

hep094

RESTRICTED - POLICY

Mr Blake Sol B4
Dr Rejman HC(M)1
Mr Brown IRU
Mr Paley FCIA FLIP
Mr Kelly CA OPU2

From Roger Scofield
Date 10 February 1995

copies
Ms Roughton
Mr Shaw
Dr Metters
Mr Heppell
Mr Podger

HEPATITIS C - PAYMENTS SCHEME - CONTINGENCY PLANNING

Summary

This paper notes Ministers' public position against making payments to those inadvertently infected by hepatitis C through the use of blood or blood products provided by the NHS; considers whether if Ministers wanted such a payments scheme could one be provided; how it might be structured and the likely cost; and the possible role of a discretionary trust in making grants to those suffering from the social and financial effects of such infection. It addresses this issue against the background of a possible generic model of response to such non-negligent damage, and work already put in hand to assist those infected with HCV in this way.

Status of the paper

This paper is being circulated to a limited audience on a need to know basis and should not be divulged to anyone else. It has been prepared purely on a contingency basis.

Background

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 is being put in hand to trace, counsel and, where appropriate, treat those concerned.

A number of writs have been served on Regional Transfusion Centres alleging negligence. Lawyers within the Department and the NBA are considering the sequence of events and the principle 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.

It is no part of this paper's purpose to consider the strength or weakness of the case for negligence. But if there is any question of such a charge sticking then the sooner a settlement can be achieved the better. Likewise if for whatever reason there is a likelihood that the Government will have to make payments of any kind then the sooner that decision is made the better.

Any payment made to one group of patients is likely to create pressure for similar treatment from other groups. The paper at Annex A seeks to establish some common philosophy and puts forward a generic model of response to non-negligent damage.

The claim for a payments scheme for hepatitis C victims is 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 B describing the circumstances and terms of that settlement.

(It would be helpful to read these two annexes before proceeding).

The circumstances in which Ministers might wish to offer some sort of payments scheme

Ministers are on record as;

- i) being against a no fault compensation scheme;
- ii) not accepting that there was any negligence so far as hepatitis C infection was concerned;
- iii) having no plans to make any payments to those concerned.

Departmental lawyers are presently considering the strength of the Departments claim that there was no negligence involved. The outcome of this will be a key factor in determining future policy. In parallel a number of solicitors, including those who were involved in the HIV litigation, are preparing writs on behalf of those affected. It is believed that many of their clients have access to legal aid and these cases may therefore be pursued for a long time.

In the recent debate in the Lords and in exchanges in the Commons Opposition members have said that this was the Governments position in the HIV case; but eventually they had to bow to public opinion and pay up. Similar reactions have come from the solicitors representing the litigants and from the Haemophilia Society. It must be acknowledged that the Government might have to reconsider its position if determined cross party support were to emerge, especially if this was fuelled by a major Press campaign.

Meanwhile there is considerable pressure on the National Blood service, whose blood stocks remain at critical levels, and a massive campaign against the NBA's reorganisation plans for the Transfusion centres. This has included a programme of disinformation about the safety of the blood supply. The recent Panorama programme about hepatitis C gave a misleading impression to the effect that anything up to 500,000 people might have been infected and since the programme was primarily about the blood service it might have been inferred that this was the cause.

Against this background there is a case for taking a pro-active approach to resolving outstanding claims for financial compensation whilst denying liability and making some flexible provision for meeting any reasonable needs for the future. This would be only 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.

Rationale for payments

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 penalised the Department. 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;

They might also include an element for personal "injury" or loss of some benefit such as:

- i) anxiety
- ii) reduced prospects of marriage or parenthood; etc.

These are areas on which legal advice would be essential.

Advantages of the HIV settlement

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

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 most instances some have continued in work;
- iii) In a number of cases money awarded has been spent unwisely and those concerned have become a charge to 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. Nearly half of all people receiving blood transfusions die within one year of receiving them from their underlying medical condition. 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

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

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. Proof of infection and use of blood products were the two essential criteria for payment. Whilst if there was clear evidence that the claimant had been infected by some other route (eg, by use of infected needles) they could be disqualified this rarely happened.

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 provided limited flexibility to cope with certain unexpected circumstances.

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 provided 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. However the scheme should not be unnecessarily limited so far as the agent or process is concerned.

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;
- iii) eggs, semen or embryos.

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 but it does not require a new scheme.

Targeting the monies where they are most needed

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:

- * Many people infected with HCV may enjoy a long period without any symptoms appearing.
- * A proportion of these 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.

- * 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health. This can cause liver damage and mortality.
- * Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years.
- * In addition a small proportion will develop primary liver cancer after a further time.
- * 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.

Recently Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be helpful to some patients but as yet its 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.

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.

Problems in targeting the monies

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:
 - infection
 - acute hepatitis
 - chronic hepatitis
 - cirrhosis
 - hepatic carcinoma
- 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.

- 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 and it would be best to concentrate on the future. 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 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 trust

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.

The Macfarlane Trust already has considerable experience of working in this way and so far there seems to have been considerable satisfaction with the way in which it has been able to put the money where it is most needed, even though HCV is much less likely to be transmitted in this way than HIV.

Inclusion of partners and children

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.

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.

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

We are not yet clear about the numbers involved 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.

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

The Haemophilia Centre Directors estimated that there were about 3000 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.

This leaves 2000 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.

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.

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 above) then the potential membership of a payments scheme would be 5000.

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 £300 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 £400 million.

If the payments were confined to those who suffered chronic hepatitis C then these levels might be reduced by 50% to, say, £150 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 £50 million.

If this same amount of money, say £50 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.

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. Some estimates have been made at Annex C to show the possible effects.

Funding of the scheme

No provision has been made in PES for such payments. At the time of the Haemophilia settlements the case was eventually accepted that these should be a charge to the contingency fund in the year when they were first made. Thereafter they were included within normal PES settlements.

It is for consideration whether in present circumstances with Programme Costs limited one could expect any special treatment beyond the cost being taken into account as an additional pressure.

The total cost would not fall in the first year but would fall over a number of years perhaps extending for, say, [60] years to come.

Extension of the ambit of such schemes

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)

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.

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 which would be empowered to make payments in support of clearly demonstrable need across a wide spectrum of cases. The levels of such support would be much lower than would be involved in negligence claims and below what might be payable in a general no-fault scheme. The advantage would be that it was better targeted to meet the needs of those who qualified.

Experience in other European countries

Although the EU has become increasingly active in promoting self sufficiency and standards for blood safety, as yet no directives have sought to take over National decision making on the tests to be undertaken on donated blood. Nor has any consensus emerged concerning the way in which those who have been damaged non-negligently should be treated. It will be interesting to see what emerges over the next few years in both areas.

Meanwhile Ministers may wish to be informed of developments in other countries as regards litigation on HCV infection and on any payments schemes which have been introduced. IRU have been asked to make discrete enquiries.

Preliminary Conclusions

1 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 to the heirs of those deceased. Some of those involved died shortly after being infected from their underlying medical condition 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.

2 The HIV Payments scheme has been supplemented by a discretionary grant making trust also administered by the same trustees which has made additional payments to the same group of people but on the basis of their financial and social need. This has worked very well.

3 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 since the impact of the disease varies so much between individuals and over time 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 £400 million.

4 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. 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.

5 The best targeting of resources might be obtained by establishing a discretionary trust under which all those infected by HCV as a result of NHS treatment would be eligible. Grants would be made, subject to availability, to those who could demonstrate that they were suffering hardship as a result of the financial or social consequences of their illness. This might cost, say, £50 million (spread over 50 years but heavily front loaded).

6 The target group would be 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; of extending it further to cover any other blood borne viruses and / or extending it to cover any infection brought about by the transfer of body fluids, tissues or organs. Such extensions might increase the cost of a discretionary grant to, say, £70 million.

7 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.

8 Any initiative to introduce a discretionary trust should be taken within a wider context which would seek to improve the public's understanding of the risks involved in any medical intervention; a greater commitment on the part of medical staff to ensure that patients are given the full facts concerning risks and benefits before treatment is undertaken; and a comprehensive plan to ensure that the safety of blood supplies is beyond reproach and that public confidence in this is restored.

9 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.

Next steps

This paper has been prepared on a contingency basis against the possibility that more serious consideration will need to be given to setting up some sort of payments scheme. It is very much a first shot and it would be worth taking this further through discussion between a small group of officials. This should include whoever takes over the policy on medical accidents and no fault compensation in the new Public Health Group.

Subject to any advice from copy addressees I would propose inviting addressees to participate in such a meeting in the near future.

R M T Scofield
CA OPU
EH303 Ext: GRO-C