hep149

RESTRICTED - POLICY

Mr Abrahams APS/M(H)

From Roger Scofield

Date 6 April 1995

Hep C file

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PAYMENTS FOR THOSE INFECTED WITH HEPATITIS C THROUGH BLOOD TRANSFUSION/BLOOD PRODUCTS

1 Your minute of 30 March asked for advice on how a payments scheme might be constructed which would provide assistance to those suffering life threatening complications caused by hepatitis C contracted through blood transfusions and blood products. I attach a paper which sets out the key objectives of the Haemophilia Society's campaign; gives the general background to the look back exercise and describes the main features of such a scheme. Since the paper is necessarily complex I have also provided a summary.

2 The paper follows M(H)'s request that a plan for some sort of scheme be prepared. Whether this is desirable or inevitable should not be assumed to be the case. Indeed <u>it is the exact opposite of the position that the Government generally and Health Ministers in particular have taken to date.</u>

No fault compensation

3 The Government opposes no-fault compensation for five reasons;

i) the proof of causation is still needed, and it could be just as difficult to establish that medical treatment had caused injury - and that it was not a foreseeable and reasonable result of treatment - as it would be to prove that someone had been negligent;

ii) there would be unfairness to others, in that those disabled as a result of a medical accident would be compensated but those disabled as a result of disease would not:

iii) it is quite possible that the costs falling on the NHS could increase substantially and this would inevitably reduce the amount available for direct patient care;

iv) negligence in the health care field is not considered to be fundamentally any different from negligence in any other walk of life, where claims for compensation are resolved through the courts; the present system arguably has a deterrent effect on malpractice and no-fault compensation could conceivably make doctors less careful.

v) in those countries which have such a scheme, the amounts payable are very small in comparison to what a case would win in the courts. For example, some of the countries which had schemes had to top up the standard no fault compensation payments in the case of HIV transmission by blood products.

Provision of existing statutory services

4 There are a number of ways in which those infected non-negligently can be helped, including the full range of health, social and security services provided by the government. These provide a "safety net" albeit at a somewhat lower level than might be offered under a no fault compensation scheme. But no distinction is made between those whose condition or injury was caused by heredity, by disease or as a result of NHS treatment. In particular:

i) the NHS provides health care needs;

ii) social needs may be met through the local authorities;

iii) a whole range of social security benefits are provided by DSS (some on a means tested basis and some obtainable by all).

Negligence

5 Ministers have denied that the Department have been in any way negligent and indeed the Haemophilia Society representatives have been at pains to make clear that their campaign is not in any way based on such a charge. Those patients who were infected were given the best treatment available at the time.

HIV settlement as a precedent

6 The HIV settlement is being quoted as a precedent. There were special factors applying to that situation. Both groups shared the tragedy of becoming infected with HIV through medical treatment and were considered to be a special category through:

i) the nature of the HIV infection which was believed to be invariably fatal;

ii) the significant lifestyle implications of HIV, including public hostility etc.;

iii) in the case of the infected haemophilia patients the problems of HIV which were superimposed on the health, social and financial disadvantages they already suffered as a result of their hereditary haemophilia.

Undertakings to Treasury

7 It was an express condition of that settlement between DH Ministers and the Treasury that it should be ring fenced to include only haemophilia patients infected with HIV. The Treasury were concerned that such a settlement would give rise to claims from other groups. They felt vindicated when the scheme had to be extended to include those infected with HIV through blood transfusions. The same undertakings were given concerning ring fencing. Ministers could not give a guarantee that any new scheme would not lead to further claims. As a minimum the position on CJD would need to be resolved.

Funding

8 The size and overall cost of any of the schemes described in the attached paper are considerable, even accepting that they would be paid over a long period, perhaps extending to 30 years. There is no provision for such payments in existing baselines. At the time of the Haemophilia settlements most of the money was found by an in-year claim on the Reserve in the year when they were first made. Thereafter further payments have been found from PES settlements. In the present public expenditure climate Treasury would strongly resist a claim on the Reserve for hepatitis C and expect the department to find the money from its existing provision. Thus any money spent on a hardship scheme would probably be at the direct expense of direct health care.

Justification for a special scheme

9 Finally, and perhaps most importantly, there would need to be a clear policy justification for establishing a special payments scheme. Inevitably this would need to be argued, initially with the Treasury and probably the cabinet as a whole, as well as be defensible before the PAC if such payments were challenged.

Accuracy of Estimates

10 The definitions and cost estimates contained in this paper are the best available at the present time. Further work will be needed if the proposal is to be taken further.

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PAYMENTS FOR THOSE INFECTED WITH HEPATITIS C THROUGH BLOOD TRANSFUSION/BLOOD PRODUCTS

SUMMARY

1 The Haemophilia Society have launched a campaign to persuade the Government to make payments to people with haemophilia who were infected with hepatitis C as a result of blood products provided in the course of NHS treatment. They have made clear that they are not claiming negligence but parity of treatment between those infected with hepatitis C and those infected with HIV who were given special payments. So far as negligence is concerned the patients with hepatitis C received the blood products at least four years before there was any test for hepatitis C and therefore no question of negligence could arise.

2 Whilst there are a number of anomalies and contradictions in what the society's representatives have said it is understood that what they really want is access to a hardship fund which would give payments to those who were actually suffering sickness and financial hardship as a result of the infection.

3 The objectives of their campaign include guarantees of adequate resources for treatment and research and a public education programme to show that ordinary social contact is not a means of transmission of hepatitis C.

4 The Government have already acknowledged that a number of people have been infected with hepatitis C by blood, through transfusions (approx 3000 are still alive), and by blood products (approx 3000 more), and have put in hand a look back exercise to trace, counsel and where appropriate treat those infected. Ministers have stated that they will do all they can to care for those involved including preparation of good practice guidance, improved access to treatment, funding of research and support of self-help groups. To this extent a number of the society's objectives are already in hand.

5 Ministers have so far been adamant that they would not consider payments to those involved. The Government is opposed to a general no fault compensation scheme and Ministers have claimed that the HIV settlement was only reached because of the special features of the case. (See covering minute paras.3-6)

6 The Society has received support from the Opposition and a number of senior members from the Government's own ranks. They claim that the circumstances are essentially similar and there is a case in equity to provide comparable support. Moreover they believe that in the end the Government will have to yield and it would be better to do that now rather than let the matter drag on.

7 M(H) wishes to consider establishing a scheme which would be better targeted than that created by the HIV settlement.

8 The HIV payments scheme was widely accepted when it was introduced in 1990 and has been administered in an exemplary manner by the Macfarlane Trust. It made payments ranging from £41,500 to £81,000 to all those infected with HIV through blood or blood products including payments to the heirs of those deceased. Some of those involved died from their underlying medical condition, shortly after being infected with HIV and the award went to their estate. Others, though infected have since enjoyed good health and show no sign of terminal illness. Yet others died leaving their family inadequately provided for. On the whole the scheme did not provide a very satisfactory way of channelling such funds as were made available to where they were most needed, although there was equality in the way the payments were made.

9 The HIV Payments scheme was predated by a discretionary grant making trust (administered by the same trustees) and this has made additional payments to the same group of people on the basis of their financial and social need. This has worked well although there have been some complaints concerning perceived inadequacies.

10 It would be technically feasible to set up a payments scheme for those infected with HCV through blood or blood products on a similar basis to that provided under the HIV settlement. However any payments scheme needs to be related to the degree of harm experienced. In this case the impact of the disease varies between individuals and over time and some of those infected will suffer no adverse effects whatsoever, apart from anxiety. For this reason a straight payment per capita would be an inappropriate way of targeting funds. Moreover the total cost of such a scheme, assuming similar levels of payment, might be as much as £500 million.

11 If costs were not to rise uncontrollably it would be essential to demand the same degree of proof of causation as for the HIV scheme; indeed proof of causation will need to be tighter as most cases in the UK are thought to arise from intravenous drug abuse. It may be necessary to do special tests to determine whether the recipient's Hep C status is the result of transfusion or otherwise.

12 It might be possible to link payments to the severity of the illness against a predetermined set of clinical or social milestones but this would put a heavy burden on the clinicians caring for the patients and might lend itself to some abuse. Such a scheme would not be a no-fault compensation scheme by a different name. The scheme would be intended to provide for those who have been harmed by NHS treatment (HCV infected blood or blood products) in a way that is proportional to the harm experienced. If such a scheme could be made to work the cost might be reduced to £150 million, assuming death benefits remained at the same level.

13 The best targeting of resources might be obtained by establishing a discretionary trust or Government agency under which all those infected by hepatitis C as a result of NHS treatment would be eligible. Grants would be made, subject to availability, to those who had either reached predetermined stages in their illness or who could demonstrate that they were suffering hardship as a result of the financial or social consequences of their illness. Provision would also be made for dependants. This might cost, say, £50 million (spread over 30 years but heavily front loaded).

14 The target group would be all those infected by blood and blood products but there would be a case for extending this to anyone who was infected by HCV as a result of NHS treatment, irrespective of the route of transmission (eg. including transplantation of tissues and organs); of extending it further to cover any other blood borne viruses (eg HTLV and CMV) and / or extending it to cover any infection brought about by blood, blood products or the transplantation of tissues or organs (eg. CJD). The Department is currently involved in litigation concerning claims for damages from individuals who allege that they developed CJD as a result of NHS treatment. Such extensions might increase the cost of a discretionary grant to, say, £100 million.

15 Treasury agreement would be needed for any departure from our present Departmental position and they are likely to resist the introduction of a scheme for those infected with hepatitis C. For the HIV payments schemes, following negotiations with the Treasury, we were able to make an in-year claim on the Reserve to fund these payments. But in the current public expenditure climate we believe that Treasury would resist such a claim for hepatitis C and expect the Department to meet the cost from its existing provision.

16 The setting up of such a payments scheme, or discretionary grant making trust, might bring to an end the constant claims for no fault compensation and avoid damaging publicity, especially at a time when the Department and the NBA need to build confidence in the safety of the blood supply.

17 The Macfarlane Trust could not be used in its present form to provide the sort of payments envisaged but new trusts, or a Government agency, could be established which would build upon the experience which has been gained to date. The pros and cons of such administrative vehicles would need to be discussed further with our lawyers and, in due course, and subject to Ministers agreement, with the chairman and secretary of the Macfarlane Trust.

18 Further work is required to test this analysis and to consider in greater detail how such schemes might be applied; and to improve our estimates of the numbers involved and the likely costs.

CA OPU
6 April 1995

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PAYMENTS FOR THOSE INFECTED WITH HEPATITIS C THROUGH BLOOD TRANSFUSION/BLOOD PRODUCTS

Purpose of the paper

6 April 1995

1 The Haemophilia Society has launched a campaign to persuade the Government to make payments to those suffering from haemophilia who have been infected with hepatitis C through contaminated blood products. This paper considers a) what the Society is asking for; b) what Ministers have agreed in the context of the Look back exercise, c) the extent to which the HIV settlement provides a precedent and/or model for a payments scheme, and d) considers how a suitable scheme might be constructed.

General Background

2 It is accepted that a number of people have been infected with hepatitis C virus as a result of blood or blood products provided by the NHS. A package of actions has been put in hand to trace, counsel and, where appropriate, treat those concerned.

3 A number of writs have been served on Regional Transfusion Centres alleging negligence. We understand from the Chairman of the UK Haemophilia Directors Organisation that two solicitors firms are primarily involved in respect of haemophiliacs. Deas, Mallen and Souter of Newcastle appear to be advising their clients that generic claims are unlikely to succeed, but there have been a couple of clinical negligence cases which have succeeded (inappropriate treatment). Keith Park of Liverpool (Graham Ross) have been much more aggressive and are trying to encourage all haemophiliacs to sue. The Haemophilia Society is giving their members the names of the solicitors, but are not currently advising either way. In England and Wales any haemophiliacs who received payment for HIV cannot sue for hepatitis C under the terms of the settlement.

4 Lawyers within the Department and the NBA are considering the sequence of events and the principal reports and papers to decide the strength of the Department's defence should the matter come to court. Meanwhile Ministers have stated publicly that the Government does not accept that there was any negligence and that they have no plans to make payments to those infected.

5 Claims for a payments scheme for hepatitis C victims are being made more specifically against the background of the settlement of the HIV litigation. This eventually covered both people with haemophilia infected by blood products and patients who were infected with HIV through blood transfusions. A note is provided at Annex A describing the circumstances and terms of that settlement.

6 Any payment made to one group of patients is likely to create pressure from other groups for similar treatment. The paper at Annex B seeks to establish a common approach to such claims and provides a generic model of response to non-negligent damage.

The Haemophilia Society's campaign to date

7 The Society's Press Release marking the launch of the campaign is attached as Annex C. The chief objectives of the campaign are as follows:

i) More equitable treatment in financial terms between those people with haemophilia infected with hepatitis C through contaminated blood products and those infected with HIV through contaminated blood products. Specifically:

a) An across the board ex-gratia payment to all those infected with HCV through contaminated blood products;

b) Access to a hardship fund for those who become ill and the dependants of those who die;

c) As a matter of urgency, payments to those who are already ill and the dependants of those who have died

ii) Adequate resources for haemophilia centres to enable them to provide the best possible treatment and care for people with haemophilia and hepatitis;

iii) Adequate resources for research into the prognosis and treatment of hepatitis C

iv) A public education programme that provides reassurance about the methods of transmission of hepatitis C and explains that ordinary social contact is not a means of transmission.

8 The society's case has been represented to Ministers by Mr Chris Hodgson, a constituent of M(H)'s and a Vice-Chairman of the society; and by John Marshall MP who came to see M(H) last week accompanied by Sir Terrence Higgins MP and Sir Geoffrey Johnson Smith MP.

9 So far there have been two starred questions and a short debate in the Lords all initiated by Lord Ashley and supported by Baroness Jay. In the Commons there has been 1 EDM and Ministers have had 16 PQs and 100 PO cases (of which 80 have been specifically about haemophiliacs). Officials have dealt with a further 50 TO cases.

10 Those promoting the society's cause were all involved in the (successful) HIV campaign and the events leading to the setting up of the Macfarlane Trust. They have stressed that they do not want to launch a major initiative involving the media, along the lines of the HIV campaign, but are quite prepared to do so if they believe this to be necessary. They believe the Government

will eventually have to come to some agreement and that this should be done quickly and with as little publicity as possible. A meeting of interested MPs is to be held at the House after Easter.

Announcement of Look back exercise

11 PS(H) announced 11 January 1995 that the Government had accepted the recommendations of the Advisory Committee on Microbiological Safety of Blood and Tissues for Transplantation (MSBT) and were setting in hand a UK-wide look back exercise to trace, counsel and where appropriate treat those who had been infected with hepatitis C through blood transfusions. A working party has been established which has prepared guidance on procedures for the look back exercise and on counselling and treatment options. That guidance was issued 3 April and the exercise is proceeding. It is hoped to complete the main part of he programme by the summer.

12 Ministers stated that everything would be done that could be to ensure that those affected received the best treatment and this might involve preparation of good practice guidance, research and support of self help groups.

13 Although the look back is specifically targeted at those who were affected through the blood transfusion route it has been acknowledged that the same principles apply to those infected through blood products. Nearly all haemophilia patients being treated with blood products prior to 1986 will have been infected in this way. Officials are in touch with the Directors of the Haemophilia centres to ensure that good practice guidance is available and that access is ensured. Discussions are in-hand about funding, including the cost of new drugs recently licensed. A grant has been approved to fund an initiative by the Haemophilia Society to identify the best way to help those who are affected by both haemophilia and hepatitis C.

14 Thus action is already in hand which will meet points (ii) and (iii) of the campaign objectives. We shall discuss with the society what action might be taken, possibly by them, to meet their fourth point about a public education initiative.

15 This leaves the main point about a payments scheme.

The Department's position

16 The Government has been firmly opposed to a general no-fault compensation scheme. Ministers have so far stood firm against any special payments in respect of hepatitis C and have claimed that the circumstances surrounding the HIV settlement were wholly exceptional. It was considered firstly that the patients with haemophilia were at "double jeopardy", from both their pre-existing condition and the fact that they had contracted HIV. Secondly there was stigma attached to HIV; and thirdly there was the much greater likelihood of sexual transmission to spouses. It has to be agreed with hindsight that the similarities between HIV and HCV are easier to identify than the differences and Ministers have had difficulty in holding this line.

17 If Ministers consider that the case for a payments scheme is admissible or that public, media and political pressure may in the end force further concession, then there is a case for taking a pro-active approach now, to resolving outstanding claims for financial compensation whilst denying liability and making some flexible provision for meeting any reasonable needs for the future. This might be seen as just one part of a wider campaign to restore public confidence in the safety of the blood supply and persuade more people to donate blood on a regular basis.

18 The remainder of the paper assumes that Ministers do accept the need for some sort of payments scheme in respect of hepatitis C but for it to be targeted so as to get best value for money.

Rationale for payments

19 Before looking at payments schemes in detail it is important to establish a clear rationale including what any monies would be intended to be used for. If liability is not admitted, it would be inappropriate to make payments which implied the Transfusion Service, the NHS or the Department were at fault. They might be justified if they compensated the individual for expenses they incurred as a result of the injury but which they would not have incurred otherwise. Examples might include:

i) loss of earnings through sickness;

ii) increased costs as a result of illness;

iii) increased insurance premiums;

iv) death and the support of any dependants.

20 Claims might also be made for personal "injury" or anxiety or reduced prospects of marriage or parenthood etc. but these intangibles are probably best ignored. These are areas on which legal advice would be essential.

Advantages of the HIV settlement

21 Quite apart from obvious similarities in the circumstances, if any payments scheme were to be introduced, consideration would need to be given as to whether the HIV settlement provides a relevant starting point. In its favour is:

i) the fact that it exists;

ii) it commanded wide support at the time;

iii) it has been administered by the Macfarlane Trust in an exemplary fashion;

iv) the payment levels have been set and provide some yardstick of what is seen as appropriate;

v) introduction of such a scheme could be presented as an extension of an existing payments scheme rather than the opening up of a new one.

Disadvantages of the HIV settlement

22 Against that there have emerged a number of deficiencies in the scheme and if another settlement were to be made consideration would need to be given to ways in which these might be overcome. They include the following:

- i) At the time of the settlement it was believed that those infected with HIV would all progress to full AIDS and die within a few years; in fact there are a number of people who were infected 15 or more years ago and who are still in good health and showing no sign of terminal illness;
- ii) Likewise it was expected that those concerned would be unable to support themselves. Whilst this has been the case in some instances most have continued in work until they develop the later stages of AIDS
- iii) In a number of cases money awarded has been spent unwisely and those concerned have become a charge on the State;
- iv) Likewise monies made available for spouses or children have sometimes been spent by the primary beneficiary and on death nothing has been left for their families;
- v) Payment under the schemes has been on the basis that the applicant was clearly infected and that they had become infected as a direct result of action by the NHS. People receiving nearly half the blood transfusions die from their underlying medical condition, within one year of receiving them. Thus many people died after suffering no, or very little, ill effects from the infection, but nevertheless they, or their estate, benefitted from the scheme.

Improved targeting

23 For all these reasons any new scheme would ideally need to be much better targeted so that such money as might be made available would:

- i) go to those whose lives had genuinely been affected for the worse as a result of their infection;
- ii) be better preserved for the benefit of any family or children;
- iii) be much more flexibly targeted so that help was given to those whose medical condition warranted it rather than to all those infected on the same basis.

The target group

24 The HIV scheme was initially for the benefit of those who were suffering with haemophilia and had been infected with HIV as a result of using infected blood products provided by the NHS as well as those where the blood products were from commercial sources, on the basis that had the NHS provided sufficient blood products, then there would have been no need for commercial products. Proof of infection and use of blood products were the two essential criteria for payment. It was accepted that the likelihood of these individuals, even if known to be homosexuals and /or drug mis-users, being infected by these other means was small.

25 The subsequent scheme took account of the fact that a number of people had been infected with HIV through blood as a result of transfusions. Provision was also made to allow for a small number of cases where individuals had been infected through tissue transfer or organ transplant. The scheme was very different since proof was required that it was indeed the blood which caused the HIV. A lot of people with HIV and AIDS from other causes, have had blood transfusions either for the AIDS itself of for other reasons.

26 In the case of hepatitis C the target group should include anyone who has been infected in the UK, whether as a result of NHS or independent sector treatment, as a result of blood or blood products produced by the NHS which have subsequently been found to be infected with HCV. The majority of those infected by blood would have had transfusions and many of those infected by blood products would be haemophilia patients. Proof of causation with hepatitis C would need to be tighter as most cases in the UK are thought to arise from intravenous drug abuse. It might be necessary to undertake special tests to determine whether the recipient's hepatitis C status was the result of transfusion or otherwise. The scheme should not be unnecessarily limited so far as the agent or process is concerned.

27 In early 1994 Baxter announced internationally that some batches of their intravenous immunoglobulin (Gammaguard) had transmitted hepatitis C. There were approximately 40 cases in England and Wales. This product was used in the UK on a named patient (unlicensed) basis when licensed alternatives were available. Any Payment scheme would need to exclude such individuals. It is understood that the company is making an offer of compensation to infected individuals.

28 As with HIV, provision would probably need to be made to extend the scheme to other groups who might have been infected with hepatitis C by routes other than blood. These might include recipients of i) tissue; ii) transplanted organs; and iii) eggs, semen or embryos. For tissues, organs and gametes the scheme could be limited to those infected through NHS treatment. However, for blood and blood products those transfused in the private sector using products from the Blood Transfusion Service would need to be covered.

29 A clause might be inserted to take account of any other

possibilities at the discretion of the SofS. In the HIV scheme this requires the agreement of the Treasury.

Targeting the monies where they are most needed

30 The impact of HCV on individuals varies greatly from one to another and over a period of time. Although the full life history of the disease is still unclear, present indications are that:

i) Many people infected with HCV may enjoy a long period without any symptoms appearing.

ii) A proportion of these (20% approximately) may eliminate the virus from the body completely and no longer be infectious. All others are likely to remain infectious and might transmit the virus through blood or much less easily through other body fluids.

iii) 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health. This can cause liver damage and mortality.

iv) Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years.

v) In addition a small proportion will develop primary liver cancer after a further time.

vi) Certain patient groups may have a worse prognosis and a more rapid disease progression, eg. immuno suppressed patients, those co-infected with HIV and/or hepatitis B, and alcohol abusers.

31 Recently Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be helpful to some patients but as yet its long term efficacy seems to be limited to about 20%. It is likely that other drugs and improved treatment regimes will be developed which will improve the management of the disease. But the way ahead is by no means clear at this stage.

32 From the above it will be seen that to give a fixed sum to all those infected irrespective of the course of their disease would be a very poor way of targeting money.

Issues concerning the targeting of monies

33 However such targeting would itself present difficult problems:

i) If money were to be awarded according to the outcome or severity of the disease it would require readily definable "trigger points" to determine who should be paid and when.

ii) Medical examples might include the onset/confirmation of:

- infection
- acute hepatitis
- chronic hepatitis
- cirrhosis
- hepatic carcinoma
- death from liver disease

iii) Such stages would be difficult to define precisely and clinicians in charge could come under great pressure to provide the necessary certification if significant sums of money were involved. The cost of setting up more formal medical tribunals would need to be taken into account.

iv) Social milestones might be:

- certifiable sick leave
- permanent unemployability
- onset of terminal stage
- death from liver disease.

v) If monies were always given after the event then it would be of little immediate help and the estate would be more likely to benefit than the individual.

vi) If the purpose was to alleviate suffering as much as possible it can be argued that not much could be done to help those who had already died from liver disease and it would be best to concentrate on the future. However those directly affected would no doubt challenge such an exclusion. It might be possible to take account of any hardship cases where the family of those who had died were left inadequately provided for.

vii) Another important issue would be the right of the individual to run their own life and make decisions and plans for their future.

Use of a discretionary grant making trust or agency

34 It is for consideration whether instead of introducing a payments scheme whereby fixed sums of money were awarded to individuals as of right, a trust fund could be set up whereby the trustees could make discretionary payments to a clearly defined group of individuals to meet their financial and/or social needs. The actions of the trustees would need to be codified as much as possible so that equality of treatment could be demonstrated but it is possible that such an arrangement would provide considerably greater flexibility and allow changes to be introduced in the targeting as experience was gained.

35 The Macfarlane Trust already has considerable experience of working in this way and so far there seems to have been general satisfaction with the way in which it has been able to put the money where it is most needed, although inevitably there have been some complaints about inequality and inequity of treatment.

36 The deeds of the existing trust would not permit extension to cover hepatitis C. It is always difficult to vary a trust deed. The Macfarlane Trust is moreover specific to the needs of haemophiliacs and the needs of those infected with HIV through blood transfusions is cared for by the Eileen Trust. The two trusts share chairman and several trustees and use the same office and some of the staff. It would certainly be possible to set up one, or probably two, new trusts to cover the hepatitis C situation. The aim would be to gain maximum benefit from and commonality with the existing trusts.

37 However if a new payments scheme were to cover a much wider mandate then there might be benefit in establishing a separate base altogether.

38 It would equally be possible to set up an agency as an arm of Government to make such grants. The pros and cons need to be discussed with our lawyers and if we were to go ahead with the chairman and secretary of the Macfarlane Trust.

Inclusion of partners and children

39 A main route for transmission of HIV is through sexual intercourse. It can also be transmitted from mother to child. A number of partners of those infected and some children were also infected in this way. The HIV settlement therefore made specific provision;

i) for all those who were infected whether directly or indirectly;

ii) to take account of those who had marriage and family responsibilities.

40 The Macfarlane Trust similarly addresses these wider needs. There is no reason why the deeds of a new discretionary trust should not provide similar powers, even though HCV is much less likely to be transmitted in this way than HIV.

The numbers involved, the rates of payment and the possible costs

Numbers

41 We now have effective means of killing the virus in blood products and all donations are tested routinely. The number of people infected through blood products and blood transfusions is therefore finite and falling. On the other hand their medical condition is steadily deteriorating.

42 The Haemophilia Centre Directors estimated that there were about 4000 patients with haemophilia alive today who had been infected with HCV. Of these perhaps 1000 were also infected with HIV and under the HIV settlement had given up any claim for compensation for HCV infection. They were eligible for support from the Macfarlane Trust who do not differentiate between social needs arising from one virus as against the other.

43 This leaves 3000 with haemophilia who were infected with HCV and who have currently no claim on any support funds. All of these would have contracted the infection before 1985, after which the blood products were routinely heat treated. Such patients might be expected to suffer the impact of their hepatitis C over the next two or three decades. The combination of haemophilia and HCV is particularly debilitating and this will cause increased morbidity and earlier death in perhaps half the patients. Some of them will die of old age or other diseases before the HCV becomes a decisive factor.

44 We are not yet clear about the numbers infected through blood transfusion but an appointment has recently been made, jointly by PHLS and NBA, for a senior lecturer to undertake epidemiological research into the numbers exposed to infection.

45 The transfusion centre directors have estimated that there are about 3000 people who are alive today who have been exposed to HCV infection through having received blood from a donor who has since been found to be anti-HCV positive.

46 If awards were made to all those who are alive and who have been infected with HCV (and who are not ineligible to apply - see paragraph 42 above) then the potential membership of a payments scheme would be 6000.

Costs

47 If payments were made at the same rates as for the HIV scheme where the average claimant received about £60,000. (The range is between £80,500 for a married person with family to £41,500 for a single person) then the total cost would be of the order of £360 million. This would almost certainly represent a top side estimate. If the scheme were to be extended to include deceased patients the total might increase to say £500 million.

48 The same degree of proof of causation would be needed as in the HIV schemes. This was much less for haemophiliacs than for blood transfusion recipients. If this were not done then the number applying could increase very significantly.

49 If the payments were confined to those who suffered chronic hepatitis C then these levels might be reduced by 50% to, say, £180 million and if the payments were graduated so that only those who actually died of liver failure (or for whom liver failure was entered as the primary (or secondary) cause of death, then the figure might come down to £60 million.

50 If this same amount of money, say £60 million, were provided to fund a discretionary grant making trust then it would provide the equivalent of £10,000 for every person who was qualified to participate. This could be used to make one off, or regular, payments according to need.

51 If the scope of the scheme or discretionary trust were to be extended to include other viruses and routes of transmission the costs would increase accordingly. The range of possibilities is shown in Annex D. This is not exhaustive and needs to be developed further to include estimates of the numbers involved in each case. A maximum round arm cost estimate might then be £100 million.

Funding of the scheme

52 There is no provision for such payments in existing baselines. At the time of the haemophilia settlements most of the money was found by an in-year claim on the Reserve in the year when they were first made. Thereafter further payments have been found from PES settlements. In the present public expenditure climate Treasury would strongly resist a claim on the Reserve for hepatitis C and expect the Department to find the money from its existing provision.

53 The total cost would fall over a number of years perhaps extending for, say, 30 years to come.

Extension of the ambit of such schemes

54 The above comments have been devoted primarily to assisting those who have been infected by HCV. If such a scheme were introduced then there might be pressure to provide the same or similar benefits for those infected with other blood borne viruses (eg. HTLV1, HTLV2, Hepatitis B) or by other routes (eg. Organ transplants, other body fluids such as semen, or other products such as human insulin or human growth hormone)

55 Whilst one of the main objections to such schemes is that they might set off a chain reaction and encourage expectations of a no fault compensation scheme it has to be acknowledged that the logic of the situation would justify similar treatment.

56 Since the Government is likely to come under increased pressure to settle the CJD litigation and public opinion is generally supportive of some form of recompense where patients are perceived to have been "injured by the NHS", there might be merit in introducing a discretionary trust or agency which would be empowered to make payments in support of clearly demonstrable need across a wider spectrum of cases. The Secretary of State

would decide after discussion with the Treasury which categories would be included. This might be limited to those infections transmitted by blood, blood products and other substances of human origin.

57 The levels of such support would be much lower than would be involved in negligence claims and might be similar to those payable in a general no-fault scheme in other countries. The advantage would be that it was better targeted to meet the needs of those who qualified.

58 The Transfusion Service and the Department may even now be vulnerable because we are not screening for viruses that are rare in the UK donor population such as HTLV1. There are a number of such viruses which may be present in blood and for which there is a test available but where the numbers of donations and potential recipients is so small that the cost of testing would be out of all proportion. This would be a suitable justification for including infection with such a virus in a wider scheme.

Experience in other European countries

59 Although the EU has become increasingly active in promoting self sufficiency and standards for blood safety, there is a directive on blood products (EEC/381/89) but not on blood. Guidelines following on from this directive give some strict requirements regarding testing, eg. HIV, HepC and HepB, but some additional tests are at the discretion of national authorities. The Committee for Proprietary Medical Products (CPMP) of DGIII is addressing this apparent barrier to trade and it is hoped that harmonisation of these additional requirements will take place in the near future. No consensus has emerged concerning the way in which those who have been damaged non-negligently should be treated. It will be interesting to see what develops over the next few years in both areas.

"No fault compensation"

60 The Haemophilia Society has frequently used the term "no fault compensation" in its campaign. It must be clearly understood that any scheme introduced would require a) that there was evidence that the vast majority of those affected would drop any litigation and that b) anyone who was accepted under the scheme would specifically sign away any rights to further claims against the Department.

CA OPU
6 April 1995

ANNEX A

RESTRICTED - POLICY

THE DEPARTMENT'S RESPONSE TO HIV INFECTION

Litigation

1 A number of writs were taken out against individual medical practitioners, against HAs and the Department; the final number was over 1000 in England and Wales. It was decided to bring them together effectively as a class action. A settlement out of court was eventually reached but the indications were that the courts would not have upheld the case for negligence against the Department This was accepted in the final presentation by Counsel on behalf of the haemophiliacs. The motive for settling was as much to bring the matter to conclusion and to save the enormous costs of taking it to court, most of which would have come out of public funds since a high proportion of the litigants were legally aided.

Non-financial help

2 The Government has commissioned extensive research into all aspects of HIV infection and its treatment and management. Good practice guidance is available to the Field. Patients receiving treatment for haemophilia have been carefully screened for HIV infection and extensive counselling and support services set up, run both by NHS haemophilia centres and by the Haemophilia Society in the form of a self-help initiative. The latter has been supported by the Department through S64 funding. A limited process of "look back" has been undertaken for those receiving transfusions of infected blood. However since no cure or effective treatment has yet become available the motive has largely been to limit possible further transmission.

Financial assistance

3 In 1988 the original Macfarlane Trust was set up to address the social needs of those concerned. In 1989 a sum of £20,000 was given to each infected haemophiliac as an ex gratia payment allowing court action to proceed. In December 1990 the Government agreed to special payments for HIV infected haemophilia patients in return for settlement of outstanding litigation. A scheme of payments for those infected with HIV and their dependants was introduced and the original trust was allowed to continue in respect of social need.

4 In 1992 following a campaign on behalf of those infected with HIV through blood transfusion, the Government extended the payments to this group, concluding that they too were a very special case.

5 Both groups shared the tragedy of becoming infected with HIV through medical treatment and were considered to be a special category through:

i) the nature of the HIV infection which was believed to be invariably fatal;

ii) the significant lifestyle implications of HIV, including public hostility etc.;

iii) in the case of the infected haemophilia patients the problems of HIV which were superimposed on the health, social and financial disadvantages they already suffered as a result of their hereditary haemophilia.

6 A discretionary trust (The Macfarlane Trust) was set up in order to enable payments to be made to those suffering particular hardship. The trustees established scales of support for those in need so that as far as was possible there was equality of treatment to all those who applied.

Scale of payments made

7 The solicitors representing the haemophiliacs originally asked in 1989 for payments of £250k per individual giving an approximate figure of £300 million for all 1200 patients. Three months before exchange of expert witness reports was due, the solicitors approached the department and offered to settle for £90 million. They then came back on subsequent occasions and eventually the department agreed to offer £42 million to bring the litigation to an end.

8 At the suggestion of the Haemophiliacs' solicitors this was broken down between patients, partners and children as follows:

Single person infected	under 18	£21,500
	over 18	£23,500
Married person infected		£32,000
Married person with children		£60,500
Infected intimate adult spouse/ partner		£23,500
Child who is married		£23,500
other child		£21,500

In addition the non-infected partners of all infected persons were awarded £2000 each to compensate them for the worry of possible infection.

9 The same rates, together with the additional £20,000 originally paid to the haemophiliacs, were applied to the those infected through blood transfusions. No adjustment was made for inflation over the two years. A discretionary trust (The Eileen Trust), was set up, along similar lines to the original Macfarlane Trust, to take care of the social needs of those infected through blood transfusions.

Cost to date

10 The costs of the haemophilia payment scheme have reached £81 million. (This includes £15 million paid to the Macfarlane Trust for the special needs of HIV haemophilia patients and their families.) Costs of the scheme of payments for those infected with HIV through blood or tissue transfer has reached £3.5 million including £0.5 million paid to the Eileen Trust for the special needs of this group.

CA OPU
10 February 1995

ANNEX B

FEATURES OF A COMPREHENSIVE SCHEME

1 There are certain features which would be likely to be common to any payments scheme for people who had been subject to non-negligent harm as a result of NHS treatment. If a common scheme was established it would need to take account of the following factors:

i) Any scheme should of course make provision for the effects of treatment that results in sexually transmissible infections (eg. HIV and hepatitis C), which have implications for the spouse, or in extreme cases other family members.

ii) There is also for the spouse and family the social dimension of providing care for those who can no longer look after themselves.

iii) Some patients who have been subject to a non-negligent event, for example transfusion of blood from a hepatitis C donor, may suffer no ill effects whatsoever. In others any resulting harm will follow after a prolonged interval.

iv) Some of the writs that have been taken out in these circumstances alleged anxiety and other mental problems as justification for compensation.

v) Lastly, in this list of criteria is the question of whether the harm alleged resulted from NHS treatment or some other cause resulting from the patients behaviour.

2 As a starting point Ministers would need to decide which NHS treatments, alleged to cause non-negligent harm should come within the scheme.

3 Fitting all these features together, the attached algorithm might present a way forward. At each stage (marked 1 to 6) of the process a different set of objective criteria would need to be applied. Taking the vaccine damage and the Macfarlane Trust as precedents, it would be preferable to have these assessments made by a panel independent of Government and set up for the purpose.

4 One also needs to decide whether an Appeal mechanism is required.

5 Ministers would no doubt wish to keep a tight control on the type of treatment admissible under the scheme, rather than allow that decision also to be made by the panel. The Treasury would be likely to resist any mechanism that effectively opened up the system to a wide range of treatments.

6 Whether such a scheme is affordable would depend on the level of payments awarded, and that would turn on the question of harm suffered by the patient (and relatives). However the scheme would have the advantage of providing an equitable system open to those who believe that as a result of NHS treatment they have suffered non-negligent harm.

Dr J S Metters
17 February 1995