WITNESS STATEMENT FROM DR R J PERRY

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

Matters to be included in the statement

Whether, in the 1970s or early 1980s, Dr Perry or, to his knowledge, any of his colleagues at the Protein Fractionation Centre (PFC), ever:

(a) considered the practice of collecting blood from penal institutions and the increased risks of hepatitis, including non-A, non-B hepatitis, from such donations,

(b) considered whether the practice of collecting blood from penal institutions should continue, and

(c) made any recommendations in respect of that practice.

SNBTS DOCUMENT REQUEST No:

2010/00031

INTRODUCTORY COMMENTS

Prior to my appointment within SNBTS I was employed as Chief Analyst in the Regional Sterile Supply Unit of the West Midlands Regional Health Authority. This new NHS unit was established for the large scale pharmaceutical manufacture of sterile injectable preparations for the region and my role included the development and management of Quality Control systems and procedures necessary for the commissioning and operation of the unit within standards of Good Pharmaceutical Manufacturing Practice applicable to the industry in general.
In March 1981 I was appointed in SNBTS as Quality Control Inspector in the Protein Fractionation Centre (PFC). This was a new post. Its role, inter alia, was to develop and implement Quality Assurance systems and controls as part of a programme to bring the Centre into compliance with modern standards of Good Pharmaceutical Manufacturing Practice. I reported to the PFC Director (Mr J G Watt).
In January 1984 I was appointed Acting Director of PFC following the departure of Mr Watt. This appointment was made substantive in 1985 reporting formally to the Committee of Management of the CSA and responsible for all activities of the Centre – subject to the responsibilities and duties of the SNBTS National Medical Director.
Clearly I had no involvement in or knowledge of discussions, actions or decisions on the above or other issues prior to March 1981.

BACKGROUND INFORMATION RELEVANT TO THE ISSUE

Before responding to the specific questions raised it is important to understand the organisational framework, accountabilities and responsibilities in place at that time.
Throughout the period in question the SNBTS was (and remains) a centrally funded division of the CSA. Although widely regarded as a national service providing blood components, plasma products and services for Scottish patients the management arrangements and accountabilities within the service provided a high degree of professional autonomy for its constituent Regional Centres and the PFC. Effective leadership and coordination of policies and strategy for the service was provided by the National Medical Director although the ultimate professional responsibility and independence of Regional Centres was always respected and observed. Within this arrangement, which was typical of the UK and some other European countries, the National Medical Director exercised managerial control through persuasion, consultation and ultimately consensus when seeking to establish a collective national position.
It was therefore clearly evident and understood at that time that the responsibility for the recruitment, selection and testing of donors rested with Regional Transfusion Centre Directors who, it was understood, would take account of appropriate and contemporaneous UK guidelines.
So far as PFC was concerned therefore plasma supplied to the centre for processing was accepted on the understanding that donors had been recruited and blood had been collected, tested and processed according to appropriate UK standards and under the ultimate supervision and

responsibility of the Regional Director. Accordingly donor selection and epidemiology did not arise as issues for PFC intervention. However, during this period PFC did have a pressing interest in plasma quality but primarily concerning FVIII content, methods for separation and freezing and transport and a number of studies were carried out in an attempt to improve and optimise the yield of FVIII from plasma.
Latterly during this period PFC and Regional Centres worked more closely on the development of quality systems and standard operating procedures for the processing and testing of plasma but this did not extend to issues of donor selection which, at that time, would have been accepted as the exclusive responsibility of Regional Directors and their medical staff. This situation remained largely unchanged until reorganisations of the service in the 1990's.
In its original Licence Applications to DHSS Medicines Division for FVIII information on donor selection practice or policy was neither supplied by PFC/SNBTS or requested by the UK Licensing Authority.

STATEMENT IN RESPONSE TO SPECIFIC QUESTIONS

Whether, in the 1970s or early 1980s, Dr Perry or, to his knowledge, any of his colleagues at the Protein Fractionation Centre (PFC), ever considered the practice of collecting blood from penal institutions and the increased risks of hepatitis, including non-A, non-B hepatitis, from such donations.

I have been unable to find any documentary evidence of any formal (or informal) consideration of this topic within PFC either before my appointment in March 1981 or subsequently. However the letter from Dr Cash to Mr Watt dated 5th July 1982 clearly seeks his view on the topic of prison donors. The wider content of the letter suggests to me that this letter will also have been sent to Regional Directors also seeking their views on the topics mentioned. The letter was passed to me with the suggestion that we should discuss (annotated by Mr Watt) and a tick next to this suggestion perhaps indicates that this discussion took place. Unfortunately I can find no evidence and have no recollection of this. There is no record of Mr Watt having replied to the letter although it is possible he discussed the content with Dr Cash.
I am aware of the references cited in the Preliminary Report which describes the discussions and actions of SNBTS Directors in relation to prison donors which took place during the above period. Mr Watt will have participated in these discussions but I have no recollection of or record of having been briefed or consulted on the content of these Directors discussions. I have been unable to find any record of an instruction or request to myself or other PFC staff to take any action in response to these discussions. Indeed since the Directorial discussions were in any event inconclusive it is unlikely that any action would have been requested.
Finally, following the departure of Mr Watt at the end of 1983 and my appointment as acting Director in Jan 1984 I do not recall any further consideration of collecting blood from penal institutions either between Directors (which by this time I would now be party to) or elsewhere – probably because the practice ceased in Scotland in March 1984.

It is of course possible that throughout this period PFC staff generally would have been aware of the SNBTS practice of collecting blood from prison donors as part of their background knowledge of SNBTS activities. It is equally possible that many would have held personal views and casual discussions on whether or not this was appropriate practice. However I am not aware of any substantive or formal consideration of the issue in PFC between 1981 and 1984.

Whether, in the 1970s or early 1980s, Dr Perry or, to his knowledge, any of his colleagues at the Protein Fractionation Centre (PFC), ever considered whether the practice of collecting blood from penal institutions should continue.

It follows from the above that I have found no record and have no recollection of any consideration of whether the practice should continue or cease.
However, again I would expect that a number of staff held personal views and periodic casual discussions on the subject – though again this is conjectural.

Whether, in the 1970s or early 1980s, Dr Perry or, to his knowledge, any of his colleagues at the Protein Fractionation Centre (PFC), ever made any recommendations in respect of that practice.

I can find no record and have no recollection of any recommendations from myself, Mr JG Watt or any other staff on this practice. I cannot exclude the possibility that the topic was discussed periodically between Mr JG Watt and other SNBTS Directors but I can find no evidence that such discussions produced substantive recommendations or proposals.

Drafted by Dr R J Perry – September 2010

Statement of Truth

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

GRO-C

Signed .....

Dated 25 January 2011

C1 – "UNSUITABLE DONORS" – RESPONSE BY DR R J PERRY TO THE UNDERNOTED SUPPLEMENTARY QUESTION POSED BY THE PENROSE INQUIRY BY EMAIL DATED 20 DECEMBER 2010

Subject to answering the following query, Dr RJ Perry should be asked to sign, date and return his draft statement (A18060). Dr Perry should be provided with a copy of the under noted papers[1] and asked whether he was aware of these papers at the time of their publication and what, if any, conclusion he would draw from them, either at the time or now, about the appropriateness of collecting blood from Scottish prisons, including any possible or likely increased incidence of NANBH from such donations.

RESPONSE

I joined the SNBTS in March 1981 and prior to that time had no knowledge of the work of blood transfusion services or plasma fractionation.
Clearly therefore I was not aware of the paper by Wallace et al at the time of its publication in 1972. This paper outlines the data obtained on the prevalence of Australia Antigen (now known as hepatitis B) in the blood donor population in the first year of full testing for this virus in the West of Scotland between October 1970 and October 1971. The increased risk of hepatitis from prison donors compared with the general non institutionalised donor population is clearly identified. My understanding is that the risk of hepatitis associated with transfusion products was widely (internationally) recognised in 1970 prior to the introduction of any form of testing for hepatitis. My understanding of the guidance available at that time (eg WHO) was that the collection of blood from prison or institutionalised donors was to be encouraged and this view was reinforced by official UK Home Office policy which considered that allowing prisoners to become donors would help with their rehabilitation, and that it would be socially and psychologically undesirable to exclude prisoners from the donor population. Later DHSS guidance (1975) recognised the increased risk of hepatitis B from the prison donor population but also suggested that *'there is probably an equally high risk in other groups of the population, e.g. drug addicts, who are not so easily identified in advance as prisoners, if they can be identified at all'*. DHSS guidance continued to state that as long as donations were screened for HBsAg there was no reason to cease collecting from prisons. Finally in the textbook 'Blood Transfusion for Clinicians' published in 1977 and written by Dr John Wallace, the senior SNBTS director at the time, stated that as *'the incidence of*

[1] (1) Wallace et al, "Total screening of blood donations for Australia (Hepatitis Associated) antigen and its antibody", BMA, 11 March 1972:663-664 (SGH.002.9831) and (2) Barr et al, "Hepatitis B virus markers in blood donors in the west of Scotland", Medical Laboratory Sciences, 1981;38:405-407 (SNB.008.0002)

HBs antigenaemia among male prisoners in Scotland is less than 1 per cent using the most sensitive techniques of testing...it is socially and psychologically undesirable to exclude prisoners... acceptance of prisoners as donors helps to rehabilitate, and some of these volunteers become regular donors after release.'

My understanding from my general knowledge of international practice at that time is that the practice of collecting donations from the prison donor population was not markedly different to that of the wider UK, Europe or the US.

I do not possess an expert historical knowledge of the evolutionary understanding of hepatitis and its impact on donor selection in the 1970's. However I am not aware of any information which existed at that time which might have suggested an increased risk of non-B hepatitis from a prison donor population. Indeed the international discovery of a form of hepatitis associated with transfusion which was neither hepatitis B or hepatitis A (ie NANB hepatitis) did not occur until the mid 1970's in the US. Thus in 1971 Wallace et al or their international contemporaries would have had no knowledge of the implications of their findings for NANB hepatitis and it seems appropriate that they and others would continue to be guided in their decisions by the prevailing guidance.

By today's standards and with the comprehensive knowledge now available it is clearly possible to conclude that this early study by Wallace et al provided early evidence of an elevated risk of hepatitis (though certainly not NANB hepatitis) in the prison donor population which could have resulted in a discontinuation of this practice. It is however not possible, at least for me, to reconstruct the sociological, medical and political considerations which led to its widespread continuation.

Concerning the later publication by Barr et al in 1981, I was similarly not aware of this at the time of its publication having only recently joined the SNBTS.

This publication reinforced the data from the above study a decade earlier and demonstrated a five fold higher incidence of HBsAg positive donations in the prison donor population compared with the general donor population. The publication concerned only hepatitis B and made no attempt to draw conclusions on NANB hepatitis. By this time however, despite there being no UK (DHSS/SHHD) revision of guidance on the collection of blood or plasma from prison institutions, both WHO and ISBT (International Society of Blood Transfusion) had revised their guidance to recommend that blood collection should not be undertaken from populations showing a higher level of hepatitis than in the general donor population or from 'correctional institutions'. Equally however there was, I believe, few reliable data which might have suggested that an elevated incidence of Hepatitis B could be extrapolated to the incidence of NANB hepatitis.

Had I been called upon to draw conclusions from this publication at the time I would probably have drawn similar conclusions to those of the SNBTS Regional Directors ie that the collection of blood from institutionalised donors and which was subject to reliable testing for hepatitis B (HBsAg) was justified on the basis of securing a secure blood supply particularly during holiday periods. I would also have concluded from the information available at that time that a deferral of institutionalised donors would have had no impact on the safety of plasma products (FVIII, FIX etc) with respect to NANB hepatitis because of the estimated (~0.5%) prevalence of NANB hepatitis in the general donor population.

With the benefit of the epidemiological information now available I would conclude that a decision to discontinue blood collection in the light of these published data would have prevented some cases on NANB hepatitis to recipients of blood

components but would have had little or no impact on the safety of plasma products such as FVIII or FIX made from large plasma pools.

Drafted by Dr R J Perry – December 2010

Statement of Truth

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

GRO-C

Sig.....

Dated....25 January 2011.....