Department of Health

PARLIAMENTARY QUESTION

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Title (For Parly's use only):

Question:

The Lord Jenkin of Roding - To ask Her Majesty's Government whether the Department of Health's report Self-Sufficiency in Blood Products in England and Wales, published on 27th February, is a complete account of the circumstances leading to the infection of National Health Service patients with HIV and hepatitis C due to contaminated blood products.

MP: JENKIN OF RODING, LORD

Parliamentary Branch Action QUESTION COPIED TO:-	Referred to	Date	Referred to	Date
	Ms Flint	12/4		

PARLIAMENTARY RELATIONS UNIT

FINAL MINUTE

1. Reply approved by:

Name	*William Connon*	Building	*Wel Hse*
		Room	*530*
Branch	*General Health Protection*	Ext	GRO-C
		Date	*12 April 2006*

2. Reply composed by:

Name	*Zubeda Seedat*	Ext	GRO-C
Room	*530*	Building	*Wel Hse*

3. The following special points should be noted:

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LORD JENKIN OF RODING (CONSERVATIVE):

The Lord Jenkin of Roding - To ask Her Majesty's Government whether the Department of Health's report Self-Sufficiency in Blood Products in England and Wales, published on 27th February, is a complete account of the circumstances leading to the infection of National Health Service patients with HIV and hepatitis C due to contaminated blood products.

SUGGESTED REPLY

The scope of the report published on 27 February was to examine key issues around self sufficiency in blood products in the 1970's and early 1980's. The review was commissioned following comments about the failure to implement the policy on self sufficiency in blood products during this period.

Bull Points/Key Facts

- Prior to 1989, the hepatitis C virus had not been identified and there were no tests to screen blood donations for the virus.

- As there was no test to identify the presence of either the HIV and hepatitis C viruses, scientists could not be sure that any particular heat treatment had actually worked until they reviewed the effects of the resultant products on patients.

- Many patients would have died or suffered permanent joint damage without treatment with blood products, and there was pressure on clinicians from patients, patient groups, and parents of children with haemophilia to provide treatment with concentrate factors. This was because it could revolutionise the lives of many haemophiliacs by providing much more effective treatment and by enabling many of them to treat themselves (thus avoiding the need to attend hospital).

- There was no professional consensus that infection with the hepatitis C virus was a serious condition until the end of 1980s – many experts believed it was a mild non-progressive condition.

- The combination of these factors meant that initially clinicians prescribed blood products without all the knowledge that would have enabled them to make a properly informed judgment about the balance of risk involved. Even after the risks became better understood there were many cases where it was considered that the benefits far outweighed the risks.

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

<u>Policy on Self Sufficiency</u>

- The money announced by David Owen - up to £500,000 about half of which would be recurring - was allocated to Regional Transfusion Centres to increase plasma supplies to Bio Products Laboratory.

- The evidence clearly shows that considerable efforts were made to achieve self-sufficiency in clotting factors in the 1970s. The fact that this was not achieved appears to be linked with the increase in demand for clotting factors at the time.

- Self sufficiency continued to be the aim of Ministers throughout the 1980s and substantial investment was put into a new plant for BPL.

- The production target for factor VIII was achieved within the 2 year timescale envisaged by David Owen. However, it was not enough to achieve self sufficiency, demand for clotting factors increased dramatically during the 1970s partly because treatment practices were developing (such as prophylactic treatment of children with large quantities of clotting agent);

- The money was linked to a target of 275,000 blood donations to be used annually for the preparation of Factor VIII concentrate and 100,000 for cyroprecipitate.

Q&A

PUBLIC INQUIRY

Why won't the Government agree to a public inquiry?

We have considered the call for a public inquiry very carefully. However, as previously stated, the Government does not accept that any wrongful practices were employed and does not consider that a public inquiry is justified. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.

IMPORTATION OF PLASMA

Why doesn't the report address the issue of imported plasma?

The review was set up to examine the issues around self-sufficiency in blood products. It was not tasked to explore the issues relating to the importation of plasma.

What about plasma sourced from "Skid Row" donors?

There has been concern that plasma was sourced from so called "skid row" donors in the US and that these products may carry a higher risk of transmitting hepatitis. However, blood products contain plasma pooled from many thousands of donors, and only one donation needs to carry the virus to infect the whole batch. Regardless of the source, or of the manufacturer of the plasma used, all products were potentially contaminated with the Hepatitis C Virus, as a result of the need for pooling and the prevalence of the virus in blood donor populations around the world.

Most products transmitted the Hepatitis C Virus whether they were sourced from commercial or volunteer origin.

There is evidence that plasma was sourced from prisons in Arkansas?

Clinicians were able to choose between the BPL product or purchase imported products according to their clinical preference. Concern has been expressed that commercial products may have been sourced from prisoners in the USA. It is our understanding that some Haemophilia Directors would request details of donor facilities from which plasma was sourced. However, we do not know how common this practice was.

We know that Bio Products Laboratory (BPL) have never taken plasma from US prisoners.

BPL has only ever collected at plasma centres against donor specifications that exclude people in American prisons. Also, since the plasma is collected in fixed site centres it is difficult to see how those in prison could donate. The US Food and Drugs Administration recommendations are that those who have been incarcerated for more than 72 hours in the last 12 months should not donate until 12 months after the last day of incarceration. BPL have checked and can confirm that all their previous suppliers operate this criteria. In addition to this criteria all plasma centres require evidence of a permanent fixed address prior to donation and this cannot be a hostel. If BPL find out that the above criteria have not been adhered to, say a prisoner lies about the 72hr incarceration rule, then they withdraw the plasma.

In 2002, Yvette Cooper said that if there was proof that plasma had been used from prisoners/ skid row donors then it would be investigated. Why has this not happened?

We have undertaken enquiries on this issue. We have established that BPL only used plasma collected from UK blood donors until 1998. We also know that clinicians were able to choose between the BPL product or purchase imported products according to their clinical preference. It is our understanding that some Haemophilia Directors would request details of donor facilities from which plasma was sourced. However, we do not know how common this practice was.

TRANSMISSION OF HEPATITIS C INFECTION VIA BLOOD PRODUCTS

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

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

What was known about the hepatitis infection known as non-A non-B hepatitis?

The existence of a further hepatitis virus was proposed in the mid seventies after it was shown that there were cases of post-transfusion hepatitis not caused by either of the hepatitis A or hepatitis B viruses. The illness was called "post transfusion non-A, non-B hepatitis". Its diagnosis required that both hepatitis A and hepatitis B were excluded as causes.

Hepatitis C was only identified following major advances in molecular biological techniques. At the time of its identification, the virus could not otherwise be detected, visualised or grown in cell culture. It has since been shown that hepatitis C is the causative agent in the majority of cases of post-transfusion non-A, non-B hepatitis.

Was human plasma from paid US donors used for haemophiliacs in the UK?

Blood products, including plasma, from paid US donors were used in the UK. [These blood donations are made as safe as current technology allows].

In order to make products successfully, the pooling of donated plasma donations was required. This is still the case, and pool size while it has reduced over time, remains in the thousands. Regardless of the manufacturer or the plasma used, all products were potentially contaminated with the Hepatitis C virus, as a result of the need for pooling and the prevalence of the virus in blood donor populations around the world. This was a universal problem in countries with well developed haemophilia services.

Clinicians knew about the risks?

In the 1970's and early 1980's clinicians knew about the risks of non A and non B hepatitis (NANBH). However, the prevailing opinion at the time was that NANBH caused a mild and often asymptomatic illness. The more serious consequences of hepatitis C, which may take 20-30 years to develop, only became apparent after full characterisation of the virus in 1989 and the development of tests for its recognition.

Were patients informed about the risks?

We are not aware of any evidence that clinicians deliberately misled patients about the risks of clotting factors. The seriousness of hepatitis C was not fully appreciated until at least the mid 1980's and this is possibly why clinicians might not have emphasised it as a risk factor, bearing in mind the beneficial impact of clotting factors on the quality of patients lives.

When was heat treatment introduced?

In the 1980s heat treatments were developed to inactivate HIV which was also transmitted by blood and blood products. HIV was however much more sensitive to heat than hepatitis C and while early heat treatment got rid of HIV, we now know that hepatitis C was still inadvertently transmitted through blood products. From the mid 1980s a range of heat treatments were developed that eliminated both HIV and hepatitis C.

Why did you not implement a test sooner?

Hepatitis C was not fully characterised until 1989. It was after this period that the C100-3 antibody test became available. This produced a high number of false-positive and negative results. Screening of blood donations for hepatitis C virus commenced in September 1991 when a validated test became available.

When was a test for screening blood for HIV introduced?

1985.

IF PRESSED: How many haemophiliacs have been infected with Hepatitis C and HIV through blood products?

We estimate that 1240 people with haemophilia were infected with HIV and around 3000 with hepatitis C before viral inactivation of blood products began in the mid 1980s.

IF PRESSED: Data is not collected on the number of haemophilia patients infected with hepatitis C through blood and blood products and who have since died.

How many have died?

Around 866 patients with HIV have died. Most of those with HIV are likely to be co-infected with hepatitis. C.

The Macfarlane Trust currently has 391 registrants.

DESTRUCTION OF DOCUMENTS

How can the report have any credibility, when you have admitted that papers have been destroyed?

We have always stated that the review is based on surviving papers. The report was commissioned to establish the facts around the achievement of self sufficiency in blood products, based on available papers.

You deliberately destroyed documents.

We regret that papers have been destroyed in error. There has been no deliberate attempt to destroy past papers.

Officials have established that, during the HIV litigation in the early 1990's many papers from that period were recalled. We understand that papers were not adequately archived and were unfortunately destroyed following the litigation.

Officials have also established that a number of files on the Advisory Committee on the Virological Safety of Blood (ACVSB) between May 1989 – February 1992 were unfortunately destroyed in error. These papers were destroyed between July 1994 and March 1998.

Release of papers in Scotland

We are aware that before Christmas the Scottish Executive released many documents concerning haemophilia patients infected with

Hepatitis C through contaminated blood and blood products in the 1970s and 1980s. The decision by the Scottish Executive to release information is supported by the Department.

Why won't you release documents in response to requests made under the FOI Act?

Since the Freedom of Information Act came into force we have had several requests under the Act. We have been unable to meet most requests for a number of reasons. In most cases DH are not the holders of the documents requested; and some of the requests would exceed the £600 limit applied to cases.

We have been able to provide papers relating to a research project and a copy of a Medicines Control Agency Inspection Report on Blood Products Laboratory.

What doesn't the report address the issue of Lord Owen's papers that were shredded?

The review was never intended to consider why papers from Lord Owen's private office were destroyed. Papers kept by Ministerial Private Offices are not kept after a change of Government.

If pressed: They are either shredded or handed back to the relevant policy section.

I have asked for this to be checked. This may have been the practice 25 years ago but it is not what we do now so we need to be absolutely sure of this.

GRO-C 5/4/06

SELF SUFFICIENCY IN BLOOD PRODUCTS

Why did we not become self sufficient?

The evidence shows 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 increase in demand for clotting factors at the time, not to any failure to implement Ministerial initiatives.

For how long did the Department pursue the aim of self sufficiency?

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

More funding should have been made available

The report indicates that self sufficiency continued to be the aim of Ministers throughout the 1980s and substantial investment was put into a new plant for BPL which opened in the mid 1980s. NHS production of clotting factors continued to rise. However, so did the demand for the product. Self sufficiency turned out to be a continually moving target which was never achieved.

Were Ministers advised that funding was insufficient?

There is no evidence to suggest that funding was insufficient. We know that the production target for factor VIII estimated in 1975 and set for June 1977 was attained. The facts are that although NHS production of clotting factors continued to rise, so did the demand for the product. Self sufficiency turned out to be a continually moving target which was never achieved.

Ministers approved substantial investment to redevelop BPL. £1.3m was assigned to the short term development at BPL and £21m to the building of a new fractionation facility.

Self Sufficiency would have prevented the infection of patients

Self sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. Blood products are made with pooled plasma from many thousands of donations (20,000 to 60,000 units). Even if the UK had been self sufficient, the prevalence of hepatitis C in the donor population would have been enough to spread the virus throughout the pool. That is why the infection of haemophiliacs with hepatitis C is a world wide problem

Who undertook the review?

A DH official was recruited for three months (October 2002-December 2002) to undertake the review. The task was completed by independent consultants.

Will you be making all the references available?

The report has numerous references, many of which are already in the public domain. We are currently considering a request under the Freedom of Information Act to release internal papers.

RECOMBINANT ROLL-OUT

Will you confirm funding for recombinant treatment from next year?

Officials at the Department of Health have been closely monitoring the implementation of this programme over the past 2 years. The Government remains committed to this programme and we are currently considering options for future funding of this important treatment. I regret that we have been unable to announce a decision on funding. We hope to make an announcement shortly.

HEPATITIS C EX-GRATIA PAYMENT SCHEME

Why does the Scheme exclude widows and dependents?

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

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

The payments are too small

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

Disparity with Macfarlane/Eileen Trust payments

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

day to day payments. That said, the lump sums are comparable to those made by the Macfarlane and Eileen Trusts.

The Skipton Fund is distinct and has not been designed to compensate for bereavement.

Disparity with Canadian scheme

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

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

Comparison with Irish scheme

The Irish Government set up their hepatitis C compensation scheme following evidence of negligence by the Irish Blood Transfusion Service.

A judicial inquiry, the Finlay report, found that "wrongful acts were committed". It is important to stress that the blood services in the UK have not been found to be similarly at fault. Compensation is therefore

being given in very different, specific circumstances in Ireland that do not apply in the UK.

TRANSMISSION OF vCJD THROUGH BLOOD AND BLOOD PRODUCTS

Are blood products safe?

The safety of blood and blood products used in the NHS is of paramount importance. Every reasonable step has been taken to minimise any risks. The UK has an exceptionally good track record of blood safety. The current high level of safety are achieved by screening out potential high risk donors and further testing every unit of donated blood for the presence of infections.

To date there have been three possible cases of vCJD transmission through blood transfusion. Even before these cases came to light, the Government had introduced a range of precautionary measures to minimise the risk of vCJD transmission through the blood supply. We keep these measures under ongoing review, taking expert advice.

In 2004 you undertook an exercise to notify recipients of blood products about the results of a risk assessment exercise carried out by the Health Protection Agency (HPA). Do you know how many patients are at risk ?

In September 2004, the HPA conducted a patient notification exercise about the possible transmission of vCJD through blood products. The CJD Incidents Panel made recommendations to the Department based on a risk assessment carried out by Det Norske Veritas Consulting. The

risk assessment was considered by the Spongiform Encephalopathy Advisory Committee, the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, and the Committee on Safety of Medicines. Selected groups of patients, which included haemophilia patients, were notified about the results of this risk assessment exercise for blood products.

In developing this patient notification strategy, our key consideration was the patients themselves. The HPA worked closely with patient representatives and clinicians to ensure as far as possible the best support for patients. However, it is very uncertain whether any recipients of plasma products could have become infected with vCJD via this route.

The exercise to collect information on the number of haemophilia patients considered to be at risk of exposure to plasma products which may be implicated with vCJD is on-going. This is a complex exercise and it will be some time before the United Kingdom Haemophilia Centre Doctors' Organisation can provide this data.

NICE-recommended treatment for hepatitis C

NICE published guidance on the use of combination therapy (pegylated interferon with ribavirin) for the treatment of hepatitis C in January 2004, which is currently being reviewed in relation to the treatment of mild chronic hepatitis C. Further guidance is expected from NICE later this year.

We have placed statutory obligations on the NHS to implement NICE recommendations and funding for NICE-recommended treatments is included in allocations to Primary Care Trusts.

There may be a variety of reasons why countries such as France and Germany appear to treating more hepatitis C patients than here such as a higher hepatitis C prevalence in those countries and a greater professional and public awareness of the infection. We are funding a national hepatitis C awareness campaign for health care professionals and the public to reduce the number of undiagnosed infections so that those found to be infected can be referred for specialist assessment and treatment, if needed.

Hepatitis C Action Plan for England

- We recognise the importance of hepatitis C as a public health issue. This is why we published our *Hepatitis C Action Plan for England* which sets out a framework for the Department, the NHS and others to improve the prevention, diagnosis and treatment of hepatitis C.

- In addition, alongside unprecedented increases in NHS funding, we have provided central support for key aspects of implementation of the *Hepatitis C Action Plan for England,* such as raising awareness and improving epidemiological surveillance.

- Raising health care professional and public awareness of hepatitis C is a key factor in improving prevention, diagnosis and treatment. This is why we are running a national hepatitis C awareness campaign.

- The awareness campaign, launched in 2004, has so far included:

    - the launch of a hepatitis C information pack that has gone to all GPs and practice nurses - this includes guidance on testing for hepatitis C;

    - a new NHS hepatitis C awareness website;

    - a new national hepatitis C freephone information line;

    - features in health care professional journals, regional/national newspapers and consumer magazines;

    - advertorials in consumer magazine;

    - On-line advertising on Friends Reunited;

    - provision of a hepatitis C briefing pack for media agony aunts, doctors and the Guild of Health Writers;

    - an innovative photography exhibition of portraits of people with hepatitis C that was launched in Leicester Square in March and is touring regional cities using local patient case studies – Nottingham, Brighton, Bristol, Newcastle, Plymouth, Sheffield, Reading, Leeds, Liverpool and Manchester. The exhibition is due to visit several more cities during April and May;

    - A health promotion resource for young offenders – a CD that combines music with messages about hepatitis C – was launched last month.

- It is encouraging that the awareness campaign appears to be leading to increased diagnosis of hepatitis C, which is one of its key aims. We are keeping

the nature and scale of the awareness campaign under review. We will consider the need to strengthen it, if necessary.

- Responsibility for implementation of the Hepatitis C Action Plan at the local level lies with Primary Care Trusts and their local partners. They are best placed to assess what is needed in their areas. We have asked Strategic Health Authorities to ensure that local arrangements are in place to provide appropriate services.

- There have been unprecedented increases NHS funding in recent years, most of which has been devolved to the local level, as the planning and provision of local services is best determined by local NHS organisations.

- We welcome the Health Protection Agency's (HPA) first annual report on hepatitis C (13 December 2005). It provides useful information for those involved in implementing the *Hepatitis C Action Plan for England*. It provides a baseline against which to monitor progress in future years.

Hepatitis C infected health care workers

- We have issued guidance to the NHS (August 2002) to protect patients from the risk of hepatitis C infection being transmitted during invasive (exposure prone) procedures[1]. This guidance, which is based on expert advice from the Advisory Group on Hepatitis, follows 5 incidents reported in the UK in which 15 patients have been infected with hepatitis C by infected health care workers during such prone procedures.

- The guidance restricts health care workers who are known to be infected with hepatitis C from carrying out exposure prone procedures following 15 reported health care worker to patient hepatitis C transmissions in the UK. It also recommends testing of health care workers who are about to start careers or training that rely on the performance of exposure prone procedures and health care workers who believe that they may have been exposed to infection.

- Hepatitis C infected health care workers who are treated successfully with antiviral drug therapy (i.e. are hepatitis C virus RNA negative 6 months after the course of treatment has ended) will be able to return to performing exposure prone procedures at that time (subject to a further check 6 months later).

- Hepatitis C testing of most health care workers is unnecessary, as they do not carry out procedures (exposure prone procedures) that pose a risk of infection to patients. Department of Health guidance on hepatitis C infected health care workers advises that risk of transmission does not warrant testing all health care workers who carry out invasive (exposure prone) procedures.

- The Department published a consultation document in 2003 entitled *Health Clearance for Serious Communicable Diseases: New Health Care Workers* that proposes that health care workers who will carry out exposure prone procedures should be cleared for hepatitis C. A final version is due to be published in the next few months.

[1] Exposure prone procedures are those in which there is a risk that injury to the health care worker could result in exposure of the patient's open tissues to the blood of the health care worker. Such procedures occur mainly in surgery (including some procedures in minor surgery carried out by GPs), obstetrics & gynaecology, dentistry and some aspects of specialist nursing and midwifery.

Haemophilia and Hepatitis C

Haemophilia

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

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

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

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

Hepatitis C infection

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

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

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

Many patients who acquire hepatitis C will live out their normal lifespan. Hepatitis C infection is cleared in about 20-40% of those infected, but persists in about 60-80% to become chronic infection. Some of those with chronic infection will have only mild liver damage, many with no obvious symptoms. About 20% of patients with chronic

infection develop cirrhosis after 20-30 years. Of these, about 1-4% per year will develop liver cancer.

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

Hepatitis C treatment

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

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

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

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

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

Hepatitis C Action Plan for England

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

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

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

A number of funding streams will support the Action Plan. A major component has been included in PCT allocations to support the National Institute of Clinical Excellence (NICE) recommended combination drug treatments for moderate/severe liver disease caused by hepatitis C. Other activities that are being supported include raising professional and public awareness, improving surveillance, offering hepatitis C testing to injecting drug users and the work done by the voluntary sector.

Funding for NICE recommendations is included in PCTs' allocations and there is also a statutory obligation on the NHS to implement NICE recommendations so that clinical decisions made by doctors involving NICE recommended treatments or drugs can be funded.

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

On 13 December 2005, the HPA published the first annual report on hepatitis C in England. The HPA report arises from the Action Plan. It presents data on the extent of infection and related liver disease in 2004 and summarises current action. It is intended as a baseline report against which future developments can be compared, and as a background resource for commissioners and providers in implementing the Action Plan -http://www.hpa.org.uk/hpa/publications/hepC_2005/default.htm

Hepatitis C awareness campaign

Publication of the Hepatitis C Action Plan coincided with the launch of a health care professional awareness campaign. A hepatitis C information pack for health care professionals was sent to all GPs and practice nurses in England in July 2004, and other relevant health professionals. The pack provides essential information for health care professionals about hepatitis C, and is designed to assist them in offering advice about hepatitis C and testing to patients who may have been at risk of infection. It also includes a patient leaflet and poster. The information pack can be downloaded from the NHS hepatitis C awareness website for professionals and the public: http://www.hepc.nhs.uk

The professional awareness campaign is being followed by a public awareness campaign to increase public awareness of hepatitis C, how to avoid the risk of infection, testing for hepatitis C and treatment. The launch of the campaign on 8 December 2004 marked the introduction of a new hepatitis C telephone information line **0800 451451**. Its remit is to provide information, advice and referrals (e.g. to specialist voluntary/community organisations) to callers concerned about hepatitis C. It is designed to be a route for confidential, personal and sensitive one-to-one communication and will complement the existing NHS hepatitis C awareness website and the more general service offered by *NHS Direct*. The information line is operated by the providers of the national sexual health, drugs and alcohol telephone lines.

The public awareness campaign will use a range of methods for raising awareness e.g. features in national press and consumer magazines using case studies, where appropriate; advertorials; leaflets and posters; and an innovative photography exhibition of portraits of people with hepatitis C that was launched in Leicester Square, London in March 2005 and is touring regional cities using local patient case studies.

Haemophilia Care and treatment

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

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

- organise and provide advice on home therapy programmes.

In addition, 18 Comprehensive Care Centres (CCC) in England provide:

- prophylactic treatment programmes
- 24 hour advisory service to haemophilia centres
- specialist consultant service for all surgery including orthopaedic and dental, and specialist consultant service for infections such as HIV and hepatitis, and for genetic, and social care and any other counselling services
- a reference laboratory service for haemophilia centres, together with advice
- educational facilities for staff to promote optimal care
- co-ordination of meetings and undertaking research programmes, including clinical trials.

Haemophilia Society

The Society currently receives core funding through the DH Section 64 Grant Scheme. The Society receives £100k per annum.

Background Briefing

Background to the Review of Papers

Almost all haemophilia patients treated with blood products in the 1970's and early 1980's were infected with hepatitis C, and or HIV. Lord (David) Owen, a Health Minister in the 1970s, has publicly suggested that this might have been avoided had the UK achieved self sufficiency in blood products.

Lord Owen has said that when he was Minister for Health he allocated special finance of up to £500,000, about half of which would be recurring, in order to increase the existing production of Factor VIII (the treatment for haemophilia patients). He claims that this policy was announced in Parliament but was not fulfilled by the Department of Health. The consequences was that plasma was imported from other counties such as USA. However the serious risks of Hepatitis C, only become apparent after full characterisation of the virus in 1989 and this is not a problem unique to the UK.

In 2002, Yvette Cooper the then Health Minister asked officials to undertake an internal review of the surviving documents, roughly between 1973-1985 , to produce a chronology of events and an analysis of the key issues. The actual analysis was extended to 1991, the year that a test to screen blood donations for hepatitis C was introduced in the UK. Without this it was considered difficult to answer any detailed accusations levelled against the Department by Lord Owen and others.

CONCLUSIONS

The review of papers concludes that about 3000 patients with haemophilia treated with blood products supplied by the NHS in the 1970's and early 1980's were infected with either Hepatitis C and or HIV. Available evidence suggests that during the 1970's and 1980's the Government pursued the goal of self-sufficiency in factor VIII, in line with the World Health Organisation and Council of Europe recommendations.

In 1975, the Government allocated £0.5m, about half of which was recurring, to the NHS in order to increase plasma production. At the time this was thought adequate to achieve self-sufficiency in factor VIII by 1977. However, the demand for factor VIII in the UK increased dramatically in the late 1970's. This was because of i) longer life expectancy in patients with haemophilia ii) the increased provision of home therapy and iii) the trend towards the use of factor VIII for the prevention, as well as the management of bleeding episodes. Therefore despite the increase in both the plasma collected by the Regional Transfusion Centres (RTCs) and the amount of factor VIII produced by the NHS, it was still necessary to import factor concentrates.

The review considered the emerging and developing understanding of the seriousness of Non-A Non-B Hepatitis (NANBH; later known as Hepatitis C). It concludes that the prevailing medical opinion in the late 1970's and early 1980's was that NANBH was perceived as a mild, and often asymptomatic disease, and the advantages of treatment with factors VIII concentrates were perceived to far

outweigh its potential risks. This view was supported by patients, their clinicians, and the Haemophilia Society.

From the early 1980s, Bio Products Laboratory (BPL) a plasma fractionation plant attempted to devise an effective viral inactivation procedure. Progress was hindered by the heat sensitivity of factor VIII and lack of an appropriate animal model to investigate the efficacy of heat-treated products. However, by the time it became apparent that NANBH was more serious than initially thought, by the mid to late 1980's all domestic and imported concentrates were already routinely heat-treated and therefore conferred little risk of infection with NANBH or HIV.

The analysis of the review of papers confirms that:

We do not believe that anyone acted wrongly in the light of the facts that were available to them at the time. The RTC's and BPL did their best to ensure that blood products were as safe as possible. Clinicians acted in the best interest of their patients.

The more serious consequences of hepatitis C, which may take 20-30 years to develop, only became apparent after full characterisation of the virus in 1989 and the development of reliable tests for its recognition (in 1991).

Viral inactivation processes, heat treatment and screening tests were developed and introduced as soon as practicable (and in line with developments in other countries) whilst continuing to maintain essential supplies of blood and blood products.

There was no alternative treatment which could have been offered to haemophiliacs at that time.

Self sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. Blood products are made with pooled plasma. Even if the UK had been self sufficient, the prevalence of hepatitis C in the donor population would have been enough to spread the virus throughout the pool. That is why the infection of haemophiliacs with hepatitis C is a world wide problem

Risk management and the precautionary principle are key issues for the Health Service today. We are committed to better communication between clinicians and patients – especially on risk.

DESTRUCTION OF PAPERS

The review does not address comments by Lord Owen about the destruction of papers from his Private Office. There will be accusations that the review is incomplete because of the destruction of past papers. However, the report does state that the review is based on surviving documents from 1973.

During the HIV litigation in the 1990's many papers from that period were recalled. We understand that papers were not adequately archived and were unfortunately destroyed after the litigations. In addition, we have established that many other important documents, mostly papers and minutes of the Advisory Committee on

Virological Safety of Blood were destroyed in the 1990's. This should not have happened. During the discovery exercise for the Hepatitis C litigation in 2000 it emerged that many files were missing. An internal investigation was undertaken, by colleagues in Internal Audit, to establish why files were destroyed.

This concludes that, "The decision to mark the files for destruction was taken at a time of major organisational change in the Department, ie: the implementation of the Functions and Manpower Review (FMR), which resulted in two experienced members of staff leaving the relevant section. We believe that the upheavals of the FMR process probably resulted in either

- a delegation of responsibilities without proper instruction, or
- an assumption of responsibility without proper authorisation".

DELAY IN CONCLUDING THE REVIEW

Due to a number of pressures, there has been a long delay in finalising the review report commissioned in 2002. A draft report was submitted to the Blood Policy Team in January 2003 following a three month assignment by a DH Official. However there were a number of outstanding issues which had to be resolved before the report could be finalised and submitted to Ministers.

There were a number of unsubstantiated statements in the report which had to be checked for accuracy, a lengthy list of references to the report had to be drawn up and an executive summary to be included. In 2004, officials commissioned independent consultants to analyse the papers and finalise the report. We have also consulted with colleagues in the devolved administrations, BPL, National Blood Service and some clinicians for factual accuracy.

REFERENCES

The report contains a substantial number of references to published scientific papers but also to internal documents. We are currently considering a request under the Freedom of Information Act to release all the references.

RESPONSE FROM THE HAEMOPHILIA SOCIETY

The Haemophilia Society has been extremely critical of the Self Sufficiency Report. A copy of a recent letter from Margaret Unwin, the Chief Executive is attached at Annex A.

Review of Internal Trawl of Papers on Self Sufficiency in Blood Products

Aims of the Review

(i) Review documents held by the Department and for the period 1973 to 1991, identify key documents and produce a chronology of events. Interviews with officials, clinicians and others active in this area at the time may be necessary to build up a full picture.

(ii) Produce an analysis of the key issues, including:

- the development of policy on UK self sufficiency in blood products, the factors that influenced it and the reasons why it was never achieved;

- the ability of NHS blood products fractionators to produce the volumes of product required;

- the evolving understanding of the viral risks associated with pooled blood products, both domestically produced and imported, and how this influenced policy;

- the developing technologies to enable viral inactivation of blood products and the timing of their introduction in the UK.

(iii) Summarise these findings in a report for Ministers.

Press Release

Review published on infected blood products

Published:
Monday 27 February 2006
Reference number:
2006/0076

A review in to how patients were infected with Hepatitis C and HIV through contaminated blood in the 1970s and early 1980s, was published today.

This review focussed on documents from 1973 to 1991 to produce a chronology of events and analysis of the key decisions which were taken at that time. The question of why England and Wales did not achieve a policy of self-sufficiency in blood products and whether this would have avoided infection rates, was given particular attention within the review.

The report concludes that:

- Nobody acted wrongly in the light of the facts that were available to them at the time.
- Every effort was made by the Government to pursue self sufficiency in blood products during the 1970s and early 1980s
- The more serious consequences of Hepatitis C, only became apparent in 1989 and the development of reliable tests for its recognition in 1991.
- Tests to devise a procedure to make the Hepatitis C virus inactive were developed and introduced as soon as practicable
- Self sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. Even if the UK had been self sufficient, the prevalence of hepatitis C in the donor population would have been enough to spread the virus throughout the pool.

Public Health Minister Caroline Flint said:

"We have great sympathy for those people, and their families, who were infected with hepatitis C and HIV from contaminated blood products in the 1970s and early 80s.

"The review based on the available evidence, concludes that clinicians acted in the best interest of their patients in the light of the evidence available at the time. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in technology, which could not have been implemented before this time.

Related links
Self-sufficiency in blood products in England and Wales: A chronology from 1973 to 1991
Notes to editor

1. The Review of Papers can be found at the link above.
2. The Review was set up in 2002 by Public Health Minister Yvette Cooper.

3. The Skipton Fund was set up in July 2004 to administer the UK-wide ex gratia payment scheme for people infected with Hepatitis C through contaminated NHS blood and blood products. The Macfarlane Trust was set up in 1988 to provide financial assistance for haemophiliacs infected with HIV through contaminated blood products.
4. Media enquiries only to Sophie Coppel at the Department of Health Media Centre on 020 7210 5707. For public enquiries contact the public enquiries line on 020 7210 4850.

World Haemophilia Day

19 April (the date this PQ is answered) marks World Haemophilia Day. Lord Morris of Manchester will be hosting a lunchtime reception, between 12 noon – 2pm on the House of Lords Terrace.

Bayer Healthcare are sponsoring the event, which will be attended by patients, carers, clinicians, Haemophilia Society staff and politicians. PS(PH) will be attending the event and has agreed to make a short speech.

Lord Jenkin of Roding

Lord Jenkin has recently become engaged in the issues concerning haemophilia patients infected with blood products.

In December 2004, we received correspondence from Lord Jenkin who asked for access to papers going back to the period when he was Secretary of State for the DHSS (May 1979 - Sept 1981) on the issue of haemophilia patients infected with Hepatitis C through contaminated blood products. This letter was prompted by a letter Lord Jenkin received from GRO-A a haemophilia patient infected with hepatitis C and HIV through blood products. Under Civil Service Guidance, former Ministers are allowed reasonable access to the papers of the papers of the period then they were in office. Lord Jenkin received two replies from Lord Warner on 27 January and 10 March 2005 about the issue of haemophilia patients infected with hepatitis C and DH record keeping.

Following a meeting with Sir Nigel Crisp on 13 April 2005, we were asked to identify files on this issue so that Lord Jenkin could go through the papers. We contacted both the Departmental Records Office and the National Archives to retrieve files for the period 1979 -1981. There were a limited number of files going back to this period, unfortunately many of the files from that period have been destroyed. However, we made available those files which were held, and agreed to releasing some documents which Lord Jenkin indicated that he would like to make available to GRO-A

Lord Jenkin has now released these documents to GRO-A but has notified him about the fact that a number of files have been destroyed. This generated some media interest, accusing officials of a "cover up".

Lord Jenkin wrote again to Sir Nigel Crisp, on 25 October 2005, indicating that he would like a further meeting to explore why files for the 1970's and 1980's were destroyed. Sir Nigel replied on 1 December, declining his request for a meeting, however the response set out fully our understanding of why papers had been destroyed. We understand that a copy of this letter has been made available to members of the Haemophilia community.