

Working Group
on
Medical Negligence and Periodic Payments

Report (Module 2)



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THE HIGH COURT
FOUR COURTS
DUBLIN 7

The Hon. Ms. Justice Mary Irvine

14th March, 2012

The Hon. Mr. Justice Nicholas Kearns
President of the High Court
Four Courts
Dublin 7

Re: Working Group on Medical Negligence and Periodic Payments

Dear President

I am pleased to report that the Working Group on Medical Negligence and Periodic Payments has just completed the second module of its deliberations. Accordingly, I now enclose for your attention the Report of the Working Group in respect of Pre-action Protocols.

I am also pleased to confirm that the Working Group has recently embarked on a third and final module, wherein it will consider and report upon the potential value of case management in certain types of Clinical Negligence litigation.

Yours sincerely


Mary Irvine

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23rd March 2012

Chapter 1 : Introduction

Establishment and terms of reference of the Working Group

On the 18th February 2010, the President of the High Court established a Working Group on Medical Negligence Litigation and Periodic Payments, with the following terms of reference:

1. To examine the present system within the courts for the management of claims for damages arising out of alleged medical negligence and to identify any shortcomings within that system.
2. To make such recommendations to the President as may be necessary in order to improve the system and eliminate the shortcomings.
3. To consider whether certain categories of damages for catastrophic injuries can or should be awarded by way of Periodic Payments Orders and to make such recommendations to the President as may be necessary.
4. To provide the President with such draft Legislation, Regulations, and Rules of Court as may be necessary to give effect to the Working Group's recommendations.

The President appointed Mr. Justice John Quirke, Judge of the High Court, as chairperson of the Working Group (referred to henceforth in this report as "the Group"). In view of his retirement from the Bench, Mr. Justice Quirke was succeeded as chairperson by Ms. Justice Mary Irvine, Judge of the High Court in the course of the Working Group's deliberations.

The Group particularly wishes to record its gratitude to Mr Justice Quirke for the unfailing dedication and courtesy with which he stewarded the Group's activities as chairperson.

Working method

The Group adopted a modular approach to its Terms of Reference. Module 1 concerned periodic payments, a report ("the First Report") on which was presented to the President on the 29th October 2010.¹ Module 2 is concerned generally with the conduct and management of clinical negligence litigation.

The Group met on nine occasions for the purposes of Module 2 of its deliberations. Reference is made in the First Report to the process of consultation which the Group undertook. The Group reiterates its appreciation of the contributions of those who made submissions as part of the consultation exercise, which was also of considerable assistance to it in its deliberations in Module 2.

The membership of the Group for the purposes of Module 2, in addition to its successive chairpersons, was as follows, in alphabetical order,:

Mr. Michael Boylan, Partner, Augustus Cullen Law Solicitors

Mr. Ciaran Breen, Director, State Claims Agency

Mr. John Casey, CEO, Motor Insurance Bureau of Ireland

¹ The report may be accessed at:
[http://www.courts.ie/Courts.ie/library3.nsf/\(WebFiles\)/5CEE419C4A5959BC802577DC0055C9F4/\\$FILE/Medical%20Negligence%201.pdf](http://www.courts.ie/Courts.ie/library3.nsf/(WebFiles)/5CEE419C4A5959BC802577DC0055C9F4/$FILE/Medical%20Negligence%201.pdf)

Ms. Tara Downes, solicitor in the Office of Legal Service, HSE (replacing Ms. Eunice O’Raw during her absence on leave)

Mr. Patrick Hanratty, Senior Counsel

Mr. James Kehoe, Fellow, Society of Actuaries in Ireland

Mr. Mike Kemp, CEO, Irish Insurance Federation

Mr. John Kenny, Department of Justice

Mr. Justice Vivian Lavan, Judge of the High Court

Mr. Denis McCullough, Senior Counsel

Ms. Gráinne O’Loughlen, Registrar, Personal Injuries, Courts Service

Mr. Ciaran O’Rorke, Partner, Hayes solicitors

Ms. Máire Reidy B.L., Judicial Fellow

Mr. James Reilly, Patient Focus

Mr. Noel Rubotham, Courts Service

Mr. Brendan Savage B.L., Special Assistant

Ms. Marie Coady was Secretary to the Group.

The subject-matter of Module 2

The submissions received by the Group have highlighted the particular difficulties and challenges presented by the conduct of clinical negligence litigation. Those criticisms reflect observations from other sources on this type of litigation.

In his seminal report on civil justice reform, “Access to Justice”,² Lord Woolf devoted a separate chapter to medical negligence, indicating that it had become “increasingly obvious that it was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants in a number of respects”, citing an excessive disproportion between costs and damages in such cases; the incidence of unacceptable delay; the frequency with which unmeritorious cases were pursued and extent to which clear-cut claims were defended; the lower success rate of such claims; and the intensity of suspicion and lack of co-operation between the parties, in comparison with other areas of litigation.

In *Payne v. Shovlin*,³ the Supreme Court, having observed that the cost of clinical negligence litigation had become so high that smaller claims could rarely be litigated because of the disproportionate cost involved, endorsed Lord Woolf’s view that the most significant factor contributing to excessive costs was “the climate of mutual suspicion and defensiveness which is still all too prevalent in this area of litigation”, rather than complexity in the law or procedure. The Supreme Court noted that “there is no separate division of the High Court for medical negligence cases nor any effective case management system whereby procedures can be simplified and costs kept to a minimum.”⁴

At the time Lord Woolf commenced his deliberations, no procedural regime existed in England and Wales specifically to address the particular attributes of and challenges presented by clinical negligence litigation. While new rules of court governing personal injuries actions were introduced to facilitate the operation of the provisions of the Civil Liability and Courts Act 2004 relating to such actions, those rules

² Woolf, “Access to Justice” Final Report, London, HMSO (1996).

³ [2007] 1 I.R. 114.

⁴ Ibid., pages 124 to 125.

are very much a product of the particular requirements of the 2004 Act for personal injuries actions generally, and a similar procedural deficit continues to exist in this jurisdiction in relation to clinical negligence litigation.

The task of the Group in this Module under the first head of its terms of reference as mentioned above is to develop a comprehensive procedural model - based in rules of court and related protocols - for the conduct of clinical negligence actions, together with any supporting provisions required in the form of primary legislation.

Drawing again upon the first head of the terms of reference, the Group would intend to consider in a third and last Module the potential of case management to expedite and minimise the costs of clinical negligence litigation, in a manner which meets the requirements of justice.

Chapter 2: Executive Summary

1. The Group recommends the introduction of a pre-action protocol, as contained in Appendix 1 of this report, governing claims by a person, or a personal representative or dependant of a deceased person, for damages for negligence, breach of statutory duty or breach of contract arising from any act or omission concerning -
 - the provision of a health service (including any dental service) to that person,
 - the carrying out of a clinical, medical or surgical procedure (including any dental procedure) in relation to that person,
 - the carrying out of a clinical or medical diagnosis, investigation or research (including any dental diagnosis, investigation or research) in respect of that person,
 - the provision of medical advice and information (including any dental advice and information) to that person, or
 - the provision of clinical or medical treatment or care (including any dental treatment or care) to that person.
2. The Group considers that the introduction of a pre-action protocol would confer various benefits, as follows:
 - (a) a pre-action protocol should secure earlier disclosure of patient records than currently is the case, thus facilitating an informed consideration by the parties of any potential claim or defence;
 - (b) a pre-action protocol would afford an opportunity for parties to settle the dispute between themselves or to explore alternative dispute resolution options where appropriate - thus reducing the number of claims which ultimately proceed to litigation;
 - (c) where a claim did proceed to litigation, a pre-action protocol would identify at a much earlier stage the issues which should ultimately be in dispute; and
 - (d) a pre-action protocol would provide an appropriate context - particularly where a respondent healthcare provider would have an appropriate statutory protection for the purpose - for a patient to seek, and in appropriate circumstances obtain, a suitable apology in respect of the adverse event experienced.
3. The Group is satisfied that a protocol along the lines of that recommended by the Clinical Disputes Forum in England and Wales would, with some modifications, serve as the most appropriate model for this jurisdiction, subject to certain issues being addressed in primary and secondary legislation.
4. The Group recommends that the protocol appended should regulate and prescribe time limits for the stages of request for records, response to request for records, notification of claim, letter of claim and response to claim.
5. The Group recommends that seven weeks should be permitted for provision by the healthcare provider of clinical records to the patient and that the protocol should enable time limits to be extended by agreement of the parties.
6. Acknowledging the potential of a pre-action protocol to facilitate recourse to mediation, early neutral evaluation and other types of ADR to resolve certain types of clinical negligence claim, the Group

considers that the protocol should allow for suspension of the time limits applicable under it where the parties have agreed in writing to refer a dispute to mediation or arbitration.

7. The Group considers that a requirement to send a letter of notification prior to the making of a formal claim would enable identification of the relevant clinical records, alert clinical personnel affected and indemnifiers and insurers and facilitate early liaison between those parties with a view to ensuring that an informed response is made to the subsequent letter of claim.

8. The Group recommends that the operation of the protocol be reviewed by the Superior Courts Rules Committee after a period of, say two years from its introduction, with the benefit of input from the legal profession and other interested bodies to ascertain whether changes in the protocol are required or further powers need to be given to the court to secure compliance.

9. The Group recommends that provision be made by statute for the rule-making authority of the court rules committees to be expanded to enable the making of rules of court to provide for the prescribing of pre-action protocols regulating the conduct of claimants and prospective defendants, including the prescribing of time-limits, in particular with respect to causes of action to which the pre-action protocol is intended to apply.

10. The new rule-making power should extend to the prescribing of the charges leviable and recoverable in respect of the provision of copies of documentation and other materials (including materials in electronic form) in response to a request made under a pre-action protocol.

11. The Group considers that non-compliance by a prospective party with an obligation under the protocol should, provided it is substantial in nature, operate to relieve the other party of the requirement to comply with that party's obligations under the protocol. Where the party affected is a claimant, they would thereupon be entitled to institute proceedings in respect of the claim. Furthermore, non compliance with the protocol should be a factor which the court may take into account when determining liability for costs in the event that proceedings are issued.

12. Where a third party healthcare provider fails to comply with a request under the protocol to disclose records, the prospective claimant should, where they commence proceedings in respect of the claim in the absence of the relevant information, be entitled to recover their costs of any subsequent application for non-party discovery against that provider necessitated by the non-disclosure prior to commencement of the proceedings, together with such further costs incurred by the claimant in the proceedings as the court may consider fairly attributable to such non-disclosure.

13. The Group recommends that provision should be made in rules of court that where an offer to settle is made in the letter of claim or in the response to the claim under the pre-action protocol, the court in any proceedings which may subsequently be commenced in respect of the claim shall have regard to any such offer in awarding the costs of those proceedings. This would require provision to be made by statute that section 17 of the Civil Liability and Courts Act (concerning the exchange of formal offers in personal injuries actions) be dis-applied in an instance where an offer of settlement had been made in accordance with the protocol. The rules of court providing for lodgement and tender would equally require to be amended to facilitate the recommendation.

14. The Group recommends that provision should also be made by statute enabling a claimant who has made an offer of settlement in a letter of claim sent under the pre-action protocol, and who recovers not less than that amount in subsequent proceedings on foot of the cause of action concerned, to recover

interest on the amount of the offer from the date of its being made and up to the date of judgment in the proceedings concerned.

15. The Group considers that, if the protocol is to succeed in the objective of facilitating expressions of apology, protection would require to be afforded by statute to an expression of apology made by a healthcare provider or medical professional. An apology made by or on behalf of a defendant in relation to a claim for clinical negligence should not be treatable as an admission of fault or liability, express or implied, operate to avoid or otherwise affect a contract of or any entitlement to insurance, or be taken into account in determining fault or liability. Furthermore, such an apology should not be admissible in any proceedings as evidence of fault or liability on the part of the person making it.

16. Provision should be made by statute requiring clinical records producible under the pre-action protocol to be provided in electronic form where so requested. Charges for production of such records should be linked to those payable on an application under the Data Protection Acts - currently €6.35 - and should cover the expenses of scanning, copying or replication otherwise of a record requested, but subject in all cases to a maximum charge of €100 by the healthcare provider requested. A maximum charge of €5.00 should be chargeable for radiology material supplied on a CD-Rom.

17. While the subject of limitations periods is not the focus of the Working Group's remit, the Group is of the view – a view supported by a number of submissions made to it in the course of its consultation exercise – that the current limitation period of two years applicable to personal injuries actions generally is too restrictive and does not take account of the particular complexities associated with clinical negligence claims and the extent of their reliance on expert evidence of various types. The Working Group recommends that an extension of the two year limitation period to three years for clinical negligence claims, as striking the appropriate balance between the legitimate interests of claimants and respondents to such claims.

Chapter 3: A Pre-action Protocol

Introduction

A key recommendation of Lord Woolf's "Access to Justice" report⁵ in relation to medical negligence litigation sought to require prospective claimants and defendants, by means of a pre-action protocol, to engage with each other prior to the commencement of any litigation -

- to exchange information so as to enable them to consider alternative means of resolving any dispute,
- to seek settlement before litigation and,
- in the event that this was not feasible, to facilitate the expeditious conduct of proceedings.⁶

Lord Woolf explained the general rationale for pre-action protocols as follows:

"What is needed is a system which enables the parties to a dispute to embark on meaningful negotiation as soon as the possibility of litigation is identified, and ensures that as early as possible they have the relevant information to define their claims and make realistic offers to settle."⁷

In the context of medical negligence litigation, it was recognised that the pre-litigation stage can generate significant cost and delay, due to various factors. Medical care providers may have difficulty in establishing the factual position due to inadequate incident reporting or records or may be reluctant to investigate fully an incident on receipt of a request for records given uncertainty as to whether a claim will ensue. Medical professionals and hospital personnel have been reluctant to concede negligence, apologise to or otherwise engage with claimants, fearing damage to reputation or career. On the other hand, patients may often delay in bringing claims, or give short notice of their intention to sue, inhibiting timely investigation of an incident, which may in the result only take place after proceedings have commenced.

The "Access to Justice" proposals envisaged a pre-litigation procedure in the area of medical negligence claims as meeting a number of objectives, viz. to:

- “(a) encourage early communication between claimants and defendants, and ensure that any appropriate apology or explanation is always offered to the claimant;
- (b) set a challenging but realistic target for disclosure of medical records by defendants;
- (c) ensure that the claimant knows what options are available (including ADR) and what each will involve;
- (d) require the parties to consider whether joint instructions to an expert would be possible, at least on some of the issues in the case; and
- (e) provide an early opportunity for defendants to identify cases where a full investigation is required.”⁸

⁵ Woolf, op.cit.

⁶ Woolf, op.cit., Chapter 10, para. 1.

⁷ Woolf, op.cit., Chapter 10, para. 4.

The pre-action protocol governing clinical disputes was developed by the Clinical Disputes Forum, an umbrella organisation which had been established in 1996 on foot of Lord Woolf's recommendations, coming into effect as part of the new Civil Procedure Rules in April 1999. A revised version of that protocol has now been prepared by the Clinical Disputes Forum. The Lord Chancellor, Lord Irvine, when launching the original protocol, stated,

“Pre-action protocols are, in many ways, the key to the success of the civil justice reforms. If they do not work our major procedural reforms will be weakened.”⁹

In assessing the experience of the various pre-action protocols introduced under the Civil Procedure Rules (CPR), the authors of the leading commentary on those rules posed the question “Have the protocols been a success?” and answered “Anecdotally, without a doubt. New litigation post CPR has reduced by 80 per cent in the High Court and 25 per cent in the County Court - the protocols ...are certainly a factor in this.”¹⁰

The provisions of the Clinical Negligence Pre-action Protocol in England and Wales will be examined in greater detail later in this Chapter.

Disclosure

In its 2008 report, “Building a Culture of Patient Safety”,¹¹ the Commission on Patient Safety and Quality Assurance pointed to the importance – as disclosed in various international studies - of open communication with a patient who has suffered an adverse experience in their medical care or treatment, as a means of assisting the patient to cope with the event, meeting the particular information needs which a patient has in such circumstances and providing an opportunity for an apology in the event of error. The Commission noted:

“When an error or adverse event occurs, healthcare professionals may be faced with a difficult dilemma in deciding whether and what to tell the patient. On the one hand disclosure is advocated by patients, safety experts and ethicists; yet on the other hand professionals are conscious and fearful of potential litigation. Although such fears are understandable, studies show that error disclosure reduces patients' inclination to sue. Many patients who believe they have been the victim of incompetent care take legal action simply to find out exactly what happened to them and to prevent recurrence. International evidence shows that the vast majority of patients who are injured by medical errors never sue. Although no approach to disclosure is without risk, there is no evidence to suggest that a policy of open disclosure increases liability.”¹²

A policy of openness also benefits the healthcare system and contributes to good medical practice. In the UK, the National Patient Safety Agency of the National Health Service has noted that “[c]ommunicating effectively with patients, their families and carers is a vital part of the process of dealing with patient safety incidents in healthcare”.¹³

In its “Guide to Professional Conduct and Ethics for Registered Medical Practitioners”, the Irish Medical Council, in the section “Adverse Events”, advises practitioners:

⁸ Woolf, *op.cit.*, Chapter 15, para. 38.

⁹ Quoted in “Civil Procedure” (The White Book), London Sweet & Maxwell (2009), page 2306.

¹⁰ *Ibid.*, pages 2306 to 2307.

¹¹ Report of the Commission on Patient Safety and Quality Assurance, Department of Health and Children 2008, Chapter 4, “Patients, Carers and Service-Users as Partners”.

¹² At page 78 of the report.

¹³ Patient Safety Alert: “Being open”, NPSA/2009/PSA003 (November 2009), paragraph 2.

“Patients and their families are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm. Therefore you should:

- acknowledge that the event happened,
- explain how it happened,
- apologise, if appropriate, and
- give an assurance as to how lessons have been learned to minimise the chance of this event happening again in the future.”¹⁴

The General Medical Council in the UK, in its statement of principles and values entitled “Good Medical Practice”, states:

“Being open and honest with patients if things go wrong

30. If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects.

31. Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not allow a patient's complaint to affect adversely the care or treatment you provide or arrange.”¹⁵

In its recent official response to the NHS Future Forum report,¹⁶ the UK Government committed to impose on healthcare providers a new contractual requirement to be “open and transparent in admitting mistakes”, in order to “strengthen transparency of organisations and increase patient confidence”.

A common law duty of disclosure?

Some uncertainty exists as to whether a healthcare provider has a duty at common law to provide to a patient access to information or records concerning the patient's treatment.¹⁷ The Supreme Court of Canada has held¹⁸ that such a duty exists on the basis of the *fiduciary* relationship which obtains between a medical practitioner and patient. La Forest J, delivering the Court's judgment, stated:

“The fiduciary duty I have described is sufficient to protect the interest of the patient. The trust-like “beneficial interest” of the patient in the information indicates that, as a general rule, he or she should have a right of access to the information and that the physician should have a corresponding obligation to provide it. The patient's interest being in the information, it follows that the interest continues when that information is conveyed to another doctor who then becomes subject to the duty to afford the patient access to that information.

There is a further matter that militates in favour of disclosure of patient records. As mentioned earlier, one of the duties arising from the doctor-patient relationship is the duty of the doctor to act with utmost good faith and loyalty. If the patient is denied access to his or her records, it may not

¹⁴ “Guide to Professional Conduct and Ethics for Registered Medical Practitioners”, Medical Council, 7th Edition 2009, page 19.

¹⁵ “Good Medical Practice”, British Medical Council. The publication may be viewed at: http://www.gmc-uk.org/guidance/good_medical_practice/contents.asp

¹⁶ “Government response to the NHS Future Forum report”, June 2011 (CM 8113).

¹⁷ See Jones, “Medical Negligence”, 3rd ed., London, Thomson Sweet & Maxwell (2003).

¹⁸ *McInerney v MacDonald* [1992] 2 S.C.R. 138.

be possible for the patient to establish that this duty has been fulfilled. As I see it, it is important that the patient have access to the records for the very purposes for which it is sought to withhold the documents, namely, to ensure the proper functioning of the doctor-patient relationship and to protect the well-being of the patient. If there has been improper conduct in the doctor's dealings with his or her patient, it ought to be revealed. The purpose of keeping the documents secret is to promote the proper functioning of the relationship, not to facilitate improper conduct.”

Some judicial comment in England – albeit not forming the basis for the decisions concerned – has favoured the proposition that a duty of “candid disclosure” on the part of a medical or other healthcare professional may exist, whether under contract (where such is the basis for treatment) or in tort. In *Lee v. South West Thames Regional Health Authority*¹⁹, the Court of Appeal, while “reluctantly” dismissing an appeal against a refusal to order pre-discovery under the English rules of court of a report which had been brought into existence at the request of a prospective defendant after the possibility of litigation had become known, stated:

“It should never be forgotten that we are here concerned with a hospital-patient relationship. The recent decision of the House of Lords in *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 2 W.L.R. 480 affirms that a doctor is under a duty to answer his patient's questions as to the treatment proposed. We see no reason why this should not be a similar duty in relation to hospital staff. This duty is subject to the exercise of clinical judgment as to the terms in which the information is given and the extent to which, in the patient's interests, information should be withheld. Why, we ask ourselves, is the position any different if the patient asks what treatment he has in fact had? Let us suppose that a blood transfusion is in contemplation. The patient asks what is involved. He is told that a quantity of blood from a donor will be introduced into his system. He may ask about the risk of AIDS and so forth and will be entitled to straight answers. He consents. Suppose that, by accident, he is given a quantity of air as well as blood and suffers serious ill effects. Is he not entitled to ask what treatment he in fact received, and is the doctor and hospital authority not obliged to tell him, “In the event you did not only get a blood transfusion. You also got an air transfusion”? Why is the duty different before the treatment from what it is afterwards?

If the duty is the same, then if the patient is refused information to which he is entitled, it must be for consideration whether he could not bring an action for breach of contract claiming specific performance of the duty to inform. In other words, whether the patient could not bring an action for discovery, albeit upon a novel basis.”²⁰

In *Naylor v Preston Area Health Authority*²¹, Sir John Donaldson MR canvassed the possibility that such a duty might arise as a part of the duty of care of a medical carer in tort:

“I personally think that in professional negligence cases, and in particular in medical negligence cases, there is a duty of candour resting upon the professional man. ... This also appears to be recognised by the Medical Defence Union, whose view is that “the patient is entitled to a prompt, sympathetic and above all truthful account of what has occurred”: *Journal of the Medical Defence Union*, Spring 1987, p. 23. It was also the view (admittedly obiter) of myself and Mustill L.J., as expressed in our judgment in *Lee v. South West Thames Regional Health Authority* [1985] 1 W.L.R. 845, 850. In this context I was disturbed to be told during the argument of the present

¹⁹ [1985] 1 WLR 145. Sir John Donaldson MR delivered the Court's judgment.

²⁰ *ibid.*, at pages 850 to 851.

²¹ [1987] 1 WLR 958.

appeals that the view was held in some quarters that whilst the duty of candid disclosure, to which we there referred, might give rise to a contractual implied term and so benefit private fee-paying patients, it did not translate into a legal or equitable right for the benefit of N.H.S. patients. This I would entirely repudiate. In my judgment, still admittedly and regretfully obiter, it is but one aspect of the general duty of care, arising out of the patient-medical practitioner or hospital authority relationship and gives rise to rights both in contract and in tort. It is also in my judgment, not obiter, a factor to be taken into account when exercising the jurisdiction under Order 38 with which we are concerned.”

Statutory provisions on pre-action disclosure

At present, the Data Protection and Freedom of Information legislation provide the statutory basis of an individual’s entitlement to access clinical records concerning them, there being no provision in statute – along the lines of the UK’s Access to Health Records Act 1990 – which would specifically facilitate disclosure for the purposes of pursuit of a clinical negligence claim.²²

The Data Protection Acts 1988 and 2003 confer on an individual a right, on giving notice in writing, to -

- be informed by a data controller²³ whether the data processed by or on behalf of the data controller include personal data relating to the individual;
- if it does, be supplied by the data controller with a description of the categories of data being processed by or on behalf of the data controller and the personal data constituting the data of which that individual is the data subject, the purpose or purposes of the processing, and
- have communicated to him or her in intelligible form the information constituting any personal data of which that individual is the data subject.²⁴

The Freedom of Information Acts 1997 and 2003, afford, subject to exceptions and qualifications, a right of access by individuals to records held by public bodies concerning them,²⁵ the Health Service Executive being such a public body. Access to personal information²⁶ is available where the information concerned relates to the requester, or an individual to whom the information relates consents to its disclosure to the requester.²⁷

Section 8 of the Civil Liability and Courts Act 2004 places an onus on a claimant in respect of personal injuries to notify in writing the person against whom the claim is to be made of the nature of the wrong alleged to have been committed by him or her, within two months from the date of the cause of action²⁸ or

²² The Department of Health and Children circulated a discussion document on a Health Information Bill in 2008, the objects of which were stated to include

- to establish a legislative framework to enable information – in whatever form - to be used to best effect to enhance medical care and patient safety, and
- to underpin an effective information governance structure for the health system generally.

It is understood that the Bill is currently in process of being drafted.

²³ “data controller” means a person who, either alone or with others, controls the contents and use of personal data: section 1, Data Protection Act 1988.

²⁴ Section 4, Data Protection Act 1988, as amended.

²⁵ Section 6, Freedom of Information Act 1997.

²⁶ “personal information” includes information about an identifiable individual that is held by a public body on the understanding that it would be treated by it as confidential and encompasses “information relating to the educational, medical, psychiatric or psychological history of the individual”: section 2, Freedom of Information Act 1997.

²⁷ Section 28(1) and (2) of the 1997 Act.

²⁸ “date of the cause of action” means (a) the date of accrual of the cause of action, or (b) the date of knowledge, as respects the cause of action concerned, of the person against whom the wrong was committed or alleged to have been committed, whichever occurs later: section 8(2) of the 2004 Act.

as soon as practicable thereafter. In the event that this is not done, the court hearing a subsequent action for damages may -

- (a) draw such inferences from the failure as appear proper, and
- (b) where the interests of justice so require—
 - (i) make no order as to the payment of costs to the plaintiff, or
 - (ii) deduct such amount from the costs that would, but for this section, be payable to the plaintiff as it considers appropriate.²⁹

The opportunity for apology

In a community-based survey conducted for the 2003 initiative to reform the NHS's approach to dealing with clinical negligence,³⁰ almost 60% of respondents who had suffered injury as a result of medical treatment indicated that they considered an apology, explanation or inquiry into the cause of the incident as the most appropriate remedy. 11% indicated that they regarded financial compensation as the most appropriate remedy. In more serious cases, 15% of respondents indicated they would have been satisfied by an apology and 35% sought support in dealing with the consequences. The proportion indicating a preference for financial compensation rose in accordance with the severity of the incident but did not exceed 15% in any severity category.³¹

An exercise in 2001 to evaluate the NHS complaints system regarding negligent treatment disclosed lack of explanations and apologies to patients or their families as one of the primary sources of complaints.³²

This research indicates the significance of an apology and other measures short of financial compensation in meeting at least certain types of complaint by patients following adverse incidents.

Peart J in *O'Connor v Lenihan*³³ - a case involving a claim arising out of organ retention - has noted that -

“our legal system is not conducive to such steps [i.e. by way of apology] being taken by defendants exposed to a claim for damages once fault might be seen to be acknowledged by such an apology, and are inhibited from taking a step which perhaps in other circumstances they would wish to take in order to assist those who have suffered distress and hurt.”

In its report “Alternative Dispute Resolution: Mediation and Conciliation” of November 2010,³⁴ the Law Reform Commission recommended that statute should provide that an apology (including an apology made by a health care practitioner³⁵ in respect of any care or treatment) made by or on behalf of a person who may become or who is a party in a personal injuries action, whether before or after any action has been initiated in court, in respect of a matter to which any such action may relate or relates (a) does not constitute an express or implied admission of civil liability by that party, and (b) is not relevant to the determination of civil liability in the action. The Commission further recommended that evidence of an

²⁹ Section 8(1), Civil Liability and Courts Act 2004.

³⁰ Donaldson, op. cit..

³¹ Donaldson, op. cit., Chapter 4, para. 2.

³² Donaldson, op. cit., Chapter 4, para. 4.

³³ High Court, 9th June, 2005, and cited in the Law Reform Commission's Consultation Paper “Alternative Dispute Resolution” (LRC CP 50 – 2008), Chapter 6, page 222

³⁴ (LRC 98-2010).

³⁵ This expression was intended to cover a registered medical practitioner, dentist or nurse.

apology made by or on behalf of a person as set out above in respect of a matter to which the action relates is not admissible in any civil proceedings as evidence of civil liability of the person.³⁶

In the last decade, legislation has been introduced in many common law jurisdictions facilitating the making of an apology by dissociating it from an admission of liability or rendering it inadmissible as evidence in court in civil liability cases.³⁷ One commentator has described the various approaches in the provisions concerned:

“The definition of apology used is either the ‘statement of regret or benevolent gesture’ which stops short of admitting fault (a ‘partial’ apology) or the ‘full’ apology which includes an admission of fault. Most of the provisions protect only partial apologies. Some provisions deem the apology not to be an admission of liability while others only limit admissibility in court. Some provisions directly prevent an apology from affecting insurance contracts. The Canadian provisions also prevent apologies from making time run under limitation acts. The scope of matters where the protection applies also varies. Many provisions in the United States restrict apologies to certain aspects of medical practice or some other aspect of personal injury. In Australia some jurisdictions restrict them to certain areas of tort law.”³⁸

The English provision - section 2 of the Compensation Act 2006 – is somewhat minimalist in approach, and the explanatory note states that it is intended to reflect the existing law. Section 2 provides:

“An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty.”

By contrast, section 2 of British Columbia’s Apology Act 2006 appears to be the most comprehensive provision in effect. It provides:

- “2. (1) An apology made by or on behalf of a person in connection with any matter
- (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter,
 - (b) does not constitute a confirmation of a cause of action in relation to that matter for the purposes of section 5 of the Limitation Act,
 - (c) does not, despite any wording to the contrary in any contract of insurance and despite any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available to the person in connection with that matter, and
 - (d) must not be taken into account in any determination of fault or liability in connection with that matter.
2. (2) Despite any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any proceeding and must not be referred to or disclosed to a court in any proceeding as evidence of the fault or liability of the person in connection with that matter.”

³⁶ Chapter 7.47 and 48.

³⁷ See survey in Vine, "Apologies and Civil Liability in England, Wales and Scotland: The View from Elsewhere" [2007] University of New South Wales Faculty of Law Research Series 61.

³⁸ Vine, *op. cit.*

Alternative Dispute Resolution (ADR)

Exchange of information between patient and medical or health carer is also a pre-requisite to the facilitating, where feasible, of a resolution by means alternative to litigation of a patient complaint.³⁹

A commentator on the use of ADR to resolve disputes in respect of healthcare has noted:

“The crisis within the healthcare system is caused in large part by the use of the adversarial process alone to resolve medical malpractice disputes, breaking down trust between doctor and patient. The cost of this breakdown of trust cannot be overestimated and must be considered together with the monetary cost of increasing litigation and medical insurance. Doctors are becoming more defensive in practising medicine. Patients are losing confidence in doctors, seeing them primarily as safeguarding their own interests to the detriment of patient treatment and care.”⁴⁰

Mediation as a possible approach to resolving patient complaints is already a feature of the legislative regime governing the medical profession. The Medical Practitioners Act 2007 provides for the possibility of mediation in relation to a complaint – including a complaint of professional misconduct or poor professional performance - made against a registered medical practitioner. The Preliminary Proceedings Committee of the Medical Council, whose function it is to give initial consideration to such complaints, is required, if in its opinion a complaint is one that could be resolved by mediation or other informal means, to inform the Council of that opinion, and the Council is empowered to refer the complaint for resolution by mediation or other informal means.⁴¹ The Council has prepared guidelines under the 2007 Act for the resolution of complaints by mediation.⁴² Mediation under the 2007 Act may not, however, include the payment by any party of any financial compensation.⁴³

Recourse to mediation or other informal means of resolving a complaint requires the consent of the complainant and the practitioner concerned.⁴⁴ A consent to such recourse by a registered medical practitioner complained of may not be taken as an admission of any allegation,⁴⁵ and statements and responses in the course of the mediation process are not admissible in any disciplinary, civil or criminal proceedings.⁴⁶

Similar provisions facilitating recourse to mediation have been introduced in the Health and Social Care Professionals Act 2005⁴⁷ in respect of complaints against members of designated or social care professions and in the Pharmacy Act 2007⁴⁸ concerning complaints against registered pharmacists, and a like facility was envisaged for complaints against registered nurses or registered midwives in the Nurses and Midwives Bill 2010, which had not been enacted prior to dissolution of the last Dáil.

Section 15 of the Civil Liability and Courts Act 2004 empowered the court on the application of a party in an action for personal injuries to direct that the parties meet to discuss and attempt to settle the action in a mediation conference chaired by a mediator appointed by agreement of all the parties or by the court.

³⁹ See, e.g., Maguire, “Alternatives to Litigation in Medical Negligence Actions” (1993) 11 ILT 250; Mills, “ “We Need to Talk”—Mediation in the Clinical Setting in Ireland” (2010) 16(2) MLJI 64.

⁴⁰ Ward, “Mediation: An Invaluable Component of Any Alternative Dispute Resolution Forum within the Irish Healthcare System” (2001) 7(2) MLJI 63.

⁴¹ Section 61, of the Medical Practitioners Act 2007.

⁴² The guidelines may be viewed at: <http://www.medicalcouncil.ie/Professional-Standards/Mediation-Guidelines/>

⁴³ Section 62(6) of the Medical Practitioners Act 2007.

⁴⁴ Section 62(3) of the Medical Practitioners Act 2007.

⁴⁵ Section 62(4) of the Medical Practitioners Act 2007.

⁴⁶ Section 62(5) of the Medical Practitioners Act 2007.

⁴⁷ See sections 55 and 56 of the Health and Social Care Professionals Act 2005.

⁴⁸ See sections 37, 40 and 58 of the Pharmacy Act 2007.

The Law Reform Commission, in its report “Alternative Dispute Resolution: Mediation and Conciliation”⁴⁹ referred to above recommended that the State Claims Agency should, where appropriate, consider and attempt ADR processes, including mediation and conciliation, in the resolution of medical negligence cases,⁵⁰ and that an early neutral evaluation scheme be introduced for personal injury claims, including any claims arising out of medical treatment. Early neutral evaluation was envisaged as:

“a process that occurs at an early stage of civil proceedings in which the parties state the factual and legal circumstances to an independent third party (the “early neutral evaluator”) with suitable knowledge of the subject matter of the dispute, and in which the early neutral evaluator provides an evaluation to the parties as to what the likely outcome of the proceedings would be if the claim proceeded to a hearing in court.”⁵¹

The Commission also recommended that provision be made in the Code of Conduct for Mediators and Conciliators, which it considered should be introduced, for the use of early neutral evaluation in personal injuries claims.⁵²

The Clinical Negligence Pre-action Protocol in England and Wales

Aims and objectives

The protocol expresses as its general aims the maintenance or restoration of the patient/healthcare provider relationship and the resolution of as many disputes as possible without litigation. Specific objectives of the protocol are stated under a number of headings, as follows:

“Openness

- to encourage early communication of the perceived problem between patients and healthcare providers;
- to encourage patients to voice any concerns or dissatisfaction with their treatment as soon as practicable;
- to encourage healthcare providers to develop systems of early reporting and investigation for serious adverse treatment outcomes and to provide full and prompt explanations to dissatisfied patients;
- to ensure that sufficient information is disclosed by both parties to enable each to understand the other’s perspective and case, and to encourage early resolution.

Timeliness

- to provide an early opportunity for healthcare providers to identify cases where an investigation is required and to carry out that investigation promptly;
- to encourage primary and private healthcare providers to involve their defence organisations or insurers at an early stage;
- to ensure that all relevant medical records are provided to patients or their appointed representatives on request, to a realistic timetable by any healthcare provider;

⁴⁹ Op. cit..

⁵⁰ Paragraph 7.12 of the report.

⁵¹ Paragraph 7.24 of the report.

⁵² Paragraph 7.25 of the report.

- to ensure that relevant records which are not in healthcare providers' possession are made available to them by patients and their advisers at an appropriate stage;
- where a resolution is not achievable to lay the ground to enable litigation to proceed on a reasonable timetable, at a reasonable and proportionate cost and to limit the matters in contention;
- to discourage the prolonged pursuit of unmeritorious claims and the prolonged defence of meritorious claims.

Awareness of Options

- to ensure that patients and healthcare providers are made aware of the available options to pursue and resolve disputes and what each might involve.”

Good practice commitments

The protocol also sets out a list of “good practice commitments” which should be adhered to respectively by healthcare providers and by patients and their advisers. Healthcare providers are expected to: observe commonly accepted standards of clinical governance; set up adverse outcome reporting systems and learn from such incidents; engage in effective communication with patients; and establish efficient and effective systems of recording and storing patient records. In the event of an adverse incident, healthcare providers should:

“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.”⁵³

Patients and their advisers should: report any concerns and dissatisfaction to the healthcare provider as soon as is reasonable to enable advice to be given and appropriate action to be taken; consider the full range of options available to the patient following an adverse outcome, including a request for an explanation, a meeting, a complaint, and appropriate dispute resolution methods alternative to litigation; and inform the healthcare provider on being 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.

The Protocol Steps

A revised version of the protocol has recently been prepared by the Clinical Disputes Forum. This version, which has not yet been approved by the Civil Procedure Rules Committee,⁵⁴ essentially envisages the following steps being taken or matters being considered by the parties:

1. A request for records by the patient or their adviser should be made providing sufficient information to alert the healthcare provider where an adverse outcome has been serious or had

⁵³ Para. 3.4 of the protocol.

⁵⁴ It is understood that this version of the protocol was considered by the Criminal Justice Council Protocol Oversight Committee at the end of 2010, which agreed in principle to submit a revised Protocol, incorporating the amendments contained in the CDF document, to the Civil Procedure Rules Committee. However, the contents of the Clinical Negligence pre-action protocol, in common with various other pre-action protocols, are now subject to review in light of the conclusions and recommendations of Lord Justice Jackson in his “Review of Civil Litigation Costs” (final report) of December 2009. These are considered later in this chapter.

serious consequences and should be as specific as possible as to the records required. Requests for copies of clinical records are to be made using a form appended to the pre-action protocol, adapted as necessary.⁵⁵

2. The copy records requested should be provided, using the forms of response appended to the protocol, within 40 days of the request at a cost not exceeding the statutory charges permissible,⁵⁶ and where the healthcare provider is in difficulty in complying with the request within 40 days, the problem should be explained quickly and details given of the efforts being made to resolve it.

3. Where the healthcare provider fails to provide the health records within 40 days, the patient or their adviser may apply to the court for an order for pre-action disclosure.

4. Additional health records required by the patient or the healthcare provider from a third party should in the first instance be requested by or through the patient. Third party healthcare providers are expected to co-operate. An application to the court to require a third party to make pre-action disclosure may ultimately be required.

5. Following receipt and analysis of the records, and the receipt of an initial supportive medical report dealing with breach of duty and/or causation, the claimant should consider sending a Letter of Notification - guidelines as to the content of which are contained in the protocol - to the healthcare provider as soon as practicable. This letter - which would introduce a new stage in the sequence of steps required by the Protocol currently in force - should confirm that the case is still being investigated and that it is premature to send a Letter of Claim, but advise the healthcare provider that the claimant has obtained supportive independent expert evidence about breach of duty and (if this has been obtained) causation and that the case is likely to result in a Letter of Claim being sent in due course. The claimant should at the same time send a copy of the Letter of Notification to the National Health Service Litigation Authority or other relevant Medical Defence Organisation or indemnity provider (where known).

6. The healthcare provider (and any defence organisation sent a copy of the Letter of Notification) should acknowledge the letter within 14 days of receipt and should identify who will be dealing with the matter.

7. On receipt of a Letter of Notification the healthcare provider should then consider whether or not to undertake its own investigations into the case and whether or not to obtain its own expert evidence, in anticipation of its having to respond to a Letter of Claim later on.⁵⁷

8. There should be a reasonable lapse of time between a Letter of Notification, which should only be sent where supportive expert evidence as to breach of duty and/or causation has been obtained, and any later Letter of Claim. Attempts to misuse this two-stage process may be met with costs sanctions.

⁵⁵ The form is appended to the revised version of the pre-action protocol available on the Clinical Disputes Forum's website at : <http://www.clinical-disputes-forum.org.uk/files/projectfiles/ProtocolFull.doc>

⁵⁶ In England, a maximum of £10 plus photocopying and postage is chargeable under the Access to Health Records Act 1990 and the Data Protection Act 1998.

⁵⁷ Whether or not the claimant sent a Letter of Notification and whether or not the healthcare provider initiated investigations upon its receipt would be taken into account by the court when considering the extent to which either party has complied with its obligations under the Protocol, and when considering the extent to which it is reasonable for a healthcare provider to have an extension of time for its Letter of Response.

9. If on analysing the records received and considering any further advice, the patient or their adviser decides that there are grounds for a claim, they should then send, as soon as practicable, a Letter of Claim in the form recommended by the protocol – the level of detail being varied to suit the particular circumstances - to the healthcare provider or potential defendant. The Letter of Claim should contain sufficient information to enable the healthcare provider/defendant to commence investigations and to put an initial valuation on the claim. Specifically, the letter should -

- contain a clear summary of the facts on which the claim is based, including the alleged adverse outcome,
- contain the main allegations of negligence,
- describe the patient's injuries, and present condition and prognosis,
- outline the financial loss incurred by the plaintiff with an indication of the heads of damage to be claimed and the scale of the loss, unless this is impracticable,
- in more complex cases, provide a chronology of the relevant events, particularly if the patient has been treated by a number of different healthcare providers,
- refer to any relevant documents, including health records and
- if possible enclose copies of any of those which will not already be in the potential defendant's possession.

The letter should be copied to the National Health Service Litigation Authority where the original is sent to an NHS Trust or Independent Sector Treatment Centre.

10. Any offer to settle the claim which the patient or their adviser may wish to make at this early stage (possibly including any costs incurred to date) should be supported by a medical report which deals with the injuries, condition and prognosis, and by a schedule of loss and supporting documentation. The level of detail necessary will depend on the value of the claim. Medical reports may not be necessary where there is no significant continuing injury, and a detailed schedule may not be necessary in a low value case.

11. The healthcare provider should acknowledge the Letter of Claim within 14 days of receipt and identify who will be dealing with the matter.

12. The healthcare provider should, within four months of the letter of claim,⁵⁸ provide a reasoned response (a recommended template form of which is provided) and in that response:

- if the claim is admitted, should say so in clear terms;
- if only part of the claim is admitted, should make clear which issues of breach of duty and/or causation are admitted and which are denied and why;
- indicate if it is intended that any admissions will be binding;
- if the claim is denied, should include specific comments on the allegations of negligence and if a synopsis or chronology of relevant events has been provided and is disputed, the healthcare provider's version of those events;

⁵⁸ In the original version of the protocol, the period allowed had been three months. The extended period was incorporated into the official version in 2010.

- where additional documents are relied upon, e.g. an internal protocol, should provide copies;
- if the patient has made an offer to settle, should respond to that offer, preferably with reasons, and accompany any offer made in reply by any supporting medical evidence, and/or by any other evidence in relation to the value of the claim which is in the healthcare provider's possession.

13. Where the parties reach agreement on liability but need time to agree on the value of the claim, they should seek to agree a reasonable period.

14. The protocol recommends that the parties should consider an alternative form of dispute resolution procedure to litigation, and seek to agree which form to adopt. The protocol notes that should proceedings issue, the claimant and defendant may be required by the court to provide evidence that alternative means of resolving their dispute were considered. The protocol warns parties that if it, including the recommendation to consider ADR, is not followed, the Court must have regard to that conduct when determining costs.

15. Proceedings should not be issued until after four months from the letter of claim, unless there is a limitation period difficulty and/or the patient's position needs to be protected by early issue.

Compliance and sanctions

The Civil Procedure Rules provide that the court has discretion as to whether costs are payable by one party to another; the amount of those costs; and when they are to be paid. In deciding what order to make in relation to costs, the court must have regard to all the circumstances, including the conduct of all the parties. The conduct of the parties includes conduct before, as well as during, the proceedings and in particular the extent to which the parties followed the Practice Direction (Pre-Action Conduct) or any relevant pre-action protocol.⁵⁹

Under the terms of the Practice Direction governing pre-action conduct generally, the court will expect the parties to have complied with this Practice Direction or any relevant pre-action protocol. The court may ask the parties to explain what steps were taken to comply prior to the start of the claim. Where there has been a failure of compliance by a party the court may ask that party to provide an explanation.

If, in the opinion of the court, there has been non-compliance, the sanctions which the court may impose include:

1. staying (i.e. suspending) the proceedings until steps which ought to have been taken have been taken;
2. an order that the party at fault pays the costs, or part of the costs, of the other party or parties;
3. an order that the party at fault pays those costs on an indemnity basis;
4. if the party at fault is the claimant in whose favour an order for the payment of a sum of money is subsequently made, an order that the claimant is deprived of interest on all or part of that sum, and/or that interest is awarded at a lower rate than would otherwise have been awarded;

⁵⁹ Civil Procedure Rules 44.3(1), 44(4)(a) and 44(5)(a).

5. if the party at fault is a defendant, and an order for the payment of a sum of money is subsequently made in favour of the claimant, an order that the defendant pay interest on all or part of that sum at a higher rate, not exceeding 10% above base rate, than would otherwise have been awarded.⁶⁰

Offers to settle

In the First Report, the Group explained the relevant Civil Procedure Rules (Part 36) as they concerned offers to settle (known as “Part 36 offers”) making provision for periodical payments.⁶¹ The salient aspects of the procedure are as follows.

Offers to settle may, under Part 36, be made at any time, including before the commencement of proceedings.⁶² Following reforms of which came into operation in 2007, a single approach to offers of settlement has been adopted to offers made before and after commencement of proceedings. A defendant is no longer required to make a payment into court. Unless the parties agree otherwise in writing, where a Part 36 offer by a defendant that is or includes an offer to pay a single sum of money is accepted, that sum must be paid to the offeree within 14 days of the date of acceptance or an order for an award of provisional damages or awarding periodical payments, unless the court orders otherwise. If the accepted sum is not paid within the 14 days or other period agreed, the offeree may enter judgment for the unpaid sum.

Part 36 offers must, among other requirements, specify a period of not less than 21 days within which the defendant will be liable for the claimant’s costs if the offer is accepted.

If a Part 36 offer is accepted, the claim will be stayed. Where a Part 36 offer is accepted within 21 days or longer if offered, the claimant will be entitled to his costs of the proceedings up to the date on which notice of acceptance was served on the offeror.

Where a claimant fails to obtain a judgment more advantageous than a defendant’s Part 36 offer, the court will, unless it considers it unjust to do so, declare the defendant entitled to his costs from the date on which the relevant period expired and interest on those costs. Where judgment against the defendant is at least as advantageous to the claimant as the proposals contained in a claimant’s Part 36 offer, the court will, unless it considers it unjust to do so, declare the claimant entitled to:

- (a) interest on the whole or part of any sum of money (excluding interest) awarded at a rate not exceeding 10% above base rate (GL) for some or all of the period starting with the date on which the relevant period expired;
- (b) his costs on the indemnity basis from the date on which the relevant period expired; and
- (c) interest on those costs at a rate not exceeding 10% above base rate.

Experience of the operation of the protocol in England and Wales

In his wide-ranging review of civil litigation costs in England and Wales conducted in 2008 and 2009, Lord Justice Jackson stated that it was clear from the extensive comments received during his consultation exercise that the three separate pre-action protocols governing claims for personal injury, disease and illness and clinical negligence, respectively, “are regarded as making a valuable contribution. The majority of personal injury claims and a substantial minority of clinical negligence claims are

⁶⁰ Para. 4.6, Practice Direction – Pre-Action Conduct

⁶¹ Pages 35 to 36 of the report.

⁶² Civil Procedure Rule 36.3(2)(a).

resolved during the protocol period.”⁶³ However, Lord Justice Jackson had a number of concerns in relation to the operation of the clinical negligence protocol as follows:

“Settlement is not usually achieved during the protocol period. The evidence ... shows that only a minority of meritorious clinical negligence claims are settled before issue of proceedings. In the majority of such cases the claimant issues proceedings before settlement is achieved. This factor generates unnecessarily high costs.....

... I conclude that excessive costs are being incurred in relation to meritorious clinical negligence cases which ought to (but do not) settle early, for seven reasons:

- (i) There is no effective control over the costs which claimant lawyers may incur before sending a letter of claim or between the date of the letter of claim and the date when proceedings are issued.
- (ii) When NHS Trusts and similar bodies receive letters of claim, they sometimes fail to notify the NHSLA⁶⁴.
- (iii) In a number of cases it is not possible for the defendant’s advisers to investigate the claim “from scratch” within three months, starting on the date when the letter of claim is received. Thus the limited period allowed to defendants by the protocol can lead to proceedings being issued unnecessarily.
- (iv) Although the MDU and MPS⁶⁵ normally obtain independent expert evidence upon receipt of a letter of claim, the NHSLA seldom does so. Instead, the NHSLA usually relies upon comments obtained from the clinicians involved or others at the relevant NHS Trust.
- (v) In some cases the defence team fails to come to grips with the issues until too late.
- (vi) In some cases either the claimant’s advisers or the defendant’s advisers send protocol letters which do not comply with either the letter or the spirit of paragraphs 3.14 to 3.25 of the protocol. For example, the claimant may not provide quantum information or the defendant may not give proper reasons for denying liability.
- (vii) On some occasions the defendant is willing to settle without admitting liability, but the protocol makes no provision for this.

... It is also clear from the extensive comments received that (a) a number of amendments to these protocols merit consideration and (b) there are significant problems of non-compliance.”⁶⁶

Lord Justice Jackson rejected the suggestion – contained in the version of the protocol proposed by the Clinical Disputes Forum - that there be a requirement for a letter of notification in advance of the letter of claim required by the protocol, taking the view that it would “add an unwelcome layer of complexity”. Instead, he recommended that the time allowed for the response letter under the protocol be increased from three months to four months - a measure since taken in the amendment of the official version of the protocol in 2010. He also recommended that any letter of claim sent to an NHS Trust or Independent

⁶³ Lord Justice Jackson, Final Report “Review of Civil Litigation Costs”, December 2009, Chapter 35, para. 5.8, page 352.

⁶⁴ The NHS Litigation Authority, which handles negligence claims for the nationalised health sector.

⁶⁵ The Medical Defence Union and Medical Protection Society – medical practitioner defence organisations.

⁶⁶ Lord Justice Jackson, *op. cit.*, Chapter 23, para. 4.8, page 240.

Sector Treatment Centre should be copied to the NHSLA, so as to remove the potential for delay in the NHSLA being notified by such bodies.

Lord Justice Jackson recommended that where the NHSLA is proposing to deny liability in respect of any claim (other than a frivolous one), it should obtain independent expert evidence on liability and causation during the four month period allowed for the response letter.

He considered that failure by some defendants to address the issues during the protocol period should be addressed by better liaison between (a) claimant solicitors and (b) the defence organisations.

To facilitate settlement in cases where a defendant will not admit liability but where, its insurers are prepared to pay a reasonable sum to settle the claim, Lord Justice Jackson recommended a three month moratorium on the issue of proceedings, to enable the parties to make efforts to settle. Should the claimant commence proceedings during that period without good reason (such as expiry of the limitation period), the claimant would not be entitled to recover the costs referable to those proceedings during the three month period.⁶⁷

Notwithstanding the powers conferred on the court to ensure compliance with pre-action protocols referred to earlier, Lord Justice Jackson noted “serious problems” of non-compliance⁶⁸ and recommended that, in the event of non-compliance causing serious prejudice to a claimant or respondent, the affected party should be entitled to apply to court for various directions as follows:

- (i) that the parties are relieved from the obligation to comply or further comply with the protocol;
- (ii) that a party do take any step which might be required in order to comply with the protocol;
- (iii) that the party in default do pay such costs as may be summarily assessed by the court as compensation for losses caused by that default;
- (iv) that the party in default do forego such costs as may be specified in the event that it subsequently secures a favourable costs order;
- (v) if the case is in the fast track (available to less complex cases under the Civil Procedure Rules case management regime), that the fixed costs regime do cease to apply to that case.⁶⁹

The Group was extremely fortunate in having available to it during this Module - as during the previous one – the advice and assistance of Mr. Steve Walker, CEO, National Health Service Litigation Authority, Mr. Matthew McGrath, Litigation Partner, Beachcroft Solicitors, UK and Ms. Lisa Jordan, Partner, Irwin Mitchell Solicitors, UK, who met the Group and provided information on the operation of the protocol to date from a practitioner’s perspective. The Group was also very privileged to have the benefit during this Module of the views of His Honour Judge Graham Jones, chairperson of the Working Party reviewing the Pre-Action Protocol associated with the Civil Procedure Rules for England and Wales, who was most generous in imparting to the Group, from a judge’s perspective, his considerable experience of and insight into the management of clinical negligence litigation in that jurisdiction.

The views expressed to the Group by the legal practitioners consulted were, it is fair to say, more positive than the assessment by Lord Justice Jackson. The Group was informed that the Clinical Negligence Pre-

⁶⁷ Lord Justice Jackson, *op. cit.*, Chapter 23, para. 4.7 et seq., pages 240 to 241.

⁶⁸ Chapter 39, para. 6.1, page 396.

⁶⁹ *Ibid.*, Chapter 39, para. 6.2, page 396.

action Protocol had worked well in practice, gaining wide acceptance both by claimants and respondents and their advisors, as was attested by the very limited extent of amendments made to the protocol when it was re-issued recently.⁷⁰ The protocol had assisted in rendering the handling of claims for clinical negligence more straightforward.

The Group understands that the facility to make an offer of settlement was rarely availed of in catastrophic injury cases, as special damages could not be finalised within the time frame of the pre-action protocols. It noted the apparent experience in England and Wales that very few catastrophic injury cases were settled prior to the issue of the proceedings. Nonetheless, the general view of the UK experts was that the pre-action protocols were invaluable in the larger cases. The availability of expert reports prior to the issue of the proceedings was seen as critical to identifying cases, regardless of the magnitude of the injury, in which liability was not properly at issue, and in ensuring that clinical negligence proceedings, regardless of the potential compensatory value of the injuries, were focused from the start on the correct liability and causation issues.

It was acknowledged that the operation of the protocol did have drawbacks. The expectation is that there will be a final answer on breach of duty and causation within a four-month period. In higher-end catastrophic cases, however, defendants will find it difficult to respond within four months, due in part to the limited number of experts available in the UK on particular issues. The protocol had also led to the front loading of fees: indemnifiers and insurers are required to invest significant amounts at the front end of every potential case with the prospect that a proportion of these will probably never proceed. Overall, however, it was suggested that pre-litigation protocols save significant expense, in encouraging an exchange of information and early offers.

The protocol had not led to any noticeable increase in the volume of interlocutory applications. Even where disclosure is not made by a respondent health provider within the 40 days, legal advisors are aware that they are en route so they do not tend to bring an application to court.

The Group had concerns about the impact of the protocol on the ability of a claimant to issue proceedings within the limitation period. However, it would appear that the provision in the protocol allowing for proceedings to be issued within the four month period from issue of the letter of claim where there is a limitation period difficulty, provides sufficient safeguard in this respect. The Group notes that, while the general time limit in the UK for actions in respect of personal injuries is three years from the date on which the cause of action accrued or the date of knowledge (if later) of the person injured,⁷¹ provision exists allowing the court to dis-apply the limitation period, if having regard to the degree of prejudice likely to result to the parties respectively, it appears to it equitable to allow an action to proceed.⁷²

⁷⁰ In particular, the time to respond to a letter of claim was enlarged to 4 months from 3 months.

⁷¹ Section 11, Limitation Act 1980.

⁷² Section 33, Limitation Act 1980. In applying this section, the court is required to have regard to all the circumstances of the case and in particular to—

- (a) the length of, and the reasons for, the delay on the part of the plaintiff;
- (b) the extent to which, having regard to the delay, the evidence adduced or likely to be adduced by the plaintiff or the defendant is or is likely to be less cogent than if the action had been brought within the limitation period;
- (c) the conduct of the defendant after the cause of action arose, including the extent (if any) to which he responded to requests reasonably made by the plaintiff for information or inspection for the purpose of ascertaining facts which were or might be relevant to the plaintiff's cause of action against the defendant;
- (d) the duration of any disability of the plaintiff arising after the date of the accrual of the cause of action;
- (e) the extent to which the plaintiff acted promptly and reasonably once he knew whether or not the act or omission of the defendant, to which the injury was attributable, might be capable at that time of giving rise to an action for damages;
- (f) the steps, if any, taken by the plaintiff to obtain medical, legal or other expert advice and the nature of any such advice he may have received.

It was noted that, by contrast with the notification required under section 8 of the Civil Liability and Courts Act 2004, the letter of claim cannot be prepared until the various issues bearing upon the claim have been identified.

Other pre-litigation regimes

It has been observed that “[p]re-action protocols do not appear to be a standard feature of the litigation landscape in North American jurisdictions.”⁷³ Of the other common law jurisdictions, Australia has perhaps been foremost in the adoption of pre-action procedures in civil litigation generally.

Queensland was one of the first jurisdictions within Australia to introduce pre-action procedures, by means of the Personal Injuries Proceedings Act 2002 and amendments to other legislation, and various types of personal injury claim in that jurisdiction are now governed by detailed pre-action procedures. The main purpose of the 2002 Act was expressed as being “to assist the ongoing affordability of insurance through appropriate and sustainable awards of damages for personal injury”. The 2002 Act includes quite onerous and detailed provisions for notification of claims and compulsory disclosure of information and documents within prescribed periods, and requires the holding of a compulsory conference and mandatory exchange of final offers between the parties prior to litigation.

A respondent receiving a valid notice of claim must, amongst other obligations, take reasonable steps to inform himself, herself or itself about the incident alleged to have given rise to the personal injury to which the claim relates, give the claimant written notice whether liability is admitted or denied; and if contributory negligence is claimed, the degree of the contributory negligence expressed as a percentage; and if the claimant made an offer of settlement, inform the claimant whether the respondent accepts or rejects the offer. Where no offer has been made, the respondent must invite the claimant to make a written offer of settlement. The respondent must also make a fair and reasonable estimate of the damages to which the claimant would be entitled and make a written offer, or counteroffer, of settlement setting out in detail the basis on which the offer is made, or settle the claim by accepting an offer made by the claimant.

At Commonwealth level, the Civil Dispute Resolution Act 2011 was enacted with the express objects:

- to change the adversarial culture often associated with disputes;
- to have people turn their minds to resolution before becoming entrenched in a litigious position; and
- where a dispute cannot be resolved and the matter proceeds to court, to ensure that the issues are properly identified, thereby reducing the time required for a court to determine the matter.

The 2011 Act seeks to achieve these aims by requiring parties to file a ‘genuine steps statement’ when commencing a civil action, specifying the steps the party has taken to resolve the issues or, if no steps were taken, explaining why not. Non-compliance with this requirement does not bar commencement of proceedings, but the court may, in the event of non-compliance by a party, award costs to the compliant party.⁷⁴

⁷³ Victorian Law Reform Commission Report “Civil Justice Review” (May 2008), Chapter 2 (“Facilitating the Early Resolution of Disputes without Litigation”) para. 3.2.

⁷⁴ Australian Law Reform Commission report “Managing Discovery: Discovery of Documents in Federal Courts” (ALRC Report 115) Sydney (May 2011), Chapter 11 (“Pre-action Protocols and Other Alternatives to Discovery”).

Submissions to the Group

Practitioners who made submissions to the Group were broadly supportive of the need for a pre-trial regime requiring disclosure and providing an opportunity for apology or settlement. Dissatisfaction with the inadequacy of the information available in the notice under section 8 of the Civil Liability and Courts Act 2004 was a recurring theme of submissions, while a number of practitioners pointed to the unrealistic time frame envisaged in section 8 within which a claimant was expected to give notice of the nature of his or her claim. This latter issue will be further considered in the next Chapter.

Conclusions

The need for a pre-action protocol

The Group is satisfied that the resolution of claims for clinical negligence and the conduct of any litigation of such claims would be substantially improved by the introduction of a pre-action protocol.

A pre-action protocol should secure earlier disclosure of patient records than currently is the case, thus facilitating an informed consideration by the parties of any potential claim or defence. It is acknowledged, however, that compliance by healthcare providers in particular will require both a change in the existing culture and additional commitment of resources to meet timescales for release of such information.

Such a protocol should reduce the number of clinical negligence claims which ultimately proceed to litigation, by affording an opportunity for parties to settle the claim or to consider alternative dispute resolution options where appropriate.

Currently, many such claims are commenced before they have been fully investigated and issues of causation, liability and quantum are often only properly evaluated long after the institution of proceedings and the incurring by the parties of considerable costs and expenses. In the result, many claims employ a “scattergun” approach at the outset for want of sufficient investigation and disclosure. A pre-action protocol would serve to accelerate the process of disclosure and evaluation, and to narrow down issues to those legitimately in dispute. Even where a claim did proceed to litigation, the protocol would have served to identify at a much earlier stage the issues which should ultimately be in dispute in the proceedings.

A protocol would also provide an appropriate context - particularly where a respondent healthcare provider would have an appropriate statutory protection for the purpose - for a patient to seek, and in appropriate circumstances obtain, a suitable apology in respect of the adverse event experienced.

The Group is satisfied that a protocol along the lines of that recommended by the Clinical Disputes Forum, and described in detail above, would, with some modifications, serve as the most appropriate model for this jurisdiction, subject to certain issues being addressed in primary and secondary legislation as mentioned below.

The Group notes the concern expressed by Lord Justice Jackson that the introduction of a requirement to send a letter of notification prior to the making of a formal claim would add a further stage to the pre-action steps. However, the Group considers that the giving of such notice would enable the healthcare institution to commence identification of the records relevant to the incident alleged and alert all clinical personnel affected and (as appropriate) the State Claims Agency or insurers. This would facilitate early liaison between those parties with a view to ensuring that an informed response is made to the subsequent letter of claim, within the four month period envisaged for reply to that letter.

The Group also notes the difficulties identified by Lord Justice Jackson in securing compliance with the clinical disputes and other protocols, and recommends that the operation of the protocol be reviewed by the Superior Courts Rules Committee after a period of, say two years from its introduction, with the benefit of input from the legal profession and other interested bodies to ascertain whether changes in the protocol are required or further powers need to be given to the court to secure compliance.

Claims subject to the protocol

It will be necessary to define with some precision the nature of the cause of action to which the pre-litigation regime would apply. The Group offers the following definition as the one most likely to encompass the various types of adverse incident which would give rise to a claim by a patient:

- “Any claim by a person, or a personal representative or dependant of a deceased person, for damages for negligence, breach of statutory duty or breach of contract arising from any act or omission concerning -
- (a) the provision of a health service (including any dental service) to that person,
 - (b) the carrying out of a clinical, medical or surgical procedure (including any dental procedure) in relation to that person,
 - (c) the carrying out of a clinical or medical diagnosis, investigation or research (including any dental diagnosis, investigation or research) in respect of that person,
 - (d) the provision of medical advice and information (including any dental advice and information) to that person,
 - (e) the provision of clinical or medical treatment or care (including any dental treatment or care) to that person, or
 - (f) implantation of, or a defect in, a device or material implanted in that person for medical or cosmetic reasons.”

Content of the protocol

A draft of the protocol recommended by the Group is appended at Appendix 1. The Group acknowledges the assistance provided to it in settling this draft by the current pre-action protocol for clinical negligence disputes in England and Wales and that proposed by the Clinical Disputes Forum by way of further development of the current protocol.

The Group recommends that the protocol appended should regulate the stages of request for records, response to request for records, notification of claim, letter of claim and response to claim, and to that end has prepared template documentation underpinning these stages, as follows -

- Application for clinical records (Form 1 scheduled to the draft protocol).
- First Response to the application for clinical records (Form 2).
- Second Response to the application for clinical records (Form 3).
- Letter of Notification of an intended claim (Form 4).

- Letter of Claim (Form 5).
- Letter of Response (Form 6).

A flowchart of the process is set out at Appendix 2.

The Group recommends that the same time limits for compliance be prescribed as apply under the English protocol, save that seven weeks should be permitted for provision by the healthcare provider of clinical records to the patient and that the protocol should enable those time limits to be extended by agreement of the parties.

Time limits

The Group recommends that the parties to a claim to which the protocol applies should be entitled by agreement in writing to effect a suspension for a specified period of the limitation period affecting the cause of action concerned, on the basis that a party against whom the suspension would operate should be entitled to apply to the court to vacate the suspension should the other party fail to comply with a requirement of the protocol. For the sake of clarity, the form of written agreement concerned should require to be prescribed, preferably by rule of court. It is appreciated that this would require an amendment of the Statute of Limitations (Amendment) Act, 1991.

Court powers and court rule-making authority in respect of the pre-action stage

The introduction of pre-action protocols in England and Wales was facilitated by the remit of the court rule-making authority in that jurisdiction, which is significantly broader than that enjoyed by the court rules committees in this jurisdiction.

The entitlement in that jurisdiction to secure, prior to commencement of an action, disclosure from a likely party to the prospective action, is conferred by section 33(2) of the Senior Courts Act 1981,⁷⁵ and the rules prescribed by virtue of that provision.⁷⁶

Insofar as sanctions for non-compliance with the requirements of the protocol are concerned, Rule 3.1(4) of the Civil Procedure Rules for England and Wales provides that “[w]here the court gives directions it will take into account whether or not a party has complied with ... any relevant pre-action protocol”. Rule 3.1(5) provides that “[t]he court may order a party to pay a sum of money into court if that party has, without good reason, failed to comply with a ... relevant pre-action protocol.” Rule 3(9)(1)(e) provides:

“On an application for relief from any sanction imposed for a failure to comply with any rule, practice direction or court order the court will consider all the circumstances including ... the extent to which the party in default has complied with ... any relevant preaction protocol”.

⁷⁵ Originally named the Supreme Court Act 1981 but renamed as mentioned above by the Constitutional Reform Act 2005, see also section 52 of the County Courts Act 1984. Section 33(2), as amended and extended, provides:

“(2) On the application, in accordance with rules of court, of a person who appears to the High Court to be likely to be a party to subsequent proceedings in that court, the High Court shall, in such circumstances as may be specified in the rules, have power to order a person who appears to the court to be likely to be a party to the proceedings and to be likely to have or to have had in his possession, custody or power any documents which are relevant to an issue arising or likely to arise out of that claim—

(a) to disclose whether those documents are in his possession, custody or power; and
(b) to produce such of those documents as are in his possession, custody or power to the applicant or, on such conditions as may be specified in the order—
(i) to the applicant’s legal advisers; or
(ii) to the applicant’s legal advisers and any medical or other professional adviser of the applicant; or
(iii) if the applicant has no legal adviser, to any medical or other professional adviser of the applicant.”

⁷⁶ Rule 31.16, Civil Procedure Rules.

Rule 44.3(4) provides that “[i]n deciding what order (if any) to make about costs, the court must have regard to all the circumstances, including ...the conduct of all the parties” and Rule 44(5)(a) provides that “[t]he conduct of the parties includes ... conduct before, as well as during, the proceedings and in particular the extent to which the parties followed ...any relevant pre-action protocol”.

The Superior Courts Rules Committee’s authority extends to the making of rules for “pleading, practice and procedure generally...in all civil cases...”. Unlike the position in England and Wales,⁷⁷ that committee’s remit does not expressly encompass the prescribing of requirements in respect of persons or granting of remedies (such as pre-action discovery) in respect of controversies which have not yet become the subject of court proceedings.

The Group recommends that provision be made by statute for the rule-making authority of the court rules committees to be expanded to enable the making of rules of court to provide for the prescribing of pre-action protocols regulating the conduct of claimants and prospective defendants, including the prescribing of time-limits, in particular with respect to causes of action to which the pre-action protocol is intended to apply. The new rule-making power should extend to the prescribing of the charges leviable and recoverable in respect of the provision of copies of documentation and other materials (including materials in electronic form) in response to a request made under a pre-action protocol.

Compliance and sanctions

The Group considers that it would place undue pressure on already burdened court lists and judicial resources to provide for access by the parties to the court for sanctions prior to the commencement of proceedings in the event of non-compliance with a requirement of a pre-action protocol. The Group considers that non-compliance by a prospective party with an obligation under the protocol should, provided it is substantial in nature, operate to relieve the other party of the requirement to comply with that party’s obligations under the protocol. Where the party affected is a claimant, they would thereupon be entitled to institute proceedings in respect of the claim. Furthermore, non-compliance with the protocol should be a factor which the court may take into account when determining liability for costs in the event that proceedings are issued.

Where a third party healthcare provider fails to comply with a request under the protocol to disclose records, the prospective claimant should, where they commence proceedings in respect of the claim in the absence of the relevant information, be entitled to recover their costs of any subsequent application for non-party discovery against that provider necessitated by the non-disclosure prior to commencement of the proceedings, together with such further costs incurred by the claimant in the proceedings as the court may consider fairly attributable to such non-disclosure.

Limitation period

While the subject of limitations periods is not the focus of the Working Group’s remit, the group is of the view – a view supported by a number of submissions made to it in the course of its consultation exercise – that the current limitation period of two years applicable to personal injuries actions generally is too restrictive and does not take account of the particular complexities associated with clinical negligence claims and the extent of their reliance on expert evidence of various types. The difficulties which the two year period thus presents are further complicated by the requirement in section 8 of the Civil Liability and Courts Act 2004 that a claimant send a letter of claim within two months of the date of the cause of action

⁷⁷ See in particular section 33 of the Supreme Court Act 1981 in that jurisdiction.

arising, in default of which the client may be sanctioned in costs or suffer adverse inferences being drawn as to the claim.

The Working Group considers that an extension of the limitation period to three years for clinical negligence claims would strike the appropriate balance between the legitimate interests of claimants and respondents to such claims, and so recommends.

Alternative dispute resolution

The Group acknowledges the potential which exists for mediation, early neutral evaluation and other types of ADR to resolve certain types of clinical negligence claim, and considers that the pre-action protocol should facilitate recourse to ADR.

The Rules of the Superior Courts⁷⁸ already permit the court, on the application of any of the parties or of its own motion, to adjourn proceedings and invite the parties to use an ADR process to settle or determine the proceedings or issue, or, where the parties consent, refer the proceedings or issue to such process. Where the parties decide to use an ADR process, the court may make an order extending the time for compliance by any party with any provision of the rules or any court order in the proceedings.

The pre-action protocol should similarly allow for suspension of the time limits prescribed by it where the parties have agreed in writing to refer a dispute to mediation or arbitration.

Offers of settlement: costs

An incentive needs be provided to parties to engage actively during the pre-litigation stage in attempts to settle. Insofar as costs are concerned, the rules of court now give recognition, in actions where the lodgment and tender provisions of the rules do not apply, to the making of “Calderbank” offers, viz. offers to satisfy a claim which are made by one party to another on a “without prejudice” basis save as to the issue of liability for costs. The court, in considering the awarding of the costs of such an action may, where it considers it just, have regard to the terms of any offer in writing sent by any party to any other party or parties offering to satisfy the whole or part of that other party’s claim or counterclaim.⁷⁹

In conjunction with the introduction of the pre-action protocol, provision should be made that where an offer to settle is made in the letter of claim sent under the protocol, or an offer to settle made by the healthcare provider in their response given under the protocol, the court in any proceedings which may subsequently be commenced in respect of the cause of action concerned shall have regard to any such offer in awarding the costs of those proceedings.

In the First Report,⁸⁰ the Group considered the rules of court governing lodgement of money or the making of a tender in satisfaction of a claim, and section 17 of the Civil Liability and Courts Act 2004, which provides for the making of formal offers by parties to personal injuries actions (or in the case of the defendant, as an additional option, the giving of notice that (s)he is not prepared to pay any sum in settlement of the action). Implementation of the preceding recommendation would, it is recognised, require provision to be made by statute that section 17 be dis-applied in an instance where an offer of settlement had been made in accordance with the pre-action protocol. The rules of court providing for lodgement and tender would equally require to be amended to facilitate the recommendation.

⁷⁸ Order 56A, rule 2.

⁷⁹ Order 99, rule 1A, Rules of the Superior Courts. Similar provision is made in the Circuit Court Rules.

⁸⁰ See pages 29 to 31 of the report.

Quite apart from these considerations, the Group notes the lack of clarity in section 17 of the 2004 Act as to the sequence in which formal offers may be made by the respective parties, as remarked upon by the High Court in *O'Donnell v McEntee*⁸¹ and *Aherne v Waterstone*⁸², and recommends that consideration be given to amending the section to determine expressly the sequence in which such offers are to be made.

Offers of settlement: interest

Provision should also be made by statute enabling a claimant who has made an offer of settlement in a letter of claim sent under the pre-action protocol, and who recovers not less than that amount in subsequent proceedings on foot of the cause of action concerned, to recover interest on the amount of the offer from the date of its being made and up to the date of judgment in the proceedings concerned.

Statutory protection for an apology

The Group considers that, if the protocol is to succeed in the objective of facilitating expressions of apology, protection would require to be afforded by statute to an apology made by a healthcare provider or medical professional in respect of a cause of action to which it relates.

An apology made by or on behalf of a defendant in relation to a claim for clinical negligence should not be treatable as an admission of fault or liability, express or implied, operate to avoid or otherwise affect a contract of or any entitlement to insurance, or be taken into account in determining fault or liability. Furthermore, such an apology should not be admissible in any proceedings as evidence of fault or liability on the part of the person making it.

Charges for production of clinical records

Currently, practice differs as to the amounts charged for production of records, and records may be produced in hard copy in circumstances where it would be greatly more convenient and less costly for all concerned were the information to be produced in electronic form or on CD-Rom. Provision should be made by statute requiring medical records required to be produced in accordance with the pre-action protocol in electronic form where so requested. The charges prescribable for production of records under the new rule-making power proposed above should be linked to that payable on an application under the Data Protection Acts - currently €6.35 - and should allow for a scale of charges to cover the expenses of scanning, copying or replication otherwise of a record requested, but subject in all cases to a maximum charge of €100 by the healthcare provider requested. A maximum charge of €5.00 should be chargeable for radiology material supplied on a CD-Rom.

Assessment of clinical negligence claims

The Group noted that proposals were publicised last year for the referral of clinical negligence claims to an assessment board along the lines of the Personal Injuries Assessment Board. The Group recommends that, before further consideration is given to these proposals, time be afforded to test the potential of a pre-action protocol to secure resolution of such claims in the pre-litigation stage.

⁸¹ [2009] IEHC 563

⁸² [2010] High Court (Quirke J), unrep.

APPENDIX 1

Draft Pre-action Protocol (Clinical Negligence Claims)

I. Scope

This Protocol applies to any claim by a person, or a personal representative or dependant of a deceased person, for damages for negligence, breach of statutory duty or breach of contract arising from any act or omission concerning -

- (a) the provision of a health service (including any dental service) to that person,
- (b) the carrying out of a clinical, medical or surgical procedure (including any dental procedure) in relation to that person,
- (c) the carrying out of a clinical or medical diagnosis, investigation or research (including any dental diagnosis, investigation or research) in respect of that person,
- (d) the provision of medical advice and information (including any dental advice and information) to that person,
- (e) the provision of clinical or medical treatment or care (including any dental treatment or care) to that person, or
- (f) implantation of, or a defect in, a device or material implanted in that person for medical or cosmetic reasons,

and references to “claim” in this Protocol shall be construed accordingly.

II. Objectives

The objectives of this Protocol are to -

- (a) facilitate, where appropriate and, the resolution at the earliest possible opportunity of any dispute concerning a claim without the need for recourse to litigation,
- (b) where it has not been possible to avoid litigation in respect of a claim, ensure that the issues of fact or law are identified as soon as possible so as to assist the preparation for trial of the proceedings in a manner which is just, expeditious and likely to minimise costs.

III. Steps to be followed

1. A patient or his or her advisor requesting records from a healthcare provider for the purpose of (a) considering whether a claim should be made or (b) pursuing such a claim, should –

- (c) provide sufficient information to indicate to the healthcare provider whether an adverse incident or outcome has been serious or has had serious consequences and
- (d) identify the records required as specifically as possible.

A **request for copies of records** should be made in **Form 1** in the Schedule to this Protocol (“the Schedule”), adapted as may be necessary.

2. The healthcare provider should reply initially to that request within **2 weeks** in **Form 2** in the Schedule, and should provide the copy records requested, in **Form 3** in the Schedule, adapted as may be

necessary, within **7 weeks** of the request [at a cost not exceeding the amount or amounts prescribed by rule of court].

3. Where the healthcare provider is not reasonably in a position to comply with the request within 7 weeks, the healthcare provider should explain to the claimant or the claimant's adviser the reasons for this and the efforts being made to comply with the request.

4. Where the healthcare provider fails to provide the requested records within 7 weeks, the patient or the patient's adviser may in any proceedings commenced subsequently in respect of the claim, recover their costs of any subsequent application for discovery against that provider necessitated by the non-disclosure prior to commencement of the proceedings, together with such further costs incurred by the patient in the proceedings as the court may consider fairly attributable to such non-disclosure.

5. Additional health records required by the patient or the healthcare provider from a third party should in the first instance be requested by or through the patient.

6. A third party healthcare provider should provide the requested records within **7 weeks** of the request [at a cost not exceeding the amount or amounts prescribed by rule of court].

7. Where a third party healthcare provider fails to provide the requested records, within 7 weeks, the patient may, in any proceedings commenced subsequently in respect of the claim, recover their costs of any subsequent application for non-party discovery against that provider necessitated by the non-disclosure prior to commencement of the proceedings, together with such further costs incurred by the patient in the proceedings as the court may consider fairly attributable to such non-disclosure.

8. Following receipt and consideration of the records, and *provided* an initial supportive medical report dealing with breach of duty and/or causation has been received, the patient or the patient's adviser should send a **Letter of Notification** to the healthcare provider as soon as practicable using **Form 4** in the Schedule. The patient or the patient's adviser should at the same time send a copy of the Letter of Notification to the State Claims Agency or relevant Medical Defence Organisation or indemnity provider (where known).

9. The healthcare provider (and the State Claims Agency or relevant Medical Defence Organisation or indemnity provider sent a copy of the Letter of Notification) should acknowledge the letter within **14 days** of receipt and should identify who will be dealing with the matter.

10. On receipt of a Letter of Notification the healthcare provider should then consider whether or not to undertake its own investigations into the case and whether or not to obtain its own expert evidence, in anticipation of its having to respond at a later stage to a Letter of Claim.

11. Where the patient or the patient's adviser, having analysed the records received and considered any further advice, decides that there are grounds for a claim, they should then send, as soon as practicable a **Letter of Claim** in **Form 5** in the Schedule, adapted as may be necessary. The patient or the patient's adviser should at the same time send a copy of the Letter of Claim to the State Claims Agency or relevant Medical Defence Organisation or indemnity provider (where known).

12. Where the patient or the patient's adviser wish to make an offer to settle the claim at this stage, such offer should be supported by a medical report which deals with the injuries, condition and prognosis, and by a schedule of loss and supporting documentation.

13. The healthcare provider should reply acknowledging the Letter of Claim within **14 days** of receipt and indicating who will be dealing with the matter on its behalf.
14. The healthcare provider should, within **four months** of the Letter of Claim, send a Response to the Letter of Claim in **Form 6** in the Schedule, adapted as may be necessary.
15. Where the parties reach agreement on liability but need time to agree on the value of the claim, they should seek to agree a reasonable period within which to conclude agreement on its value.
16. If unable to agree liability and /or quantum, the parties should consider an alternative dispute resolution procedure (ADR) to litigation, and seek to agree which form to adopt. In the event, however, that proceedings issue, the claimant and defendant may be required by the court to provide evidence of what form or forms of ADR were considered.
17. Proceedings should not be issued until after at least **four months** from the Letter of Claim, unless a limitation period for the commencement of proceedings for the claim would expire within that period or the commencement of such proceedings is otherwise necessary to protect the patient's interests.
18. The parties may extend by agreement any of the time limits prescribed by this Protocol.

IV. Non-compliance generally

1. The following paragraphs apply without prejudice to paragraphs 4 and 7.
2. In the event that a party does not comply with a requirement of this Protocol, the other party shall be relieved of his or her obligations under the Protocol.
3. Where the party affected is a claimant, he or she may, subject to any limitation period prescribed by law, thereupon institute proceedings in respect of the claim.
4. Non-compliance by a party with this Protocol may be taken into account by the court when determining liability for costs in the event that proceedings are issued.

Schedule

FORM 1

APPLICATION BY OR ON BEHALF OF A PATIENT TO A HEALTH CARE PROVIDER SEEKING
COPIES OF THEIR HEALTHCARE/MEDICAL RECORDS WHEN A CLAIM IS CONTEMPLATED

This should be completed as fully as possible

Insert

Health Care Provider

Name

and

Address

TO: Healthcare / Medical Records Officer of
Hospital/Doctor/or other Health Care Provider

| | | |
|----------|---|--------|
| 1 | Full name of patient (including previous surnames) | |
| (a) | Address now | |
| (b) | Address at start of treatment | |
| (c) | Date of birth (and death, if applicable) | |
| (d) | Hospital ref. no if available | |
| (e) | | |
| 2 | This application is made because the patient is considering | |
| (a) | A claim against you/your hospital as detailed at para 3 below | YES/NO |
| (b) | Pursuing an action against someone else | YES/NO |
| 3 | If the answer to Q2(a) is 'YES' provide details of: | |
| (a) | The nature of the claim in contemplation | |
| (b) | A description of the treatment(s) received | |
| (c) | The approximate date(s) of the event(s) involved | |
| 4 | If the answer to Q2(b) is 'YES' insert | |
| (a) | the name(s) of the proposed defendant(s) | |
| (b) | whether legal proceedings have been commenced | |
| (c) | if appropriate, the record number of the proceedings | |
| 5 | Where clinical records are sought from a hospital specify: | |
| (a) | the department(s) where treatment was received | |

| | | |
|---|---|--|
| (b) | the name of consultant in charge of the treatment | |
| 6 | We confirm we will pay reasonable copying charges | |
| 7 | We request prior details of : | |
| (a) | photocopying and administration charges for healthcare / medical records | |
| (b) | number of and cost of copying x-ray and scan films | |
| 8 | Details of any other relevant information, particular requirements, or any particular documents <u>not</u> required (e.g. copies of computerised records) | |
| 9 | Whether, in lieu of hardcopy, the applicant will accept records by electronic mail | YES/NO |
| | Signature of Solicitor | |
| | Name | |
| | Address Ref. | |
| | Telephone Number | |
| | Fax Number | |
| | Email Address | |
| Signature of patient* Signature of parent or next friend if appropriate* | | <i>Please print name beneath each signature. Signature of child under 18 years also requires signature by parent</i> |
| Signature of personal representative where patient has died* | | |

*Where applicant is not legally represented.

FORM 2

FIRST RESPONSE TO APPLICATION FOR HEALTHCARE/MEDICAL RECORDS

| | | |
|-----------------|---|--|
| Name of patient | | Our Ref. |
| Address | | Your Ref. |
| 1 | Date of receipt of patient's application | |
| 2 | We intend that copy clinical records will be forwarded by email within 7 weeks of that date | YES/NO |
| 3 | We intend that copy clinical records will be dispatched within 7 weeks of that date | YES/NO |
| 4 | We require pre-payment of (a) photocopying charges (b) administration charges | (a) YES/NO (b) YES/NO |
| 5 | If estimate of (a) photocopying and/or (b) administrative charges requested for pre-payment, the required amount(s) will be | (a) € /notified to you (b) € /notified to you |
| 6 | The cost of x-ray and scan films will be | € /notified to you |
| 7 | If there is any problem, we shall write to you within those 7 weeks | YES/NO |
| 8 | Any other information | |
| | Please address further correspondence to | |
| | Signed | |
| | Print Name | Title: |
| | Direct telephone number | |
| | E-mail | |
| | Direct Fax number | |
| | Dated | |

FORM 3

SECOND RESPONSE TO APPLICATION FOR HEALTHCARE/MEDICAL RECORDS

| | | |
|-----------------|--|--------------------------|
| Name of patient | | Our Ref. |
| Address | | Your Ref. |
| 1 | We confirm that the enclosed copy healthcare / medical records are all those within the control of the healthcare provider, relevant to the application which you have made to the best of our knowledge and belief, subject to paras. 2 – 5 below | YES/NO |
| 2 | Details of any other documents which have not yet been located | |
| 3 | Date by when it is expected that these will be supplied | |
| 4 | Details of any records which we are not producing | |
| 5 | The reasons for not doing so | |
| 6 | An invoice for (a) photocopying charges and/or (b) administration charges is enclosed | (a) YES/NO (b) YES/NO |
| | Signed | |
| | Print Name | Title: |
| | Direct telephone number | |
| | E-mail | |
| | Direct Fax number | |
| | Dated | |

FORM 4

TEMPLATE FOR THE LETTER OF NOTIFICATION

(ESSENTIAL CONTENTS)

The Letter of Notification should confirm:

1. The claimant's name, address, date of birth, etc.;
2. Dates of allegedly negligent treatment or other incident the subject of the notification;
3. Events giving rise to the claim, including:
 - a clear summary of the facts on which the claim is based;
 - details of other relevant treatments to the claimant by other healthcare providers.
4. Which healthcare / medical records have been obtained by the claimant. Where possible, details of the records obtained should be provided in the form of a document index (if not provided previously).
5. Whether a supportive expert opinion has been obtained on either or both of breach of duty and causation.
6. That this is a case which is proceeding, but that it is premature for the claimant to send a Letter of Claim at this stage while further investigations remain pending. Where possible the claimant should give an approximate time estimate for provision of the Letter of Claim.
7. That the claimant may have reasonable needs that could be met by rehabilitation treatment or other measures.
8. An invitation to the healthcare provider to consider commencing investigations into this case at this stage.
9. That failure to do so will be a factor that can be taken into consideration when considering the reasonableness or otherwise of any subsequent application for an extension of time for the Letter of Response.
10. An invitation to the recipient to inform his/her/its indemnifier (if any) of the letter's contents.

FORM 5

LETTER OF CLAIM

ESSENTIAL CONTENTS

The Letter of Claim should set out:

1. The claimant's name, address, date of birth, etc.
2. Dates of allegedly negligent treatment or other incident the subject of the claim
3. Events giving rise to the claim, including:
 - a clear summary of the facts on which the claim is based;
 - details of other relevant treatments to the claimant by other healthcare providers.
4. Allegations of breach of duty and causal link with injuries, including:
 - an outline of the main allegations or a more detailed list in a complex case;
 - an outline of the causal link between the allegations and the injuries complained of;
 - whether a supportive expert opinion has been obtained on either or both of breach of duty and causation
5. Details of the claimant's injuries, condition and future prognosis with a condition and prognosis report, if appropriate.
6. Request all clinical records (if not previously provided) which request should:
 - specify the records required;
 - if other records are held by other providers, and may be relevant, say so;
 - state what investigations have been carried out to date, e.g. information from the claimant and witnesses, any complaint and the outcome, if any clinical records have been seen or experts advice obtained.
7. Whether the claimant seeks an apology and or explanation
8. Documents relied upon:
 - in more complex cases a chronology of the relevant events should be provided particularly if the claimant has been treated by a number of different healthcare providers.
 - any relevant documents should be referred to, including health records, and if possible enclose copies of those which will not already be in the healthcare provider's possession.
9. Funding information.
10. An estimate of costs incurred by the claimant to the date of the letter of claim should be included.

OPTIONAL INFORMATION

- What investigations have been carried out.
- An offer to settle (open for acceptance until the Letter of Response is due to be served) with supporting medical evidence and / or a schedule of loss with supporting evidence if possible.
- Where an offer to settle is made, the claimant should provide details as to the approximate time spent by the claimant's solicitors in investigating the complaint to that point in time, or attach a letter from the claimant's solicitors providing this information.
- Suggestions for obtaining expert evidence.
- Suggestions for meetings, negotiations, discussion or mediation.
- Any reasonable needs not hitherto notified that could be met by rehabilitation treatment or other measures.

ADDITIONAL ENCLOSURES

- Clinical records request form and claimant's authorisation.
- Expert report(s).
- Schedules of loss and supporting evidence, even where an offer is not being made.

FORM 6

RESPONSE TO LETTER OF CLAIM

ESSENTIAL CONTENTS

The Letter of Response should:

1. Provide requested records and invoice for copying:
 - explain if records are incomplete or extensive records are held and ask for further instructions;
 - request additional records from third parties.
2. Comment on the events alleged and/or chronology:
 - if events are disputed or the healthcare provider has further information or documents on which they wish to rely, these should be provided, e.g. an internal Protocol;
 - details of any further information needed from the claimant or third party should be provided.
3. (If this is so) set out that breach of duty and causation are accepted wholly or in part:
 - this should be set out in clear terms and in particular which alleged breaches of duty and causation are admitted or denied and why;
 - suggestions might be made for resolving the claim and/or requests for further information.
4. (If this is so) set out that breach of duty and/or causation are denied:
 - a bare denial will not be sufficient. Specific responses to the allegations of breach of duty and causation should be given. If the healthcare provider has other explanations for what happened, these should be set out as fully as possible;
 - confirm whether any denial is based on receipt of independent expert evidence;
 - suggestions might be made for the next steps, e.g. further investigations, obtaining expert evidence, meetings/negotiations or mediation, or an invitation to issue proceedings.
5. (If this is so) set out that breach of duty and causation are denied but the healthcare provider nevertheless wishes to explore settlement, together with any proposals for a time period to be agreed by the parties to try and resolve the claim without the need for the issue of legal proceedings.
6. Where the patient or their advisor has made an offer to settle in their Letter of Claim, provide a reasoned response to that offer.
7. If the claimant has requested details of the healthcare provider's costs incurred to the date of the letter of response, provide these details.

OPTIONAL MATTERS

Reply to any request made for an apology and/or explanation and, if an apology is being given, and state the basis for the apology given.

Make an offer to settle if the claimant has not made one, or a counter-offer to the claimant's offer with supporting medical evidence and /or a counter-schedule of loss if appropriate

Possible enclosures:

- Clinical records.
- Annotated chronology.
- Expert reports.

APPENDIX 2



