

*To consider*

## Confidentiality Guidance

### Issue

1. Whether Council approves the revised guidance on confidentiality and the proposals for its promotion and implementation. The paper identifies the issues that generated the most debate and comment during consultation.

### Recommendations

2.
  - a. To consider the guidance on the public interest test (Annex B, paragraphs 36-54) and whether we have found the right balance between the interests of society and of the individual (paragraphs 10 -14).
  - b. To consider whether in paragraphs 41 and 42 of the draft guidance we have provided sufficient advice on judging when it is 'practicable' to seek patients' consent to disclosure or to anonymise records for use in research or for other secondary purposes (paragraphs 15-20).
  - c. To consider whether, and if so, in what terms, it is appropriate to refer to 'safe havens' in the guidance (paragraphs 21-25).
  - d. To consider the Supplementary Guidance on *Reporting gunshot and knife wounds* (Annex B, pages 28-31) and to consider whether we have found the right balance between the need to provide a confidential health service to those in need of immediate medical care, and the need to ensure the police are able to protect the community and prevent or detect serious crime (paragraphs 26-32).
  - e. To approve the draft guidance (Annex B) for publication, taking into account amendments agreed by Council (paragraphs 8-33).

- f. To approve the proposals for implementation (paragraphs 36-50).

### **Further information**

3. If you require further information about this paper, please contact us by email: [gmc@gmc-uk.org](mailto:gmc@gmc-uk.org) or tel. 0161 923 6602

## **Background**

4. Key Aim 4 of our 2009 Business Plan is to encourage and support doctors in the delivery of high-quality healthcare by providing accessible, up-to-date guidance on standards and ethics. The Business Plan commits us to the following objective in relation to this aim:

To update and reissue our advice to doctors on standards and ethics guidance, ensuring it is fit for purpose in a changing healthcare environment, focusing on end of life care, confidentiality and research.

5. Our current guidance was last reviewed and reissued in 2004. This followed a period of debate and uncertainty about the application of the common law and the Human Rights Act to the use and disclosure of medical data.

6. In 2007, our Standards and Ethics Committee agreed to review the guidance and set up a working group chaired by Dr Henrietta Campbell, the former Chief Medical Officer for Northern Ireland. Annex A provides further background information about the legal issues, the working group, the development of the draft guidance and the consultation process.

7. The development of the guidance was overseen by the Standards and Ethics Committee. This Council has not had an opportunity to discuss the draft during its development. We have now adopted a new model of working which will involve engagement with Council members from the early stages of projects to their completion.

## **Discussion**

8. The draft guidance at Annex B comprises a core booklet (pages 4 to 23) which sets out the principles that underpin good practice, and provides advice on key issues such as disclosures in the public interest. It takes into account the differing legal frameworks in the four UK countries; and is consistent with the guidance issued by other bodies with responsibility for the management and use of medical records, including the UK health departments and the Information Commissioner's Office.

9. To support the high level advice in the core booklet, we have drafted seven pieces of supplementary guidance which give more detailed advice on issues of particular concern to doctors:

- a. Reporting concerns about patients to the Driver Vehicle and Licensing Agency (covering Scotland, England and Wales) and the Driver and Vehicle Agency (Northern Ireland).
- b. Disclosing records for financial and administrative purposes.
- c. Reporting gunshot and knife wounds.
- d. Disclosing information about serious communicable diseases.

- e. Disclosing information for insurance, employment and similar purposes.
- f. Disclosing information for educational and training purposes.
- g. Responding to criticism in the press.

*Disclosures in the public interest (paragraphs 36-54 of the draft guidance)*

10. Paragraph 36 of the draft guidance describes the public interest test. This test is key to many decisions about disclosing information without consent; and it is important that it is clearly expressed and accurately reflects the requirements of the common law and of Article 8 of the European Convention on Human Rights.

11. In paragraph 36 we describe the necessary balancing of the harms likely to arise from non-disclosure against the possible harm to the patient, and to the overall trust between doctors and patients, arising from the release of information. The subsequent paragraphs provide further interpretation.

12. In the consultation 75% of respondents agreed that the advice is helpful, 19% disagreed and 6% were not sure. Of those who commented, equal but small numbers argued that we had given insufficient weight either to the value of confidentiality to the individual:

‘There will only be very few cases in which disclosure without the service user’s consent will be appropriate’ – Doctor

or to the value of disclosing information for research or other ‘public good’ purposes:

‘But more could be made of information that is needed for the public good – the public good is as legitimate as protection of the public from harm’ – NHS organisation.

13. It was also suggested that we should give more weight to the public interest in a confidential medical service:

‘The description of the public interest test does not make clear enough that that the maintenance of overall trust between doctors and patients is itself a matter of public interest’ – Body representing patients and public.

14. The Working Group concluded that as, a significant majority of respondents supported the balance we had struck between the individual’s and society’s needs, no change should be made to weight the test either in favour of disclosure in the public interest, or in favour of protecting individual’s confidentiality.

**Recommendation:** To consider the guidance on the public interest test (Annex B, paragraphs 36-54) and whether we have found the right balance between the interests of society and of the individual.

*Research and other secondary uses of patient information (paragraphs 39-49 of the draft guidance)*

15. The use of patient information for research, education and training and administration addresses the issues that caused most concern in our existing guidance (see Annex A, paragraphs 7-11). The guidance continues the advice in the 2004 guidance that doctors should use anonymised data for research or other secondary uses of data, or seek patients' consent to the use of identifiable data, wherever practicable.

16. In the consultation, 66% of respondents agreed that the consultation draft represented an appropriate balance between protecting and providing information for secondary uses, 14% indicated that the balance was not appropriate, and 20% were not sure.

17. The Medical Research Council (MRC) 'strongly supports clarification of the area of secondary use of records for research'. The MRC described the consultation draft guidance as 'helpful guidance and standards for researchers' and the specific advice on reasonableness and practicability as consistent with MRC guidance in this area.

18. A number of respondents expressed concern at the imprecision of the word 'practicable' and the explanation in footnotes 14 and 15 (Annex B, page 12):

a. 'The word practicable could be a weasel word unless you define what that means very clearly' – Doctor.

b. 'The guidance ... does not make explicit when it would not be reasonably practicable to anonymise or code the information' – The National Aids Trust.

19. The BMA expressed concern that inadequate efforts are often made in practice to obtain patients' consent for secondary uses of patient information and that the draft guidance does not represent an appropriate balance between respect for patients' privacy and the important secondary uses of patient identifiable information.

20. The Working Group concluded, however, that the guidance should not attempt to define 'practicable' further, because the length, format, age and number of records would all vary; and because no single formula for assessing 'practicability' would be appropriate to all circumstances.

**Recommendation:** To consider whether in paragraphs 41 and 42 of the draft guidance we have provided sufficient advice on judging when it is 'practicable' to seek patients' consent to disclosure or to anonymise records for use in research or for other secondary purposes.

21. Paragraphs 47 and 48 of the draft guidance support the use of 'safe havens' and temporary staff to undertake the sometimes onerous tasks of anonymising information or seeking patients' consent to its disclosure for secondary uses or so that suitable patients might be invited to participate in research.

22. Our position on the use of safe havens was broadly supported by 69% of those responding to the consultation including research and government bodies, such as the Academy of Medical Sciences, the Information Services Division of NHS Scotland and research and development leads in the Department of Health (England). Some of those bodies also asked us to place an explicit duty on doctors to contribute to or otherwise support research and other secondary uses.

23. The BMA, the Patient Information Advisory Group, which has since been re-constituted as the Ethics and Confidentiality Committee (ECC) and the National Information Governance Board also supported the introduction of safe havens in principle, but expressed concerns about the lack of a clear legal basis for disclosures to safe havens and to the use of, or further disclosure of, identifiable information by them. They argued that we should not refer to safe havens until it was clear that disclosures to them would be lawful.

24. The Working Group concluded that the initial disclosure of patient identifiable information to safe havens might be justified in the public interest without the need for approval from the ECC of the National Information Governance Board, or other statutory support, and that the work of the Information Services Division in Scotland gave some encouragement to that view. Furthermore, the Information Centre would be seeking approval from ECC for disclosure of identifiable data to safe havens in due course, and the Government had indicated that it would continue to consider the appropriate legal structures for the different types of processing that might in future be carried out using safe havens.

25. The Working Group revised the draft guidance to reflect more clearly the roles of Privacy Advisory Committees in Scotland and in Northern Ireland and the different legal and practical frameworks for secondary uses in those countries. The Working Group concluded that the draft guidance represented a pragmatic and workable solution to the problems faced by researchers across the UK.

**Recommendation:** To consider whether, and if so, in what terms, it is appropriate to refer to 'safe havens' in the guidance.

### *Reporting gunshot and knife wounds*

26. This section of supplementary guidance brings together separate, but very similar guidance notes on reporting gunshot wounds and knife crime. Information about the development of this guidance is at paragraphs 12-15 of Annex A.

27. In the consultation we asked whether the guidance should cover both knife and gunshot wound, and 77% of respondents agreed that it should. However, detailed comments revealed some serious disagreements about the public interest in alerting the police to gunshot and especially knife wounds. Some respondents believed that any involvement of the police would deter people from seeking medical attention when they most needed it. The Royal College of General Practitioners argued that 'to make disclosure mandatory ... could do more harm than good'. One doctor summarised their experiences:

'Most patients I treat do not want the police involved. They are from a part of society that distrusts/hates the police. There are often warrants out for their arrest. I would expect that [if] my patients knew I would inform the police they would not attend A&E and mortality from these wounds would increase. We already have patients & their friends not calling ambulances for stab wounds to avoid the police being aware of the events.'

28. The Police Service of Northern Ireland, on the other hand, wrote in terms that appear to reflect the majority of respondents' views:

'Doctors should be under a positive obligation to report all gunshot and knife wounds to the police irrespective of the wishes of the patient. Failure to make such disclosures in a timely fashion to police could inhibit the prompt investigation of crime and lead to the loss of forensic and witness evidence. This in turn could further endanger the public if offenders remain at large following an incident as they could commit further crime or make good their escape.'

29. A small number of respondents asked why we were extending the guidance on gunshot wounds to include knife wounds and why these forms of violence should be subject to special arrangements.

30. The supplementary guidance differs from the core guidance only in requiring disclosure of the fact that an unnamed person has been harmed by a gunshot or knife. This is intended to help the police assess whether other patients, hospital staff and others in the community may need protection from further immediate violence in what is likely to relate to gang crime. It also helps them compile reliable statistical data which can be used to reduce crime in particular areas.

31. The decision to disclose the identity of the victim of gun or knife crime is taken on the same grounds as for the victim of any other crime, and can be justified in the public interest to 'assist in the prevention, detection and prosecution of serious crime, especially crimes against the person. When victims of violence refuse police assistance, disclosure may still be justified if others remain at risk, for example from someone who is prepared to use weapons' (paragraph 51 of the draft guidance).

32. The Working Group made changes to the draft to highlight the need for a two-stage process, but concluded that at present the disclosure of the fact of gun or knife injuries represented a fair balance between the wider needs of society and the protection of individual privacy.

**Recommendation:** To consider the Supplementary Guidance on *Reporting gunshot and knife wounds* (Annex B, pages 28-31) and to consider whether we have found the right balance between the need to provide a confidential health service to those in need of immediate medical care, and the need to ensure the police are able to protect the community and prevent or detect serious crime.

33. The new draft guidance also includes new or expanded advice on protecting information, sharing information with patients' partners, families or carers; genetic and other shared information; disclosing information about serious communicable diseases and responding to criticism in the press.

**Recommendation:** To approve the draft guidance (Annex B) for publication, taking into account amendments agreed by Council.

#### *Next Steps*

34. We will make any further changes to the draft agreed by Council, and then obtain Counsel's opinion on the draft guidance to ensure its consistency with the law across the UK. We will also commission the Word Centre to re-edit the draft for plain English.

35. The guidance will be launched in September 2009. Copies of the core guidance will be distributed to all doctors with *GMCtoday* in September 2009 and the core and supplementary guidance will be published on-line with web-links to the various resources signposted.

#### Implementation

36. We will take a range of approaches to publicise the guidance and help doctors put it into practice. We will also seek ways of improving understanding of confidentiality issues among patients and the public.

37. There is almost universal agreement on the principle that the information doctors learn from or about patients in their professional capacity should be regarded as confidential. However, there is confusion about what this means in practice, for example, when disclosures without consent are justified, or who has access to information within the health services and how the health services store and use information.

38. Our approach to implementing the guidance should therefore focus on the issues of difficulty, directed to the specific groups within the profession most likely to encounter them. At the same time, we will work to improve public understanding of how records are used in health services in the provision of care and for wider benefits including audit, research and teaching.

#### Promoting guidance to the profession

39. We will work with other professional bodies and organisations to promote subject areas within the guidance, focussing particularly on the supplementary guidance issues. For example:

- a. We will work with the UK health departments, the College of Emergency Medicine, the Associations of Chief Police Officers and others to maximise understanding of and compliance with the advice on reporting gunshot and knife wounds.

b. We have established good relations with several professional groups, charities and patient groups with an interest in the advice on disclosing information about serious communicable diseases, and will seek their help in promoting good practice to their members and stakeholders.

c. Occupational health doctors and their professional and representative bodies were concerned about aspects of the guidance on disclosures for insurance, employment and similar purposes. We can use this as an opportunity for ongoing work to explain the reasons for our guidance and to ensure it is reflected in specialty-specific advice and implemented in practice.

40. The press team and colleagues in public relations and external affairs were integral to the promotion of the consultation, which engaged a wide professional audience. Their continued involvement in promoting the guidance will be central to our building on that good foundation to reach a wider professional, public and patient audience for the guidance and related learning materials.

41. We are exploring other ways to promote the guidance and the principles it outlines. Much of this is at an early stage, but includes:

a. Screensavers to highlight the importance of locking computers and not sharing passwords: the problems of IT systems and work practices that serve to undermine these good practices were raised as part of the review and have been mentioned in ethical enquires received by the Standards and Ethics Team.

b. Templates for doctors to download and adapt for use in providing information to patients about how their information will be used: it was a recurring theme of the consultation that this is an onerous task and that the NHS 'doesn't do fair processing notification'. The provision of templates outlining the main uses of patient information might improve the accuracy of information included in practice leaflets and promote both more realistic expectations on the part of patients and better practice on the part of healthcare teams.

#### Implementing the guidance

42. We can also use our website as a means of communicating with the profession. We have already started to develop cases in the *Good Medical Practice in Action* format relating to confidentiality, and will consider whether it would be helpful to produce more detailed case studies analysing for example, the decision-making process needed before disclosing information in the public interest.

43. Again, we propose to work with partner organisations to develop and disseminate case studies and other learning materials focussing on, for example:

a. Primary care commissioners' access to patient identifiable information for financial audit of general practice, especially related to Quality and Outcomes Framework (QOF) reviews.

- b. Disclosing details of patient's serious communicable diseases to their sexual partners or to facilitate the testing of their children if they refuse to consent.
- c. Alerting the DVLA/DVA to concerns about patients' fitness to drive in the absence of a definite diagnosis
- d. Responding to complaints, e.g. from partners of deceased patients about the care given in their final illness.
- e. Supporting victims of domestic violence in seeking help without making unconsented disclosures.
- f. Disclosing information to the police for purposes of preventing, detecting or prosecuting serious crime, e.g. by helping doctors to identify the threshold for disclosure.

44. We can also consider whether we can use our website in other ways, for example by hosting 'webinars' or other interactive events.

#### Patients and the public

45. We will explore the possibility of working with patient/public partners in producing and promoting a short guide for patients on the principles, relevant examples of when it is appropriate for doctors to share information and when and how patients can expect to be asked or told about such disclosures. We have traditionally avoided publishing short versions of our guidance to avoid any risk of confusion in considering fitness to practise issues. However, with careful drafting we may avert any serious risk of inconsistencies arising.

46. During the consultation phase of the project, the information needs of carers emerged as an area in which there is a need and desire for more or clearer advice. Despite efforts to incorporate advice on providing information to vulnerable adults' carers and on the information needs of parents who care for children during their transition to adulthood, we are aware that this is an area which could be developed further.

47. The Princess Royal Trust for Carers was particularly helpful and interested in this issue and has offered to work with us in developing materials or undertaking other work to promote the confidentiality rights of vulnerable adults while maximising support for carers, whose ignorance of important details can be detrimental both to patients' health and to carers' own wellbeing.

48. We will offer the learning materials as a resource to others in their own work in educating students, doctors and other health professionals, complaints investigators, patients and the public about confidentiality issues.

49. In addition to developing the materials we will work with colleagues within and outside the GMC on raising awareness and developing a better appreciation of the issues addressed in the guidance. We will of course seek and accept invitations to talk about the guidance and to engage in any relevant activities that present an opportunity to promote respect among the profession for patients' confidentiality.

50. We will continue to use the expertise and interest of Working Group members in these activities.

**Recommendation:** To approve the proposals for implementation.

### **Resource implications**

51. To publish 240,000 copies of the guidance will cost approximately £50,000. There will also be some additional costs for postage, shared with the normal costs of sending *GMCtoday* to all registered doctors.

52. The cost of each set of cases for *Good Medical Practice in Action* is about £21,000. Other costs for developing web-based cases which are more reliant on text are likely to be considerably less. We have allocated a total budget of £25,000 for learning materials and other costs involved in the implementation plan for 2009. This excludes the cost of *Good Medical Practice in Action*, which is budgeted for separately.

### **Equality**

53. Issues of how this guidance might impact on different equality groups were considered throughout the review. The reported concerns about barriers to Asian women accessing confidential health services was one of the issues we sought to find out more about, for example through a focus group with the Minority Ethnic Women's Network (MEWN) in Wales. The particular concerns of HIV-positive patients, offenders and incapacitated or otherwise vulnerable patients, such as victims of domestic violence, were identified in the review as groups with potentially heightened confidentiality concerns. We have drafted an Equality Impact Assessment and, in planning for raising awareness of and implementing the guidance, we will continue to consider the impact of the guidance on these and other equality groups.