Assistance to individuals who are Haemophiliacs and have Hepatitis C

SPEECH

[Material in square brackets to be omitted if times is short]

I congratulate the Hon Member on his success in the ballot. The situation of people with haemophilia who have had the misfortune to contract also Hepatitis C, adding to the difficulties they already have to face is one which I know concerns a number of Hon Members and it has been raised in the House on a number of occasions. Only last week I answered an oral question on the subject from my Hon Friend the Member for Hendon South was answered only last week, who also initiated the adjournment debate at the end of the last session. Early Day Motion No 3 this session has the support of 233 members.

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I am also aware ✓

Let me say straight away that I have great sympathy for those patients who have become infected with hepatitis C through blood transfusions or blood products.

The Haemophilia Society originally launched their campaign for help for people in this situation in the spring. The Hon Member may be aware [has mentioned] that the Society has recently issued an interim report on its Hepatitis C impact study.

I have read the Haemophilia Society report. It graphically describes the sorts of problems experienced by some sufferers who find they now have to contend with the effects of Hepatitis C infection, on top of those of haemophilia. I am sure that I am not alone in having my heart-strings tugged by these accounts by patients. But as the House has been told on previous occasions, the fact that we have the greatest sympathy for the patients does not lead us to conclude that that we should make special payments to them, since no fault or negligence on the part of the NHS has been proved, or indeed alleged.

The great benefits to patients of medical procedures rarely come without some risk. It is important to remember that it is not always possible, at the time that treatment is given, to fully appreciate the risk or to avoid suspected or known risks. In the case of each individual patient a balance must be struck between the benefit to be gained versus any possible risk. The patients we are now discussing received the best treatment available in the light of medical knowledge at the time.

Most haemophilia patients infected with hepatitis C were so infected before blood products were treated to destroy viruses in 1985 and well before tests for Hepatitis C became available. Before then the only way to safeguard blood was to limit those from whom blood was taken by a system of self deferral. This excluded amongst others, those known to be suffering from hepatitis or any other liver disease; drug misusers; and men who had sex with other men.

I think that the basic facts are quite straightforward and not in dispute. The figure of 3,100 for those infected quoted in the recent Haemophilia Society report is substantially in line with the Department's own assumptions. Indeed, the true figure may be rather higher - perhaps nearer 4,000.

A figure of a total 50 deaths from Hepatitis C in patients with haemophilia has been suggested - it was cited for instance in the Early Day Motion tabled recently. While every death is a tragedy for the individual concerned, and their family and friends, it is important to keep a sense of proportion. That figure relates to the period since 1988. I understand from the United Kingdom Haemophilia Directors that of 126 haemophilia patients known to have died in 1993, 12 showed the cause of death as liver disease of which hepatitis C may have been the cause. But 8 of these were also HIV positive.

It has been argued that the fact that ex-gratia payments were made to those who contracted HIV through blood or blood products means that payments should also be made in the present case. However we accepted that the patients who, tragically, contracted HIV through NHS treatment were a very special case and the Government made provision for them because of their very special circumstances.

Those affected were all expected to die very shortly, although it has since become clear that fortunately this is not always the case. This meant that there might also be significant numbers of young children who had lost a parent, or perhaps both if the disease had been transmitted also to their partner.

Sufferers were also subjected to stigmatism and a whole range of other social problems. They had their doors daubed with graffiti, their children were not allowed to mix with other children at school.

Without ignoring or wishing to minimise the problems, there is generally a different prognosis for most of those who have contracted Hepatitis C.

Many people infected with Hepatitis C may live for a long period without any symptoms appearing. 50% of sufferers may progress to chronic hepatitis with varying degrees of good or ill health. Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. The majority of those years will be trouble free in terms of ill health , and as I have mentioned, only a small proportion will die of liver disease.

The Haemophilia Society's report of its Hepatitis C impact study makes a contribution to our understanding of the effect that Hepatitis C in this situation. We understand that the final report of the study is to be published in 1996.
But the report apparently relates to only a small sample of cases, which is not necessarily representative. Nor does it affect the main issue which is whether in the absence of fault or negligence, payments should be made to people who received the best treatment available at the time.

As I have said, infection with the virus will not necessarily lead to Hepatitis, but if it should it can be treated with the drug Alpha Interferon. Alpha Interferon is not a universal panacea for hepatitis patients. It can have unpleasant side effects and it is still not clear whether a permanent cure is possible. However, it has been shown to have real benefits for a proportion of sufferers and we have said all along that those people who could benefit from it should be able to receive Alpha Interferon

My Department is supporting an initiative by the Haemophilia Society to undertake a study into the best way to support its members who are infected with hepatitis C, and has made available £91,000 in 1995/96, with a commitment to further funding in 1996/97 and 1997/98 for this purpose.

My Department is also looking into what appropriate research may be undertaken to increase knowledge of hepatitis C, its natural history and optimal treatment.

[There have been allegations that patients whose consultants wish to prescribe Alpha Interferon have been refused treatment due to a lack of resources. My predecessor said during the adjournment debate on 11 July that the Department of Health would investigate to see what could be done to ensure that the treatment promised was provided.]

There have been calls on the Government to allocate funds specifically for the testing, treatment and counselling of patients who may have the hepatitis C virus. I have to say this would not be an efficient approach. It is Government policy to allocate NHS funds to the purchasers of health care and to leave it to them to decide what services they wish to purchase. These decisions are based on an assessment of need that take account of local circumstances and characteristics, within the framework of national policies and priorities.

Resources are allocated directly to health authorities using a national formula, which uses forecast population projections adjusted for age, relative health need and geographical variation in the cost of providing services. Purchasers are responsible for assessing the health needs of all their local residents, deciding which services to purchase and where to place contracts. These principles apply to the funding of treatment for Hepatitis C, as well as appropriate counselling and testing. Purchasers will need to take into account the fact that Alpha Interferon is now available to treat Hepatitis C in their purchasing plans and to discuss this with local providers.

The UK blood services are currently undertaking a look back exercise to trace, counsel, and where necessary treat those at risk of Hepatitis C through blood transfusions. Records of those donors identified as hepatitis C positive after September 1991, when routine testing of blood donations was introduced are being checked and recipients of their previous donations traced.

We shall do all we can to assist those who have been affected in this way.

[**Only if specific questions of these points have been raised :** The advice of the Chief Medical Officer in his letter of 3 April was that all anti-HCV positive patients found as a result of the transfusion lookback should be referred for further assessment to a specialist with an interest in the condition. The management of these patients requires the use of appropriate treatment regimes and the expertise to decide on the optimum duration of therapy. It is for the specialists working with their Health Authority, as purchaser, to address the issue of costs, based on their funding priorities.]

I come back to what Ministers have explained before - that it is the Government's view that the most effective use of resources is to seek to improve the understanding, management and treatment of the condition. This is the best way to minimise the impact of the disease on individual patients and their families, such as those which the Haemophilia Society's recent report illustrates.

To summarise : we recognise Members' concern for those who in addition to having Haemophilia, have also contracted Hepatitis C. Patients received the best treatment available in the light of medical knowledge at the time.

If we were to make payments in this case, when no negligence had been proved, there could be others who could argue that although they had been affected in different ways they were entitled to payments, even though no fault on the part of the NHS was proven. The Government has never accepted the case for a no fault scheme of compensation for medical accidents. We do not feel that, in the absence of proven negligence on the part of the NHS there is a case for using monies which would otherwise be used for the care and treatment of other NHS patients to make special payments to those affected.

[I sympathise with those who have been infected with Hepatitis C through blood or blood products and would in no way wish to minimise either the physical suffering which may result or the worry which they and their family may experience. But each situation has to be looked at on its merits and in the light of all the relevant facts. Those who have contracted Hepatitis C are not also subject to all the additional problems experienced by HIV sufferers, who were accepted as being a very special case. Hepatitis C is generally less severe than HIV. Many people infected with Hepatitis C may live for a long period without any symptoms appearing, or may never experience any at all.]

The experience of other countries which have decided to make payments to those infected with Hepatitis C has strengthened the Government's view that ex-gratia payments should not be made in the present case. The costs of the New Zealand scheme have proved to be extremely high, some 1% of the gross domestic product - equivalent to some £6 billion in the UK. In addition to practical difficulties the scheme effectively denies access to the courts. I understand that in Sweden payments under the no-fault compensation scheme are much lower; but the authorities have found it necessary to make additional payments to those infected with HIV.

[**Include only of this has been raised in debate :**

Mention has been made of the fact that the Irish government has proposed the setting up of a tribunal to determine payments for individuals infected with Hepatitis C, from blood or blood products, as well as women following use of anti-D.

Officials have had discussions with Irish officials. But we do not see any reason to change our stance. Most countries have decided not to make payments to those who have contracted Hepatitis C, even where they have made such payments where HIV has been contracted.]

I have however already outlined the measures we are taking which will benefit to sufferers and their families.

I want to end my pointing out that it important to remember that although infection has sadly occurred in these circumstances, it does not alter the fact that the UK record of blood safety is among the best in the world. An expert committee advises Ministers on tests to be applied in the light of the latest medical and scientific developments. And the system of deferral means that those at greatest risk of carrying infections which might be transmitted through blood or blood products are excluded from donating.

BULL POINTS

1. Government currently considering how best to offer support and help to those infected with Hep C.

2. The Department is already supporting an initiative by the Haemophilia Society to undertake research into the best way to support its members who are infected with HepC.

3. "Look back" exercise under way to trace, counsel and where necessary treat those infected through blood transfusion.

4. General scheme of no fault compensation for medical accidents unworkable and unfair.

5. Government recognised those infected with HIV through NHS treatment a very special case.

6. Payments to those infected with HepC through NHS treatment would be very costly. Others would argue that they too were deserving. Funds could be better used elsewhere in the NHS.

7. Hepatitis C generally less severe than HIV was thought to be when special payments agreed. Some carry HepC virus without any ill effect. HepC does not have the same social stigma as HIV.

8. The Haemophilia Society's interim Hepatitis C Impact study makes a contribution to our understanding of the effect that Hepatitis C has on those with haemophilia. But it contains no new facts which would justify a change in the Government's position.

9. The fact that the Irish Government has agreed to make

payments does not alter our view. Most other countries have decided not to make payments to those who contracted HepC.

10. Our voluntary donor system, among best in the world, underpins safety of blood supply. Safeguards - deferral of at risk donors, testing of donations, virucidal steps - kept under review.

11. We are also in touch with the Haemophilia Society allegations of problems with the provision of Alpha Interferon for those thought likely to benefit from it.

Q & A

I. QUESTIONS SPECIFIC TO HAEMOPHILIACS

II. QUESTIONS SPECIFIC TO RECIPIENTS OF BLOOD TRANSFUSIONS

III. QUESTIONS COMMON TO BOTH GROUPS -

(a) payments and other help to sufferers, including treatment
(b) severity of and screening for Hep C

I. QUESTIONS SPECIFIC TO HAEMOPHILIACS

HAEMOPHILIA PATIENTS INFECTED WITH HEPATITIS C : SOURCE

Most haemophilia patients were infected with hepatitis C before blood products were treated to destroy viruses in 1985. These patients received the best treatment available in the light of medical knowledge at the time.

NUMBERS OF HAEMOPHILIA PATIENTS AFFECTED?

We believe the overall figure for the number of individuals infected may be approximately 4,000 (including 1,000 who also infected with HIV). [A recent Haemophilia Society report published on 4 December 1995 suggests the slightly lower figure of 3,100 people infected].

NUMBERS OF DEATHS

Figures are not collected centrally for haemophilia patients who have contracted hepatitis C through contaminated blood, or for those who have died. A figure of a total 50 deaths since 1988 has been suggested, but in many of these there are likely to have been other contributory factors. I understand from the United Kingdom Haemophilia Directors that of 126 haemophilia patients known to have died in 1993, 12 showed the cause of death as liver disease of which hepatitis C may have been the cause. But 8 of these were also HIV positive.

WHAT WILL BE DONE TO ASSIST THE HCV INFECTED HAEMOPHILIA PATIENTS?

It is the Government's view that the most effective use of resources is to seek to improve the understanding, management and treatment of Hepatitis C. This is the best way to minimise the impact of the disease on individual patients and their families, such as those which the Haemophilia Society's recent report illustrates.

The Department is already supporting an initiative by the Haemophilia Society to undertake research into the best way to support its members who are infected with HepC, with a grant of over £90,000 this year [with agreement in principle to funding for a further 2 years].

ENCOURAGE DOCTORS TO USE RECOMBINANT FACTOR VIII ?

The safety of blood products depends on a number of factors which taken together reduce as far as possible the risk of viral transmission. These include screening of donors, plasma pool testing and the ability of the manufacturing process to remove and inactivate viruses. Recombinant Factor VIII that is currently available uses albumin which is a blood product as a carrier, so the risk of infection cannot be completely ruled out. It is also significantly more expensive than Factor VIII derived from human plasma, and clinicians may need to be convinced that the extra costs involved have demonstrable benefits.

VAT ON RECOMBINANT FACTOR VIII

That is a matter for Customs and Excise. [**If pressed :** The question of whether value-added tax is chargeable on Factor VIII products turns on whether they are derived from human blood. My Department has provided technical advice to HM Customs and Excise on that issue. While recombinant products do contain human albumin which is derived from human blood, that it is not the active ingredient of the product of the product, but is used only as the stabiliser/carrier for the active ingredient (which is not itself derived form human blood.)

It is for clinicians to decide what products are used in the light of available resources and the needs of individual patients. Factor VIII derived from human plasma is used for the majority of patients and is exempt from value-added tax.

WHY ARE WE NOT SELF-SUFFICIENT IN BLOOD PRODUCTS ?

The UK is self-sufficient in blood and many blood products. However, for some, such as Factor VIII, commercial products which satisfy liscencing conditions are used. It is up to clinicians whether to use UK or imported products.

II. QUESTIONS SPECIFIC TO RECIPIENTS OF BLOOD TRANSFUSIONS

NUMBERS OF BLOOD TRANSFUSION RECIPIENTS INFECTED WITH HEPATITIS C

Some 3,000 infected patients who are alive today are likely to be identified by the look back exercise [relating to earlier donations of those who donated blood after September 1991, when testing for Hepatitis C commenced].

"LOOK BACK" TO TRACE BLOOD TRANSFUSION RECIPIENTS

The UK blood services are currently making good progress with a look back exercise to trace, counsel, and where necessary treat those at risk, which started this spring.

[Records of those donors identified as hepatitis C positive after September 1991 are being checked and recipients of their previous donations are being traced.]

We shall do all we can to assist those who have been affected in this way.

HELP TO THOSE IDENTIFIED THROUGH LOOK-BACK EXERCISE

The advice of the Chief Medical Officer in his letter of 3 April was that all anti-HCV positive patients found as a result of the transfusion lookback should be referred for further assessment to a specialist with an interest in the condition.

III. QUESTIONS COMMON TO ALL THOSE INFECTED WITH HEPATITIS C

(a) Payments and other help to sufferers, treatment

WHAT PLANS DOES THE GOVERNMENT HAVE TO MAKE SPECIAL PAYMENTS TO THOSE AFFECTED?

As my predecessor said in the debate in July, the Government has great sympathy for those infected with hepatitis C as a result of NHS treatment. But as no fault nor negligence on the part of the NHS has been proved, we have no plans to make special payments.

IRISH REPUBLIC IS MAKING PAYMENTS

This does not alter our view. Most other countries have decided not to make payments to those who contracted HepC,, even where they are making such payments to those who contracted HIV

WHY TREAT DIFFERENTLY FROM PATIENTS INFECTED WITH HIV THROUGH NHS TREATMENT?

We accepted that the patients who, tragically, contracted HIV through NHS treatment were a very special case and the Government made provision for them because of their very special circumstances.

Those affected were all expected to die very shortly and were subjected to significant social problems, including ostracism.

COSTS OF PAYMENTS

If an exception were to be made for the patients who may have been infected with hepatitis C through blood or blood products there would be others who would argue that they too were deserving.

GOVERNMENT HELP FOR THOSE INFECTED WITH HEPATITIS C

The Government is currently considering how best to offer help and support for those infected with hepatitis C. This could include encouragement of research into the condition and guidance to the NHS on best practice where there is a clinical consensus.

We are aware that guidelines on the management of Hepatitis C have been prepared by Haemophilia Centre directors and that the Haemophilia Society have also produce a document]

PUBLIC EDUCATION

Education of professionals and the public has already started - for instance through the CMO letter issued in April in connection with the look-back exercise.

SHOULD NOT ALL PATIENTS WITH HEPATITIS C BE OFFEREED ALPHA INTEFERON ?

Alpha Interferon is not suitable for all patients with proven hepatitis. Only 20% of infected individuals are likely to have long-term benefit, and it is suggested that treatment works best in the early years following infection. The drug has unpleasant side-effects and should not be used when the patient already has cirrhosis or severe liver damage.

Calls for all patients infected with HCV but who have not developed hepatitis cannot be justified. It must be a clinical decision.

[Prior to the licensing of the 2 brands of alpha Interferon for treatment of patients infected with hepatitis C (November 1994 and January 1995) purchasers were often unwilling to pay for treatment using this unlicensed drug. Treatment is expensive (approximately £5000) and clinicians must decide in individual cases whether it is appropriate to prescribe this drug.]

PATIENTS WHO ARE THOUGHT SUITABLE BEING DENIED ALPHA INTERFERON

As we promised during the July adjournment debate, my Department is looking into allegations of problems with provision of alpha interferon for treatment of haemophilia patients infected with hepatitis C. Officials are in contact with the Haemophilia Society seeking any information they have about the nature and extent of the problem. So far, evidence of any problems has been very limited.

FUNDING FOR TREATMENT ETC OF HEPATITIS C

It is Government policy to allocate NHS funds to purchasers of healthcare and to leave it to them to decide what services they wish to purchase to meet local needs within the framework of national policies and priorities. They, in consultation with local providers are in a far better position to know about local needs than Ministers or central government officials.

BEST USE OF RESOURCES

We have already stated that, rather than paying compensation, the most effective use of resources is to seek to improve understanding, management and treatment of the condition, so as to minimise the impact of the disease on patients and their families.

WHY NOT INTRODUCE NO FAULT COMPENSATION FOR MEDICAL ACCIDENTS

The Government are opposed to a no-fault compensation scheme, which would be unworkable and unfair. [It would also divert money, possibly large sums, which could otherwise be available for other purposes within the NHS.]

VACCINE DAMAGE PAYMENTS

The scheme set up under the Vaccine Damage Act does not provide a precedent for special help for those who have contracted Hepatitis C through blood or blood products. Vaccines are given to the healthy as a matter of public policy. On the other hand recipients of blood or blood products are given this treatment for their own benefit in the normal course of medical care for their disorder.

PRESSURE FOR COMPENSATION FOR HUMMAN GROWTH HORMONE PATIENTS WHO MAY BE AT RISK OF CONTRACTING CREUTZFELT JAKOB DISEASE

We do not accept that there are grounds for awarding financial compensation over and above the services and benefits available to patients under the NHS and Social Security Acts.

(b) Severity of, and screening for, Hep C

HEPATITIS C AND ITS SEVERITY

Many people infected with HCV may enjoy a long period without any symptoms appearing.

Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. A much smaller number, about 1% may progress to liver cancer.

WHY WAS HEPATITIS C NOT ELIMINATED BEFORE IT GOT INTO THE BLOOD SUPPLY?

In the absence of any reliable test for HepC the only way to safeguard blood was to limit those from whom blood was taken by a system of self deferral.

This excluded from donation those known to be suffering from hepatitis or any other liver disease; drug misusers; and men who had sex with other men.

WHEN WAS ROUTINE SCREENING FOR HCV INTRODUCED?

Screening was introduced in September 1991, when reliable tests first became available.

WHY WAS ROUTINE SCREENING FOR HCV INTRODUCED IN 1989?

Expert advice was that these tests should not be introduced when they first became available in 1989 because of deficiencies. These first tests had too large a number of false positive and false negative results and no satisfactory confirmatory tests were available.

The Department of Health funded several trials of the first and second generation anti-Hepatitis C test kits. Screening was introduced in late summer 1991, following advice from the Advisory Committee on the Virological Safety of Blood (ACVSB) that satisfactory kits had become available together with confirmatory tests.

WHICH OTHER COUNTRIES DID INTRODUCE HCV TESTING BEFORE BRITAIN?

We do not have precise details of the date at which each country introduced Hepatitis C testing. We do know that some did introduce testing before the UK.

But it must be remembered that in some of these cases the incidence of Hepatitis C in donors is considerably greater than in the UK; also in UK the general health of donors is the best in the world.

[If **pressed** : The expert committee, which advises ministers on these issues, discussed at the time the course of action pursued by some other countries. The view of the committee was that neither the screening test nor the PCR confirmatory test should be introduced at that time because it was not reliable enough (in particular, it generated a high level of false negative results).

BACKGROUND NOTE

Representations

1. A Haemophilia Society's campaign, launched on 14 March 1995, calling for a number of actions to address the problems of haemophilia patients who have contracted hepatitis C from contaminated blood products, including financial assistance similar to Government help for HIV infected haemophilia patients.

2. It has been known for many years that the majority of haemophilia patients will have been infected with hepatitis C through NHS treatment and we have expected a campaign to be mounted along the lines of that for HIV.

3. Representations concerning compensation this year comprise :

- a debate in the House of Lords on 15 March

- an adjournment debate on 11 July

- 2 Lords Oral Questions from Lord Ashley of Stoke (PQs 1037 and 1634)

- 4 House of Commons written Questions (PQs 2429, 2895 and 3638 and 4480)

- a recent House of Commons Oral Question (PQ 175)

- 5 Early Day Motions (864, 1053, 1054 and 1219 in 1994/95 and 3- with 233 names - in 1995/96)
  (copies, and related briefing appended)

- some 300 letters to Ministers

Not all will necessarily have referred specifically to haemophiliacs.

Numbers infected

4. The precise number of patients infected with hepatitis C virus by blood and blood products as a result of NHS treatment is unknown. Almost all the haemophiliacs treated prior to 1985 will have been infected. This would give a figure of about 3000 who are not already covered by the HIV payment scheme. It is estimated that 3000 live patients will be identified as a result of the lookback exercise of patients who had blood transfusions. The total number of patients infected with hepatitis C from blood transfusion could be well in excess of this figure.

Reason for not making payments

5. The Department cannot dispute that some people have been infected through NHS treatment but deny negligence. Although patients received the best treatment available based on existing knowledge it has to be recognised that not all medical interventions are risk free. Risks may be evident at the time of treatment or may be discovered later. If payments were to be offered for each such incident we would soon slip into a general no fault compensation scheme. The Government is opposed to a no-fault scheme, which would be unworkable and unfair.

Comparison with HIV

6. The Government accepted that the patients who, tragically, contracted HIV through NHS treatment were in a different position from others and made provision for them because of their very special circumstances. Those affected were all expected to die very shortly and were subjected to significant

social problems, including ostracism. In the case of the infected haemophilia patients, the problems of HIV were superimposed on the health, social and financial disadvantages they already suffered as the result of their hereditary haemophilia.

7. Hepatitis C is different to HIV. Many people infected with Hepatitis C may enjoy a long period without any symptoms appearing. 50% of sufferers may progress to chronic hepatitis with varying degrees of good and ill health. Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. The majority of those years will be trouble free in terms of ill health and only a small percentage will actually die of liver disease. Ministers have therefore made clear that they have no plans for a payments scheme.

8. The Haemophilia Society stated in their original press release that over 40 haemophilia patients have died through infection with hepatitis C virus. (Recent EDMs give the figure now as 50, which does not seem improbable as it presumably includes a figure for 1994.) It is important to retain a clear sense of proportions and timescales. The figure of 40 quoted by the Society related to the 5 year period 1988 to 1993 and this is out of a figure of over 4000 who are positive from hepatitis C (ie 1%). In 1993 12 haemophilia patients died with the cause of death shown as liver disease. This was out of 126 haemophilia patients known to have died in that year. Of these 12, 8 were also HIV positive. Without seeking to minimise the tragedy these are small numbers when weighed in the balance of the good that treatment has brought to many of these and countless others. As a comparison the number of haemophilia patients who have died of AIDS is 619 out of 1238 who are HIV positive (ie 50%).

HGH recipients at risk of CJD

9. Some of those treated with Human Growth Hormone (hGH) are not felt to be at risk of developing Creutzfeldt Jakob Disease (CJD). The Department has resisted calls for a public enquiry on the grounds that one would not be appropriate all the time legal action is being taken. As you will see from the note attached. The court case is being resisted on the grounds that the collection and treatment complied with the best scientific and clinical practice at that time.

10. HGH patients have also been calling for compensation. Again, Ministers have been resisting this on the grounds that:

-there is as yet no evidence of negligence. Ministers are not prepared to consider spending NHS money unless there is evidence of negligent harm.

- a settlement including compensation would provide an unwelcome precedent for other similar cases - eg. Hep C!

- again, consideration of a settlement and compensation is inappropriate until Counsel have had an opportunity to consider the strength of the defendants' case.

Haemophilia Society Campaign

11. The Haemophilia Society launched a campaign on 14 March 1995 seeking government action for haemophiliacs who had contracted Hepatitis C through blood or blood products. The Society stressed in its press release that it was not seeking legal compensation through the courts with a view to allocating blame or liability. However the Society said that

it believed there wass a clear moral case for the government to provide immediate assistance for those people with haemophilia infected with the virus.

12. The objectives of the campaign were stated to be:

- More equitable treatment in financial terms between those people with haemophilia infected with hepatitis C through contaminated blood products and those infected with HIV through contaminated blood products, specifically:

- An across the board ex-gratia payment to all those infected with hepatitis C through contaminated blood products.

- Access to a hardship fund for those who become ill and the dependants of those who die.

- As a matter of urgency, payments to those who are already ill and the dependants of those who have died.

- Adequate resources for haemophilia centres to enable them to provide the best possible treatment and care for people with haemophilia and hepatitis.

- Adequate resources for research into the prognosis and treatment of hepatitis C.

- A public education programme that provides reassurance about the methods of transmission of hepatitis C and explains that ordinary social contact is not a means of transmission.

Haemophilia Society HepC Impact study

13. A Haemophilia Society report published on 4 December 1995

claims that some 3,100 haemophiliacs have been infected with Hep C as a result of treatment with contaminated blood products. The fact of infection is not at issue and if anything the true figure may be slightly higher. It is reasonable to suppose that the published evidence is emotively and selectively used to support the Society's conclusions. Only 18 separate individuals are quoted. Overall the effects described of Hep C on peoples' lives is not in dispute.

14. The aim of the report will be to demonstrate that those infected with HepC are suffering significant and immediate problems, to support the claim for compensation. It asks the Government to take immediate action and provide funding for :

- financial support for individuals
- a public education programme
- treatment and care
- further research into Hepatitis C

The report contains no new evidence that affects the current policy line on compensation.

Position in other countries

15. The Irish government has proposed the setting up of a tribunal to determine payments for individuals infected with Hepatitis C, from blood or blood products, as well as women following use of anti-D. The levels of compensation being offered are fairly low.

16. DH officials have had discussions with Irish officials, but do not see any reason for DH to change its stance. Most countries have also decided not to make payments to those who have contracted Hepatitis C, even where they have made such payments where HIV has been contracted.

17. We believe that Austria and the Republic of Ireland are the only European countries committed to making any payments

to haemophiliacs, but the amounts payable are small. A table is enclosed setting out the best information we can currently obtain.

Departmental action

18. The Department is supporting an initiative by the Haemophilia Society to undertake a study into the best way to support its members who are infected with the virus, with a grant of over £90,000 this year [with agreement in principle to funding for a further 2 years].

19. The Health Departments have mounted a UK wide look back exercise to trace, counsel, and where necessary treat those who may be at risk of hepatitis C through blood transfusion. The start of the exercise was announced on 4 April 1995. Officials will be reporting back to Ministers shortly.

20. DH are considering other steps which could be taken to ensure for example that: treatment is made available and that any additional research which might be required to improve the understanding, treatment and management of those affected be investigated. DH is also giving sympathetic consideration to appropriate requests for support from any self help groups which might be able to provide cost effective assistance to their members.

21. So far there has been no concerted legal action. Only a handful of writs have been issued so far (against the blood transfusion service and in one case the SoS for Scotland). None are likely to go to court this year. (There have been two writs recently naming the SoS, as well as a health authorities. The first does not involve a haemophiliac. Details of the second are not known.)

22. Haemophilia Society have been advised by their Directors that they are unlikely to win on negligence generally .

Costs were payments to be conceded

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23. Officials best estimates of making payments in affected cases range from :

* £50m minimum for a hardship fund only (spread over 30 years but with a heavy initial cost.

* Between £350m and over £1,000m for a voluntary settlement of any litigation, along the lines of that in HIV cases.

Each system could be expensive to operate administratively. (This assumes that schemes would need to include those infected with HCV through transfusions, not just haemophiliacs.)

Recombinant Factor VIII

24. This is a form of Factor VIII which is not produced from blood products. Recombinant Factor VIII is significantly more expensive than plasma derived (41p per unit as compared with 25p per unit). Figures for 1993 showed 135.5 million units used to treat 2,300 patients with haemophilia A, which would mean a difference of £22m per annum. The usage of Factor VIII increases year on year and so the increased cost in 1995 is likely to be significantly higher.

25. The current exclusion criteria, testing and manufacturing procedures appear able to destroy most viruses other than parvovirus. This is a common virus, where over 50% of children are immune by the age of 15. Most individuals have only mild symptoms, the exception being immunocompromised individuals, patients with red cell aplasia and foetuses.

26. UK law provides that therapeutic products derived from blood or blood products are exempt from VAT. Customs and Excise have recently ruled that the recombinant product - which some clinicians consider safer than the product derived form human plasma, is not so exempt. Customs took technical advice from DH before giving the ruling. It is based on the fact that while the recombinant product uses human albumin, this is only a stabiliser, not the active ingredient. Both customs and DH Ministers have recently been asked questions about the position.

27. The current position is in line with the treatment of these products in other EC countries. Any change in UK law would first require agreement to a change in the EC directive, which would require unanimity, which is unlikely to be easily or speedily achieved. However this is one of the areas where the Government will be asking the EC Commission to bring forward proposals to modernise the directive in the light of scientific developments and changes in business practice since it was adopted. However the present exemptions are based on the belief that is not right for products derived from freely donated blood to be taxed, while the same argument does not apply to synthetic products.

28. The Haemophilia Society and others are pressing for a change in the Customs ruling and/or extra finance to allow doctors to continue to prescribe the more expensive recombinant product. However, apart from long-term possibility of review of the EC directive on which domestic law is based, we see no need for any action. Products derived solely from human plasma remain available, are not subject to

VAT, and are considered to have a good safety record.

BRIEFING FOR THE PRIME MINISTER: 4 DECEMBER 1995
HEPATITIS C

I have great sympathy with those who may have been inadvertently infected with Hepatitis C through NHS treatment.

I am confident that the patients concerned received the best treatment available in the light of medical knowledge at the time. Since 1991, when a reliable test became available, all blood donations have been tested for Hepatitis C to prevent such infection.

Arrangements have been made to trace, counsel and - if necessary - treat those who may have been infected through blood transfusions. The Department of Health is also supporting an initiative by the Haemophilia Society to study the best way of supporting those who are infected with the Hepatitis C virus.

HepC impact study

* This is a small sample but we welcome the report as a contribution to our understanding of the effect that Hepatitis C has on sufferers and their families.

* Public education has already been started - for example the CMO letter of 3rd April 1995.

* As promised in the July adjournment debate, DH are looking into allegations of problems with the provision of alpha interferon. [I am aware that the Haemophilia Directors have prepared guidelines on the management of Hepatitis C and that the Haemophilia Society have also produced a document.]

* DH are currently considering several proposals on further research.

Compensation ?

What the hon. member is asking for is compensation for patients where, tragic though their circumstances are, no fault and no negligence on the part of the NHS has been proved.

The House will understand the significance and implications of such a move. The principle involved is not one which can or should be lightly breached.

My RHF SofS for Health has reiterated the policy of his predecessors, most recently in evidence to the Health Select Committee (July 1995), that he does not believe 'no-fault compensation' is a sensible use of NHS resources.

Precedent already established by HIV

In the case of patients inadvertently infected with the HIV virus, the decision was taken, in light of their very special circumstances. Those affected were subject to significant social problems and were all expected to die very shortly.

HEPATITIS C

Background

Haemophilia Society HepC Impact study

A Haemophilia Society report published on 4 December claims that some 3,100 haemophiliacs have been infected with Hep C as a result of treatment with contaminated blood products. The fact of infection is not at issue and if anything the true figure may be slightly higher. It is reasonable to suppose that the published evidence is emotively and selectively used to support the Society's conclusions. Only 18 separate individuals are quoted. Overall the effects described of Hep C on peoples' lives is not in dispute.

The aim of the report will be to demonstrate that those infected with HepC are suffering significant and immediate problems, to support the claim for compensation. John Marshall has tabled an oral PQ for answer on Tuesday 5 December, no doubt timed to co-incide with the report, which is likely to generate some press coverage on the same day. The report contains no new evidence that affects the current policy line on compensation.

Republic of Ireland

We are aware that the Irish government has proposed the setting up of a tribunal to determine payments for individuals infected with Hepatitis C, from blood or blood products, or in women following use anti-D.

TABLE

PAYMENTS FOR HCV AND HIV IN EUROPEAN COUNTRIES

Country	HIV	HCV	COMMENTS
Austria	£664 monthly for infection with blood/blood products. Death - £1992 - £232 monthly to surviving children while dependent	As for HIV	3* cases so far paid for HIV from infected blood. Money for fund from Federal Government, some of the Lander and pharmaceutical industry. [* This figure can only be a tiny proportion of those infected.]

Denmark	Recent announcement (March 1995) of £2m fund for the 89 infected haemophilia patients. [Information in 1990 indicated that a flat rate of £20,000 - £25,000 Government ex-gratia was being offered - no info regarding whether this was paid at that time]	No payment scheme	Announcement of fund followed recent Danish court ruling stating that decisions by the National Health Board and the country's largest drug manufacturer were irresponsible but not culpable.

Country	HIV	HCV	COMMENTS
Eire	Haemophilia payment system similar to that in the UK and similar amounts. Apparently no HIV blood transfusion cases yet.	Commitment to pay compensation, major outbreak of HCV following IV anti-D treatment. ?? Tribunal to be set up	We are aware that patients in Ireland are currently suing commercial manufacturers of blood products despite the payment scheme. In the UK a condition of the payment scheme was that litigation should not proceed.

France	Public fund set up in 1989 with payments varying from £4,000 to £17,000, with additional £3,000 for a dependent child and an extra £10,000 if the patient dies from AIDS. However, major court cases have occurred in France, and the main way to obtain payment would be through suing as for HCV.	No payment system - law suit must be brought on a individual basis.	The payments referred to for HIV, came partly from the French Government and partly from the Underwriters of blood transfusion establishments. There is some confusion about how many patients were made, and whether these payments are still currently available or whether they have been superseded by various litigation.

Country	HIV	HCV	COMMENTS
Germany	Previously manufacturers paid HIV infected haemophilia patients (£15,000-£165,000) under legal liability. May 1995 German Government announced a new HIV relief law paying those who had become infected with blood or blood products (approximately 1300 people) and non-infected dependents of already deceased infected people (approximately 450 people). Payment £1300 per month if have AIDS or £650 if not yet AIDS.	No payment.	Detailed scheme on HIV only recently announced. Contributors to fund DM100m Government, DM100m German Red Cross, DM50m Lander and contributions from the pharmaceutical companies. Beneficiaries have to give up all legal claims.

Greece	No payment scheme.	No payment scheme.	Recent case in courts resulted in substantial damages. State to appeal to a higher court, and depending on outcome may decide to set up a payment scheme (?? for HIV).

Country	HIV	HCV	COMMENTS
Portugal	Payment scheme for haemophilia patients infected with imported blood products. Amount decided by an arbitration court, maximum £48,000 per patient.	No payment scheme	
Sweden	Fund covering a number of items such as the loss of income, funeral expenses, allowances to surviving relatives as well as a lump sum of up to £44,200 depending on age.	Payments only available for those infected after 1990, when a test was available for HCV. Payment depend on age and degree of disability (eg for a 25 year old 5% disability £2,012, 75% disability £22,100). No figures for numbers involved, presumably extremely small.	The no fault compensation payments in Sweden are small, and so separate funds were set up.

We have no details of any payment schemes for Belgium or Netherlands. A report by Mrs Adrianna Ceci in 1993 to the European Parliament, referred to payment for HIV infected haemophiliacs in Spain of £15,000 and Italy £9,000.

Different countries have different social security and public health systems. In many countries medical treatment of infected patients is covered and social security payments are available to those unable to work or for their dependents.

KEY FACTS

1. Safety measures

- self deferral of donors who may be at risk of infection.
- heat treatment of blood products to destroy viruses introduced in 1985.
- testing of all donations for hepatitis C introduced September 1991 (testing of donations for HIV introduced in 1985).

2. Numbers infected with hepatitis C

- exact numbers of patients infected with HepC through NHS treatment not known.
- most haemophilia patients infected with HepC before blood products (Factor VIII and factor IX) heat treated to destroy viruses. Around 4,000 may be affected (1,000 of whom have already received payments under the HIV haemophilia settlement.) (The Haemophilia Society recently suggested a figure of 3,100)
- information from the Haemophilia Centre Directors is that of 126 haemophilia patients known to have died in 1993, 12 showed the cause of death as liver disease, of which hepatitis C may have been the cause.
- in addition, look back exercise thought likely to identify some 3,000 blood transfusion recipients who are alive who are HepC positive

3. Hepatitis C and its severity

- HepC is a blood borne virus.
- 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health.
- HepC can cause liver disease and mortality.
- some patients may respond to interferon treatment.
- perhaps 20% of infected patients will develop cirrhosis, sometimes after 20-30 years.

4. Payments to patients infected with HIV through NHS treatment

Costs of the HIV Haemophilia payment scheme have reached over £80 million. (This includes £15 million paid to the Macfarlane Trust for the special needs of HIV haemophilia patients and their families.)

Costs of the scheme of <u>payments for those infected with HIV through blood or tissue transfer</u> has reached <u>some £4 million</u> including £0.5 million paid to the Eileen Trust for the special needs of this group.

5. Actions being considered by DH on hepatitis C

(a) Government currently considering how best to offer help and support for those infected with hepatitis C. This could include

-encouragement of research into the condition.
-guidance to the NHS on best practice where there is a clinical consensus.

(b) A "look back" exercise is well under way to trace, counsel, and where necessary treat those blood transfusion recipients who may be affected.

(c) The Department is already supporting an initiative by the Haemophilia Society to undertake research into the best way to support its members who are infected with HepC. (Their project grant for 1995/96 is £91,937, with agreement in principle to funding for a further 2 years.)