THE PENROSE INQUIRY

Witness Statement of Dr Ewa Brookes

Issue in respect of which a statement is sought

Hepatitis C

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

a) prisoners; and

b) donors who had a history of jaundice, and who were negative for Hepatitis B when the existence of Non-A Non-B Hepatitis was known and its presence could not be excluded

I, Dr Ewa Brookes say as follows:-

General Comments

On receiving the Penrose Inquiry schedule I was concerned to find that it immediately referred to "higher-risk" donors.

It has always been my belief that blood transfusion, a serious treatment for serious conditions, can never be completely free of risk but it is the intention of BTS at all times to optimise the safety of patient, donation and donor.

The BTS has never, and still does not intentionally take donations for therapeutic use from "higher-risk" donors. With advances in testing methods or the emergence of new hazards, some donations, previously acceptable, come to be considered unsafe, and the donors deferred. BTS does not decide alone but seeks updating advice from experts in relevant fields.

With respect to NANB hepatitis, the viruses causing Hepatitis A and Hepatitis B. were identified and testing methods devised. It then became evident that there remained other viral causes of hepatitis, to which the portmanteau phrase NANB was applied. Once the Hepatitis C virus was identified and tests for the markers of the virus were devised and applied, it became evident that this explained another major part of the causes of chronic viral hepatitis.

Preliminary Comments on Acceptance of Blood from Prisoners and Prison Sessions

The narrative that follows, with respect to my time in London, must start with the caveat that it is based entirely on recall and my memories of about 35 years ago. I have no personal documentation to confirm the date of the events, or discussions held at staff meetings. Indeed, reading some of the papers extracted from the archives for this Inquiry shows me how problematic my recall of dates, in particular, can be.

However, I did go to 3 sessions held in a large London prison to see for myself, and the experience left an impression.

In the 1970s when I was working as a Consultant in the South London Regional Transfusion Service, donor sessions were held in prisons.

Screening tests for HBs Ag were in use (with confirmation by the Public Health Laboratory Service) and close interest, in collaboration with PHLS, was taken in the results. Figures in my Centre were emerging which suggested a higher incidence in donations from prisons than from general public or industrial sessions.

In addition from the early 1970's the central PHLS laboratory at Colindale was receiving monthly reports of HBs Ag incidence from each English transfusion centre.

It was long-standing Government policy that the BTS should visit prisons to:-

- permit prisoners to make some restitution to society.
- do something which many of the community did, to help their return to normal life after release.

There was some reassurance to BTS that the Prison Medical Officer would pre-select prison volunteers, excluding those with an unsuitable history, or anaemia.

I decided to look further into this. (I had worked as a session medical officer during my training, and sometimes after my appointment as consultant when there was difficulty in providing session medical cover, so I was familiar with donor session routine).

I scheduled myself as session medical officer on three successive sessions in a London prison (I think in late 1978/79, no detail of exact dates) and in summary:-

- While volunteers might mention a past history of jaundice, or a self-limiting illness long ago, any admission of recent injury, or an illness which might be a sign of weakness, e.g. heart disease or diabetes, was never made.
- If admission was made, (one man told me of a myocardial infarct three weeks before) it was whispered, for fear of making him appear, to the other prisoners, vulnerable.
- Apart from the obvious attraction of a group of professionally courteous women as donor assistants, prisoners had a change of activity and an easier day after donating, so were keen to do so.

Following these sessions, I made an appointment to meet the Prison Medical Officer, a senior and very busy man, indicating the reasons for the BTS prison sessions and the expectation that volunteers were pre-screened. I was forcefully advised that he had duties in more than one prison and many much greater problems than those of donor selection.

I took this information back to my Director and the Senior Staff Meeting in my Transfusion Centre. It reinforced previously held concerns and the decision was made to phase out prison and young offenders sessions. The desirability of stopping donor sessions in prisons and other corrective establishments was taken to an NBTS Directors meeting where it was felt that, in view of the Government recommendation outlined above, this decision should not be made nationally without further consultation.

When I took up my appointment in Dundee (25/5/1981) there was much to be done with regard to all aspects of the Centre's work.

Two linked major matters were:-

- preparation for the first visit of the Medicines Inspectors (M.I.).
- progressive increase in the provision of fresh frozen plasma frozen within 8 hours of collection (FA FFP) to PFC, towards the UK and SNBTS goal of self-sufficiency in FVIII.

On 25.3 .82 M.I. inspected Dundee Regional Centre.
The main criticism was of the premises, but the matter of prison sessions arose.

I confirmed my understanding that, in line with government policy, donor sessions were held in prisons and young offenders institutions in all regions in Scotland, including Tayside.

I regarded M.I. as a helpful critic and expressed my concerns. (These were later reflected in their general report of 4/6/1982, Item 7a and Prelim. Report ref 57, p118, 5.61).

The Medicines Inspectors had commented adversely on the practice of collecting blood from prisons and young offenders institutions. Professor Cash brought back a report from a NBTS Directors meeting of concern at the higher HBs Ag detection rates from prison sessions; consequently some had stopped, others were considering stopping, prison sessions.

The matter was placed on the Agenda for the SNBTS Directors meeting of 29/3/1983.

In discussion, I expressed my strong view that I thought the prison and young offenders sessions should be stopped, on the basis of my experience in London.
Although opinion was divided, it became evident that those Directors who wished to discontinue prison sessions, could do so.

I think it is important to say that people are discharged continuously from penal institutions and return to the community, so "higher-risk" volunteers are not confined to prisons.

The striking feature I observed in the prison setting was that the prisoners were wary and fearful of each other (more, it seemed, than of the warders) and dared not appear vulnerable.

If they subsequently attend public sessions, they need not fear to give straightforward answers concerning their health etc. in order to be advised appropriately. The worry is that some may be less than altruistic and, for instance, use the donor session as a "health check", not admitting anything to cause deferral. But volunteers who have never been in prison may also fail to mention history thought significant by BTS, perhaps because they do not wish to, have forgotten or do not think it important.

In Dundee, immediately following the Divisional meeting of 29/03/83 I asked the Organising Secretary to phase out prison and young offenders sessions over the coming year.

The Centre's programme of donor sessions was generally confirmed for one year ahead, and outlined for the coming year. There is a limited number of venues suitable, large enough for the purpose and available at the time required (ref. "Standards for the Collection and Processing of Blood and Blood Components, etc. - a DHSS publication that was regularly revised).

The Organising Secretary had already been set objectives different from the past. The drive for self-sufficiency in factor VIII meant a tremendous change of direction in the planning of sessions, and major changes to ways of working in the Centre.

Previously, the most efficient and cost effective way of collecting blood was to maximise the provision of whole blood and this meant the largest possible attendance at each venue.

To maximise plasma suitable for factor VIII meant getting as much as possible separated and frozen within eight hours of donation.

This required the organisation of smaller sessions, more of them, more day sessions to make best use of the laboratory day and limit overtime and the cost of it, and more nearby sessions, so that in the course of the session, batches of blood could be relayed back to the laboratory for processing.

Into this change of programme I added the request that all prison and young offenders sessions should also be phased out. Although a small proportion of sessions, they were, of course, daytime sessions.

So the Organising Secretary felt heavily burdened, but worked hard, in collaboration with the senior chief MLSO (post later renamed Laboratory Manager) and laboratory staff to plan and implement a coordinated program, maximise return of blood for FA FFP; to produce platelets as well as the required plasma- reduced blood and to keep all as cost effective as possible. Information provided to me by SNBTS confirms that the last prison session in Dundee was held on 2/8/1983.

Matters to be included in the statement

(1) **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 cannot specifically comment on what discussions took place in SNBTS in the 1970's because I took up my post in Dundee in May 1981 and at that time such donors were accepted.

However I know that the recommendations of Dr Maycock's group were accepted by the SNBTS (and UK) and were applied nationally, including within my previous post in London. These recommendations were based on the best advice available at the time from experts consulted by Dr Maycock's group.

(2) 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.

Homologous serum jaundice, as it was previously called, was a known risk attaching to the use of blood, plasma and serum. It was referred to in "Notes For Transfusion", (in copy from 1963) and clinicians were required to report to the Transfusion Director any case of jaundice or hepatitis occurring within approximately six months of a transfusion, together with the serial numbers of the containers (recorded in the laboratory cross-match records and in the patient's notes) of blood and products so that donors could be investigated and any unused material withdrawn.

Up to the time when HBs Ag testing became available (approx 1971/72) the exclusion of almost all donors giving a history of jaundice (I believe those reporting jaundice in infancy due to Rhesus haemolytic disease were acceptable) or the retrospective investigation of cases of post-transfusion hepatitis, in an attempt to link particular donors to an incident, were the only ways of trying to prevent/reduce cases of post-transfusion hepatitis.

The situation changed when HBs Ag testing was introduced and various scientific groups, including the blood transfusion services, began to study the results. It became evident that a large proportion of carriers of HBs Ag gave no history of liver disease or jaundice.

Accordingly the advice of the expert Advisory Group was applied in relation to selection of donors.

(3) 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.

Blood donor sessions were held in the transfusion centre itself and as mobile sessions, in suitable venues around the region.

The donor team included a clerical officer, donor assistants with their team leader, one or two assistants trained in carrying out finger stick haemoglobin tests, a driver technician who drove the vehicle carrying staff and equipment (including refrigerated storage) and was responsible for the proper care of the precious packs of donated blood, and the session medical officer.

Training. All members of the team were trained in the courteous, considerate and professional care of the donor and the donation, as outlined in the "Guidance for the selection, medical examination and care of blood donors".

Session medical officers were fully registered medical practitioners who were not in a position to commit themselves to full-time work or night-time duties, but could undertake work in the hours offered by donor sessions. They had to be proficient at venepuncture, being able to insert a blood collection needle into a donor's vein accurately, quickly and as painlessly as possible.

They received a copy of the "Guidance" and training at the start of their work with BTS. Subsequently, updating information could be provided by letter or preferably, by meetings with Centre medical, nursing, and donor office staff where discussion and feedback could take place. They worked to the Centre's guidelines, and referred back to the Regional Centre medical staff (consultants and associate specialists) any difficult queries about donor history for further consultation and advice to donor.

In outline, the procedure at a typical donor session was as follows:-

The prospective donor was welcomed and asked to read the donor questionnaire, which included the phrase "Please tell us if you have ever suffered from HEPATITIS (JAUNDICE) or been in contact with a case in the past six months".

The donor was then interviewed by the clerk who linked the donor's identity to their donation number and went through the health check with the donor, who then signed to confirm they had read and understood.

The haemoglobinist again confirmed the donor's identity, then carried out a finger- stick test to exclude anaemia. If the test resulted in a low reading, the donor was deferred, the medical officer took a venous sample for a full blood count to be done later by the hospital hematology department and permission to contact the donor's GP, with their name and contact details, was obtained. (In Dundee, from new donors, samples for blood grouping and microbiology were also taken, so as to ascertain as much as possible before the second visit but I do not know whether this was done in other regions).

When a medical query arose, if the medical officer could resolve it, a note was made on the donor's record and the donation accepted; or temporary deferral advised; or, because the medical officer considered further clarification was required, donation was deferred, GP details obtained and the query referred to regional centre medical staff.

If a positive reply to the HEPATITIS (JAUNDICE) question was given, the donor was referred to the session medical officer, donation was deferred, GP details obtained and the report referred back to the regional centre staff.
Thus the donor's medical history was checked at several stages; the questionnaire, the interview with the clerical officer, and, just before donation, the medical officer.

The donor's memory was prompted at these points and sometimes e.g. in the five minutes of the actual donation, or on the rest bed afterwards, they might mention something to staff that had just come to mind. It was then referred to the medical officer for further consideration.

After a satisfactory history and blood check, the donor was made comfortable on the donation bed by the donor assistant, the medical officer again confirmed the donor's identity, placed the collection needle in the vein and the assistant stayed with the donor during the 5 to 6 minutes of donation.

The donor then rested till they felt ready to take refreshment (the tea and biscuits) and leave the session.

The team leader continuously scanned all donors in the hall, principally for signs of fainting or nausea etc. but also noticed other things, sometimes sufficient to refer to the medical officer for further check, thus the assessment of donors did not really end till they were fully recovered and off the premises.

Donor Selection Guidelines, which are mainly concerned with donor deferral, have been greatly improved over the years and have been constantly and anxiously discussed to try to optimise the safety of the patient, the product and the donor. Good staff training is a vital part of this process. In my view, staff experience and long service is just as important.

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

"Standards for the Collection of Blood", "Guidance for the selection of donors etc." and "Notes For Transfusion" were, I believe, intended to be applied nationally. I think the Working Party of 1983 was updating the "Guidance" and "Notes" of 1977.

(I was one of that working party and left the minutes, and my handwritten notes and backing papers, in the Dundee Centre's files when I retired. Enquiry from the Dundee Director's secretary and the National Records Management Officer at the PFC indicates that Dundee's records from that far back have been discarded).

The intention was that "Notes For Transfusion" and "Guidance for the selection of donors" should be used by Regional Transfusion Centres in all parts of the UK. As special cases arose from time to time in individual regions, annotations for local application would be made. For this reason, as well as because of microbiological advances etc, it was valuable to have a revision, by a national working party, from time to time.

(5) 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.

a) Before the introduction of HBs Ag testing, virtually all donors giving a history of jaundice or hepatitis were excluded from donation, so continuation of this practice may not have caused difficulty in maintaining sufficient supply of blood.
However only a small percentage of the population volunteer, so careful consideration needs to be given to any blanket exclusion.

b) My recollection is that when tests for HCV came into use only quite a small proportion of those who tested positive had a history of jaundice. The evolution of knowledge confirmed that a history of jaundice would not have excluded most infective donors.

(6) Dr Brookes' discussions with colleagues in England and in Scotland in the early 1980s on the practice of collecting blood from penal institutions and the consideration given at that time to the risk of hepatitis including, in particular, NANB hepatitis, from blood collected from such institutions.

(7) Who were the other members of Dr Entwistle's Working Party on the Selection and Care of Blood Donors and what was the process by which the Working Party produced the documents "Guidance for the Selection [etc] of Donors" and "Notes on Transfusion" (SGF.001.0377 and SGF.001.0397)?

My experience and view of prisons is given in the preliminary comments on page 1-3 of this draft statement. Additionally, in 1983, the SNBTS National Director had asked me to raise the matter of prison sessions in the working party on Selection of Donors and when I did, I was advised by the chairman that there was nothing to discuss, it being his understanding that all English Transfusion Centres had stopped holding prison sessions. After the meeting I reported this to the Scottish National Director who asked me to ring round informally to check. I contacted 12 of the 14 Directors. In the minutes of the SNBTS Directors Meeting of 8th December 1983, item 3h, it is recorded that of the 12 Directors I had contacted, 11 were not holding prison donor sessions.

Regrettably, all my records about the Working Party on the Selection of Donors/Notes for Transfusion have been discarded. There is an existing note stating that the party consisted of four members. I recall that Dr Entwistle was chairman and Dr Anne Collins, Director of Newcastle, now deceased, also attended the meeting on 30th June 1983. I have no memory of a fourth member of the group. This may be a failure of my memory, or it is just possible that the fourth member was from the Northern Ireland BTS and, because of the troubles of the time, was unable to reach the airport to travel to the meeting, a difficulty which sometimes occurred.

The purpose of the working party was to produce updated versions of the "Guidance" and "Notes" of 1977. The work was done mainly by correspondence.

Initially the Chairman requested contributions from all Transfusion Centres, BPL and PFC, through the working party members or direct to himself. He collated these into a first draft which he sent to working party colleagues for initial comment.

On particular points I think he consulted experts outwith the field of blood transfusion.

Further updating comments were incorporated into the second draft, which I circulated to Scottish colleagues. As an example, I sought the advice of John Watt in PFC about the nomenclature of products in "Notes" to ensure terms would be understood throughout the UK.

On 30/6/83 the working party spent the day intensely scrutinising the then current draft and all additional contributions. The Chairman considered that, with these additions, we had reached the final draft.

Dr. Collins and I wondered whether some parts needed further consideration, my particular concern being to ensure that differences occurring in Scotland were appropriately explained.

However, understandably, all Centres wanted the drafts finalised, issued and put into use. When Dr. Entwistle in September issued the final draft I circulated it to Scottish colleagues, asking them to send any proposed last minute amendments directly to him.

In the event, the final draft was discussed at the SNBTS Directors meeting of 8/12/83 and accepted.

Signed: Ewa Brookes .....

DR EWA BROOKES

Date: 26th January 2011 .....