SMART 2007/0059

—

Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE ENGLAND

—

European Commission
Directorate General Information Society

Brussels

—

Table of Contents

1 Documents

1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf,

	Country profiles: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
[RD9]	Communication from the European Commission, "A Community framework on the application of patients' rights in cross-border healthcare", 2 July, 2008, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf
[RD10]	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, http://ec.europa.eu/health-eu/doc/com2008414_en.pdf
[RD11]	European Commission, IDABC, eID interoperability for public government services (with country profiles): http://ec.europa.eu/idabc/en/document/6484/5938
[RD12]	European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): http://ec.europa.eu/idabc/en/chapter/6000
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of eHealth,http://www.ehma.org/projects/default.asp?NCID=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML
[RD15]	Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf
[RD16]	International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm, (with country monographs)

2 Glossary

2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
  - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication**: information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth**: a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record**: a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature**: data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription**: a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare**: the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people's health, including preventive, curative and palliative infections, whether directed to individuals or to populations.
- **Health professional**: a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising

activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification**: using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier**: attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management**: Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient**: any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary**: subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;.
- **Registration**: process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine**: exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

2.2 Acronyms

CBSS.....	Crossroads Bank for Social Security
EHR.....	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
GP.....	General Practitioner
HiT.....	Health in Transition

OCSP	Online Certificate Status Protocol
PKI	Public Key Infrastructure
NRN	National Register Number
SIS	Social (security) Information System
SSCD	Secure Signature Creation Device
SSIN	Social Security Identification Number
TTP	Trusted Third Party

3 Introduction

3.1 General overview of the English healthcare system

The NHS in England is one of the country's major employers. As at September 2006 it employed almost 1,000,000 persons with expenditure of £97,196 million. A figure equivalent to £1,915 per head of population[1]. A comprehensive and recently updated (2007) overview of the English healthcare system can be found in eHealth strategy and implementation activities in England Report in the framework of the eHealth ERA project Author(s): Vicky Jones, EPSRC Carol Jollie, Centre for Health Management, Tanaka Business School, Imperial College London
www.ehealth-era.org/database/documents/ERA_Reports/England_eHealth_ERA_Country_Report_final_07-06-2007.pdf
From the executive summary of this report, we reproduce the following important observations:
The NHS in England is the responsibility of the Department of Health which operates under the direction of the Secretary of State for Health in England. NHS Connecting for Health is an integral agency of the Department of Health that is responsible for delivering the National Programme for IT for the NHS in England. The Department of Health is also part of the UK Government, and is responsible for representing the UK internationally in health matters, liaising with the other "home countries" (Scotland, Wales and Northern Ireland) as appropriate.
The Department of Health comprises a number of divisions with specific health policy or professional responsibilities; eg for public health, nursing, research and development, the office of the Chief Medical Officer which is responsible for offering expert medical advice to the whole department, the directorates responsible for leadership and a range of central management functions as well as ensuring regional implementation of national policies and monitoring the performance of health authorities, and, finally, there is a separate Minister of State with responsibility for public health. Key decisions about healthcare are taken by separate local NHS bodies but overall strategy is left to the Department of Health.
The current structure for health administration in England came into effect on 1 July 2006 when the number of Strategic Health Authorities (SHAs) reduced from 28 to 10. The boundaries of the majority of the new SHAs are coterminous with Government Office Regions (GORs). SHAs report to the Department of Health. Health services are divided into primary and secondary services. Secondary care includes services provided by hospitals, mental health provision and ambulance services. Primary care covers general practice, dentistry and ophthalmic services and is delivered by Primary Care Trusts. Following a primary care trust reorganisation in October 2006 there are now 152 Primary Care Trusts. Although overall strategy and policy is directed by the Department of Health, a fundamental element of the Government's strategy for the NHS is to encourage decentralisation of public

[1] United Kingdom Health Statistics 2008. Office of National Statistics

services and the creation of a patient-led NHS. An example of local control and ownership of health delivery is the channeling of funding for health care services through Primary Care Trusts as the main commissioning body for their area. The government has also created a new type of NHS Trust - NHS Foundation Trusts - which have been created to devolve decision-making from central Government control to local organisations and communities so that they are more responsive to the needs and wishes of their local people.
A not insignificant private medical sector exists alongside the NHS and indeed one of the key elements behind many recent NHS reforms in England has been the desire to forge closer links between the NHS and private medical sectors in order to ensure speedier treatment for patients. Given the dominant position of the NHS, this report will focus on developments in this area although issues such as a data protection and qualifications required of health professionals are common across the sector.

3.2 Use of ICT in the English healthcare sector

There are no recent and reliable data on the use of ICT by English specialists, hospitals or pharmacies. A recent (2007) report on the use of ICT by *general practitioners* in England has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe" (Empirica):
http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
From the United Kingdom country brief, we take over the following key findings:
"The United Kingdom can be regarded as one of the European frontrunners in eHealth use among General Practitioners. In all areas under observation (use of local and networked EHRs, exchange of administrative patient data, and computer use in consultation), usage rates are among the highest found in the EU27, Iceland and Norway.
In terms of infrastructure, 97% of the British GP practices use a computer. Nearly the same share of practices (95%) have an Internet connection. In the UK broadband represents the most common form of access to the Internet. Broadband connections are used in 73% of the British GP practices.
In contrast to most other European countries, the United Kingdom scores well with regard to all aspects of eHealth use covered by the survey – an exception being made for ePrescribing. This good position relates to the local use of a computer for consultations and data storage as well as to the networked transmission of patient data. With regard to the availability of a computer in the consultation room as compared to the actual use of the PC in consultations with the patients, there is nearly no gap as both availability and use are nearly universal (97% and 95% of practices respectively). Decision Support Systems (DSS), either for diagnosis or for prescribing purposes are also widespread. They are used in around 80% of British GP practices. This use rate places Britain well above the EU27 average of 62%.
The storage of electronic patient data is common practice in the United Kingdom. Medical patient data is stored in digital form in nearly all GP practices. The United Kingdom shows results that are above the EU27 averages with respect to the storage of all types of medical patient data.

The networked transmission of identifiable electronic patient data is also comparatively well established in the United Kingdom. One out of three GP practices exchange administrative data with other care providers, a percentage which is far above the EU27 average. The only country showing even higher use rates is Denmark (74%). The transmission of electronic patient data to reimbursers is also most common in the UK, Denmark and the Netherlands, in all of which around 45% of GP practices transfer admin data to reimbursers. In the United Kingdom the use of electronic networks for the transmission of medical patient data is also quite well established. Already 85% of GP practices receive results from laboratories via electronic networks. 26% of GP practices exchange data with other health care providers. Only ePrescribing is not yet established in the United Kingdom. It is used by only 5% of GP practices. The still relatively low use rate of ePrescribing can be attributed to the fact, that an ePrescribing system has only been introduced in 2005 and for England only.

3.3 National eHealth strategy

The NHS in England is undertaking what is reported to be one of the largest IT projects ever undertaken outside the military sector. With a budget currently in excess of £12.4 billion the National Programme for Information Technology has been described by Leslie Willcocks, Professor in Information Systems at the London School of Economics, as being "at the outer reaches of known territory"[2].
In contrast to the approach adopted by the NHS in other parts of the United Kingdom which has sought to achieve compatibility with a range of existing systems produced by different manufacturers, for England, it has been suggested, "the catchphrase of the NPfIT became "ruthless standardisation".[3]

An overview of the English eHealth policy can be found in the December 2006 ERA Report "eHealth strategy and implementation activities in England" (Authors: Vicky Jones, EPSRC Carol Jollie, Centre for Health Management, Tanaka Business School, Imperial College Londonhttp://www.ehealth-era.org/database/database.html#England
For our Study, the following observations, adapted from this report, are important:
The Government's main national programme for healthcare system development in England is the *NHS Plan*, which included plans for increasing investment in information technology, electronic booking of appointments for patient treatment, electronic medical records for patients, electronic prescribing of medicines, connecting GP practices to NHSnet to give patients improved diagnosis, information and referral, telemedicine facilities and improved access to information resources on latest treatments and best practice for staff.

[2] http://www.computerweekly.com/Articles/2008/01/08/228789/the-nhss-12.4bn-national-programme-for-it-experts-give-their.htm

[3] http://www.computerweekly.com/Articles/2008/04/24/230414/hc2008-learning-lessons-from-the-national-programme-for.htm

The government's vision for IT to support implementation of the *NHS Plan* is set out in the Department of Health's strategic document, *Delivering 21st Century IT Support for the NHS – a national strategic programme*, which was published in 2002. This national strategic programme is concerned with major developments in the deployment and use of Information Technology (IT) in the NHS. It aims to connect delivery of the NHS Plan with the capabilities of modern information technologies to:

• support the patient and the delivery of services designed around the patient, quickly, conveniently and seamlessly

• support staff through effective electronic communications, better learning and knowledge management, cut the time to find essential information (notes, test results) and make specialised expertise more accessible

• improve management and delivery of services by providing good quality data to support National Service Frameworkss, clinical audit, governance and management information.

The Department of Health is responsible for national plans in England. The 10 regional Strategic Health Authorities are responsible for coordination and performance-managing the progress of local NHS bodies towards the take-up of the National Programme for IT (NPfIT) in the NHS.

The NPfIT, launched in 2002, is one of the largest public sector health IT projects in the world and aims to provide authorised access to patient information whenever and wherever it is needed. Its stated objective is to implement an 'integrated IT infrastructure and system for all NHS organisations in England by 2010', which enables patients to make informed health choices and which increases the efficiency and effectiveness of clinicians and other NHS staff. NPfIT aims to achieve these goals by:

• Creating a NHS Care Records Service (NHS CRS) to improve the sharing of patients' records across the NHS and also provide patient access to their own health records.

• Making it easier and faster for general practitioners (GPs) and other primary care staff to book hospital appointments for patients.

• Providing a system for electronic transmission of prescriptions.

• ensuring a secure broadband network infrastructure is in place to connect all NHS bodies in England.

• Creating a Picture Archiving and Communications System

The NHS CRS will be introduced gradually in stages across England over several years from 2007. It will mean that over time, NHS organisations will increasingly keep care records on computers that link together. This will allow staff quicker access to information in a safe and secure way across organisational boundaries. Patients themselves will also have access to an essential summary of their records. Introducing the NHS CRS will take several years. It will enable paper and film records, which can be more difficult to access, to be phased out.

In September 2006, NHS Connecting for Health invited Primary Care Trusts (PCTs) to participate in Early Adopter implementations of the Summary Care Record. The Early Adopter Programme started at the end of 2006, focuses on the General Practice element of the Summary Care Record, enabling access by appropriate health care professionals within a given Primary Care Trust (PCT) area. The Early Adopter Programme will be fully evaluated, including an independent evaluation, before a full roll out begins. It will be several years before the Summary Care Record is rolled out across England.

Choose and Book is a national service that, for the first time, combines electronic booking and a choice of place, date and time for first outpatient appointments. It revolutionises the current booking system, with patients able to choose their initial hospital appointment, and book it on the spot in the surgery or later on the phone or via the internet at a time that is more convenient to them. Research has consistently shown that patients want to be more involved in taking decisions and choosing their healthcare. The majority of patients who are offered choice view the experience as positive and valuable.
Since summer 2004 the Choose and Book service has been introduced across England. The experience of early adopters has been used to help accelerate the implementation to every health community in the country. From 1 January 2006 all patients requiring a first outpatient appointment have been offered a choice of at least four providers.
The *Electronic Prescription Service* will enable electronic prescriptions to be generated, transmitted and received so that pharmacists and other dispensers can dispense against them. Over time, dispensers will also be able to submit these electronic prescriptions to a reimbursement authority in order to claim payment. By 2007, every GP surgery (for use by the GPs, nurses and other prescribers working from the surgery) and community pharmacy and other dispensers will have access to the service. In due course, prescribers working from other locations such as walk-in centres or dental practices, will also be included.
N3 is the name for the NHS National Network which provides fast, broadband networking services to the NHS. This high speed network will make it possible to deliver the reforms and new services needed to improve patient care, such as: choose and book, NHS Care Records Service, Electronic Transmission of Prescriptions, Picture Archiving and Communication Systems. N3 is vital to the delivery of NPfIT, providing the essential technical infrastructure through which benefits to patients, clinicians and the NHS from NPfIT can be realised.
The *Picture Archiving and Communication Service* enables images such as x-rays and scans to be stored electronically and viewed on screens, so that doctors and health professionals can access the information and compare it with previous images at the touch of a button.

3.4 Regulatory framework for patients' summaries

In common with many aspects of NHS operations no legislative reforms have been necessary to introduce electronic patient summaries. Legally, patient records have always been regarded as the property of the NHS rather than of the patient. The key legal requirement is that the records should comply with the requirements of the Data Protection Act 1998. Some issues have arisen concerning the extent to which patient consent might be obtained. In evidence before the House of Commons Health Committee in 2007, the Department of Health stated that:

> At first, the Summary Care Record will contain only basic information such as known allergies, known adverse reactions to medications and other substances (e.g., peanuts) acute prescriptions in the past 6 months and repeat prescriptions that are not more than six months beyond their review date...In due course more information will be added

> about current health conditions and treatment[4]

It is proposed that the initial record will be created except where a patient opts out of granting consent. This approach has been endorsed by the Information Commissioner's Office in evidence before the House of Commons Health Committee:

> If patients are informed that they can exercise a proper choice over what happens to their information on the basis of transparency, and they have the opportunity and time to make that choice, it is consistent with the requirements of the Data Protection Act to provide it on an opt-out basis.[5]

Such an approach appears to conflict with the Recommendations of the Article 29 Working Party in its Working Document on the Processing of Personal Data Relating to Health in Electronic Records[6] where it was stated that 'opt out solutions will not meet the requirement of being 'explicit''[7]. Some stress was placed by the Commissioner on the availability of other grounds under the Data Protection Act as justifying processing but there is room for doubt how far these are consistent with further comments from the Article 29 Working Party emphasising that justification for processing must be found under the criterion of necessity rather than mere utility.

3.5 Regulatory framework for telemedicine

Telemedicine as a specific concept does not feature prominently in NHS reforms but is implicit in many developments such as the NHS Direct service[8]. This provides patients with access to a library of medical advice and also to a telephone assistance service. Staffed largely by nurses this answers calls from patients on a 24 hour service and in cases deemed urgent will either make arrangements for a patient to receive out of hours care at a hospital, emergency GP centre or on the basis of a home visit by a GP.

Although not specifically related to telemedicine the issue has been raised in other contexts whether a doctor is obliged to physically attend a patient. There does not appear to be any general legal principle requiring this. NHS Direct makes heavy use of the telephone and nurse advisers for consulting and advising patients. In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se give rise to potential liability unless in all the circumstances of that particular case, the giving of telephone advice alone was unreasonable and not supported by a reasonable body of medical opinion.

[4] The Electronic Patient Record. Sixth Report of Session 2006-7 at page 24.

[5] http://www.parliament.the-stationery-office.co.uk/pa/cm200607/cmselect/cmhealth/422/7051002.htm

[6] WP 131 (2007)

[7] At page 9

[8] http://www.nhsdirect.nhs.uk/

3.6 Regulatory framework for electronic prescriptions

Traditionally prescriptions have been issued on approved forms with the details of the medication hand written by the prescribing doctor and signed by that person[9]. Regulations have been required to be made to allow the requirements of writing and signature to be complied with electronically. The National Health Service Pharmaceutical Services Regulations 2005[10] provide that

> 71. - (1) A Primary Care Trust shall prepare, maintain and publish a list (to be called the ETP list) of all chemists in its area who participate in the ETP service.
> (2) The list referred to in paragraph (1) shall include -
> (a) the name of the chemist; and
> (b) the address of the premises at which the ETP service is provided.
> The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005[11] inserted the following provision into the NHS (General Medical Services Contracts) Regulations 2004 (SI 2004/291):
> 39A. - (1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if -
> (a) the contractor holds a contract with a Primary Care Trust which is specified in directions issued by the Secretary of State under section 17 of the (National Health Service) Act 1977 as being a Primary Care Trust which can authorise its contractors to use the ETP service[16];
> (b) the patient to whom the prescription relates has -
> (i) nominated one or more dispensers in his NHS Care Record,
> (ii) confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription in question, and
> (iii) consents to the use of an electronic prescription on the particular occasion;[12]

Those regulations also inserted into the NHS (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627), regulation 38A, in similar terms to regulation 39A above.

[9] Before the introduction of electronic prescriptions there were already other options (for most medicines) apart from writing out the prescription by hand which had been available for some time e.g while the signature had to be signed in ink, other parts of the prescription did not have to be handwritten in ink – for instance they could be typed or written on carbon paper or computer generated. Therefore it was not the case of jumping from handwritten prescriptions to electronic prescribing. Also, over the last 10 years or so a number of other independent prescribers apart from doctors and dentists have been given the power to write prescriptions e.g nurse independent prescribers.

[10] SI 2005 No 641

[11] SI2005 No 893.

[12] Reg 39A

Effectively, the regulations envisage a phased introduction of the system of electronic prescriptions as different areas and medical practices install the necessary hardware and software. The regulations provide further for advanced electronic signatures, defined in the following terms

(a) uniquely linked to the signatory,
(b) capable of identifying the signatory,
(c) created using means that the signatory can maintain under his sole control, and
(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable

to be accepted as equivalent to traditional signatures.[13]

3.7 Overview of relevant legislation

Although as described above, some legislative changes have been necessary to pave the way for systems such as e-prescriptions, the fact that the great majority of medical services are provided by the Government means that no legislative provision has been necessary to initiate eHealth procedures in general. The most important changes have been:

- article 15 of the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830) ("the POM Order")
- The Medicines for Human Use (Prescribing Order) 2005 (SI 2005/765) provided for electronic prescribing throughout the UK - the legislation applies to both private and NHS prescribing. This followed on from the Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (SI 2001/2889) which amended the POM Order to permit electronic prescribing for NHS prescriptions issued and dispensed in England as part of a pilot scheme
- The Prescribing Only Medicines (Human Use) Amendment Order 2008 (SI 2008/464) which removed the restriction on the prescribing of controlled drugs by Nurse Independent Prescribers and introduced the prescribing of controlled drugs by Pharmacist Independent Prescribers

[13] Regulation 2, amending Regulation 2 of the GMS Contracts Regulations 2004. SI 2004 No 291

4 Regulatory framework for the healthcare profession

The regulatory framework for healthcare provision is largely common across the United Kingdom. As with many examples concerning regulation of professional activity the United Kingdom authorities take a somewhat "hands off" approach leaving prime responsibility to nominated professional bodies, in the present context the General Medical Council. The powers and duties of this organisation are laid down primarily in the Medical Act 1983 (as amended)[14]. The main object of the GMC, it is stated in the Act, is 'to protect, promote and maintain the health and safety of the public.'[15]

4.1 Legal conditions for the practice of healthcare

Initial medical education in England is provided almost exclusively by universities. The Medical Act 1983 lists those English universities which may offer degrees leading to entry into the medical profession with a view to practicing as a doctor. The Act provides further that the Education Committee of the General Medical Council shall:

> a) determine the extent of the knowledge and skill which is to be required for the granting of primary United Kingdom qualifications and secure that the instruction given in universities in the United Kingdom to persons studying for such qualifications is sufficient to equip them with knowledge and skill of that extent;
> (b) determine the standard of proficiency which is to be required from candidates at qualifying examinations and secure the maintenance of that standard.

Any determinations made by the Committee are binding upon the universities. Effectively, and to an extent greater than in other areas of professional education, the GMC can exercise direct control over both the syllabus of a degree course and the manner in which it is delivered.

4.2 Control over the practice of medicine

The practice of medicine in England is supervised by General Medical Council (GMC) In order to practice as a doctor, a person is required to apply for registration with the GMC. The Medical Register contains details of all registered doctors and can be consulted on line http://www.gmc-uk.org/register/index.asp
The GMC lays down standards of care expected from doctors and has the power to impose sanctions up to and including removal from the register on a temporary or permanent basis. Extensive guidance is published concerning professional standards with the main document being 'Good Medical Practice'. This can be accessed on line at http://www.gmc-uk.org/guidance/good_medical_practice/index.asp Extensive guidance is provided also on

[14] A consolidated version of the Act can be found at http://www.gmc-uk.org/about/legislation/medical_act.asp

[15] Section 1(1A)

ethical issues and can be accessed at http://www.gmc-uk.org/guidance/a_z_guidance/index.asp

4.3 Professional liability

No specific provisions exist concerning the extent of the liability of doctors within England. Because of the nature of the NHS, no contractual relationship exists between doctors and patients (although this may be the case with private medical treatment).

Medical staff will be potentially liable on a non-contractual basis under the law of negligence and recent years have seen a considerable increase in the number of claims brought against doctors. In the case of claims brought against general practitioners, the individual doctor (though his insurance provider) will be the defender. In the case of hospital based doctors, the principle of vicarious liability whereby an employer is held liable for wrongs committed by employees in the course of their duties will mean that in most cases the relevant NHS trust will be the defender.

In terms of the standard of care expected of a doctor, the law requires that they comply with the standard which would be 'accepted as proper by a responsible body of medical men skilled in that particular art'[16] Thus a higher standard would be expected of a consultant than a junior doctor. Matters may become more complex when, as is normally the case in a hospital environment, care is provided by a team of health professionals. Whilst accepting that a component of a senior team member's duty of care is to check on the work carried out by others the courts have refused to impose overall liability in cases where there was limited possibility of intervention.

In addition to civil liability there may in extreme cases of negligence be the prospect of criminal prosecution being brought. No specific test has been laid down for determining whether negligence is at such a gross level as to justify criminal prosecution. In the case of R v. Adomoko[17] the House of Lords held that this issue was one which should be left to the jury in a criminal prosecution.

4.4 Professional secrecy

Extensive obligations are imposed upon doctors in respect of maintaining the confidentiality of information provided by or concerning a patient. Many doctors still take the Hippocratic oath, although this is no longer a formal requirement. The GMC have produced extensive guidance in 'Confidentiality : Protecting and Providing Information' http://www.gmc-uk.org/guidance/current/library/confidentiality.asp This states that:

> Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care. If you are asked to provide information about patients you must:

[16] Bolam v Friern HMC [1957] 2 AllER 118 at 121.

[17] [1994] 2 All ER 79.

* inform patients about the disclosure, or check that they have already received information about it;
* anonymise data where unidentifiable data will serve the purpose;
* be satisfied that patients know about disclosures necessary to provide their care, or for local clinical audit of that care, that they can object to these disclosures but have not done so;
* seek patients' express consent to disclosure of information, where identifiable data is needed for any purpose other than the provision of care or for clinical audit – save in the exceptional circumstances described in this booklet;
* keep disclosures to the minimum necessary; and
* keep up to date with and observe the requirements of statute and common law, including data protection legislation.

In addition to providing guidance as to maintaining the confidentiality of patient information, this describes also circumstances in which disclosure of the data may be justified or even mandated. In a number of areas, statutory provision will require the disclosure of data whether in identifiable or anonymised format.

Furthermore, the Department of Health has published the "Confidentiality: NHS Code of Practice" as guidance to all those who work within or under contract to NHS organizations concerning confidentiality and patients' consent to the use of their health records – see: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1986, when the Data Protection Act 1984 entered into force, England has had general legislation protecting the individual with regard to automatic processing of personal data. The Data Protection Act of 1998 replaced the earlier statute and was intended to transpose the provisions of the European Directive 95/46/EC. The provisions of the Data Protection Act apply almost identically throughout the United Kingdom.

Although some terminological changes have been made from the wording of the Directive these are minor in most respects. The Data Protection Act refers to a living, identifiable individual' rather than the Directive's 'natural person' but other terms such as 'personal data', 'processing', 'controller', 'processor', 'third party', 'recipient' and 'consent' (art. 2 of the Directive) are identical.

In terms of the rules relating to data processing laid down in Article 6 of the Directive, the Act implements these by requiring data controllers to comply with the data protection principles contained in Schedule 1 to the Act. The Act applies with some modification in relation to processing of personal data for scientific, historical or statistical purposes. The Act provides further regarding

- the criteria for making personal data processing legitimate (art. 7 of the Directive);
- special categories of processing (art. 8 of the Directive)
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive)
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Information Commissioner can be read at http://www.ico.gov.uk/)
- liability for damages as a result of unlawful processing (art. 23 of the Directive) although the basis for the liability is limited to situations where the claimant can show damage. Distress, per se, is not a basis for compensation although a sum reflecting this may be added in cases where the claimant can establish damage or that the contravention leading to the distress related to processing for one of the special purposes listed in the Act;
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

5.2 Transposition of article 8 of Directive 95/46/EC

As far as the processing of special categories of personal data is concerned (transposition of art. 8 of Directive 95/46/EC) the Data Protection Act contains separate provisions for personal data and sensitive personal data. The term 'sensitive personal data' covers all data mentioned in art. 8.1 of the Directive and data concerning offences and criminal conviction.

Section 2 of the Act includes in the definition of sensitive personal data any data relating to a living person's physical or mental health or condition'. Sensitive personal data may only be processed where one or more of the conditions in both Schedule 2 and Schedule 3 to the Act are satisfied.

The Schedule 2 conditions are that:

1. The data subject has given his consent to the processing.

2. The processing is necessary—

(a) for the performance of a contract to which the data subject is a party, or

(b) for the taking of steps at the request of the data subject with a view to entering into a contract.

3 The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract.

4 The processing is necessary in order to protect the vital interests of the data subject.

5 The processing is necessary—

(a) for the administration of justice,

(b) for the exercise of any functions conferred on any person by or under any enactment,

(c) for the exercise of any functions of the Crown, a Minister of the Crown or a government department, or

(d) for the exercise of any other functions of a public nature exercised in the public interest by any person.

6 The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject. The Secretary of State may by order specify particular circumstances in which this condition is, or is not, to be taken to be satisfied.

The Schedule 3 conditions are that:

1 The data subject has given his explicit consent to the processing of the personal data.

2 (1) The processing is necessary for the purposes of exercising or performing any right or obligation which is conferred or imposed by law on the data controller in connection with employment.

(2)The Secretary of State may by order—

(a) exclude the application of sub-paragraph (1) in such cases as may be specified, or

(b) provide that, in such cases as may be specified, the condition in sub- paragraph (1) is not to be regarded as satisfied unless such further conditions as may be specified in the order are also satisfied.

3 The processing is necessary—

(a) in order to protect the vital interests of the data subject or another person, in a case where—

(i) consent cannot be given by or on behalf of the data subject, or

(ii) the data controller cannot reasonably be expected to obtain the consent of the data subject, or

(b) in order to protect the vital interests of another person, in a case where consent by or on behalf of the data subject has been unreasonably withheld.

4 The processing—

(a) is carried out in the course of its legitimate activities by any body or association which—

(i) is not established or conducted for profit, and

(ii) exists for political, philosophical, religious or trade-union purposes,

(b) is carried out with appropriate safeguards for the rights and freedoms of data subjects,

(c) relates only to individuals who either are members of the body or association or have regular contact with it in connection with its purposes, and

(d) does not involve disclosure of the personal data to a third party without the consent of the data subject.

5 The information contained in the personal data has been made public as a result of steps deliberately taken by the data subject.

6 The processing—

(a) is necessary for the purpose of, or in connection with, any legal proceedings (including prospective legal proceedings),

(b) is necessary for the purpose of obtaining legal advice, or

(c) is otherwise necessary for the purposes of establishing, exercising or defending legal rights.

7 (1) The processing is necessary—

(a) for the administration of justice,

(b) for the exercise of any functions conferred on any person by or under an enactment, or

(c) for the exercise of any functions of the Crown, a Minister of the Crown or a government department.

(2) The Secretary of State may by order—

(a) exclude the application of sub-paragraph (1) in such cases as may be specified, or

(b) provide that, in such cases as may be specified, the condition in sub- paragraph (1) is not to be regarded as satisfied unless such further conditions as may be specified in the order are also satisfied.

8 (1) The processing is necessary for medical purposes and is undertaken by—

(a) a health professional, or

(b) 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.

(2) In this paragraph "medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

9 (1) The processing—

(a) is of sensitive personal data consisting of information as to racial or ethnic origin,

(b) is necessary for the purpose of identifying or keeping under review the existence or absence of equality of opportunity or treatment between persons of different racial or ethnic origins, with a view to enabling such equality to be promoted or maintained, and

(c) is carried out with appropriate safeguards for the rights and freedoms of data subjects.

(2) The Secretary of State may by order specify circumstances in which processing falling within sub-paragraph (1)(a) and (b) is, or is not, to be taken for the purposes of sub-paragraph (1)(c) to be carried out with appropriate safeguards for the rights and freedoms of data subjects.

10 The personal data are processed in circumstances specified in an order made by the Secretary of State for the purposes of this paragraph.

The following comments can be made with regard to Section 2 and Schedule 3 of the Data Protection Act :

- Processing personal data concerning health on the basis of patient consent requires 'explicit consent'. This term is not defined. There is no requirement that consent be in writing although failure to obtain written consent might make it difficult for the data controller subsequently to prove the existence of consent.
- There is some debate whether positive (opt in) consent is required from the patient.
- It is to be stressed that patient consent is only one of nine factors laid down Schedule 3 to the Act as legitimizing processing (where a Schedule 2 condition is also met). The Schedule contains other conditions which might be satisfied in any given case. Further, the Data Protection (Processing of Sensitive Personal Data) Regulations 2000[18] prescribes a further set of conditions for the purposes of Schedule 3 under which processing will be legitimate by reason of being in the substantial public interest (if a Schedule 2 condition is also met)..

5.3 Information and access rights of data subjects

The Data Protection Act provides that a data subject is entitled to apply for access to any personal data about themselves together with details as to the source of any personal data and information as to the purposes for which it is being processed. Information which would be likely to cause serious harm to the physical or mental health of any person (including the data subject) is exempt from the access provisions. Information is also exempt where it would identify a third party who has not consented to its disclosure. Where it is agreed that a patient may directly view their health record, the data controller should consider whether access should be supervised by a health professional.

Under section 10 of the Data Protection Act, data subjects have the right to require a data controller to cease processing information about them where the processing is likely to cause serious damage or distress and that damage or distress is unwarranted.

5.4 Other relevant rules regarding personal data protection

Beyond the Data Protection Act, the Access to Medical Records Act 1990 provides a right of access to medical records of deceased persons.

[18] SI 2000 No 417

6 Rights and duties of healthcare providers and patients

The duties and powers of NHS bodies and primary care providers are set out in the National Health Service Act 2006 and legislation made under that Act. The legislation does in effect confer certain rights on patients. Also relevant are the National Health Service Reform and Health Care Professions Act 2002, and the National Health Service (Complaints) Regulations 2004[19]as amended which prescribe the procedures which NHS bodies must follow in dealing with complaints regarding the provision of treatment. In the event a complainant is not satisfied with the outcome of the internal complaints procedure, a reference may be made to the Healthcare Commission <http://www.healthcarecommission.org.uk/homepage.cfm>.
The complaints procedure is separate from legal proceedings. As the Department of Health notes:

> If you are taking legal action or state that you intend to start legal action then you may not also use the NHS complaints procedure, unless part of your complaint is about something not connected with the legal action. If you stop the legal action (or there are outstanding issues that have not been resolved by the legal action), then you can still use the NHS complaints procedure to pursue your concerns.[20]

6.1 Scope of the law

Section one of the National Health Service Act 2006 provides that:

> (1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement—
> (a) in the physical and mental health of the people of England, and
> (b) in the prevention, diagnosis and treatment of illness.
>
> (2) The Secretary of State must for that purpose provide or secure the provision of services in accordance with this Act.
> (3) The services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed.

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is not further specified by the law. It is open to any General Practitioner to remove a patient from his care, and breakdown in the relationship between doctor and patient is a common cause. Whilst not required, reasons should usually

[19] SI 2004 No 1768

[20] http://www.dh.gov.uk/en/Managingyourorganisation/Legalandcontractual/Complaintspolicy/NHScomplaintsprocedure/DH_4080897>

be given (unless it is inappropriate for some reason) and there should normally have been a warning first.

6.3 Right to quality care

There is no absolute right to healthcare under the National Health Service legislation. The Secretary of State has a duty to promote a comprehensive health service in England and a duty to provide a range of health services but only "to such extent as he considers necessary to meet all reasonable requirements" (sections 1 and 3(1) of the National Health Service Act 2006). Primary Care Trusts have a duty to provide or secure the provision of primary medical or dental services within their area, but only to the extent that they consider necessary to meet all reasonable requirements (sections 83(1) and 99(1) of the NHS Act 2006). There is no obligation on the Secretary of State or NHS bodies to provide particular services to a particular patient (see R v Secretary of State ex parte Hincks (1980) 1 BMLR 93). The Secretary of State and NHS bodies may take resources into account when deciding whether to provide services to a particular patient (e.g. R v Cambridge Health Authority ex parte B [1995] 1WLR 898).

Any decision or policy to refuse treatment must however be consistent with the principles of administrative law - e.g. it must be rational; the decision maker must take into account relevant considerations and ignore irrelevant ones. An irrational/unreasonable refusal of treatment would be unlawful and may be quashed by a court on a claim for judicial review (see for example, R (on the application of Rogers) v Swindon PCT [2006] EWCA Civ 392). Also, if a PCT has a general policy not to fund a particular treatment, it must consider individual cases and not exclude the possibility of providing an expensive treatment in an exceptional case (see R v North West Lancashire Health Authority ex parte A [2000] 1 WLR 977).

6.4 Right to free choice

General Practitioners provide primary medical services under the terms of a contract agreed with Government.[21]This provides that:

> Patients will continue to be free to register with any local practice that is open and practices will continue to have discretion over new patient registrations. However, it is expected that in exercising this discretion, practices will have reasonable and fair grounds for doing so.[22]

[21] http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/DH_4125637

[22] Comment: the references in the two footnotes above are to a document issued back in 2003 in effect setting out what would be in the contract if the profession voted in favour of accepting the new GMS contract.

Under the National Programme's Choose and Book procedures, patients will be offered a choice of hospital referrals when this is considered appropriate by their GP. It is open to the hospitals concerned to choose whether to accept referrals to a pool of specialists or to allow a referral to be made to named specialists[23]. Patients have no right to refer themselves to NHS hospitals (other than in cases of accident and emergency).

6.5 Rights related to information about the state of health

Under the Data Protection and Access to Health Records Acts patients have extensive rights of access to health records. A health record:

> (a) consists of information relating to the physical or mental health of an individual who can be identified from that information, or from that and other information in the possession of the holder of the record; and
>
> (b) has been made by or on behalf of a health professional in connection with the care of that individual[24]

Under both statutes it is provided that if any item of information is not readily intelligible to the patient, further explanation must accompany the record.

In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient.

Under the Data Protection Act the maximum fee that may be charged for providing copies of health records is £10 where the records are held entirely electronically, or £50 where they are held manually or in mixture of manual and electronic formats. Under the Access to Health Records Act a fee may be charged for providing copies of records and there is no cap on this fee. Under both Acts the fee that is charged for providing copies should not exceed the cost of complying with the request, and should not result in a profit for the record holder. Access requests must generally be satisfied within 40 days.

6.6 Right to give consent

The concept of consent is pivotal to the provision of health care although it is not defined in legislation. Failure on the part of a practitioner to obtain informed consent from a patient for any course of treatment would constitute a serious breach of professional standards.

6.7 Rights related to the patient's medical record

Extensive guidance has been produced by the Department of Health in the form of a code of practice on Records Management http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131747. Published in 2006 this makes recommendations on the minimum periods for which different forms of medical records should be retained.

[23] http://www.chooseandbook.nhs.uk/staff/commsmaterials/factsheet

[24] Access to Health Records Act 1990 section 1.

Also of particular relevance in the eHealth field is the Care Record Guarantee http://www.connectingforhealth.nhs.uk/nigb/crsguarantee. First published in 2005, the guarantee is reviewed annually. Its purpose is stated to be to define the extent of:

> people's access to their own records, controls on others' access, how access will be monitored and policed, options people have to further limit access, access in an emergency, and what happens when someone cannot make decisions for themselves.

As recorded previously, the Department of Health has also published the "Confidentiality: NHS Code of Practice":
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

6.8 Right to protection of privacy and intimacy

No general statutory rights exist in this respect but a Special Health Board NHS Quality has been established with the remit to:

> Work with members of the public, patients and healthcare staff, and our role is to translate the latest scientific research, expert opinion and patient experience into practical improvements that can be implemented in the health service.
> We ask five crucial questions:
> * how can the outcome of care for patients, including issues like quality of life, be improved?
> * how can we help to ensure that high standards are consistently delivered?
> * how can we ensure that everyone has fair access to health services?
> * how can patients' experience of using health services, including issues like waiting times and the quality of communication with NHS staff, be improved?
> * how can we support NHS staff to provide the most effective care and make the best use of resources? [25]

6.9 Right to representation in case of incompetence

The Mental Capacity Act 2005 applies where:

> a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.[26]

The Act provides for decision-making on behalf of such a person and also makes provision in section 5 effectively legitimising the decision of a doctor to give a patient treatment without consent where he reasonably believes that the patient would be incapable of giving consent and that the treatment is in the patient's best interests. This does not exclude liability for negligence. However, please also refer to the Mental Health Act 1983 as amended by the 2007 Act for the law relating to the treatment of those suffering from mental disorder.

[25] http://www.nhshealthquality.org/nhsqis/37.140.141.html

[26] Section 2.

In the case of children, the Family Law Reform Act 1969 provides that a person over the age of 16 is to be presumed to be competent to consent to medical treatment and associated procedures. Below this age, the House of Lords held in the case of *Gillick v. West Norfolk AHA*[27], that decisions had to be made on an individual basis. If it was considered that the child had sufficient understanding to enable him or her to comprehend the nature of treatment sought or proposed, the child's consent would be sufficient.
In the event a child is not considered to be able to consent, this may be exercised on his or her behalf by a person with parental responsibility provided the matter is within the zone of parental control.

[27] [1985] 3 AllER 402

7 Identity management in the health sector

7.1 Overview

Traditionally in England, medical records have been maintained at the point where treatment is provided. A range of different records will therefore be likely to exist for individuals being held by hospitals and general practitioners. However the need was identified to create a single identifier which could be used to link all records belonging to a particular individual. The chosen vehicle is the NHS number.

7.2 The NHS Number

Since 1997 everyone living in England who is entitled to treatment under the NHS has been allocated a NHS number. This is a randomly generated 10 digit identifier. Details of the numbers allocated to patients are passed on to GPs and Health Boards but not directly to patients themselves although they are entitled to know the number allocated to them. The number, it is stated:

> is fundamental to the National Programme for IT as the key to unlocking services such as Choose and Book, the NHS Care Records Service, and the Electronic Prescription Service. <http://www.connectingforhealth.nhs.uk/systemsandservices/nhsnumber>

7.3 The National Insurance Number

Under the United Kingdom's taxation system, a separate tax known as national insurance is dedicated to the payment of a range of social benefits and also is partly devoted to the costs of the NHS[28]. A national insurance (NI) number is issued to everyone entitled to take up employment in the United Kingdom and is used to determine eligibility for a number of services and benefits. UK citizens will be issued with an NI number automatically. Non United Kingdom citizens wishing to take up employment or claim benefits will be required to apply for a national insurance number and will be required to provide proof of identity. Although a plastic card is issued giving details of the national insurance number it is almost never necessary to produce the card. The number will need to be used for employment, tax and benefit purposes but invariably the requirement is that the individual quote the national insurance number on a form.

7.4 Use of the NHS Number

The Information Standards Board for Health and Social Care >http://www.isb.nhs.uk/> is shortly to publish detailed guidance on use of the NHS number. At a more general level:

> NHS Connecting for Health recommends that the NHS Number is, as a minimum, used on the following:
>
> - clinical records - detail and summaries
> - referrals to other organisations- including electronic bookings

[28] http://www.opsi.gov.uk/acts/acts1992/ukpga_19920005_en_17#pt12-l1g161

- clinic appointment letters
- test requests
- test results
- samples
- discharge notices
- records relating to payment by results and practice based commissioning <http://www.connectingforhealth.nhs.uk/systemsandservices/nhsnumber/background/when>

7.5 Authentication of healthcare professionals

No central state controlled register of doctors (or other health professionals) exists within England. The General Medical Council maintains a register of all persons eligible to practice as a doctor in the United Kingdom. The register may be consulted on line at <http://www.gmc-uk.org/register/search/index.asp>

A range of other professional bodies cover other categories of health professionals, generally maintaining registers of those considered fit to practice. Reference should also be made to the work of the Healthcare Commission. Established under the Health and Social Care (Community Health and Standards) Act 2003, this is an independent agency whose duties are to:

* assess the management, provision and quality of NHS healthcare and public health services
* review the performance of each NHS trust and award an annual performance rating
* regulate the independent healthcare sector through registration, annual inspection, monitoring complaints and enforcement
* publish information about the state of healthcare
* consider complaints about NHS organisations that the organisations themselves have not resolved
* promote the coordination of reviews and assessments carried out by ourselves and others
* carry out investigations of serious failures in the provision of healthcare.[29]

A White paper entitled 'Trust, assurance and safety: the regulation of health professionals was published in February 2007 <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946>.

This proposes further reform in this area and looks to bring together the work of a number of existing regulatory agencies.

[29] http://www.healthcarecommission.org.uk/aboutus/whatisthehealthcarecommission.cfm

7.6 Exchange of health-related data

The establishment of electronic personal health records is a major goal of the National Programme for IT. The development has been controversial and concerns have been expressed in many quarters regarding possible damaging consequences for patient confidentiality given the increased ease with which data may be exchanged.
A variety of solutions have been proposed including the use of, so called, sealed envelopes. The NHS Care Record Guarantee, promises that patients will be allowed a measure of control over the extent of access to different parts of their records. A briefing paper indicates that patients:

> in consultation with their clinician(s), will be able to:
> • identify one or more sets of sensitive information which should be sealed from everyone other than the author and people in the same Workgroup as the sealer;
> • for each set of sealed information, decide whether people other than the author and those in the same Workgroup as the sealer could ever gain access:
> o if "sealed", the information could be made available to users outside the Workgroup with the patient's permission, or through override in exceptional circumstances (e.g. public interest); OR
> o if "sealed and locked", users from outside the Workgroup would be unaware that the sealed information existed.

The NHS Code of Practice on Confidentiality <http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/codes> lays down internal rules for the exchange of patient data. A range of legal provisions will also be relevant, the code making specific reference to the common law doctrine of confidentiality, the Data Protection Act, the Human Rights Act and also general provisions of administrative law, in particular the Ultra Vires doctrine. Here the code notes:

> Administrative law governs the actions of public authorities. According to well-established rules a public authority must possess the power to carry out what it intends to do. If not, its action is "ultra vires", i.e. beyond its lawful powers. It is also necessary that the power be exercised for the purpose for which it was created or be "reasonably incidental" to the defined purpose. It is important that all NHS bodies be aware of the extent and limitations of their powers and act "intra vires".[30]

[30] Paragraph 36.

8 Electronic prescription

As indicated above, specific legislative provision was required in order to remove the traditional requirements that prescriptions be written and signed by the doctor responsible. Initially, the system will still retain paper based prescription forms although a bar code will be added to allow the dispensing chemist to retrieve an electronic copy of the prescription from a central server thereby removing the need to retype information into the dispensers own system.

A development of the system will allow patients to 'nominate' a particular dispensing chemist and have any prescriptions electronically sent to that location

9 General assessment

The National Programme for Information Technology has been a controversial one. Although some aspects have been introduced on schedule, other significant aspects, especially concerned with electronic patient records, have been delayed. Ongoing concerns exist as to the extent to which patient confidentiality will adequately be secured and also whether, given the vast investments made, the systems provide value for money.

Legally, problems are far fewer given the public nature of almost all aspects of health care provision. Effectively the Department of Health is implementing Government policy in respect of the modernisation of the service and remarkably little has been required by way of either primary or secondary legislation. A measure of reform was certainly needed in order to pave the way for electronic prescriptions, but this has proved an exception. Controls over the use of systems such as electronic patient records apply largely on an internal basis although there is clearly need to conform to the requirements of statutes such as the Data Protection Act 1998.

Ian Lloyd
27 June 2008

Annex: Contact details of National Correspondents

Primary Contact

Country	England
Name	Ian Lloyd
Organisation	University of Edinburgh
Position	Professor
Mailing Address	Law & Technology Centre, School of Law, University of Edinburgh Old College, Edinburgh EH8 9YL, Scotland
Work Phone	+441415483291
Mobile Phone	
Fax	+44(0)141 548 4746
E-Mail	i.j.lloyd@strath.ac.uk

Alternative Contact

Country	
Name	
Organisation	
Position	
Mailing Address	
Work Phone	
Mobile Phone	
Fax	
E-Mail	