SNBTS DOCUMENT REQUEST No:

2010/00022

Statement of Dr DBL McClelland on the matters listed in the schedule accompanying the request from the Penrose Inquiry dated 30th August 2010

I was appointed as a consultant in the South East Scotland Blood Transfusion Service (SEBTS) in 1977. My responsibilities were for the blood bank, immunology, microbiology and reagents departments. I was appointed Regional Director of SEBTS in 1979 when Dr John Cash became National Medical Director of SNBTS. I retired from SNBTS at the end of February 2009. For some months before that I had been assisting with the early SNBTS preparations for the Public Inquiry. I was requested by Professor Ian Franklin to continue with this and I accepted a part time contract with SNBTS (from April 1 2009).

As background to my response to some of the questions in the schedule, I have included as an appendix short account of my training and experience before joining SNBTS, my recollections of own knowledge about hepatitis at the time, and my recollections of the attitude to hepatitis in the SEBTS when I joined the service in 1977.

I prepared a first draft of this statement based on my own recollections and with reference to documents with which I was already familiar. I then referred to the Preliminary Report and its references. I have sought the help of the SNBTS public inquiry team in searching for some additional documents. On one occasion I consulted a former colleague who I felt might have more complete recollections than my own.

For some of the questions in the schedule that relate to the activities of the SNBTS rather than those of the individual regional transfusion services, I have been unable to provide information. This reflects the degree of independence of the regional services and their directors during the 1970's and into the 1980's. I feel it is important, by way of background, to offer a personal view of my recollections of the organisational relationships among the regional directors and the SNBTS headquarters in the years following my appointment.

The organisation known since 1974 as SNBTS has its origins in several distinct organisations that were rooted in individual hospitals and had a strong sense of local identity. Despite the

reassignment of management of SNBTS from the SNBTA to the CSA, the Regional Transfusion Centres (RTCs) remained largely autonomous entities. In respect of blood donor selection, the Regional Transfusion Director (RTD) and his/her consultant colleagues determined their own local policies and issued guidance to medical and nursing staff. Documents, for example, information for donors, session records, publicity materials etc, were designed and printed locally. There was a national logo, but even this had regional variants. Discussions between RTD's at national level were just that, and they often agreed to disagree. Moreover, the concept of clinical freedom was sacrosanct, and every donor session was overseen by a doctor who had the final say on all matters of donor selection.

Contemporary minutes of meetings of the Regional Directors indicate that for some years after 1974, there were tensions arising from the centralised management approach sought by the CSA and the regional directors' understanding of the responsibilities and authorities of their positions.

This individualism of the various services persisted well into the period covered by the Inquiry. To give one example, my own 1979 job description as regional director of the SEBTS (2) contains no indication of the managerial or professional accountability of the regional director. It refers to:

> "overall responsibility for ensuring that full range of activities in the service[1] was carried out efficiently".
>
> "In practice the responsibility for the administration of the budgets is delegated to the transfusion directors"

With respect to the national management of the service the addendum to the job description states:

> the director "will be expected to share with the other transfusion directors the responsibilities involved in co-ordinating the national service as a whole"
>
> "the transfusion directors meet regularly to discuss matters of common interest, usually with the national medical director in the chair."

It may also be worth mentioning that during the late 1970's, the headquarters of SNBTS was a

[1] described in an addendum to the job description

tiny organisation. My recollection is that it was staffed by the national medical director, one national administrator, a secretary and a clerical assistant.

From the mid 1980's, a number of changes, notably the appearance of AIDS, the commencement of regulatory inspections of the transfusion centres, the enactment of the European Directive on consumer protection, and the development of the guidelines for the Transfusion Services in the UK led to progressive convergence of practices among the UK transfusion centres.

Responses to the questions in the Schedule

Question 1

The total amount of blood collected annually from penal institutions by each Blood Transfusion Service ("BTS") in Scotland between 1975 and the cessation of the practice around 1984.

The data for SEBTS are shown in Table 1

Table 1. Donations collected by SEBTS at penal institutions 1975 to 1991

Year	Donations collected at penal institutions Region				
	West	SE	E	NE	N
1975	3532	807	952	624	Not available
1976	501	792	780	560	
1977	1462	264	886	98	
1978	1929	151	840	516	
1979	2516	689	716	450	
1980	1920	283	770	91	
1981	2274	203	609	274	
1982	1526	0	543	287	
1983	2622	0	322	176	
1984	342	0	0	0	

Question 2

(In order to place the preceding information in context), the total amount of blood collected annually by each BTS region in Scotland between 1974 and 1991

The data for the SEBTS are shown in Table 2

Data for the other services will be submitted as soon as it is available

Table 2. Total Donations collected by SEBTS 1975 to 1991 and percent contributed by donations in penal institution.

Year	Total Donations collected				
	W	SE Total (% from penal institution)	E	G	N
1975		62239 (1.30)			
1976		69878 (1.13)			
1977		75302 (0.35)			
1978		77318 (0.20)			
1979		75639 (0.91)			
1980		74537 (0.38)			
1981		73985 (0.27)			
1982		74034			
1983		72977			
1984		81232			

Question 3

When the practice of collecting blood from penal institutions stopped in each region in Scotland

Each of the SNBTS centres provided the date of the last blood donor sessions held in a penal institution. The dates are shown in Table 3

Table 3 Date of the last blood donor sessions held in a penal institution.

Region	Date of last donor session held in a penal institution
SE	18 12 1981
N	24 02 1983
NE	28 07 1983
E	02 08 1983
W	25 03 1984

Question 4

Why the practice stopped

Glasgow, Dundee, Aberdeen and Inverness

I do not remember discussions of the reasons that lead these centres to stop donor sessions in prisons and I have been unable to find documentation that adds to that referenced in the Preliminary report. I know that The Medicines Inspector's report on the Edinburgh centre that contains the reference to prison sessions SGF.001.0351 and the response to it SGH.003.5059 were available to the regional directors so they would have received the information that SEBTS had ceased prison donor sessions.

Edinburgh

I do not have a detailed recollection of discussions that lead up to the ending of donor sessions in penal institutions. My recollection is that it was due to a concern that the prison simply was not the right place for a blood donor session because the whole situation was unsuitable. We could not assume that donors were genuine volunteers or that they would not have reasons to

be less than frank in response to the routine health checks then in use. I can not recall if I was specifically concerned about hepatitis risks in donations given by prison donors, but in view of my study, training and experience before joining SNBTS, I think it is likely that I would have been aware of this as a risk. I may have read the 1972 paper by Wallace et al in the British Medical Journal[2] although I do not remember doing so. In 1979, shortly after I became regional director, I appointed a new regional donor organiser for SEBTS (Mairi McLeod). Her previous employment had been in a totally different field. I think that it was some months after her appointment that she raised concerns about prison donor sessions.

I met with Mairi (now Thornton) on 4th September 2010 while preparing this statement and simply asked her what she could recall about the prison donor sessions. Her recollection is that during 1979 and 1980 we had increasing concerns about the appropriateness of collecting blood in the prison.

I think it is unlikely that the question of risks related to homosexual behaviour was raised, since up to about 1983, it was not practice in any blood collection service, as far as I am aware, to take actions to exclude donors on the basis of sexual behaviour. (This changed rapidly, although not without considerable resistance in some quarters, with the arrival of AIDS.)

I specifically asked Mairi Thornton (MT) if she could recall any formal statement of a policy to discontinue the donor sessions at Saughton prison. She recalls that we simply booked no further sessions at Saughton after December 1981, and that although there were requests from the contact person in the prison to inform them of our next session date, we made no further arrangements to attend. Neither MT or I remember if we made a formal notification to the prison authorities of the termination of donor sessions.

[2] Total Screening of Blood Donations for Australia (Hepatitis Associated) Antigen and its Antibody
J. WALLACE, G. R. MILNE, A. BARR British Medical Journal, 1972, 1, 663-664

Question 5

The consideration given between 1975 and 1984 by those in the Scottish National Blood Transfusion Service ("SNBTS") to whether blood collected from prisons carried a higher risk of hepatitis including, in particular, non-A non-B hepatitis ("NANB hepatitis"), and whether the practice of collecting blood from penal institutions should continue.

I was not involved in SNBTS discussions before I was appointed in 1977, and I would not have attended meetings of the SNBTS Directors until 1979. I do not recall that the matter of donation by prisoners was discussed during meetings of the SNBTS Directors before the May 1983 meeting and I have not been able to locate any records of such discussions additional to those referenced in the Preliminary Report.

Both the Edinburgh and Glasgow centres had started research on hepatitis by 1970. The Glasgow studies demonstrated a higher prevalence of hepatitis B surface antigen in prison donors (Wallace Milne and Barr 1972, Wallace 1978, page 279, Barr et al 1981) and later reported an excess of raised ALT levels in prison donors. Both centres attempted to develop tests that might help to identify markers for non A non B hepatitis that could be used in donor screening. PhD projects on the detection of non A non B hepatitis were completed by Brian Dow, WSBTS (University of Glasgow: awarded 1986) and Sonia Field, SEBTS (University of Edinburgh: awarded 1984)

Prison donations were discussed in Dr John Wallace's[3] book, "Blood Transfusion for Clinicians" published in 1977. A copy of this was given to me by Dr John Cash on my appointment to SEBTS in 1977 and I read it at the time. A passage on page 279 provides an insight into the way the issue of prison donations was seen by one experienced regional transfusion director. Dr Wallace described the issue as "controversial". He also stated that

> "It has been established that within any potential donor population certain groups have a higher than average incidence of HBs antigenaemia.[4] In particular, HBs antigenaemia is more prevalent in male prisoners and in volunteers from tropical areas. Some transfusion

[3] Regional director of the West of Scotland transfusion service
[4] Presence of hepatitis B surface antigen in the blood

services have declined to accept volunteers in prisons and among immigrant populations. This ultracautious approach may be doubly undesirable ... visits to prisons can often be arranged when the general intake of blood is low because of the holiday season. The incidence of HBs antigenemia among male prisoners in Scotland is less than 1% using the most sensitive technique of testing, thus generous offers of useable donations would be lost by placing a total embargo on prison donations."

Reading this passage again after many years, I can only interpret it as implying (a) a high level of confidence that testing donations with a very sensitive test for HBsAg (Ausria II, Abbot Laboratories).and removing all donations with positive test results would virtually exclude the risk of transfusion transmitted hepatitis B and (b) a belief that provided hepatitis B transmission was avoided, the blood would be safe. This seems somewhat at odds with the statements on page 273 and 274 of Dr Wallace's book that refer to "other infective agents that might transmit hepatitis such as the predicted virus C", and to the fact that hepatitis B screening may only detect 25% of cases of post transfusion hepatitis. I think this apparent inconsistency must be a reflection of the prevailing sense at the time that hepatitis, if not due to hepatitis B virus, was not a serious condition.

Dr Wallace also makes the case that it is socially and psychologically undesirable to exclude prisoners from the donor population on the basis that acceptance of prisoners as donors helps them to rehabilitate.

Question 6

Whether the cessation of the practice of collecting blood from penal institutions led to any difficulties in maintaining a sufficient supply of blood in Scotland

I can comment only on the situation in SE RTC. I have no recollection that stopping prison blood collections caused supply problems in that region. I think it is unlikely that it caused shortages since the only prison session (Saughton prison) provided 0.3% to 1.3% of all SE donations of the total collections in the region (Table 2). I do recall discussions at meetings of the regional directors during which concern was expressed about the effects of losing the

prison donations in the West of Scotland. I do not know if in Glasgow, Aberdeen, Dundee or Inverness shortages were attributed to stopping prison donor sessions.

Question 7

Whether the witness was aware of the evidence produced by the NBTS for England and Wales around July 1974 that the incidence of hepatitis B in donors from prisons was approximately five times greater than the incidence in donations from the general public (SGH.001.7095). If so, what, if anything, did the witness do in response to that information?

I have no recollection of being aware of this report before receiving the document SGH.001.7095 from the Inquiry. I do not recall being present at any meeting of SNBTS Directors at which it was discussed.

Question 8

Whether the witness was aware of the letter dated 6 January 1975 by J Garrott Allen (Stanford) to Dr William Maycock (Blood Products Laboratory) warning of the increased risk of hepatitis, including NANB Hepatitis, from the blood of prisoners (SGH.004.6061). If so, what, if anything did the witness do in response to the concerns raised in that letter?

I have no recollection of being aware of this letter before receiving the document SGH.001.7095 from the Inquiry. I had seen Dr Garrot Allan's book published in 1972[5] as this was in the book collection of SEBTS at or soon after the time I was appointed. This contains extensive data from Dr Allan's many years of investigations on post transfusion hepatitis in paid and non paid donors.

Question 9

Whether the witness was aware of the letter dated 1 May 1975 by H Yellowlees, Chief Medical Officer, England and Wales, to all Regional Medical Officers on the subject of blood donation and hepatitis (SGH.003.0187) and whether the witness agreed with the advice contained in that letter i.e. that it was not necessary to discontinue the collection of blood from prisons provided that all donations were tested for hepatitis B using a sensitive test. What was the sensitivity of the tests used to screen for hepatitis B at that time?

[5] Allen JG The epidemiology of posttransfusion hepatitis. Stanford, California, LC 72-78524 1972

(a) I do not recollect having seen this document until I read reference SGH.003.0187 of the Preliminary report.
(b) I cannot say how I would have viewed the advice in the letter, had I seen it in 1975 or shortly after. The SEBTS stopped blood donor sessions in Saughton prison (the only penal institution in our donor session programme) at the end of 1981.
(c) The sensitivity of the two types of test for hepatitis B in use in SNBTS in 1975 is given in Table 4.

Table 4 Sensitivity of various tests for detection of HBsAg that were in use in 1975

Type of test	**Detection limit of HBsAg in blood**
Reverse Passive Haemagglutination	100 ng/ml
Radioimmunoassay –	1-2 ng/ml

Question 10

Why the SNBTS continued to collect blood from penal institutions following the Medicines Inspectorate's adverse comments on that practice in March/May 1982 (SGF.001.0086, SGF.001.0351 and SNB.008.7582).

I think that the main argument in favour of continuation would have been that collection of blood in prisons made an important contribution to blood supply at times such as holiday periods when collection from the general public was more difficult. Dr John Wallace in his 1977 textbook, made a strong case for donation by prisoners (see reply to question 5 above) and I suppose that this view may have persisted within the SNBTS into the early 1980's

Question 11

At their meeting on 29 March 1983 (SGH.001.0002), why the SNBTS Directors were unable to agree on future policy in respect of collecting blood from penal institutions.

I do have a recollection of this matter being discussed at a Directors' meeting, but I do not recall any specific points that may have been made in favour of or against continuing blood donor sessions in prisons. I think it is likely that opinions differed about the impact on the blood supply for the different regions of ceasing prison blood collections.

Question 12

At the meeting at the National Institute for Biological Standards and Control on 9 February 1984 to discuss the infectious hazards of blood donors (SNF.001.3109) Dr McClelland advised that certain policies had been adopted in Scotland to minimise the risk of transmission of infection. The main strategies were stated to include the avoidance of high risk communities, such as prisons. When was the strategy referred to at the meeting of avoiding high risk communities such as prisons adopted and implemented and why? Was it adopted and implemented in each of the Scottish regions at the same time and, if not, why not?

I have found no notes of my contribution to that meeting, so I do not know how accurately the minute reflects what I said. I think that my remarks would have related to donor selection in relation to both AIDS and hepatitis. By early 1984, AIDS was already a major preoccupation for the blood transfusion services. It was in relation to AIDS that the term "high risk group" began to be used widely.

In relation to blood collections in prisons, the last SNBTS blood collection in a prison took place shortly after that meeting, on 25th March 1984. Donor selection procedures had already been changed with the intention of excluding groups likely to be at higher risk of HIV. Since Hepatitis B and HIV are transmitted by similar routes, the HIV donor exclusions would be expected to have reduced risk of other blood transmitted infections.

The cessation of blood donor sessions in prisons did not occur at the same time in all the Scottish transfusion services (Table 3)

Question 13

The report in July 1984 by Drs Follett and Dow on their three year research project, "Non-A, non-B hepatitis in the West of Scotland" (SGF.001.2060) noted (a) that screening of blood from prisoners detected 10 times more donations with grossly elevated ALT levels compared to other donors and (b) that the vast majority of drug abusers with elevated ALT levels admitted being heroin addicts and a considerable

proportion were prisoners. The Report noted that these findings had discouraged the SNBTS from visiting prisons to obtain blood for transfusion purposes. To whom, and when, were these findings communicated? (i.e. that (a) screening of blood from prisoners detected 10 times more donations with grossly elevated ALT levels compared to other donors and (b) that the vast majority of drug abusers with elevated ALT levels admitted being heroin addicts and a considerable proportion were prisoners). What action was taken, by whom and when, in reliance on these findings?

This is a report to the grant giving body (Scottish Hospitals Endowment Research Trust). I had no involvement in the research project. I know that some of the data were included in a contribution by Dr Ruthven Mitchell to an exchange of opinions published in the journal Vox Sanguinis in 1983 to which I also contributed.[6] I do not have any other recollection of when, how or to whom the findings were communicated. It would be quite usual for Dr Dow – as a PhD student - to have given presentations of the findings of his research as the work progressed. By the date of the report to SHERT in July 1984, all SNBTS blood collections in prisons had stopped, the last recorded session being held on 25 03 1984. I cannot say to what extent the cessation of these sessions was influenced by communication of interim findings of Dr Dow's research. There was considerable activity in SNBTS over this period in relation to the matter of testing donors for elevated ALT levels. This is covered in a witness statement that has been requested from me by the Inquiry.

Question14

The extent to which, if at all, between 1975 and 1984, the SNBTS discussed with officials from the SHHD the practice of collecting blood from penal institutions, the increased risks of hepatitis, including NANB hepatitis, from prison donations and whether the practice of collecting blood from such institutions should continue.

The SHHD was represented by one of its senior doctors (Dr AE Bell, Dr John Forrester and in more recent years by Dr Aileen Keel) at the meetings of the SNBTS directors. Through this representative SHHD would have had access to all of the discussions and all the papers for these meetings. I am sure that there were frequent communications between the National Medical Director and the SHHD. I do not know if other SNBTS personnel discussed these

[6] Mitchell R. in: International Forum Vox Sang 1983:44 ;57-59

matters with SHHD. I do not have any recollection of being personally involved in discussions with the SHHD on the subject of prison donor sessions between 1977 (when I joined SNBTS) and 1983.

Question 15.

On 12 January 1983 Edinburgh and SE Scotland BTS produced a response to the Medicines Inspectors' Report (SGH.003.5059). The response stated, as regards prisons and borstals, "We do not visit these regularly. No such sessions have been held for two years. These donors will only be used in an emergency". When and why did Edinburgh and SE Scotland BTS stop collecting blood from prisons? Did Edinburgh and SE Scotland BTS collect any blood from prisons after 12 January 1983 and, if so, why?

The last SEBTS prison session was held in Saughton prison, Edinburgh on 18 12 1981. SEBTS did not collect blood from prisons at any date after 18 12 1981. I do not think that I can add to what I have already said in my response to question 4 about the reasons for stopping prison donor sessions.

Question 16

Whether the SNBTS accepted the recommendation in the 2nd report of Dr Maycock's Advisory Group on the Testing for the Presence of Hepatitis B Surface Antigen (1975) (SGH.003.0079) that blood from donors with a history of jaundice or hepatitis could be accepted if the donor tested negative for hepatitis B surface antigen. If so, why that recommendation was accepted given that such donors may have suffered from jaundice or hepatitis as a result of NANB hepatitis, which possibility could not be excluded by testing.

I do not remember being a part of discussions about this report. I think it is probable that SNBTS accepted the recommendation of a Government - appointed expert group on which SNBTS was represented (by Dr John Wallace). I joined SNBTS two years after the publication of this report. I would have been aware of its existence some time after that, as it is referred to in Dr John Wallace's 1977 book, and also in his chapter in Clinics in Haematology, February 1976, which was edited by Dr Cash. I am not aware that I have seen any SNBTS documents that refer to discussions of this report. The "National Blood Transfusion Service Memorandum on the selection, medical examination and care of blood donors" 1977 (3) appears to embody the Maycock recommendation as it states that

> "Individuals who give a history of jaundice or hepatitis or in whose blood anti HBsAg is present may be accepted as donors providing that they have not suffered from jaundice or hepatitis in the previous twelve months....."

This period was early in the evolution of knowledge about Non A Non B hepatitis.

> "The first solid indication that an additional form of hepatitis existed came from the analysis of PTH (post transfusion hepatitis) after it had become possible to show that a large percentage of PTH was neither hepatitis A nor hepatitis B (Prince et al 1974, Alter et al 1975, Feinstone et al 1975" [7]

The importance of the condition had not at this time been fully appreciated by many concerned with these decisions. Because no causative agent could be identified there was no specific test for NANB and knowledge of the natural history and the epidemiology was lacking. It was not possible to know that individuals could become infected without having evidence of jaundice or indeed any clinical features. Nor could it be known that once an individual was infected their blood could continue to contain the infectious agent for many years in the absence of any symptoms or that some forms of chronic liver disease would eventually be discovered to be caused by chronic infection.

Question 17

The consideration given by the SNBTS between 1975 and 1991 to the exclusion of donors at a higher risk of transmitting NANB hepatitis, including the exclusion of donors with a history of jaundice or hepatitis

These years could be divided into the period 1975 to 1983, which predate the beginning of activity in the UK directed to the emerging problem of AIDS and the period 1984 to 1991
During the 1970's, two of the SNBTS centres were sufficiently concerned about non A non B hepatitis SNBTS to obtain grant support to employ PhD students to undertake research projects in the hope of identifying a specific marker that could be used to identify and exclude

[7] Quoted from Gerety RJ ed, 1981, Non A Non B hepatitis, ISBN 0-12-28060-8, page 13-14

potentially infectious donations.. In common with many other groups around the world that were pursuing the same goal, the SNBTS researchers failed to find a usable test.

Over the period 1981-1983, SNBTS personnel participated in the hepatitis working group of the MRC blood transfusion research committee and the regional directors' working party on transfusion associated hepatitis. Through these groups, SNBTS pursued proposals for a prospective controlled study to reassess the incidence of ALT elevations in transfusion recipients and evaluate the impact of donor ALT testing on the incidence of post transfusion NANB hepatitis. Although supported by the working group on transfusion associated hepatitis, and apparently submitted for funding, this study was not funded and did not take place.

SNBTS also undertook and published a study of ALT levels in blood donors and the clinical features associated with normal and elevated ALT levels, sought funding - on several successive years – for the introduction of donor ALT testing and carried out a substantial evaluation of the available systems for donor ALT testing. The activity related to surrogate tests for non A non B hepatitis is in my statement on that topic.

Question 18

The procedures in place within the SNBTS between 1975 and 1991 for the exclusion of donors at a higher risk of transmitting NANB hepatitis, including the exclusion of donors with a history of jaundice or hepatitis

These years could be divided into the period 1975 to 1983, which predate the beginning of activity in the UK directed to the emerging problem of AIDS and the period 1984 to 1991 during which there were a number of major developments including the introduction of new blood safety measures to minimise risks associated with AIDS and the emergence of a specific test for the virus responsible for most cases of Non A Non B hepatitis.

During the first period I believe that the measures taken by SNBTS were essentially those described in the the National Blood Transfusion Service Memorandum on the selection, medical examination and care of blood donors (2) although to date I have not located donor selection guidance documents used by SNBTS earlier than 1982

"individuals who give a history of jaundice or hepatitis or in whose blood anti HBsAg is present may be accepted as donors providing that they have not suffered from jaundice or hepatitis in the previous twelve months..."

My recollection is that some of the SNBTS services modified this policy, restricting acceptance to donors with a jaundice history under the age of 12 years, and that the rationale for this was that in that age group, where there was any evidence of infection with a hepatitis virus it was almost always found to be antibody to hepatitis A virus. I am still seeking some documentary evidence of this policy.

From 1983 onwards, donor selection measures aimed at reducing the risk of AIDS were introduced. In 1985 testing for HIV antibody was implemented. These measures would also have reduced the risk of NANB PTH. This was later shown by the fact that the prevalence of HCV in Scottish donors when HCV testing was introduced was about 10 fold less than in the general population. [8]

Question 19

Whether there were national policies in that regard and/or whether each SNBTS region had its own practices and policies.

I am not aware that there was a national policy. My understanding is that all the SNBTS regions had based their procedures on the "National Blood Transfusion Service Memorandum on the selection, medical examination and care of blood donors" but I do not have documentary evidence of this. I have not reviewed each region's documentation on donor selection.

Question 20

Whether, if all donors with a history of jaundice or hepatitis had been excluded from giving blood, (a) that is likely to have caused any difficulties in maintaining a sufficient supply of blood and (b) the extent to which post-transfusion hepatitis C in Scotland is likely to have been reduced

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[8] Prevalence and epidemiological characteristics of hepatitis C in Scottish blood donors.
Crawford RJ, Gillon J, Yap PL, Brookes E, McOmish F, Simmonds P, Dow BC, Follett EA.
Transfus Med. 1994 Jun;4 (2):121-4 PMID: 7921048

History of jaundice as a donor screening test.

It can be difficult or impossible to learn from a brief blood donor assessment whether an individual has had jaundice or hepatitis in the past, especially in the case of individuals who have never received the results of a specific test for one of the hepatitis viruses. Not everyone understands the terms or has an accurate memory of what may have been a mild illness. Many individuals have a recollection of being told that they were jaundiced as a baby, and this may often be due to a cause other than infection with a hepatitis virus. Published data on the frequency of a history of jaundice among donors may be greatly influenced by the judgement of different donor selection staff and so may be of uncertain reliability.

Impact on blood supply

This would depend on the proportion of donors judged to have positive history. I am aware of the following data from the UK. Crawford et al 1979 reported that 2.8% of West of Scotland donors gave a history of jaundice; Follett et al (1980) [9] found a similar figure (2.6%) in the same population. Tedder et al 1980 [10] imply that 3.8% of North London donors had a jaundice history, although detail in their publication is insufficient to interpret with confidence. In contrast, Hopkins et al 1980[11] reported that 8.5% of donors in South East Scotland gave a jaundice history.

Assuming that the lower figure of around 3% is correct, exclusion of donors with a jaundice history would probably not have had a major impact on supply, but this is essentially speculation.

Impact on post transfusion non A non B hepatitis

Maycock et al 1975 stated that they had found no evidence that recipients of blood from donors with a history of jaundice had an increased risk of post transfusion hepatitis. I am not aware of any studies reported since 1975 that have investigated this.

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[9] Follet EAC et al Vial hepatitis markers in blood donors with a history of jaundice. Lancet February 2, 1980; 246

[10] Tedder RS et al Viral hepatitis markers in blood donors with a history of jaundice. Lancet March 15, 1980;595

[11] Hopkins R et al Blood donors with a history of jaundice Lancet match 15, 1980;596

Some evidence is available about a surrogate marker (ALT) in donors with and without a jaundice history. Brian Dow's research found that donors with a history of jaundice had very similar ALT levels to those without this history. (Table 5) He also found that most donors with a jaundice history reported that the illness had been in childhood, and where any virus marker was found it was usually evidence of past hepatitis A infection.

Table 5 Range of SGPT (ALT) levels in different blood donor categories according to different cut-off levels (Modified Table 4.3 from Brian Dow PhD thesis

Donor Category	Number tested	Normal levels <35	>35	>92	>125
Prison	5057	4835 (95.6%)	222 (4.4%)	49 (0.96%)	36 (0.7%)
Others	4980	4855(97.5%)	125 (2.5%)	4 (0.08%)	3 (0.06%)
Jaundice History	484	471 (97.3%)	13 (2.7%)	0	1 (0.20%)
TOTAL	10521	10161 (98.6%)	360 (3.4%)	54 (0.51%)	40(0.38%)

With respect to antibody to hepatitis C virus, Crawford et al 1994, found that only 5.9% of the donors who had been found to be HCV positive gave a history of jaundice, suggesting that the result of this questioning would not be an effective screening test. This is consistent with observations that the natural history of hepatitis C infection does not typically include early episodes of jaundice. The infection can be asymptomatic for a long period after exposure, so it cannot be assumed that donors carrying the virus would recall any episode of jaundice or hepatitis.

From the above information, I am unable to estimate the size of any possible impact of an exclusion of donors with a history of jaundice on the incidence of post transfusion hepatitis, but I think it is unlikely is that any effect would have been large.

DBL McClelland
13 October 2010

References

1 Job description for regional director post, SEBTS, 1979

2 Memorandum on the selection, medical examination and care of blood donors 1977

Appendix 1

Background

The following is a short account of how I came to work in the BTS, my own knowledge at the time, and my recollections of the attitude to hepatitis in the SEBTS when I joined the service in 1977. I have provided this in case it is of any value in conjunction with my replies to the specific questions.

Before joining SNBTS I worked in internal medicine, and trained in gastroenterology and hepatology. I had personal experience of hepatitis while a junior doctor in Edinburgh Royal Infirmary when I was hospitalised with a severe episode in 1969. This was around the start of the Edinburgh epidemic of hepatitis associated with renal dialysis. The mortality among renal patients who developed hepatitis was 24% and among hospital staff it was 31 % [12]

During an MRC clinical training fellowship, I was involved in clinical research on immunity and infection in the gastrointestinal tract, and through this I encountered a number of patients who suffered from hypogammaglobulinaemia which is a form of primary immune deficiency in which there is a profound lack of the body's normal antibody defences. At that time (early 1970's) the only treatment that could offer protection against recurrent infections was the administration of human immunoglobulin. The only form of immunoglobulin product then available could not be safely given by the intravenous route but had to be given by intramuscular injection. This was a very painful procedure, especially distressing for young

[12] Mathiesen et al Dialysis – associated hepatitis in Edinburgh 1969-1978 Revs Inf Dis 1982 4 : 619-637 PMID 6812192

children, and its effectiveness was limited by the small doses of immunoglobulin that could be administered. This lead me to realise that there was need for a preparation of human antibody that could be administered safely by intravenous injections and it was in pursuit of this goal that I began to work with SNBTS.

During my training in gastroenterology before I joined SNBTS I had studied liver diseases and had read many papers about infections of the liver. I clearly recall that one preoccupation during the early 1970's was the problem of determining the cause of disturbed liver function tests after surgery in the absence of any useful diagnostic tools. To give one example, we did not know how to distinguish "halothane hepatitis" which was thought to be a reaction to a widely used anaesthetic from hepatitis that might be due to an unidentifiable transmissible agent. While preparing this statement I have realised that - for what it is worth - I do not have any recollection that blood transfusion figured prominently in these discussions.

I was familiar with the studies of Krugman and Giles[13] and others that delineated the characteristics of two forms of transmissible hepatitis. I was well aware of the risks of hepatitis among residents of institutions. My own experience both as a patient and as a clinician involved in the care of patients had made me very aware of the risk of contracting viral hepatitis in hospital work, and the seriousness of the illness.. I also knew that among the hospital staff who had died during the Edinburgh outbreak there was a member of the SEBTS laboratory staff and at least one medical colleague of Dr John Cash.

I clearly recall that when I began to work in the BTS, it was quite evident that the staff of the Edinburgh were acutely aware of the risks of hepatitis being transmitted by blood, following the deaths of colleagues during the Edinburgh hepatitis outbreak. I also learned that both Dr Robert Cumming (regional director preceding Dr Cash) and later Dr Cash had been quick to respond to the emerging knowledge of hepatitis B. Dr Cash brought the materials for the early test for Australia Antigen from Dr Alfred Prince's laboratory in New York in 1969, and Dr PC Das was given responsibility for establishing the testing laboratory in 1970. Following the

[13] Infectious hepatitis. Evidence for two distinctive clinical, epidemiological, and immunological types of infection.
Krugman S, Giles JP, Hammond J.
JAMA. 1967 May 1;200(5):365-73. No abstract available. PMID: 4164595

Rosenheim report in 1972, Dr Cash and Dr Duncan Pepper in SEBTS established a system that allowed red cells to be held in quarantine for about 6 months until the donor had re attended and been re tested for hepatitis B. This was an important contribution to the safety of patients with chronic renal failure dependent who were dependent on regular red cell transfusions. I believe that this programme was unique in the UK.

Staff of the hepatitis laboratory included a young scientist (Dr Robert Hopkins) who had been employed by Dr Cash to develop hepatitis testing. He and Dr PC Das developed a novel haemaglutination test for HBsAg that was used in SEBTS as more sensitive replacement for the very first generation of HBsAg tests which used very insensitive immunoprecipitation techniques. His Edinburgh University PhD awarded in 1977 "Hepatitis B Antigen and Blood Transfusion" describes this work. Dr Hopkins then embarked on research aimed at finding a specific marker of Non A Non B hepatitis in the blood.[14] (Edinburgh University PhD Sonia Field) [15] I think that it was through Dr Hopkins that I was first made aware of the aware of the work by Barr et al in the West of Scotland BTS showing the high rate of hepatitis B in prison donors in the West of Scotland. [16]

[14] Hopkins R et al Particulate structure derived from the serum of hepatitis non-A non-B implicated donor. Med Lab Sci 1983;40:77-79 PMID 6408336

[15] Field S et al Retrospective investigations of transfusion related non A non B viral hepatitis associated with M2 antigen. Eur J Clin Microbiol 1985; 4: 412-414 PMID2412814

[16] Total Screening of Blood Donations for Australia (Hepatitis Associated) Antigen and its Antibody J. WALLACE, G. R. MILNE, A. BARR British Medical Journal, 1972, 1, 663-664

Statement of Truth

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

Signed.....

Dated.....28.07.2021.....