

EDITORIAL

# Public health and data protection: an inevitable collision or potential for a meeting of minds?

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*'Public health is the arena in which clinical medicine, epidemiology, management, politics, and the law all meet—or perhaps more accurately, collide.'*<sup>1</sup>

This quote from a publication on data protection surprisingly, but not uniquely omits 'the public' from the public health arena. Recently it has been suggested that changes in data protection legislation may jeopardize public health practice and research. In this paper we summarize current data protection legislation and guidance and discuss the implications of these for public health practice. In addition we discuss recent changes to legislation and guidance in relation to established medical ethical principles and argue for a greater involvement of the public in the debates that will inform development of legislation in this area.

## Legislation and Guidance

### European Data Protection Act 1998<sup>2</sup>

This sets out legal requirements for the use and handling of personal data for all member states of the European Union. A requirement of the act is that informed consent is obtained before personal data is shared between organizations. An important feature of the 1998 act, which replaces the 1984 act, is that it applies not only to electronic data but also to written records. Section 33 of the act provides for various exemptions with respect to the use of personal data for research purposes. Data may be exchanged between organizations for the purpose of research providing that the research is not used to support measures relating to particular individuals or could cause damage or distress to individuals. In addition, the aim of the research must be compatible with the original disclosed purpose for which the data was collected. This last requirement has been viewed by the UK House of Lords Select Committee for Science and Technology as potentially inhibiting important medical research (see below).

The act also states that in all circumstances requirements of Common Law must be upheld. In most countries Common Law

### Legislation and Guidance relevant to data protection in public health practice

Legislation	Countries covered
European Data Protection Act 1998	Member states European Union
National Standards to protect patients' personal medical records	US
Health and Social Care Bill	UK
Guidance	Countries/groups covered
Declaration of Helsinki	Global, anyone involved in health research
General Medical Council Guidance	Doctors working in the UK
House of Lords Select Committee report on human genetic databases	Any researchers in the UK

requires that anyone who receives information on the understanding (explicit or implicit) that it is confidential, must not disclose that information without consent or other strong justification. Finally the act prohibits transfer of data outside of the European Union, unless legislation in the non-European country ensures adequate protection.

### National standards to protect patients' personal medical records—US legislation<sup>3</sup>

This new US legislation was announced in December 2000 and took immediate effect. It places stringent limitations on the 'non-consensual use of health information' and extends cover from electronic data only to all types of personal health information, including 'oral and paper communications'. Disclosure of information without consent is permissible under current public health law—for example in the case of communicable disease surveillance or the reporting of adverse drug reactions. In the case of research, local regulatory bodies can waive the need for consent but only in circumstances where there is a clear public health importance to the research and obtaining consent is not possible or would seriously prejudice the research results.

### Health and Social Care Bill—UK<sup>4</sup>

The Health and Social Care Bill was rushed through the last stages of the British parliament in May 2001 before parliament was dissolved in the lead-up to the general election. In response to some of the concerns raised by the House of Lord's Select Committee (see below) the bill contains a clause which provides for the use of identifiable patient information, without consent,

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when use clearly promotes and protects the health of the public and where obtaining consent is not feasible. Any organization wishing to obtain permission to waive the requirement for consent must apply to a new body, which will be set up under the act, called the Patient Information Advisory Group. The Patient Information Advisory Group will be made up of representatives from the British Medical Association, General Medical Council, Medical Research Council, Public Health Laboratory Service and a group representing patients. It will examine each request to waive consent, obtain evidence and then present this to the Secretary of State for Health who will make the final decision. Under the act fully anonymized data can be shared between organizations for the purpose of research, education and audit, but health care providers have a duty to inform their patients that their medical information may be used for these purposes.

### Declaration of Helsinki<sup>5</sup>

The Declaration of Helsinki was developed as a statement of ethical principles to guide medical research involving human subjects. It was originally assumed that the declaration related only to research in which there was direct involvement of humans. The latest revision endorsed by the World Medical Association in October 2000 made clear that the declaration has a broader application: 'Medical research involving human subjects includes research on identifiable human material or identifiable data'. At a recent conference in South Africa to discuss the implications of the revised declaration, it was suggested that adherence to all parts of the declaration could prohibit important public health research, focusing as it does on the direct researcher-patient relationship, as opposed to indirect contact, for example through routine data sources or medical records. However, it has been argued that for research on patient records the informed consent requirement of the declaration is waived if access to the clinical record is: essential to the research; consent is not practicable; the research is of sufficient merit and may benefit the patient(s) whose records are studied; and that when results are obtained and published individual patients will not be identifiable or contacted by the researchers.<sup>6</sup>

### UK General Medical Council guidance

The UK's General Medical Council (GMC) produced guidance on *Confidentiality: Protecting and Providing Information* in September 2000.<sup>7</sup> The guidance requires doctors to obtain patients' consent to disclose medical information except in exceptional circumstances, for example where the law requires disclosure. In the case of disclosure of information for the purposes of epidemiology, public health safety, education, medical audit and health service administration, the guidance states that doctors should still obtain the individuals' consent to use identifiable data (including the provision of patient lists of names and addresses with no other medical details) or arrange for members of the health care team to fully anonymize the data. It has been argued that this guidance is a far greater threat to public health practice and research in the UK than is current legislation.<sup>8,9</sup>

### The House of Lords Select Committee on Science and Technology report on human genetic databases—UK<sup>10</sup>

The House of Lords Select Committee on Science and Technology report on human genetic databases expresses the committee's

concerns that requirements in both the European Data Protection Act and the GMC guidance could seriously inhibit legitimate medical research. They distinguish between primary use of data (collected directly from patients or research participants for a specific purpose) and secondary use of data (use of existing data for purposes other than those for which they were originally obtained). In the case of primary use of data the committee acknowledged that informed consent should always be obtained and that this requirement is clearly established in law. For the secondary use of medical data for research purposes the committee felt that current legislation was unclear and that the Data Protection Act could be interpreted as prohibiting secondary data use because of the requirement for data to be used only for purposes compatible with those for which it was originally collected. This was viewed as potentially damaging to legitimate medical research and therefore the public good. They recommended that '*... the government establish a Medical Data Panel to provide a single, clear process for approving projects involving the secondary use of NHS and medical data ... to advise the government on the interpretation of the Data Protection Act in its application to medical data, and if necessary ... advise on possible amendments to the legislative framework*'.

The main focus of the report is the use of genetic databases. The committee recommended that written consent should be obtained for participation in research involving the collection and retention of biological samples and that samples should not be retained without this consent. The report goes on to suggest that parliament and the research community strongly encourage public participation in research: 'should be ... pointed out that ... the medical treatment that all receive is based on studies carried out on very many earlier patients and that the request is for them to provide similar help for future generations'.

### Case law

Legal precedence is established with successful case law. In the area of data protection and public health practice or research we could only identify one relevant case. In May 1999 Justice Latham in a high court ruling in the UK found in favour of a patient who claimed that his rights to confidentiality had been breached by forwarding of fully anonymized data to The General Practice Research Database.<sup>11</sup> However, in December 1999 this ruling was overturned by the High Court in England who concluded that exchange of fully anonymized patient data for the purpose of public health practice or ethically approved medical research was permissible under current law.<sup>11</sup>

### Implications for Public Health Practice and Research

Although some of the guidance states that custodians of medical information should inform patients of all the uses that may be made of their medical information, the exchange of fully anonymized data for the purpose of public health practice and research appears to be permitted under current legislation in Europe and the US. This interpretation is supported by the results of the court case discussed above.<sup>11</sup> The following discussion relates to areas of public health practice where non-anonymized access to medical data may be required. In this situation the legislation is ambiguous since it relies on the

subjective principle that public benefit from exchange of information outweighs the requirement for consent and this has not been tested in case law.

### Research quality

Public health researchers may rely on access to medical records for health needs assessment, service evaluations and epidemiological research. If we assume that access to patient records for these purposes requires individual patient informed consent the effect on research quality will be determined by the proportion of individuals who refuse consent, or in the case of old data are simply not contactable, and any systematic differences between these individuals those who give consent. At present knowledge in this area is limited. In one randomized trial a request for consent to access medical records had no effect on the level of response, though 13% of those in the intervention arm refused to give consent for data from their records to be accessed.<sup>12</sup> No comparisons were made between those who gave consent and those who did not and this study only included general practice patients aged 65–74 years. In a study of adult (over 18 years) asthma and angina patients a similar proportion (10%) of participants refused consent for their clinical records to be reviewed by researchers.<sup>13</sup> Those who refused consent did not differ from those who gave consent in terms of mean age, gender, self-reported severity of symptoms or satisfaction with clinical care. In the British Women's Heart and Health Study only 14 (0.38) out of 4286 women aged 60–79 have refused consent for their records to be accessed (details from the author DAL). In a UK study 3921 randomly selected adults were asked how happy they would be for access to their medical records to be granted in a number of different theoretical scenarios defined by who would be accessing the records, the purpose of the access and details of what was contained in the records including patient identifiers. Preliminary analysis of the results suggests that on the whole the public are happy to provide access to their medical records. Individuals from higher social groups, older adults and men were found to be more likely to state that they were happy to provide outside access to their records than other groups (D Shickle, University of Sheffield, personal communication). How these theoretical beliefs would be reflected in a non-hypothetical situation is uncertain.

Record linkage provides a powerful tool for the study of the natural history of diseases, the aetiology of rare diseases or where a long lag period between exposure and outcome may exist, for example in the case of a drug exposure which may increase risk of a disease many years later. The process of linkage of individual data from a number of sources, such as primary care records, secondary care records, prescribing and mortality data, requires patient identification and in many countries is not permitted because this is believed to breach data protection laws. A further effect of the legislation on public health research relates to the ability to obtain an appropriate sampling frame. A large amount of research in the UK and other countries relies on medical staff providing researchers with a list of patient's names and addresses to be used as a sampling frame. Although no medical details are given, the provision of names and addresses is clearly not anonymous and this is likely to be in breach of European and US legislation.

The problems of accessing non-anonymized medical information for research purposes could be solved by supporting

health-care providers to become directly involved in the research. For example by extracting and anonymizing data and/or undertaking the sampling procedure and making initial contact with the patients. The obvious difficulty with this solution is that many health-care providers will not have the time, skills or interest to be this involved in research. Those who are skilled and interested in research are unlikely to have patient populations that are representative of the general population. For example in UK primary care, 'research practices' tend to be larger, better organized and in more affluent areas than primary care practices in general. This will not only affect the generalizability of research findings and limit the extent to which the effects of social inequalities can be assessed, in some areas of research it may have an effect on widening health care inequalities since those practices involved in research are likely to benefit most and most quickly from important findings.

### Public health surveillance

Public health surveillance has been used to guide disease prevention and control since the 15th century.<sup>14</sup> The success of surveillance programmes in the area of infectious diseases has led to the development and use of surveillance tools in a number of other disease areas, reflecting the diversity of contemporary public health practice. Examples include chronic disease registers and surveillance of environmental and occupational hazards. Although provision in both US and European law ensures that infectious disease surveillance is not adversely affected by data protection regulations this is not necessarily the case for other chronic disease surveillance systems. In the UK the GMC guidance specifically states that the automatic transfer of personal data onto disease registries without individual patient consent is unacceptable. Representatives of the UK Association of Cancer Registries believe that this guidance is unworkable and that coverage will fall from the current situation of over 90% for most cancers to considerably less.<sup>9</sup> One consultant oncologist has stated that the regulations will '*effectively wreck legitimate epidemiological research*'.<sup>15</sup> The House of Lords Select Committee on Science and Technology raised concerns about this issue and, in evidence to the committee, Professor Hilary Thomas on behalf of the GMC said that their guidance had been misinterpreted. The select committee recommended that '*As a matter of urgency ... the GMC should make it clear that ... doctors are not required to obtain signed consent before data are passed to disease registries. Instead, patients need simply to know that data about them may be used in this way. Such clarification may require a rewording of the GMC guidelines to put their position beyond doubt*'.<sup>10</sup> The GMC believe that the formation of new Patient Information Advisory Groups through whom cancer registries can apply to the Secretary of State to be exempt from the consent requirement (see Health and Social Care Bill above) solve any difficulties in this area and to date have not reworded their original guidance. Many clinicians and researchers remain concerned and believe that this bureaucratic process will have a negative effect on the coverage, and therefore accuracy, of the registries.<sup>16</sup>

### Global public health

The requirement within the European Data Protection Act to ensure adequate data protection legislation in non-European countries, before exchange of information, may present difficulties

for control of infectious, food-borne and vector-borne diseases in some situations and may restrict international multicentre collaborative research. Section 30<sup>1</sup> allows the Secretary of State for each European State to order certain information to be exempt from this requirement. Many developing countries do not have clear data protection legislation and it is important that governments in developed countries ensure that effort is made to support necessary research in developing countries. Ethical standards that apply in developed countries should apply equally in developing countries but the European Data Protection Act should not be used to support a stance that excludes developing countries from participating in the global research agenda.

## Data Protection Legislation and Medical Ethics

Medical ethics is guided by the principles of benevolence, non-maleficence, justice and autonomy.<sup>17</sup> The principle of benevolence means that health-care professionals have a responsibility to do good for those whom they treat. Taken together with non-maleficence it is suggested that if a health-care professional cannot do good in a particular situation, then at least they should do no harm. In recent interviews on television and radio (Newsnight, BBC2, 18 May 2001; Today Programme, Radio 4, 19 May 2001) Professor Sir Richard Peto, Director of the clinical trial service and epidemiological studies unit in Oxford, has pointed out that the legitimate sharing of confidential data between health-care providers and researchers has for many years provided good for both individuals and the population through important treatment and public health advances. There is no evidence of harm ever having been caused by this exchange of information whereas restricting data exchange for public health research and practice has the potential to cause damage to public health.

The principle of justice is closely linked to the ideal of equity—treating those with equal need equally.<sup>17</sup> The new guidance and legislation may result in health research being increasingly concentrated in ‘research practices’ that tend to serve the most affluent patient groups. It would be unjust for groups in society to be denied both the choice to participate in health research and the ability to benefit from it.

Autonomy refers to an individual’s rights to freedom of will, thought and action and is most closely linked with the practice of informed consent.<sup>17</sup> Until recently the primary guiding principle of medical ethics has been that of benevolence, for example in the past doctors would often withhold cancer diagnoses from patients in the belief that to know the truth would do them only harm and no good.

Since the 1970s, particularly in the West, there has been a shift in emphasis and greater prominence given to autonomy as a guiding principle.<sup>18</sup> With this shift in emphasis the difficulty in balancing individual rights with those of the whole society has become an important issue. It has been suggested that in the area of medical research the utilitarian theory of moral philosophy is an appropriate theoretical guide.<sup>6,19</sup> A utilitarian approach seeks to gain the greatest good for the greatest number of people. However, a pure utilitarian approach could potentially remove all respect for autonomy. For example, it could be argued that greatest benefit for the greatest number would be achieved if everyone donated blood, but few would argue that a law be

passed to force everyone to become blood donors. The concept of a ‘rule utilitarian approach’ has therefore been developed which tries to balance conflicts between individuals and the greater good of society, by setting explicit limits or rules.<sup>20</sup> In the case of use of non-anonymized data from medical records there is a need currently to determine what these limits should be. Those who will be most affected either at an individual or societal level—the general public—need to be involved in decisions about the balance between individual rights and the greater societal good. However, to do so they need to be presented with all relevant information regarding the likely consequences of setting the limits at different points.

Poor quality public health research and practice is, we believe, unethical—it will do no good and may harm. It would be unjust if research became concentrated in certain groups, for example the more affluent or better educated. Autonomy may be infringed if individuals are denied the right to choose whether or not to support public health research and disease surveillance. Finally a balance is required between the rights of individuals to the best quality health care and their responsibility to the broader public health needs of society.

## The Way Forward—Increasing Public Awareness and Involvement in the Debate

In the UK the Medical Research Council is collecting examples from researchers and public health practitioners of situations where the new regulations may have a detrimental public health impact. The American Association of Epidemiology has called on its members to similarly monitor the effects of the new US legislation. One objective of a proposed Federation of European Epidemiologists is to monitor data protection legislation and its impact across member countries. The purpose of these exercises is to inform future debate and changes to legislation. These are important activities but for an effective solution the results and future debate need to be shared not just with health professionals, politicians, managers and legal experts but with the wider public. There has been very little involvement of the general public in the development of current legislation. It is unfortunate that this legislation which deals with public rights of access and control over personal information is written in archaic legalistic language that most members of the public would find impossible to understand. Much of the current debate and background to the development of guidance in this area seems to assume that the public value confidentiality above all else. In the area of public health research and practice this assumption has rarely been tested, may be incorrect and may deny many individuals the right to be involved in something which they feel is valuable to the greater good of society and themselves.

The media rarely discuss the impact of data protection legislation on public health practice but instead link the issue to scandals such as the organ retention case.<sup>21</sup> The discovery that organs have sometimes been removed at post-mortem examination and inappropriately retained without informed consent is not about the legitimate exchange of health care information between professionals for public health research and practice, and it is unlikely that this would have been prevented by tighter data protection legislation. We believe that a fully informed debate involving the public could lead to the ideal situation where health-care users, without any need for

individual consent, acknowledge and accept that information from their medical records will at times be used for important health research with full ethical approval and with maintenance of their confidentiality. If the public are not involved in this process and are not fully informed of the important issues then public health practice could be damaged by a citizenship who view public health practitioners and researchers as self-interested and conspiring to promote their own aims and prejudices rather than to promote public health.

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