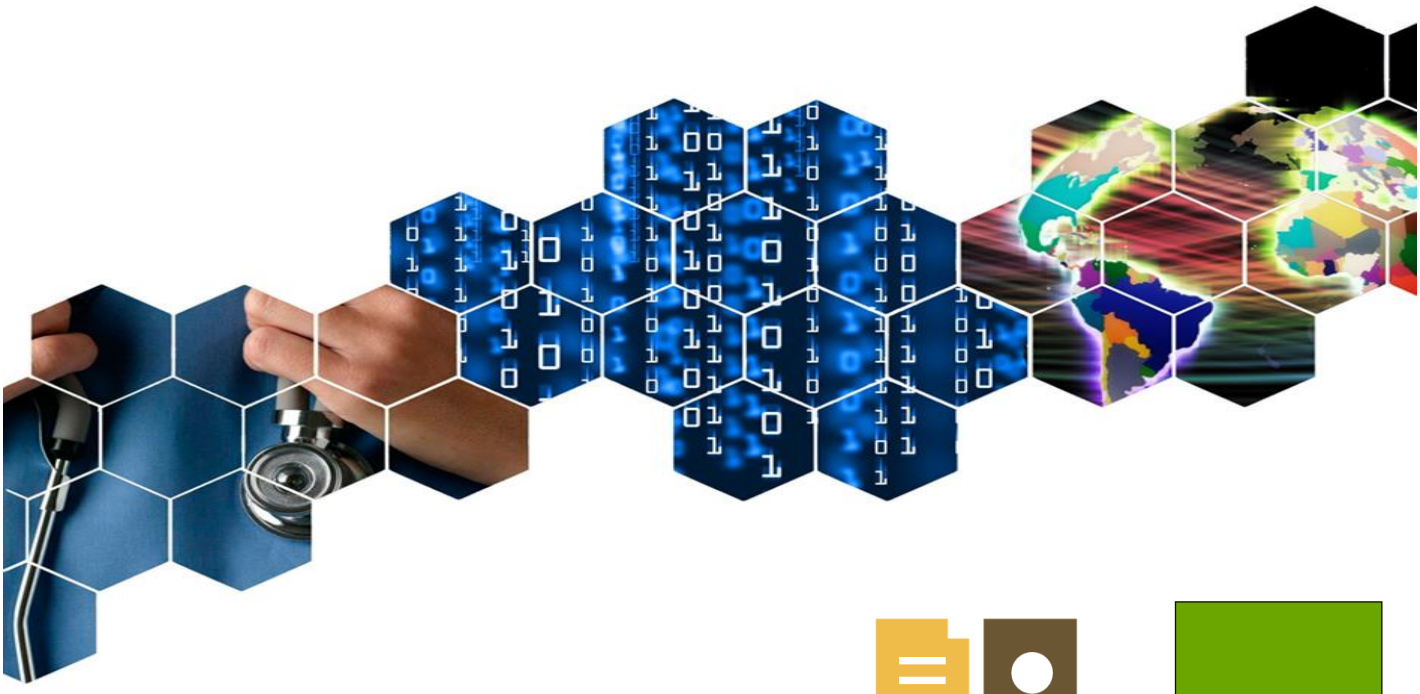
Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services

Contract 2013 63 02

Overview of the national laws on electronic health records in the EU Member States

National Report for Ireland



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Executive Summary

1. Stage of development of EHRs in Ireland

The development of EHRs is at an early stage in Ireland and there is no specific legislative framework regulating EHRs. However some legislative progress in the area is expected in 2014.
Despite the lack of a legislative framework a range of ICT initiatives have been undertaken in the healthcare sector

The competent authorities in charge of the implementation of eHealth policies are:

- the Department of Health
- the Health Service Executive
- the Health Information and Quality Authority
- the Office of the Data Protection Commissioner

2. Summary of legal requirements applying to EHRs

The requirements of data protection law, the general law relating to consent, and general legal rules relating to liability apply in respect of electronic heath records. Contractual arrangements are entered into for the exchange of patient data in the context of cross border treatment. There are some other 'soft law' instruments such as guidelines and policies in the area, for example, of record retention and management, which do not have strict legal force but should nonetheless be taken into consideration.

3. Good practices

There is no comprehensive national system of EHRs in operation in Ireland at this time but electronic records exist in the large majority of general practice settings and in other hospitals and clinics. Examples of good practice in relation to these records include:

Healthcare providers are required to register with the Data Protection Commissioner. The Data Protection Commissioner has developed guidelines in relation to the data protection issues arising in the healthcare area. See: Guidelines for the Medical and Health Sector: available at http://dataprotection.ie/viewdoc.asp?m=m&fn=/documents/guidance/5a.htm.

A range of other policies and guidelines set out good practice requirements relating to the handling of health data. These include:

Health Service Executive:

- Record Retention Periods Health Service Policy 2013 available at: http://www.hse.ie/eng/services/list/3/hospitals/ulh/staff/resources/pppgs/rm/recret2013.pdf
- Code of Practice for Healthcare Records Management, 2007 available at http://www.hse.ie/eng/services/Publications/services/Hospitals/NHO_Code_of_Practice_for_Healthcare_Records_Management_Version_2_0.pdf

Irish College of General Practitioners and General Practice IT Group:

- A Guide to Data Protection Legislation for Irish General Practice, 2011
- No Data, No Business: Information Communications Technology (ICT) Security Guidelines, 2008

HIQA:

- Guidance on Messaging Standards for Ireland available at http://www.hiqa.ie/publications/guidance-messaging-standards-ireland

4. Legal barriers

The primary legal barriers for the deployment of EHRs in Ireland and their cross border transfer to other EU Member States include the following:

- The lack of a legal framework for the operation of EHRs.
- The lack of a unique patient or healthcare provider identifier in Ireland. This matter is being addressed by the passage through the parliament of the Health Identifiers Bill 2013.
- The non-transposition into Irish law of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
- Legislation in relation to controlled drugs requires that prescriptions must be signed, which is perceived to raise challenges in relation to e-prescribing.

Contents

List of abbreviations

EHRs	Electronic Health Records
HIQA	Health Information and Quality Authority
HSE	Health Service Executive

1. General context

1.1. EHR systems in place

The eHealth Strategy which was published by the Department of Health in December 2013 acknowledges that "successful reform of healthcare systems and delivery is highly dependent on realising the potential of eHealth as a change catalyst and enabler in addressing the challenges of new and existing models of healthcare". The strategy proposes the establishment of a new entity, eHealth Ireland, which will have responsibility for overall governance around eHealth implementation including funding, legal enabling, public awareness, stakeholder engagement and building the "eHealth Ecosystem". eHealth Ireland will manage projects with healthcare delivery groups based on overall national priorities. It will encourage local and regional innovation where possible and promote funding and project collaborations with private industry. Potential priority projects identified for eHealth Ireland include the following: National Health Identifier Infrastructure; ePrescribing Systems; Online Referrals and Scheduling; Telehealthcare; Development of Patient Summary Records; Online Access to Health Information and a National Patient Portal. The eHealth strategy also indicated that a new IT strategy for the health system as a whole would be published in early 2014 by *eHealth Ireland*. At the time of writing eHealth Ireland has not yet been established and the IT strategy has not been published.

For the moment, there is no single electronic health record as such. Examples of ICT activities in the healthcare area identified by the eHealth strategy report as currently underway are:

1. the National ICT Integrated Services Framework project, the aim of which is to develop a suite of nationally-defined standards to facilitate interoperability of eHealth systems in Ireland.
2. Healthlink, a web-based messaging service which allows secure transmission of clinical patient information between hospitals, healthcare agencies and general practitioners in real time
3. the St. James' Hospital Blood Product Traceability project which involves the placing of a 2-dimensional barcode is placed on all blood products to enable them to be traced through the supply chain.
4. iheed, a remote healthcare training project.
5. Caredoc. a not-for-profit remote services organisation led by GPs which provides Doctor-on-Call, Telephone Nurse Triage and Community Intervention Team support services. The latter service involves community nurses remotely monitoring and managing patients healthcare from the home or care setting via rugged tablet devices. The patient records (held by GPs and other carers) are updated electronically in real time via the tablet device.
6. The National Integrated Medical Imaging System, a picture archiving and communications system and radiology information system;
7. GP Mail, an internal GP 'whitelist' messaging system;
8. MedLis, a laboratory information system portal that allows traceability and access to post/view results;
9. Diabetes Shared Care, a diabetes database connecting hospitals and patients, and
10. Online Single Assessment Tool for assessing and classifying elder frailty and identifying appropriate services.

Other projects that are in place include an epilepsy-specific Electronic Patient Record developed at Beaumont Hospital, Dublin and the MHIS EPR (Mental Health Information System Electronic Patient Record) at Saint John of God Hospital, Dublin.

1.2. Institutional setting

There are a number of authorities/agencies in Ireland with competency in the area of healthcare whose remit would include the management of patient records and the development of policies and procedures for the introduction of EHRs in the future.

- The Department of Health is a Government department whose primary role is to support the Minister for Health in formulating and evaluating policies for the health services. The Department also has a role in the strategic planning of health services in consultation with the Health Service Executive (HSE), the voluntary sector, other government departments, and other interests.
- The Health Service Executive (HSE) - The HSE has responsibility for delivering public health and personal social services in Ireland. It is a national organization operating throughout Ireland with a workforce of 100,000 people, and it came into operation on 1 January 2005. So, the Department of Health decides health policy in Ireland and the HSE is responsible for delivering services.
- The Health Information and Quality Authority (HIQA) was established under the Health Act 2007 to underpin patient safety and quality in the newly restructured health service. A core function of HIQA is to set standards on safety and quality of services and to monitor enforcement of these standards in an open and transparent way. Other functions of HIQA include:
    - Undertaking investigations into the safety, quality, and standards of services where it is believed that there is a serious risk to the health or welfare of a person receiving services.
    - Carrying out reviews to ensure best outcomes/value for money for the resources available to the HSE.
    - Inspecting and registering designated residential care services for older people, for example nursing homes, children, and for people with disabilities; monitoring of foster care services, day facilities, and children's detention centres.
    - Undertaking Health Technology Assessments to inform the decision making for safety and quality.
    - A central role in health information development and the implementation of the recommendations set out in the National Health Information Strategy.
    - Evaluating information available on services provided by the HSE and other service providers and on the health and welfare of the population, identifying information deficiencies, and advising the HSE and Minister accordingly.
- Office of the Data Protection Commissioner - The office of the Data Protection Commissioner was established under the 1988 Data Protection Act. The Data Protection Commissioner is responsible for upholding the rights of individuals as set out in the Acts, and enforcing the obligations upon data controllers. The Commissioner is appointed by Government and is independent in the exercise of his or her functions. Individuals who feel their rights are being infringed can complain to the Commissioner, who will investigate the matter, and take whatever steps may be necessary to resolve it.
- eHealth Ireland - In the eHealth Strategy published by the Government in December 2013 it was decided that the optimum model for delivery of the recommendations in the Strategy is a dedicated and focused entity with specific oversight and responsibility for Ireland's eHealth implementation. It commits to the establishment of a new entity called "eHealth Ireland" as an independent entity headed by a Chief Information Officer who will work with the key business organisations within the health service to drive forward the strategy and ensure that key IT systems are implemented on time and to budget. eHealth Ireland will operate in partnership with and build on work already underway by government and state agencies such as the Health Services Executive ICT Directorate and SRG, the Health Information and Quality Authority (HIQA) and Enterprise Ireland. It will have responsibility for overall governance around eHealth implementation including funding, legal enabling, public awareness, stakeholder engagement and building the eHealth Ecosystem. It will initially be

established on an administrative basis within the System Reform Group (SRG) of the HSE but will be transformed over time into an independent entity within a new institutional framework for shared services for the health sector as a whole. At the time of writing, eHealth Ireland has not yet been established although recruitment of the Chief Information Officer has already commenced.

1.3. Legal setting and future legal development

There is no specific legislation in place yet in Ireland for the implementation of eHealth policies. HIQA was established on 15 May 2007 under the Health Act 2007 and one of its statutory functions is health information development and the implementation of the recommendations set out in the National Health Information Strategy.

In 2008, the Department of Health undertook a public consultation exercise on a proposed Health Information Bill which had the following aims:

- to establish a legislative framework to enable information, in whatever form, to be used to best effect to enhance medical care and patient safety throughout the health system,
- to facilitate the greater use of information technologies for better delivery of patient services, and
- to underpin an effective information governance structure for the health system generally.

During this consultation a number of points were raised concerning the proposed legislation specifically in relation to EHRs:

- The nature of a National Electronic Health Record is yet to be determined.
- A range of significant issues will have to be addressed, including determining what will be in the record, who is going to standardise the information and data and so forth.
- The approach should be to encourage and facilitate in a safe, secure and cost effective manner the creation of and electronic exchange of personal health and social services information between health professionals and ancillary staff for diagnostic, treatment, therapeutic and public health purposes and for health research purposes.
- A standards based approach is essential rather than an "obligatory or one size fits all approach for all health care uses" on cost, practical and legal reasons.
- In the context of the EU Directive on the application of patients' rights in cross-border healthcare it is necessary to examine the need for a shared system across Member States as patient mobility creates the imperative for patient records systems in different EU countries to be compatible.
- The security of any national health records system must be the most important factor in deciding whether or not to run a centralised or decentralised system.
- Generally speaking, provided necessary safeguards are put in place and the purpose of collecting the information is fully explained to individuals and the general public, mandatory provision of a minimum dataset is usually the best way to achieve the necessary coverage and data quality.
- Several submissions felt that the EHR system should allow for automatic data capture by research information systems where a project is ethically approved and consent has been given by the individual.
- The Data Protection Commissioner referred to the privacy challenges posed by NEHR systems. Its position is that the putting in place of appropriate [high standard] safeguards for the processing of data in an EHR would be best achieved via a specific legislative provision that would also allow individuals the option, should they wish to exercise it, not to have their
- information included in a national system. Autonomy for the individual, comprehensive systems security and access controls were identified as crucial for the credibility of EHRs.
- HIQA pointed out that the legal implications surrounding an EHR system "could be different between, for example, an emergency/summary record and a virtual cradle-to-grave

comprehensive record, the latter having the potential to be significantly more complex". It considered it appropriate for explicit consent to be required from individuals to participate initially in an EHR system. It also submitted that individuals should have the right: to exclude or hide ("sealed envelope") portions of the record from access by others; to withdraw their participation in the scheme at any time; and to see who has accessed their record at any stage.

- Some submissions questioned why an individual should have the right not to participate in a National Electronic Health Records system. They also felt that it would be better to establish an NEHR from the bottom up (as per the Finnish model) rather than bottom down (as with the UK model). Accordingly, the legislation should facilitate electronic linkages between service providers.

Work is still on-going in relation to the development of the Health Information Bill to capture the comments above and many other issues to be contained in the Bill. Publication of the general scheme of the Bill is expected in 2014. However, it appears that the initial intention to provide an enabling framework for National EHR Systems has been replaced by a focus on supporting inter-operability through standards. Work on standards is being undertaken by HIQA and also by the HSE under the National ICT Integrated Services framework project. The development of these standards will be complemented by the introduction of legislation providing for the assignment of unique health identifiers to individuals and healthcare providers. This takes the form of the Health Identifiers Bill which is currently going through the parliamentary process – see Table 2.1.2.

Pending the introduction of more specific provisions, general data protection legislation is relied upon to address the data protection issues arising. The relevant legislation is: The Data Protection Acts 1988 – 2003.

2. Legal requirements applying to EHRs in Ireland

2.1. Health data to be included in EHRs

2.1.1. Main findings

There is no specific legal framework for EHRs as yet in Ireland. The Government intends to introduce a Health Information Bill during 2014. The stated objectives of the Health Information Bill are to establish a legislative framework to enable information, in whatever form, to be used to best effect to enhance medical care and patient safety throughout the health system, to facilitate the greater use of information technologies for better delivery of patient services, and to underpin an effective information governance structure for the health system generally. The Bill is not expected to define EHRs or specify their content.

The Government published the Health identifiers Bill in late 2013 and it is currently progressing through the legislative process. The Bill provides for the assignment of unique health service identifiers to individuals to whom a health service is being, has been, or may be provided and for the assignment of unique identifiers to health services providers.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)		It is understood that the Health Information Bill will not specify the content of an EHR. Originally it was intended that the Bill would include a section dealing with this but it was dropped due to a lack of consensus on what should be contained in the EHR.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?		N/A
Is there a definition of EHR or patient's summary provided in the national legislation?		N/A
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?		N/A
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?		N/A
Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?		N/A
Are there any specific rules on identification of patients in EHRs?		N/A
Is there is a specific identification number for eHealth purposes?	Health Identifiers Bill 2013	The Bill provides for the assignment of unique health service identifiers to individuals to whom a health service is being, has been, or may be provided and for the assignment of unique identifiers to health services providers. A national register of individual health identifiers (the IHI) and a national register of health services providers containing the identifiers is established by the Bill. The IHI is accessible only to specified persons under the Bill

Questions	Legal reference	Detailed description
		while the register of health services providers identifiers will be publicly accessible. The Bill also provides for the processing of the IHI and the other identifying particulars relating to the individual in the IHI Register including the disclosure of such information to authorised disclosees. An IHI in itself will be a number containing no personal data and the IHI register will contain no clinical information.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

There are no specific rules in Ireland imposing requirements on institutions hosting EHR data. However, data protection legislation applies to the hosting and management of such data.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
Are there specific national rules about the hosting and management of data from EHRs?	Data Protection Acts 1988 – 2003	No specific rules on EHRs, the requirements of the Data Protection Acts 1988 – 2003 apply. The data quality principles (s.2) and the conditions for the processing of sensitive data (ss.2A and 2B) apply to the hosting and management of data from EHRs.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Data Protection Acts 1988 – 2003	No specific rules on EHRs, the requirements of the Data Protection Acts 1988 – 2003 apply. Providers of health services are required to register with the Data Protection Commissioner.
Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?		No specific rules on EHRs,
In particular, is there any obligation to have the information included in EHRs encrypted?		No.
Are there any specific auditing requirements for institutions hosting and processing EHRs?		No.

2.3. Patient consent

2.3.1. Main findings

There are no specific national rules in Ireland relating to consent with respect to EHRs. The requirements of Data Protection Law apply, in particular the fair obtaining requirements must be met which incorporates a requirement that the patient must be informed about the identity of the data controller and the purposes for which the data is intended to be processed. Consent to the processing of medical data must be obtained unless one of the exceptions in the Acts applies.

Ireland has a National Consent Policy since 2013 which applies to all health and social care services provided by or on behalf of the HSE. Although it does not strictly have the status of legal rules, it is mandatory for all HSE service providers to comply with its provisions.

The European Parliament and Council Directive 2011/24/EU on the application of patients' rights in cross-border healthcare has not yet been fully transposed into Irish law.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
Are there specific national rules on consent from the patient to set-up EHRs?		No.
Is a materialised consent needed?		N/A.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?	Data Protection Acts 1988 - 2003	The Data Protection Acts contain in s.2(1) a requirement that personal data be obtained and processed fairly. That requirement is elaborated upon in s.2D which requires that the identity of the data controller and the purposes for which the data are intended to be processed are notified to the data subject.
Are there specific national rules on consent from the patient to share EHRs data?	Data Protection Acts 1988 - 2003	Under data protection law, processing of medical data can only take place where one each of the conditions of processing provided for in ss.2A and 2B are met. Section 2A transposes Art.7 of Directive 96/446/EU into Irish law while s.2B transposes Art.8. In the case of both s.2A and s.2B, processing is permissible if the data subject consents to such processing. Section 2A requires consent simpliciter while s.2B requires "explicit consent". In the absence of consent, s.2A permits processing for example, where it is necessary to prevent injury or other damage to the health of the data subject. Section 2B permits processing of sensitive personal data, including medical data, in the absence of consent where, for example, processing is necessary for medical purposes and is undertaken by a medical professional. 'Medical purposes' is defined to include "the purpose of preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health care services." In 2013, the Health Service Executive published a National Consent Policy which applies to all health and social care services provided by or on behalf of the HSE. Although it does not strictly have the status of legal rules, it is mandatory for all HSE service providers to comply with its provisions. It states at para 7.6 that service users have a right to expect that information about them will be held in confidence by those who provide health and social care services to them. Confidentiality is central to trust in

Questions	Legal reference	Detailed description
		this relationship. Staff are expected to comply with the provisions of the Data Protection Acts as outlined above. The policy on confidentiality also applies if a third party, such as a family member, makes a complaint regarding the care of a service user. It states that it is essential in these circumstances to ensure that the service user has consented to their personal information being made available for any internal investigations/reviews. The policy states that sharing of information on a strict 'need to know' basis between staff involved in a service user's care is essential to the provision of safe and effective care. Similarly, an integral component of modern health and social care is the use of audit and quality assurance programmes to ensure that the care provided is of the highest quality when benchmarked against national and international standards. It advises that while explicit consent from the service user is not usually sought in these circumstances, it is good practice to make service users aware that such practices occur and that safeguards exist to ensure that their personal information is protected.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		N/A
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?		N/A
Are there requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs?	Data Protection Acts 1988 -2003	S.2D of the Data Protection Acts requires that the identity of the data controller and the purposes for which the data are intended to be processed are notified to the data subject.
Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-		N/A

Questions	Legal reference	Detailed description
border situations)?		
Are there specific rules on patient consent to share EHRs data on a cross-border situation?		N/A. The European Parliament and Council Directive 2011/24/EU on the application of patients' rights in cross-border healthcare states that the Data Protection Acts apply to the sharing of data in cross-border healthcare. The Directive has not yet been fully transposed into Irish law.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

There is no specific legislation relating to the creation, accessing and updating of EHRs in Ireland. However, a range of Data Protection and/or Freedom of Information provisions may be relevant. In particular, the provisions of the Data Protection Acts relating to the processing of sensitive personal data are relevant to the accessing of such data. Also, the data subject's access rights provided for under Data Protection law can be used by patients to access EHR content. Both Data Protection law and Freedom of Information law provide for mediated access to health data in specific circumstances.

The Health Identifiers Bill will permit the use of individual health identifiers by persons outside the State subject to a number of conditions.

2.4.2. Table on creation, access to and update of EHRs

Questions	Legal reference	Detailed description
Are there any specific national rules regarding who can create and where can EHRs be created?		No.
Are there specific national rules on access and update to EHRs?	Data Protection Acts 1988-2003	Only as required by the Data Protection Acts. Health professionals may be entitled to access medical records on the basis of S.2B of the Act which permits processing of sensitive personal data, including medical data, in the absence of consent where, for example, processing is necessary for medical purposes and is undertaken by a medical professional. "Medical purposes" is defined to include "the purpose of preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health care services." "Health professional" includes a registered medical practitioner, within the meaning of the Medical Practitioners Act 1978, a registered dentist, within the meaning of the Dentists Act 1985 or a member of any other class of health worker or social worker specified by regulations made by the Minister. In relation to updating EHRs, Section 2 (1) (b) of the Data Protection Acts requires that data controllers ensure that personal data is accurate, complete and, where necessary, up-to-date.
Are there different categories of access for different health professionals?	Data Protection Acts 1988-2003	Only as required by the Data Protection Acts. Health professionals may be entitled to access medical records on the basis of S.2B of the Act. "Health professional" includes a registered medical practitioner, within the meaning of the Medical Practitioners Act 1978, a registered dentist, within the meaning of the Dentists Act 1985 or a member of any other class of health worker or social worker specified by regulations made by the Minister.
Are patients entitled to access their EHRs?	Data Protection Act 1988-2003 and Freedom of Information Act 1997-2003	Patients have the right to access their personal records, which would include EHRs under both the Data Protection and Freedom of Information Acts.
Can patient have access to	Data Protection Act	Patients are entitled to access EHRs under both the Data Protection and Freedom of

Questions	Legal reference	Detailed description
all of EHR content?	1988-2003 and Freedom of Information Act 1997-2003	Information Acts. However, under both Acts there is a provision for mediated access. In relation to data protection, the Data Protection (Access Modification) (Health) Regulations, 1989 (S.I. No. 82 of 1989) provide that health data relating to an individual should not be made available to the individual, in response to an access request, if that would be likely to cause serious harm to the physical or mental health of the data subject. Under the Freedom of Information Act, section 28(3) provides that access may be denied where release of the record might be prejudicial to the person's physical, or mental health, well-being or emotional condition. Where access is denied, Section 28(4) states that the information may be provided through a nominated health professional.
Can patient download all or some of EHR content?		No.
Can patient update their record, modify and erase EHR content?		No.
Do different types of health professionals have the same rights to update EHRs?		N/A
Are there explicit occupational prohibitions (e.g. insurance companies/occupational physicians…)?	Data Protection Act 1988-2003; Disability Act 2005	Only as specified by the Data Protection Acts and the Disability Act. The Disability Act 2005 Part IV prohibits the processing of genetic data in certain contexts. Section 42 provides that the data subject (customer/patient/employee etc.) must give informed consent to the processing of genetic data. It is an offence under the Disability Act section 42 subsection 4 to process genetic data for insurance or employment purposes in the absence of consent. Section 43 of the Disability Act states that family history information will be processed in accordance with regulations to be made by the Minister for Justice but these have not been introduced. The Data Protection Commissioner has also approved guidelines for insurance companies in relation to genetic test results. These are available at: http://www.insuranceireland.eu/media/documents/20130626_Code_of_Practice_Final.pdf

Questions	Legal reference	Detailed description
		Section 12A of the Data Protection Acts imposes obligations with respect to prior checking of prescribed data processing. The processing of genetic data in relation to the employment of a person has been prescribed for the purposes of S 12A by the Data Protection (Processing Of Genetic Data) Regulations 2007.
Are there exceptions to the access requirements (e.g. in case of emergency)?	Data Protection Act 1988-2003	Only as specified by the Data Protection Acts. Section 2B permits processing of sensitive personal data, including medical data, in the absence of consent where, for example, processing is necessary for medical purposes and is undertaken by a medical professional. "Medical purposes" is defined to include "the purpose of preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health care services." Section 2B also permits processing in the absence of consent where it is necessary to prevent injury or other damage to the health of the data subject or another person or serious loss in respect of, or damage to, property or otherwise to protect the vital interests of the data subject or of another person in a case where (I) consent to the processing cannot be given by or on behalf of the data subject or (II) the data controller cannot reasonably be expected to obtain such consent, or the processing is necessary to prevent injury to, or damage to the health of, another person, or serious loss in respect of, or damage to, the property of another person, in a case where such consent has been unreasonably withheld.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		No. In practice evidence would be sought from the person seeking access to establish that they are a health professional as defined.
Does the patient have the right to know who has accessed to his/her EHRs?		No specific mechanism is provided for.
Is there an obligation on health professionals to update EHRs?	Data Protection Acts 1988-2003	Obligations to keep health records up to date arise under the Data Protection Acts (s.2(1)(b)). The Medical Council's Guide to Professional Conduct and Ethics (7th ed. 2009) also states at para 23.1 that doctors have a duty to maintain accurate and up-to-date patient records either in manual or electronic form.
Are there any provisions	The Freedom of	The Freedom of Information Act 1997 (Section 28(6)) Regulations 1999 (SI 47 of 1999)

Questions	Legal reference	Detailed description
for accessing data on 'behalf of' and for request for second opinion?	Information Acts 1997-2003	provide for the granting of access to records of personal information to the parents or guardians of individuals in certain circumstances. Those whose records may be accessed are children (under 18) and individuals who at the time of the request have a mental condition or mental incapacity or severe physical disability, the incidence and nature of which is certified by a registered medical practitioner and who are incapable of exercising their rights under the Act. Access to the records of such persons will only be granted where, in the opinion of the head of the body holding the records, this would be in their best interests.
Is there in place an identification code system for cross-border healthcare purpose?	Health Identifiers Bill 2013	This is being introduced. Section 12 of the Bill provides for the use of individual health identifiers, and the accessing of the National Register of Individual Health Identifiers, in another Member State.
Are there any measures that consider access to EHRs from health professionals in another Member State?	Health Identifiers Bill 2013	This is being introduced. The mechanism employed by the Health Identifiers Bill for allowing persons outside the state to use individual health identifiers and to access the National Register of Individual Health Identifiers is an agreement which will be entered into between the Minister for Health and "an equivalent person" in another Member State. An "equivalent person" is defined in s.12(1)(b) as a person who, in the opinion of the Minister, is the equivalent in the other Member State of a health practitioner or 'relevant body' (the meaning of which is to be set out in regulations to be introduced under the Health Identifiers Act). An agreement made under s.12 must specify all the matters that the Minister considers appropriate to the processing of an individual's relevant information, or the accessing of the National Register of Individual Health Identifiers and must include the following: (a) the name, address and other contact details of the equivalent person; (b) the name and other contact details of the person nominated to deal with queries in relation to the agreement; (c) the specific activities for which the equivalent person can process an individual's relevant information or access the National Register of Individual Health Identifiers; (d) the measures that the equivalent person is to put in place to limit access to the register; and (e) sanctions for any breach of the agreement.

Questions	Legal reference	Detailed description
		Section 12(3) requires the Minister to consult with the Data Protection Commissioner prior to entering into an agreement under s.12 and the Commissioner has the power under s.12(4) to review the operation of an agreement at any time and to report to the Minister on his or her findings. The Minister, in turn, has the power to take such action as the Minister considers appropriate arising from that report.

2.5. Liability

2.5.1. Main findings

Most legal actions against doctors in Ireland are founded on the principles of negligence as a tort or civil wrong. Negligence is doing or omitting to do something that a reasonable person would do in the circumstances in order to avoid harm to others. Therefore one must take care to prevent harm to anyone who might reasonably be affected by one's actions. There are four aspects to establishing a claim of negligence:

- the existence of a duty of care;
- breach of the duty of care by falling below the required standard of care;
- causation, that is, that the harm suffered by the plaintiff was caused by the breach of duty;
- proof of injury or damage.

Medical negligence actions seek to provide compensation to the patient in circumstances where a doctor carried out his or her duty incompetently as result of which the patient was injured. A doctor may also be liable for not doing something, such as failing to diagnose an illness or refer a patient for further tests or specialist treatment.

There are no specific legal principles on medical negligence requirements related to the use of EHRs.

In relation to other potential liabilities such as breach of privacy, the provisions of the Data Protection Acts 1988-2003 apply.

2.5.2. Table on liability

Questions	Legal reference	Detailed description
Does the national legislation set specific medical liability requirements related to the use of EHRs?		No
Can patients be held liable for erasing key medical information in EHRs?		N/A
Can physicians be held liable because of input errors?		N/A. Save in accordance with general negligence principles.
Can physicians be held liable because they have erased data from the EHRs?		N/A. Save in accordance with general negligence principles.
Are hosting institutions liable in case of defect of their security/software systems?		N/A. Save in accordance with general negligence principles.
Are there measures in place to limit the liability risks for health professionals (e.g. guidelines, awareness-raising)?		N/A. The Medical Council is a statutory body which regulates registered medical practitioners in Ireland. The Council publishes standards of practice in relation to professional conduct and ethics which includes guidance in relation to maintenance of records, confidentiality and privacy. Breaches of these standards may result in disciplinary proceedings being instituted against a medical practitioner. The Guide does not specifically deal with EHRs.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Data Protection Acts 1988-2003	N/A. Save in accordance with data protection law. In particular, section 7 of the Data Protection Acts establishes a statutory tort under which data controllers and data processors owe a duty of care in certain circumstances towards the data subject. This leaves open the possibility that breach of the provisions of the Data Protection Acts could result in negligence proceedings the successful conclusion of which could result in an award of damages being made to the injured party.
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		No
Are there liability rules related to the	Data Protection Acts 1988-	N/A. Save in accordance with data protection law – see above.

Questions	Legal reference	Detailed description
misuse of secondary use of health data?	2003	

2.6. Secondary uses and archiving durations

2.6.1. Main findings

There are no specific legal requirements relating to the archiving of EHRs. The requirements of Data Protection law must be considered.

The Health Service Executive has published a record retention policy which sets out minimum retention period for records which apply regardless of the medium on which they are held.

The Disability Act 2005 also prohibits the processing of genetic data in certain contexts.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
Are there specific national rules on the archiving durations of EHRs?	Data Protection Acts 1988-2003	Only as specified by the Data Protection Acts. Under Section 2B(1)(b) (xi) of the Data Protection Acts processing of sensitive data may be authorised by regulations made by the Minister for reasons of substantial public interest. No such regulations have been introduced. While there are no specific legal requirements relating to the archiving of EHRs the Health Service Executive (HSE) has published a record retention policy: *Record Retention Periods Health Service Policy 2013.* The minimum retention period for records provided for in the policy apply to records of all types regardless of the medium on which they are held.
Are there different archiving rules for different providers and institutions?		No
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?	Data Protection Acts 1988-2003	Data protection law establishes an obligation not to retain data for longer than is needed; S.(2)(1)(c) of the Data Protection Acts provides that personal data shall have been obtained only for one or more specified, explicit and legitimate purposes and shall not be kept for longer than is necessary for that purpose or those purposes.
Are there any other rules about the use of data at the end of the archiving duration or in case of closure of the EHR?	Data Protection Acts 1988-2003	Yes, in data protection law. See above.
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Data Protection Acts 1988-2003	Under the Data Protection Acts, processing of sensitive personal data must comply with the principles of fair obtaining and processing. This includes a requirement that the data must have been obtained only for one or more specified, explicit and legitimate purposes, must not be further processed in a manner incompatible with that purpose and must not be kept longer than is necessary for that purpose. If these requirements are met, there are exceptions in the Acts which allow the secondary use of such data for other purposes, such as statistical, research or other scientific purposes subject to conditions which include consent of the data subject, or the protection of his/her vital interests, or the necessity to process the data for the performance of a

Questions	Legal reference	Detailed description
		function of Government (not an exhaustive list).
Are there health data that cannot be used for secondary use?	Disability Act 2005	The Disability Act 2005 Part IV prohibits the processing of genetic data in certain contexts. Section 42 provides that the data subject (customer/patient/employee etc.) must give informed consent to the processing of genetic data. It is an offence under the Disability Act section 42 subsection 4 to process genetic data for insurance or employment purposes in the absence of consent. Section 43 of the Disability Act states that family history information will be processed in accordance with regulations to be made by the Minister for Justice but these have not been introduced. The Data Protection Commissioner has also approved guidelines for insurance companies in relation to genetic test results. These are available at: http://www.insuranceireland.eu/media/documents/20130626_Code_of_Practice_Final.pdf
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?		No
Does the law say who will be entitled to use and access this data?	Data Protection Acts 1988-2003	Only as specified by the Data Protection Acts. See Section 2B as described above
Is there an opt-in/opt-out system for the secondary uses of health data included in EHRs?		No

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

There is no centralised EHR system in place in Ireland. However, local systems exist in general practice and in some individual hospitals. There are no legal requirements regarding inter-operability but HIQA and the HSE are in the process of developing standards in this area.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
Are there obligations in the law to develop interoperability of EHRs?		No. One of the priority areas identified in the recent eHealth Strategy (2013) is the development of interoperability standards. The Health Information and Quality Authority (HIQA) has a statutory remit to implement recommendations in the National Health Information Strategy.
Are there any specific rules/standards on the interoperability of EHR?		No. HIQA is currently working on the development of interoperability standards. The eStandards Advisory Group has been established by HIQA with representation from all stakeholders: HSE, the Dept. of Health, patient groups, GPs etc. Although the title of the group is advisory, they have sub groups who actually develop standards. The Group has not focused on EHRs as such because the building blocks are not yet in place but they have done work on messaging standards between GPs and hospitals (working closely with Healthlink). Work is also being undertaken by the HSE in the area of standards under the National ICT Integrated Services Framework (ISF). The purpose of the **ISF** project is to develop a standards based framework for applications, information, communications and technical architecture in Irish Healthcare. In particular, the ISF seeks to deliver a single information systems framework to provide for integration and sharing of data and information which will act as a foundation for the EHR and a National Patient/ Client Portal.
Does the law consider or refer to interoperability issues with other Member States systems?		No

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

No legislation has been introduced to allow for ePrescriptions. At present prescriptions must be in ink or otherwise so as to be indelible and be signed by the person issuing it with his usual signature.

2.8.2. Table on the links between EHRs and ePrescriptions

- ***Infrastructure***

Questions	Legal reference	Detailed description
Is the existence of EHR a precondition for the ePrescription system?		No. At present prescriptions must "be in ink or otherwise so as to be indelible and be signed by the person issuing it with his usual signature": The Misuse of Drugs Regulations, 1988, SI No. 328 of 1988, Reg.13. No legislation has been introduced to allow for ePrescriptions.
Can an ePrescription be prescribed to a patient who does not have an EHR?		N/A

- ***Access***

Questions	Legal reference	Detailed description
Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?		N/A
Can those health professionals write ePrescriptions without having access to EHRs?		N/A

3. Legal barriers and good practices for the deployment of EHRs in Ireland and for their cross-border transfer in the EU.

Good practices:

Healthcare providers are required to register with the Data Protection Commissioner.

The Data Protection Commissioner has developed guidelines in relation to the data protection issues arising in the healthcare area. See: Guidelines for the Medical and Health Sector: available at http://dataprotection.ie/viewdoc.asp?m=m&fn=/documents/guidance/5a.htm

A range of other policies and guidelines set out good practice requirements relating to the handling of health data. These include:

Health Service Executive:

- Record Retention Periods Health Service Policy 2013 available at: http://www.hse.ie/eng/services/list/3/hospitals/ulh/staff/resources/pppgs/rm/recret2013.pdf
- Code of Practice for Healthcare Records Management, 2007 available at http://www.hse.ie/eng/services/Publications/services/Hospitals/NHO_Code_of_Practice_for_Healthcare_Records_Management_Version_2_0.pdf

Irish College of General Practitioners and General Practice IT Group:

- A Guide to Data Protection Legislation for Irish General Practice, 2011
- No Data, No Business: Information Communications Technology (ICT) Security Guidelines, 2008

HIQA:

- Guidance on Messaging Standards for Ireland available at http://www.hiqa.ie/publications/guidance-messaging-standards-ireland

Legal barriers

The primary legal barriers for the deployment of EHRs in Ireland and their cross border transfer to other EU Member States include the following:

- The lack of a legal framework for the operation of EHRs.
- The lack of a unique patient or healthcare provider identifier in Ireland. This matter is being addressed by the passage through the parliament of the Health Identifiers Bill 2013.
- The non-transposition into Irish law of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
- Legislation in relation to controlled drugs requires that prescriptions must be signed, which is perceived to raise challenges in relation to e-prescribing.