
5 – Confidentiality Guidance - Annex A

Background

1. In February 2007 the Standards and Ethics Committee (SEC) agreed to oversee a review of the guidance *Confidentiality: protecting and providing information* (and accompanying Frequently Asked Questions), which was published in 2004. The Confidentiality Review Working Group was established under the chairmanship of Dr Henrietta Campbell, former Chief Medical Officer for Northern Ireland.

Working Group membership

Dr Henrietta Campbell Chair

GMC members

Professor Ian Hughes	Lay SEC member
Dr John Jenkins	Medical member, chair of SEC
Mrs Patricia Moberly	Lay SEC member
Dr Nicola Toynton	Medical SEC member

External members

Dr Claire Eatock	Lay, public member of the Patient and Public Reference Group
Dr David James	Royal College of Psychiatrists representative
Sir Mark Walport	Director of the Wellcome Trust

Scoping the review

2. To establish the priorities for and scope of the review, we commissioned a literature review on Public and Professional Attitudes to Privacy of Healthcare Data (available at www.gmc-uk.org/confidentiality).

3. We held meetings with or received written submission from the following representatives of organisations with a particular interest in this guidance:

- a. Information Management Branch, DHSSPS Northern Ireland.
- b. British Medical Association Ethics Team.
- c. Patient Concern.
- d. Information Policy Branch, NHS Connecting for Health, Department of Health (England).
- e. Terence Higgins Trust.
- f. Academy of Medical Sciences.
- g. Information Commissioner's Office.
- h. Scottish Executive Health Department.
- i. Royal College of Physicians.
- j. Royal College of General Practitioners.
- k. UK Clinical Research Collaboration.

4. These respondents were asked for their views on:

- a. The most important confidentiality issues now and in the future.
- b. Significant organisational and legal changes since 2000.
- c. Whether the GMC should continue to publish advice on this topic, given that the departments of health, Information Commissioner and others do so; and
- d. Whether there were any major omissions in the existing guidance.

Initial consultation

5. To build on the scoping work and broaden the range of views sought to inform the review, in January 2008, the Working Group issued a call for contributions to the review through an initial consultation. Respondents were asked about similar issues to those in the scoping exercise and on some key principles agreed by the Working Group. Despite the shortness of time of time for publicising the initial consultation, we received 100 responses. The majority of respondents said that:

- a. Confidentiality remained an important professional value, not just a contractual or legal obligation.
- b. There was a continuing need for guidance from the GMC given our role as the UK-wide regulator responsible for holding doctors to account.
- c. The key issues for doctors in this area and which should therefore be considered in the scope of review were:
 - i. Electronic health records (especially the National Care Record Service) with concerns expressed that doctors might be held accountable for the failures of a national system over which they had no control.
 - ii. Secondary uses of patient data, with concern that our current guidance impedes research involving patient identifiable data where the potential harm to patients' privacy is small.
 - iii. Information technology, as an area in addition to electronic health records, where there was concern about the unintentional disclosure of patient identifiable data as a result of increased electronic storage and transfer of data.
 - iv. The criminalisation of HIV and related issues previously covered in our guidance on *Serious Communicable Diseases*.
 - v. Issues relating to children and young people and particularly relating to child protection proceedings and the rights of young people to confidentiality when sexually active (these issues and others relating to children and young people are covered in our recently published new guidance, [0-18 years: guidance for all doctors](#) (2007)).

6. A fuller summary of responses to this consultation is available at www.gmc-uk.org/confidentiality or on request.

Development of the guidance

Use of data in research and for other 'secondary' purposes

7. Our guidance on confidentiality was the subject of considerable debate and, sometimes, controversy between 1998 and 2004. This arose from disputes about the application of the common law, the scope of the Data Protection Act 1998, and the impact of the Human Rights Act 1998. During this period we were threatened with judicial review by patient and professional groups. When we published guidance in 2000, the research community, in particular, argued that our interpretation of the common law would put research in general, and the work of disease registers in particular, in jeopardy.

8. The position was largely resolved by legislation to establish the Patient Information Advisory Group (now the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB)) and the introduction of the Health Service (Control of Patient Information) Regulations 2002 which apply in England and Wales. Those regulations enable health information to be passed on for use by cancer registers, and for other specified purposes, without patients' consent. Disclosures of information for individual projects within the purposes specified in the Regulations are approved by the ECC.

9. We issued revised guidance in 2004 that reflected the new legal position and more formally acknowledged the practical difficulties of obtaining consent to the disclosure of information for research and other 'secondary' purposes. Since then the research community has continued to raise concerns about the difficulties of accessing reliable data for research. There have been a number of reports and reviews which have addressed this question in whole or in part. These include the report of the Care Record Development Board on Secondary Uses of Data, the Academy of Medical Sciences report *Personal data for public good: using health information in medical research* and the data sharing review commissioned by the Ministry of Justice and carried out by Sir Mark Walport and the Information Commissioner, Richard Thomas. These reports have acknowledged the difficulties inherent in the current arrangements and have proposed a range of possible resolutions, in which the use of 'safe havens' – centres that store, protect and code or anonymise data for use in research and other secondary uses – is a common theme. In Scotland there is already an established secondary uses service in the Information Services Division of the NHS Commons Services Agency.

10. However, there is no clear legal basis for disclosure of identifiable information to safe havens without consent. In England, the NHS Information Centre is leading work to define the information governance standards and a compliance framework for safe havens and to secure support from the ECC of the NIGB using the powers in the NHS Act 2006. ECC has jurisdiction in England and Wales. In Scotland there are no current proposals to address the legal position, and no challenges have been made in the courts to the current arrangements. We understand that, in Northern Ireland, consideration is being given to the need for the introduction of a legal means to use identifiable data without consent.

11. The Working Group has taken the view that, since our guidance applies across the UK, it is reasonable to recommend the use of the services provided by safe havens in circumstances where it is not practicable for doctors to seek consent or to anonymise or code data. This service is already available in Scotland and is likely to be introduced in England in the next year.

Reporting Gunshot and Knife Wounds

12. Our guidance *Reporting Gunshot Wounds – Guidance for Doctors in Accident and Emergency Departments* (2004) was developed with the Association of Chief Police Officers and with the support of the British Association (now College) of Emergency Medicine.

13. The guidance requires doctors to ensure the police are informed as soon as possible whenever a person with a gunshot wound seeks treatment. This initial disclosure is only of the fact that a person had been injured by a gunshot wound. A separate decision to disclose the identity of the patient is taken on the usual public interest test grounds, if the patient does not wish to talk to the police. The guidance was based on the view that gunshot wounds are a special category: any gunshot wound raises at least some question about public safety. Even accidental shootings involving lawfully held guns raise serious issues for the police about a person's suitability to hold a gun licence.

14. In 2007, the Home Office asked us to consider introducing parallel guidance requiring doctors to report all knife injuries to the police. This followed considerable publicity about knife crime involving young people and concerns about the possible level of unreported knife attacks. We agreed to consider the issue as part of the wider confidentiality review. We were concerned about broadening the guidance as there seemed to be no basis on which to distinguish between knife crime and violent crime using other or no weapons. However, in response to further requests from the Government, we agreed in August 2008 to publish interim guidance with the Department of Health (England) on reporting knife wounds.

15. The Working Group agreed that the two pieces of advice should be combined as a single piece of guidance supplementary to the core confidentiality guidance, and questions about this issue were included in the consultation.

Formal consultation

16. In June 2008 the Working Group considered recommendations on a revised draft of the guidance based on analysis of the consultation responses. It recommended a draft for formal consultation to the Standards and Ethics Committee, which was approved. A formal consultation on revised draft core and supplementary guidance was launched on 8 September 2008 via the GMC's online, public consultation site.

17. To raise awareness of the consultation, we wrote to approximately 2000 organisations and individuals across the UK, including those who had previously expressed an interest in this topic or our guidance generally, inviting them to participate. The circulation list included medical bodies, patient representative bodies and charities, other professional regulators, NHS employers and government health departments. The contact list was expanded to include those known to be particularly affected by or interested in confidentiality issues.

18. The consultation was publicised in *GMCtoday*, on the GMC website, by press release and using a podcast featuring Sir Graeme Catto on our own and doctors.net websites.

19. Two separate questionnaires were issued to help respondents structure their responses. One provided detailed explanation of the issues and changes to the guidance and was aimed primarily at informed individuals and organisational representatives. The second shorter questionnaire focused on key issues around confidentiality, did not rely on respondents reading the draft guidance and was aimed at organisations with limited resources and at individual doctors, patients or other members of the public.

Meetings

20. In addition to the opportunity to respond to the written consultation, meetings were arranged across the UK to offer opportunities to discuss key issues in the guidance. In summary the following were held:

- a. Meetings with relevant and interested organisations (including the Terence Higgins Trust, Hepatitis C Trust, Stonewall, Princess Royal Trust for Carers, Health Service Ombudsman, College of Emergency Medicine, Department of Work and Pensions and the Association of Chief Police Officers).
- b. A focus group held in Cardiff with minority ethnic women, arranged through Minority Ethnic Women's Network (MEWN).
- c. Roundtable meetings which brought together professional and patient/public organisational representatives with an interest in the guidance in Cardiff, Belfast, Edinburgh and London.
- d. A Parliamentary lunch at which interested peers and MPs were given an opportunity to consider the draft guidance and discuss some of the key questions.

Responses

21. We received a total of 224 written responses to both the long and short consultation questionnaires. Overall the majority of respondents agreed with the principles and positions taken. Many respondents submitted comments in addition to answering the questions (both those in agreement and disagreement) and these were used by the Standards and Ethics Team, along with records of discussions at the meetings, to prepare an analysis report which was considered by the Working Group in March 2009. The guidance was revised following this meeting, circulated to the Working Group and Standards and Ethics Reference Group, and now presented to Council for approval for publication.

22. A detailed analysis of responses to the consultation was considered by the Confidentiality Review Working Group at its final meeting on 16 March 2009 and is available from the office along with the consultation draft guidance and questionnaires.

23. A summary of the responses to the consultation is currently being prepared and will soon be published on the website.

Audit of the review

24. We have commissioned Professor Celia Davies to undertake an audit of our formal consultation process. Professor Davies is a sociologist whose long research career has included the study of health professions and their regulation.

25. The primary aim of the audit is to assess the transparency and fairness of the process adopted for capturing and analysing responses to the formal consultation. The audit will be completed by the end of August 2009, prior to the launch of the guidance and the audit report will be available on request.

Impact assessments

26. We drafted an equality impact assessment as part of the review process, which we referred to during and after the formal consultation and, in planning for raising awareness of and implementing the guidance. The written consultation documents asked respondents to consider the impact of the guidance on particular communities or groups as they answered questions, and highlighted those areas of the guidance where we thought such issues might arise. We also included a question at the end of the consultation asking for further comments on equality issues. Although the response to this was small, we have up-dated the assessment to reflect responses. We will continue to update it in considering the impact of the guidance on equality and diversity groups. A copy of the equality impact assessment is available from the office.

27. We have also started drafting a wider impact assessment, which was informed by the formal consultation questionnaires and meetings. We will continue to consult with colleagues in Strategy and Planning on the need to further develop the assessment.

Feedback

28. We will shortly be contacting all those who responded to the consultation providing a summary of the analysis of the consultation and the account of the development of the guidance as a whole. We will also let respondents know when the guidance is launched and how they can access the printed booklet and the electronic version.