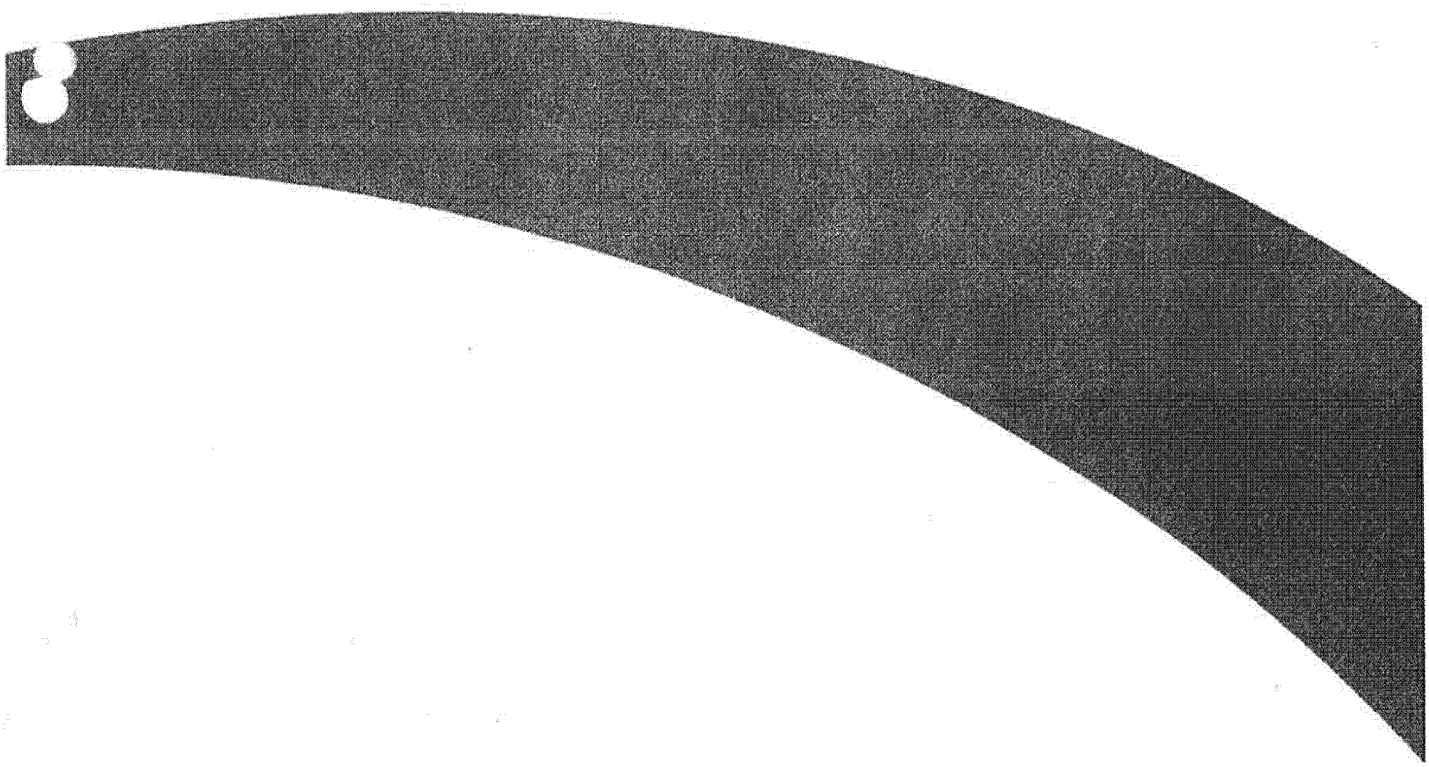

Government response to Lord Archer's Independent report on NHS supplied contaminated blood and blood products

First published 20 May 2009
Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

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Executive summary

This document sets out the Government's response to the report and recommendations of Lord Archer's independent inquiry, published on 23 February 2009. The inquiry examined the events of the 1970s and early 1980s, which resulted in the infection of many patients with HIV and/or hepatitis C through NHS treatment with blood and blood products.

Government Response to Lord Archer's Independent Report on NHS Supplied Contaminated Blood and Blood Products

This document sets out the Government's response to the report of Lord Archer's independent inquiry, published on 23 February 2009. The inquiry examined the events of the 1970s and early 1980s, which resulted in the infection of many patients with HIV and/or hepatitis C through NHS treatment with blood and blood products.

This Government acknowledges and deeply regrets the tragic outcome for many patients and their families, who have suffered as a result of the very treatments which should have transformed their lives for the better.

We welcome this report. Lord Archer and his fellow inquiry members have undertaken a comprehensive and detailed review bearing in mind the difficulty of examining events which took place over 20 years ago.

Our commitment to making information available about past events

Efforts to make properly-informed assessments of the relevant events and decisions taken throughout the period in question, that is the fifteen year period 1970 to 1985, are constrained by the incompleteness of the documentary record, for which this and former governments have apologised. We acknowledge that the loss or misplacement of some official documents has led to suspicion that we have 'something to hide'. We have been very open about these mistakes, and have made every effort to collect and release the relevant papers. Over 5,500 documents have already been placed on the Department of Health website, and we have said that where we identify any further relevant documents, they will also be released, subject to safeguards such as not releasing personal data. Further papers have been identified, which are being released today. We do not believe they add to our knowledge of events in those years. However, we are releasing them in keeping with our commitment to release, in line with

the Freedom of Information Act, all relevant documents that we hold on the safety of NHS blood and blood products from 1970 to 1985. We are pleased to see that Lord Archer discovered no evidence of malicious destruction of relevant records.

Assessing the evidence

The introduction in the 1970s of clotting factors made from human plasma as a treatment for haemophilia vastly improved the quality of patients' lives. However, during the late 1970s and early 1980s, the majority of haemophilia patients in regular treatment received clotting factors infected with HIV and/or hepatitis C before it became possible to detect or destroy these viruses. This problem affected many countries.

Internationally, at that time, experts were divided in their views about the infection risk associated with blood, especially clotting factors which were made from pooled donations. There were a few who advised that the risk was worryingly high. However, the prevailing medical opinion did not support this view. Hepatitis C was then thought to be a mild and often asymptomatic infection. We now know that a small proportion of chronically infected people may develop severe liver disease.

There has been criticism of past Governments' management of the objective to achieve self-sufficiency in blood products in England and Wales during the 1970s and much of the 1980s. Funds were allocated in 1975 to increase plasma production, but proved insufficient as demand for clotting factors increased dramatically during the next few years because of the success of the new treatments. It also became clear in 1979 that the Blood Products Laboratory required significant upgrading and, in light of the greater demand, expansion to meet the goal of self-sufficiency, and it remained necessary to continue to import clotting factor concentrates. The evidence shows that many doctors and patient representatives supported importation, on the basis that assessment of the balance of risks at that time favoured continued availability of treatment. Some of those representing patients with haemophilia felt there were dangers in absolute self-sufficiency, primarily because reliance on a sole supplier might have led to a shortfall, possibly endangering the lives of patients.

The Department of Health reviewed its surviving documentary evidence from the period when the decision to pursue self-sufficiency was made available, and has found no evidence to

suggest that the hepatitis C outbreak in the late 1970s and early 1980s in this country could have been avoided if self-sufficiency had been achieved. By the early 1980s there was evidence that commercial (US) and UK plasma concentrates carried a similar risk of transmitting hepatitis. The review[i] was published in 2006, and is available on the Department of Health's website

In 2006 the Department commissioned a further review of all the documents held between 1970-85 relating to non-A, non-B hepatitis. These mainly refer to the UK's drive to achieve self-sufficiency in blood products, to the reorganisation of the Blood Products Laboratory, and to measures taken to safeguard the blood supply and blood products from contamination by HIV/AIDS and viral hepatitis. A copy of the review report was published in May 2007, together with all the references[ii].

Reducing the viral risks from blood - where are we now?

The introduction of heat treatment in 1985 removed the risk of both HIV and of hepatitis from blood products. Testing of all donations for HIV was introduced in 1985. Testing for hepatitis C was introduced in 1991 when suitable, effective tests became available. An antibody test was developed in 1989, but was not approved for use in the UK because it was both insufficiently specific and sensitive.

Since the mid 1980s the measures in place to assure the safety and quality of human blood and blood components and blood products manufactured from them have developed significantly. All blood donations are now routinely tested for HIV and hepatitis viruses. European Directive 2002/98/EC sets standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components.

Blood products, such as clotting factors, which are manufactured from pooled plasma donations, are regulated in accordance with the Community code for medicinal products as defined in Directive 2001/83/EC as amended.

Following collection from previously screened donors, individual donations are tested for the presence of viral markers. The donations then contribute to a plasma pool, which is also tested for viral markers.

Upon completion of manufacture, blood products are tested for compliance with specification by the manufacturer. In addition, before final release to the market, all batches of blood products undergo independent testing by EU 'Official Medicines Control Laboratories'

vCJD

Variant CJD remains a threat. It does not behave like a conventional (viral or bacterial) infectious agent, and there is currently no screening test available. We have implemented a series of measures to protect the blood supply, and continue to monitor the situation closely, together with our expert advisory committees.

To further reduce residual vCJD and viral risk to haemophilia patients from donor-sourced products, we have made synthetic clotting factors available for all patients for whom they are suitable. We are providing £46million to the NHS in 2009/10 to help fund the purchase of clotting factors. The latest versions of synthetic clotting factors contain no human or animal derivatives and are therefore free from the risk of blood borne infection. Since their introduction into clinical practice world wide, there have been no confirmed reports of transmission of infectious agents by these products.

Support and services for those affected - the future

Previous Governments have introduced and funded ex-gratia payment schemes to provide financial relief for those affected. Those schemes have paid out a total of £142million to patients and their dependents since 1988.

We are committed to ensuring that people with haemophilia, and others who have been infected with hepatitis C and/or HIV from blood and blood products are well cared for, supported in their communities and fully informed about how best to look after their health. We have carefully considered Lord Archer's recommendations, and are responding in as positive a way as possible at the current time, bearing in mind the constraints on public funds.

Recommendation 1 - A statutory committee to advise the Government on the management of haemophilia

We understand Lord Archer's desire to establish a committee by statute to advise Government on the management of haemophilia in the United Kingdom. Our view is that it is better to build on existing arrangements and expertise, rather than risk disrupting or duplicating those arrangements via legislation.

We therefore intend to build on the existing UK-wide partnership of the Haemophilia Alliance, which consists of patients, haemophilia doctors, and others involved in their care. The Alliance is jointly chaired by the Haemophilia Society and the haemophilia doctors' organisation. We will invite the Alliance to meet with Government twice yearly and the Department of Health will host, and fund, these meetings. This will enable the Government to receive advice from the Alliance on matters relating specifically to the care of haemophilia patients. We will also ensure strong links are made between the Alliance and the independent advisory committee on the Safety of Blood Tissues and Organs (SaBTO).

Representatives from the Health Departments in Scotland, Wales and Northern Ireland will be invited to participate in this new formal arrangement.

Recommendation 2 - Haemophilia patients and their partners to receive any tests recommended by the statutory committee

Any new relevant tests for transfusion transmitted infections would be offered to haemophilia patients, and their partners, in light of advice from the Haemophilia Alliance.

Recommendation 3 - All blood donors to receive the same tests (recommended by the statutory committee)

The independent advisory committee on the Safety of Blood, Tissues and Organs already advises on tests for blood donors and will continue to do so.

Recommendation 4 - Free prescriptions and free access to other services "not freely available under the NHS including...GP visits, counselling, physiotherapy, home nursing and support services" for those infected

The first part of this recommendation is in line with the Government's policy intentions on prescription charges in England. The Prime Minister announced last year that the Government intends to progressively phase out prescription charges in England for patients with long term conditions. We have asked Professor Ian Gilmore, President of the Royal College of Physicians, to undertake a review of prescription charges in England that will consider how to implement and phase in the Prime Minister's commitment. The review is due to report to Ministers in the Summer. We will consider what, if any, further action is required in England in relation to this recommendation following the Gilmore review.

GP visits, counselling, physiotherapy and home nursing are already available in England under the NHS where needed.

The provision of non-residential social care services, such as domiciliary care, in England is a matter for local authorities. They have discretion over whether and how much to charge for services. However, DH statutory guidance to local authorities on charging for non-residential social care services already makes it clear that they that they should assess and take into account service users' specific needs and costs associated with their condition or disability. This would include any additional costs related to living with HIV or Hepatitis C.

Recommendation 5 - Secure future of Haemophilia Society by adequate funding

We will commit, with immediate effect, £100,000 per annum funding to the Haemophilia Society for the next five years. The Society is also due to receive £80,000 funding from the Department of Health over the next two years, and they will continue to be eligible for project-specific grants, along with other third sector organisations.

Recommendation 6 - Financial assistance should be increased and take the form of prescribed periodic payments.

The Macfarlane Trust and Eileen Trust provide ex gratia lump sum and discretionary payments to, respectively, haemophiliacs and others, who contracted HIV from infected blood and blood products, and their dependents. Over £45m has been paid out to date and there are currently around 600 beneficiaries.

The Government recognises Lord Archer's concern about financial relief. We therefore intend to increase the funding available to the Macfarlane and Eileen Trusts to allow them to move to a system of annual payments for infected individuals. The current average annual payment is around £6,400. We intend that, in future, payments of £12,800 per annum would be made to each infected individual, thus eliminating the need for them to make repeated detailed applications. We will also increase the funding available to the Trusts so that the Trustees can make higher payments to dependents. Payment to dependents will continue to be decided on a case-by-case basis - and left to the decision of the Trustees.

The Skipton Fund provides lump sum payments to people infected with hepatitis C from infected blood and blood products. £97m has been paid out to date to over 4000 individuals.

The Skipton Fund will continue to make payments to people infected with hepatitis C and I commit to reviewing it in 2014 when the Fund will have been in existence for ten years.

We will begin implementation immediately. We will need to amend the terms of the Trusts to permit these changes, but we will liaise with the Charity Commission and the Trusts themselves to ensure required changes to the Trust Deeds are made as quickly as possible to enable the Trusts to distribute this increased funding.

Recommendation 7 - Access to insurance by providing premiums or setting up separate scheme

The Association of British Insurers (ABI) has assured us that insurers do not treat haemophiliacs or those infected only with HIV or hepatitis C differently from people with other pre-existing conditions. In all cases, a person's insurability and level of premiums are determined through assessment of their individual risk.

The increased payments we are making available will help people infected with HIV to meet higher insurance premiums they may face.

Recommendation 8 - A look back exercise to identify any others who may be infected

We commit to funding a look-back exercise this year for patients with bleeding disorders to identify any others who may be infected. The UK haemophilia doctors' organisation has confirmed they will undertake this exercise.

References

[i] Self-Sufficiency in Blood Products in England and Wales. A chronology from 1973 to 1991. Department of Health 2006.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4130917

[ii] Review of Documentation relating to the Safety of Blood Products 1970-1985 (non-A, non-B Hepatitis)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074950