**Quality and Outcomes Framework (QOF) visits and patient confidentiality – further GPC interim guidance**

This guidance updates the statements published by the General Practitioners Committee on 1 and 19 October 2004.

**Introduction**

The GPC has received a number of enquiries about the imminent Quality and Outcomes Framework visits and the preservation of patient confidentiality. The Code of Practice on Confidentiality was published at the beginning of September and is available on the Department of Health website:

www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4088718&chk=6qzD1b

However, there has been considerable confusion amongst practices and Primary Care Organisations in interpreting the Code. This is a complex area of law and we have been working with the Department of Health and lawyers to clarify the law, and Counsel's opinion is being taken. We will let you know as soon as we have this opinion.

In the interim, we recognise that practices and Local Medical Committees, as well as Primary Care Organisations, need advice. This guidance is set out below.

**Data protection Act**

QOF visits will mean that patient records are the subject matter of audit for financial or probity purposes and as such, third party assessors will have access to patient identifiable information.

Under the Data Protection Act, under most circumstances, there is a requirement that, in order to allow access to patient records, either:

- express and informed consent is obtained from the patient, or
- patient records are completely anonymised.

**Anonymisation**

In order to ensure compliance with the Data Protection Act, records need to be completely anonymised. This goes further than deleting names and addresses on the face of the record. It would mean assessing the content of the record to ensure that there are no references within the record which would identify the patient.

If records cannot be ***completely*** anonymised and there is a resultant breach of confidentiality or if patients have not given express and informed consent, there may be a significant level of medico-legal risk to practices.

The 'low-tech' manual methods of anonymisation e.g. photocopying & Tipp-Ex etc, may involve a risk that patients' records will not be completely anonymised, if the anonymisation is not carried out properly. Moreover it is likely to be highly work-

intensive and time-consuming and not within the spirit of a high trust/low bureaucracy contract.

**The IT approach**
The Department of Health are working on an IT solution to enable complete anonymisation of patient records, which will be available as a pilot in November. We believe that this is very likely to resolve the issue of anonymisation of patient records and are working with the Department on guidance. This guidance and further information will be available very shortly.

**Patient consent**
In the absence of IT functionality ensuring complete anonymisation, the GPC believes that, where there is a risk that patient identifiable data could be discovered by assessors, seeking of patients' express and informed consent is the best method of ensuring that practices can allow access to their patient records for this round of visits. Consent needs to be informed and explicit. This means that the patient must have sufficient information in order to make a decision about whether to allow access to their records. The GPC believes that the PCO should obtain this consent.

Implied consent, either through information in patient leaflets, posters in surgeries, or through other means, is not sufficient.

**QOF Achievement Payments**
The Statement of Financial Entitlements states that practices must comply with any **reasonable** inspection or review to get paid. Paragraph 5.43 states that practices should "co-operate fully with any reasonable inspection or review".

The GPC believes that an inspection is unreasonable if it puts undue strain on practices whether financially or administratively to comply with Data Protection Act or where as a result of this, practices cannot comply with the Regulations unless they risk breaching the law. Withholding payment to GPs on this basis would be unfair and unreasonable.

**QOF Visits**
To avoid any possible breach of the Data Protection Act, the GPC believes that practices should **not**:

- allow QOF assessors access to incompletely anonymised patient records, if informed patient consent has not been obtained

- attempt the 'low-tech' manual methods of anonymisation e.g. photocopying and Tipp-Ex etc., as this involves a risk that patients' records will not be completely anonymised, if the anonymisation is not carried out properly.

Practices **should**:

- co-operate with QOF assessors as fully as reasonably possible at the QOF visit

- discuss with their PCO a process for obtaining patient express and informed consent prior to the visit. LMCs may well wish to carry out these discussions on behalf of their local practices. We believe that the most practical approach is for

PCOs to obtain consent. This approach would also ensure the integrity of the audits, as practices would not have prior information about which records will be accessed.  We are aware that many PCOs are already taking a sensible approach either by obtaining patient consent prior to the visits, allowing postponements or taking a very ‘light-touch’ approach in order to allow this round of visits to go ahead as planned.

- discuss any planned course of action with the PCO before making any final decisions. Obtaining consent may mean deferring this part of the QOF visit until consent is obtained. Other aspects of the visit can go ahead, or it may be more sensible to defer the whole visit until consent has been obtained

- refer their PCO to the Strategic Health Authority, if agreement about an approach cannot be reached with the PCO.  SHAs have been informed by the Department of Health that PCOs should take a pragmatic approach to the QOF visits, allowing delays to the visits or at least that part of the visit that requires access to patient-identifiable data until the legal position has been satisfactorily clarified. SHAs are, in turn, passing this message to PCOs

- seek advice from their Local Medical Committee about any issue of concern. LMCs that are not able to resolve local problems, even after taking the above approach, should inform the GPC.

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