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STATEMENT OF
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I am a Principal in HS1A (Health Services). I have been in this post for about 2½ years. The factors that led up to the heat treatment of Factor VIII had been established before I took over this post but I am familiar with the issues involved.

BLOOD TRANSFUSION GENERALLY

Whole blood is taken from a blood donor. The blood basically consists of red cells, white cells and the liquid element which is called plasma. The plasma can be separated in the process of taking the donation or can be separated later from an ordinary donation. If it is separated afterwards it is done at the Regional Blood Transfusion Centre.

The red and white parts of the blood need to be used within a month but the plasma can be frozen and stored before processing

From the plasma you can get a variety of blood products which can be used for different conditions. One of the products that can be obtained is called Factor VIII.

HAEMOPHILIA — NEED FOR FACTOR VIII

In a healthy individual it is the Factor VIII that enables blood to clot. This would occur not only for the surface of a wound but also internally. The Factor VIII can be missing in varying degrees and causes haemophilia. According to the amount of Factor VIII missing, the person suffers from haemophilia in varying degrees.

The significance of Factor VIII in blood clotting has been known for decades but it was not until the mid-1970s that it was sufficiently refined to be able to be used on its own.

Nowadays it is used both immediately after an injury so as to aid clotting but it is also used as a prophylaxis to assist before any injury occurs.

Factor VIII is only available from human blood. There is no artificial equivalent.

This country does not produce enough Factor VIII of its own. On average, I suppose we have produced about 20-30% of what we need. The balance has been imported. This situation is about to change. A new Blood Products Laboratory is about to become on stream and that will make us completely independent so far as this product is concerned.

The Factor VIII that we have imported over the last years has mostly come from the United States.

THE BLOOD TRANSFUSION SERVICE

Each regional Health Authority has a blood transfusion centre. The centre is funded through the Regional Health Authority as part of its expenditure. There may be one actual centre or they may have outlying buildings as well.

Each regional transfusion centre has a director. The directors meet together as a body. The body is subject to the supervision of this Department. The Department issues guidance in the form of health notices and health circulars.

Each transfusion centre is run by a consultant who is an expert in transfusion medicine. We would never seek to interfere in his clinical judgement. But on matters of management judgement, each regional transfusion centre would be entitled to go its own way.

TREATMENT OF FACTOR VIII

Up till 1983 anybody who offered blood was accepted. At that time there was no test to identify the HIV antibodies or the virus itself.

In fact in 1983 no one was absolutely sure that the disease was transmitted by virus - this was not known until early 1984.

In 1983 we decided as a precautionary measure to ask donors to defer themselves if they adopted high risk behaviour.

It was only in July 1982 that there occurred the first cases anywhere of people with haemophilia developing AIDS. These cases occurred in the United States.

The first case of people in this country suffering from haemophilia and developing AIDS occurred in August 1983.

We needed to be very careful in this area because in November 1983 one of the Ministers (I think Lord Glen Arthur in the Lords but I can check) said that there was no positive link between blood and AIDS. That, strictly speaking, was correct at the time because we were not positive but by November 1983 there were fairly firm suspicions of this link. But Indeed our own suggestion that blood donors in high risk behaviour should defer themselves had been introduced in August 1983, three months before the Minister's statement.

(I can now confirm that it was Lord Glen Arthur).

So far as we know, people complied with our request.

We had a publicity campaign ensuring that every single donor, on every occasion that he gave blood, received a leaflet pointing out what the high risk behaviour was and asking him to defer himself if he felt within those categories. As the category of high risk conduct widened we changed the leaflet to bring it up to date.

People received a copy of this leaflet when they first made the appointment to give the blood so that they could get it and read it at home. The whole idea of having them read it at home was to avoid difficulties at the donating session itself. We did not want people being put under pressure at the donating session. We wanted them to be able to read the leaflet and consider their position and avoid giving blood by making the decision in their own home and not being put under pressure at the session itself.

There is evidence that after the campaign began the number of people donating blood dropped. This was especially so in areas where we thought we had a high number of homosexual donors.

In the course of 1983, around the world a heat treatment was being developed for Factor VIII to eradicate the hepatitis element which was known to be transmitted through that.

When, in early 1984, it became apparent that AIDS was transmitted through a virus it was decided that the heat treatment that had been developed for hepatitis should be applied to Factor VIII for AIDS purposes as well.

The situation at that time was that in order to live, a haemophiliac would have to have some Factor VIII. He could be offered untreated Factor VIII or Factor VIII that had been heat treated. The only way at that time of knowing whether or not the heat treatment had been successful was if the individual did or did not develop AIDS at some later stage.

In October 1984 it became established that heat treatment could be successful in inactivating the HIV virus. That was research carried out in the United States. We knew this research was going on. It was reported in the usual medical press.

In February 1985 there was then evidence that the heat treatment of Factor VIII was being successful in preventing the spread of AIDS in that way.

We have always maintained that heat treated Factor VIII that was imported became more widely available from October 1984. From January, 1985 all imported Factor VIII was heat treated.

We have always maintained that our own Factor VIII comes from a purer resource. Blood is donated in this country by volunteers. In the United States you get paid for doing it.

From April 1985, all Factor VIII produced in this country was heat treated.

The net effect of that is that since January 1985 all imported Factor VIII has been heat treated, and since April 1985 all home-made Factor VIII has been heat treated.

Heat treatment is not something that could have been introduced before the time that it was introduced. The heat treatment process requires a much purer product which was not available until the time that the heat treatment began. It was the obtaining of the purer product that, if anything, delayed the introduction of the process of heat treatment rather than not knowing the process of heat treatment itself.

+ for HIV antibodies.

The business of
~~All this business about~~ getting donors to defer themselves if they were in a high risk category, and heat treating factor VIII, was taking place ~~against a background of the fact that~~ at ~~that~~ a time when we did not have any simple test for identifying either ~~the~~ HIV ~~virus~~ or the HIV antibody in a blood donation ~~from a donor at the time that he gave blood~~.

The American Food and Drugs Administration in about April 1985, ~~I think (I can check the date)~~ approved a much quicker form of test. This was introduced in the United States in May 1985 and meant that from May 1985 blood taken from a donor in the United States could be taken, then taken to a laboratory where it could be quickly and efficiently tested for the antibodies to the HIV ~~virus~~.

Any infected blood was ~~thrown away~~ not used.
A similar
~~That~~ test was introduced in this country in October 1985.

There were very good reasons for the delay between ~~the~~ a test being used in the United States in May and getting it being introduced in this country in October.

First of all, we had to make sure that the test was accurate. We could not allow a test to go into wide use that would produce too many false positives, which would be expensive in terms of blood, or too many false negatives which would be falsely reassuring. The early tests that were carried out were not so satisfactory that the testing system could be introduced straight away. The testing procedure improved over the months prior to its final introduction.

Another important factor for not introducing it straight away was the fact that we wanted to make sure that when it was introduced in the blood transfusion service it was also available at the GUM clinics.

If we had introduced ~~a quick, efficient and accurate~~ testing for antibodies to ~~the~~ HIV ~~virus~~ only at blood transfusion centres ~~only~~, then we ~~were assured~~ feared that those centres would be inundated with homosexuals offering to give blood solely to find out their viral status. This would have been very ~~inefficient~~ dangerous and something that we wanted to avoid so far as we could. It was not, therefore, until October of that year that we had the test available to be issued to GUM clinics so that it could be used there.

The test is not, of course, of any value if the blood is taken during the window period (the period between ~~which~~ the individual becomes infected ~~but before which~~ and the antibodies become identifiable)

For that reason we have continued to tell high risks donors not to give blood and we ~~both the screening of blood at the donating sessions and the heat treatment subsequently~~. have continued to heat treat Factor VIII.

Even if blood is found to be free of HIV antibodies after tests, ~~clean after the test after the donation~~ the Factor VIII derived from it is still heat treated.

In the process of making the Factor VIII the ~~Factor VIII~~ plasma from thousands of donations is all mixed together and treated simultaneously. It was partly for this reason that so many people became infected because it only needed one blood donation to be infected for a large quantity of Factor VIII to be infected.

The new blood products laboratory which is due to open soon is at Elstree. This is run within the NHS but is run very much on commercial lines. It will eventually make this country self-sufficient in Factor VIII. It was given the go ahead in 1981 before the problems concerning AIDS were ever known about. Building started in 1983 and to produce a factory of that complexity in 5 years is not bad going at all.

During that time, we had no alternative but to import Factor VIII since we simply did not have enough of our own to go round.

~~Throughout this period we had no alternative but to accept Factor VIII from abroad. We had to accept it in whatever condition it was in.~~ The alternative to not ~~accepting it and~~ using it would have been to ~~allow the haemophiliacs to die~~. put haemophiliacs live at risk.

The Factor VIII itself is available only on prescription from a doctor so ultimately it would be a doctor prescribing precisely what type of Factor VIII to use. The advice of doctors specialising in haemophilia, and of the Haemophilia Society throughout the period has been that the risks involved in not taking Factor VIII when it was needed, were much greater than the risk of getting AIDS ~~from a transfusion~~.

There certainly have been occasions of people who have gone for long periods of time without needing any Factor VIII, and then had one accident for which they needed some Factor VIII and have then contracted AIDS from that transfusion.

We believe there are about 1,200 haemophiliacs that have been infected with AIDS as a result of receiving Factor VIII in this way. There are a total, we believe, of about 7,000 people with haemophilia though some of those are not severely affected. In fact, we suspect that about two-thirds of those severely affected with haemophilia have become HIV positive as a result of receiving contaminated Factor VIII. I believe about a hundred of those have then gone on to develop full-blown AIDS.

I know nothing of the particular case of Mr GRO-A. So far as I am aware, this Department has not received any writs concerning matters like this. The Scottish Office in Scotland has. We have, in the past, had inquiries and requests for information from E Rex Makin & Co. ?