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Our ref: PVC/EG-LAT/O/0505393-00

Your ref:

30 July 2005



PRIVATE AND CONFIDENTIAL

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Dear Dr Hutton

**Re: Confidentiality and Disclosure of Information:
General Medical Services (GMS), Personal Medical Services (PMS) and
Alternative Provider Medical Services (APMS) Code of Practice 2005**

Further to my earlier letter of 19 July 2005, I am sorry for the delay, but I am pleased to offer the following comments that you may wish to share with your members.

The utilisation and disclosure of information held by practices is becoming increasingly complex, and there is a degree of inconsistency emerging.

Practices need to be aware that in addition to any legal requirements, the doctors need to act in accordance with the ethical guidance laid out by the GMC in its booklet, "Confidentiality: Protecting and Providing Information" (April 2004). This can be accessed through the GMC Website at www.gmc-uk.org in the "Ethical Guidance" section, however I enclose the paragraphs mentioned specifically. It is important that practices (contractors) act in such a way as to allow doctors to meet the standards set by the GMC.

Mr Ward has focussed his reply on the issues that are within his field of competence, and avoided comment on areas outside of this.

Paragraph 1 of the GMC guidance lays out some general principles. This states that where doctors are asked to provide information about patients they must:

- inform patients about the disclosure, or check that they have already received information about it;
- anonymise data where unidentifiable data will serve the purpose;

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- be satisfied that patients know about disclosures necessary to provide their care, or for local clinical audit of that care, that they can object to these disclosures but have not done so;
- seek patients' express consent to disclosure of information, where identifiable data is needed for any purpose other than the provision of care or for clinical audit – save in the exceptional circumstances described in the GMC's booklet;
- keep disclosures to the minimum necessary; and
- keep up to date with and observe the requirements of statute and common law, including data protection legislation.

The process of anonymising

Practices are encouraged to use anonymised data where this will serve a purpose.

Where practices wish to generate **anonymised or aggregated data** for any purposes, it has been argued that this counts as **processing** as far as the DPA is concerned.

Where **sensitive personal data** was to be anonymised, the practice might therefore be expected to consider obtaining the patient's expressed consent to do so. However, Simon Brown LJ judged that if the disclosure of anonymised data was not a breach of confidentiality, then the process of anonymising could not be either. It therefore seems excessive to obtain consent to anonymise information, as long as practices had informed patients of this as part of their "fair processing information".

Consequently, if the practice wish to **generate** anonymised / aggregated information for use other than for the provision of health care to an individual patient, it seems that to increasingly the expectation will be for practices to have informed patients of this possibility, and given them an opportunity to object. It seems practices would wish to ensure that they have taken all reasonable steps to inform patients such as through the use of notices/posters, video screenings, the practice information leaflet and at the time of registration. The wording of these would need to be sufficiently broad to cover all the circumstances envisaged.

Once the information is available in anonymised form it can be used for other purposes without additional consent.

Requests from PCTs for information

Where a PCT requests information from a practice, paragraph 11 of the Code of Practice says:

"They should explain to practices the precise purpose for which this is required and who will gain access. Generally patients who present for care are assumed to consent to the required information sharing between clinicians for the purposes of their individual health care needs, and those in the NIS to whom they are accountable. Ensuring that patients understand how such information may be shared underpins this assumption and is therefore extremely important. Where appropriate

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clinical and non-clinical staff may need to discuss consent issues with patients and check patient understanding”.

The GMC's guidance is reinforced in paragraph 13 of the Code which includes:

“13 The standard and constraints that apply to the holding, using and sharing of information are important components of NHS Information Governance. The Code of Practice reflects the NIS Information Governance principles and key standards in relation to the disclosure of, or access to, information. The NHS Information Governance toolkit is available at www.nhs.uk/infogov/igl. The key governance principles are that:-.....

.....

- (iii) Information should be disclosed or otherwise shared by contractors on a “need to know” basis;*
- (iv) Where PCTs need to obtain information from contractors, the minimum necessary information should be determined and the disclosure limited accordingly;*
- (v) Where, exceptionally, there is a need for PCTs to seek access to or to obtain information beyond that generally required for their day to day business, and where access to patient identifiable information is necessary (see paragraph 30-32), the process of obtaining such information will be open to audit and appropriate scrutiny – such as by a Strategic Health Authority, NHS auditors, or Caldicott Guardians;*
- (vi) Where data is required that identifies an individual patient, the patient's consent may be necessary, depending on the circumstances and purpose for which the data is required (see paragraphs 30-32).”*

Paragraph 22 of the Code states:

“There are circumstances where it will not be practical for anonymised information to be generated in order to satisfy the purposes of third parties... Where any of these apply, care must be taken to ensure that disclosure of information is lawful”.

Paragraph 23 goes on to describe the circumstances in which PCTs may require access. These include checking financial management, checking payments under the Quality and Outcomes Frameworks (QOF), reviewing contractors' performance, internal audit, fraud investigations and the contractors' compliance with its contract.

Under these circumstances where a PCT requests information that is **anonymised or aggregated**, and patients have been informed that anonymised data may be disclosed, have consented to the processing of confidential personal data, or the data is already available in that format it could be disclosed..

However if **identifiable data/information** is requested (perhaps after anonymised data is examined), further consideration must be given to obtaining specific consent.

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Paragraph 16 of the GMC's "Confidentiality" guidance states:

"Express consent is usually needed before the disclosure of identifiable information for purposes such as ... epidemiology, financial audit or administration.... If the patient withholds consent, or consent cannot be obtained, disclosures may only be made where they are permitted by law or can be justified in the public interest."

The GMC give further advice in relation to disclosures in the public interest in paragraphs 22 to 29 of their guidance.

It would seem prudent that practices take steps to inform all patients:

- how their anonymised data will be used;
- that sometimes their data will be looked at, and an anonymised version produced, and
- that they have a right to object to the disclosure.

Paragraph 30 of the Code of Practice makes it clear that requests from PCTs to obtain access to information that identifies individual patients should be limited. It also makes it clear that **the decision to disclose such information will rest with the contractor** (ultimately the contractor's decision must ensure that the doctors are able to fulfil their ethical obligations to the GMC). It goes on to detail a number of instances where it the Department of Health Considers it would be lawful for practices to disclose information. These include:

- Where practices are unable to anonymised data that is needed to support the wide functioning of the NHS such as the QOF annual review process.
- Where the PCT is investigating and assuring the quality and provision of clinical care.
- In relation to the management of the Contract.
- Where the PCT considers there is a serious risk to patient health and safety.
- Investigation of suspected fraud, or other criminal activity.

The GP Contractual Regulations do authorise PCTs to access practice records, and the Code of Practice, reminds contractors that they may be in breach of their contractual provisions where they fail to disclose information.

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Ultimately it is the contractor that would be responsible for disclosing information, but needs to allow the doctors to fulfil their obligations to the GMC.

It seems that it would be in practices' interests to routinely inform patients of how their information might be used within the practice, and that they may be required to disclose anonymised or identifiable information to the PCT, and the purposes for which this may become necessary.

They would wish to be able to demonstrate that they had taken **all reasonable steps** to inform patients how their data would be used, and that they could object. Whenever possible **anonymised** information should be used.

Prior to disclosing **identifiable** confidential information it seems that practices would wish to be able to show that they had:

1. Had sought to inform patients how their information might be used, that they had a right to object, and had not done so.
2. Sought to persuade the PCT to accept anonymised data where this would serve the purpose.
3. Where identifiable data was to be disclosed that this was the minimum necessary for the purpose.
4. That they had considered obtaining individual patient consent, and patients had consented to the disclosure of identifiable information, or the practice could justify disclosing in the absence of such consent.

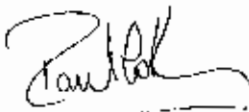
Where the disclosure of identifiable information was requested, and patient consent was withheld, or a practice did not feel able to justify disclosing information in the public interest, then a PCT would be able to consider obtaining a court ruling.

I hope that this is helpful to your members. However, please feel free to contact me should you have any outstanding concerns. The MDU would also be pleased to advise individual members.

Additionally, please quote your reference number **0505393-00** on all correspondence. This will ensure an efficient and prompt reply.

With best wishes.

Yours sincerely



Dr Paul Colbrook
Medico-Legal Adviser

Enc: GMC extract, "Confidentiality: Protecting and Providing Information",
paragraphs 1, 16, 22 to 29.

EXTRACT FROM GMC PUBLICATION

Publication title: Confidentiality: Protecting and Providing Information

Patients' right to confidentiality

Principles

1. Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care. If you are asked to provide information about patients you must:
 - inform patients about the disclosure, or check that they have already received information about it;
 - anonymise data where unidentifiable data will serve the purpose;
 - be satisfied that patients know about disclosures necessary to provide their care, or for local clinical audit of that care, that they can object to these disclosures but have not done so;
 - seek patients' express consent to disclosure of information, where identifiable data is needed for any purpose other than the provision of care or for clinical audit – save in the exceptional circumstances described in this booklet;
 - keep disclosures to the minimum necessary; and
 - keep up to date with and observe the requirements of statute and common law, including data protection legislation.

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Disclosures where express consent must be sought

16. Express consent is usually needed before the disclosure of identifiable information for purposes such as research, epidemiology, financial audit or administration. When seeking express consent to disclosure you must make sure that patients are given enough information on which to base their decision, the reasons for the disclosure and the likely consequences of the disclosure. You should also explain how much information will be disclosed and to whom it will be given. If the patient withholds consent, or consent cannot be obtained, disclosures may be made only where they are required by law or can be justified in the public interest. Where the purpose is covered by a regulation made under s60 of the Health and Social Care Act 2001, disclosures may also be made without patients' consent. You should make a record of the patient's decision, and whether and why you have disclosed information.

The public interest

Disclosures in the public interest

22. Personal information may be disclosed in the public interest, without the patient's consent, and in exceptional cases where patients have withheld consent, where the benefits to an individual or to society of the disclosure outweigh the public and the patient's interest in keeping the information confidential. In all cases where you consider disclosing information without consent from the patient, you must weigh the possible harm (both to the patient, and the overall trust between doctors and patients) against the benefits which are likely to arise from the release of information.
23. Before considering whether a disclosure of personal information 'in the public interest' would be justified, you must be satisfied that identifiable data are necessary for the purpose, or that it is not practicable to anonymise the data. In such cases you should still try to seek patients' consent, unless it is not practicable to do so, for example because:
- the patients are not competent to give consent (see paragraphs 28 and 29); or
 - the records are of such age and/or number that reasonable efforts to trace patients are unlikely to be successful; or
 - the patient has been, or may be violent; or obtaining consent would undermine the purpose of the disclosure (eg disclosures in relation to crime); or
 - action must be taken quickly (for example in the detection or control of outbreaks of some communicable diseases) and there is insufficient time to contact patients.
24. In cases where there is a serious risk to the patient or others, disclosures may be justified even where patients have been asked to agree to a disclosure, but have withheld consent (for further advice see paragraph 27).

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25. You should inform patients that a disclosure will be made, wherever it is practicable to do so. You must document in the patient's record any steps you have taken to seek or obtain consent and your reasons for disclosing information without consent.
26. Ultimately, the 'public interest' can be determined only by the courts; but the GMC may also require you to justify your actions if a complaint is made about the disclosure of identifiable information without a patient's consent. The potential benefits and harms of disclosures made without consent are also considered by the Patient Information Advisory Group in considering applications for Regulations under the Health and Social Care Act 2001. Disclosures of data covered by a Regulation are not in breach of the common law duty of confidentiality.

Disclosures to protect the patient or others

27. Disclosure of personal information without consent may be justified in the public interest where failure to do so may expose the patient or others to risk of death or serious harm. Where the patient or others are exposed to a risk so serious that it outweighs the patient's privacy interest, you should seek consent to disclosure where practicable. If it is not practicable to seek consent, you should disclose information promptly to an appropriate person or authority. You should generally inform the patient before disclosing the information. If you seek consent and the patient withholds it you should consider the reasons for this, if any are provided by the patient. If you remain of the view that disclosure is necessary to protect a third party from death or serious harm, you should disclose information promptly to an appropriate person or authority. Such situations arise, for example, where a disclosure may assist in the prevention, detection or prosecution of a serious crime, especially crimes against the person, such as abuse of children.

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Children and other patients who may lack competence to give consent

Disclosures in relation to the treatment sought by children or others who lack capacity to give consent

28. Problems may arise if you consider that a patient lacks capacity to give consent to treatment or disclosure. If such patients ask you not to disclose information about their condition or treatment to a third party, you should try to persuade them to allow an appropriate person to be involved in the consultation. If they refuse and you are convinced that it is essential, in their medical interests, you may disclose relevant information to an appropriate person or authority. In such cases you should tell the patient before disclosing any information, and where appropriate, seek and carefully consider the views of an advocate or carer. You should document in the patient's record your discussions with the patient and the reasons for deciding to disclose information.

Disclosures where a patient may be a victim of neglect or abuse

29. If you believe a patient to be a victim of neglect or physical, sexual or emotional abuse and that the patient cannot give or withhold consent to disclosure, you must give information promptly to an appropriate responsible person or statutory agency, where you believe that the disclosure is in the patient's best interests. If, for any reason, you believe that disclosure of information is not in the best interests of an abused or neglected patient, you should discuss the issues with an experienced colleague. If you decide not to disclose information, you must be prepared to justify your decision.

Wording extracted from GMC Website – 16-07-2005

GMC Website: www.gmc-uk.org