phg foundation

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# A Consultation by the General Medical Council to inform their Guidance on Confidentiality: The Response of the PHG Foundation

## Introduction

The PHG Foundation is the successor body to the Public Health Genetics Unit and Cambridge Genetics Knowledge Park. Its purpose is to enable and foster the responsible and evidence based application of biomedical science for the benefit of human health. Amongst its specific objectives is the fostering of a social and regulatory environment receptive to the application of biomedical science for health, but at the same time imposing an appropriate, equitable and proportionate regulatory burden. The Foundation has a particular interest in genetic research and its impact upon clinical and public health services.

1. **Is maintaining confidentiality an important professional value for the medical profession, or is it simply a contractual and legal obligation?**

   Confidentiality is a fundamental principle which underlies good medical practice. Its importance has been recognised at every regulatory level from international declarations such as the Declarations of Helsinki and Geneva, to statutory law. Whilst recognising the central place of confidentiality, the PHG Foundation would wish the GMC to emphasise that confidentiality is not an absolute requirement and may be over-ridden. The GMC has in the past set out with great clarity the circumstances where it might be legitimate to do so. We have reservations that recent attempts to satisfy concerns about public trust and data security have tended to promote a 'tick-box mentality' and would prefer to encourage a more reflective and proportionate approach, based on general guidance about the circumstances in which confidentiality might legitimately be breached.[1]

2. **Should the GMC be producing guidance, given that guidance is issued by a few different bodies (GMC, departments of health, Information Commissioner)?**

   Like any other professional body which combines regulatory and disciplinary functions, the GMC has a distinctive role. Experience has shown that advice from the GMC may be particularly influential upon its stakeholders.[2] Whilst the GMC may

[1] Such as the call for 'intelligent trust' or 'intelligent accountability': O O'Neill (2002) Autonomy and Trust in Bioethics. See also the Academy of Medical Sciences (2006) *Personal Data for Public Good: Using Health Information in Medical Research*.

[2] When the GMC confidentiality advice was revised in 2000, the change in practice that arose as a result necessitated prompt legislative intervention in the form of the Health and Social Care Act 2001 and supporting regulations, (the Health Service (Control of Patient Information) Regulations 2002) to enable data to continue to be sent without consent to cancer registries, and for certain types of research to proceed without explicit consent. However these additional bureaucratic hurdles have had significant impacts on certain categories of research (Academy of Medical Sciences (2006) *op. cit.*; C Metcalfe et al, Low risk research using routinely collected identifiable health information without informed consent: encounters with the Patient Information Advisory Group. *J Med Ethics* 2008;34;37-40; C Jackson et al, Assessing the impact of the requirement for explicit consent in a hospital-based stroke study *QJ Med* doi:10.1093/qjmed/hcm152.

be particularly well placed to provide examples of cases which resonate with doctors by way of illustration, it is incumbent upon the GMC to take a leadership role and to ensure that any guidance they produce reflects the need to maintain an appropriate balance between the protection of patient confidentiality and the public interest. For example, the PHG Foundation would not wish to see any revision having the effect of making doctors unduly cautious about sharing data for research, particularly if that research involves the processing of secondary data for epidemiological research.

**3. What do you see as the most important confidentiality issues now and in the future which are relevant to doctors and the GMC?**

It is likely that developments in European law (prompting changes to national legislation in the form of the Human Rights Act 2000 and the Freedom of Information Act 2000) are not yet fully played out. European case law has already refined some areas of confidentiality law[3] and organisational changes seem to be encouraging an increasingly individualistic account of confidentiality. This might challenge well established uses of genetic information for clinical and research purposes. Given that genetic susceptibility testing for common complex diseases is already well developed, the prospect of rolling out such testing into primary care over the next decade is likely to challenge individualistic models of data sharing.

**4. What have been the big organisational and legal changes in relation to confidentiality since 2000, when we last substantially reviewed our guidance?**

We suggest that some of the most significant changes are as follows:

**The Health and Social Care Act 2002 and the Health and Social Care Bill 2007**

Section 60 of the HSCA (now superseded by section 251 of the National Health Service Act 2006) provided for class exemptions[4] to the requirement for consent where certain types of data (such as that relating to cancers and communicable diseases) are processed for 'public health' purposes. Although initially introduced as a transitional measure PIAG is due to be replaced by the National Information Governance Board when the Health and Social Care Bill 2007 is implemented later this year.

**The Human Tissue Act 2004**

The Human Tissue Act 2004 has introduced a regulatory framework which requires consent to be sought for using human material for a variety of purposes. By establishing a criminal offence preventing the non-consensual analysis of DNA it has implications for clinical practice where genetic information is shared between family members for diagnosis and treatment.

[3] See for example *Campbell v. MGN [2004] 2 AC 457; HL and R (Axon) v. Secretary of State for Health [2006] 2 WLR 1130.*

[4] Although the exemptions modify the obligation of confidentiality, the Data Protection Act still applies to data processed for these purposes.

### The Mental Capacity Act 2005

This Act provides a legislative framework which enables those lacking capacity to continue receiving treatment or care together with a mechanism for individuals who lack capacity to be involved in research. It sets out the basis for establishing 'best interests' and proxy decision makers.

### Organisational developments
### Electronic patient record systems

The implementation of electronic patient record systems has implications for doctors and supporting staff. In future access to summary care record systems will be dependent upon establishing a legitimate relationship and role based access. Doctors (particularly in the primary health care sector) will be responsible for establishing that their patients wish to participate in the summary care record scheme. They will also have to manage any explicit opt-outs and take account of additional access controls on those records by negotiation.[5]

### Using technology to promote better systems

The NHS has introduced IT mediated information governance systems which requires trusts to be more systematic in their approach to information governance and to justify departures from national guidance. Similarly the use of integrated application systems for research will be a useful tool to prompt researchers to take account of all relevant law. However we are concerned that the unreflective use of automated systems could promote an overly cautious approach from health professionals which fails to support legitimate departures from established practice. In our view, laws in this area (not withstanding their complexity) can justify prima facie breaches of confidentiality in the public interest (such as the non-consensual use of an individual's personal data for epidemiological research) provided that to do so is necessary and proportionate to the protection of health.

**5. What do you think of the current form of the guidance – for example, should we be more or less specific or detailed in our advice or about the same?**

The guidance provides the right amount of detail in our view.

**6. Would a web-based resource of examples or case studies, which could be kept up to date and amended as necessary, be helpful?**

It would be helpful to provide specific examples of where breaching confidentiality might be in the public interest. Examples might include allowing genetic information data about one family member to be released to laboratories as a control, so to allow appropriate mutation analysis to be carried out for the benefit of another relative, particularly if the release of that information could be justified by reducing

[5] These may range from sealing and/or locking particularly sensitive information or refusing to participate in the scheme at all.

the potential harms to other family members. Other examples might include allowing secondary or epidemiological research to proceed on the basis that it was likely to cause minimal harm and promote significant public benefit.

**7. Are there any major omissions in the current core guidance? If so, what are they?**

It is claimed that the NHS Care Record Guarantee[6] sets out the ethical basis for using personal medical data within the NHS. The Guarantee cites some instances where medical information may be lawfully shared (where for example disclosure is required by law). In other instances a finely balanced judgment may be required which is ultimately informed by the context of a particular case, such as where a competent child does not want medical information shared with a parent. Any revisions to the guidance should reflect this complexity.

**8. What is wrong with our existing core guidance? In particular, can you point to text which is confusing, inaccurate or inconsistent with the law or other relevant guidance? (Please be as specific as possible).**

In the context of research the guidance implies that it is always easy to distinguish between clinical audit and research. In practice the boundaries are not always clear. It is also important to stress that the law is evolving and does not remain static.

**9. Can you give examples of difficult decisions doctors have to make about confidentiality and the disclosure of information? (This should help us identify issues on which we can give practical advice in the guidance to replace the Frequently Asked Questions. Please do suggest solutions to the problems you identify).**

See examples already cited.

**10. How might we make our confidentiality guidance more useful and accessible to patients and the public?**

The Connecting for Health 'Healthspace' function could be developed to inform and educate the public about how their medical data is routinely used, and to seek their consent to use it in extended ways.[7]

**11. How could we make our confidentiality guidance more useful to doctors?**

Since many decisions to breach confidentiality and disclose personal information may be finely balanced relying heavily upon the exercise of appropriate clinical judgment and context, it would in our view be helpful to set out statements of principle which physicians could apply to guide their actions in each particular circumstance.[8] The guidance could also integrate other sources of advice so doctors could compare

[6] NHS Care Record Guarantee (2007) at http://www.connectingforhealth.nhs.uk/nigb/crsguarantee/crs_guarantee.pdf

[7] Such as by giving a general consent to participate in research approved by a research ethics committee.

[8] This mechanism is used in legislation such as the Data Protection Act 1998 and the Mental Capacity Act 2005.

recommendations from other sources, (such as the Information Commissioner's office, or research organisations such as the MRC).

**PHG Foundation**
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