To consider

Making Amends - A Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS

Issue

1. The need to decide the terms in which the Council wishes to respond to Making Amends, a consultation paper published in June 2003.

Recommendation

2. a. To agree the proposed response to the consultation paper (paragraphs 9-11 and Annex C).

b. To agree that the response should be finalised in light of comments at the meeting (paragraph 12).

Further information

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Background

4. *Making Amends* was issued by the Chief Medical Officer for England in June 2003. It invites comments on 19 recommendations, which apply to England only, by 17 October 2003. Although the paper is aimed mainly at NHS organisations, it raises a number of issues in which we have an interest. The full report is available online at www.doh.gov.uk, with hard copies available on request. A summary of recommendations is attached at Annex A.

5. In July 2001, following recommendations in the Kennedy report on events in Bristol, the CMO announced a wide-ranging review of possible reforms to the way clinical negligence is handled. The remit included consideration of:

   a. 'No fault' compensation schemes (as operated in New Zealand and Sweden, for example).
   
   b. Whether the medical treatment and care costs element of any compensation should continue to be based on the costs of private, rather than NHS, treatment.
   
   c. The use of structured settlements rather than lump sum payments.
   
   d. Greater use of mediation and other ways of resolving disputes.

6. The paper draws on work by an advisory group, MORI research, and literature reviews. It outlines the origins, and strengths and weaknesses, of the present system of medical litigation. The paper explores three options (summarised in Annex B to this paper) before proposing a composite approach which will involve:

   a. An investigation of an incident leading to the alleged harm and the resulting harm.
   
   b. Provision of an explanation to the patient of what happened and action proposed to prevent repetition.
   
   c. Development and delivery of a package of care including remedial treatment or continuing care as necessary.
   
   d. Payments for pain and suffering, and the costs of care or treatment which the NHS could not provide.

7. This proposed approach is said to be more responsive to the needs of patients and beneficial to doctors. The reforms aim to move away from the culture of blame and adversarial proceedings, towards systems that promote learning.

8. The basis of the reforms, and their implications, are summed up as follows:

   ‘…There is world-wide impetus now behind the emphasis on creating an open system in which errors are recognised as most often being due to systems weaknesses in which the individual who made the mistake is at the end point of a chain of events rather than its instigator. This perspective sees safer, higher quality care being driven by investigation and learning in a climate largely free from blame and fear. The National Patient Safety Agency (NPSA) is leading this work in England and Wales.’ (Chapter 8, paragraph 3).
Discussion

9. The main features of the proposed reforms are:
   a. Introducing an NHS Redress Scheme to provide investigations when things go wrong; remedial treatment, rehabilitation and care when needed, explanations and apologies and financial compensation in certain circumstances (recommendation 1).
   b. Setting a new standard of care for after event/after-complaint management – with compliance to be assessed by the new Commission for Healthcare Audit and Inspection (recommendation 6).
   c. As part of the reform of the NHS complaints procedure, removing the current rule that requires a complaint to be halted pending resolution (recommendation 8).

10. Two recommendations are of particular relevance to the GMC:
   a. A duty of candour should be introduced, with exemption from disciplinary action when reporting incidents, with a view to improving patient safety (recommendation 12).
   b. Documents and information collected for identifying adverse events should be protected from disclosure in court (recommendation 13).

11. Annex C addresses these two recommendations from a GMC perspective, in the form of a draft response.

   **Recommendation:** To agree the draft response to the consultation paper (Annex C).

12. The response will need to be finalised following the discussion at the Council meeting. Council Members are asked to agree that the President, with input from the Chairman of the Standards Committee, finalises the response.

   **Recommendation:** To agree that the response should be finalised in light of comments at the meeting.

Resource implications

13. There are no resource implications.

Charitable status

14. The recommendation in this paper is compatible with our charitable status and with charity law.

Equality

15. The recommendation in this paper does not raise any equality or diversity issues
Options considered in *Making Amends*

**Continue tort reforms**

1. One of the options considered was allowing the reforms of the current tort system to bed in (as set out in *Access to Justice*, a report by Lord Woolf, 1996) as this would be sufficient to address problems and concerns relating to the legal process for resolving medical disputes. But this is rejected because even a modified court based process could not address the issues raised which include:

   - Who can, and cannot prove ‘negligence’ remains a lottery;
   - There is little support for patients and claimants;
   - There is no incentive to report, or learn from errors;
   - The adversarial nature undermines the doctor/patient relationship;
   - It is lengthy, complex and costly; and
   - Even patients who receive compensation remain dissatisfied if there is no accompanying explanation or apology.

**No fault compensation**

2. The report looks at schemes operating around the world, which allow claims to be settled more quickly; have lower legal and administrative costs; reduce the conflict between claimants and clinicians and encourage reporting of error because of the removal of ‘blame’. However, adopting a true no fault scheme is rejected because:

   - Overall costs are far higher than the tort system.
   - It is difficult to distinguish harm from the natural progression of a disease.
   - There are implications for the Human Rights Act 1998 if the right to go to court is removed as a result of introducing a no fault scheme.
   - It is still necessary to prove ‘causation’.

**Tariff-based national tribunal**

3. Establishing a national tribunal backed by a tariff setting out fixed rates of compensation for clinical negligence is considered, (as in criminal cases) but rejected because:

   - Relatively low level of awards by comparison to clinical negligence cases.
   - Low satisfaction levels from claimants.
   - Lack of flexibility in award levels to reflect the circumstances of the injured patient.
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Comments by the General Medical Council

This paper sets out the GMC’s views on the consultation document, and makes reference to the specific recommendations which are of most importance to the GMC.

General comments

1. The GMC is the statutory body responsible for protecting the public by maintaining a register of doctors who are competent and fit to practise medicine. Our statutory purpose is to protect, promote and maintain the health and safety of the public and we therefore welcome the stated aim of the proposed reforms as being more responsive to the needs of patients, and beneficial to doctors.

2. We are aware of the difficulty of balancing the need to protect patients and the public interest, with the desirability of ensuring that everything possible is done to promote learning from adverse incidents.

3. In recognition of this the GMC, along with the Government and the NHS signed a statement for a commitment to quality. A Commitment to Quality, A Quest of Excellence: A Statement on behalf of the Government, the Medical Profession and the NHS was issued by the Government in June 2001.

4. We therefore recognise and endorse the role that learning from adverse incidents should play in preventing future incidents. But we are also aware that in striking this balance, the protection of patients must come first. In the light of this our comments on the specific recommendations set out below, highlight factors where we feel that the proposals might actually weaken the accountability of individual doctors for their actions and in doing so undermine the GMC’s role in the protection of patients.

5. The consultation document raises issues which are of particular importance to the GMC and which relate to the following statutory responsibilities:

   a. Establishing standards of good medical practice, which reflect what society and the profession, expect of doctors.

   b. Dealing firmly and fairly with doctors whose fitness to practise is questioned.

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1 A Commitment to Quality, A Quest of Excellence: A Statement on behalf of the Government, the Medical Profession and the NHS was issued by the Government in June 2001.
Recommendation 12: ‘A duty of candour should be introduced with exemption from disciplinary action when reporting incidents with a view to improving patient safety’

‘In 1987, Sir John Donaldson, then Master of the Rolls said “I personally think that in professional negligence cases, and in particular in medical negligence cases, there is a duty of candour resting on the professional man”. There has however been no binding decision of the courts on whether such a duty exists. The Law Society’s code of professional conduct for solicitors requires them to notify their clients if they become aware of a possible negligent act or omission. Such a duty, which would give statutory force to the General Medical Council’s Code of Good Medical Practice for doctors, should be introduced in legislation to require all healthcare professionals and managers to inform patients where they become aware of a possible negligent act or omission. The concomitant of the duty of candour should be provisions providing for exemption from disciplinary action by employers or professional regulatory bodies for those reporting adverse events except here the healthcare professional has committed a criminal offence or it would not be safe for the professional to continue to treat patients’ (chapter 8).

The principles and purpose of the duty of candour

6. One of the founding principles of our guidance is openness and honesty with patients. This includes informing patients when things have gone wrong. As this recommendation explains, Good Medical Practice places a duty on doctors to explain to patients who have suffered harm during medical treatment:

   ‘If a patient under your care has suffered harm through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You must explain fully and promptly to the patient what has happened and the likely long and short term effects. When appropriate you should offer an apology…’ (paragraph 22, GMP 2001).

7. Our guidance does not tie the duty of candour to acts or omissions which are or may be negligent. This was intentional. Our guidance is focused on the needs of patients, which are likely to remain the same, whatever the cause of the harm.

8. We also recognise, as a separate issue, the importance of doctors learning from adverse events and taking part in processes that can improve the overall standard of care. We deal with this in Good Medical Practice under the heading Maintaining your performance:

   ‘You must work with colleagues to monitor and maintain the quality of the care you provide and maintain a high awareness of patient safety. In particular, you must:
   • Take part in confidential enquiries and adverse event recognition and reporting to help reduce risk to patients.’

   (paragraph 12, Good Medical Practice 2001)
9. The recommendation in *Making Amends* is not clear about the purpose of the duty of candour. The report emphasises the need for adverse event reporting and the benefits this should bring, but does make clear how a duty of candour to patients will lead to improvements in patient care. Further, the recommendation for legislation relates only to events which raise ‘possible negligence’. This has two significant problems:

a. It requires individual clinicians to make a judgement about whether an adverse event in a patient’s care constitutes a ‘possible negligent act or omission’. This is a question of law, which clinicians are not well-placed to make. Problems could arise if a doctor defended a decision not to inform a patient (or others) on the grounds that they judged it did not raise a question of possible negligence.

b. It creates a two-tier approach, which may lead some clinicians to see a hierarchy of importance in explaining adverse events to patients, with those which may involve negligence being given priority. In addition it establishes a link between the duty to inform patients and the avoidance of disciplinary or court action, suggesting that doctors should not be expected to explain events to patients unless they were offered protection from complaints. The effect may be to undermine the principle that, as an integral part of good practice, patients should always be informed when something has gone wrong.

10. The combination of these effects may be to leave patients who have suffered harm, but where no negligence issues arise, without proper information about what has happened.

11. We believe that it would be simpler and clearer for clinicians to explain all adverse events to the patients they affect, and report them to the employing body and/or an appropriate body such as NPSA.

*Imposing a statutory duty of candour*

12. We also question whether placing a statutory duty of candour on doctors is appropriate. In general, parliament and the courts have left decision-making in health care to the professions (or professionally-led regulation), in recognition of the large element of clinical judgement which must be exercised to respond to circumstances and patients’ best interests. The proposal that there should be a statutory duty of candour seems contrary to this general policy.

13. The benefits of placing a statutory duty on doctors are not explained in the Report. There may be an assumption that a statutory duty will be more easily enforced, or that compliance will be better than with guidance or contractual obligations. However, it is far from clear that this would be the case. Experience suggests that in the absence of monitoring and/or penalties for failing to comply with the law, custom and practice can quickly take over from strict adherence to the requirements of legislation. For example, the Human Tissue Act was poorly understood and implemented by doctors involved in retaining and using organs and tissue. Furthermore, introducing formal monitoring arrangements or penalties for non-compliance may impose new costs, does not comply with the overall objective to avoid fostering a ‘blame’ culture, and may not be effective in the long-run.
14. We believe that professional standards and guidelines are better means of ensuring that doctors act appropriately in the complex and extremely varied circumstances they face. Local and national complaints procedures are more accessible to patients than the courts, and more likely to be able to consider concerns about reporting effectively.

15. Legislation should replace guidance from professionally led regulatory bodies only as a last resort, where the objective cannot be realised without imposing legal obligations. We think a ‘duty of candour’ would be unlikely to meet this test. There is evidence that reporting levels can increase by other means. For example the recent National Audit Office report *Achieving Improvements Through Clinical Governance* argues that learning from adverse incidents requires a culture where staff believe they will be treated openly and fairly, and that changes will result from reporting incidents. Barts and the London Trust promoted a change in culture, provided guidance on what to report and how and increased feedback to those who reported incidents. The outcome was a 40% increase in the number of reported incidents.

16. Introducing a statutory requirement to inform patients about possible negligence cases relies on a coercive rather than a co-operative approach. Providing guidance to clinicians on how and when to raise questions of error or negligence with patients and how to report incidents so that lessons can be learned may have better results.

17. The GMC and other regulatory bodies could also play a part in informing clinicians about their professional responsibilities and explaining more fully the scope and purpose of their own disciplinary procedures. We could, for example, explain that the GMC is not seeking to act on occasional one-off mistakes and/or that acting responsibly when mistakes have occurred would be considered as part of the circumstances and evidence when assessing information about a doctor’s fitness to practise.

*Exemption from disciplinary action*

18. The GMC’s fitness to practise procedures aim to protect the public interest by dealing firmly and fairly with doctors whose fitness to practise is called into question. The Council has statutory powers in order to enable it to take appropriate action when a complaint is received, where it relates to the practitioner’s conduct, professional performance or health.

19. We are concerned that any statutory provision providing exemption from disciplinary action for those reporting such incidents would compromise our ability to ensure that patients are adequately protected, and appears incompatible with the GMC’s statutory duty in relation to fitness to practise.

20. The consultation document does go on to say that individuals will not be exempt from disciplinary action where a criminal offence has been committed or it would not be safe to continue to treat patients. We are unclear however, as to how it could be established that the practitioner was safe to practise without the case having been investigated and, if necessary, determined through the fitness to practise procedures? As it stands, it appears that the proposal would prevent the GMC even from investigating the matter.
21. In addition, there will be cases where although the above criterion is not met in that a doctor is not unsafe to treat patients, the GMC would nevertheless wish to be able to take account of an incident in the event that there were further such incidents, which taken together, suggested that the doctor’s fitness to practise was impaired to a degree justifying action on registration.

22. The GMC would need to be assured that our ability to protect the public interest would not be compromised. We would also like to see further clarification of the factors to be taken into account when deciding whether a doctor would be exempt from disciplinary action.

Recommendation 13: ‘Documents and information collected for identifying adverse events should be protected from disclosure in court’

23. The fitness to practise procedures are designed to enable investigation and consideration of concerns that are referred to the GMC. As part of the procedures, the GMC has statutory powers (as set out in Section 35 of the Medical Act 1983), to require disclosure of information.

24. We are not clear whether the proposed statutory provision to provide legal protection for adverse event reports provided locally or to a national body such as the NPSA, would affect our powers when carrying out an investigation. We note that the protection would only apply to reports of adverse events where full information on the event is also included in the medical record, but would like clarification of how it is envisaged that such a power would work.

25. If the intention behind the proposals is to provide an exemption to our Section 35 powers, then this recommendation would also appear to be incompatible with our statutory role and we would therefore wish to see some further explanation.

26. We would be happy to discuss any of these comments in more detail, and look forward to further discussion before plans for legislation are finalised.

General Medical Council

15 October 2003