LORDS ORAL PQ 115/2000/2001
Date of Answer 18 December 2000

The Lord Morris of Manchester – To ask Her Majesty's Government what recent new help they have given to those who were infected with hepatitis "C" by contaminated National Health Service blood products and the dependants of those who have since died in consequence of their infection.

LORD HUNT:

ON 31 OCTOBER THE NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE (NICE) RECOMMENDED THAT PATIENTS SUFFERING FROM MODERATE OR SEVERE HEPATITIS C SHOULD BE GIVEN THE COMBINATION THERAPY (ALPHA INTERFERON WITH RIBAVARIN). HEALTH AUTHORITIES HAVE BEEN ASKED TO IMPLEMENT THIS RECOMMENDATION. MY DEPARTMENT WILL ALSO MAKE FUNDING AVAILABLE TO THE HAEMOPHILIA SOCIETY OVER THREE YEARS TO HELP IMPROVE COUNSELLING FOR PEOPLE WITH HAEMOPHILIA INFECTED WITH HEPATITIS C.

LORDS ORAL BRIEFING - PQ 115

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BULL POINTS

- We are determined to ensure that people with haemophilia and hepatitis C are increasingly well cared for in the NHS, supported in their communities and more fully informed about how best to look after their health

- NICE recently recommended that patients suffering from moderate or severe hepatitis C should be given the combination therapy (interferon with ribaravin) and we have asked the NHS to put this in place quickly. The NHS allocations announced earlier this year include provision for funding the NICE recommendations.

- We have asked HAs and NHS Trusts to provide recombinant Factor 8 for haemophiliacs for new patients and children under 16 from April 1998. Factor 9 on the same basis from 1999. Patients outside the agreed categories can receive the treatment if it is prescribed for them.

- We have commissioned research totalling £1 million on hepatitis C in the population generally – its natural history, prevalence, transmission and treatment.

- We are working with the UK Haemophilia Centre Doctors Organisation and the Haemophilia Society to ensure that

counselling provision is available and accessible to all haemophiliacs with hepatitis C. The Society have applied for a Section 64 project grant (2000–03) for a counselling and advice project for hepatitis C sufferers.

- **We have reviewed the decision taken by the previous Government not to offer financial assistance to haemophiliacs infected with hepatitis C through blood products. Our decision was that an exception could not be made to the general rule that compensation or financial help is only given when the NHS, or individuals working in it, have been at fault.**

- **The Haemophilia Society receives an annual grant of £100,000 to support its administrative costs and we have also funded the Society's HIV and hep C co-infected seminar held in January 2000.**

Key Facts

1. Approximately 11,000 people have haemophilia and related bleeding disorders in the UK.

2. 500 are infected with HIV (800 have already died). Most of those with HIV are co-infected hepatitis C. (5% to 6% of all haemophiliacs are co-infected).

3. About 4000 haemophiliacs have hepatitis C.

4. Approximately 2000 – 3000 of haemophiliacs have neither HIV nor hepatitis C.

5. An estimated 200,000 to 300,000 people in the population as a whole are infected with hepatitis C. The majority of the people infected are unaware of their hepatitis C status. In the general population infection is related to IV drug misuse. The infection is only poorly transmitted through sex or intimate contact.

Supplementaries and background

TREATMENT

Why isn't recombinant (synthetic) Factor 8 and Factor 9 available to all haemophiliacs and not just new patients and children under 16?

There is no evidence that recombinant Factors are more effective or safe than plasma-based products. However, we recognised the fears of parents of children and indeed all those receiving blood products about infectious agents which may as yet be unrecognised and transmissible through blood. We therefore instructed health authorities to provided recombinant products to new patients and children under 16 with haemophilia. Patients outside these categories can receive them if they are prescribed for them. I will be meeting with the Haemophilia Society on 20 December to discuss this issue further.

Background

Recombinant Factor 8 is a synthetic clotting product used in the treatment of haemophilia. Understandably, when action was being considered to protect the public against the theoretical risk of vCJD, people with haemophilia and their families were particularly worried in case vCJD could be transmitted through blood.

We asked NHS Trusts and Health Authorities to make recombinant Factor 8 available to new patients and children under 16 from 1 April 1998 and Factor 9 from April 1999. Patients who receive the recombinant product will continue to receive it after age 16.

The requirement to provide these products for young people and new patients does not mean that others outside these categories cannot receive the treatments, if they are prescribed for them. However many clinicians will be deterred by the additional costs of using recombinant products.

Scotland, Wales and Northern Ireland have adopted a policy of providing recombinant clotting factors for all patients. Haemophilia Society will meet PS(L) on 20 December to discuss this issue further.

What treatment is available for those haemophiliacs who now have hepatitis C as a result of NHS treatment?

The outlook for the treatment of hepatitis C is improving. In 1995 the first treatment, an antiviral therapy, became available. Interferon with ribavirin was licensed last summer. The National Institute for Clinical Excellence (NICE) were asked to review all the evidence on the effectiveness of ribavarin and alpha interferon therapy and having assessed the evidence to give recommendations on its clinical effectiveness. On 31 October NICE published its recommendations that patients suffering from moderate or severe hepatitis C should be given a combination of the drugs.

Background

The indications are that the newly licensed combination therapy (alpha interferon with ribavirin) is considerably more effective than interferon monotherapy (40% against 20% or less). On **31 October 2000** guidance was issued to all NHS bodies and clinicians following recommendations made by the National Institute for Clinical Excellence (NICE) that patients suffering from moderate or severe hepatitis C should be given a combination of the drugs interferon alpha and ribavirin. The NHS allocations announced earlier this year included provision for funding the NICE recommendations

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COUNSELLING

What is being done to improve counselling services for haemophiliacs and haemophiliacs with hepatitis C?

This year we are working with the Haemophilia Alliance (the Haemophilia Society and the UK Haemophilia Centre Doctors Organisation) to ensure that counselling provision is available and accessible to all haemophiliacs and haemophiliacs with hepatitis C. This will include providing funding towards a project by the Haemophilia Society to provide counselling and advice for people with haemophilia infected with hepatitis C.

Background

The Haemophilia Society consider that there is not enough counselling for people with haemophilia infected with hepatitis C. Counselling may be particularly needed at certain times by haemophilia patients, for example to inform decisions about genetic testing, before and after hepatitis C testing, and when new therapies become available. DH has agreed to provide Section 64 project funding to the Haemophilia Society to support a project to provide advice and counselling for haemophiliacs infected with hepatitis C through blood products.

What is being done to improve NHS care for haemophiliacs?

We have issued guidance to the NHS that that Comprehensive Care Centres should provide a service for haemophiliacs to include clinical services for patients, advice on treatment programmes, home therapy programmes and counselling for patients and relatives. This year we are working with the Haemophilia Alliance (the Haemophilia Society and the UK Haemophilia Centre Doctors Organisation) on a proposed national service specification for haemophilia services.

Background

NHS Executive Guidance in HSG (93)30 set out the functions of Haemophilia Centres and CCCs respectively. It stated that both CCCs and haemophilia centres have to provide the following:

- clinical service from experienced staff, day or night, at short notice
- laboratory service capable of carrying out all necessary tests for the definitive diagnosis of haemophilia and monitoring therapy
- participation in quality assurance and audit
- an advisory service to patients and close relatives on matters specific to haemophilia, and an advisory service to GPs
- maintenance of records and a register of patients attending the centre
- counselling patients and relatives in privacy
- organise and provide advice on home therapy programmes.

In addition, CCCs provide:

- prophylactic treatment programmes
- 24 hour advisory service to haemophilia centres

- specialist consultant service for all surgery including orthopaedic and dental, and specialist consultant service for infections such as HIV and hepatitis, and for genetic, and social care and any other counselling services

- a reference laboratory service for haemophilia centres, together with advice

- educational facilities for staff to promote optimal care

- coordination of meetings and undertaking research programmes, including clinical trials.

COMPENSATION

Alan Milburn and John Denham signed an EDM in Opposition calling on the Government to consider giving financial assistance to haemophiliacs infected with hepatitis C. Why have you changed your mind?

When we came into office we reviewed the decision taken by the previous Government not to offer financial assistance to haemophiliacs infected with hepatitis C through blood products. We met the Haemophilia Society and spent some time carefully considering the evidence they presented. Our decision – and it wasn't an easy one to take – was that we could not make an exception in this case to the general rule that compensation or financial help is only given when the NHS, or individuals working in it, have been at fault.

Background

At present, compensation is, in general, paid only where legal liability can be established. The underlying principles are clear-cut and independently established under the common law. They apply to personal injury cases in general - not only those arising from health care. Compensation is payable where 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 the negligence.

The Government has every sympathy with people who suffer adversely as a consequence of medical treatment and understands and shares the anxieties of those who are concerned at the difficulties associated with compensation. We are currently reviewing a range of issues around compensation, and in particular concerning the whole problem of litigation in the NHS and how best to tackle this, including the issue of how the way in which the NHS deals with clinical negligence claims can be improved. We are continuing with this work and are currently considering how best to take this forward.

<u>If pressed</u>:

Although a 'no fault' compensation scheme does offer some advantages, in the context of the NHS, the disadvantages are that some schemes can divert money away from patient care where it is most needed. Nor do they really address the broader concerns that many have, such as an explanation of what went wrong and the assurance that it will not happen again.

There is no difference between haemophiliacs who acquired HIV through blood products and those who acquired hepatitis C the same way. Why are those with hepatitis C not being compensated?

In general, compensation is only given for those who suffer negligent damage from NHS treatment. In the late 80s/early 90s a special payments scheme was set up for those haemophiliacs who were infected with HIV through blood products. This was because of the exceptional circumstances – life expectancy at the time for haemophiliacs with HIV was dramatically reduced and there was no treatment. In addition, there was huge stigma attached to those infected no matter how the infection was acquired.

Background

1. 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.

2. 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.

Compensation for haemophiliacs with hepatitis C: why is this different from variant CJD?

The decision not to compensate people with hepatitis C stems from the well established policy that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. It was simply not possible prior to 1985 to make blood products free from hepatitis C in sufficient quantities to treat all haemophiliacs in the UK.

The plight of individuals and families affected by v CJD is, by contrast the result of a unique set of circumstances for which society as a whole must bear a moral responsibility.

Background

1. The Government is making £1 million available to fund care packages centrally and is strengthening the support that the national CJD Surveillance Unit is able to provide by recruiting additional staff and establishing a Managed Care Network to provide clinical and practical advice to those taking on responsibility for the care of patients with vCJD for the first time.

2. This does not change the long-standing policy in this country that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. We are *not* talking about no-fault compensation but ex-gratia payments for a group of people who because of exceptional circumstances, have endured and are enduring a particularly harrowing ordeal.

SAFETY OF BLOOD AND BLOOD PRODUCTS

The Department of Health knew in the late 1970s that Factor 8 (clotting factor) carried a high risk of contamination. Why was nothing done about it?

The technology for eliminating hepatitis C from blood products whilst maintaining their effectiveness was not developed until the mid 1980s. The risk from hepatitis was widely known but it was simply not possible until the mid 1980s to produce effective clotting factors for the treatment of haemophilia which were free from that risk.

Background

The quantity and quality of blood products increased significantly during the late 1970s, but known to transmit viral infections in particular hepatitis. Hepatitis B and later hepatitis C or "nonA, nonB hepatitis" existed since the beginning of blood transfusion medicine and were associated with the new blood products. Because blood plasma goes into large pools (20,000 to 60,000 units) for the manufacture of blood products, and because of the prevalence of hepatitis C, all haemophiliacs using blood products were infected with hepatitis C before heat treatment was introduced in the mid 1980s. Hepatitis C was not fully characterised until 1989 and there was no reliable screening test for it until 1990/91.
gh blood products. From the mid 1980s a range of heat treatments were developed that eliminated both HIV and hepatitis C.

Is UK blood safe?

Almost every medical treatment including blood transfusion is associated with some risk. For this reason doctors need to consider the need for any blood transfusion very carefully with their patients. Three major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion in the UK is very safe, that it is becoming even safer with improving technology, and that infection due to blood transfusion is now very rare.

Are blood products safe?

Since the mid 1980s blood products for haemophiliacs have been treated to destroy hepatitis C, hepatitis B and HIV as well as a range of other viruses. **Fresh blood** cannot be virally inactivated because the chemical treatments would destroy the blood.

What about variant CJD, what action has been taken to protect the UK blood supply?

The risk that variant CJD might be transmissable to patients through blood or blood products remains theoretical.. However, The Government has acted on expert advice to minimise this theoretical risk to patients White cells are now removed from blood for transfusion (leucodepletion) and all blood products manufactured in the UK are made from imported plasma. These precautionary measures were introduced on the basis that transmission of variant CJD through blood might possibly occur in the absence of clinical disease.

Background - Blood Safety

1. Almost every medical treatment including blood transfusion is associated with some risk. For this reason doctors need to consider the need for any blood transfusion very carefully with their patients. Three major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion in the UK is very safe, that it is becoming even safer with improving technology, and that infection due to blood transfusion is now very rare.

2. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. However, we have already taken significant action to reduce the theoretical and unquantifiable risk of transmitting vCJD through the blood supply.

3. On the advice of SEAC, all blood for transfusion has the white cells removed through a process called leucodepletion. This is because current research indicates that any infectivity from transmissible spongiform encephalopathies that might be present in blood would be most likely to be linked to white blood cells.

4. On the advice of the Committee of Safety of Medicine, all blood products used in the UK are made from imported plasma.

PUBLIC INQUIRY

Scotland have had an inquiry into hepatitis C . Why not in England? [Report published 24 October 2000]

The Scottish investigation was not a general inquiry into the history of hepatitis C and blood products. It looked specifically into whether Scottish haemophilia patients were exposed to the risks of hepatitis C longer than they should have been, given the state of knowledge at the time and the fact that Scotland developed successful heat treatment later than England. I do not think that there is a case for saying that there needs to be a similar investigation into the situation in England.

Having considered the report, Scottish Ministers concluded that:

- there was no evidence that the relevant authorities did anything other than their best for patients;
- consequently, the NHS should not pay compensation for non-negligent harm to the small number of haemophiliacs in Scotland who contracted Hepatitis C during the period covered by the report.

Why hasn't there been a Public Inquiry into the hepatitis C scandal?

I can understand the wish to know exactly what happened in the 1970s and 1980s – it's a complex story. However, all the information is in the public domain and I do not believe that anyones interest would be best served by a public inquiry.

PREVIOUS LORDS PQS

LORD MORRIS OF MANCHESTER – HAEMOPHILIA AND HEPATITIS C

It should be noted that Lord Morris is President of the Haemophilia Society and continues to press the case for financial assistance for haemophiliacs with hepatitis C.

PQ 3552 – March 1998

Lord Morris of Manchester – HMG whether they have received any representations from the Haemophilia Society concerning people with haemophilia infected with hepatitis C through the NHS, and what reply was given.

Baroness Jay – The Haemophilia Society made representations concerning this. SoS also met representatives of the Society on 10 September 1997 to hear their accounts of the effects on the lives of those with haemophilia and their families.

Lords debate 5 June 1998

Lord Morris of Manchester – what new help is intended for people with haemophilia who were infected with hepatitis C in the course of NHS treatment or, in the case of those who have died, for their dependents.

PQ4698 – June 1998

Lord Morris – What further representations have they had from the Haemophilia Society following the debate on 5 June about financial assistance.

Baroness Jay – We will be replying to the Haemopilia Society after considering the points raised in their letter of 24 June.

PQ 5867 – November 1998

Lord Morris of Manchester – whether they will place a copy of Baroness Hayman's reply to the Haemophilia Society letter of 24 June in the Library of the House.

Baroness Hayman – a copy will be placed in the Library.

PQ5082 – June 1988

Lord Morris of Manchester – How many people with haemophilia have been infected with hepatitis C.

Baroness Jay - 4,000 people with haemophilia were infected with hepatitis C through blood products. Haemophilia Society assess that the total figure is 4,800

PQ 2447 June 1999

Lord Morris of Manchester – Where was if officially stated that the social stigma of HIV were important considerations in the grant of special payment to NHS patients infected with HIV

Baroness Hayman – SoS gave the view when he wrote to the Haemophlia Society on 28 July 1998

PQ 2609 June 1999

Lord Morris of Manchester – Any change in policy between this and the last Government in relation to social stigma to the giving of special treatment and financial help.

Baroness Hayman – made careful assessment of request for scheme for hep C. Took account of high level of stigma attached to HIV in the 80's when scheme was introduced.

PQ 2610 - June 1999

Lord Morris of Manchester – will Government consult the Haemophilia Society about remedying the social stigma which can attach to infection with hepatitis C.

Baroness Hayman – We are working with the Society and providing funding for their youth information project.

PQ 2839 – July 1999

Lord Morris of Manchester – representations received about the distinction between people with haemophilia with HIV and hep C.

Baroness Hayman – We have had a letter from the Haemophilia Society on this. The representations have not convinced the government to alter its decision about the special payments scheme.

PQ 3435 October 1999

Lord Morris of Manchester – how many England, Welsh and Northern Irish patients were given clotting factor treatment in Scotland 1985 – 1987

Reply - Lord Hunt – 190 vials heated at less than the current conditions were sent to England and Wales. Northern Ireland was and still is supplied with clotting factors made in Scotland.

PQ 3436 – October 1999

Lord Morris of Manchester – review treatment of people with hep C so that they are not denied Interferon/ribavirin on grounds of cost.

The therapy received Marketing Authorisation in May 1999. The NHS Helath Technoloyg is funding research to establish the effectiveness of early treatment of hepatitis C with alpha interferon or with interferon and ribavirin. NICE is considering the treatment for hepatitis C.

PQ 235 – November 1999

Lord Lester of Herne Hill – publish documents relevant to the death of people with hep C after being given Factor 8 referred to in Observer article.

Reply – The documents, a letter from Dr Richard Lane of the Blood Products Laboratory to DH officials and a paper by officials advising Ministers on the future of BPL have been placed in the House of Lords Library.

Lords Unstarred question - 20 March 2000

Lord Morris of Manchester - what further help is the Government considering for people who were infected with hepatitis C by contaminated NHS blood products and the dependants of those who have since died.

(Copy of the debate attached).