Note of meeting with Dr. Patricia Hewitt, Deputy Director of North London Blood Transfusion Centre, Deansbrook Road, Edgware, Middlesex.

The North London Blood Transfusion Centre collects blood from donors at three fixed centres and from mobile clinics. The fixed centres are at Deansbrook Road, (DBR) Edgware, Middlesex, West End Donor Centre (WEDC) Margaret Street, London W1 and St. George's Square, Luton, (Luton) Bedfordshire. The donor centre at Luton was opened in 1988. The Deansbrook Road Centre is open five days a week and four Saturdays each year. The West End Donor Centre is open five days per week. St. George's Square Luton is open Monday to Saturday lunch-time.

Mobile clinics collect blood each day. There are 23 mobile clinics. In addition there are five sessions for the Blood-mobile vehicle. The collecting pattern was slightly different before the fixed centre in Luton was opened.

At each of the thee fixed sites there is one medical officer on the site while donors are present together with clerical staff. In addition there is at least one Sister and a number of Registered Nurses or State Enrolled Nurses who are trained as phlebotomists together with a number of donor attendants.

In each mobile clinic there is a medical officer who acts as the phlebotomist together with two driver/receptionists and a team of donor attendants. One of the donor attendants is senior and he is called the team leader.

The weekly figures for the collection of blood from 1973 are readily available. There are also annual summaries.

We provide a return to the Department of Health on form NBB 47. It gives information about the number of donations, new donors, the blood components produced and the amount of blood and blood components issued. We have the form 47's back to 1980 readily available.

A donor who has given blood before at a particular site becomes a member of that donor panel. The records of each member of the panel go to the collection site whether that donor has been sent a notification that we are collecting at the site on a particular day or not. For public sessions we send individual notifications to donors whom we wish to attend to give blood. A clerical officer selects the donors who are sent notifications. Each donor is called at roughly six monthly intervals. At work places no individual notification to the donors is sent.

If a donor has given blood before and is a member of the panel his record card should be available. One side of the card shows his name, address, date of birth, telephone number if available and blood group. It also shows whether he has any particular antibodies. It does not give all of the information about antibodies which the lab might use. On the reverse side of the card there is a record of the donations which that donor has given. It gives the date of donation, the unique donation number for each donation and a record of his haemoglobin. Haemoglobin is recorded as a pass or fail. If the person's haemoglobin is

sufficiently high they are recorded as a pass. If they have failed the figure is shown.

About one third of the donors whose initial pass/fail test shows a fail become passers when their haemoglobin is tested more accurately. 13.5 g/dl is a pass for a male and 12.5 g/dl for a female. Those have always been the figures. The donor card then shows the volume of blood removed. The normal amount is 450 mls, plus/minus 10%. If it is within 10% of 450 mls then the figure is recorded as 450 mls. On some earlier records the card would show the word "full" which meant that a "normal" donation had been given. That is equivalent to 450 mls, plus or minus 10%. If the amount collected was outside the 10% tolerance then the volume of blood collected is shown. Since 1985 we have routinely collected 250 mls of blood from small donors. The card then shows the initials of the donor attendant who cared for the donor and the medical officer or nurse who performed the venepunture. There is then a space for any comments.

The blood bags are collected in trays and taken back to the Blood Transfusion Centre. Most of the blood would be taken back to the Centre within 6 hours of collection.

Someone attending who has never been a donor before is booked in as a new donor. Blood would be taken from them in the same way but their blood is collected in a single pack rather than in a multiple pack. The multiple pack is used for known donors, it enables the blood to be divided into its consituent components in sterile conditions.

A donor who has donated blood elsewhere for whom no record card

is available and who does not have his certificate book with him would be treated as a new donor. A donor would be treated as known if he had given blood in the previous two years elsewhere in the UK and had his certificate book with him.

Each donor is shown a notice giving a list of conditions that must be declared That is form NBTS/110. The form was amended in October 1985 to include the information that the donors blood would be tested for the Aids virus. (samples of the old and new forms to be provided). That form has to be signed by the donor. A single form provides space for 112 donors to sign. The form is about to be amended once again.

If a potential donor declares to the receptionist one of the conditions listed on form NBTS 110 (eg hepatitis) then he would be told to go and see the doctor before going any further. With certain minor conditions, (eg hay fever) then the receptionist would tell the donor to mention that to the doctor before giving blood. The receptionist is not seen in private. All donors are asked to sign the form before they are seen by a doctor.

In October 1985 we started displaying a notice to tell donors that their blood would be tested for "the Aids virus" HIV. The notice said that donors who thought that they were at risk of infection they should not give blood. The notice also told them where they could go if they wanted to have a test. The notice was purely about Aids.

Each donor has his haemoglobin tested before giving blood. A lancet is used to make a tiny incision on a finger and a drop of blood is taken into a pipette by capillary action. The droplet

of blood is allowed to fall into a solution of copper sulphate. If the droplet sinks, this is an indication to the donor attendant performing the test that the haemoglobin is sufficiently high or not. If they pass that test and are otherwise eligable, donors may give blood. If a "fail"result is produced then another drop of blood is taken. That is then tested in a portable haemoglobinometer in order to determine the actual haemoglobin level. The level is then recorded on the card.

If a donor was eligible to give blood then, since late 1983, we have given each donor a leaflet about Aids. We have also given donors a questionnaire to fill in. This commenced in July 1984 in one static clinic (WEDC) and was extended to all clinics by July 1985. The questionnaire is filled in in private at a screened desk. The donor is asked to read the leaflet and fill in the questionnaire. The questionnaire has been changed on numerous occasions.

The first memorandum is dated 25th April 1985. It sets out the procedure to be followed. A further procedure was set out in a subsequent memorandum dated 9th July 1985. An instruction was given in a memorandum written by me dated 17th July 1985 saying that the Aids questionnaire will be in routine use on all sessions starting on Monday 29th July 1985. The revised questionnaire was then used. The questionnaire was then revised again in November 1985. The change reflected the difference in definition of the first "high risk" group. The questionnaire was revised again in February 1986. On that occasion, we told donors that donations from those who responded positively to the questionnaire would not be used for transfusion purposes instead

of saying that it would be used "for research purposes". The questionnaire was revised again on 20th October 1986. On this occasion we revised the categories of "high risk" groups in line with the advice given by the DHSS in the donor Aids leaflet. We added two further categories. First, we included people who had visited or lived in Africa since 1977 and had sexual contact there and haemophiliacs who had received unheated blood products since 1977. The questionnaire was revised again on 3rd February 1987. I sent a memorandum out on that day including the new form which revised the risk categories. The new categories were prostitutes and men who had had sex with a female prostitute in the previous 18 months. On 2nd February 1987 a memorandum was sent out dealing with the number of missing questionnaires. The donor completes the form by ticking a box. Donors do not sign the form but each form is labelled with the unique donation number which will be used for that donor's blood.

We introduced the questionnaire into our West End Donor Centre in mid July 1984. Following our use of that questionnaire we wrote a paper which was published in the British Medical Journal in . After using it in our West End Donor Centre, we introduced the form at Deansbrook Road. At our West End Centre, a significant proportion of donors responded positively to the questionnaire. At Deansbrook Road there was a much lower positive response rate, as we had predicted, in view of the different donor demography. We felt the questionnaire was a useful back up to the DHSS leaflet and since mid 1985 have used it in all of our collecting centres. So far as I know no one else in England or Wales uses that questionnaire.

The donors are instructed that if they are in a "risk group"

(although the phrase "risk group" is no longer commonly used) they should tick "yes" and should not give blood. Donors are told that if it is absolutely impossible for them to go away without donating blood (because they do not wish to reveal to their fellow workers that they cannot give blood) they should still tick "yes" and we would see that their blood is not used. The completed questionnaires are put into a ballot box by the donors.

When the blood is returned to the centre it is returned with the ballot box containing the forms. The forms are then checked before the blood is processed. If the clerical staff are not available the processing laboratory staff would check the forms. If the form is marked "yes" then the procedure is for the clerical officer to enter that in the computer which "holds" the blood. She would then go and physically remove the bag of blood. There is a written procedure setting out what she should do (obtain copy of written procedure). Some donors look at the forms at the donor clinic and then ask to speak to a doctor. Some people use the forms to put details rather than to put "yes". Anyone who is doubtful is treated as a positive until I or my deputy or the microbiologist say that they may be treated as a negative.

All of our blood donors on all occasions fill in the questionnaire.

Whole blood may be divided into three useful components, red cells, plasma and platelets. We also collect plasma, as opposed to whole blood. Plasma is only collected at the three static centres. We have separate panels of plasma donors. A plasma

donor has whole blood extracted. The plasma is then separated by a machine from the red cells and the red cells are given back to the donor. Plasma donors donate by appointment. They are seen at regular intervals. They are generally given appointments every two to three weeks. To be a plasma donor the person has to be capable of being a regular attender and to have good veins. Initially, we asked our plasma donors to fill in the questionnaire on each attendance. However, they were attending so regularly that we stopped requiring them to fill in the form on each occasion. Instead, they now fill in the questionnaire on each occasion that we have changed the wording of the questionnaire.

The venepuncturist is expected to check that the donor is eligible to give blood before actually extracting blood or plasma. That means that the donor is within the age limits, has not taken any medication which would affect the blood, has not recently travelled to a Malarial are and has filled in the Aid questionnaire.

Blood and plasma taken from donors is put in "quarantine" at the Centre. The blood will then stay there until it has been tested.

The tests performed at our transfusion centre are the same as those performed at all the transfusion centres in England and Wales. One laboratory performs test for the ABO and Rh blood groups. A separate microbiology laboratory tests the blood for (1) Hepatitis B surface antigen, (2) Syphilis and (3), a proportion of the blood is tested for CMV (cyto-megalo virus). Once the tests have been done the blood is labelled with its

ABO and Rh (if a new donor). Donations from established donors are labelled with the ABO and Rh group at the clinic, this is checked at the Centre with the result of the new laboratory test. A check is then made that all the microbiology tests are negative and the blood would then be released to the issue side of the fridge.

The vast majority of blood collected from previous donors (donors on the donor panel) is put into the processing laboratory. That means that the blood is usually divided into red cells, platelets, and plasma. All three parts would be in quarantine until the same tests that I have described above are performed. The platelets are put into a quarantine incubator until the tests have been performed. They are then put into the issue incubator. The plasma is frozen and when the results are available the plasma is either issued to the hospitals for use or to the Blood Products Laboratory at Elstree.

When platelets and some or all of the plasma are removed from a blood donation, "packed" or concentrated red cells are then left. The red cells can then be used by the hospitals.

Plasma from plasma donors is also put into the processing laboratory. The majority would not be processed but would go directly for freezing in quarantine until it had been tested.

Until 1988 blood from new blood donors (previously untested donors) remained unprocessed. It was issued as whole blood. That is because it is potentially a waste of effort to pool the plasma from new blood donors before testing. An adverse microbiology result from only one unit of the pool would mean

that the whole pool could not be used. Where a person has been tested before by the transfusion service it is thought appropriate for their plasma to be pooled before testing because the risks of an adverse result are significantly less.

Until 1988 new donors blood was always issued as whole blood. In 1988 we started to process single units from new blood donors. We removed the plasma. We were able to do that because when we moved to our new premises we could freeze more single units. Before, our facilities were such that we had to pool before freezing.

The biggest pool we create is five litres of plasma. That is the plasma from twenty to twenty five donors. That is the standard size for a pool produced at a transfusion centre in England or Wales. Only plasma is pooled and once the plasma has been pooled it is frozen and then quarantined until the individual donations in the pool have been tested. Pooled plasma is only issued to the Blood Products Laboratory. Now that we are capable of freezing more single units we also provide the BPL with single units of plasma. [provide documents showing the volume of plasma to BPL]. Until 1989 the Blood Products Laboratory set us targets for plasma production based on our resident population. The Blood Transfusion Service was told how much plasma was required. I refer to the letter written by Dr. Contreras to Mr. Kenny, the Regional General Manager dated 23rd November 1984. BPL had set, in September 1984, fresh plasma "targets" for us. They were as follows :-

| Year | Plasma Collection Target |
|---|---|
| 1983/84 | 10640 kg |
| 1984/85 | 14560 kg |
| 1985/86 | 20230 kg |

| | |
|---|---|
| 1986/87 | 26110 kg |
| 1987/88 | 30520 kg |
| 1988/89 | 31955 kg |

During the year 1983/84 our production was 9959 kg. The plasma target figure set by BPL for 1984/85 was originally 13825 kg but during the year it was increased to 14560. When the operational programme for 1985/85 was written it was anticipated that the maximum amount of plasma sent to BPL during the year 84/85 would be of the order of 14000 kg. In the short term programme for 1986/87 we anticipated collecting 17703 kg of fresh frozen plasma in excess of the target for 1985/86 which was then 15980.

The requirement was set by BPL in conjunction with the Haemophilia Reference Centre directors. The Blood Transfusion Service played no part in determining how much plasma had to be provided. [provide correspondence about targets] Until last year we never met our target for the provision of plasma to the BPL. We are now over producing. In April 1988 a system of cross charging was introduced between the Blood Products Laboratory and the Transfusion Service.

In the Transfusion Service we have always had to balance the various demands placed upon us. There are conflicting needs. Surgeons in the United Kingdom often use whole blood. That is blood from which the plasma has not been removed. If we supplied more whole blood to the surgeons that meant that there was less plasma available for the BPL to use. We also provide platelets. Each unit of platelets requires about 50 mls of plasma. Our provision of platelets to patient in hospitals meant that we could not provide as much plasma to the Blood Products Laboratory.

We have been producing about 100,000 units of platelets per annum. They are used especially to the treatment of leukaemias and for bone marrow transplants. We provide platelets for the bone marrow transplant units at the Hammersmith Hospital, Great Ormond Street Hospital, The Royal Free Hospital the Westminster Hospital and University College Hospital/Middlesex Hospitals (until April 1988).

To divide the blood into the three parts, red cells, plasma and platelets the blood is centrifuged. The plasma and platelets are taken off first. The plasma with platelets is then centrifuged again to settle out the platelets.

Of the 450 mls in the bag 200 to 225 mls would be of red cells. As much plasma as possible is removed from the red cells. That means about 200 mls. If you are making platelets then about 50 mls of plasma must be left with the platelets, leaving about 150 mls of plasma. In other words, when we are not making platelets we are able to send 200 mls rather than 150 mls of plasma from the bag of whole blood originally collected to the BPL.

100,000 units represents about 50% of the blood donations obtained by our Centre. The figure has remained fairly constant since 1984. As we have collected more blood we have produced more platelets. [provide figures]

Cryoprecipitate was first described in the early 1970's. Cryoprecipitate can be produced on demand by us. We could use all of the plasma we have to make cryopreciptate. There is no real limit on the production. It is demand led. If the clinicians were asking us to produce more cryoprecipitate than we

did produce we would have produced more. If all the blood was used to produce cryoprecipitate then we would not have been able to provide any plasma to the Blood Products Laboratory. The only limit on the amount of cryoprecipitate would be from the size of the freezing capacity. About 15 mls of cryoprecipitate would be obtained from 150 mls of plasma. The clotting factors are precipitated out from the plasma. Cryoprecipitate contains the clotting factors, like Factor VIII, and Fibrinogen.

I have been asked about the link between a person having had hepatitis and their having HIV. Hepatitis can be a sub clinical illness and not everyone who has had hepatitis will know that they have had it. Only a proportion of the people who have hepatitis, whether it is clinical or sub clinical become carriers of hepatitis B. Hepatitis A is the classical "yellow jaundice". It does not have a carrier state and except in very rare cases it cannot be transmitted by blood transfusion. It is only possible to transmit hepatitis A virus while you are in the incubation stage. During the incubation stage with hepatitis A the person feels very unwell and so is unlikely to wish to donate blood. There has therefore been no question of screening for hepatitis A in the Blood Transfusion Service.

Because hepatitis B has a carrier state and is often a sub clinical illness it was probably the most common cause of a blood transfusion death until tests for hepatitis B were found.

The test for hepatitis B was discovered in the early 1970's. It was introduced early on at the North London Blood Transfusion Service. Dr. Dane, a virologist who was involved in the work which led to a test being discovered is an honorary staff member

of the North London Blood Transfusion Centre.

There is a direct test for the hepatitis B virus. That is to say that the virus itself is found by the test rather than the test finding something which shows that the virus has been there.

Hepatitis non A non B is diagnosed by exclusion. It has been recognised for a long time that it can be transmitted by blood transfusion. It is probably now the most common cause of post transfusion hepatitis. A large number of the people who have hepatitis NA NB have a sub clinical illness. A proportion, the amount of which is disputed, may go on to develop chronic liver disease and eventually liver cirrhosis.

In the last year we have been doing studies on hepatitis NA NB. The actual virus has not been identified. A proportion of the people who have raised ALT (a liver enzyme, alaine aminotransferase) have been found to be capable of transmitting NANB, similarly, a proportion of people who have an antibody to one part of the hepatitis B virus (the anti-core antibody) also seem to have an increased chance of transmitting hepatitis NA NB. In conjunction with the Manchester and Bristol Blood Transfusion Centre we are looking at the incidence of the two markers in a donor population. Under 1% of our donors have the anti-core antibody. That is 0.8%. About 2 to 3% have an elevated ALT.

The second study that we are carrying out is a prospective follow-up of blood recipients to see how many develop NA NB. We are looking for that by performing serial blood tests.

In 1988 the Americans introduced a policy of testing for

anti-core antibody and performing ALT tests. They would then not take blood from people who had the anti-core antibody or who had abnormal ALT.

We are looking to see what proportion of donors we would lose if we followed that policy. We are been asked to do that by the National Director, Dr. Gunson.

It now appears that the majority of the NA NB population have hepatitis C. The HCV (Hepatitis C Virus) test is only available on a research basis. It is not yet used in America for the blood transfusion service there. It is likely to get FDA approval in spring 1990. It is possible that Dr. Gunson will reccomend to the DH that the HCV test should be introduced in the UK transfusion centres as soon as it gets FDA approval in America. We have been asked to budget for performing HCV tests next year (1990).

All donors are tested for hepatitis B whether or not they have a history of hepatitis. Those who have a history of hepatitis who are negative for HBslg are allowed to donate blood. In 1989 we introduced a policy of testing all donors with a history of hepatitis since childhood for hepatitis B core antibody and for antibody to HCV.

It is of interest to note that the test for Syphilis could be thought of as an indirect test. It tells you that the person has had Syphilis or a similar infection but you cannot tell whether they are in an infectious state at the time of the test from the fact that they have a positive result. It could be said that the test for Syphilis is an indirect test for HIV, since some of the

population which has had Syphilis may have also been exposed to other sexually transmitted infections such as HIV.

Dr. M. Contrereas is the director of the North London Blood Transfusion Centre. The Transfusion Centre directors met quarterly until this year. Their meeting are minuted. We have the minutes available from 1984 onwards. When we moved premises recently the earlier documents were destroyed in the move. In 1984 Dr. Gunson was the transfusion adviser to the Department of Health. He has since become the National Director of the Blood Transfusion Service. Prior to the appointment of a National Director there was discussion amongst the Regional Transfusion directors about whether a National Director was required. The Department of Health then commissioned a study team and after they reported a National Director was appointed. Although there is a National Director each centre is funded by its own Regional Health Authority. We are funded by North West Thames Regional Health Authority and Dr. Gunson has no budgetary control over us.

(para 92(d)) Mr. Martina is the donor organiser at North London Blood Transfusion Centre and he has been in post for many years. Dr. Contrereas was appointed the director of the Centre in 1984 when Dr. Davies retired. At about the time of her appointment the Regional Health Authority asked us to provide an annual plan. I have provided copies of the annual plans that we have prepared.

(para 92(g)) In September 1983 the DHSS issued the first information leaflet for donors about Aids. It was coloured grey and entitled "AIDS. And How it Concerns Blood Donors". It identified groups of people who appeared to be particularly susceptible to Aids. The

first group was "Homosexual Men Who Have Many Different Partners". In late 1984 we altered that part of the form by over printing that phrase and substituting for the first category "Practising Male Homosexuals and Bisexuals". This was because our discussions with other experts and with homosexuals led us to believe that the original definition was too narrow and did not include all these at risk of HIV infection.

The donor leaflet was revised by te DHSS on many occasions. The second leaflet issued by the DHSS was coloured pale orange and entitled "AIDS Important New Advice for Blood Donors". It was issued in January 1985. The third leaflet was coloured pale green and entitled "AIDS Important Information for Blood Donors" and issued in September 1985. The fourth leaflet was coloured bright yellow and entitled "AIDS What You Must Know Before You Give Blood" and was issued in September 1986. The fifth leaflet was coloured dark green and entitled "AIDS Think Before You Give Blood". It was issued in July 1987. Attached to my copy of that leaflet is a memorandum which I wrote dated 3rd August 1987. The memorandum recorded our belief that we did not agree totally with the wording on the leaflet and that we would be continuing to use our own donor questionnaire which I have already mentioned. We show people the leaflets issued by the DHSS to potential blood donors as we are required to do by the DHSS. However, we still insist that our donors fill in the questionnaire which we have prepared.

(para 92 (r)) Instructions have been given to members of our staff working in donor clinics on what to do if they suspect that a person would come within one of the "risk groups". These instructions were given befoe the introduction of the donor questionnaire and

testing of all blood for the presence of anti-HIV.

Blood is destroyed in the usual way if it is found to have been given by a person who is not eligible to donate blood.

We screened blood donations for anti HTLV 3 from 23rd September 1985. A letter was written by Dr. Contreras dated October 1985 to all consultant haematologists who obtain blood from our Centre. On 25th October 1985 Dr. Contreras received a letter from Dr. Alison Smithies at the DHSS enquiring about our stock of blood and blood components. Dr. Contreras replied to her in a letter dated 29th October 1985.

As the documents show, the national start date for testing blood and blood products for anti HTLV 3 was 14th October 1985. Because we knew that blood donated before that date would still be in stock on the date we started testing earlier than the agreed date. We wanted to be sure that all blood we issued on and after that date had been tested.

Once the (anti-HTLV III) HIV test was introduced no blood or blood products could be routinely issued on the day of donation. From start to finish the test took three hours.

Five or six manufacturers were producing test kits for anti-HTLV-III in 1985. The first test kits were available in early 1985. However, the first kits were not necessarily suitable for use in a transfusion laboratory although they may have been suitable for testing a few patients a day who presented and wanted a test carried out. The Americans routinely tested donated blood for HIV from March 1985 when the kits were given

FDA approval. The Department of Health Commissioned a report from Dr. Mortimer at the PHLS to do an assessment of the suitability of the various kits for the blood transfusion work. Most Blood Transfusion Centres piloted the few kits to see which suited them best before 14th October 1985. We did our own pilot study with the Wellcome kit and others in summer 1985. Wellcome's kit used a different methodology to other manufacturers' kits. It was preferred in the United Kingdom. Only one or two Transfusion Centres are not using the Wellcome kit now. The test kits have been refined from time to time and manufacturers would generally withdraw the old kit when the new one became available. It is important to make a distinction between a test kit that would do a small number of tests each day and the kit that we required. We required a test kit which would be reliable and would do up to 1000 tests each day. Wellcome supply us with the whole test kit.

(para 91) A variety of surrogate tests to detect individuals possibly at risk of AIDS have been used in the past. For example, in San Francisco they tested individuals blood for the anti-core antibody. There were also a variety of immunological markers which were looked for. These tests may have been valuable as research tools but they were impractical for blood transfusion centres in the UK, lacked sensitivity and specificity, and were not justified for use in an area with a low incidence of Aids.

We have performed a study on the blood donated by people who responded to our questionnaire forms by indicating that their blood should not be transfused. We have tested such donors for the anti-core antibody.

The medicines inspector has inspected our laboratory on a number of occasions. Since 1975 he has inspected on [ ]

We hold correspondence and documents relating to the issue of Factor VIII supplied to us by BPL. Dr. Ardeman, the consultant haematologist at Edgware General Hospital acts as the "arbitrator" between the various hospitals who receive their Factor VIII from us. In the final analysis he would determine the allocation of Factor VIII between the competing interests of the different hospitals. He did not receive any Factor VIII himself.

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