THE EXPERT GROUP ON FINANCIAL AND OTHER SUPPORT

PRELIMINARY REPORT SEPTEMBER 2002

Commissioned by the
Scottish Executive
St Andrew's House
Regent Road
Edinburgh
EH1 3DG

SE/2002/214

FOREWORD

When the Group was set up, it was invited to make preliminary recommendations in advance of its final report. This report contains the Group`s preliminary conclusions and a number of recommendations. As is made clear in the body of the report, the Group has identified a number of other issues which it intends to address in its final report. These include reporting on the current dispute and compensation mechanisms in Scotland for dealing with clinical negligence and fault based compensation in relation to the provision of health services, and on determining whether there is room for improvement.

The Group believes that its preliminary recommendations merit consideration by the Scottish Executive prior to submission of the final report.

Donald M Ross

Lord Ross
Chairman, Expert Group

For further information, please contact:

Moira Milligen
Secretary
Expert Group on Financial and Other Support
Ground East Rear
St Andrew's House
Edinburgh
EH1 3DG

Tel: GRO-C
E-Mail: Moira.Milligen@ GRO-C
Fax: 0131 244 2989

CONTENTS

1. INTRODUCTION

ORIGINS OF THE GROUP

1.1 The establishment of the Expert Group has its origins in discussions around the situation of patients who have been infected with the Hepatitis C virus (HCV) via blood. In the 1980s, people were infected with HCV as the result of NHS treatment, blood transfusion or treatment with blood products, (principally blood clotting factors supplied to haemophiliacs but also other products such as immunoglobulin). It is estimated that 14,000 people in the UK may have contracted HCV from blood or blood products. Many of them will have been very ill at the time of treatment and possibly 60% may have died from causes other than HCV infection. Some people also contracted HIV (human immunodeficiency virus) in exactly the same way as those with HCV.

1.2 At the time the patients were infected, HCV and HIV had not been identified and there was no test available to screen for them in blood donations. The Government therefore took the view that the NHS was not negligent. This patient group was not offered any compensation because of the general principle, which was a fundamental part of Government policy, that 'the NHS did not pay compensation when it had not been negligent'.

DEVELOPMENTS AFFECTING PEOPLE INFECTED WITH HCV OR HIV FROM BLOOD TREATMENT

1.3 The UK government offered financial support via the Macfarlane and Eileen Trusts to people who contracted HIV from blood and blood products provided by the NHS. This support was a mixture of one-off compensation payments and ongoing financial support – made either to the persons affected or, in cases where that person was deceased, to their dependants. The rationale for making these payments was largely based on the presumption made at the time that HIV would inevitably and swiftly progress to death. No equivalent payments were made to people who contracted HCV from blood and blood products provided by the NHS. However, in 2001 a number of people who claimed to have been infected in this way raised an action in the English High Court under the Consumer Protection Act 1987 (CPA). The resultant judgement by Mr Justice Burton established that blood contaminated with HCV was a 'defective product' for the purposes of the Act and the English blood services were therefore liable to pay compensation. The Scottish Executive decided that NHSScotland would make payments to persons whose circumstances were analogous to those who were eligible for awards under the High Court judgement.

1.4 Many people who contracted HCV from blood and blood products provided by the NHS were unable to take advantage of this judgement however. This was partly because CPA did not come into force until 1 March 1988 and it did not apply at the time when they were infected. The time bar provisions linked to CPA excluded many others. In particular, liability under CPA ceases 10 years from the date when the person was treated with the defective product. Some people did not discover that they had the virus until after they were already time-barred by this provision.

The Consumer Protection Act 1987 (CPA)

1.5 The CPA implemented the Product Safety Directive. This strict liability legislation meant that negligence was no longer the only issue where the NHS might have a legal duty to pay compensation. It was therefore necessary to modify the principle about when the NHS does not pay. In Scotland, the modification quoted in the remit of our Group was adopted as follows:

> 'The NHS does not pay compensation when it has no legal liability for the harm suffered by the patient.'

The Recommendations of the Health & Community Care Committee of the Scottish Parliament

1.6 Having considered a petition calling for compensation for 'HCV in blood' patients, the Health and Community Care Committee of the Scottish Parliament recommended ex gratia financial and other appropriate practical support should be made available for this group of patients. The Health and Community Care Committee recommended 'financial and other appropriate practical support' rather than compensation, partly because they felt that the term 'compensation' is linked to the concept of fault and partly because they felt that money was only one of the things that patients needed to help them lead a reasonable life. They recommended that the level of financial assistance 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

1.7 The Committee's recommendation was based on the following principles:

- HCV patients were morally entitled to the same compensation as HIV patients;
- HCV patients were morally entitled to similar support to that given in the support package provided for people who had contracted vCJD from food;
- the unfairness of some people being able to benefit from the CPA judgement but not others.

1.8 The Scottish Executive did not agree with this recommendation. It felt that it was a deviation from the principle that the 'NHS does not pay when it has no legal liability for the harm suffered by the patient' and that it would be essential for any new compensation system to be judged against agreed and published criteria and that these criteria would need to be transparent, equitable and universally applicable. Furthermore, any new system that deviated from the principle should balance the needs of the total patient population against those of any group being provided with financial support.

1.9 The Health and Community Care Committee also recommended the establishment of an Expert Group to look at the current compensation system and propose alternatives. The Executive agreed to the establishment of such a group and that it would examine situations where people have been harmed but the NHS is not at fault. It also agreed that the situation of 'HCV/HIV in blood' patients should form part of its wider considerations.

1.10 A list of Members of the Expert Group is attached at Annex A.

TERMS OF REFERENCE

1.11 The terms of reference of our Group as given by the Minister for Health and Community Care and agreed by the Health and Community Care Committee of the Scottish Parliament are:

- To consider circumstances in which a system of financial and other support might be available to people who have been harmed by NHS treatment in Scotland in circumstances where there is unlikely to be liability on the part of NHSScotland and to apply general principles which are consistent, equitable and transparent for all.

- The situation of patients who have contracted HIV and/or Hepatitis C from blood transfusion or treatment with blood products should form part of the wider considerations.

- Preliminary recommendations should be made by the end of July 2002 and should include whether the current system should be changed and, if so, what changes should be made and whether any of these changes should be applied retrospectively.

- Consideration should also be given to the current dispute and compensation mechanisms in Scotland for dealing with negligence and fault-based compensation to determine if there is room for improvement. Any recommendations should be brought forward by the end of December 2002.

Notes

In considering the above–

1. The group should note the existing approach that "*the NHS does not pay compensation when it has no legal liability for the harm suffered by the patient*" and consider whether this is appropriate
2. Any recommendations should be based on achieving a workable balance between the following tests:

   Any alternative arrangements should:

a) not inhibit innovation and creativity in NHSScotland

b) be consistent with efficient health service operation

c) represent a fair deal for <u>all</u> patients

3. The group should take into consideration the findings of the Review of Clinical Negligence by the Department of Health in England – taking due account of any factors that are likely to affect their applicability to the Scottish situation. It should also look at the approach to medical compensation adopted in the Republic of Ireland.

4. The group should take into consideration the findings of the Review of Mediation in the Health Service in Scotland by the Royal Society of Edinburgh, and the Scottish Executive Report on the Evaluation of the NHS Complaints system.

1.12 We noted in discussions that our consideration of what constituted 'NHS treatment in Scotland' should not be confined to hospital treatment and should include all aspects of the NHS including primary care and dentistry.

1.13 We are aware that our remit cannot be changed as the Minister for Health and Community Care had agreed it with the Health and Community Care Committee of the Scottish Parliament but we consider it is acceptable for us to agree a common interpretation of it. Some members had difficulty with the phrase in the first element of the remit 'where there is unlikely to be liability on the part of NHSScotland' and suggested that this might usefully be interpreted as 'where liability on the part of NHSScotland was unknown'.

1.14 This preliminary report concentrates on patients harmed by NHS treatment where there is unlikely to be any liability on the part of the NHS Scotland. However, it has been necessary to consider the first part of our remit in the wider context of the clinical negligence system.

EVIDENCE

1.15 We considered a wide range of oral and written evidence for this report. A full list of the evidence considered is at Annex B.

1.16 For the second part of our work and our final report due at the end of December 2002, we will also consider, *inter alia,* the following matters:

- The Scottish Executive's review of the NHS complaints procedure.
- A more detailed examination of the clinical negligence system in Scotland including provisional damages.
- Reviewing the burden of proof
- The Report of the Findings of the Review of Mediation in the Health Service in Scotland by the Royal Society of Edinburgh.
- The Report of the Findings of the Review of the Clinical Negligence System by the Department of Health in England.
- The Lord Chancellor's Department's Consultation Paper 'Damages for Future Loss: Giving the Courts the Power to Order Periodical Payments for Future Loss and Care Costs in Personal Injury Cases', March 2002.

2. PRELIMINARY CONCLUSIONS AND RECOMMENDATIONS

No-Fault Compensation

2.1 Chapter 3 and Annexes B-E set out the evidence considered on no-fault compensation systems in this country and in other jurisdictions. We conclude that no-fault compensation may have advantages, including: speed; reduction in legal costs; and reduction of stress on the part of claimants and health professionals. However, there are also disadvantages in that it tends not to encourage improvements of quality of care as a result of lessons learned. Furthermore, in both the Swedish and New Zealand schemes, because the issue of fault has not been entirely eliminated, we feel the end result is a bureaucratic system which tries to tackle the complex issues of negligence and causation without the benefit of legal expertise. We feel that these are major disadvantages.

2.2 We conclude that the issue of no-fault compensation is so extensive and complex that we cannot make meaningful preliminary recommendations on it by the end of July 2002. We will consider no-fault further in the second part of our work.

People who have contracted HIV or HCV as a result of receiving blood, blood products or tissue transfer from NHSScotland

2.3 We considered the arrangements already in place to provide financial support for those infected with HIV through blood, blood products or tissue transfer via the Macfarlane and Eileen Trusts and are impressed by the principles underlying these schemes.

2.4 We conclude that the fact that people who contracted HIV as a result of receiving blood, blood products or tissue transfer from the NHS received compensation whilst people who contracted Hepatitis C virus (HCV) in exactly the same way did not, is inequitable. We are of the view that this inequity should be addressed by introducing new arrangements

The Scottish Legal Aid System

2.5 We noted from the evidence submitted by the Scottish Legal Aid Board (SLAB), that the process of applications for increases in Advice and Assistance and submission of accounts by Solicitors, is to be revised and improved. We will consider issues in relation to access to legal aid further in the second part of our work.

2.6 **Other areas considered for reform**

- Priority Treatment for People who have been harmed by NHS Treatment

We considered evidence on a scheme for priority treatment for war pensioners operating within the UK and on a scheme in the Republic of Ireland that allows priority treatment for patients who contracted Hepatitis C from infected blood and blood products. We conclude that priorities for treatment should be assessed on the basis of clinical need only without regard to whether any previous NHS treatment was the cause of the harm.

- Reversing the Burden of Proof

We briefly considered the concept of reversing the burden of proof so that the onus of proof rests on the NHS rather than the claimant and decided to give it further consideration in the second part of our work.

- Retrospective ex gratia payments linked to 'Defective Product' concept

We considered the merits of introducing a scheme which would enable ex gratia payments to be made to patients who had been harmed before 1 March 1988 (the date the Consumer Protection Act (CPA) came into force) linked to defective products and practices as a result of NHS treatment in Scotland. We decided not to make any preliminary recommendations on this proposal.

- Access to relevant clinical and legal experts

We noted that unlike England, Scotland has been unable to establish an extensive pool of lawyers experienced in clinical negligence. Reasons for this may include the fact that the criteria for receiving legal aid is stricter in Scotland than in England and the ability to recover legal costs is more restrictive in Scotland. Another difficulty for claimants in Scotland is in finding medical experts to assist with their claim. We will consider these issues in greater depth in the second part of our work.

- Other Issues

We have identified the following issues which we think need to be considered in greater depth in the second part of our work:

a). the time it takes for claims to reach settlement;

b). the difficulties claimants may experience in gaining access to medical records.

2.7 Preliminary Recommendations

Recommendation 1

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:

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 not due to the Hepatitis C virus, the above payments should pass to their Executors. Where their death was 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

Recommendation 2

The Scottish Executive should consider how it could fund and develop other mechanisms for supporting people who suffer from HCV. In particular, additional support in the following areas should be considered:

- Access to understandable information on HCV
- Counselling Services
- Access to information on benefits available
- Assistance with assurance and insurance
- Setting up a pro-active publicity campaign spearheaded by the Health Education Board for Scotland.

Recommendation 3

The Scottish Executive should invite SLAB to consider the following:

a) proceeding with the development of the template on Advice and Assistance as soon as possible;

b) including in the template provision for meeting/negotiation with the defender;

c) including in the template provision for class actions as well as individual clinical negligence cases;

d) updating the guidelines to the profession;

e) introducing an 'interests of justice' test for civil legal aid applications in clinical negligence cases;

f) proceeding towards the making of staged payments.

3. THE CONTEXT

NEGLIGENCE AND THE CURRENT CLINICAL NEGLIGENCE SYSTEM IN SCOTLAND

3.1 We consider it advisable to set down broad definitions for certain words or phrases referred to in this Report in order to set the context for some of our considerations. These are as follows:

- *Negligence*

Negligence is a failure to exercise a duty required by law to show reasonable care, when doing or omitting to do something, in order to avoid loss or harm to others.

- *Causation*

As well as proving breach of duty, a pursuer must also prove that the breach of duty caused the loss or harm complained of, or at least materially contributed to it.

- *Standard of Proof*

In civil actions, apart from exceptional cases, the onus of proof is on the pursuer, and the onus may be discharged on a balance of probabilities.

- *Professional Negligence*

A medical practitioner, like others exercising professional skills, must display and apply reasonable care and a reasonable standard of professional competence. There is no automatic liability for accidents, and the test often depends on what is usual and normal practice. Deviation from usual and normal practice is negligence only if the course of action adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care. (*Hunter* v *Hanley* 1955 SC 200) However, the practice relied on must have been accepted by a responsible body of medical experts skilled in the field, their opinion must have had a logical basis, and the experts must have applied their minds to the comparative risks and benefits. *(Bolitho v City and Hackney Health Authority 1998 AC 232)*

- *Statutory Liability*

Statutes may impose a standard more exacting than that of taking reasonable care. A statute may impose absolute liability, independently of negligence, and the defender will be liable, even if he has taken all reasonable care to prevent the harm complained of, provided it is proved that there was a breach of the statutory duty, and that the breach caused the harm.

- *Damages*

Damages are a sum of money paid as compensation for loss, injury or damage resulting from an act or omission of the defender which is in breach of a duty owed. The award of damages is intended to put the injured party as nearly as may be in as good a position as he was in before the loss occurred.

- *Compensation*

Compensation is a wider term than damages, and covers the provision of something to the injured person (or the injured person's dependants in the case of death) in consequence of the injury or harm, and for the purpose of removing or alleviating its ill effects.

- *Ex gratia*

Anything *ex gratia* is done without recognising any legal obligation to do so. An *ex gratia* payment is one made without any admission of liability under contract or negligence or otherwise, and in the context of this Report represents compensation to cover hardship.

- *Provisional Damages*

Provisional damages for personal injuries may be awarded where there is admitted or proved to be a chance that at some definite or indefinite time in the future, the injured person will, as a result of the act or omission which gave rise to the cause of action, develop some serious disease or suffer some serious deterioration in his physical or mental condition. In such circumstances, provisional damages are assessed on the assumption that the injured person will not develop some serious disease or suffer some serious deterioration in his condition. Future damages may then be awarded if he does develop the disease or suffers the deterioration.

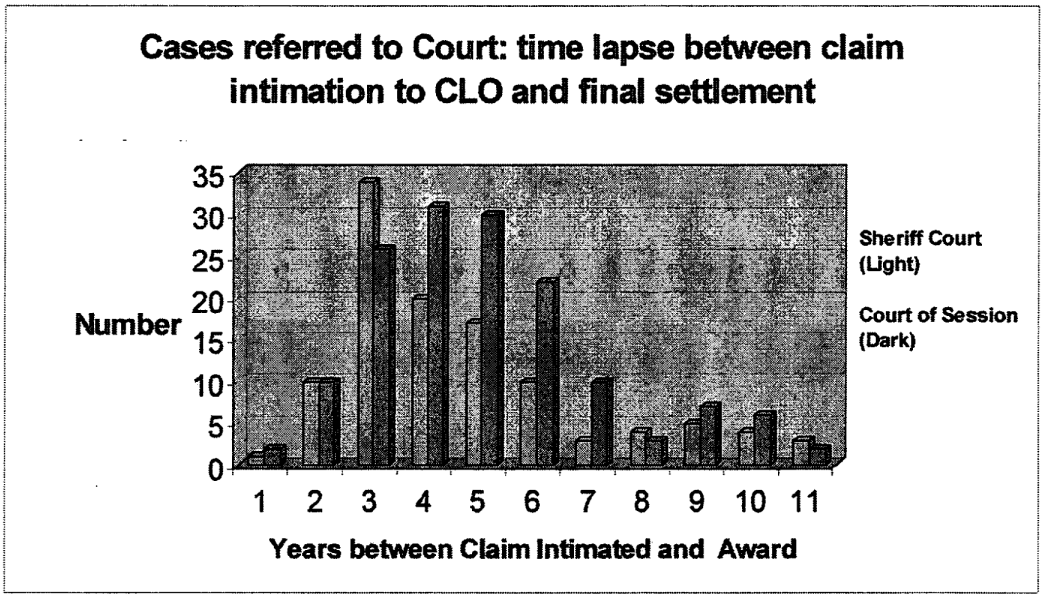
3.2 Whilst the review of compensation mechanisms is a matter for our second [and final] Report in December 2002, we gave some preliminary consideration to the current situation in Scotland. Our focus was the secondary care sector where the Central Legal Office (a Division of the Common Services Agency) deals with all claims for clinical negligence and for which data is readily available.

3.3 Clinical negligence claims against Independent Family Health Service providers and private healthcare practitioners are handled by defence organisations. These organisations regard their claim handling business as commercially sensitive and therefore data on this is not available for us to consider.

3.4 The level of claims for clinical negligence lodged against NHS Trusts and Boards in Scotland over the last 4 years has remained relatively constant at an average of some 500 per year. In the normal course of events, approximately 70% of those claims will be abandoned or dismissed whilst, again on average, some 160 cases a year will settle with a compensation award. If the 160 cases reflected the normal case mix, then about 40% (65) will be subject to legal proceedings of which only 20 will actually go to proof, ie the formal leading of evidence by parties before a judge.

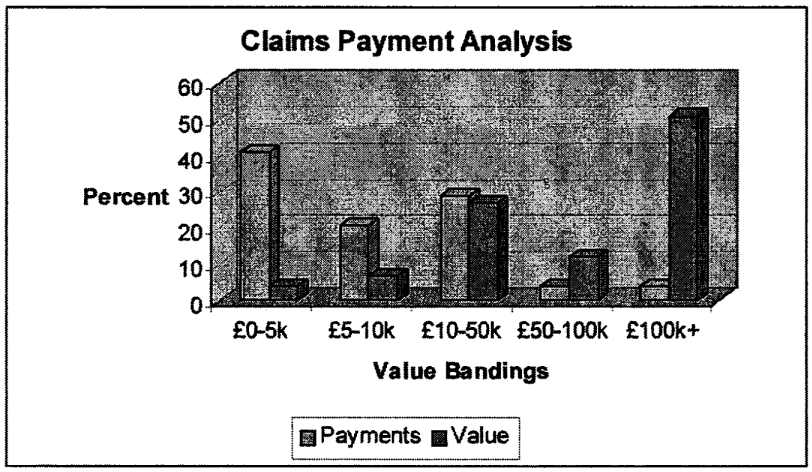
3.5 A limited data analysis suggested that 50% of claims settled in any one year will have been lodged up to 4 years previously. The remaining 50% will include cases where the incident or claim date is over 20 years ago, although the bulk will be for claims lodged no further back than 8 years previously. The majority of the 'long standing' claims are for birth injury cases. The following Table 1 provides an analysis of the time lapse between claim intimation and settlement for those cases that are subject to legal proceedings.

Table 1



3.6 Over the last 5 years, settlement costs have risen from £4 million in 1997/98 to an estimated £7.5 million in 2001/02, although latter increases include a small number of individually large awards. Table 2 below provides a percentage analysis of claim payments over the same period and illustrates that, on average, 50% of payments are generated by only 4% of claims for which a settlement results.

Table 2



3.7 We also drew some initial comparisons with the position in England based on 1999/2000 data. Bearing in mind that the usual comparator is that Scotland will be 10% of England activity/costs, we noted that in terms of claims received Scotland was 5%, for claims

outstanding the figure is 6.5%, for provisions – 1.5% and, in terms of settlement costs, only 1%.

3.8 We will be considering the Department of Health (DH) Report of their Chief Medical Officer's review of clinical negligence arrangements at a later stage (see below). However, we are aware that a main driver in the DH review is the need to reduce significantly the cost of clinical negligence in England. Whilst the initial findings reported above suggest that the immediate financial problem in Scotland is less significant than that faced by NHS in England, there are other difficulties with the operation of the clinical negligence system in Scotland. These are discussed in more detail in Chapter 6.

3.9 Whilst lowering the cost of settlements in Scotland should be no less an objective, we consider the focus in the second stage of our review will be more on how easy or otherwise it is for claimants to access and travel through the compensation process. In this context 'compensation' should not simply be regarded as providing financial recompense, it is equally about the way and manner a patient's grievance or concern is managed and then appropriately addressed.

THE REVIEW OF CLINICAL NEGLIGENCE BY THE DEPARTMENT OF HEALTH, ENGLAND

3.10 The Department of Health in England established a review group under the Chairmanship of the Department's Chief Medical Officer, in October 2001. The Report of the English Review Committee will be published shortly and will be considered in the second part of our work.

THE COMPENSATION SCHEME IN OPERATION IN THE REPUBLIC OF IRELAND

3.11 We considered evidence on the compensation system in the Republic of Ireland for persons infected with HCV through administration of infected blood and blood products, including the Annual Report of the Hepatitis C Compensation Tribunal, the Report of the Consultative Council on Hepatitis C – March 2002 and the conclusions of the Report of the Tribunal of Enquiry into the Blood Transfusion Service Board.

3.12 The Irish Government established the Hepatitis C Compensation Tribunal on 16 December 1995 as a non-statutory scheme of compensation. This followed the publication of a Report in January 1995 by an Expert Group into the contamination of the Anti-D blood product in Ireland. [Anti-D is a blood product routinely administered to some pregnant women to prevent death or serious illness of the baby from Rh Haemolytic Disease.]

3.13 The initial contamination arose as a result of plasma being accepted by the Irish Blood Transfusion Service Board (BTSB) from a patient who was infected with HCV virus undergoing therapeutic plasma exchange. In a separate, subsequent, incident, BTSB manufactured and distributed Anti-D from plasma obtained from another patient infected with HCV.

3.14 Consequently, supplies of Anti-D Immunoglobulin manufactured from the plasma obtained from these patients were contaminated with the virus. Recipients of the

contaminated Anti-D subsequently donated blood – causing further contamination of blood supplies.

3.15 A further Report in March 1997 (the sworn judicial inquiry into the contamination of the Anti-D product) concluded that the contamination of the Anti-D supply should have been avoided and was due to wrongful practices on the part of BTSB. Following publication of the Report, the Tribunal was placed on a statutory footing with effect from 1 November 1997 by means of the Hepatitis C Compensation Tribunal Act 1997 and related Statutory Instruments.

3.16 We concluded from the evidence that the priority treatment provisions operating in the Irish scheme were interesting and are discussed further in Chapter 6. The scheme itself, however, is fault based and therefore not directly relevant for our consideration of no-fault compensation for the first part of our work.

EX GRATIA SCHEMES IN OPERATION IN THE UK AND IN OTHER JURISDICTIONS

3.17 We considered the provisions of some existing schemes that provide assistance, including the Macfarlane and Eileen Trusts, the vCJD scheme, the Criminal Injuries Compensation Act, the Pneumoconiosis etc (Workers' Compensation) Act 1979, the Vaccine Damage Payments Act 1979 and the compensation scheme in operation in the Republic of Ireland for persons infected with HCV through administration of infected blood and blood products. The evidence we considered on these schemes is set out in more detail in Annex E. We noted that all of these compensation schemes retain some test of causation or some limit on compensation.

NO FAULT COMPENSATION

3.18 There has been extensive research and literature on the subject of no-fault compensation, commencing with the Pearson Commission, established in 1973 to consider the current compensation system for all forms of personal injury. The Commission received 865 written submissions from 766 organisations and individuals between 1973-78. They also held 225 meetings in the UK and 252 overseas. The Pearson Commission recommended that a no-fault scheme for medical accidents should not be introduced at present (1978) but that the schemes in New Zealand and Sweden should be studied further.

3.19 Two Private Members Bills were brought to the Westminster Parliament in 1991 by Harriet Harman MP and Rosie Barnes MP, in an attempt to introduce no-fault compensation for medical injury. Both Bills failed. They did not define 'medical accident' or eligibility for compensation satisfactorily and also lacked procedural frameworks to ensure professional accountability. The Government of the day responded by saying that it had no intention of interfering with the right of the citizen to bring an action in tort.

3.20 We considered evidence on the no-fault compensation systems in operation in the UK, New Zealand, Virginia, Florida and Sweden. (Annexes B-E refer.) In the short time available to us, we concluded that on the face of it, the Swedish scheme's figures showed a significant saving. However, these figures need careful interpretation as there may be other reasons for this, eg other social insurance programmes meeting medical expenses and wage losses due to medical injury.

3.21 A no-fault-based compensation system may have advantages, including speed and reduction in legal costs and stress on complainants and health professionals. However, there are also major difficulties with no fault compensation as it ignores the important issues of accountability and quality of care. Whilst no system should focus only on fault, if there is fault, it is essential that it be identified to enable lessons to be learned, quality of care improved and dangerous practices avoided.

3.22 We conclude that no-fault compensation is too extensive and complex a subject for us to be able to make any meaningful recommendations at this stage. However, our view is that there is a place for some form of limited ex-gratia system in the circumstances outlined in Chapter 4.

THE MORI SURVEY

3.23 We considered evidence from the MORI Survey commissioned by the English Advisory Committee on the Review of Clinical Negligence. The results of the MORI Survey are summarised in Annex D.

4. PEOPLE WHO HAVE CONTRACTED HIV OR HCV AS A RESULT OF RECEIVING BLOOD, BLOOD PRODUCTS OR TISSUE TRANSFER FROM NHSSCOTLAND

BACKGROUND

4.1 We were asked to consider as part of wider considerations 'the situation of patients who have contracted HIV and/or HCV from blood transfusion or treatment with blood products'. The background is set out in Chapter 1 and Annex E.

4.2 Presently people who have contracted HIV through receiving blood, blood products or tissue from the NHS benefit from the arrangements via the Macfarlane and Eileen Trusts, whereas people who contracted HCV under exactly similar circumstances do not. We believe that infection with HCV brings about adverse effects for the people involved similar to those experienced by people infected with HIV. Furthermore, the way in which people were infected with HCV was exactly the same as those who became infected by HIV. We feel that this represents an inequity that should be addressed by introducing new arrangements.

4.3 We considered evidence on a scheme which might operate on broadly similar principles to that of the Macfarlane and Eileen Trusts. This would mean recommending that each person who could demonstrate that they were infected with HCV as a result of receiving blood, blood products or tissue from the NHSScotland , would receive a lump sum ex-gratia payment. We also considered evidence from the publication by the Scottish Executive entitled 'Hepatitis C: Essential Information for Professionals' which suggests that:

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

Of the 80% who do not:

- around 20% may never develop physical symptoms;
- 60% will develop long-term symptoms of liver damage – with the potential to progress to cirrhosis, liver cancer or liver failure.

CONCLUSIONS

4.4 We conclude that we should have regard to the loss suffered by the individual in recommending new arrangements for Hepatitis C sufferers. Furthermore, we conclude that the support arrangements for people suffering from the disease should be improved.

4.5 We consider that our recommendations below are consistent with our remit. We gave consideration to whether the recommendation for a discretionary Trust would represent a 'fair deal for all patients' as indicated in Note 2(c) of our remit. The proposed arrangements address an inequity between two groups of patients who were harmed by exactly the same set of circumstances (i.e. the inadvertent provision of blood, blood product or tissue contaminated with a virus). We therefore feel that the recommendation does satisfy this test.

4.6 We appreciate that spending resources of this nature inevitably means that money is being used which would otherwise be spent on health care in general. However, we feel the circumstances justify the introduction of these new arrangements for Hepatitis C sufferers.

ESTIMATIONS OF COST

4.7 We believe funding the proposed discretionary Trust (excluding operating overheads) is likely to cost between £62m and £89m. This would comprise £2.5m in awards made at £10,000, £49.4m in awards made at £50,000, and between £10m and £37m in awards that are assessed on the basis of Common Law Damages. The cost would be spread over a number of years due to the time it is likely to take for people to become aware of their condition and for the condition to progress to a relevant trigger point.

RECOMMENDATIONS

4.8 We recommend the following:

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:

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 not due to the Hepatitis C virus, the above payments should pass to their Executors. Where their death was 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.

4.9 We further recommend:

The Scottish Executive should consider how it could fund and develop other mechanisms for supporting people who suffer from HCV. In particular, additional support in the following areas should be considered:

- Access to understandable information on HCV
- Counselling Services
- Access to information on benefits available
- Assistance with assurance and insurance
- Setting up a pro-active publicity campaign spearheaded by the Health Education Board for Scotland.

5. THE SCOTTISH LEGAL AID SYSTEM

CLINICAL NEGLIGENCE CASES

5.1 The Scottish Legal Aid Board's (SLAB) civil legal aid system contains no separate classification for clinical negligence; it is subsumed within a far larger reparation category. Detailed information on civil legal aid applications, grants and costs is not therefore available. However, a broad analysis done by SLAB estimates that in 2000-2001 the number of civil legal aid applications relating to clinical negligence was around 310; the number of applications granted was around 160.

5.2 A small sample of final accounts received for cases granted in the last three years showed varying costs, ranging from £50 to more than £12,000. Using the average cost of the sample, and the estimated number of grants in 2000-2001 as indicators, SLAB estimate the gross cost (including VAT) to the public purse as being around £450,000 per year. The net cost to the public purse would, however, be lower as a result of being offset by any financial contributions from applicants and award of expenses or damages in successful cases.

5.3 SLAB's analysis showed greater activity as regards advice and assistance with around 1,400 intimations for 2000-2001. By June 2001, 664 accounts were submitted for intimations received in 1999-2000. Payments ranged from £0 to £1,600. The total sum was just over £170,000. The total cost to the public purse will increase once all accounts are submitted, but not all intimations result in an account. The costs of some cases are wholly covered by financial contributions from applicants. Also, if a case is resolved under advice and assistance and a financial award is made, it is, as in civil legal aid, used to cover the costs.

5.4 We noted from the evidence submitted by the Scottish Legal Aid Board (SLAB) on access to legal aid in Scotland that SLAB's role is very much an administrative one. SLAB is working towards a more strategic approach on how legal aid is delivered in accordance with the recommendations of the Justice 1 Committee of the Scottish Parliament.

5.5 In England, there is a contractual basis for clinical negligence cases whereby cases are considered on the basis of wider public interest and special case units have been established. Scotland operates the system of Advice and Assistance. In clinical negligence cases, a lot of preliminary evidence is necessary and this means that solicitors could be applying for increases several times.

5.6 After initial interview with the client, noting his precognition, and coming to the view that there may be a case of clinical negligence the solicitor will intimate the claim and, if liability is not admitted, may then seek to obtain the client's medical records, with a view to submitting them to an expert for an opinion.

5.7 Increases are often sought for a particular procedure which solicitors are sometimes recommended to adopt in such cases; this involves going through the medical records with the client and then submitting them to a 'collator' to ensure that they are complete and in order before they are presented to the expert.

5.8 The Board does not grant increases to follow this procedure invariably in every case. In any case in which an increase is sought for either of these purposes, it needs to be justified by reference to the circumstances of the individual case. If the Board is not satisfied that one or other or both steps are necessary for a cost-effective approach to dealing with the matter, then the increase will be curtailed accordingly.

SLAB's REFORMS

5.9 SLAB is aware that some of the processes in Advice and Assistance require to be updated and are developing a template to enable the submission of applications for increases and accounts by Solicitors electronically to simplify and speed up the process. They are also considering moving towards staged payments and interim re-imbursement for Advice and Assistance where there is no indication that repayment will be made.

5.10 In England, the whole process for applying for legal aid is simpler as an automatic increase is available in the form of a limited certificate. It would not be possible to introduce a limited legal aid certificate in Scotland under the Legal Aid (Scotland) Act 1986. However, some of the reforms being considered by SLAB, particularly those relating to Advice and Assistance, should simplify the process considerably in Scotland.

5.11 SLAB has provided guidelines for the profession on the requirements for certain cases. However, there is limited guidance available on obtaining legal aid for pursuing class actions. This is particularly relevant for the work of our Group in relation to Hepatitis C sufferers whose actions failed.

5.12 Civil legal aid will not be granted until SLAB is satisfied on probable cause, reasonableness, and financial eligibility. In clinical negligence cases it may be difficult for an applicant to obtain the expert evidence required to demonstrate probable cause. In criminal cases, the test applied by SLAB is whether it is in the interests of justice that legal aid be granted.

CONCLUSIONS

5.13 We conclude that it is desirable that the legal aid system should be able to deal with class actions as well as individual clinical negligence cases.

5.14 We would like to be involved in the development of the revised guidelines but realise that this may not be possible as the Group is due to conclude its work by the end of 2002.

5.15 `We conclude that it would be easier for applicants to obtain legal aid in clinical negligence cases if the 'interests of justice' test were adopted and SLAB should consider the introduction of such a test in clinical negligence cases.

5.16 We will consider further issues in relation to access to legal aid and the development of specialist legal/medical experts further in the second part of our work.

RECOMMENDATIONS

5.17 Having considered a presentation from the Director of Legal Services at SLAB and the evidence submitted, we recommend that the Scottish Executive should invite SLAB to consider the following:

- proceeding with the development of the template on Advice and Assistance as soon as possible;
- including in the template provision for meeting/negotiation with the defender;
- including in the template provision for class actions as well as individual clinical negligence cases;
- updating the guidelines to the profession;
- introducing an 'interests of justice test' for civil legal aid applications in clinical negligence cases;
- proceeding towards the making of staged payments.

6. OTHER AREAS CONSIDERED FOR REFORM

6.1 In this chapter, we consider the following:

- Priority Treatment for People who have been harmed by NHS Treatment.
- Reversing the Burden of Proof.
- Retrospective ex gratia payments linked to 'Defective Product Concept'.
- Access to relevant clinical and legal expertise.
- Other issues.

PRIORITY TREATMENT FOR PEOPLE WHO HAVE BEEN HARMED BY NHS TREATMENT IN SCOTLAND

6.2 We considered evidence on 2 existing schemes – priority treatment for war pensioners in the UK and for HCV patients in the Republic of Ireland.

Priority Treatment for War Pensioners

6.3 In 1953, hospitals run by the Ministry of Pensions for the treatment of war pensioners were transferred to the NHS. The Government gave an undertaking that there would be priority examination and treatment for war pensioners[1] in NHS hospitals for the condition for which the war pensioners received a pension or gratuity. Priority is not given for unrelated conditions. The Transfer of Functions (Ministry of Pensions) Order 1953 passed the financial and administrative responsibility for the provision of medical and surgical services for war pensioners to Health Departments. In Scotland, funding was transferred to NHS Boards to cover the cost of providing these services.

6.4 Priority in out-patient services provided and funded by the NHS Board of residence include:

> supply and repair of artificial limbs, nursing equipment, hospital treatment expenses, dental treatment, eye tests, hearing aids, chiropody, skilled nursing care, orthotic devices, elastic hosiery, wigs and other aids and appliances considered medically necessary for their condition.

[1] A war pensioner was previously classed as someone who has a pension or receives a gratuity for disablement caused by armed service during the 1914-18 and 1939-45 wars and services since 1945. With effect from 29 July 1996 the term 'War Pensioner' also includes those people who were injured or disabled as a result of service in the Armed Forces of the Crown either before 4 August 1914 or between 1 October 1921 and 2 September 1939.

The Compensation Scheme in Operation in the Republic of Ireland for HCV Patients

6.5 The Irish government provides ring fenced funding to ensure priority treatment for people who have contracted HCV from blood transfusion or blood product that includes:

- each specialist HCV Unit to have a Specialist Liver Consultant or Hepatologist and a nurse/counsellor
- no patient to wait more than an hour for their scheduled appointment with a clinician
- no patient to wait more than two weeks for an appointment
- each Unit to have a designated ward area for testing, treatment or biopsy
- no patient to wait more than one month for an appointment for counselling
- minimum of five days hospital admission for anti viral therapy if patient requests it

6.6 The ring-fenced expenditure associated with providing this priority treatment has risen from 8.34m euros in 1998 to 13.01m euros in 2002 – giving a total to date of 51.65m euros (£32.89m).

Discussion

6.7 We considered whether 'priority treatment should be given to people harmed by NHS treatment where there is unlikely to be liability on the part of the NHSScotland'. Such a scheme could be considered to have the advantage of being in line with the principles of fairness and equity as it could be said that the NHS was prepared to make every effort to minimise the adverse effect of any harm it had caused. However, if treatment were prioritised for all patients harmed by NHS treatment, this would include people who had consented to the risk. We felt that this was undesirable and it would be preferable for any such scheme to be restricted to circumstances where neither the patient nor the health service were aware of the risk involved.

6.8 Furthermore, such a scheme would be resisted by those patients not covered by the scheme but who felt that their clinical need was greater than those receiving the priority treatment.

Conclusion

6.9 We recognise that a scheme of priority treatment could be said to be advantageous for a limited group such as war pensioners. However, we do not consider such a scheme would be equitable in the wider context of patients harmed by NHS treatment. We conclude that any prioritisation of treatment should be based on clinical need rather than the fact that injury occurred through NHS treatment. We therefore do not wish to make a recommendation to introduce priority treatment for those harmed by NHS treatment in this report. However, we remain concerned about the need for treatment for people harmed in this way. We feel it is important that the Scottish Executive ensures that resources are made available to provide for treatment and monitor the position.

REVERSING THE BURDEN OF PROOF

6.10 Clinical negligence differs from other personal injury litigation in the parties' greater reliance on expert medical evidence for issues of causation and liability. Causation is more difficult to establish than in other personal injury cases because the effects of the allegedly negligent treatment must be distinguished from those of the patient's underlying condition which gave rise to the need for treatment.

6.11 We considered the proposal that 'the burden of proof which currently rests with the claimant, should be transferred to NHSScotland'. We also considered evidence prepared by Russell Levy, a partner in the Solicitors firm of Leigh, Day &Co which formed part of a submission to the English Review Group on Clinical Negligence by the Association of Personal Injury Lawyers.

6.12 We recognise that reversing the burden of proof may have certain advantages including encouraging a less adversarial process, moving away from a blame culture and a reduction of expenditure on clinical negligence cases. However, it is a complex issue and we propose to give this further consideration in the second part of our work.

RETROSPECTIVE EX GRATIA PAYMENTS LINKED TO 'DEFECTIVE PRODUCT' CONCEPT

6.13 We considered the pros, cons and potential challenges of introducing a scheme which enables ex gratia payments to be made to patients who had been harmed before 1 March 1988 by a defective product as a result of NHS treatment in Scotland – in circumstances where it is likely that responsibility for the defect rested with NHSScotland.

6.14 Such a scheme would enable payments to people who were infected with HCV as a result of receiving blood transfusions or being treated with blood products, whose infection occurred before the Consumer Protection Act 1987 (CPA) came into force. However, payments would not be provided for those infected after March 1988 who were unable to take legal action under the CPA because of time-bar considerations. That group would remain a disaffected group with a very clear moral argument that they are being treated unfairly.

6.15 We considered whether the scheme would be less arbitrary if it were extended to include defective 'practices' as well as defective products and if it was not restricted to harm incurred prior to March 1988. Such a scheme could also be restricted to cover harm resulting from defective products and practices that were unknown to both the patient and the health service at the time the treatment was administered. It might also allow for other forms of support and not be restricted to financial compensation.

6.16 An obvious difficulty in terms of defining defective practice is that clinical practice changes constantly: thus, a practice which would have been regarded as perfectly normal in the 1950s (such as removing tonsils at an early stage to prevent later problems) can often be frowned upon some years later. In our view, including defective practice as a ground for compensation would run the risk of leading to excessively conservative medicine, with clinicians reluctant to change practice as soon as might otherwise be desirable.

6.17 We also felt that there was likely to be great difficulty in defining the scope of such a scheme in a way that would enable it to be administered effectively, that would not raise issues about the retrospective application of legislation and that would not give rise to an open-ended and potentially very large contingent liability which may adversely affect future spending on health services in Scotland.

6.18 For these reasons we do not wish to make a preliminary recommendation in favour of such a scheme at this stage. We have however made recommendations for ex-gratia payments in Chapter 4 to address a specific inequity for patients who have contracted HCV as a result of receiving blood, blood products or tissue transfer from NHSScotland.

ACCESS TO RELEVANT CLINICAL AND LEGAL EXPERTS

6.19 Lawyers in Scotland who are active in reparation or damages practices (of whom there are many) should be able to act in clinical negligence cases ideally following the appropriate specialist training. Notwithstanding this, a view has been expressed that people in Scotland experience difficulty in finding a solicitor to pursue their case. Reasons for this include the criteria for receiving legal aid being stricter in Scotland than in England, and that the ability to recover legal costs is more restrictive in Scotland. Both act as a disincentive for lawyers to take on clinical negligence cases. Unlike England, Scotland has been unable to establish an extensive pool of lawyers experienced in clinical negligence.

6.20 Another possible difficulty for claimants in Scotland is in finding medical experts to assist with the claim. This may be due in part to the fact that Scotland has a relatively close knit medical community and, therefore, consultants and others are reluctant to place themselves in a position of having to judge and give an opinion on the actions of colleagues. In England, Action for Victims of Medical Accidents (AVMA) has been instrumental in developing a panel of medical experts but, despite their efforts, it has not proved possible to do likewise in Scotland.

OTHER ISSUES

6.21 We have identified the following issues which we think need to be considered in greater depth in the second part of our work:

- the time it takes for claims to reach settlement;
- the difficulties claimants may experience in gaining access to medical records.

6.22 We will consider the issues in paragraphs 6.19-6.21 in greater depth in our final report due in December 2002. For this purpose, we will invite the relevant professional bodies to provide us with further information.

ANNEX A

MEMBERS OF THE EXPERT GROUP ON FINANCIAL AND OTHER SUPPORT

Lord Ross, Chair
Vice-President, Royal Society of Edinburgh and Chair of the Mediation Group

Pat Dawson
Head of Policy, Royal College of Nursing, Scotland

Philip Dolan, Chairman
Scottish Haemophilia Group Forum

GRO-A

Dr John Garner
Chairman, BMA, Scotland

Maureen Henderson
Director of Nursing, South Glasgow University Hospitals NHS Trust

Ranald Macdonald
Legal Adviser, National Health Service Scotland Central Legal Office

Fiona Mackenzie
Chief Executive, Forth Valley NHS Board

Professor Sheila McLean
Director, Institute of Law and Ethics in Medicine, Glasgow University

Sheila McGoran
Chief Officer, Lanarkshire Health Council

Frank Maguire
Solicitor/Advocate, Thompsons, Glasgow

Arnold Simanowitz
Chief Executive, Action for Victims of Medical Accidents, Croydon

Dr Charles Swainson
Medical Director, Lothian University Hospitals NHS Trust

Dr Sue Whyte
Chair of the Scottish Academy of Royal Colleges and Faculties and Chair of the Scottish Joint Consultants Committee (SJCC)

Special Advisers

Peter Beaton) Scottish Executive Justice Department
Chris Naldrett) Scottish Executive Health Department
Bob Stock) Scottish Executive Health Department

Secretariat

Moira Milligen, Scottish Executive Health Department
Kate McLaughlin, Scottish Executive Health Department.

ANNEX B

LIST OF EVIDENCE CONSIDERED

Access to Legal Aid in Scotland -presentation by the Director of Legal Services, the Scottish Legal Aid Board

The Annual Report of the Hepatitis C Compensation Tribunal 2000. (published by the Government of the Republic of Ireland)

Annual Report 2000/2001: The Scottish Legal Aid Board

Corporate Plan 2002/03: The Scottish Legal Aid Board

Clinical Negligence: How do patients see the issues and options for Reform? (Presentation – Arnold Simanowitz, Chief Executive, of Action for Victims of Medical Accidents and Member of the Expert Group.)

Context of the System as it exists at present [The NHS Complaints Procedure, Handling Clinical Negligence and other claims. Dispute Resolution – Scottish Executive policy, The Current System of Redress. (Presentation – Pam Whittle, Scottish Executive.]

Defining 'Medical Misadventure' Lessons from New Zealand' (Paper) (Ken Oliphant)

Guidelines on Reparation Cases: The Scottish Legal Aid Board

'Hepatitis C: Essential Information for Professionals' Guidance produced by the Scottish Executive, August 2002

'Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the mid-1980s" (Paper) (SE Health Department)

Hepatitis C Compensation Tribunal (Annual Report 2000).

Literature Review – Evaluating Policy Alternatives for Patient Compensation (Paul Fenn, Alistair Gray, Neil Rickmann, Stephen Dixon. Commissioned by the Department of Health, England, Review of the Clinical Negligence System.)

No Fault Compensation Schemes and Other Support Arrangements within the UK [Macfarlane and Eileen Trusts, vCJD Scheme and Compensation, The Criminal Injuries Compensation Scheme (CICS), Pneumoconiosis Act 1979, CICA cases, Tariff of Injuries, Vaccine Damage Payments Scheme, the Scheme in Operation in the Republic of Ireland, Operating CICS.] (A discussion paper prepared by the Secretariat.)

The MORI Survey - (Paul Fenn, Alistair Gray, Neil Rickmann.-Commissioned by the English Advisory Committee on the Clinical Negligence System

No Fault Systems in Operation in Other Countries (A No-Fault Compensation Scheme for Medical Accidents. Discussion paper by Michael A Jones, Professor of Common Law, University of Liverpool.)

Origins of the Expert Group and the Interface with HCV in Blood Issues (Presentation – Bob Stock, Health Planning and Quality, Scottish Executive.

Perspectives on Clinical Negligence Litigation in Scotland - presentation by Ranald MacDonald, Legal Adviser, Scottish Health Service, Central Legal Office and Member of the Group and Chris Naldrett, Finance Policy, Scottish Executive and Adviser to the Expert Group.

Priority Treatment for People who have been harmed by NHS Treatment [Discussion paper prepared by the Secretariat for the Expert Group. Existing Schemes: priority treatment for war pensioners, costs of the scheme, travel expenses for war pensioners, the compensation scheme in operation in the Republic of Ireland for Hep C patients.]

The Report of the Health & Community Care Committee on Hepatitis C 'Hepatitis C Heat Treatment of Blood Products for Haemophiliacs in the mid 1980s

The Report of the Tribunal of Inquiry into the Blood Transfusion Services Board (published by the Government of the Republic of Ireland)

Retrospective Ex Gratia Payments linked to 'Defective Product Concept' [Discussion Paper prepared by Bob Stock, Health Planning and Quality, Scottish Executive.]

Reversing the Burden of Proof [Discussion paper submitted by Russell Levy, a partner in Solicitors Leigh, Day & Co, which formed part of a submission to the English Review Group on Clinical Negligence by the Association of Personal Injury Lawyers.]

Review of Health Services available for persons who contracted Hepatitis C through the administration within the state of blood or blood products. (Consultative Council on Hepatitis C – March 2002.)

Scheme of Payments For Those Infected with HIV Through Blood or Tissue Transfer: The Scottish Office Home & Health Department April 1992

The Swedish Patient Insurance System – 8 Years of Experience (Paper) (Carl Oldretz, Skandia Insurance Co, Stockholm Sweden.)

Evidence was also heard from a number of people who suffer from Hepatitis C

THE LITERATURE REVIEW

7. The Chief Medical Officer's Advisory Group in England on the Review of the clinical negligence system commissioned a literature review from a team of researchers at Nottingham University. The Literature Review was commissioned on the basis that a necessary part of any reform process is understanding how systems (and reforms) have worked elsewhere. For example, the apparent cheapness of 'no fault' schemes in New Zealand and Sweden have been questioned by some academics. The Nottingham University team therefore undertook a brief literature review of the work done by economists in this area. Time constraints meant that they could not consider the work of others in this field, eg lawyers, sociologists, medics. The main questions addressed in the Literature Review revolved around American Clinical negligence reform and the New Zealand and Swedish no-fault schemes as these were the dominant jurisdictions in the Literature search.

Results of the Review

8. We considered the results of the Literature Review which attempted to discover what evidence exists in relation to the impact of both existing and proposed alternatives in delivering the 2 objectives of compensation and deterrence.

- In Section 3 of the Literature Review, the researchers examine the evidence on the costs and effectiveness of alternative patient compensation schemes. Section 3.1 examines the extent to which the evidence suggests that systems based on negligence perform valuable functions by considering the following issues:

  - The costs of running a negligence system.

  - Is the negligence system a high-cost lottery which compensates only on (relatively) random basis? Evidence suggests this is not an accurate criticism[2].

  - Does the negligence system provide deterrence? Evidence on analysis of US automobile compensation[3] (some States have negligence and others have no-fault) concludes that fatal accidents are 5-9% more likely under no-fault.

  - Does the negligence system lead to defensive medicine? The researchers find that evidence is mixed. Early evidence[4] (in New York State) found significant links between several obstetric procedures and previous claims experience. Subsequent work[5] fails to find any link between clinicians' previous claims history and the treatment by several obstetrics procedures. These are all US studies and the results might not be easily imported into the UK.

  - Are there any net benefits in running a negligence system? Available evidence suggests that a positive net benefit is plausible[6].

[2] UK Fenn and Rickmann 1999.
[3] Cummins et al 2001.
[4] Localio et al (1993).
[5] Sloan et al 1997.
[6] Weiler et al.

- Section 3.2 examines the evidence on the following no-fault schemes:

  - Sweden and Finland operate non-tort schemes in conjunction with generous and comprehensive social insurance schemes. The Swedish scheme separates investigations into patient claims through the Patient Compensation Insurance (PCI) from those into physician activity which are dealt with by the Medical Responsibility Board (MRB). On the face of it, evidence shows that the Swedish system's figures show a significant saving[7] but these figures need careful interpretation as there are other reasons for this, eg other social insurance programmes meet medical expenses and wage losses due to medical injury.

  - The New Zealand system. In 1972, New Zealand moved to a no-fault system of compensation for accidents – the Accident Compensation Scheme (ACS). Evidence showed that this system provided a reasonable screen for causation, provided compensation in particular to events that would be unlikely to receive tort awards but may not provide much deterrence[8].

  - Utah and Colorado

    In 1992, Utah and Colorado instituted research programmes into their handling of medical negligence claims as a response to the level of tort litigation. Two studies[9] sampled medical records from Utah and Colorado for 1992. These were reviewed to detect the number of compensable events according to the Swedish avoidability criterion. The authors suggest that these studies demonstrate 2 points:

    (1) a no-fault scheme can be constructed to compensate more individuals at no more costs than under a tort-based scheme and;

    (2) it is possible to quantify the extent of the trade-off between patient access and overall cost that such schemes imply.

Conclusion

9. We concluded that the evidence from the Literature Review highlighted legitimate doubts about the ability of schemes like those in operation in New Zealand and Sweden to provide suitable deterrence.

---

[7] Danzon 2001.
[8] Paterson 2001.
[9] Stoddart et al 1997 and Stoddart and Brennan 2001.

THE MORI SURVEY

10. The MORI Survey was commissioned by the English Advisory Committee on the Review of Clinical Negligence. The Survey was carried out during the period 26 October 2001-16 November 2001 to obtain some quantitative information on the frequency and severity of any illness, injury or impairment that a population sample perceived themselves to have experienced as a result of any medical treatment or care they had received.

11. A questionnaire was designed to provide data on the incidence of such adverse events and where they occurred to assess where they happened, their severity in terms of health and employment, the response considered most appropriate, whether a legal claim was pursued, and the amount of compensation considered acceptable. In addition, demographic information was obtained on respondents' age, sex, region, level of qualification/education, social class and household income.. The following provides a summary of the main results.

Results

12. The questionnaire was administered in face to face interviews to a randomly selected sample of adults – 3638 men and 4568 women, giving a total sample size of 8,206. In total, 4.8% (395) of the sample believed that over the last 3 years they had suffered some illness, injury or impairment that in their view was caused by their medical treatment or care.

13. There was no evidence of significant differences in this response by sex, and although there was regional variation, the differences were not statistically significant. There was clear evidence that the proportion responding positively declined with increasing age and was inversely associated with social grade. Also there was some evidence of a lower positive response rate in higher income groups.

Location of Reported Incidents

14. The largest single category of events 55% (216) occurred in NHS hospitals, followed by General Practitioners 25% (99).

Impact on Health and Work

15. 55% of those reporting some event claimed that it was insignificant, emotional only or minor and temporary but 28% reported a temporary or permanent major disability and almost 30% claimed that the event had had a permanent impact on their health.

16. Responses to impact on work were similar with 55% stating impact was not relevant, non-existent or minor; 35% reported having to take at least 1 month off work because of the event and around 25% stated that they had to take at least 1 year off work.

17. 47% of reported events that happened in an NHS hospital could be classified as relatively minor in terms of their impact on health, but this rose to 69% for events that were related to GP care.

Responses that respondents considered most appropriate to the event that occurred

18. The most common response considered appropriate was an apology or explanation (34%) followed by an inquiry into the causes (23%) or support in coping with the consequences (16%). 11% thought that financial compensation was the most appropriate response. The figures show some correlation between the severity of the event and the response considered most appropriate – as the severity of increases, the proportion of respondents considering an apology or explanation the most appropriate response falls from 45% to 15%, while the proportion expressing a preference for support in dealing with the consequences rises from 5% to 35%. The proportion of those considering financial compensation the most appropriate response rises with the severity of the event but not significantly (no more than up to 15%).

Respondents who pursued a legal claim for financial compensation

19. 11.4% stated that they had pursued a legal claim for financial compensation. Of the remainder, the main reasons given for not pursuing a claim were that the respondent did not want financial compensation (36.7%) or that it had not occurred to them (19.5%). There is some correlation between the proportion stating that financial compensation was most appropriate and the severity of the event, but in no instance did the proportion who sought financial compensation via a legal claim rise above 15%.

Amount of compensation

20. 60% stated that they did not want financial compensation. 26% volunteered a figure, the mean amount that these respondents were willing to accept was £41,700.

Conclusion

21. We noted that the survey showed that a relatively low proportion of those experiencing an illness, injury or disability as a result of their medical care considered financial compensation to be an appropriate response.

ANNEX E

'NO-FAULT' COMPENSATION SCHEMES IN OPERATION IN THE UK AND OTHER COUNTRIES

1. We use 'no-fault' to refer to compensation which is obtained without the need to proceed against the person responsible for the harm.

2. We have had no-fault schemes in operation in Britain since the 1897 Workmen's Compensation Act. We consider the provisions of some of these schemes below.

The Macfarlane and Eileen Trusts

3. The Macfarlane Trust was established in 1988 to assist people throughout the UK who contracted HIV from contaminated blood products in the late 1970s and early 1980s. The support offered was a mixture of one-off compensation payments and ongoing financial support. When it was established, the Trust had 1,240 haemophiliac registrants; 808 of whom have since died. The expenditure to date is £68 million in one-off compensation payments, plus £27 million in ongoing payments. These ongoing payments are a mixture of regular monthly payments and one-off grants for a wide range of needs, eg travel, education, special equipment, gaps in the statutory benefits system.

Payments made to dependants

4. Dependants are eligible for support until the age at which they cease full-time employment.

5. All registrants receive £255 per month, plus an extra £50 per month if they are on income support and £61 if they are receiving disability living allowance. A review 2-3 years ago showed that 70% of registrants are largely dependent on income from the Trust plus state benefits. In 1992 the Trust was augmented by the Special Payments Scheme. This paid out £0.7m in ex gratia compensation to 12 non-haemophiliacs who contracted HIV because of blood, blood products or tissue transfer. In 1993 this was augmented by the Eileen Trust, which provided ex gratia ongoing payments to this non-haemophiliac group and has paid out £0.5m.

6. We noted that the establishment of the Macfarlane and Eileen Trusts was an exception to the principle that the NHS does not pay compensation when it has no legal liability. The rationale for this exception was largely linked to the presumption made at the time that HIV would inevitably and swiftly progress to death.

VCJD Scheme

7. The scheme will provide for payments to be made in respect of 250 cases of vCJD up to a maximum of £55 million. If numbers exceed 250 cases, the scheme will be reviewed. The scheme makes compensation for the experience of vCJD for the patient; the experience of vCJD for the patient's immediate family and/or carers; costs incurred by the patient and family as a direct result of the patient's suffering from vCJD and future losses caused to the patient's dependants as a result of his/her death from vCJD.

8. In April 2001, regulations came into force ensuring that payment of compensation to vCJD victims or their families would not be taken into account for the purposes of calculating income-related social security benefits nor be subject to 'claw-back' under the social security recovery scheme.

The Criminal Injuries Compensation Authority

9. The Criminal Injuries Compensation Authority administers the criminal injuries compensation scheme which operates throughout England, Scotland and Wales. They pay compensation to people who have been victims of a violent crime or those injured trying to apprehend criminals or prevent a crime. Since 1 April 1996, the level of compensation has been determined according to a scale, or tariff, set by Parliament.

10. The scheme reflects the basic elements of common law claims for personal injury and wrongful death, but the size of awards paid in recognition of victims' injuries — and not linked to their financial loss — is fixed according to the tariff.

11. When applicants have also suffered financial loss, through loss of earnings or earnings capacity, cost of medical or other care, or because they were dependent on someone who was murdered, they may apply for additional compensation. The Authority decides the amount of money they are entitled to by looking at all the available information on their financial circumstances before and since the crime occurred.

12. We noted that this is an example of a scheme where the definition is in very general terms and which is then left to develop by interpretation. It is also an example of a scheme where there is an attempt to give some kind of figure for pain and suffering on a tariff basis.

Pneumoconiosis etc (Workers' Compensation) Act 1979

13. This scheme was set up to pay compensation to people who are unable to recover damages from their employers as they are no longer in business. Diseases covered in the Act include pneumoconiosis; diffuse mesotheliona (asbestos-related cancer); diffuse pleural thickening (asbestos-related); primary carcinoma of the lung (only if accompanied by asbestosis or diffuse pleural thickening – this qualification is intended to distinguish asbestos-related lung cancer from that caused by other factors and byssinosis (associated with cotton dust exposure).

14. As well as being designed as a cushion for cases which cannot be successful in a civil sense because no employer is in business, the scheme very much 'piggy backs' on the qualifications of Industrial Disablement Benefit and uses that as a base to give payments in accordance with league tables.

Vaccine Damage Payments Act 1979

15. The Vaccine Damage Payments Act 1979 which came into force on 22 March 1979, introduced a scheme of payments for those severely disabled as a result of vaccination. Where the Secretary of State is satisfied that a person has been severely disabled and that, on the balance of probabilities, this is as a result of vaccination against any of the diseases specified in the Act and associated regulations, a tax-free one-off lump sum is payable

[currently £100,000]. Severe disablement is assessed as being disablement to the extent of 80% or more.

16. The payment is not compensation but is designed to ease the present and future burdens of those suffering from vaccine damage and their families. A payment under the scheme does not prejudice the right of the disabled person to pursue a claim for damages through the courts.

The Scheme in Operation in the Republic of Ireland for Compensation for Hepatitis C Patients

17. We considered details of the Compensation Tribunal set up in the Republic of Ireland to compensate patients who were diagnosed Hepatitis C positive resulting from receiving a blood transfusion, blood product or Anti-D (within the State), and noted that it was essentially a fault-based system. Nonetheless, it provided an insight into how a compensation system was operating. We found the 'other support arrangements' associated with the scheme very interesting. These are discussed further in Chapter 6.

NO-FAULT COMPENSATION SCHEMES IN OPERATION IN OTHER JURISDICTIONS

18. We considered evidence on no-fault schemes in New Zealand and Sweden which are very different in scope. The New Zealand Scheme is a general scheme and provides compensation for personal injury by any type of accident – road, domestic, work, medical etc). A person who has an entitlement under the Scheme is barred from raising a tort action. The Swedish Scheme is specifically for medical accidents and the patient remains entitled to bring a tort claim.

The New Zealand Scheme

19. The scheme provides statutory entitlements for all persons who suffer personal injury by accident 'Personal Injury by accident' includes the death of a claimant, physical injuries, eg a strain, mental injury suffered as a consequence of physical injuries or mental injury caused by certain criminal acts. Claimants seeking compensation for medical accidents must have suffered "personal injury caused by medical misadventure" which is defined as "personal injury caused by medical error or medical mishap".

'Medical Error'

Medical error is "the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances". This, by definition, requires proof equivalent to that of proving negligence; that is malpractice, in the same way as a medical malpractice claim under tort law. Non-negligent errors constitute medical misadventure *only* if they fall within the definition of 'medical mishap'.

'Medical Mishap'

Medical mishap, however, is very narrowly defined and is, therefore, highly restrictive in its application. It is defined as an "adverse consequence of treatment when, (a) the treatment given to a claimant, is given properly, and is given by or at the direction of a registered health professional; and (b) the adverse consequence is suffered by the claimant; and (c) the adverse consequence is 'severe'[10]; and (d) the likelihood that treatment of the kind that was given would have the adverse consequence is 'rare'[11].

Claimants not successful in claiming 'medical mishap', must establish 'medical error' which effectively requires proof of negligence on the part of the registered health professional. The result is that in the majority of cases in which claimants seek compensation for 'medical misadventure', proceedings are likely to turn into actions to prove medical negligence or malpractice.

20. The Accident Compensation Corporation ('the ACC') and registered insurers are responsible for administering the scheme. A potential claimant simply lodges his/her claim with the appropriate insurer. The receiving insurer then has to investigate the claim and determine whether or not the claimant is actually covered and, if so, decide what statutory entitlements the claimant should receive. The insurer has two months to investigate the claim and inform the claimant of its decision. The insurer is also under an obligation to inform the claimant about review and appeal rights. Should the claimant, therefore, disagree with the decision of the insurer, he/she can apply for a review of the decision.

21. Currently, employers and earners pay premiums. Income from tax on petrol sales and motor vehicle annual relicensing fees is also paid to the ACC. The premiums paid, as well as the injury costs, are then assigned to one of six accounts. The scheme used to be run as a "pay-as-you-go" scheme with enough money being raised each year to cover the cost of all claims paid in that year irrespective of when the injuries happened or how long their effects were expected to last. In 1998, however, the Government announced its decision to move the basis of the ACC premium collection towards a fully funded approach.[12] Premiums would be set at a level to cover current costs and to establish reserves sufficient to fund all previous accidents. Consequently, premiums for both employers and earners include a full-funding surcharge aimed at building up reserves over the next 10 to 15 years to meet the liability for the future cost of current claims.

The Swedish Scheme

22. While the system in New Zealand is comprehensive, the Swedish system applies only to injuries sustained in the medical care environment. It has been in place since 1 January 1975, though conditions may be revised from time to time. It came into being following

[10] An adverse consequence is 'severe' if it results in the claimant dying; or being hospitalised as an inpatient for more than 14 days; or suffering significant disability lasting more than 28 days in total.

[11] An adverse consequence is 'rare' if the probability is that the adverse consequence would not occur in more than 1% of cases in which treatment is given. A medical mishap will not be 'rare', however, if the risk was known to the insured before the treatment was commenced.

[12] Reported in the ACC, Annual Report 1998 at 11.

discussions among politicians, medical professionals and insurers in order to indemnify so-called 'therapeutic injuries'.

23. Being based on employers' no-fault compensation principles, there is no dedicated legislation. Instead, the system exists by common agreement among parties. Though it was set up to provide more objective grounds of compensation than those provided by civil law, claimants retain the right to claim in the courts. In principle, civil damages will be paid only if the victim can prove negligence or intent on the part of the person causing injury.

24. The financial structure of the system is based on insurance, which is compulsory for health care providers. County Councils (who bear most of the cost of health care insurance) made a public pledge to accept liability for and to compensate certain injuries in connection with health or medical treatment. The scheme was not designed to compensate for general misfortune and/or accident *per se*; nor for sickness nor disability benefit. These are covered by other legislation. Under the Swedish system, liability is borne by the health care providers, who will have paid premiums to a consortium of insurers. Premiums correspond to actual indemnity and administrative costs, because awards reflect civil awards. From the literature it appears that the system is cost-effective.

25. The Swedish system is based on the principle of ' avoidability'. Adjudicators investigate whether (1) an injury resulted from treatment, (2) the treatment in question was medically justified, and (3) the outcome was unavoidable. If the answer to the first query is yes, and the answer to either the second or third queries is no, the claimant receives compensation. But before a patient is eligible for compensation, they must have spent at least 10 days in the hospital or endured more than 30 sick days. This threshold eliminates minor claims.

26. However, the Swedish system is still not without some of the difficulties encountered anywhere in the world, regardless of the compensation system in place. An example is iatrogenic injury in which it may be impossible to tell whether an infection was caused by the patients' own bacteria or by hospital bacteria, which even the strictest hygiene may be unable to prevent. For these reasons, a policy was needed to make the scheme more comprehensive and to compensate some unavoidable complications rising from medically indicated treatments, while not indemnifying *every* treatment or infection. A Schedule was therefore drawn up which set out those circumstances under which compensation is *not* to be paid. All other circumstances are covered, if they fit within the criteria already mentioned and the provisions of the scheme.