1. Introduction

1.1 The fundamental right to respect for private life and the legal obligation of confidentiality are firm tenets of UK law which protect the dignity, autonomy and reputation of citizens, spare them unwanted intrusion, and preserve their trust in the medical system. The report published in January 2006 by the Academy of Medical Sciences (‘the Academy’), ‘Personal data for public good: using health information in medical research’, endorses all these reasons for the protection of confidences and privacy in health care. However, it draws attention to the need to focus in a close and exacting way on other public interests, in particular the public interest in secondary data research—that is, research based on data originally collected for a purpose other than research which does not involve interaction with the patient.

1.2 Secondary data research identifies important causes of disease and epidemics, demonstrates the long-term effects of treatment, and helps improve the provision of services. Its secondary nature means that very large numbers of patients can be studied with complete coverage of particular populations, producing more reliable results. The duration and costs of the research are also reduced relative to ‘primary’ research. However, for reasons explained below, it is often impossible or impracticable to complete this research with anonymised data or by seeking individuals’ consent in every case. If the important health benefits of this research are to be realised, some interference in the right of privacy is required. These benefits could also be said to ground a moral duty to support the research where the benefits are substantial and the interference with privacy is not disproportionate. The area of research most affected is large scale epidemiological studies.

1.3 The Academy’s principal message is that despite efforts to balance the benefits of research with the protection of privacy, the current English regulatory framework is
failing to satisfactorily support secondary data research, in part because of its failure to distinguish such research from more interventionist research. The report describes several examples and evidence that such research is frequently rejected or effectively blocked by too many delays, costs, and restrictions, despite the negligible risks entailed.

1.4 After a wide ranging inquiry, the Academy attributes the problems not to prohibitions entrenched in laws but to confusing and overly complex regulation, excessive bureaucracy, legal defensiveness, and a disproportionate focus on individual autonomy and privacy by those who interpret and apply the laws. To rectify the imbalance the Academy’s report makes recommendations in the following areas:

   1. Legal interpretation;
   2. Improving regulatory processes;
   3. Developing good practice in research using personal data, including better processes for anonymising data, seeking consent, notifying patients and citizens of how their medical records are used in research, and securing health information against misuse and improper disclosure;
   4. Harnessing the opportunities of the NHS National IT programme;
   5. Engaging the public.

These are currently being taken forward in a variety of fora, including the UK Clinical Research Collaboration, the Department of Health, the Wellcome Trust, the Medical Research Council and the Royal College of General Practitioners.

1.5 The purpose of the Legal Symposium is to gather a group of legal experts to analyse the legal conclusions and to debate the regulatory recommendations, bearing in mind that these are part of a wider set of recommendations.

2. Primary Issues Calling for Clearer Legal Interpretation

2.1 The Academy suggests that the way forward lies in a sensible and balanced interpretation of existing legal provisions and concepts. The principal issues include:

   • The Public Interest Defence in the Common Law of Confidentiality:
     To what extent may health information be used for medical research without consent or full-anonymisation according to the public interest defence? How should the ‘right to respect for private life’ and the principle of proportionality be applied in the context of medical research?
Section 60 of the Health and Social Care Act 2002: Is the scheme in s.60 of the Health and Social Care Act 2002 for setting aside obligations of confidence in, *inter alia*, medical research meeting its original objectives? Did it supplant the common law public interest defence (or provide an optional route for clarifying that an activity involves no breach of confidence)?

Principles 1 and 2 of the Data Protection Act 1998: To what extent is the principle of fair processing in the Data Protection Act 1998 qualified in the context of medical research by s.33(2) and Part II of Schedule 1? To what extent may health information be used for medical research without consent or full-anonymisation according to Condition 8 of Schedule 3?

The Concept of Consent: More particularly, is ‘general’ consent or ‘opt-out’ consent recognised as valid consent by the law?

3. Further Elaboration

3.1 Common Law of Confidentiality and the Public Interest Defence

3.1.1 The Academy’s report accepts that secondary data research involves information that is both confidential and private and thus entails a breach of confidence if the information is used without the subject’s consent or full-anonymisation² and the research cannot be shown to be in the public interest. However, it stresses that the organisations regulating data and research tend to emphasise the need for consent or anonymisation without appreciating how impractical this can be, and fail to give appropriate scope to the public interest defence.³

3.1.2 The organisations identified as regulators include research ethics committees, the Department of Health, the Patient Information Advisory Group (‘PIAG’), the General Medical Council, NHS trusts (and those advising them) and, in respect of data protection laws, the Office of the Information Commissioner and NHS data protection officers.⁴

*Difficulties with Consent*⁵

3.1.3 The Academy explains that research often takes place at a distance, both temporally and geographically, from the collection of the data. As a result, the person communicating with the subject is probably someone other than
the investigator (thus in a poor position to seek unequivocal consent) and the issues warranting research may not be known until later. In some circumstances seeking consent can compromise effective population coverage, cause distress or harm to the individual or family members, lead to bias in the research data, or prevent appropriately large studies with statistical significance. A substantial number of individuals lack the legal capacity to consent to medical research. The practicality of seeking consent also turns on the definition of consent (see below 3.4.2 - 3.4.5).

Difficulties with Full-Anonymisation of Data

3.1.4 Full-anonymisation is often impracticable because identifiable data is needed to assess/avoid double-counting, for longitudinal research which adds data to existing records, for linkage between data sets, to validate data by cross-checking a sample of electronic records against paper records, when identifiers contain information useful to the research (e.g. postcodes, ethnic origins of a surname), when anonymisation is too laborious, and when the data is unusual (e.g. rare diseases). The burden of constructing and managing partially anonymised data sets is considerable, and often determines the quality of the subsequent research.

The Scope of the Public Interest Defence

3.1.5 For many years, lawyers advising on medical confidentiality have interpreted the public interest defence as requiring evidence of an overriding public interest. Given the special relationship between patients and their doctors, this was said to call for very strong public interest considerations. Iniquity and serious, imminent risks to public safety were thought to qualify, but not much else. Although it is still correct to say that an ‘overriding public interest’ must be demonstrated, the Academy calls for better recognition of the nuances of the test and that it is now ‘more carefully focused and more penetrating’. The interference must be prescribed by law and necessary for one of the legitimate purposes specified in Article 8(2) of the Human Rights Act 1998 (e.g. the protection of health).

3.1.6 The Academy suggests that regulators of data and research mistakenly interpret the word ‘necessary’ to mean ‘indispensable’, whereas it ought to be interpreted as meaning that the data use corresponds with a pressing
social need, the degree of interference in privacy is *proportionate* to the legitimate interest pursued (i.e. the protection of health), and the interference is kept to a minimum.\textsuperscript{12} It suggests that secondary data research poses, in many cases, a minor interference to a patient’s privacy or autonomy because it tends to use limited parts of a record, to reversibly-anonymise data, to operate an opt-out consent protocol, and to observe strong security measures. The interference is considerably less grave than that discussed in case law where health records are shared, or putatively to be shared, with police, employers, local councils, insurers, parents of a *Gillick* minor,\textsuperscript{13} the media, social security agencies, prison officers and mental health tribunals. In research the data is used to develop or contribute to *generalisable* knowledge (expressed, for example, in theories, principles, and statements of relationships). It is not used to make decisions affecting the particular individual (e.g. to deny services, to bring proceedings) and it is rare for it to cause distress.\textsuperscript{14} The Academy also stresses the benefits of secondary data research for wider populations,\textsuperscript{15} which furthers the argument that the privacy interference occasioned by records-based research is proportionate. It calls for these points to be more readily recognised by regulators, particularly where large-scale epidemiological studies are proposed.

3.1.7 Some of the criteria relevant to determining whether research constitutes a necessary and proportionate interference are: the size of the sample or cohort; the numbers who are untraceable; the cost burden in seeking consent; the risk of statistical bias affecting the scientific validity of the investigation; the speed and extent to which data is anonymised; and the strength of the security measures taken to protect the data from onward disclosure. An upper threshold of ‘minimal risk’ could also be considered.\textsuperscript{16} This would be consistent with non-consequentialist ethics of medical research\textsuperscript{17} as well as the consequentialist balancing that is typical of judicial decisions to date.

3.2 *Section 60 of the Health and Social Care Act 2001*\textsuperscript{18}

3.2.1. In the late 1990s confusion about the public interest defence, the new Data Protection Act 1998 and the Court of Appeal’s decision in *ex p Source Informatics*\textsuperscript{19} led the General Medical Council to recommend, in professional guidance, that doctors should not register cancer diagnoses with cancer
registries unless the patient consented. This seriously jeopardised the statistical significance of the registers, with drastic implications for public health monitoring and research.

3.2.2 Parliament’s response was to enact s.60 of the Health and Social Care Act 2001 and associated regulations in 2002, which apply in England and Wales. Together these allow the Secretary of State to grant dispensation from obligations of confidentiality when it is impracticable to seek consent or fully-anonymise data and where identifiable patient data relating to diagnosis or treatment of cancer is processed for public health monitoring or medical research (amongst other purposes). Extending beyond cancer registries, the new laws also allow the Secretary to authorise processing of confidential patient information to make the data less readily identifiable, to contact individuals to seek their consent to use the information in medical research, to link data sources, to validate data, or to audit health services (amongst other purposes). Conditions apply (e.g. the approval must be reviewed annually), and the Secretary of State cannot release data users from other obligations under the Data Protection Act 1998. The Secretary of State considers the views of PIAG established under s.61 before granting approval, meaning that, in practice, applications for dispensation of obligations from confidentiality are made to this arms-length body.

3.2.3 The Academy broadly supports this framework and recommends its continuation. However, it questions two points. It criticises the lengthy delays associated with applications made to PIAG. In addition, it questions the view, reinforced by statements by PIAG, that s.60 approval is mandatory if data is to be used without consent for medical research. The Academy is more persuaded by the view that s.60 was intended to provide a process for clarifying obligations of confidentiality, rather than replacing the common law public interest defence. That argument is based upon the legislative history of s.60, and on the fact that it would be unworkable for every incidence of data processing without consent for purposes listed in the 2002 Regulations to be approved under the s.60 process. Research, clinical audit and anonymisation of data would grind to a halt. Parliament could not have intended this. If this were more widely acknowledged the delays and costs associated with the statutory process might be avoided in some circumstances (i.e. when the common law defence of public interest would serve just as well).
3.3 Principles 1 and 2 of the Data Protection Act 1998

3.3.1 It is a requirement of the first Data Protection Principle (DPP) under the Data Protection Act 1998 that personal data must be ‘fairly’ and ‘lawfully’ processed.

*Lawful processing*

3.3.2 To be lawful, the processing of health records must meet a condition in both Schedule 2 and 3. The most relevant conditions in Schedule 3 are Condition 1—the data subject has given his explicit consent to the processing of personal data—and Condition 8—the processing is necessary for medical purposes (including preventative medicine and medical research) and is undertaken by a health professional, or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.

3.3.3 A point the Academy makes in relation to Condition 8 is that the word ‘necessary’ in the phrase ‘necessary for medical purposes’ should be interpreted in accordance with the Human Rights Act 1998. It follows that the type of medical research permitted in the absence of consent under Condition 8 of the Data Protection Act is identical to the sort of research permitted under the public interest defence in the common law of confidentiality (see above 3.1.5-3.1.7). This symmetry is simple and sensible, but often overlooked by the organisations controlling data and research.

*Fair processing*

3.3.4 Another legal bottleneck is the view that even if it is lawful to use data for research without consent (per Condition 8 of Schedule 3 and the common law public interest defence), individual patients must be notified of the research as a consequence of the ‘fair processing’ condition in DPP 1 if they have not previously been advised that research may take place. This duty falls on both the researcher and the organisation making data available for research. The information to be relayed to the individual is known as the ‘fair processing information’. This interpretation of the law inhibits
research for the same reasons that it can be difficult to seek consent (see above 3.1.3).

3.3.5 A point the Academy tries to get across is that the fair processing condition is not as absolute as it is often said to be. Two qualifications relevant to medical research are set out in Part II of Schedule 1. Consideration may be given to what is ‘practicable’ and whether contacting an individual would involve ‘disproportionate steps’. For example, it is not practicable to give fair processing information to an unaccompanied unconscious patient prior to emergency research (e.g. research on methods of resuscitation). Disproportionate steps may be involved if the records are old and the last known address out of date. A researcher relying on the qualifications for disproportionate steps should record the reasons for his view.

3.3.6 The Academy also endorses the view that a further relaxation is set out in s.33(2) of the Data Protection Act 1998. This section states that where personal data is processed for historical or statistical research, the operation of the second DPP is modified. Ordinarily the second DPP restricts data processing to the manipulations which are compatible with the purposes for which the data was obtained. In effect, these are the manipulations compatible with the purposes listed in the fair processing information. For example, if an individual is notified that personal data will be processed by a Hospital Trust to diagnose their ailment, the second DPP means it may be processed for compatible reasons such as routine treatment but nothing further. S.33(2) alters this rule, stating that further processing of personal data only for statistical and historical research purposes (which meets ‘relevant conditions’) is not to be regarded as incompatible with the purposes for which they were obtained. Accordingly, processing for reasons of statistical and historical research is permissible whatever the purposes listed in the fair processing information, provided the relevant conditions defined in s.33 are met. The underlying justification is that a reasonable citizen recognises the likelihood and importance of statistical and historical research and accepts it as not being a disproportionate interference in their private life if it meets the relevant conditions.

3.3.7 The counter-argument to the Academy’s view is that s.33(2) has no implication whatsoever for the duty to provide fair processing information. The duty remains intact and s.33(2) simply means that if a researcher
notifies the subject that their data will be processed for research he or she will not breach the second DPP if they use it for statistical or historical research. The Academy rejects this argument because it renders s.33(2) otiose. Even without s.33(2), researchers could work in this way without breaching the second DPP.

3.4 The Concept of Consent

3.4.1 Despite consent being an important pillar of research ethics, there is much debate about the conditions that must be met for consent to authorise research. Three issues are particularly controversial—the legitimacy of implied consent, ‘opt-out’ consent, and general consent.

3.4.2 For ethical and policy reasons, the Academy was drawn to the idea that implied consent and ‘opt-out’ consent should be recognised as valid forms of consent for secondary data research. The risks involved are substantially less than those involved in drug trials and research on post-mortem remains, and it seems broadly acceptable to members of the public. However, it recognised that these types of consent did not meet the legal requirement of ‘explicit consent’ in Condition 1 of Schedule 3 of the Data Protection Act 1998. Researchers relying on these sorts of consent would therefore need to demonstrate that their research was necessary for medical purposes according to Condition 8 of Schedule 3 (i.e. a proportionate interference with the right to a private life). The Academy also realises that these forms of consent authorise a breach of medical confidentiality in limited circumstances only, and probably fail to meet the well-established rule in Strasbourg jurisprudence that waiver of a right guaranteed by the Convention, in so far as it is permissible, must be established in an unequivocal manner.

3.4.3 General consent, also known as blanket consent, takes a non-specific form such as, “I consent to my personal health data being used in research projects approved by an independent ethics committee”. It is not uncommon to collect consent in this form at the time of medical treatment. Unlike implied and opt-out consent, the issue here is not that the fact of agreement is ambiguous, but that the content of what is being agreed to is unclear. Although individuals regularly consent to loosely worded propositions in commercial and domestic transactions, there is an
observable trend amongst those regulating data and research to insist that requests for consent include a high level of specificity. This is based on the ethical view that detailed information is integral to autonomous decision-making\(^38\) and that general consent is disempowering because it gives subjects an all-or-nothing choice.\(^39\) The problem with this position is that general consent is often the only feasible strategy due to the high cost and bureaucratic complexity of volunteering more specific information, particularly where consent is sought years in advance or from thousands of people (e.g. the UK Biobank study).

3.4.4 From a legal perspective the validity of general consent is not a straightforward matter. This is because different standards of consent may be applicable to different types of obligations, and confidentiality has a fluid jurisprudence that draws upon equity, contract, tort and human rights.\(^40\) Furthermore, a general maxim would need to be applied carefully given the wide circumstances in which a person might signal the waiver of rights.\(^41\) However, a few preliminary points can be made.

3.4.5 General principles of contract and tort suggest that blanket authorization unlimited in duration, subject matter, purpose or recipient, validly authorises a breach of confidence if it were objectively reasonable for the researcher to believe the subject knew they were giving broad consent, the subject had an opportunity for reflection, there was nothing unconscionable about the researcher’s behaviour, and it is logically regarded as reasonable by a responsible body of medical opinion.\(^42\) For example, general consent may be insufficient if the research was particularly controversial or involved highly sensitive information, or if the researcher knew particular questions were proposed but deliberately concealed this to avoid a refusal. In contrast, fiduciary law and European human rights law are more demanding but, provided the subject understands that he is giving broad and open consent and the implication it has on his legal rights,\(^43\) the additional strictures are not likely to affect the validity of general consent.\(^44\) Insofar as tort, fiduciary and human rights law underpin confidentiality, it is probably necessary to volunteer information about significant risks the subject undertakes by giving general consent (if any), but an atomised description would not be called for.\(^45\) Article 2(h) of the European Data Protection Directive 95/46/EC defines data subject consent as ‘any freely given specific and informed indication of his wishes by which the data subject signifies his
agreement to personal data relating to him being processed’. This might require some further specificity but the degree is not clear.

4. Other issues

4.1 The Symposium is also an opportunity to discuss other issues not covered in this summary, for example:

- The burden of proof necessary to establish a defence of public interest and DPA Condition 8 (Daly\textsuperscript{47} ‘anxious scrutiny’ review c.f. ‘ostensibly credible’);
- Wider themes of over-implementation and regulatory creep;
- Reasons for intense regulatory scrutiny but so few complaints concerning medical research and confidentiality;
- The meaning of ‘personal data’ since Durant v FSR\textsuperscript{48} and its implications for medical research;
- What degree of anonymisation renders health information non-confidential information? (c.f. ex p Source Informatics);
- Implications of DPP 5 for the retention of data for medical research;
- Data controller/data processor contracts;
- The relative benefits of the government secondary user service (more trustworthy?);
- Administrative powers of the NHS to share data for research purposes;
- Data security principles;
- Data transfer outside the EU;
- Differences in the Scottish regulatory framework;
- Rights to privacy and confidentiality post-mortem;
- Whether research ethics committees should consider legal rules on consent, confidentiality and privacy when giving their opinions.

The Symposium is organised by the Academy of Medical Sciences, the Public Health Genetics Unit, the Faculty of Law, University of Cambridge, and the Centre for Intellectual Property and Information Law.

The organisers are especially grateful to Mills & Reeve for their generous sponsorship of this event.
Endnotes

* Dr Liddell is a member of CIPIL, PHGU and served as the independent Legal Adviser to the Academy’s Working Group.

1 http://www.acmedsci.ac.uk/images/publication/Personal.pdf (last visited 13/06/06). ‘Report’.


3 For similar views from an organisation representing patients: J Gillott, Human Rights, Privacy and Medical Research: Analysing UK Policy on Tissue and Data (Genetics Interest Group, 2006).

4 Report 32-40.

5 Report 58-63.


7 This affects research on the diseases, conditions and atypical drug reactions that affect people with mental illness, intellectual disability, age-related illness and critical illness.

8 Report 46-49.


12 In contrast with Axon paras 67-69, there is no strong evidence to suggest patients would stop seeking medical assistance if they knew their records might be shared with bona fide medical researchers: Report 69-72.

13 The Academy also stressed its view that there is a broad measure of public support for minor interference with privacy for secondary data research: Report 69-72.


18 Although few patients object in principle to their diagnosis being logged with the registry, there are several reasons why it is nevertheless difficult to obtain consent: some patients are in denial about the diagnosis; some fail to understand the importance of cancer registries; and some lack legal competence.


20 The Academy questions whether conditions independent of Schedules 2 and 3 must be met to constitute lawful processing, but notes that the practical implications of this debate are probably not significant: Report 24.

21 The transitional provisions in Schedule 8 are also relevant in some circumstances.

22 And the European Convention on Human Rights which influenced the European Data Protection Directive 95/46/EC.

23 More precisely, the legal person who qualifies as the ‘data controller’.

24 This information includes the identity of the data controller or any nominated representative, the purposes for which the data are intended to be processed and any further information that is necessary in order for the processing to be regarded as fair having regard to the circumstances. These requirements apply whether the data controller obtains the data from the data subject or from elsewhere.

25 A definition of emergency research is set out in s.32(8) of the Mental Capacity Act 2005.
Data Protection (Conditions under Paragraph 3 of Part II of Schedule 1) Order 2000 (SI 185). Further conditions apply if the individual has requested in writing the fair processing information.

'relevant conditions' are defined in s.33(1). They include: (a) that the data must not be processed to support measures or decisions with respect to particular individuals, and (b) that the data must not be processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject.

Assuming these were lawful.

See also European Data Protection Directive 95/46/EC Recital 34 and Article 6.

Consent is presumed from the surrounding circumstances, for example general social norms (e.g. patients who consent to medical treatment are presumed to agree to their information being shared with the full medical team) or the subject's behaviour (e.g. a patient who, on seeing the doctor prepare a needle, rolls up his sleeve is presumed to consent to the injection).

Consent is presumed until a patient contacts the researchers or their health service to advise that they object to the research.

Report 57-58, 65, 66.


A point contested by O. O'Neill: op. cit., n. 17.

G. Laurie, Genetic Privacy (CUP, Cambridge, 2002).


Bowater v. Rowley Regis Corporation [1944] KB 476, CA (Scott L.J.).

Valid consent in the law of battery is even less demanding, resting as it does on a different set of public policy objectives.


The doctor/patient relationship is not an established category of fiduciary relationship. The researcher/subject relationship is also unlikely to be fiduciary in nature. Cf Canadian law: Miller, C. Weijer, 'Fiduciary Obligation in Clinical Research' (forthcoming 2006) Journal of Law, Medicine & Ethics. Supposing, for the sake of argument, that the researcher/subject relationship were fiduciary it would probably be necessary to show that the research activity poses no more than minimal risk since research, by definition, is designed to suit the interests of a wider population of people as opposed to the best interests of the individual owed the fiduciary duty.


Emphasis added.
