

2N35A
Quarry House
Quarry Hill
Leeds
LS2 7UE

14 June 2005

Dear Colleague,

The Shipman Inquiry: Fifth Report: *Safeguarding Patients: Lessons from the Past – Proposals for the Future*

Meeting at Southampton, July 12

In February a colleague and I went to the StHA Primary Care Contracting Leads Meeting and indicated that we would be interested in discussing the issues around implementing Shipman in more detail with PCT staff. Since then I have met Primary Care leads from North London and the West Midlands.

I have a particular interest in recommendations relating to Primary Care. I will also be happy to discuss other recommendations with you. We also want to consider the issues raised by other Inquiries into poor clinical performance such as Neale, Alyling and Kerr/Haslam. They have some commonality of issues with Shipman.

I would like to discuss the practical difficulties that you have already identified, or that you can foresee, around the implementation of the Shipman and other recommendations. I have identified some of the issues below and look forward to discussing them, and others, with you next month. This is not an exhaustive list, but it will help us focus on the issues. You can download the recommendations from the Inquiry website at <http://www.the-shipman-inquiry.org.uk/home.asp>

Issues for discussion

1. Should the powers of PCTs be extended to let them issue warnings and to impose financial penalties on GPs in respect of misconduct?
2. Do you have any information about how PCTs are currently using their list management powers?
3. Are the PCTs in your area in a position to provide advice to GP practices on good recruitment procedures and offer support in drafting job specifications and advertisements?

- 4 Do you have many single handed practices? What support do you offer them?
5. Would a standard reference form, developed for use in connection with appointments to GP practices help improve standards? Do you have any examples of good or poor practice?
6. Should there be a central database for doctors and, if so, who should manage it? What do you see as the main issues?
7. Dame Janet recommends that there should be a GP practice accreditation scheme, similar to the one being developed in Scotland. Do you have views on that?
8. Dame Janet recommends that there should be a national system for monitoring GP patient mortality rates. Also, that GP practices should have a death register. Do you have any views on how this could be achieved?

I look forward to meeting you on July 12th.

Yours sincerely

Code A

Code A

Deputy Project Manager
Shipman Implementation Team
Tel: 0113 254 5786
e-mail: rab.harkins@dh.gsi.gov.uk

Background note

Dame Janet Smith published her fifth report in December. The report concentrates on GPs and primary care and explores how the systems operating in the NHS at the time allowed Shipman to evade notice. These include the complaints process and the fitness to practise procedures operated by the GMC. Some of the recommendations have implications for other health professionals and regulatory bodies.

Dame Janet has made 109 recommendations covering:

- Handling complaints and concerns, whistleblowing
- Clinical governance
- Monitoring and primary care
- The constitution of the GMC and its disciplinary procedures (Fitness to Practise)

Our task is to develop the Departmental response to Dame Janet's recommendations. There is currently a three-pronged approach to this task. There are two project teams. One covers whistleblowing and complaints and the other appraisal, discipline, monitoring and the GMC. The Chief Medical Officer (CMO) has also set up a review group.

Ministers have asked CMO to provide advice on further measures that are necessary to:

- Strengthen procedures for assuring the safety of patients in situations where a doctor's performance or conduct pose a risk to patient safety or the effective functioning of services;
- Ensure the operation of an effective system of revalidation;
- Modify the role, structure and functions of the General Medical Council.

This review will cover recommendations 49-109. CMO issued his *Call for Ideas* to seek the views of anyone who has useful input that can be taken account of in consideration of options for change. This is not intended to pre-empt the findings of his advisory group but will help inform their consideration of the options. The closing date for responses was 13 May. Further details can be obtained from the Department of Health website.

Annex A

Shipman Inquiry Fifth Report – Safeguarding Patients: Lessons from the Past – Proposals for the Future

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RECOMMENDATIONS

This Summary contains only a brief statement of each of my recommendations. To understand the reasoning behind each recommendation, the reader must refer to the Chapter(s) in which the evidence relating to it is described and the paragraph(s) of Chapter 27 in which the issues are discussed. The relevant references accompany each recommendation or set of linked recommendations.

Handling Complaints and Concerns

The Lodging of Complaints

1. I endorse the provision contained in the draft National Health Service (Complaints) Regulations (the draft Complaints Regulations), whereby patients and their representatives who wish to make a complaint against a general practitioner (GP) will be permitted to choose whether to lodge that complaint with the GP practice concerned or with the local primary care trust (PCT). I recommend that the time limit for lodging a complaint be extended from six to twelve months. (Chapter 7, paragraphs 27.15–27.16 and paragraph 27.18)
2. Steps should be taken to improve the standard of complaints handling by GP practices. (Chapter 7 and paragraph 27.17)
3. Draft regulation 30 of the draft Complaints Regulations, which would require GP practices to provide PCTs with limited information about complaints received by the practice at intervals to be specified by the PCT, should be amended. GP practices should be required to report all complaints to the PCT within, say, two working days of their receipt. The report should comprise the original letter of complaint or, if the complaint was made orally, the practice's record of the complaint. The PCT should log the complaint for clinical governance purposes and, if it considers that the complaint raises clinical governance issues, it should 'call in' the complaint for investigation. (Chapter 7 and paragraphs 27.19–27.23)

The Investigation of Complaints

4. There should be statutory recognition of the importance of the proper investigation of complaints to the processes of clinical governance and of monitoring the quality of health care. (paragraph 27.26)

The First Triage

5. On receipt by a PCT of a complaint about a GP, a 'triage' (the first triage) of the complaint should be conducted by a member of the PCT's staff who is appropriately trained and experienced and has access to relevant clinical advice. The object of the first triage should be to assess whether the complaint arises from a purely private grievance or raises clinical governance issues. (paragraphs 27.27–27.30)

'Private Grievance Complaints'

6. 'Private grievance complaints' should be dealt with by appropriately trained PCT staff. The objectives in dealing with such complaints should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence between doctor and patient. (paragraph 27.31)

The Second Triage

7. 'Clinical governance complaints' should be investigated with the dual objectives of patient protection and satisfaction and of fairness to doctors. They should be referred for a further triage (the second triage) to a small group comprising two or three people – for example, the Medical Director or Clinical Governance Lead, a senior non-medical officer of the PCT and a lay member of the PCT Board. The object of the second triage should be to decide whether the complaint is to be investigated by or on behalf of the PCT or whether it should instead be referred to some other body, such as the police, the General Medical Council (GMC) or the National Clinical Assessment Authority (NCAA). (paragraphs 27.32–27.33)

The Investigation of 'Clinical Governance Complaints'

8. The investigation of 'clinical governance complaints' should not be undertaken by PCT staff. Instead, groups of PCTs should set up joint teams of investigators, who should be properly trained in the techniques of investigation and should adopt an objective and analytical approach, keeping their minds open to all possibilities. (paragraphs 27.35–27.49)

9. All 'clinical governance complaints' (save those which do not involve serious issues of patient safety and where the underlying facts giving rise to the complaint are clear and undisputed) should be referred to the inter-PCT investigation team. The objects of the investigation should be to reach a conclusion as to what happened and to set out the evidence and conclusions in a report which should go to the PCT with responsibility for the doctor. If the investigators are unable to reach a conclusion about what happened

because there is an unresolved conflict of evidence, they should say so in their report.
(paragraph 27.50)

Acting on the Investigation Report

10. On receipt of the investigation report, the PCT group which carried out the second triage should consider what action to take. It might be appropriate to refer the matter to another body, such as the GMC or the NCAA. Alternatively, it might be appropriate for the PCT to take action itself, e.g. by invoking its list management powers. If the report of the investigation team is inconclusive, because of a conflict of evidence, the case should be referred to the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), under a power which should be included in the amended draft Complaints Regulations when implemented. (paragraphs 27.52–27.54)

The Effect of Concurrent Proceedings

11. Neither an intention on the part of the complainant to take legal proceedings, nor the fact that such proceedings have begun, should be a bar to the investigation by a NHS body of a complaint. In circumstances where the NHS body is taking disciplinary proceedings relating to the subject matter of the complaint against the person complained of, a complainant should be entitled to see the substance of the report of the investigation on which the disciplinary proceedings are to be based and should not merely be informed that the investigation of his/her complaint is to be deferred or discontinued.

12. In some circumstances, it may be necessary for a NHS body to defer or discontinue its own investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. However, a NHS body should never lose sight of its duty to find out what has happened and to take whatever action is necessary for the protection of the patients of the doctor concerned. It should also provide such information to the complainant as is consistent with the need, if any, for confidentiality in the public interest. The relevant provisions of the draft Complaints Regulations should be amended to reflect these principles. (paragraphs 27.55–27.61)

The Role of the Healthcare Commission

13. The draft Complaints Regulations, when implemented, should include a power enabling PCTs to refer a complaint to the Healthcare Commission for investigation at any point during the first stage of the complaints procedures. Cases raising difficult or complex issues or involving issues relating to both primary and secondary care might be referred to the Healthcare Commission for investigation at the time of the second triage, or later if the investigation by the inter-PCT investigation team raises more complex issues than were

initially apparent. Referral to the Healthcare Commission should also take place in cases where an inter-PCT investigation team has found that it cannot reach a conclusion because there remain unresolved disputes of fact. The purpose of the referral would be for the Healthcare Commission to carry out any further necessary investigation and, if appropriate, to set up a panel to hear oral evidence about the facts in dispute and to decide where the truth lay. (paragraphs 27.52 and 27.62–27.71)

Complaints in the Private Sector

14. Complaints procedures in the private sector should be aligned as closely as possible with those in the NHS, so that a complainant who does not receive a satisfactory response to his/her complaint from a private sector body can proceed to a second stage of the complaints procedures to be conducted by the Healthcare Commission. (paragraphs 27.72–27.74)

Handling Concerns

15. Concerns expressed about a GP by someone other than a patient or patient's representative (e.g. by a fellow healthcare professional) should be dealt with in the same way as patient complaints. Such concerns should be investigated (where necessary) by the inter-PCT investigation team or, in a case raising difficult or complex issues, by the Healthcare Commission. Consideration should be given to amending the relevant provisions of the draft Complaints Regulations to permit the Healthcare Commission to accept and investigate concerns referred to it by a PCT or other healthcare body without the need for a reference from the Secretary of State for Health. (paragraphs 27.77–27.78)

Standards

16. Objective standards, by reference to which complaints can be judged, should be established as a matter of urgency. These standards should be applied by those making the decision whether to uphold or reject a complaint and by PCTs and other NHS bodies when deciding what action to take in respect of a doctor against whom a complaint has been upheld. When established, the standards by reference to which complaints are dealt with must fit together with the threshold by reference to which the GMC will accept and act upon allegations, so as to form a comprehensive framework. (paragraphs 27.79–27.82)

Support for Complainants

The 'Single Portal'

17. In order to ensure that, so far as possible, complaints and concerns about health care reach the appropriate destinations, there should be a 'single portal' by which complaints or concerns can be directed or redirected to the

appropriate quarter. This service should also provide information about the various advice services available to persons who are considering whether and/or how to complain or raise a concern, including advice services for persons who are concerned about the legal implications of raising a concern. (Chapter 11 and paragraphs 27.83–27.88)

The New Arrangements

18. About two years after the Complaints Regulations come into force in their entirety, an independent review should be commissioned into the operation of the new arrangements for advising and supporting patients who wish to make a complaint. Any deficiencies identified by that review should be corrected. (Chapter 7 and paragraphs 27.89–27.90)

Disciplinary Procedures

19. The powers of PCTs should be extended so as to enable them to issue warnings to GPs and to impose financial penalties on GPs in respect of misconduct, deficient professional performance or deficient clinical practice which falls below the thresholds for referral to the GMC or exercise of the PCT's list management powers. (Chapter 7 and paragraphs 27.91–27.102)

The Use of Prescribing Information as a Clinical Governance Tool

20. Steps should be taken to ensure that every prescription generated by a GP can be accurately attributed to an individual doctor. Only then will the data resulting from the monitoring of prescribing information constitute a reliable clinical governance tool.

21. Regular monitoring of GPs' prescribing should be undertaken by PCTs. Special attention should be paid to the prescribing of controlled drugs. Doctors who have had a problem of drug misuse in the past or who are suspected of having a current problem should be subjected to particularly close scrutiny. When a restriction is placed on a doctor's prescribing powers, this information must be made available (preferably by electronic means) to those who need to know, especially pharmacists. (Fourth Report, Chapters 5 and 12 of this Report and paragraphs 27.103–27.104)

The Use of Mortality Data as a Clinical Governance Tool

22. The Department of Health (DoH) must take the lead in developing a national system for monitoring GP patient mortality rates. The system should be supported by a well-organised, consistent and objective means of investigating those cases where a GP's patient mortality rates signal as being above the norm. (Chapter 14 and paragraphs 27.105–27.107)

23. Every GP practice should keep a death register in which particulars of the deaths of patients of the practice should be recorded for use in audit and for other purposes. (paragraph 27.108)

24. PCTs should undertake reviews of the medical records of deceased patients, either on a routine periodic basis (if resources permit) or on a targeted basis limited to those GPs whose performance gives rise to concern. (paragraph 27.109)

Appraisal in the Context of Clinical Governance

25. The purpose of GP appraisal must be made clear. A decision must be taken as to whether it is intended to be a purely formative (i.e. educational) process or whether it is intended to serve several purposes: part formative, part summative (i.e. pass/fail) and/or part performance management.

26. If appraisal is intended to be a clinical governance tool, it must be 'toughened up'. If that is to be done, the following steps will be necessary. Appraisers should be more thoroughly trained and should be accredited following some form of test or assessment. Appraisers should be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by GPs from another PCT. Standards should be specified, by which a GP 'successfully completes' or 'fails' the appraisal. All appraisals should be based on a nationally agreed core of verifiable information supplied by the PCT to both the appraiser and the appraisee. (Chapter 12 and paragraphs 27.110–27.116)

The Use by Primary Care Trusts of Their List Management Powers

27. The Family Health Services Appeal Authority (Special Health Authority) or its proposed successor, the NHS Litigation Authority, should collect and analyse information relating to the use made by PCTs of their list management powers. Such analysis would assist the DoH in providing guidance to PCTs about the types of circumstance in which they might properly use their powers. (Chapter 5 and paragraph 27.117)

Practice Accreditation Schemes

28. The Government should consider the feasibility of providing a financial incentive for the achievement of GP practice accreditation by means of an accreditation scheme similar to that operated by the Royal College of General Practitioners in Scotland. (Chapter 5 and paragraph 27.118)

Support for Single-Handed and Small Practices

29. The policy of the DoH and of PCTs should be to focus on the resolution of the problems inherent in single-handed and small practices. More support and encouragement should be given to GPs running single-handed and small practices. In return, more should be expected of such GPs in terms of group

activity and mutual supervision. The DoH should take responsibility for these initiatives. (Chapters 9 and 13 and paragraphs 27.119–27.120)

The Recruitment and Appointment of General Practitioners

30. PCTs should be willing and able to provide advice to GP practices on good recruitment practice and should also be willing to offer support in drafting job specifications and advertisements. They should be prepared, if requested, to assist in sifting applications (if multiple applications are received) and in making the necessary checks on applicants before the interview stage, so as to exclude in advance any applicants who are unsuitable. However, this latter exercise may be too much of a burden for PCTs unless and until the Inquiry's recommendations for greater information to be placed on the GMC's website and for the creation of a central database of information about doctors (see below) are implemented. (paragraphs 27.121–27.128)

31. A standard reference form should be developed for use in connection with appointments to GP practices. PCTs should insist that a reference is obtained from the doctor's previous employer or PCT. In the case of a PCT, the reference should be signed by the Medical Director or Clinical Governance Lead. (paragraph 27.129)

32. When recruiting a new member, GP practices should canvass and take account of the views of their patients about the kind of doctor the practice needs. (paragraphs 27.130–27.137)

General Practitioners' Personal Files

33. PCTs should keep a separate file for each individual GP on their lists. That file should hold all material relating to the doctor which could have any possible relevance to clinical governance. If a doctor moves from one PCT to another, the file (or a copy of it) should be sent to the new PCT. It might be helpful if the DoH were to establish national criteria for the content of the files to be kept by PCTs. (paragraph 27.138)

The Raising of Concerns

Facilitating the Raising of Concerns by Staff in General Practice

34. Every GP practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns about the clinical practice or conduct of a healthcare professional within the practice. Staff should be encouraged to bring forward any concerns they may have openly, routinely and without fear of criticism. In the event that a member of the staff of a GP practice feels unable to raise his/her concern within the practice, s/he should be able to approach a person designated by the PCT for the purpose. The contact details

of that person should appear in the written policy. The designated person should make him/herself known to all practice staff working in the PCT area. PCTs should ensure, through training, that practice staff understand the importance of reporting concerns and know how to do so.

35. The written policy should contain details of organisations from which staff can obtain free independent advice. If the 'single portal' is created, in whatever form, the policy should set out contact details of that also. (Chapter 9 and paragraph 27.139)

Facilitating the Raising of Concerns by Staff in the Private Sector

36. The Healthcare Commission should require all private healthcare organisations to have a clear written policy for the raising of concerns. Steps should be taken to foster in the private sector the same culture of openness that is being encouraged in the NHS. (Chapter 11 and paragraph 27.140)

Support at a National Level for Those Who Wish to Raise Concerns about Health Care

37. Consideration should be given to amending the Public Interest Disclosure Act 1998 in order to give greater protection to persons disclosing information, the disclosure of which is in the public interest.

38. Written policies setting out procedures for raising concerns in the healthcare sector should be capable of being used in relation to persons who do not share a common employment.

39. There should be some national provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of doing so. It might be possible to link this helpline with the 'single portal' previously referred to. (Chapter 11 and paragraph 27.141)

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

40. There should be a central database containing information about every doctor working in the UK. This should be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest, such as the Healthcare Commission, the GMC, the NCAA and the DoH.

41. The database would contain, or provide links to, information held by the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service. It would also contain records of disciplinary

action by employers, details of list management action by PCTs, any adverse reports following the investigation of a complaint, any adverse findings by a Healthcare Commission panel or by the Healthcare Ombudsman and details of any findings of negligence in a clinical negligence action and settlement of a clinical negligence claim above a pre-determined level of damages. It should also contain certain other information. Doctors would be able to access their own entries to check the accuracy of the information held.

42. Private sector employers should be required to provide relevant information as a condition of registration with the Healthcare Commission. Deputising services should also be required to provide information and should be able to access the database through the relevant PCT.

43. Information about unsubstantiated allegations or concerns should not be included on the central database. Instead, the doctor's entry on the database should be flagged to indicate that confidential information is held by a named body. Access to that information would depend on who was asking for it and for what purpose and would have to be determined at a high level. (paragraphs 27.142–27.149)

Further Information to Be Provided to Primary Care Organisations

44. GPs should be required to disclose to the relevant PCO the fact that a clinical negligence claim has been brought against them, the gist of the allegation made and, when the time comes, the outcome of the claim. A failure by a doctor to make full declarations to a PCO as required by the National Health Service (Performers Lists) Regulations 2004 should be regarded as misconduct of sufficient gravity to warrant referral to the GMC. (paragraphs 27.150–27.154)

Information Available to the Public and Patients

45. The GMC should adopt a policy of tiered disclosure to apply to all persons seeking information about a doctor.

46. The first tier should relate to information which is relevant to the doctor's current registration status, together with certain information about his/her past fitness to practise (FTP) history. First-tier information should be posted on the GMC website and should also be disclosed to anyone who requests information about the doctor's registration. The periods of time for which information should remain at the first tier should depend on the nature of the information. When the relevant period expires, the information should be removed from the website. It should be replaced by a note indicating that there is further information which can be obtained by telephoning the GMC. That information should then be available at the second tier.

47. Disclosure of information at the second tier should be made to any person who makes a request about a doctor's FTP history. All information

which has at any time been in the public domain should remain available to enquirers at the second tier for as long as the doctor remains on the register. (paragraphs 27.155–27.197)

Information That Should Be Given to Patients of a Practice

48. In all cases where a GP's registration is subject to conditions, or where s/he has resumed practice after a period of suspension or erasure, patients of any practice in which the GP works should be told. A letter of explanation which has been approved by the PCT should be sent to all patients. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or who has previously been subject to an order for suspension or erasure. (paragraphs 27.198–27.199)

The General Medical Council

The General Medical Council's Role in the Wider Regulatory Framework

49. The GMC should ensure that its publications contain accurate and readily understandable guidance as to the types of case that do and do not fall within the remit of its FTP procedures. (Chapters 18 and 25 and paragraph 27.201–27.202)

Separation of Functions

50. There must be complete separation of the GMC's casework and governance functions at the investigation stage of the new FTP procedures and this must be reflected in the Rules. (Chapter 25 and paragraph 27.205)

51. The adjudication stage of the FTP procedures must be undertaken by a body independent of the GMC. This body should appoint and train lay and medically qualified panellists and take on the task of appointing case managers, legal assessors (if they are still necessary) and any necessary specialist advisers. It should also provide administrative support for hearings. (Chapter 25 and paragraphs 27.206–27.209)

52. Consideration should be given to appointing a body of full-time, or nearly full-time, panellists who could sit on the FTP panels of all the healthcare regulatory bodies. (Chapter 25 and paragraph 27.207)

The Statutory Tests

53. The GMC should adopt clear, objective tests to be applied by decision-makers at the investigation and adjudication stages of the FTP procedures. The tests that I recommend are set out at paragraphs 25.63 and 25.67–25.68. The tests should be incorporated into the Medical Act 1983 and/or the Rules. The draft Guidance for FTP panellists should be amended so that it is

consistent with the provisions of Section 35D of the Medical Act 1983 and rule 17(2)(k) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 (the November 2004 Rules). (Chapter 25 and paragraphs 27.211 and 27.261)

A New Route to Impairment of Fitness to Practise

54. The Medical Act 1983 should be amended to add a further route by which there might be a finding of impairment of fitness to practise, namely 'deficient clinical practice'. (Chapter 25 and paragraph 27.212)

Standards, Criteria and Thresholds

55. Urgent steps should be taken to develop standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the investigation and the adjudication stages of the FTP procedures and on restoration applications. (Chapters 17–25 and paragraphs 27.213–27.229)

56. The Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) should be invited to set up a panel of professional and lay people (similar in nature to the Sentencing Advisory Panel) which should assist in the process of developing the necessary standards, criteria and thresholds. (Chapter 21 and paragraph 27.230)

57. Steps should be taken to ensure that FTP panels determining cases in which issues of deficient professional performance arise apply a standard which is no lower than that set for admission to general practice. (Chapter 24 and paragraph 27.231)

The Investigation Stage

The Preliminary Sift: the Test for Jurisdiction

58. Rule 4 of the November 2004 Rules, which sets out the test to be applied by the Registrar on receipt of an allegation, should be amended to give greater clarity. The test that I recommend is set out at paragraph 25.115. (Chapter 25 and paragraph 27.232)

Preliminary Discussions with and Disclosure to Employers and Primary Care Organisations

59. The November 2004 Rules should be amended to make formal provision for the GMC routinely to communicate with employers and with primary care organisations (PCOs) before deciding what action should be taken in response to an allegation and giving the GMC power to require from the doctor the necessary details to enable it to make such communication.

Communication should take place in all cases other than in the case of an allegation which is so serious that it obviously requires further investigation or in the case of an allegation which is plainly outside the GMC's remit. (Chapters 18 and 25 and paragraph 27.234)

The Treatment of Convictions

60. Where a doctor has committed a criminal offence in respect of which a court has imposed a conditional discharge, that offence should be dealt with by the GMC in the same way as if it were a criminal conviction. (Chapters 18 and 25 and paragraph 27.232)

The Power to Direct Investigations

61. The November 2004 Rules should be amended so as to give case examiners, and Investigation Committee (IC) panels in cases where the case examiners have disagreed, the power to direct investigations. (Chapter 25 and paragraph 27.235)

Case Examiners

62. Case examiners should be advised that they should not take mitigation into account when making their decisions and that they should consult a lawyer if they are in any doubt as to whether the available evidence is such that there is a realistic prospect of proving the allegation. (Chapter 25 and paragraph 27.236)

Performance and Health Assessments

63. The November 2004 Rules should be amended to give case examiners, and IC panels in cases where the case examiners have disagreed, the power to direct that an assessment of a doctor's performance and/or health should be carried out. (Chapter 25 and paragraph 27.237)

64. The GMC should develop an abridged performance assessment to be used as a screening tool in any case in which an allegation is made which potentially calls into question the quality of a doctor's clinical practice. (Chapter 24 and paragraph 27.237)

65. In order to avoid doctors undergoing multiple performance assessments, the GMC should investigate the development of a modular assessment. (Chapter 24 and paragraph 27.237)

66. The November 2004 Rules should be amended to include a provision whereby reports of performance assessments should be disclosed by the GMC to doctors' employers or PCOs as soon as possible after receipt. (Chapters 24 and 25 and paragraphs 27.238–239)

Letters of Advice

67. The power to send letters of advice should be incorporated into the Rules and clear criteria for the sending of such letters should be prepared. (Chapter 25 and paragraph 27.240)

The Issuing of Warnings at the Investigation Stage

68. The GMC should reconsider its proposals for the issuing of warnings at the investigation stage. (Chapter 25 and paragraph 27.241)

The Procedure for Cancelling Hearings before a Fitness to Practise Panel

69. Rule 28 of the November 2004 Rules, which provides for the cancellation of hearings before a FTP panel, should be amended so as to provide that a decision to cancel must be taken by an IC panel and that the reasons for the cancellation must be formally recorded. Both the doctor and the maker of the allegation should be notified in advance of the fact that cancellation is being considered and both should have the opportunity to make representations.

70. There should be regular monitoring and audit of the number of applications to cancel FTP panel hearings and of decisions to cancel and the reasons for those applications and decisions. Those reasons should be scrutinised with a view to taking steps to minimise the number of cases in which referrals are subsequently cancelled. The number and reasons should be placed in the public domain on an annual basis. (Chapters 20 and 25 and paragraph 27.242)

Consensual Procedures

71. If the GMC pursues its present intention to extend the use of voluntary undertakings to cases other than those raising issues of adverse health or deficient performance, the disposal of such cases should take place in public at the adjudication stage and not in private as part of the investigation stage. (Chapter 25 and paragraph 27.243)

Revival of Closed Allegations

72. The November 2004 Rules should be amended to make provision for the revival of closed allegations. The usual 'cut-off' period should be five years but it should be possible, in exceptional circumstances and in the interests of patient protection, to reopen a case at any time. (Chapter 25 and paragraph 27.244)

Review of Investigation Stage Decisions

73. Reviews of investigation stage decisions should be carried out by an independent external commissioner. The circumstances in which a review may take place should be extended to cover decisions of the Registrar to reject an allegation rather than to refer it to a case examiner. (Chapter 25 and paragraph 27.245)

Voluntary Undertakings in Cases with a Health Element

74. The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of health assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to health should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a health screener. If a case is to be closed on the basis of a health assessment, the decision should be taken by two case examiners, one medically qualified and one lay, and, if they disagree, by an IC panel. (Chapter 25 and paragraph 27.246)

Voluntary Undertakings in Cases with a Performance Element

75. The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of performance assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to performance should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a performance case co-ordinator. If a case is to be closed on the basis of a performance assessment, the decision should be taken by two case examiners, one medically qualified and one lay, and, if they disagree, by an IC panel. (Chapter 25 and paragraph 27.248)

The Adjudication Stage

Investigation

76. There should be an explicit power in the Rules to allow the GMC to undertake any further investigations it considers necessary after a case has been referred to a FTP panel and before the panel hearing. (Chapter 25 and paragraph 27.250)

Case Management

77. In the event that the GMC retains control of the adjudication stage, the GMC committee charged with governance of the adjudication stage should audit the work of case managers. Case management should apply to cases with a performance element. (Chapter 25 and paragraph 27.252)

78. FTP panellists should be warned that they should exercise caution about drawing adverse inferences from a failure to comply with case management orders. (Chapter 25 and paragraph 27.253)

Legally Qualified Chairmen

79. In the event that the GMC retains control of the adjudication stage, it should appoint a number of legally qualified chairmen who should, as an experiment or pilot, preside over the more complex FTP panel hearings. The results of the pilot scheme should be scrutinised to see whether there are benefits, whether in terms of the improved conduct of hearings, more consistent outcomes, improved reasons and/or fewer appeals. (Chapter 25 and paragraph 27.254)

Evidence

80. As part of their training, FTP panellists should be advised about their discretion to admit hearsay evidence and other forms of evidence not admissible in a criminal trial. Panellists should also be advised, during training, that it is entirely appropriate for them to intervene during FTP panel hearings and to ask questions if they feel that any issue is not being adequately explored. (Chapters 21 and 25 and paragraph 27.255)

Standard of Proof

81. The GMC should reopen its debate about the standard of proof to be applied by FTP panels. The civil standard of proof is appropriate in a protective jurisdiction. It is arguable that the criminal standard of proof is appropriate in a case where the allegations of misconduct amount to a serious criminal offence. (Chapters 21 and 25 and paragraph 27.256)

Notification of the Proposed Outcome of a Hearing

82. The GMC should abandon its intention to notify doctors, at the same time as sending notice of referral of their case to a FTP panel, of the outcome it will be seeking at the FTP panel hearing. (Chapter 25 and paragraph 27.257)

Reasons for Findings of Fact

83. FTP panels should be required to give brief reasons for their main findings of fact. (Chapters 21 and 25 and paragraph 27.258)

Referral of a Case after a Health or Performance Assessment

84. Rule 17(5)(b) of the November 2004 Rules (which permits a FTP panel, on receipt of a report of a health or performance assessment, to refer the

allegation back into the investigation stage for consideration of voluntary undertakings) should be revoked. (Chapter 25 and paragraph 27.259)

Evidence to Be Received

85. Rule 17(2)(j) of the November 2004 Rules should be amended to make clear what types of further evidence should be received before a FTP panel decides whether a doctor's fitness to practise is impaired. That evidence should include the doctor's previous FTP history with the GMC or any other regulatory body. Rule 17(2)(l) should be amended to make clear what categories of evidence might be received after a finding of impairment of fitness to practise but before determination of sanction. (Chapter 25 and paragraph 27.260)

Warnings

86. The Medical Act 1983 should be amended to permit a FTP panel to issue a warning in a case where it has found that a doctor's fitness to practise is impaired but not to a degree justifying action on registration. (Chapter 25 and paragraph 27.261)

Undertakings

87. Rule 17(2)(m) of the November 2004 Rules, which permits a FTP panel to take into account written undertakings entered into by a doctor when deciding how to deal with the doctor's case, should be revoked. If it is to be retained, the rule should be amended to make clear that undertakings can be taken into account only at the stage of deciding on sanction, after findings of fact and a decision about impairment of fitness to practise have been made. In that event also, provision should be made within the Rules for supervision of the doctor to ensure compliance with undertakings, for the holding of review hearings in cases where a doctor has given undertakings and for dealing with a breach of an undertaking. (Chapter 25 and paragraphs 27.262–27.263)

The Need for Supervision

88. Throughout the period that a doctor's registration is subject to conditions imposed by a FTP panel or to voluntary undertakings, someone within the GMC (preferably a case examiner) should take responsibility for monitoring the doctor's progress and for ensuring, so far as possible, that s/he is complying with the conditions imposed or undertakings given.

89. In every case where a doctor is continuing to practise subject to conditions or voluntary undertakings, a professional supervisor should be appointed to oversee and report on the doctor's progress and on his/her compliance with the conditions or undertakings. In a case where a doctor's health is an issue, a medical supervisor should be appointed.

90. Any breach of a condition imposed by a FTP panel or of a voluntary undertaking (save for the most minor breach) should result in the doctor being referred back (or referred) to a FTP panel so that consideration can be given to imposing a sanction which affords a greater degree of protection to the public. (Chapter 25 and paragraphs 27.264–27.266)

Review Hearings

91. The November 2004 Rules should be amended to ensure that there is at least one review hearing in all cases where a period of suspension or conditions on registration have been imposed, unless there are exceptional reasons why no such hearing should take place.

92. The arrangements set out in the draft General Medical Council (Fitness to Practise) Rules 2003 (the 2003 draft Rules), whereby any necessary gathering of evidence in preparation for a review hearing would be undertaken by a specially appointed case examiner, should be reinstated.

93. In all but exceptional cases, a doctor whose registration has been suspended should be required to undergo an objective assessment of his/her fitness to practise before being permitted to return to practice. That assessment should be considered by a FTP panel at a review hearing and a decision should be taken as to the doctor's fitness to practise. A doctor who has been the subject of conditions on his/her registration should be required to go through the same process. Doctors who are the subject of voluntary undertakings should also be required to undergo such an assessment before their undertakings are permitted to lapse.

94. The GMC's primary role should be one, not of remediation of doctors, but of protection of patients. If a doctor who is subject to conditions or voluntary undertakings undergoes an assessment in the circumstances described above, and the assessment reveals that s/he does not meet the required standard, consideration should be given to taking the steps necessary to remove the doctor from practice. He or she should not be permitted to 'limp on' with repeated periods of conditional registration and no real hope of meeting the standard for unrestricted practice. (Chapters 22, 24 and 25 and paragraphs 27.249 and 27.267–27.274)

Applications for Restoration to the Medical Register

95. The arrangements set out in the 2003 draft Rules, whereby any necessary gathering of evidence in preparation for a restoration hearing should be undertaken by a specially appointed case examiner, should be reinstated.

96. Every doctor whose application for restoration to the register has reached the second stage of the procedure should be required to undergo an

objective assessment of every aspect of his/her fitness to practise. The doctor should not be restored to the register unless s/he has met the required standard.

97. Doctors who are restored to the register should be required to have a mentor whose task it will be to monitor, and report to the GMC on, their progress in practice. (Chapters 24 and 25 and paragraphs 27.275–27.277)

Cases involving Drug Abuse

98. A thorough investigation of the circumstances underlying allegations of misconduct involving drug abuse should be conducted. The full facts should be established, including the circumstances in which the abuse began.

99. The GMC should commission research into drug abusing doctors and the outcomes of their cases following supervision under the health procedures. (Chapter 23 and paragraph 27.278)

Transparency

100. Every aspect of the FTP procedures in which either doctors or makers of allegations have a direct interest should be set out in the Rules. In addition, the GMC should publish a FTP manual, containing all its relevant Rules and its guidance for panellists, case examiners and staff, together with any relevant Standing Orders.

101. Clear statistical information should be collected and published by the GMC. The GMC should publish an annual report which should amount to a transparent statement of the year's activities in respect of the FTP procedures. (Chapter 25 and paragraphs 27.279–27.280)

Audit

102. The GMC should carry out audits of various specific aspects of its procedures, in addition to its other routine auditing activities. (paragraphs 27.203, 27.232, 27.233, 27.240 and 27.241)

Revalidation

103. The arrangements for revalidation should be amended so that revalidation comprises, as required by section 29A of the Medical Act 1983, an evaluation of an individual doctor's fitness to practise. (Chapter 26 and paragraphs 27.281–27.282)

104. The annual report referred to at 101 above should include clear statistical information about the number of applications for revalidation and their outcomes. It should amount to a transparent statement of the year's revalidation activities. (paragraph 27.280).

Independent Review

105. In three to four years' time, there should be a thorough review of the operation of the new FTP procedures, to be carried out by an independent organisation. This task should be undertaken by or on the instructions of the CRHP/CHRE. (paragraph 27.307)

Constitution

106. The GMC's constitution should be reconsidered, with a view to changing its balance, so that elected medical members do not have an overall majority. Medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition. (paragraphs 27.310–27.312)

Public Accountability

107. The GMC should be directly accountable to Parliament and should publish an annual report which should be scrutinised by a Parliamentary Select Committee. (paragraph 27.314)

The Council for Healthcare Regulatory Excellence

108. Section 29 of the National Health Service Reform and Health Care Professions Act 2002 should be amended so as to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' and findings of 'no impairment of fitness to practise', as well as in respect of sanctions which it believes were unduly lenient.

109. There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC. (Chapter 21 and paragraph 27.283)