

The Development of *Confidentiality* (2009)

September 2009

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PART ONE - CONTEXT

Introduction

1. This document outlines the development of Confidentiality (2009). This new guidance replaces [Confidentiality: Protecting and providing information](#) (2004) and accompanying [Frequently Asked Questions](#). Confidentiality (2009) is accompanied by seven pieces of supplementary guidance on a variety of topics, some of which were addressed in the FAQs but others which are new:

- reporting concerns about patients to the DVLA or to the DVA
- disclosing records for financial and administrative purposes
- reporting gunshot and knife wounds
- disclosing information about serious communicable diseases
- disclosing information for insurance, employment and similar purposes
- disclosing information for education and training purposes
- responding to criticism in the press

The role of the General Medical Council (GMC)

2. The GMC is the regulatory body for the medical profession in the United Kingdom. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. More information about the GMC's role is available on our [website](#)¹.

Setting standards

3. The GMC is responsible for advising the profession on medical ethics (under the *Medical Act* 1983). Until the beginning of 2009 the Standards and Ethics Committee (SEC) was responsible for developing and reviewing this advice. Following implementation of changes to the Council's constitution and working methods, the Committee has now been replaced by the Standards and Ethics Reference Group (SERG).

4. The GMC's core ethical guidance, [Good Medical Practice](#)² (2006) describes what is expected of all doctors registered with the GMC. The guidance consists of high level principles which apply to all doctors on the register, regardless of specialty, grade or whether they work in the private or public sector. It is therefore necessarily broad, but is supported by supplementary guidance in the form of the core guidance:

- [0-18 years: guidance for all doctors](#) (2007)
- [Confidentiality: Protecting and Providing Information](#) (2004)
- [Consent: patients and doctors making decisions together](#) (2008)
- [Management for Doctors](#) (2006)
- [Research: The Role and Responsibilities of Doctors](#) (2002)
- [Withholding and withdrawing life-prolonging treatments: Good practice in decision-making](#) (2002)

All our ethical guidance is accessible via our [Guidance on good practice](#)³ pages.

Background to the review

5. Since 1971 we have published advice of increasing length on confidentiality, with discrete guidance on the topic first published in 1995. Revised guidance published in 2000 was the subject of considerable public debate, with disputes about the common law and concern from the research community that the guidance put unreasonable restraints on the use of identifiable information about patients to the detriment of research and improvements in knowledge about health and disease.

6. The guidance published in 2004 updated the 2000 edition and did not represent a thorough review. The main changes were to take account of diverging legal positions across the UK countries and ensure consistency with Department of Health (England) and Scottish Government Health Directorates' guidance on confidentiality.

7. In 2007 the Standards and Ethics Committee (SEC), taking account of evidence of the role that our guidance played in an environment where the law is far from conclusive and suggestions that there was too much guidance from various bodies on this topic, agreed to a thorough review of the guidance. The review would ensure that the guidance was up to date, fit for purpose and accurately reflected the current legal position in all four home countries.

Confidentiality Review Working Group

8. A Working Group, led by an external chair was established to take forward the review on behalf of the SEC. Dr Henrietta Campbell, the former Chief Medical Officer for Northern Ireland, was invited to chair the group which comprised medical and lay members of the SEC as well as external members, to provide expertise in psychiatry and research, where some of the most difficult questions arise. The Working Group met four times between December 2007 and March 2009.

9. 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*](#)⁴.

10. We held meetings with the following representatives of organisations with an interest in this area of work or in our guidance:

- Information Management Branch, DHSSPS Northern Ireland
- British Medical Association Ethics Team
- Patient Concern
- Information Policy Branch, NHS Connecting for Health, Department of Health (England)
- Terence Higgins Trust
- Academy of Medical Sciences.
- Information Commissioner's Office
- Scottish Government Health Directorates
- Royal College of Physicians

11. In the absence of meetings, we asked the Royal College of General Practitioners and UK Clinical Research Collaboration to comment on questions around which the other meetings were based. These representatives were asked for their views on:

- the most important confidentiality issues now and in the future;
- significant organisational and legal changes since 2000;
- whether the GMC should continue to publish advice on this topic, given that the departments of health, Information Commissioner and others do so and;
- whether there were any major omissions in the guidance?

PART TWO – INITIAL CONSULTATION

12. To build on the scoping work, an initial consultation was held from January to February 2008 on similar issues. Despite a lack of time for publicising the consultation, there were 100 responses with a fairly even split between participants registering as individuals and those registering on behalf of an organisation. The majority of individual respondents were doctors, followed by other healthcare professionals and the majority of those responding on behalf of an organisation were employers. Responses are summarised below.

- An important professional value or simply a legal and contractual obligation?

13. All respondents felt that the duty to maintain confidentiality was an important professional value, but many highlighted the need for clarity about the extent to which it would be possible to always maintain confidentiality and others commented on the importance of remembering that it was supported by contractual and legal obligations.

- A continuing need for GMC guidance?

14. Despite the availability of guidance from other relevant bodies (e.g. the Information Commissioner) the majority of respondents said that the GMC should continue to produce guidance. Respondents commented that our role as UK-wide regulator meant that the standards against which doctors were to be judged must be articulated by us. Respondents also commented that there was need for guidance from the GMC to address the difficult *grey areas* which were not or could not be dealt with through contracts and the law as long as it was consistent with other guidance on these matters.

- Important confidentiality issues, organisational and legal changes since 2000 which are relevant to doctors and the GMC

15. The issues raised and taken into account in revising the guidance included electronic health records (National Care Record Service); secondary uses of patient data; information technology (in addition to electronic records) and those relating to children and young people including disclosure in relation to child protection proceedings and the rights of young people to confidentiality when sexually active –

all of which are covered in our recently published new guidance [0-18 years: guidance for all doctors](#) (2007).

16. Other issues raised included cross-government information sharing, the law (e.g. on data protection, freedom of information, human rights, human tissue and mental capacity legislation), interagency working, crime, genetics and sharing records for out of hours care.

- Any omissions in the guidance or examples of where the guidance is confusing, inaccurate or inconsistent with the law?

17. A few respondents highlighted instances in the guidance where they found specific paragraphs to be in conflict (either with each other, or guidance from other bodies) or where there appeared to be confusion or misinterpretation of particular issues, such as who comprises a healthcare team for the purposes of clinical audit.

- Any examples of difficult decisions doctors have to make?

18. Many examples were submitted in response to this question, including disclosures in relation to serious communicable diseases (SCDs); criminal activity; the distinction between ostensibly similar clinical audit or observational research activities; dual roles (e.g. occupational health doctors); and genetic and other shared information (where information about one person might also be information about another). Some of the issues raised are in fact already covered in our guidance, but others reveal a misunderstanding of the guidance; both suggest a need for clarification and clearer links between the core and supplementary guidance.

- Format of the guidance

19. The majority of respondents felt the guidance achieved a good balance between general principles and more detail in the *Frequently Asked Questions* whilst some indicated a lack of awareness of the FAQs. There was also support for web-based case studies to illustrate the principles in practice.

PART THREE - FORMAL CONSULTATION

20. Based on analysis of the responses, the Working Group considered recommendations on a revised draft of the guidance at its meeting in June 2008. The group recommended a draft for formal consultation to the SEC 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. Views were sought on draft core *Confidentiality* and supplementary guidance

Written consultation

21. To raise awareness of the consultation, we wrote to approximately 1400 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.

22. The consultation was publicised in *GMCToday*, on the GMC website, via issue of a press release and using a *podcast* which the President recorded to invite doctors to respond (it was downloadable from the GMC and 'doctors.net' website).

23. 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 rather than the draft guidance and was aimed at smaller organisations and individual doctors, patients and other members of the public and was also used as a template for discussion at most of the meetings.

Meetings

24. 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.

Meetings held during the formal consultation

- Relevant and interested individual organisations invited to discuss key issues in the draft guidance, 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.
- Focus group of patients held in Cardiff arranged with the help of the Minority Ethnic Women's Network (MEWN).
- Meetings with professional, public and patient representative bodies with an interest in the guidance were held in the four counties with some meetings focusing on themes including secondary uses of information, vulnerable adults and serious communicable diseases.
- Parliamentary lunch for interested peers and MPs to consider the draft guidance and discuss some of the key questions.

PART FOUR – RESULTS OF THE FORMAL CONSULTATION

Responses to the written consultation

25. There were 224 responses to the written consultation (54% long and 46% short). Of the responses, 56% were from individuals and 44% organisations. Respondents were also asked to categorise themselves according to fixed categories or select 'other' and provide a description themselves.

	Full consultation	Short consultation
Respondent Category	Number	Number
Individual		
Doctor	43	35
Medical educator (teaching, delivering or administrating)	3	3
Medical student	-	-
Healthcare professional or staff (other than a doctor)	4	6
Member of the public	5	9
Other healthcare professional	-	2
Other (please give details)	7	9
Individual Total (126)	62	64
Organisation		
Body representing doctors	11	5
Body representing patients or public	2	6
Government department	4	1
Independent healthcare provider	-	-
Medical School (undergraduate)	1	1
Postgraduate medical institution	-	1
NHS/HSC organisation	11	7
Regulatory body	2	4
Other (please give details)	13	2
Blanks	15	12
Organisation Total (98)	59	39
Total	121	103

Summary of responses

26. The long and short responses, together with notes of the meetings, were analysed by members of the Standards and Ethics Team. The final analysis report considered by the Working Group was quite lengthy; what follows is a summary. The percentages reported throughout this summary relate to long consultation questions. Not all the long consultation questions were replicated in the short questionnaire; where they were, a relevant response analysis is given and percentages reported here relate to the number of respondents answering that question rather than responding to the consultation as a whole (e.g. of the 78 people who answered the question, 83% agreed...).

Levels of agreement

27. The aim of the questionnaire was to determine whether respondents agreed or disagreed with the principles established in the draft guidance and then to determine whether the guidance as drafted was clear.

28. All questions about the principles in the draft guidance drew a positive response from a majority of respondents (ranging from 58 to 91%) indicating that they agreed with the stance taken. Comments explaining or qualifying the yes/no/not sure response provided the substance of analysis, along with answers to more open questions, e.g. about what more we might say on various issues.

Analysis of questions relating to the core draft guidance

29. The analysis that follows is grouped under the chapter headings used in the guidance.

Principles

30. 88% of respondents to question 1 agreed that the guidance in this section provided a useful introduction to the relevant principles that doctors should consider when they hold or share patients' personal information. The description of key principles in this section of the guidance (and expanded upon in the rest of the guidance) was welcomed by some as 'easily read and understood', and 'sensible and pragmatic'.

Protecting information

31. This section was drafted to reflect the increasing use of information technology, including the move towards electronic health records. The draft guidance on electronic health records included new advice on the responsibilities of doctors, which differ according to their role. We explicitly stated, following concerns raised during the initial consultation, that doctors are not expected to assess the security standards of large scale computer systems provided for their use.

32. 76% of respondents to question 3 agreed that the revised guidance properly reflected the differing responsibilities of doctors, as users or managers of health data, with some respondents saying that the guidance in this section was 'reassuringly proportionate' and 'clear and concise'. Others expressed concerns about the security of large-scale electronic health records systems and sought to reopen debates about the basis on which data might be added to the summary care record, which the Working Group agreed was outside the scope of this guidance; the disclosure of information touches on the legal and ethical aspects of confidentiality in a way that questions about data storage do not. One respondent suggested it would be good to reiterate the fact that the obligation to raise concerns applied as much to confidentiality and information governance as other areas, a change we have made.

33. 81% of respondents to question 2 agreed that doctors should follow UK health departments' guidance on the retention and disposal of health records, whether or not they work in the health services. In response to respondents' suggestions, references to guidance on records management in the devolved countries have been added to the footnote.

Disclosures required by law

34. 70% of respondents to question 4 agreed that the various regulatory bodies and powers referenced in the draft guidance were helpful; but there was some concern that the layout was unclear. A lengthy footnote has therefore been incorporated into a legal annex which allows for some context and easier reading.

35. 29% of respondents to question 5 said that there were other bodies or powers that should be included, although few of the suggestions were of obvious relevance

to most doctors' work. The legal annex is not exhaustive and instead signposts the reader to a selection of bodies, a summary of their most relevant powers and reference to codes they publish about how they use their powers.

Disclosing information with consent

36. Questions on this section of the guidance focused on circumstances in which patients may give implied consent to disclosure, for example where information is shared within the healthcare team or with others providing care for the purposes of providing or supporting the provision of care for that patient.

37. 75% of respondents to question 6 agreed that most people understand and accept that information must be shared within the healthcare team in order to provide their care, and that doctors' responsibility should be to make sure that information explaining this is 'readily available' to patients. Comments in response to this question suggested that we could be clearer about what was meant by information being 'readily available'. As a result, explanatory text in a footnote in the draft guidance was incorporated into the text to clarify what was meant.

38. Respondents were also asked about their understanding of who made up the 'healthcare team' (question 7 asked whether it was reasonable to include administrative and other staff who support the provision of care). 82% agreed with the description. There were some doubts about whether particular people (prescribing advisers and social workers for example) could be healthcare team members and these concerns were considered seriously by the Working Group. The guidance was amended to more clearly focus on the role performed and the contribution to the patient's care made by those who might be regarded as team members, rather than on job titles.

39. 71% of respondents to question 8 agreed that, if information explaining that personal information will be shared within the healthcare team is 'readily available' to the patient and the patient does not object, the patient's consent could be implied. This was a reassuringly high level of agreement, considering the change from the previous guidance that advised doctors to check patients' understanding. 14% were unsure and comments revealed that this was partly due to a lack of clarity around what was meant by 'readily available'. However, 51% of respondents to short question 3 indicated that doctors should check patients' understanding, indicating that making sure information was readily available was not good enough. There was some concern that the change in our guidance might make consent 'invalid', especially in the absence of any positive indication on the patient's part, however irrelevant it might be to the disclosure of information. The Working Group rejected this view, noting that most patients understand that information must be shared to provide their care, that most doctors do not routinely check patients' understanding, and endorsed the guidance, subject to the revisions already mentioned and to promote as a good 'rule of thumb' a test of whether patients would be surprised to learn how their information is being used.

40. A small number of respondents expressed concerns about the advice on disclosure for local clinical audit, both from those who argued that all audit could be undertaken without consent, and from those who argued that the use of identifiable

information - even for local clinical audit – was a temporary and ultimately unsatisfactory measure. Most respondents were supportive of the model outlined in the guidance and it was therefore retained, but the Working Group agreed that the overarching duty in *Good Medical Practice* (2006) to participate in local clinical audit and to contribute to National Confidential Inquiries should be added as a result of a respondent's helpful suggestion.

Disclosures for which express consent should be sought

41. Most respondents were supportive of this section of the draft guidance, recognising the high value some patients place on the control of their information when employers and others need information for purposes other than their care or treatment.

42. As a result of suggestions made by respondents, specific reference to our supplementary guidance on *Disclosing information for financial and administrative purposes* (which includes guidance on QOF post-payment verification) and to the *Data Protection (Processing of Sensitive Personal Data) (Elected Representatives) Order 2002* and the Information Commissioner's advice on the same were added.

43. 75% of respondents to question 9 agreed that the examples of disclosures for which express consent is usually required (insurance applications, occupational health purposes and financial audit) were good examples to explain the principle. Some changes were agreed to improve clarity and to take account of existing and forthcoming changes to the contractual obligations on GPs to share information for purposes of patients' benefits applications, and to reinforce a principled approach to the purpose of consent, rather than a pedantic focus on the means by which it is given and recorded.

44. 80% of respondents to question 10 agreed that doctors should offer to show patients reports they write for third parties *before* they are sent. There was some disagreement from individual doctors and bodies representing occupational health doctors on whether this would be practical and about the additional burden it would involve compared with the minimum legal requirements of the Access to Health Reports Act 1988. Some respondents were clear that the process described in the draft guidance was already widespread good practice.

45. The Working Group and the SERG considered carefully the representations made, preferring the view that the draft guidance represented useful clarification and should help doctors to ensure that patients understand and agree to relevant disclosures. The Working Group noted the submissions about the pointlessness in showing 'reports' to patients when they included simple confirmation of fitness to work to which patients were very unlikely to object. We have amended the draft to more strictly define the circumstances in which reports should be shown, to avoid unnecessary burden on doctors as well as patients, their employers and others.

Disclosures in the public interest

46. The guidance in this section covers perhaps the most difficult area of decision-making for doctors. The draft guidance retained the basic test from the

current guidance which explains when personal information can be disclosed in the public interest without the patients' consent and in exceptional cases where patients have withheld consent.

47. The draft guidance was generally very well received. We have revised the main test to improve clarity by advising doctors to compare the *harms* disclosure is intended to avoid with the *harms* of breaching confidentiality (the old guidance compared harms with benefits) and to emphasise the public interest in a confidential health service much more clearly. This is an aspect of the balancing exercise that can be overlooked and we hope this clarification will help doctors make what can be very difficult decisions.

48. Specifically, 75% of respondents to question 11 found the draft guidance helpful. Of those who commented, there were small, but equal numbers arguing that we had given insufficient weight either (a) to the value of confidentiality or (b) to the value of disclosing information for research or other 'public good' purposes. Some respondents asked for examples in this part of the guidance, but this was not a common request. On balance, the Working Group concluded that, although it is generally helpful to give examples, the inclusion of any here would be difficult as the basic test has to be broad enough to be applied to a very wide range of circumstances and inclusion of some might suggest exclusion of others. Additionally, this principle is illustrated in the sections following on from paragraph 36 and in the supplementary guidance where there is much more scope to explore the issues in question by reference to more specific circumstances.

Disclosures for [research and other] secondary uses

49. This new, distinct section of the guidance was introduced to explain how the guidance on disclosures in the public interest applies in the case of disclosures for the purposes commonly described as 'secondary uses' (including research, epidemiology, public health surveillance, health service planning and education and training). Overall, it was seen by the majority of respondents to the consultation to be a helpful addition to the guidance, even if many of the principles are unchanged.

50. 66% of respondents to question 14 agreed that the new guidance represented an appropriate balance between protecting and providing information for secondary uses. However, 20% of respondents were unsure and 14% disagreed, with much of the concern focusing on the imprecision of the word 'practicable' in relation to anonymising or coding data and the explanation given within the draft guidance.

51. The new draft guidance stated that the task of seeking patients' express consent to disclosures, or of anonymising or coding data for secondary uses, could be given to an 'honest broker' in a 'safe haven' or to somebody from outside the healthcare team if they were bound by contractual obligations of confidentiality.

52. 74% of respondents to question 15 agreed that this represented a reasonable way to ensure that information is available for secondary uses when it is impractical for the healthcare team to do the work. Others, while supportive of safe havens in principle, expressed concerns about the lack of a clear legal basis for disclosures to safe havens and about their roles and governance.

53. With the helpful suggestions of respondents to the consultation and by engaging with the organisations closely involved in this work, we have clarified the current state of development of safe havens in England and Scotland; the roles and remit of the National Information Governance Board in England and Wales, and the Privacy Advisory Committees in Scotland and Northern Ireland; and made clear the preference for these organised and regulated solutions to the ad-hoc incorporation of administrative staff into healthcare teams to anonymise information or seek patients' consent for disclosure. With regard to the latter, the responsibilities of doctors who 'delegate' to temporary team members was emphasised in revisions to the text and in a new footnote. We have not included reference to other possible solutions that are in early stages of development, but will revisit them in due course.

54. A few respondents suggested that inadequate efforts are sometimes made to anonymise information or to seek patients' consent to disclosure for research and other secondary uses, and that the draft guidance did not provide sufficient guidance on judging when it is 'practicable' to seek patients' consent to disclosure or to anonymise. The Working Group rejected the idea that objective criteria about the time or costs involved might be used in this context. Council debated the issues, paying particular regard to the view expressed by some that this left too much to the discretion of doctors and might be relied upon for disclosures when inadequate efforts were made to seek consent, but decided that the draft, which was supported by the majority of respondents, represented a reasonable balance.

55. A number of minor changes to improve both accuracy and clarity of this section of the guidance were made at the suggestion of respondents.

Disclosure to protect the patient or others

56. The guidance in this section addressed the public interest in disclosing information without consent to protect third parties from risks of serious harm. We sought to clarify in the revised draft that, while a doctor might encourage a patient to consent to disclosure for their own protection, a competent adult patient's refusal should usually be respected. In the consultation document we mentioned domestic violence as an example to illustrate this principle in practice; i.e. where a patient might refuse consent to disclosure to the police, even if they were at risk of further violence.

57. Overall, nearly all respondents to the consultation supported the distinction between public interest disclosures to protect third parties and the respect that should normally be given to competent adults' refusal to consent to disclosure, although many hankered for some discretion in exceptional cases. We have redrafted the guidance to make this distinction much clearer still, and at the same time clarified doctors' responsibilities when concerned that incapacitated adults are at risk of abuse or neglect. We have retained 'usually' to allow some scope for exceptional cases, such as serial abuse of young adults whose mental capacity (as defined in legislation) is not in question, but who might be particularly vulnerable and unable to act in their own interests.

58. Specifically, 72% of respondents to question 16 agreed that doctors should respect a competent adult patient's refusal to consent to disclosure, even if this left

them (but nobody else) at risk of death or serious harm. Nearly 20% of respondents were unsure. During the consultation meetings, where it was possible to discuss the issues in more depth, respondents agreed that the guidance was right in principle but that it might feel like a difficult thing to do. The views of the Association of Chief Police Officers and NHS Scotland's Gender Based Violence Group were particularly influential in helping our understanding of the risks to the individual in not disclosing (domestic violence tends to escalate) and to society (if victims of violence feel unable to seek confidential medical advice and treatment). The guidance was revised to emphasise the doctor's role in providing information and assistance to victims of domestic violence to encourage consensual disclosure.

59. Respondents' representations about other exceptions, such as might arise in occupational health if a patient refuses to consent to disclosure and continues to endanger themselves from an occupational risk (in circumstances where others are not at risk) were persuasive. Following legal advice, however, we decided not to include them, since it was not feasible to address the legal duty of care that might arise in exceptionally rare circumstances. The legal advice suggested respondents might have misunderstood the true legal position.

60. The Working Group rejected suggestions that readers of this section might be confused about the legal duty to report notifiable diseases, which is addressed in the section on disclosures required by law and in supplementary guidance on serious communicable diseases.

Disclosures about patients who lack capacity to consent

61. The draft guidance on disclosures about patients who lack capacity to consent outlined the main considerations for doctors when deciding whether to disclose information about patients who lack capacity, brought up to date to reflect the mental capacity legislation in force across most of the UK. New guidance on sharing information with patients' partners, carers, relatives and friends was also included in an attempt to disentangle some difficult issues around communicating with those close to a patient.

62. 78% of respondents to question 17 agreed that the draft guidance was consistent with the legal framework where they lived and worked. 20% were unsure (surprisingly few given the specific knowledge required to answer the question).

63. 81% of respondents to question 18 supported the principle that it was reasonable to assume that patients who lack capacity would want those closest to them to be kept informed of their general condition and prognosis. A number of respondents commented that this was a reasonable assumption but that there were notable exceptions, such as in the case of sensitive conditions (for example HIV). Some respondents also commented that more clarity was needed when talking about 'those close to a patient' and queried whether there was, or should be, a hierarchy. On the whole, this new guidance was seen to be helpful and well written.

64. The Working Group agreed that information about patients' general condition and prognosis was unlikely to involve disclosure of sensitive information about, for example, serious communicable diseases; and that any effort to define 'those close

to the patient' or to include a hierarchy of relationships would be inappropriate in the circumstances.

65. Some minor clarification was included to avoid any impression that confidential information should be disclosed when listening to others' concerns about a patient's health. We plan to work with partners in this area in developing further materials, if not detailed guidance, on the information needs of carers, which emerged during the consultation as a real challenge if competent adult patients refuse to consent to disclosure. In addition, changes were made to provide clarification (in a footnote and by reference to the Information Commissioner's guidance) on the limits to patients' right to access information provided by others about the patient.

Genetic and other shared information

66. This was a topic on which many respondents to our initial consultation suggested guidance would be welcome. The guidance explained that both genetic and some other personal information about one patient might at the same time also be information about others with whom the patient shares genetic or other links. In recognition of both the complexity and novelty of the topic, the advice from other bodies is referred to and our own advice kept brief. We asked whether this brief advice was a useful addition to the guidance.

67. 64% of respondents to question 20 felt this new advice was a useful addition to the guidance but a sizeable minority (29% of respondents to the same question) were unsure and 7% said it was not helpful. There were a number of specific suggestions for additions to the guidance but no suggestions that the principle itself should be amended. A few respondents suggested it added little or nothing to the main guidance on disclosures in the public interest, although one suggested it was worth restating in this context, given doctors' lack of clarity in what is still seen as a novel area of ethics.

68. Given that the majority did find it useful, we have retained the guidance, but added a further source of information and of course the guidance can be revisited in future to see whether it remains helpful or could be expanded.

Disclosure after a patient's death

69. This longstanding advice was revised to provide examples of when doctors should disclose information after a patient's death (taken from old *Frequently Asked Questions*). 51% of respondents did not feel that there were any other examples of when doctors should disclose information after a patient's death, 27% were unsure and 22% felt there were (some of these did not comment further and several of the suggestions were not relevant enough to warrant specific reference in this section of this guidance). References to disclosures authorised under section 251 of the NHS Act 2006 and to National Confidential Inquiries or for local clinical audit were included at the suggestion of respondents.

70. Respondents' comments suggested confusion about the role of patients' surviving relatives or 'next of kin' in 'authorising' disclosures for purposes such as

complaints investigations or to other relatives, and about the meaning and effect of the Access to Health Records Act 1990. Revisions were made to improve clarity on both issues and to include reference to the Access to health Records (Northern Ireland) Order 1993.

71. At the working group's own suggestion, brief advice about archives of deceased patients' records and the specialist advice available from the national archives has been included.

General questions on the detail, consistency and clarity of the core guidance

72. 90% of respondents to question 22 (does the [core] guidance contain the right level of detail?) thought that it was 'about right' with the remaining 10% feeling that it was 'not detailed enough'. The various revisions have, in general, only added to the detail.

73. 61% of respondents said the guidance was clear or very clear; 5% thought it was unclear. Comments included that the draft was a 'great improvement on the earlier document', 'easily read and understood' and gave 'easy access to the relevant section'. Comments submitted by the respondents who said the guidance was unclear mainly reiterated disagreement with earlier points of principle discussed elsewhere in the analysis.

74. We asked whether there were any important inconsistencies between the draft guidance and guidance published by other relevant bodies (Information Commissioner, health departments, etc.). 33% of respondents to this question stated that there were no inconsistencies that they could see. 49% were unsure and their comments were largely queries that had already been addressed in the guidance or about issues we have already agreed would not fall within the remit of the guidance (mainly about children and young people). 18% (eight respondents) said there were inconsistencies and seven offered comments, all of which related to occupational health (addressed in analysis on *disclosures for express consent* above).

Analysis of responses relating to the supplementary guidance

75. We consulted on seven pieces of supplementary guidance, explaining how the principles in the core guidance apply in a range of situations that doctors ask us about or find difficult.

Reporting concerns about patients to the Driver and Vehicle Licensing Agency (DVLA) or Driver and Vehicle Agency (DVA) (Northern Ireland)

76. The vast majority of respondents supported our position on disclosures to the DVLA or DVA about patients who are unfit to drive and cannot be persuaded to stop. Some inaccurate media reporting of this guidance, which is little changed from our existing guidance, caused some confusion but also resulted in some interest in the consultation.

77. 65% of respondents found the guidance clear. 36% of respondents thought the guidance should make reference to particular conditions that would be likely to

raise concerns (e.g. epilepsy, addiction, serious mental illness), and suggested a range of conditions), 31% said that it should not and 33% said they were unsure. Those answering that it should make reference to specific conditions argued that this would provide additional clarity, while those who said no, argued that a list of conditions could be misleading by not being exhaustive and would go out of date. The Working Group preferred the latter view, and to refer readers to the DVLA's own guidance.

78. The Working Group rejected suggestions that the guidance should make reference to the particular dangers of professional drivers, since that might suggest inappropriate laxness in reporting concerns about others. It similarly decided against extending the guidance to cover concerns about patients who continue to drive despite losing their licence through unfitness.

Disclosing information for financial and administrative purposes

79. This supplementary guidance restates the preference for using anonymised information or seeking consent for disclosures for secondary uses, but explains that some systems and processes may prevent best practice.

80. 82% of respondents answered that supplementary guidance on this subject was a useful addition to the core guidance, one respondent answered no and 15% were unsure. Responses included those arguing that patient identifiable information was vital for the role of employing/contracting health service organisations in checking financial probity and other uses and those who argued that these guidelines eroded ethical principles by accepting that some systems would not be capable of allowing data to be anonymised or coded.

Reporting gunshot and knife wounds

81. Our guidance, [Reporting Gunshot Wounds: Guidance for Doctors in Accident and Emergency Departments](#) was published in 2004. That guidance was developed on the basis that this was a special category: any gunshot wound raises at least some question about public safety; even accidental shootings involving lawfully held guns raise serious issues about the person's suitability to hold a gun licence. Disclosures about knife and other blade or sharp instrument injuries are not so straightforward, because there are no licensing requirements for knife ownership and because disclosure of accidental and self-inflicted injuries involving knives are not always justified in the public interest. It is also not always obvious to doctors which injuries are caused by violent crime. Despite these differences, we did issue joint guidance with the Department of Health on reporting knife and blade wounds that result from violent attacks. The draft guidance combined the two.

82. We asked whether respondents agreed that the guidance should cover the knife injuries as well as gunshot wounds: 77% agreed that it should, with 9% disagreeing and 14% unsure. 57% of respondents thought that the guidance was clear and 63% of respondents agreed that doctors should tell the police whenever a patient arrives at hospital with a gunshot wound (even if it is the result of an accident) or a knife wound as a result of a violent attack. There was some concern that the guidance might deter those who most need it from seeking medical

attention, while others argued that this particular form of violence was on the increase and there was therefore a responsibility to provide information to the police.

83. As a result of comments received, the guidance has been revised to clarify the two-stage approach of: notifying the police whenever a patient arrives with a gunshot or knife wound (so that they can assess the risk to the patient and others and gather statistical information about the gun and knife crime in the area); and then making a decision about disclosing identifiable information in the public interest if the patient refuses to speak with the police.

84. This clarification might go some way to addressing the concern expressed by a few respondents that reporting might deter people from seeking medical attention, but fundamentally Council disagreed with the balance of interests expressed in this view. Along with the College of Emergency Medicine, the Association of Chief Police Officers and government, Council sees the serious harm of gun and knife crime as justifying public interest disclosures and requiring a duty to report the fact, if not the detail, of all such incidents. The disclosure of personal information where a patient withholds consent must necessarily remain a matter for judgement on a case-by-case basis.

85. While children were generally 'out of scope' for this review, having been addressed so recently in our [0-18 Years: guidance for all doctors](#) (2007), some specific attention to the child protection concerns that arise when a young person presents with a knife wound, whatever the circumstances, has been added to the guidance in response to consultation respondents' comments.

Disclosing information about serious communicable diseases

86. This supplementary guidance draws on advice in the withdrawn GMC booklet, [Serious Communicable Diseases](#)¹. It explains how doctors should balance the particular need to ensure that patients who have or may have serious communicable diseases can trust their doctors to respect their confidences, against the public interest of protecting others, including known sexual contacts, from the risk of infection. It also explains the legal and ethical challenges which can arise when healthcare workers pose a risk to patient or when they or others are exposed to a risk of infection from a needlestick or similar injury involving a patient who has or may have a serious communicable disease.

87. Overall, the guidance on serious communicable diseases was welcomed as an important area in which specific guidance has been lacking since we withdrew our stand-alone guidance on the topic in 2006. Specifically, we asked whether the guidance represented a reasonable balance between doctors' duty of confidentiality and the public interest in disclosing information to protect others from the risk of infection. 67% answered that it did, 13% disagreed and 20% were unsure. 68% of respondents thought the guidance was clear or very clear; 33% were neutral.

88. As with the gunshot and knife wound guidance (see above), we have responded to particular concerns about the welfare of children and young people by

¹ http://www.gmc-uk.org/guidance/archive/serious_communicable_diseases_1997.pdf

including guidance on disclosing information to arrange testing and treatment when their parents refuse to consent. We have dropped the only example of risk (biting) that might justify unconsented disclosure of patients' status to others providing care on the basis of advice from the UK Advisory Panel on Blood Borne Viruses that there are no documented cases, and that the hypothetical risk should not prohibit infected healthcare workers working with patients who might bite. We have made minor amendments to improve clarity around the seriousness of STIs that might prompt disclosure, contact tracing without disclosing patients' identity, and the information that doctors should give patients about protecting others. And having taken extensive advice about the legal, ethical and practical implications of the advice, we have retained our guidance on including SCDs on medical certificates of cause of death.

Disclosing information for insurance, employment and similar purposes

89. This supplementary guidance addresses the roles in which doctors sometimes face 'dual obligations'. It explains the consent requirements for disclosing information for purposes such as insurance claims as well as the doctor's continuing duty of confidentiality when employed by or contracted to patients' employers or others with whom patients might wish or expect to control the disclosure of personal information.

90. 85% of respondents (to question 43) agreed that the roles (occupational health doctor, police surgeon, sports doctor, etc.) listed in guidance were good examples of when doctors might face dual obligations. 70% of respondents (to question 44) described the guidance as clear. Comments submitted by respondents reiterated those provided in response to the questions on *Disclosures for which express consent should be sought*.

Responding to criticism in the press

91. This was new guidance developed in response to queries from doctors who have been criticised by the press and have struggled to respond. In the guidance we have sought to balance the continuing duty of confidentiality against the risk that unfair or inaccurate public criticism of the doctor might undermine confidence and trust in the doctor's practice or a health service with which that doctor is associated. It outlines the dangers of responding to press criticism and the limited extent to which doctors can comment in some circumstances.

92. The guidance was very widely welcomed and 74% of respondents agreed that the guidance strikes the right balance between maintaining patient confidentiality and doctors' occasional need to respond to misleading criticism. 20% were unsure and 6% (2 respondents) answered thought it did not.

93. A few respondents clearly indicated a belief that patient confidentiality should not override the right of a doctor to defend his or her reputation and a minority stated that patients who disclose personal information in complaining about doctors or their treatment in the press give up all rights to confidentiality. The vast majority however, felt that the guidance as drafted struck the right balance between patients' and doctors' rights. The only change made was a technical clarification about avoiding

disclosures by inference or omission, *except to the extent necessary to deny an allegation.*

Disclosing information for education and training purposes

94. This supplementary guidance covers the use of information about patients in published case studies and in medical education and training. It also outlines some principles for involving school and college students in doctors' practice.

95. 66% of respondents agreed that it was practicable and sufficient to use anonymised information for most medical educational purposes, 17% disagreed and 17% were unsure. 66% of respondents agreed that it was usually practicable to seek patients' express consent for trainees to have access to patients' personal information when it was not practicable to use anonymised information whilst 11% disagreed and 23% were unsure.

96. 69% of respondents agreed that in the absence of any indication about incapacitated patients' preferences, it was reasonable to allow students and trainees to have access to their personal information to the limited extent that it was necessary for their education and training.

97. Some complex issues arose in the context of publishing case studies, i.e. whether that falls within the definition of medical purposes at Schedule 3 of the Data Protection Act. The Information Commissioner's advice, and respondents' responses, helped us resolve to retain the advice we had put out to consultation.

98. The specific issue of school and college students' *observation* (changed from *participation* at respondents' helpful suggestions) of patients' care (with consent) excited some concerns, but the Working Group and SERG preferred the view supported by majority of respondents that school and colleges students' work experience with doctors is important in helping them to decide on a career in medicine and that, if sufficient seriousness is taken toward explaining their responsibilities, students can have the maturity to respect patients' confidences. The draft has been amended to reflect this and the responsibility schools and colleges in explaining and enforcing these responsibilities.

PART FIVE – POST CONSULTATION PROCESS

Approving the guidance for publication

99. The analysis report was considered by the Working Group at its meeting on 16 March 2009, following which the guidance was revised and presented to Council for approval. Council approved the guidance for publication at its meeting on 7 May 2009.

100. The draft guidance was reviewed by Counsel in England, Scotland and Northern Ireland to ensure that it was consistent with the legal framework relevant to confidentiality in each of the four UK countries.

101. The guidance has been given plain English approval by the Word Centre.

Audit

102. We commissioned an audit of this process, which was undertaken by Professor Celia Davies (Visiting Professor, London School of Economics) and you can read the [audit report](#) which finds ‘that here is a great deal to be commended in the process that was set in train for this consultation’ (page 2) and makes a number of recommendations for future practice.

103. We are grateful to Professor Davies for her report and are happy to take forward the recommendations in the report which we hope will help us improve our consultation process further. In response to some of the specific recommendations:

- *Always prepare a statement of the reasons for undertaking a public consultation with stakeholders, integrating this as a strategy with the current mission of the GMC (recommendation 1).*

104. We agree that it is important to be explicit about the reasons for undertaking a public consultation and intend to implement this recommendation as soon as possible.

- *Name groups/ subgroups of stakeholders who are considered relevant to a particular consultation; test this stakeholder mapping widely, and identify the most appropriate ways to collect information from the different groups – particularly in cases where the survey is not ideal (recommendation 2).*

105. We are committed to improving our methods for identifying and involving those who are considered relevant to a particular consultation and will continue to explore ways in which to ensure that our stakeholder mapping exercises are fit for purpose.

- *Focus particular attention on state of the art thinking for identifying and engaging patients, patient groups, carers and the wider public in consultation processes, and draw from the full range of methodologies available (recommendation 3).*

106. Over the last five years we have continued to develop innovative ways to seek the views of individuals – doctors, patients, carers and other members of the public – as well as representatives of organisations. This has included use of a citizen’s jury, public meetings and forum theatre to try and reach the varied audiences who are affected by our guidance. We will continue to explore which methods are best suited to our consultations and consolidate our knowledge.

107. Further recommendations on improving the process such as timetabling a mid-point review and ensuring that a timeline is kept and regularly updated (which can also help with an audit) are helpful suggestions which we will take up. And finally, Professor Davies recommends that we consider commissioning research on stakeholder satisfaction, which we will explore in the context of our broader plans to evaluate our work, including our current processes for consulting.

Launching the guidance

108. *Confidentiality* (2009) will be launched on 28 September 2009 and will be available on the GMC website. A copy of the guidance will be sent to all registered doctors (approximately 230,000) with the September 2009 edition of *GMCToday*.

109. The guidance will come into effect on **12 October 2009**.

Next steps

110. We are currently developing plans for promoting the guidance to ensure that it is known and understood by doctors.

We would like to take this opportunity to thank all those who contributed to the review and took the time to send us their comments or participate in meetings during the consultation process.

For more information on the review or to read the new guidance visit www.gmc-uk.org/confidentiality or contact the Standards and Ethics Team on 020 7189 5404 or standards@gmc-uk.org

¹ www.gmc-uk.org

² http://www.gmc-uk.org/guidance/good_medical_practice/index.asp

³ <http://www.gmc-uk.org/guidance/index.asp>

⁴ Available at www.gmc-uk.org/confidentiality