HEALTH NEWS BRIEFING

ASSOCIATION OF COMMUNITY HEALTH
COUNCILS FOR ENGLAND AND WALES

PATIENT CONFIDENTIALITY

- IMPLICATIONS OF NEW GUIDANCE FROM THE GENERAL MEDICAL COUNCIL

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GENERAL MEDICAL COUNCIL – INTERIM GUIDANCE ON PATIENT CONFIDENTIALITY

Implications for Patients' Rights

1. Introduction

1.1 Respect for the confidences of patients is enshrined in the Hippocratic Oath. Patients provide information to their doctors on the tacit understanding that it will not be passed on to others. It is assumed that patients will not trust their doctors with vital information if they do not believe that this information will be respected and most importantly, kept secret.

1.2 The General Medical Council (GMC) has responsibility for maintaining the medical register and defining standards of medical practice[1]. The GMC issues guidance to doctors in the UK. Its guidance on patient confidentiality has formed the basis of the common law of confidentiality in relation to medical records. Issues around patient confidentiality have been the subject of much discussion of late and the GMC are now making changes to their guidance on the subject. While many of these changes are to be welcomed, the interim guidance which has been issued, contains guidance concerning the release of patient identifiable information for the purposes of clinical and financial audit, which if followed, will undermine patient rights of confidentiality.

2. The law

2.1 In the UK there is currently no general legislation to protect privacy or confidentiality. The Data Protection Act 1984 contains a series of protective measures in relation to personal information that is stored in an automated form. In addition to having rights to access information stored about them, individuals have some rights in relation to unauthorised disclosure of this information[2] and can pursue a claim for compensation in the event that

[1] Medical Act 1983
[2] Section 23 of the Data Protection Act 1984

disclosure is made to third parties without their consent. A complaint may also be made to the Data Protection Registrar. Much confidential patient information is stored in written form and thus falls outside the remit of this Act.

2.2 The UK Government is required to enact new data protection legislation in order to comply with European Directive 95/46 EU. The Data Protection Act 1998 will extend data protection principles, including that of the duty of confidentiality, to material stored in written and other forms. It will apply to patient records. The Government says that this Act will be brought into force some time this year.

2.3 The first data protection principle[3] in the Data Protection Act 1998 provides that sensitive data may not be processed (the definition of processing includes disclosure) unless certain criteria are fulfilled. At least one of the criteria in both Schedules II and III of the Act must be fulfilled before disclosure, the most relevant ones in this context being:

(i) the data subject has given his consent, or
the processing is in his vital interests, or
the processing is necessary for the exercise of government or public functions in the public interest
(Schedule I),
and
(ii) the processing is necessary for medical purposes
(Schedule II).

The term 'vital interests' is not defined in the Bill. There are concerns about possible inappropriate constructions of the term. The office of the Data Protection Registrar has indicated that it should be seen in the context of life and death issues.

The above criteria are broad enough to permit a wide range of activities involving the disclosure of patient identifiable information.

[3] Schedule 1 Paragraph 1 Data Protection Act 1998

2.4 In addition to the above, the Data Protection Act 1998 requires all processing to be carried out fairly and lawfully[4]. As there is no other legislation providing a duty of confidentiality, lawfully means in accordance with the common law (judge-made law), not in breach of the criminal law and in accordance with the terms under which the data holder is registered. Over the years the courts have built up a series of common law principles to provide some protection against breaches of confidentiality. The common law, together with rights enshrined in the European Convention of Human Rights, provide some protection to individuals against unauthorised release of personal information. The common law permits disclosure by doctors of medical records and other patient identifiable information on a need to know basis, to other medical staff involved in the care of a patient, on the assumption that health professionals work as a team and that patients give implied consent to the sharing of information in order to facilitate their diagnosis and treatment. The courts have not considered whether the principle of presumed patient consent to disclosure applies to the practice of release of information to personnel carrying out audits, where those staff are not involved in the treatment or care of the patient. However leading counsel has expressed the view that the common law principle of implied consent cannot be applied in relation to disclosure beyond the team providing care and certainly not where the patient is unaware of the disclosure[5].

2.5 As the law presently stands, a patient who discovers that his notes have been disclosed in a form which contains identifiable personal information, without his/her consent to a third party, be it to researchers, staff engaged in pharmaceutical or financial audit, or others, has grounds to commence proceedings for breach of confidentiality and to seek damages. Patients who become aware of an imminent unauthorised disclosure of information, from which they can be identified, can seek to prevent that disclosure by obtaining an injunctive order from a court.

2.6 The common law duty of confidentiality in relation to personal medical information has, in the main, been based upon GMC guidance issued in

[4] as above
[5] Michael Beloff QC 1994

'Advice on Standards of Professional Conduct and of Medical Ethics', known as the 'Blue Book'[6] The GMC published new guidance in 1995, but its content in relation to the duty of confidentiality was essentially unchanged. It remains to be seen whether the courts will be prepared to impose existing common law principles against doctors following the latest guidance, or whether they will take the more pragmatic line which would mean an effective endorsement of these changes. In the meantime, patients will not know who has access to their records and what legal protection they have against disclosure to those carrying out audit.

2.7 The law on what constitutes consent to disclosure is less clear. However, in view of the stance taken by the courts to date, it is unlikely that consent can be implied beyond the assumption that a patient is aware that information disclosed to a health professional will be made available to others engaged in their diagnosis, treatment and care.

3. The Patient's Charter

3.1 The rights detailed in the Patient's Charter include the right to have the contents of their medical records kept confidential and the right to chose whether or not to take part in medical research or medical student training. In addition to rights, the Charter details national standards, including 'respect for privacy, dignity and religious and cultural beliefs'.

3.2 There are no statutory provisions or common law judgements which detract from or in any way challenge the rights and standards on privacy and confidentiality contained in the Patient's Charter.

4. GMC Guidance

4.1 Guidance on doctors' duty of confidentiality to their patients used to be found at sections 76 to 89 of the GMC code[7]. It is this code which the courts have

[6] W v Egdell [1990]
[7] 'Advice on Standards of Professional Conduct and of Medical Ethics',

relied upon as providing the basis of the common law on doctors' duty of confidentiality to their patients.

4.2 In 1995 the GMC issued new guidance which, in most respects replicated the contents of the previous guidance. In relation to disclosure of information for the purposes of medical research the GMC stated that *'every reasonable effort must be made to inform the persons concerned, or those who may properly give permission on their behalf, and that they may, at any stage, withhold their consent to disclosure.'*[6] Further, under the heading 'Teaching and Audit' it was stated *'Patients' consent to disclosure of information for teaching and audit must be obtained unless the data have been effectively anonymised.'*

4.3 The General Medical Council has for some time been considering changes to their guidance to doctors on their duty to protect patient confidentiality. In December 1998 the GMC issued a consultation document detailing the changes they proposed. In January 1999 interim guidance was produced. The GMC are continuing to discuss its contents with the Department of Health. We have been advised that the DoH has asked for further changes to the guidance to permit wider access to patient records for the purposes of clinical and financial audit. It is understood that the GMC intend to issue a final version of this guidance later this year.

4.4 The interim guidance, while stating that patients have a right to expect that doctors will not disclose any personal information about them unless they give permission, moves away from earlier strictures and effectively permits the release of information to health authority or NHS trust staff who are not part of the health care team and to staff employed by other organisations working on behalf of NHS bodies to facilitate financial and clinical audit.

4.5 Paragraph 25 deals with disclosures for the purpose of education and audit. It states:

'Staff from outside the health care team may anonymise records, provided they are properly trained and authorised by the health authority, NHS trust or

comparable body to carry out this work, and are subject to a duty of confidentiality in their employment. The data must be used only for clinical or medical audit or for medical education. Information about the use of records, and patients' rights to object must be made accessible to patients through practice or hospital leaflets, and in notices in waiting areas.'

As the law currently stands, providing access to anyone outside the health care team, even for this purpose, amounts to a breach of confidentiality unless the patient has consented. The GMC proposes that the staff carrying out anonymisation of patient records should be properly trained and authorised by the health authority, NHS trust or comparable body. However, there are no guarantees as to the standards of training and of requirements of authorisation and both may be meaningless in practice.

4.6 Of even greater concern is the advice to be found at paragraph 26.

'Where it is not possible to anonymise the data you should obtain explicit consent to disclosure, where that is practicable. Where it is not practicable, you should make information available to patients, as described in paragraph 25.'

Consequently if doctors do not consider anonymisation to be possible (this may be because the patient's condition is such that he or she can be identified from it, or perhaps because of the time or cost involved in carrying out the anonymisation of the records) and it is not practicable to obtain explicit consent to disclosure (again this may be because of the time and resources involved), doctors can justify disclosure if they have leaflets available or a notice in their waiting area, to alert patients of disclosure of their records outside the health care team and the patient has not objected. This guidance will have the effect of undermining the requirement that patient consent is required before disclosure in such circumstances.

4.7 The limited safeguard of referral to a research ethics committee before disclosure of identifiable personal medical information without consent is only stated to apply where the information is to be used for medical research - paragraph 27. The definition of medical research cannot be said to include clinical audit.

[8] Paragraph 15 Confidentiality. Guidance from the General Medical Council.

4.8 At paragraph 33 of the guidance, doctors are advised that there will be no question of serious professional misconduct where doctors allow access to patient files for financial audit and other administrative purposes without patient consent, if the doctor is satisfied that patients have been informed previously. This is unsatisfactory. No limits are prescribed as to who should be treated as an auditor for these purposes. It is possible to envisage situations in which pharmaceutical and medical appliance manufacturers and suppliers describe their activities as auditing patient information. How are patients to be reassured that personal and identifiable information will not be passed to firms for commercial purposes? It may be that patients will not want health authority staff to have such access either, but their opportunities to withhold consent are being whittled away. The Caldicott committee identified over 60 routine reasons for the transfer of identifiable patient information. Patients are largely unaware of these.

4.9 The statement in this guidance that a doctor must be satisfied that a patient has been informed previously, is no guarantee against the release of information based solely on a doctor's assumption that all patients will have seen a notice to this effect in the waiting area. In any case, such notices are unlikely to itemise all the routine disclosures that commonly occur within the NHS.

5. Protecting Patients' Rights to Confidentiality and to Effective Consent.

5.1 The GMC's interim guidance does not accord with either the rights and standards provided for in the Patient's Charter or with existing common law requirements.

5.2 ACHCEW considers that doctors should be required to obtain consent from patients when considering the release of identifiable information outside the health care team, except where;

- the patient is incapable of giving consent, but this has been given by those authorised to act on their behalf,

- disclosure is specifically required by statute, e.g. notification of infectious diseases,
- disclosure has been ordered by the courts,
- disclosure is necessary in order to prevent a serious crime or serious harm to another person.

5.3 Patients cannot be taken to have consented to a practice of which they are unaware. Many patients will be unaware of leaflets and notices in doctors' waiting rooms detailing to whom disclosure of medical records may be made. However, doctors are being told that whether or not patients have seen or understood the implications of these notices, those who do not raise objections will be considered to have consented to disclosure of personal identifiable information from their medical records.

5.4 ACHCEW considers that consent cannot be implied from a failure to object where there is no guarantee that the patients will be aware of what is being proposed because they;

- do not see the notice
- cannot read or cannot read English
- do not understand the implications of disclosure.

5.5 Where disclosure of identifiable information is required for the purpose of audit, patients should be individually and fully advised of any proposed disclosure of information from their medical records and a duty should be placed on the health professional to ensure that the patient concerned understands the request. Only then should a failure to object to taken as implied consent.

5.6 To date, ACHCEW has attempted to influence the GMC by responding to the consultation. Representations have been made to Ministers. Other organisations are now being approached. It is to be hoped that a number of them will be prepared to join forces with ACHCEW in voicing their concerns.

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