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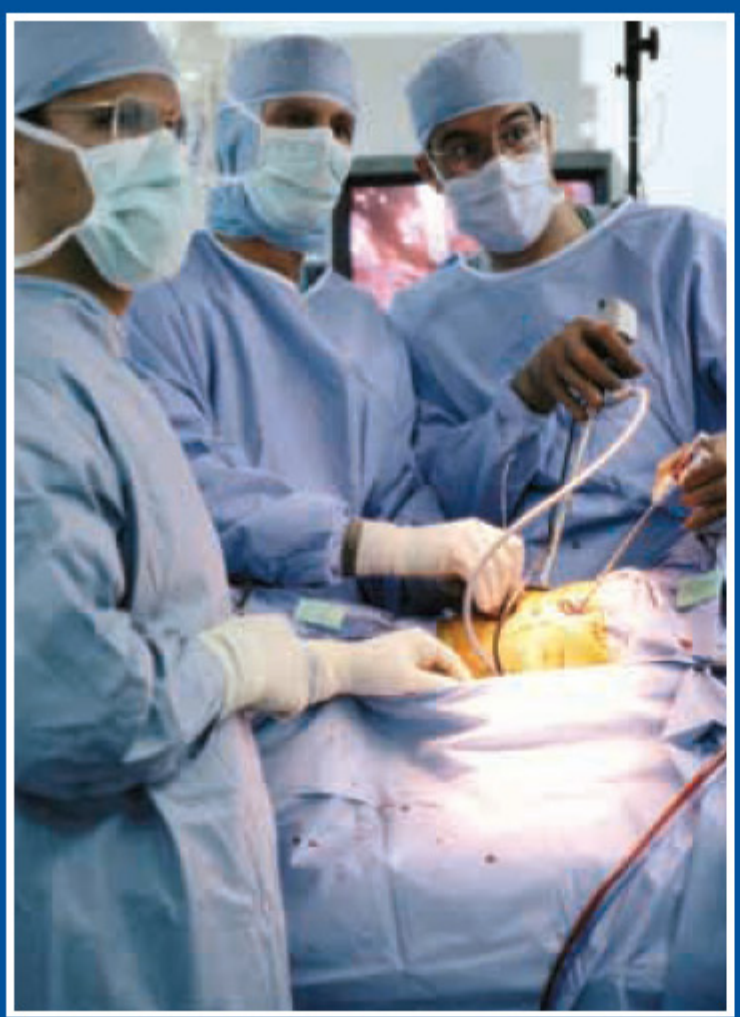
Northern Ireland Audit Office

Report by the Comptroller and Auditor General for Northern Ireland



Compensation Payments for Clinical Negligence

NIA 112/02

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J M Dowdall
Comptroller and Auditor General

Northern Ireland Audit Office
3 July 2002

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List of Abbreviations

A&E	Accident and Emergency
Board	Health and Social Services Board
CESDI	Confidential Enquiry into Stillbirths and Deaths in Infancy
CHI	Commission for Health Improvement
CNCF	Clinical Negligence Central Fund
CNST	Clinical Negligence Scheme for Trusts
CREST	Clinical Resource Efficiency Support Team
CSA	Northern Ireland Central Services Agency
DFP	Department of Finance and Personnel
DHSSPS	Department of Health, Social Services and Public Safety
DoH	Department of Health (England and Wales)
HPSS	Health and Personal Social Services
HSS	Health and Social Services
MDO	Medical Defence Organisation
NAO	National Audit Office
NHS	National Health Service
NIAO	Northern Ireland Audit Office
NICE	National Institute for Clinical Excellence
SCIE	Social Care Institute for Excellence
SHSSB	Southern Health and Social Services Board
Trust	Health and Social Services Trust

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Executive Summary

1. The overall potential burden of clinical negligence on the health and personal social services in Northern Ireland increased significantly during the 1990s with the outstanding liability for clinical negligence claims estimated at £121 million at March 2001. During the 10 year period from 1991 to 2001, £55 million was paid in compensation. The annual number of new claims raised has remained relatively static over the six years to 1999-2000, although there was an increase in 2000-01.

2. The Northern Ireland Audit Office (NIAO) has reviewed the incidence and nature of known clinical negligence, based on payments and claims made in the health and personal social services and elsewhere.

General Comment

3. The Department has welcomed this Report. In its view, it has been timely and should assist it in its ongoing efforts to secure improvements in the quality of services provided to patients, as well as improving procedures surrounding the administration of clinical negligence compensation claims.

Main Conclusions and Recommendations

Introduction and Background

4. Long established case law within the law of negligence has set out the circumstances in which a doctor can be adjudged as having been negligent. These are based around the duty of care a doctor has towards his patient and whether a breach of that duty has caused damage. Successful claimants will be entitled to compensation for injuries and other losses flowing from such a breach (paragraphs 1.1 to 1.5).

The Extent and Financial Impact of Claims on Health Service Resources

5. There were 3,532 outstanding claims in March 2001, compared to an estimated 1,899 in March 1995, an increase of 86 per cent over 6 years. In the 7 years to March 2001, 4,173 new claims were made, ranging from 530 in 1994-95 to 708 in 2000-01. There were 23,000 outstanding claims against the NHS in England in March 2000. The equivalent figure for Wales was 1,600 claims. In the context of HPSS activity levels, the number of claims made in Northern Ireland is relatively small and many claims do not lead to a financial settlement (paragraphs 2.3 and 2.4).

6. Although the Health Boards have not been directly responsible for the provision of health care since April 1996, following the establishment of Trusts from April 1993 onwards, Boards were the legal respondents for 33 per cent of the outstanding claims at March 2001, when the outstanding liability in the Boards' accounts was stated as £83.5 million (paragraphs 1.7 and 2.7).

7. Since 1996-97, most new claims have been issued against the 19 Trusts, particularly those providing only acute services. The specialty with the most claims outstanding was obstetrics and gynaecology, followed by accident and emergency and general surgery. It seems probable to us that the high number of claims in obstetric and gynaecology reflects not only the degree of risk, but also the fact that children are automatically eligible for legal aid (paragraphs 2.8 to 2.10).

8. We were surprised at the dearth of basic information held centrally on clinical negligence throughout the HPSS, given the significant and substantial increases in the estimated liability since 1990-91. The Department's guidance, issued in 1998, required each Trust to set up and maintain a database with information on all claims for litigation. The Department has advised us that it had taken steps to ensure that both Boards and Trusts hold comprehensive information on all outstanding claims. The sizeable backlog of unresolved claims reinforces the need, for the purposes of monitoring and control, for Trusts and Boards to maintain their own standard databases (paragraphs 2.13 and 2.15).

9. The Department should ensure that it has access to basic information about claims for clinical negligence, so that it is able to inform itself and disseminate, in summary form, this information

throughout the HPSS. The Department agrees with this recommendation and sees any future changes in HPSS structures as facilitating wider partnership. We welcome the Department's recognition of the need and value of a central database and urge that steps are taken to implement this as soon as possible (paragraphs 2.13 and 2.16).

10. The Department told us that, because it recognises the right to seek redress for clinical negligence as an important legal and human right, it places an overriding importance on ensuring that individuals with genuine claims are facilitated to achieve their rights. Nonetheless, we would point out that there is an acute awareness of the vulnerability of the HPSS to litigation. Most Trusts expect the level of claims to continue to remain the same or to increase (paragraph 2.12).

11. Although alleged incidents of negligence represent a small fraction of all in-patient/A&E episodes, and not all claims are valid, they have undoubtedly been a drain on public funds at a time when there are insufficient resources to match the demands that are being made on the health services. There must be a concern that, in the absence of hard information about the extent of negligence under investigation, the fear of litigation may encourage the practice of defensive medicine (paragraph 2.14).

12. The valuations of the possible costs of claims for clinical negligence have increased significantly. This has been largely as a result of the more detailed estimating process required under the revised accounting guidance. However, NIAO considers that these estimates have not been reflected in the actual experience of claim settlements, which would suggest, on the basis of settlements over the 7-year period to 31 March 2001, the likely outturn of all existing claims to be approximately £65.6 million (paragraph 2.35).

13. The valuation of claims in the 1999-2000 accounts raises a number of questions. First, some bodies have disclosed contingent liabilities and others have not. Second, the size of the provision reflects estimates which suggest a considerable increase in the number of cases settled and a high proportion of cases likely to result in a compensation payment by the HPSS. If the estimating process has been robust in relation to when existing cases are going to be settled, we would urge individual Boards and Trusts to ensure

that their preparations to respond to the potential increase in workload are adequate. Third, if the professional advice indicates a high probability of payment of either compensation or damages, we believe that HPSS bodies need to question whether or not they should prolong the defence of difficult cases with the end result that they incur unnecessary additional expenses. This point is developed in Part 4 (paragraph 2.36).

14. The Department needs to be aware of the financial costs arising from clinical negligence and it is advised to carry out a more detailed comparison to ensure that a full picture is available of how Northern Ireland compares with England, Scotland and Wales (paragraph 2.37).

15. The Department and HPSS bodies need to be well informed as to the cost of cases. This is critical, given the wide variation in the costs of individual settlements, the increasing average value of settlements, and the amounts incurred in expenses as a proportion of the overall costs (including the cost of legal advice provided under contract). Between 1994-95 and 2000-01, the HPSS cleared 2,132 claims for clinical negligence. Of the 670 claims which resulted in compensation, HPSS bodies were not able to provide details as to the settlement amounts and fees for all claims. Data was provided for 626 claims and the expenses (mainly legal costs) for 538 claims (319 cases for Boards and 219 cases for Trusts). For these 538 cases, the overall cost was £32.3 million. These figures include £9.7 million in legal costs. Individual settlements ranged from less than £1,000 to £1.2 million. We strongly recommend that the HPSS should maintain a database of all cases resolved, including those withdrawn or closed without payment of compensation. The Department accepts these recommendations (paragraphs 2.25, 2.28 and 2.38).

16. The value of this information would be further enhanced if, prior to the introduction of this register, all Boards and Trusts had reviewed their outstanding claims to identify those which are suitable for immediate closure and that all claims should be reviewed at least once a year with a view to closure. This would provide the HPSS with greater assurance as to the proportion of claims which are likely to be pursued. We commend the diligence of those bodies who have regularly reviewed cases and note that some have achieved a relatively high rate of successful rebuttals. We also welcome the Department's agreement that more consistent reviews of cases should be carried out across all Boards and Trusts. We would emphasize the importance of the regularity of such reviews (paragraph 2.39).

17. The proportion of claims closed without a compensation payment shows that many patients opting for litigation are ultimately unsuccessful. Overall expenditure, particularly on smaller settlements, suggests that litigation may be an inefficient way of addressing critical medical mishaps. In response to this, the Department told us that the right of patients to seek redress, and the checks and balances enshrined within the legal system made it difficult for the HPSS to seek to make changes unilaterally. However, the Department also told us that the HPSS would be responsive to alternative approaches if these were developed in conjunction with the appropriate authorities (paragraph 2.40).

18. We welcome the new arrangements for the central funding of clinical negligence compensation and acknowledge that these should help to eliminate the disadvantages, in terms of equity, perceived by some HPSS bodies. We are concerned that the current funding arrangements do not serve to encourage HPSS bodies to minimise exposure to risk and we believe that the Department and HPSS bodies should be more active in attempting to reduce the projected costs of future negligence (paragraphs 2.51 and 2.52).

19. We are of the view that there could be greater use of structured settlements, which are currently voluntary. The Department said that it endorsed the use of structured settlements but we consider that it should be more proactive in promoting these in appropriate cases, although we recognise that, ultimately, the take up of such settlements is a matter for the plaintiffs to determine, with their advisers (paragraph 2.53).

20. It is clear to us that the quality of financial estimating of future negligence and the sharing of information and experience have been the real weaknesses in the operation of the Clinical Negligence Central Fund in the first two years of its operation, although we accept the Department's contention that new accounting arrangements have led to a greater emphasis on obtaining accurate forecasts. There has been concern within the Department that the feedback of information on clinical negligence cases has been poor and that the absence of sharing of information has brought with it the risk of similar incidents unnecessarily occurring at different hospitals (paragraph 2.54).

21. We note the Department's view that the introduction of the central funds has done much to provide stability in the management of the financial consequences of clinical negligence cases for individual Trusts and Boards. Notwithstanding this, there remains scope for improving the in-year forecasts of cash requirements and the sharing of information and experience. Mechanisms now need to be introduced by, and monitored by, the Department whereby the lessons to be learnt from the wide range of adverse clinical incidents that occur across Northern Ireland can be shared with other clinicians and administrators elsewhere in the HPSS. Procedures across the Service can then be adjusted and good practice protocols introduced, where these are considered necessary or desirable. There is also an underlying need to be sure that the staff employed to process clinical negligence cases have the skills and understanding necessary to be able to identify such lessons (paragraph 2.55).

22. We note that the Department advised Boards and Trusts in March 2001 that it retained the right to review the new arrangements if information was not provided in a timely and reasonably accurate way, and it warned of possible delays in reimbursement of compensation and costs if timetables were not met. We are concerned that when qualitative information on procedures and remedies was required to be provided, between April 1998 and March 2001, there was no evidence that any review of the limited information that was provided, had taken place (paragraph 2.56).

Claims Experience

23. Many claims made do not result in the payment of any compensation because, although many of them were related to events which had an adverse impact upon patients and their families, in terms of being able to prove negligence, they were weak claims. Clearly, compensation should not be paid where a patient has failed to prove a breach of the duty of care or when the breach has not caused injury or damage. However, in other circumstances, patients and their families should be able to seek redress. While it is the patient's right to pursue a claim by litigation, to opt for a route which ultimately involves litigation is not necessarily in the best interests of patients or the health service, where at present, there is no process for the early screening of all claims to refute those which are clearly not negligent (paragraph 3.5).

24. We reviewed 322 of the 326 cases settled in the 3 years to 2000-01. In 1998-99, the average time taken to settle claims was over 6½ years, with one case taking over 12 years. In 1999-2000, the pattern for settlements was virtually identical, though the longest time was 30 years. In 2000-01, the average time taken was over 7 years, with the largest time taken being over 40 years for a birth-related case (paragraph 3.8).

25. The Department has stressed that clinical negligence is a very particular form of litigation, with a unique legal process. We recognise that delays in the processing of compensation claims are not always the fault of the relevant HPSS bodies. They are also usually beyond the immediate control of the Department. However, the time taken to process claims for clinical negligence should be capable of being shortened. An average time of 4 or 5 years to settle a claim and claims which run for over 10 years point to inefficiencies in the system and are clearly matters of concern (paragraph 3.15).

26. Redress for patients who believe that they have been the victims of clinical negligence cases takes almost twice as long to resolve as other actions brought before the same Courts. We urge the Department to take whatever measures are possible, within its means and recognising the legal rights of all concerned, to promote the earlier resolution of claims (paragraph 3.16).

27. To illustrate some of the factors influencing the outcome of cases, we examined 20 cases which were settled in 1998-99 with a payment of compensation. We recognise that settlements may result from a single weakness in the defence of a case. However, we are concerned that there were multiple weaknesses in the majority of the cases examined (paragraphs 3.17 and 3.30).

28. In 19 of these cases, the HPSS agreed to settle out of Court and the 20th case went to Court but was ultimately settled out of Court. In all cases the HPSS had identified weaknesses in its defence of cases. These have been sub-divided into clinical, administrative and personnel related weaknesses. Clinical factors occurred in 19 cases. As well as mistakes by staff or missed and mis-diagnosis, sub-optimal procedures were the most persistent clinical factors in the case studies. Non-clinical factors occurred in 12 of the case studies. These included problems with records, personnel and testimony. The case studies are set out in the main body of the report (paragraphs 3.22 to 3.24 and Appendix 1).

29. The clinical factors identified provide evidence of what can go, and what has gone, wrong, sometimes with tragic consequences. Many of the clinical factors are avoidable. The non-clinical factors which have emerged from the case studies point to serious failings in some areas of health service administration. The Department has stressed that staff have done their best with existing resources and we clearly recognise that, if unlimited resources were available to the HPSS, significant improvements could be made. Similarly, we acknowledge that all records cannot be kept indefinitely and that staff in the HPSS, particularly junior medical staff, often leave and work outside Northern Ireland. Nevertheless, most of the non-clinical factors are also avoidable and many improvements could be made without a major resource implication (paragraphs 3.31 and 3.32).

30. It is disturbing that, in 30 per cent of the selection of cases reviewed, there were gaps in the medical records. NIAO's sample is not a statistical one, and it does not necessarily follow that there are gaps in 30 per cent of all medical records. Nevertheless, the quality of records is particularly worrying, considering that the state of medical records and the potential impact on any subsequent review of the records (especially where a claim for negligence is pending) was recognised as far back as 1983. We recognise that there are constant pressures on the Department and HPSS bodies to reduce administration costs, but there are some non-clinical support areas which are of such fundamental importance to the clinical efficiency of the health service that sufficient resources must be applied, if the service is to operate efficiently and effectively (paragraphs 3.25 to 3.29 and 3.33).

31. The Department must assure itself that the quality of medical records being kept in the Northern Ireland Health and Personal Social Services is of a standard which does not compromise the present and future health and well-being of patients and we welcome the assurances that it has given us, regarding its ongoing efforts at improving record-keeping. However, we recommend that the Department commissions an early review to establish the extent of the problems identified by this report, particularly with regard to records kept (paragraph 3.34).

32. It came to our attention, during our review of cases, that a number of cases, where settlements were made out of Court, had confidentiality clauses inserted within the terms of the settlements. We understand these to have been mainly at the insistence of the

defendants to the claims. We consider the use of such clauses questionable. There may occasionally be exceptional circumstances, where a Court might impose some restriction to protect a plaintiff's identity, for example, if that plaintiff is a minor, but in the majority of cases, confidentiality seems inappropriate, when payments of public money are involved. We therefore welcome the Department's assurance that it is committed to taking immediate action to ensure that confidentiality clauses are not included in clinical negligence settlements and we note its recent acknowledgement to the Public Accounts Committee about the inappropriateness of confidentiality clauses (paragraph 3.18).

33. The processes for handling medical negligence claims have clearly not been satisfactory in minimising delay. Within the case studies examined, we believe that 17 of the 20 cases could have been resolved earlier than was the case. In some cases, there was a delay in disclosing medical records, in others, the HPSS recognised liability long before settlement took place. In some cases, the HPSS delayed hiring an independent medical expert or there was a delay in an expert witness giving advice or presenting a report to the plaintiff. Examples of cases arose where there was no early contact between the parties or where HPSS staff were unavailable to attend Court or where former staff could not be traced. There were also cases where the plaintiff experienced delay in obtaining legal aid for a claim (paragraphs 3.35 to 3.51).

34. It is important that, where the standard of care was clearly reasonable, the Health Service should defend its position robustly. It is also important that it should, at all times, exercise good judgement, even when the advice is that the case is difficult to defend. It would appear that, in many of the case studies, the HPSS has refrained from admitting liability where the case has been difficult to defend. We are concerned that around one half of all existing claims were made over three years ago. Although some claims will take longer to resolve than others, all claims, irrespective of their individual merits, should be addressed and resolved as soon as possible. We consider that the case studies provide some indication of problems associated with clinical negligence litigation processes which need to be addressed (paragraph 3.51).

35. There is evidence that more cases have been concluded in recent years. For example, in 1994-95, some 122 cases were closed or settled. In 2000-01, this figure had increased to 479. We welcome this trend, though over the same period, the number of claims outstanding has risen from 1,899 to 3,532 (paragraph 3.52).

36. Some factors identified as obstacles to early resolution might not be capable of remedy. Some cases will by nature or context (or both), be particularly sensitive and it may take longer for experts to investigate and advise. Also, either party must be allowed the right to seek adjournment of hearings for legitimate reasons. However, we consider that the other delaying factors are not beyond the capacity of the Department and others to redress and we recommend in the report, good practice that should be promulgated and monitored by the Department, the HPSS and by third parties (paragraphs 3.53 to 3.57).

37. At the centre of all this, the Department should ensure that all HPSS bodies, which are likely to be subjected to compensation claims for clinical negligence, have in place a proper case management system which provides a central and accountable control over the progress of each case from original knowledge or notification of the incident through to settlement and clearance (paragraph 3.58).

Access to Justice

38. We noted the findings of Lord Woolf in his Report on "Access to Justice" and his recommendations which led to a Pre-Action Protocol for the Resolution of Clinical Disputes. We also note that the Department has recommended the adoption, by Boards and Trusts, of the Protocol and that it intends to actively promote it and monitor adherence to the procedures. The views expressed to us during our investigations show that there is a broad consensus within the HPSS for a change away from the current adversarial arrangements and we would therefore urge the Department to follow up the issue of the Protocol to ensure that it is being implemented (paragraphs 4.1 to 4.5, 4.7 and 4.18)

39. The Department, HPSS and many other bodies are deeply interested in, and some are inextricably involved in, the issues surrounding clinical negligence. The Northern Ireland Court Service told us that the Group consulted with a wide range of medical interests and its membership included a former Permanent Secretary from the Department of Health and Social Services. Nevertheless, we think that it was an oversight on the part of the

Reform Group that it did not consult the Department or the HPSS on arrangements in Northern Ireland. We also consider that implementation of some of the Group's recommendations is vulnerable to the risk of delay. For NIAO, the main issue is how the recommendations, as framed, will achieve a material reduction in the excessive costs and delays in litigation (paragraph 4.9 and 4.22).

40. We note that the Northern Ireland Court Service will initiate and drive the pre-action protocol consultation process which will take account of the protocol used in England and Wales, although variations will be considered where there are good reasons advanced during the consultation process. We recommend that the Court Service fully engage with the Department during this consultation process and that the Department, in turn, engage in, and contribute to, the reform process (paragraph 4.23).

Minimising Exposure

41. NIAO considers that a survey of risk management conducted for the Department by consultants was very timely and potentially useful, as it provided an independent view of the steps that had been taken to date by individual HPSS organisations. It was also a major contribution to the identification of the risks faced by the HPSS. We recognise that there are many examples of decisions taken by the HPSS and the Department, which have been informed by appropriate risk assessments and best practice. Nevertheless, the survey's findings suggest that there remains scope for further improvements and, given that the Department of Finance and Personnel had issued general guidance on risk management in 1994, we would have expected further progress on this front (paragraphs 5.3 to 5.7).

42. Although the consultants identified good progress in a number of areas by some HPSS bodies, the identified gaps in risk management will need to be addressed by the Department and the HPSS to ensure consistent good practice across the service. It is disappointing that action in response to the survey has been delayed, given the high expectations of the Department. A permissive approach to the implementation of good risk management has not brought the results that are required. We

would, therefore, expect the Department to be able to provide positive assurance of substantial progress in risk management within HPSS bodies, by 2003 at the latest (paragraphs 5.8 and 5.9).

43. As a matter of priority, approaches should be made to organisations on those risk management issues where they had not achieved full compliance (including those who did not provide the documentation to enable an assessment to be made). The Department should actively encourage all those to raise their performance to at least the second highest banding of full compliance, and it should monitor progress towards compliance (paragraph 5.10).

44. We welcome the various initiatives that have been taken to enhance quality and standards of care, which the Department informed us form part of a much wider agenda to achieve improvements in services and in the experience of individual service users. We also recognise and welcome the awareness within the HPSS of the need to minimise exposure to negligence as part of broader efforts to enhance the standards of care. The Department needs to clarify how it expects contract monitoring to operate, in relation to quality of care provision. We suggest that the Department should also remind all clinical staff of the importance of clinical audit and its contribution to enhancing standards of care (paragraphs 5.13, 5.18 and 5.19).

45. We welcome the Department's confidence in its ability to introduce new arrangements shortly, aimed at enabling doctors to demonstrate their high level of clinical practice. This will provide a significant opportunity to set up the new processes and procedures required. Further improvements need to be accompanied by a modernisation of associated processes. It is surprising that any group of professional staff, largely funded by the taxpayer, has not been subject to a system of annual appraisal, particularly when the existing sanctions have been too severe, too legalistic and too prolonged for them to be applied in practice (paragraphs 5.20, 5.26 and 5.31).

46. We also welcome the efforts made to date to improve the quality of clinical care and clinical governance. We note that the consultation periods for the Department's recent proposals have now ended and look forward to the Department's announcement of early action (paragraph 5.30).

47. Any arrangements for recording adverse events need to be clear and unambiguous and it is important that the Department is assured that adverse events are disclosed, not just for the purposes of accountability, but also as a means to improve standards in the HPSS and to the avoidance of future error (paragraph 5.32).

48. The impact of poor performance is disproportionately large when measured against the scale of poor performance. Like clinical negligence, poor performance has multiple effects. Also, like clinical negligence, the causes of poor performance are largely avoidable and any strategy to minimise this should be addressed. We hope that there will soon be arrangements to assure the public that, in all cases, they will be treated by a doctor who is well-trained, highly competent and up-to-date in their practice, and that where there are shortcomings, these are promptly addressed by internal mechanisms, or if exceptionally serious, by external intervention (paragraphs 5.33 and 5.34).

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Part 1: Introduction and Scope

Background

1.1 Clinical negligence occurs when a claimant is able to prove in a civil action all of the following:

- that the defendant owed the claimant a legal "duty of care";
- that there was a breach of this duty; and
- that the breach caused personal injury or damage.

1.2 The first of these tests is usually easy for patients to prove against the relevant authority as a Health and Social Services (HSS) Trust or a HSS Board (prior to the establishment of Trusts) and their employees owe a duty of care to patients. The other two tests are more difficult to prove.

1.3 Generally, the law of negligence will condemn as negligent any act or omission which falls short of a standard to be expected of a "reasonable man". In actions for clinical negligence, there is long established case law which holds that a doctor has not been negligent "if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art" (the "Bolam test")[1], though this was modified in 1997, where the professional opinion is not capable of withstanding logical analysis[2] . The practical form of a test for negligence is that a judge will hear evidence from experts in the particular branch of medicine after which he must decide whether the doctor's actions were to an acceptable standard. Often there are several acceptable ways of doing something and compliance with any of these will mean that there was no breach of the duty of care. The same test applies to other professional staff such as nurses, midwives and speech therapists.

1.4 The breach of the duty of care must also be shown to have caused damage. If there is a breach of a duty of care but there has been no damage, then there is no negligence. If there has been a breach of a duty of care and there has subsequently been injury or damage, the test which is often applied is to assess whether the damage would have occurred if there had been no negligence. If it would have occurred, then the health service will not be liable for that damage.

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1 Bolam v. Friern Hospital Management Committee, 1957

2 Bolitho v. City and Hackney Health Authority, House of Lords, 1997

1.5 Successful claimants will be entitled to compensation for injuries and other losses flowing from a breach of this duty. Damages awarded are solely to reimburse any losses attributable to the negligence. They are not designed to punish the defendant.

1.6 Until 1 January 1990, clinical negligence was not covered by Crown indemnity. Previously, doctors and dentists were contractually obliged to subscribe to one of the recognised medical defence organisations (MDOs) to indemnify them while working in the health service. An increase in claims led to annual subscriptions rising from £40 in 1978 to £1,080 in 1988. In 1988, clinicians who had whole-time contracts or worked wholly in the National Health Service (NHS) had two-thirds of their subscriptions reimbursed by the Government. Further proposed increases in subscriptions led to the health service assuming full responsibility for clinical negligence, including the expected liabilities associated with existing claims. In the Republic of Ireland, doctors and dentists have continued to rely on the MDOs for indemnity, with subscriptions set to take account of the risk associated with a particular specialty. We were advised that, in the highest risk specialty of obstetrics, the annual premium for consultants there could be as high as £60,000.

1.7 In Northern Ireland, responsibility for the handling of claims was delegated to the Health and Social Services Boards (Boards). Following the establishment of HSS Trusts from April 1993 onwards, this responsibility has been shared with the Trusts, with Trusts only handling claims for incidents which occurred after they attained Trust status.

1.8 The overall potential burden of clinical negligence on the Health and Personal Social Services (HPSS) in Northern Ireland increased significantly during the 1990s with the outstanding liability for clinical negligence[3] claims (including contingent liabilities[4] of £22.7 million) estimated at nearly £121 million at 31 March 2001 (see Figure 1). The increase between 1998-99 and 1999-2000 is largely explained by the revised approach adopted by the HPSS for the quantification of the outstanding liability as required by a new accounting standard which was implemented for the first time in 1999-2000. On a comparable basis, the Department of Health, Social Services and Public Safety (referred to as "the Department" or DHSSPS) has calculated that the 1998-99 figures would have been £112 million (including contingent liabilities of £18 million).

3 For definition of Clinical Negligence Claims – see paragraphs 1.1 to 1.4

4 For definition of Contingent Liabilities – see paragraph 2.21

1.9 During the 10-year period from 1991 to 2001, approximately £55 million was paid in compensation (see Figure 1). In 1999-2000, the Department provided recurrent funding of £4.8 million to the Boards to meet compensation payments for clinical negligence. The Department said that the annual number of new claims raised has remained relatively static over the six years to 1999-2000, although there was an increase over this level in 2000-01. In England, Scotland and Wales, the equivalent figures for that year were £373 million, £3.5 million and £26.9 million respectively. Although NIAO did not include the private sector in its study, we noted that the largest indemnifier of general practitioners in the United Kingdom paid out £78 million in compensation in 2000, most of which went direct to patients. These matters are further discussed in Part 2, in which these payments are reviewed against the level of claims made.

Figure 1

Payments and Liabilities in respect of Clinical Negligence

Year	Payments *1	Potential Liability at 31 March *2 (including Contingent Liabilities and Provisions from 1999-2000)
	£m	£m
1991-92	2	15
1992-93	3	17
1993-94	6	22
1994-95	5	29
1995-96	3	40
1996-97	4	41
1997-98	6	58
1998-99	12	70
1999-00 *3	5	122
2000-01 *3	9	121
Total	**55**	

Source: DHSSPS

Notes: *1 Payments fluctuate because of the timing of settlement of cases.
*2 The Potential Liability figures represent the maximum cost to the HPSS of all known outstanding claims against it succeeding.
*3 1999-2000 and 2000-01 figures include contingent liabilities of £22 million and £23 million respectively, as required by the revised valuation approach (see paragraph 2.22). Provisions were not included in the accounts in earlier years.

The NIAO Examination

1.10 The Northern Ireland Audit Office (NIAO) reviewed the incidence and nature of known clinical negligence, based on the payments and claims made in the HPSS and elsewhere. We examined the arrangements for the administration and funding of claims and how the main systems for dealing with claims from those who allege negligence operated in practice

1.11 This Report is in five parts, including this one. Part 2 considers the extent and financial impact of negligence. It includes a review of caseload, the calculation of the extent of liability and details on recent settlements. It also considers the arrangements made for the funding and accounting treatment of compensation claims. Part 3 examines the arrangements for the handling of claims, given the length of time taken to resolve many claims. Parts 2 and 3 have been informed by a survey of claims for compensation and practices within HPSS bodies to deal with these claims. We have also examined a selection of individual claims where there has been a financial settlement. In England, where there have been similar problems in handling claims, legal proceedings have been significantly reformed. These, and developments in Northern Ireland, are covered in Part 4. Finally, Part 5 contains a review and description of risk management and of the measures taken, nationally and locally, to minimise exposure to negligence and compensation claims.

1.12 In the course of our examination, we consulted a large number of clinicians and officials employed by the Department, the Boards, the Trusts, the Central Services Agency (CSA) and the Eastern Health and Social Services Council, the statutory patient representative body in that Board's area. We also examined the position in England, Wales and Scotland through discussion and references to reports on clinical negligence published recently by the National Audit Office (NAO)[5], the Auditor General for Wales[6] and Audit Scotland[7]. We also consulted the Northern Ireland Court Service, and legal experts in progressing clinical negligence claims, both in the public and private sectors.

5 Handling Clinical Negligence Claims in England, NAO, May 2001 [HC 403]

6 Clinical Negligence in the NHS in Wales, Auditor General for Wales, February 2001

7 Overview of the NHS in Scotland 1999-2000, Audit Scotland, December 2000

1.13 The reports produced by other audit bodies indicate that the subject of clinical negligence is one that has prompted interest and concern throughout the United Kingdom. In support of this view, it is interesting to note that the Law Society of Northern Ireland recently stated that millions of pounds in legal costs could be avoided if companies used lawyers for mediation instead of litigation[8]. A spokesman added that "the NHS is losing several hundreds of millions of pounds in fees and damages arising from medical negligence and many of those could be resolved by a more inclusive process, a discussion, an explanation and showing a caring face". In addition, the Chief Medical Officer for England has said that "fundamental reform of clinical negligence is long overdue. The current system is slow and bureaucratic. It does not work for NHS patients or for NHS staff"[9].

8 Irish Times, 14 March 2002

9 Chief Medical Officer for England, referring to the issue of consultation document on "Clinical Negligence: What are the Issues and Options for Reform?" issued by Department of Health in August 2001, reported in BMA News, 13 April 2002

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Part 2: The Extent and Financial Impact of Claims on Health and Social Services Resources

Outstanding Claims

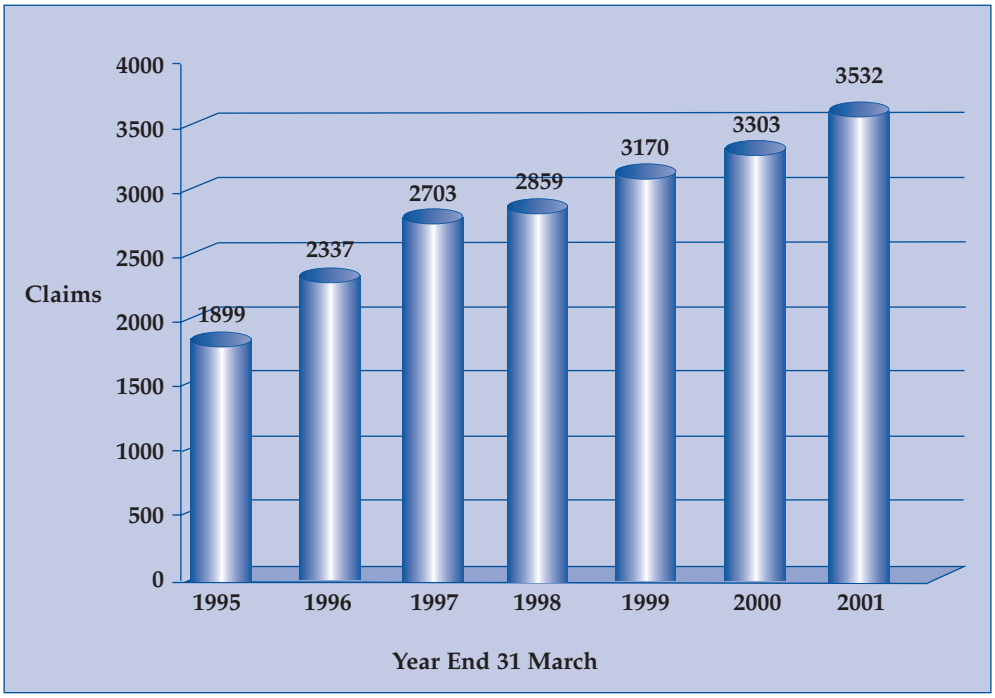
2.1 The financial extent of the potential liability for all outstanding claims for alleged clinical negligence is disclosed annually in Board and Trust accounts and, in aggregate, in the summarised accounts of the HPSS. To complement this information, early in the study, we sought further details on the extent of outstanding claims for compensation for alleged clinical negligence. The Department pointed out that, in line with the practice elsewhere in the United Kingdom, details of individual claims are not held centrally. We were surprised by this, in view of the widespread concern amongst health service officials about clinical negligence and the consequent financial risk. Consequently, we obtained the necessary data directly from Trusts and Boards by undertaking a survey.

2.2 Following our survey we noted that, at organisational level within the HPSS, there are deficiencies in the way information is held on clinical negligence claims and payments. In 1998, the Department issued guidance requiring that, as a minimum, Trusts should maintain a comprehensive database of information on clinical negligence, including information on quantitative and qualitative aspects of all outstanding claims. All of the Boards already had databases. However, a minority of Trusts still do not have one. In addition, when we sought information on claims, some bodies had to obtain the information from their legal service providers. The Department has now indicated that it will ensure that detailed information on outstanding claims is held centrally as well as by the individual HPSS bodies affected.

2.3 As a result of the survey which we undertook of all Boards, Trusts and Agencies throughout the HPSS, we can report that there were 3,532 outstanding claims at 31 March 2001, compared to an estimated 1,899 at 31 March 1995, an increase of 86 per cent over 6 years (Figure 2) with a year-on-year increase of 7 per cent in 2000-01. Some organisations (including some of the larger ones) were not able to supply precise details as to outstanding claims in the early part of the survey period. In the 7 years to 31 March 2001, 4,173 new claims were made, ranging from 530 in 1994-95 to 708 in 2000-01(Figure 3). In 2001, the National Audit Office estimated that there were some 23,000 outstanding claims against the NHS in England at 31 March 2000, including 10,000 new claims in that year. The Auditor General for Wales reported that the equivalent figure for Wales was over 1,600 claims (see paragraph 1.12).

Figure 2

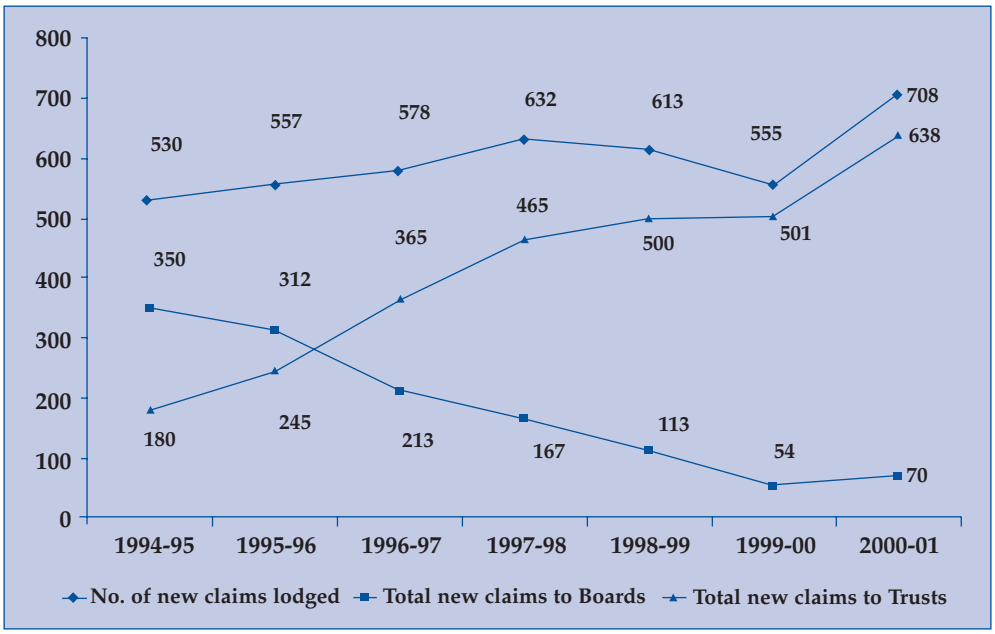
Outstanding Clinical Negligence Compensation Claims



Source: NIAO Survey and Analysis

Figure 3

New Clinical Negligence Claims: 1994-95 to 2000-01

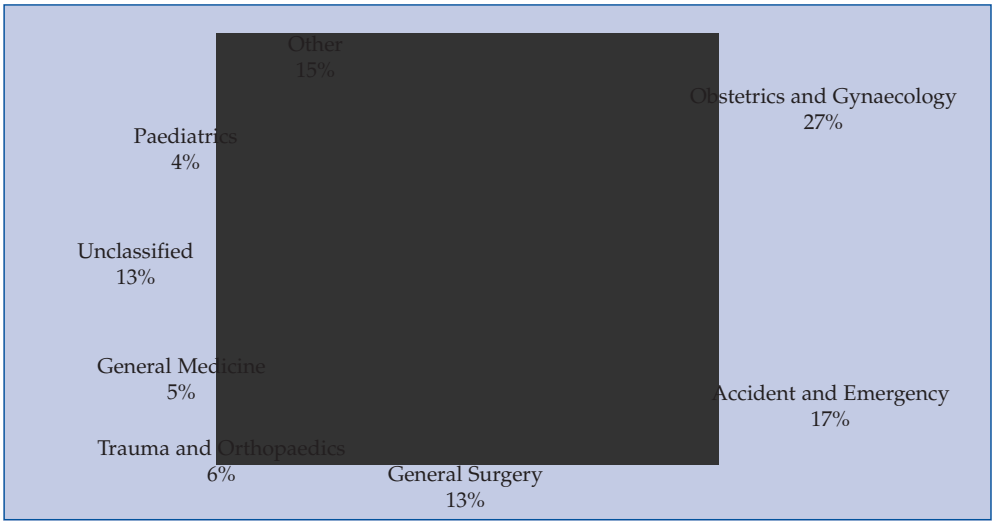


Source: NIAO Survey and Analysis

2.4 In the context of HPSS activity levels, the number of claims made in Northern Ireland is relatively small and many claims do not lead to a financial settlement. However, a study into the incidence of adverse events and negligence in hospitalised patients in America suggested that the extent of medical negligence may be understated, as research indicated that 3.7 per cent of acute hospital patients are the victims of medical error and of these, 27.6 per cent are as a result of medical negligence[10]. In Northern Ireland terms, taking acute and maternity patients, this would amount to some 15,700 adverse events of which 4,300 would be due to negligence. However, this would understate the likely level of potential negligence claims as it does not include accident and emergency, which, in practice, is the second highest claiming specialty (see Figure 4).

Figure 4

Clinical Negligence Claims by Specialty: 31 March 1999



Source: NIAO Survey and Analysis

2.5 In its recent report (see paragraph 1.12), the National Audit Office (NAO) referred to a pilot study conducted in two London hospitals, which found that "about ten per cent of patients admitted to acute hospitals experienced an adverse event, about half of which were preventable with current standards of care"[11]. Although the pilot study did not examine whether any of those incidents resulted from care that would be judged to be negligent, it is from this and the other pools of error referred to above, that victims of negligence are drawn.

10 "Incidence of adverse events and negligence in hospitalised patients: Results of the Harvard Medical Practice Study II" New England Journal of Medicine 324: 377-384 (1991)

11 Adverse Incidents in British Hospitals: Preliminary Retrospective Record Review, Vincent C, Neale G, and Woloshynowych, M, British Medical Journal 2001, 322.

2.6 Many potential litigants may be deterred by the inability to access legal aid. The NAO found that 74 per cent of all claims brought in England were supported by legal aid but that only 48 per cent of the adult population were eligible for legal aid for such cases. A paper prepared for the NHS Executive in England, in evaluation of a limited pilot of 12 mediation cases, reported that "patient groups have long argued that the civil justice system remains inaccessible to victims of medical negligence…..that funding a negligence claim is extremely difficult and that cases with merit and smaller value claims are often not filed because of the high transaction costs associated with litigation…In addition to the direct costs of funding their own case, claimants in the British tort system are exposed to a double financial risk of having to pay their opponent's costs…should they lose their case"[12] . It has also been suggested that the fear of litigation has led to the practice of defensive medicine where more activity may be carried out in some cases, in the form of tests etc, than is clinically necessary. This concern has been expressed by a number of authorities, including the British Medical Association, the Secretary and Shadow Secretary of State for Health and clinicians.

2.7 Although the Boards have not been directly responsible for the provision of health care since 1 April 1996, they were the legal respondents for 33 per cent (1,153) of the outstanding claims at 31 March 2001. At 31 March 2000, the total outstanding liability in the Boards' accounts was £91.3 million, (including provisions of £73.5 million and contingent liabilities of £17.8 million), 72 per cent of the total for all HPSS bodies. In 2000-01, these figures had reduced to £83.5 million (including provisions of £64 million and contingent liabilities of £19.5 million). The number of claims still outstanding against the Boards reflects the length of time it takes to handle claims. The valuation placed on claims against the Boards, reflects the fact that the more serious incidents (especially those involving babies and children) often take longer to fully manifest themselves, and when litigated, take longer to resolve.

2.8 Since 1996-97, most new claims have been issued against the 19 Trusts. Within the Trusts, the largest number of claims are against those Trusts which provide only acute services and the fewest claims are against those Trusts which provide, solely, community and personal social services.

12 Mediating Medical Negligence Claims: An Option for the Future?, Mulcahy L, Selwood M and Netten A, November 1999

2.9 We asked Boards and Trusts to identify the outstanding claims, at 31 March 1999, by specialty (Figure 4). The specialty with the most claims outstanding at that date was obstetrics and gynaecology (27 per cent), followed by accident and emergency (A&E) (17 per cent) and general surgery (13 per cent). Other specialties with over 100 outstanding identified claims were trauma and orthopaedics (6 per cent), general medicine (5 per cent) and paediatrics (4 per cent). Together, they accounted for 72 per cent of all outstanding claims.

2.10 It seems probable to us that the high number of claims in obstetrics and gynaecology reflects not only the degree of risk, but also the fact that children are automatically eligible for legal aid. Also, for adults (with the exception of those with a mental disability), legal action has to be taken within 3 years of the patient becoming aware of the alleged breach of care or from the breach itself. For minors, it is extended to their 21st birthday.

2.11 The many claims for which no specialty could be identified is due to two factors. Firstly, many claims are vague as to the negligence which is being alleged and HPSS bodies treat these as a low priority until they receive better information. Second, when the Southern Health and Social Services Board (SHSSB) set up a claims database in April 1996, it decided to exclude outstanding cases which were not, at that time, being actively pursued by patients. When surveyed, there were over 140 such cases. The Board has since advised the Department that the cases may not result in a settlement.

2.12 The Department told us that, because it recognises the right to seek redress for clinical negligence as an important legal and human right, it places an overriding importance on ensuring that individuals with genuine claims are facilitated to achieve their rights. Nonetheless, we would point out that there is an acute awareness of the vulnerability of the HPSS to litigation. Most Trusts expect the level of claims to continue to remain the same or to increase. This is attributed to a perceived greater willingness, by patients with higher expectations, who are now more educated and rights conscious, to resort to litigation. Other reasons may include the greater publicity given to cases of negligence, advertising by legal firms who specialise in compensation claims, and the higher profile given to clinical governance, where organisations are being held more accountable for the quality of service they provide.

NIAO Comments and Recommendation

2.13 We were surprised at the dearth of basic information held centrally on clinical negligence throughout the HPSS, given the significant and substantial increases in the estimated liability since 1990-91. The Department's guidance, issued in 1998 (see paragraph 2.2) required each Trust to set up and maintain a database with information on all claims for litigation. The Department has also advised us that it had taken steps to ensure that both Boards and Trusts hold comprehensive information on all outstanding claims. We welcome the Department's recognition of the need and value of a central database and urge that steps are taken to implement this as soon as possible.

2.14 Although alleged incidents of negligence represent a small fraction of all in-patient/A&E episodes, and not all claims are valid, they have undoubtedly been a drain on public funds at a time when there are insufficient resources to match the demands that are being made on the health services. There must be a concern that, in the absence of hard information about the extent of negligence under investigation, the fear of litigation may encourage the practice of defensive medicine.

2.15 Between 1994-95 and 2000-01, the number of outstanding cases increased by 86 per cent, with a 7 per cent increase in the most recent year, and we note that those involved in claims handling expect that the burden of litigation will continue to increase. There is a sizeable backlog of unresolved claims. This reinforces the need, for the purposes of monitoring and control, for Trusts and Boards to maintain their own standard databases, as recommended by the Department.

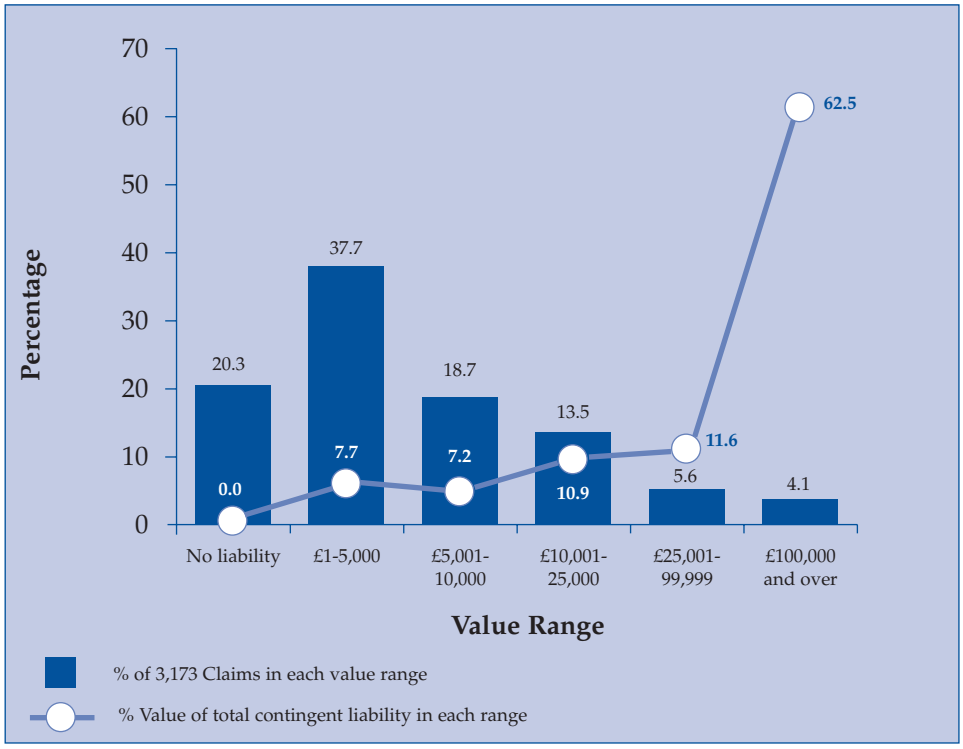
2.16 We recommend that the Department should ensure that it has access to basic information about claims for clinical negligence, so that it is able to inform itself and disseminate, in summary form, this information throughout the HPSS. The Department agrees with this recommendation and sees any future changes in HPSS structures as facilitating wider partnership.

Valuation of Claims

2.17 We asked all HPSS bodies for details of the liabilities outstanding against them as at the end of 1998-99 (Figure 5). Less than 10 per cent of all cases were valued at over £25,000, but they accounted for 74 per cent of the contingent liability, whilst 58 per cent of claims were valued at £5,000 or less (including 20 per cent for which no valuation had yet been made).

Figure 5

Spread of Contingent Liability at 31 March 1999



Source: NIAO Survey and Analysis

2.18 The average valuation of claims increased from £15,000 in 1994-95 to £30,000 in 1999-2000, falling back to £28,200 in 2000-01. The higher average valuations in recent years are due to a combination of factors:

- the adoption of what the Department views to be the prudent practice of assigning a nominal value, for example £5,000, to all new claims;

- the tendency for the valuations which have been reserved in the accounts to be increased as cases are actively progressed. This

is required under accounting guidelines. As a consequence, the best estimates of claims may increase or decrease as the claims progress;
- inflation;
- a greater scope in the damages which are alleged;
- a substantial increase in awards by courts to cover the costs of long-term care (the "Wells"[13] factor); and, most significantly,
- a change in generally accepted accounting practice, under which a more prudent approach is taken to calculating potential liability.

2.19 The valuation of claims is based on the advice of the external legal advisers of HPSS bodies. These included specialist barristers, when there was a possibility that the claim would go to Court. Prior to 1999-2000, although counsel costs were included in estimates, there were inconsistencies in the treatment of the costs of legal advice offered by the authorities' solicitors. The liabilities in some bodies did not include legal costs, as legal experts were often employed on block contracts to provide legal services to the organisation during the year and their costs were accounted for in the general expenditure of that body. In others, a separate estimate was made. In one Trust, where two firms of legal advisers were used, the claims handled by one firm included a calculation for legal costs, whereas the other firm made no such estimate in their claims.

The Accounting Treatment

Provisions

2.20 For 1999-2000, the accounting policy changed to comply with generally accepted accounting practice[14]. As a result, all claims have now to be evaluated on the basis of three different forecasts of liability – the highest, the lowest and a middle value. The probability of each of these forecasts occurring is estimated, the percentages adding up to 100 per cent. An estimate is also made as to the number of years before the claim is expected to be settled. The forecasted liabilities are multiplied by their respective probabilities to produce a total expected value. This is then discounted at the rate of 6 per cent a year for each year that is expected to elapse before settlement takes place. The discounted value is then disclosed in the accounts as a provision or potential expenditure.

13 Wells v. Wells, 1999

14 Financial Reporting Standard (FRS) 12: Provisions, Contingent Liabilities and Contingent Assets: Accounting Standards Board, 1998

Contingent Liabilities

2.21 Previously, clinical negligence liabilities in the HPSS had been accounted for as contingent liabilities. A contingent liability is a liability about which there is no certainty that it will ever occur[15]. Although it appears in the accounts, it has no effect upon the organisation's balance sheet value. A provision is a liability which is deemed certain to occur, but there is uncertainty as to the amount and timing. As it does impact upon the organisation's balance sheet, the estimated costs are subject to audit scrutiny and must be capable of validation.

2.22 In 1999-2000, the accounts of the Boards and Trusts had year-end provisions of £100 million and contingent liabilities of £22 million. In the 2000-01 accounts, the respective figures were £98.0 million and £22.7 million. Paragraph 1.8 explains the reason for the substantial increase in reported liability in these two years over previous years. In Figure 6, the provisions for clinical negligence compensation in Northern Ireland, in 1999-2000, are shown against provisions in the other parts of the United Kingdom.

2.23 NIAO identified several factors which had contributed to the substantial increase in liability. Firstly, all claims had to be assigned a valuation, whereas previously, many claims had not been re-evaluated annually. The valuation was to be on the basis of the best estimate from legal advisers. Secondly, because of time constraints, HPSS bodies did not consider all their claims in detail. In the interests of prudence and reflecting legal advice, they assigned high probabilities in most claims to the higher two of the three estimates of liability, whereas historically, most of the cases closed so far, have not resulted in either compensation or damages (see Figure 7). Given that this was the first year for which detailed provisions had to be accounted for, health bodies encountered some difficulties in arriving at these estimates. For the first year, the appointed auditor of the Eastern Health and Social Services Board reported to the Board that there was considerable uncertainty as to the accuracy of the provision, although he did not qualify the Board's accounts. However, by the second year, he reported that greater reliance could be placed on the estimated provision for 2000-01. Third, earlier resolution leads to a greater liability and there was some evidence that the HPSS was optimistic as to the number of cases that are expected to be settled in the near future. For example,

15 FRS 12 defines this fully as (a) a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence of one or more uncertain future events not wholly within the entity's control; or (b) a present obligation that arises from past events but is not recognised because: (i) it is not probable that a transfer of economic benefits will be required to settle the obligation; or (ii) the amount of the obligation cannot be measured with sufficient reliability.

in the three years to 31 March 2000, the Royal Group of Hospitals Trust cleared 82 cases. In the information underlying the accounts for 1999-2000, the same Trust expected to clear 249 cases by 31 March 2003.

Figure 6

United Kingdom - Comparison of Clinical Negligence Provisions at 31 March 2000

	Total Provisions £ million
Northern Ireland	100
England	2,600
Wales	111
Scotland[16]	38

Source: Audited Accounts

16 The difference between the provisions and contingent liabilities for clinical negligence in England and Scotland were discussed at the PAC at Westminster in June 1998. The Comptroller and Auditor General (UK), HM Treasury and the Scottish NHS confirmed that the audited figures for provisions and contingent liabilities for clinical negligence in England and Scotland were prepared on a comparable accounting basis. They were not aware of any evidence-based explanation for the differences between the levels of provision and contingent liability in Scotland and those in England. (Memorandum to 2nd Report of 1998-99 Session of Committee of Public Accounts on NHS (Scotland) Summarised Accounts 1996-97 [HC 102], December 1998).
At a Symposium on Medical Practice and the Growth of Litigation, held in June 2000, the Royal Society of Edinburgh submitted the view that "the lower number of claims in the NHS in Scotland as compared to England might be due to a number of factors including the fact that it is more difficult to obtain legal aid for medical negligence claims in Scotland than in England, the fact that medical practices tend to be smaller in Scotland, the fact that there are relatively more general practitioners per head of population than in England, and the fact that there may be less of a 'claims culture' north of the border".

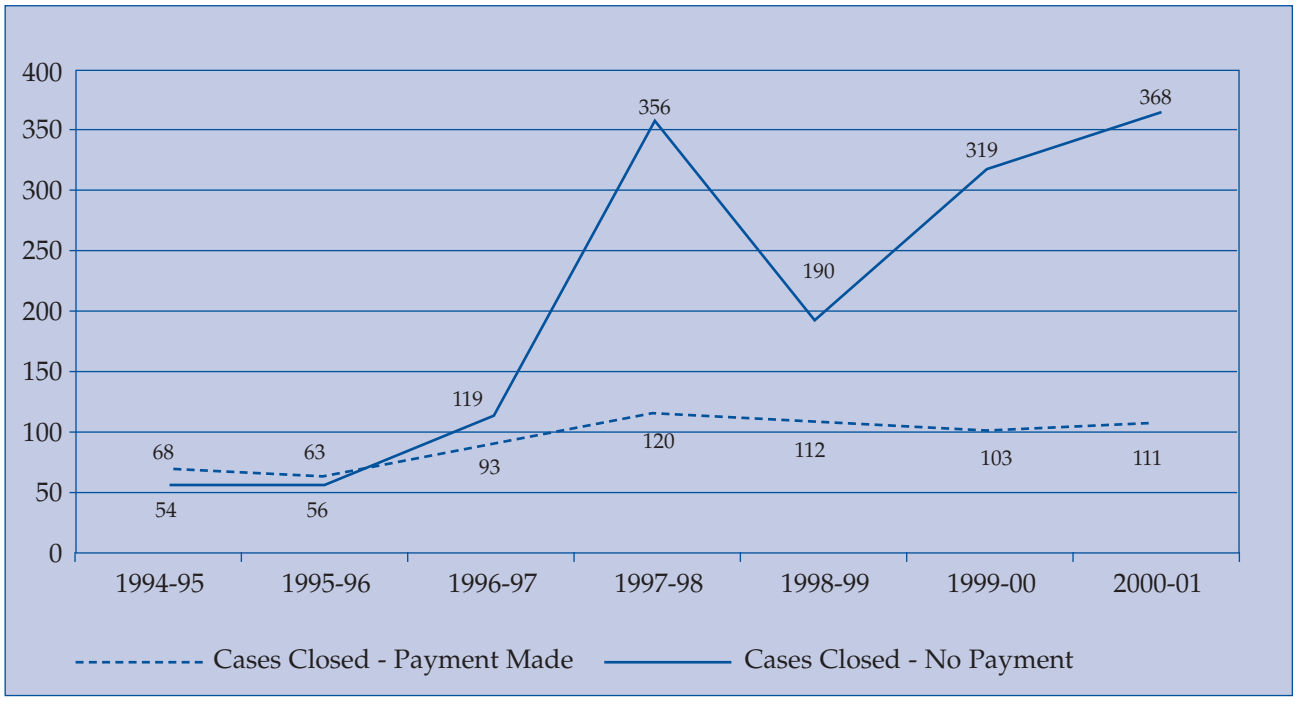
Figure 7

Analysis of Cases Closed between 1994-95 and 2000-01

(a) Detail

Year	Boards		Trusts		Totals		Percentage Totals	
	No Payment	Payment	No Payment	Payment	No Payment	Payment	No Payment	Payment
1994-95	54	68	0	0	54	68	44%	56%
1995-96	55	60	1	3	56	63	47%	53%
1996-97	109	71	10	22	119	93	56%	44%
1997-98	330	82	26	38	356	120	75%	25%
1998-99	90	64	100	48	190	112	63%	37%
1999-00	192	56	127	47	319	103	76%	24%
2000-01	272	45	96	66	368	111	77%	23%
Totals	**1,102**	**446**	**360**	**224**	**1,462**	**670**	**69%**	**31%**

(b) Summary



Source: HSS Boards and Trusts

2.24 The Department told us that it would be wrong to draw the conclusions that because a high proportion of cases in the past has not resulted in settlement to the plaintiff, that a similar proportion of existing or current cases would have a similar outcome in the future. The Department has also stressed that all claims are valued on the basis of legal opinion, by experts in this field of litigation, not by a subjective analysis of likely future trends. NIAO accepts both these points, but would also draw attention to the evidence presented by Figures 7(a) and 7(b) which shows that there is a considerable difference between the number of cases, on which a valuation had been estimated, which have been closed, with no payments made, with those on which payments were made. The trend, in recent years, has been for this gap to widen. Thus, a greater proportion of cases are being closed, without a settlement. This, inevitably, has an impact on the accuracy of the estimated potential liability to the HPSS, with the cost being less than envisaged (see paragraph 2.32).

Settlements and Closure of Cases

2.25 Between 1994-95 and 2000-01, the HPSS cleared 2,132 claims for clinical negligence (see Figure 7). Of those claims:

- 69 per cent (1,462) had been withdrawn or closed;
- compensation was made in 31 per cent (670) of cleared claims;
- less than 3 per cent of the total went to court (54 cases); and
- 29 per cent were settled out of court.

2.26 For Great Britain, there is no directly comparable centralised data to much of that produced by NIAO for Northern Ireland. However, the NAO estimated that, for Trusts in England, in 1999-2000, "62 per cent of claims cleared (under the Existing Liabilities' Scheme) were abandoned by the claimant or otherwise resolved without financial outcome and the remainder had a financial settlement in the patient's favour". The figure for Wales was 60 per cent. Under the Clinical Negligence Scheme for Trusts (which deals with claims where the related incident occurred after April 1995) some 83 per cent of claimants had withdrawn their claims by May 2000. The overall figure for Northern Ireland for that year was 74 per cent, with an average of 69 per cent of cases cleared without payment in the 7 years to 2000-01.

2.27 In Northern Ireland, the Boards cleared 1,548 cases in that period, of which 71 per cent were withdrawn and 28 per cent were settled out of Court. Of the 584 claims disposed of by Trusts in the same period, 62 per cent had been withdrawn and 36 per cent had been settled out of Court.

2.28 Of the 670 claims which resulted in compensation, HPSS bodies were not able to provide details as to the settlement amounts and fees for all claims. Data was provided for 626 claims and the expenses (mainly legal costs) for 538 claims (319 cases for Boards and 219 cases for Trusts). For these 538 cases, the overall cost was £32.3 million. These figures include £9.7 million in legal costs. Individual settlements ranged from less than £1,000 to £1.2 million. For the three years from April 1998, the compensation paid (excluding legal costs) was less than £25,000 in over 70 per cent of all settlements. There has been a general increase in the average cost of settling a case and a general increase in the number of cases settled annually.

2.29 Although on average, expenses account for some 30 per cent of the compensation paid, in many instances the costs of reimbursing lawyers, experts and witnesses is more than the compensation paid to successful claimants. This often happens in cases where the settlement is less than £20,000. In 2000-01, this happened in 31 per cent of such cases, with a further 31 per cent having expenses which were at least half the value of the compensation paid. NAO reported that in England, for claims closed in 1999-2000 with a settlement value of over £10,000 where the incident occurred before April 1995, the cost of litigation exceeded the value of damages paid to patients, in 75 per cent of all settlements under £20,000.

2.30 The costs quoted to us did not include the costs of legal services provided under annual contract. NIAO estimates these costs to be up to £0.5 million per year. Also, it is clear from the information supplied for settlements made in the 3 years to 2000-01 that, in many cases, the settlement amounts were significantly lower than the reserves placed against them. Settlements in each of the 3 years were 55 per cent, 67 per cent and 69 per cent lower than the reserves placed against them.

2.31 The NIAO survey results point to significant differences in policies and practices within the HPSS to closing claims. The

Northern Board reviews all cases every six months with a view to the possible closure of inactive cases. Since April 1994, that Board has made payments in 101 cases out of a total of 503 closed cases (20 per cent). Although some HPSS bodies, for example, the Eastern Board, and the Mater Infirmorum and Craigavon Hospital Trusts, have made commendable efforts to secure early closure of inactive cases, for others it has not been a high priority. However, one Trust, Down Lisburn, advised us that the NIAO survey had prompted it to review all cases, which resulted in 17 cases being closed in 1999-2000, though only 3 were closed in 2000-01. 134 cases were outstanding at that Trust at 31 March 2001. Another Trust, Belfast City Hospital, indicated that it would now be reviewing cases with a view to possible closure. 8 cases were closed at that Trust in 1999-2000 and 10 in 2000-01, though 308 cases were outstanding at 31 March 2001.

2.32 With regard to the valuation attached to claims, the Department has explained to us the detailed analysis that underpins the estimates in terms of the assessment of the probability of success of a claim and date of settlement, the likely costs involved and the need specifically, to base the valuations on legal advice on such issues. NIAO acknowledges this, but considers that a greater allowance might be made for the past experience of significant numbers of claims not leading to settlement and of the valuation of the actual settlements compared to the provisions set. If the average rate of settlement for Northern Ireland over the last 7 years (31per cent - see Figure 7) is used to calculate the potential compensation payable against the 3,532 claims outstanding at 31 March 2001 (see paragraph 2.3), the result would be £65.6 million.

2.33 This is significantly lower than the current HPSS estimate but it remains a substantial sum of money and indeed would exceed the amount (£55.2 million) paid in compensation for clinical negligence between 1991-92 and 2000-01 (see Figure 1 at paragraph 1.9). The Department has emphasised that it must give full regard to the legal advice it receives on the potential liability in specific cases but has indicated that it will discuss with the HPSS auditors the extent to which past experience of the proportion of cases leading to settlement can be legitimately factored in to the assessments of future liabilities pertaining to existing cases.

2.34 The analysis above does not take account of the probable financial impact of future claims, which on past trends (see

paragraph 2.3) would total approximately 596 a year. Using the methodology adopted above, this would equate to an annual increase in provision of around £11 million, but changes to the valuation of existing claims would impact on this and the actual increase will depend on the number of cases raised and their probability of success.

NIAO Comments and Recommendations

2.35 The valuations of the possible costs of claims for clinical negligence have increased significantly. This has been largely as a result of the more detailed estimating process required under the revised accounting guidance. However, NIAO considers that these estimates have not been reflected in the actual experience of claim settlements, which would suggest, on the basis of settlements over the 7-year period to 31 March 2001, the likely outturn of all existing claims to be approximately £65.6 million.

2.36 The valuation of claims in the 1999-2000 accounts raises a number of questions. First, some bodies have disclosed contingent liabilities and others have not. Second, the size of the provision reflects estimates which suggest a considerable increase in the number of cases settled and a high proportion of cases likely to result in a compensation payment by the HPSS. If the estimating process has been robust in relation to when existing cases are going to be settled, we would urge individual Boards and Trusts to ensure that their preparations to respond to the potential increase in workload are adequate. Third, if the professional advice indicates a high probability of payment of either compensation or damages, we believe that HPSS bodies need to question whether or not they should prolong the defence of difficult cases with the end result that they incur unnecessary additional expenses. This point is developed in Part 4.

2.37 The Department needs to be aware of the financial costs arising from clinical negligence and it is advised to carry out a more detailed comparison to ensure that a full picture is available of how Northern Ireland compares with England, Scotland and Wales.

2.38 The Department and HPSS bodies need to be well informed as to the cost of cases. This is critical, given the wide variation in the costs of individual settlements, the increasing average value of settlements, and the amounts incurred in expenses as a proportion of the overall costs (including the cost of legal advice provided under contract). We strongly recommend that the HPSS should maintain a database of all cases resolved, including those withdrawn or closed without payment of compensation. The information held should include the hospital, the specialty, some basic details of the incident, the date and time of the incident, and the time taken to resolve the case, the costs incurred including any settlement costs and all expenses. The costs of legal advice provided by the HPSS's solicitors on clinical negligence claims is treated as a legal expense. While the arguments of legal advisers may, in some cases, undoubtedly lead to lower settlement costs, in others, it may not. The cost of such advice should, therefore, be disclosed separately. The Department accepts these recommendations.

2.39 The value of this information would be further enhanced if, prior to the introduction of this register, all Boards and Trusts had reviewed their outstanding claims to identify those which are suitable for immediate closure and that all claims should be reviewed at least once a year with a view to closure. This would provide the HPSS with greater assurance as to the proportion of claims which are likely to be pursued. Although each claim has to be considered on its merits, and the proportion of closed cases which result in compensation payments will vary across HPSS bodies, we commend the diligence of those bodies who have regularly reviewed cases and note that some have achieved a relatively high rate of successful rebuttals. We also welcome the Department's agreement that more consistent reviews of cases should be carried out across all Boards and Trusts. We would emphasize the importance of the regularity of such reviews.

2.40 The proportion of claims closed without a compensation payment shows that many patients opting for litigation are ultimately unsuccessful. Overall expenditure, particularly on smaller settlements, suggests that litigation may be an inefficient way of addressing critical medical mishaps. In response to this, the Department told us that the right of patients to seek redress, and the checks and balances enshrined within the legal system made it difficult for the HPSS to seek to make changes unilaterally.

However, the Department told us that the HPSS would be responsive to alternative approaches if these were developed in conjunction with the appropriate authorities. We discuss alternative approaches in Part 4.

Funding Arrangements

2.41 Initially, the Boards were able to fund negligence from two sources. The first source was the resources that had previously been used to reimburse doctors' subscriptions to the medical defence organisations (MDOs). The second source was the reserve funds which the MDOs had accumulated to meet future NHS liabilities, but had transferred to a central fund held by the Department of Health (DoH) in England. These funds were for any settlement which exceeded £300,000, and provided for 80 per cent of the excess.

2.42 The reserve funds held by DoH were exhausted by the mid-1990s and in response, the Clinical Negligence Scheme for Trusts (CNST) was introduced, which became effective in England from 1995-96. CNST, to which all hospital Trusts in England belong, is an insurance-oriented scheme which requires its members to comply with risk management standards. Compliance with these allows for discounts on premiums paid, according to the level of compliance. It is administered by a separate agency, the NHS Litigation Authority, which manages the bulk of litigation and maintains a central database of claims. The Welsh and Scottish health authorities, through the Welsh Risk Pool and the Clinical Negligence and Other Risks Indemnity Scheme, operate risk management schemes in Wales and Scotland respectively, providing pools of funds, sourced by contributions, as required, from health services bodies.

2.43 In May 1995, the Department asked a working group of HPSS finance officers to consider the possibility of establishing a mutual scheme for Northern Ireland. The group reported in September 1995, concluding that the benefits of a mutual scheme outweighed those of the alternatives considered, but advising that further consideration was required due to the possibility of significant costs in establishing such a scheme. The Department advised NIAO that, in their opinion, Northern Ireland was too small to justify a mutual scheme. However, it believed that the risk management standards set out by CNST could be applied to Northern Ireland.

2.44 After consultation involving senior finance officers in the Boards and the Trusts, the Department introduced the Clinical Negligence Central Fund (CNCF) which took effect from 1 April 1998. The CNCF clarified the position with regard to the funding of settlements by Trusts who had been concerned for some time about their exposure to large settlements. The CNCF, which was administered by CSA, reimbursed Trusts for the costs of settlements. Until March 2000, these reimbursements were funded through contributions from the Boards, calculated on a capitation basis.

2.45 Up to 1999-2000, the funds allocated to Boards by the Department under the previous arrangements to cover the costs of negligence, totalled £4.8 million, distributed on a population basis. However, settlements have borne little relation to the provision of funding. In 1997-98 and 1998-99, there was a shortfall in funds, particularly in 1998-99, with two Boards - the Eastern and Western Boards - not being fully funded to meet the costs of their own settlements. In February 2000, the Department provided an additional £4.3 million, based partly on population and partly on 1998-99 settlements.

2.46 The Department established a review group to look at the financial aspects of clinical negligence and to make recommendations for improvement. This group reported in March 2000[17]. The Department accepted the main recommendation that the CNCF be extended to meet the costs of all claims (those relating to Boards as well as Trusts). This would be funded directly by the Department. The report also recommended:

- consideration of a more centralised approach to the claims handling process by those with responsibility for claims handling, including the establishment of a central database; and
- consideration of the establishment of a review body to deal with all risk management issues in clinical negligence.

2.47 The procedure now, is that when Boards and Trusts submit a payment request in respect of each claim, they are expected to disclose the dates of claim and settlement, the amount of the settlement and the legal costs and a brief description of the incident and the specialty involved. Boards and Trusts are also required to

17 Review Group: Financial Aspects of Clinical Negligence. DHSSPS, 2000.

make annual submissions to the Department and to CSA of all potential settlements in the current financial year and quarterly estimates of expected settlements in the following quarter. This is to enable CSA to estimate the potential funds required. Qualitative information was also to be provided on procedures and remedies. In turn, this information was to have been reviewed by a Department - led team which included representatives from Boards and Trusts, who were to assess the issues involved and lessons to be learnt. An annual report was to be produced on the more strategic issues identified in the cases, their implications for the HPSS generally and the way forward.

2.48 In the first two years following the introduction of the CNCF (see paragraph 2.44), not all Trusts who applied for reimbursement complied with the Department's requirement for full submission of information on clinical negligence claims. Of the Trusts which did fully comply, there appears to have been no strategic review of that information. We note that the Department issued new guidance in March 2001, in which it indicated that the qualitative information on procedures and remedies referred to in paragraph 2.47, was no longer required to be submitted to the CSA, although this information was to be held at local level. We also noted that the forecasting information provided by Trusts was inaccurate. For example, the Trusts estimated that they would pay out a total of £5.9 million in the 12 months to September 1999, whereas in that period, reimbursement was requested for £1.2 million, 20 per cent of the estimate.

2.49 In the two years to 31 March 2000, the Trusts submitted requests for reimbursement totalling £1.7 million, of which almost £1.0 million related to actual settlements. Trusts within the Eastern Board area requested some 67 per cent of the total amount requested, whilst the Board itself met only 42 per cent of the total liability. In contrast, Trusts in the Western Board area made no requests for reimbursement, whilst the Board itself met 16 per cent of the liability. This was perceived as a significant inequity[18]. However, with the removal of cost sharing on a capitation basis and with the Department now absorbing costs across the HPSS, it considers that funding is more equitable.

18 Report of the Review Group: Financial Aspects of Clinical Negligence, DHSSPS, March 2000 - Executive Summary

Structured Settlements

2.50 In May 1998, the Department produced guidance on structured settlements. Settlements that include provision for ongoing care have traditionally comprised a single lump sum, which is calculated on the basis that, if prudently invested, it would provide adequate cover for the expected remainder of the plaintiff's life. Structured settlements allow for the plaintiff to receive, instead, part of the damages in the form of annual tax-free instalments, that is, providing a stream of future payments guaranteed for life, usually index-linked to the Retail Price Index. The Department told us that it strongly endorses the use of structured settlements and in its guidance, it prescribed that structured settlements should always be considered when the cost is likely to exceed £250,000 but could also be considered for lower awards. However, structured settlements are voluntary and to date, there have been only two such settlements.

NIAO Comments and Recommendations

2.51 We welcome the new arrangements for the central funding of clinical negligence compensation and acknowledge that these should help to eliminate the disadvantages, in terms of equity, perceived by some HPSS bodies.

2.52 We are concerned that the current funding arrangements do not serve to encourage HPSS bodies to minimise exposure to risk. We are aware of the revised arrangements that have been introduced in Scotland and Wales and the longer-standing arrangements through CNST in England. We are conscious that these may not be wholly appropriate for Northern Ireland. However, we believe that the Department and HPSS bodies should be more active in attempting to reduce the projected costs of future negligence.

2.53 As a separate issue, we are of the view that there could be greater use of structured settlements, which are currently voluntary. The Department said that it endorsed the use of structured settlements but we consider that it should be more proactive in promoting these in appropriate cases, although we recognise that, ultimately, the take up of such settlements is a matter for the plaintiffs to determine, with their advisers.

2.54 It is clear to us that the quality of financial estimating of future negligence and the sharing of information and experience have been the real weaknesses in the operation of the CNCF in the first two years of its operation, although we accept the Department's contention that new accounting arrangements have led to a greater emphasis on obtaining accurate forecasts. There has been concern within the Department that the feedback of information on clinical negligence cases has been poor and that the absence of sharing of information has brought with it the risk of similar incidents unnecessarily occurring at different hospitals.

2.55 We note the Department's view that the introduction of the central funds has done much to provide stability in the management of the financial consequences of clinical negligence cases for individual Trusts and Boards. Notwithstanding this, there remains scope for improving the in-year forecasts of cash requirements and the sharing of information and experience. Mechanisms now need to be introduced by, and monitored by, the Department whereby the lessons to be learnt from the wide range of adverse clinical incidents that occur across Northern Ireland can be shared with other clinicians and administrators elsewhere in the HPSS. Procedures across the Service can then be adjusted and good practice protocols introduced, where these are considered necessary or desirable. There is also an underlying need to be sure that the staff employed to process clinical negligence cases have the skills and understanding necessary to be able to identify such lessons.

2.56 We note that the Department advised Boards and Trusts in March 2001 that it retained the right to review the new arrangements if information was not provided in a timely and reasonably accurate way, and it warned of possible delays in reimbursement of compensation and costs if timetables were not met. We are concerned that when qualitative information on procedures and remedies was required to be provided, between April 1998 and March 2001, there was no evidence that any review of the limited information that was provided, had taken place.

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Part 3: Claims Experience

Survey of HPSS

3.1 In our survey, we provided a list of factors and asked HPSS bodies to indicate which of those factors had been present in the cases which they had settled. We also asked each body to list the three main reasons why plaintiffs had been unsuccessful in obtaining a financial settlement. The responses from fourteen HPSS bodies are summarised in Figure 8.

Figure 8

Factors in the Settlement and Successful Defence of Cases

Factors influencing Settlements:	Number of HPSS Bodies
Mistakes by doctor	11
Mistakes by other staff	10
Inadequate procedures/protocols	10
Communication problems	9
Absent/inadequate medical records	6
Poor clinical practice	6
Evidence of defence witnesses	5
Latent organisational failure	4
Inadequate equipment	2
Factors influencing Successful Defence:	
Good medical records	9
Good defence witnesses	6
Claims handling procedures	4
Good evidence	4
Good procedures and protocols	3
Other factors *	11

* - see paragraph 3.4

Source: NIAO Survey and Analysis

3.2 The current thinking on medical error and risk reduction has emphasised the impact of systems failures rather than medical error being due to unpredictable one-off events. Our survey results suggest that in the HPSS, mistakes and communication failures have been viewed as more significant causes, in settling cases.

3.3 In the successful defence of claims, the HPSS is highly dependent on the strengths or weaknesses of the relevant medical records, protocols, clinical practice and the evidence (and availability) of defence witnesses. Indeed, a single weakness in the defence of a claim may be sufficiently serious to impel the HPSS to eventually seek a financial settlement.

3.4 The classification of other factors in the successful defence of claims can be sub-divided into two main categories. The first category covers claims which were inherently weak. The second category covers claims which failed largely because of the inability of the plaintiff to progress the case, rather than negligence being disproved. Examples of both categories can be illustrated by some of the actual responses to the survey:

- *"No case to answer in the first place."*
- *"Allegation could not be sustained following the discovery of medical records."*
- *"Lack of strong evidence by the plaintiff."*
- *"Statute barred."*
- *"Plaintiff may not be eligible for legal aid."*
- *"Lack of progress by plaintiff's solicitors."*
- *"Patient dies."*

NIAO Comments

3.5 The survey information quoted in paragraphs 3.1 to 3.4 is a summary of the nature of claims which are made against the HPSS and examples of actual cases are given later in this Part. There are two points which need to be made in relation to unsuccessful claims. Firstly, many claims made do not result in the payment of any compensation because, although many of them were related to events which had an adverse impact upon patients and their families, in terms of being able to prove negligence, they were weak

claims. Clearly, compensation should not be paid where a patient has failed to prove a breach of the duty of care or when the breach has not caused injury or damage (see paragraph 1.1). However, in other circumstances, patients and their families should be able to seek redress. While it is the patient's right to pursue a claim by litigation, to opt for a route which ultimately involves litigation is not necessarily in the best interests of patients or the health service, where at present, there is no process for the early screening of all claims to refute those which are clearly not negligent. The question of whether to opt for litigation or to take another path to resolve disputes over medical treatment, is followed up in Part 4, where the problems associated with the current arrangements are discussed and an alternative protocol proposed (see particularly, paragraphs 4.1 to 4.7).

3.6 In some cases, claims may fail, despite having merit. For example, a claimant may not be eligible for, or may not be able to obtain, legal aid; a claimant may select legal representatives with no expertise in the handling of clinical negligence claims; or claimants may die, which clearly will have an immediate impact on any compensation payable.

Time taken to Process Claims

3.7 As no independent data was available on how long it took to process claims, NIAO incorporated this line of enquiry into its survey. Unsurprisingly, there was a general perception among HPSS staff interviewed that resolution of cases was a lengthy process. In response to our enquiries, a range of factors was quoted as presenting obstacles to securing early resolution of actions for clinical negligence:

- the process is plaintiff driven and beyond the HPSS's control;
- legal aid provides no financial deterrent from running cases;
- there is no requirement to share expert medical evidence;
- little contact takes place between the parties during the case;
- any contact usually occurs close to the Court hearing date;
- Court hearings are often postponed which inconveniences HPSS staff and plaintiffs;
- there is an unwillingness on the part of the HPSS to admit to mistakes; and
- plaintiffs are embittered by long running cases.

3.8 NIAO asked HPSS bodies, where there had been compensation payments, to provide details of all cases settled in the three years to 2000-01. For 1998-99, 110 (98 per cent) of the 112 cases settled (see Figure 7), for 1999-2000, 101 (98 per cent) of the 103 cases and all of the 111 cases settled in 2000-01 were reviewed. In 1998-99, the average time taken to settle claims from the date of the original incident was over 6 1/2 years. Once the HPSS was initially contacted by the plaintiff's solicitors, it took an average of over 4 years to settle the claim. The longest running claim (which was in obstetrics and gynaecology) took 12 years to settle. The pattern for settlements in 1999-2000 was virtually identical to that for 1998-99. The longest time taken (30 years) was for a general surgical procedure conducted in 1970 (Settlement £100,000; Costs £73,527). Another claim took almost 12 years from the date of initial contact between the plaintiff's solicitors and the HPSS (Settlement £600; Costs £1,734). In 2000-01, the average time from the date of the incident to the claim was 2 1/3 years, and from the claim to the settlement, 4 3/4 years, ie an average of over 7 years in total, with the largest time taken being 40 years for a birth-related case and 16 years for a general surgery case.

3.9 We recognise that there can be legitimate reasons for the length of time taken to process cases from the date of the original incident. The date at which the claimant realises that the problem emanates from a clinical intervention may be some time after the event and the Department suggested that, in some cases, it may be in the interests of the claimant to delay matters until such time as the consequences have fully materialised. In England, the processing of claims under the main clinical negligence scheme has taken longer, though the figures are not directly comparable as they relate to a specific value of claim made before a specific date. NAO has reported that, for claims closed in 1999-2000 with a settlement value of over £10,000, where the incident occurred before April 1995, it took an average of 5 1/2 years to settle claims from the date of claim and over 7 years from the date of the incident. The NAO average excludes cases of cerebral palsy and brain damage, where claims took an average of 12.1 and 10.3 years respectively from the incident to the payment of damages. Such cases have been included in the Northern Ireland averages. The Auditor General for Wales reported that, in their sample, it took 2 1/2 years to settle from the date of the claim and 4 1/3 years from the date of the incident.

3.10 Figure 9 shows the length of time taken between claims and settlements in those cases settled in 1998-99 and 1999-2000. This data was also analysed for each of the 20 cases examined by NIAO and the spread of results is shown in Figure 10 at paragraph 3.21.

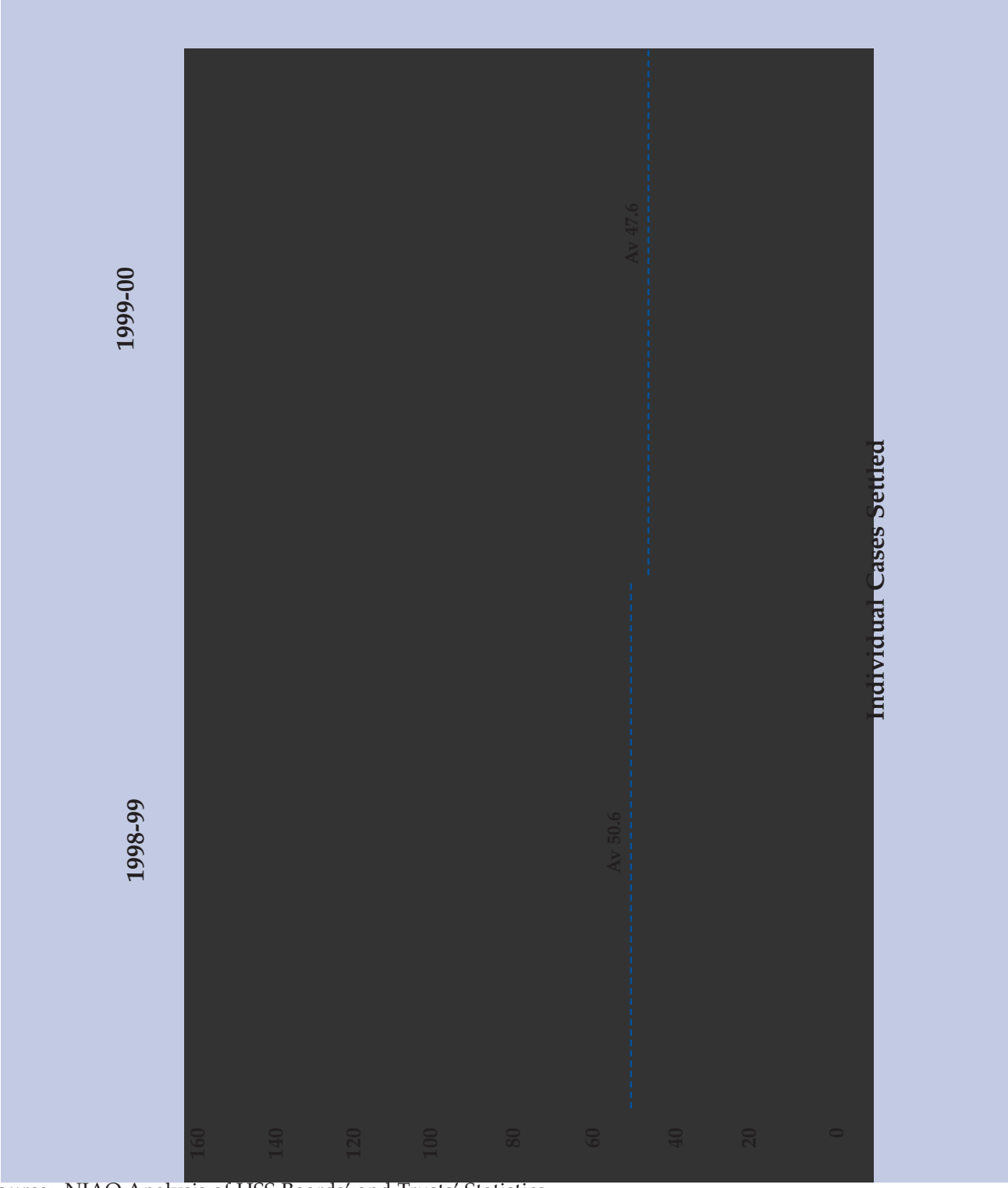
3.11 We were advised that cases involving minors took longer to resolve and that this might account for the length of the overall average time taken to settle cases. The settlement information for the last three years was further examined and the settlements relating to the specialties of obstetrics, gynaecology and paediatrics were identified (32 in 1998-99, 25 in 1999-2000 and 35 in 2000-01). The average time taken to process these cases was longer, but their overall effect on the average length of time taken to settle – 5 months longer in 1998-99, 2 months longer in 1999-2000 and 6 months longer in 2000-01 - was not significant.

3.12 The time taken to dispose of clinical negligence cases was also considered within the context of the time taken to process other civil actions in Northern Ireland. The interim report of a review into the Civil Justice System in Northern Ireland[19] noted that in 1996, for the Queen's Bench Division of the High Court, there was an interval of 21 months between the date on which the cause of an action arose and the issue of a writ and there was a further 27 months between the issue of the writ to the start of the trial or the disposal of the case. The review also referred to survey work by the Law Society of Northern Ireland on people's experiences of the legal process. When it came to satisfaction with the time taken to resolve their problem, 51 per cent took the view that it was too lengthy.

19 "Review of the Civil Justice System in Northern Ireland: Interim Report" Civil Justice Reform Group, Belfast, April 1999.

Figure 9

Cases settled in 1998-99 and 1999-2000: Length of Time Taken from Claim to Settlement



Source: NIAO Analysis of HSS Boards' and Trusts' Statistics

3.13 NIAO identified the settlements which would have been heard in the High Court, (that is, those with a reserve of £15,000 or more) and found that in 1998-99, there had been an average interval of 38 months between the original incident and the issue of a letter of claim and a further 62 months for the claim to be resolved. The claims disposed of in 1999-2000 were processed more quickly (37 months and a further 54 months respectively) but this was still approximately twice the average time taken for other cases heard in the High Court. The position had worsened again in 2000-01, with the times being 36 months and 67 months respectively.

3.14 The Northern Ireland Court Service was unable to comment on cases which did reach Court. However, it observed that the relatively small number of cases that do reach Court are usually more complex and therefore, by their very nature, take longer to process.

NIAO Comments and Recommendations

3.15 The Department has stressed that clinical negligence is a very particular form of litigation, with a unique legal process. We recognise that delays in the processing of compensation claims are not always the fault of the relevant HPSS bodies. They are also usually beyond the immediate control of the Department. However, the time taken to process claims for clinical negligence should be capable of being shortened. An average time of 4 or 5 years to settle a claim and claims which run for over 10 years point to inefficiencies in the system and are clearly matters of concern.

3.16 Redress for patients who believe that they have been the victims of clinical negligence cases takes almost twice as long to resolve as other actions brought before the same Courts. It is significant that just over half of litigants in civil actions generally are not satisfied with the length of time taken to resolve their problem. Although clinical negligence litigants were not surveyed, there is no reason to believe that they would be any less dissatisfied with the length of time taken to resolve cases. To address these concerns, the Civil Justice Reform Group has made recommendations which will encourage a co-operative approach among interested parties to reduce unnecessary delays in the system. We urge the Department to take whatever measures are possible, within its means and recognising the legal rights of all concerned, to promote the earlier resolution of claims.

Case Studies

3.17 To illustrate some of the factors influencing the outcome of cases, we examined 20 cases (described as cases A to T) which were settled in 1998-99 with a payment of compensation. This was not a statistical sample. These cases covered a number of specialties (taking into account the specialties of the claims outstanding) in the four Boards and in five Trusts and resulted in a wide range of high, medium and low cost settlements, including some cases which were settled in less than four years. In addition, the selection was not biased towards either clinical or non-clinical cases although, in the event, a large proportion of the cases reviewed resulted from non-clinical factors. In all cases, the terms of the settlement included a confidentiality clause with no admission of liability. The total outlay was almost £5.7 million, of which approximately £4.2 million (74 per cent) related to compensation and £1.5 million (26 per cent) to costs. The combined costs of the cases selected are understated as in 18 cases, the costs of the HPSS's solicitors were not readily available and are not included. The costs exceeded the awards in 4 cases with a further 7 having costs accounting for over 50 per cent of the value of the awards. The majority of these were cases settled for under £10,000 but the conscious selection of a number of lower value settlements in our examination, would have contributed to this result.

3.18 It came to our attention, during our review of cases, that a number of cases, where settlements were made out of Court, had confidentiality clauses inserted within the terms of the settlements. We understand these to have been mainly at the insistence of the defendants to the claims. We consider the use of such clauses questionable. There may occasionally be exceptional circumstances, where a Court might impose some restriction to protect a plaintiff's identity, for example, if that plaintiff is a minor, but in the majority of cases, confidentiality seems inappropriate, when payments of public money are involved. We therefore welcome the Department's assurance that it is committed to taking immediate action to ensure that confidentiality clauses are not included in clinical negligence settlements and we note its recent acknowledgement to the Public Accounts Committee about the inappropriateness of confidentiality clauses.

3.19 Of the twenty cases, the initial outlay was over £1 million for three of those cases [**A, B, C**]. In one case [**B**], the costs of £658,000

exceeded the compensation which was finally agreed, although the HPSS recovered £360,000 towards the settlement and associated costs from the insurance company involved. In a further four cases, the total cost of each was over £100,000 [**D, E, F, G**]. The selection also included six cases where the total cost of each was less than £10,000 [**H, I, J, K, L, M**]. A synopsis of the relevant points of some cases is given in the following paragraphs. The remaining cases are noted in Appendix 1.

3.20 In examining the case details, we were looking to ascertain:

- how cases are handled;
- the factors which lead to the HPSS seeking a settlement;
- why there are delays in resolving cases; and
- whether the cases corroborated the survey and interviews.

3.21 Most settlements are made after the plaintiff has taken the claim to the Courts. In 3 of the 20 case studies, resolution was achieved, without recourse to court proceedings, in 21, 11 and 56 months respectively. One of these, Case J, is quoted below. The other 17 cases examined took an average of 58 months. Figure 10 shows the length of time following an incident (a) before claims were made and (b) before a settlement was reached.

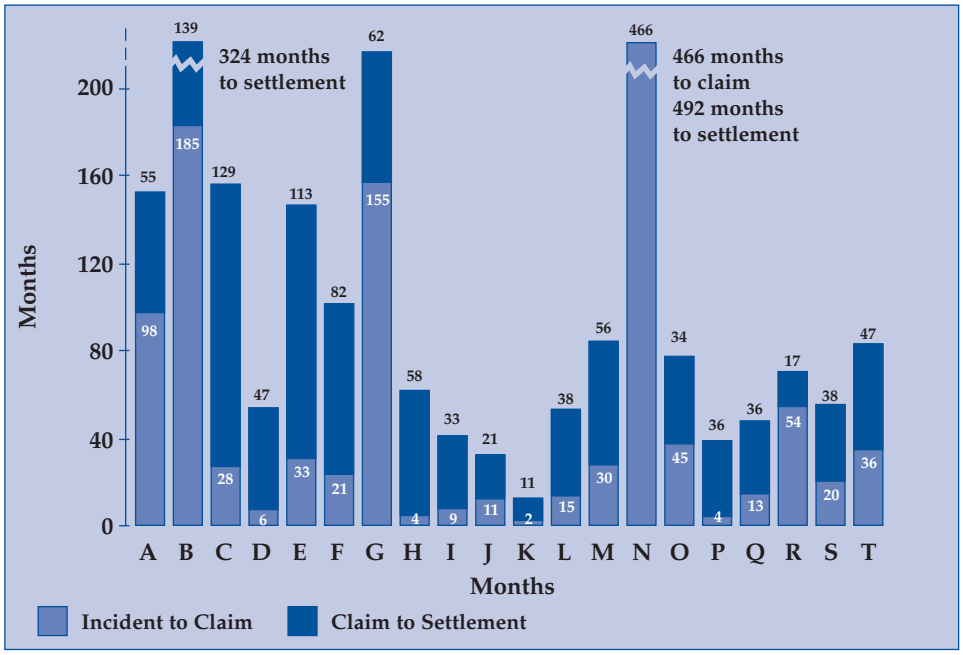
Case J (also see paragraph 3.47)

The death of a patient, three days after attending A&E, had already been the subject of a coroner's inquest. After being informed by its solicitors that a relative of the plaintiff would issue proceedings, the HPSS body authorised its solicitors to seek an early settlement.

(Settlement £4,000; Costs £2,815)

Figure 10

Selection of Cases Settled in 1998-99. Time taken from Incident : (a) to Claim and (b) to Settlement



Source: NIAO Analysis of HSS Boards' and Trusts' Case Statistics

Factors in Settling

3.22 In 19 (95 per cent) of the settlements selected, the HPSS agreed to settle out of Court. From examination of the case files, NIAO noted that the Board or Trust had documented reasons why they had decided to settle the claim. In the twentieth case which did go to Court, (and which was ultimately settled out of Court) the HPSS had identified weaknesses in its defence of the case, but on the basis of expert advice, thought they were insufficient to prejudice a successful defence. The weaknesses which the HPSS identified in all these cases and the frequency with which they occurred are listed at Appendix 2. They have been sub-divided into clinical, administrative and personnel related weaknesses.

3.23 The clinical factors occurred in 19 cases. These factors provide corroboration for the responses in the survey which attributed settlements to mistakes by staff. As well as mistakes or missed and mis-diagnosis, sub-optimal procedures were the most persistent clinical factors in the case studies. Examples of clinical factors are illustrated in the boxed sections below.

Case N

The plaintiff had an appendectomy in 1958. He attended his general practitioner complaining of abdominal pain and was referred to hospital. The hospital visits included outpatient attendances in 1983 and 1989, (also an example of a condition not being corrected on a subsequent occasion), but an error in the surgical procedure was not discovered until a medical examination in October 1996.

(Settlement £35,000; Costs £10,794 - HPSS recovered £13,660 towards the settlement and associated costs, from the insurance company involved.)

Case O

The plaintiff sued over the intravenous administration of a drug injection which he alleged contained an antibiotic drug to which he was allergic and from which he subsequently developed an adverse reaction. The HPSS was advised by an independent expert that the drug should have been administered orally, because intravenous administration brings with it substantial inherent problems.

(Settlement £7,500; Costs £10,665)

3.24 The non-clinical factors occurred in 12 (60 per cent) of the case studies. There are eleven different factors but most of these can be grouped into three categories. An example of each is quoted below:

- **Records:** gaps in records, records lost or destroyed, lack of documentation;
- **Personnel:** staff could not be traced or were unavailable to attend court, or had died, former staff refusing to testify; and
- **Testimony:** conflicting and/or unreliable testimony.

Case C (also see paragraph 3.47)

This was a birth-related case, in which the plaintiff contracted a cerebral palsy in 1985. In January 1993, the solicitors acting for the HPSS advised that a successful defence of this case was prejudiced by:

- loss of the foetal heart monitoring records;
- incomplete ante-natal records;
- a lack of recollection on the part of the midwifery staff; and
- the non-availability of any hard information as to why a period of almost three hours prior to the birth of the child remained undocumented.

(Settlement £1.12 million; Costs £135,723)

Case B

In this case, the plaintiff, as a young child, had suffered massive brain damage after an operation in 1971, leaving her physically and mentally handicapped. The case went to Court in 1997. Amongst the medical staff involved, at least one had died, another was not called because of health problems and a third who was living in the United States of America had to be persuaded to attend Court. Also, the HPSS did not have any witnesses who were able to give evidence to cover a particular period of one hour in 1971.

(Settlement £500,000; Costs £657,780 - HPSS recovered £360,000 towards settlement and associated costs, from insurance company involved.)

Case H (also see paragraph 3.45)

An elderly person sustained a hip fracture after falling off a chair while being assisted by an Occupational Therapist. After legal action was started, the responsible medical staff advised that they did not foresee any problems with liability. However, the advice from the nursing staff was that it would not be possible to prove that the required level of close supervision had been provided.

(Settlement £6,250; Costs £2,680)

Medical Records

3.25 Although clinical practice of a high standard is of the utmost importance, the ability of the HPSS to defend a claim of negligence is highly dependent on a high standard of medical record keeping. In litigation, good clinical practice at the time of the incident needs to be reflected in the evidence provided by the notes. Where there is inconsistency or contradiction between the medical records and the evidence of staff, primacy is given to the notes made at the time.

3.26 NIAO noted for each case study, the number of factors which led to a settlement (see Figure 11). It is significant that in most of the case studies, settlement was influenced by two or more factors connected to the details of the case. For example, in Case N, in addition to the clinical factors already referred to in paragraph 3.24, the HPSS was also compromised in the defence of the claim due to the destruction of all charts from the plaintiff's outpatient attendances in 1983 and 1989.

Figure 11

Number of Factors leading to Settlement of Cases

Number of Factors	Number of Cases
1	7
2	6
3	2
4	2
5	3

Source: NIAO Analysis of Case Files

3.27 The important issue of medical records has frequently been examined in the past. In 1993, the Department set up the Regional Group on Medico-Legal Litigation (with representatives from the Department, the Boards and CSA). At its inaugural meeting, the CSA's Director of Legal Services referred to the problems of poor quality record keeping, which were said to handicap Trusts and Boards in mounting a defence. Although guidance had been issued by the Department as far back as 1983, the condition of storage and the lack of indexing often meant that records needed could not be found or were not in a fit state to use.

3.28 In 1995, a subsidiary group of the Medical Protection Society was commissioned by the HPSS to carry out an audit of medical records and case notes. It reported that the medical records examined "were generally substandard. Many of the folders were both bulky and damaged. It was difficult to ensure correct identification. A lack of consistency in filing and format made it difficult to access relevant clinical information. These deficiencies can not only prejudice the successful defence of any claim but may also jeopardise appropriate clinical management"[20].

3.29 The Department recognises the importance of maintaining adequate medical records. It told us that case notes audits against agreed standards of good practice are a common feature of clinical audits and a number of initiatives have been taken to improve medical charts and coding. It believes there has been a significant improvement in recent years in the quality of records kept.

20 Audit of Medical Records and Case Notes, Medical Claims Management Services Ltd, March 1995

NIAO Comments and Recommendations

3.30 We recognise that settlements may result from a single weakness in the defence of a case. However, we are concerned that there were multiple weaknesses in the majority of the cases examined.

3.31 The clinical factors identified above provide evidence of what can go, and what has gone, wrong, sometimes with tragic consequences. The case reviews, alone, do not provide sufficient evidence for any party to come to an overall conclusion as to the standards of medical practice. However, many of the clinical factors are avoidable.

3.32 The non-clinical factors which have emerged from the case studies point to serious failings in some areas of health service administration. The Department has stressed that staff have done their best with existing resources and we clearly recognise that, if unlimited resources were available to the HPSS, significant improvements could be made. Similarly, we acknowledge that all records cannot be kept indefinitely and that staff in the HPSS, particularly junior medical staff, often leave and work outside Northern Ireland. Nevertheless, most of the non-clinical factors are also avoidable and many improvements could be made without a major resource implication.

3.33 It is disturbing that, in 30 per cent of the selection of cases reviewed, there were gaps in the medical records. NIAO's sample is not a statistical one, and it does not necessarily follow that there are gaps in 30 per cent of all medical records. Nevertheless, the quality of records is particularly worrying, considering that, as indicated in paragraphs 3.27 and 3.28, the state of medical records and the potential impact on any subsequent review of the records (especially where a claim for negligence is pending) was recognised as far back as 1983. We recognise that there are constant pressures on the Department and HPSS bodies to reduce administration costs, but there are some non-clinical support areas which are of such fundamental importance to the clinical efficiency of the health service that sufficient resources must be applied, if the service is to operate efficiently and effectively.

3.34 The Department must assure itself that the quality of medical records being kept in the Northern Ireland Health and Personal Social Services is of a standard which does not compromise the present and future health and well-being of patients and we welcome the assurances that it has given us, regarding its ongoing efforts at improving record-keeping. However, we recommend that the Department commissions an early review to establish the extent of the problems identified by this report, particularly with regard to records kept. It should ensure that any recommendations made by the review are implemented without delay, taking into account any recommendations made, and initiatives taken in Great Britain, such as those emanating from the Commission for Health Improvement, the National Institute for Clinical Excellence and the National Patient Safety Agency (see paragraphs 5.11 and 5.12).

Delays in Settlement of Cases

3.35 Within the case studies, we identified 13 different factors which delayed a settlement. These are described in paragraphs 3.36 to 3.50. Some delays were attributable to the plaintiff's side or to the wider public sector. On the face of it, we believe that 17 (85 per cent) of the cases could have been resolved earlier. We found clear evidence that the HPSS had recognised 14 (70 per cent) cases as being either difficult or indefensible. For 12 (60 per cent) of the cases, out of Court settlements were negotiated after they were listed for hearing and of the remaining cases, one had been preceded by an inquest and another was settled after the HPSS was put on notice that the case would be listed.

Disclosure of Medical Records

3.36 Most claims are initiated by a letter of claim from the plaintiff's solicitor, which is usually accompanied by a standard request for all medical records relating to the plaintiff to be made available within six weeks under the Administration of Justice Act (1970). In 8 (40 per cent) of the cases, at least 6 months elapsed before all the records requested were provided. The longest delay noted was one of 41 months - **Case E.** Without medical records, the patient cannot obtain the services of a medical expert and will be unable to obtain legal aid, even if eligible.

HPSS recognised liability long before settlement

3.37 In 6 cases (30 per cent) there was an early recognition of liability. However, in most of those cases, the HPSS waited for the plaintiff to exhaust the legal process. An example of this is **Case L.**

Case L

The plaintiff had suffered a fracture, which had not been diagnosed in two attendances at hospital. This case took 38 months to resolve. After 31 months, the HPSS wrote to the consultant surgeon at the hospital where the alleged negligence occurred, arguing for settlement of the case. They justified this course of action by referring to a report prepared by the surgeon 30 months earlier, although there had been disagreement, between the clinicians involved, as to whether negligence had taken place. However, settlement was not sought until the plaintiff's solicitors tried to set a date for a Court hearing.

(Settlement £3,000; Costs £2,185)

Case F is a case where there was a relatively early acceptance of liability but there was a substantial further delay to settlement because of other matters.

Case F (also see paragraph 3.49)

The plaintiff was a minor who was left significantly handicapped following a surgical procedure. This case took 82 months to resolve. 33 months into the claim, the HPSS recognised, on the basis of their expert's report, that liability could not be denied. Liability was formally admitted to the plaintiff 3 months later but another 46 months passed before the case was settled. In this case the main delay was caused by negotiations over the sums to be paid.

(Settlement £575,000; Costs £104,695)

HPSS delayed hiring an independent medical expert

3.38 In four cases, NIAO considered that the delay caused by hiring an independent medical expert was a factor in delaying settlement. Early referral of the case to an independent expert would be expected to have facilitated early resolution. Instead, there was a tendency for the HPSS to delay seeking independent medical advice until the legal process had moved to an advanced stage.

Case D

The plaintiff was left unable to work in his trade, after a medical accident whilst having surgery carried out on his wrist. The case lasted 47 months. After 9 months, the HPSS recognised that the claim would be difficult to defend and Junior Counsel advised likewise over 2 years later. The case was delayed for a number of reasons, including the time taken for disclosure of the medical records, and the plaintiff's own expert only reporting 27 months after the initial claim. The HPSS sought independent medical advice, to help in assessing quantum, because of the issue of special damages, some 43 months into the claim, after it was listed for hearing. Although this delay was considered to be of benefit to the defendants, it did result, not only in additional legal costs, but also in more compensation as the sums agreed reflected the impact of the "Wells" case, wherein the additional costs of long-term care were taken into account (see paragraph 2.18).

(Settlement £70,000; Costs £41,679)

Delay in expert witness advising the HPSS

3.39 It is crucial for appropriate expert witnesses to be engaged and to report to the HPSS defendants within a reasonable time.

Case A

In this case, liability focused on whether the risks involved had been properly explained to the plaintiff. It was also complicated by the fact that, since the original incident, clinical thinking as to the extent of that risk had evolved. During the case, the HPSS's independent expert submitted a number of informal opinions, but took 30 months to formally report.

(Settlement £1.2 million; Costs £263,834)

Lack of early contact between the parties

3.40 There is currently no mechanism to compel early contact. Contact is more likely to occur in negotiations after the case has been listed for hearing. It is not uncommon for cases to be settled close to, or even on the day of the hearing. HPSS staff advised us that, although settlements at the "door of the Court" were generally preferable to a hearing in Court, the listing of cases for hearing meant health service staff having to make themselves available for

possible appearances in Court. Even a simple case would require the availability of at least three clinicians - the doctor involved in the original incident, the HPSS's expert witness and the plaintiff's expert witness - and this increases with more complex cases, which involve more than one specialty or sub-specialty. **Case P,** which was a day case procedure, involved three different doctors in the treatment of the patient. One had been involved in the pre-operative assessment, another had performed the operation and a third had seen the patient after the operation. **Cases P** and **E** are useful illustrations of how an adversarial process is not always the best way to resolve issues and it imposes additional costs.

Case P

The plaintiff had undergone a surgical procedure but subsequently suffered scarring and other abnormalities. There were concerns that the plaintiff might have been trying to exaggerate her ongoing symptoms. However, in negotiations, the HPSS's solicitors viewed the scarring and concluded that it was so substantial that the case would have been virtually indefensible in Court with regard to liability.

(Settlement £10,000; Costs £5,949)

Case E

This was a birth-related case in which the plaintiff suffered brain damage. The issues revolved around the standards of obstetric care and of immediate post-natal care. Some 12 years later, the case was settled out of Court.

(Settlement £500,000; Costs £155,503)

HPSS staff unavailable to attend Court

3.41 Judges may allow hearings to be postponed at the request of either party.

Case I

In this case, which took 38 months to resolve, settlement took place after the case was adjourned twice due to the unavailability of staff appearing on behalf of the HPSS. The costs awarded included £2,250 charged by the plaintiff's expert witness in connection with the cancelled court hearings.

(Settlement £3,500; Costs £5,739)

Securing the co-operation of professional staff

3.42 Securing the involvement of staff connected with the original incident is sometimes difficult. Many procedures are performed by various grades of junior doctors, most of whom are on short-term contracts. Staff movement is unavoidable. There are instances where former staff could not be traced (for example, **Cases J, P, Q and R**) or were traced only after extensive enquiries (**Cases S, P, E, B, C and G**). Although many former staff did co-operate with the HPSS, there is no compulsion on them to do so and indeed, a key witness in **Case P** (see paragraph 3.40) refused to assist the HPSS. However, there is scope for current staff to slow the resolution of cases as demonstrated by the following case.

Case Q

This case, which arose out of an unsuccessful varicose vein operation, lasted 36 months. The consultant involved took 23 months to prepare an internal report which denied liability. The case had been listed for hearing, but the plaintiff's solicitors agreed not to press for listing. The internal delay also delayed the hiring of an independent expert to advise the HPSS. Finally, when the case was due to be heard in the High Court, the consultant, who had retired, was abroad on holiday. However, prior to the booking of the holiday, the HPSS's solicitors had advised the Trust as to the date of the Court hearing with a view to getting confirmation as to whether the retired consultant was available to attend the hearing.

(Settlement £8,750; Costs £6,690)

Delay in plaintiff receiving a report from an independent expert

3.43 In six (30 per cent) of the cases reviewed, it took at least 10 months after disclosure of the medical records for the plaintiff to obtain a report from an independent medical expert. Under current procedures, independent experts for the plaintiff are key to the progressing of litigation.

Plaintiff experienced delay in obtaining legal aid for claim

3.44 In three (15 per cent) of the cases, the HPSS's papers indicated difficulties and delays which the plaintiff had encountered in securing legal aid. In two of the cases, **H** and **M,** the circumstances of which are described below, the delays were significant and in the third, **Q,** a hearing had to be adjourned.

3.45 It has been recognised that, within the civil justice system in Northern Ireland, both parties, but predominantly plaintiffs, face long delays in the processing of applications for legal aid. The interim report of the Review of the Civil Justice System (see paragraph 3.12) referred to the Legal Aid Annual Report for 1996-97. For that year, 74 per cent of ordinary (non-matrimonial) civil legal aid certificates were processed from registration to issue in under 39 weeks. For England and Wales, 81 per cent of civil legal aid applications were processed in 2 weeks.

Case H (also see paragraph 3.24)

The Legal Aid Department delayed giving authority for the plaintiff to instruct an independent expert. Once the independent expert did report, the claim was resolved within 5 months. However, the claim ran for 58 months and there was a gap of 38 months between the disclosure of records and the independent expert reporting.

(Settlement £6,250; Costs £2,680)

Case M

The plaintiff was a minor who had a dislocated finger which was not diagnosed on a first attendance at A&E. In December 1995, the plaintiff's solicitors were asked to furnish their medical evidence on a "without prejudice" basis. In May 1998, the plaintiff received a full Legal Aid Certificate to prosecute the action. Settlement was agreed soon after and was finalised in October 1998, which was 56 months after the plaintiff had submitted the letter of claim.

(Settlement £1,250; Costs £1,304)

Representation of plaintiff

3.46 We were advised, both through survey and interview, that the outcome of cases is influenced by whom the plaintiff selects to be represented. A legal-aided plaintiff can be frustrated in processing the case by unsuitable legal representation and few are re-directed to more expert solicitors.

3.47 These factors may decide not only whether a claim is pursued, but also the level of the settlement negotiated. In two of the cases sampled (**Cases C** and **B**), the plaintiffs changed their solicitors with beneficial results. In another two cases (**Cases J** and **P**), there was an indication that lack of awareness on the part of the solicitors representing the plaintiff had resulted in lower settlements and lower costs. In a fifth case (**Case E**), the Board told us that there had been a considerable difference in the quality of the expert witnesses, with the HPSS being advised by the world's leading authority on a particular aspect of obstetrics.

Case C (also see paragraph 3.24)

In a birth-related case which lasted nearly 11 years, the HPSS asked the plaintiff, who had suffered a serious cerebral palsy, to supply more details on the loss and damage allegedly suffered, as in the Statement of Claim. This is a common response by defendants to a Statement of Claim. Usually, these details are supplied within a few months. The plaintiff took almost 7 years to supply these details and only after he changed the solicitors representing him (7 months after the HPSS indicated that they would seek to have the case struck out). In fact the HPSS was advised by the plaintiff's new solicitors that the papers which they had inherited were "an absolute mess". The plaintiff secured a substantial settlement 10 months after these details were supplied.

(Settlement £1.12 million; Costs £135,723)

Case J (also see paragraph 3.21)

Following negotiation between the respective solicitors, the plaintiff agreed to accept a lower settlement on the basis of contributory negligence. The HPSS solicitors acknowledged that the contributory negligence argument may, however, not have been accepted to the same extent in a Court hearing.

(Settlement £4,000; Costs £2,815)

Plaintiffs change or widen the scope of damages claimed

3.48 The open ended nature of the legal process allows the plaintiff to amend the statement of claim. This often means that the plaintiff widens the scope of damages claimed with a consequential increase in the damages claimed. This occurred in six of the case studies, four of which were either birth-related or severe injury cases.

Referral of Case to Experts

3.49 NIAO noted that in more complex cases, those where the plaintiff had suffered serious injury and would be requiring longer term care, there was a range of experts who had evaluated the plaintiff's condition.

Case F (also see paragraph 3.37)

NIAO found that 19 separate expert reports had been compiled on behalf of the plaintiff. In this case, these are listed at Appendix 3 in the chronological order in which they were released. Ten of these reports were completed after liability was admitted. The majority of these were financial in nature and related to quantum, not causation. In response, the HPSS asked for a further six expert reports, although only three were ever obtained.

(Settlement £575,000; Costs £104,695)

Use of Forensic Accountants

3.50 In four cases, it was clear that the damages claimed by the plaintiff were based on the work of forensic accountants, as they resulted from the quantification of factors such as the future costs of care and loss of earnings. In all four cases, the final settlement agreed was substantially less than what the plaintiff was seeking. In monetary terms, it ran from £425,000 to £1,200,000 less. In two of those cases, the HPSS employed its own forensic accountants. In **Case A** (see paragraph 3.39), they disputed a claim of £2,400,000 arguing that it should be £580,000 and in **Case B** (see paragraph 3.24), they evaluated the overall loss to be £636,000 as opposed to £1,383,000 as quoted by the plaintiff's advisers.

NIAO Comments and Recommendations

3.51 The processes for handling medical negligence claims have clearly not been satisfactory in minimising delay. It is important that, where the standard of care was clearly reasonable, the Health Service should defend its position robustly. It is also important that it should, at all times, exercise good judgement, even when the advice is that the case is difficult to defend. It would appear that, in many of the case studies, the HPSS has refrained from admitting liability where the case has been difficult to defend. We are concerned that around one half of all existing claims were made over three years ago. Although some claims will take longer to resolve than others, all claims, irrespective of their individual

merits, should be addressed and resolved as soon as possible. We consider that the case studies provide some indication of problems associated with clinical negligence litigation processes which need to be addressed.

3.52 Notwithstanding the point made about individual cases in paragraphs 3.35 to 3.50, there is evidence that more cases have been concluded in recent years. For example, in 1994-95, some 122 cases were closed or settled (see Figure 7). In 2000-01, this figure had increased to 479. We welcome this trend, though over the same period, the number of claims outstanding has risen from 1,899 to 3,532 (see Figure 2).

3.53 The obstacles to early resolution quoted in paragraph 3.7 are valid. However, we would also point out:

- that the process is not solely plaintiff driven. For example, there are the delays in the HPSS releasing records and in certification from the legal aid system;
- the fact that there is a lack of deterrence to legal aided plaintiffs running cases to Court, should not obscure the reality that the general unavailability of legal aid prevents many more actions for negligence;
- for every case settled in Court, another eight are settled out of Court;
- that Court dates are also postponed at the behest of the HPSS;
- that the case studies also provide evidence that some clinicians do take a dispassionate view of alleged negligence within their area of responsibility and advise those handling the claim accordingly; and
- that long running cases have an adverse effect upon defendants as well as on plaintiffs. It is not necessarily the length of time which alienates the parties, but the perception that the process does not discourage the other party from the use of delaying tactics.

3.54 Some of the factors identified might not be capable of remedy. Some cases will by nature or context (or both), be particularly sensitive and it may take longer for experts to investigate and advise. Also, either party must be allowed the right to seek adjournment of hearings for legitimate reasons. The Department considered that provisions for enhanced monitoring of the

movements and conduct of doctors within and across international boundaries would be of some benefit to health service bodies, from a clinical negligence perspective, but equally, it had concerns about the human rights of individuals in such a situation. In addition, NIAO notes that, if oral testimony differs from the medical or nursing records, primacy will be given to the written record at the time in question.

3.55 We consider that the other delaying factors are not beyond the capacity of the Department and others to redress. On the basis of the case studies, when there is an allegation of clinical negligence, we recommend that the following good practice is promulgated and monitored by the Department and observed by the HPSS:

- the HPSS immediately investigates the claim with the fullest co-operation from the staff involved in the original incident;
- there is early and constructive contact between the parties;
- there is early involvement of independent medical experts;
- early reporting by experts;
- where there is early recognition of liability, the HPSS does not prevaricate in disclosing it to the plaintiff;
- medical records are disclosed expeditiously;
- there is responsible and restrained use of experts; and
- two or more experts should not be used where one would be sufficient.

3.56 The Department/HPSS should take appropriate steps, once a claim has been made, to encourage plaintiffs to ensure that:

- the allegations of negligence are as specific as possible and all known or perceived effects on the plaintiff are disclosed to the HPSS. The submission of amended claims should require the endorsement of a recognised third party;
- they choose solicitors who meet a pre-determined standard of competence for handling clinical negligence cases;
- there is early and constructive contact between the parties; and
- there is early involvement of independent medical experts.

3.57 Action on the part of third parties, which would assist in delivering improvement to the process, includes:

- the determination of the plaintiff's eligibility for legal aid without long delay (in weeks rather than months).

3.58 At the centre of all this, the Department should ensure that all HPSS bodies, which are likely to be subjected to compensation claims for clinical negligence, have in place a proper case management system which provides a central and accountable control over the progress of each case from original knowledge or notification of the incident through to settlement and clearance. The Department should also require regular monitoring returns from each HPSS body and should take action, through an accountable point within the Department, to intervene where progress does not appear to be sufficient. A high level report on clinical negligence, brought to the attention of senior management on a regular basis, should always feature as a part of the Department's corporate monitoring system.

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Part 4: Access to Justice

The Woolf Report

4.1 In July 1996, Lord Woolf published a report on the rules and procedures of the civil courts in England and Wales[21]. It was endorsed by the present Lord Chancellor, and a rolling programme of reform was begun in England and Wales in April 1999, which included the introduction of new civil procedure rules.

4.2 Lord Woolf singled out clinical negligence cases for particular scrutiny and found that the existing arrangements were failing to meet the needs of litigants in a number of respects. Specific criticisms were:

- the disproportion between costs and damages, especially in lower value claims;
- the delay in resolving claims;
- the lengthy pursuit of unmeritorious claims: likewise the defence of clear-cut claims;
- the success rate was lower than in other personal injury litigation; and
- extreme suspicion and lack of co-operation between the parties.

4.3 Lord Woolf identified the pre-litigation stage as one of the major sources of costs and delay due to:

- inadequate incident reporting and record keeping in hospitals, and staff mobility;
- claimants having to pay for an expert to establish if the claim is viable;
- there often being a long delay before a claim is made;
- defendants not fully investigating every incident because of a lack of resources and delay in investigations because many cases do not proceed after a request for records;
- patients often giving inadequate notice of their intentions as to whether or not they will pursue a claim; and
- doctors and other clinical staff being reluctant to admit negligence or apologise to claimants for fear of damage to their professional reputations or career prospects.

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21 "Access to Justice" (The Woolf Report): Lord Chancellor's Department, 1996.

4.4 Lord Woolf recommended that patients and their advisers, and healthcare providers, should work more closely together to try to resolve disputes co-operatively, rather than proceed to litigation. The report specifically recommended a pre-action protocol for medical negligence cases. In July 1998, a multi-disciplinary body which had been set up with an aim of finding less adversarial and more cost effective ways of resolving disputes, produced the Pre-Action Protocol for the Resolution of Clinical Disputes. This was prepared after extensive consultation with most of the key stakeholders in the medico-legal system and had the endorsement of many key organisations. Since April 1999, the protocol has had statutory force as part of new Civil Procedure Rules and Practice Directions which covers both the pre-litigation stage and after proceedings have been issued. The protocol also advances good practice commitments (see Appendix 4), which places obligations on healthcare providers and also patients and their advisers.

4.5 An illustration of the likely sequence of events in healthcare situations governed by the protocol is presented in Figure 12. The objectives of pre-action protocols as outlined in the relevant practice direction of the Civil Procedure Rules are:

- to encourage the exchange of early and full information about the prospective legal claim;
- to enable parties to avoid litigation by agreeing a settlement of the claim before the commencement of proceedings; and
- to support the efficient management of proceedings where litigation cannot be avoided.

DHSSPS and HPSS Reaction to Woolf

4.6 The Department's general position on claims is that HPSS bodies have no option but to defend themselves in all proceedings, even if it is probable that a settlement will have to be negotiated at some stage. Not to do so, would encourage higher settlements and potentially vexatious claims. It considers that HPSS bodies are not at liberty to dictate to patients how to redress wrongs they feel they have suffered. It is solely a matter for patients and their legal advisers to decide on the process they feel is in their interests to address their grievances.

4.7 However, the Department welcomes the development of the pre-action protocol in response to the Woolf Report. In January 1999[22], the Department issued the protocol as best practice in dealing with clinical negligence litigation and highly recommended the application of the protocol in dealing with clinical negligence disputes. Given the developments in this area, the Department intends to review the application of the protocol and promote its use, although the pre-action protocol consultation process, which is aimed at securing input from all interested parties, will be initiated and driven by the Northern Ireland Court Service.

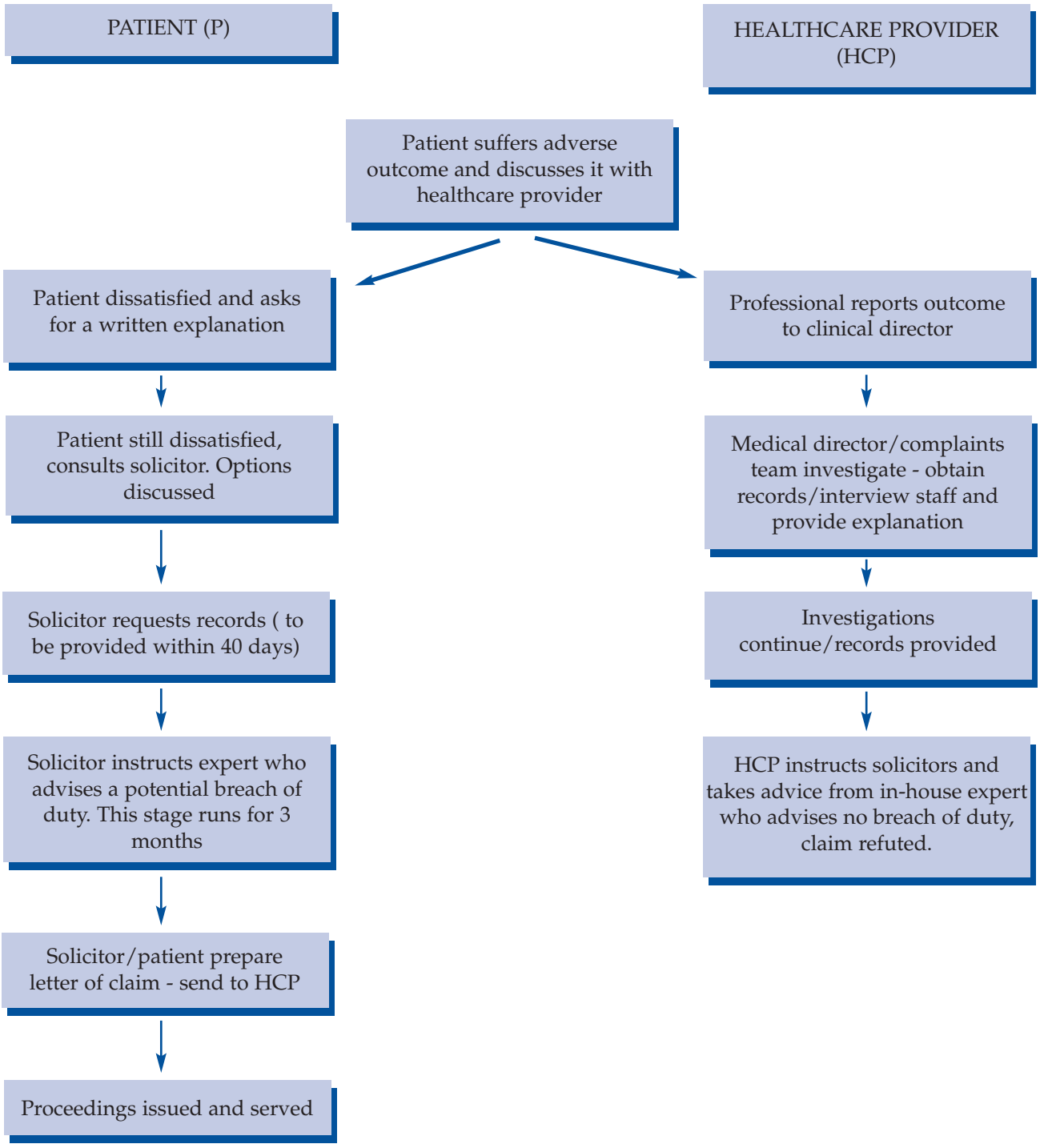
4.8 All of the Boards and most of the Trusts consulted, also expressed support for Woolf or an equivalent which should lead to the swifter and earlier resolution of cases. However, there was a lack of evidence as to Boards and Trusts having considered and acted upon the guidance issued by the Department.

22 Clinical Negligence Claims Handling - Pre-Action Protocol for the Resolution of Clinical Disputes, HSS(F) 20/98 Supplement No 1, DHSS, 21 January 1999.

Figure 12

Pre-Action Protocol for the Resolution of Clinical Disputes

Illustrative Flowchart



Civil Justice Reform Group

4.9 In February 1998, the Lord Chancellor announced the establishment of a Civil Justice Reform Group for Northern Ireland, charged with examining ways of increasing the accessibility, efficiency and effectiveness of the civil justice system against the background of the changes being implemented in England and Wales.

4.10 The Group reported in June 2000[23]. It made it clear that it sought to ensure that its reforms created a system in which:

- litigation will be avoided wherever possible, through the promotion of pre-action protocols, offers to settle and alternative dispute resolution; and
- litigation will be less adversarial and more co-operative, through pre-action protocols, increased transparency in evidence and discovery, rationalised pleadings and adherence to an over-riding objective by which parties are obliged to assist Courts in dealing with cases expeditiously, fairly and proportionately.

Its general view as to the pattern and scale of civil litigation was that an "excessively" adversarial environment had not developed in Northern Ireland and that, whilst delay and expense are significant problems, they are not so great as in England and Wales. However, the Group observed that many of Lord Woolf's strictures did apply and these weaknesses required serious consideration.

4.11 The Group's report considered clinical negligence actions separately and concluded that the pre-action problems identified by Lord Woolf applied equally to Northern Ireland. Consultation responses indicated a general lack of co-operation between parties at all stages of the claim. The report noted that for one frequent defendant, 75 per cent of cases in which legal costs were incurred were not pursued by the plaintiff.

23 "Review of the Civil Justice System in Northern Ireland: Final Report" Civil Justice Reform Group, Belfast, June 2000.

4.12 The report referred to several distinct procedural factors. Firstly, the medical evidence exchange provisions in the Rules of the Supreme Court and those of the County Court do not apply to clinical negligence. This was a factor which had been emphasised to NIAO on audit visits. HPSS staff were aware that, pre-Woolf, the rules in England and Wales had allowed for the earlier exchange of medical evidence.

4.13 Second, since November 1998, a separate list for clinical negligence has been operating in the High Court. Unlike the general list, the call over of the clinical negligence list has been in front of a High Court judge as opposed to staff within the Northern Ireland Courts Service. The expressed aim was to increase the effectiveness of judicial case management. One HPSS provider informed us that in the first 18 months, this initiative had not been particularly effective because of unpreparedness on the part of both plaintiffs and defendants. The review itself made no comment on the effectiveness to date of the initiative.

4.14 The Group noted that clinical negligence is associated with significant difficulties concerning the substantive law on questions of breach, causation and damage and these difficulties are to some extent, responsible for the excessive cost of litigation. Evidential problems are perhaps exacerbated in Northern Ireland as suitable experts may often only be found outside the jurisdiction. (The case studies in Part 3 provide examples of the parties having recourse to medical experts outside Northern Ireland). The Group acknowledged wider impacts; for example, doctors and other medical staff giving evidence are removed from their primary responsibilities with consequences for the care of patients. The Group advised that such matters fell outside its terms of reference.

4.15 The report made the following recommendations on clinical negligence:

- all expert reports, without reference to whether they or the expert are to be used at trial, should be shared with all parties. Exchange of such evidence should happen as early as possible in the litigation timetable;
- the unique problems presented by clinical negligence cases make it appropriate for there to be a stronger degree of procedural direction and case management;

- increased communication and co-operation should be encouraged between opposing parties involved in clinical negligence disputes;
- the adoption of a clinical negligence pre-action protocol, framed after wide consultation with legal and healthcare professionals, defence organisations and patient support groups within this jurisdiction;
- any such pre-action protocol, as well as any rules of court drafted to facilitate the exchange of medical evidence should provide for sequential exchange;
- there should be intensive judicial case management of litigation in the High Court. Claims proceeding in the High Court should be subject to a directions hearing before a Queen's Bench judge; and
- The Law Society and the Bar Council should provide and encourage their members to undertake training in clinical negligence litigation, leading to formal accreditation.

4.16 A number of those who consulted with the Group had raised the possibility of restricting clinical negligence practice to those with specialist training (the consultees did not include either the Department or any of the HPSS bodies). The Group argued that it would be economically and geographically unrealistic to restrict this relatively limited area of work to a small number of firms. Moreover, there would appear to be no more justification for restricting legal representation than to any other specific area of legal expertise. They contended that the unique difficulty of clinical negligence litigation stemmed primarily from a culture of non co-operation, lack of transparency and protectionism rather than any inherent complexity.

4.17 The Northern Ireland Court Service has indicated that, whilst work is ongoing on the required legislative amendments, the revised procedural arrangements advocated by the Group will not be in place until 2003. In its view, this is a measured delay, which allows for simultaneous commencement and holds out the prospect of greater success in the form of a fully functioning system.

Civil Justice Reform Evaluation

4.18 In March 2001, the Lord Chancellor's Department released its emerging findings of its evaluation of the Civil Justice Reforms in England and Wales. Among its key findings, it reported that:

- there had been a drop in the number of claims issued;
- pre-action protocols were working well;
- settlements at the door of the Court were fewer and the number of cases settled before the hearing day had increased;
- there had been a greater use of Alternative Disputes Resolution; and
- the time taken between issue and hearing for those cases which go to Court had fallen.

It also reported that sources external to the Lord Chancellor's Department showed that, with one or two exceptions, the civil justice reforms had been well received overall.

NIAO Comments and Recommendations

4.19 NIAO notes that the Department has recommended the adoption, by Boards and Trusts, of the Pre-Action Protocol for the Resolution of Clinical Disputes and that it intends to actively promote the Protocol and monitor adherence to the procedures. The views expressed to us during our investigations show that there is a broad consensus within the HPSS for a change away from the current adversarial arrangements and we would therefore urge the Department to follow up the issue of the Protocol to ensure that it is being implemented.

4.20 We acknowledge that the Civil Justice Reform Group was considering the civil justice system in Northern Ireland as a whole and not just the elements relating to clinical negligence and we recognise the Group's conclusion that, in view of this, the civil justice system may not currently merit a "Woolf" style package of reforms. However, it is significant that the report considered that the pre-action problems identified in England and Wales, applied equally to Northern Ireland.

4.21 Defendants are not always aware that cases will at some stage be abandoned. Once a case has been raised against it, the HPSS has an obligation to investigate the matter and defend itself appropriately against proceedings. The Department believes that, not to do so, could encourage additional malicious claims. We recognise that the work of defending claims incurs expenditure and in cases that are not pursued by the plaintiff, such expenditure would otherwise have been avoidable. Although it was outside the Review's terms of reference, we noted the Reform Group's recognition that the cost of litigation is excessive relative to the compensation payable. For clinical negligence in Northern Ireland, these costs are also disproportionately incurred by the taxpayer through the health service and the legal aid budgets. Furthermore, this cost is increased in cases where one, or even both parties have to obtain medical experts from outside Northern Ireland.

4.22 The Department, HPSS and many other bodies are deeply interested in, and some are inextricably involved in, the issues surrounding clinical negligence. The Northern Ireland Court Service told us that the Group consulted with a wide range of medical interests and its membership included a former Permanent Secretary from the Department of Health and Social Services. Nevertheless, we think that it was an oversight on the part of the Reform Group that it did not consult the Department or the HPSS on its report on arrangements in Northern Ireland. We also consider that implementation of some of the Group's recommendations is vulnerable to the risk of delay, though we acknowledge the Court Service's explanation of the reasons for delay. For NIAO, the main issue is how the recommendations, as framed, will achieve a material reduction in the excessive costs and delays in litigation.

4.23 We note that the Northern Ireland Court Service will initiate and drive the pre-action protocol consultation process which will take account of the protocol used in England and Wales, although variations will be considered where there are good reasons advanced during the consultation process. We recommend that the Court Service fully engage with the Department during this consultation process and that the Department, in turn, engage in, and contribute to, the reform process.

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Part 5: Minimising Exposure

Risk Management

5.1 Professional practice within clinical and social care in the HPSS is informed by and reflects the management of risk. The Department has pointed to examples of this, including the steps taken by the medical profession to ensure the practice of safe medicine, Royal Colleges' accreditation of training, quality of care protocols for specific disease management, social care protocols, multi-disciplinary assessments of people in the community and discharge from hospital, staffing consideration for new developments, revised clinical and social care governance arrangements, new prescribing arrangements for specific drugs, theatre protocols and domiciliary care protocols. The Department also told us that risk management is not a new management technique as far as health and social care is concerned, but rather it is an approach to professional practice which for many years has been embedded in the interaction between service professionals and service users.

Department of Finance and Personnel Guidance

5.2 The Department of Finance and Personnel (DFP) has defined[24] risk management as:

- identifying the risks Government faces, eg damage to or loss of assets, claims from third parties, professional liability etc;
- estimating the size of possible losses and claims, and the frequency with which they are likely to arise;
- identifying the possible options for dealing with risk and appraising their costs and benefits;
- selecting and implementing the best solution; and
- monitoring and regularly reviewing the performance of that solution.

5.3 In July 1994, DFP circulated a risk management guidance note to Departments emphasising the need to establish throughout each Department and those bodies for which they were responsible a positive attitude towards the control of risk – "a risk management

24 "Government Accounting Northern Ireland, DFP, May 1996

culture". In November 1998, following a request by DFP for information on progress, DHSSPS commissioned a survey of all HPSS bodies to determine the level of application of risk management methods and the implementation of best risk management practices.

5.4 The survey was conducted by risk management consultants, who reported in February 1999[25]. The report noted that the Department wanted to stem the tide of the increasing number and costs of claims of compensation for clinical negligence and it hoped to use the survey results to develop and issue an exemplar risk management strategy document and/or a risk management manual for the HPSS. The Department has emphasised that their intention was that the survey would be a positive process. In particular, it hoped that there would be changes, some of which would lead to:

- improvements in the quality of treatment and care for patients and clients;
- a safer environment for patients and clients, staff and the public;
- reductions in injuries to patients and clients;
- financial savings from reduced risks;
- increases in patient and client activity;
- an improved public image; and
- improved staff morale and productivity.

5.5 The consultants' general impressions were that "there is a good level of awareness by all the HPSS organisations, of the need for them to take positive action to develop rigorous systems for risk management". Their report noted that "there is a good level of compliance in most HPSS organisations in the fields of non-clinical /care risk management". However, "although there are pockets of good practice, in general there is a very limited amount of risk management information available to the Boards of the respective organisations. Where this does exist, it rarely provides information in respect of risks in direct patient/client care". The consultants found that there was "a growing acknowledgement … of the need for more robust and focused co-ordination of the risk management activity …" but considered that "in many of the Trusts, risk management may be seen by the line managers, senior clinicians and other professionals, as a peripheral activity…". The consultants concluded that "it is vital that the HPSS organisations establish

25 Northern Ireland Health and Social Services Executive: A Survey of Risk Management in the HPSS Organisations. Healthcare Risk Resources International, February 1999.

robust risk management programmes for assessing and managing risk to underpin their need to enhance and assure the safety of the services which the Boards commission and the Trusts provide". Details of the methods used and the consultants' summary of each of the issues examined is given at Appendix 5.

5.6 The Department advised us that, given that the work contained the assessment of individual organisation processes, the report has not been formally disseminated around the HPSS, although most bodies have been advised of their own ratings against the HPSS average.

NIAO Comments and Recommendations

5.7 NIAO considers that the survey of risk management was very timely and potentially useful, as it provided an independent view of the steps that had been taken to date by individual HPSS organisations. It was also a major contribution to the identification of the risks faced by the HPSS. We recognise that there are many examples of decisions taken by the HPSS and the Department, which have been informed by appropriate risk assessments and best practice, ranging from key decisions about the profile of acute services to improvements in the safety of blood products and the operation of individual medical devices. Nevertheless, the survey's findings suggest that there remains scope for further improvements and, given that DFP had issued general guidance in 1994, we would have expected further progress on this front.

5.8 We acknowledge that the Department intended to conduct a survey and not a detailed audit. Nevertheless, although the consultants identified good progress in a number of areas by some HPSS bodies, the identified gaps in risk management, as illustrated in Appendix 5 will need to be addressed by the Department and the HPSS to ensure consistent good practice across the service. The consultants' report reinforces, in many places, the findings of NIAO during our examination.

5.9 It is disappointing that action in response to the survey has been delayed, given the high expectations of the Department (see paragraph 5.4). A permissive approach to the implementation of good risk management has not brought the results that are required.

We would, therefore, expect the Department to be able to provide positive assurance of substantial progress in risk management within HPSS bodies, by 2003 at the latest.

5.10 As a matter of priority, approaches should be made to organisations on those risk management issues where they had not achieved full compliance (including those who did not provide the documentation to enable an assessment to be made). The Department should actively encourage all those to raise their performance to at least the second highest banding of full compliance, and it should monitor progress towards compliance.

Developments in England and Wales

Clinical Intervention

5.11 In June 1998, the then Secretary of State for Health announced measures aimed at ensuring fair access to effective, prompt, high quality health care. These measures to monitor, and if necessary to improve, the quality of care were introduced against a background of ongoing publicity about adverse clinical practice, for example, over cardiac surgery at Bristol Royal Infirmary. Subsequently, legislation was passed, the main provisions of which include:

- the introduction of National Service Frameworks, which set out what patients can expect to receive from the health service in major care areas or disease groups;
- the establishment of a new special health authority, the National Institute for Clinical Excellence (NICE). Its primary function is to produce and disseminate clinical guidelines and good practice examples based upon evidence of clinical and cost effectiveness. An equivalent body was also created for Scotland;
- the promotion of clinical governance arrangements at local level. This is underpinned by a statutory duty of quality being placed on the Chief Executives of health bodies; and
- the creation of the Commission for Health Improvement (CHI), which will review NHS Trusts on a rolling basis and, if requested by the Government, can intervene directly where clinical problems have been identified.

5.12 Other developments included the Department of Health publication in 1999 of "Supporting Doctors, Protecting Patients" which addressed the small minority of problem doctors working within the NHS (an equivalent document was also produced for Scotland) and the establishment of the National Patient Safety Agency, which aims to introduce a streamlined approach to dealing with errors and mistakes to ensure that lessons are learnt and spread throughout the health service. It will be a mandatory requirement to log all failures, mistakes, errors and near-misses.

Developments in Northern Ireland

Provider Initiatives

5.13 NIAO welcomes these various initiatives to enhance quality and standards of care. The Department informed us that these form part of a much wider agenda to achieve improvements in services and in the experience of individual service users. Some of this on-going work is outlined in paragraphs 5.21 to 5.28. However, when reviewing these matters with the Trusts, there was little evidence of sharing between providers of initiatives taken to date. This lack of information sharing increases the risk of the same mistakes and failings being repeated across the HPSS, and also the risk of staff, who change employers, repeating those mistakes. This can be illustrated by an example given to us by a provider of legal services, who informed us that they had been consecutively reviewing files relating to different claims against different Trusts and noticed the involvement of the same doctor in both cases of alleged negligence.

5.14 Providers suggested that the existence of clinical incident reporting systems was no guarantee that all appropriate incidents were reported. Also, the current arrangements had no provision for incidents to be centrally reported to a regional body. In relation to protocols, they advised that protocols did not extend to a number of long-established procedures. The Department said that more could be done to ensure consistency across the service and in central reporting of untoward incidents.

5.15 Similar concerns were identified in a report of the House of Commons Health Committee on adverse clinical incidents and outcomes in medical care[26], suggesting that the situation in

26 "Procedures Related to Adverse Clinical Incidents and Outcomes in Medical Care" Health Committee, 6th Report of 1998-99 Session (HC 549-I)

Northern Ireland is not unique in the United Kingdom. A particular concern was the existence of poorly performing doctors who were making the same mistakes over a period of time. The Committee received submissions by patients who did not consider that the performance of these doctors had been adequately addressed or that doctors were properly accountable for their actions. Another concern was whether Trusts in England and Wales adequately investigated and managed adverse incidents so to avoid future mistakes and ensure lessons were learned early.

Commissioner Stipulations

5.16 We enquired as to the steps taken by Boards, in their role as major health commissioners, to contribute to standards of care. We were informed of their attempts to maintain standards through quality standards in the contracting guidance which was reviewed and updated every year. Trusts viewed the stipulations as high level statements of intent. The comments made by Trusts within one Board area were generally negative, with comments being made such as: that the stipulations were not as demanding as the standards of the Royal Colleges and the King's Fund; that, although they completed quarterly monitoring reports as contractually required, there was little further scrutiny by the Board to validate compliance; and that the stipulations were vague and non-specific, which, to some Trusts, made compliance easy, whilst, to another, they made it difficult to achieve compliance.

5.17 Although it accepts that there is a role for Boards to stipulate some key initiatives, the Department does not see service and budget arrangements (not contracts) between Boards and Trusts as the vehicle for the comprehensive documentation of all standards or for delivering the improvements necessary. It referred to the "framework for setting standards, delivering services and improving monitoring and regulation in the HPSS" that has been outlined in the consultation document "Best Practice – Best Care" (see Appendix 6 (B)) and told us that the new arrangements, to be introduced following the consultation process, would be promulgated shortly.

NIAO Comments and Recommendations

5.18 We recognise and welcome the awareness within the HPSS of the need to minimise exposure to negligence as part of broader efforts to enhance the standards of care. We recognise and accept the Department's view that quality and standards must be driven by a more comprehensive, constructive and focused emphasis on all of the key issues which are part of this concept. We agree that it would not be appropriate to use the contracting/commissioning process solely for this purpose, but we feel that it has an important role to play in ensuring that the commissioning of health care is linked to accepted quality standards.

5.19 Consequently, we consider that the Department needs to clarify how it expects contract monitoring to operate, in relation to quality of care provision. We suggest that the Department should also remind all clinical staff of the importance of clinical audit (see paragraph 5.24) and its contribution to enhancing standards of care.

5.20 We welcome the Department's confidence in its ability to introduce new arrangements shortly, following the consultation period on "Best Practice – Best Care". This will provide a significant opportunity to set up the new processes and procedures required.

Confidential Inquiries

5.21 Although there is no statutory framework for clinical governance in Northern Ireland, there are existing quality frameworks. There has been a significant range of "audit" work of clinical performance in the HPSS. There has also been participation in national, publicly funded, regular confidential enquiries managed by the Royal Colleges, including the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) and the Confidential Enquiry into Perioperative Deaths. CESDI, which commenced in 1993, aims to improve understanding of the ways in which risks of death in late foetal life and infancy might be reduced.

CREST

5.22 Since 1988, there has been a locally based source of clinical advice in the Clinical Resource Efficiency Support Team (CREST), established by the Department but separate from its formal advisory machinery. To date, CREST investigations have reflected major clinical priorities, major diseases which are a heavy burden on society or problems common to the whole of the United Kingdom. Where there have been external guidelines or other relevant sources of advice, CREST has considered such advice and refined it for adoption within the HPSS. Risk analysis or clinical negligence have not influenced the selection of topics, although CREST advised us that clinical negligence considerations have been a factor in some of the recommendations made in individual topics. In addition, the Department told us that the guidance issued by CREST reflects best practice and consequently is based on professional assessments of how the risks associated with the condition and issues being considered are best managed. An example of this, given to us by the Department, is the guidance issued in 2001 on the Management of Severe Pre-Eclampsia and Eclampsia (severe high blood pressure in pregnancy).

5.23 CREST also told us that it had to reject many topics referred to it for possible consideration because of limited administrative support. CREST studies generate an ongoing commitment in the form of an implementation strategy and a clear indication of a subsequent audit to ensure compliance. Some CREST initiatives have been discontinued because of the pressure imposed by higher priorities. One such example was the co-authorship of a booklet with a medical defence society on the keeping of medical records. Our concerns about medical records are set out in paragraphs 3.25 to 3.34.

Clinical Audit

5.24 Within the HPSS, there has also been a considerable amount of clinical audit activity. Clinical audit has been defined as a quality assessment and improvement mechanism in which health professionals peer review their practice, on a multi-professional basis, compare it to best practice and introduce improvements in line with their findings. The Department told us that regular participation in clinical audit is an essential requirement of all

hospital doctors. Originally driven by the requirements of the Royal Colleges, it has now become an obligatory part of clinical appraisal with which all doctors must comply for revalidation by the General Medical Council.

Confidence in the Future

5.25 In October 2000, the Department issued a consultation document on the prevention, recognition and management of poor performance of doctors in Northern Ireland[27]. It recognised that there were weaknesses in the current procedures for managing deficient performance (see Appendix 6A), and it was conscious that the public reputation of the medical profession as a whole had been damaged by the poor performance of a few. It accepted, therefore, that there was a need for the modernisation of processes in the HPSS. The Department expressed its ultimate aim to be to assure the public "that the doctor who treats them is well-trained, highly competent and up-to-date in his or her practice". A key recommendation in Confidence in the Future was the introduction of appraisal for all medical staff. Since April 2001, in line with the rest of the United Kingdom, this has been introduced for consultant medical staff. It is the intention that similar arrangements will be introduced for general medical practitioners.

Best Practice - Best Care

5.26 In April 2001, the Department issued proposals in a further consultation document, [28] to enable doctors to demonstrate their high level of clinical practice. The proposals were aimed at providing a framework for:

- setting clear clinical standards for services from a single source within the Department;
- putting clinical and social care governance arrangements in place to ensure local accountability for the services delivered;
- extending regulation to cover a wider range of services; and
- establishing a more independent monitoring and inspections arrangement against the standards set.

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27 "Confidence in the Future for Patients and for Doctors": A consultation document on the prevention, recognition and management of poor performance of doctors in Northern Ireland. DHSSPS, 2000.

28 Best Practice - Best Care, A Framework for Setting Standards, Delivering Services and Improving Monitoring and Regulation in the HPSS, DHSSPS, April 2001

5.27 The setting of clear service standards are intended to provide staff with the confidence and knowledge that they are using the most up-to-date evidence of best practice. In addition, service users should be confident that the same standards for care are being applied to all who use the HPSS, no matter where they live. By seeking to link with NICE and the Social Care Institute for Excellence (SCIE) – both English bodies – this will ensure that the HPSS has access, in a timely manner, to the most up-to-date guidelines available, and the best use can be made of resources and expertise elsewhere.

5.28 The introduction of clinical and social care governance arrangements will mean that staff will receive the proper support to train and continuously keep up with new developments. The imposition of a statutory duty of quality on chief executives of HPSS organisations, is intended to assure the quality of services delivered, in the same way that financial probity is now covered. The introduction of new independent monitoring and inspection arrangements will provide an independent check that standards are being applied and staff are being supported across the HPSS. Legislation will be required to implement some of the proposals, including the introduction of a statutory duty of quality, the proposal to extend regulation to cover a wider range of services, and the establishment of independent monitoring and regulation arrangements. The Department told us that a formal announcement would be made soon.

National Patient Safety Agency

5.29 The Department is also currently considering the way forward for Northern Ireland in light of the establishment of the National Patient Safety Agency in England. It said that it will ultimately be for the Minister to take a decision on the way forward for Northern Ireland in light of the establishment of this body.

NIAO Comments and Recommendations

5.30 We welcome the efforts made to date to improve the quality of clinical care and clinical governance. We note that the consultation periods for the Department's recent proposals have now ended and look forward to the Department's announcement of early action.

5.31 We strongly agree that further improvements need to be accompanied by a modernisation of associated processes. It is surprising that any group of professional staff, largely funded by the taxpayer, has not been subject to a system of annual appraisal, particularly when the existing sanctions have been too severe, too legalistic and too prolonged for them to be applied in practice.

5.32 Any arrangements for recording adverse events need to be clear and unambiguous and it is important that the Department is assured that adverse events are disclosed, not just for the purposes of accountability, but also as a means to improve standards in the HPSS and to the avoidance of future error.

5.33 We note the views of the Department on the problem of poorly performing doctors. On the evidence in Parts 3, 4 and 5 of this report, the impact of poor performance is disproportionately large when measured against the scale of poor performance. Like clinical negligence, poor performance has multiple effects. Also, like clinical negligence, the causes of poor performance are largely avoidable and any strategy to minimise this should be addressed.

5.34 NIAO hopes that there will soon be arrangements to assure the public that, in all cases, they will be treated by a doctor who is well-trained, highly competent and up-to-date in their practice, and that where there are shortcomings, these are promptly addressed by internal mechanisms, or if exceptionally serious, by external intervention.

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Appendices

Appendix 1
(paragraph 3.19)

Remaining Case Studies Examined

CASE G

This was a birth-related case in which the plaintiff had contracted Erb's Palsy which left her with a permanent deformity of her right arm and shoulder. The claim took over 5 years to resolve and settlement took place 5 days before the Court hearing, when it was decided that the strengths of the plaintiff's claims were significant and that it would be preferable to settle.

(Settlement £125,000; Costs £37,151)

CASE K

The plaintiff alleged negligence in connection with misdiagnosis of a pregnancy which miscarried. This claim was preceded by an official complaint to which the Trust made a formal apology. The claim was settled in less than a year.

(Settlement £800; Costs £343)

CASE R

The plaintiff was a young child who had been involved in a car crash. It was alleged that the plaintiff was suffering from a malaligned leg due to too short a period of immobilisation in plaster (the plaster cast also fell off). The HPSS settled because of no available x-rays taken at the time when the plaintiff was put into plaster.

(Settlement £15,000; Costs £13,957)

CASE S

A patient died from a pulmonary embolism, 3 days after a first attendance in A&E and 2 days after a re-attendance. One of the Trust's own consultants and an independent expert advised that an unplanned re-attendance requires a higher standard of care and attendance than a first attendance. The claim was settled in just over 3 years.

(Settlement £22,500; Costs £9,143)

CASE T

The plaintiff was admitted for a routine hernia operation and required emergency resuscitation due to an allergic reaction to the powder in latex medical gloves. The plaintiff's medical records had previously been noted that she had had an allergic reaction to latex gloves on a previous occasion. This claim was resolved within 4 years.

(Settlement £7,500; Costs £5,288)

Factors Leading to Settlement of Cases in Sample Examined

Factor	Frequency
Clinical	
Mistake or missed/mis-diagnosis	6
Sub-optimal procedure	5
Condition not corrected after second procedure	3
Failure to fully explain risk	2
Weaknesses in post-operative monitoring	2
Lack of constant supervision	1
Unplanned re-attendance at A&E	1
Delay in referral for treatment	1
Failure to review X-rays and make timely diagnosis	1
Surgery performed differently from what was explained prior to the operation	1
Failure to perform tests	1
Gaps in training of clinician	1
Administrative and Personnel	
Gaps in records kept	6
Unavailability of staff to attend court	3
Records lost or destroyed	3
Conflicting testimony	2
Staff could not be traced	2
Lack of documentary evidence	2
Reliability of testimony	1
Staff had died	1
Staff did not remember	1
Lack of communication	1
Refusal of former staff to get involved	1

Source: NIAO fieldwork

Appendix 3
(paragraph 3.49)

Case F: Expert Reports* prepared for Plaintiff

1. Consultant Paediatrician (December 1992)
2. Consultant Surgeon (undated)
3. Consultant Surgeon (undated)
4. Psychiatrist (July 1997)
5. General Practitioner (November 1996)
6. Consultant (undated)
7. Consultant Paediatrician (March 1997)
8. Consultant ENT (Ear, Nose and Throat) Surgeon (August 1997)
9. Consultant Physician (September 1997)
10. Educational Psychologist (December 1994)
11. Educational Psychologist (August 1996)
12. Educational Psychologist (August 1996)
13. Nursing Care (April 1997)
14. Forensic Accountant (June 1997)
15. Architect (May 1997)
16. Educationalist (January 1998)
17. Educational Psychologist (January 1997)
18. Neurologist (December 1997)
19. Psychiatrist (undated)

Note: * arranged in chronological order in which tranches of the reports were released.

Appendix 4

(paragraph 4.4)

Civil Procedure Rules in England and Wales

Good Practice Commitments

(extract from "Pre-Action Protocol for the Resolution of Clinical Disputes" - Clinical Disputes Forum, July 1998)

Healthcare providers are asked to:

- ensure that key staff, including claims and litigation managers, are appropriately trained and have some knowledge of healthcare law, and of complaints procedures and civil litigation practice and procedure;

- develop an approach to clinical governance that ensures that clinical practice is delivered to commonly accepted standards and that this is routinely monitored through a system of clinical audit and clinical risk management (particularly adverse outcome investigation);

- set up adverse outcome reporting systems in all specialties to record and investigate unexpected serious outcomes as soon as possible. Such systems can enable evidence to be gathered quickly, which makes it easier to provide an accurate explanation of what happened and to defend or settle any subsequent claims;

- use the results of adverse incidents and complaints positively as a guide as to how to improve services to patients in the future;

- ensure that patients receive clear and comprehensible information in an accessible form about how to raise their concerns or complaints;

- establish efficient and effective systems of recording and storing patient records, notes, diagnostic reports and X-rays and to retain these in accordance with Department of Health guidance (currently for a minimum of eight years in the case of adults, and all obstetric and paediatric notes for children until they reach the age of 25); and

- advise patients of a serious adverse outcome and provide on request to the patient or the patient's representative an oral or written explanation of what happened, information on further steps open to the patient, including, where appropriate, an offer of future treatment to rectify the problem, an apology, changes in procedure which will benefit patients and/or compensation.

Patients and their advisers are asked to:

- report any concerns and dissatisfaction to the healthcare provider as soon as is reasonable to enable that provider to offer clinical advice where possible, to advise the patient if anything has gone wrong and take appropriate action;

- consider the full range of options available following an adverse outcome with which a patient is dissatisfied, including a request for an explanation, a meeting, a complaint, and other appropriate dispute resolution methods (including mediation) and negotiation, not only litigation; and

- inform the healthcare provider when the patient is satisfied that the matter has been concluded: legal advisers should notify the provider when they are no longer acting for the patient, particularly if proceedings have not started.

Appendix 5
(paragraphs 5.5 and 5.8)

"A Survey of Risk Management in the HPSS Organisations"

Report by Healthcare Risk Resources International - February 1999

Methodology

1. The survey assessed the 26 HPSS bodies against 12 specific risk management areas. The consultants graded the level of compliance on a score of 1 to 10 for each area in each organisation. A mark of 7 or more was equated to achieving full compliance. An overall average mark for each area was awarded, but the consultants emphasised that the averages, in some cases, disguised wide variations between organisations.

Assessment of Issues and Ratings Awarded

Issue 1 - Risk Management Strategy Document - Rating: 5
"Almost all Trusts have produced a risk management strategy document. However, most are limited in their contents and a variety of models have been developed. It appears that greater efforts need to be made in order to ensure that the Strategy is endorsed fully by the Board of the Trust concerned and that **all** managers, clinicians and other professionals are fully aware of its contents. With regard to the four Boards and three Agencies, none of them has a contemporary, formal risk management strategy document."

Issue 2 - Risk Profiling - Rating: 6
"There is evidence of a reasonable amount of risk assessment activity with Health and Safety issues in all the organisations, but a limited amount of risk profiling of clinical and care services on a regular basis in Trusts. Where clinical risk assessments have been made, these have tended to be one-off focused risk reviews of particular, worrying clinical services (eg maternity) where there have already been indications of the need for investigation. The emphasis required is for a rolling programme of proactive risk assessments, as part of the organisation's normal business plan, covering every clinical, care and support service in a three-year cycle."

Issue 3 - Incident Reporting - Rating: 7
"There is generally a good level of reporting of incidents relating to Health and Safety issues, slips, trips and falls, with a great deal of data accumulated. Whilst in some of the organisations this is converted into meaningful management information, there is an inconsistent patchwork of manual and data processing systems in use for doing so. The major deficiency relates to the very limited and, therefore, probably significant under-reporting of clinical incidents and "near misses". A major effort is needed in almost all Trusts to improve in this area."

Issue 4 - Patient Records - Rating: 5
"There was a low level of compliance with this issue amongst the majority of Trusts. There is no doubt that inadequately prepared patient records, or records which are unavailable when needed, contribute to unsafe clinical care and indeed, can lead to claims of negligence being lost. Accordingly, there is a real need for most Trusts to develop an explicit policy document incorporating all of the elements shown, and for there to be a system in place for the routine audit of compliance with the policy."

Issue 5 - Clinical Audit - Rating: 5
"The consultants identified very few examples of multi-disciplinary clinical audit being used as a robust tool for risk reduction and risk control. However, there were many more instances of uni-disciplinary audit (for example, medical audit and nursing audit) and limited progress towards the development of integrated care management."

Issue 6 - Complaints - Rating: 7
"In almost all the HPSS organisations, there were excellent systems for managing complaints from patients, their relatives and the public. Furthermore, the consultants found a lot of evidence to show that the systems are used effectively. This is not considered to be a high priority for improvement. However, because of the widening management agenda generally, it is necessary for the organisations to take steps to avoid complacency in this crucial area of risk management."

Issue 7 - Policies and Procedures - Rating: 6
"In all the organisations visited, there were many examples of excellent policies and procedures. However, in some cases, these were noted to be out-dated and, in a few instances, related to the predecessor organisation…Whilst there is much good practice in this arena, the importance of up-to-date, easily understood, clinical and other policies, procedures, guidelines, treatment protocols and agreed standards cannot be over-emphasised in relation to risk reduction. Often, a major cause of risk is that members of staff are individually uncertain of what is expected of them, particularly in emergency

situations. This can be compounded when other members of the same team have different understandings about what actions should be taken in such situations."

Issue 8 - Communications - Rating: 6
"Generally, the HPSS organisations performed well under this heading. The majority visited had developed detailed communication strategies…Nearly all organisations visited had identified a senior manager to act as a focal point for overseeing external communications with relevant organisations and individuals. The approach…with combined healthcare and social service organisations, provides a significantly improved opportunity for interface between professionals engaged in clinical or social care input."

Issue 9 - Supervision of Junior Staff - Rating: 6
"In general, with regard to most non-clinical junior staff, there are effective systems in place for supervising their activities. However, consultants found few examples of formal, written procedures for ensuring that clinical staff have ready access to advice and support from their seniors. This does not imply that such processes are not in place, but these do need to be made more explicit. This is a particularly vulnerable arena in the context of clinical risk and needs more focused attention."

Issue 10 - Assessing Competence - Rating: 6
"This is an area which HPSS organisations are taking increasingly seriously and many areas are being addressed and reviewed. In addition, all organisations appear to have effective arrangements for individual performance review for staff. However, the consultants are concerned in particular about issues (dealing with procedures to verify the qualifications, references, police checks, health status and competence of all locum and agency staff to fulfil the duties required by the HPSS organisation, and the procedure for informing all staff of their responsibility to limit their actions to those for which they are competent), where they saw very limited evidence that the appropriate methodologies and procedures had been formulated. These are matters which need to be addressed urgently, as they can have a major impact on enhancing the risks to patients/clients in particular, but also to the organisation generally."

Issue 11 - Health and Safety and Related Issues - Rating: 8
"The consultants found examples of good work having been undertaken in all organisations regarding Health and Safety and related issues. Indeed, it is from these foundations that many of the risk management programmes have been built. The only point of concern with this issue is the possibility that some organisations may lose sight of the need to be continually vigilant in meeting on-going statutory and legislative requirements in this arena.

Organisations cannot afford to become complacent in their pursuit of the wider challenging agenda, and should build on and maintain their current successes with Health and Safety and related issues."

Issue 12 - Claims Management - Rating: 6

"The consultants found few examples of a claims management policy in accordance with the detailed and helpful framework set out in (the Department's circular). It is likely that, because of the generally under-developed claims management function in most organisations, there is an excessive reliance on solicitors to manage claims of negligence. This incurs many costs which could be avoided if claims managers were given suitable training and more status within their organisation to genuinely manage the claims and the solicitors too. It is also important to note that, because of the central funding mechanisms for claims, there appears to be little financial or other incentive for HPSS organisations to pay more attention to this function."

Appendix 6
(paragraphs 5.17, 5.25 and 5.26)

DHSSPS Consultation Papers

(A) "Confidence in the Future for Patients and for Doctors" (October 2000)

1. Weaknesses recognised by the Department within the current system:

- processes may be initiated as a result of a single serious incident which itself may only be the culmination of a pattern of deficient or deteriorating practice;
- the over reliance of the current system on disciplinary action, rather than prevention, early identification and remedy;
- the legalistic nature of current procedures, which deter the taking of early action;
- a lack of clarity between the roles of the General Medical Council and the HPSS in ensuring satisfactory performance;
- poor processes for the identification and support of sick doctors;
- a tendency to shift the problem by allowing problem doctors to change employer; and
- the protracted timescale for dealing with the problem.

2. The consultation document suggested that these issues could be addressed by a compulsory and comprehensive annual appraisal of all aspects of every doctor's practice, supplemented by compulsory participation in clinical audit; and programmes of continuing medical education and continuing professional development.

(B) "Best Practice - Best Care" (April 2001)

3. Proposals made on:

- **Setting Standards - Improving Services**, with three options offered:
  - establishment of independent body to research and appraise the evidence of new drugs and technologies or existing procedures based on HPSS priorities;
  - establishment of internal body within the Department for such appraisal; and

- making arrangements with other standard setting bodies such as NICE and filtering standards and guidelines from such bodies.

- **Delivering Services, and Ensuring Local Accountability**, through the introduction of a system of clinical and social care governance, backed by a statutory duty of quality and supported by continuous professional development.

- **Improving Monitoring and Regulation of Services**, with proposals for:
  - the introduction of an independent means of monitoring the delivery of services;
  - the extension and improvement of the range of social care services currently regulated; and
  - the improvement and extension of the current regulation of private and voluntary healthcare services.

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