Y9/5.

Dr Lewis

Attached is briefing for CMO's visit to Newcastle, this covers Haemophilia Reference Centres and haemophilia issues.

GRO-C

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cc: Dr Harris
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Dr Moore
Mr Arthur

Newcastle Royal Victoria Infirmary is one of the six Haemophilia Reference Centres (circular on Haemophilia Care attached). Dr Peter Jones is the Director. Whereas nearly all the other Haemophilia Reference Centres (HRC) provide a Supra Regional Service, Newcaslte draws its patients only from Northern Region.

This may be due to the geographical remoteness of the Centre and the relative proximity of Scotland who has its own two centres. From records held at Oxford we know that Dr Jones' Centre treats approximately 150 pateints with haemophilia A a year. Numbers of patients with other coagulation disorders are not available, but Dr Jones has told me that he has a number of patients with haemophilia B. Whilst Dr Jones does not return his results on his patients with HIV infection to Oxford, he has on many occasions stated publicly that 79% of his patients have HIV infection. He returns his results on patients with AIDS to CDSC and through this record we are aware of 9 patients with AIDS and 5 of whom have died. He has also stated that 83% of his patients with HIV infection are now suffering from some HIV related effect. (See attached newspaper report) Dr Jones' experience of HIV infection in haemophiliacs and the number of patients affected with AIDS or ARC is far in excess of that in the country generally. National results show that overrall 44% of patients with haemophilia A have HIV infection, 60% of patients with severe haemophilia A are infected and out of over 2000 patients with haemophilia A who are on regular treatment 30 have now been notified as having AIDS.

SAFETY OF BLOOD PRODUCTS

We became aware in 1982 that haemophiliacs in the USA were contracting AIDS. Although the mechanism of infection was not known, it was presumed that it had been transmitted through use of blood prouducts, such as Factor VIII and Factor IX. Blood plasma from as many as 30,000 donors is pooled to make Factor VIII. One infected donation could contaminate a whole batch.

The first account of experimental work which showed that HIV in Factor VIII could be inactivated by heat treatment was published in October 1984 (Morbidity and Mortality Weekly Report 1984, Vol 33, 589-91). This work led to the National Haemophilia Society of the USA advising that heat treated Factor VIII should be considered for haemophiliacs even though its protection against AIDS remained to be proven. Similar advice was published in the UK in December 1984 (Lancet 1984, Vol 2, 1433-1435).

Factor VIII produts which had been heat treated to prevent the transmission of hepatitis were under development by several manufacturers throughout 1984 but with limited availability. The realisation that heat treatment procedures could also inactivate HIV led to the wider availability of these Factor VIII products after October 1984. Heat treated Factor VIII from the USA was available for clinicians to prescribe on a named patient basis to patients in the UK from the end of 1984.

From April 1985 heat treated Factor VIII was produced by the Blood Products Laboratory at Elstree. In October the new product Factor VIIIY was introduced. From all the evidence this product is highly acceptable to the patients. Virgin patients receiving it and closely monitored show no evidence of non A non B

hepatitis, a much hardier (virus)? than HIV.

At present around 75% of Factor VIII is imported. All Factor VIII is now made from screened donations and is heat treated.

Before heat treated Factor VIII was generally available many haemophiliacs had been infected. Present figures show that of ~~2941~~ haemophiliacs, ~~current CDR figure (May 87) 959 (32.6%)~~, tested 937 (32%) have been found to have antibodies to the AIDS virus. Some have already developed AIDS, others can be expected to do so.

There is no evidence to suggest that haemophiliacs are now at risk of AIDS. No instances of infection have been associated with the licensed heat-treated commercial Factor VIII made from screened donations products imported or from the BPL product.

Withdrawal of Armour Factor VIII

In February 1986, the CSM reviewed two cases which Dr Jones had suggested showed that Armour Factor VIII (which was heat treated but made from unscreened donations) had transmitted HIV. Both CSM and the Expert Advisory Group on AIDS decided the evidence was insufficient for action to be taken at that time. They agreed to maintain a close scrutiny.

By June 1986 the unscreend Armour Factor VIII was clearly implicated in HIV transmission. It was formally withdrawn but since it had not been allowed to be imported since 1985 residual stocks were small.

In October 1986 as a safety measure, Factor VIII made by Armour from screened plasma was also written by the Company after

discussions with the CSM. This was because the heat treatment used by the Company was considered less rigorous than other manufactures.

Counselling help for those haemophiliacs with AIDS

To help those who were previously infected the Government has so far provided `60,000 to each of the 6 Haemophilia Reference Centres in England and Wales so that they can provide a counselling service. A further allocation of `44,000 has been made to each Centre for the coming year (87/88). (A total of `624,000)

Compensation for Haemophiliacs

There has never been a general State scheme to compensate those who suffer the unavoidable adverse effects which may arise from some medical procedures. Compensation can only be awarded by the courts when negligence has been proved. However all the facilities of the NHS and a range of Social Security benefits are avaliable to those who suffer illness, unemployment or loss of earnings as a result of infection with HIV or as a result of contracting AIDS itself.

Officials have worked with the Haemophilia Society to develop an "Informatoin Pack" for these haemophiliacs to help them both to get to know which benefits they would be eligible to claim, and how to go about doing so. We will do all we can to help in this way.

The Vaccine Damage Payments Act has been suggested as a precedent for compensation, however the circumstances are completely different.

Vaccines are given to the healthy as a matter of public policy to protect the health of all individuals. On the other hand haemophiliacs are treated in the course of medical care for their disorder. There is no public policy promoting particular drugs for their treatment.

Compensation for Haemophiliacs

Compensation for victims of medical accidents

Compensation to victims of medical accidents is payable only

if legal liability is established on the grounds of negligence.

Compensation has to be claimed within a period laid down by law (usually three years) but this can vary in some instances.

The patient would need to obtain independent legal advice relating to his or her individual case. An independent organisation, Action for Victims of Medical Accidents which is run by a lawyer, helps people to contact suitable lawyers and also holds a list of medical experts willing to advise in litigation cases.

Other medical accidents

Individuals react to drugs in different ways and there are unfortunately circumstances where side effects are associated with many other commonly used drugs. It is not therefore practical to give specific examples.

'No fault' compensation

The idea of a 'no fault' compensation scheme based on loss of faculties rather than proving negligence in the Courts has been looked at previously.

The Royal Commission for Civil Liability and Personal Injury (the Pearson Commission) reported in 1978; it had considered a possible compensation scheme for personal injuries arising from medical 'accidents'. After studying evidence from other countries, the Commission concluded that such a scheme should not be introduced in this country at present and recommended that

negligence should continue to be the basis of liability for most medical injuries.

Vaccine Damage Payments Act 1979

Some people have suggested that there is a parallel under the Vaccine Damage Payments Act 1979, but this is not the case. Vaccines are given to the healthy as a matter of public policy to protect the health of individuals. The Vaccine Damage Payments Act recognises that a finite risk is incurred and provides financial assistance for those children who become vaccine damaged.

On the other hand haemophiliacs are treated in the normal course of medical care for their disorder. There is no public policy promoting the use of Factor VIII for their treatment.

Social Security Benefits Available

However all the facilities of the NHS and a range of social security benefits are available to those who suffer illness, unemployment or loss of earnings as a result of infection with HIV or as a result of contracting AIDS inself.

The sort of benefits which haemophiliacs could claim for examples are:

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| Income maintenance benefits available to people incapable of work | : Sickness benefit (contributory)<br>Invalidity benefit "<br>Severe diablement allowance (non-contributory) |

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| Benefits aimed at the extra costs of disability | : Attendance allowance Mobility allowance (also invalid care allowance paid to people caring for AA recipients) |
| Income related benefits to top up other benefits which do not meet specified requirements | : Supplementary benefit Housing benefit |

THE NEW BLOOD PRODUCTS LABORATORY (BPL)

Background Note

1. The BPL processes plasma from blood donors in England and Wales to make a variety of blood products. Primarily these are a) coagulation factors Factor VIII and Factor IX etc b) albumin c) immunoglobulins.

2. The new BPL will process 450,000 litres of plasma to make England and Wales self sufficient in these products. Their value to the NHS has been estimated at `60m.

3. When approval for the new laboratory was given, it was recognised that early completion would give financial benefits since our dependence on imported blood products would stop. A 'fast track' design and build contract was therefore used. There is inevitably less precision on cost and time in such a contract since designing and building proceed together. The original estimates of `21.1m cost and completion in late 1985/early 1986 have been exceeded.

4. Present estimates are `60m cost and completion by May this year. The Duchess of Gloucester opened the laboratory on the 29 April.

5. A complex plant cannot go into full production at once. It is estimated that it will take a year to reach full production ie during 1988.

Non A non B Hepatitis

All the evidence so far available suggests that the process BPL

use to produce Factor VIII Factor and IX which includes heat at 80% for 72 hours is superior to any commercial process in that the product does not transmit non A non B hepatitis. However, the clinical trials are not yet complete.

There are no tests for non A non B hepatitis as the causative agent has not been determined. Surrogate tests, alanine transfer [ALT] and hepatitis B core antibody are used by American blood banks to screen donations. These are not used in the UK on the basis that their use would exclude only 40% of the donationw transmitting non A non B. Furthermore there is insufficient evidence for the transmission of this infection in the UK. A proposal to study the problem is with RMD at present.