TOPIC C1

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

C1a) prisoners; and

C1b) 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.

1. Whether and to what extent SNBTS considered the risk from continuing to accept donations of blood from prisoners or other 'higher risk' donors in the late 1970s and early 1980s.

There is no evidence showing that before 1982 (when the Medicines Inspectorate reported) there was any consideration by SNBTS of the risk posed to recipients of blood or blood products from continuing to accept donations of blood from prisoners or other "higher risk" donors. There are no documents from the late 1970s and early 1980s showing concern or discussion of the topic. The evidence is that at a national (Scottish) level detailed consideration was given to the higher risk posed by the collection of blood in prisons because of the advent of the crisis posed by AIDs rather than the concerns expressed by the Medicines Inspectors and the literature and data concerning the risk from hepatitis Pervading the whole approach to "higher risk" donations (and a theme consistently running through the other hepatitis topics with which the Inquiry is concerned) was the prevailing mistaken attitude within the UK in the late 1970s early 1980s not to view Non A non B hepatitis as a serious problem[1]. It is unclear as to why this was so and it is difficult to explain when set against the contemporaneous data[2].

2. Whether a decision to continue to collect blood from prisons was taken and by whom.

The decision following the meeting of the SNBTS directors on 29 March 1983 appears to have been that Regional Transfusion Directors were free to continue to collect blood from prisons. There is no evidence that any of the Regional Transfusion Centres recorded a policy decision to stop collecting blood in penal institutions[3]. It seems that those responsible

[1] [Day 9 22/03/11; 44 (6) to 45 (5) and 22/03/11 165 (13) to 166 (18)]
[2] [Day 9 22/03/11; 44 (20); 50 (18)].
[3] [see Day 9 22/03/11 - 35 (14) in relation to Edinburgh]

for decision making wanted to keep their options open rather than closing off the possibility of collecting blood from prisons in the future. As late as 12 January 1983 Edinburgh maintained in its response to the Medicines Inspectorate that prison donors would only be used in an emergency but it is noteworthy that the minutes for the meeting of the SNBTS directors for 29 March 1983[4] record that all Directors present said that sessions were held in all regions.

3. The role of the SHHD in the decision making process during the relevant period.

According to Professor Cash there was no SNBTS management decision because such decisions required consensus or an instruction from SHHD. Neither was forthcoming. Professor Cash stated that guidance was sought from the DHSS but none came[5] There is no basis in any documents or from any other witness that any decision required unanimity or that it was necessary to refer the matter to SHHD. Professor Cash's assertion that he was not "the boss"[6] is difficult to accept particularly when one looks at subsequent decisions scrutinised by the Inquiry. He had the experience, personality, expertise, strength of character, confidence and respect to assert his authority when he chose to do so. The idea that Professor Cash would or could be dictated to by "poor old" Dr. Graham Scott (as the SHHD medical officer responsible at the material time for the Blood Transfusion Service was described) is risible.

4. When, by whom and the reasons for any decision to cease collecting blood from prisons.

There is no record of a recorded policy decision to stop collecting blood in penal institutions. This does not necessarily mean that no decision was taken. Professor Cash indicated that the abandonment by Edinburgh of collection in prisons came as a complete surprise to him. The impression that his evidence leaves is that at the time he (and others) may have considered that donor selection was not a matter for the Medicine Inspectors and that the latter should stick to questions of good manufacturing practice. This attitude ignores the inextricable link between the two. The documentary evidence is that it was only after adverse comment from the Medicines Inspectorate that the particular risk posed by prison collections was discussed at a national level. There is no record of SNBTS taking a decision to stop collecting blood from prisons. Professor Cash who had responsibility for the matter, as National Director at the material time, left it to individual RTDs to decide whether and

[4] [SGF.001.0234]
[5] (see statement WIT003.0120)
[6] [Day 10 23/03/11; 42 (11)]

when to collect blood from prisons. Thereafter over a period of time Regional Transfusion Directors decided for themselves to stop including prisons in planning collection schedules for the future. These decisions were not publicised although it was commented in July 1984 "The vast majority of abusers with elevated ALT levels admitted being heroin addicts and a considerable proportion were prisoners. These facts have also helped dissuade SNBTS from visiting prisons to obtain blood for transfusion purposes"[7]

5. Whether the risks to recipient patients were properly taken into account.

Throughout the relevant period it was known and appreciated that donations from prisons posed a higher risk[8]. The large scale production of pooled plasma products made from thousands of donations led to a drive for self-sufficiency because of the dangers of accepting blood from "paid donors". The very same characteristics that made "paid donors" objectionable such as unreliable histories, dissolute lifestyles, increased risk of parenteral transmission and questionable motivation all existed in the prison population long before the Medical Inspectors reports[9] and even longer before the last donation was accepted at Glasgow on 25 March1984. No attempt was made to justify the donations obtained from prisons in the early 1980's as being necessary because of any specific emergency. There is no evidence of any significant difficulty in supply after collection from prisons ceased. On the contrary the evidence discloses that ceasing to collect blood from prisons did not affect the blood supply[10]

Sight appears to have been lost of the need to be discriminating in relation to "voluntary" donations. The traditional "Tinker tailor soldier sailor rich man poor man beggar man thief" approach referred to by Dr. Ruthven Mitchell prevailed long after it was justified. His decision to carry on collecting at prisons into 1984 is incomprehensible not least because of the tiny amount obtained by that time. None of the other witnesses from the SNBTS attempted to justify the continuation of the policy of collection on this basis. Dr McClelland and Cash were unaware of the advice from the CMO (England and Wales contained in the letter of 1 May 1975[11]. Dr McClelland when confronted with the advice years later regarded

[7] Follett/Dow reported in July 1984 [SGH002.8040]
[8] [Day 10 23/03/11 59 (18)]
[9] [SGF.001.0086 and SGF.001.0351]
[10] [Day 9 22/03/11; 163 (7) to 164(5)] and see PEN.010.003]

[11] [SGH0030187]

it as surprising because he thought "we should have stopped sooner". He said that "once we sort of started to think about the issue, it became very obvious that we were going to stop[12]. A different attitude was (and is) maintained by Dr Mitchell[13]. This different attitude ignores the "high risk" posed by collection of blood in prisons see letter from D Haythornwaite, Medicines Inspectorate, to Dr Cash dated 4 June 1982[14]. Such evidence as the Inquiry heard relating to what occurred at collection sessions suggested that donors were not subjected to a penetrating or thorough examination of their lifestyles before being accepted. Professor Leikola's gave evidence was that the study by Helske[15] demonstrated that prisoners there were associated with a high risk of acute and chronic hepatitis. Thus in Finland from 1974 collections ceased mainly to avoid transmission of Hepatitis B but it was considered that there might be other, unknown viruses as well[16]. By the mid 1970's it was appreciated that post transfusion hepatitis was being caused by blood-borne virus or viruses other than hepatitis A and hepatitis B. It was appreciated that the risk from hepatitis B was greater among certain groups. Despite the lack of reliability (at least initially) of hepatitis B testing no significant alteration to donor selection procedure appears to have occurred. It was also understood that Non A Non B hepatitis was blood borne[17]. It is submitted that recipients of blood and blood products were placed at unnecessary risk from the Mid 1970's onwards because of the failure to take into account the potential danger posed by Non A Non B hepatitis and to introduce more selective donor policies[18]. In 1976 The International Society of Blood Transfusion "Criteria for the selection of blood donors" provided

"In spite of recently developed tests for the detection of HBsAg, only a relatively small proportion of carriers can presently be detected. No routine screening test is presently available for the detection of hepatitis A virus, or other viral agents that cause transfusion-associated hepatitis. It follows, therefore, that some general precautions should be taken in an attempt to reduce the risk of such viral agents being transmitted from donor to recipient. Prospective donors should be excluded if it is known that they: 1. Give a history of viral hepatitis at any time, except during the first months of life. (This rule

[12] [Day 9 22/03/11; 76 (15) -77 (7)]
[13] [Day 9 22/03/11; 164 (19) -165 (23)]
[14] [SNB.008.7582]
[15] [LIT.001.003]
[16] [Day 13 29/03/11 37 (5) – (15)]
[17] [PEN0020559; LIT0010363;LIT0013657;LIT0010189]
[18] The letter dated 6 January 1975 written by Dr J Garrott Allen to Dr William Maycock expressing concern about obtaining blood from paid and prison donors makes the risks clear and also that there were agents other than Hepatitis A and B at work. This letter was quoted verbatim in the World in Action programme broadcast later that year which Dr Cash must have seen at the time. He must have been aware of the terms of this important letter at the time since he wrote to the BMJ in January 1976 commenting that the editing of the programme gave a misleading impression. Dr Cash appeared to have forgotten about this when he gave his evidence.

may not be acceptable in all countries and may have to be modified where viral hepatitis is endemic) … 5. Are suspected to be parenteral drug addicts … 7. Are inmates of a correctional institution"[19]

If the primary consideration had been reducing the risk to the recipients of blood to a minimum then this advice would have been followed.

6. The decision making process relative to acceptance of donors with a history of jaundice and whether the decisions were taken in the best interests of patients.

Cogent evidence was given by Dr. Gillon among others that acceptance of donors with a history of jaundice made no significant difference to increasing the risk of transmitting Non A Non B hepatitis as a result of blood or blood products. What is not clear on the evidence is precisely when and how the policy outlined in the second report (1975) of the DHSS Advisory Group on Testing[20]was adopted by the SNBTS. The evidence is that the policy had been adopted by 1983[21]Scotland. There was no national (Scottish) policy. The Regional Transfusion Centres were autonomous. As a result it is difficult to discover what the donor selection policy was, how it was arrived at, how it was applied and how it came to be reviewed. The driving force for change was the HIV crisis. Thereafter donor selection policies evolved. The decision making process was slow, reactionary rather than pro-active and obscure. These features of the decision making process remained in place well into the late 1980s when the dangers from Non A Non B hepatitis began to be better understood.

[19] See DHF0012672
[20] "for the Presence of Hepatitis B Surface Antigen and its Antibody"
[21] See WIT0030129