

Confidentiality and the public interest in medical research – will we ever get it right?

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ABSTRACT – Developments over the last decade in legislation and professional guidance on confidentiality and medical research in the UK are reviewed. Despite the General Medical Council's guidance, and recent changes to the common law on confidentiality in England and Wales, confusion remains about what is lawful and professionally acceptable in the handling of identifiable data. The GMC has contributed to this confusion. Professional bodies should jointly produce new guidance. The Health and Social Care Act 2001 is a temporary legislative solution. Public consensus is required on an acceptable balance between the citizen's right to privacy and the responsibility of society – to which all citizens belong – to protect the public health. The Government should survey public opinion, inform NHS patients better, initiate wide public debate, and legislate to protect both citizens' rights and medical research that is demonstrably in the public interest. Registration of cancer and communicable diseases should become statutory.

KEY WORDS: cancer, communicable diseases, confidentiality, epidemiology, legislation, medical research, privacy, professional guidance, public health

Requirements for patients to consent to processing of their identifiable healthcare information have increased since the 1990s. The pendulum has swung away from implied consent, the basis of medical research for decades, but now disparagingly summarised as 'trust us, we're doctors'. The trend seems justifiable, natural and right. But are the issues that simple? In this article, we discuss confidentiality and consent in the context of legislation and professional guidance on medical research over the past decade. We consider the responsibilities of doctors and medical researchers in clinical and population-based research, and what might be lost if these complex issues are viewed too rigidly. We also consider some of the steps required to achieve a suitable balance between the inherently conflicting notions of personal autonomy and collective responsibility in medical research and public health surveillance.

Legislation and professional guidance

Royal College of Physicians

Less than 10 years ago, a Royal College of Physicians working group with non-medical members reviewed the ethical procedures for studies involving the use of personal medical records. It concluded: 'There is a duty to use available information for the general good where this can be done without detriment [to individuals]'.¹ It specified that research involving direct contact with patients did require both individual consent and independent ethical review of the protocol, but that research requiring only access to medical records – *without direct patient involvement* – should not require explicit individual consent or independent ethical review, provided that four conditions were met. In essence, these were that a senior doctor subject to a professional code of practice should obtain explicit consent to access the records from their official custodian or from the patient's clinician, that the data would be handled under a strict code of confidentiality with severe penalties for breaching it, and that no individual could be identified from any publication.

The emphasis on a *duty* to use information for the general good is in stark contrast with the position today. In less than a decade, the constraints on non-profit medical research for the public good have significantly increased, without obvious benefit to the public. For national studies, it can now take a year just to obtain ethical clearance from up to 200 research ethics committees.

Caldicott Guardians

In December 1997, a committee chaired by Dame Fiona Caldicott made recommendations on the use of health data containing personal identifiers outside the context of the patient's clinical care, for purposes such as public health and epidemiology, audit, and financial management.² It recommended that a senior health professional should take on the role of 'Caldicott Guardian' for each NHS hospital, health authority and primary care group/trust, and in other NHS agencies handling patient-identifiable information. The report set out six general principles

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(Box 1), and a five-year programme of improvement at each NHS entity was based on 18 key areas, such as training in confidentiality, clarification of roles, processes for risk assessment, the detection and monitoring of incidents involving patient-identifiable information, and information for patients. An NHS Executive letter in January 1999 called for action plans to demonstrate progress in meeting the recommendations.³

European and UK law

The Data Protection Act 1998⁴ and the Human Rights Act 1998⁵ were introduced to bring UK law into line with European legislation.^{6,7} The eight principles of the Data Protection Act (Box 2) are similar in scope to those of the Caldicott guidance.

The European Directive of 1995 on the protection of individuals with regard to the processing of personal data covered all types of data transfer, including health data.⁸ Article 8(3) specifies certain exemptions from the requirement to have the patient's consent for the use of identifiable data, namely when the data are

required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

Box 1. The six Caldicott principles.

- to justify the purposes of data collection
- not to use patient-identifiable information unless absolutely necessary
- to use the minimum patient-identifiable information necessary
- access to patient-identifiable information should be on a strict 'need-to-know' basis
- everyone should be aware of their responsibilities
- everyone should understand and comply with the law

Box 2. The eight principles of the Data Protection Act 1998.

- 1 Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless:
 - at least one of the conditions in Schedule 2 is met, and
 - in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.
- 2 Personal data shall be obtained for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- 3 Personal data shall be adequate, relevant and not excessive in relation to the purposes for which they are processed.
- 4 Personal data shall be accurate and, where necessary, kept up to date.
- 5 Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
- 6 Personal data shall be processed in accordance with the rights of data subjects under this Act.
- 7 Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- 8 Personal data shall not be transferred to a country or territory outside the European Economic Area, unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

The research exemption resembles the Royal College of Physicians guidance published the previous year.

The Data Protection Act also provides a research exemption from the requirement for patient consent. Essentially, it allows research using identifiable data that have been fairly obtained, provided those data are not used to make decisions about individual data subjects, their use would not cause substantial damage or distress, and they are not published in such a way as to enable identification of individuals. Even though the Act provides for research, the wording is complex (Box 3), and the requirements for 'fair processing' have led to confusion in the research community about what data can lawfully be obtained and transmitted.^{9,10} Concern also surfaced in Parliament, because the legality of cancer and other disease registries under the Act was being called into question.¹¹

Remarkably, the Information Commissioner herself acknowledged the extent of confusion about the use and disclosure of health data for research in 2002:¹²

The [Data Protection Act] presents a number of significant challenges to data controllers in the health section. Over the course of the last year, I have seen a significant increase in the number of requests for assistance from individuals ... it is clear that many practitioners are confused between the requirements of the Data Protection Act and those of the various regulatory and representative bodies within the section including the [General Medical Council, the Medical Research Council and the British Medical Association]. To some extent the advice issued by these different bodies may reflect their different roles. To some extent it may also reflect misunderstandings of the requirements of the Act. It is a common misconception, for instance, that the Act always requires consent of data subjects to the processing of their data. At the same time, as private litigation increases throughout society, many health service bodies have adopted a more cautious approach to the use and disclosure of patient data, fearing that uses and disclosures of data which previously seemed unexceptional might attract action for a breach of confidence. (emphasis added)

The House of Commons Select Committee on Science and Technology, having heard evidence of similar concerns about

research using cancer patient information, recommended in July 2000 that 'as a matter of urgency, the advisory group on patient confidentiality should address the concerns posed by the 1998 Data Protection Act regarding the registration of cancer'. It also recommended that 'the Government should introduce legislation to make the registration of cancer a legal requirement, both to ensure the completeness of cancer registry data and to ensure access to those data for legitimate research purposes'.¹³ We consider legislative avenues below.

Common law

The common law duty of confidence means that a patient's consent is normally required for the transfer of identifiable data obtained in confidence during medical consultation, unless there is an overriding public interest.¹⁴ In 1999, the Court of Appeal ruled that the transfer of anonymised information about prescription sales from pharmacists to the marketing company Source Informatics Ltd did not constitute a breach of pharmacists' common law duty of confidentiality, primarily because the data were anonymised.¹⁵ The court rejected the Department of Health's wide definition of privacy, and invited the Government to legislate if it wished to regulate such transfers. An attempt to do this failed in 2001, when the relevant clause in the Health and Social Care Bill was withdrawn.

Even though the Source Informatics case did not address the use of identifiable patient information for medical research or public health surveillance – we are not aware of any UK court ruling that does so – the case did raise concerns that, without the patient's explicit consent, a doctor might be challenged under the common law of confidence for reporting to the Public Health Laboratory Service an infection of public health impor-

tance that is not statutorily notifiable,¹⁶ or for notifying a malignancy to a regional cancer registry. A temporary legislative solution to this problem was later provided by the Health and Social Care Act 2001 (see below).

Professional guidance

Before that legislative solution was in place, however, new guidance on confidentiality was issued to all doctors by the General Medical Council (GMC) in September 2000.¹⁷ This greatly complicated the situation, and the viability of medical research and public health surveillance in the UK continues to be adversely affected by subsequent developments. The guidance effectively prohibited data transfers for cancer registration without the express consent of each patient (Box 4). The implied threat that doctors who released identifiable information to cancer registries in what had been the usual way for many years could suddenly expect court proceedings or a disciplinary hearing was clearly intended to be coercive. The impact on cancer registries and related surveillance systems was predictable. Longstanding data collection arrangements rapidly began to fail, not just for cancer^{18–20} but also for communicable diseases.²¹ Many research projects were delayed or blocked.^{22,23}

The GMC guidance was designed to clarify the duties of a doctor under existing legislation. Instead, it was heavily criticised by the medical profession and others,^{24–28} and it led to widespread confusion about whether doctors needed explicit patient consent to fulfil their public health responsibilities.^{29–34}

One doctor pointed out:

I don't expect patients just to tolerate the kind of work that the cancer registries and epidemiologists do: I believe they would be astonished if it weren't done. Epidemiology is the foundation on which all preventa-

Box 3. Data Protection Act 1998: section 33 – Research, history and statistics.

33. – (1) In this section:–

'research purposes' includes statistical or historical purposes;

'the relevant conditions', in relation to any processing of personal data, means the conditions:–

- (a) that the data are not processed to support measures or decisions with respect to particular individuals, and
- (b) that the data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject.

(2) For the purposes of the second data protection principle, the further processing of personal data only for research purposes in compliance with the relevant conditions is not to be regarded as incompatible with the purposes for which they were obtained.

(3) Personal data which are processed only for research purposes in compliance with the relevant conditions may, notwithstanding the fifth data protection principle, be kept indefinitely.

(4) Personal data which are processed only for research purposes are exempt from section 7 if:–

- (a) they are processed in compliance with the relevant conditions, and
- (b) the results of the research or any resulting statistics are not made available in a form which identifies data subjects or any of them.

(5) For the purposes of subsections (2) to (4) personal data are not to be treated as processed otherwise than for research purposes merely because the data are disclosed:–

- (a) to any person, for research purposes only,
- (b) to the data subject or a person acting on his behalf,
- (c) at the request, or with the consent, of the data subject or a person acting on his behalf, or
- (d) in circumstances in which the person making the disclosure has reasonable grounds for believing that the disclosure falls within paragraph (a), (b) or (c).

*tive medicine is based. Without it, much would be just anecdote and small drug trials. This move to tie its legs together can only be motivated by some unthinking adherence to an abstract philosophical doctrine about privacy. The point of the principle of confidentiality was to protect the patient from untoward disclosure of information which could be used to his or her detriment. It should not be a moral absolute, at so great a cost.*³⁵

The chairman of one local research ethics committee described the GMC guidance as a greater threat to medical research than the Data Protection Act.³⁶

In November 2000, in response to rapidly mounting concern about the impact of its guidance, just six weeks after its publication, the GMC 'performed a giant U-turn'³⁷ and placed a one-year moratorium on its guidance.³⁸ In December, the Government modified the Health and Social Care Bill, then going through the parliamentary process, in order to provide a measure of legal protection for medical research and public health surveillance systems. In May 2001, when the Health and Social Care Act became law, the GMC agreed to make its guidance coherent with Section 60 of the Act when the relevant regulations were approved by Parliament.³⁹ Amended guidance was drafted by the GMC in June 2001, but not published.

In evidence to the House of Commons Select Committee on Science and Technology in February 2002, the GMC noted (Ev. 68⁴⁰):

we fully support the work of cancer registries and of other research, epidemiology and surveillance, which is vital in protecting and enhancing the public health ... [We] have agreed that the practical difficulties which doctors face in seeking consent to disclosures ahead of the implementation of new systems will be taken into account if complaints about disclosures are made to the GMC.

Not surprisingly, doctors in medical research and public health surveillance saw that declaration of GMC support as lukewarm. It elicited a tart rejoinder from the Commons Select Committee in March 2002: 'This does little to reassure those working in the field that it remains permissible to supply data to cancer registries, and it fails to mention that the moratorium has been extended' (para 35⁴⁰). The Select Committee's report went on to describe the GMC guidance on confidentiality as 'very

ill-advised' and 'highly damaging to information gathering for medical research and cancer registration'.

Modification of the common law obligation of confidence

The Medical Defence Union (MDU) further confused the picture in October 2002. Its newsletter, issued to all doctors, stated that the Health Service (Control of Patient Information) Regulations '[do] not change a clinician's duty of confidentiality'.⁴¹ This view is simply wrong. As Lord Falconer QC, the responsible Cabinet Minister, put it in *The Times* in May 2001, Section 60 'provides a power to ensure that personal information needed to support essential research activity can be provided without the consent of individuals and without breaching the common law of confidentiality'.¹⁴ The Health Service Regulations brought that legal power into force from 1 June 2002. Regulation 4 is crystal clear. Helpfully entitled 'Modifying the obligation of confidence', it reads:

*Anything done by a person that is necessary for the purpose of processing confidential patient information in accordance with these Regulations shall be taken to be lawfully done despite any obligation of confidence owed by that person in respect of it.*⁴²

In short, the common law on confidence has indeed been modified. If your activities fall within the terms of this new regulation⁴² under Section 60 of the Health and Social Care Act 2001,⁴³ you are not in breach of the common law of confidence.

The transfer of patient information to cancer registries for the surveillance of health and disease in cancer patients is now explicitly exempted from the common law on confidentiality by Regulation 2. Equivalent transfers to the Public Health Laboratory Service for the recognition, control and prevention of communicable disease and other risks to public health are also explicitly exempted from the common law on confidentiality by Regulation 3.⁴²

Patient consent is therefore *not* required for the transfer of identifiable data for cancer registration, for infectious disease reporting, or for other medical research projects approved by the Patient Information Advisory Group under Section 60 regulations (see below). The Department of Health even wrote to all NHS Chief Executives in September 2002: 'All organisations are asked to

Box 4. Confidentiality and public health in conflict.

The GMC guidance (6 September 2000):

Monitoring public health and the safety of medicines and devices including disclosures to cancer and other registries

27 The automatic transfer of personal information to a registry, whether by electronic or other means, before informing the patient that information will be passed on, is unacceptable save in the most exceptional circumstances. These would be where a court has already decided that there is such an overwhelming public interest in the disclosure of information to a registry that patients' rights to confidentiality are overridden; or where you are willing and able to justify the disclosure, potentially before a court or to the GMC, on the same grounds.

The National Cancer Plan (27 September 2000):

6.25 The public health benefits depend on the completeness of cancer registration in the population. The government is determined to secure the future of cancer registration and will take the necessary action to ensure this.

continue submitting information to cancer registries and can be assured that it is legitimate to do so.⁴⁴

The MDU later agreed that 'the regulations make it lawful to pass on the information but do not introduce new requirements for doctors to do so' (Lee M, MDU, personal communication, 6 November 2002), but declined to publish a correction in its newsletter.

In November 2002, the GMC again deferred publication of its revised guidance to Spring 2003.⁴⁵

So, two years after publication of the GMC guidance, 18 months after the GMC agreed to revise it,³⁹ one year after the GMC's evidence to Parliament that it would be updated when Section 60 regulations were passed (Ev.67⁴⁰), nine months after stinging criticism of it by an all-party Select Committee of MPs,⁴⁰ and six months after Parliament actually approved the regulations to modify the law on confidence,⁴⁶ the original guidance was still the only relevant document on the GMC's website.¹⁷

This extraordinary delay in amending the GMC's flawed professional guidance on confidentiality has caused much confusion and unnecessary delay in research.

Health and Social Care Act 2001 and the Patient Information Advisory Group

Section 60 of the Health and Social Care Act 2001 gives the Health Secretary powers to allow identifiable patient data to be used in specific circumstances without the patient's consent. Those powers have to be specified in secondary legislation (Statutory Instrument). They are subject to stringent parliamentary control. Both the Commons and the Lords must debate and approve any regulations or amendments to them (affirmative procedure).

Section 61 sets up a new statutory body, the Patient Information Advisory Group (PIAG), answerable to the Secretary of State, to draft and administer the regulations under Section 60. PIAG has patient, legal and professional representation, including GMC Council members and public health professionals. It has met quarterly since December 2001. The first regulations were approved after extensive debate in both the Commons⁴⁷ and the Lords⁴⁶ in May 2002. The Health and Social Care Act does not modify the Data Protection Act 1998 in any way. It applies only to England and Wales.

Under the 2001 Act, PIAG must review the Section 60 regulations annually. If it decides that a particular activity authorised under the regulations can now be done without recourse to identifiable data, the Secretary of State must revoke the relevant regulation.

PIAG has so far taken a conservative approach to the use of identifiable information, turning down most applications or asking applicants to provide further information.⁴⁸ Applications from the Public Health Laboratory Service and the UK Association of Cancer Registries were approved only after PIAG was convinced that their handling of patient-identifiable data in long-standing public health surveillance activities was justifiable, subject to strict confidentiality arrangements,⁴⁹ and consistent with the requirements of the Data Protection Act.

The Government views support from Section 60 and PIAG as

Key Points

Striking a balance between the confidentiality of identifiable health data and medical research aimed at improving the public health is now an issue in many countries

Widespread confusion exists about what is lawful and appropriate in the UK for data handling in medical research

The Health and Social Care Act 2001 provides only temporary legislative support for public health surveillance and medical research using identifiable data

Professional guidance is currently inadequate, and inconsistent with the law

New legislation is required, based on wide public debate, a settled consensus on the right balance, and public health leadership from the Department of Health

'transitional' measures, however, until either anonymisation completely obviates the need for patient identifiers, or adequate measures for obtaining patient consent can be instituted. As Minister John Denham MP put it: 'as soon as we can, we will take away that support'.⁵⁰

Longer-term legislative support for medical research that will continue to need access to identifiable data has not been planned. Consequently, the future of public health surveillance and medical research in Britain remains uncertain.

Double standards

When Parliament was debating new legislative support for medical and public health research that would further protect the rights of individuals during the period 2000–2002, a casual observer might well have concluded that a major and secretive revision of the status quo was in progress. Tendentious or ill-informed commentary surfaced in both tabloid and serious press^{51–56} and web newscasts,⁵⁷ with lurid headlines such as 'Spies in the surgery'⁵⁸ or 'Milburn demands patients' case notes from doctors'.⁵⁹

Many databases of identifiable information are used in the wider interests of society to make decisions about named individuals. Expecting the police to protect society against crime without a database of identifiable information would be considered absurd. Equally, asking the Inland Revenue to ensure that we all pay the right amount of income tax to the state without an identifiable database would be unthinkable. When the security of such systems is breached, society does not demand that they are closed down, or even that the perpetrators are fired. In 2003, Inland Revenue staff were caught trawling confidential tax databases both maliciously (for information about ex-spouses) and for profit, selling juicy snippets about the tax affairs of celebrities to tabloid newspapers. The press calmly reported that new rules would be brought in shortly.⁶⁰

The contrast between press criticism of legislation designed to tighten the control of confidentiality in research and the lenient

reporting of repeated, deliberate breaches of confidentiality for malice or profit in the Inland Revenue could hardly be more striking. The press clearly applies double standards when reporting on confidentiality and the public interest. Media treatment of a breach of confidentiality by medical researchers, whether accidental or deliberate, would probably be very severe.

Double standards also apply outside the research domain. In 2002, there was media uproar about legislation passed by the European Parliament further extending police powers to access individuals' telecommunications logs without their knowledge or consent.^{7,61,62} In bizarre contrast, some newspapers have recently engaged expensive barristers to argue that the intimate details of celebrities' lifestyles are so clearly in the public interest that they must be published, regardless of distress caused to the subject. Occasionally, such sophistry even succeeds in court. The Institute of Public Policy Research has now called for a review of what should be considered as being in the public interest when media intrusion threatens individuals' privacy.⁶³

The future

In future, a fair balance between the rights of individuals and the public health of the society to which all individuals belong will be central to achieving a settled consensus on the use of identifiable information in health surveillance and medical research. The issue is under discussion in Australia, Canada, Estonia, France, Germany, Japan, the USA and elsewhere. In the USA, the problem has been described as achieving 'the proper balance between protection of the records [and making them] accessible for patients' care and health education, research, and public-health surveillance'.⁶⁴

Informing patients and the public

A key theme in data protection legislation is that individuals should be made more aware of how information about them is used. In a patient-oriented NHS, this is clearly desirable. Most patients being treated within the NHS are likely to be unaware that their data are being transferred between NHS entities, or why these transfers might be justified for public health purposes. The stress laid by the Medical Research Council in 2000⁶⁵ on ensuring that patients are aware of potential uses of their data is one of the main differences from the Royal College of Physicians guidance issued six years earlier.¹

Lack of knowledge does not necessarily imply lack of public support for research activities of public benefit, however. In Germany, where cancer registration has been restricted by law for decades because of historical concerns about abuse of personal files by the state, a large representative survey of the public commissioned by government in 1983 nevertheless showed that 88% were in favour of cancer registration, and 78% would want their data to be reported and analysed if they developed cancer, even though medical associations were afraid that reporting would affect confidential doctor-patient relationships.⁶⁶ Unpublished data from a large public survey in Canada in 2001

also strongly support the use of individual data for health surveillance and research (Holowaty E, personal communication, April 2002). In Australia, New Zealand, Canada, USA, and the Nordic countries, where cancer is statutorily notifiable, we are not aware of evidence that patients have become reluctant to disclose information to healthcare professionals – a frequent but untested assertion in the UK debate – or of campaigns to repeal the underlying legislation.

Consent

The effect of imposing a uniform requirement for informed consent on *bona fide* research should be considered. The computer systems to handle information on consent do not exist and would require substantial effort to develop. Obtaining individual consent to submit information for cancer registration is impossible if patients have not been given or do not acknowledge the diagnosis, a situation that may affect 4–14% of cancer patients.⁶⁷ Incomplete consent would give rise to unquantifiable bias that would render much public health information useless.⁶⁸

The Department of Health has acknowledged this point. In a consultation paper on the handling of human organs and tissue after the Alder Hey incident, it noted that public health surveillance must be both reliable and sufficiently comprehensive that changes can be tracked over time, adding: 'if significant levels of patients did opt out of such surveys, this would call into question their validity, with possible adverse implications over time for public health itself'.⁶⁹

Obtaining informed consent from all patients at each NHS contact would be costly and impractical:

There are unscalable practical barriers to seeking consent from the whole population ... How quickly can you get informed consent, and explain why you want it? Will three minutes tacked on to the first consultation with a GP be enough? A tick-box? Who will keep a central record? What about the patient with Alzheimer's who can't give consent? What if you change your mind? What if you switch GPs? What if you never go to a GP, but just pitch up in [accident and emergency] one day? It is a far bigger undertaking than the census, and it is hard to imagine it ever happening. It would be far easier to legislate to protect the work of cancer registries and other organisations concerned with epidemiology and health services research, to ensure that the confidential data they need could never be used for non-medical purposes. That would protect the public and promote new medical knowledge.³⁵

Baroness Northover addressed the balance to be struck between private autonomy and the public interest in the Lords in March 2001:

As my noble friend Lord Lester of Herne Hill put it in [his] advice to the GMC, 'the public interest test for lawfully interfering with a patient's right to protection of confidential information and of personal privacy ... is whether there is a pressing social need and whether the interference is proportionate to the purpose'.¹⁸

In May 2001, Baroness O'Neill of Bengarve summarised the difficulty of treating confidentiality and consent as 'the primary, paramount principle' when dealing with all identifiable data:

I doubt whether informed consent can be a feasible general principle in public health. It is the fundamental principle in clinical ethics, in the clinical encounter. It never has been the fundamental principle in public health, where we have always had to look to other principles of legitimation. We cannot ask each individual whether he or she approves the current standards for water monitoring and for many other facilities. So public health has to be taken in a different way. I fear that an attempt to reintroduce informed consent as the crucial principle at every stage in matters of public health is likely to lead us back to the rather formulaic and inadequate conceptions of informed consent, or merely pro forma conceptions, that used to obtain.¹⁰

Her authoritative voice provides a rare counterweight to the reflex view emanating from the Department of Health in the last few years that the basic principle of *all* identifiable data exchange must be patient consent.⁷⁰

Similarly, Dr Bill Lowrance, the US expert on confidentiality in research, argued in his detailed report on the UK situation in 2002 that current thinking about informed consent is premised on the clinical encounter, whereas in modern healthcare systems with highly complex data flows, such a form of consent is unlikely to be adequate for all purposes.⁷¹ The adverse implications of requiring informed consent for the use of all identifiable information in research have also been pointed out by experts in the UK.^{25,72,73} Their views have been echoed by specialists from the fields of pathology, public health laboratory sciences, primary care and general practice, oncology, mental health and clinical audit.^{74–79}

A majority of the public, if properly informed, might well agree with Doll and Peto that patients' rights should be balanced by their responsibilities:

The right to medical care should ... generally continue to include the responsibility to allow the information gained in its course to be used for the benefit of others who develop a similar disease, or are at risk of developing it. Confidential sharing of information about patients between doctors and bona fide medical research workers (with exceptions only in particular cases) has done no harm and has achieved much good. Why destroy it?²⁴

What can be done?

Public discussion

A broad debate on the principles of autonomy and consent is required. It has been foreshadowed by the Minister for Public Health, Yvette Cooper MP:

There are vital questions around patient confidentiality which are central and do need to be respected with modern communication systems and modern information systems. There is also huge potential to use large amounts of information which we have in the NHS for all kinds of purposes that we were never able to do before. This does raise important ethical questions and important concerns which have to be resolved.⁸⁰

Such a debate requires leadership from the profession and from Government. The Department of Health promised a major public information campaign in 2001, but nothing happened.

The Chief Medical Officer and the Department's senior public health officials should now have the courage to speak up for medical research and public health surveillance, on which health policy relies so heavily. They should explain to the public why, despite the underlying principle of patient consent for data collection, identifiable data must for some purposes be collected without consent, for research that harms no-one and benefits everyone.⁸¹

Lowrance has also appealed for wider consultation with the public on these issues, arguing that 'trust will be nourished if the public understand what is done and why, and if health organisations and researchers understand the concerns and preferences of the public.'^{71,82} Public trust in the Government on such matters is clearly an issue. Civil liberties campaigners will at least ensure that the debate is lively.^{83,84}

Public information

The public need to be more aware of how data are used, and of the benefits of research. The NHS must inform patients and the public better about what happens to their data, about the uses made of it and the research that flows from it, and about the mechanisms for ensuring its confidentiality. This will require wide debate, and leadership from the Department of Health.

Survey of public attitudes

Public health surveillance systems for communicable disease are crucial to the health of the public. Verity and Nicoll have noted the vulnerability of these systems to the loss of professional and public confidence, and pointed out that such systems have not been adequately considered in legislation or guidance on confidentiality.⁸⁵ One critic commented that 'the onus is on doctors to persuade legislators and society that public health surveillance is morally equivalent to the other circumstances in which consent and confidentiality can be waived.'⁸⁶ He added that public response to requests for authorisation to use identifiable data in surveillance and research might be more positive than anticipated. The available evidence from Germany and Canada supports this.

The Government should consider carrying out a careful survey of public opinion, large enough to be statistically robust, and with suitable background information to enable adequate responses. The results should be the basis of wider debate aimed at reaching a settled public consensus.

Professional guidance

The GMC, the Royal College of Physicians, the Medical Research Council and the British Medical Association have all produced guidance in this area. Confusion arises from the inevitable differences in opinion and emphasis, as the Information Commissioner has pointed out. Coherent professional guidance produced jointly by these bodies might carry greater weight. It might also simplify the task of researchers who must follow such guidance, and of ethics committees who must interpret it.

At the very least, the GMC should finally revise its guidance, and take a more balanced account than it has done so far of the societal benefits of ethical and confidential research requiring the use of identifiable data without consent.

Legislation

In the last 10 years, the UK framework of legislation and professional guidance on confidentiality, medical research and the public interest has become a complex farrago quite beyond the comprehension of most mortals, including the professionals most directly affected by it. It is even materially different in the constituent countries of the UK.

Over the same period, public apprehension about abuse of confidentiality has risen. Both the law and professional regulation are in need of comprehensive reform.

Section 60 of the Health and Social Care Act is a miscellaneous provision at the end of a massive statute covering a wide range of NHS political issues. The Government has already emphasised its temporary nature, and the entire Act will be modified or repealed after the next change of government anyway. This is not the way to legislate on medical research and public health surveillance issues which are far wider than the boundaries of the NHS, and which will remain important for the foreseeable future, whatever the system of healthcare provision.

In a complex society that needs a continuous stream of medical research with identifiable data in order to sustain the health of the public, these issues require a settled consensus on broad questions of autonomy and consent. It would be an abdication of Government responsibility for the long-term health of the public if such medical research and public health surveillance were not allowed to continue.

A durable solution for the twenty-first century is required, such as the laws that have made reporting of many infectious diseases a statutory requirement since the 1880s.

The Government should now legislate to protect the privacy of confidential health data; to make the registration of cancer and infectious disease a statutory requirement; and to protect the capacity for confidential and controlled use of identifiable data – without consent where the public interest requires it – in public health surveillance and non-profit medical research. Such uses of identifiable data should be subject to enforceable professional safeguards on data handling and to legal safeguards so that individuals are not harmed and cannot be identified in any report or publication.

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References

- 1 Working group to the Royal College of Physicians Committee on Ethical Issues in Medicine. Independent ethical review of studies involving personal medical records. *J R Coll Physicians Lond* 1994;**28**: 439–43.
- 2 The Caldicott Committee. *Report on the review of patient-identifiable information*. London: Department of Health, London, 1997. www.doh.gov.uk/confiden/crep.htm#foreword
- 3 Department of Health. *Protecting and using patient information: a manual for Caldicott Guardians*. London: Department of Health, 1999. www.doh.gov.uk/confiden/cgmcom.htm
- 4 Data Protection Act 1998. c.29. www.uk-legislation.hmso.gov.uk/acts/acts1998/19980029.htm
- 5 Human Rights Act 1998. c.42. www.hmso.gov.uk/acts/acts_1998/19980042.htm
- 6 Brahams D. UK: impact of European human rights law. *Lancet* 2000; **356**:1433–4.
- 7 Anon. United Kingdom of Great Britain and Northern Ireland. In: *Privacy and human rights 2002: an international survey of privacy laws and developments*. London: EPIC and Privacy International, 2002: 375–92.
- 8 European Parliament. Protection of individuals with regard to the processing of personal data and on the free movement of such data. Directive 95/46/EC, 0031–0050. http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0046&model=guichett
- 9 Strobl J, Cave E, Walley T. Data protection legislation: interpretation and barriers to research. *BMJ* 2000;**321**:890–92.
- 10 O'Neill of Bengarve. Health Service Regulations 2002. *Lords Hansard* 2002;21 May:c746–7. www.publications.parliament.uk/pa/ld200102/ldhansrd/vo020521/text/20521-21.htm
- 11 Howe F. Health and Social Care Bill. *Lords Hansard* 2001;22 March:c1679–80. www.parliament.the-stationery-office.co.uk/pa/ld200001/ldhansrd/vo010322/text/10322-40.htm
- 12 Information Commissioner (Elizabeth France). *Use and disclosure of health data: guidance on the application of the Data Protection Act 1998*. Wilmslow, Cheshire: Information Commission, 2002.
- 13 House of Commons Science and Technology Committee. *Cancer research – a fresh look. Volume I – report and proceedings of the Committee*. London: The Stationery Office, 2000. www.parliament.the-stationery-office.co.uk/pa/cm199900/cmselect/cmsctech/332/33202.htm
- 14 Lord Falconer of Thoroton. Privacy law and medical research. *The Times*, 17 May 2001:21.
- 15 Lord Justices Simon Brown, Aldous, Schiemann. *R v Department of Health, ex parte Source Informatics Ltd*. All England Law Reports [1 All ER]; 2000: 786–801. London, Court of Appeal, Civil Division.
- 16 Evans B, Catchpole M, Mortimer P, Gregor S. Continued reporting of infections to the Communicable Disease Surveillance Centre: understanding the confidentiality and consent issues. *J Publ Hlth Med* 2003; **24**:233–238.
- 17 General Medical Council. *Confidentiality: protecting and providing information*. www.gmc-uk.org/n_hance/good/secret.htm, accessed 18/11/2002.
- 18 Northover L. Health and Social Care Bill. *Lords Hansard* 2001;

- 22 March:c1685. www.parliament.the-stationery-office.co.uk/pa/ld200001/ldhansrd/vo010322/text/10322-40.htm
- 19 BBC News. *Patient secrecy rules 'preventing research'*. news.bbc.co.uk/1/hi/health/1339258.stm, accessed 19/5/2001.
- 20 Naysmith D. Health and Social Care Bill (Standing Committee E). *Commons Hansard* 2001;8 February:c479.
- 21 Turnberg L. Health and Social Care Bill. *Lords Hansard* 2001;26 February:c1086-8. www.publications.parliament.uk/pa/ld200001/ldhansrd/vo010226/text/10226-11.htm#10226-11_head0
- 22 Peto J. Research and privacy. *The Times*, 29 May 2001:13. www.thetimes.co.uk/article/0,,59-2001181050,00.html
- 23 Channel 4 News. *Cancer research halted*. www.channel4news.co.uk/home/20010521/story03.htm, accessed 19/5/2001.
- 24 Doll R, Peto R. Rights involve responsibilities for patients. *BMJ* 2001; **322**:730.
- 25 Al-Shahi R, Warlow C. Using patient-identifiable data for observational research and audit: over-protection could damage the public interest. *BMJ* 2001; **321**:1031-2.
- 26 Helliwell T. Cancer registries fear collapse. *BMJ* 2001; **322**:730.
- 27 Turnberg L. GMC's position on confidentiality. *The Times*, 6 November 2000:19.
- 28 Ballantyne A. Silence that could be a death sentence: the right to privacy threatens a vital register of information on cancer. *The Times*, 27 October 2000:22.
- 29 Adam D. Data protection law threatens to derail UK epidemiology studies. *Nature* 2001; **411**:509.
- 30 Leslie SJ, Webb DJ. GMC's guidance may inhibit research. *BMJ* 2001; **322**:1601-2.
- 31 Sasieni P, Cuzick J. Routine audit is an ethical requirement of screening. *BMJ* 2001; **322**:1175.
- 32 Kmietowicz Z. *Confusion reigns as data law continues to threaten research*. www.biomedcentral.com/news/20010516/03, accessed 21/1/2003.
- 33 Silman AJ, Macfarlane GJ. Effects of changes to Data Protection Act. *Lancet* 2001; **357**:1452.
- 34 Paterson ICM. Consent to cancer registration – an unnecessary burden. *BMJ* 2001; **322**:1130.
- 35 Traynor B. Medical research threatened by patient consent. *Guardian*, 12 April 2001:16. <http://society.guardian.co.uk/healthandsocialcarebill/story/0,7991,472239,00.html>
- 36 Ellis SJ. GMC is greater threat to research than the Act. *BMJ* 2001; **322**:890.
- 37 Illman J. Cancer registries: should informed consent be required? *J Natl Cancer Inst* 2002; **94**:1269-1270.
- 38 General Medical Council. *Statement on confidentiality and cancer registries* (8 November 2000). www.gmc-uk.org/news/current/cancer_registries.htm, accessed 15/5/2001.
- 39 General Medical Council. *Revision of 'Confidentiality: protecting and providing information'* (Document12b and minutes of GMC Council meeting 22 May 2001). www.gmc-uk.org, accessed 18/11/2002.
- 40 House of Commons Science and Technology Committee. *Cancer research – a follow-up*. London: The Stationery Office, 2002. www.parliament.the-stationery-office.co.uk/pa/cm200102/cmselect/cmsctech/444/44402.htm
- 41 Lee M. New legislation on confidentiality: to disclose or not to disclose? *MDU News*, 2 October 2002:3.
- 42 The Health Service (Control of Patient Information) Regulations 2002. SI/2002/1438. www.legislation.hms.gov.uk/si/si2002/20021438.htm
- 43 Health and Social Care Act 2001. c.15. www.uk-legislation.hms.gov.uk/acts/acts2001/20010015.htm
- 44 Department of Health, Section 60 support for cancer registries. *Chief Executive Bulletin* 2002;20-26 September 2002: Item 5. www.doh.gov.uk/cebuletin26september.htm#5
- 45 General Medical Council. *Confidentiality – review of GMC guidance and development of Department of Health Code of Practice*. (para 11 and Annex A in document 15a for GMC Council meeting 5 Nov 2002). www.gmc-uk.org, accessed 18/11/2002.
- 46 Health Service (Control of Patient Information) Regulations 2002 – Motion for Approval. *Lords Hansard* 2002; 21 May: c725-8. www.publications.parliament.uk/pa/ld199900/ldhansrd/pdvn/lds02/text/20521-17.htm#20521-17_d10
- 47 Draft Health Service (Control of Patient Information) Regulations 2002. *Commons Hansard* 2002;15 May:c3-c30. www.parliament.the-stationery-office.co.uk/pa/cm200102/cmstand/deleg3/st020515/20515s01.htm
- 48 Information Policy Unit. Patient Information Advisory Group minutes. www.doh.gov.uk/ipu/confiden/index1.htm
- 49 Coleman MP, Muir CS, Ménégos F. Confidentiality in the cancer registry. *Br J Cancer* 1992; **66**:1138-49.
- 50 Denham J. Health and Social Care Bill (Standing Committee E). *Commons Hansard* 2001;8 February:c480.
- 51 Anon. Patient confidentiality: who's looking at your notes? *Economist*, 1 June 2002:32.
- 52 Anon. Medical records: whose file is it anyway? *Economist*, 1 June 2002:14.
- 53 Dillan J. Ministers to snoop on patients' private medical records. *Independent on Sunday*, 5 May 2002:1. www.independent.co.uk/story.jsp?story=292074
- 54 Meikle J. Bodies of evidence: clinical information is confidential. Or is it? *Guardian*, 7 September 2002:10. www.guardian.co.uk/bigbrother/privacy/yourlife/story/0,12384,785836,00.html
- 55 Anon. *Excess powers*. *Financial Times*, 3 May 2001:18.
- 56 Browne A. Lives ruined as NHS leaks patients' notes. *Observer*, 25 June 2000. www.observer.co.uk/uk_news/story/0,6903,336271,00.html
- 57 Anon. Fears over disclosure of private medical records. www.ananova.com/yournews/story/sm_581583.html, accessed 18/11/2002.
- 58 Johnston L. Spies in the surgery. *Sunday Express*, 6 May 2001:32.
- 59 Carr-Brown J. Milburn demands patients' case notes from doctors. *Sunday Times*, 5 May 2002:7.
- 60 Kite M. Starstruck taxmen caught selling celebrity secrets. *The Times*, 16 January 2003:1. www.timesonline.co.uk/newspaper/0,,173-544629,00.html?gavalidate
- 61 Millar S. Europe votes to end data privacy: law will allow police to spy on phone and net traffic. *Guardian*, 31 May 2002:1.
- 62 Norton-Taylor R, Millar S. Privacy fear over plan to store email. *Guardian*, 20 August 2002:1. www.guardian.co.uk/uk_news/story/0,3604,777526,00.html
- 63 Institute of Public Policy Research. *Ruled by recluses: privacy, journalists and the media after the Human Rights Act*. London: Institute of Public Policy Research, 2002.
- 64 Greenberg DS. US Senate weighs proposal on medical privacy. *Lancet* 2002; **359**:1585.
- 65 Medical Research Council. *Personal information in medical research*. London: Medical Research Council, 2000.
- 66 Ministry of Youth, Family and Health. *Cancer register – cancer registration. The attitudes and readiness of resident citizens of the Federal Republic*. Bonn, Federal Republic of Germany: Ministry of Youth, Family and Health, 1983.
- 67 Gavin AT, Fitzpatrick D, Middleton RJ, Coleman MP. Patients' denial of disease may pose difficulty for achieving informed consent. *BMJ* 2002; **324**:974.
- 68 Brewster D, Coleman MP, Forman D, Roche M. Cancer information under threat: the case for legislation. *Ann Oncol* 2001; **12**:145-7.
- 69 Department of Health. *Human bodies, human choices: the law on human organs and tissue in England and Wales. A consultation report*. London: Department of Health, 2000.
- 70 Information Policy Unit. *Building the information core: protecting and using confidential patient information – a strategy for the NHS*. London: Department of Health, 2001.
- 71 Lowrance WW. *Learning from experience: privacy and the secondary use of data in health research*. London: Nuffield Trust, 2002.
- 72 Wald NJ. Use of personal medical records for research purposes. *BMJ* 1994; **309**:1422-4.
- 73 Wald NJ, Law M. The threat to the use of records and stored blood samples in medical screening research. *J Med Screening* 2001; **8**:59-60.

- 74 Cox P. Obtaining individual consent may hinder studies (reply to Using patient identifiable data without consent). *BMJ* 2001;**322**:858.
- 75 Roberts L, Wilson S. Argument for consent may invalidate research and stigmatise some patients (reply to Using patient identifiable data without consent). *BMJ* 2001;**322**:858.
- 76 Al-Shahi R, Warlow C. Using patient identifiable data without consent – authors' reply. *BMJ* 2001;**322**:859.
- 77 Bahadur G, Whelan J, Ralph D, Hindmarsh P. Gaining consent to freeze spermatozoa from adolescents with cancer: legal, ethical and practical aspects. *Human Reprod* 2001;**16**:188–93.
- 78 Dudeck J. Informed consent for cancer registration. *Lancet Oncol* 2001;**2**:8–9.
- 79 Furness P. Over-reaction is damaging research. *Daily Telegraph*, 24 December 2002:19. www.telegraph.co.uk/opinion/main.jhtml?xml=%2Fopinion%2F2002%2F12%2F24%2Fdt2401.xml
- 80 Cooper Y. Cancer research – a fresh look. *Minutes of evidence*, 14 June 2000, Q.531. www.parliament.the-stationery-office.co.uk/pa/cm199900/cmselect/cmsctech/332/0061403.htm
- 81 Coleman MP. Opinion: A matter of privacy. *Financial Times*, 28 May 2001. <http://news.ft.com>
- 82 Lowrance WW. *Privacy and health research. A report to the US Secretary of Health and Human Services*. Washington, DC: DHHS, 1997.
- 83 Wadham J. Big brother: private lives. *Guardian*, 14 September 2002:22.
- 84 Raab C. Privacy in the public interest. *Guardian*, 21 September 2002:16. www.guardian.co.uk/print/0,3858,4503467,00.html
- 85 Verity C, Nicoll A. Consent, confidentiality, and the threat to public health surveillance. *BMJ* 2002;**324**:1210–13.
- 86 Manning D. Consent, confidentiality, and the threat to public health surveillance – Comment: Don't waive consent lightly – involve the public. *BMJ* 2002;**324**:1213.