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Legal and ethico-legal issues in e-healthcare research projects in the UK ☆

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Abstract

This report first gives an overview of e-healthcare research activity in the UK. It then summarises available information concerning legal hurdles and issues faced by these projects, provides an overview of work being carried out to investigate these hurdles, and considers some of the proposals put forward to overcome them. It is an initial scoping review (using both literary and web-based resources)—rather than a systematic or analytical review—of e-health which addresses specific strands relating to legal and ethico-legal issues and identifies activity in these areas. It is hoped that this preliminary scoping exercise will stimulate further research and analysis.

Keywords: E-healthcare; Research; UK; Legal; Ethico-legal

What is e-healthcare and what is the UK's activity in this area?

A comprehensive review of the various definitions of e-health (care) has recently been carried out as part of a National Health Service Service Delivery and Organisation (NHS SDO) scoping study (Pagliari et al., 2004). Pagliari et al. (2005) concluded that the field is best served currently by the definitions, set out below:

> e-health is the use of emerging information and communications technology, especially the Internet, to improve or enable health and healthcare. (T. Eng, 2001 as cited in Pagliari et al., 2005) and e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology. (adapted from Eysenbach, 2001, as cited in Pagliari et al., 2005)

Dierickx in Callens (2003) highlighted four main applications of e-health:

1. Information management (medical journals, scientific/health research (including public health investigations, cancer registration, studies of medical products), bioinformatics and genetic data research).

☆ This paper has been written by the author, a Solicitor (non-practising), as a review of activity relating to legal and ethico-legal issues in e-healthcare research projects in the UK and is not intended to be exhaustive. If any issue referred to in the paper is to be relied on, appropriate, specific professional advice should be sought.

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2. Consultation and communication.
3. Pharmaceutical sales.
4. Intervention.

This report concentrates predominantly on e-health scientific research projects falling within the first application. Research using databases developed from data initially collected for other purposes has made and has the potential to make far-reaching contributions to health (Lowrance, 2002). Organisations bodies funding and carrying out or influencing e-health (care) research projects in the UK are summarised in Fig. 1. Fig. 1 also highlights those organisations and bodies focusing specifically on legal and ethico-legal issues. The advances in information technology and its use within the NHS allow much wider and more accurate epidemiological studies to be carried out than was previously possible (Singleton, 2004). The international development of "the Grid" which has been described as "the middleware infrastructure supporting e-science" (Hey & Trefethen, 2002, 2003) is becoming increasingly important in this field.

A detailed discussion of the objectives of all of the above projects is outside the scope of this short report.

Legal and ethico-legal issues in e-healthcare research projects

There are many legal and ethico-legal issues relevant to e-healthcare research projects and there is a vast body of information relating to the governance of medical research databases. Although each project has its own unique set of issues those set out below recur and have been addressed in many of the publications, papers, reports and workshops cited.

The legal and ethico-legal issues include:

1. Privacy and use of patient data in health research. This includes issues relating to the derivation and processing of medical data, issues concerning the nature of consent, anonymisation or pseudonymisation of data, confidentiality and the use of the medical record for scientific research (Buchan, 2002; Callens, 2003; Kalra et al., 2003;Lowrance, 2002; Pagliari et al., 2004; Purves, Wilson, & Gibson, 2000; Royal Society City and Industry Dialogue, 2003; Singleton & Bowie, 2001; Singleton, 2004; TWG6 White Paper). These emerge as the dominant legal issues to arise from the web-based search.
2. Security issues (Caldicott, 1997, and Data Protection Act 1998 and Pagliari et al., 2005).
3. Issues concerning the transfer of medical data outside the EU and across national boundaries (Callens, 2003; Lowrance, 2002).
4. Licensing and exploitation issues (Callens, 2003; Lowrance, 2002).
5. Malpractice and product liability issues (Callens, 2003).
6. Intellectual property, ownership and liability issues arising around scientific collaboration agreements and relating to medical/patient data which is input into projects and databases and emerging data or results (Cukier, 2004; David & Spence, 2003; Hey &Trefethen 2003; Pagliari et al., 2004; Purves et al., 2000; Newiss, 2003 in Royal Society Science, City, Industry Dialogue, 2003).
7. Certification, self-regulation, standards and accreditation issues (Alexander & Harding, 2003; Pagliari et al., 2004).
8. Legal acceptance of electronic documentation.
9. Public health laws and the balancing of the public interest against individual rights to privacy (Lowrance, 2002; Singleton, 2004).
10. Research ethics guidelines and regulations (Lowrance, 2002; Pagliari et al., 2004; Singleton, 2004).

In the UK, the common law duty of confidentiality, law of negligence and contract law are all relevant in varying degrees in the context of the above issues. Throughout the UK the common law requires consent for disclosure of identifiable data unless there is a legal provision authorising or requiring disclosure of data or an overriding public interest in the disclosure.

In England and Wales, legislation of most relevance is the European Data Protection Directive (Directive 95/46 EC) and its associated Data Protection Act 1998, the Human Rights Act 1998, the Human Tissue Act 2004, Access to Health Records Act 1990 and Section 60 of the Health and Social Care Act 2001 (providing an exemption from the common law on confidentiality and giving the Secretary of State for Health control over the use of NHS data for patient care or activities serving the public interest). The Freedom of Information Act 2005 together with The Re-Use of Public Sector