PARLIAMENTARY QUESTION

DEPARTMENT OF HEALTH

PQ08281	2002/2003
Lords Starred	

The Lord Morris of Manchester - To ask Her Majesty's Government what further consideration they have given to introducing a financial assistance scheme for haemophiliacs and other National Health Service patients infected with hepatitis C by contaminated National Health Service blood products; and what action they are taking in this regard.

For Answer on:	16/09/2003
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MP (Party):	LORD MORRIS OF MANCHESTER (LAB)

DRAFT REPLY TO REACH PARLIAMENTARY BRANCH BY

12:00 Monday 8 September 2003

PARLIAMENTARY RELATIONS UNIT

FINAL MINUTE

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3. The following special points should be noted:

Malcolm Chisholm, the Minister for Health in Scotland, is appearing before the Scottish Parliament's Health Select Committee tomorrow (Tuesday 9 September). The outcome of this appearance may affect the attached briefing (but not the answer). Should it prove necessary, we will update Baroness Andrews at the briefing meeting on Wednesday morning.

Lords Starred Oral– PQ08281 – Lord Morris of Manchester

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PQ08281 2002/2003

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MORRIS OF MANCHESTER (LAB):

The Lord Morris of Manchester - To ask Her Majesty's Government what further consideration they have given to introducing a financial assistance scheme for haemophiliacs and other National Health Service patients infected with hepatitis C by contaminated National Health Service blood products; and what action they are taking in this regard.

SUGGESTED REPLY

I am pleased to be able to report that my Right Honourable friend the Secretary of State for Health made an announcement on 29 August that the Government has decided to establish a financial assistance scheme in England for people infected with Hepatitis C as a result of being given blood or blood products by the NHS.

PQ08281

Key Supplementary Questions

Voluntary Organisations

Will my Noble Friend acknowledge the efforts that the Haemophilia Society has made over the years in campaigning for such a scheme to be introduced?

I can acknowledge that the Society has consistently lobbied for such a scheme and has had a number of meetings with successive Ministers and Government officials to pursue its case.

How will the Government involve the Haemophilia Society [or X voluntary organisation] in working out the details of the scheme?

We shall certainly seek the views of patient organisations as discussions on a proposed scheme progress.

Scheme Parameters

How long will it be before further details of the Scheme are made available and payments can commence?

I am unable to provide a substantive response on that at this stage. As my Right Honourable Friend stated in his announcement ~~last Friday~~ on 29 August the exact details of the payments have yet to be worked out, as have the details of the scheme itself. What I can say is that discussions on these issues are progressing.

Can you provide further details of [X aspect of the scheme]? [Eligibility, size of awards, payments to widows/dependants, dates, application process]

I am unable to provide specific details at this time, as these are yet to be worked out. What I can say is that this and many other issues will be given due consideration as the scheme is developed.

Who will benefit from the Scheme?

The financial assistance scheme has been established for people infected with Hepatitis C as a result of being given blood or blood products by the NHS. The exact eligibility criteria are still being worked out.

Will the scheme only benefit haemophiliacs or will it cover all people infected with Hepatitis C as a result of treatment with NHS blood/blood products?

All people infected with Hepatitis C as a result of treatment with NHS blood or blood products will benefit from the scheme.

People co-infected with HIV

Will people infected with Hepatitis C qualify for the new scheme if they are already receiving financial assistance from similar HIV schemes?

This is one of the many details that are still to be worked out.

Is the government aware that in order to receive financial assistance from HIV schemes, people were required to sign a waiver undertaking not to make further claims against the government and won't this prevent people co-infected with HIV and Hepatitis C from claiming against the new scheme?

We are aware of the waiver and will ensure that this issue is considered during deliberations.

Government decision to make payments

With so many issues yet to be resolved why has the announcement been made now?

Following an announcement by the Scottish Executive in January, discussions have been taking place between DH and the SE officials to ensure that patients infected with Hepatitis C by blood or blood products benefit from an ex gratia payment scheme. These discussions have progressed well and whilst the detail has still to be worked it was felt important to make the existence of this work known now.

Is this compensation?

This is not compensation. That implies we are compensating people for a wrong done to them. That is not the case. In carrying out NHS treatment, we have a duty to take every reasonable care to make it safe, using the processes available at the time. That is what we did. Nevertheless, some people have inadvertently become infected with Hep C and some of them have become ill. We believe it is right to give them financial assistance to help them.

This is a U-turn isn't it?

We have not changed our position on compensation. The new Secretary of State believes payments to patients infected with Hepatitis C by blood/blood products were justified, on compassionate grounds. That is his judgement. (Clearly different Secretaries of State may have different views on particular issues.)

What about other people seeking compensation from the NHS in similar cases?

The Hepatitis C scheme does not set a precedent. We look at each case on its merits. We have already made payments to people infected with HIV through blood. There is also a vCJD scheme which did not set a precedent.

Scotland/Republic of Ireland issues

To what extent will DH be basing its scheme on the Scottish Executive's model, announced in January?

Officials from the Department and the Scottish Executive have already met to discuss their proposals. This dialogue is set to continue and officials will be working in close co-operation to work out the details of the scheme.

The awards proposed by the Scottish Executive are significantly smaller than those already made to people infected with Hepatitis C in Ireland.

We are still working out the payment details of the scheme. The Executive's proposals will be considered during our discussions.

The situation in Ireland is totally different to that in the UK. There, the Government compensated people after it was found that the contamination of the Irish blood supply should have been avoided, and was due to wrongful practices on the part of the Irish Blood Transfusion Service Board. The sizes of the Irish awards have to be viewed in this context and it is therefore impossible and unfair to compare the two schemes.

The NHS introduced measures to reduce the risk of transmitting Hep C in blood or blood products as soon as the technology existed to do so.

<u>Recent history of issue (to remain confidential)</u>

On 29 January 2003 the Health Minister for Scotland, Malcolm Chisholm, announced that he was prepared to establish an ex gratia payment scheme for people in Scotland who had been infected with Hepatitis C as a result of treatment with NHS blood/blood products.

The Department of Work and Pensions initially considered this a social security issue (that is, that the payments would effectively be benefits) and therefore not within devolved competence. After discussions, the Scottish Office and DWP asked the Law Officers to advise.

In June, the Law Officers advised that a scheme would be accepted as within devolved competence (Scotland were not informed at this stage). The issue was then passed to DH to take the lead. After meeting with Ministers from Treasury, DWP and the Scottish Office, SofS decided that a similar scheme in England, Wales and NI would be prescient.

In July, SofS wrote to Malcolm Chisholm informing him that a scheme would be accepted as within devolved competence. Instead of going it alone, he asked that officials from DH and the Scottish Executive discuss the Executive's plans, and draw up initial proposals for "a similar type of scheme elsewhere in the UK".

In late August, as a result of mounting pressure on Malcolm Chisholm for movement on this issue, SofS decided to make public the plans to introduce a scheme in England. On 29 August a press release was issued by DH announcing Mr Reid's intention to establish a financial assistance scheme in England (see next page).

The devolved assemblies in Wales and Northern Ireland issued simultaneous press releases. The Scottish Executive confirmed that the devolution issue had been resolved and that a scheme would now be worked up.

Current situation

Following the announcements, officials from the four Health Departments (E/W/S/NI) will be meeting on 11 Sept to continue discussions on what form the scheme may take, size of awards, eligibility criteria etc. Following this, proposals will be fully developed and then submitted to the relevant Ministers for approval. The scheme is expected to be launched in the Spring.

The Haemophilia Society were pleased by the announcement and have already written to SofS to thank him for agreeing to set up a scheme. They are keen to be involved in the scheme's development and would like their proposed package of financial payments (submitted to DH in June 02) to be considered.

The views of voluntary organisations will be considered, although they are unlikely to be consulted on key issues, such as the size of awards etc. DH feels that they can usefully contribute on a number of areas, including the administrative mechanisms of the scheme (application process, appointment of Trustees etc) and the customer focus aspects of the scheme (ensuring claims are dealt with efficiently and payments made promptly etc).

2003 Friday 29th August 2003

HEPATITIS C PAYMENT SCHEME ANNOUNCED

Health Secretary John Reid has decided to establish a financial assistance scheme for people infected with Hepatitis C as a result of being given blood products by the NHS.

Mr Reid said: 'After becoming Secretary of State, I looked at the history of this issue and decided on compassionate grounds that this is the right thing to do in this situation.'

'I have therefore decided in principle that English Hepatitis C sufferers should receive ex-gratia payments from the Department of Health.'

The details of the payments have yet to be worked out.

Notes to Editors:

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Key Facts

- Hepatitis C virus identified in 1989.

- People are still living who were infected with hepatitis C through blood and blood products:
    - approximately 3,000 with haemophilia
    - an estimated 5,000 in 1995, were infected through blood transfusion, some of whom will have since died.

- Around two-thirds are likely to develop some kind of long-term symptoms and around a fifth will develop cirrhosis of the liver over 20 years. A small proportion of people with cirrhosis will develop liver cancer.

- An estimated 240,000 people in the United Kingdom (200,000 in England) or 0.4% of the population have chronic hepatitis C infection. The majority of the people infected are unaware of their hepatitis C status.

- Approximately 7,000 people have haemophilia.

- 500 are infected with HIV (800 have already died). Most of those with HIV are co-infected with hepatitis C.

- Around 3000 haemophiliacs who were treated before 1985 have hepatitis C. In 1985 it became possible to remove viruses from blood clotting products using heat treatment (fresh blood cannot be heat treated).

<u>Bullet Points</u>

- The Secretary of State has 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 will introduce a scheme to make ex gratia payments to English Hepatitis C sufferers. The devolved administrations in Scotland, Wales and Northern Ireland will also provide ex-gratia payments.

- The Department supports the core function of the Haemophilia Society with a 3 year Section 64 Grant of £100,000 for 3 years from 2001/02 to 2003/04. Further funding for projects have previously been awarded to the Society including a 3 year grant of £20,000 for setting up a counselling service for haemophiliacs (now in the final year of funding).

- NICE has published guidance on the use of combination therapy (interferon alpha with ribavirin) for the treatment of hepatitis C. We have provided additional funding and placed statutory obligations on the NHS to implement NICE recommendations so that clinical decisions made by doctors involving NICE recommended treatments or drugs can be funded. Pegylated interferon for the treatment of hepatitis C, which appears to be more effective that conventional interferon, is in NICE's seventh work programme (publishing anticipated November 2003).

- 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 published proposals designed to achieve this in our consultation paper, *Hepatitis C Strategy for* England in August (2002). We will be producing a hepatitis C action plan in the next few months setting out how the strategy will be implemented, taking into account the consultation responses and meetings with stakeholders.

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

Chronology

Date	Event
1974	Seminal paper on hepatitis in haemophiliacs published showing about 80% of hepatitis due to hepatitis virus(es) other than hepatitis A & B [non-A non-B hepatitis identified as hep C in 1988]
1985	Heat Treatment introduced to inactivate HCV in blood products (1987 in Scotland). Before this date some 4,000 haemophiliacs were infected with HCV in England through contaminated blood products, 2,800 of whom are estimated to be still living.
Mid/late 1980s	Seriousness of non A, non B hepatitis becomes better understood in the medical and scientific community.
1988	The Macfarlane Trust is set up by Government to make regular payments to haemophiliacs (and their dependants) with HIV/AIDS through infected blood products.
10 May 1988	Press announcement of identification of hepatitis C by Chiron Corporation of America and development of a prototype screening test. Results published in April 1989.
May 1990	US introduces hepatitis C screening of blood donors.
1990/91	Ex-gratia payments awarded to 1,280 haemophiliacs infected with HIV through infected blood.
September 1991	A screening test to identify blood donors with HCV was introduced across the UK. Before this, at least 10,000 people in England may have contracted the virus from infected blood transfusions. Of these, around 5,000 are estimated to be still living but only 669 have been positively identified through a look back study.
1993	The Eileen Trust is set up by Government to make payments to those non-haemophiliacs who were infected with HIV through contaminated blood.
28 July 1998	Frank Dobson announces that compensation will not be paid to haemophiliacs infected with hep C through contaminated blood, this is line with the principle of no-fault compensation.
26 March 2001	Damages awarded in the High Court in England on a strict product liability basis under the Consumer Protection Act 1987 (CPA) to 114 people infected with HCV through blood transfusion (ie those identified through the look back). Damages went to those infected between 1 March 1988 (the date the CPA came into force) and September 1991 (the introduction of HCV screening of blood donors). [NB: Claimants can only take action under the CPA within 10 years of the injury. Those who did not join the group action are therefore timed out.]
July 2001	Susan Deacon announces a decision to award an out of court settlement to those who had already raised an action under the CPA in Scotland.

2 October 2001	The Scottish Parliament Health Committee calls for financial support for people infected with HCV through blood. The Committee stressed that they were not advocating that all injury caused though NHS treatment should be compensated. However they argued that, as a matter of fairness, HCV infected blood recipients should receive the same kind of assistance as those infected with HIV (ie through the Macfarlane Trust). The Committee did, however, reject the Haemophilia Society's call for a public inquiry having found no evidence of negligence on the part of the Scottish National Blood Transfusion Service.
December 2001	The Health Committees report is debated in the Scottish Parliament. Scottish Ministers refuse to give a commitment to implement the Health Committee's recommendation and come under considerable political pressure. Malcolm Chisholm concedes that "the door is not closed" on this issue.
Date	**Event - Scotland**
10 January 2002	Malcolm Chisholm announces "a four point plan to support HCV sufferers", including the establishment of an expert group to consider changes to the current system of dealing with patients who have suffered harm, with a focus on blood recipients infected with HCV.
March 2002	Scottish Expert Group on Financial and Other Support established under the Chairmanship of Lord Ross. The remit included: • to consider whether a system of financial and other support might be available to people who have been harmed by NHS treatment in Scotland in circumstances where there is unlikely to be liability on the part of NHS Scotland and to apply general principles which are consistent equitable and transparent; • the situation of patients who have contracted HIV and/or hepatitis C from blood transfusion or treatment with blood products should form part of the wider considerations; • preliminary recommendations should be made by the end of July 2002.
12 June 2002	Haemophilia Society present PS(PH) with a proposed financial payments package for haemophiliacs infected with HCV in England costing £500m over 10 years. PS(PH) agreed to examine the proposal. A formal response has not yet been given to the Haemophilia Society.
4 November 2002	Malcolm Chisholm phones SofS to inform him that: • the Expert Group were about to publish a preliminary report calling for financial and other practical support for all people infected with HCV through blood, blood products and tissues. • Scottish Ministers felt they had to offer something, probably payments to people once they become seriously ill and that

	an announcement would be made on 6 November. SofS said that he thought this would be a grave mistake and that once the principle that we'd established had been breached, then we were on a slippery slope to payments running into the millions across the UK. He said he thought Malcolm Chisholm needed to tough it out. Malcolm Chisholm said that the advice he had was that this was a devolved matter for the Scots, however he wasn't sure this was right. SofS subsequently asked officials to find some way of showing that the Scots don't have the devolved power to go it alone on this, and thereby prevent them going ahead with any kind of announcement on 6 November.
Date	**Event**
5 November 2002	Malcolm Chisholm wrote to Andrew Smith to say that Scottish Ministers were looking at the possibility of ex gratia financial payments for hepatitis C “victims” to “relieve suffering and hardship”. He added “we would expect the average monthly payment to individuals under the scheme to be of the order of £500 per month”. Andrew Smith’s views were sought on the competence issue. He was also asked for support in developing a scheme where the payments are discounted in assessing means tested benefits. Initial legal advice from DH and DWP lawyers is that a payments scheme from public funds would appear to fall within the definition of a social security scheme and would therefore be a reserved matter under Schedule 5 of the Scotland Act 1998. A response from Andrew Smith to Malcolm Chisholm communicating this was sent on 6 November. SofS made further attempts to persuade Scottish Ministers not to make any undertakings on a payment scheme but was unsuccessful.
6 November 2002	Scottish Expert Group publishes its preliminary report. It’s recommendation for a payments scheme is based on the following principles: • HCV patients were morally entitled to the same compensation as HIV patients; • HCV patients were morally entitled to similar support to that given in the support package provided for people who contracted vCJD from food; • the unfairness of some people being able to benefit from the CPA judgement but not others.

	Malcolm Chisholm made clear at a meeting of the Health Committee that he would not accept the recommendations of the Expert Group. He indicated that the Scottish Executive wished to find a way of helping people with HCV who had suffered long-term harm (eg those with cirrhosis or liver cancer) but made no commitment to what form of support might be offered.
20 November 2002	SofS meets Helen Liddell to discuss hepatitis C payments
29 January 2003	Malcolm Chisholm made a statement to the Scottish Parliament Health Committee on the financial assistance scheme he would like to introduce if the devolution and social security issues are resolved. The proposals would include: Paying a lump sum of £20k to all people living who still have the virus A further £25k to those who have developed cirrhosis There was no indication given that there would be payment for people who have had the virus and then cleared it after treatment; or for the relatives of people who have died as a result of Hep C infection.
June 2003	The Office of the Solicitor to the Advocate General for Scotland has sought the opinion of the Law Officers (on 30 January) on the following: • whether a compensation scheme is within the devolved competence of Scottish Ministers; • whether if the Scottish Executive introduced a scheme which the Law Officers thought was outside competence, they would consider it appropriate to either raise proceedings in the Court of Session or to refer the issue to the Judicial Committee of the Privy Council. The Law Officers are likely to take a month or so to reach a view.

Continued under 'Recent History of Issues/Current Situation' Page 11

Other Supplementary Questions

Self Sufficiency

Will you review your decision not to hold a public inquiry in the light of the Noble Lord Owen's public statements that when he was Minister of Health in 1975 he made a commitment to make the UK self-sufficient in clotting factors within 18 months?

We have examined the Department of Health's files for that period. These indicate that the resources promised by the Noble Lord when he was Minister of Health were allocated to the then Regional Transfusion Centres to increase production of plasma for the Bio Products Laboratory.

The money was linked to a target of 275,000 blood donations to be used annually for the preparation of Anti-Haemophilic Globulin concentrate and 100,000 donations for cyroprecipitate. This target was achieved within the 2 year timescale envisaged by the Noble Lord and, as a direct result, the Bio Products Laboratory increased its production of concentrate from 5 million international units in 1976 to 11 million international units in 1977. However, given the rapid growth in demand for these products at the time, this was not enough to achieve self sufficiency.

Although self sufficiency continued to be the aim of Ministers for a number of years, and NHS production of concentrate continued to increase, the rising demand for clotting factors meant that commercial products continued to be imported.

None of this evidence, which officials have now made available to the Haemophilia Society, suggests that Parliament was misled or that a public inquiry is warranted.

Was the failure to achieve self sufficiency in the 1970s considered by Frank Dobson in his 1997 review which looked at the case for compensation for haemophiliacs with hepatitis C and a public inquiry?

No. The evidence is that considerable efforts were made to achieve NHS self sufficiency in clotting factors in the 1970s. The fact that self sufficiency was not achieved appears to have been linked to the massive increase in demand for clotting factors at the time not to any failure to implement Ministerial initiatives. The case remains that there is no evidence of liability for the tragic infection of haemophiliacs with hepatitis C and I cannot see that a public inquiry is warranted.

Background:

Self-sufficiency continued to be the aim of Ministers for a number of years and NHS production of concentrate continued to increase. But the rapidly rising demand for clotting factors at that time necessitated the importation of commercial products as well to meet demand. Thus, failure to achieve self sufficiency was linked to the massive increase in demand for clotting factors at the time not to any failure to implement Ministerial initiatives.

Government strategy on hepatitis C, including funding issues

Why has the Government published a strategy on hepatitis C?

We published a hepatitis C strategy for England on 14 August 2002 in recognition of its importance as a public health issue and the need to strengthen services for its prevention, diagnosis and treatment. This was highlighted by the Chief Medical Officer in the infectious diseases strategy, *Getting Ahead of the Curve*. (The strategy document is available on the Department of Health website at http://www.doh.gov.uk/cmo/hcvstrategy)

How was the strategy developed?

The strategy was developed with the assistance of any expert steering group of health professionals, academics and representatives from the voluntary and community sectors, including a patient representative. The steering group also involved other key stakeholders in its work.

What are the main messages of the strategy?

The main messages of the strategy are that the Government and key stakeholders, (such as NHS commissioners and service providers), need to:

- Raise professional and public awareness of hepatitis C;
- intensify efforts to prevent new cases of hepatitis C infection;
- increase diagnosis of people at current or past risk of infection;
- assess and offer treatment (where indicated) to people who have hepatitis C infection; and
- improve the evidence base through epidemiological surveillance and research.

This strategy will be implemented in partnership with the voluntary/community sector and local communities.

It is intended that the strategy will form the basis of an action plan as proposed in the Chief Medical Officer's infectious diseases strategy *Getting Ahead of the Curve*. This action plan will be published within the next few months, following the consultation exercise. It will serve as a clear framework setting out actions that need to be taken by Government, the NHS and others to secure improvements in the prevention, diagnosis and treatment of hepatitis C.

Hep-C funding in general

What funding is available to support the Hepatitis C Strategy?

A number of funding streams will support the Strategy. A major component has been included in HA 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, and the work done by the voluntary sector. The Department funds harm reduction activities associated with injecting drug use via its central budget for Drug Misuse and a component of the local HIV prevention funding is used for health promotion for injecting drug users.

Apart from the hepatitis C drugs treatment money, how much has been provided for these other activities?

- Central funding of around £3 million over two years (2003/04, 2004/05) has been allocated for raising professional/public awareness and improving surveillance.
- Funding for the voluntary sector specifically for hepatitis C projects which are aimed at raising public awareness and giving advice and support to people who either have hepatitis C, or may be at risk of infection with hepatitis C has been increased and currently stands at around £0.2 million for 2003/04.
- HIV prevention funding includes health promotion for injecting drug users. From 2002/3 HIV prevention is funded through main NHS allocations and £55 million has been included for the coming year. From the returns collected under the AIDS (Control) Act, approximately 14% (1999/2000) of the separate allocation (before mainstreaming) was spent on injecting drug use.
- The Department also has a central budget for drug misuse, for the National Treatment Agency of £243.6million for 2003/04. In addition the National Treatment Agency has been allocated £1million this financial year to increase testing for hepatitis C amongst injecting drug users currently accessing drug treatment services.

Do NHS bodies have to fund drugs and treatment recommended by NICE appraisal guidance?

In October 2000, NICE published recommendations on the use of combination therapy (interferon alpha with ribavirin) for the treatment of moderate to severe chronic hepatitis C. We have recently placed statutory obligations on the NHS to implement NICE recommendations and the additional funding we have provided to the NHS should mean there are no issues regarding variations on accessibility of treatment across the country.

As recently announced, pegylated interferons for the treatment of hepatitis C will be in NICE's seventh work programme. They are due to publish their recommendations in November 2003.

What is the point of NICE recommendations if they are ignored by the NHS?

The Government has placed statutory obligations on the NHS (principally Health Authorities and Primary Care Trusts) to fund treatments recommended by NICE. From 1 January 2002, the NHS will have 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.

Funding for hepatitis C drug treatments

What funding has been provided to the NHS to fund combination drug therapies for hepatitis C?

We expect NHS bodies to fund NICE recommended technologies from their general allocations as we have included funding in these allocation for this purpose.

They will be funded from general allocations to the NHS. Over the years 2002-03 to 2007-08, we are making the largest sustained increase in funding of any 5 year period in the history of the NHS – the average annual real terms increase will be 7.5% (England) a year over and above inflation. This means an extra £34 billion over the same period for the NHS.

What is the treatment of HCV-HIV co-infected patients?

Because HCV and HIV share some risk factors and transmission routes, a number of patients become infected with both viruses e.g. haemophiliacs. Chronic HCV appears to progress to serious disease more rapidly in such co-infected patients, and now that the prognosis for HIV has improved with the use of highly active retroviral therapies, the liver disease is an increasingly serious problem. Treatment of HCV-HIV co-infection, and possible drug interactions, are currently the subjects of much clinical debate.

Hepatitis C research

How much funding will the Department make available for hepatitis C research to improve the knowledge base?

In 1996/7 the Department of Health (DH) made £1 million available for research into the prevalence, transmission and natural history of HCV. In addition to this, DH funding for research has been targeted at the treatment of mild chronic hepatitis C (£1.1 million – research due to be published in 2003) and studies relating to hepatitis C and intravenous drugs misuse (£0.5 million – these projects all began between April 2000 and January 2001). Over the last 5 years, the Medical Research Council (MRC) has made new awards for research into hepatitis C at its own units and universities/other institutes of about £4 million. The annual actual MRC spend is around £0.8 million per year.

We are assessing the need for further funding in the light of the consultation exercise on the document *Hepatitis C Strategy for England*.

Raising awareness of hepatitis C

What will be done to raise professional awareness of hepatitis C?

We are proposing to build on work already done in raising professional awareness of hepatitis C. In 2002 and 2003, the Department of Health funded regional conferences to raise awareness of hepatitis C for primary care and public health professionals. These events were well attended. We supplemented these events with a professional briefing pack that was sent to all GPs and practice nurses, and other relevant health professionals in England in March 2002. The pack includes a patient leaflet to be used in patient consultations.

We are considering options for further central awareness-raising activities such as more conferences and briefings in professional journals and newsletters. This should promote professional awareness-raising at the local level.

What will be done to raise public awareness of hepatitis?

We are proposing to develop a health promotion campaign for the general population to raise awareness of hepatitis C. This will be measured and non-alarmist and provide clear information about hepatitis C infection, how it may be avoided, and testing and treatment services.

What has been done already to raise awareness of hepatitis C?

We are funding work with the voluntary sector, specifically the British Liver Trust, Mainliners - which runs the National Hepatitis C Resource Centre - and the Haemophilia Society, to provide information and advice for the general population, for those at higher risk of acquiring hepatitis C infection, injecting drug users in particular and health professionals. We are also funding the UK Assembly on Hepatitis C. This is a project for people with hepatitis C, which aims to facilitate improvements in patient self-help and promote patient advocacy.

To raise professional and public awareness and to promote good practice, the Government has produced guidance for the NHS on the purchasing of services for and clinical management of injecting drug misusers, which includes advice about hepatitis C. The Department published guidance on hepatitis C for those working with drug users in April 2001. This guidance should ensure that professionals give drug users clear and consistent messages to reduce the risk of infection and to reduce harm associated with hepatitis C infection for those already infected.

The Department has also funded regional seminars, which were held in 2002, to raise professional awareness of hepatitis C in those working with drug users, and how to reduce the risk of transmission and later ill health. Almost 400 drug workers, managers of services and commissioners of drug services attended these events.

We have also issued advice for health care workers on infection control for blood-borne viruses. Guidance on the prevention of blood-borne virus transmission in renal dialysis units was published in August 2002 and distributed to the NHS.

Advice on minimising the risk of hepatitis C infection is also included in Department of Health leaflets for the public e.g. on sexually transmitted diseases and travelling abroad.

In 2002 and 2003, Department of Health funded regional conferences to raise general awareness of hepatitis C among primary care and public health professionals . These were well attended. These have been supplemented by a professional briefing pack that was sent to to all GPs and practice nurses, and other relevant health professionals in March 2002. The pack includes a patient leaflet to be used in patient consultations. Further such conference are planned this year.

Hepatitis C screening/testing

Why has the Government not introduced universal screening for hepatitis C?

We are a relatively low prevalence country for hepatitis C and universal screening is not justified. The main 'at risk' groups are current and past injecting drug users.

Those who have been at risk of exposure to hepatitis C and who seek testing should be offered advice and made aware of the implications of a positive test. Those who test positive should be referred to a specialist for confirmatory testing, further assessment and treatment if appropriate. They should also be advised about minimising the risk of transmitting infection to others and on the need to limit alcohol intake to reduce disease progression. Those who test negative are advised about ways of avoiding further exposure, as there is no vaccine against hepatitis C.

We are intending to publish guidance on hepatitis C testing during 2003.

Stigma/discrimination and hepatitis C

People with hepatitis C suffer are stigmatised and face discrimination. What is the Government doing to tackle this?

We are aware that some people with hepatitis C may feel that they suffer social prejudice and discrimination. This may, in part, represent a lack of public knowledge about the disease. The strategy should assist in increasing public knowledge and understanding of hepatitis C and act against stigmatisation and discrimination.

Hepatitis C and Insurance

There is anecdotal evidence that people with hepatitis C are discriminated against by insurers – what is the Government doing about this?

We understand from the Association of British Insurers, the industry's umbrella body, is that applicants who are infected with hepatitis C should not automatically face increased premiums or refusal of cover. Many people with hepatitis C will live out their normal lifespan and not progress to serious liver disease but some may develop cirrhosis and liver cancer. There will therefore be a range of outcomes for insurance applications from people with hepatitis C, depending on the individual case. These will range from standard rates to a small weighting through to a greater weighting or refusal of cover.

Vaccine against hepatitis C

Is the Government seeking a vaccine for Hepatitis C?

There is currently no vaccine to protect against hepatitis C infection, and one is unlikely in the near future. The virus is known to mutate (leading to a change in molecular structure) at a particularly rapid rate, which makes the development of an effective vaccine difficult.

A number of centres around the world are involved in research into a vaccine against hepatitis C; we are not aware of research in this country, and the Department is not supporting such research.

Transmission of hepatitis C infection via blood

When did the NBS start screening for hep C?

A screening test for Hepatitis C was introduced on 1 September 1991 in the UK.

Since screening of hep C began, what are the chances of being infected with Hep C through blood?

Less than 1 in 2 million (for England).

How many cases of hep C since screening began?

There have been two cases of transfusion transmitted HCV infection (from anti-HCV tested blood) reported since October 1995.

Background Briefing

Existing compensation schemes

Vaccine damage payment

The Vaccine Damage Payment (VDP) scheme is a UK public health measure not social security legislation. The scheme provides a tax-free lump sum payment (£100,000) where serious mental or physical damage has been caused by the administration of vaccines against specified diseases.

The scheme was established in 1978 when payments were made on an extra-statutory basis. This was followed by the Vaccine Damage Payment Act 1979 which put the scheme on a statutory footing. The scheme is designed to cover routinely recommended vaccines in the childhood immunisation programme. The diseases specified in the Act are diphtheria, tetanus, pertussis, poliomyelitis, measles, rubella (german measles), tuberculosis, smallpox [vaccinations up to 1 August 1971],mumps, Haemophilus influenzae type b and meningitis C.

The Secretary of State must be satisfied that a person is severely disabled as a result of vaccination against any of the diseases specified in the Act. Up to 16 June 2002 in order to receive a payment the disabled person had to be at least 80 per cent disabled. This disability threshold has now been reduced to 60 per cent. Claimants who are less disabled will not receive a payment.

Payment is not compensation, but is designed to recognise the extra costs falling on the children and families concerned. The VDP scheme does not require negligence to be established. Payment of a VDP does not prejudice the right of the disabled person to pursue a claim through the courts, though the VDP would be offset against any damages. There has never been a successful court case in the UK but there are several hundred cases working their way through the legal system at the moment. Around 900 payments have been made, the majority of which were paid in the first few years of the scheme. An average of three to four payments are now made every year

The Macfarlane Trust

The Macfarlane Trust was set up in 1988 following a campaign by the Haemophilia Society on behalf of those people with haemophilia who had contracted HIV infection through contaminated blood products in the late 1970s and early 1980s.

The remit of the Trust as stated in the Deed, is:

" to relieve people suffering from haemophilia who as a result of receiving infected blood products in the UK are suffering from AIDS or are infected with HIV and who are in need of assistance or their needy spouses, and other dependants after the death of the person".

The spend to date for the Trust is:

- £24m initial settlement in 1990 (£20k to each individual)
- £44m in a further settlement in 1991 (amounts varied)

- £25m to date via monthly payments, single grants and special winter payments. Payments by the Trust to surviving registrants, their widows and dependent children currently total around £2.8m p.a.

Individuals who have received payment

- 1240 with haemophilia and HIV

- 39 infected dependents (partners).

The Eileen Trust

The Eileen Trust was established in 1993 to assist people, other than those with haemophilia, who contracted HIV through contaminated blood products. The Trust's objectives are "to relieve those qualifying persons who are in need of assistance or the needy dependants of qualifying persons and the needy dependants of qualifying persons who have died". The Eileen Trust provides similar services to the Macfarlane Trust but on a smaller scale.

CJD Compensation Scheme

The Government has set up a vCJD compensation scheme, which will provide for payments to be made in respect of 250 cases of *variant* CJD up to a maximum of £55 million. On top of the £55 million Trust fund, in recognition of the exceptional circumstances, the Government will pay an additional £50,000 to each victim or their family. The Government is making this further commitment to a maximum of 250 cases.

Austria	There are no financial support programmes for haemophiliacs who were infected with Hepatitis C through blood and blood products. However, the Austrian Government set up a compensation fund for donors of blood and blood plasma who were infected with Hepatitis C as a consequence of their donation. The fund is financed entirely by the Government. It was set up at the end of 2000 and payments started in 2001. Compensation is available for all people who can give credible evidence that they were infected with Hepatitis C through a blood or blood plasma donation and where a court has confirmed this evidence.
Belgium	No scheme at the moment, however we are told one is planned.
Denmark	Information not yet available
Finland	No scheme
France	No scheme
Germany	There are no financial support programmes for haemophiliacs who were infected with Hepatitis C. The Federal Government and the Laender Government has opposed any form of compensation. However, financial assistance was given to some 2,700 women who were infected with Hepatitis C through blood plasma vaccinations in the former German Democratic Republic (GDR) They were initially only paid a small compensation by the Federal Government in 1990, after West German courts had ruled that the vaccinations had been punishable offences. In July 2000 the Federal Government passed legislation for more generous and systematic financial compensation. Under this new system, women in the former GDR who were infected with Hepatitis C through blood plasma vaccinations and whose ability to work is reduced by at least 30% as a consequence of that infection, receive payments of between EUR250 and EUR1000 per month.
Greece	No scheme
Holland	No scheme
Irish Republic	The Hepatitis C Compensation Tribunal was set up in 1997 to assess applications. The total cost – including administration – is expected to reach some £400m (Irish). The biggest single award to an individual to date has been £1.6m to compensate for the loss of a number of year's high earnings. An advertisement has been placed in the Irish press reminding people of deadline for claims.

	A further judicial inquiry is currently under way in Ireland looking at the causes of hepatitis C and HIV infection in haemophiliacs through blood products. Legislation is also before the Irish Parliament to extend the Compensation Tribunal to haemophiliacs infected with HIV through blood products. Haemophiliacs with HIV in Ireland received the same ex-gratia payments as those in the UK in the early 1980s but have successfully campaigned to be included in the more generous hepatitis C scheme.

Italy	The Rome Civil court found Italian Ministry of Health guilty of negligence in 1998 after a class action by 385 haemophiliacs who had contracted the HIV virus and/or hepatitis C. In all, over 5000 haemophiliacs have contracted Hepatitis C and or HIV through tainted blood products distributed in Italian public hospitals from 1976 to 1992. The Health Ministry was therefore obligated to compensate these individuals. Individuals are entitled to a monthly cheque, for life. The amount varies from case to case, however on the average it is approximately €1,110.00 every two months. In addition all medical care and related pharmaceuticals are to be provided free of charge. Those infected with Hepatitis C through tainted blood can request compensation within a maximum of three years from the moment they become aware of being infected.
Luxembourg	No scheme
Portugal	No scheme
Spain	Compensation scheme. A committee to develop a census of affected people was set up .The criteria for inclusion was: 1. Being haemophiliac or suffering from an inherited blood coagulation disorder. 2. Having received treatment with concentrated blood coagulation factors within the public health system. 3. Having developed hepatitis C. 4. that hepatitis C has been developed by means of the following tests: - Presence of antibodies anti-HCV with RNA-HCV positive by PCR. - Showing high levels of transaminases three times in a six-month period. All those included in the census (census approved 21.11.00) will have the right to receive €18,030.36 as a one off payment - free of tax.. If the person has died, his/her children (under 18 years old) and those with a disability 18 years old or older will receive this sum in equal part. If there are no children, the spouse not legally separated will receive the sum or the person who has been living with him/her for a period of at least two years before the death. If there is no spouse, his/her parents will receive the sum. Other initiatives to provide support to those affected by giving information and encouraging research into this disorder will be developed. Those affected will have a period of four months from the date the law comes into force to claim for this compensation. In order to get

	access to this payment; the person must reject other claims made due to HCV transmission in any other public health administration and health centre within the national health system. Those who have been found guilty of an offence for transmitting the HCV will not be able to receive this payment.
Sweden	Compensation is available from pharmaceutical companies but limited to social and psychological suffering not physical damage.

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 virus that can infect and damage the liver. The virus is found in the blood of people who have this disease. Hepatitis C is spread primarily by contact with the blood of an infected person. Currently the main route of transmission in the UK by the sharing of contaminated equipment by injecting drug misusers. Other less important routes of transmission include from infected mother to baby at birth, or by sexual intercourse with an infected person. There is also a risk of transmission if skin piercing/tatooing is not carried out in a hygienic manner.

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.

The majority of patients who acquire hepatitis C will live out their normal lifespan. Hepatitis C infection is cleared in about 20% of those infected, but persists in about 80% to become chronic infection. Most 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. Studies carried out in a number of countries so far have generally indicated that about 1-5% of patients with chronic infection may develop liver cancer.

Hepatitis C virus

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. Prior to the introduction of viral inactivation of blood products in 1984, and before 1991 when the screening of blood donors was introduced, some recipients of blood and blood products were inadvertently infected.

Many patients who acquire hepatitis C will live out their normal lifespan. Hepatitis C infection is cleared in about 20% of those infected, but persists in about 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

Drug treatment for hepatitis C

Until relatively recently the only treatment available for hepatitis C was interferon alpha, which has a limited success rate (around 20% of those treated) and is not suitable for all patients. However, trials on the use of combination drug therapy have shown encouraging results and the first of these, Rebetol (interferon alpha with ribavirin), is successful in clearing infection in around 40% of cases. NICE issued its advice on ribavirin and Interferon combination therapy for hepatitis in October 2000. Provision has been made in the current SR settlement for funding the implementation of these recommendations, as a component of the aggregate cost pressure likely to arise from the NICE guidance.

NICE guidance states that in general this treatment is not recommended for current injecting drug misusers. However if a prescribing clinician is reliably assured that re-infection, compliance and drug interactions pose no problems, a person in this group might be considered to combination therapy. Former injecting drug users and those on oral substitute treatment need not be excluded from therapy.

With funding from DH, evidence-based clinical guidelines for the treatment of patients with hepatitis C have been drawn up by the British Society for Gastroenterology, the British Association for the Study of the Liver, and the Royal College of Physicians. They were published in July 2001 and, in line with recommendations from the European Association for the Study of the Liver, include which patients should be treated, the optimal treatment and how patients on treatment should be monitored.

The NHS Health Technology Assessment Programme is funding research to establish the effectiveness of the early treatment of chronic hepatitis C with Interferon alpha or a combination of interferon and ribavirin.

A modified, slow-release form of interferon – pegylated alpha interferon - became available in April 2001. It appears to be more effective than conventional interferon, and only requires once weekly injections, rather than three times weekly with conventional interferon. A recent randomised trial comparing treatment with pegylated alpha interferon plus ribavirin with conventional alpha interferon plus ribavirin was reported in *The Lancet* on 22 September 2001. The results showed that pegylated alpha interferon plus ribavirin was more effective in clearing the virus than conventional standard interferon alpha plus ribavirin. This new treatment has is currently being assessed by NICE and they are due to report in November 2003.

Development of a national hepatitis C strategy

1. In recognition of the emerging public health significance of hepatitis C and growing professional and public concern, Ministers announced the establishment of a steering group by inspired written Parliamentary answers in March 2001.

2. The steering group was chaired by Professor Howard Thomas, Imperial College School of Medicine, London, who is a world authority on hepatitis C. Its membership comprised health professionals, academics and representatives from the voluntary and community sectors, including a patient representative. The terms of reference of the Steering Group were as follows:

> *To oversee development of the Department's strategic approach to hepatitis C by bringing together issues relating to prevention, control and treatment and to produce a document within the year, for consultation with the NHS, professional bodies and the voluntary and community sectors.*

3. With the assistance of the steering group, the Department published a consultation paper, *Hepatitis C strategy for England* on 14 August 2002. The closing date for comments was 15 November 2002. The strategy proposes:

- Raising professional and public awareness of hepatitis C;
- Improving the evidence base through epidemiological surveillance and research;
- Intensifying efforts to prevent new cases of hepatitis C infection;
- Increasing diagnosis of people at current or past risk of infection; and
- assessing and offering treatment (where indicated) to people who have hepatitis C infection.

4. It is envisaged that the strategy will form the basis of an action plan as proposed in the Chief Medical Officer's infectious disease strategy, *Getting Ahead of the Curve*. The action plan is due to be published within the next few months.

Hepatitis C research

1. In 1996/7 the Department of Health (DH) made £1 million available for research into the prevalence, transmission and natural history of HCV. In addition to this, DH funding for research has been targeted at the treatment of mild chronic hepatitis C (£1.1 million Health Technology Assessment project – research due to be published in 2003) and studies relating to hepatitis C and intravenous drugs misuse (£0.5 million – these projects all began between April 2000 and January 2001). Over the last 5 years, the Medical Research Council (MRC) has made new awards for research into hepatitis C at its own units and universities/other institutes of about £4 million. The annual actual MRC spend is around £0.8 million per year.

Research topics highlighted in the Hepatitis C Strategy

2. During the course of the Strategy development some gaps in research were identified and these included

- Survival of hepatitis C virus - particularly methods for effectively rendering injecting equipment safe using readily available products.
- Mother to baby transmission - internationally co-ordinated research is needed to determine if elective caesarean section or other obstetric interventions reduce risk of transmission during pregnancy and/or childbirth to reduce hepatitis C transmission.
- Modelling the effectiveness of different prevention activities. Mathematical modelling could be a useful adjunct to decisions about where to target prevention resources to have maximum effect.
- Behavioural research – research into `prevention of initiation to injection' is needed to inform harm reduction work
- Complementary and alternative medicine - evidence is needed from large and well-designed studies to evaluate the effectiveness of CAM in the management of hepatitis C.

3. We will be assessing the need for further funding in the light of the consultation exercise on the document *Hepatitis C Strategy for England.*

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 £100,000 per annum (until 2003/04) in core funding via the Section 64 Grant Scheme, from the Department of Health. This is a substantial sum. In 1998 it was reduced from £188,000 in a move to shift the emphasis towards project work, and we are fully committed to working with the Society on a range of projects.

- We are also giving the Society £20,000 pa over 3 years (2000/01 to 2002/3) for a further project to develop improved counselling provision for people with haemophilia.

Recent (last 12 months or so) Lords PQs

Lords Written PQ9673 – July 2002

The Lord Morris of Manchester - To ask Her Majesty's Government what consideration they are giving to the resolution approved on 24th May by the General Assembly of the World Federation of Haemophilia calling on all governments to provide financial recompense for the suffering caused to people with haemophilia by iatrogenic infection by the hepatitis C virus; and what information they have on the schemes for recompense already adopted or proposed by Ministers in other states in the European Union

Lords Written PQ10672 – July 2002

The Lord Morris of Manchester - To ask Her Majesty's Government what representations have been received from the Haemophilia Society by Ms Hazel Blears, the Parliamentary Under Secretary of State for Health, further to her meeting in June with the Society on financial assistance for haemophilia patients infected with hepatitis C by contaminated National Health Service blood products; what consideration the Department of Health's financial-economic team have given to the proposals; and what reply is being sent to the Haemophilia Society.

Lords Written PQ 00799 – October 2002

The Lord Morris of Manchester - To ask Her Majesty's Government, further to the Written Answer by the Lord Hunt of Kings Heath on 9th October (WA 26), whether the National Health Service policy in England for the treatment of chronic hepatitis C is different from that in Scotland since 2000 in respect of positive appraisal guidance, access to recombinant blood products and addressing the compensation of patients infected with contaminated National Health Service blood products; and, if so, why.

Lords Starred Oral PQ00058 – November 2002

The Lord Morris of Manchester – To ask her Majesty's Government what implications for NHS patients identically affected in other parts of the UK follow from the findings of the expert group appointed by the Scottish Executive to consider financial and other practical support for patients infected with Hepatitis C by contaminated NHS blood, blood products or tissue

Lords Written – PQ 01244 – December 2002

To ask Her Majesty's Government what details they have of the blood donor in Scotland found recently to have vCJD and from whom plasma had been used to manufacture haemophilia treatment by the National Health Service; and what guidance they are giving to patients who could be affected.

Lords Starred Oral– PQ01574 January 2003

Lord Morris of Manchester - To ask Her Majesty's Government what new help they are considering for people infected with hepatitis C by contaminated National Health Service blood products, and for the dependants of those who have since died as a result of their infection.