THE PENROSE INQUIRY

WITNESS STATEMENT – DR RUTHVEN MITCHELL

OCTOBER 2010

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**

PREAMBLE

I welcome this opportunity to submit this statement. Also, to acknowledge the dedicated and meticulous attention given by all of my staff to the collection, care and maintenance of voluntary blood donors, and their donations, in West of Scotland since I became Regional Director in 1978, in succession to the late Dr John Wallace. At that time Mr George Milne MPS was Deputy Scientific Director. Together, these highly motivated staff, including Mr Archie Barr FMILS and others, endeavoured to adopt and adapt testing of blood donations, or markers of transmissible disease, including Hepatitis B, Hepatitis C and AIDS virus. In the progression of this statement I am not certain that all of the files which were accumulated are still in existence since the relocation of the West Centre from The Law Hospital in Lanarkshire into Glasgow. Throughout the life of the UK transfusion services it was always thought that donors were selected on the basis of "tinker, tailor, soldier, sailor, rich man, poor man, beggar man, thief", great efforts are made to avoid any discrimination.

My memory which goes back over 25 years until I retired in December 1995, having been Director from 1978 to 1995. I regret that I cannot remember all the details of the considerable amount of information which accumulated and was stored in a specially built records room. In the absence of these, I have endeavoured to answer the questions raised from my memory and some documents received from SNBTS. Shortly before the Law Centre was decommissioned I had a last nostalgic visit where I found the old records in considerable disarray.

Penal institutions

Paragraphs 1 and 2

(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.

(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.

Table to be provided by SNBTS

SNBTS DOCUMENT REQUEST No:

2010/00028

Paragraphs 3, 4, 5 and 6

(3) When the practice of collecting blood from penal institutions stopped in each region in Scotland.

(4) Why the practice stopped.

(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.

(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.

Collection of blood from penal institutions ceased in each region of Scotland in the early 1980's. Again I am not sure of the exact date for each individual region but these are available centrally and the last session in the West of Scotland was in March 1984. The idea of visiting prisons was the practice at the time and up until March 1984. Up until then the HBV test was available and being improved upon. More importantly the added dimension of HIV was emerging. The practice of visiting penal institutions was determined by the then known collection and mass screening of donations. Dr John Wallace and colleagues began testing in the early 1970's with small gifted amounts of anti serum and Hepatitis B virus from Professor Albert Prince. This was firstly to familiarise themselves with the techniques required and an enthusiastic team at the West went about improving early methods by using home grown anti serum from human and animal sources, using internal resources. Notably as I recall our first human donor of anti Hepatitis B was in fact a short stay prisoner in one of the penal institutions in the West. As time progressed more of the simple techniques such as immunodiffusion were modified and new tests introduced as they became available in the international literature and by personal contact with other workers. During this time much of the work undertaken by the West BTS staff and others resulted in commercial manufacturers seeking comparative evaluations of their test kits which were also being developed. Other Regional Transfusion Centres came to the regional laboratories in the West for instruction and discussion to allow them to proceed and further develop the tests in their local regions. During this time all donations giving a positive detection were not issued for clinical use but were stored as archive panels of material for such evaluations in the future. Much of this work was done within existing resources and spoke highly of the motivation of all the staff involved. The policy at that time, and always since then, has been to keep out donations if there is any doubt about their efficacy for clinical use, the maxim being "if in doubt keep it out". These panels formed the foundation of standardised test samples of varying degrees of difficulty and these were distributed within Scottish Regions and elsewhere in order to give staff confidence in their ability to quality assure the tests. These panels were selected with varying degrees of difficulty in detection and were widely used throughout the Service and in the United Kingdom. By late 1983 reliable and robust, sensitive and specific tests that could be used for rapid mass screening of donations had been found and developed, facilitating the next morning/day testing, with blood entering the blood stocks for clinical use within 24 hours of collection, or less.

During the period 1975 to 1984, discussions were held within the Scottish Service, and elsewhere, on a national and international basis, as can be seen from the magnitude of scientific papers, meetings and symposia produced at that time. All the information was difficult to evaluate because a) donor populations varied from region to region and country and country; b) methods of assessment and recording of data varied from region to region and country to country; c) reported methods of testing varied from region to region and country to country, depending on resources and technical abilities available; d) it was known that, included in the term homologous jaundice (serum transmitted jaundice), there was likely to be other variant entities which could be transmitted in the absence of anti Hepatitis B activity. This was clearly stated by Dr Harvey Alter a well known United States worker in the field who said "I think that I shall never see a virus called

Non-A Non-B". Nevertheless, as knowledge accumulated, it became clear that in some populations, including prisons, drug abusers, homosexuals and other risk groups, there was a risk of onward transmission to others. For this reason most Regional Transfusion Centres in the UK had made changes to their routine evaluation of the ability of donors to donate. Donor recruitment literature was modified from time to time on a national basis but individual printing and stationery was undertaken regionally. Such practices undoubtedly had a potentially serious effect on donor recruitment. Those who had volunteered to be blood donors at no cost could perceive themselves to pose a risk of infecting others by their altruistic gift. However if discontinued from the donor panel this could result in great social and economic problems at the workplace and in the home. One of the best descriptions of this is given by Dr John Wallace in his book "Blood Transfusion for Clinicians". An example of the upheaval which might arise occurred in the West where a donor known to be positive for Hepatitis B virus was injured in a mountaineering accident, rescue teams including the Police were alarmed when they discovered the casualty was Hepatitis positive and the newspapers at the time carried lurid descriptions of the Police Land Rover being incinerated because of the irrational fear of infection. The headline in the newspapers read "The killer that came down from the mountain". For this and other reasons the SNBTS was anxious to protect donors as well as to protect patients, and the duty of care was evident since it was obvious that persons found positive for Hepatitis B in the 5% of the volunteer donors was reflected in the general population, whereas 95% did not donate but would demonstrate similar results and portals of entry other than blood transfusion.

Paragraphs 7, 8 and 9

(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?

(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?

(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?

The correspondence referred to in these paragraphs was not known to me since I did not attend regional transfusion directors meetings at that time. Nevertheless I was aware of much of the scientific literature and it was clear that the prevalence of Hepatitis B among prisoners varied very much from place to place and country to country and continent to continent, and the other possible entry points for Hepatitis in the general population. I was certainly aware that it might not necessarily mean that donors from prisons should be discontinued provided they were Hepatitis negative at the time of donation.

Regarding the sensitivity of tests. I am grateful to Mr Archie Barr for additional information on sensitivity in and around the 1970's. His memory like mine is as best as we can recall. Around 1970 to 1971, when centres were using CIEOP, Dr Wallace and others determined to test the capacity of all centres in Great Britain on their ability to detect positive and negative donations by the methods used in each laboratory. Glasgow prepared a group of 20 samples which were despatched on a Monday to arrive in all British centres by Wednesday of a particular week. Each centre was to add these into their routine daily screening programmes and by Friday report the results to Glasgow. The unknown samples were made up of 20 donations, 8 positive for HBsAG, 8 positive for anti HBsAG and 2 completely negative for either marker. Although most centres

returned their results within the week and clearly performed the tests during their normal daily routine some centres were slow to report their findings and it was suspected that they had had other reference laboratories examine the samples or there was some degree of inter laboratory collusion. We got results for named RTCs including PHLS laboratories which were coded and results kept separate from any laboratory or medical worker. A paper was delivered by Mr Barr at a meeting in the Sheffield RTC under the directorship of the late Dr Bowley, chaired by Mr George Milne, Deputy Director in Glasgow. All of the results were discussed. Most RTCs had performed quite well and as a result some laboratories tightened up their procedures to achieve some uniformity of performance since the dictum by Glasgow was "not good for a day, but good every day"! Thereafter in the mid 1970's all RTCs in Great Britain were performing at a comparable standard. Mr Barr then recalls being invited to a WHO meeting in Geneva involving international delegates to discuss in specialist groups the quest for uniformity of test methods. The meeting lasted 4 days with delegates of variable knowledge of what was desirable, and the report was to be prepared and circulated. Mr Barr did not receive a copy of the final report and so far as I can recall no such report was received. Neither Mr Barr nor I have had any sight of the documented information but it may reside in the records of the West BTS or elsewhere. Thereafter a British Standard (containing Glasgow material) for HBsAg was issued by the National Institute for Biological Standards and Control (NIBSC) in 1980 and designated to contain an arbitrary 100 British units per ampoule. Later this was adopted as a WHO standard and the British international standard of 100 i.u. per ampoule. The standard then had been set and all RTCs and others would be required to detect at least 2 international units. By this time further tests for RPHA and RIA had been evaluated and Glasgow was able to detect this standard with no difficulty. It is to be noted that such uniformity of performance was initiated in Glasgow and introduced throughout Great Britain, with Glasgow accounting for half of the Scottish donations.

Paragraphs 10 and 11

(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).

(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.

SNBTS continued to collect blood from all previous donation sites from 1982 for the reasons given above, namely the lack of agreement by many national and international workers on the efficiency and reliability of information, including various tests. For the reasons I have already stated any donation found positive by any of the test methods in the West of Scotland was considered non-issuable and additional work was undertaken to try and establish the true nature of the test positive. It is to be noted that some tests by certain manufacturers showed variable results and lack of consistency which affected inability to establish a national policy leading from CIEOP, through RPHA and RIA methods.

I do not know the number of penal institutions nor the number of prisoners in each. Figures are available centrally.

Paragraph 12

(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?

Avoidance of high risk communities stated by Dr McClelland was generally agreed by 1984 when good confirmatory tests were available, or tests of equal specificity and sensitivity. Secondly, I cannot recall an exact start date being given but just immediately prior to these dates it was known that the AIDS virus was becoming recognised and arrangements were being made to commence testing for this. Certainly that was a major factor in the years 1983, 1984 and beyond. Most European centres had start dates at different times, some later than Scotland. (See paragraph 15) The Medicines Inspector Report on Glasgow makes no mention of prison collections. There were international differences and, even in USA, prisons were still being discussed in 1995.

Paragraph 13

(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?

In 1984 Dr Brian Dow was a member of my scientific staff attached to the Virology Department laboratory at Ruchill Hospital. He was recruited as a qualified Microbiologist with an interest in Virology, and joined us at a time when his expertise would complement the work of those already engaged in Hepatitis research and testing. For this reason he was encouraged to do a doctorate in Philosophy (Phd), and to work in close co-operation by being seconded about twice per week to the Virology laboratory at Ruchill Hospital, under Professor Norman Grist and Eddie Follett. This lab was designated as the true reference laboratory for the SNBTS. Specimens and donations were sent there for confirmation. Some required much additional expertise, equipment and resources to undertake more advanced and more time consuming tests, which were not available to the BTS. The findings of Dr Dow and Dr Follett were regularly noted and debated, and it was anticipated that much of their work would add to the screen tests ultimately to good effect for Non-A Non-B Hepatitis and possibly viruses D, E and F variants. Individuals showing elevated ALT test were given to the regional virus laboratory for Non-A Non-B evaluation.

Paragraph 14

14) 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.

Discussions between the SNBTS and the SHHD in the period 1975 to 1984 were regular and held between the National Medical Director and SHHD officials. Such officials also attended RTD and co-ordinating group meetings of directors, as required.

Paragraph 15

(15) The minutes of the meeting of the SNBTS Directors on 13 September 1983 (SNF.001.0072) record that it was felt that a blanket decision to cease visiting prisons would be a mistake. Dr Mitchell is noted as stating that it would be unfortunate if such a recommendation was to be included in the "Red Book" of good manufacturing practice. What was the "Red Book"? Why was Dr Mitchell of that view?

The Red Book was a compendium of good blood transfusion practice which was bound in red coloured covers, hence the name Red Book. It covered many aspects of what was considered to be good practice at the time of writing, using the best knowledge available in an effort to standardise practice throughout the United Kingdom. Individual chapters were written by teams of authors, or individuals with specialist knowledge. The book ran to many pages and covered many subjects, one of which concerned donor selection. My view at that time was that if information in the book was to be used as a "mandatory" requirement then readers might have doubts about such instructions since they were aware of literature reviews to which I have already alluded. At that time Scotland was well advanced in these matters and much thought was given to constructing algorithms for courses of action for the care and selection of blood donors and their onward progress through the system. Examination of the Minutes of meetings from 1983 provide the following:-

A. The Scottish Directors' Meeting of 29th March 1983 reported all were using prison donor sessions and Dr Brookes was to discuss with the Entwhistle Committee on Donor Care and Selection. Three important events then occurred;

B. On 27th and 29th July 1983, in the document referenced 2700, it asked "at a recent meeting of the Medicines Inspectorate Action Group, concern was expressed about the collection and use of blood from borstals and prisons. Blood transfusion centres in Scotland are making use of these (particularly prisons) and some, at least, of the English transfusion centres were also understood to do so. The group considered the practice to be highly questionable because of the incidence of homosexuals and homosexual activity in prisons, and the present unease about the incidents of AIDS among this group of people. The Group asked to be kept advised of the departmental policy on the practice of collecting and using blood from borstals and prisons and I shall be grateful if you would let me have a note about this which I can pass on. One further point, is this something which might usefully be referred to the proposed revision of the Red Guide?" signed MB2.

C. On 23rd August 1983, reference 2727, from probably DOH, replied to Minute of 27th July "Up to individual RTCs to decide sessions and AIDS due to be discussed at the RTD in September 1983 recognising that this was already discussed in Scotland and need to consult the Home Office since they have "in the past been very much in favour of blood donations by prisoners"." Signed HS1A.

D. On 23rd August 1983 Dr Brookes reported to Dr Cash from the Working Party on the Selection of Donors/Notes on Transfusion shared by Dr Entwhistle that in England and Wales "these sessions had already stopped".

This cannot be so since HSIA 2727 on the same day, August 23rd 1983, is at variance and contradicts the statement from the Donor Selection Working Party where HSIA was "seeking Home Office Advice".

It was further reported in the same Scottish RDT Minute of 13th September 1983 at which my notes on the NBTS 188th meeting of 18th May 1983 was discussed. It was noted that the NBTS Directors were due to discuss the matter and the DHSS would wish to consult the Home Office who had been anxious previously to encourage donations in prisons. This part of my statement covers in some detail my comments on the Red Book. So far as I am aware, by the end of 1983 no response was received from DHSS and I decided to go ahead with plans to abandon prison sessions, which by that time had already been scheduled for the early part of 1984.

There is also an SHHD memorandum from G Murray to Mr Clive Wooler of 22nd November 1983 and subsequent correspondence concerning Medicines Inspectorate discussions up until the end of December 1983, where no reference is made to penal institutions.

Paragraph 16

(16) The minutes of the meeting of the SNBTS Directors on 8 December 1983 (SNF.001.0178) record that Glasgow and West of Scotland BTS was the only Scottish region to continue holding donor sessions in prisons. Why did Glasgow and West of Scotland BTS continue to hold donor sessions in prisons at that time? In which prisons were sessions held? When and why did Glasgow and West of Scotland BTS stop holding donor sessions in prisons?

The Glasgow Regional Transfusion Centre's last young offenders visit was in March 1984 as I have already stated. By the time of the Regional Transfusion Centre meeting on 13 September 1983, the results of Non-A Non-B testing of donations using data of Dr Dow and Dr Follett were being considered, although the early tests were non specific. As I already stated, information about the AIDS virus was becoming pressing and its mode of transmission, including blood and body fluids, was considered as a major portal of entry considering that people's lifestyles were changing, and that it might also be seen in other groups of society. For these reasons the decision to abandon prison sessions was taken and prison governors were contracted personally. They were all most disappointed to accept this and I attended the last session and met the governor of Glenochil Institution in March 1984.

Donors with a history of jaundice or hepatitis

Paragraph 17

(17) 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.

The tests recommended by Dr Maycock's advisory group in 1975 were based on tests known to give inaccurate results and, not until better tests were developed, such as discussed earlier, did the Scottish Directors feel confident in advising universal screening.

Paragraphs 18 and 19

(18) 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.

(19) 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.

The question of exclusion of donors at a higher risk of transmitting Non-A Non-B Hepatitis was given consideration by the SNBTS during the period 1975 to 1991. It was discussed many times, and acted upon, as testing for markers of Hepatitis B and C began to evolve. Donors with a history of jaundice were noted at the time of volunteering, using the volunteer donor questionnaire given to each prospective donor. Any with a history of Hepatitis would be excluded at that time. All donors, including those self certified as being healthy, were seen by a medical officer on duty at the session. If they gave a history of jaundice at any time the donor was questioned more carefully and the session questionnaire completed to reflect such additional information as was given to medical officers. If the medical officer was unsure of the cause of the donor's jaundice then this would be noted on the donor's records and sent with the donation to the Regional Centre where appropriate tests would be conducted, always subject to limited availability of tests, non

specificity, lack of sensitivity and lack of ability to undertake mass screening within the resources available. This meant in the early stages, when resources were stretched, selective testing of donations and sometimes testing of pools of 8 or 10 donors, with re-testing of individuals found to give doubtful reactions. Such donations would, of course, not be bankable.

Paragraph 20

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

Directors and staff at the Regional Transfusion Centres met regularly to discuss progress, although no two Regions were the same in their capacity to collect and test donors. In the West of Scotland for example, there were large conurbations of people and industry, and in more remote areas, different socio economic groups. Donor questionnaires and donor publicity were generally agreed nationally and printing of the necessary documentation was carried out locally by a Regional Transfusion Donor Organiser and their staff making sure that they conformed to national guidelines. On the whole, progress was as I have indicated, with Regional Transfusion Centres implementing the test or tests available at the time, subject to resources or manpower and testing materials, such that, by early 1980's, all Regional Transfusion Centres in Scotland were testing by tried and reliable methods.

Paragraph 21

(21) 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.

Excluding all donors with a confirmed, or suspect, virus carriage by reason of jaundice or Hepatitis would have an adverse effect on recruitment and retention of volunteers in the West of Scotland and elsewhere. I have already indicated some of the problems earlier in this statement, especially the long public holidays, permanent factory closures, ship yard and steel factory closures and the withdrawal of the American Navy from Holy Loch. I recall speaking with the Glasgow Director of Industry in his office, asking that donors made redundant or retired by factory closures should, if possible, despite their immediate problems, be remembered as blood donors, and that the Blood Transfusion Service still needed them, although the factory work session was closed and they might have difficulty finding a suitable session near and convenient to their homes. Since all donations which were 'doubtful' were not bankable, it is unlikely that any suspect donations would be issued for clinical use to avoid any form of transmission. Where blood components such as platelets, with a shelf life of 3-5 days, were needed, or other short life products, these donations were given priority and tested on the day or earliest possible time, to exclude any likelihood of Hepatitis transmission from very fresh blood or blood platelets. Because of the lower positivity rate in the tests among female donors I recall at one time it was suggested that all of selected blood be obtained from only female blood donors! A history of previous donations being involved in any clinical case of jaundice always meant donor exclusion. Testing of donations by the tests which were gradually developed, evolved from having little effect, to probable avoidance of post-transfusion Hepatitis. The number of patients would be variable because of the difficulty in reporting by hospital and other sources as subsequently found in look back and look forward programmes. With the advent of interferon treatment, such look back studies were attempted but these were difficult to undertake. During shortages of blood, apart from efforts to obtain additional donations, it was not unknown for me to have to issue at every major holiday and festive holiday in the West of Scotland, cautionary letters to Haematologists, indicating that blood supplies were limited and, on occasions, could fall to as low as a 2-3 day supply. At that time it might have been necessary to introduce a rationing system whereby Haematologists were given a selection of donations, some relatively fresh, some moderately fresh, and others near their normal life expectancy time. Haematologists then had to decide their priorities, including scheduled and emergency surgery, and minimise, wherever possible, the use of blood and/or packed red cells

and blood products. It was always taught that blood is a dangerous drug and should be used only where absolutely necessary.

In 1955, under a Ministry of Defence project, a large drying plant for the manufacture of freeze dried human plasma was opened at the Law Centre in the West of Scotland. This was a very substantial undertaking and continued making various types of dried plasma until the Unit was closed on 31 December 1982. Throughout this time dried plasma was made from pools of 10 donations yielding 3-4 bottles of dried plasma so as to minimise the size of the donation pool, and any risk of disease transmission. Any plasma produced was of course stored for a minimum of 6 months before use in order to ascertain if any donor pool had been implicated in any case of notified post transfusion Hepatitis. Thereafter, bottles of plasma were issued on a first in first out basis (FIFO), and each bottle had an information label about the use and the need to report any untoward reaction about the product, including the phenomenon of Hepatitis. As well as time expired freeze dried plasma, additional supplies of freeze dried fresh plasma were prepared using fresh donations. Collection of such raw plasma was time determined and, for this reason, a large mobile laboratory was introduced so as to minimise the delay between the donor and the separation and freezing of plasma. Similar arrangements were made for the production of cryoprecipitate from single donor and small donor pools of fresh plasma. Because of clinical need for rapid volume expansion in cases of major accident, the region had to set a balance between supplying plasma to the drying plant and the developing Protein Fractitionation Centre at Edinburgh. This became more evident as the need for potent coagulation product self sufficiency was adopted. As methods of viral deactivation were being developed at the Protein Fractitionation Centre, increasing demands for plasma were achieved by stratagems including:-

1. Increasing the issue of concentrated red cells;

2. Maximally plasma reduced red cells with the addition of diluent to restore the total volume for clinical use;

3. The use of new anti coagulants to increase the shelf life of donations from 3 weeks to 4 or 5 weeks;

4. The introduction of clinical use of plasma volume substitutes in addition to PFC albumins;

5. The additional increments in the number of plasmapheresis donors and increase return frequency of donor attendances;

6. Increasing the frequency of ordinary donations by more frequent call up of regular donors from 6 months to 3 months; and

7. Extending the age limits from 17 years to 70 years of age.

8. Introduction of a red cell clearing house system.

As prison sessions stopped efforts were made to publicise the need for donors but these were not very fruitful, despite the additional costs involved. Nevertheless, for these reasons, donor numbers were generally kept up, but throughout the 1970's and 1980's additional blood mobiles were deployed, one in 1973, one in 1977 and one in 1982. The attached graph shows the overall additional donor intake over this period and the high value of the blood mobiles. I recall on one occasion, together with Miss Morag Corrie and others, visiting a transfusion centre in the Netherlands where there was massive use of plasmapheresis donors for the production of large amounts of cryoprecipitate and fresh frozen plasma. Some of these donors were donating every 3-4 weeks and could quickly earn over more than 1,000 credits. Scotland did not go so far as this, but increasing demand in Scotland meant that some donors were contributing at a very high level. One advantage of holding on to the drying plant whilst the PFC was endeavouring to make concentrated products available from large donor pools was, for example, dealing with the Lockerbie disaster, where 1,000 units of dried plasma were despatched from the Law BTS

immediately to supply the Dumfries laboratory. In other Regional Disasters stocks could be available at short notice.

Supplementary Comments

The number of penal institutions throughout Scotland varies. The West, having the largest population, has the most institutions. It supplies about 50% of all the donations collected in Scotland. The region has about 30 major hospitals, 3 private hospitals and 6 area Health Boards. Each area associated hospital is supplied on a clinical need basis, though at one time it was suggested that Boards should be charged individually for services. Penal institution donors were encouraged for a variety of reasons as well as availability, such as the sense of contributing to society; the restoration of personal worth and rehabilitation and release.

The service was not seen to be class, ethically or geographically conscious and did not have donors of first and second class, wanted and unwanted. I have known donors insist that they have a right to donate. Even in prisons, prison staff were included in the donation register and every donor was considered a volunteer before, during and after a custodial sentence, and not to be thrown to the winds on release. No element of personal gain was evident, except that perhaps of doing some good.

It was only subsequently that donors' previous and present lifestyles began to challenge these requirements at different times throughout the world. Discontinuing of any donor had engendered feelings of rejection and anxiety for perhaps perceived wrong doing, which in many cases was unfounded and spurious. Such problems were not confined only to penal institution members. I recall great anxiety among submariners, military establishments, life actuaries, life insurance companies, mortgage companies, sports foundations and almost every other walk of life where volunteer donating of blood is considered. Laboratory tests became more widespread and reliable, senior, RTC staff were able to provide explanations and help in the management of HBsAg positive individuals, whilst at the same time trying to persuade the healthy in society to take their place as regular donors. It can be truly said that there is still no substitute for human blood and it is still the best treatment for hemorrhagic shock in the 21st century. In saying this all teachers in blood transfusion departments have always taught blood is a dangerous drug which should always be used with caution although so much effort goes into keeping it safe and wholesome.

It is to be noted that whenever press comments appeared concerning HBsAg, HCV and HIV there would be a commensurate sudden appearance of "donors" over the following few days in an effort to obtain free tests, since some were reluctant to go to their own general practitioners or other sources of such information. It was even known for donors to travel between regions in order to check results from their initial tests. They would even offer to pay for tests and might even impersonate others. The service had to remain constantly vigilant.