SELF SUFFICIENCY IN BLOOD PRODUCTS IN ENGLAND AND WALES

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BACKGROUND

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.

HAEMOPHILIA CAMPAIGN

There are several haemophilia pressure groups who have campaigned for compensation and a public inquiry into why haemophilia patients received infected blood products. They argue that the Government and some clinicians knew about the risks, yet allowed infected products to be used in their treatment. Publication of this report is unlikely to satisfy these groups. They will continue to make demands for a public inquiry.

KEY POINTS

- 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.

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 see no reason why the latter cannot be released on request but for reasons of sheer volume, we have resisted supplying a complete set of documents with publication of the report.

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. It is estimated that around 1,240 people with haemophilia were infected with HIV, many were co-infected with Hepatitis C. Around 3,000 haemophilia patients were infected with Hepatitis C.

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.

Bull Points

- 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.

- 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.

Elephant Traps

- Self-sufficiency turned out to be a continually moving target which was not achieved.
- Additional funding was not made available to match the growing increase in the use of clotting factors.
- Some patients may not have been informed about the risks.
- Clinicians left to their own devices.
- The review cannot be complete, when DH has owned up to the fact that papers from the 1970's and 1980's have been destroyed.

Q&A

SELF SUFFICIENCY IN BLOOD PRODUCTS

Lord Owen has said publicly that when he was Minister for Health he allocated "millions of pounds" to make the UK self sufficient in clotting factors within 18 months. This commitment was announced in Parliament but was not fulfilled by the Department of Health.

The review indicates that the resources (£500k, initially half of which would be recurring) promised by Lord Owen 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 Factor VIII concentrate and 100,000 donations for cyroprecipitate. This target was achieved within the 2-year timescale envisaged by Lord Owen. However, given the rapid growth in demand for these products at the time, this was not enough to achieve self-sufficiency.

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.

How much funding was made available?

£500k, about half of which would be recurring was allocated to Regional Transfusion Centres to increase production of Factor VIII. This allocation was linked to a target of 275,000 blood donations to be used annually for the preparation of Factor VIII concentrate and 100,000 donations for cryoprecipitate.

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

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 import 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.

What about plasma sourced from prisons in Arkansas?

We have been advised by BPL, that to the best of their knowledge 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.

At the time (from the 1970s – 1980s), we were not self sufficient in blood products and 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.

Repeat point above about the transmission of the Hepatitis C Virus.

Why did Ministers commission this review?

Lord Owen has said that there was a failure to implement a commitment he made in the 1970s to make the UK self-sufficient in clotting factors for haemophiliacs, when he was Health Minister. Critics claim that the failure to implement this policy resulted in patients being infected with plasma imported from the US in the 1970's. Ministers agreed (in 2002) to a review of the surviving papers between, roughly, 1973-[1991] to establish the facts and put together a chronology of events.

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.

Why has it taken so long to conduct the review?

We regret that it has taken a long time to finalise the report, however there have been a number of other pressing issues which officials have had to give priority to. Ministers are pleased that the report has been completed and have agreed to publish it.

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.

Where can I can copies of the report?

The report is available on the DH website at www.dh.gov.uk

Will you make the references public?

Published references are already in the public domain. We will make available any requests for internal documents on request.

Note for internal use: there are two references which we are trying to track down. These were missing from the folder of references put together by the consultants.

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.

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.

When did a test for hepatitis C become available?

The test used to detect Hepatitis C was introduced in the UK in September 1991. The development and introduction of this test marked a major advance in microbiological technology and could not have been implemented before this time.

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.

What is Factor VIII?

Factor VIII is used in order to produce a firm clot and stop the bleeding.

<u>IF PRESSED:</u> 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.

<u>IF PRESSED</u>: 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.

What is BPL

The Bio Products Laboratory (BPL) is part of NHS Blood and Transplant. It is a factory producing manufactured human plasma derivatives (eg immunoglobulins and clotting factors) for the NHS. Since the introduction of the NHS internal market it has operated on a commercial basis competing directly with a handful of major multinationals for its share of the NHS market.

BPL collections

UK plasma was provided to BPL from the National Blood Centres, previously the Regional Transfusion Centres (RTC). Each donation had a bar code identifying the blood collection centre it was sent from. BPL was not provided with donor information and therefore has no way of tracing these donors. The donor information is/was held by the National Blood Services (NBS/RTC).

HEPATITIS C EX-GRATIA PAYMENT SCHEME

What is the Government doing to compensate people who have contracted hepatitis C through blood products or blood transfusion?

An ex gratia payment scheme (known as the Skipton Fund) was set up in 2004 for people inadvertently infected with hepatitis C as a result of NHS treatment with blood or blood products.

Every person in the UK who was alive on the 29 August 2003 and whose hepatitis C infection is found to be attributable to NHS treatment with blood or blood products before September 1991 is eligible for the payment. There are two levels of payment. £20k is payable to patients infected with hep C before September 1991. An additional £25k will be paid if the claimant has developed cirrhosis, liver cancer or if they require a liver transplant.

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.

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.

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.

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.

HEPATITIS C ACTION PLAN FOR ENGLAND

Why isn't the Government doing more to tackle hepatitis C?
We recognise the importance of hepatitis C as a public health issue, as highlighted in the Chief Medical Officer's infectious disease strategy, Getting Ahead of the Curve, and the need for effective prevention, testing and treatment.

This is why we have set a clear national framework for action to tackle hepatitis C in the Hepatitis C Action Plan for England. 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 of hepatitis C and improving epidemiological surveillance.

How is implementation being monitored?

Responsibility for implementation at the local level is the responsibility of 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. On a national level, the Health Protection Agency will be tracking the impact of some aspects of the Action Plan through epidemiological surveillance.

Why hasn't the Government provided ring-fenced funding for implementation of the Hepatitis C Action Plan for England?

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.

What is the Government doing to raise awareness of hepatitis C?

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 funding ongoing health care professional and public awareness campaigns. Local awareness-raising on the back of the DH campaign will be crucial.

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;
- web based 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 2005 and is touring regional

cities using local patient case studies – Nottingham, Brighton, Bristol, Newcastle, Plymouth, Birmingham, Sheffield and Leeds visited so far. Several more cities to be visited in 2006;

- A health promotion resource for young offenders – a CD that combines music with messages about hepatitis C and other blood-borne viruses – was launched in November 2005.

Shouldn't the awareness campaign be more high-profile?

We are keeping the nature and scale of the awareness campaign under review. We will consider the need to strengthen it, if necessary. It is encouraging that the awareness campaign appears to be leading to increased diagnosis of hepatitis C, which is one of its key aims.

Why aren't we treating more patients with hepatitis C as some other European countries appear to be doing?

There may be a variety of reasons for differences in the apparent numbers of patients treated in this country compared to other parts of Europe, such as a higher hepatitis C prevalence in those countries and better professional and public awareness. One of the aims of the Hepatitis C Action Plan for England is to increase professional and public awareness so that undiagnosed infections are reduced and those infected referred for specialist assessment and treatment, if indicated.

NICE has issued guidance to the NHS on interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C in January 2004. The NHS has a statutory obligation to provide NICE-recommended treatments, and funding for this is included in allocations to Primary Care Trusts.

What is being done to prevent hepatitis C infection in injecting drug users?

The Hepatitis C Action Plan for England highlights the need for intensified action to prevent new infections in injecting drug users. This is why we have funded the National Treatment Agency for Substance Misuse (NTA) to carry out a national audit of needle exchange schemes, which will be used to inform future provision and monitoring. In 2006/2007, the NTA and Health Care Commission are planning to carry out a "National Improvement Review" of harm reduction services for injecting drugs user against established quality criteria.

In 2005/2006, it is estimated that over £500m will be spent on drug treatment. All Drug Action Teams will get further substantial increases in their allocations between 2006 and 2008. The extra funding in the last few years has led to record numbers of drug users engaging in treatment and an increase in the numbers successfully completing treatment. This is good news, as there is clearly a link between getting people into treatment and reducing the risk of blood-borne virus transmission.

What about injecting drug use in prisons?

There are several initiatives underway in prisons to reduce the risk of hepatitis C transmission from injecting drug use, including guidelines on the clinical management of drug users in prisons; the introduction of disinfecting tablets for the cleansing of injecting equipment for prisoners who continue to inject drugs illicitly whilst in prison; and from April 2006, Prison Health will introduce a national programme of improved assessment and management of substance misusers so that treatment is based on need, including access to needs-based treatment, such as substitution programmes.

What is being doing to increase diagnosis of hepatitis C?

We have issued the NHS with clear guidance on hepatitis C testing, backed up by an awareness campaign for health care professionals and the public, including a new NHS hepatitis C awareness website and a national hepatitis C freephone information line.

How will you monitor progress on increasing hepatitis C diagnosis?

We have set a national outcome indicator of the total number of laboratory diagnoses of hepatitis C reported to the Health Protection Agency - we would expect to see this number increasing over coming years as more people are tested. It is encouraging that the awareness campaign appears to be leading to increased diagnosis of hepatitis C, which is one of its key aims.

Why don't we have 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.

Why don't we have universal antenatal screening for hepatitis C?

The Government's Advisory Group on Hepatitis and the National Screening Committee do not currently recommend routine antenatal screening for hepatitis C as, unlike HIV or hepatitis B, there are no well-proven or safe means of reducing the risk of transmission of hepatitis C from mother to baby, and there are currently no drug therapies licensed for treating children. This is line with US guidelines, those of the World Health Organisation and a consensus statement produced by the European Association for the Study of the Liver.

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.

What are you doing to minimise the risk of vCJD?

Since the theoretical possibility of transmission of vCJD by blood and blood products was first considered, a range of precautionary measures have been introduced to minimise the risk to vCJD transmission:

-From December 1997, blood components, plasma products or tissues obtained from any individual who later develops vCJD, have been withdrawn/recalled.

-In July 1998, we announced that plasma for the manufacture of blood products, such as clotting factors, would be obtained from non-UK sources.

-From November 1999, white blood cells (which may carry a significant risk of transmitting vCJD) have been removed from all blood used for transfusion.

-In August 2002 we announced that fresh frozen plasma for treating babies and young children born on or after 1 January 1996 would be obtained from the USA. In July 2005, this was later extended to all children up to the age of 16.

- Since April 2004 individuals who have had a transfusion of whole blood components since January 1980 are excluded from donating blood. This has been extended to include apheresis donors and donors who are unsure if they had previously had a blood transfusion (August 2004).

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.