

### HEALTH COMMITTEE: 31 JANUARY 2006: ISSUES RAISED

1. This note sets out my response to the issues raised in the Health Committee on 31 January.

#### Process for lookback and tracing of Hepatitis C cases

2. I undertook to respond fully to the Committee on the public health aspects of this, and the arrangements that are in place for traceability. I set out details in my letter of 31 January of the lookback exercise that was undertaken in 1995. It is not the case that no efforts have been made to trace and inform people in Scotland who have contracted Hepatitis C from blood transfusions.

3. SNBTS recognises that it has a duty of care to patients who contract or may have contracted infection through a transfusion of blood components or products. Since 1985 it has maintained an archive of all donations of blood which is linked to a computer record of the issue of blood from a blood bank to a named patient. This linkage does not provide complete coverage across Scotland for the period involved. The archive, however, enables SNBTS to test donations back to 1985 which might be implicated in transmission of Hepatitis C and provides the basis for lookback and tracing possible infections from blood donation.

4. Following the introduction of testing in 1991, considerable work was carried out to trace any links between blood donors infected with Hepatitis C and patients who had received infected blood. A pilot exercise was carried out in Edinburgh, and this developed the methodology for a lookback exercise which was undertaken by UK blood services from 1995, and completed in 1997.

5. The lookback exercise was based on tracing the past donations of blood donors found to be infected with Hepatitis C. Where this was the case, a thorough search of records was carried out with the aim of identifying recipients of the blood and offering them counselling and testing for the virus. A helpline was also established for members of the public who wanted further information about Hepatitis C and blood transfusion. Any patients who were worried or unwell were advised to speak to their GP, and tell him or her when they had a blood transfusion. The GP could then assess whether anything needed to be done. Patients could also be referred if necessary to their local transfusion centre for advice and counselling.

6. This lookback exercise was carried out as follows:

- Where a returning blood donor was identified as infected with Hepatitis C after 1991, records were identified for any donations made prior to September 1991 and for each blood component made from these donations;
- SNBTS identified which hospital blood bank (or alternative uses, such as quality assurance) components had been sent to;
- Where there was a computer record of the blood bank issue to a named recipient, the recipient was identified and the responsible clinician was notified. In the absence in some areas of an IT link, blood banks were requested to identify recipients through hospital records;
- The clinician who had been responsible for care of the patient at the time of transfusion was then asked to inform the patient, and arrange for counselling and testing as necessary.



## 7. The results of the lookback for Scotland were:

- |   |      |
|---|------|
| • Hepatitis C positive donors who had given before 1991 | 360  |
| • Donations by these donors                             | 1658 |
| • Components prepared from these donations              | 2026 |

<i>of which</i>	traced	1,356
	not traced	670

(this will consist mainly of components not transfused, and will also include those not traced through hospital records)

- |   |     |
|---|-----|
| • Number of recipients identified by hospitals                                    | 880 |
| • Potentially eligible for counselling and testing                                | 266 |
| <i>of which</i>   |     |
| counselled and tested positive  | 133 |
| counselled and tested negative  | 70  |
| other – declined; not appropriate for testing; results not reported back to SNBTS | 63  |
| • Deceased  | 536 |
| • Not traceable   | 78  |

**Note:** These figures relate to the final lookback report in June 1998. The lookback was a complex operation, requiring the coordination of reports from a number of centres over several years, and involving records of donations going back over a long period prior to 1991. There were some changes in the reported total number of donors who were identified during the course of the lookback programme. This was due to double counting of some donors that was later recognised and corrected, and to the inclusion of some donors who subsequently proved to have no previous donation – hence the difference in the figures in my letter of 31 January 2006 which relate to the period up to October 1997, before the figures were finally validated.

8. The lookback exercise was concluded in 1997. It was considered that at that point most donors who were likely to return would have done so. However, there may still be some donors who are infected with Hepatitis C, but have not returned to donate since donor testing was introduced. Also, it is possible that clinicians have been unable in some cases to identify through hospital records, living recipients of infected donations. Where SNBTS is informed of any patient who is discovered to be infected with Hepatitis C - and transfusion may have been the route of infection - a full investigation is carried out, as detailed below.



9. Where returning blood donors from pre-1991 test positive for Hepatitis C, or where patients present with Hepatitis C infection which may be linked to blood transfusion, SNBTS investigates thoroughly the background and circumstances to these cases and initiates lookback procedures so that any patients potentially affected can be offered counselling and testing. The patient's hospital case notes from the time of the transfusion are examined to identify the donation numbers of the transfusion that they received. This allows SNBTS to trace archived specimens of blood from the original donations. These can then be tested to find out if they were, or were not, the cause of the Hepatitis C transmission. If this is confirmed, the patient's doctor is informed. Other donations from the implicated donor are then traced within the archive and tested. Any positive results lead to a search for the recipient of those positive donations so that the recipient themselves may be informed and offered advice and testing.

10. During the period 1998-2004 SNBTS investigated 32 potential transfusion-transmitted infections related to Hepatitis C. In half of these cases - 16 - the blood units transfused were negative and it was possible to rule out transfusion-related transmission. A number of cases could not be resolved because they relate to transfusion before the donor archive was established in 1985 or in some cases, because hospital records were not available. In six cases a blood transfusion - received before testing for hepatitis C commenced - was identified as the possible source of infection and appropriate follow-up action was taken to trace any other recipients from the donor involved.

11. The results of these investigations indicate that the number of cases of Hepatitis C now arising which result from blood transfusions before 1991 is very small. I am satisfied that SNBTS does have effective arrangements in place for tracing donors and recipients where there is a suspected link between Hepatitis C and blood transfusions, and that these will ensure that any new suspected cases emerging are fully investigated and followed up.

12. Since the introduction of donor screening for Hepatitis C in 1991, there has been an extremely small chance of acquiring Hepatitis C infection through blood transfusion. SNBTS is not aware of any reports of infection with Hepatitis C through blood transfusion over this period. Because there is a short "window period" after infection where tests will not identify the Hepatitis C virus if a donor has been very recently infected, there cannot be absolute certainty that no episodes of transmission will have occurred. However, the risks are extremely small - of the order of one in half a million.

13. In relation to the widely quoted figure of 3,500 people in Scotland infected with Hepatitis C through blood transfusions, as we made clear in evidence, this is a statistical estimate which was prepared for the Expert Group chaired by Lord Ross on Financial and Other Support in 2003, based on work by Dr Kate Soldan, an epidemiologist at the Department of Health's Public Health Laboratory Service Communicable Disease Surveillance Centre. The figure depends on a number of assumptions to estimate the prevalence of Hepatitis C from blood transfusion or tissue transfer, and will be subject to a range of error. The work was based on testing blood donations for Hepatitis C antibodies after the introduction of tests in 1991, and using this information to estimate the prevalence of Hepatitis C from blood transfusions (or tissue transfer) in the population as a whole. As this is a statistical estimate, it cannot be used as a basis for tracing individuals infected with Hepatitis C. Because of the age and state of health of those receiving transfusions, it is likely that many of those receiving transfusions or tissue will have died, often from the underlying condition for which they received the transfusion.

### Transmission of Hepatitis C

14. Concern was raised about possible routes of secondary infection with Hepatitis C through sexual intercourse, or other close social contacts. Mother to baby transmission does occur but appears to be uncommon, with upper estimates of 6% across the UK. Sexual transmission of Hepatitis C is possible but uncommon. The evidence indicates that there is a 3% life-time risk of transmission (there is no risk of Hepatitis C transmission through everyday social contact). Because of these risks - and for a number of other reasons - it would be normal clinical practice to inform a patient where a diagnosis of Hepatitis C had been clearly made.

15. Before 1991, however, when the relevant test became available, it was not possible for a clear clinical diagnosis of Hepatitis C to be made, because tests before this date were non-specific for the virus, which was not isolated until 1989. Up until that date, there was in any case no clinical consensus that NonA-NonB Hepatitis constituted a serious medical condition.

16. In many cases infection with Hepatitis C does not give rise to related symptoms for many years after the event, another reason why the specific diagnosis might not be made, at least initially.

### Anti-D

17. Antibodies for intramuscular administration - such as Anti-D - are prepared from blood plasma. Anti-D has been provided by SNBTS since 1968 for the prevention of rhesus sensitisation in women whose blood group is Rh-negative, and there has been no evidence of any Hepatitis C transmission.

### Informing patients

18. Questions were raised about the position in relation to current practice where people diagnosed with Hepatitis C have not been told about it. This is a matter mainly of professional practice for clinicians in relation to their patients. We are fully committed to a patient-centred approach which involves the sharing of information and decisions about treatment with patients. This would also be in line with best professional practice.

19. GMC guidance states that good communication between patients and doctors is essential to effective care and relationships of trust. Good communication includes giving patients the information they ask for or need about their condition, its treatment and prognosis. In relation to serious communicable diseases - which includes Hepatitis C - GMC advice (issued in October 1997) is that doctors must obtain consent from patients before testing for a serious communicable disease. The information provided when seeking consent should be appropriate to the circumstances and to the nature of the condition or conditions being tested for. If a doctor diagnoses a patient as having a serious communicable disease, they should explain to the patient the nature of the disease and its medical, social and occupational implications, as appropriate; ways of protecting others from infection; and the importance to effective care of giving to the professionals the information which they need to know about the patient's disease or condition.

20. Where blood donors test positive for Hepatitis C, they are informed and counselled by SNBTS. They will then be referred to their GP, or to a liver clinic as appropriate. SNBTS then initiates the lookback and tracing procedures which are described in para 9 above.



### Supply of blood products

21. In terms of the supply of blood products, there was a clear professional and scientific consensus - reflected in the policy of the government and the SNBTS at the time – that the best way to safeguard the blood supply from viral infection was to monitor and control carefully blood donations. For this reason it was a key aim of policy to achieve self-sufficiency in Scotland in the supply of blood products. Factor VIII concentrate that was later shown to be safe with respect to Hepatitis C as a result of heat treatment became available from SNBTS in 1987.

22. While Scotland became self-sufficient in blood products, and this was a key safeguard against viral infection, it remained possible for clinicians to prescribe alternative commercial products, including products imported from other countries. There were various possible reasons for this. Clinicians may have believed that specific products were more effective, or more suitable for their patients. Given that such products were licensed for use in the UK, they would have been regarded as equally safe and clinicians were entitled to prescribe them if they wished. In 1987, 2% of blood Factor VIII products purchased were from commercial/ non-SNBTS sources. This included products to treat some specific conditions (for example, von Willebrand's Disease) which were not available from SNBTS.

23. The issue was raised as to whether we are still receiving blood products from outside the country, or from relatively high-risk sources such as prisoners. It is worth mentioning at this point that some blood products - in particular, blood clotting factors for the treatment of haemophilia - are now produced using recombinant technology, rather than being made from human plasma. This further reduces the risk of viral contamination.

24. Products fractionated in Scotland are now produced from plasma which is imported from other countries to limit the risk of transmission of vCJD through blood. These supplies are obtained wherever possible from unpaid donors, in line with long standing SNBTS policies. However, pressures of international demand for plasma mean that it is sometimes necessary to use paid plasma sources in order to maintain the supply of essential products for NHS patients. This imported plasma has never been sourced from the prison population. Careful analysis of the risk profile of donors is undertaken, and all suppliers are inspected by SNBTS and approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

25. Advances in regulatory standards and viral inactivation procedures mean that, in general, blood products from both private and public suppliers are now considered a low risk category by regulatory agencies.

### Donations from prisons in Scotland

26. It is the case that for many years SNBTS did collect blood from prisons in Scotland. At no time was blood imported by SNBTS from US prisons. SNBTS practice reflected the general policy of the government and other UK blood services at the time, and donors from prisons were subject to the same screening and medical checks as other donors. This practice took place at a time when there was no evidence to suggest that there were particular safety or viral infection risks involved. Indeed it was regarded as enabling prisoners to make a positive contribution to society, and encouraging their rehabilitation, and also made a significant contribution to the blood supply in Scotland.



27. In the early 1980s, when concerns about the potential for viral infections to be transmitted through blood began to grow, Medicines Inspectors recommended that the practice of collecting blood from prisons should be reviewed. The collection of blood from prisons was then phased out and stopped by March 1984. Blood collected from prisons made an important contribution to overall blood supplies, and had to be replaced from other sources and there was no unreasonable delay in bringing collection from prisons to an end. There is no specific evidence that blood supplies from prisons in Scotland represented a higher risk than supplies from other sources, nor is there any evidence of a direct link between prison donations and individual instances of viral infection.

#### **Donations from US military personnel**

28. As far as donations from US military personnel are concerned, SNBTS did in the 1980s - and continues to - collect blood from volunteer non-UK nationals resident in the UK. Normal practice in terms of monitoring and - where necessary - exclusion of donors was followed. Epidemiological data now available indicates that blood donors from US military bases in Scotland did not carry any higher risk of transmitting viral infections than the indigenous population<sup>1</sup>.

#### **Clinical trials**

29. Concerns were expressed as to comments from clinicians about failure to agree a compensation scheme for patients participating in clinical trials.

30. The papers released on Hepatitis C include correspondence in relation to eligibility for compensation for patients taking part in clinical trials. This took place around the introduction of the SNBTS heat-treated Factor VIII product in 1987. Although there were concerns expressed by clinicians about compensation arrangements, these issues were resolved and did not delay the introduction of a heat-treated Factor VIII product which was safe in terms of the transmission of Hepatitis C.

#### **Independent testing of documents**

31. The Committee has raised the issue of whether the information that has been released has been tested independently. The documents we have released are a primary evidence source, and record events as they occurred and were seen by the people and organisations taking part at the time. It would be possible to test the background and context of these documents through the testimony of witnesses. However, witnesses would be speaking of their recollection of events that took place 20 or more years ago. There is a risk that these recollections would not be completely clear, or would involve a degree of hindsight, and that it would be difficult to establish a more complete or accurate picture of what occurred. We would not accept that there is a need to test these documents further.

#### **Council of Europe resolution**

32. The Council of Europe is a political intergovernmental organisation. Its recommendations to governments set out policy guidelines on issues such as legal matters, health, education, culture and sport. Its recommendation R (83) 8 makes a number of recommendations in relation to AIDS<sup>2</sup>. These make no specific reference to Hepatitis, although some are generally relevant to combating transmission of viral infection through blood.

33. The recommendations dealt with the use of coagulation factor products prepared from large plasma pools; informing physicians and recipients of the risks of blood products; and providing blood donors with information. Policy in Scotland in relation to blood products fully reflected these principles and recommendations.



34. The risks of large plasma pools were recognised and appropriate warnings were provided on products. SNBTS also pursued a policy of maintaining self-sufficiency and, as noted above, Factor VIII concentrate that was later shown to be safe with respect to Hepatitis C as a result of heat treatment became available from SNBTS in 1987. Treatment with factor concentrates was generally the preferred option of clinicians in treating haemophiliacs at this time because of the improved clinical outcomes (including life expectancy) and quality of life they offered. As far as Hepatitis C is concerned, it was well known in 1983 that there were risks of hepatitis from blood products and this information was included in product labels and leaflets. In addition to having two warnings about hepatitis in product information leaflets, SNBTS products carried a warning of hepatitis on the bottle label and two warnings on the box containing the bottles.

35. In terms of informing patients, decisions on how best to treat and inform individual patients are, as noted above, generally the responsibility of the clinician involved. There is no question, however, that it would be best clinical practice for patients to be fully informed of their condition, and of any tests carried out and the results. Clinicians would be expected also to explain any risks of treatment to their patients. However, as previously mentioned, this has to be seen in the context that Non-A, Non-B Hepatitis (later identified as being predominantly caused by Hepatitis C) was not at this time seen as necessarily being a serious medical condition.

36. Steps were also taken by SNBTS to ensure that potential donors in high risk groups were excluded from donation. Clear warnings were provided to blood donors by SNBTS in 1983, specifically in relation to risks of transmission of AIDS. Based on information about at risk groups from the USA, the following groups were asked to refrain from donating blood: homosexual men; women who continually have multiple sexual partners; partners of bisexual men; anyone who abuses drugs; and anyone who has been in contact with a case of AIDS.

#### **Inspection of PFC manufacturing processes and facilities**

37. Questions were raised in relation to manufacturing standards at the Protein Fractionation Centre, and possible safety implications. The operations of the Centre were essential in achieving self-sufficiency in the supply of blood products in Scotland. This was widely recognised as a key risk reduction and safety measure.

38. The operations of the Centre were inspected on a regular basis by the Medicines Inspectorate during the 1980s although under Crown Immunity PFC was not at the time required to hold a manufacturing licence. This involved applying pharmaceutical industry standards to the operation of SNBTS, and inevitably identified areas for improvement in practice. The deficiencies and improvements required were addressed and dealt with by SNBTS. There is no evidence that these had serious implications for product safety, and or that they were in any way linked to the transmission of infection through blood products.

39. Reference was made to the statement that PFC has "unequivocally endangered the lives of patients". This is contained in a letter of 1988 released under the terms of FoI from the-then Medical Director of SNBTS. The letter continues, "The two recorded occasions since it was commissioned in 1975 (the second just months ago) were of course investigated and it is my view that breaches of GMP (Good Manufacturing Practice) could not be ruled out".



40. The first occasion is believed to relate to a batch of Factor VIII which was found to be contaminated with bacteria. This batch, however, failed the routine quality control test for sterility, and was not released for use. In this case, therefore, the GMP system in place was effective in protecting patients. Following this incident an independent expert investigation was carried out to determine the cause. This was identified as probably due to the failure of a membrane-filter used to remove bacteria from the solution immediately before aseptic dispensing.

41. The second occasion concerned the infection of a small number of patients with Non-A, Non-B Hepatitis from a batch of SNBTS intravenous immunoglobulin. This was one of a number of similar incidents across the world at the time which affected both publicly-owned and commercial manufacturers of plasma products. These infections occurred before the Hepatitis C virus was identified, but at a time when Non-A, Non-B hepatitis was a known risk, and were discovered as a result of careful monitoring of patients. Subsequently, when a test for the Hepatitis C virus became available, no evidence of infection was found in this batch. SNBTS nevertheless accepted that it was the most likely source of infection to the patients involved. The transmission of Non-A, Non-B Hepatitis by this batch was described by SNBTS medical staff, and published in medical journals, soon after the event and has thus been in the public domain for some time.

<sup>1</sup> During the 1980s the prevalence of Hepatitis C virus infection among deployed US military personnel was estimated to be 0.4%. During this period the prevalence of Hepatitis C among the population of Scotland is estimated to have been approximately the same (Hawkins R, et al. Risk of viral hepatitis among military personnel assigned to US Navy ships. *J Infect. Dis.* 1992; 165: 716-719. Brodine S., et al. The risk of human T-cell leukaemia virus and viral hepatitis infection among US marines stationed in Okinawa, Japan. *J. Infect. Dis.* 1995; 171: 693-696)

<sup>2</sup> Recommendation No R (83) 8 of the Committee of Ministers of the Council of Europe recommends the governments of member states:

to take all necessary steps with respect to the Acquired Immune Deficiency Syndrome and in particular:

- to avoid wherever possible the use of coagulation factor products prepared from large plasma pools; this is especially important for those countries where self-sufficiency in the production of such products has not yet been achieved;
- to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks;
- to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating.

