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Monday 24 May 1999 PQ 2032/1998/99
Lords Oral

THE LORD MORRIS OF MANCHESTER

To ask Her Majesty's Government what recent assessment they have made of the special needs of people with haemophilia, who were infected with hepatitis C during NHS treatment, and the dependants of those for whom the infection proved fatal.

BARONESS HAYMAN

We made a thorough assessment in 1998 of whether it would be right to introduce a special payment scheme for people with haemophilia infected with hepatitis C through NHS treatment. We concluded that this would not be appropriate and that such patients should continue to obtain support as necessary through the benefits system in the same way as other NHS patients who have suffered non negligent harm.

## KEY FACTS/BULLET POINTS

### Numbers infected/deaths

- estimated 4,000 people with haemophilia were infected with hepatitis C through NHS treatment (about 90 have died, and a small number, 6 or 7, await liver transplants).

### Compensation

- Compensation is only paid if the NHS has been at fault.
- A no fault compensation scheme would reduce the money available for patient care.

### Comparison with HIV special payments

- The HIV special payment scheme introduced in 1988 was an exception.
- Reflected the stigma and widespread public fear of AIDS in the 1980s, and the fact that HIV infection was then rapidly fatal.

### Haemophilia Society campaign

- Moving and forceful campaign but we could not agree their request
- Funding the Society's Hep C Youth Information and Support project.

### Treatment for hepatitis C

- All identified cases of infection through blood or blood products are referred to a specialist for assessment and treatment as appropriate.
- Licensed Interferon alpha effective in about 20% of patients; new combination therapies effective in about 40% of patients in trials.

### Entitlement to benefits

- People with haemophilia infected with hepatitis C may be eligible for benefits such as Disability Living Allowance.
- We are working to make eligibility for these benefits easier to understand.

# HAEMOPHILIA SOCIETY - CONTACT AND HELP

The Haemophilia Society and their members led a moving and forceful campaign for a special payment scheme for people with haemophilia infected with hepatitis C. I was pleased to meet with them on 21 January.

We discussed a range of issues including the treatments which are being developed, and the difficulty of treating those co-infected with HIV and hepatitis C. I know that the Society were distressed that we were unable to introduce a special payment scheme for those infected with hepatitis C. I emphasised to them that we can help in constructive, forward looking ways, by supporting projects like their proposed seminar on the problems of treating those with both HIV and hepatitis C.

We are funding their Hepatitis C Youth Information and Support project which I hear is progressing well. Officials and the Society will meet again shortly to discuss other projects.

(see also Youth Information and Support Project.)

## HEPATITIS C YOUTH INFORMATION AND SUPPORT PROJECT

We are funding the Haemophilia Society's Hepatitis C Youth Information and support project - just over £56,000 in 1998-99 and up to £26,000 in the current financial year. I hear this is progressing well – the Society are developing it with great thought, in full consultation with the membership.

The project will provide clear and relevant information for young people with haemophilia who are infected with hepatitis C, on issues such as relationships, starting a family, employment and education. It will also provide information and advice for parents and family. It will raise the profile of the needs of these young people amongst health professionals and develop partnerships to meet those needs.

We have assured the Society that we are willing to work with them on appropriate projects.

## REDUCTION IN CORE GRANT

The Society currently receives £100,000 per annum in core funding. Last year it was reduced from £188,000 in a move to shift the emphasis towards project work. The Society were encouraged to apply for the hepatitis C Youth Information and Support Project which we are now funding.

# COMPENSATION/NO FAULT COMPENSATION

Compensation is payable when it can be shown that a duty of care is owed by the NHS body; **and** there has been negligence (act or omission); **and** there has been harm; **and** the harm was caused by negligence.

There are 3 exceptions to the "no fault, no compensation" rule: ex gratia payments by NHS bodies on the merits of individual cases, within delegated limits; the Vaccine Damage Payment Scheme; and the HIV special payment scheme introduced because of the circumstances and climate of the time.

There are periodic calls for no fault compensation for harm arising from NHS treatment. However such a scheme would not be an easy answer, and arguably it would not be at all fair.

> There would be a substantial increase in costs falling on the NHS, reducing the money available for direct patient care.
>
> those with a congenital disability or disabled through the natural progression of an illness not caused by NHS treatment would not be covered – that would require a general no fault compensation scheme for accidental harm in any context.

# REASONS FOR A SPECIAL PAYMENT SCHEME FOR HIV BUT NOT HEPATITIS C

The special payment scheme for those infected with HIV (Human Immunodeficiency Virus) was introduced in 1988. At that time there were very strong public attitudes to HIV – of stigma, and widespread fear of a new and untreatable fatal infection which was sexually transmitted. The payment scheme has continued since then.

The same circumstances do not apply to hepatitis C. We accept that those infected in this way do face difficulties, as do other NHS patients and groups of people who unfortunately suffered unforeseen harm which could not have been avoided. We aim to support those with haemophilia infected with hepatitis C through the benefits system, where appropriate, and through a number of projects which we support through the Haemophilia Society.

**MORAL CASE FOR A SPECIAL SCHEME** (Haemophilia is a complex condition, hepatitis C infection superimposed on it; comparable circumstances to HIV, stigma attached to hepatitis C as for HIV, insurance problems.)

NHS treatment has transformed the lives of people with haemophilia. Modern care prevents bleeding into joints and the consequent disabling arthritis which follows. People with haemophilia can now live normal lives, and do not face early death. Hopes were raised.

In the 1970s/80s the blood products became widely available and were the best treatments. The safety processes (viral inactivation) now used were not available until 1985 however. These were introduced as soon as modern scientific advance and technology allowed. Today synthetic (recombinant) products are becoming more available.

There are other patients or patient groups who suffer inadvertent harm as a result of treatment for an existing condition. We decided it would not be fair to make special payments which would reduce the funds available to the NHS

## COSTS OF A SPECIAL PAYMENT SCHEME

Our estimate of the possible cost of a special payment scheme was only one aspect of a wide ranging consideration of the issues. (Ethics, equity, morality, legality.)

We estimated the cost of a special payment scheme for people with haemophilia infected with hepatitis C as in the order of £220 million. This was based on approximately three thousand people and the overall payments to date (£90 million) for those with haemophilia infected with HIV through NHS treatment with blood products. The estimate did not include start up costs or the costs of managing the process.

# PREVALENCE/EFFECTS OF HEPATITIS C

General population - estimated 250,000 to 300,000 people with hepatitis C in UK. (Estimates vary from 0.1 – 1% of the population). Risk is higher for male, older, heavy drinkers. The greatest risk is for needle sharing drug misusers (up to 80% of IV drug users are infected).

Haemophiliacs - approximately 80% of haemophiliacs infected. (Approx 4000 out of 6,000.

About 20% of those infected clear the infection spontaneously. Even when the infection is not cleared, many patients remain symptom free for 20 to 30 years, and are only diagnosed when liver inflammation becomes more advanced. About 20% of infected patients develop cirrhosis. Of those, 25% may develop primary liver cancer.

A small percentage of haemophiliacs infected with hepatitis C will die of liver disease. So far, 90 - 100 have died, out of the estimated 4,000 infected. 6 or 7 on list for a liver transplant.

Sexual transmission is low. (Prevalence rate in regular sexual partners of infected people is less than 5%.)
Risk from household contact is very low.

## HEPATITIS C TREATMENT

Treatments for hepatitis C are being developed. The only drug currently licensed for the treatment of hepatitis C is **interferon alpha,** injected 3 times weekly for 6-18 months. Side effects can be unpleasant and treatment is effective in about 20% of patients.

Combination therapy being developed - Ribavirin in combination with interferon alpha. Available now in clinical trials (named patient basis). Trials show approx 40% sustained response rate.

Ribavirin for use in combination with interferon alpha is expected to be licensed in Europe and the UK in June (next month). Combination therapy is already licensed in the United States.

There is some information which suggests that the treatment of haemophiliacs who have hepatitis C has a lower success rate. This may well improve with time, with combination therapy and the development of further antiviral agents.

## AVAILABILITY OF TREATMENT FOR HAEMOPHILIACS WITH HEPATITIS C

Patients should receive adequate and appropriate services wherever they live in the country. We would expect NHS Health Authorities and Trusts to take account of the particular circumstances of people with haemophilia infected with hepatitis C through NHS treatment.

If treatment is refused, officials will discuss the circumstances with the Health Authorities and Trusts concerned.

We recognise the important contribution of good clinical guidelines to consistency of treatment.

Guidelines on the use of alpha interferon and other antivira drugs (when licensed) in the treatment of hepatitis C are being developed. They will be evaluated by St George's guidelines group endorsed by the Department of Health.

## EARLIER PREVENTION OF INFECTION – SHAMEFUL LACK OF A PUBLIC ENQUIRY (HAEMOPHILIA SOCIETY)

New safety measures such as viral inactivation have been introduced as the science developed and the technology became available.

Before 1985, the only safeguard was to ask those at risk not to donate. (Eg those suffering from hepatitis or other liver disease, drug misusers, men who had sex with other men.)

Since 1985 blood products for haemophiliacs have been treated to destroy hepatitis C, hepatitis B and HIV as well as a range of other viruses. (Risk from some other viruses remains.)

Screening of blood donors was introduced in Sept 1991. (The viral inactivation processes used for manufactured blood products cannot be used on cellular blood components for transfusion.) Early screening tests for hepatitis C were available from 1989 but had too many false positives and false negatives. Expert advice was not to introduce these early tests because they were not accurate enough to allow proper screening of the blood supply.

## BENEFITS (CUTS IN BENEFITS)

We aim to ensure that benefits are efficiently directed, so that they are received by those who need them. At present some people may be missing out. A person with haemophilia who meets the conditions for a benefit will receive it in the same way as other eligible people.

The main benefit for severely disabled people of working age is Disability Living Allowance. Entitlement does not depend on whether or not the claimant is working or on specific disabilities. It is awarded on the basis of the effects of the disabilities on the person's care and/or mobility needs. Other benefits are available to help with normal day to day living.

All decisions on entitlement are based on information provided by individuals themselves (with consideration of information from others, eg GPs or social workers).

There is no specific monitoring of benefit claims from people with hepatitis C.

## NEW VARIANT CJD

The emergence of new variant CJD reminds us forcefully that our knowledge is at best limited. Clinical advances are made, but we cannot guarantee the absolute safety of any medical treatment, and this applies to blood and blood products.

We are making very effort to ensure that our blood and blood products are as safe as we can reasonably make them.

On expert advice we have required the blood service (1) to remove white blood cells from blood destined for transfusion and (2) to import plasma to make blood products. These are purely precautionary measures, as there is no evidence whatever that nvCJD is transmitted by blood or blood products.

Almost all blood products now available using non-UK plasma. [Anti D made from non-UK plasma will become available from today (24 May) as planned.

The perceived threat of nvCJD caused extra worry for those with haemophilia and their families. For this reason we required the NHS to provide recombinant (synthetic) Factor VIII and Factor IX for new patients and children under 16.

# RAGE

We have not changed our position on compensation for those affected by radiotherapy treatment. Compensation is, apart from very exceptional circumstances, paid only when legal liability can be established. We are considering a number of issues raised by RAGE in the light of the Secretary of State's initiative on "Reducing Litigation in the NHS" which he started last year and to which members of RAGE kindly contributed.

We hope that quality initiatives and increased awareness of the problem will reduce new cases of adverse effects from radiotherapy. Clinical oncology departments have received guidance and models of good practice, and each department has to produce a quality manual. Our general quality agenda will reinforce good practice in this area.

The cancer support charities produced three information leaflets for patients, which were funded centrally. We have now funded a leaflet on pelvic radiotherapy and two others will follow shortly, so that patients are well informed.

**MYODIL (Diagnostic agent put into the spinal cavity.)**

(arachnoiditis – chronic inflammation and thickening of the membrane which covers and protects the brain and spinal cord)

A number of people who claimed to have suffered damage (arachnoiditis) as a result of the use of Myodil took legal action against the manufacturers, Glaxo. We understand that in 1995, without admitting liability, Glaxo agreed a settlement of £7 million to be shared among the 426 plaintiffs. The Government was not a party to the action.

The Myodil Action Group is campaigning on behalf of potential claimants whose concern is that they were excluded from the award offered by Glaxo. The Group sought Government compensation and we gave careful consideration to the Group's concerns. However we were advised that in the case of Myodil there was no basis on which the Department of Health or the medicines licensing authority would be found liable or negligent.

We could not treat the Group's request differently from other cases where patients have suffered as a result of NHS treatment which was not negligent and we advised them of this in February.

## BETA INTERFERON

The NHS received guidance on prescribing for relapsing remitting multiple sclerosis (RRMS) in 1995, when Marketing Authorisations for beta interferons were in the pipeline. Clinicians were asked to initiate and continue prescribing through hospitals.

That existing guidance continues to apply. New guidance is being prepared on the use of beta interferon for secondary progressive multiple sclerosis and the Department of Health will shortly be consulting widely.

There are now three licensed beta interferon drugs for RRMS. One Marketing Authorisation has been extended for the secondary progressive form of MS (SPMS). There is a continuing lack of firm information about the clinical and cost effectiveness of the beta interferons.

The government is committed to ensuring that newer treatments are introduced into the NHS as fast as possible where they represent a genuine therapeutic advance and are cost effective. We are likely to ask NICE to prepare guidance on the place of beta interferon in the NHS among the range of interventions and services available for MS sufferers

## BACKGROUND

## THE LORD MORRIS OF MANCHESTER

Lord Morris, as a well known supporter of rights for those with a disability, has asked a number of questions prompted by the Haemophilia Society.

On 29 April there was a debate on his PQ about benefit take up: "To ask Her Majesty's Government what further action they propose to increase the take-up of social security benefits.

Lord Hoyle has written in support of the Haemophilia Society's campaign.

On another (related) issue, Lord Ironside is pressing for compensation for damage caused through radiotherapy for breast cancer, with the organisation RAGE.

## BACKGROUND

## BENEFIT TAKE UP

The main disability benefits are Disability Living Allowance and Attendance Allowance. Current expenditure on these is £8 billion. If the take up rate increased to 90%, expenditure would rise to £13 billion.

Take up estimates for the Disability Living Allowance (DLA) and Attendance Allowance are based on the disability follow up to the Family Resources Survey. DLA has two components, and the provisional estimates of take up are: care component 30% to 50%, mobility component 50% to 70% . The estimated take up for Attendance Allowance is 40% to 60%.

Disability Living Allowance and Attendance Allowance are complex benefits based on care needs and, in the case of DLA, mobility needs. It is not easy for people to know whether they fulfil the conditions for entitlement. We are working with the Disability Benefits Forum to make it easier for people to understand whether they may be entitled to these benefits.

Ultimately the key to improving take up of benefits lies in modernising the welfare system which the Government is actively pursuing.

# CONTINUATION OF HAEMOPHILIA SOCIETY CAMPAIGN

## BACKGROUND

The Haemophilia Society has made it clear that it will continue to press for a special payment scheme.

Recent (House of Commons) PQs include:

Roger Godsiff (current Ordinary written, PQ2045) "if he will assess the benefits of providing financial assistance schemes for people who contracted hepatitis C through contaminated blood products as a result of NHS treatment." Roger Godsiff met with, and wrote to Baroness Jay last year in support of special payments.)

Sir Geoffrey Johnson Smith MP – how was the estimated cost of a special payment scheme for hepatitis C reached (referring to £220million estimate)

Roger Berry MP – how many haemophiliacs infected with hepatitis C have chronic liver disease/other significant health problems; how many were infected and how many are alive

Andrew Stunnell MP – what representations received

Dafydd Wigley MP – how many people in UK have hepatitis C, how many contracted it through contaminated blood products; make a statement on basis of HIV special payment scheme; what progress made in compensating people

Sir Alastair Goodlad MP – what projects to be promoted with the Haemophilia Society

Audrey Wise MP – how many infected, is their condition being monitored

## BACKGROUND

## SPECIAL PAYMENT SCHEME FOR HAEMOPHILIACS WITH HIV

The Macfarlane Trust operates the special payment scheme for haemophiliacs infected with HIV through blood products. It was established in 1988 with an initial sum of £10 million. It receives a S.64 grant for its administrative costs and blocks of funding as necessary for disbursing to its registrants. There have been approx 1200 registrants, with about 500 remaining. Since 1988 the Trust has received £20.5 million, disbursed £20.1 million and invested £7.5 million. (The investments yield money). Additionally, as a settlement to avoid litigation, registrants received further ex gratia sums of £24 million and £42 million in 1990 and 1991.

There are different types of payment made by the Macfarlane Trust: regular monthly payments and one off payments for specific difficulties.

Lady Hayman is due to meet the Trust on June 17 to discuss their Strategic Review, undertaken to establish the right direction for itself. Currently the remaining registrants are receiving a relatively favourable level of financial support, including help in setting up home. The Strategic Review was conducted with the involvement of the Haemophilia Society, who were the pressure behind the initial establishment of the special payment scheme for haemophiliacs with HIV.

The Eileen Trust, administered by the Macfarlane Trust, makes payments to non haemophiliacs infected with HIV. It is much smaller, with about 70 registrants and £4 million expenditure to date.

## RAGE

Registered charity and self help group for those who have suffered permanent damage as a result of radiotherapy treatment for breast cancer. Press for compensation, for a register of those affected and for a gradation of the severities.

Many of the injuries are severe and the claim is that women were not given enough information on possible risks (a theme being taken up by some haemophiliac correspondents). In many cases RAGE claim excessive doses of radiotherapy were given.

Court action beginning in 1994 took a sample of cases, and negligence in treatment was not found. In 1998, 40 claims identified which might have some chance of success. NHSLA made an offer to settle the limited group. 9 women have settled, for figures ranging from £45k to £170k. Negotiations continue in a further three cases.

Departmental guidance on quality assurance issued in 1991, further document with models of good practice 1994. Confidential audit of case histories carried out by Royal College of Radiologists; RCR guidelines on management of women with adverse effects issued by NHS Executive 1995. Anecdotal evidence from RAGE members suggests guidelines not working well in some areas. Reiteration of the guidance to clinical oncologists to be done by RCR. Future cases of harm likely to be reduced, but not removed. Signs can develop 10 years after treatment.

Similar organisation COU-RAGE represents those damaged by radiotherapy for other conditions. They concentrate on advice and counselling and have no compensation campaign at present.

## BACKGROUND

## NO FAULT COMPENSATION

In general, payable only when legal liability can be established. Underlying principles independently established under common law. Apply to personal injury cases in general, not just NHS care:

Duty of care owed – negligence – harm – harm caused by negligence.

Exceptions: NHS bodies may make ex gratia payments on merits of individual cases. Delegated limits are £1million where clinical negligence involved and settlement has been negotiated following legal advice. £50,000 in other cases, including non-negligent harm;

Vaccine Damage Payment Scheme (established on public health grounds under Vaccine Damage Payments Act 1979)

HIV special payment scheme for haemophiliacs and non-haemophiliacs infected with HIV through blood or blood products, haemophiliac scheme established 1988, non-haemophiliac scheme 1991.

Royal Commission on Civil Liability and Personal Injury (Lord Pearson 1978) came down against compensation for non-negligent harm in clinical accidents.

No reliable estimates of cost – widely cited independent scheme in late 1980s suggested £235 million a year. Uprating for inflation would give £360 million a year estimate. Cost of meeting negligence claims rose from £60 million in 1990/91 to £200 million in 1996/97.

Under no fault compensation scheme amounts paid to individuals would be small compared with negligence claims but number of_claims would be very large. Might introduce "no fault culture"- reduce reassurance to patients and diminish clinical accountability.

# INITIATIVE TO REDUCE LITIGATION IN THE NHS – CONTRIBUTION TO DISCUSSION BY LADY IRONSIDE AND OTHERS

In April 1998 SofS wrote to large audience, including RAGE, seeking their views on reducing litigation. An options paper was put to Ministers in April 1999 and Ministers are considering. Individual contributions to the exercise included **Lady Ironside**, who argued that individual Quality Assurance procedures (eg ISO 9002 standards in UK Radiotherapy Treatment Centres and the framework document for commissioning cancer treatment services) should be extended to all parts of the service. She observed that the civil justice system did not help those who were unable to fund their own cases or who did not qualify for legal aid and that a "compensation package" similar to that for haemophiliacs with HIV should be introduced.

Other suggestions included a system for open reporting and fast track compensation and clearer warnings of possible side effects, with patient input. Mediation should be extended, and standards raised through clinical audit.

## BACKGROUND

## BETA INTERFERON

May help in the treatment of multiple sclerosis, one of the most common diseases of the central nervous system. Usually strikes in early adulthood. Disability can vary from impairment of speech, vision and movement to complete paralysis. The cause is unknown.

Since the 1995 guidance on prescribing BI for relapsing remitting MS (RRMS) through hospitals, three BI drugs have been licensed (ie received Marketing Authorisations)– Betaferon, Avonex and Rebif.The Marketing Authorisation for Betaferon has now been extended for the secondary progressive form of MS (SPMS).

The Department proposed new guidance, highlighting continuing uncertainty surrounding the evidence on clinical and cost effectiveness for both RRMS and SPMS, referring to plans to ask NICE to prepare authoritative guidance and recommending cautious prescribing policies for SPMS.The circular was sent as a draft to the MS Society and the drug manufacturers. It was not interpreted as intended and a revised draft will be issued making clear that it relates to BI for SPMS and that the existing guidance on RRMS still applies.

Most HAs now have procedures in place for treating suitable RRMS patients with BI through specialists. They adopt a range of funding policies(ie budgetary sources). Where there is specific funding patients usually have to wait when funds are exhausted. To best of knowledge, only Cambridge and Huntingdon, and NE Devon HAs have no funding provision but expect Trusts to meet costs. HAs often delegate BI prescribing decisions to Trust neurologists. Their views on effectiveness differ, hence variations in prescribing rates.