PQ00028 2005/2006

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LORD MORRIS OF MANCHESTER (LABOUR):

The Lord Morris of Manchester - To ask Her Majesty's Government what further consideration they are giving to providing financial help for the dependants of patients who have died in consequence of being infected with hepatitis "C" by contaminated National Health Service blood and blood products.

SUGGESTED REPLY

The Government has great sympathy for the pain and hardship suffered by the widows and dependants of those inadvertently infected with hepatitis C. However, as previously stated we have no plans to alter the existing financial arrangements regarding dependents of people infected with hepatitis C.

Supplementary Questions

Why does the Scheme exclude Widows and Dependents?

The underlying principle of the Skipton Fund payments is that they should be targeted to help alleviate the suffering of people living with inadvertent hepatitis C infection.

The Government has great sympathy for the pain and hardship suffered by the widows of those inadvertently infected with hepatitis C, but the fund is not designed to compensate for bereavement. This is a fair and reasonable approach, bearing in mind that there is limited funding available.

How many widows/dependants will miss out?

I'm afraid that I am unable to provide MNF with a substantive answer to that question. He/She will appreciate that it is very difficult to provide an accurate estimate of the number of dependants of people who have been inadvertently infected with hepatitis C and who have since died.

How many will benefit/how much will scheme cost?

MNF will appreciate that due to the nature of this scheme, a number of assumptions have to be made when calculating these figures. Although haemophiliacs are a well-documented group, estimates on the number of non-haemophiliacs who may come forward are difficult to project. However, what I can say is that the Department will honour all valid claims.

However, our best estimates are that as many as 7,000 people could benefit from the scheme.

Payments too small

I believe that the scheme strikes the right balance and ensures that we are able to make value for money payments while not adversely affecting the rest of the health service. They are fair and reasonable and I hope that they will help to alleviate some of the problems experienced by people who have been affected.

Funding for the Scheme

The scheme has a UK wide remit. Therefore all the Health Administrations contribute towards funding the ex-gratia payment scheme.

In England funding will be available from Central Departmental Budgets.

To date we have made the following amount available to the Fund:

2004/05	£70,087,000
2005/06	£5m

If strongly pressed – it is estimated that the scheme will cost DH ~£150m

Comparison with Irish scheme

I have set out in detail in this house the position with regards to the Irish Scheme. The Irish Government set up their hepatitis C compensation scheme following evidence of negligence by the Irish Blood Transfusion Service.

A judicial inquiry, the Finlay report, found that "wrongful acts were committed". It is important to stress that the blood services in the UK have not been found to be similarly at fault. Compensation is therefore being given in very different, specific circumstances in Ireland that do not apply in the UK. I do not believe that the Irish scheme creates any precedent for us.

Disparity with Canadian scheme

It is important to make a distinction here. The awards being made in Canada follow class action brought against the Canadian government. A settlement agreement was reached with the federal government, and as such the payment structure was based on claims for punitive damages. The compensation from the federal government is limited to those infected between 1986 and 1990.

Subsequent inquiries found that wrongful practices had been employed, and criminal charges were made against organisations including the Red Cross Society, who were responsible for screening blood in Canada at the time. We do not acknowledge any such wrongful doing in England, so it is unfair to compare the two schemes.

Those conditions in Ireland and Canada do not apply in the UK.

Disparity with Haemophilia Society/Lord Ross recommendations

Although the reports by the Haemophilia Society and Lord Ross were considered during our deliberations, unfortunately it has not been possible to meet their recommendations on the payment structure of the scheme. These recommendations were made without prior knowledge of the pressures on the health budget, and we have had to weigh the issue of making payments against all the other demands on the budget.

Disparity with Macfarlane/Eileen Trust payments

The Skipton Fund, unlike the Macfarlane and Eileen Trusts, is not a charitable trust. It has been designed to make lump sum, ex gratia payments on compassionate grounds and will not be making follow up or day to day payments. That said, the lump sums are comparable to those made by the Macfarlane and Eileen Trusts.

I acknowledge that other schemes do include dependants under their eligibility criteria but would stress again that the Skipton Fund is distinct and has not been designed to compensate for bereavement.

Payments not structured

We have tiered the payments to reflect the natural progression of a person's illness. However, for the benefit of all involved, we have tried to avoid a complex and ambiguous payment structure. By providing two lump sum payments on the basis of well-defined criteria, the disbursement system will be efficient and consistent.

Second payment

A group of experts met to define an exact trigger point for the second payment, and a test to determine if a person qualifies for the payment. Similarly, we sought advice on devising an application form, and to determine the level of evidence required to support a claim.

Involvement of Haemophilia Society

Officials have consulted with the Haemophilia Society since the scheme was announced in August 2003.

I understand that representatives met with officials and the Parliamentary Under-Secretary of State for Public Health during the course of the Department of Health's deliberations.

Establishment of an Appeals Panel

Any applicant who does not agree with the outcome of their application to the Fund will have the opportunity to apply to an appeals panel.

There has been a delay in establishing the appeals procedure. However, I would like to assure you that officials, in consultation with colleagues in the devolved administrations, are currently developing this procedure. I have asked that an appeals procedure is established no later than the beginning of the summer recess. When appeals can be heard, the Skipton Fund will inform all those affected.

If pressed: The number of people who have indicated that they wish to appeal is currently 31.

Scheme administration

At the time of setting up the scheme, the senior management team at the Macfarlane Trust indicated their willingness to help administer the Skipton Fund as a result of their expertise and experience in this area.

Appointment of Directors:

Three Trustees and the Chairman and Chief Executive of the Macfarlane Trust were asked to take on the role of Directors and company secretary for the Skipton Fund on an interim basis. This decision was made so that we could make progress with establishing the Skipton Fund. The Trustees have a background in management, administration and working with haemophilia patients. DH have been seeking advice about the recruitment of Directors to the Skipton Fund on a permanent basis.

Staffing:

There are now two members of staff employed by the Skipton Fund. This includes an administrator and a scheme assistant (previously there were four staff employed by the Fund, the scheme administrator and three scheme assistants). In addition, support services, including financial assistance are provided by staff members of the Macfarlane Trust.

Agency Agreement

The Agency Agreement is in the final stages of drafting and will be finalised with the Devolved Administrations and other stakeholders by the end of the Summer recess.

Clearance of virus

Those who were inadvertently infected with hepatitis C and who have cleared the virus following treatment will be eligible in exactly the same way as those who have not. However, those who suffered from acute hepatitis C and cleared the virus spontaneously will not be eligible to apply for payments.

How was the scheme devised

The establishment of a scheme has not been taken lightly and has required significant research, analysis and organisation to ensure it is well thought out, fair and inclusive, and ultimately a success.

As was the case for other similar payment schemes, such as the Macfarlane Trust, the drawing up of the scheme was co-ordinated by officials in the Department of Health. As this is a UK wide scheme, their counter-parts in Scotland, Wales and Northern Ireland were also heavily involved. Colleagues from other Government departments such as the Department for Work and Pensions and the Treasury also provided assistance.

During our deliberations, we held meetings with a number of charitable organisations including the Haemophilia Society, the Hepatitis C Trust and the Macfarlane Trust. We chose to meet with these groups because of their involvement in the setting up of similar schemes and/or because of their representative constituencies. We also considered the views of other groups and individuals through correspondence.

In addition, we have been advised by the National Blood Service, leading hepatologists and consultant haematologists.

Number of payments made

	Stage One Applications	Stage Two Applications
Application forms dispatched	4569	408
Total Completed Applications received	3583	405
Number of Applications paid	3114	366
Number of Applications	246 (declined)	24 (deferred)
Number of Applications Which have not been satisfactorily completed and have been returned	156	13
Total Amount Paid to claimants	£62,280,000	£9,150,000

Is there a deadline for applications?

No. The scheme will run indefinitely.

Identification of potential claimants

The Department published its *Hepatitis C Action Plan England* in June 2004, which set out key actions for Government, the NHS and others to improve the prevention, diagnosis and treatment of hepatitis C. One of the focuses of the plan is on increasing the diagnosis of people at current and past risk of infection. This should help to identify people who are not aware that they have been infected with hepatitis C following a blood transfusion.

We will also work with the Haemophilia Society and United Kingdom Haemophilia Centre Doctors Organisation to raise awareness of the scheme amongst those people with haemophilia.

Many of those who are aware of their infection contacted the Department prior to the launch of the scheme.

Hepatitis B

I'm sorry to have to confirm that people infected with hepatitis B as a result of treatment with NHS blood or blood products will not be eligible for this scheme. The Government has great sympathy for people who were inadvertently infected with hepatitis B before the introduction of national screening in 1972, but has no plans to introduce a similar scheme for hepatitis B.

Recombinant clotting factors

MNF has taken this opportunity to ask about progress on the rollout of recombinant clotting factors. Throughout the roll-out programme we have been working with key stakeholders including the Haemophilia Society, clinicians, Primary Care Trusts and others to put in place a strategy and monitor the roll out of recombinant products.

The provision of recombinant treatment is being phased, I am pleased to say that in January 2004 those patients born between 2 April 1962 and 26 February 1982 started to receive recombinant treatment. Those patients born before 2 April 1962 are eligible for treatment with recombinant products in this financial year.

The Chairman of the United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) wrote to all Haemophilia Doctors at the start of this calender year requesting that those remaining patients should be asked for their consent and switched to recombinant products as soon as possible after 1 April 2005. This was at the request of the Forward Planning and Monitoring Group on the Roll Out of Recombinant Clotting Factors.

Public inquiry

It is important to stress that despite the Department of Health decision to make ex gratia payments, the position with regards to accepting liability has not changed. The Government does not accept that any wrongful practices were employed and does not consider a public inquiry justified, as we don't believe that any new light would be shed on this issue as a result.

Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.

Scotland

There is additional pressure on the Scottish Parliament for a public inquiry but this is also being resisted on similar grounds.

Review of internal papers on the issue of self-sufficiency in blood products

An informal review to clarify the facts surrounding the drive for UK self sufficiency in blood products in the 1970s and 1980s was commissioned in July 2002. I have asked officials to complete work on this as quickly as possible.

We will of course send a copy of the report to those people who have expressed an interest in the issue of self sufficiency in blood products.

Freedom of Information Act

We have had five FOI requests in connection with the issue of haemophilia patients infected with hepatitis C through contaminated blood products.

Our responses have been variable. This is because we have established that in some cases the relevant files have been destroyed. Some of the requests exceed the £600 limit applied to cases. In three of the cases we have been able to provide some information.

Key Facts

The Skipton Fund became operation on 5 July 2004.

Every person alive on 29 August 2003 and whose infection is attributable to NHS treatment is eligible

Initial payment of £20,000, then £25,000 if cirrhosis develops or if claimant has liver cancer/transplant

Also eligible - People co-infected with HIV; those infected by an eligible claimant; those successfully treated

Cut off point for scheme is September 1991 (date of introduction of donor screening for hep C)

Bullet points

Skipton Fund

- The Secretary of State decided on compassionate grounds that establishing a financial assistance scheme for people infected with Hepatitis C is the right thing to do. As such, the Department of Health, together with officials in the devolved administrations introduced a scheme to make ex gratia payments to Hepatitis C sufferers.

- Interested organisations were invited to participate in discussions and comment on key elements of the scheme.

- **NICE recommendations**

  - NICE published guidance on the use of combination therapy (pegylated interferon with ribavirin) for the treatment of hepatitis C in January 2004, which is currently being reviewed.

  - We have placed statutory obligations on the NHS to implement NICE recommendations and are introducing measures to achieve better access to NICE-recommended therapies. As part of these proposals, it is intended that information about NICE-recommended drugs prescribed and dispensed in hospitals will be available to the NHS. This will enable SHAs to compare uptake of drugs by NHS hospitals in their area with the national distribution and take any necessary action to improve uptake. This information will also be available to the Healthcare Commission which have indicated that assessing the implementation of NICE guidance will be one of their key priorities.

  - There may be a variety of reasons why countries such as France and Germany appear to treating more hepatitis C patients than here such as a higher hepatitis C prevalence in those countries and a greater professional and public awareness of the infection. The Hepatitis C Action Plan for England is being underpinned by centrally funded professional and public awareness campaigns to reduce the number of undiagnosed infections so that those found to be infected referred for specialist assessment and treatment, if needed.

Hepatitis C Action Plan for England

- We fully recognise the importance of hepatitis C as a public health issue and the need to have in place effective prevention, testing and treatment services. We have set out key actions to achieve this in our *Hepatitis C Action Plan for England.*

- Most NHS funding, which is at historic levels, is now passed on to local NHS organisations so that they can make decisions about local needs and services. Implementation of the Action Plan at the local level, therefore, is a matter for Primary Care Trusts and their local partners. Strategic Health Authorities (SHAs) have been asked to ensure that local arrangements are in place to provide appropriate services.

Safety of blood/vCJD

The safety of blood and blood products used in the NHS is of paramount importance. Every reasonable step is taken to minimise the risks during blood transfusion.

To date there have been two possible cases of vCJD transmission through blood transfusion. Even before these cases came to light, the Government introduced a range of precautionary measures to minimise the risk of vCJD transmission through the blood supply.

Background Briefing

Press release announcing details of scheme (23 January 2004)

Health Secretary John Reid today announced a scheme by which, people infected with Hepatitis C from NHS blood or blood products will be eligible to receive ex-gratia payments from the Department of Health.

Every person in the UK who was alive on the 29 August 2003 and whose Hepatitis C infection is found to be attributable to NHS treatment with blood or blood products before September 1991 will be eligible for the payments.

The ex-gratia payment scheme means that:

- people infected with Hepatitis C will receive initial lump sum payments of £20,000.
- those developing more advanced stages of the illness - such as cirrhosis or liver cancer - will get a further £25,000; and
- people who contracted Hepatitis C through someone infected with the disease will also qualify for payment

Mr Reid said:

"I'm pleased to be able to announce the details of this scheme today.

"I felt it was important that English Hepatitis C patients should receive these payments on compassionate grounds. It's clear that providing assistance is the right thing to do.

"I believe that these are fair and reasonable payments and I hope that they will help alleviate some of the problems people who have been affected in this way are experiencing. I'm also glad that people who receive awards from the scheme won't have the worry of losing their social security benefits as a result."

In addition to people currently infected with Hepatitis C the scheme will also include people who have cleared the virus as a result of treatment. Those infected as a result of the virus being transmitted from someone who was infected from blood or blood products will also be eligible to receive payment as will people who were infected with HIV as well as Hepatitis C.

The Department is currently setting up the independent body that will administer the scheme and arranging for the necessary benefit legislation to be amended. It is hoped that the scheme will start operating in April this year. Payments to eligible claimants will follow soon after that.

The Health Secretary said:

"We have ensured throughout our negotiations that the scheme would be easily accessible for eligible patients. It's important that people making a claim are not going to be bogged down with bureaucracy.

"We are pressing forward with the essential work that remains to be done in finalising the scheme, including how the application process will work for awards. We will be working with organisations such as the Haemophilia Society and Hepatitis C Trust on this to help ensure the procedures are as user friendly as possible."

A publicity campaign is being planned with the relevant organisations to ensure that eligible claimants know how to make an application to the scheme.

Notes for editors

1. As announced the ex-gratia scheme would make lump sum payments of £20,000 to all of those who now have Hepatitis C from blood, with a further £25,000 when people reach a more advanced stage of illness.
2. On 29 August 2003 John Reid, Secretary of State for Health announced that, on compassionate grounds, he had decided to establish a financial assistance scheme in England.

3. Since then discussions have been taking place between officials of the four UK administrations to explore the benefits and feasibility of administering the proposed national schemes through a single UK scheme and to make the necessary arrangements to resolve the benefit issue. Today's announcement confirms the satisfactory outcome of those discussions.

4. The scheme will be administered on a UK wide basis by a new independent operation which will be called the Skipton Fund. The scheme will be uniform across the UK. The management of the Fund will be associated with that of the Macfarlane and Eileen trusts.

5. The 'advanced stage' of illness that triggers eligibility for the £25,000 has now been defined as when a patient develops cirrhosis, liver cancer or if they have received a liver transplant. A team of medical experts is currently developing a protocol that will enable the existence of cirrhosis to be assessed using only existing biopsy data or the results of non-invasive tests.

6. Legislation affecting social security benefits will be amended at the first opportunity to ensure that people receiving payments from the scheme are not penalised as a result.

7. General eligibility for payments is defined in terms of having received blood, blood products or tissue from the NHS before September 1991. No payments will be made in respect of those who have died before 29 August 2003 when the original announcement was made or to people who have cleared the virus spontaneously. In the case of eligible people who die between 29 August 2003 and the time when the scheme is in a position to make payments, then the payments will be made to their dependants.

8. People who have been infected with HIV through blood, blood products or tissue

on in the past, and have in addition contracted Hepatitis C in the same way, will be eligible for payments from the scheme in the same way as those who have only been infected with Hepatitis C.

9. It will be assumed that people who have developed Hepatitis C after being treated with Factor VIII or Factor IX blood clotting factor concentrates were infected as a result of that treatment. Virtually all haemophiliacs will fall into this category.

10. Where people have received compensation from other sources in connection with their infection, this will be deducted from any award they are entitled to under the scheme. The scheme will not reimburse legal costs incurred in obtaining that compensation, in unsuccessfully attempting to obtain compensation or in preparing a claim for payment from the scheme itself.

11. A further announcement will be made once the position is reached where claims can be processed through the scheme. This will make clear exactly what claimants need to do in order to make an application. People in England and Northern Ireland who have not already registered an interest with the Department of Health and who would like to have information on making a claim when this becomes available should not contact the Macfarlane Trust but should leave their contact details with the Department by calling 020 7210 4850 or by emailing dhmail@doh.gsi.gov.uk.

12. For media enquiries only, please contact the Department of Health Media Centre on 020 7210 4860/5287

Written Ministerial Statement to HoC (26 January 2004)

Hepatitis C – Ex-gratia payment scheme

The Department announced in August of last year the setting up of an ex-gratia payment scheme for people infected with Hepatitis C from National Health Service blood or blood products. Since that announcement, work has progressed on the detail of the scheme.

The UK scheme will award eligible claimants with initial lump sum payments of £20,000 to all those who now have Hepatitis C from blood or blood products, with a further £25,000 being awarded when people reach a more advanced stage of illness.

We feel that these are fair and reasonable payments and hope that they will help alleviate some of the problems people who have been affected in this way are experiencing.

Work is on going to set up the independent body that will administer the scheme and to introduce the necessary legislation so that people will not lose their social security benefits as a result.

In the course of negotiations we have been able to define a further level of detail on eligibility and scheme administration which will be advantageous to claimants. In particular, bureaucracy will be minimised for people making a claim, in recognition that it will be difficult for some people to gather evidence from twenty years ago.

The scope of the scheme has also been extended to include people who have cleared the virus as a result of treatment and to those infected as a result of the virus being transmitted from someone who was infected from blood or blood products. The scheme will also consider people who were infected with HIV as well as Hepatitis C in the same way as those only infected with the Hepatitis C virus.

Work is progressing on finalising the application process for awards and setting up the independent body that will administer the scheme. Organisations such as the Haemophilia Society and Hepatitis C Trust will be fully involved in that work to help ensure the procedures are as user friendly as possible.

We will work with the relevant organisations to ensure claimants know what to do to make an application.

Hepatitis C ex-gratia payment scheme to launch

Published:
Thursday 3 June 2004

Reference number:
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The Skipton Fund, the body set up to administer the UK-wide ex gratia payment scheme for people infected with Hepatitis C from NHS blood or blood products, will launch and begin processing applications on July 5 2004.

From today, people can register their details with the Skipton Fund to ensure that they are sent application forms and guidance on how the scheme will work.

Public Health Minister Melanie Johnson said:

"I'm pleased to announce that the Skipton Fund will soon be able to start processing claims. This is good news for claimants and I am keen to encourage everyone who is entitled to apply to come forward."

"Further to our consultation with patient groups and experts in this area, I am now confident that the application process will be efficient and user-friendly. In addition, claimants can be sure that their applications will be dealt with fairly."

"This is an important initiative which will go some way towards improving the lives of those inadvertently infected with hepatitis C."

People wishing to take forward an application and who are not already registered on the Department of Health's confidential mailing list, can contact the Skipton Fund for a copy of the Registration Form. Those registered on the mailing list will be sent a Registration Form shortly, and need do nothing in the meantime.

Related links

Skipton Fund (external link)

Notes to editor

1. People who wish to make a claim can register their details with the Skipton Fund by sending in a Registration Form. This can be obtained from the Skipton Fund or downloaded from the Fund's website. All people who have registered with the Skipton Fund will be sent an application form together with comprehensive guidance on how the scheme works and how to use the form.

2. People who have registered an interest in the scheme through the Department of Health's confidential mailing list will be sent details of the Skipton Fund and a Registration Form shortly.

3. Applications will be processed from Monday 5 July.

4. Health Secretary John Reid, and his counterparts in Scotland, Wales and Northern Ireland announced the details of the hepatitis C ex gratia payment scheme on 23 January 2004. The scheme will provide payments to those inadvertently infected with hepatitis C as a result of NHS treatment with blood or blood products.
5. Agreement between the Health Ministers of the four UK government administrations led to the establishment of the Skipton Fund to administer a common UK-wide scheme.

6. The scheme will make lump sum payments of £20,000 to all those who now have Hepatitis C from blood, with a further £25,000 when people reach a more advanced stage of illness.

7. The 'advanced stage' of illness that triggers eligibility for the £25,000 is defined as when a patient develops cirrhosis, liver cancer or if they have received a liver transplant.

8. Legislation affecting social security benefits and residential care charging has been amended to ensure that people receiving payments from the scheme are not penalised as a result.

9. General eligibility is defined in terms of having received blood, blood products or tissue from the NHS before September 1991. No payments will be made in respect of those who have died before 29 August 2003 or to people who have cleared the virus spontaneously in the acute phase of the disease. In the case of eligible people who die between 29 August 2003 and 5 July 2004, the payments will be made to their estate. Where eligible persons who die after 5 July 2004, payments will only be made to their estate if the eligible person had applied to the Skipton Fund whilst they were still alive.

10. People who have been infected with HIV through blood, blood products or tissue on in the past, and have in addition contracted Hepatitis C in the same way, will be eligible for payments from the scheme in the same way as those who have only been infected with Hepatitis C.

11. People who have cleared the virus as a result of treatment or who have cleared it spontaneously after a period of chronic infection will be eligible for payments from the scheme.

12. It will be assumed that people who have developed Hepatitis C after being treated with Factor VIII or Factor IX blood clotting factor concentrates were infected as a result of that treatment. Virtually all haemophiliacs will fall into this category.

13. If people have received compensation from other sources in connection with their infection, Skipton Fund will not make any deduction from any award to take account

of this. [Please note that this position has been revised since the publication of the original details of the scheme on 23 January 2004]

14. Applicants will only need to provide basic personal details to the Skipton Fund but will need to ask their doctor to complete the main section of the application form which details information to support their eligibility.

15. If the Skipton Fund decides that an applicant is not eligible for payment they will write explaining the reason for this decision. The applicant can then apply to an independent appeals panel, which will most likely be chaired by a QC.

16. Applicants will not need legal advice when completing the application form and they will not be asked to sign any waiver. The scheme will not reimburse legal costs incurred in making a claim or in appealing against a decision by the Skipton Fund.

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Recent History and Current Situation

The hepatitis C financial assistance scheme was announced on 29 August 2003 by the then Secretary of State, John Reid. Ministers from the devolved administrations in Scotland, Wales and Northern Ireland made simultaneous announcements.

Officials from all four Departments of Health, in consultation with patient organisations and clinical experts, worked together to develop a UK wide scheme which will benefit all people inadvertently infected with hepatitis C. The scheme will be funded proportionately by the four Administrations.

The details of the scheme were announced on 23 January 2004. The eligibility criteria for the scheme and the payment structure are outlined in the attached press statement.

Macfarlane Trust officials have agreed to administer the fund, but only by association ie. the Skipton Fund will be completely independent of the Macfarlane Trust.

The Haemophilia Society (of which Lord Morris is President) has been involved in discussions about the scheme with officials and Minister. The Society is unhappy that the payments have not matched the recommendations made in their report, and that dependants will be excluded. The Society has renewed its media and parliamentary campaign to highlight these concerns and officials suspect that they may have inspired this PQ.

Basis of Skipton Fund payment structure

The levels of payments proposed by DH are based on proposals made by the Scottish Executive ie. an initial payment of £20,000 and a further payment of £25,000 if a persons liver disease advances to a medically defined trigger point, probably cirrhosis.

This structure was adopted after comparison with the level of payments made by the Macfarlane and Eileen Trusts and the recommendations made by the Lord Ross expert group in Scotland. The Trusts were established to provide financial assistance to people inadvertently infected with HIV as a result of NHS treatment with blood or blood products.

The proposed payments for the hepatitis C scheme are broadly in line with the initial one-off payments made by the Macfarlane and Eileen Trusts and recommended by the Ross group. However, the lump sum payments do not take into account continued financial support (monthly and incidental payments) which is provided by the Macfarlane and Eileen Trusts and recommended by the Ross group.

The Haemophilia Society's Working Group recommended far higher payment levels, as would be expected from an independent patient organisation. However, their recommendation to stagger payments according to the claimants' need has been taken on board and is reflected in the addition of a second payment on reaching a medically defined trigger point.

The Haemophilia Society's recommendations are based on the Canadian model for compensating victims of the Canadian 'tainted blood scandal'. The Canadian government has accepted liability on the basis that it could have introduced a test for donor blood in 1986 but did not fully implement the test until 1990. DH assumes no such liability and it is therefore unfair to compare the two schemes.

A summary of the level of financial assistance provided by each of the other schemes listed above is overleaf.

Macfarlane Trust payments

Established to financially assist haemophiliacs inadvertently infected with HIV as a result of NHS treatment with infected blood products.

- Single adult - £43,500
- Married adult without dependant children - £52,000
- Adult with dependant children - £80,500
- Children under 18 - £41,000

Payments are also made to infected intimates (ie. those who have been infected with HIV by a close relation eg. mother, husband, partner)

Monthly payments of between £255 to £650 depending on whether partners are also affected and the number of dependant children. In addition, single grants are paid which are generally health related.

Eileen Trust payments

Established to financially assist non-haemophiliacs inadvertently infected with HIV as a result of NHS treatment with infected blood or tissues.

Infant - £41,500
Single adult - £43,500
Married adult without dependant children -£52,000
Infected person with dependent children - £80,500

Infected intimates of the above -

Adult spouse/partner - £23,500
Child who is married - £23,500
Other child - £21,500

Haemophilia and Hepatitis C

Haemophilia

People with haemophilia are mostly male, with women being carriers. Some female carriers also present mild symptoms of the disease and require treatment especially for surgery and at childbirth. Some rarer forms of haemophilia affect both sexes equally.

The number of people with haemophilia is likely to be increasing slightly. With the development of blood products to treat the disorder in the 1960s/70s, people with haemophilia increasingly had families. While genetic counselling and termination is a possibility, this is often difficult in a family with a history of haemophilia especially where there are good treatments and the family want male children.

In about one third of cases there is no family history of haemophilia, and the condition has arisen as a result of spontaneous genetic mutation.

Approximately 7,000 people have haemophilia and related bleeding disorders in the UK. 500 are infected with HIV (800 have already died). Most of those with HIV are co-infected with hepatitis C. (5% to 6% of all haemophiliacs are co-infected). About 3000 haemophiliacs have hepatitis C. Approximately 2000 – 3000 of haemophiliacs have neither HIV nor hepatitis C.

Hepatitis C infection

Hepatitis C is a blood-borne virus can infect and damage the liver. Hepatitis C is spread primarily by direct contact with the blood of an infected person. Currently the main route of transmission in the UK is by the sharing of contaminated equipment by injecting drug misusers.

Other less important routes of transmission are when health care workers are exposed to the blood of an infected patient; from infected mother to baby at birth; by sexual intercourse with an infected person; and by skin piercing and tattooing when sterile equipment is not used. Theoretically, household spread is also possible via the sharing of blood-contaminated toothbrushes and razors.

Safety measures are in place to prevent infection via the receipt of blood and blood products. Every blood donation has been tested for hepatitis C since 1 September 1991. Since the mid 1980s the plasma used to manufacture blood products (such as clotting factors for haemophiliacs) has been treated to remove viruses such as Hepatitis B & C and HIV.

Many patients who acquire hepatitis C will live out their normal lifespan. Hepatitis C infection is cleared in about 20-40% of those infected, but persists in about 60-80% to become chronic infection. Some of those with chronic infection will have only mild liver damage, many with no obvious symptoms. About 20% of patients with chronic infection develop cirrhosis after 20-30 years. Of these, about 1-4% per year will develop liver cancer.

Current information suggests that the prevalence (current level) of chronic hepatitis C infection may be around 0.4 % of the general population (i.e. about 240,000 people in the United Kingdom and about 200,000 in England). The incidence (new infection) of hepatitis C is not known, as the virus is usually acquired without symptoms. There is likely to be an increase in the diagnosis of hepatitis C in the next 10 years as individuals who have carried the virus for some time are identified through wider testing of groups who have been at risk.

Hepatitis C treatment

NICE published recommendations in January 2004 on the use of combination therapy (pegylated interferon and ribavirin) for the treatment of moderate to severe chronic hepatitis C in adults. The aims of treatment are to prevent progression to serious liver disease (cirrhosis and primary liver cancer). There is evidence that the treatment can clear the virus in between 45% to 85% of patients, depending on the virus genotype.

The most accurate way of assessing liver damage in patients with chronic hepatitis C is by microscopic examination of a small sample of tissue taken from the liver (percutaneous liver biopsy). This permits determination of both the degree of inflammation and the amount of scarring (fibrosis). The microscopic appearance of the liver is currently used to determine which patients should be offered treatment.

Around 40-45% of patients who have undergone liver biopsy show evidence of moderate to severe inflammation of the liver, and are thus eligible for treatment under the current guidelines (provided there are no contraindications). At present, patients with minimal disease are not offered immediate antiviral treatment. Such patients should be kept under periodic review to assess whether their disease is progressing.

Chronic hepatitis C does not always result in severe liver damage. The treatment, which may have to be given for up to a year (and involves self injection) can have unpleasant and difficult side effects, and people taking it can fee unwell. Unfortunately, even with newer treatments, not everyone will have a favourable response. At present, therefore, treatment is limited to those people who clearly need it to prevent progression to serious liver disease.

The Government has placed statutory obligations on Primary Care Trusts to fund treatments recommended by NICE. Since January 2002, the NHS has had 3 months from the date of publication of each Technology Appraisal Guidance to provide funding so that clinical decisions made by doctors involving NICE recommended treatments or drugs can be funded. John Reid set out plans on 14 June 2004 to ensure that patients across the country have equal access to NICE-recommended treatments. MS(D) set out the detail of this in a letter to the NHS

Hepatitis C Action Plan for England

CMO highlighted the public health importance of hepatitis C in his infectious diseases strategy, *Getting Ahead of the Curve*, published in 2002. Later that year, DH consulted on proposals to strengthen services for prevention, diagnosis and treatment and improve epidemiological surveillance and research (*Hepatitis C Strategy for England*).

Hepatitis C Action Plan for England, published on 29 June 2004, sets out a framework to implement those proposals. The action plan summarises current knowledge about hepatitis C (e.g. epidemiology and natural history) and Government measures to date. It then sets out ongoing and new actions in four key areas:

- Surveillance and research
- Increasing awareness and detection of undiagnosed infections
- High-quality health and social care services
- Prevention

A number of funding streams will support the Action Plan. A major component has been included in PCT allocations to support the National Institute of Clinical Excellence (NICE) recommended combination drug treatments for moderate/severe liver disease caused by hepatitis C.

Other activities that are being supported include raising professional and public awareness, improving surveillance, offering hepatitis C testing to injecting drug users and the work done by the voluntary sector.

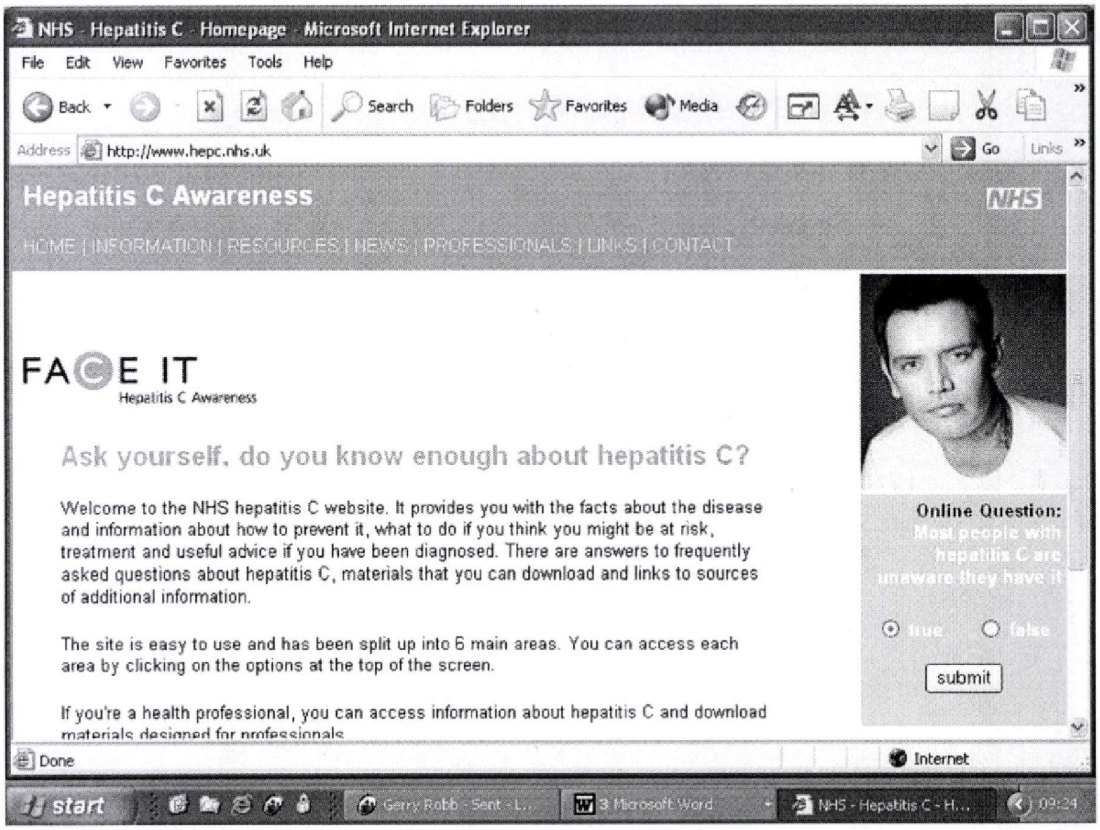
Funding for NICE recommendations is included in PCTs' allocations and there is also a statutory obligation on the NHS to implement NICE recommendations so that clinical decisions made by doctors involving NICE recommended treatments or drugs can be funded. The Secretary of State for Health set out plans on 14 June 2004 to ensure that patients across the country have equal access to NICE-recommended treatments.

In line with *Shifting the Balance of Power*, most NHS funding is now passed on to local NHS organisations so that they can make decisions about local needs and services. There has been substantial increased investment in the NHS. For example, expenditure on the NHS in England, for the period 2003/04 to 2007/08, is planned to increase on average by 7.3 per cent a year over and above inflation. Over three years, this will take the total spend on the NHS in England from £69bn in 2004-05 to £92bn in 2007-08. This is a significant increase over historic levels of growth.

Hepatitis C awareness campaign

Health care professionals

- The professional awareness campaign was launched formally on the same day as the action plan (29 June 2004).
- The launch consisted of the distribution of a professional education pack, including a briefing paper with guidance on hepatitis C testing, a patient leaflet and a poster. The pack was sent mainly to primary care professionals.
- A new NHS hepatitis C awareness website was also launched – www.hepc.nhs.uk - although to date this has only been promoted to professionals. The professional briefing paper, patient leaflet and poster are available on the website.



Ask yourself, do you know enough about hepatitis C?

Welcome to the NHS hepatitis C website. It provides you with the facts about the disease and information about how to prevent it, what to do if you think you might be at risk, treatment and useful advice if you have been diagnosed. There are answers to frequently asked questions about hepatitis C, materials that you can download and links to sources of additional information.

The site is easy to use and has been split up into 6 main areas. You can access each area by clicking on the options at the top of the screen.

If you're a health professional, you can access information about hepatitis C and download materials designed for professionals

Online Question: Most people with hepatitis C are unaware they have it

● true ○ false

submit

- Munro & Forster Communications (M&F), our public relations agency, have promoted news coverage and features in health care professional journals. There has also been two pieces in *CMO's*

Update, which goes to all doctors.

- We have embarked on programme of visiting key health care professional conferences with a hepatitis C awareness stand.

- The professional awareness campaign builds on previous work with primary care professionals i.e. 8 regional hepatitis C awareness-raising seminars for primary care professionals in 2002 and 2003, including GP speakers and attenders, and a hepatitis C professional briefing pack for primary care professionals sent to all GPs and practice nurses in March 2002.

The public

- The public awareness campaign was launched by CMO on 8 December 2004.

- There has been deliberate gap between the start of the professional and public awareness campaigns to allow health care professionals to get up to speed. The public awareness campaigns will be consist of a range of initiatives over the next two years in the first instance, including the following elements, some of which are still provisional:

FACE IT
Hepatitis 'C' Awareness

- A new Hepatitis C Information Line (0800 451451), similar to those already provided for sexual health, drugs and alcohol;

- Promotion of the new NHS hepatitis C awareness website – www.hepc.nhs.uk;

- Promotion and widespread availability of the existing patient leaflet;

- Leaflets targeting people who may have been at risk of hepatitis C in the past;

- The use of a hepatitis C infected celebrity for media interviews (David Marks, one of the original Beach Boys who raises hepatitis C awareness in the US. There are no currently known UK celebrities with hepatitis C);

- A public exhibition of photographic portraits of people with hepatitis C, including interviews with the photographer (who also has hepatitis C), David Marks (see above) and the photographer's subjects about their stories, perhaps with a visit by PS(PH) or CMO;
- Promoting features in national press, men's and women's magazines and ethnic minority media;
- Engaging media doctors, agony aunts and TV/radio soaps to provide information about hepatitis C;
- Music nostalgia polls on the NHS hepatitis C website promoted on radio and at festivals;
- Commissioning production of a short TV documentary about people living with hepatitis C for terrestrial/digital broadcaster;
- Section 64 funding of the hepatitis C voluntary and community sector for activities connected with awareness-raising.

- The professional and public awareness campaign is being funded from a dedicated central budget. Expenditure in 2004/5 was about £0.7 million and in 2005/6 will be about £1.5 million.

Haemophilia Care and treatment

Care for haemophilia sufferers is provided through a national network of Haemophilia Centres, which provide basic management and treatment, run by a Haemophilia Centre Director. These provide:

- 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, 18 Comprehensive Care Centres (CCC) in England 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
- co-ordination of meetings and undertaking research programmes, including clinical trials.

Haemophilia Society

The Society currently receives core funding through the DH Section 64 Grant Scheme. The Society receives £100k per annum. This is a substantial sum.

Recombinant Clotting Factors

(Please note this issue is not directly linked to the hepatitis C scheme but is topical and Lord Morris/the Haemophilia Society have previously taken a strong interest)

On 12 February the Government announced investment of an extra £88m to provide haemophilia patients with synthetic clotting factors. The £88 million will be allocated as follows: 2003/04 - £13 million; 2004/05 - £21.7 million; 2005/06 - £53.4 million.

In 1998 the Government provided funding to place all haemophilia patients under 16 on synthetic clotting factors. These patients have continued to receive synthetic products as they have grown older. The extra funding announced will extend the availability of synthetic clotting products to adult haemophilia patients.

Since the announcement we have been working with key stakeholders including the Haemophilia Society to design a programme for rolling out access to these products to older age groups. The roll out will be phased in by age and will take time to achieve because of the large volumes of product involved. In this financial year the vast majority of patients should be receiving the new treatments.

The £88 million should provide recombinant clotting factors to the roughly 1500 severe haemophilia patients over the age of 21/22. It is estimated these patients will require in the region of 200 million units of clotting factor a year.

Previous PQ on hepatitis C scheme (5 February 2004)

Hepatitis C

Lord Morris is President of the Haemophilia Society. There were a number of oral questions tabled when the scheme was set up. However, over the past months there have instead been written questions tabled on the subject. The last few questions and answers are below.

PQ00040 The Lord Morris of Manchester - To ask Her Majesty's Government what is their latest information on the number of patients with haemophilia whose National Health Service treatment could have involved the use of blood from donors now known to have had variant Creutzfeldt-Jakob Disease

Suggested reply (not yet been cleared)

The United Kingdom Haemophilia Centre Doctors' Organisation is currently collecting information on the number of haemophilia patients considered to be at risk. When this exercise has been completed we will be in a position to provide an estimate on the number of haemophilia patients who have been exposed to plasma products possibly implicated with vCJD.

PQ00039 The Lord Morris of Manchester - To ask Her Majesty's Government when they expect recombinant treatment to be available for haemophilia patients throughout England; and to how many such patients it is currently unavailable.

Suggested reply

This is the third and final year of the recombinant roll-out programme. All haemop
eligible for treatment with recombinant products in this financial year. Data on the
United Kingdom Haemophilia Centre Doctors' Organisation. However, figures are
quarter of this financial year.

PQ03229 The Lord Morris of Manchester - To ask Her Majesty's Government whi
decreed the powers of the Skipton Fund to exclude from financial support from th
haemophilia patients who have died from HIV infection by contaminated National
products; and when.

PQ03228 The Lord Morris of Manchester - To ask Her Majesty's Government wh
decreed the powers of the Macfarlane Trust to include the provision of financial su
haemophilia patients who have died from HIV infection by contaminated National
products; and when.

Suggested reply

The two distinct schemes administered by the Skipton Fund (established last year) and the Macfarlane Trust (established in 1988) have been established for different purposes.

PQ02842 To ask Her Majesty's Government whether it is in keeping with natural justice to provide financial support for widowers of haemophilia patients who died contaminated National Health Service blood products, but not for those widowed in consequence of hepatitis C infection from the same source and by the same route.

Suggested reply

I refer the noble Lord to the reply I gave on 23 February 2005, (*Official Report*, Col. WA214.

PQ01928 - To ask Her Majesty's Government, further to the Written Answer by the Lord Warner on 31st January (WA 10), what is the justification for denying financial help from the Government-funded Skipton Fund to widows of haemophilia patients whose deaths were attributable to hepatitis C infection from contaminated National Health Service blood products, when financial help is available from the Government-funded Macfarlane Fund to widows of patients whose deaths were attributable to HIV infection from the same source.

Suggested Reply

The Government has great sympathy for the pain and hardship suffered by the widows of those inadvertently infected with hepatitis C. However, it has always been clear that the ex-gratia payment scheme is for those living with the virus and is not designed to compensate for bereavement.

The schemes administered by the Skipton Fund and the Macfarlane Trust have been established for different purposes and are two distinct schemes.