This statement is made on behalf of the Claimants (1)
Dr L Kay (2)
Statement No: 1 (3)
Date made: 2000 (4)

IN THE HIGH COURT OF JUSTICE **1998-A-458**
QUEEN'S BENCH DIVISION

RE: HEPATITIS LITIGATION

B E T W E E N:

A. AND OTHERS

Claimants

And

THE NATIONAL BLOOD AUTHORITY

Defendants

WITNESS STATEMENT OF DR LESLEY KAY
of GRO-C **London** GRO-C

Introduction

1. I graduated from the University of Newcastle upon Tyne in 1974. In 1975 I trained as a Senior House Officer in haematology. I then had a three year rotation as a General Medical Registrar working at the Dryburn Hospital, Durham, the Royal Victoria Infirmary and General Hospitals, and Blood Transfusion Service, Newcastle upon Tyne. On completion of my Registrar rotation I obtained a Senior Registrar post in 1979, specialising in haematology now based at the Freeman, Royal Victoria and General Hospitals, Newcastle upon Tyne.

2. My post graduate qualifications are: MRCP (1977), MRCPath (1982), FRCP (1990) and FRCPath (1994).

3. I have held or currently hold the following National Appointments:
   (a) 1989-1993: Council of British Blood Transfusion Society.

(b) 1990: Served on the Department of Health Blood Transfusion Directors Committee on Guidelines for Autologous Transfusion.

(c) 1992 to the present: Secretary of the Autologous Transfusion Special Interest Group, British Blood Transfusion Society.

(d) 1993 to the present: CPA Inspector for Haematology.

(e) 1994 to the present: Independent Health Care Association Representative on the Special Advisory Committee on Haematology for Clinical Pathology Accreditation.

Sunderland

4. In 1982 I was appointed Consultant in Haematology in the Sunderland Health District. I was one of two Consultant Haematologists. The other was Dr David Gough. We were of the same status.

5. As a Consultant Haematologist to Sunderland Health District I was responsible for the Haematology Departments at Sunderland General and Sunderland Royal Infirmary. I remained a Consultant Haematologist at Sunderland until leaving early 1990.

6. My seven years at Sunderland were most enjoyable. It was busy general haematology. I had responsibility at District level for a small group of haemophiliacs. At that time haemophilia was managed in such a way that each Regional Health Authority provided a specialist Reference Centre to whom Districts referred patients for advice and treatment. The North East Regional Health Authority Reference Centre was at the Royal Victoria Infirmary, Newcastle upon Tyne, led by the Director, Dr Peter Jones.

7. The majority of the haemophiliacs for whom I was responsible had Factor VIII deficiency, some Factor IX and a few Von Willebrand's disease.

Research

8. In 1980s I published two short textbooks. The first was *Clinical Blood Transfusion* of which I was joint author with Professor Huehns. This was published by Churchill and

Livingstone in 1985. My second book was *Essentials of Haemostasis and Thrombosis* published by Churchill and Livingstone in 1988 of which I was the sole author.

9. Research for my first book commenced in 1983 and coincided with the increasing awareness in the United Kingdom of the HIV tragedy which was emerging in America. As I researched so I found that one American response to the risk of HIV transmission in blood transfusion was to revive the old system of autologous transfusion. This was the first I had heard of the technique. It had not been covered in my pre-qualification training nor had I heard of it in my post-qualification experience even as a Consultant Haematologist.

10. I found autologous transfusion had been successfully practised between the Wars in the United Kingdom. It had been used in ectopic pregnancies when the mother has a tubal burst. The practice had been revived in America in the late 1960s and 1970s (pre-HIV) in response to two pressures. First, the growing awareness of transmitting Hepatitis B infection in blood transfusion and second the shortage of blood brought about by new techniques in cardio pulmonary bypass surgery. These new techniques focused on the Chicago State Tuberculosis Sanatorium. The surgical technique involved required the transfusion of substantial amounts of blood which could not be met by existing homologous supplies. The Chicago response was to adopt a policy of blood self sufficiency for use in transfusion (in its various forms). The method adopted was large scale pre-deposit of autologous blood. The Chicago initiative was the first large scale pre-deposit programme which led to the publication of papers establishing such pre-deposits were safe and economic, even in elderly cardio thoracic patients who, as a group, are particularly vulnerable. Pre-deposit autologous transfusion has various benefits which I shall explain later but undoubtedly a major benefit is the elimination of the risk of acquiring a viral infection from homologous blood.

11. The discovery of the retrovirus causing Aids and the realisation it could be transmitted by blood and blood products led the Council on Scientific Affairs of the American Medical Association to advise doctors to recommend the utilisation of autologous

blood in preference to homologous blood wherever possible (Council on Scientific Affairs, *Autologous Blood Transfusion* - Journal of the American Medical Association 256-2378-80 (1986). In 1987 the American Association of Blood Banks quickly responded by setting up an Autologous Blood Resource and Information Department to encourage awareness amongst doctors of the benefits and availability of autologous donations. Other reasons for preferring autologous blood to homologous blood were also recognised. For example, the fact that it would avoid non specific febrile reactions - *Some Unfavourable Effects of Blood Transfusion* in Blood Transfusion in Clinical Medicine, Eighth Edition (1988) - Mollison Engelfriet and Contreras (EDS) and avoid the risk of non A and non B hepatitis *Detection of Anti bodies to the Hepatitis C Virus in prospectively followed Transfusion Recipients with acute and chronic NANB Hepatitis* - New England Journal of Medicine 321 1494-7 (1989) Alter Purcell Shik.

12. Autologous blood also avoided the risk of HTLV1 - *The Epidemiology of the Human T cell Lymphotorpic virus type 1 and type 2; etiologic role in human disease*. Transfusion 31, 67-75 (1991) Manns and Blattner and possibly reduced the rate of cancer recurrence following surgery.

13. Today autologous transfusion is common place throughout the United States. Whilst recognition that it is practical dates from the late 1960s and early 1970s there is no doubt in my mind that the major impetus in favour of autologous transfusion dates from 1983/1984 and the understandable wish of patients and clinicians to eliminate the risk of acquiring HIV through blood transfusion.

14. There are three methods of autologous transfusion:-

    (a) Pre-deposit for use in elective surgery - typically knee and hip replacements and hysterectomies;

    (b) Intra-operative salvage. This occurs in major surgery. The patient's blood is sucked out of, say, the chest cavity and the red cells are centrifuged off, washed in normal saline and reinfused. The entire procedure takes minutes

only. It is very safe. The primary use of intra-operative salvage is in cardio vascular surgery such as aortic replacement;

(c) Post operative re-infusion. This is of limited use. A patient may not bleed during surgery (such as a knee replacement) but in the post operative stage the wound bleeds; in this form of autologous transfusion the blood is collected and reinfused.

The need for Autologous Blood Transfusion

15. On 17th January 1987 I published a paper in the British Medical Journal *The Need for Autologous Blood Transfusion*. I introduced my paper saying:-

> *Last week's suggestion that people who have had casual sex in the past four years should not donate blood will have further imperilled Britain's supply of blood for transfusion. It will also encourage further consideration of collecting the patient's own blood before an elective operation and then transfusing it into him during the operation, if necessary. The Americans and Australians are already using autologous blood transfusion and it will surely come soon in Britain and other countries. Anxiety of our transmitting the human immuno deficiency virus (HIV) is not the only stimulus to autologous blood transfusion. There are also worries about transmitting non-A and non-B Hepatitis and an increasing need to use donated blood for purposes other than transfusion as whole blood ....*
>
> *By 1984 in the United States about 1% of all cases of the acquired immune deficiency syndrome (AIDS) had been related to blood transfusion but by 1986 the figure had risen to 2% of adult and 13% of childhood cases. About 90% of cases of Hepatitis after transfusion are caused by non-A and non-B viruses. Non-A and non-B Hepatitis often causes chronic active Hepatitis or cirrhosis and develops in up to 10% of the blood recipients of the United States. Other infections transmissible by transfusion are cytomegalovirus infection, malaria and syphilis.*
>
> *Autologous transfusion eliminates these risks of serious infection and also avoids sensitisation to red cell, white cell, and platelet antigens in donor*

blood....

Autologous blood transfusion was first undertaken on a large scale in 1962 for operations including pulmonary lobectomy and cholecystectomy. Other groups then began to provide autologous blood for many elective operations and by 1974 a third of American blood banks offered autologous transfusion, although it was underused because of apathy by patients and doctors and the administrative problems of starting a new system alongside an already functioning one. A similar sporadic and underused system developed in Australia but in both countries since 1980 the fear of AIDS among the general public has created a new demand for autologous transfusion and the resurgence of interest among doctors. In November 1986 the Council on Scientific Affairs of the American Association call for education of doctors and the benefit and availability of autologous transfusion. As yet, few laboratories in Britain provide the service, although it has been advocated.

16. After describing the methodology I concluded my paper saying:-

The disadvantages of autologous blood transfusion are mainly logistical. The setting up of such programmes needs scrupulous attention to detail and co-operation between surgeons, anaesthetists, local blood banks and central transfusion services. In the present climate patient compliance is unlikely to be a problem.

There are few comparisons of the cost effectiveness of autologous and conventional transfusion programmes. The consensus appears to be that there is an initial "Start up" cost because autologous transfusion is usually provided in the centres at which the operation is to be done rather than in centralised regional transfusion laboratories. Once the service is in place and use increases, however, the unit costs fall and are eventually offset by reduced patient morbidity and the diversion of unused blood for use by other patients. Some have claimed an overall reduction in costs. Another benefit is the recruitment of people who might otherwise never have considered it into the population of blood donors.

Better tests for detecting HIV may eventually become available but we still have no reliable way of identifying non-A non-B viruses. Furthermore, AIDS is the third potentially fatal virus found to be transmissible by blood - and may not be the last. Several otherwise healthy people succumbed to Hepatitis B and the other viral diseases before these were eliminated from transfused blood. Autologous transfusion would have prevented many of these deaths. To continue to ignore this method of supplying blood is short-sighted.

17. My 1987 BMJ paper was based on the experience which I had gained as a Consultant Haematologist in Sunderland and my research, both within the United Kingdom and abroad. At paragraph 3(b) of this Witness Statement I record my membership of the Department of Health Transfusion Committee on Guidelines for Autologous Transfusion from 1990. There had been earlier recommendations and guidelines but limited to pre-deposit (rather than all aspects of autologous transfusion) published by the British Committee for Standards in Haematology Blood Transfusion Taskforce in 1988 (BCSH 1988).

Autologous Blood Transfusion for Surgery and Trauma: Benefits and Methods Available - 1988

18. In 1988 Dr Noble and I published *Autologous Blood Transfusion for Surgery and Trauma: Benefits and Methods Available* in Haematology Reviews 1988, volume 2, pages 305-326. When talking to haematologist colleagues I found that the general level of awareness of autologous transfusion was similar to mine before I had embarked on my research; for all practical purposes it was an unknown technique. This paper was an attempt to provide an overview in the hope that our research may prove helpful to others. In the *Introduction* we said:-

The record of homologous blood transfusion (HBT) both with respect to safety and supply remains excellent. The possibility of transmitting Aids with HIV anti-body negative blood has been calculated as only 1:1,000,000. However, the number of blood donors has decreased in recent years and the prevalence of HIV in the donor population will increase. Autologous transfusion is a

means of both contribution to the pool of available blood and avoiding the risks of homologous transfusion. HBT can be minimised in the first instance by avoiding unnecessary transfusion and increased use of haematinics. Autologous transfusion programmes have existed for many years in Australia and the USA and the spotlight has fallen on them again owing to the threat of Aids. Pre-operative donation for elective surgery, haemodilution and intra-operative transfusion can individually or in combination supply a large part of blood requirement. They should be used more frequently in order to avoid existing risks of HBT, the threat which Aids poses in the near future and to free available donor blood for other use.

Under the head of *RISKS OF HOMOLOGOUS BLOOD TRANSFUSION* we said under the sub-heading of *Infective*:-

Non A and non B hepatitis is most usually defined as a persistent elevation in Alanine Amino Transferase (ALT) in the absence of other detectable hepatitis viral disease or other underlying liver abnormality. It is the most common infective complication of HBT.

[We then gave various figures for the estimated incidence in various countries and continued]

... Although patients with NANB hepatitis are usually anicteric it often results in longstanding elevation of ALT and may result in chronic active hepatitis. Six of the fourteen cases in a Swedish trial had deranged liver function for more than one year and of three of those meriting liver biopsy all had chronic active hepatitis. Cytomegalovirus may also be transmitted by HBT as may hepatitis B, despite surface antigen screening which is not a perfect means of excluding infectious donors. Up to 10% of post transfusion hepatitis may be owing to hepatitis B... Transfusion associated hepatitis and Aids New England Journal of Medicine 317, 242-45 (1987) - JR Bone.

19. Under the heading of *PRE-DONATED AUTOLOGOUS BLOOD TRANSFUSION* and the subheading of *Advantages* we said:-

Autologous blood transfusion (ABT) not only avoids the risks of future

homologous transfusion, it also confers several advantages. It stimulates erythropoiesis so that this is maximal at operation, enabling any red cell loss not covered by pre-deposited blood to be restored rapidly. It reduces haematocrit resulting in improved organ perfusion, which together with a stimulated increase in 2, 3 diphosphoglycerate results in improved oxygen delivery to the tissues. It reduces the demand for homologous blood, particularly as many autodonors would not meet the criteria for homologous donation and/or would not otherwise be giving blood. Finally another overlooked advantage of ABT is that it increases patient confidence and gives a feeling of participation in the preparation for surgery.

20. Under the heading of *Disadvantages* we said:-

The most major disadvantage is the logistical difficulty of arranging sufficient pre-donations within the available time, excluding all but elective operation planned well in advance. Motivation of participating surgeons and patients is paramount to ensure sufficient blood is collected and to avoid disruption of operating lists which results in waste. Those patients for whom venesection would be dangerous must be excluded from participating (Table 1) and anaemic or bacteraemia patients must be deferred. The autologous blood collection clinic must be supervised by the consultant haematologist and good liaison between blood bank staff, anaesthetists, surgeons and secretarial staff is essential.

21. Under the heading of *Cost* we said:-

The relative cost of autologous donation is difficult to calculate; the materials cost the same and the testing is cheaper than for HBT, but the decentralised labour and administrative costs are higher and a smaller proportion of the blood reaches a useful fate. In the USA the cost per unit has been variously estimated at $4.14 cheaper and $15.00 more expensive (equivalent to one hour and 20 minutes additional medical and administrative time).

22. We then examined various methods of autologous transfusion concluding (page 322):-

> *Several methods are available by which the use of donor blood can be minimised. The most important is to ensure that blood transfusion is really necessary in the first place. ...The use of autologous blood by whichever method chosen will then further reduce the need for donor blood with all its risks. However, autologous blood is unlikely to completely replace shed blood when reinfusion techniques are used and some patients for elective surgery will not be fit to donate their own blood pre-operatively. Patients requiring emergency surgery and those who have marrow failure will continue to need donor blood. Autologous blood transfusion was one of the earliest methods of blood replacement, which became superseded only because of the efficient network of Blood Transfusion Service Laboratories which grew out of the experiences of World War II. It should again find a place as a compliment to this service, allowing those who are eligible to provide themselves with the safest available source of blood, and preserving standard donor blood supplies for those who really need them.*

Autologous Blood Transfusion - 1988

23. In October 1988 I published an article in Hospital Update entitled *Autologous Blood Transfusion*. Under the heading of *History of Autologous Blood Transfusion*:-

> *The concept of autologous blood transfusion is not new having been suggested in 1874 by Highmore after he had lost a patient from post partum haemorrhage. The first person to use autologous blood transfusion was Duncan during treatment of a patient with crush injury to his legs received in a railway accident in 1886. By 1936 auto transfusion was a well used method of blood replacement. However, the need to replace large volumes of blood during the treatment of battlefield casualties in the Second World War led to the development of safe, efficient systems for homologous blood replacement. These were rapidly adapted for civilian use and in the post war years autologous blood transfusions became rare. Not until the early 1960s was the use of autologous blood reconsidered, possibly because by that time demand*

for blood and its products were increasing and the hazards of homologous blood transfusions were becoming apparent ....

24. In my figure 1 I set out the hazards of homologous blood transfusion and the respective incidence:-

Viral non-A, non-B hepatitis	*7-12% of transfusions*
Hepatitis B	*Very low*
HIV (AIDS virus)	*Current estimation is one transmission per million units*
Cytomegalovirus	*Causes morbidity in transplant recipients, neonates and pregnancy*
Syphilis	*Extremely rare*
Malaria	*Rare*
Chagas' disease	*Rare*

25. The origin of my figure that blood transfusion brought a 7-12% incidence of NANB Hepatitis was Contreras, Blood Transfusion in Clinical Medical, 9th Edition, page 730, quoting Dienstag '90, Gastroenterology, 117-118.

Methods of Autologous Blood Transfusion

26. On 8th September 1989 I published this article in the Practitioner which is a Journal of post graduate medicine. In my introduction I said:-

The general public are better informed on medical matters and have a high expectation of what can be provided than ever before. Nowhere is this better illustrated than in the field of blood transfusion where the initial stimulus to re-examine autologous blood transfusion was largely patient-generated. It began in the United States in the early '80s when it was realised that acquired

immunodeficiency syndrome (AIDS) had a similar epidemiological pattern to hepatitis B.

A blood-borne virus was a prime candidate and so people in these so-called high risk groups were requested to refrain from donation. The identification of human immunodeficiency virus (HIV) in 1983 allowed for the development of a test for its corresponding antibody by 1985, but it soon became clear that seroconversion could take three to six months, and sometimes even longer, following infection.

Although HIV infection is the problem the general public wish to avoid when requesting autologous blood, the medical profession has additional concerns. Other slow viruses such as T-cell leukaemia virus 1 (HTLV1) causing tropical spastic paraparesis and human T-cell leukaemia HIV2, the second AIDS virus and the non-A, non-B hepatitis viruses may be also be blood transmitted. However HIV1 is the only one of these viruses routinely screened for at present in the UK.

The pill and penicillin have removed the obvious barriers to instant intimacy, but slow-acting and insidious sexually transmitted viruses will take longer to have their cultural impact, so new viral challenges to blood transfusion safety cannot be ruled out. For these reasons it is sensible to use the patient's own blood to cover surgery or trauma whenever possible. Autologous transfusion avoids all the well known hazards of donor blood except those of misidentification (tables 1 and 2) ...

27. In table 2 under the heading *Infectious hazards of blood transfusion* I reported:-

			Availability/utilisation of tests to detect infection	
Virus	***Disease***	***Post-transfusion Incidence***	***In UK***	***Elsewhere***
Non-A, non-B hepatitis	*Hepatitis*	*8-11%*	*None*	*Indirect* (USA only)*
Hepatitis B	*Hepatitis B*	*Rare (10% of all post-transfusion hepatitis)*	*Yes*	*Yes*
HIV1	*AIDS*	*26 in one million units screened (US)*	*Yes*	*Yes*
HIV2	*AIDS*	*None reported in UK*	*Selective*	*Yes (West Germany)*
HTLV1	*Human T-cell leukaemia & tropical spastic paraparesis*	*6.37% in Japan 1 in 4000 (US)*	*No*	*Yes (Japan and USA)*
HTLV2	*Hairy cell leukaemia*	*Very rare*	*No*	*No*
CMV	*Pneumonia/ hepatitis/ encephalitis*	*Only affects neonates, the immunosuppressed or foetus in some pregnant women*	*Yes for selected recipients*	*Yes for selected recipients*
Parvovirus	*Marrow depression*	*Only occurs in rare hereditary anaemias*	*No*	*No*
Other organisms *Treponema pallidum*	*Syphilis*	*Very rare*	*Yes*	*No*
**At present in the United States donors with levels of the liver enzyme ALT over 35iu/1 are excluded as an indirect measure*				

28. The origin of my figure of 8-11% for post-transfusion incidence of NANB hepatitis was the USA. I am not aware of any reliable UK figures.

29. My 1988 paper is best thought of as a description of a technique which was not, in principle new, but which had fallen into disuse in the post-war years following the establishment of the Regional Blood Transfusion Service. In my opinion the knowledge that HBV; NANB (later HCV) and HIV were potentially life threatening viruses capable of being transmitted in blood transfusion reinforced earlier respectable arguments advanced by others in favour of autologous transfusion. What the 1988 paper did not do was to report the results of the first large scale autologous transfusion trial in the United Kingdom. It was to be a further four years before I published those results in Haematology Reviews 1992, Volume 7, page 17-25 *Predeposit Autologous Blood Transfusion, Logistics and Costs in the Public and Private Sector in Britain.*

Whilst I make no mention of it in my 1988 paper I had in fact embarked on such trial in Sunderland in September 1987. I completed the trial in December 1989. It was the experience gained in that trial which led to my 1992 paper.

My 1992 Paper

30. In the 1992 paper I said under the heading of *INTRODUCTION*:-

> *Pre-deposit Autologous Blood Transfusion has been very slow to develop in Britain compared with other Western European Countries and the USA. The experience of one committed haematologist first in the National Health Service and then in the Private Sector has highlighted some of the logistical and financial problems which may explain why British patients are being denied this service and help to improve availability in the future.*

31. Under the heading of *BACKGROUND* (but omitting the references as listed in my paper) I said:-

> *The discovery of the retrovirus causing AIDS and the realisation that it could be transmitted by blood and its products led the Council on Scientific Affairs of the American Medical Association to advise doctors to recommend the utilisation of autologous blood in preference to homologous blood by an appropriate means wherever possible. The American Association of Blood banks quickly responded by setting up an Autologous Blood Resource and Information Department to encourage awareness amongst doctors of the benefits and availability of autologous blood in 1987. Other reasons for preferring autologous blood to homologous were also being recognised. For example, the fact that it would avoid non-specific febrile reactions, avoid the risk of non A and non B hepatitis, HTLV1 and possibly reduce the rate of cancer recurrence following cancer surgery also encourage the re-examination of the use of autologous blood.*

32. Under the heading of *A NATIONAL HEALTH PROVIDED SERVICE* and the sub-heading of *Funding* I reported:-

In Sunderland in September 1986 these considerations led to the presentation of a proposal to set up a feasibility study to examine logistics and costs of providing a pre-deposit autologous blood transfusion service for elective orthopaedic surgery. Initially it was hoped that a joint study with the Northern Regional Blood Transfusion Service could be set up, so that blood testing for groups HIV, HBsAg, syphilis would be a uniform standard and enable unused blood to be diverted for use by others. Because the Blood Transfusion Service Laboratory did not wish to be involved it was decided to test blood locally but to destroy any unutilised blood rather than divert it. Funding for the project was the biggest single difficulty. It was presented in turn to three District committees all of whom approved it and supported it, but were unable to grant finance because of problems in meeting pre-existing clinical service demands and financial targets. The DHSS was approached but was unable to fund a local project. The Regional Health Authority was approached and eventually granted £36,000 to fund the pilot study for one year. The project therefore did not start until September 1987, a full year from the original proposal.

33. Under the sub-heading of *Methods* I said:-

Meetings between managers of the acute surgical unit, directors of nursing, consultant surgeons, anaesthetists, surgical secretaries, the consultant haematologist and the autologous team were set up to explain the project, encourage patient recruitment and encourage continuity of service on the orthopaedic surgical unit so that cancellation of lists would not cause wastage of blood. Laboratory, ward and theatre staff were also informed of the project and correct handling for autologous blood.

All patients scheduled for major elective orthopaedic surgery were offered the opportunity to store their own blood for forthcoming surgery. They were asked to store the amount usually crossmatched by orthopaedic surgeons, that is 4 units for hip replacement and 2-3 units for knee replacement. The initial offer was made by post in a detailed but simple leaflet, the procedure was then

re-iterated at their first autologous clinic visit. All those accepting autologous blood were asked to complete the questionnaire similar to that used by the Blood Transfusion Service to ascertain fitness to donate and the fitness of their blood for subsequent storage. All were asked to sign a consent form explaining the procedure, the fact that tests for HIV and syphilis etc would be done, and that homologous blood might still be necessary ... All salaries, consumables and capital items were costed to a single budget, under the control of the unit accountant. The first year of the project was so successful that further funding was granted. In total the service ran from September 1987 to December 1989.

34. Under the sub-heading of *Results*:-

From 8th September 1987 to December 31st 1989 a total of 789 patients were referred. Because of publicity in the local press a number of non-orthopaedic surgical and maternity patients requested autologous blood. They were allowed to pre-deposit but were not systematically actively offered the service as were orthopaedic patients. Over 90% of patients offered the service wished to use it...

35. I then explained our exclusion criteria and gave certain data in tables 2, 3, 4a and 4b, 5a and 5b, 6 and 7.

36. I reported on the economics under *COSTS OF PROVISION OF AUTOLOGOUS BLOOD*:-

Figure 1 shows a graph of the cumulative costs of autologous blood provision over the period of the project, all the costs described earlier have been included except those of testing for HIV, HBsAg and syphilis. It can be seen that at the peak of activity the costs per unit of blood excluding infectious disease testing could be as low as £17 per unit. At that time testing for the 3 infectious diseases cost approximately £3, bringing the price up to around £20 per unit. However, this price does not include capital depreciation (14.5%

NHS formula) "Management overheads" (4.5%) nor "unseen costs" (NHS formula 10%). Adding these factors in brings the price up to £25.80 per unit at 1989 prices. Uplifting this for inflation equates to approximately £30.18 at 1991 prices.

37. Whilst it does not appear from my paper these costs compared with £25 per unit for NHS homologous blood at 1989 prices and £30 at 1991 prices, ie roughly equivalent. Thus, if we were allowed to dispense with testing, which seems superfluous if going back to same individual, autologous would actually have been cheaper.

38. Under the heading of *DISCUSSION* I reported:-

The experience of one proponent of pre-deposit autologous provision in Britain illustrates several problems which may help to explain why autologous provision is still rare in this country. In many American States patients must by law receive homologous blood only after signing a consent form which explains all possible adverse effects, and must be offered the alternative of autologous blood wherever possible. In major American centres 20% of all blood supplied by the Red Cross is autologous, for example Tucson. In West Germany autologous provision is routine for most elective surgery, supplying 90% of all elective orthopaedic surgery in major centres. In France autologous provision is undertaken by the Blood Transfusion Services. Up to 10% of all the blood they provide is autologous.

A major inhibition to pre-deposit autologous provision in Britain is the financial constraint which has been placed on hospitals in the NHS to encourage efficient use of resources. This has meant that "New" activities requiring "New" money have met with difficulty in funding despite being considered worthwhile as illustrated in this paper. Another inhibition has been an initial reluctance on the part of the Blood Transfusion Service to participate in autologous provision - as illustrated by this paper. This is now diminishing as autologous provision is realised to be a complement rather than a threat to the blood supply. Those giving blood just before or during

surgery would not be considered as standard donors anyway, so an entirely new source of blood is being tapped.

Perhaps another significant inhibition to pre-deposit services in Britain are the guidelines laid down by the British Blood Transfusion Directors Committee on Autologous Transfusion. They are much stricter than the American Association of Blood Banks Guideline as is shown in Table 8 and so exclude significant numbers of patients. The fact that screening for infectious diseases is mandatory, increases the costs considerably and makes no sense if the blood is only to be used for the original donor. Were the donor not an autologous patient their unscreened blood would be passing through the laboratories and exposed at surgery anyway. Any mishap due to clerical error would be far more likely to cause immediate fatal consequences due to ABO mismatch than long-term problems due to unscreened viruses. The fact that a small proportion of their blood is sealed in a plastic pack seems no justification for it to receive special screening, provided it is correctly and distinctively labelled and stored separately from standard donor blood.

By contrast funding is not difficult to obtain in the private sector, however because of its more fragmented nature, communication is less easy and recruitment of patients tends to be slower.

39. My paper concluded:-

The results of projects such as the one in Sunderland have encouraged further NHS provision. In Summer 1989 it was decided that the service had proved feasible and cost effective and the Northern Regional Health Authority decided to grant £180,000 to enable the service to be extended to five further Districts under the Northern Regional Blood Transfusion Service. Results of this pioneering Regional Service are eagerly awaited, and should give encouragement to others...

The new financing arrangement for the NBTS where crosscharging and realistic pricing of blood products has been instituted to fund the service, may further encourage the use of autologous blood. Revision of the British

Guidelines for autologous pre-deposit blood provision is currently underway and if they become less restrictive will enable more patients to benefit from this simple and cost-effective method.

40. I left Sunderland in May 1990 to take up the position of Clinical Haematologist at the AMI Group's Hospitals, which are major private hospitals undertaking comprehensive and complex private medicine and surgery. Each clinic has an Intensive Care Unit. At the same time I was appointed Clinical Director of the laboratory responsible for haematology, bio chemistry and micro biology. The laboratory offers both an internal service to the Clinic and also a comprehensive laboratory service to other busy private London hospitals. Hospitals served were the Harley Street Clinic, Princess Grace and Portland Hospitals, increasing to include Wellington in 1995.

41. At the time of my departure Northern Regional Health Authority was starting up the extension of the pre-deposit service in five further Districts. It was most encouraging but not to last. For a combination of reasons (not least competing priorities for funds) interest in pre-deposit autologous transfusion waned and by 1992 the Sunderland experiment was effectively at an end. Accepting there is ample scope for genuine differences and seldom one answer exclusive of all others to matters of professional opinion, I was sad at the ultimate outcome. At Sunderland we had proved that pre-deposit autologous transfusion was practical, safe and cost effective. Whilst I am sure others will disagree, I remain convinced that failure to develop autologous transfusion within the National Health Service represents a major missed opportunity.

42. As the Clinical Haematologist in charge at the Harley Street Clinic I have continued to recommend pre-deposit autologous transfusion to the Clinic patients but the take up is very low. On average we probably have 36 pre-deposit transfusions a year. Those patients who do participate in pre-deposit autologous transfusion tend to fall into two groups. First, patients from abroad such as Americans, Australians, French and Italians who are familiar with the concept in their own country. Second, United Kingdom doctors and their relatives.

43. I am Secretary of the Autologous Special Interest Group of the British Blood Transfusion Society. I have written numerous articles on the topic. In 1993 I published one such paper *Autologous predonation of blood for elective surgery* in Current Practice in Surgery. Under the heading *Controversies in autologous predonation* I said:-

> *Despite the fact that autologous predonation has been practised since the early 1960s, some controversies concerning its use persist. (See Autologous Blood Transfusion: current issues cited in reference.)*
>
> *Some argue that if blood is destined solely for the original donor then there is no need to go to the expense of screening for infectious disease, since, were that patient not an autologous donor, his blood would be exposed in theatre and pass through laboratories with no-one being aware of its infectious state. Conversely, if it is so thoroughly tested why are we not permitted to utilise it for other patients if it is unused by the original donor, a process known as "crossing over"? At present guidelines on both sides of the Atlantic insist on complete screening for infection and discourage (in UK prohibit) "crossing over".*
>
> *The wisdom of "crossing over" blood from patients who may be on medication is certainly open to question but screening for infectious disease if the intention is solely to retransfuse the blood to its owner seems over-cautious. The argument is that the blood might accidentally be transfused to someone else. If this lamentable mishap should occur however, the consequences of an ABO mismatch will be far more immediate, life threatening and recognisable than any transmission of infection. Within National Blood Transfusion Service laboratories it may well be easier to treat all blood exactly the same, and test autologous collections as for standard donor blood. However, until the Blood Transfusion Service can guarantee provision of user-friendly nation-wide autologous donor facilities, autologous clinics at District General Hospital level will be needed to fill the gap. For them screening for HIV 1 and 2, hepatitis C and no doubt soon also HTLV1 is time consuming and*

expensive.

The availability of autologous donor clinics is patchy. The National Blood Transfusion Service laboratories in Newcastle upon Tyne and North London provide autologous donor clinics, but most others do not have regular sessions. However interest is growing and the recent establishment of the multidisciplinary Autologous Blood Transfusion Special Interest Group of the British Blood Transfusion Society, whose aim is to promote research into and practice of all methods of blood conservation, may help to bring autologous blood to more patients. In USA, approximately 1 in every 20 units transfused is autologous, and in one blood transfusion centre over 1 in 7 units collected is an autologous unit. The fact that in most American states it is now mandatory that written informed consent of the patient is required before blood transfusion may have stimulated this level of provision.

It is well known that UK patients who have contracted hepatitis C and HIV through standard red blood transfusion have sought recompense from the Government which may eventually lead to a similar need to obtain written informed consent prior to blood transfusion. There is no doubt that, should patients require transfusion to cover surgery, autologous blood by whatever method is the preferable option.

44. Whilst I remain an enthusiast of autologous transfusion I have to say that in the years since I embarked on the Sunderland trial I have found comparatively modest support from colleagues within the United Kingdom, particularly those haematologists practising in the National Health Service. I am aware that colleagues have different views as to the merits of autologous transfusion. I respect their entitlement to hold opinions substantially different to mine. I would, however, like to correct certain facts and draw attention to certain matters which are sometimes overlooked:-

(a) It is true that pre-deposit is not suitable for anaemic patients but that does not exclude autologous transfusion entirely. The anaemic patient can still benefit from intra-operative salvage or post operative reinfusion.

(b) Pre-deposit is not appropriate in those cases where the need for transfusion

originates in trauma (because the time and place cannot be pre-determined) but this does not exclude intra-operative salvage. There is a case very well known to me where Dr Dafydd Thomas, an anaesthetist at Morriston Hospital, Swansea, saved the lives of three young patients who had sustained massive internal injuries. Dr Thomas found himself faced with a need for a large volume of blood which could not be met from the hospital's homologous reserve so he resorted to intra-operative salvage and saved their lives.

(c) With homologous blood there is always a risk of immuno suppression due to an influx of foreign antigens into the body. There is increasing evidence that patients who have autologous transfusions develop fewer post operative infections (both in the wound and in the chest) whilst reducing the length of their stay in hospital and thus cost. The reason is that by transfusing with their own blood they have not been subjected to foreign antigens with the risk of compromising their immune systems and hence they are better able to fight infection.

(d) There is an argument for saying (but at this stage it is a theoretical argument only) that cancer patients coming to surgery have a better prospect of post operative recovery when transfused with their own blood rather than homologous blood. The thinking is that there is less of a challenge to the immune system therefore allowing effective tumour-immunity preventing cancer recurrence. It is, however, important to make the point that there is respectable research to the contrary and the point is not established yet one way or the other.

(e) Patients receiving autologous transfusions report significant psychological benefit. They feel they are contributing to their own management and care. This was my experience at Sunderland. 54 of my Sunderland patients went through autologous transfusion twice. For example, they would have one hip replaced and then the other. The fact that 54 patients returned for repeat autologous transfusion is some indication that the patients were happy with the concept, both in theory and practise.

(f) Blood donations from friends and relatives are not generally to be encouraged

but there is one exception to this and that is a mother donating blood to the child. Both in theory and practise a mother's blood is preferable to third party donor blood, provided blood is irradiated to prevent graft versus host disease.

HCV Screening Assays

45. I introduced anti HCV 1.0 screening assays at Sunderland some time in the four weeks ending November 1989. I know this because of an entry I made in my 1989 Diary. It reads:-

> *Ortho Hep C test order number A-2422 (charged to) Dr Kay research fund one pack 480 (tests) £1,152 + VAT or £1,080 (with) VAT exempt certificate. (Will arrive) end Oct to Mid-late Nov 5 - plate box, 480 wells = 375 actual tests.*
>
> The assay was produced by the Chiron Corporation of America under the trade name of Ortho. It was my decision. I saw it as a major step forward.

46. The test had just become available. My recollection is that *Ortho* were, at that time, the only company licensed by the Chiron Corporation of America. I met the inventor of the test following a talk he had given at the BBTS meeting at Durham in September 1989. I invited him to a meeting at my laboratory in Sunderland and he explained how to obtain the test. My research fund paid for the tests but they were performed by the Micro Biology Laboratory at Sunderland District General Hospital. The test was readily available and easy for any laboratory familiar with the Elisa technique to perform.

47. There were two aspects to my introducing the assay in Sunderland. First, as a research exercise I screened all my autologous patients. Second, I screened on a routine basis those non-autologous patients I was seeing in the Haematology Clinic who I thought had liver disease. Over the time we used it we found about three positives which we sent down to Dr John Barbara in London to check by RIBA. All proved to be false positives.

48. From Autumn 1989 through into early 1990 (remembering I took up my new post in London in May 1990) I had informal discussions with representatives of the Northern Regional Blood Transfusion Service asking whether it was their intention to use the new HCV assay to screen donations given in blood transfusion sessions. The clear message was that Northern Region wished to postpone the introduction of the assay until all Blood Transfusion regions were ready to proceed. Again, the argument was based on administration and economics. If certain regional Blood Transfusion Services introduced the assay in advance of others so there would be consequences. First, those introducing the assay would have to bear assay costs which were not falling on others which could lead to misconceived arguments that expenditure in one Regional Transfusion Service was higher than others. Second, there was a fear that those introducing the assays sooner rather than later would shame others into following suit before they were ready administratively and economically.

49. **I believe the facts stated in this Witness Statement are true.**

Signed: **……..**
DR LESLEY KAY MB BS; FRCP FRCPath

Dated the day of 2000