Revenge payments. payments dependant. orphans widows.

Lords Starred Oral– PQ01574 – Lord Morris of Manchester

✓ ownership of LRT
Long-term position

* ✓ what dependants get update.
- update figures - Key facts. [old briefing]
- ✓ Lord Acnar - compensation for victims of crime
- Refugees - screening of staff Hep C.
- Scotland - DWP.
* - latest figs on what it will cost England.
- details of Haem Repct - costs

Lords Starred Oral– PQ01574 For Answer on 13 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.

Suggested Answer:

We have enormous sympathy with those affected by this tragedy. There are no new initiatives planned specifically for these individuals. However, a strategy to achieve effective prevention, testing and treatment services for all hepatitis C sufferers has been published for consultation. An action plan to implement this strategy will be produced in the next few months.

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).

Recombinant Clotting Factors

- All patients with severe haemophilia under age 21 in England and Northern Ireland are entitled to treatment with recombinant clotting factors. Scotland and Wales provide recombinant for all haemophilia patients. and Northern Ireland.

- It has been 2 years since the Haemophilia Society asked Ministers to make a commitment to extend the provision of recombinant to all haemophilia patients in England.

- The Government is considering the case for extending provision to all other haemophilia patients. A decision will be made shortly. All other haemophiliacs are receiving high quality plasma-derived products from the US where there is no evidence of vCJD.

- If funding is provided, recombinant clotting factors will be phased in over a period of a least 4 years.

- There is no evidence world-wide that CJD or vCJD has ever been transmitted through blood or blood products.

Bullet Points

- 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)

- The Department support 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).

- 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.

LORD MORRIS ORAL: SPECIAL PAYMENTS TO PEOPLE WHO CONTRACTED HEPATITIS C (HCV) THROUGH BLOOD

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 .
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.
Current position	The Scottish Executive will develop options for a payments scheme which they will test with their own and DWP lawyers to establish whether: • they have the necessary powers under the Scotland Act 1998 to operate the scheme on their own; • existing social security regulations allow payments under the scheme to be disregarded in the calculation of income support etc.

SUPPLEMENTARIES

Compensation for haemophiliacs infected with hepatitis C

Is there not a moral case for compensating haemophiliacs infected with hepatitis C?

We deeply regret that so many people with haemophilia were infected with hepatitis C through blood products. However, we do not believe that financial assistance for people infected with hepatitis C through blood is justified.

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

If Scotland agrees to provide ex-gratia payments to hep C sufferers will England follow?

The report published on 6 November from the Scottish Expert Group on Financial and other Support was commissioned by the Scottish Executive and its recommendations on hepatitis C relate only to those people who contracted hepatitis C from blood or blood products provided by the NHS Scotland. It does not have implications for patients in other parts of the United Kingdom.

The Government's position remains as stated on many previous occasions in both Houses. We do not believe that financial assistance for people infected with hepatitis C through blood is justified. That position has not changed.

Background: **No fault compensation**

The Government has every sympathy with people who suffer adversely as a consequence of medical treatment and understand and shares the anxieties of those who are concerned with the difficulties associated with compensation.

The Government hold the view that where a patient has suffered damage as a result of negligence then they should be able to seek redress. However, the current position is that compensation can only be paid where negligence has been proved and liability established.

In June (2002)The Haemophilia Society presented the Government with their report on financial assistance for haemophilia patients infected with hepatitis C by contaminated National Health Service blood products. When will the Government make their response to this report?

We are continuing to consider the Haemophilia Society's detailed report and will respond as soon as this has been completed.

When did the previous Government last consider the issue of compensation to haemophiliacs with hepatitis C?

The previous Government decided prior to 1995 (exact date is not known) that compensation would not be payable.

What benefits can people with haemophilia claim?

People with haemophilia may be able to claim incapacity and disability benefits, if as a result of their condition they were able to satisfy the medical criteria for these benefits.

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

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

Why has a Trust similar to the Macfarlane Trust not been set up to help those infected with hepatitis C via blood products.

The Macfarlane Trust was set up in 1988 to provide support to haemophiliacs inadvertently infected with HIV via blood products. At the time the Trust was set up there was no effective drug treatment to offer those infected with HIV and their expectancy was short. Hepatitis C is a different disease and 20% of those infected will clear the virus themselves others will remain well and never develop liver disease. Fortunately we also have drug treatments to offer those who develop serious liver disease and experience with these drugs has shown that the infection can be cleared in around 50% of those infected.

Haemophiliacs who were infected with hepatitis C would have been infected over 17 years ago, this means that hepatitis C infection and liver damage would have progressed to a serious condition.

Compensation for haemophiliacs with hepatitis C: Why is this different from Variant CJD?

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

The plight of individuals and families affected by vCJD is, by contrast the result of a unique set of circumstances for which society as a whole must bear a moral responsibility. Variant CJD is a particularly distressing condition. It is incurable, inevitably fatal and devastating in its impact on sufferers and their families alike. Furthermore, many of its victims are young people with most of their adult lives before them. The Government considers - even though we are advised that we are unlikely to be legally liable - that it is right to make payment to the victims and their families in recognition of their wholly exceptional situation and the fact that the Government is their last resort for help.

Consumer Protection Act and Burton Judgement

As a result of Mr Justice Burton's Judgement on 26 March 2001, will the Government now compensate those people with haemophilia who have hepatitis C through infected blood products?

The outcome of the "Burton Judgement" does not alter our position on compensation. Damages were awarded on a "no fault" basis, not on the basis of negligence. Although Governments have occasionally made ex-gratia payments to patients in a "no fault" situation for example in the case of haemophiliacs with HIV and the families of people with vCJD – these have been in truly exceptional circumstances which do not apply to hepatitis C.

How much money has been paid to those patients who have hepatitis C as a result of blood transfusions under the "Burton Judgement"?

Total Payments made by the National Blood Authority (NBA)

Damages:	£2,237,092
Defendants Costs:	£4,318,489
Claim Costs:	£3,571,804

Totalling: £10,127,385

The outstanding estimate for NBA payments ie. what is left to pay in addition to the above is £3,353,168. There is also £3.5m set aside for 2nd tier claims if medical conditions worsen.

How much money has been paid to those patients who have hepatitis C as a result of blood transfusions under the "Burton Judgement"?

Total Payments ~~made~~ by the National Blood ~~Authority (NBA)~~

Damages:	£2,354,347.24	
Defendants Costs:	£3,591,556.47	
Claim Costs:	£2,615,202.66	
Totalling:	**£8,568,398.79**	

The outstanding estimate for NBA payments ie what is left to pay in addition to the above is:

Damages:	£2,983,379.92
Defendents Costs:	£676,653.75
Claim Costs:	£1,259,413.78
Totalling:	**£4,912,155.03**

Therefore the total amount to be expended (as calculated to-date) equates to £13,480.553.82. There is also £3.5m set aside for 2nd tier claims if medical condition worsens.

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.

But you have instigated an internal review, why?

We have now employed an official for a short period to undertake a detailed review of the surviving papers between, roughly, 1973 and 1985 and put together a chronology of events. Without this it will be difficult to answer any detailed accusations levelled against the Department by Lord Owen and others.

Background:

Yvette Cooper originally agreed to an internal trawl of papers after lobbying initially by Lord Morris (President of the Haemophilia Society and a tireless campaigner on haemophilia issues) and later Michael Connarty, Chair of the All Party Parliamentary Group on Haemophilia. Lord Owen also re-entered the fray in an article in the Newcastle Journal last summer (the Journal often runs stories reflecting the viewpoint of Haemophilia Action UK). He has since been quoted on R4 The World Tonight & You and Yours. He was also due to attend a meeting alongside Lord Morris and Michael Connarty with PS(PH) on this issue in July this year but was unable to attend at the last minute.

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.

Treatment – Recombinant (Synthetic) Factors 8 and 9

It is almost 2 years since the Haemophilia Society asked the Government to give an undertaking to provide recombinant for all haemophilia patients in England. When will you take a decision?

The Government is still considering whether to make recombinant clotting factors available to all haemophiliacs in England taking full account of representations made by the All Party Parliamentary Group on Haemophilia, the Haemophilia Society, the United Kingdom Haemophilia Centre Doctors Organisation and others. We hope to announce our decision shortly.

It is understood that it will cost the NHS an additional £50 million a year to supply clotting products to all haemophiliacs. Is this the reason for the delay?

The Government is not delaying a decision on the provision of recombinant clotting factors. It is considering the issue. All haemophiliacs are already receiving effective treatment for their condition.

Are there medical reasons why Recombinant Factor 8 &9 are not made available to all haemophiliacs already?

It is generally accepted by United Kingdom clinicians that recombinant and plasma derived clotting factors are equally effective in treating clotting disorders.

In guidelines produced by the United Kingdom Haemophilia Doctor's Organisation, comparisons between the two types of product revolve around their relative safety, bearing in mind that no medicinal product can ever be completely free from risk.

An advantage of recombinant products, where they are entirely free of human albumin, is that they eliminate the risk from blood borne viruses and the theoretical risk from vCJD. However, plasma derived clotting factors are tightly regulated by European and United States authorities to minimise the risk of viral transmission. This is achieved by the screening of donor blood and the anti-viral measures taken during manufacture. By ceasing to use UK plasma in the manufacture of blood products, the Government has already taken steps to reduce the unknown risks from vCJD.

What action will the Government take in light of the recent figures from the Marketing Research Bureau which highlights that the UK has the lowest provision of recombinant product for the use of people with haemophilia in the developed world?

In England, all haemophilia patients up to the age of 21 years receive recombinant clotting factors. The Government is considering the case for extending provision to all other haemophilia patients.

Background

On 17 December 2002 The Haemophilia Society published research findings from the Marketing Research Bureau regarding the availability of recombinant products in 17 developed countries. The research indicated that England & Wales came bottom.

Michael Connarty MP (Chair of the all party group on haemophilia) has tabled an EDM (No. 417) on 19 December 2002, highlighting the Society's report and calling on the Government to make synthetic alternative to blood products available to all people with haemophilia.

The table below shows the availability of recombinant to people with haemophilia cross 18 countries in the developed world.

Rank	Country	Recombinant provision
1	Ireland	100%
2	Canada	97%
3	Denmark	85%
4	France	70%
5	Austria	65%
6	Belgium	62%
7	Japan	61%
8	Sweden	58%
9	United States	58%
10	Norway	45%
11	Italy	39%
12	Germany	35%
13	Netherlands	33%
14	Australia	32%
15	Spain	26%
16	Portugal	25%
17	United Kingdom	24%

Figures are from the Marketing Research Bureau based on figures available at the start of 2001.

LIFE RESOURCES INC

The Department of Health announced last month that they had purchased a US Plasma Company "Life Resources". What checks were made on the company's safety standards?

The Department's objective in purchasing Life Resources (LRI) is to ensure the availability of high quality plasma product for NHS patients. Before making the purchase, the Department wanted to satisfy itself that the company's safety and quality standards were fully compliant with the rigorous regulatory requirements enforced by the US Food and Drug Administration and the UK Medicines Control Agency.

All the company's plasma centres were inspected by the NHS Bio Products Laboratory (BPL). BPL were satisfied that LRI not only meet all the required regulatory standards but that the good quality systems were in place to ensure that that these standards are rigorously and consistently applied. The Department was also assured by the fact that LRI have supplied BPL with high quality, problem free plasma since 1999.

Why has the Department bought this company?

The preference would have been to continue purchasing plasma from the US using long-term contracts. However, no contracts for the volume of plasma required by BPL were available. Of the remaining options, an independent financial analysis confirmed the purchase of Life Resources to be the most cost-effective means of securing the sustainable long-term supplies of non-UK plasma the NHS needs.

Why is it necessary to go to the US for plasma?

Large volumes of plasma are required for medicinal product manufacture, especially immunoglobulin. The US is the preferred source of plasma given the well established pool of donors, the absence of BSE or vCJD, the well regulated environment and the developed collection industry. No significant exports of plasma from anywhere other than the US have been identified.

But hasn't there been a case of vCJD in the US?

There has been one case of vCJD in the US but the person was British and had spent most of their life in the UK. This is therefore being treated as a UK, rather than a US, case of vCJD.

Why not obtain plasma from Europe?

We looked at this to see if it were possible. Independent plasma collectors in Europe produce an estimated 260,000 litres per annum. Most of this is believed to be committed to long-term contracts with blood product manufacturers. Even all of it would not be enough to meet BPL's needs (450,000 litres pa in 2004).

What other options were considered?

The other options considered were:

- setting up managed centres in the US to secure a supply of raw plasma for BPL;
- purchasing all finished products from third party suppliers and closure of BPL;

- purchasing of MCA approved plasma from the open market for BPL to process.

How much has the Department paid for Life Resources?

The Department of Health has purchased the trade and assets of Life Resources for an up front payment of £48.8m with a further £21m tied into the performance of the company up until the end of 2006. The Department has paid a commercial price for the business assets based on same analysis as a private sector purchaser would have undertaken.

How can this be justified?

Without this deal, the NHS would probably have faced serious shortages of life-saving blood products.

But this is public money

We are paying a fair commercial price for the business. This has been confirmed by our independent financial advisers.

What have you bought exactly?

On the advice of our independent financial advisers, we purchased the trade and assets of Life Resources.

Is this a profit making company?

Yes.

How can you justify spending public money on buying a profit making US company?

This is the best and most cost-effective way to secure a constant supply of the plasma the NHS needs. This has been confirmed by an independent option appraisal.

How will these profits be spent?

They will either be spent in improving and expanding the business or will return to the UK Government. There are no other shareholders.

How will the company be managed?

We have set up an effective management structure for the company

Where are the company's plasma collection centres?

Life Resources operates 24 collection centres at various locations in the US.

Will Bio Products Labpratory pay for its plasma?

Yes. The plasma will be purchased by BPL are market rates.

Why US plasma? What about plasma from Europe or elsewhere?

At present Europe does not produce sufficient plasma to meet its own need for blood products. A substantial proportion of the products used in Europe is manufactured from US plasma. The US provides the best opportunity to secure high quality supplies of plasma and has the added advantage of having no known indigenous cases of BSE or vCJD. Plasma currently used in the NHS comes from the USA.

Our action mirrors the steps taken by major pharmaceutical companies who are also seeking to secure their supply of plasma predominantly in the US.

Why can't we go back to using UK plasma?

We stopped using UK plasma because of the unknown and unquantifiable risk of transmission of vCJD through blood. In the absence of a properly validated screening test for vCJD or proof that vCJD is not transmitted via blood, a return to using UK plasma is not an option.

Doesn't this fly in the way of European self sufficiency

We looked to see if the plasma we needed could be bought in Europe. However, surplus plasma is not available in Europe in anything like the quantity needed by BPL (450,000 litres a year by 2004, 500,000 litres by 2006).

Will the plasma donors be paid?

Yes. They receive an average of $22 per donation.

Aren't there safety risks from plasma from paid donors?

The safety of plasma-derived blood products is not affected by whether the donor is paid or unpaid. This is because, in addition to the screening of donors for the major blood borne viruses (eg HIV & Hepatitis B & C), all blood products are heat or chemically treated to remove any viral contamination that escaped the screening process.

How do you ensure the safety of plasma products?

The safety of plasma-derived medicinal products is ensured by the application of a large number of complementary measures. These include inspections of collection and manufacturing facilities, selection of donors, screening of individual donations and testing of pooled plasma units for markers of infection with known viruses and, very significantly, the application of validated production processes which are capable of inactivating and/or removing a range of viruses.

But isn't unpaid blood donation safer?

There is no evidence from clinical studies and pharmacovigilance that paid plasma donation contributes an increased risk of viral transmission

via plasma-derived medicinal products. The safety of plasma-derived medicinal products is optimised by the stepwise application, in the course of collection, manufacture and batch release testing, of a number of complementary measures. Their safety is not dependent on the use of unpaid donors. Nearly 50% of the total amount of plasma-derived medicinal products used in Europe originate from remunerated donors.

Haemophiliacs want synthetic not plasma derived products. Why won't the Government fund those?

Ministers are considering the case for provision of recombinant clotting factors and hope to make a decision very soon. The purchase of Life Resources secures supplies of plasma products for a wide range of patients, not just those with haemophilia.

Who is the average Life Resources donor?

More than 50% of the centres are located in cities or towns with large college populations where the great majority of donors are drawn from the college population. The rest are located in mostly small cities where the donor population consists of local residents.

Is the main source of support of the donors monies paid to them as a result of their donating plasma?

No. It is, at most, supplemental income. The average Life Resources donor donates approximately 12-14 times per annum with an average donation payment of $22. Therefore, most donors receive less than $300 each year for plasma donations. Even if a donor donated the maximum legal amount of times each year (104) the total monies received would be less than $3,500. It is virtually impossible to live anywhere in the U.S. on less than $70 per week.

Are any Life Resources plasma donors homeless people or transients?

No. All Life Resources collection facilities operate under the highest standards required by the US Food & Drugs Administration and, in addition, they follow strict industry requirements. Life Resources centres operate strict rules that limit donors to established residents of the local community. All new donors are checked through a National Donor Deferral Registration system to determine if they have been permanently rejected at any time by any other plasma collection facility.

How do Life Resources centres advertise for donors?

All advertising is done at the local level and consists of print, radio, and TV. Most advertising stresses, life-saving reasons for donating, generally indicates the length of time the donor spends at the centre and does state that the donor will be compensated for his/her time. Compensating the donor for his/her time has been accepted in the U.S. for almost 50 years and there is no statistical information that indicates that finished product produced today from paid donors is any more or less safe than from unpaid donors.

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.

How will the strategy be delivered?

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 £1.3 million over two years (2002/03, 2003/2004) has been allocated for raising professional/public awareness and improving surveillance. Funding for future years will be dependent on Ministers decisions about SR2002.

- Funding for the voluntary sector specifically for hepatitis C projects and for projects which are directed at prevention activities for injecting drug users in general has been increased and currently stands at around £0.2 million for 2002/2003.

- 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 £175.7million for 2002/03.

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.

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

On 5 December 2001, the Government announced that it would meet its commitment to ensure that patients receive drugs and treatments recommended by NICE on the NHS if deemed appropriate by their clinicians. We have issued directions requiring health authorities and Primary Care Trusts to provide appropriate funding for recommended treatments.

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 will be 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, the Department of Health funded regional conferences to raise awareness of hepatitis C for primary care and public health professionals. About 800 professionals attended these events. 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. (This will build on existing activities within schools and with young people in relation to injecting drug use).

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 are intending to fund a further series of seminars later this year.

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 will be published in the near future.

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.

Department of Health funded regional conferences to raise general awareness of hepatitis C among primary care and public health professionals were held in 2002 and about 800 health care professionals 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.

What is the current treatment for hepatitis C?

The NICE has published recommendations on the use of combination therapy (interferon alpha with ribavirin) for the treatment of moderate to severe chronic hepatitis C. With the additional funding we have provided to the NHS, these should spread the most effective use of the therapy through the NHS, and reduce variation from one area to another. We have recently placed statutory obligations on the NHS to implement NICE recommendations.

What about pegylated interferon?

As recently announced, pegylated interferons for the treatment of hepatitis C will be in NICE's seventh work programme.

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.

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.

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

What development and progress is there on 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 NOTES
Hepatatis C compensation schemes in EU countries	
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.

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.

Hepatitis C Compensation in the Irish Republic

Between 1977 and 1994, a large number of women in the Irish Republic were infected with hepatitis C from contaminated Anti-D immunoglobulin produced by the Irish National Blood Service. An expert group set up by the Irish Government found the Blood Service to have been at fault, and the same conclusion was reached by a later judicial inquiry. The decision to set up a compensation scheme followed these conclusions and the threat of litigation, which the Irish Government believed they would lose. Infection with hepatitis C in this way is unique to the Irish Republic.

It was also established that around 100 of the infected women were blood donors, recycling hepatitis C infection through the blood supply until screening was introduced in 1991. The Irish Government therefore decided to extend the compensation scheme to all people infected with hepatitis C through blood products and blood transfusion.

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 years high earnings. An advertisement has recently 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.

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 not yet been assessed by NICE, but is included in its 7th wave work programme work programme from April 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

Research funded to date

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
- coordination 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.

CURRENT ACTIVITY IN SCOTLAND
To be updated in light of recent events.

Haemophiliacs with Hep C and Insurance

The Scottish Executive is exploring ways to support those who were suffering long-term harm as a result of their infection with Hepatitis C. The Scottish Parliamentary Committee on Health and Community Care had recently provided a report on the situation of patients who had been infected with Hepatitis C as a result of receiving blood from the NHS. The report identified difficulty in obtaining financial services – particularly insurance and mortgages – as being a major area where all people suffering from Hepatitis C were disadvantaged. The Executive met with the financial services sector on 9 December to explore whether there were ways in which this might be overcome.

PS(PH) had previously given an undertaking to consider the scope for a joint meeting to see if there is anything that can be done to improve the situation. Unfortunately, PS(PH) was unable to attend the meeting with Scottish Ministers on 9 December. We will seek to arrange a similar meeting.

PREVIOUS LORDS PQS
LORD MORRIS OF MANCHESTER - HAEMOPHILIA AND HEPATITIS C

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

PQ 3552 - March 1998

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

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

Lords debate 5 June 1998

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

PQ4698 - June 1998

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

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

PQ 5867 - November 1998

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

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

PQ5082 – June 1998

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

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

PQ 2447 June 1999

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

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

PQ 2609 June 1999

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

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

PQ 2610 - June 1999

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

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

PQ 2839 – July 1999

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

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

PQ 3435 October 1999

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

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

PQ 3436 – October 1999

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

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

PQ 235 – November 1999

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

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

Lords Unstarred question - 20 March 2000

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

Lords Oral PQ 115 – 18 December 2000

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

PQ 832 – 29 January 2001

Lord Morris of Manchester - what recent meetings Health Ministers have had with the haemophilia community to discuss their concerns; and whether there is any action they will be taking as a result of these meetings

PQ 922 –February 2001

Lord Morris of Manchester - how many adults with haemophilia in England are currently receiving (a) plasma-derived haemophilia treatment products and (b) recombinant treatment products.

PQ 923 –February 2001

Lord Morris of Manchester - To ask Her Majesty's Government what would be the additional cost to the National Health Service of treating with recombinant genetically engineered products all adults with haemophilia in England currently receiving plasma treatment products.

PQ 921 - February 2001

Lord Morris of Manchester - further to the Written Answer by the Lord Hunt of Kings Heath on 29th January on haemophilia patients and vCJD in blood products, what consultations the Department of Health had with the Haemophilia Society, as the national patient group, to help

determine what information should be provided to haemophilia patients about the fact that a blood donor whose plasma was used in haemophilia products had been found to have vCJD; and whether in future the Department will consult the Haemophilia Society on the management of such incidents.

PQ 924 – February 2001

Lord Morris of Manchester - what differences exist between the provision of recombinant genetically engineered haemophilia treatment product in England, Scotland, Wales and Northern Ireland.

PQ 925- February 2001

Lord Morris of Manchester - further to the Written Answer by the Lord Hunt of Kings Heath on 29th January on haemophilia patients and vCJD in blood products whether all adults with haemophilia in England will in future be treated with recombinant genetically engineered treatment products, as is provided for children under 16 in England and all haemophilia patients in Scotland, Wales and Northern Ireland.

PQ 1195 – February 2001

The Lord Morris of Manchester - To ask Her Majesty's Government, further to the Written Answers by the Lord Hunt of Kings Heath on 5th and 12th February on the provision of recombinant clotting factors (WA 92 and WA 13), when they expect to announce the outcome of the consideration they are currently giving to making this treatment available to all adult haemophilia patients in England; and how their estimate of the cost at £50 million is computed.

Lords Oral PQ 1524 – 26 March 2001

Lord Morris of Manchester – what ne w help they are considering for people with haemophilia who have been infected with life-threatening illnesses by contaminated National Health Service blood products.

Lords Written PQ 1791 –29 March 2001

The Lord Morris of Manchester -To ask Her Majesty's Government whether Health Ministers will meet representatives of the Haemophilia

Society to discuss how society members might play a role in the working groups and committees appointed to consider improvements to the national framework managing the use and distribution of blood products to people with haemophilia.

Lords Written PQ 1790 –29 March 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what are the working groups and committees appointed to consider improvements to the national framework managing the use and distribution of blood products to people with haemophilia; and what are their terms of reference and current membership

Lords Oral PQ 1754 - 29 March 2001

The Lord Morris of Manchester – To ask Her Majesty's Government what consideration they have now been able to give to the judgement of Mr Justice Burton in the High Court on 26 March concerning contaminated blood supplied by the National Blood Authority.

Lords Written PQ 1958 – 5 April 2001

The Lord Morris of Manchester - To ask Her Majesty's Government when they expect to be able to respond to Mr Justice Burton's judgment in the High Court on 26th March concerning contaminated blood supplied by the National Blood Authority; and whether their response will be reported first to Parliament.

Lords Written PQ 2053 – 17 April 2001

The Lord Morris of Manchester - To ask Her Majesty's Government, further to the Written Answer by the Lord Hunt of Kings Heath on 5th April (WA 130), whether their response to Mr Justice Burton's judgment in the High Court on 26th March concerning contaminated blood supplied by the National Blood Authority will be reported first to Parliament.

Lords Oral PQ 2032 – 23 April 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what further help they are considering for people who

were infected with hepatitis C by contaminated blood products and the dependants of those who have since died in consequence of their infection.

Lords Written PQ 2391 – 5 May 2001
The Lord Morris of Manchester - To ask Her Majesty's Government whether the Haemophilia Society were invited to participate in any stage of the work of the Advisory Group on Hepatitis "C" chaired by Professor Howard Thomas; and what other voluntary groups were invited to participate.

REPLY

The Hepatitis C Strategy Steering Group has only just begun its work, and is aiming to produce a consultation paper by the end of the calendar year. We are intending to include the Haemophilia Society in the consultation exercise with the National Health Service, professional bodies and the voluntary and community sectors.

I refer my Noble Friend to the reply I gave my Noble Friend, Lord Faulkner of Worcester on 26 March at col WA4-5 for details of the membership of the Steering Group.

Lords Written PQ 2469 – 11 May 2001
The Morris of Manchester - To ask Her Majesty's Government what representations the Prime Minister and other Ministers have received from the Haemophilia Society concerning people with haemophilia who were infected with hepatitis "C" by contaminated National Health Service blood products; what replies have been sent; and what action they are taking

Lords Oral PQ 1141 – 15 October 2001

The Lord Morris of Manchester – To ask Her Majesty's Government what further consideration they are giving to the Haemophilia Society's call for a public inquiry into the infection of haemophilia patients with hepatitis C by contaminated National Health Service blood products.

Lords Written PQ 1402 – 22 October 2001

The Lord Morris of Manchester - To ask Her Majesty's Government

how many haemophilia patients were infected with hepatitis C by contaminated National Health Service blood products; and how many have since dies in consequence of their infection.

Lords Written PQ 1401 – 22 October 2001

The Lord Morris of Manchester - To ask Her Majesty's Government how many people now diagnosed with vCJD were blood donors before diagnosis; and how many haemophilia patients are known to have been, or could have been, treated with blood products linked to these donors.

Lords Written PQ 2361 – 16 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what differences in provision for haemophilia patients now exist in England, Scotland, Wales and Northern Ireland, taking into account differences in (a) entitlement according to age, (b) where the patient lives, and (c) any other relevant factors.

Lords Written PQ 2491 – 19 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what estimate thsy have made of the number of people with haemophilia whose National Health Service-prescribed treatment has included blood from donors who have since died of vCJD

Lords Written PQ 2489 – 19 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government how many haemophilia patients have now died after infection with HIV by contaminated National Health Service blood products; and how many more are now (a) seriously and (b) terminally ill

Lords Written PQ 2490 – 19 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government how many haemophilia patients have now died after infection with hepatitis C by contaminated National Health Service blood products; and how many
more are now (a) seriuosly and (b) terminally ill.

Lords Written PQ 2488 – 19 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government how many people with haemophilia now rely on the National Health Service for their medical treatment.

Lords Written PQ 2494 – 19 November 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what study the Department of Health has made of the case of the schoolboy with haemophilia, a patient at the Royal Manchester Children's Hospital, Pendlebury, who was given blood from a donor who had vCJD and has since died; why the child's entitlement to Recombinant Factor VIII was not honoured; and with whom the responsibility lies for the distress now inflicted on the family.

REPLY

In early 1997 this child received Factor VIII from a batch that included plasma from a donor who developed variant CJD in 2000. Following guidance from the UK Haemophilia Centre Doctors Organisation, the child's consultant visited the parents in January 2001 to give them this information. Counselling and support were also provided. The child has received recombinant Factor VIII since May1998 as soon as possible after NHS Trusts were instructed by the Government to provide these products to all new patients and children under 16.

Lords Written PQ 3096 – 6 December 2001

The Lord Morris of Manchester - To ask Her Majesty's Government what steps have been taken to inform haemophilia patients whose NHS-prescribed treatment included blood from donors who subsequently died of vCJD; and, further to the Written Answer by the Lord Hunt of King's Heath on 29th November (WA 71) that patients cared for by HIV-infected healthcare workers will be notified on the basis of the level of risk of exposure, whether they will take similar steps in the case of haemophilia patients who have received blood from donors who subsequently died of vCJD.

Lords Written PQ 4381- 21 January 2002

The Lord Morris on Manchester - To ask Her Majesty's Government how many people with haemophilia have now been infected with hepatitis C and HIV respectively by contaminated National Health Service blood products; and what is current;y being done to assess and implement new technologies to deal with (a) existing and (b) emerging pathogens in blood components supplies by the National Blood Service.

Lords Oral PQ4335 - 6 February 2002

The Lord Morris of Manchester – To ask Her Majesty's Government when they now expect to provide recombinant treatment for people with haemophilia irrespective of age or where they live in the United Kingdom.

Lords Written PQ5224 – Feb/March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government, further to the answers by the Lord Hunt of Kings Heath concerning recombinant treatment for people with haemophilia on 6th February (HL Deb, cols. 629-630), whether they will now set out in detail the basis on which it was stated that there is no evidence "that recombinant clotting factors are more efficacious than plasma-based products" or "that there is an issue of safety between different products"; and whether they will provide the sources that justify both statements.

Lords Written PQ5266 – Feb/March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government what was the cost of making recombinant treatment available to people with haemophilia in England in each year since the treatment was introduced; and whether the Department of Health's estimates for the next financial year include any provision for making the treatment more widely available.

Lords Written PQ5316 – Feb/March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government how many infections have been recorded from the prescription for haemophilia patients of recombinant clotting factors; how many

recorded infections there have been to date from prescribing plasma products; and whether they will detail the infections caused by each treatment.

Lords Written PQ5320 – Feb/March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government how many haemophilia patients, in the course of their National Health Service treatment, have to date received blood from donors who subsequently died of vCJD.

Lords Written PQ5326 – Feb/March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government what screening test for vCJD is available to assure haemophilia patients that they are not being exposed to risk by the prescription of plasma and not recombinant products.

Lords Written PQ6568 – March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government, how many recorded incidents of infection there have been (a) among children under 16 with haemophilia, since recombinant treatment was introduced for them in 1998; and (b) among adults with haemophilia using plasma-derived products since the same date.

Lords Written PQ 6699 – March 2002

The Lord Morris of Manchester - To ask Her Majesty's Government from what date the United Kingdom Haemophilia Doctors' Organisation has advised them and patients that recombinant is the treatment of choice for haemophilia patients on grounds of safety; what consideration was given to that advice when the Lord Hunt of Kings Heath said on 6th February (HL Deb, cols. 629-630) that there is no evidence "that there is an issue of safety between different products"; and what consultation the Department of Health has had with the Organisation since his assurance.

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.