Chapter 4

REFECTIONS ON THE SNBTS APPROACH TO SELF SUFFICIENCY

4.01 Introduction

4.011 I am aware that SNBTS has already lodged a briefing paper on self sufficiency with the Inquiry Team. I commend this authoritative paper to the Team. The comments in this Narrative will seek only to expand on certain management aspects of this topic.

4.02 The Definition(s) of Self Sufficiency

4.021 There is no doubt this topic deserves some attention because by the mid 1980s the definition originally used by DHSS was substantially different from SHHD, and these differences gave rise to tensions between the Departments, which ultimately effected the work of the SNBTS and led to tragic consequences for haemophilia patients in England and Wales.

4.022 On the 15 December 1980 Martin Flannery MP, in an Adjournment Debate in the House of Commons on the Blood Transfusion Service, drew to the attention of the Under Secretary of State for Health and Social Security (Sir George Young – currently Leader of the House of Commons) the dangers of the fragmented and uncoordinated management of the NBTS, the long standing under investment in plasma collection and fractionation in the UK, the escalation in demand for plasma products (notably factor VIII for modern haemophilia care) and how this was increasingly being met by the purchase of commercial products, which carried a higher risk of transmitting viruses than those supplied by the NHS (C4-1). Sir George advised the House that, among other things, DHSS was 'working with Scotland to establish the extent to which the Scottish fractionation plant could contribute to the needs of other parts of the UK'; that it would be 'several years' before the appropriate redevelopment of the BPL facility was completed; and that the principle of self sufficiency (as defined by WHO) 'is one that the Government fully endorsed.....though it must inevitably be a long term aim'. But Sir George added self sufficiency may not be affordable and that the NBTS might never be able to supply sufficient plasma needed for self sufficiency. With regard to the fragmented management of the NBTS – no action would be taken. This would remain in the hands of RHAs and DHSS would not issue guidance on this aspect of service provision. Sir George closed by stating that the NBTS 'plays a vital role in the NHS – a role that the Government will continue to support'

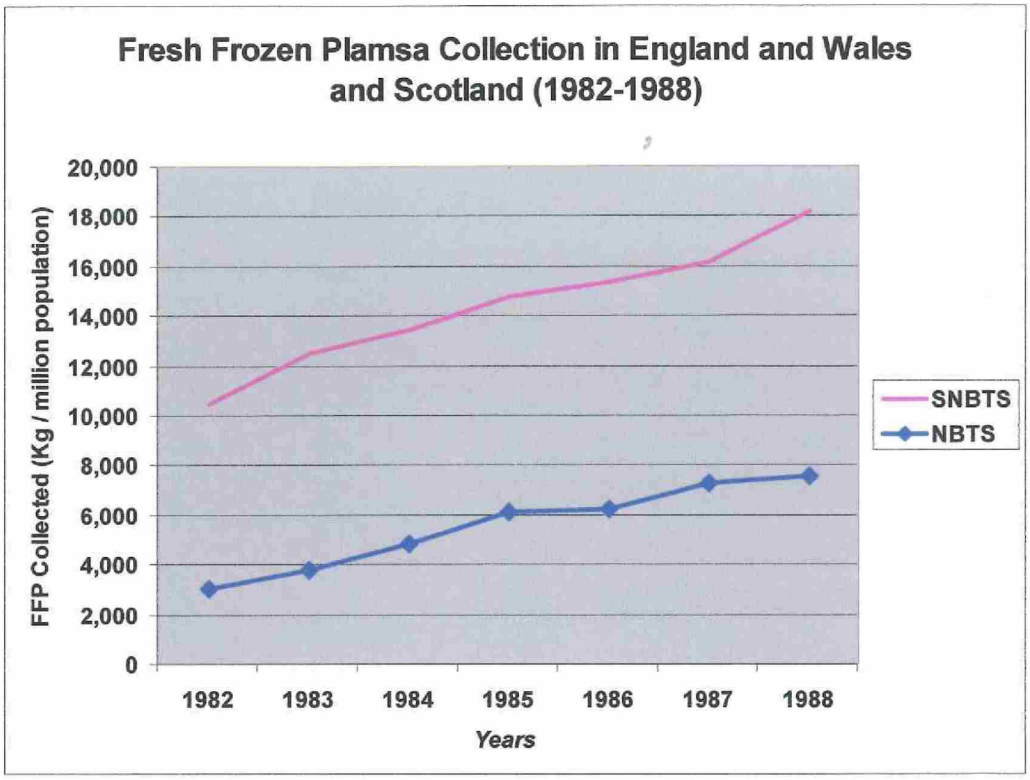
4.023 This Ministerial statement must have been drafted by a team of civil servants who were fully briefed on the potential hazards of commercial coagulation factor

concentrates, and, since 1975, had sufficient evidence on what was required in the UK to begin developing a programme of self sufficiency (C2-18a). It seems probable that this civil service team included Dr E Harris (DHSS, DCMO) with whom the SNBTS was to have close contact (see 3.03 and 3.05), Dr D Walford (DHSS PSMO), Dr J Holgate (DHSS, PMO) who was a key DHSS representative on the CSM and influenced NIBSC activities, Dr G Calder (DHSS, DCP) who was to be appointed SHHD Chief Pharmacist in 1983 and Mr G Hart (Asst Sec., DHSS, Supplies Division and later to become Secretary SHHD in 1990 and Perm. Sec., DHSS in 1992). In June 1980, some months before Sir George Young's statement, a letter in the British Medical Journal by Dr Peter Jones (Haemophilia Centre Director, Newcastle upon Tyne) described in some detail the potential dangers of imported coagulation factor concentrates and the grave state of the blood transfusion services in the UK, which he advised had been described at a recent meeting of ABRA (an organisation representing the US plasma fractionation industry) 'as a disgrace to be included in a fourth world' (C4-1a). In September 1981 a group of UK Haemophilia Directors concluded that the increased risk of symptomatic hepatitis was between 4-20 times higher when commercial concentrates were used (C4-1b).

4.023 In mid the 1980s, following several conversations with Dr Gunson, I concluded that the DHSS's definition of self sufficiency had been modified significantly and, in a letter to the Haemophilia Society in October 1990, this was confirmed by the CMO (Sir Donald Acherson) (C4-2). It seemed clear that the moral imperative for self sufficiency had been shifted to the prescribing physician. Government was now doing something they had denied throughout the 1980s – deliberately limiting the NHS supply in England and Wales and promoting a market place in which the purchase of commercial sources of coagulation factor concentrates would be encouraged. This development was a cause of some concern in certain NHS quarters (C4-3 and C4-4 and C4-4a) and rejoicing in others (C4-5). What I recall was of a particular concern to me was that I was unaware of any efforts by the HCDs in England and Wales or the UK Haemophilia Society, in the early 1980s, to put pressure on HMG to address the serious difficulties the NHS coagulation concentrate suppliers were in - despite the fact that HCDs were in close contact with DHSS officials (C4-4b). I was later to recall concluding that the decisions in 1980 by Sir George Young's team to reject the creation of an integrated NBTS which was no longer managed and funded by RHAs, and the signal from DHSS to RHAs in August 1981 that there would be no extra funding to support increase plasma collection programmes (C3-13) determined the fate of many haemophilia patients in England and Wales. This did not apply to Scotland. By December 1980 'the horse had bolted'; in terms of plasma supply, fractionation capacity and forecasts of future demand, the SNBTS was already on course for self sufficiency.

4.024 The differences in performance between the SNBTS and NBTS were substantial and a source of concern in both DHSS and SHHD. The plasma collection data are shown in figure 1..

Figure 1



4.03 Some Operational Attitudes of the SNBTS

4.031 In the 1980/90s the SNBTS, though centrally funded, saw itself primarily as a confederation of local organisations responsible for supporting a unique bridge between sick and well (donor) in different communities. Moreover, we believed our Centres were an integral part of the local NHS – no different to hospital X-ray departments or hospital laboratories; responding to the needs of local clinicians and not charging for products destined for the NHS. Because of the position taken by SHHD and associated Scottish Ministers, the SNBTS never saw itself, unlike the NBTS, competing in a market place against commercial suppliers. Finally, the SNBTS saw no difference in its moral responsibility to provide for the patient requiring 2 units of blood for a simple hip operation, or 100 units of blood for a liver transplant or the continuing factor VIII needs of a haemophilia patient. Whatever it took, which included giving much consternation to hard pressed politicians and civil servants, the SNBTS sought to place first its obligations to both parts of the communities it served. In this regard, we had some reason to believe in 1980 that the majority of UK HCDs preferred coagulation factor concentrates derived from unpaid donors. It followed that, unlike the NBTS, the SNBTS sought and were able to respond to these clinical preferences.

4.032 There have been those who believed that, with regard to self sufficiency, there was some sort of step change in the late 1970s. For the SNBTS this was not so. In the 1960s our successors learnt to work closely with clinical colleagues and SHHD officials, and in so doing ensured that sufficient Anti-D immunoglobulin was available from local donors for all Rhesus negative pregnant women in Scotland, thereby virtually eliminating haemolytic disease of the new born. In the 1970s the dangers of virus contamination of freeze dried plasma were recognised and major investments were made (the creation of PFC) to produce virus inactivated large pooled alternative products (albumin). It followed that by the time I was appointed NMD in 1979 the SNBTS had already set in place the earliest beginnings of a programme for self sufficiency – but this time with reference to coagulation factor concentrates. This time it was particularly serious because, unlike albumins solutions and immunoglobulin preparations the commercial option for haemophilia patients was considered to be 'high risk'.

4.033 Viewed from another perspective, however, there were indeed major changes in the late 1970s: the arrival of technology that delivered pooled coagulation factor concentrates which as yet could not be subjected to virus inactivation processes. Thus there was an escalation in clinical demand which was so great that many sister national blood transfusion services were severely challenged, as were prescribing physicians when they sought to balance patient benefit against harm. In many respects, perhaps because it happened in a country which had so publicly promoted the gift relationship and claimed it was enshrined within its national blood transfusion service (C2-3), the most painful of those challenged was the NBTS. During the 1970s, the NBTS had not, as the Scots had done, invested in much needed new infrastructures and practices, and thus by the late 1970s it was apparent that the NBTS was about to be overwhelmed by the escalating demands of haemophilia care. Thus, supported by Ministers and DHSS officials, the NBTS walked away, leaving more than 50% of its duty of care to haemophilia patients to those who had concentrates in abundance but which were known to be more frequently contaminated with potentially lethal viruses.

4.034 Finally, it should be emphasised that the SNBTS did not define self sufficiency as meeting all plasma product demands. We did not have sufficient research or regulatory services capacity to meet that sort of challenge. However, in the 1990s we included in our self sufficiency portfolio: albumin preparations, intramuscular immunoglobulin preparations, virus safe coagulation factor concentrates, intravenous immunoglobulin preparations and fibrin glue in sufficient quantities to meet SHS needs. This portfolio must have represented approximately 95% of the combined range of products available from all commercial sources.

4.04 The Paid Donor

4.041 There can be no doubt that some commercial fractionators found it difficult to accept the work and predictions of Allen, with respect to the dangers of paid donors (C2-16) and preferred to hold to the now infamous claims of the FDA in 1978: 'no available data demonstrated that final plasma derived products from volunteer donor plasma carry a lower risk of transmitting hepatitis to recipients than do similar products manufactured

from paid donors' (C4-6). These fraudulent claims were still espoused by the corporate body representing the interests of the US commercial plasma fractionators in 1991 (C4-7), despite the publication in 1990 of direct (PCR) evidence of a higher virus (HCV) load in products and plasma pools derived from paid donors versus unpaid donors (C4-8 and C4-9). However, there was also evidence that the occasional factor VIII concentrates derived from paid donor plasma might have no evidence of HCV contamination (C4-10). This was an important observation for it demonstrated that there were populations of paid donors where the prevalence of viral infections was no different from unpaid donors. Thus the proposals outlined in 3.172 would have been worth the CSM's consideration.

4.042 A contributory factor to the heat of this debate may have been that the WHO and EU consistently failed to address the fact that unlike the UK some countries (for instance Sweden, Spain, Italy and Luxenbourg) made payments, in some form, to voluntary blood and /or plasma donors (C4-10a).

4.043 There is no doubt that in many ways the EU (Directive 89/381) did much to promote the value of the unpaid donor (C4-12a) and by 1994 this influenced the attitudes of major US commercial players in this field (C4-13) and the development of significant improvements in the quality of paid donor plasma (C4-14), which could have been on offer had it been pursued by the CSM many years before.

4.05 Plasma Pool Size

4.051 Ever since the pioneering studies of Allen (C2-16), batch pool size (the number of different donors) has been an issue with regard to infectivity of plasma products. In the context of yield and therefore profitability, managers of commercial fractionation facilities have looked to increase pool size. For those not concerned with profit but with restrictions on plasma availability in a self sufficiency scenario there also existed a pressing desire to maximise yields. Thus there has been much debate over the years on the right balance between safety and 'viability' with regard to pool size.

4.052 There was a view in the early 1980s, among some UK Haemophilia Centre Directors, that when the fractionation pool size for NHS products was larger than 3500 donors per batch then the acknowledged benefit conferred on products from unpaid donors (with regard to infectivity) might be lost (C4-11). Subsequent HCV contamination studies (C4-8 and C4-9) did not support this view and HIV studies have revealed that the actual virus load is an important feature of infectivity (C4-12). Conversely, commentators had suggested that very low levels on viral contamination of products may induce some degree of immunity (C4-12b). On the other hand large pool sizes increased the opportunity of batch contamination by more than one virus, which the experience in the Edinburgh dialysis hepatitis outbreak had suggested was potentially very dangerous (C2-1).

4.053 It has always been my understanding that PFC pool sizes for coagulation factor concentrates, throughout the 1980s and 1990s, erred strongly in favour of safety and yet our yield remained acceptable. I am advised that PFC pools sizes from 1975-1981 never exceeded 300 litres (1500 donors) and from 1981-1991 never exceeded 1000 litres (5000 donors). This compares with maximum pool sizes of 7200 donors during 1985 for BPL (C4-15) and 20,000 donors for a commercial plasma fractionation facility in 1990 (C4-16).

4.054 On a number of occasions in the 1980s, in conversation with MCA Inspectors, I raised the issue of whether it would be possible for the CSM to specify maximum pool size for imported coagulation factor concentrates, when issuing a Product Licence. On every occasion I was advised that my suggestion was 'too political' and would not be allowed to reach the CSM's Biological Subcommittee agenda.

4.06 Good Manufacturing Practice Standards

4.061 All the evidence available points to the fact that despite the efforts of SHHD officials (following the announcement that Crown Immunity applied to the SNBTS) to prevent interactions between MCA Inspectors and PFC staff, unofficial professional communications were maintained. Thus, while our commercial rivals throughout the 1980s advised their customers that NHS products were being produced in substandard facilities, PFC managers sought to ensure, by applying for Product Licences (against the wishes of SHHD) that, although MCA Inspectors considered that the manufacturing environment at PFC was unacceptable, the safety and efficacy of their products had been subject to some sort of external peer review.

4.062 There is no doubt that the UK clinical teams never seemed to consider the quality of the regulatory control on US derived products which were purchased in the 1980s. It has never been clear to me to what extent MCA Inspectors, during this period, were involved in the processes of inspecting both US plasma collection and fractionation facilities which led to the granting of by CSM of Manufacturing and Product Licences. What seems certain is that the MCA ignored the Council of Europe Committee of Ministers 1981 recommendation on regulatory requirements for imported plasma products (C3-132). Indeed I have reason to believe that UK prescribed commercial products derived from plasma sourced by international plasma brokers was never subject to any form of regulation. Certainly, there is good evidence that the regulatory activity of MCA's counterparts in the US at this time (the FDA) was seriously flawed (C2-16a). As a consequence the commercial US fractionators were operating in a regulatory vacuum; there was little or no regulatory control over donor selection, the quality of donation testing and the critical IT support needed for these functions. Many of these facts were known to the Committee on Safety of Medicines. I have often concluded that throughout the 1980s, despite the potentially deleterious effect of Crown Immunity, the quality of good manufacturing practice across the UK BTS, with respect to plasma collection, donation testing and fractionation, was considerably higher in the UK than in the US. If that judgement is correct then in Scotland this largely came about because of the level of the commitment of RTDs, PFC and some MCA staff, and was despite the activities of DHSS and SHHD. Moreover, it can be argued that the known dangers of US derived

plasma products did not solely depend on the use of paid donors and large pool sizes. Substantial improvements in safety could have been delivered if the CSM/MCA had become engaged in the regulation of the quality of plasma collection and donation testing. This was not done.

4.063 There is no doubt that the claim made to prescribing physicians by the providers of commercial plasma products in the UK throughout the 1980s that the NHS providers were manufacturing in facilities which contravened the Medicines Act (1968) were correct. In February 1991 the Minister (Stephen Dorrel) misleading sought to explain this position by claiming that this was because of Crown Immunity (C4-17). In fact Crown Immunity was invoked by Ministers because they were not prepared to invest in fractionation facilities that met the requirements of the Medicines Act (1968). This position did no change until external (European) pressure developed - the issue of the EU Directive 89/381 (see 4.10). This Directive led to the abolition of Crown Immunity and to Ministers now demanding that NHS manufacturers of plasma products performed under the full authority of the Medicines Act (1968).

4.07 Miscellaneous SNBTS Contributions to Enhancing Transfusion Safety

4.071 Aside from its unique work with NIBSC (see Chapter 3.11) the SNBTS developed several other programmes which I believe led to improved transfusion safety.

4.072 **National Medical Register** On a number of occasions in the 1980s we became aware that known high risk donors were donating in one region and then donating in another, in order to get their infectivity status (usually HIV) further checked. This became of such concern that we developed what was called The Medical Register – when a high risk donor was detected their details was placed in a confidential national register and systems were introduced in which access to this information was available at all SNBTS donor sessions (C4-18). I had reason to believe this was a world first development and of course brought benefit to all receiving blood, blood components and plasma products in Scotland (C4-19).

4.073 **National Serum/Plasma Donation Sample Archive** In 1985 Dr Duncan Pepper (SNBTS, HQ Laboratory) presented a paper to the Directors which promoted the idea of establishing a long term serum/plasma donation sample archive. As I recall, this idea did not become standard practice throughout the SNBTS until 1991 (C4-20), though from 1985 onwards several regional centres maintained local archives (C4-21). These archives proved to be of much assistance during both look back and virology kit testing evaluation programmes.

4.074 **Optimal Use of Blood Initiative** In 1980/81, during the planning of the aborted MRC clinical trials of albumin versus crystalloids (3.063), I became increasingly aware that the way clinicians used red cell transfusions had been developed in World War II and had never been subject to any form of clinical trial. I recall in the early 1980s, at a meeting in Geneva, I arrogantly claimed that I believed (I had no evidence) that 40% of the red cell transfusions in the UK were not indicated. Whilst the ethical demands placed on clinical trials in the 1980s in this area would prohibit their development, it seemed possible that some considerations could be given to examining the way blood was used

which might, in due course, diminish the exposure of patients to the many complications of blood transfusions. I took the view that there was merit in blood transfusion personnel being involved in any such exercise, not least because the outcomes might affect our blood and recovered plasma collection programmes and thus the management of plasma product self sufficiency.

4.075 I have no records of our earliest activities in this area but am aware that in 1988 I drew our interests to the attention of the Dr Ian Macdonald (CMO, Scotland) and note that I had already recruited Dr Brian McClelland (Director SEBTS) to lead and develop this difficult programme (C4-22). By 1992 it was clear that Dr McClelland was making progress (C4-23). This remarkable SNBTS initiative, led by Dr McClelland, has been supported by the EU and I believe has had a significant impact of the safety and availability of blood transfusions practice, worldwide (C4-24).

4.076 **Batch Dedication** In 1983/84, as the SNBTS moved into surplus supplies of factor VIII, we advised the clinical teams that further improvements in safety were now possible, if arrangements were made to reduce the number of batches patients to which individual patients were exposed. As I recall this development was well underway by early 1985.

4.077 **Thrombogenicity of Factor IX Concentrates** In 1974/75 I led a team which began the development of techniques which enabled plasma fractionators to detect and discard those batches of factor IX and II,VII, IX and X concentrates which had the potential to give rise to fatal episodes of thrombosis (C4-24a). These pioneering studies have proved of significant and continuing value in making these concentrates safe, worldwide.

4.08 DDAVP

4.081 In 1973/74 I led a team which discovered that a synthetic antidiuretic peptide, 1-desamino-8-D-arginine-vasopressin (DDAVP), when given intravenously stimulated a release of large quantities of factor VIII in healthy volunteers (C4-25). The question arose would this peptide give rise to a release of factor VIII in patients with mild or moderate haemophilia A. The answer came in 1981 (C4-26) and from that point on DDAVP has played a major role in the management of mild and moderate haemophilia A leading to many patients not requiring factor VIII concentrates at all. DDAVP's contribution to reducing the exposure of mild and moderate haemophilia A patients, worldwide, to HIV and HCV have been claimed to be significant (C4-27).

4.09 Self Sufficiency: 'The Rise and Fall and Rise again from Grace in Scotland'

4.091 There is no doubt that the SNBTS paper on self sufficiency accurately records the remarkable outcomes of the service's drive towards self sufficiency in the 1980s and its temporary 'fall from grace' in the early 1990s. The author rightly emphasises that the major operational factors in this programme were the long range predictions of need and the performances of PFC (fractionation) and RTCs (plasma collection). I am not

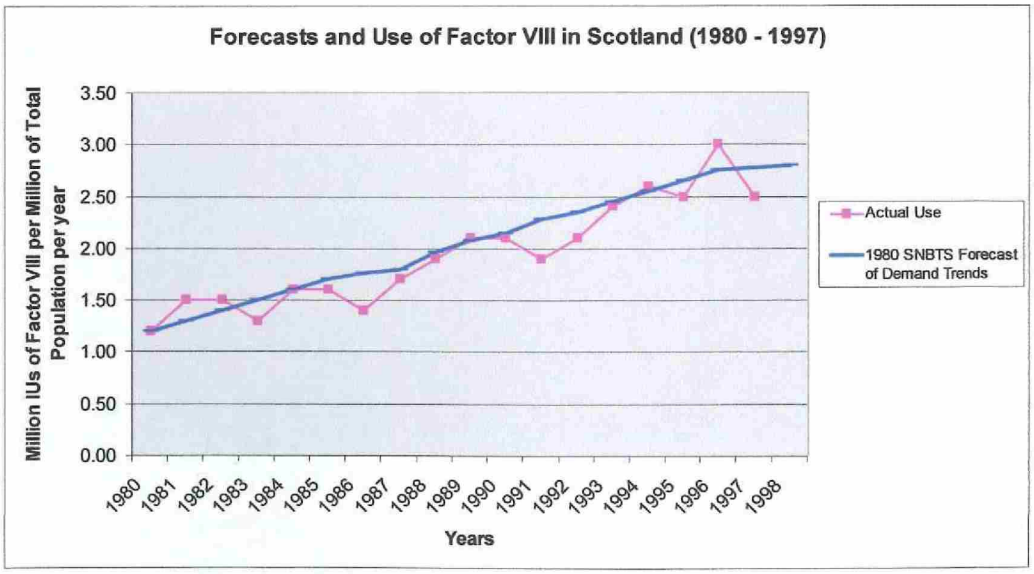
qualified to add much to the excellent review of the challenges and triumphs of PFC and BPL but believe it may of value to provide some more detail on other activities.

4.092 **Predictions of demand** Reference has already been made to the early difficulties we had in obtaining accurate information on the purchase of commercial plasma products for haemophilia care (3.072). The actual effect of this problem on predictions of demand should not be exaggerated, not least because the quantities of commercial coagulation factor concentrates used in Scotland were relatively small. At most it produced an anxious wobble in the mutual trust between SHHD, SNBTS and SHS HCDs However, when in the late 1980s we began to obtain information from hospital pharmacies it was revealed that albumin preparations had been purchased, at significant cost to Health Boards, when there were more than adequate stocks in PFC.

4.093 The original predictions of demand for factor VIII in Scotland were made (by me) in 1980. They arose from extensive consultations with many UK and international HCDs. The results were forwarded to the CSA and subsequently considered by the CSA's BTS subcommittee. I recall the derision of Dr Graham Scott (DCMO, SHHD) when commenting on these predictions at the BTS subcommittee! He declared they were 'gross exaggerations', well beyond DHSS estimates and advised extreme caution with regard to supporting future SNBTS planning.

4.94 The reaction of the SHS HCDs was cautiously supportive, and, in the event and much to my surprise, our 1980 planning predictions came close to reality (see Figure 2).

FIGURE 2



4.095 In hindsight, I believe it is possible that the reactions of Dr Scott in 1980 contributed much to the sustained rejection by SHHD of our requests for modest funding in the early 1980s to increase our harvest of recovered plasma, using Optimal Additive Solutions (OAS) and the commencement of a modest programme of plasmapheresis. (C4-27a and C4-27b). This rejection was the major cause for our 'fall from grace' in

1988/89 – we ran out of sufficient plasma to cope with the increasing clinical demand, and the anticipated fall in fractionation yields as we moved to introduce a high purity VIII concentrate. This was not understood by SHHD (C4-28, C4-28a) and the consequences for the SHS Health Boards and patients were significant (C4-28b). The SNBTS briefing paper (and Figure 1 above) show that soon after this crisis our plasma collections increased substantially after SHHD had released funding to permit the introduction of OAS and plasmapheresis. We rapidly returned to 'Grace'. PIG TAIL 1975.

4.096 **Kick Starting Self Sufficiency in Scotland in 1975** The beginnings of the SNBTS programme for self sufficiency go back to the days when our predecessors planned the investment for PFC. But this investment could not have been realised without the development of a major plasma collection programme in Scotland from the existing ordinary blood collections (recovered plasma). This recovered plasma programme had its origins in Edinburgh and Inverness after I met Dr Ian Cooke the Director of the Inverness Centre in late 1974. I recounted what I had seen in the San Francisco General Hospital in 1969 (2.33e) – the use of plasma depleted red cells –and how I believed it opened up an opportunity to access massive quantities of recovered plasma (210ml from each donation). I advised Dr Cook that we had obtained the support of three senior anaesthetists in the Royal Infirmary Edinburgh (Drs Griffiths, Masson, and Professor Robertson) to promote the use of plasma depleted red cells for routine use, in preference to whole blood.

4.097 Soon after I was appointed NMD in 1979, I persuade colleagues in the other SNBTS Centres on the Inverness/Edinburgh approach. This required considerable local liaison with clinicians and we were greatly helped by the three Edinburgh anaesthetists who promoted our cause through the Scottish Society of Anaesthetists. By 1982 more than 60% of all blood donations in Scotland were subject to recovered plasma extraction and we were approaching self sufficiency in factor VIII concentrates (C4-32).

4.098 No account of the Inverness/Edinburgh kick start in the mid 1970s would be complete without reference to the pigtail blood bag. The pigtail system was invented in the Edinburgh Centre and was designed to create a bag configuration which allowed us to abandon the high cost multiple closed blood bag system and transfer to a very low cost option. Although the pigtail bag system was conceived and designed in the Edinburgh Centre it was initially made by Fenwal UK – a division of a large US corporation which had more than 70% of the world market for plastic blood bags. Fenwal UK invited Dr Jenkins, Director of the Brentwood RTC to evaluate their new product and he proved to be an enthusiastic supporter. Within less than 6 months of the project starting Fenwal pulled out and were replaced by an Australian company – Tuta (C4-31).

4.097 Our pigtail blood bag system enjoyed support outside the UK (C4-33 C4-33a) at the 1978 International Society of Blood Transfusion Congress (C4-33b). None the less, despite the fact that we had calculated that if introduced throughout the UK it would generate savings in excess of £1million per annum (C4-33b), it did not survive. The reasons for this were controversial (C4-33c). Fenwal (Mr Joe O'Sullivan, UK General Manager and Dr Jenkins, RTD, Brentwood) insisted that DHSS had ordered the company to stop their pigtail bag development. On the other hand, DHSS officials insisted it was a marketing decision made by Fenwal in the US. There is no doubt that SHHD officials

made numerous efforts, by communicating with DHSS colleagues (Dr. E Harris and Dr J Holgate) (C4-34), to modify DHSS's hostility to the pigtail system (which was not shared by the MCA Inspectors). In the event the demise of the pigtail blood bag system was viewed in some quarters as a win/win for Fenwall and DHSS; the former had its profits protected and the latter avoided the embarrassment of dealing with a situation in which there was an Australian low cost blood bag system option for a precipitous increase in NBTS fresh plasma for fractionation. This must be seen as a critical error of judgement by DHSS officials. It was to have a significant impact on patients in England and Wales throughout the 1980s. This was not so in Scotland; SHHD, knowing that SNBTS could generate sufficient recovered plasma to deliver self sufficiency, targeted increased SNBTS funding to cover the transfer out of the pig tail system, which had been 'demanded' by DHSS.

4.098 **High Purity Factor VIII Concentrates** In the late 1980s many clinical teams world wide were persuaded by commercial providers of factor VIII that there would be much advantage in transferring to using high purity factor VIII concentrates, on the basis that such preparations would diminish the degree of immune down regulation in haemophilacs and that this would be of particular benefit to those who had already acquired HIV. It is not my intention to explore this topic in depth, save to say that I am advised that the concerns expressed by SNBTS commentators on this development at the time (C4-28c) may now be shared by others. Suffice it to say that the SNBTS was propelled into delivering a high purity VIII by the market place and this was supported by SHHD. This was achieved by working closely with the CNTS in Lille. As I recall because of an exchange in technology between PFC and CNTS Lille, there was no requirement for either party to purchase intellectual property (C4-29). This did not apply to BPL who licensed the technology from a commercial fractionation company, at a very considerable annual cost to the NHS.

4.099 **European Plasma Fractionation Association (EPFA)** It is not widely known that the SNBTS was the prime mover in establishing this Association. Members were from the non-profit sector and its primary purpose was to provide a mechanism whereby these organisations would have access to EU Ministers in the same way as a similar organisation provided for commercial fractionation interests (C4-30). Of no less importance was the intention that members could look to exchange technology without licensing costs. I am advised that EPFA has, particularly after the issue of the EU Directive 89/381, done much to promote European self sufficiency. For the SNBTS one of its members (CNTS, Lille) did much to assist PFC to introduce a new high yielding/low cost technology for the production of high purity factor VIII.

4.10 Impact of EU Directive 89/381

4.101 It is of interest that many senior Blood Transfusion Service colleagues in Europe were invited by their Governments to represent their interests in the development of the 89/381 EU Directive. An exception to this was the UK.

4.102 This lack of consultation was discussed on many occasions by Dr Gunson and myself, and we came to the conclusion, after consultation with European colleagues, that the central problem for the UK government was that it was known that the emerging

Directive would address the issues raised by the WHO in 1975, with regard to self sufficiency and the relative safety of an unpaid plasma source.

4.103 It came as no surprise to ether Dr Gunson or my self that soon after the Directive was released DHSS announced the abandonment of Crown Immunity for the blood transfusion services and the creation of a new authority – the National Blood Authority (NBA). Thus, at long last, the management of the fragmented and dysfunctional blood transfusion services in England and Wales would be unified. At the same time enhanced management arrangements were put in place for the interface between NBTS and BPL.

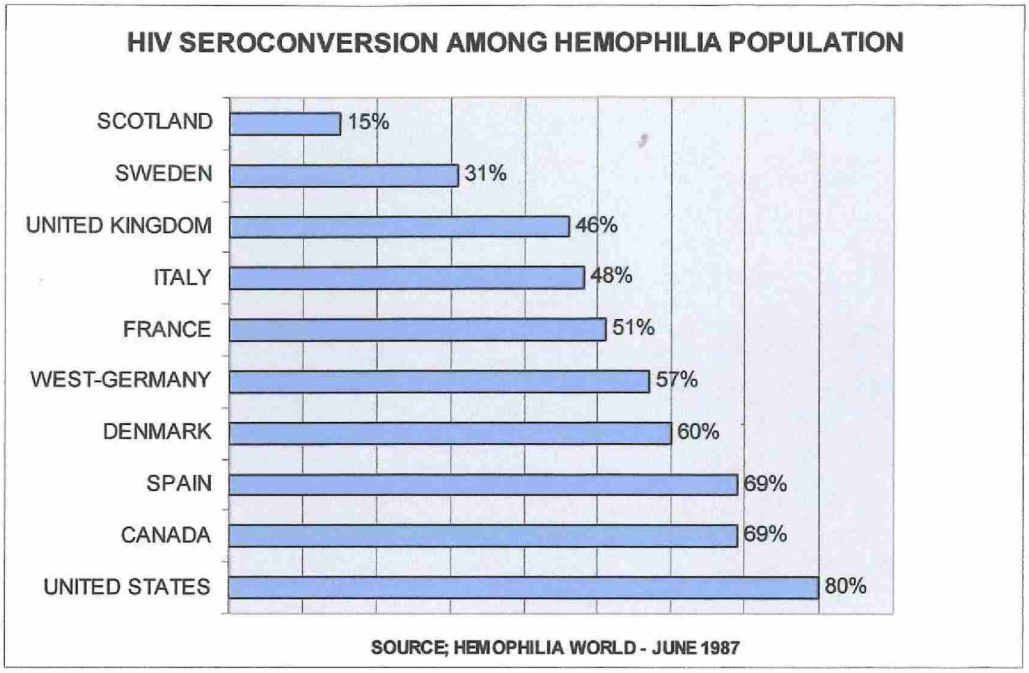
4.104 For the SNBTS the withdrawal of Crown Immunity associated with the release of 89/381 coincided with the release of funding to make good the deficits at PFC which had been identified in 1980. Moreover, funding was now available to meet the request made in 1982 – to introduce Optimal Additive Solutions and plasmapheresis.

4.11 Outcomes

4.111 Many of the outcomes of the SNBTS self sufficiency programme are well summarised in the SNBTS briefing paper. It should be emphasised that these went much further than the supply of coagulations factors for haemophilia patients.

4.112 Clearly, in terms of assisting the healing process after spontaneous bleeds, supporting patients through surgery and contributing to prophylaxis, the SNBTS products for haemophilia patients did the job. Beyond this it is certain that the availability of sufficient SNBTS products also contributed to minimising Scotland's haemophilia patients' exposure to commercial coagulation factor concentrates. During the critical years when the commercial concentrates were particularly dangerous there is some evidence of protection from HIV (C4-35 and see Fig.3). I am only aware of indirect evidence for HCV (C4-8), but it is possible that the UK HCDO's database may reveal more substantive information (C4-8a). (With respect to Figure 3, Professor Pim van Aken has recently advised that the 1987 figure for the Netherlands was 13%)

FIGURE 3



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Chapter 5

REFELECTIONS ON THE INTRODUCTION OF KIT EVALUATIONS AND DONATION TESTING FOR VIRUS MARKERS

5.1 Introduction

5.12 I am aware that briefing papers on these topics have been lodged with the PI Team. The comments below will seek only to expand on certain management aspects of these topics. With regard to all management matters relating to the introduction of virus marker donation testing, SNBTS deferred to SHHD and SHHD to DHSS.

5.13 My interest in validation programmes for kits designed to detect virus markers in blood donations began in 1972 (C5-1).These studies confirmed the work of a WBTS team in the 1970/71 who undertook a multi-centre UK study of the quality of HBsAg testing. The outcomes revealed differences in sensitivity between laboratories and that this was largely explained by the different technologies and standards used (C5-1a). A surprise in the WBTS study was the modest performance of some of the UK's premier PHLS reference laboratories, which was in sharp contrast to the good performance of participating BTS Centres. These studies led to the development of ideas on the need for working standards which in due course led us to NIBSC (3.11), the need for the development of an SNBTS expertise in donation testing kit evaluation (C5-2 and C5-3) and some caution with regard to accepting the professional advice of virologists not engaged in this technically demanding area.

5.14 In 1983 Treasury officials conveyed their concern to SHHD that not all SNBTS Centres were using the BPL (NHS) manufactured RIA kit for HBsAg donation testing. Aside from the fact that this policy position ran contrary to the DHSS policy on plasma products (clinical freedom and the market place) DHSS were not aware that the quality (sensitivity) of the BPL assay was inferior to that available from commercial sources (C5-4). In due course, we believe this episode contributed to DHSS's decision to instruct BPL management to transfer their technology and intellectual property to Wellcome Diagnostics Ltd. This transfer occurred soon after Dr Richard Tedder (working at the Middlesex Hospital) was appointed an external consultant virologist both to PHLS (and there worked closely with Dr Philip Mortimer) and the North London Blood Transfusion Service (working closely with Dr John Barbara). I was later to discover that throughout

much of the 1980s Dr Tedder was contracted to Wellcome Diagnostics with a remit to develop viral marker blood donation testing kits. Dr Gunson advised me that Dr Tedder's association with Wellcome was known to DHSS officials. Dr Diane Walford was an MRC Fellow working in the North London Blood Transfusion Centre in 1976 with a special interest in virology and entered DHSS in 1977. She became DCMO in 1989 and Director of PHLS in 1993. Dr Hilary Pickles (DHSS) did much support work for Dr Jeremy Metters (DCMO, DHSS and Chairman, ACVSB). As I recall, all these individuals influenced DHSS's contributions to the introduction of virus marker blood donation testing in the UK throughout the 1980s. In some instances this gave rise to concern (C5-3a).

5.14 The selection of donation testing kits is dominated by balancing optimal sensitivity (safety of recipients) and specificity (care for donors). Those responsible for maintaining the supplies of blood, blood components and plasma products had a continuing concern both for the disruption in the personal lives of donors and the knock on effect this could have on overall supplies to patients (C5-4a). Moreover, different kits can reveal different populations of donors who are believed to be falsely positive (C5-5). It goes without saying that the SNBTS Directors believed that the provision of sound confirmatory testing programmes (to weed out false positives) was a moral imperative. This view was not shared by many colleagues south of the border, both with regard to HIV and HCV donation testing, though it is possible their views were influenced by funding shortages.

5.2 HBsAg Donation Testing

5.21 The introduction of HBsAg donation testing in the UK in 1972 was not well managed. The technology used between different centres varied greatly in sensitivity and efforts made by the Departments of Health to manage the process were unsophisticated and not evidence based. In retrospect, we would regard the issue of the DHSS CMO's letter in 1975 on prison donations, at a time when the quality of HBsAg testing was being challenged, as unfortunate.

5.3 HIV Donation Testing

5.31 Much of the detail on this topic has been covered elsewhere (see 3.142).

5.32 As expected, after the introduction of HIV donation testing in October 1985 a series of new kits and modification of existing kits emerged. Despite representations through Dr Gunson, I was unable to interest DHSS in the creation of a UK mechanism for kit evaluation – an issue which later led SNBTS to establish, with the support of SHHD, its own facility (C5-4b, C5-4c and C5-4d). Similarly, it appeared in 1985/86 that DHSS had little interest in encouraging high quality confirmatory testing for blood donors. This issue was also taken up by the SNBTS Directors (C5-5) and, with the support of SHHD, we established in 1989 our own Microbiology Reference Centre (C5-4e). These developments were introduced in Scotland to respond to the needs of blood donors and to the instruction the received from Medicines Division that: 'those with product licences

must supply quality assurance and performance evaluation information on the screening procedures currently carried out for antibodies to HIV and for HBsAg' (C3-105). All the evidenced acquired in the 1980s led us to conclude that this critical work should not be contracted out to DHSS/PHLS.

5.33 On 6 September 1988 a meeting (organised by Mr Paton, SHHD) took place in SHHD, attended by CLO representatives, Dr Ludlam, several SHHD officials and myself, to discuss the anticipated legal actions associated with the transmission of HIV from blood/blood products (C5-6). I recall providing a list of areas where I felt the SHS was vulnerable. One of these was the kit evaluation saga. Despite much effort I have not been able to obtain (from either SHHD or CLO) a copy of any Minutes of this meeting, nor my personal notes. Of interest also is that the provision of this list did not change the performance of SHHD officials when the time came to consider HCV donation testing kit evaluation in 1990/91.

5.4 HCV Donation Screening

5.41 As I recall the first attempt SNBTS made to engage with those developing HCV donation screening kits was in the summer of 1988 (C5-7). By June 1989 we had access to Ortho HCV kits and on 2 August our evaluation of this kit began in WBTS (C5-8) and a report lodged in December 1989 (C5-9). Using 2700 random SNBTS donors, the SNBTS team concluded that first generation Ortho HCV Kit had acceptable specificity and sensitivity but there was some evidence of batch variation. SHHD and Dr Gunson were briefed on this evaluation programme (C5-10) and Dr Gunson advised that the NBTS had also undertaken similar studies (C5-10a). In November 1989 I was advised that Ortho had obtained an export permit for their kit (C5-10b) and that they now believed they had a satisfactory confirmatory test (C5-10e). In October 1989 we advised CSA/SHHD that we believed we had a viable option to start HCV donation screening and confirmed it could be commenced sometime between April-June 1990 (C5-10c and C5-10d). I was aware from close Australian and French colleagues that all their centres had commenced HCV donation screening in February 1990 and March, respectively and, as I recall, I informed SHHD of these developments.

5.42 I recollect that SHHD were extremely anxious to learn that, both in England and Scotland, the blood transfusion services had taken the initiative themselves to assess the Ortho test kit. I was reminded by SHHD (Dr MacIntyre) that no further action was possible without the clearance from DHSS. We were further advised that the mechanisms for this clearance, and source of Ministerial advice, would be centred on the work of the newly formed (April 1989) DHSS Advisory Committee on the Viral Safety of Blood (ACVSB). It seemed clear that because our initial studies on the Ortho kit had not been authorised/sponsored by ACVSB that they were in some way invalid.

5.43 In January 1990 I was advised that consideration of HCV donation testing kits by ACVSB had been deferred (C5-10f). Efforts to ascertain why the topic had been deferred were not productive, but Dr Gunson advised that the DHSS expert virologists (Dr Tedder and Dr Mortimer) were greatly concerned that the work already done by UK

BTS staff had been done without their supervision. Dr Gunson also advised that he believed there were other pressures in DHSS directed towards slowing down the introduction of testing. In the meantime, I advised SHHD that HCV donation testing seemed to have been authorised in the USA on 8 February 1990 (C5 -10g), though subsequent information suggested the official FDA authorisation may have been on 2 May 1990 (C5-10h). On 26 June 1990 I briefed SNBTS Directors on the status of HCV donation testing in Europe (C5-10 L). On 15 May we were advised by Ortho that their anticipated confirmatory test system was now on the market (C5-10i).

5.44 The deferred consideration of HCV donation testing by ACVSB took place on 23 April 1990. Despite the fact that members knew that HCV screening had commenced in France, Belgium, Luxembourg, Finland and Australia, and would soon start in the Netherlands they concluded that the scientific evidence base was sufficiently weak to recommend that HCV screening should not be commenced in the UK. I was advised that there were two members (Dr Gunson and Dr Perry) who did not support this conclusion and insisted that there was sufficient evidence to recommend the commencement of screening as soon as possible. Dr Gunson called to brief me soon after the meeting and Dr Perry confirmed the position in a note dated 2 May 1990 (C5-10k).

5.45 On 15 May 1990 Abbott advised it had a first generation HCV donation testing kit available (C5-10j) and I proposed to Dr Mitchell (WBTS) a similar study to that undertaken with the Ortho kit and suggested we used our best efforts to engage Dr Gunson, on the grounds that he was a member of the ACVSB and this would best ensure a joint NBTS/SNBTS validation exercise was developed and possibly recognised by ACVSB (C5-11). In the event Drs Gunson and Mitchell designed a UK multi-centre study in which the Ortho and Abbott kits were compared (C5-12). The final results of this study were released in November 1990 (C5-13 and C5-14). Once again the adequacy of the first generation Ortho test was confirmed. In addition Abbott had a satisfactory second option. I had no doubt that both test systems were viable options for the commencement of HCV donation testing in the UK. In November 1990 it was clear that the SNBTS had lost over 6 months since our proposed starting date of April 1990 (running with the Ortho system) had been made to SHHD.

5.46 On 23 November 1990 Dr Mitchell advised me that at the 21 November 1990 ACVSB meeting it was agreed that Ministers would be advised that HCV donation screening should commence as soon as possible and that Dr Gunson had been requested to gather information on what resources and special arrangements were required to secure this objective (C5-15). Dr Mitchell also advised that the Committee were aware that there were second generation tests about to be made available by both Ortho and Abbott but members had agreed that these could be assessed after routine screening had begun with the first generation kits. None of this critical management information came to the SNBTS from CSA/SHHD, despite the fact that SHHD had representation on the ACVSB. Some time in December 1990 Dr Gunson called me and advised that there were 'very serious difficulties' in funding the introduction of HCV donation testing in England and Wales. He none the less issued a memo to the English and Welsh RTDs on the 22 January 1991 signalling that DOH had cleared the lines for a start of HCV donation

screening (C5-15f). As far as I can recall the difficulties seemed to be that DHSS had advised English RHAs that there would be no allocation of additional funds for HCV donation testing; the funding would have to come from existing RHA budgets and would have to cover donation screening, confirmatory testing, donor counselling/care. These difficulties were later confirmed in 'Dear General Manager' letter from DHSS to RHAs dated 31 May 1991 (C5-15g) as did evidence that because of severe funding problems in England and Wales there would be regions unable to deliver optimal confirmatory testing and agreed ways of handling screen positive donors (C5-15h). I advised Dr Gunson that arrangements were already in place in Scotland for all these functions to be funded and we were 'ready' to go (C5-15b and C5-15c) and that February 1991 was 'a runner' (C5-15d). There is no doubt this news was received by Dr Gunson with great consternation. He repeatedly expressed his concern that the SNBTS might 'break ranks'. There is also no doubt that the announcement of the Minister of State at the Scottish Office with responsibility for Health (Mr Michael Forsyth) on 28 July 1991 (C5-15i) confirmed the different approaches between two regions of the UK regarding support for blood safety.

5.47 To the best of my recollection it was at the ACVSB meeting on 25 February 1991 that the decision, made in November 1990 and promulgated by Dr Gunson on 22 January 1991, to commence HCV donation testing using the first generation kits must have been reversed, though the Minute of this meeting does not appear to confirm this, nor subsequent developments. In this regard it is noteworthy that 4 days before the February ACVSB meeting DHSS ((Medicines Devices Directorate) signalled a DHSS decision that there would be an 'immediate' evaluation of the second generation kits (C5-16). This was later confirmed 4 days before the ACTTD meeting on the 25 March 1991. I subsequently challenge Dr Gunson on this development and contrary to his claim could find no evidence that the two kit manufacturing companies intended to withdraw abruptly their first generation kits. Indeed I was aware that the Netherlands had commenced HCV donation screening on the 1 January 1991 – using first generation kits. I was certain, in February/March 1991, that there would be ample evidence that these companies had convinced themselves and independent scientists that the specificity and sensitivity of the second generation kits were improved – albeit modestly (C5-17b) and there was no need for us to mount a second major trial. But most concerning of all was had the SNBTS been permitted to use the first generation kits from June 1990 (as requested) (C5-10c and C5-10d), we would have withdrawn perhaps as many as 450 infected donations by the time we actually started in September 1991. The reasons for yet another delay were a great concern to me. I was aware that whilst Wellcome Diagnostics had captured a significant part of the UK HIV donation screening market their HCV research programme had stumbled such that even by September 1991 they did not have an HCV kit ready for the market. In due course I raised this issue with the CMO (Scotland) for I believed there may have been conflicts of interest for some members of ACVSB (C5-10m) and this may have contributed to the delay.

5.48 In Justice James Burton's judgement of March 2001 (para 156), it is implied that it was the Advisory Committee on Transfusion Transmitted Diseases (ACTTD) meeting on 25 March 1991 which made the crucial decision on the need to evaluate the second generation kits which gave rise to the further delay in introducing routine HCV donation

screening in the UK. I do not believe this conclusion is not correct; the decision was made elsewhere and Dr Gunson was instructed to 'get the ACTTD on board'. The fact is Dr Gunson had great difficulties and spent much of the week end of the 23/24th March persuading me that the decision, to which he claimed he was strongly opposed, had been taken at the 'highest level' and without any consultation with him He also advised that SHHD had given their fullest support and that DHSS, in advance of the 25 March ACTTD meeting, had already taken steps to provide funds for the trial participants (C5-16 and C5-16a). I confess I caved in and ever since have regretted it. Dr Gunson advised all UK RTDs of the position on 3 April 1991 (C5-15e). His communication clearly indicated that the decision was one made by DHSS. Once again SNBTS received no briefing from SHHD, but I briefed my colleague Mr MacIntosh (SNBTS General Manager) on my concern.

5.45 There is no doubt that, as expected, the 2nd generation HCV donation testing kits were an improvement on the 1st generation kits, both with respect to sensitivity and specificity (C5-17 and C5-17a). But, as I recall, these improvements proved to be modest - as expected from the briefing received from Dr Gillon (SNBTS), who attended the 2nd International Symposium in Los Angeles in November 1990 when the first Ortho results were put into the public domain (C5-17b). Thus the gains in using the 2nd generation kits for the introduction of screening in October 1991 rather than using 1st generation kits starting in April 1991 were significant but small.

5.46 A brief note on the events in Newcastle in April/ May 1991 is relevant. The Director of the Newcastle Blood Transfusion Centre was a reluctant contributor to the 2nd generation HCV kit trial; reluctant because he felt there was an ethical imperative to commence total screening as soon as possible after the 1st generation trial (the position adopted by ACVSB in November 1990). In agreeing to contribute to the 2nd generation trial all centres had agreed to complete the work and await further instructions when to commence full screening. In the event, in May 1991the Newcastle centre director declared his intention to continue full screening, without consideration of the rest of the UK BTS (C5-17f). It is not known to me how he was able to fund this development but what clearly emerged was that nobody, including Dr Gunson or Dr Metters (DCMO, DHSS and Chairman of ACVSB), felt able to intervene. In the event it was the SNBTS who advised Dr Gunson that a way forward was to contrive a formal extension of the 2nd generation kit trial (C5- 17c). It has always been my view that this Newcastle episode raised significant anxieties as to who had the duty of care for the safety of blood at the regional level. In Scotland the evidence from the 1970s with respect to HBsAg testing, and in the 1980s and 1990s with regard to detecting HIV and HCV contaminated blood donations, indicated it was SHHD that bore the prime duty of care - in the context of permitting the SNBTS to introduce new donation screening programmes. I believe the Newcastle saga also triggered the beginning of the end of the authority of the ACVSB, though some believed this had occurred in 1990 when the BPL Board (on which were DHSS officials) unilaterally announced it required ALT donation testing for a major part of its plasma input (C5-17d and C5-17e). More certain of its demise was the information received in July 1993 (C5-17g).

5.47 For some time after the introduction of HCV donation screening in England and Wales, the RTCs had serious problems in obtaining PCR confirmatory tests such that consideration was given to transferring some of this work to Scotland (C5-18a). Some of my colleagues believed the English reference microbiologists had serious technical problems in establishing reliable PCR HCV confirmatory tests, which at that time was a common problem. With the exception of one centre, I doubted this and in due course a good technical concordance was demonstrated between the main UK reference laboratories (C5-18). There is no doubt that one of the virologist close to DHSS (Dr Mortimer, PHLS) fought a long battle to prevent the routine use of PCR testing for final confirmation test before screen reactive donors were counselled (C5-18b). He lost. On the other hand Dr Gunson insisted that the primary problem with confirmatory testing in England was the reluctance of DHSS to release funding to the reference laboratories and this was confirmed on several occasions (C5-19). None of these problems existed in Scotland. Partly due to the support given by SHHD it transpired that SNBTS had one of the outstanding HCV research and references services in the world - led by Drs Follet, Yap and Simmonds.

5.48 After September 1991 the arrival of new HCV donation testing kits onto the UK market was considerable. In discharging our responsibilities for the safety of patients, the care of donors and value for money, the SNBTS had already established, with the support of SHHD, a system by which these offered kits, and those which claimed to be improvements on those already in use, were thoroughly assessed within the SNBTS (see above 5.19 and C5-4b, C5-4c and C5-4d). This programme greatly expanded after 1991 and Directors agreed that without this formal quality assessment kits would not be used in Scotland for routine screening. There is no doubt this unique (to Scotland) development enhanced the quality of our blood and plasma sources. We believed this was in part our response to the responsibilities place on us by the MCA. In a sense, we established a licensing process – which proved to be a cause of some consternation south of the border (C5-20, C5- 21, C5-22 and C5-23). In due course we sought to make this development an UK one. In this regard, we were not prepared to hand it over to PHLS, in part because we believed PHLS had been party to many of the problems in the area of donation testing, and, ever since the 1970s, we had remained concerned at their level of commitment to and interest in the needs of blood transfusion services. For obvious reasons therefore, we were keen to see NIBSC involved (see 3.11 and C5-24). This proved unacceptable to the Chairman of DHSS's Advisory Committee on Viral Safety of Blood (C5-24) and Dr Gunson did not respond to a request for support (C5-26); no further action was taken.

5.49 Throughout much of 1988, as a result of the problems with the introduction of HIV donation testing, I prevailed upon Dr Gunson to ensure that DHSS had access to more independent and better transfusion/ microbiological advice. He made it clear to me that he could not support this proposal because it would be rejected by DHSS. In view of this rejection I advised Dr Gunson that it was my intention to seek SNBTS Directors' support to establish an SNBTS team to which colleagues from south of the border, including the two DHSS expert microbiology advisers, would be invited. As Dr Gunson later observed this 'did the trick'; there was established **the Advisory Committee on**

Transfusion Transmitted Diseases (ACTTD) to advise the UK BTS Directors which had its first meeting in February 1989. Soon thereafter DHSS established **the Advisory Committee on Viral Safety of Blood (ACVSB)** which had its first meeting in April 1989. It has always been my view that ACTTD did an excellent job. However, efforts to ensure that it had some form of reporting/advisory lines to ACVSB were vigorously rejected by DHSS. The most significant effort in this regard was made by the newly appointed Chairman of ACTTD, Dr Ferrydoun Ala in 1993. So persistent was Dr Ala's demand for this operational link that DHSS instructed Dr Gunson to remove him from the Chairmanship. This he did.

5.50 Some further mention should be made of the **Advisory Committee on Viral Safety of Blood (ACVSB)**. This committee was established in April 1989. A far as I recall its remit was: 'to advise DOHs on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for immediate use and for plasma processing'. Dr Gunson always insisted that this committee's creation was a response to my criticisms of the performance of the DHSS's management of the AIDS crisis of 1984/85 (C5-27). These criticisms included the professional limitations of the small, unaccountable and (DHSS) dependent virology advisory team, and the way DHSS had excluded and ignored blood transfusion service virology and management expertise. In the event the apparent increase in transparency and a wider accountability of the ACVSB was an illusion. Members of ACVSB were 'sworn' to the official secrets act; no mechanisms were permitted by which senior managers of the UK blood transfusion services could have access to ACVSB agendas and therefore offer collective professional advice. Finally, the proposal that DHSS should have more independent and relevant virology expertise was rejected. The ACVSB virology expertise remained as it was for the AIDS saga - professionally limited and locked in to a dependency culture on DHSS service contracts. All these concerns were conveyed to SHHD officials but no responses were ever received. The fact is that SHHD officials attended ACVSB meetings, were aware of SNBTS's concerns at the lack of an appropriate (corporate) professional in-put and were indirectly party to the decisions which gave rise to the delays in the introduction of HCV donation testing in the UK. These delays, in my view, were primarily due to difficulties DHSS had in agreeing with English RHAs a funding package for the introduction of HCV donation testing and little to do with risk benefit between first and second generation HCV testing kits. As I recall, there were no similar funding problems in Scotland and in theory, therefore, SHHD could have instructed CSA/SNBTS to commence HCV donation testing, subject to concerns about the Gulf War, soon after January 1991 or even April/June 1990. They did not; nor did they keep SNBTS managers appropriately briefed on the causes for the delay.

5.51 In conclusion it is pertinent to record the outcomes of the first 6 months of HCV donation screening in Scotland. 151 donations were confirmed HCV positive (C5-28). It is also pertinent to recall that SHHD's contribution to the HCV donation testing management saga was a cause of wider concern in Scotland (C5-29 and C5-30).

Chapter 6

Miscellaneous Matters

6.0 SNBTS Management

6.01 Whatever judgements are made of the SNBTS's performance throughout the period of review, there is no doubt its many and significant achievements were delivered against a background of numerous management challenges. From a personal view, the 'first among equals' position of the national medical director created many difficulties, many of which were diminished by a remarkably generous group of professional colleagues . In due course I persuaded SHHD that this concern was valid and in 1990 appropriate adjustments were made.

6.02 The management and scientific competence of both the Common Services Agency and the Scottish Home and Health Department were, on occasions, a cause of embarrassment and frustration. The CSA's Blood Transfusion Subcommittee meetings frequently revealed that most members had not read the briefing papers and at all times deferred to the SHHD members. The subordinate position (vis a vis DHSS) of the Scottish Home and Health Department meant that Scotland's blood transfusion services were too frequently caught up in management tensions between English regional health authorities and Whitehall. In short, there was a shortage of leadership, transparency and accountability.

6.1 Politics

6.11 There is no doubt that in the period (1975/76) when Lord Owen was Secretary of State for Health and Social Services the parlous state of the NBTS and its associated fractionation facility was evident to all, as were the soultions. The unique opportunity to

make the necessary changes were rejected and/or ignored. Because of the subordinate position of SHHD to DHSS the influence of this management inertia in Whitehall extended to Scotland.

6.13 The DHSS civil service team (Sir Patrick Nairne (Perm Sec), Sir Henry Yellowlees (CMO) and Dr Ed Harris (DCMO)) which advised Lord Owens in 1975 were still in place for the new Government in 1979; Sir Patrick until 1981, Sir Henry until 1984 and Dr Harris until1992. It is therefore not surprising, particularly with the distraction of creating the NHS market place, that effective reform – the creation of the National Blood Authority - did not take place until 1992.

6.14 Lord Archer, in his Independent Public Inquiry Report, dated 23 February 2009, noted that the UK Haemophilia Society, supported by the World Federation of Haemophilia, has campaigned for a Public Inquiry since 1988. Lord Morris, the current Chairman of the Society, has argued that 'a Public Inquiry would yield lessons to be learnt for the future and help victims and those bereaved to come to terms with their experience'. In response to this campaign DHSS declared that 'we do not consider a Public Inquiry is justified as we do not believe that any new light will be shed on this issue'. It is not certain to me what DHSS considers to be 'new light', but I am certain that if the evidence available to Lord Archer and Justice James Burton is considered to be definitive, then there is indeed a good deal of new light which, in the interests of the patients and their relatives, should be made available.

6.15 I am aware that Lord Archer did not have the powers to compel anyone to give evidence or produce documents, and that his budget was little over £75,000. It is my understanding that this Inquiry has those powers (though I am uncertain to what extent this applies to institutions south of the border) and a budget in excess of £75,000. I am also aware that Lord Archer, in his deliberations promoted by the UK Haemophilia Society, looked for lessons to be learnt and to support victims and bereaved relatives in England only.

6.16 Lord Archer advises that Lord Owen prevailed upon a succession of Parliamentary Ombudsmen to investigate whether in the 1970s there had been some maladministration. On each occasion he was advised that there was no prima facie evidence for maladministration – because all the relevant DHSS documents had been destroyed.

6.17 In any consideration of politics regard should be given to the extra-ordinary events in New York in June 1977 (2.40) when I was advised that my promotion of national self sufficiency did not enjoy HMG support. In the subsequent decade I could not find fault with this conclusion.

6.20 The UK Haemophilia Society

6.21 I have to confess that, after my experiences at the World Federation of Haemophilia (WFH) Congress in New York in June 1977 (2.40),I concluded that, at that time, both the WFH and the UK Haemophilia Society were firmly in the control of the commercial plasma fractionation companies; I was advised that quite substantial amounts of money were involved and that these monies were often used to fund travel and subsistence at national and international conferences. It came as no surprise to me that throughout the late 1970s and early 1980s the UK Haemophilia Society actively promoted the interests of the commercial concentrate suppliers.

6.22 In 1988 the UK Haemophilia Society offered the SNBTS support in lobbying government to assist our faltering self sufficiency programme (C6-1). This was the period when we all knew that self sufficiency was about to become an EU political imperative. However, the Society failed to give any support to the SNBTS's successful drive for self sufficiency in the period 1975-85. I was advised by Mr John Prothero that senior Society officials were aware the PFC Shift saga in 1977 and did not intervene. All the evidence points to the fact that the Society took no action to find out what was going on in Scotland and use this to lobby the DHSS for change in England and Wales. It has always been my view that Society's silence in the late 1970s, with regard to supporting NHS coagulation factor supplies, contributed to the disasters in the early 1980s and that this was compounded by their activities, in political circles, in favour of commercial concentrates.

6.23 It may not be well known that Lord Morris was a junior Heath Minister with Lord Owen and thus in 1975 was part of the team which sealed the fate of so many haemophilia patients. It follows that that Lord Morris may provide an important insight into the thinking of DHSS officials in the period 1975-79.

6.30 Destruction/Removal of Documents

Personal Files

6.301 As I recall, it was some time in the autumn of 1992, soon after I had moved my office back to the Headquarters Unit, at Ellen's Glen Road, that my former PA (then PA to the new general manager Mr MacIntosh) advised me that there had been a fire in her office and that all of my old files (which she had forgotten to transfer to my new PA) had been destroyed. I was deeply troubled by this news because I sensed my former PA (who I had worked with for more than 15 years) was deeply distressed. Later I discovered there was no evidence of a fire (charring or smell) in my former PA's office and the campus site Fire Officer had not been informed of the incident. Of concern too was that Mr Macintosh made no mention of a fire in his PA's office, which was contiguous with his own.

6.302 I spent much time reflecting on the whether my files had been deliberately destroyed and if so who would want such an outcome? These reflections eventually, led me to recall the meeting in SHHD on 6 September 1988 at which I listed the documents we possessed which I believed would be embarrassing for SHHD in the event of any HIV litigation (C6-2 and C6-3). As I recall, this list was a cause of some concern to those SHHD officials in attendance. (No minutes/notes of this meeting have ever emerged from SHHD or CLO, nor has a copy of the briefing note I supplied been found in my files).

6.303 Such was my concern that I requested my new PA to arrange for the lock to the room housing the bulk of our files to be changed and that under no circumstances would anyone - other than myself and my PA - have access to the files in this room, unless cleared by myself.

6.304 In October 1994, while I was in Australia, the SNBTS General Manager attempted to gain access to our files. My PA courageously advised him that this was not possible until I returned. On return I spoke to Mr MacIntosh and, among other things, advised that if he wanted the document filing room for other functions, then this could be readily resolved by finding an alternative secure location. I was shocked to learn that Mr MacIntosh favoured option for these documents was destruction.

6.305 A safe and secure haven for these documents, arranged by Mr MacIntosh, proved not to be so. Bizarrely we were alerted to this by my former PA (who had reported the problem of the fire) and was now working in SHHD. The information proved to be correct and I removed all the papers to the library of the Royal College of Physicians of Edinburgh. I am advised that several requests were subsequently made by SHHD to transfer these papers from the College to SHHD. On all occasions this was denied, but the offer for the provision of copies has always been open but until the announcement of the Inquiry was never taken up. Copies of these papers have formed the major evidence base for this personal narrative; the originals were lodged with the Inquiry team.

6.306 I believe all the above information can be corroborated from other sources.

Files from Dr Gunson's Office

6.307 In the preparation phase for the Hepatitis C court action before Justice James Burton (2001) I was provided, by NBTS solicitors, with a set of papers which were copies of communications between Dr Gunson and my self. Of interest was to discover that copies of a significant number of these documents were not in my own files. In due course I offered to return these papers to the solicitors but was advised that this was not necessary and, if I wished, that they were mine.

6.307 I considered it important that the SHHD officials had sight of these documents and approached Dr Aileen Keel (SHHD). Dr Keel expressed an interest and the documents were transferred on condition that they were returned.

6.308 Some months later I contacted Dr Keel requesting the return of the documents (C6-4). Dr Keel advised that 'things had moved on' and that on the advice of SHHD lawyers the papers had been impounded by SHHD and would not be returned (C6-5). I was concened with this turn of events because I had not taken the precaution to copy the Manchester documents which were missing from my personal files, which were still lodged in the College.

6.309 I consulted several lawyers and was advised that SHHD's action was an act of theft and that the matter should be pursued (C6-6). In due course I spoke to Ranald Macdonald (CLO) and believe it was, in part, his and Susan Murray's (CLO) good offices which led to the return of the documents - all of which have been lodged with the Inquiry team. I later invited Dr Keel to explain why this action had taken place (C6-7) but have received no response.

Other 'Happenings'

6.310 I am aware that a considerable number of Dr Mitchell's (WBTS) personal files were destroyed at the time of the transfer of the WBTS to the Gartnavel Hospital site.

6.311 I have been advised that all my personal files (between 1994 and 1997) have been destroyed as have all Mr MacIntosh's files. I understand this may have taken place soon after Mr MacIntosh's precipitous departure.

6.312 In the course of the preparations for this Inquiry I became aware that a number of relevant files prepared by Dr Jim Smith (SNBTS Expert Adviser) were removed from his office at BPL, while he was on holiday, and have never been seen again.

6.40 Conflicts of Interest

6.401 On two occasions in the 1980s, in New York (1977) and Washington (1985), I was advised that the London based lobbyists for commercial plasma fractionation industry were in close touch with opinion formers in Whitehall. I took this to mean that efforts were being made to persuade some politicians and officials to support policies which ensured access for commercial suppliers of coagulation factor concentrates to a significant slice of the UK market. In the event I believed this lobbying was successful and the outcomes was made public in 1990 by DHSS's clarification of it's commitment to a version of self sufficiency in which clinical freedom with a multi supplier market

place took pride of place (C4-2). This policy brought much joy to the commercial suppliers (C4-5) but in 1992 there was consternation from them with the creation of the NBA, which they envisaged would create a self sufficiency programme in England and Wales similar to that in Scotland and thus a massive fall in revenue (C6-8).

6.402 There is comment in Starr's book on the way prescribing physicians were given financial rewards for supporting a particular brand of commercial factor VIII concentrate. As I recall Starr did not cite this practice in the UK. I was never aware of any evidence that this was taking place anywhere in the UK, though it was well known that one English Haemophilia Director, for a period of time, had a consultancy with one of these companies. That said, I was aware that in the heat of the debate about the need for high purity concentrates, for instance, some clinicians wondered whether this practice might be taking place in the UK (C6-9).

6.403 Reference has been made in several sections of this narrative to a concern I, and others, had for several years that at least one of the expert virologist advising DHSS on the introduction of virus marker donation testing (Professor Richard Tedder), was actively involved as a consultant to Wellcome Diagnostics with a specific remit to develop these test kits. Professor Tedder was also an external consultant to the North London BTS (Dr John Barbara) and PHLS (Dr Philip Mortimer, another DHSS expert virologist adviser). Many of us believed that, because DHSS had brokered the deal whereby BPL's manufactured donation kit testing for HBsAg was transferred to Wellcome Diagnostics, DHSS was committed to the long term support of Wellcome in the virus marker donation testing field. I had several discussions with Dr Gunson on this topic, notably during the HCV donation testing kit evaluation fiasco in March 1991, and was advised by him that DHSS were aware of the position of their expert adviser.

6.404 I had assumed Dr Gunson had alerted DHSS colleagues to my concerns, but by June 1992 I had no evidence of this and briefed the CMO (Scotland) (C6-10). In July the CMO (Scotland) advised me that the problem had been addressed by DHSS colleagues and that Professor Tedder had been removed from membership of a hastily transformed ACVSB (C6-11). The expert virologist concerned remained a member of the ACTTD and in September 1992 I persuaded Dr Gunson that it was important that all members of this Committee were given an opportunity to make known to their colleagues whether they had any conflicts of interest (C6-12). This was not delivered until October 1993 (C6-13); my long held concerns were confirmed and, as I recall, Dr Gunson stood down as Chairman of ACTTD which, like the ACVSB, was also unexpectedly modified and renamed.

6.405 It is of interest to note that, at some time in 1992, Wellcome Diagnostics sold their HCV donation testing kit development to Murex Diagnostics Ltd and in July 1992 Murex offered the purchased Wellcome technology for assessment to the SNBTS (C6-14). It is my understanding that this was the technology developed by Professor Richard Tedder and which clearly was not ready for the UK assessment in late 1990/early 1991.

6.406 Footnote: I have always enthusiastically supported NHS/Academic researchers engaging with UK industry to develop new technologies – indeed the SNBTS has a track record of doing this. But I have also believed that if an individual finds him/herself in a position of advising Ministers then there is an imperative to make it known if there are any conflicts of interest. It is not known to me whether Professor Tedder discharged this responsibility. More importantly is the burden of responsibility of officials to ensure that those who advise them declare any conflicts of interest. What evidence I have (verbal briefings from Dr Gunson) leads me to conclude that these conflicts of interest were known to officials (which may include SHHD officials) and may have influenced the process leading to the introduction of HCV donation testing throughout the UK.

Narrative **REFERENCE INDEX**

CHAPTER 1

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C1-2	Thatcher Era Uncovered (Guardian 20/12/09)
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