NQL 21/1

ADVICE TO MINISTERS

Minister for Health & Community Care

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

Purpose

1. To provide the additional briefing/advice requested by PS/Minister for Health and Community Care in her minute of 15 April 2005.

Priority

2. Urgent – For Minister's appearance before the Health Committee on 10 May.

Background

3. Speaking notes, lines to take and background briefing for 10 May are now included within the attached briefing pack.

Conclusion

4. That the Minister notes the content of the briefing pack.

Sandra Falconer
Health Planning & Quality
GRO-C
4 May 2005

ADVICE TO MINISTERS

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
Deputy Minister for Health & Community Care					X

PS/HD
Press Health
Douglas Campbell - Senior Special Adviser
Derek Munn – Special Adviser
Ian Gordon, Service Policy and Planning
Andrew MacLeod, Health Planning & Quality
Dr Aileen Keel, DCMO
Jan Marshall, OSSE
Sylvia Shearer, HP&Q

ADVICE TO MINISTERS

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT

Briefing Pack

Annex A - Opening statement

Annex B - Top lines

Annex C - Allegations/Lines to take

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- **(ii) FOI – new evidence**
- **(iii) Knowledge of Hepatitis C**
- **(iv) Heat treatment**
- **(v) Testing**
- **(vi) Patient information and choice**
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- **(viii) Self Sufficiency**

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Annex E - Remit and Findings of Heat Treatment report

Annex F - Timeline

Annex G - Brix note on vCJD

Sandra Falconer
Health Planning & Quality
GRO-C
4 May 2005

ANNEX A

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT
HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

HEPATITIS C

Opening statement

I welcome this opportunity to give evidence on the issues surrounding the infection of people with Hepatitis C through NHS treatment with blood and blood products.

May I first say that I have great sympathy for those affected and their families. I can understand how difficult it must be to come to terms with living with what can be a serious and distressing condition like Hepatitis C, and the knowledge that this has occurred through medical treatment. That, of

course, is why we have established the Skipton Fund scheme.

Can I also pay tribute to the role of this Parliament, and the present and previous Health Committees, for the interest they have taken in this issue. It is because of this interest that we are able here today to have this discussion.

The purpose of today's evidence is to consider whether there is now a case for an independent public inquiry to look at the reasons for the events that took place and responsibility. There have of course already been a number of inquiries – by the Scottish Executive Health Department, by this Committee, by the Lord Ross Expert Group - into different aspects of this tragedy.

We are not clear what the benefits from a further inquiry would now be. We are looking at events that took place mainly between 20 and 30 years ago. At the time these events took place, there was not an understanding of the basic science involved. There were indications of an unidentified virus which affected blood supplies, and there was a scientific debate about how important this was and the precautions which should be taken.

But, as you know, it was not until 1989 that the Hepatitis C virus was specifically identified, although heat treatment of blood concentrate products meant that these were safe from Hepatitis C from 1987, and by 1991 measures

were in place to screen blood donations and safeguard the blood supply.

All these events took place some considerable time ago. It would be very hard in my view to carry out any serious investigation and examination of the issues at this distance in time. Many potential witnesses will no longer be in the same positions, and may not have a full recollection of key events. I do not say an inquiry is impossible, but I do believe it would be difficult and unusual to carry out an inquiry after such a time lapse.

Perhaps more important, when we come to consider responsibility, we need again to take account of the state of knowledge and understanding that professionals and patients had

at the time. Maybe if we had known then what we know now this tragedy could have been avoided. But we did not. There were as I have said reasonable people who worried that something was wrong, but there was not a clear consensus of scientific opinion, at least until the later 1980s. It would be a great mistake to call for or conduct a public inquiry on the basis of 20/20 hindsight.

We also need to consider what people are looking for from a public inquiry, and what benefits would follow from it. An inquiry might bring us a greater understanding of some aspects of what happened. It might establish more clearly some roles and responsibilities. But the real question is whether there would be practical lessons that would help

us, and those affected, and improve health services in the future.

We have already taken steps to ensure as far as we can that Hepatitis C cannot now be transmitted through NHS treatment with blood or blood products. We live in a very different climate in terms of a precautionary approach to health care and openness than we did 10 or 20 years ago.

I can understand that an inquiry would offer patients and patient groups their "day in court" so to speak, an opportunity publicly to set out their position and to question those whom they believe to be responsible for what took place. I can understand that, and I do not underestimate it. But

this cannot in itself justify the time and expense involved.

Also clearly patients want to know who was responsible. They understandably want to see accountability, closure. I really do not believe this would happen. There would still be unanswered questions, and difficulty in determining where responsibilities really lay for some of the reasons I have given.

I am not sure that we could really have prevented much of what took place, and we cannot really now right the harm that was done. I do not believe an inquiry would help us, or ultimately bring real benefits for those who have to live with Hepatitis C as a result of these unfortunate events.

ANNEX B

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

HEPATITIS C

Top lines

- Infection with Hepatitis C took place at a time when the nature of the condition and its effects were not fully known. We are not convinced that a public inquiry would easily be able to establish responsibility for the events that took place, or that there are real lessons to be learned that have not already been learned;

- If there are still unanswered questions about responsibility, then a public inquiry will not offer real closure for those affected by Hepatitis C;

- We are aiming to publish as far as we can the documents which we hold. We do not believe from Freedom of Information requests or other sources that there is new evidence coming forward.

- During the 1980's hepatitis C was a suspected but unknown variant of hepatitis. It was recognised that there were risks from "nonA-nonB hepatitis" – as it was called at the time. There was clinical and scientific debate, and varying views, as to the seriousness of the risks but no clear consensus view that this was a condition which could have serious complications. The scientific debates which took place in conferences and peer-reviewed journals are a matter of public record.

- The hepatitis C virus was first positively identified in 1989, and from around this time there was general acceptance that this was a clinical condition which could involve serious complications, including in some cases cirrhosis and liver cancer.

- Clinicians had to weigh the risks of treatment against the benefits. Haemophilia is a serious condition which can cause death and disability. The introduction of blood concentrates (Factor VIII and Factor IX) during the 1970s was a significant step forward in treatment which allowed home treatment. The risks at that time were recognised, but were not seen as serious

- Blood products (SNBTS Factor VIII/ Factor IX) used in the NHS in Scotland for the treatment of haemophilia were safe from 1987 onwards (SNBTS Factor IX – 1985) when heat treatment developed by SNBTS had the effect of inactivating the hepatitis C virus. Testing and screening of blood donors was introduced in 1991, when reliable tests became available

- It is suggested that patients were not told that they had Hepatitis C, or were not fully informed of the risks of treatment. While the general risks associated with blood products have been known over a long period, these were not at first considered serious and no reliable test was available before 1989. There is no real evidence that information was withheld from patients, but it is possible given the state of knowledge that they were not fully informed at an early stage.

- It is always possible to argue – looking back – that some steps should have been taken earlier. The real issue is whether there was unreasonable delay in the light of how consensus knowledge developed over time. Judge Alison Lindsay concluded in relation to Ireland in 2002:

"The Tribunal has formed the view from this evidence that the consensus which existed in the late 1970s and early 1980s that NANB hepatitis was relatively mild or benign did change as the results of studies became available showing the condition to have potentially serious consequences for some people infected by it. A number of experts came to regard it as a serious disease with significant long term consequences, especially and increasingly in the period after approximately 1985. That view did not, however, come to be universally held in the relevant medical and scientific communities until after 1989."

ANNEX C

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

(i) PUBLIC INQUIRY

Allegation	Lines to take
Other countries (Ireland, France etc) have all held public enquiries and these have found officials, governments and clinicians to be at fault – sometimes resulting in criminal proceedings	• Not convinced that there are any lessons to be learnt that have not already been learnt. • Not convinced that any officials or NHS staff acted wrongly in the light of the facts that were available to them at the time. • I have commissioned a literature review of all of the files held with a view to publishing relevant documents. • This should provide a full picture from the written record of what happened

(ii) FOI – new evidence

Allegation	Lines to Take
New evidence has become available under Freedom of Information e.g. "Collection from prisons and borstals" "Medicines Inspectorate criticism of SNBTS facilities"	• I do not believe that the information released constitutes new evidence to support the call for a Public Inquiry. • The last collection by SNBTS from prisons and borstals was in March 1984. • Investment and action was taken to rectify the shortfalls identified by the Medicines Inspectorate. • I have requested officials be as open and transparent as possible. • I have commissioned a literature review of all of the files held with a view to publishing relevant documents. • This should provide a full picture from the written record of what happened

(iii) KNOWLEDGE OF HEPATITIS C

Allegation	Lines to Take
Knew about the risk from Hepatitis C in concentrates and withheld the information from patients/public	• Risks continuously discussed in medical journals and at conferences attended by patient organisations. • Product information leaflets warned of risk. • The hepatitis C virus was first positively identified in 1989, and from around this time there was general acceptance that this was a clinical condition which could involve serious complications, including in some cases cirrhosis and liver cancer.
Knew about the risk from Hepatitis C in concentrates and did nothing to protect patients	• As above. • Clinicians thought the benefits outweighed the risks this belief genuinely held. • The main alternative treatment (cryoprecipitate) was not as effective and was not itself free of the risk of transmitting Hepatitis C. • Haemophilia is a serious condition which can cause death and disability. • The introduction of blood concentrates (Factor VIII and Factor IX) during the 1970s was a significant step forward in treatment which allowed home treatment.
Should not have prescribed commercial products because was known these carried a greater risk than NHS products	• risk was thought to be negligible. • products were licensed by 'MCA'.
Some commercial products more dangerous than others – should not have prescribed these	• Probably incorrect – a misinterpretation of what it says in some documents

(iv) HEAT TREATMENT OF BLOOD PRODUCTS

Allegation	Lines to Take
Should have introduced effective heat treatment earlier	• Covered extensively in the SEHD investigation (Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid 1980s) – service did the best it could. • The investigation has been criticised for not being independent and objective but the evidence supported the findings of the report. • Different research regimes were followed in England and Scotland – with the result that Scotland introduced the finally agreed treatment method later than England (but achieved national coverage sooner).

(v) TESTING

Allegation	Lines to Take
Should have introduced Hepatitis C screening earlier	• A specific test for the Hepatitis C virus only became available after the virus was identified in 1989. • Screening of donations was introduced in September 1991 when a reliable test became available.

(vi) PATIENT INFORMATION AND CHOICE

Allegation	Lines to Take
Patients were not properly informed of the risk	• Has to be viewed in the context of the risk controversy. • There is no real evidence that information was withheld from patients, but it is possible, given the state of knowledge at that time that they were not fully informed at an early stage. • Nowadays risk management and the precautionary principle are key issues for the Health service.

	Committed to better communication between clinicians and patients – especially on risk.
Patients not informed of results of tests showing they had Hepatitis C	• Have no evidence of this. • If tests were surrogate tests then they just show liver malfunction and clinician might have decided it was not useful to tell patient this and/or 40% link to Hepatitis C was insufficient basis for alarming patient. • While the general risks associated with blood products have been known over a long period, these were not at first considered serious and no reliable test was available before 1989.
A more comprehensive look back exercise should have been undertaken	• Would have been very resource intensive not justified by potential benefits

(vii) ACCESS TO MEDICAL RECORDS

Allegation	**Lines to Take**
Patients' medical records are being withheld/destroyed as part of a conspiracy to cover up past incompetence	• No evidence that this is the case. • Understand that there have been difficulties finding records from 20-30 years ago and, in the case of batch numbers of concentrates, difficulty in interpreting them. • Prior to 1993, the guidance issued to service only required medical records be retained for 6 years. • There were certain exceptions to the guidance on retention of records and in the case of genetic disorders (which include haemophilia) no specific time frame was set – it being left to medical discretion.
Suspicious gaps in medical records coinciding with periods when clinicians might be considered to have been negligent.	• No evidence that this is the case. • Understand that there have been difficulties finding records from 20-30 years ago and, in the case of batch numbers of concentrates, difficulty in interpreting them.

(viii) SELF SUFFICIENCY

Allegation	Lines to Take
Should have set in place measures to achieve UK self sufficiency earlier so there was no need to use commercial products	• It took quite a long while for the NHS to build up capacity to meet demand. Scotland did achieve this and was able to supply sufficient Hepatitis C safe product to meet demand in Scotland. • Aware that clinicians continued to prescribe a commercial product in preference to "home produced". Decisions on this were made by individual clinicians. Different products had different levels of efficacy and different side effects and these may have been very patient specific.

Annex D

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

Background Notes

(i) Public Inquiry

1. Situations in other countries entirely different. In Ireland (the most frequently quoted) the Finlay Tribunal did find fault but it concerned a specific incident involving Anti D (not FVIII or IX) and subsequent poor management which resulted in the entire Irish blood supply being contaminated.
2. Following consideration of the report on Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid 1980s the previous Health Committee concluded that the allegation that the SNBTS was negligent during the 1980s in allowing Hepatitis C infected blood to enter into circulation was dealt with fairly exhaustively. The Committee also raised doubts as to the usefulness of carrying out any further inquiry on the questions of fault on the part of the SNBTS
3. The resource implications of holding a Public Inquiry are high. Many people involved at the time are either dead or retired, and it would be difficult to carry out a thorough investigation and examination of the issues.
4. A Public Inquiry would not necessarily succeed in establishing clearly roles of responsibilities in the events that took place and the accountability of individuals and organisations.
5. The SNBTS senior staff required to support a lengthy PI could seriously affect the effectiveness of SNBTS to maintain its core business.
6. The publicity could adversely affect the current donor base.
7. At the time in question (the 1980s) there was no Devolved Government, therefore the scope of a PI now could only address Scottish issues. This could result in dissatisfaction in its limitations
8. A Scottish PI would raise issues for the UK Government. The Executive would need to establish how willing they were to participate and to what extent. The UK Government line is that there is no new evidence to support a PI.
9. The organisations involved such as MCA are UK. Standards worked to at the time were agreed nationally (UK).

(ii) FOI – new evidence

1. Minutes of various meetings involving SNBTS Regional Directors, Haemophilia Directors and English Regional Directors were released in December and January.

2. The documents revealed that concern had been raised by the Medicines Inspectorate about SNBTS collecting donations from Prisons and borstals and this hit the news. The last collection was in March 1984.

3. Medicines Inspectorate Reports critical of SNBTS facilities have subsequently been issued in response to an FOI request. It is likely that there will be further media cover.

4. Enquiries of the Scottish National Blood Transfusion Service and colleagues in the Department of Health suggest that the following papers have also been released:

   DH - (i) a 1979 Medicines Inspectorate Report of BPL at Elstree; and
   (ii) Currently considering whether to release the second Annual Report (1979) of a research project on Studies of an Epidemiology and chronic sequelae of Factor VIII and IX associated Hepatitis. (We had been given a copy of the 1980-81 report of this Study by campaigners and have subsequently released copies of this paper under FOI.)

   SNBTS – has responded to an inquiry in relation to the vCJD communications exercise conducted last year.

5. Additional papers may have been sought from other sources but we have no way of knowing what may have been provided.

6. DH has just received a request from BBC Scotland seeking papers on Hepatitis C from 70s and 80s for a documentary about haemophiliacs. GRO-A has previously mentioned that a programme was being made.

7. We are currently dealing with a FOI request for papers relating to HIV infection from 1979 to 1994. The papers reveal the discovery of 20 November 1984 of a number of haemophiliacs who had been found to have the antibodies to HIV following treatment with an SNBTS product and a meeting of Scottish haemophiliacs on 19 December 1984 to allow HD to explain the positions.

(iii) Knowledge of Hepatitis C

1. During the 1980's it was recognised that there were risks from "nonA-nonB hepatitis" – as it was called at the time. There was clinical and scientific debate, and varying views, as to the seriousness of the risks but no clear consensus view that this was a condition which could have serious complications. The scientific debates which took place in conferences and peer-reviewed journals are a matter of public record.

2. This divergence of opinion continued until at least 1985 after which an increasing number of experts came to regard it as a serious disease with significant long term consequences. That view did not come to be universally held in the relevant medical and scientific communities until after 1989.

3. Numerous published articles in eminent medical journals, such as the Lancet, in the 1970s and 1980s that record information, interest and controversy on this issue. This was also the conclusion of Judge Alison Lindsay in the 'Report of the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters' (September 2002) in Ireland.

4. The hepatitis C virus was first positively identified in 1989, and from around this time there was general acceptance that this was a clinical condition which could involve serious complications, including in some cases cirrhosis and liver cancer.

(iv) Heat Treatment

1. It was known that both cryoprecipitate and concentrates were capable of transmitting viruses – notably Hepatitis A and Hepatitis B. However, the discovery that they could transmit HIV brought about an intense effort to develop methods of eliminating or neutralising this virus.
2. The main method adopted for inactivating viruses was by heat treating the products. This was a procedure that required great care if it was not to render the product unfit for use in treating haemophilia. Researchers experimented with different temperatures and durations in an effort to find the optimum conditions.
3. Almost fortuitously it was discovered that the heat treatment developed to deal with HIV was effective in inactivating Hepatitis viruses, although further refinement was necessary to get the best conditions.
4. Blood products (SNBTS Factor VIII/ Factor IX) used in the NHS in Scotland for the treatment of haemophilia were safe from 1987 onwards (SNBTS Factor IX – 1985) when heat treatment developed by SNBTS had the effect of inactivating the hepatitis C virus.

(v) Testing

1. Prior to the development of a specific test the only tests available were surrogate tests that detected hepatitis in the more traditional sense of inflammation of the liver. As such they could not uniquely detect the Hepatitis C virus (or NANB as it was known then) – the results had to be interpreted and the inflammation could be due to other causes (including heavy drinking). If the two main surrogate tests were used together then it was reckoned 40% accuracy could be achieved – with a significant risk of false positives.
2. Apart from the implications for individual patients, there was concern that use of the surrogate tests for screening would mean many donors would be deferred unnecessarily with serious consequences for blood supplies. As a result, few countries adopted the tests for screening – although a few did. The UK did not.
3. The fact remains that many clinicians would have continued to prescribe the products even when there was a positive test because, at that time, it was believed the benefits of treatment outweighed the risks.
4. Specific 1st generation tests were available in March 1990 and second generation tests in April 1991. Screening of donations was introduced September 1991.

5. Re 1st generation tests, would need to argue not good enough – in fact the service waited for the 2nd generation tests because they were already in the pipeline and known to be better. Burton (High Court in London) opined that service should have rolled out 1st generation tests and DH lawyers felt this could not be contested.
6. Heat treatment of blood products continued in parallel because it had transpired there were other advantages and because it may also perform a prophylactic function in respect of as yet unidentified harmful agents.
7. Once screening of donations was in place UK blood services undertook a look back exercise. If any donor was identified as having Hepatitis C and it was established that they had previously donated then archived samples from previous donations were retrieved and tested. Any patient who might have been infected as a result of receiving blood products from the infected donor was informed.
8. This approach was not capable of identifying everyone infected by blood products. This is because some infected donors who gave blood prior to the introduction of screening will not have come forward again and will not therefore have been picked up by the screening process.

(vi) Patient information and choice

1. It is always possible to argue – looking back – that some steps should have been taken earlier. The real issue is whether there was unreasonable delay in the light of how consensus knowledge developed over time. Some clinicians had serious worries about the seriousness of Hepatitis C infection as early as the mid 1970s (and in consequence about the use of commercial products). But many experts also took the view that it was a mild, non-progressive condition and the benefits outweighed any adverse consequences.

2. In reality many of patients would have died without the treatment.

(vii) Access to medical records

1. Patients infected with Hepatitis C from blood products have attempted to obtain their medical records in most cases to pursue civil cases against the manufacturers of commercial US blood products (some cases have apparently been successful).
2. Patients also want to see what their clinicians knew and didn't tell them.
3. Despite public allegations that records are being withheld or deliberately destroyed we have not been given any direct evidence that this is the case.

(viii) Self sufficiency

1. Initially most FVIII products were commercial products imported from the US and it took quite a long while for the NHS to build up capacity to meet total UK demand.
2. Scotland achieved this before England but even then clinicians continued to prescribe a significant proportion of commercial product in preference to home produced. We don't know the reasons for this since the decisions were made by individual clinicians and not (generally) driven by any central imperatives. The fact that there were so many different products around is testimony to the fact that they had different levels of efficacy and different side effects and these may have been very patient specific.
3. A clinician may well have taken a medical view that a particular commercial product provided the best treatment outcome for a particular patient. Notwithstanding the fact

that concerns were being raised about the seriousness of Hepatitis C infection, clinicians will have known that all Factor VIII and IX products (both commercial and NHS) were licensed by the Medicines Division of the DHSS (the predecessor of the Medicines Control Agency – now MHRA) and are likely to have taken this as an official endorsement of their safety.

4. It is alleged (and probably true) that, at least initially, the source of the material for the US commercial products was prisoners and paid donors likely to be drug addicts (Skid Row blood). This doesn't of course matter if your pathogen inactivation procedures are 100% effective and/or what is being transmitted is relatively benign

ANNEX E

CALL FOR PUBLIC INQUIRY IN RELATION TO HAEMOPHILIA TREATMENT HEALTH COMMITTEE APPEARANCE – 10 MAY 2005

Report on Hepatitis C and the Heat Treatment of Blood Products for Haemophiliacs in the mid-1980s

Remit

- to examine evidence about the introduction of heat treatment in Scotland for Factor VIII in the mid 1980s, to assess whether patients in Scotland with haemophilia were exposed to the risks of the hepatitis C virus longer than they should have been, given the state of knowledge at the time;

- to examine evidence about the information given to patients with haemophilia in the 1980s about the risks of contracting the hepatitis C virus from blood products.

Findings

- the Scottish National Blood Transfusion Service were around 18 months behind the Bio Products Laboratory in England in producing a heat-treated product which was subsequently found to have eliminated the hepatitis C virus;

- there were understandable technical reasons why this was the case:

  - there was no test to identify the presence of the virus, so scientists could not be sure that any particular heat treatment had actually worked until they reviewed the effects of the resultant products on patients;
  - the heating process could easily render blood products unusable, and different types of heating and freeze-drying processes and equipment had to be tried in order to obtain a usable product;

- once SNBTS had managed to develop a suitable heat-treated product, they were quickly able to produce sufficient for domestic demand;
- no evidence of any policy by Haemophilia Centre Directors deliberately to mislead patients about the risks of hepatitis.

ANNEX F

Timeline

1970 All blood donations tested for Hepatitis B

1975 Italian scientists describe asymptomatic liver disease in haemophiliacs, possibly due to use of blood products (Factor VIII/IX) because of large donor pools

1983 Scotland self-sufficient in Factor VIII

1984 Scottish blood supply found to be contaminated with HIV

1985 All blood donations tested for HIV

Heat-treated Factor IX product which was later shown to be HCV safe developed

1987 Heat-treated Factor VIII product which was later shown to be HCV safe developed

1988 Paper in *The Lancet* suggests heat-treated factor VIII free from NANB

1989 Hepatitis C DNA code isolated

1991 Routine screening and testing of blood donors introduced

1992 UK scientists suggest haemophiliacs exposed only to heat–treated products show no evidence of HCV infection

ANNEX G

DO NOT change any of the information in the shaded rows. Click on the buttons marked Lead Minister, Lead Official and Next Review on the toolbar above and choose from the selections. Link to hot issue guidance - click here

SUBJECT	**!Plasma products - vCJD risk assessment exercise**		
Lead Minister	Minister for Health and Community Care		
Category	!! Archived HD Hot Issue Notes	**Next Review**	18/05/2005
Lead Official	Bob Stock	**Telephone**	GRO-C
Note Owner	Sandra Falconer	**Division**	Health Planning and Quality
Telephone	GRO-C	**Department**	HD
Modified By	Sandra Falconer	**Last Modified**	03/05/2005 10:54

Freedom of Information

It is important that the information in this BriX note is as comprehensive and detailed as possible. The Freedom of Information (Scotland) Act 2002 will apply to these BriX notes and they could be made publicly available.

For further information on the implications of the Freedom of Information (Scotland) Act 2002, contact the Freedom of Information Unit. Their intranet page can be found using the following link: http://intranet/content/departments/lps/cps/foi.htm

Accusations & Criticisms

Always complete all fields

- Thousands who received blood products prior to 1999 are to be warned they may be incubating variant Creutzfeld-Jacob Disease (vCJD)
- DH(E) refused to reveal outcome of the Health Protection Agency (HPA) UK-wide risk assessment of plasma products ahead of notification to patients who may be affected.

(Also see Brix notes *vCJD transmission from Blood Transfusion)*

Rebuttal lines to take

- Grossly unfair on the patients involved to discuss the results of the risk assessment exercise before patients are informed of the outcome.
- Patients who have received plasma products and have concerns about the vCJD risk assessment mentioned in press reports on 29 and 30 August should be reassured that, if they are affected, that they will be contacted by their doctor/s shortly.
- Patients will then be able to discuss with their doctor, in a sensitive and appropriate manner, how the latest information may affect them and their

treatment.

Patients who are concerned can contact the Health Information Line 0800 22 44 88.

Facts, statistics & background

- The HPA has calculated the level of risk of infectivity of plasma product and this varies for each product dependant on the number of donors who contributed to the plasma pool and the detail of the fractionation process involved in its production.
- The HPA has also classified products into high, medium or low risk as follows:

Level of risk	Dose likely to be sufficient to transmit vCJD	Products
High	one dose	Factors VIII & IX and antithrombin.
Medium	repeated doses	Intravenous immunoglobulin and some albu
Low	very large numbers of doses given infrequently in lifetime.	Intramuscular immunoglobulin, Anti-D

- Approx. 120 people in Scotland who have been treated with UK-sourced pooled factor concentrates or antithrombin between 1980 and 2001 are thought to be in the high risk group. These people will be covered by the notification exercise (50 haemophiliacs, 20 primary immune deficient patients, 30 recipients of Defix (Warfarin reversal treatment) and 20 recipients of Albumin. In addition, (as a precautionary approach) approx. 500 haemophiliacs have been informed about the situation.

- HPA worked with patient representatives and groups in relation to the arrangements for patient notification in September. The notification included:

    - All people treated regularly with plasma products for blood-related conditions and who may have been exposed to implicated plasma products (e.g. patients with bleeding disorders; immuno deficiencies), are being contacted by the specialist doctor responsible for their care.

- Hospitals tracing other people who received implicated plasma products (e.g. for emergency treatment of severe burns), and arranging to have the additional risk assessed and notification of patients where this is considered appropriate. (The tracing and assessment process may take a number of weeks, and, where treatment took place a number of years ago, it may not be possible to find out who received the implicated plasma products.)

- People who have received intramuscular immunoglobulin (e.g. anti-D for Rhesus negative pregnant women; human normal immunoglobulin travel prophylaxis for hepatitis A), are not considered to be at potential additional risk and no action is needed.
- In the UK as a whole, 23 plasma donations from donors who subsequently developed vCJD were used to produce 174 batches of products.
- In Scotland 15 implicated batches were produced. The total number of bottles of each product is as follows:

Product	No of batches	No of bottles
Factor VIII	2	1435
DEFIX	1	834
Albumin	12	11,514

- The majority of Scottish haemophiliacs who have received implicated PFC batches of Factor VIII and DEFIX have already been traced. However, some may have received BPL products.

- Precautions to be taken will include asking 'at-risk' patients:
  - NOT to donate blood, tissues and organs
  - to INFORM doctors, dentists and other health professionals of their possible vCJD exposure before invasive clinical procedures so extra infection control precautions can be taken where appropriate.

Potential Pitfalls and other sensitivities

- Currently no method for screening blood donations for vCJD and has long gestation period (hence need for precautionary approach).
- It may not be possible to trace all patients who may have received implicated products.