Witness Name: Marc Turner
Statement No.:WITN3530085
Exhibits: WITN353086-
WITN3530101
Dated: 27/10/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF MARC TURNER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 and dated 8th April 2021 addressed to Craig Spalding.

I, Marc Turner, will say as follows:

1. Name: Marc Leighton Turner
2. Address: Scottish National Blood Transfusion Service, The Jack Copland Centre, 52 Research Avenue North, Heriot-Watt Research Park, Edinburgh EH14 4BE.
3. Date of Birth GRO-C 1959.

4. Qualifications:
    a. Bachelor of Medicine, Bachelor of Surgery, University of Manchester
    b. Doctor of Philosophy, University of Edinburgh
    c. Master in Business Administration (Life Sciences), Open University
    d. Fellow of the Royal College of Physicians of Edinburgh
    e. Fellow of the Royal College of Physicians of London
    f. Fellow of the Royal College of Pathologists

5. I am the current Medical Director of the Scottish National Blood Transfusion Service (SNBTS), a position which I have held since 1st April 2011. My principal responsibilities relate to medical and scientific professional leadership of the organisation and

oversight of clinical governance including compliance with SNBTS's legal and regulatory responsibilities under SNBTS's Blood Establishment Authorisation (BEA), Human Tissue Authority (HTA) licence and Advanced Therapy Medicinal Product (ATMP) manufacturing licences. I provide line management to the Medical and Clinical Scientist staff, the Tissues, Cells and Advanced Therapies Directorate, the Patient Services Directorate and the National Microbiological Reference Unit.

6. Please note that although I have been a member of the organisation since 1994, during the earlier parts of my career I held relatively junior positions and only started to take on Consultant responsibilities in 1997 and managerial responsibilities in 2001.

7. Due to the passage of time there is no longer anyone currently working in the organisation who was involved at a senior medical, scientific or managerial level prior to around 1997. Therefore the testimony of the current senior management of SNBTS is based on, and constrained by, current knowledge of the organisation and field, the documentary evidence available to us and input from current SNBTS colleagues. Where former SNBTS colleagues have been consulted, this has been agreed with the IBI legal team. Such former SNBTS colleagues who have contributed to the text are identified as having done so below and within the relevant sections of this response in italics:

    a. Dr Jack Gillon, former Consultant in Donor Medicine, Edinburgh and SE Scotland Regional Transfusion Centre: Questions 1 to 5, 8, 11a, 12, 15, 17, 18b, 19, 26, 27 and 29.
    b. Dr Brian McClelland, former Regional Director, Edinburgh and SE Scotland Regional Transfusion Centre: Questions 4 and 12.
    c. Professor Ian Franklin, former Medical Director, SNBTS: Questions 25 and 30.

8. We have provided exhibits when referencing internal SNBTS documents or those documents that may not be otherwise easily accessible such as specialist medical or scientific publications. We have not provided exhibits for documentation readily accessible in the public domain but have provided hyperlinks where we felt that they may be helpful to the Inquiry or the general reader. SNBTS is happy to provide documents that the Inquiry has any difficulty accessing.

Q1 - An account of all steps taken to identify and warn patients who may have been treated with HIV infected blood and/or blood products, since the virus was conclusively identified in 1984. Please include any 'look-back' patient notification exercises and details of any awareness campaigns to publicise the risk, including exercises and campaigns that were considered but rejected.

Dr Jack Gillon has contributed the following response:

9. *The virus responsible for Acquired Immunodeficiency Syndrome (AIDS) was in fact identified in 1983, and was initially designated Human T-cell Lymphotropic Virus III (HTLV-III). In the latter half of 1984 commercial test kit companies and academic centres for virology in the USA, UK and France developed testing methods for the identification of antibodies to the virus in infected subjects. The first commercially available kits for routine testing of specimens in large numbers were first released to transfusion services in the USA in April 1985, though difficulties with supplies initially led to a patchy introduction. Nevertheless, the US transfusion services jointly agreed that they would attempt to identify previous recipients of blood from donors now found to be positive for the virus, and coined the term "lookback" for this process. A time limit of 5 years was put on this retrospective search for affected patients, reflecting the length of time the virus was thought to have been present in humans.*

10. *In the UK test kits were not available for routine testing until later in 1985, though some preliminary testing was carried out in the transfusion services. While this was in progress a working party of the UK Regional Transfusion Directors was set up with a remit to develop procedures and protocols for screening of donors, confirmatory testing and communication with and further management of donors found to be positive. The report produced by the working party was accepted by the Regional Directors at their meeting on 11 July 1985. This included a statement that efforts should be made to trace recipients of donations found to be positive and to inform the consultant in charge of the patient (Report of the Working Party of the UK Regional Transfusion Directors Committee "Screening of blood donors for anti-HTLV III in Regional Transfusion Centres, 11 July 1985") (DHSC0000406). This report formed the basis of standardised procedures implemented after a training exercise for donor centre staff held at SNBTS Headquarters in the run-up to the implementation of routine screening on 15 October 1985. Full testing commenced in October 1985, by which time the UK transfusion services had agreed to carry out lookback on the same basis as in the USA.*

Procedures were agreed and standardised and staff trained before testing commenced.

11. *A full description of the background to lookback, its history and evolution, the debate about its practicality and effectiveness and the outcome in the SNBTS are to be found in the document prepared for the Penrose Inquiry entitled 'Lookback: Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV' (PEN.017.2220) (PRSE0004042).*

Dr Jack Gillon's contributory response ends.

12. *SNBTS is responsible for general communications with regard to blood donation but responsibility for general communications with regard to patient health lies with the Government, Health Boards and public health authorities.*

Blood donor awareness.

13. With regard to donor awareness, we have identified an information leaflet published by SNBTS in November 1984 (PRSE0000286) asking people in at risk groups not to donate blood which we understand was sent to all active blood donors and made available at donor sessions. Some of the media coverage associated with the November 1984 leaflet also references the earlier set of leaflets made available to donors 18 months earlier (WITN3530086 and WITN3530087) but SNBTS has been unable to find a copy of this original leaflet. However we have identified a minute of a meeting of the SNBTS Coordinating Group dated 30th August 1983 which refers to each Transfusion Centre having a supply of leaflets which could be distributed subject to the lifting of an embargo on their release throughout the UK following a statement by the Minister of Health (WITN3530088: 696_067 – 30/8/83 - minute - publicity leaflets re AIDS).

Public awareness

14. With regard to public awareness we have identified a public health information leaflet published by the Scottish Health Education Group in December 1984 ('Some facts about A.I.D.S') which mentions people who have received a blood transfusion from an infected donor and people with haemophilia as being at high risk of AIDS virus

(DHSC0003710_078). There was also a high profile national AIDS awareness campaign in 1987 led by the Department of Health and Social Security (DHSS) which involved release of a public information film ('AIDS: Don't Die of Ignorance') and the distribution of leaflets to every household in the UK.

15. In 1983 and 1987, SNBTS undertook qualitative and quantitative research on attitudes to blood donation in collaboration with the University of Strathclyde's Advertising Research Unit which provides some insight into the level of awareness of the risk of AIDS in the general public in these two time frames. The first report published in May 1984 "The Scottish Public's Attitude to Blood Donation" (WITN3530089) was initiated in 1983 prior to widespread awareness of AIDS. The second report: "The Scottish Public's Attitudes to AIDS and Blood Donation" published in November 1988 (WITN3530090) states:

> *'The possibility of the virus being transmitted via blood makes the AIDS issue a matter of great concern for the Scottish National Blood Transfusion Service (SNBTS) [...] In relation to blood donation, two major problem areas exist: firstly, the danger of HIV infected individuals continuing to donate blood and secondly, the observed decline in blood donation levels which coincided with increasing public exposure to the AIDS issue.'*

It found that pre-session leaflets were less effective than information provided at the time of donation. The study informed the strategy that SNBTS used to address the issues identified at that time.

16. The table below provides data on the level of awareness of the risk of transmission of HIV by blood transfusion amongst donors and the general public in 1987/88. These data were transcribed and tabulated from the original document by Dr Moira Carter, former Associate Director for Donors and Transport and current COVID-19 Convalescent Plasma Programme Lead in August 2021 for ease of presentation.

Data Extracted from University of Strathclyde's Advertising Research Unit 1987/88. " The Scottish Public's Attitude to AIDS and Blood Donation"							
Please note, the percentages in the table don't total 100% which may indicate that respondents had not answered all questions or that there may be a rounding up or down effect as the % are given as whole numbers in the main report.							
Donor Status		All	Current Donor	Lapsed Donor	Ex Donor	With any history of Donation	Non Donor
		976	108	56	157	321	639
%			11%	6%	16%	33%	65%
Catching AIDS from **GIVING BLOOD**	Score	%	%	%	%	%	%
Very Likely	4	5%	5%	-	*	2%	5%
Quite Likely	3	15%	2%	8%	10%	7%	19%
Not Very Likely	2	27%	28%	29%	27%	28%	26%
Not at all Likely	1	48%	62%	62%	56%	59%	43%
Very or Quite Likely		**20%**	**7%**	**8%**	**10%**	**9%**	**24%**
Mean Score		1.74	1.48	1.46	1.52	1.49	1.85
Total of percentages presented		95%	97%	99%	93%	95%	93%
Catching AIDS from **RECEIVING BLOOD**	Score	All	Current Donor	Lapsed Donor	Ex Donor	With any history of Donation	Non Donor
Very Likely	4	12%	9%	4%	9%	8%	14%
Quite Likely	3	33%	12%	31%	31%	25%	37%
Not Very Likely	2	37%	47%	41%	37%	41%	30%
Not at all Likely	1	17%	30%	23%	19%	23%	13%
Very or Quite Likely		**45%**	**21%**	**35%**	**40%**	**33%**	**51%**
Mean Score		2.42	2.00	2.16	2.31	2.16	2.54
Total of % Presented		99%	98%	99%	96%	97%	94%

In response to these findings SNBTS increased its messaging both in respect to the safety of blood donation due to the use of single-use disposable needles and the importance of the donor selection and screening processes.

Clinical awareness.

17. The primary responsibility for ensuring that a patient gives informed consent with regard to the balance of benefit and risk associated with a medicinal product (such as

a plasma product) or other medical intervention (such as a blood transfusion) lies with the prescribing clinician.

18. With regard to blood components, Dr Brian McClelland edited the first edition of a Handbook of Transfusion Medicine in 1989 on behalf of the Directors of the UK Blood Services, which was made available to all relevant NHS and private health sector staff with the aim of giving clinicians the information that they and their patients needed around the benefits and risk of transfusion and to provide a guide to the appropriate use of blood components and plasma products (PRSE0003047). This book is now in its fifth edition (2013) and available online as well as in print version of the JPAC website (5th Handbook of Transfusion Medicine RLIT0000718). From 1990 SNBTS augmented this with a Compendium of Blood Products and Blood Component Information to provide information to clinicians about the range, indications for, and risks of its products. Subsequent EU-funded work, again led from Scotland, was the EU Optimal Use of Blood project initiated in 2006 with the aim of promoting and sharing best practice in transfusion across the EU. In 2004 Scotland started to develop the LearnBloodTransfusion e-learning modules accessible to all and mandated throughout Scotland for all involved in the transfusion process.

19. Patient information explaining the risks and benefits of transfusion was recommended in the second edition of the Handbook of Transfusion Medicine (SCGV0000099_071). It was around this time that UK Blood Services started to develop patient information leaflets. SNBTS now produces its own leaflet 'Receiving a Transfusion' the next version of which will be a UK-wide leaflet covering all blood components for transfusion to adults and children.

20. Although a consent process has always been in place for surgical and other invasive procedures, historically consent for treatments such as blood transfusion was not specifically required, unless included within the consent for a surgical procedure. In 2010 Scotland was represented in a group convened by the Advisory Committee on the Safety of Blood, tissues and Organs (SaBTO) to make recommendations on consent for transfusion. Following extensive stakeholder consultation between March and May 2010 guidance was issued in 2011 and recently updated in 2020 (SaBTO consent December 2020 Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion - GOV.UK (www.gov.uk). Since then LearnBloodTransfusion have developed an educational module on consent, patients have been offered patient information leaflets

and the opportunity to discuss the risk and benefits of, and alternatives to, transfusion (WITN3530067 SNBTS Leaflet: Receiving a Blood Transfusion). In the event that transfusion takes place in an emergency or where the patient is otherwise not in a position to give consent, patients should be given the information about risks and benefits after the transfusion as well as the opportunity to ask questions and have their concerns addressed.

21. With regard to plasma products, as a pharmaceutical manufacturer SNBTS Protein Fractionation Centre (PFC) was not permitted or expected to engage in direct contact with patients. Until 1994 the regulatory requirement was for Technical Information Leaflets directed at healthcare professionals only, these were not an appropriate vehicle for providing information to patients. The position changed in 1994 when Patient Information Leaflets became a regulatory requirement and SNBTS PFC thereafter issued appropriate patient information, approved by MHRA, with PFC products.

22. Chapters 33 and 34 of the Penrose Inquiry provide a report of that Inquiry's investigation of the historical systems in place in Scotland to inform patients of the risk of infection.

Q2 - An account of the steps taken to warn patients of the risk of HCV being transmitted through the use of blood and/or blood products since 1989 when the HCV virus was first isolated. Please include any 'look-back' patient notification exercises and details of any awareness campaigns to publicise the risk, including exercises and campaigns that were considered but rejected.

Dr Jack Gillon has contributed the following response:

23. *Commercial tests for antibodies to HCV became available early in 1990. The steps taken within SNBTS to prepare for the introduction of routine testing are described in detail in PEN.017.2220 (PRSE0004042), including the debate about the desirability or otherwise of implementing lookback in the same way as for HIV. Agreement among the UK transfusion services proved impossible to attain. However, the process was implemented in the Edinburgh and SE Scotland BTS from the official testing start date of 1 September 1991. The results for the first 6 months of testing were published in 1994 (Ayob et al, Transfusion Medicine 1994, 4; 269-272, PRSE.000.1046) (PRSE0001046), leading to renewed debate within transfusion services and the*

government. This is described in PEN.017.2220 (PRSE0004042) and a full, detailed, chronological account of the debate and its outcome, namely UK-wide commencement of HCV lookback in May 1995, is to be found in Chapter 35 of the final report of the Penrose Inquiry.

Dr Jack Gillon's contributory response ends.

24. As noted in our response to Question 1, SNBTS is responsible for general communications with regard to blood donation but responsibility for general communications with regard to patient health lies with the Government, Health Boards and public health authorities.

Donor awareness

25. The people most likely to be at risk of HCV infection were those who had used injectable drugs (@90%) who were already excluded from blood donation. Once testing commenced it was apparent that donors had a comparable prevalence (0.1%) of hepatitis C with that seen in non-exposure prone healthcare workers (0.28%). There is no figure available for the prevalence of HCV in the general population in 1991 (WITN3530091).

Public awareness

26. With regard to public awareness we are aware from the Report of the Scottish Government Short Life Working Group on the implementation of the Penrose Inquiry report (PRSE0005299) that in 1999/2000, a Scottish Needs Assessment Report on Hepatitis C listed a range of population groups who should be offered an HCV test and that this included people who had received a blood transfusion pre-1991.

27. In 2002, the Scottish Government distributed an educational Hepatitis C pack to General Practitioners (GPs) throughout the country; the list of people who should be offered a test, as above, was incorporated into the pack's literature. In 2006/07, Scottish Intercollegiate Guidelines Network (SIGN) Guidelines on the management of Hepatitis C were published; these included a list of people who should be offered a HCV test and within this list were "people who had received a blood transfusion pre-September 1991".

28. In 2007, the Scottish National Party published, in its Manifesto, a commitment to hold an inquiry into "the infection of people with Hepatitis C from NHS Treatment"; in April 2008, the Cabinet Secretary for Health and Wellbeing made a statement to the Scottish Parliament announcing the establishment of the promised Inquiry. Once established, the Inquiry issued a public call for evidence inviting all interested parties to contact the Inquiry to provide statements. These announcements, accompanied by news stories and adverts, drew public attention to the issue.

29. In 2009, within the context of the Scottish Government's Hepatitis C Action Plan, the Chief Medical Officer for Scotland sent a letter to GPs, outlining the at-risk groups (including the blood transfusion group) who should be offered a HCV test; the SIGN Guidelines, as above, were referred to.

30. In 2010, the Scottish Government sponsored a national poster campaign involving, in particular, the placement of such materials on the sides of bus shelters. In recent years, the UK Hepatitis C Trust and Hepatitis Scotland have staged major awareness campaigns around, in particular, World Hepatitis Day (July 28th). The SIGN Guidelines on the Management of Hepatitis C were updated in 2013 and again recommended that recipients of blood clotting factor concentrates prior to 1987, recipients of blood and blood components before September 1991 and of organ/tissue transplants in the UK before 1992 should be offered a HCV test.

31. In 2015, the publication of the Penrose Inquiry Report was a leading news story – one which generated, arguably, the greatest intensity ever experienced in Scotland of awareness-raising around the issue of Hepatitis C risk and blood transfusion pre-September 1991. In response to the Final Report of the Penrose Inquiry and the deliberations of its Short Life Working Group (PRSE0005299) the Scottish Government and Health Protection Scotland carried out a targeted awareness campaign as described in WITN3530092 and in our responses to Questions 37 and 38.

Clinical awareness

32. The primary responsibility for ensuring that a patient gives informed consent with regard to the balance of benefit and risk associated with a medicinal product (such as a plasma product) or other medical intervention (such as a blood transfusion) lies with the prescribing clinician. We have described the work undertaken to ensure that

clinicians were and are informed of the risks associated with blood component transfusion in our response to Question 1.

Q3 - After the introduction of HCV screening, what, if any, guidance and assistance was provided to donors found to be HCV positive in relation to the management of their illness and was this different in Scotland to that in England? Please include all anti-HCV screening, pre and post September 1991, and any pilot screening programmes.

Dr Jack Gillon has contributed the following response:

33. *From the introduction of HCV screening in September 1991 donors confirmed positive for HCV were offered face to face counselling by a member of SNBTS medical staff, including repeat testing and onward referral for appropriate further investigation and treatment. In some cases, at the request of the donor, this was carried out by the GP, who was supplied with appropriate documentation by SNBTS.*

34. *The procedures to follow in counselling such donors and ensuring appropriate medical follow-up were codified in a report (PRSE0004114) prepared by a SNBTS working party led by Dr J Gillon, Consultant responsible for donor care and selection in the Edinburgh and SE Scotland BTS, as requested by Prof J Cash, National Medical Director. This report was shared with Dr Harold Gunson, National Medical Director in the English transfusion service. It was approved by the Scottish Regional Centre Directors in September 1990 and formed the basis of guidelines employed throughout the Scottish donor service from the start of routine testing for HCV in September 1991.*

Dr Jack Gillion's contributory response ends.

SNBTS is not able to comment on whether similar arrangements were put in place in England.

Q4 - Please identify and explain any differences between HIV/AIDS and HCV look-back patient notification exercises and awareness campaigns.

Dr Jack Gillon has contributed the following response:

35. *The main differences between HIV and HCV lookbacks were that the HIV lookback was introduced uniformly across the UK from the onset of testing, and that in the case*

of HCV no time limit was put on retrospective identification of recipients once the standardised HCV lookback procedures were introduced in May 1995 (the HIV lookback was limited to 5 years prior to the index positive donation). The agreed procedures for both lookbacks are described in detail in PEN.017.2220 PRSE0004042

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Dr Jack Gillion's contributory response ends.

Dr Brian McClelland has contributed the following response:

36. *The Awareness campaign for HIV/AIDS was different in that it involved working with groups who had, in reports from the United States, already been designated as having a higher than average risk of HIV infection. The groups included gay men and people who misused injectable drugs. Among the gay community there were very considerable sensitivities about adverse publicity and hostile public reactions. For this reason a lot of our effort in Edinburgh during the early period went into developing an effective response.*

37. *The individuals most likely to be at risk of HCV infection were people who used injectable drugs. An important difference was due to the higher prevalence of Hepatitis C. The meant that a relatively large number of donors were found to have reactive, or confirmed positive results.*

38. *As I recall, the essential principles and practices of look back were very similar in the two cases.*

Dr Brian McClelland's contributory response ends.

39. In respect of public awareness campaigns SNBTS observes that in respect of HIV/AIDS these were led by the UK Government whereas in respect of HCV these appear to have been led mainly by the Scottish Executive / Government following its establishment in 1999.

Q5 - Please explain the impact that any HCV and HIV/AIDS look-back patient notification exercises and awareness campaigns had on the volume and number of blood donations.

Dr Jack Gillon has contributed the following response:

40. *We know that the numbers of donations in Scotland took two significant dips in the wake of the introduction of HIV testing, in 1984/5 and 1987/8, from nearly 340,000 per annum to around 315,000 but this was thought to be a reaction to the general publicity surrounding HIV and blood transfusion. There is no evidence to my knowledge of lookback (in the sense of tracing transfusion recipients) being associated in any way with these dips, which were reversed by active publicity campaigns (MacAskill et al, Scottish attitudes to blood donation and AIDS. BMJ, 1989; 298: 1012 - 1014) (NHBT0017512).*

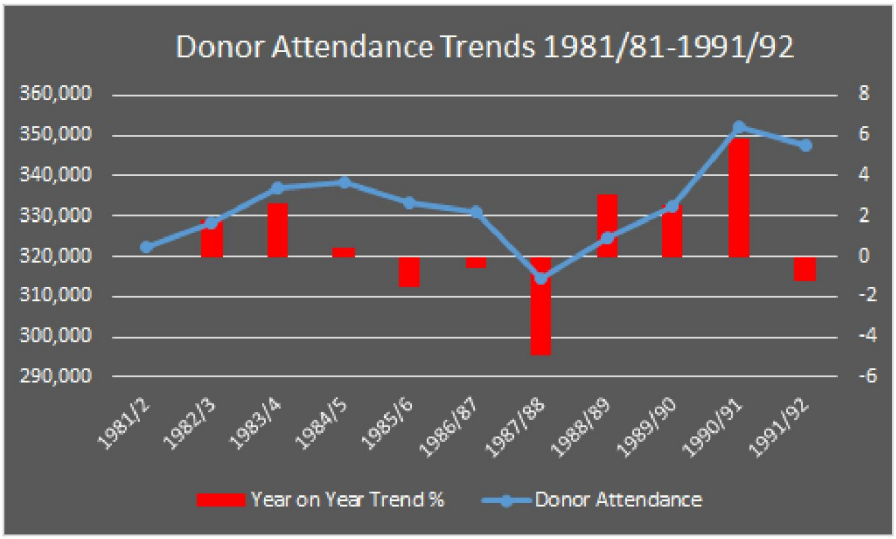
Dr Jack Gillion's contributory response ends.

41. As noted in Question 1, the observed decline in donations and new donor registrations that coincided with increased public awareness of the AIDS issue was a matter of concern for SNBTS:

	Donor Attendances	New Donors
1982/3	328,086	42975
1983/4	336,802	47269
1984/5	338,287	45267
1985/6	333,112	41146
1986/87	331,039	41803
1987/88	314,657	34073

42. SNBTS's response was to address the issues identified in the study on "The Scottish Public's Attitudes to Blood Donation and AIDS" (WITN3530090) through high profile advertising stressing the continuing need for blood donation and enhanced communications with donors on session and in all literature on the safety of the blood donation process.

43. These measures were successful as is evidenced in the diagram below:



44. Given these data it is unlikely that HIV lookback in and of itself was the major factor in the decline in blood donations over this period. We are not aware of any similar decline in blood donation in the 1990s associated with the HCV lookback.

Q6 - Please explain how, if at all, concerns over the need to ensure sufficient supply of blood donations to meet clinical demand influenced the nature and scope of any HCV and HIV/AIDS look-back patient notification exercises and awareness campaigns.

45. SNBTS thinks it unlikely that concerns around the need to ensure sufficient supply of blood donations influenced the nature or scope of HIV or HCV look-back exercises or awareness campaigns.

Q7 - In the document titled 'Penrose Inquiry Transcript, day 70 (Tuesday 29 November 2011)' (PRSE0006070 page 2) David Macintosh, stated the following of the ACVSB: "*...at no point in my appointment, in my job description, in my performance appraisal, in my target setting or in any work that I ever did in my role as general manager, I don't think this committee was ever mentioned. And I don't think that anybody in the SNBTS, certainly on the management side, you know, we who had the responsibility of spending the money wisely in the interests of patients in Scotland -- I don't think any of us felt that this committee had any locus whatsoever.*"

To what extent did this view represent the view of SNBTS towards the ACVSB either during the time of David Macintosh's appointment as chairman and general manager of the SNBTS, or at any point thereafter?

46. There is a divergence of views amongst former SNBTS colleagues on this issue, with some articulating that they had little knowledge of the ACVSB's deliberations and advice (as per Mr Macintosh's statement above) and others appearing quite familiar with the Committee. SNBTS understands that the ACVSB's deliberations were considered to be confidential and that whilst some SNBTS Directors were members of ACVSB in a professional capacity there were restrictions on what they could share with other SNBTS Directors. Whilst we cannot, with any certainty, describe the extent to which this view was representative of SNBTS as a whole at the time, we can assert that the current Senior Management of SNBTS fully recognises and supports the work of the current Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO).

Q8 - The UK wide look-back exercise was announced on 11 January 1995 (NHBT0005792), and commenced in April 1995 (NHBT0002796_002). Please provide an account of the role played by the SNBTS in the decision to undertake this exercise. Please explain whether the 1995 look-back exercise could have been implemented earlier than 1995, and if so, why this was not done.

Dr Jack Gillon has contributed the following response:

47. *As noted in answer to Question 3 above, the report on the management of positive donors after the introduction of routine testing, which was presented to Professor Cash in September 1990, recommended that lookback should be introduced at the same time (PRSE0004114). This was endorsed by SNBTS Directors. In November 1990 Professor Cash wrote to Dr Metters, Deputy CMO at the Department of Health requesting that the ACVSB/MSBT should discuss lookback (PRSE0001573) The minutes of the meeting of ACVSB/MSBT of February 1991 recorded the decision that lookback "should not be undertaken as a service" (PRSE0002280. This became accepted UK policy. However, lookback was introduced in Edinburgh and SE Scotland BTS at the onset of routine testing of donations in September and designated a "pilot study".*

48. *There was little or no further discussion of the issue until the Edinburgh group prepared a paper for publication describing their experience of lookback in the first 6 months (September 1 1991 - 29 February 1992). This was circulated widely and was published in 1994 (Ayob et al, 1994 (PRSE0001046). The conclusion that lookback was feasible and less onerous than hitherto suspected stimulated discussions at government level north and south of the border, with legal advice to the SHHD opining that lookback was inevitable. Further impetus derived from considerable media interest, including a Panorama investigation broadcast in January 1995 (NHBT0040622).*

49. *Lookback undoubtedly could have been undertaken throughout Scotland from September 1991, as testing with second generation assays was backed up with confirmatory tests including PCR for virus RNA. In England some centres used 1st generation tests with RIBA as the confirmatory test, a combination known to have a high false positive rate, and this may have been a significant reason for the reluctance to introduce lookback.*

Dr Jack Gillion's contributory response ends.

50. It is difficult for the current SNBTS Senior Management to answer this question with any certainty, but our perception is that it would have been very difficult for SNBTS to progress a formal NHS Scotland-wide lookback in light of the ACVSB/MSBT and UK Government decision that this should not be done and given that the engagement of hospital blood banks, clinicians and GPs was required to trace, test and counsel recipients.

Q9 - In a letter from Professor John Cash to Dr W Whitrow, Dr S J Urbaniak, Dr D B L McClelland, Dr R Mitchell, Dr R J Perry dated 9 July 1990 (PRSE0001133), Professor Cash stated that he had agreed with Dr Harold Gunson (National Medical Director of the National Blood Transfusion Service) that:

a. ***It would not, after we start anti-HCV donation screening, be appropriate to introduce a systematic look-back programme on previous recipients - as was done HIV-1.***

b. ***It would be appropriate, in the period before routine anti-HCV donation screening commences, to examine the anti-HCV status of donors who have been implicated in a case of reported PTH.***

Please explain the rationale for these decisions.

51. Unfortunately, as the Inquiry will be aware, Professor Cash has passed away and the extant letters and minutes we have been able to find do not shed much light on the

rationale for the decision not to initiate a targeted lookback (PRSE0003568 and PRSE0004416). Relevant background is covered in the SNBTS paper on lookback submitted to the Penrose Inquiry *(PEN.017.2220 / PRSE0004042)*, considerations mentioned therein include concerns around feasibility and cost, doubts around the clinical significance of HCV and that treatment (with interferon) was considered experimental at the time.

Q10 - In a letter from Professor John D Cash to Dr J S Metters dated 22 November 1990 (PRSE0001573), Professor Cash states:

> **"...the Scottish National Blood Transfusion Service Directors have asked me to write to you with a request that a policy of "look back" is considered by the Department of Health Advisory Committee on the Virus Safety of Blood."**

a. Please provide an account of the considerations and discussions within SNBTS, between 9 July 1990 and 22 November 1990 that resulted in this request.

52. This is covered in Dr Gillon's response to Question 8 above, in greater detail in Chapter 35 of the Penrose Report and in the SNBTS paper on lookback submitted to the Penrose Inquiry (PEN.017.2220 / PRSE0004042). In the latter document it states that:

> *'In the summer of 1990 the SNBTS Directors set up a working party to advise on policies and procedures, with particular emphasis on counselling and care of donors with positive HCV tests. In their report dated 23rd November 1990 the authors advised that lookback should be instituted from the onset of testing.*

53. *The report was well received north and south of the border, and the materials produced for donor counselling were accepted UK-wide. The proposal for lookback underwent further discussion by both the SNBTS and the NBTS Directors (in the letter cited above) and was finally rejected after referral by the SNBTS National Medical Director (NMD) to the Department of Health, London.'*

b. Why, when a test for Hepatitis C was available from 1989, an HCV look-back exercise was requested in November 1990, and national screening of donations was implemented in September 1991, was action not taken sooner to notify patients of the risk that they may have been exposed to Hepatitis C infection through the use of blood and/or blood products?

54. Notification of recipients was dependent on the implementation of targeted lookback, which itself was contingent upon the introduction of HCV testing in September 1991. The recommendation from SNBTS that lookback be introduced from the onset of

testing and the rejection of that recommendation by the Department of Health is summarised in the responses to Questions 8 and 10a above.

c. Who was responsible for seeking funding for a look-back exercise? From where would funding be sought?

55. As SNBTS General Manager, Mr David McIntosh would have been responsible for seeking funding. Mr McIntosh has indicated that to the best of his recollection lookback was funded from SNBTS internal resources.

d. What funding applications for a look-back, if any, were made?

56. SNBTS has not been able to identify any specific funding applications for look-back, however we do note that in the Progress Report from the National Blood Authority (in England) on the HCV Lookback Programme there is reference to workload and costs both for Blood Services and hospitals (DHSC0003595_036).

Q11 - In the document titled 'Annex C Category B Paper Hepatitis C' (DHSC0006348_083 page 2 paragraph 2) by Dr Graham Winyard it is stated that:

> ***"The Department is coming under increasing pressure to raise HCV awareness since the licensing of Alpha Interferon (InFa) a year ago offered a treatment for some patients with HCV (even though only some 25% will respond) and was the main reason why the "Lookback" exercise was set up last year to trace patients infected through blood transfusion in the course of NHS treatment."***

At page 3 paragraph 3, discussing the licencing of Alpha Interferon for Hepatitis C, it states:

> ***"'The availability of treatment has increased interest in the disease and provided a much stronger incentive than simply preventing transmission, for identifying those infected. It was the main reason why the "Lookback" exercise was set up to identify patients infected through blood transfusion in the course of NHS treatment."***

a. Please comment on the extent to which the licencing and availability of Interferon influenced the decision to implement the look-back exercise in 1995?

Dr Jack Gillon has contributed the following response:

57. *I am not aware of the source of Dr Winyard's assertion that the licensing of alpha interferon was "the main reason why the Lookback exercise was set up last year" (presumably referring to 1995), but it is true that in the discussion section of our paper (Ayob et al, as above, PRSE0001046) we agreed that it was an added impetus to reconsider the extant policy. It was not, however, the reason for undertaking our "pilot study". We believed that the principle of tracing recipients of potentially infectious blood had been established by the precedent of introducing lookback at the time of*

commencing screening for antibodies to HIV in 1985. The question we set out to answer was whether the same approach to HCV was logistically feasible, which we answered in the affirmative.

Dr Jack Gillon's contributory response ends.

58. SNBTS is not able to comment on the extent to which availability of Interferon influenced the UK Government's decision to initiate a national UK lookback in 1995.

b. Please explain why "simply preventing transmission" was not sufficient incentive for the implementation of a look-back.

59. SNBTS is not able to explain why Dr Winyard took this view.

Q12 - The results of a retrospective HCV look back study conducted in Edinburgh were presented for publication in Transfusion Medicine 1994, 4, 269-272 (PRSE0001046).

Dr Jack Gillon and Dr Brian McClelland have contributed the following responses:

a. Please provide the exact dates that the study commenced and concluded.

60. *The study itself ran from 1st Sept 1991 to 29th Feb 1992, however the lookback process continued unchanged in Edinburgh after the period for which data was presented in the published paper.*

b. The study comments that lookback was not being practiced in the UK. To what extent was the study intended to inform decision making around the feasibility of a larger Scottish and/or UK wide look-back?

61. *As stated in the paper, the study was aiming to assess the workload and feasibility of the lookback, as this had emerged as a prime reason for rejecting lookback as a policy to be implemented from the introduction of testing.*

c. At page 272 of the study it is stated:

> ***'The requirement to carry out a retrospective study when an HIV-infected donor is identified has not been questioned, but the greater numbers involved in the case of HCV and doubts about the efficacy of the procedure have, until now, inhibited blood transfusion centres from applying the same standards (Busch, 1991). It is the policy of the U.K. transfusion services not to carry out HCV lookbacks. If we assume one***

infected recipient per donor, we estimate that around 3,000 patients may be alive and infected with HCV as a result of transfusion in the UK based on the prevalence of HCV in Scottish blood donors and excluding haemophiliacs. Our experience confirms that the identification of these patients is a daunting task, but the availability of potentially efficacious treatment for chronic hepatitis C, in the form of a-interferon, compels us to suggest that we have a clear ethical responsibility to these patients to identify them and offer counselling, testing and, if necessary, treatment (Kolins, 1990). Many of these patients will be old and most will have only mild liver disease, but it is our view that this problem should not be ignored on logistical grounds when, in each case, there is an overwhelming responsibility to the individual patient.'

62. *The quote about the policy in the USA, in the paper authored by Dr Busch, is taken from the discussion section of our paper. We made it clear we did not share the view that HCV lookback was not justified on the grounds of lack of efficacy or impracticality. It was our view that the acceptance of lookback as applied in the case of HIV created a moral imperative to act similarly in the case of HCV, and that logistical difficulties should not deflect from that, but there were those who argued that the workload implications of the procedure were likely to be unmanageable. We felt that we had shown that this was not the case.*

d. In as much detail as you are able, please explain the basis for the estimate that 3000 patients may be alive and infected with HCV as a result of transfusion in the UK.

63. *This was a simple extrapolation from the finding of 9 patients alive and positive for HCV from a starting point of 42,697 donations over 6 months, yielding 20 confirmed positive donors, of whom 15 had donated previously. The only relevant similar data were published by Perkins et al, describing their experience of HIV lookback in San Francisco (Perkins HA et al, Blood 70, 1605 - 1610, 1987) (NHBT0017510_001). They found one living, HIV positive recipient for every positive donor. Although our results produced a slightly lower number of living recipients per donor we felt it would be reasonable to assume a relatively pessimistic view, and based our estimate on the assumption of one recipient alive and infected per donor. Using our starting prevalence for the period in question, i.e. 0.88%, we extrapolated using the total number of active donors in Scotland as the denominator. From the resulting figure of approximately 300 living recipients we extrapolated further to around 3000 for the UK on a simple population basis. This was clearly a very speculative figure, but it was simply intended to give a very crude indication of the scale of the task.*

64. *Some vindication for this estimate was provided by the early results of the UK-wide lookback that began in the UK in April 1995. In a letter from Dr Metters, Deputy CMO, to Ministers and others in December 1995 the results of the lookback to that date were provided as an appendix (WITN3530094 and WITN3530095). Dr Metters noted in his comments on these that the estimate for the whole of the UK of approximately 3000 living, infected recipients appeared to be "realistic". Furthermore, in Chapter 3 of the Penrose Report the work of Soldan et al in England and Goldberg and Schnier in Scotland (at the request of Penrose), while highlighting the difficulty in modelling reliable estimates of HCV infection in recipients with very little in the way of hard data, led to the Penrose Inquiry accepting a figure of around 2500 infected recipients overall in Scotland. Applying the mortality data to this figure would suggest that around 300 living, infected recipients was a reasonable estimate.*

65. *It may be worth adding that when a new test is introduced to a blood donor population it does not give rise to a steady positivity rate in the early stages when the disease is chronic, and has therefore accumulated in the population over time. The blood donor population consists mainly of "regular" donors, who donate on average around 1.5 - 2 times per annum, though this varies considerably. The initial testing therefore gives rise to a "hump" of these regular donors who have been carrying the agent in question. In general this "hump" will be over in around 1.5 years, thereafter resulting in a steady stream of positives only in new donors, donors returning after a period of non-attendance, and any regular donors acquiring the infection de novo. Clearly in any national population there is the potential for many sub-populations, and the extrapolations such as those described above for the entire UK population are to be treated with caution. In the event, however, these estimates were not far off the mark as revealed in the outcome of the HPA data gathered during the HCV lookback from 1995 – 1998 (SCGV0000167_192).*

Dr Jack Gillon and Dr Brian McClelland's contributory response ends.

e. What was the prevalence of HCV in Scottish blood donors, referred to? How was this prevalence calculated?

66. The prevalence in the Scottish blood donor population was determined for the period 1.9.91 - 29.2.92 by measuring the number of confirmed positive donations and expressing this as a percentage of the number of donations during that period. From this an overall prevalence of 0.1% (1/1,000) was calculated though this did vary between different regions.

f. Please explain the assumption, "one infected recipient per donor"?

67. This assumption was based on the work of Perkins et al described under 12d above (WITN3530093).

g. When was this "ethical responsibility" first recognised within SNBTS?

68. SNBTS considers that the ethical responsibility to conduct lookback was first recognised when HIV lookback was introduced in 1985.

h. What were the factors that prevented the "ethical responsibility" from being discharged?

69. SNBTS considers that this ethical responsibility was discharged, so far as possible, by the establishment of the pilot lookback in Edinburgh at the time of introduction of HCV testing and its subsequent publication and use of the results in helping to persuade the UK Government to reverse rejection of HCV lookback as policy. As discussed in our response to Question 8, it would have been very difficult for SNBTS to formally progress a national lookback in Scotland in contravention of UK Government policy given that the engagement of hospital blood banks, clinicians and GPs was required to trace, test and counsel recipients. SNBTS is not able to add substantively to the chronology of events detailed by Lord Penrose in Chapter 35 of his Final Report.

Q13 - At paragraph 6.5 of the document titled 'Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 3rd meeting, 29 September 1994' (PRSE0003670) it is stated that an SNBTS report on look back was tabled as item MSBT 3/10. Please provide a copy of the report.

70. This report is provided as PRSE0002454

Q14 - In a letter dated 22 December 1994 from Lord Fraser of Carmyllie, Scottish Office Minister for Home Affairs and Health to Tom Sackville MP, Parliamentary Under Secretary of State for the Department of Health (PRSE0001781), it is stated at page 1, paragraph 2:

> ***"Until now there have been no arrangements made to carry out any look-back exercise to identify these recipients of the infected blood and to arrange***

counselling with a view to treatment. Part of the reason for this lack of any follow up action was a concern that it would be impossible to identify all recipients of infected blood and even if it were possible there was a lack of accepted treatment which would be beneficial. It was accepted that if no effective treatment was available, informing those patients who were unaware of their situation could not be justified, since this would cause further distress and anxiety without any benefit."

Further, paragraph 2 states:

"***Following a pilot research-study carried out last year by the Edinburgh and South East Scotland Blood Transfusion Service it has been established that a look-back exercise for Scottish patients would be feasible and practicable...Failure to do so may result in a liability for loss or injury occasioned to the individuals through any failure or delay in identifying the recipients and, where clinically advised, offering treatment...the Scottish circumstances make it imperative that action is taken now."***

a. Please explain why it was considered that the lack of available treatment justified not informing patients of their condition?

71. SNBTS is not able to explain why Lord Fraser of Carmyllie was of this view.

b. In the absence of available treatment, please explain what steps people infected with HCV could take to mitigate the risks to their health, e.g. by limiting alcohol consumption, and comment upon the rationale for not informing patients in this context.

72. So far as SNBTS is aware, prior to the availability of treatment, there was little a patient could do to mitigate the risks to their health except reduce or avoid alcohol.

c. Was any consideration given to notification in order to prevent infection through sexual contact and other means of transmission?

73. This was considered as part of the rationale for supporting lookback and informing patients.

d. Please exhibit any legal advice provided to SNBTS on the issue of liability for loss or injury due to failure or delay in identifying and offering treatment to infected recipients.

74. We are not aware of SNBTS taking legal advice on this issue. It appears from his letter that Lord Fraser of Carmyllie did take legal advice but SNBTS has no access to this.

e. Please explain any contribution of SNBTS to the conclusion that, *"the Scottish circumstances make it imperative that action is taken now."*

75. SNBTS assumes that this comment refers to the publication of the Edinburgh results showing that lookback was indeed feasible (PRSE0001046). The fact that this information was put in the public domain helped to reopen the discussion about lookback and was a contribution to the decision to change the policy.

Q15 - In the document titled '*Draft Report from the MSBT Subcommittee'*(NHBT0005791 page 2) discussing the merits of introducing an HCV "Look-Back" policy, it is stated:

"Despite these reservations it is recognised that there is a duty of care that needs to be exercised towards these patients and the implicated donors"

Dr Jack Gillon has contributed the following responses: :

a. When was this duty of care to patients and donors first recognised by SNBTS?

76. *The fundamental duty of care for any blood transfusion service is to ensure that blood and blood products for transfusion are as safe and efficacious as possible in the prevailing state of scientific knowledge, while doing everything in our power not to do harm to donors in fulfilling our obligations to patients.*

77. Donors are sometimes harmed by the process of donating blood. This ranges from minor bruising at the venepuncture site to injuries sustained as a result of a faint, and rarely to precipitation of serious reactions such as myocardial infarction. The avoidance of such events is paramount, but such events cannot be entirely avoided by even the most rigorous staff training programmes, and so it is equally important that staff know how to respond to such events in order to provide the best possible care for the individual.

78. *Similarly, when a patient is harmed by a transfusion there is an obligation to respond in a positive and caring fashion in order to help that patient in any way possible. This*

could be an acute event at the bedside, or the discovery of hitherto unrecognised harm accruing at a later date.

79. *In specific terms relating to lookback it seemed clear that in the case of HIV transmission by blood it was in the patient's interest to have that information in order to facilitate prompt treatment when necessary and also to prevent onward spread of infection, and this was the first time a formal procedure of this type had been introduced, namely at the time of initiation of routine testing in October 1985 PRSE0004042 .*

b. Please provide an account of how this duty of care was discharged:
i. prior to the look-back in 1995; and

80. *In the case of HCV the benefit to the patient of being formally diagnosed was less clearcut, in that the illness was not clearly a threat to life and specific treatment was not available at that time. In SE Scotland BTS we were of the opinion that the potential benefit to the patient in the longer term and the desirability of preventing onward spread (while acknowledging that the degree of risk of sexual transmission was not well established) obliged us to make that information available to the patient. We therefore instituted lookback at the time of commencing routine screening in 1991, and reported the outcome by publishing details of our experience. This resulted in a reversal of the policy across the UK.*

ii. in respect of those patients not identified by the look-back exercise.

81. *Every effort was made to trace patients who had received potentially infected blood. Searches were only abandoned when it was clear that there was no way of identifying the recipient(s) of a particular donation.*

Q16 - Please provide an account of the steps that were taken to warn patients of the risk of HCV transmission through communication channels such as print and digital media, as well as other awareness raising campaigns such as leaflets and notices. Please also account for any differences in approach to awareness raising campaigns between the HIV and HCV look back exercises respectively.

82. Please refer to SNBTS's responses to Questions 2 and 4.

Q17 - Please explain how and why the procedures and guidelines of the 1995 look-back exercise, as set out in the letter issued by the Chief Medical Officer (Dr Kenneth C Calman) on 3 April 1995 (NHBT0002796_002), were developed.

Dr Jack Gillon has contributed the following response:

:

83. *The procedure and guidelines were derived from the work of the group tasked with this in the SNBTS in 1990 and led by me. They were updated and expanded at the request of the sub-committee of the MSBT chaired by Dr Metters, deputy CMO, of which I was a member. This ensured uniform procedures throughout the UK.*

Q18 - At pages 1 and 2 of the document titled 'Notes of Decisions and Actions from First Meeting of Hepatitis C Look Back Working Party' dated 20 January 1995 (NHBT0009715), under the heading, "Look back exercise", the following agreed action is recorded:

"It was agreed that the look back exercise should be concentrated in the first instance upon donors who had given blood prior to September 1991 and been found to be HCV anti-body positive on a subsequent visit. The services would not try to trace donors who had not come back to a Transfusion Centre since then. The work involved in doing so would be disproportionate to the benefit."

a. Please explain the work involved in tracing donors who had not returned to a Transfusion Centre and why, having regard to the duty of care owed to patients, this was considered to be disproportionate.

84. We assume this question specifically relates to tracing previous donors then it would require a search of the donor database to provide a list of all donors, past and present, and a letter or other form of communication to those people (other than those active donors who have already have been tested) asking them to attend either SNBTS or their GP to have a sample taken for testing. We are not able to determine the number of previous donors in 1991, however to give a sense of the order of magnitude, if SNBTS was to undertake such an exercise now utilising a search of its core donor database eProgesa which holds data back to 1998 then we would identify in the order of 750,000 donors of whom 85,000 we would consider active (i.e. having donated in the past 12 months), leaving 665,000 people to be individually contacted and tested (@12% of the Scottish population).

85. Between around 1987 and 1997 SNBTS utilised the DOBBIN system which was fragmented between the 5 Regional Blood Transfusion Services and could not be searched in the same way as modern information technology systems. Prior to that the organisation operated predominantly from paper records which can only be searched by hand. There is, of course, temporal attrition of donors i.e. the further back in time one goes the more donors will have moved house, become unwell or passed on themselves. In addition, as one goes back beyond the current era of integrated information technology systems, it becomes increasingly difficult to link a donor and

his/her donations to recipients though hospital blood bank information systems and/or medical notes.

b. With reference to the words, "in the first instance", please provide an account of all subsequent actions.

Dr Jack Gillon has contributed the following response:

86. *I am not aware of any subsequent actions in respect of this issue.*

Q19 - Within document NHBT0009715, under the heading, "Look back exercise", it further stated:

The Working Party considered the testing of serum samples stored from before September 1991 and agreed that Ministers should be advised that the testing of such samples would also be disproportionate, although a legal view on this should be obtained."

a. Please explain the work involved in testing stored serum samples and why this was also considered to be disproportionate, having regard to the duty of care owed to patients.

Dr Jack Gillon has contributed the following response:

87. *The only way to identify such donors would be to test any frozen samples available from their donations. Archives of frozen samples were started in some centres in the mid 1980s, one of the earliest being Edinburgh in 1984. Therefore, at best around 6 years' worth of samples might be available. Between 1981 and 1988 around 2.5 million donations were collected in Scotland (Penrose Report, Chapter 3, Table 3.14). From each donation a small aliquot was frozen in a plastic container. These were held in freezers in the testing laboratories in each centre. Both computing facilities and automation of testing samples were rudimentary in the 1980s, so full scale defreezing and testing of these samples would be a manual procedure. For Scotland at least one dedicated laboratory would be needed, and the process would stretch over several years.*

88. *The Scottish Government Short Life Working Group on the Penrose Recommendation considered this possibility in 2016 (PRSE0005299).*

89. *This Group concluded this might involve:*

- *HCV testing of stored specimens from people who donated blood between 1984 and 1991*

- *Following the identification and confirmation of HCV infected components, the tracing of recipients through hospital blood bank and patient records.*
- *For those who may have received such a donation, a further investigation to determine if they are still alive and, if so, are not already known to be HCV infected.*
- *Finally, the tracing of such individuals, making contact with them and then offering them an HCV test.*

90. *and that from the perspective of practicality/effectiveness:*

- *An enormous task involving an estimated 2 to 2.5 million specimens and associated paperwork which will need to be searched, tested and reconciled by hand. For comparison SNBTS currently tests around 250,000 samples per annum using automated testing and IT linkage.*
- *There are many issues with the reliability of the archive related to the integrity of the samples and records:*
    - *Linking tested samples to specific donors, components and the hospitals they were provided to is likely to be difficult and may not be possible in many cases due to the variety of paper-based and early IT systems used at the time.*
    - *The samples were collected in a variety of different formats in different centres and have been stored under a variety of conditions over a long period of time. In addition, assay methodologies have not been optimised for this nature. Therefore the quality of the samples and the integrity of the results cannot be guaranteed.*
    - *Hospital record retention does not extend back to the 1984-1991 period and it would be unlikely that patients who received specific components could be identified (or traced).*
    - *An effort would also need to be made to trace test positive donors to inform them and carry out confirmatory testing. Most of these people will no longer be blood donors and may have moved or themselves be deceased.*
- *This would be a major exercise, incurring significant costs and requiring 6 - 7 or more years to complete.*
- *A break in the chain of traceability in any of the above areas would negate the benefit of testing. In reality there are significant weaknesses in all areas. The likelihood of being able to trace significant numbers of infected patients through this route is small.*

- *A cost of £8 - 10 million not including the costs of patient tracing.*

91. SNBTS comment: the sample archive was not designed for the mass screening of donations - the samples represent the residual volume left over after routine microbiology NAT testing – normally around 1-2 ml. There is no legal or regulatory requirement to retain these samples, but our purpose in doing so is to aid further investigation of a donation where this is required for technical reasons, for targeted lookback or reverse lookback investigations (i.e. where a patient is identified as HCV positive and SNBTS is asked to determine whether one of his/her donations was from an infected donor) and/or for investigations into other adverse events in patients. Usually, following an investigation, there is little residual sample left. Mass screening of the archive would reduce its utility for follow up and resolution of specific patient and donor related issues (such as other infections) thereafter.

b. Please provide, as an exhibit to the written statement, any legal advice obtained on this issue.

92. SNBTS is not aware of having taken any legal advice on this issue. We note that the Minute of the Working Group meeting mentions obtaining legal advice but do not know whether the UK Government or Department of Health did so or not.

Q20 - In a letter to Dr McGovern dated 19 August 1998 (NHBT0015135_002), Dr Angela Gorman writes:

"However I feel that it is unlikely that all of Mrs [redacted] donors will either be contactable now or will have donated again since the index donation. This is not for any sinister reasons, but simply because a significant percentage of donors cease to donate every year."

Given the awareness that significant numbers of donors ceased to donate blood every year, why was the HCV look-back exercise designed to target only the recipients of repeat blood donors?

93. SNBTS is not certain what this question is asking.
By definition there would not be any recipients of first time donors who were identified as HCV positive after 1st September 1991 so targeted lookback would not be required. In a reverse lookback all donors, first-time and repeat, would be investigated.

If the question is asking why the HCV lookback was not designed to look for recipients for blood components from donors who were no longer donating at the time of introduction of the test then the answer relates to the difficulties in doing so as captured in our responses to Questions 18 and 19 above.

Q21 - Where a former donor tested anti-HCV positive in some context other than a repeat donation of blood (e.g. during medical treatment), was a look-back conducted on their previous donations?

94. Yes, provided SNBTS was or is informed.

Q22 - In the article titled 'The contribution of transfusion to HCV infection in England' by K. Soldan (PRSE0000620) it is estimated that:

Page 588: "*This estimated the number of transfusion-transmitted HCV infections from components that entered the lookback programme but fell out of the process prior to recipient testing to be 3373 HCV infections.*"

Page 590: *"Using this adjustment resulted in an estimated extra 19 525...anti-HCV-positive components issued after 1 January 1980 that did not enter the lookback programme. The entry of these extra anti-HCV positive components into the path - with the use of a 0.75 probability of infection transmission for these components (i.e. the observed proportion of anti-HCV-positive donation also positive for HCV RNA) - predicted an extra 12 606...transfused components, and an extra 9455...HCV-infected recipients of which at least 5794...are expected to have died by the end of 1995.* "

Given that, according to Soldan's assessment, the HCV look-back exercise only identified a small percentage of people infected with HCV through blood transfusions, what steps, if any, were taken to address the deficiencies of the 1995 HCV look-back?

95. This paper was published in 2002. So far as SNBTS can tell no further steps were taken at that time to try to identify people who had been infected with HCV from a blood transfusion prior to 1991.

Q23 - Was it possible for Blood Donor Centres and Haematology Departments to opt out of the 1995 look-back exercise? If so:

96. SNBTS is not aware of any Blood Donor Centres or Haematology Departments opting out of the 1995 look-back exercise. The CMO letter from Dr Calman (WITN3530095) was very explicit in the actions to be taken.

a. Please provide a list of Centres and Departments that did not participate in the 1995 look-back exercise.

97. SNBTS is not aware of any such Centres or Departments in Scotland

b. Why was the 1995 look-back exercise not made mandatory?

98. SNBTS is not able to answer this question but assumes that the Government felt that the CMO letter from Dr Calman was sufficient in this regard.

c. What steps, if any, were taken to encourage Centres and Departments to participate?

99. The CMO letter from Dr Calman was considered sufficient in this regard.

Q24 - Please provide an account of the processes and procedures to ensure compliance and consistency in the administration of the 1995 HCV look-back exercise by Blood Donor Centres, Haematology Departments and medical professionals across Scotland.

100. Dr Calman's CMO letter of April 1995 (WITN3530095) provided a detailed account of the processes and procedures to be followed with appendices providing guidelines on counselling and specimen letters etc. These would have been recorded in the Standard Operating Procedures (SOPs) of the SNBTS Quality Directorate which were the same for all SNBTS Centres.

Q25 - In a letter from Professor Ian M Franklin to Dr A Keel regarding HCV Lookback dated 28 April 1998 (PRSE0003277), it was the view of the SNBTS that the current HCV lookback should be considered to be closed:

101. PRSE0003277 – Exhibit 29

a. Please provide a copy of the minutes of *the "recent meeting of the SNBTS Medical and Scientific Committee."*

102. The minute of SNBTS Medical and Scientific Meeting April 1998 is provided (WITN3530096)

b. What was the reasoning behind the decision to close the lookback programme? What part, if any, did the availability of funding play?

Professor Ian Franklin contributed this response:

103. *It was felt that the "catch up" phase of lookback following implementation of HCV testing had achieved all it could. Over time the number of HCV positive donors who had given blood prior to 1991, then ceased to donate before returning after 1998 became very small.*

c. Why was look-back not considered to be an ongoing process?

104. Lookback was and is regarded as an ongoing part of business as usual as mentioned in the last part of Professor Franklin's letter.

d. Were those individuals that donated blood and tested positive for HCV after this date contacted?

105. Yes they were, as described previously in PEN.017.2221 / PRSE0004042. A confidential letter was sent to the donor offering a face to face meeting during which they were offered counselling, repeat testing and specialist referral as necessary.

Q26 - In relation to any deceased persons who were identified as being at risk of HCV infection through the 1995 look-back exercise:

a. What steps, if any, were taken to determine whether the death was caused by or related, either directly or indirectly, to HCV infection.

Dr Jack Gillon contributed this response:

106. *In the "Programme to identify recipients of blood infected with hepatitis C virus (HCV), April 1995 (PEN.017.2220, page 31 PRSE0004042), it is stated "Is the patient alive? No - no lookback action". The guidelines contain a sample letter from the consultant in the transfusion centre to the consultant in charge of the patient at the time of death, asking "If you know that the patient has died, please provide details of the date and cause of death." Furthermore, forms LBF1 and LBF 2 of the National Hepatitis C Lookback Programme, to which all UK transfusion centres supplied all data on patients identified by the lookback, cause of death and any evidence of liver disease were recorded.*

b. Please provide their names, date of birth, and date of death.

107. *SNBTS doesn't have this information. Any relevant data would have been held by the UK National Lookback Programme*

Q27 - Annex A to the letter of the Chief Medical Officer dated 3 April 1995 (NHBT0002796_002) states:

"Where the final HCV test result is deemed to be indeterminate this should be recorded, but no further action is required at the present time.'

Dr Jack Gillon has contributed the following response:

a. How were indeterminate test results recorded?

108. *Indeterminate test results were recorded on the donor record held by the responsible Consultant, in the computer record of the microbiology lab of the relevant Centre, and by the National Microbiology Reference Laboratory.*

b. How, if at all, were indeterminate test results followed up?

109. *Donors were not recalled immediately in the way that true positives were. They were allowed to donate again, but their record had a flag indicating that the blood should not be used. If the indeterminate result was no longer present, the record would be cleared for normal donation.*

c. Were donors with indeterminate test results informed? If so, how?

110. *Donors were informed if the indeterminate result persisted, and reassured that the extended testing (RIBA III and individual PCR) ruled out the presence of HCV. This was done initially by letter without specifying the test that was reactive, but offering a face to face meeting if the donor so wished.*

Q28 - Please provide an account of the results and findings of the 1995 look-back exercise in Scotland, including but not limited to:

a. The total number of people who were identified as being at risk of HCV infection through blood transfusions;

111. 880 recipients were identified as receiving components from a HCV positive donor, of these 880:

536 had died by 1995

78 could not be traced

266 were identified as potentially eligible for counselling and testing, of these:

133 received counselling and tested positive for HCV

70 received counselling and tested negative
63 were classed as 'other' (some were unwilling to be tested; some were elderly, very ill or had a low life expectancy; some were deemed incapable of giving consent to testing; some results were not returned to SNBTS).

b. The total number of people notified of the risk of HCV infection through blood transfusion;

112. 266

c. The number of people who were tested for HCV as a result of being notified that they were at risk;

113. 203 that SNBTS were aware of. Some people may have been tested but the results not returned to SNBTS.

d. The number of people who tested positive for HCV following notification;

114. 133

e. The number of people who tested negative for HCV following notification;

115. 70

f. The number of people whose tests results were indeterminate;

116. None to the best of our knowledge

g. The number of people who failed to respond to a notification that they were at risk of HCV infection;

117. SNBTS doesn't have this information but it must have been some proportion of the 63 people in the 'other' category above

h. An account of attempts made to establish contact with people who did not respond to notifications;

118. In this scenario it would be normal to contact the patient's General Practitioner and ask him/her to make contact.

i. How many people in total were counselled as part of the 1995 look-back exercise?

119. 203 – though some proportion of the 63 people in the 'other' category will have been counselled but elected not to be tested.

Q29 - Has there been any attempt to use the data obtained from the 1995 look-back exercise to determine the total number of infections of HCV from blood transfusions up to September 1991? If so, please provide an account.

Dr Jack Gillon has contributed the following response:

120. *Chapter 3 of the Penrose Report gives full details of statistical modelling carried out by Dr Kate Soldan, of HPA England, Prof David Goldberg and Dr Christian Schnier of Health Protection Scotland, and the Department of Health, including work carried out by Dr Soldan, and separately by Prof Goldberg and Dr Schnier at the request of Lord Penrose, using the available, but limited, data derived from the lookbacks north and south of the border.*

121. *SNBTS was not directly involved in this work and therefore a detailed account would need to be provided by the authors.*

Q30 - In a letter (NHBT0036358) of Dr Angela Robinson, Medical Director of the National Blood Authority, dated 1998, to Dr Mortimer, Public Health Laboratory Service, discussing the US Public Health Service's recommendation that all recipients of blood prior to 1992 should be tested for HCV, Dr Robinson suggests that there is no requirement for such a recommendation in the UK. Is this view consistent with SNBTS' position, both then and today?

Professor Ian Franklin has contributed the following response:

122. I don't remember seeing or receiving a copy of that letter. Nor do I recall the US Public Health Service's advice. Neither do I recall any discussions in the UK blood services about advising this.

123. *SNBTS notes that this was a recommendation of the Penrose Inquiry, reviewed by the Scottish Government's Short Life Working Group and implemented by Health Protection Scotland (PRSE0005299 and WITN3530092).*

Q31 - Please exhibit to the written statement any guidance and advice provided to medical professionals to ensure they were able to identify patients in need of HCV testing because they were at risk of infection from a blood transfusion.

124. Guidance or advice was provided in Dr Calman's CMO letter (WITN3530095) and subsequently by the Scottish Government in response to the recommendations of the Short Life Working Group (PRSE0005299).

Q32 - Please provide the number of blood donors in Scotland for each month (highlighting any repeat donors within the specified period) who tested positive for HCV, from the introduction of routine screening for HCV in September 1991 (or from the earliest date that you have records) to date.

125. SNBTS does not have these data broken down by month, only by year.

126. The data between inception of HCV testing in September 1991 and December 2020 is provided in Table 6b (page 16) and Figure 1b (page 18) of the SNBTS Blood Donor Infection Surveillance Report Number 22 (August 2021) (WITN3530097).
The National Microbiology Reference Unit Quarterly Reports are provided for the period January 2021 through to June 2021 (WITN3530098 and WITN3530099).

Q33 - Please provide the number of blood donors in Scotland for each month (highlighting any repeat donors within the specified period) who tested positive for HIV, from the introduction of routine screening for HIV in October 1985 (or from the earliest date that you have records) to date.

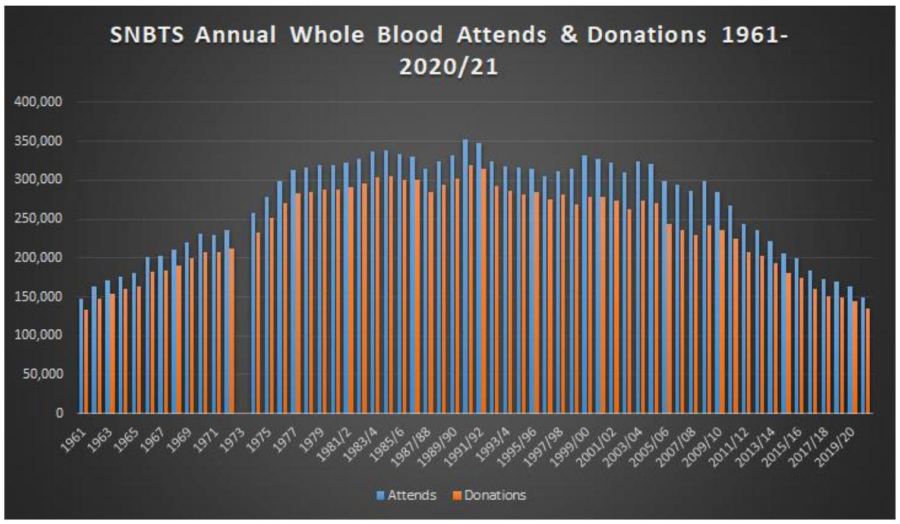
127. SNBTS does not have these data broken down by month, only by year.

128. The data between inception of HIV testing in October 1985 and December 2020 is provided in Table 6c (page 17) and Figure 1c (page 18) of the SNBTS Blood Donor Infection Surveillance Report Number 22 (August 2021) (WITN3530097).

129. The National Microbiology Reference Unit Quarterly Reports are provided for the period January 2021 through to June 2021 (WITN3530098 and WITN3530099).

Q34 - Please provide the number of blood donations and the number of separate donors, for each permanent Blood Donor Centre, area and region, for each month from earliest records to date.

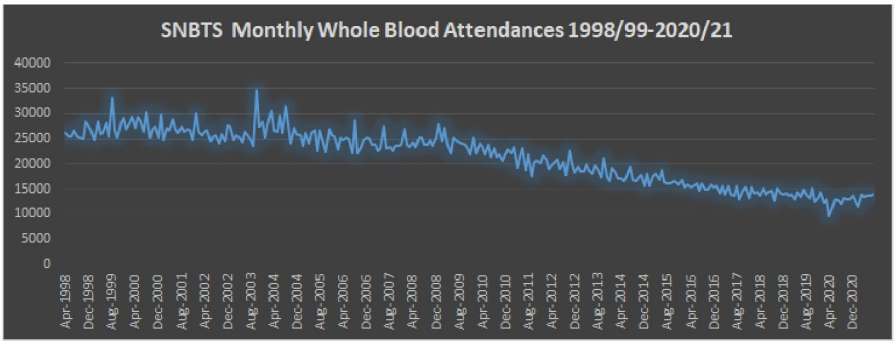
130. The detailed data on donations from each region for monthly donations is only available from January 1998 when the SNBTS Blood Management system Progesa was fully implemented. The historical records are incomplete but we have assembled the annual national collection figures from 1961 to date in the figure below:

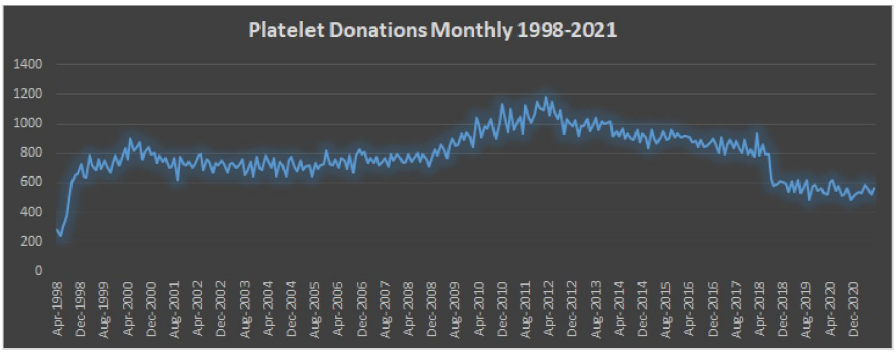


131. The data between 1961 and 1998 was assembled from the following sources:

- Data from 1961 to 1972 is derived from a report prepared for SNBTA.
- We don't have data for 1973.
- The data on donations from 1974-1984 was compiled manually for the Penrose Inquiry. We have estimated the attendances for this period by factoring in the deferral rate.
- The data from 1985-96 was derived from a historical report that contains regional donor attendances and we have estimated donations using the deferral rate as above.
- The data for 97/8 and 98/99 were derived from the SNBTS annual reports

132. Data from April 1998-July 2021 was derived from the SNBTS Blood Management System eProgesa Database and is therefore from a fully validated source. The annual (or semi-annual) data for whole blood and platelets for this period is presented graphically below:



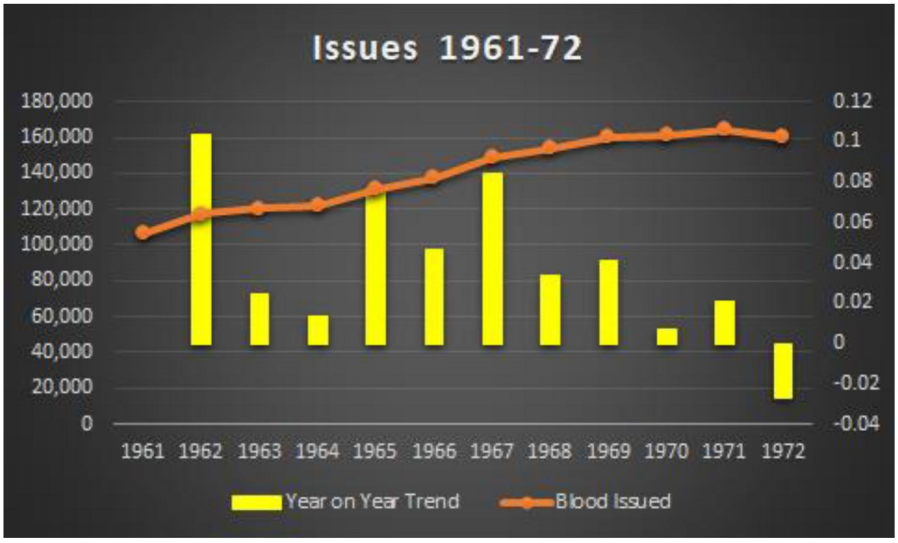


The full data for this period broken down by month and region is provided in WITN3530100.

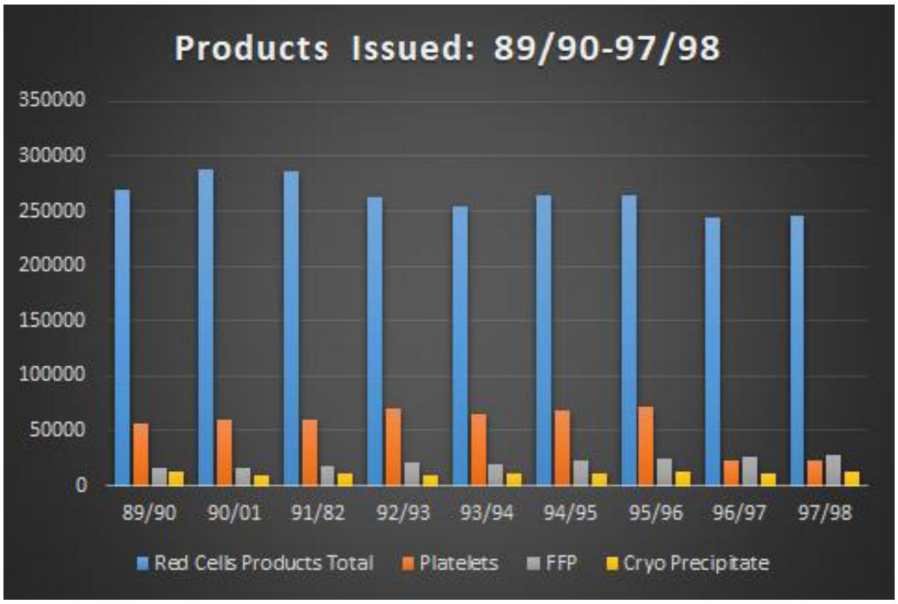
Q35 - Please provide the number of blood transfusions provided by the NHS Scotland (to include predecessor organisations) within Scotland for each year from earliest records available to date.

133. The detailed data on monthly blood component issues from each region is only available from January 1998 when the SNBTS Blood Management system Progesa was fully implemented (please note though that blood components issued from SNBTS to hospital blood banks do not necessarily equate with units transfused). Prior to this SNBTS has no comprehensive data on issues of components. We have two data sets that relate to:

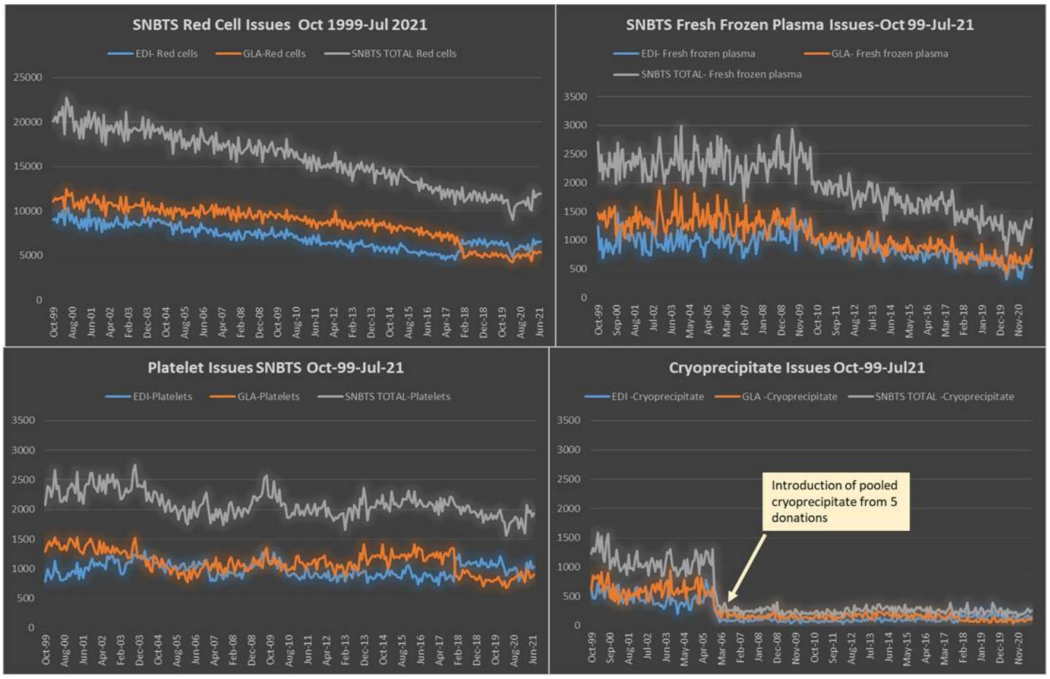
- 1961-1972 derived from an SNBTA report



- 1989-97 derived from SNBTS Annual reports

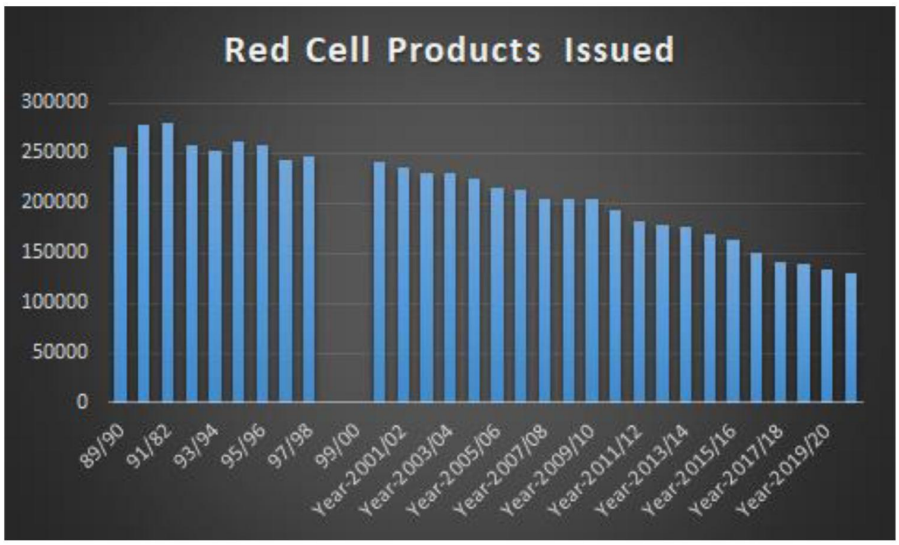


134. Data from October 1999 - July 2021 was derived from the SNBTS Blood Management System eProgesa Database and is therefore from a fully validated source. The annual data for red cells, platelets, fresh frozen plasma and cryoprecipitate is presented graphically below:



135. The full data for this period broken down by month and region is provided in Exhibit 35.

136. The figure below provides the most comprehensive data on Red Cells issued that SNBTS can provide



Q36 - At page 15 of the SNBTS Report provided to the Penrose Inquiry (PRSE0004042), it is stated that no formal report was requested from SNBTS in 1998. Please provide copies of any reports prepared by SNBTS during and at the conclusion of the 1995 look-back exercise

137. A letter from Professor Ian Franklin to Dr Aileen Keel, Scottish Office, dated 28th April 1998 (Exhibit 29), contained a report prepared by Dr J Gillon, dated 9 April 1998, which detailed the results of the Lookback in Scotland up to that date (SCGV0000167_192). These results were provided by the Health Minister to the Health Committee of the Scottish Parliament on 31 January 2006.

Q37 - At the final paragraph of Chapter 35 of the Penrose Inquiry Report (PRSE0005017) - 'An Investigation into the Steps Taken to Identify the Individuals Who Were Infected (Look-Back)' it is recommended "that the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV." This was the only recommendation made by Lord Penrose in the Inquiry report.

Following this recommendation, the Scottish Government established a Short-Life Working Group, comprised of SNBTS and Scottish Government, with the following terms of reference:

- **To assess the extent of the problem– i.e. estimated numbers of living HCV-infected individuals who acquired their infection through blood transfusion in the UK pre-1991 and who remain undiagnosed and the estimated number of living HCV-infected individuals who acquired their infection through the receipt of plasma products pre-1987 and who remain undiagnosed.**

- **To monitor the impact of the media coverage, following the publication of the Penrose Report and its recommendation, on HCV testing uptake and HCV positive yield in the relevant population.**
- **To review past and current interventions to promote the diagnosis of HCV-infected individuals as above.**
- **To consider if any further national/centralised action should be taken to identify such individuals in the context of action already taken and the likelihood of appreciable benefits.**
- **To oversee the implementation of any additional national/centralised intervention if such an intervention is recommended by the Working Group and approved by Scottish Government.**

a. Please explain the contribution of SNBTS to the development of the Terms of Reference of the Short-Life Working Group.

138. SNBTS did not contribute to the development of the Terms of Reference for the Short-Life Working Group.

b. Having regard to the Terms of Reference of the Penrose Inquiry, which includes the following Terms:

"*7. To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland, including NHS Boards and the Scottish National Blood Transfusion Service ("SNBTS"), their officers and employees and associated agencies, once hepatitis C and HIV were identified, to trace individuals who might have become infected with one or both of them as a result of receiving blood or blood products; and to identify any other or further steps that might reasonably have been taken to trace such individuals"*

"9. *To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland including NHS Boards and the SNBTS, their officers, employees and associated agencies to inform individuals who might have received infected blood or blood products of the risks associated with their treatment for themselves and their families; and to offer treatment to any individual at risk, and to identify any other or further steps that might reasonably have been taken to inform and to treat such individuals."*

Please explain why a further review by the Short-Life Working Group was considered necessary, rather than implementing the recommendation of Lord Penrose to take, *"...all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV."*

139. This question would be better addressed to the Scottish Government, but our understanding is that the purpose was not to review the findings of the Penrose Inquiry but to consider what steps could be taken to implement his recommendation using the approach laid out in the Terms of Reference.

Q38 - The "Report of a Scottish Government Commissioned Short Life Working Group" was provided to Scottish Government on 8 July 2016 and published in August 2016 (PRSE0005299). The report made the following recommendations:

> **Delivering a targeted awareness campaign focussed solely on individuals who received a blood transfusion pre-September 1991;**
>
> **The identification and written offer of an HCV test to a group of (up to 71) plasma product factor recipients who are as yet not known to have been HCV tested;**
>
> **A Chief Medical Officer letter should be sent to all clinicians in Scotland to remind them of certain risk factors (including pre-September 1991 blood transfusion and injecting drug use) and clinical (including otherwise unexplained Alanine Aminotransferase liver enzyme level) indicators for HCV infection and making them aware of the recent advances in therapy and thus the benefits of HCV testing.**

a. Please explain how these recommendations were implemented.

140. SNBTS was not involved in the implementation of these recommendations which, to the best of our knowledge, were led by Health Protection Scotland, the Haemophilia Directors and the Chief Medical Officer respectively.

b. How many people infected with HCV by transfusion were identified following implementation of the recommendations?

141. SNBTS does not hold these data but notes the information published by the Scottish Government on 6th May 2021 in response to a Freedom of Information request: Implementation of second recommendation of the Penrose Short Life working group: FOI release - gov.scot (www.gov.scot).

142. '*Based on the information we received from Health Protection Scotland (HPS) in 2018, of 69 patients whose status was investigated as a result of the Short Life Working Group recommendation, 33 patients were traced by CHI linkage analysis, and 36 could not be traced.*

143. *Of those traced, 20 were alive and 13 had died.*

144. *Nine letters were issued to patients' GPs. 8 patients were contacted, one was found to have moved outside of the UK. An additional one of the patients identified as being in England was having testing arranged for them at the time that HPS provided information to the Scottish Government. In addition, seven of those identified as living*

in Scotland had already, in the interim, been identified as being HCV negative and four of those identified as living in England had also already been tested for HCV.

145. *Of the 8 patients tested following letters to their GPs, 1 tested positive for HCV.'*

146. The website also includes a paper on an evaluation of the impact of media coverage of publication of the Penrose Inquiry report and the awareness raising campaign on HCV testing among blood transfusion recipients (McLeod A, Weir A, Hutchinson S, Goldberg D. Impact of media coverage of the Penrose Inquiry and an awareness-raising campaign on Hepatitis C test uptake among historic blood transfusion recipients (WITN3530092). The paper concluded that the total number of HCV tests was significantly higher in the week following the publication of the Final Report of the Penrose Inquiry and the number mentioning previous transfusion was significantly higher for 3 weeks. However, there was no significant increase following the awareness-raising campaign. Overall HCV positivity amongst those tested was 3.7%, but <1% for the previous transfusion group. The authors concluded that the impact of both intense media coverage and the government-funded awareness raising campaign in terms of HCV test uptake was modest and short-lived.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 27th October 2021

Table of Exhibits

Date	Notes/ Description	Exhibit number
1984	Nov 1984 Press Release	WITN3530086
1985	Jan 1985 Press Release	WITN3530087
1983	1983 Minutes of Meeting of Co-ordinating group	WITN3530088
1984	MacAskill et al Research Report – The Scottish Public's attitudes to blood donation and AIDS	WITN3530089
1988	MacNeill et al Research Report - The Scottish Public's attitudes to blood donation and AIDS	WITN3530090
2006	Hutchinson *et al*., Hepatitis C Virus Infection in Scotland: Epidemiological Review and Public Health Challenges. Scottish Medical Journal 2006, 51; 8-15.	WITN3530091
2019	Mcleod *et al*, J Viral Hepat 2019; 26: 93-100	WITN3530092
1987	Perkins HA *et al*, 1987, Blood 70, 1605 - 1610	WITN3530093
1995	Dr Metters Letter Appendix – Interim Report on Hepatitis C Lookback Exercise	SCGV0000166_035
1995	Dr Metters – Hepatitis C – Look Back	WITN3530094
1995	Dr Calman CMO Letter	WITN3530095
1998	SNBTS MSC April 1998 minutes	WITN3530096
2021	SNBTS Blood Donor Infection Surveillance Report Number 22	WITN3530097
2021	The National Microbiology Reference Unit Quarterly Reports are provided for the period January 2021 to March 2021	WITN3530098
2021	The National Microbiology Reference Unit Quarterly Reports are provided for the period April 2021 to June 2021	WITN3530099
2021	IBI R92 Q34 Collections	WITN3530100
2021	IBI Exhibit R92 q 35 Issues	WITN3530101