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Expert Group.

Falconer S (Sandra)

From: Stock RG (Bob)
Sent: 03 December 2002 16:50
To: Minister for Health and Community Care
Cc: Deputy Minister (McAveety) for Health and Community Care; Deputy Minister (Mulligan) for Health and Community Care; PS/HD Health; Keel A (Aileen); Robson G (Godfrey); Holme C (Chris); Hamilton FM (Fiona); Falconer S (Sandra); Milligen M (Moira); Lodge T (Trevor)
Subject: Briefing for HCCC meeting 11 Dec

Routine (but useful for Mr Chisholm to see before 0830 meeting on Thursday)

Please find attached briefing for the HCCC meeting covering aspects relating to the preliminary report of the Expert Group on Financial and Other Support (including broader issues linked to 'HCV in blood'). Update on DWP discussions is on page 11. Also attached is a 'lines to take ' document.

I understand from Trevor Lodge that HCCC want to discuss vCJD (presumably in the context of blood services) on 11 Dec. Separate briefing will be supplied for this issue.

Bob Stock
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GRO-C

Briefing for HCCC 11 Dec.doc

LINES TO TAKE.doc

BRIEFING ON 'HCV FROM BLOOD' etc [FOR 11/12/02 MEETING WITH HCCC] RESTRICTED POLICY AND LITIGATION

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THE DISEASE

Health effects

1. HCV is a blood borne virus causing liver disease. It is a potentially virulent disease, but can lie dormant for a lifetime and can even disappear spontaneously. In these respects it is very different from HIV.

2. Most people who become infected with HCV are unaware of it at the time. Some people may briefly feel unwell, or may have nausea and vomiting and, rarely, jaundice.

3. Symptoms, though not common, may also include muscle aches and a high temperature, mild to severe fatigue, loss of appetite, weight loss, depression or anxiety, pain or discomfort in the liver, poor memory or concentration and alcohol intolerance. Many of these symptoms are not specific to HCV infection.

4. Many with chronic HCV will have no symptoms, while others will feel unwell to varying degrees. Most people will remain well and without symptoms for a number of years and this makes the infection difficult to recognise.

5. Disease progression and severity is very variable and patients may not become symptomatic until their liver disease is advanced.

6. The severity of symptoms does not necessarily equate to the extent of liver damage. Some patients will report quite severe symptoms with no clinical signs of liver disease, while cirrhosis can be present without any obvious symptoms.

Disease progression

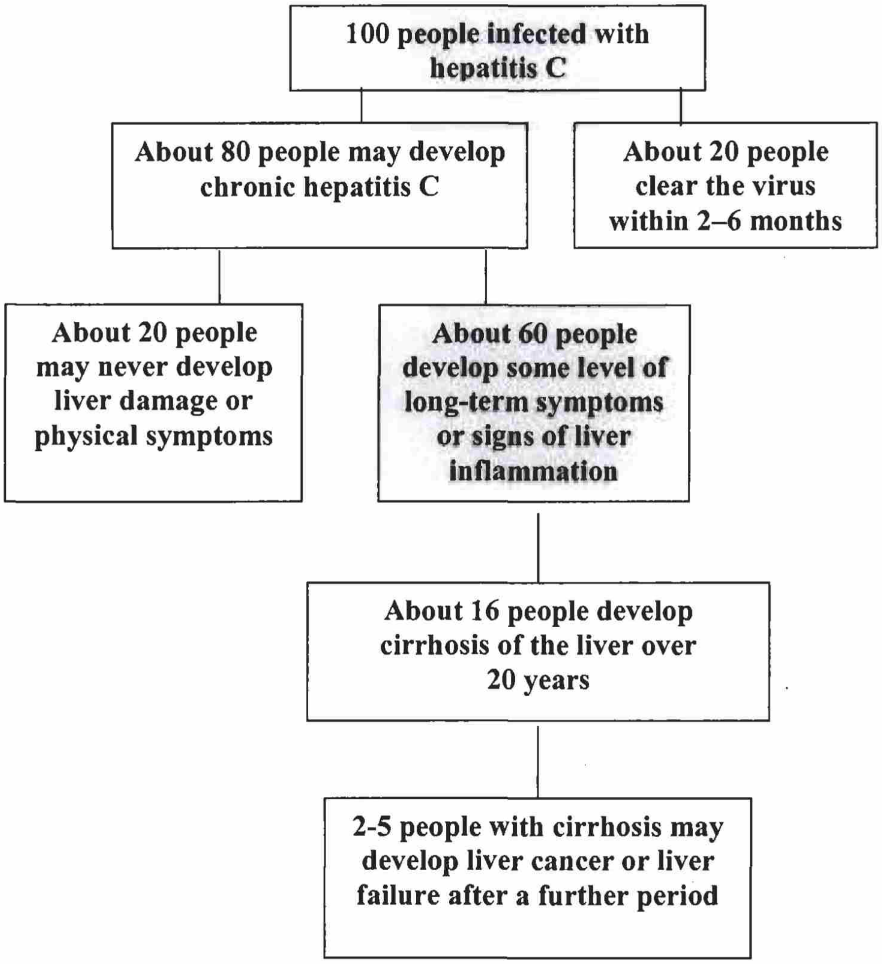
7. Current evidence suggests that:

- around 20% of those infected with hepatitis C infection will clear the virus at the acute stage.

8. Of the 80% who do not:

- some will remain well, and never develop liver damage;
- many will develop only mild to moderate liver damage (with or without symptoms);
- about 20% will progress to cirrhosis of the liver over a period of 20 years;
- a proportion of those with cirrhosis will progress to liver failure or primary liver cancer.

9. An example of the possible overall progression of the disease is illustrated below. It should be noted that understanding of the natural history of HCV is incomplete and the figures below should be considered as approximations:



HCV INFECTION VIA BLOOD AND BLOOD PRODUCTS

History

10. The Hepatitis C virus was identified in 1989 after which specific screening tests were developed to detect the presence of the virus in blood.

11. Screening of all blood donations was introduced in the UK in September 1991.

12. All supplies of Factor VIII blood clotting factor were heat treated to make them HCV-safe from mid 1987 onwards. In the period December 1984 to mid 1987 an imported heat treated product was supplied which was likely to have reduced the possibility of HCV infection.

13. All supplies of Factor IX blood clotting factor were heat treated to make them HCV-safe from October 1985.

Look-back exercise

14. Scottish National Blood Transfusion Service (SNBTS) instituted a look-back exercise aimed at identifying people who may have been put at risk. Arguably, this might have started earlier than it did. It operated on the principle of identifying people carrying the virus when they offered themselves for blood donation. All persons who had received blood transfusions or blood products in the past that included material from a donor identified as HCV positive were contacted and 133 persons identified. However, some donors infected with HCV will not have donated further after screening was introduced. No measures have been taken to identify these donors or to contact people who might have been infected by material donated by them.

Allegations of negligence

15. The Haemophilia Society and the Manor House Group continue to allege that the UK blood transfusion services and DoH were negligent in not taking action to reduce the risk earlier than they did. They allege that the risk from HIV and HCV had been known in medical circles for a long time before DoH acknowledged it and the infection of many individuals could have been avoided if imports of blood and blood products from the US had been stopped (this allegation is mainly relevant to HIV infection). Lord Owen, Labour Health Minister 1974-76 has alleged maladministration and, based on his evidence, there is an attempt to bring a criminal prosecution against the UK government. The Chief Constable of Dyfed-Powys (acting on behalf of the Association of Chief Police Officers) is said to have contacted the Crown Prosecution Service with a view to seeking clarification as to the issues must be considered prior to considering any investigation.

Numbers affected (for summary see Annex A)

16. We estimate that 4000 people may have been infected with HCV via blood and blood products in Scotland. Many of these will have been very ill at the time of the transfusion with infected blood and possibly 60% may have died from other causes.
Of these we estimate 3500 people were infected via blood or tissue (of whom 800 may still be alive), and 500 haemophiliacs via blood clotting factors (of whom 365 may still be alive)

17. These are much greater numbers than for HIV. The main reason for this is that HIV incidence in the UK at the time was low (most of those infected were haemophiliacs who had received blood clotting factor imported from the US) so that very few people contracted HIV from blood transfusions. In contrast, HCV incidence in the UK was relatively high and also HCV screening was introduced several years after HIV screening.

18. The estimate of 3500 people infected via blood or tissue was produced by epidemiologists at the Department of Health's Public Health Laboratory Service Communicable Disease Surveillance Centre following a specific request from the Expert Group secretariat. Since the scheme recommended by the Group included payments to the dependants of the deceased, an estimate of the number of people originally infected (as opposed to those still surviving) was essential to being able to cost the scheme.

19. The estimate of 500 haemophiliacs infected via blood clotting factors was obtained by taking the 343 HCV antibody-positive cases associated with receipt of "*blood factor*" recorded by the Scottish Centre for Infection and Environmental Health (SCIEH) (at 31 December 2001), increasing this figure slightly to take account of cases as yet undiscovered and adding a further 135 persons estimated to be now deceased (estimate provided by the Chairman of UK Haemophilia Directors Committee).

20. Some sources have expressed surprise that the 4000 figure has 'suddenly emerged' – hinting that the Executive has deliberately inflated the figure mentioned at the time of the January debate (530) in order to make the cost of the Expert Group recommendation appear unrealistically high.

21. The 530 figure referred to the number of people identified by the SCIEH recording scheme and who we therefore know were infected (this figure has now increased to 568). The SCIEH figures cover cases associated with receipt of "*blood or tissue*" (non-haemophiliacs) and those associated with receipt of "*blood factor*" (haemophiliacs). Haemophiliacs are under constant medical supervision so almost all will be aware of their HCV status, but only those non-haemophiliacs whose blood fortuitously needs to be tested for other reasons will show up in the SCIEH scheme. The SCIEH figures are therefore likely to include only a proportion of the total of non-haemophiliacs infected.

22. In contrast, the 4000 figure is a prediction based on information obtained in the English look-back exercise and the HCV prevalence at the time – extrapolated to generate figures applicable to Scotland. It is an estimate of all those infected (irrespective of whether they are now alive or dead and irrespective of whether the infected person's HCV status has been discovered at this point of time).

HCCC REPORT (see Annex C)

23. HCCC records in its 17th report 2001 that it was persuaded by the moral case for providing financial assistance. In recommending "a mechanism for providing financial and other appropriate practical support" it argued against lump sum payments – suggesting instead that financial assistance be awarded on the basis of need.

24. In the text of the report it argues that this assistance should be provided as a matter of fairness to individuals who "have suffered serious long-term harm". In its recommendation it explains that need should encompass both physical and psychological loss, and include redress for practical difficulties such as the inability to obtain an affordable mortgage or life assurance.

25. HCCC was at pains not use the word compensation – which it felt had connotations of fault.

EXPERT GROUP'S RECOMMENDATION ON HCV COMPENSATION

The recommendation

The Scottish Executive should establish and fund a discretionary Trust as a matter of urgency that will make ex gratia payments to all people who can demonstrate, on the balance of probabilities, that they received blood, blood products or tissue from the NHS in Scotland* and were subsequently found to be infected with Hepatitis C virus, as follows:

[*Final report will add "*before the dates when they were made HCV safe*"]

a) an initial lump sum of £10,000 to cover inevitable anxiety, stress and social disadvantage;

b) an additional lump sum of £40,000 to those who develop chronic hepatitis C;

c) in addition, those who subsequently suffer serious deterioration in physical condition because of their Hepatitis C infection e.g. cirrhosis, liver cancer or other similar serious condition(s), should be entitled to additional financial support (on an ongoing basis if necessary) as may be assessed appropriate by the Trust. This financial support should be calculated on the same basis as common law damages taking account of the payments made under a) and b) above;

d) where people who would have been beneficiaries of these arrangements are deceased and their death was <u>not</u> due to the Hepatitis C virus, the above payments should pass to their Executors. Where their death <u>was</u> due to the Hepatitis C virus, the Trust should provide for payments to be made to dependant children, spouses, partners or parents, as appropriate.

e) people who receive any payment under legal liability arising from alleged negligence or breach of statutory duty, from the Scottish Ministers, or any of the constituent authorities of the NHS in Scotland, in respect of having been infected with Hepatitis C should not qualify for these arrangements;

f) people who are already in receipt of payments linked to HIV infection from the Macfarlane Trust, Macfarlane Trust Special Payments Trust, Eileen Trust or the associated government Scheme of Payments should have these payments taken into account when additional financial support is assessed for the purposes of c);

g) people who have become infected with Hepatitis C as a result of the virus being transmitted from a person infected by blood, blood products or tissue from the NHS in Scotland shall be dealt with by the Trust on a similar basis to those who have been infected directly in this manner

Lord Ross press release

"The Group felt strongly that it was wrong that people who have contracted HCV through receiving blood, blood products or tissue from the NHS in Scotland should be treated less favourably than people who have contracted HIV under similar circumstances.

The Group therefore concluded that lump sum payments and additional financial support should be made to such HCV sufferers, and that, in assessing such payments, regard should be had to the loss suffered by the individual.

It also concluded that support arrangements for such people should be improved. The Group recognised that the cost of these provisions would be considerable, but it was satisfied that such payments were necessary to avoid injustice to people who have contracted HCV through receiving blood, blood products or tissue from the NHS in Scotland."

Features of the Group's recommended scheme

- payments would be made to <u>all</u> patients who contracted HCV from 'blood' before safety measures were put in place.
- even patients who are symptomless, or who have cleared the virus would be eligible for some payment – with larger amounts for those with chronic HCV and for those with more serious damage (eg cirrhosis).
- does not require applicant to prove HCV infection caused by NHS treatment – only that they had treatment and were subsequently infected
- allows for payments to the dependants or Executors of the deceased (estimate 1165 surviving in Scotland out of 4000 infected – of which only 233 have a strong likelihood of having cirrhosis or worse).
- payments to people who received blood, tissue or blood products from the NHS in Scotland – <u>not</u> to people who were infected elsewhere (even if resident in Scotland).

Scottish Executive response

<u>At HCCC 6 November</u>

- It is probably best to start by reminding you of the Group's remit.
- Firstly, we asked the Group to look at our existing approach to no-fault compensation and advise whether that should be changed. They have found themselves unable to make any meaningful recommendations on this issue at his stage.
- Secondly, we asked them to advise on whether improvements could be made to the existing system for handling fault-based compensation. That work is still ongoing and should be complete by the end of the year.
- The group has however made one recommendation for improvement in this area. It relates to the procedures used by the Scottish Legal Aid Board (SLAB). We have passed that recommendation to SLAB for their consideration.
- We also asked the Group to take account of the situation of patients who have contracted HIV and/or Hepatitis C from blood transfusion or treatment with blood products – as part of their wider considerations on no-fault compensation.
- As I have already said, the report records that group has not come to any definite conclusion as to whether our general approach to no-fault compensation should be changed.
- However, they have made two recommendations that are specific to the circumstances of patients who contracted Hepatitis C from NHS blood. These are Recommendations1&2.
- Recommendation 1 calls for the Executive to implement a comprehensive scheme of ex-gratia financial support.
- We do share the Group's concern for those who through no fault of their own are suffering serious long-term harm and who are experiencing hardship. We would very much like to find a way of doing something to help them.
- But there are quite complex medical, legal and financial considerations here. Also the way in which Hepatitis C presents itself is very variable, and we need to take account of the costs of any payment scheme in the light of other health priorities.
- What we need to do is to think carefully about who needs help, and what is the best way to design a scheme and structure payments so that the individuals involved benefit fully. We want to avoid a position, for example, where we provide financial support which leads to

social security payments being withdrawn or reduced which could very easily happen in many cases.

- We need to look therefore in particular at the interface with the social security system, and devise a scheme that fits this as well as possible. My officials are looking at these issues closely with social security officials.
- I hope these matters will be resolved very soon and we can get on with helping the people that need it most. I hope I will be able to update the Committee soon.

The reaction of the Expert Group

26. Some members are, belatedly, questioning whether the cost estimates contained in their report are over-generous. Phillip Dolan alleged at the November meeting that the figure of 4000 individuals infected was a plot to deliberately inflate the cost of the scheme so as to sabotage its success. Lord Ross is unlikely to take that line as he, and many other Group members, feel the expenditure of £62m - £89m is justified.

27. The reaction of the Group is likely to be summarised by Lord Ross in his submission to HCCC as follows:

- extreme disappointment at what they see as being an outright rejection of their main recommendation.
- the Executive's line that it is necessary to hold discussions with DWP before any decision can be made is merely a delaying tactic – there should be no difficulty in DWP issuing regulations that would allow payments to be disregarded for social security purposes (just as was done for Macfarlane).
- the costs of their scheme are 'worst case' and would be spread over a number of years.
- failure to understand why we will not accept the 'bottom line' of their scheme i.e. to pay £10k to everyone – or, failing that, why we will not accept their 'top line' i.e. to pay £50k + 'common law damages' to those with cirrhosis or worse.
- belief that the Executive is unwilling to 'upset' England (the Group has seen the Hansard extract from October 22 in which Hazel Blears ruled out any scheme in England)

The equity issue

28. The recommendations of both HCCC and the Expert Group are essentially based on the concept of providing equity between 'HCV from blood' patients and 'HIV from blood' patients.

29. The HCCC recommendation that "*financial and other practical assistance be awarded on a no-fault basis*" was justified on the basis that this would be a "*matter of fairness to individuals who had suffered serious long-term harm as a result of NHS treatment*", and "*was required for reasons of consistency in recognition that HIV sufferers already receive assistance under clearly analogous circumstance via the Macfarlane Trust*".

30. The Expert Group justified its recommendation by saying that it "*addressed an inequity between two groups of patients who were harmed in exactly the same set of circumstances*".

31. These equity arguments are open to challenge on two counts:

  - The health outcomes of HCV infection are entirely different to HIV infection
  - The payment scheme recommended by the Expert Group is constructed on an entirely different basis from the Macfarlane Trust scheme.

Therefore we are not comparing like with like and the Expert Group scheme is arguably much more generous than Macfarlane in some respects.

32. This aspect of the argument would need to be used with care if we do not intend to provide a scheme that matches Macfarlane. Nevertheless it may be important to establish the fact that the Executive would not favour a scheme with the wide scope of that recommended by the Expert Group <u>even if the necessary funds could be found from outwith the Health budget.</u>

<u>Different outcomes for HCV c.f. HIV</u>

33. Current medical thinking is that HCV disease progression is as illustrated at para 9 – with possibly only 20% of individuals infected developing serious illness with implications for mortality over a period longer than 20 years. HCV infection can be successfully treated in 50% of cases. In contrast, possibly 90% of people infected with HIV are expected to develop AIDS within 10 years and there is still no accepted treatment.

34. The objective of the Macfarlane and Eileen Trusts was "*to relieve those (infected) who are suffering AIDS or are infected with HIV <u>and who are in need of assistance</u>*". At least 40% of those infected with HCV are unlikely to suffer any serious long term illness or experience associated need for assistance.
[The UK government established Macfarlane and Eileen at a time when the expectation was that anyone infected with HIV would progress swiftly to AIDS and consequential death. We now know that possibly only 10% of HIV sufferers will progress to AIDS within 2-3 years of infection]

<u>Different basis of the Expert Group scheme</u>

35. The Expert Group scheme goes beyond Macfarlane in the following ways:

- It would make payments to those who have not suffered serious illness, but only '*anxiety stress and social disadvantage*'. Arguably, in this respect it exceeds the HCCC recommendation – which focused on **'serious long-term harm'** (the phrase we have used in connection with any alternative scheme we might devise).
- The levels of lump sum award are different to those used in Macfarlane and are linked to levels of debility, whereas the Macfarlane awards were linked to marital and parental status. Macfarlane also provides monthly payments to registrants. (The overall effect of these differences is impossible to assess).
- A wider group of people would be eligible for awards in circumstances where the infected person is deceased (this is a weak argument as we do not propose <u>any</u> retrospective awards).

The social security issue

36. It is extremely desirable to ensure that awards under any new scheme are disregarded for the purposes of means-tested social security benefits. If this was not achieved, and awards were not adjusted to reflect this, then many of the recipients of the wards might gain little real benefit from them. Under the scheme proposed by the Expert Group it would probably be the individuals most seriously affected by the virus who would lose out to the greatest extent, whereas those who had only suffered 'anxiety, stress and social disadvantage' would probably be not receiving benefits in the first place.

37. The alternative would be to inflate the level of the awards so that a significant net benefit remained. It would be impossible to predict the benefits that a particular individual would

receive so the awards would need to be inflated very considerably to take into account the worst case scenario. Again, individuals whose circumstances were not sufficiently dire to merit high levels of social security payments would benefit most from such an arrangement. Also this would effectively siphon off Scottish Executive funds into the coffers of DWP.

The precedent issue

38. One of the arguments against establishing a scheme for providing ex gratia payments to 'HCV from Blood' patients is that it would create a precedent that could give rise to a financial burden on the Health Service in the future.

39. To some extent this argument is undermined by the existence of the Macfarlane Trust, the vCJD Trust and the Vaccine Damage Payment Act. However, any new scheme that went beyond the concept of compensating individuals for serious could create a new and damaging precedent. This would be particularly true of the element of the Expert Group scheme that is aimed at compensating for 'anxiety, stress and social disadvantage'.

40. The biggest concern is new diseases emerging in the future – particularly if these are characterised by long periods of latency before they result in serious harm. Variant CJD is an example of such a disease but there might well be other diseases 'in the system' that we either don't know about or don't yet realise their potential seriousness.

41. Whilst significant effort is being put into avoiding transmission of vCJD to patients (particularly through transfusion) the disease is poorly understood and we cannot exclude the possibility that these measures may be ineffective. We could then face the possibility in maybe 20 years time of an epidemic of people who have been seriously affected as a result of NHS treatment but where the NHS was not negligent. Many of these could probably sue the NHS using CPA but only if the infection occurred by means of a 'product'.

42. People who did not have recourse to CPA might well cite any previous compensation scheme for HCV 'victims' and demand similar financial support.

43. In addition, various groups are currently either seeking compensation in the courts or have attempted to do so and have failed. Any move by the Executive to pay ex gratia compensation where there is no legal liability could encourage these groups to expect and demand the same.

44. Examples are:

- RAGE (Radiotherapy Action Group) – patients with breast cancer who were harmed by radiotherapy treatment but failed to win damages in the courts.

- Myodil Action Group – seeking compensation for alleged injury following use of Myodil, a diagnostic agent

- parents currently litigating in relation to retained organs.

45. If, in the future, MMR vaccine was found to be harmful the patients involved might also seek compensation by analogy with HCV.

Possible alternative schemes

46. We have publicly announced that we would like to help "*those who through no fault of their own are suffering serious long-term harm and who are experiencing hardship*". The focus on current harm/hardship makes it clear that no payments to beneficiaries/dependants of the deceased are envisaged.

47. In practical terms cirrhosis, liver failure or liver cancer are the only conditions that can be confidently linked to HCV infection – and therefore identifiable as leading to long-term harm caused by 'HCV from blood'. There may be individuals who have HCV and are seriously debilitated in other ways but whose symptoms are either subjective or can be linked to other causative routes. It would be difficult to devise scheme criteria that would allow awards to these individuals and yet exclude others with less serious subjective symptoms

48. We initially envisaged that any alternative scheme would make monthly payments in a similar fashion to Macfarlane. However, at this stage it is not possible to rule out the possibility of it being necessary to make a lump sum award to the registrant (possibly constrained so that it can only be spent on an annuity that would provide regular income) in order to avoid loss of social security benefits.

Costs (see Annex A)

Discussions with DWP

49. SE officials met with DWP officials on 14 November to discuss social security disregard. They indicated unofficially that they would be reluctant to make specific regulations that would allow payments from a new ex gratia scheme to be disregarded for the purposes of assessing means-tested benefits if the scheme did not apply across all the UK administrations.

50. They were willing to consider ways in which a scheme might be designed so that payments would be disregarded under general rules. Their initial response was that a scheme whose purpose was compensation (rather than support for the needy) would be more likely to qualify under general rules. We believe that there is a reasonable prospect of devising a scheme that would avoid loss of social security payments. However we need to resolve the issue of competence before coming to a final conclusion.

51. We understand that DWP lawyers have been looking into the competence issue but have not yet reached a firm view. Advice from DWP officials is that they do not expect an early resolution of the matter.

NO-FAULT COMPENSATION

Expert Group view

52. In its preliminary report, submitted on 4 September, the Group stated that it could make not make meaningful recommendations by the end of July 2002 and would consider no-fault compensation further in the second part of its work. However a few days later at its meeting on 17 September it noted that "it did not wish to recommend the introduction of a general no-fault compensation scheme".

English review of 'clinical negligence'

53. In July 2001 Alan Milburn was given the go ahead for the Department of Health to produce a White Paper on reform of the clinical negligence system in England. The drivers behind the initiative were the need to stem spiralling bills in England and to improve "the claims system that is acknowledged as distressing to patients and NHS staff alike".

54. These drivers are substantially absent in Scotland. The cost of Clinical Negligence in Scotland is only a fraction of that in England with claims in 1999-2000 totalling £3.8m compared with just under £400m paid out in England.

55. The first step to the White Paper was the establishment of an Expert Advisory Group under the chairmanship of the English CMO. Its tasks were to:

i] review the current legal framework, procedures and operational arrangements for dealing with clinical negligence claims

ii] assess potential reforms against a number of laid down aspirations e.g. reducing costs, being fair and transparent, dealing with complaints and concerns quickly.

iii] recommend package of measures to address concerns.

56. Despite the emphasis on clinical negligence the group's detailed remit was very broad and included consideration of the "merits and disadvantages of different types of no-fault compensation and of fixed tariffs". We believe no-fault compensation was included for completeness, rather than because this was perceived as being of key importance.

57. The group was expected to report in January 2002 but nothing official has emerged. The official line is that it is "under active consideration". Unofficially, we understand that the group has rejected the concept of no-fault compensation.

Existing UK ex gratia compensation schemes

Macfarlane Trust

58. A discretionary charitable Trust set up in 1988 to assist people throughout the UK who contracted HIV from contaminated blood products in the late 1970s and early 1980s. Remit is to "relieve people suffering from haemophilia as a result of receiving infected blood products .....who are in need of assistance, or their needy spouses, and other dependants after the death of the (infected) person".

59. Initially provided lump sum payments of between £40K and £80k (depending on marital and parental status). Subsequently provides ongoing support – mostly in the form of monthly payments. All registrants receive £255 per month. This may rise to £383 if in receipt of specified social security benefits. Payments are increased in winter (because HIV 'victims' suffer more if they get cold). A review 2-3 years ago showed that 70% of registrants are largely dependent on income from the Trust plus state benefits.

60. The Trustees have a broad remit and a fair degree of autonomy. Eligibility is linked only to HIV infection and Health Service causation – not to any degree of debility.

61. Macfarlane provides for haemophiliac 'victims' but also administers the Eileen Trust – which provides for people who were infected via transfusion.

62. Rationale behind setting up the Trust was driven by the assumption that HIV infection progressed swiftly and inevitably to death. Although this was never conceded, the UK government may also have felt culpable because it failed to achieve its policy objective of UK self sufficiency in plasma products as early as intended – with the result that plasma contaminated with HIV was imported. This did not apply to HCV, which was already endemic in the UK population. It is worth noting that Scotland achieved self sufficiency in plasma products during the 1980s, whereas England has never achieved total self-sufficiency.

Vaccine Damage Payment Act 1979

63. Introduced as a public health measure in response to the Pearson Commission on Civil Liability and Compensation for Personal Injury. Administered by Department of Social Security – providing single, tax-free payments of £100,000 to people who, on the balance of probabilities, have suffered severe mental and/or physical disablement of 80% or more (60% from June 2002) as a result of the administration of a vaccine against a specified list of diseases.

vCJD Trust

64. Established October 2001. £55 million for the first 250 cases. The Government will review the scheme if the total exceeds 250. Lump sums are paid – £120k to the victim, £5k to the victim's family, £5k (in certain circumstances) in relation to care. Victims and family can also claim for certain specified costs. The payments are described as compensation.

65. The main argument for providing the compensation is similar to that originally used in the case of Macfarlane i.e. it was an 'exceptional' situation because many of the 'victims' were young people and the disease inevitably progresses very swiftly to death and is devastating in its impact on sufferers and families alike. In addition, the government felt there were 'wider societal reasons' for paying out – namely that there was no particular Department to whom the affected people could turn and central government was 'their last resort for help

[ALL THE ABOVE SCHEMES ARE FUNDED DIRECTLY BY TREASURY ON A UK-WIDE BASIS]

Existing ex gratia compensation schemes (outside UK)

Republic of Ireland

66. The Republic makes compensation payments to people who contracted HCV from contaminated blood.

67. The reason for this is that pregnant women continued to receive a plasma derivative contaminated with HCV for some time after the virus was identified and screening introduced. Furthermore, some of these pregnant women subsequently donated blood – with the result that the entire blood supply was potentially contaminated. An investigating tribunal decided that Blood Transfusion Service was definitely found to be at fault and that all people who had received blood transfusions etc and who contracted HCV should be compensated.

68. The payments made have been quite large – doubtless reflecting the fact that they pre-empt viable court actions for negligence. Total expenditure since 1996 amounts to £291.4m in respect of 1406 awards. 114 awards were made in during the last recorded – ranging in size from £7,869 to £762,827. The largest award made so far is £1.6m.

69. The republic of Ireland operates a "health card" system for providing health care to its population. The amount an individual normally pays for treatment depends on a means test. The Health Act was amended so that persons who had contracted HCV from Anti-D would receive various services free of charge and it also ring fenced funding to ensure priority treatment for these patients. Expenditure associated with providing this is £32.89m to date.

Canada

70. Canada has introduced a fixed payment compensation scheme for patients who have contracted HCV from blood. The size of the payment is linked to the stage of the disease.

New Zealand

71. Operates a scheme that provides statutory entitlements for people who suffer personal injury as the result of medical error or mishap (this excludes injury caused by a 'gradual process, disease or infection').

TREATMENT AVAILABLE FOR HCV

72. An estimated 35,00 people (0.7% of the Scottish population) are infected with HCV, of whom approx. 10,000 are diagnosed.

73. Combination antiviral therapy (interferon plus ribavirin) proving successful in approximately 50% of cases. Expensive (around £5000 – 10,000 per patient for 6 months treatment) and not suitable for heavy users of alcohol or those who continue to inject drugs. NHS Boards take decisions on treatment at local level.

74. SNAP (Scottish Needs Assessment Programme) report (August 2000) pointed out that combination therapy is more effective than interferon alone. Recommended that NHS Boards/Trusts consider the relative priority of provision of these drugs for their population and should take account of the cost effectiveness of the various regimens when decisions taken regarding funding of these drugs.

75. "Pegylated" interferon, which persists longer in the blood, has recently become available. In combination with ribavirin, appears to be more successful in clearing the virus than conventional Interferon and ribavirin, with efficacy rates of around 55%. The costs of using this in combination with ribavirin are not yet clear, but are likely to be higher than using non-pegylated interferon.

CURRENT MEASURES TO ENSURE THE SAFETY OF 'BLOOD'

76. The main measure taken to avoid transmission of HCV via blood transfusion and treatment with blood products is the screening of all blood donations for the virus.

77. In addition, all plasma derived blood clotting factors are subjected to heat treatment or chemical treatment to destroy a significant number of viruses that may be present including HCV. This type of treatment was introduced before screening was available and has been retained because it is non-specific and may be effective in inactivating other harmful agents – in addition to acting as a back stop in the event of any failure in the screening process.

78. Very large sums of money (£17.3m) are being invested in providing all haemophiliacs in Scotland with Factor VIII recombinant clotting factor to avoid transmission of blood borne agents, including the theoretical risk of vCJD.

79. A large amount of resource is being directed at reducing the prevalence of HCV in the general Scottish population eg through drug abuse prevention measures. A subsidiary effect of any success in this area would be to mitigate the effect of any failure in the screening process.

80. A wide range of measures is in place to avoid transmission of other harmful agents via blood transfusion and treatment with blood products. In some cases, this is achieved by screening or by chemical inactivation. Much of the plasma used for blood product manufacture is now sourced from outside the UK as a precaution against the theoretical transmission of vCJD

81. The Scottish Executive has given the go ahead for an 'Effective Use of Blood' programme. This aims to reduce the amount of blood used in transfusion and hence reduce the risk of any transfusion-related risk.

82. Notwithstanding all of the risk reduction measures in place and planned,, blood transfusion and treatment with blood products cannot be guaranteed to be risk free.

83. The processes involved in providing an effective regime of risk control are very complex and, with the best will in the world, are bound to fail occasionally.

84. New diseases and harmful agents are continually arising. Often it may take decades before they are detected, or their seriousness appreciated, by which time many people may have been inadvertently infected. And then it may take years to develop effective counter measures.

PROVIDING ADVICE TO PATIENTS ON RISK (CSBS)

85. An existing CSBS generic standard "Patient Involvement" is relevant to concerns about risk advice provided by clinicians. The standard is judged against the criteria "*Patients are provided with a clear explanation of their condition and any treatment, investigation or procedure proposed, including risks and alternatives, before agreeing on the course of action, to enable them to give informed consent.*"

86. There are 3 stages to the CSBS accreditation process:

1] Trusts undertake a self-assessment exercise of their service against the standard,

2] Self-assessment is peer reviewed on behalf of CSBS by visiting multidisciplinary team (includes healthcare professionals and members of the public),

3] CSBS publishes findings.

87. CSBS has agreed to apply the accreditation process for this standard to the field of blood transfusion and blood products.

88. Executive is setting up a meeting between CSBS, the SNBTS Clinical User Group to progress this (hopefully to take place in January). The Coagulation Factor Working Party for Scotland and Northern Ireland may also be involved at a later stage.

89. CSBS has not taken this forward earlier due to pressure of existing commitments but has recently conducted a review of the standard as applied to SNBTS operations. This concluded that the provision of information to donors meets the standard.

[The SNBTS Clinical User Group is an independent group comprised of senior clinical users of the SNBTS and representatives of donors and patients. It responds directly to the Minister for Health & Community Care. The Coagulation Factor Working Party for Scotland and Northern Ireland represents the views of NHS consumers of the blood fractionation products supplied by SNBTS for haemophilia A & B patients. It currently has no independent input.]

ANNEX A

ESTIMATED COSTS OF COMPENSATION SCHEMES

NUMBERS OF PEOPLE INFECTED IN SCOTLAND

All those infected (including those now dead)

Infected via transfusion:	3498
Infected via blood products:	500
TOTAL	3998 (~4000)

[The 'transfusion' figure is a prediction – based on a study on transfusion-related HCV infection in England undertaken by epidemiologists at the Department of Health's Public Health Laboratory Service Communicable Disease Surveillance Centre (CDSC). CDSC used data from the look-back programme and also population and HCV prevalence data relevant to the time period when the suspect transfusions were taking place. CDSC then reran the calculations to arrive at a figure for Scotland]

[The 'blood products' figure is made up of the number of HCV antibody-positive cases associated with receipt of "*blood factor*" as recorded by the Scottish Centre for Infection and Environmental Health (SCIEH) added to an estimate of those people in receipt of blood factor who are likely now to be dead (estimated by the Chairman of UK Haemophilia Directors Committee)]

Estimated numbers surviving

Infected via transfusion:	800
Infected via blood products:	365
TOTAL	1165

Survivors identified by SCIEH

Associated with *blood or tissue*:	225
Associated with *blood factor*:	343
TOTAL	568

[All assumed still to be alive. N.B. the published SCIEH figure at the time of the January debate was 530 – widely approximated to 500 in the press]

ASSOCIATED COSTS OF SCHEMES

Expert Group Recommendation

<u>Lower limit</u>

@ £10k (for anxiety, stress & social disadvantage only):

[to 20% of those infected likely to clear the virus within 2-6 months]

0.2 X 4000 X £10k = £8m

@ £50k (£10k for anxiety, stress & social disadvantage + £40k for developing chronic HCV)
[to the remaining 80%]

0.8 X 4000 X £50k = £160m

@ £50k payment based on common law damages (additional)

[to 16% of those infected likely to develop cirrhosis over 20 years – or worse]

0.16 X 4000 X £50k = £32m

SUB TOTAL (£8m + £160m + £32m) = £200m

TOTAL (assuming 31% uptake) = **£62m**

<u>Upper limit</u>

@ £10k (for anxiety, stress & social disadvantage only):

0.2 X 4000 X £10k = £8m

@ £50k (£10k for anxiety, stress & social disadvantage + £40k for developing chronic HCV)

0.8 X 4000 X £50k = £160m

@ £50k payment based on common law damages (additional)

[to 60% of those infected likely to develop cirrhosis – or worse]

0.6 X 4000 X £50k = £120m

SUB TOTAL (£8m + £160m + £120m) = £288m

TOTAL (assuming 31% uptake) = **£89m**

NOTES:

1. Average award based on **Common Law Damages** (arbitrarily) assumed to be £100k – reduced to £50k after subtracting the £50k already awarded.
[Awards based on Common Law Damages take into account suffering of the individual, associated care costs and loss of earnings. Loss of earnings will vary widely depending on both the earning power of the individual and their life expectancy. Some individuals will now be quite old –with earning considerably reduced in previous years as a result of the disease. Some may have been infected by when they were babies (as late as 1991) – their lost earnings could be very large]

2 Assumes 70% **take up rate** of from all people who would be eligible for payment in respect of infection linked to the provision of blood factor to haemophiliacs (including from relatives of the deceased). Assumes 25% take up rate from blood and tissue patients (including from relatives of the deceased). Applying these percentages to the figures of 500 and 3500 respectively gives an overall take up rate of 31%.

3 **The lower and upper limits** define the extent of uncertainty about the long-term health effects of developing chronic HCV.

16% progressing to cirrhosis over 20 years represents a best case scenario under current knowledge (some experts feel 20% is a more realistic figure).

60% progressing to cirrhosis over 20 years represents a worst case scenario in which all those who develop chronic HCV go on to develop cirrhosis or worse – but over a longer period than 20 years.

4 The **take up profile** is impossible to predict because we do not know where each of the individual survivors is in terms of their progression to more serious conditions such as cirrhosis.

5 A high proportion of those infected via blood factor will be **co-infected with HIV** and will therefore be in receipt of payments from the Macfarlane Trust. The Expert Group scheme specifies that Macfarlane payments should be taken into account when assessing those awards that are to be awarded on the basis of Common Law Damages. These estimates are not reduced to make allowance for this (because the Expert Group did not specify <u>how</u> to take account of Macfarlane payments and because the £100k assumed for Common Law Damages is arbitrary anyway).

Expert Group Recommendation

(applied 'immediately' to the survivors identified by SCIEH)

@ £10k (for anxiety, stress & social disadvantage only):

0.2 X 568 X £10k = £1.1m

@ £50k (£10k for anxiety, stress & social disadvantage + £40k for developing chronic HCV)

0.8 X 568 X £50k = £22.7m

@ £50k payment based on common law damages (additional)

0.16 X 568 X £50k = £4.5m

TOTAL (assuming 100% uptake) = **£28.3m**

Expert Group Recommendation (applied to estimated survivors only)

Estimated 1165 survivors

<u>Lower limit</u>

TOTAL (assuming 31% uptake) = £62m X (1165 ÷ 4000) = **£18m**

<u>Upper limit</u>

TOTAL (assuming 31% uptake) = £89m X (1165 ÷ 4000) = **£25.9m**

ANNEX B

PROGRESS ON POINTS MADE IN JANUARY DEBATE

MC *The financial services providers also have their role to play through the provision of **mortgages and insurance**. That area is complex, but I am committed to working with patient groups to improve it. I intend to have **exploratory talks with patients and patient groups** in the coming weeks on that matter as well as on others. **Following those talks**, I intend to **host a summit on the issue with the leaders of financial services providers**.*
MC *we will undertake a **listening exercise with patients with hepatitis C to identify any specific difficulties that they face on care and treatment**. I have already discussed that over a number of years with the hepatitis C group in Edinburgh. I look forward to listening further to that group and others throughout Scotland.*

- Listening exercise undertaken towards the end of January. Main concerns raised were:

  a] stigmatisation/discrimination arising from poor understanding in the general populace of all aspects of the disease. Also poor knowledge of the disease throughout the NHS at all levels.

  b] difficulties in getting mortgages and life/travel insurance – patients experiencing unwarranted refusal, imposition of unreasonable conditions or premiums.

- Patient organisations followed up to gather detailed information on insurance/mortgage difficulties. Officials have discussed these at meetings with the Association of British Insurers and the Council of Mortgage Lenders. Currently trying to identify a date in November when the Minister is available to meet with these organisations and with other senior officials of financial institutions. [Representatives of Haemophilia Society and Capital C are keen to attend. Hazel Blear has also indicated that would like to participate].

MC *health department officials this week met representatives of national voluntary organisations to discuss the possibility of setting up a **national resource centre to provide advice and information to those who are affected by hepatitis C and their families**. More work needs to be done on the bid that has been put in, but it has considerable potential and I am minded to look favourably on it.*

- We have offered £40,000 to the British Liver Trust and Mainliners in 2002-2003 to establish a Hepatitis C Resource Centre for Scotland. The Centre is intended to be a one-stop shop providing information on Hepatitis C infection as well as details of who to contact regarding testing and treatment in Scotland. The project is expected to secure premises (in Glasgow) shortly and open early in 2003.

MC *the chief medical officer met directors of public health from throughout Scotland and emphasised the need for all those who are involved in delivering effective health care to continue to implement and build on the Scottish needs assessment programme report on hepatitis C.*

- The Executive has recently produced an Information Pack for Professionals and a patient information leaflet on Hepatitis C. These have been widely distributed within NHSScotland, the drugs field and the Scottish Prison Service.

MC *chief medical officer also arranged a presentation for senior members of the health department to hear clinicians' perspectives on hepatitis C, on the quality of service and range of treatments that are available and on how provision might be improved. Following on from that, I have* ***asked the chief medical officer to start work to gain a clearer picture of hepatitis C prevalence to inform new recommendations*** *from him* ***on how we can equip the NHS*** *to deal appropriately with the needs of those with the condition.*

- The Executive and the Royal College of Physicians held a joint conference, on 4 July in Edinburgh, to discuss with health professionals and others working in the field the issue of treatment and care of hepatitis C patients over the longer term.

  As a result of these discussions, officials are developing plans for a hepatitis C clinical database in order to track infection more effectively. They are also meeting with clinicians and patient representatives in November to take forward the development of Managed Clinical Networks for hepatitis C patients.

- The Executive is working with the Scottish Centre for Infection and Environmental Health (SCIEH) and HEBS to assess the case for, and content of, a related public information campaign.

- The Executive has also commissioned SCIEH to undertake epidemiological modelling work to provide robust figures on which future services can be planned.

MC *the Health and Community Care Committee's report refers to "the existence of paternalistic 'doctor knows best' approach in relations between practitioners and patients at the time." We are determined to change that culture. That is reflected in the document on patient focus and public involvement that we issued last month as well as in* ***the Clinical Standards Board for Scotland generic standard on patient involvement****. Once that standard has been established, there are three stages in the Clinical Standards Board's accreditation process: self-assessment against the standard; peer review by multidisciplinary teams that include professionals and patients; and publication of the findings.* ***The Executive will meet the Clinical Standards Board in the near future to discuss how to implement*** *that process* ***in relation to blood transfusion and treatment with blood products.***
HH *We need to change the atmosphere in which doctors relate to patients and advice is given. Vast improvements have been made in that respect, but we cannot be complacent.* ***We have agreed that the Clinical Standards Board for Scotland will examine that as part of its accreditation process on patient focus. We are in active discussion with the CSBS on how best to progress that matter.*** *We are determined that the process should be thorough and objective.*

- CSBS has recently reviewed the application of its generic standards to SNBTS, and has concluded that the provision of information to donors fully meets the patient involvement standard. More work is required in relation to the development of information for patients who receive blood transfusions. We are working with CSBS, and the SNBTS Clinical User Group to establish a group to develop this information which will then be incorporated in clinical standards.

MC *I announced last month* ***an expert group to examine the current system of dealing with patients who have suffered harm and to make recommendations on how the system***

might be changed. *Much of the public debate around the issue has centred on the need for fairness. On compensation, I, too, am interested primarily in achieving a fair and equitable outcome. Crucially, I want an outcome that is fair for the many as well as the few. That is why we do not believe that it is fair to consider the question of compensation to hepatitis C sufferers in isolation. I want the group to give momentum to the debate on compensation and to* ***report back to me within six months****. I will expect the group to* ***consider the circumstances surrounding hepatitis C infection through blood and blood products as an important part of its more general work. I also expect the group to consider whether any new system should be applied retrospectively. We want the group to judge the merits of a new system in relation to three key agendas. The first of those is the promotion of innovation and creativity in the NHS. The second is efficient health service operation. The third and most important is a fair deal for all patients.***

HH *The fact that we are setting up an expert group means that* ***hepatitis C will be treated as a specific issue,*** *and that we will learn from that example and apply what is learned in the future. As Malcolm Chisholm has said, any system that suggests financial assistance would need to be fair and open so that everyone would know where they stood in advance of seeking such a payment.*

- The Expert Group on Financial and Other Support was established in March this year, under the chairmanship of Lord Ross, to consider the current system of dealing with patients who have suffered harm through NHS treatment, where NHSScotland is unlikely to have liability.
- The Group was asked to consider the circumstances surrounding Hepatitis C infection through blood and blood products as an important part of its more general remit.
- The Group's membership was drawn from patient, professional and academic groups, two members from patient groups having a direct interest in Hepatitis C.
- The Group has had 8 meetings to date and submitted its preliminary findings to the Minister on 4 September. There are 2 further meetings scheduled before submission of the Group's final report at the end of December 2002.

ANNEX C

EXTRACTS FROM THE HCCC REPORT ON HEPATITIS C

Mortgages and life assurance

Diagnosis of the disease makes it almost impossible to obtain mortgages or life assurance, and many hepatitis C sufferers cannot hold down employment because of the nature of their illness.

Negligence

We were largely persuaded by the case put by the SNBTS that the decision not to use the ALT test was predominantly a clinical one, and we acknowledge that there appear to have been a number of important reasons for not using the test. Not least among these was the risk of running out of blood supplies needed for essential medical treatment.

On the basis of the limited evidence we considered, we could take only a provisional view (on whether SNBTS was unjustifiably slow in making hepatitis C-safe factor VIII concentrate available for clinical use in Scotland). This was that there was no evidence of negligent delay on the part of the SNBTS.

Information for patients

We do not believe that there was any general policy deliberately to mislead patients. If haemophiliacs' testimony proves anything it is perhaps the existence of paternalistic "doctor knows best" approach in relations between practitioners and patients at the time. This may have involved practitioners taking treatment decisions on behalf of their patients, without disclosing all the options, in the well-intended (and, given the state of medical advancement at the time, quite possibly justified) belief that they were acting in their patients' best interests. It is regrettable that some clinicians were not more open with their patients.

Need for a public enquiry

We have doubts as to the usefulness of carrying out any further inquiry on the questions of fault on the part of the SNBTS. We agree that the Executive's report does not deal with all of the questions to which the Haemophilia Society wants answers. The position of non-haemophiliacs who contracted the hepatitis C virus, such as the petitioner Mr McKissock, was not addressed. Events before and after the mid-1980s were not examined. The non-use of the ALT test by the SNBTS was not examined. The practical consequences of hepatitis C on sufferers and their families were not considered in any detail. All of this is disappointing. Those affected want a line drawn under this matter. So do we, and, so far as those most affected are concerned we fear that another inquiry would serve only to prolong the wait.

Financial assistance

The Committee has become persuaded by the "moral" case for providing financial assistance to those individuals infected with hepatitis C through blood transfusions. The Minister for Health and Community Care has expressed concern about establishing any principle of awarding compensation for harm caused by NHS treatment simply because the treatment carried a risk, and that risk subsequently crystallised as an injury. We are in full agreement with the minister on this matter. A risk-averse NHS is in no-one's interests.

Nor are we asking the Executive to establish any new, wide-ranging precedent on the management of risk in clinical decision-making. Instead we simply seek to correct an inconsistency in the operation of an already created and narrow precedent; namely the precedent created when the MacFarlane Trust was set up.

The legal system

There is too much of an onus on aggrieved patients having to prove their case in the law courts, with justice often deferred for years as cases proceed expensively through the legal system. There must be a better way of resolving disputes between the NHS and patients.

Scheme details

Should the Executive accept the principle of our recommendation, we are content to leave it to decide the best mechanism by which to make assistance available. As regards determining appropriate financial assistance, the method applied by the MacFarlane Trust would probably be inappropriate. This is because the MacFarlane Trust awards compensation on a lump sum basis, with the precise amount awarded depending on the status of the claimant. Given that the MacFarlane Trust was set up at a time when HIV infection was regarded as being effectively 100% fatal, this approach may appear understandable. However, hepatitis C is a disease whose effects can vary widely; for some the effects are minor, while for others the disease can be life-threatening. We therefore consider that the level of financial assistance should be determined on the basis of need, having regard to the physical, psychological, or practical loss suffered by any claimant. Practical financial assistance could include, for instance, assistance with meeting mortgage or life assurance costs, while non-financial practical assistance could include the provision of counselling. Hepatitis C sufferers themselves will have views as to the sort of practical assistance they would welcome, and we would encourage the Executive to canvass and take account of their views.

Recommendations:

1. We recommend that the Executive set up a mechanism for providing financial and other appropriate practical support to all hepatitis C sufferers who have contracted the virus as a result of blood transfusions provided by the NHS in Scotland, or which involved blood or blood products produced by the SNBTS. This support should be available to all such hepatitis C sufferers whether they are haemophiliacs or non-haemophiliacs, and it should be available regardless of whether negligence in the individual case can be proven or not. It should also be available regardless of when the individual became infected with hepatitis C, although clearly anyone who became infected after the Consumer Protection Act 1987 came into force, and who has obtained adequate damages under the Act, or who has settled adequately with the Executive's lawyers, should not also be entitled to further financial assistance.

2. We recommend that this mechanism for providing financial and other support comes into operation within a period of twelve months.

3. The level of financial assistance awarded to any claimant should be determined on the basis of need, having regard to the physical or psychological loss individually suffered, and should include redress for practical difficulties such as the inability to obtain an affordable mortgage or life assurance.

4. In determining an appropriate package of assistance, and in particular in clarifying what practical help can be offered, the Executive should consult hepatitis C sufferers - both haemophiliac and non-haemophiliac.

5. We recommend that the Clinical Standards Board for Scotland oversee an investigation into the adequacy of advice on risk offered by clinicians to individuals receiving blood transfusions or being provided with blood products. Any such investigation should consider the adequacy of advice offered not just to haemophiliacs but to non-haemophiliacs as well.

6. We recommend the adoption of a protocol between the Health and Community Care Committee and the Executive that, wherever practicable, the Executive consults with the Committee before deciding upon the terms of an internal inquiry and the membership of the inquiry team, in order to increase public confidence in the process.

7. We would also recommend that the Executive establish a commission to examine the current system of negligence and fault-based compensation and to propose alternatives. This should be with a view to promote a climate of critical self-audit by all health professionals and health managers, to reduce the level of court involvement, and to establish rapid and cost-effective support and assistance for those individuals and their families who suffer unforeseen adverse effects from health interventions.

ANNEX D

LIABILITY ISSUES

CONSUMER PROTECTION ACT

Implementation date

90. Came into force on 1 March 1988 – implementing the Product Safety Directive. Strict liability legislation i.e. no need to prove negligence. 'Producer' liable if found to have supplied a defective product. CPA amended the time bar triggers in the Prescription & Limitation Act (Scotland) as follows.

10 year time bar

91. Liability ceases 10 years from the date when the person was treated with the defective product. [Courts have no discretion to override 10 year bar – even if claimant was unaware that they were infected until after the 10 year period had expired]

3 year time bar

92. Within the 10 year period, the claimants must have raised an action within 3 years of the date when they discovered certain key facts – principally that they had been infected by the defective product. [Courts have discretion to override 3 year bar, but may choose not to if they decide that it was reasonable for claimants to have discovered the facts earlier than they did]

93. If infected person dies without raising an action (and without discovering the key facts), then other parties eg the relatives, must raise an action within 3 years of the death.
[Courts have the power to override this time bar and hear cases where the 3 year period has been exceeded - more likely to do so if defendant unable to demonstrate that they were seriously inconvenienced by the claimants not raising action earlier]

The Burton judgement

94. Claimants raised a class action in the English High Court alleging that blood contaminated with HCV was a defective product under Consumer Protection Act (CPA). Mr Justice Burton agreed and instructed the National Blood Authority to pay compensation to the claimants – ranging from just under 11k to £60k in the lead cases, with an indication that claimants would be eligible for further payments if their illness worsened in the future. The expectation is that the claimant receiving the £60k award will eventually have received £210k before they die.

95. At the beginning of September 2002 DH(E) had settled 89 of the 114 cases. In one case a the expected settlement was over £500k but in most cases expected settlements were in the range £10-30k.

Scottish Executive stance on the Burton judgement

96. In August 2001 instructed Central Legal Office (CLO) acting for Scottish National Blood Transfusion service (SNBTS) – to enter into talks aimed at settling outstanding legal actions directly analogous to those considered by the English High Court. To be 'directly analogous' these actions had to be a] raised under CPA, b] supported by reasonable evidence e.g. on causation, c] legally competent i.e. not 10 year time-barred.

97. The Executive has instructed CLO:

a] not to settle claims that are 10 year time-barred,

b] to refer back for individual consideration on its merits any case that is within the 10 years, but that appears to be 3 year time-barred.

98. Practical effect of these instructions is that all haemophiliacs are excluded (because heat-treated clotting factor which was "HCV safe" was available before CPA came into force), and most other claimants are also excluded (because they have not raised a legally competent action and cannot now do so because of time bar).

99. To date, no payments have been made to those who have raised valid actions. Some claims are close to settlement but the pursuers have withdrawn from negotiations fearing that they might lose out on larger settlements recommended by the Expert Group on Financial Support.

100. The settlement process has taken longer in Scotland than in England because Scottish claimants were unable to raise a class action. As a result each pursuer has had to provide detailed information to CLO. CLO has then had to recover records, arrange assessment by expert medical advisers and where appropriate seek advice from Counsel.

101. There have been regular allusions in the press that the Executive has set aside £1m to meet these claims. We have never acknowledged such a sum.

NEGLIGENCE

102. Actions may be raised at any time after infection, but identical 3 year time bar linked to awareness applies to raising actions.

POTENTIAL LIABILITY

103. SNBTS introduced screening of blood for Hepatitis C on 1 September 1991. After that blood and blood products were 'HCV-free' – so after 1 September 2001 no action could be raised under CPA that was not be time barred under the 10 year rule.

104. Claimants can still raise actions alleging that SNBTS was negligent in not introducing screening for HCV earlier, or that they should have implemented a more thorough 'look back' exercise to identify and inform those patients who had been infected.

105. Prior to 1983/4 some of the clotting factor used by haemophiliacs was sourced from commercial companies. In that period any negligence related to contamination might rest with these companies rather than the NHS.

106. In notes that Burton produced in anticipation that his judgement might be appealed, Burton opined that screening could have been introduced earlier. There are differing opinions as to how much earlier. On one view, a surrogate marker of liver disease (ALT testing) could have been introduced before 1988. (This is not a specific test for HCV.) On another view, a more specific form of screening could have been introduced in March 1990. Lawyers acting for DH(E) in the Burton case believed there was no basis for contesting that the form of screening ultimately used could not have been introduced earlier ie in January 1991.

107. The period in which liability exists can only be definitively established in court. UK blood services would strongly contest the Burton view. The numbers of patients who might have a case in wither of the two scenarios is not likely to be large.

HCCC Meeting Dec 11
Lines to Take

LINES TO TAKE

- Share Group's concern for those who through no fault of their own are suffering serious long-term harm. Would very much like to find a way of doing something to help them.
- Need to take account of the costs of any payment scheme in the light of other health priorities.
- Need to think carefully about who needs help, and what is the best way to design a scheme and structure payments so that the individuals involved benefit fully. [Avoiding a situation where payment lead to social security payments being withdrawn or reduced]
- Need to look in particular at the interface with the social security system, and devise a scheme that fits this as well as possible.
- My officials looking at these issues closely with social security officials. Hope these matters will be resolved very soon.

Q&A

? Why has the figure of 4000 people infected never been revealed before? Previously 500 was mentioned.

A 500 figure (actually 530) was quoted at the time of the parliamentary debate in January. Refers to people known to be infected (because HCV infection recorded by SCIEH as a result of individual tests) – reflects focus at that time on 'current suffering'.

Expert Group's proposals also concerned with dependants/executors of those now dead. Necessary to commission statistical work to predict number originally infected via transfusion (3500). 4000 figure (including 500 receiving blood products) includes many now dead, mostly from other causes – leaving an estimated 1165 possibly still alive.

? Why is the Executive so reluctant to consider payments to those who have suffered psychological harm and social disadvantage?

A Back in January I argued that it was not fair to consider the question of compensation to hepatitis C sufferers in isolation – I said that if we are to have a new system here in Scotland, it must be consistent, equitable and transparent for all. However, the Expert Group has not recommended a new compensation system – so we are once again being asked to look at steps aimed at correcting what the Committee described as "an inconsistency in the operation of an existing narrow precedent i.e. the Macfarlane Trust".

Macfarlane was set up to compensate people who were seriously ill, or likely to become so (90% of people infected with HIV are expected to develop AIDS within 10 years). By contrast, possibly only 20% of individuals infected with Hepatitis C will develop serious illness with implications for mortality over a period of 20 years. Whilst there is no denying that many of the others may have suffered psychological damage or social disadvantage, providing them with compensation goes beyond the underlying objective of Macfarlane.

If we were to establish a scheme that makes payments to people who are not expected to develop serious long-term harm, then we would be creating a new, wide-ranging precedent – something the Committee previously agreed was in no-one's best interests.

Q Is it not just the case that the Scottish Executive is concerned about upsetting the UK government by implementing the Expert Group's recommendation?

A Health is a devolved matter and, whilst we always seek to co-operate with our colleagues in the UK government, the Executive has not hesitated to take unilateral action in Scotland where we have thought it necessary. But the establishment of any new ex gratia payment scheme is closely bound up with social security issues – and they are a reserved matter. So any Scottish response on this issue is necessarily going to involve discussions with the UK government.

Q Surely the Expert Group's recommended scheme can be funded out of the Health Department underspend?

A The overall cost of the Group's scheme isn't the only reason that inclines the Executive not to accept the formula it contains – there is also a real issue about creating a new, wide-ranging precedent (something the Committee previously agreed was in no-one's best interests). That is because – [see answer above]

As far as underspend is concerned, the Executive allows Health Boards and Trusts to carry forward their underspend from one year to the next. This arrangement is designed to foster good financial management and to avoid unnecessary spending at the year end solely to use up spare funds. This, together with slippage on capital projects, accounts for the majority of the health underspend in any year. [In 2001-02, £92m of the health underspend of £124m was accounted for by these two elements, leaving only £32m to meet other pressures. Forecast underspend for 2002-03 is currently about £50m, the majority of which will once again be returned to Health Boards, therefore the available funds for use on other pressures will be limited].

Notes

1 Phillip Dolan may attempt to introduce issues related to wrong doing on the part of the NHS– particularly the allegation that blood was imported from the US when it was allegedly known that there was a high risk of the blood containing viruses. Hopefully the convenor will not allow the discussion to be side-tracked in this way, but we should make the point that the purpose of the HCCC meeting was to discuss the Expert Group's report and not revisit 'old territory' – and, in any case, this has been previously considered by HCCC as part of their 'Hepatitis C Report'.

2 Nicola Sturgeon may attempt to link the discussions to the recent revelations that some individuals may have been exposed to vCJD prion as the result of receiving 'blood'. We could point out that the possibility of new diseases, with potentially serious outcomes and long latency, emerging in the future has always been one of our concerns in terms of establishing a precedent for making ex gratia payments.