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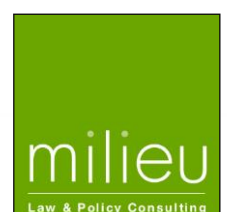
Overview of the national laws on electronic health records in the EU Member States

National Report for Lithuania

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Law & Policy Consulting

3 March 2014

Executive Summary

1. Stage of development of EHRs in Lithuania

Electronic Health Records (**EHR**) are in the initial stage of development in Lithuania. They will be implemented as a part of the State Electronic Health Services and Cooperation Infrastructure Information System (**ESPBI IS**).

The structure of the ESPBI IS will be based on a repository database: it should consist of separate databases of patients' EHRs, medical devices, classifiers, medical images, ePrescriptions, as well as reports and statistical information.

Currently, i.e. before the ESPBI IS is launched, there is no central or unified national database of patient's medical records in Lithuania. The aim is to create ESPBI IS as a single data centre, which will electronically store medical records of each resident of the state and would also integrate all internal IS of healthcare institutions into a unified system. Such integration should allow the creation, storage and transfer of EHRs according to the principle "*one resident – one EHR*". For the smaller healthcare institutions that do not own internal IS, a special eHealth portal will be created.

2. Summary of legal requirements applying to EHRs

The scope of patients' data that would be required to be transferred to the ESPBI IS database has not been clearly settled yet[1]. The current legal framework identifies EHRs as data related to patient's health, i.e. purely medical information. At the current stage of implementation of ESPBI IS, there are no particular regulations or requirements related to the cross-border sharing of patient's EHRs.

The Lithuanian national legislation provides particular requirements applicable to the institutions hosting EHRs data, e.g. data safety regulations, including technical and organizational requirements, requirements for the employees of hosting institution, etc. As the internal IS of healthcare institutions will be integrated into the ESPBI IS, the requirements are applicable both to the ESPBI IS as well as to the internal systems of healthcare institutions.

The Lithuanian legal framework does not provide any specific national rules on consent from the patient to set-up EHRs. It seems that in practice the creation of EHRs would be covered by the provision of Article 5(2)(8) of the Law on Data Protection under which it is not prohibited to process special categories of personal data (including information on person's health) where it is a legal obligation of the data controller to process such data.

In general, the Lithuanian EHR system is based on the concept that data of EHRs are the property of the patient. The patient will have a right to access all documents stored in his EHR. The legal regulation does not provide different categories of access for different health professionals. However, access to ESPBI IS would be granted for users of the system pursuant to the principle "*need to know*", i.e. in the extent necessary for their direct activities.

The national legislation does not set specific liability requirements related to the use of EHRs. Therefore, the general rules on liability are applicable. For instance the professionals could be held liable because of input errors or because they have erased data from the EHRs as well as for the

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[1] The Ministry of Health has issued very recently an order establishing the set of patients' data that is required for the integration between hospitals information systems and the ESPBI IS [Order of Minister of Health Care No: V-595 2014-05-16]. However, this occurred after the date of completion of the report and therefore the new provisions are not reflected herein.

coordination of healthcare provided to the patient in an erroneous way (whether this input was negligent, reckless, or intentional). Direct right of a patient to update, modify and erase EHR content has not been established. Therefore, the patient cannot be held liable for erasing key medical information in EHRs.

The national legislation ensures that the patient's EHR personal data is kept in ESPBI IS database throughout the life of the patient and for 3 years after his death. At the end of this period the patient's personal data is stored in the archive of ESPBI IS for the 75 years. Health data might be used for secondary purpose (e.g. scientific research or statistics) under the particular conditions as provided in applicable laws.

Currently, there is no common EHR architecture available on national level in Lithuania. Legislation only provides that the exchange of data between the internal IS of healthcare institutions and ESPBI IS shall be carried out by using indicated standards and data protocols. Cross-border issues are not regulated by the national legal framework. However the current regulation provides general principles for the exchange of patient data, medical images and ePrescriptions with other EU Member States.

Based on the current legislation EHR and ePrescription are designed as separate databases of the ESPBI IS. However it is planned that they will be part of one IS. The database of EHRs would be used as a measure of control, i.e. it should record information about issued prescription medicines and medical aids, etc. and require relevant information from EHR for the issuance of ePrescription.

3. Good practices

The Lithuanian EHR system has been initiated by the strategy document "eHealth Strategy for 2007-2015". However the development of EHRs, as well as the whole ESPBI IS is only in the initial stage of implementation.

Therefore, it is too early to tell the good practices for the development of EHRs in Lithuania. It should be also noted that based on the current initial legal framework it could be concluded that the system of ESPBI IS will be highly unified within the national level, i.e. will efficiently integrate internal IS of healthcare institutions and ensure high level of uniformity of the stored data on national level.

Furthermore the effectiveness and universality of the EHRs system should be ensured due to the fact that the patients consent would not be required for the set-up of his/her EHR. As mentioned, healthcare institutions will have a legal obligation to process such data under the laws.

4. Legal barriers

At the moment it is not yet clear how the interoperability in cross-border cases would be ensured. The main issue raised by the stakeholders is the unification of the language and classifiers used in the national systems of the Member States. Furthermore it is not clear what standards and requirements will be established for the national EHRs systems for their integration at EU level.

As regards to national regulation no legal barriers could be identified. Current system allows the development of the eHealth system. However national legislation does not set specific medical liability requirement related to the use of the EHR. Therefore, it might be hardly applicable in practice.

Contents

List of abbreviations

EHRs	Electronic Health Records
ESPBI IS	State Electronic Health Services and Cooperation Infrastructure Information System
SECR	The State Enterprise Centre of Registers is a public entity of limited civil liability incorporated by the Government of the Republic of Lithuania responsible for the administration of ESPBI IS
MoH	Ministry of Health of the Republic of Lithuania
IS	Information system

1. General context

1.1. EHR systems in place

Electronic Health Records (**EHRs**) are in the initial stage of development in Lithuania. EHRs have been already referred to as a part of the State Electronic Health Services and Cooperation Infrastructure Information System (**ESPBI IS**) by the Program for period 2009 – 2015 of Development of Electronic Health System[2] prepared by the Ministry of Health of the Republic of Lithuania (**MoH**). The first laws on EHRs have been adopted recently. The launch of ESPBI IS project was in June 2012 and the final stage of the project in the second half of 2015[3].

The ESPBI IS (in which the EHRs would be stored) will be a national system of organizational, technical and software measures aimed to develop a centralized database of healthcare information and to ensure the exchange of such information among patients, healthcare professionals and institutions. It is expected that implementation of the ESPBI IS would lead to a higher level of patients' awareness of healthcare issues, as well as to a more effective use of available resources for provision of healthcare services and would help to base those services on modern technologies.

The structure of the ESPBI IS will be based on a repository database: it is planned that it will consist of separate databases of patients' EHRs, medical devices, classifiers, medical images, ePrescriptions, as well as reports and statistical information. According to the guidelines included in the Program for period 2009 – 2015 of Development of Electronic Health System ESPBI IS will be the main tool of the implementation of eHealth in Lithuania.

There are currently 29 projects in Lithuania related to eHealth being implemented, i.e. 3 national projects, 20 with healthcare institutions IS and 6 support projects for the system in general. The 3 major national projects are being directly implemented by the MoH. Those projects include the creation of ESPBI IS, a system of archiving and exchange of medical images (MedVAIS) and the development of ePrescription. Although separated into different projects MedVAIS and ePrescription will be included into the databases of ESPBI IS which would operate as an umbrella system.

Currently, before the ESPBI IS is launched, there is no central or unified national database of patient's medical records in Lithuania. The majority of the largest healthcare institutions has their own internal IS for the administration and collection of patients' data which are in the development stage. Whereas the smaller (e.g. regional) healthcare providers still are processing patients' data by using material paper documents. As a result, people receiving treatment in different facilities are faced by unnecessary burdens, for instance, required to re-run tests.

Therefore, the aim is to create the ESPBI IS as a single data centre, which will electronically store medical records of each resident (patient) and would also allow integrating data from all internal IS of healthcare institutions into a unified system. Such integration should allow the creation, storage and transfer of EHRs according to the principle "*one resident – one EHR*". For the smaller healthcare institutions that do not own internal IS, a special eHealth portal will be created. The authorised healthcare professionals will be allowed to provide required patients data to the central database of EHR or other databases of ESPBI IS through their computers. Therefore, patients' data would be transferred to ESPBI IS either directly through a special eHealth portal or by the integration of internal IS of largest healthcare institutions.

As the implementation of EHRs and the whole ESPBI IS has only started, the specifics of particular aspects of these projects are still unclear. For instance the scope of patients' data that would be required to be transferred to the ESPBI IS database has not been clearly defined yet. The applicable

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[2] http://www.sam.lt/go.php/lit/E-sveikatos-pletros-strategija
[3] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

regulation provides a broad general list of the data that could be included into the database of EHR, i.e. specific patient data, data of health professionals and healthcare institutions. In practice healthcare institutions customize the particular scope of the content of EHRs themselves (within the limits allowed by law) and coordinate it with the authorised institutions[4]. It must be noted that current legal regulation of collection of patient's data is based on the minimal requirements mostly related to the material (paper) files of a patient. The legal acts of the MoH also provide the general requirements for the integration of the internal databases of healthcare institutions into the ESPBI IS.

As regards to the integration of data it was planned that the particular scope of the information required to be submitted to the ESPBI IS would be specified after the launch the project. However the initial stage of the ESPBI IS requires only a sufficiently small scope of patients' data. The final stage of the project is expected to be implemented in the second half of 2015.

The organizational structure of the ESPBI IS will take into account the three main subjects: the supervisor of ESPBI IS – the MoH, the main processor (administrator) of ESPBI IS – State Enterprise Centre of Registers, and other processors – healthcare institutions.

The data stored in the ESPBI IS will be accessible by the patients. The possibility to register and access the database will be allowed via a special national internet portal.

The system of the ESPBI IS is also aimed to ensure the exchange of patients' EHRs with the healthcare professionals and institutions of other Member States of the European Union. However, at the current stage of implementation of the ESPBI IS the particular rules or procedures for cross-border sharing of patient's data have not been settled yet.

1.2. Institutional setting

The main institutions involved in the development and implementation of the ESPBI IS in Lithuania are:

- **The Government of the Republic of Lithuania**

The Government of the Republic of Lithuania is the competent authority responsible for the approval of regulations and the appointment of controller of the ESPBI IS at a national level[5].

- **The MoH**

The MoH is the competent authority responsible for the coordination and supervision of the implementation of eHealth in Lithuania[6]. The general goals that shall be implemented are expressed in the Program for period 2009 – 2015 of Development of Electronic Health System [7].

- **State Enterprise Centre of Registers (SECR)**

The primary function of the SCRS is the administration of three main state registers: the Real Property Register and Cadastre, the Register of Legal Entities, and the Address Register. In fact, the SECR acts as a centre of excellence of the Lithuania's public sector in creating and developing register-data-based systems[8]. As regards the implementation of the ESPBI IS, the SECR has been appointed as the main processor (administrator) of the eHealth data system[9].

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[4] Interview with Managing Director of Centro Out-patient Clinic on 19 February 2014.
[5] Article 13[1] of the Law on Health System of the Republic of Lithuania.
[6] Article 13[1] of the Law on Health System of the Republic of Lithuania.
[7] http://www.sam.lt/go.php/lit/E-sveikatos-pletros-strategija
[8] http://www.registrucentras.lt/index_en.php
[9] Protocol No 85 of the Meeting of the Government of the Republic of Lithuania as of 15 December 2010 and decision of

- **State Data Protection Inspectorate**

The State Data Protection Inspectorate is responsible for the supervision and control of enforcement of the Law on Data Protection of the Republic of Lithuania[10]. It supervises the processing of EHRs by healthcare institutions and the compliance of users of ESPBI IS with the data protection requirements.

1.3. Legal setting and future legal development

The legal basis for the development of the ESPBI IS was set by Article 13^1 of the Law on Health System of the Republic of Lithuania which introduced the concepts of eHealth and ESPBI IS. The following regulation of ESPBI IS and EHRs has been adopted by a number of secondary legislation acts. In addition, general requirements related to data protection, creation of IS, archiving and other matters are also applicable.

Relevant legal acts and laws are enlisted below:

- **Legal framework related to the implementation of eHealth policies:**

  – Law on Health System of the Republic of Lithuania (Article 13^1 provides legal basis for development of ESPBI IS by introducing concept of eHealth and ESPBI IS).
  – Order No V-811 of Lithuanian Minister of Health dated 9 October 2007 Regarding the Lithuanian eHealth Development Strategy for 2007-2015.
  – Order No V-151 of Lithuanian Minister of Health dated 22 February 2010 Regarding the Program for period 2009 – 2015 of Development of Electronic Health System[11]
  – Order No V-570 of Lithuanian Minister of Health dated 18 June 2010 Regarding the Implementation Plan of the Lithuanian eHealth Development Programme for 2007-2015.
  – Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.
  – Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.
  – Order No V-889 of Lithuanian Minister of Health dated 7 October 2011 Regarding Approval of the Data Safety Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.
  – Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of Healthcare IS into the State Electronic Health Services and Cooperation Infrastructure Information System.
  – Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for IS of Healthcare Institutions.
  – Order No V-294 of Lithuanian Minister of Health dated 28 March 2011 Regarding Approval of Functional, Hardware and Software Architecture Model of Lithuanian eHealth system.

- **General legal framework related to health data:**

  – Order No 515 of Lithuanian Minister of Health dated 29 November 1999 Regarding Accounting and Reporting Procedures of Healthcare Institutions.

- **General legal framework related to data protection:**

Government 1057 07 September 2011.
[10] https://www.ada.lt/go.php/lit/English
[11] https://www.e-tar.lt/portal/legalAct.html?documentId=TAR.81CFCF5B92B0

- The Civil Code of the Republic of Lithuania.
- Law on Data Protection of the Republic of Lithuania.
- Law on the Rights of Patients and Compensation for Health Damage of the Republic of Lithuania.
- Order No 1T-71(1.12) of Director of State Data Protection Inspectorate dated 12 November 2008 Regarding Approval of General Requirements for Organizational and Technical Data Security Measures.

- **General legal framework related to hosting and management of data:**

- Electronic Signature Law of the Republic of Lithuania.
- Law on Documents and Archives of the Republic of Lithuania.
- Law on Management of State Information Resources of the Republic of Lithuania.
- Order No 180 of the Government of the Republic of Lithuania dated 27 February 2013 Regarding Approval of Procedures for the Establishment, Development, Modernization and Liquidation of State Information Systems.

2. Legal requirements applying to EHRs in Lithuania

2.1. Health data to be included in EHRs

2.1.1. Main findings

At the moment Lithuania has regulated only general principles and provisions as regards to the extent of data that can and may be included in the national EHR system. The particular scope of patients' data that would be required to be transferred to the ESPBI IS database has not been clearly settled yet[12].

The applicable regulation provides a broad general list of the data that could be included into the database of EHR, i.e. specific patient data, data of health professionals and healthcare institutions. In practice healthcare institutions tend to choose and customize the particular scope of the content of EHRs themselves (in compliance with applicable requirements) and coordinate it with the authorised institutions during the process of the establishment of their IS.

The current legal framework identifies EHRs as data related to patient's health, i.e. purely medical information. It is considered[13] that the particular scope of the patient's data that would be required to be transferred to national ESPBI IS database through the local IS of healthcare institutions might consist of: inpatient discharge summary; outpatient visit prescription; referral to consultations, laboratory tests, treatments; answer to referral; picture; vaccination summary; order for laboratory; laboratory results; pathology test results; ePrescriptions; prescribed medications. Also the general profile of a patient would be included.

Although at the current stage of implementation of the ESPBI IS there are no particular rules related to the cross-border sharing of patient's EHRs, it is planned that the exchange of patient data, medical images and ePrescriptions with other European Union Member States would be implemented by using epSOS and the guidance and experience of other projects as well as statutory requirements of the EU law.

It should be noted that the creation of the first unified Lithuanian electronic system of the medical terms has been also started by initiative of Lithuanian Ministry of Health in 2012. The international system SNOMED CT (Systematized Nomenclature called of Medicine-Clinical Terms) will be installed in order to allow fully describing and coding the patient's data indicated in the EHR. The project shall be finally implemented in the second half of 2015[14].

The current legal framework provides no specific rules on identification of patients in EHRs or specific identification number for eHealth purposes.

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[12] The Ministry of Health has issued very recently an order establishing the set of patients' data that is required for the integration between hospitals information systems and the ESPBI IS [Order of Minister of Health Care No: V-595 2014-05-16]. However, this occurred after the date of completion of the report and therefore the new provisions are not reflected herein.

[13] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

[14] http://sc.bns.lt/view/item.php?id=149105

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?)	Law on Data Protection of the Republic of Lithuania	The general requirements for the processing of personal data are provided in Article 3(4) of the Law on Data Protection, which states that the data controller must ensure that personal data is identical, adequate and not excessive in relation to the purposes for which they are collected and further processed.
	Order No 1057[15]	As regards to regulation of EHR content, Article 18 of the Order No 1057 provides a broad list of particular information that could be processed in EHR database of ESPBI IS, i.e.:
		− specific patient data (will statements, choices of healthcare professionals and healthcare institutions, height, weight, waist size, body mass index, blood group and rhesus factor, risk factors, lifestyle (addictions), hazardous and dangerous environmental factors, level of disability, work capacity, special needs, data of preventive health checks, vaccinations application data, codes and names of previous illnesses and medical conditions, codes and names of allergic reactions, diagnoses codes of hereditary or genetic disease of close relatives, complaints and medical history data; provided health services (in a form of statistical accounting forms), outpatient treatment or hospitalization summaries (visits statuses, diaries, medical case summaries, transcripts, etc), codes and names of diagnosed diseases or conditions, applied treatments, procedures and operations (interventions), data of long-term follow-up, medicinal treatment, application of medical devices, transfer for consulting, investigation, treatment, collected samples, performed testing, status of health insurance, issued electronic illness certificates and electronic certificates for pregnancy and maternity leave (personal identification number, name(s), surname(s), reason for incapacity, period for disability, maternity leave, birth date), issuance of permits for illness and maternity leave for circumstances unforeseen in the regulations (personal identification number, name(s), surname(s), the official certificate number, health institution, which is

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[15] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure IS.

Questions	Legal reference	Detailed description
		authorised to issue permit (personal identification number, name) period of leave), except data composing state or office secrecy;
		− data of health professionals who created electronic health records (personal identification number (personal identification number or other identification number of Lithuanian Republic resident person or foreign national), name(s), surname(s), data of license or the list of health professionals (number, type of professional qualification, status of licenses or list entry, date of withdrawal of the license or deletion from the list), number of health specialist stamp);
		− data of healthcare institutions that submitted electronic health records (legal entity registration data (legal entity or its affiliate code, name, legal form, registered address, license data of the institution, working specialist recruitment information (recruitment date, qualification (position), dismissal date, working period, cabinet number) and other).
		The particular scope of patients' data that would be required to be transferred to the national ESPBI IS database has not been settled yet.[16]
		Consequently Article 13 of the Order No V-1079 provides that the list of events and data sets can be adjusted during the implementation of the project on ESPBI IS development.
		In practice healthcare institutions tend to choose and customize the particular scope of the content of EHRs for their internal IS themselves (within the limits of the law) and coordinate it with the authorised institutions[17].
		It is considered that for the national system of ESPBI IS it would be required to transfer data related to[18]:
		− inpatient discharge summary;

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[16] The Ministry of Health has issued very recently an order establishing the set of patients' data that is required for the integration between hospitals information systems and the ESPBI IS [Order of Minister of Health Care No: V-595 2014-05-16]. However, this occurred after the date of completion of the report and therefore the new provisions are not reflected herein.
[17] Interview with Managing Director of Centro Out-patient Clinic on 19 February 2014.
[18] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

Questions	Legal reference	Detailed description
		− outpatient visit description; − referral to consultations, laboratory tests, treatments; − answer to referral; − radiological examination report; − vaccination summary; − request for laboratory test; − laboratory test results; − pathology test results; − ePrescriptions; − dispensed medications report.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	Order No V-1079[19] Order No V-89[20]	The current legal framework identifies EHRs as data related to the patient's health. For instance Order No V-1079 defines EHR as electronic data on the patient's physical or mental health status and records on activities of healthcare institutions. As regards to patient's data which shall be transferred to national ESPBI IS database through the internal IS of healthcare institutions, it is required that only the data that is directly related to the patient's healthcare actions, i.e. information related to the patient's health status and treatment process (health condition monitoring, allergies, booked/ performed research, diagnosis, services provided, appointed and issued medicines and compensatory medical devices, need for other healthcare services, etc.) are submitted (Article 8 of the Order No V-1079). Accordingly Article 30 of the Order No V-89 states that internal IS of healthcare institutions must be able to collect patient's EHR consisting of structured information on diagnosis, underlying disease, complications of healthcare services and other.
Is there a definition of EHR or patient's	Order No 1057[21]	Articles 4.1.-4.2. of the Order No 1057 provides the following definitions of

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[19] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of HealthCare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.
[20] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

Questions	Legal reference	Detailed description
summary provided in the national legislation?		electronic health item and electronic health record (EHR): – electronic health item is electronic data on the patient's physical or mental health status and records on the activities of healthcare institutions. Electronic documents are composed of electronic health items; – electronic health record (EHR) is the patient's electronic health items collected from all health institutions operating in the system. However national legislation does not provide definition of patient's summary.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?	Order No 515[22]	The current legal framework provides only general requirements on the content of EHRs. The particular scope of data stored in ESPBI IS is planned to be defined more specifically in the future[23]. As regards to current practice of healthcare institutions having their own internal IS[24], the general medical standard forms approved by MoH converted into electronic forms are used to compose the patient's EHR. Under certain circumstances, the healthcare institutions are allowed to amend or extend the information in those forms in regard with their needs. The ground for such practice is Article 2.6 of Order No 515, which provides that all mandatory health statistics, accounting and other standard forms used in healthcare institutions could be filled electronically, but must comply with the statutory requirements applicable for content of the forms. If necessary, all the records have to be printed. If the documents are being maintained electronically, the institution must ensure the compliance with the requirements of Order No 515, the Law on Data Protection the Republic of Lithuania and other applicable legal

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[21] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[22] Order No 515 of Lithuanian Minister of Health dated 29 November 1999 Regarding Accounting and Reporting Procedures of Healthcare Institutions.

[23] The Ministry of Health has issued very recently an order establishing the set of patients' data that is required for the integration between hospitals information systems and the ESPBI IS [Order of Minister of Health Care No: V-595 2014-05-16]. However, this occurred after the date of completion of the report and therefore the new provisions are not reflected herein.

[24] Interview with Managing Director of Centro Out-patient Clinic on 19 February 2014.

Questions	Legal reference	Detailed description
		acts. Article 2.7 of Order No 515 also states that if records are being signed digitally, the institutions must ensure compliance with the requirements of the Law on Electronic Signature of the Republic of Lithuania and other legal acts related to the signed data authenticity, availability and the validity of the electronic signature. Under Article 2.8 of Order No 515 digitally signed electronic records must comply with the requirements indicated in the electronic document specifications approved by the Chief Archivist of Lithuania. As a result healthcare institutions having internal IS are coordinating the content of their EHRs with the general statutory requirements applicable for the content of the standard medical forms.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Order No V-1079[25] Order No V-89[26]	The current legislation includes some rules on the use of a common terminology or coding system. Namely, by the order of Minister of Health 2011 February 23 d. No. V-164 legislated usage of ICD-10-AM (Australian modification). As well as Australian DRG clarification of Surgical interventions and Procedures. ACHI. Also relevant is the Decision of Government No. 1057 which defined the usage of classificators (eg. TLK-10, angl. ICD10 etc.). It should be noted that the creation of the first unified Lithuanian electronic system of medical terms has been started by initiative of the Lithuanian Ministry of Health in 2012. The international system SNOMED CT (Systematized Nomenclature called of Medicine-Clinical Terms) will be installed in order to allow fully describing and coding the patient's data indicated in the EHR. The project shall be finally implemented in the second half of 2015[27].
Are EHRs divided into separate categories of health data with different	Order No 1057[28]	The current legal framework does not divide EHRs data into separate categories with different levels of confidentiality.

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[25] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of Healthcare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.

[26] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

[27] http://sc.bns.lt/view/item.php?id=149105

[28] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?		However, according to Article 3 of Order No V-761 access to ESPBI IS shall be granted for users of the system pursuant to the principle "*need to know*". Therefore, users of ESPBI IS would have access rights only to the data in the extent necessary for their direct activities.
Are there any specific rules on identification of patients in EHRs?	Order No 761[29] Order No 1057[30]	The current legal framework does not provide specific rules on identification of patients in EHRs. Article 17 of Order 1057 only provides that patients' databases store general patient information, including the patient's EHR ID number. However no further requirements or rules related to the creation or use of EHR ID number have been adopted. As regards to the identification of patients accessing their EHRs, Article 15(3) of Order No 761 provides measures used to ensure information security of ESPBI IS data. Under this article each user of ESPBI IS shall be uniquely identified, i.e. must confirm his identity by providing ESPBI IS user name and password or digital qualified certificate.
Is there is a specific identification number for eHealth purposes?		The current Lithuanian legislation does not provide any specific identification number for eHealth purposes. In practice, in most cases the personal ID number is used.

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[29] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.
[30] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

The Lithuanian national legislation provides particular requirements applicable to the institutions hosting EHRs data, e.g. data safety regulations, including technical and organizational requirements, requirements for the employees of hosting institution, etc. Based on the current legal framework it could be stated that the system of ESPBI IS would be highly unified within the national level. However, the current legislation does not provide any requirements for a specific authorisation or licence to host and process data from EHRs.

Under the current legal framework the ESPBI IS organizational structure will take into account three main subjects: the controller of ESPBI IS – the MoH, the main processor of ESPBI IS – SECR, and other processors – healthcare institutions. The development of the ESPBI IS will create a single data centre which will electronically store medical records of each resident of the state and also integrate all local IS.

Particular requirements related to the operation of the ESPBI IS and the integration of IS of healthcare institutions provided in the national legislation are applicable both to the ESPBI IS and internal systems of healthcare institutions. Internal IS of healthcare institutions must be compliant with the requirements provided by the Law on Management of State Information Resources and other legal acts[31].

The Law on Data Protection provides[32] that personal data on a person's health may be processed by automatic means, also for scientific medical research purposes, and only requires notifying the State Data Protection Inspectorate. In this case, the State Data Protection Inspectorate must carry out a prior checking.

It appears that in practice particular requirements on the institution hosting EHRs data might be also established under the contracts that will be concluded between the data controllers and data processors[33].

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[31] eg Order No 180 of the Government of the Republic of Lithuania dated 27 February 2013 Regarding Approval of Procedures for the Establishment, Development, Modernization and Liquidation of State Information Systems.
[32] Article 10(3) of the Law on Data Protection of the Republic of Lithuania.
[33] Interview with Chief Specialist of the State Data Protection Inspectorate on 26 February 2014.

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?	Order No V-889[34] Order No V-761[35] Order No V-89[36]	As regards to the national ESPBI IS database, Order No V-889 provides data safety regulations, including technical and organizational requirements, requirements for the employees of hosting institution, etc. Technical safety measures required from the hosting institutions are also listed in Order No V-761. In addition internal IS of healthcare institutions must be compliant with the requirements provided for the integration with the national ESPBI IS database (Order No V-89).
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Order No 180[37]	The current legislation does not provide any requirements for a specific authorisation or licence to host and process data from EHRs. It appears that hosting and processing data of ESPBI IS would be executed by the SECR, which has been appointed as a main processor (administrator) of the eHealth data system. The smaller healthcare institutions that do not own internal IS would be allowed to connect and transfer data to ESPBI IS through a special eHealth portal that will be created. Whereas healthcare institutions creating their own internal IS would have to comply with the general requirements provided by Law on Management of State Information Resources of the Republic of Lithuania and specific requirements established by Order No 180 or other legal acts regulating the establishment of state IS.
Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff,	Law on Management of State Information Resources of the Republic of Lithuania	There are only general obligations applicable to the hosting and managing of the ESPBI IS (it would be executed by SECR as a main processor (administrator) of eHealth data system). For instance Order No V-889 establishes specific

[34] Order No V-889 of Lithuanian Minister of Health dated 7 October 2011 Regarding Approval of the Data Safety Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[35] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[36] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

[37] Order No 180 of the Government of the Republic of Lithuania dated 27 February 2013 Regarding Approval of Procedures for the Establishment, Development, Modernization and Liquidation of State Information Systems.

Questions	Legal reference	Detailed description
or technical tools/policies on security confidentiality)?	Order No V-889[38] Order No V-761[39] Order No V-89[40] Order No 180[41]	requirements for: − electronic information security management requirements (eg regarding obligation of ESPBI IS chief security commissioner to annually organize ESPBI IS risk assessment, etc); − organisational and technical requirements (eg regarding indoor installation and protection, computer hardware and software security, etc); − staff (regarding experience, skills, trainings about information security, etc). In addition Order V-761 provides: − the list of required technical and other safety measures (eg regarding computer hardware security, etc); − requirements for safe processing of electronic information (eg regarding data entry, modification, renewal and destruction procedures, etc); − requirements for the providers of services necessary for the ESPBI IS functioning; − control procedures for safe data reporting to users of the ESPBI IS; − etc. As regards to internal IS of healthcare institutions Order No V-89 sets specific obligations regarding safety requirements, technical tools and others, eg: − to be compliant with the requirements and technical conditions required for the integration with the ESPBI IS; − to ensure possibility to use electronic signatures (digital certificates); − to ensure that IS would have Lithuanian user interface; − etc.

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[38] Order No V-889 of Lithuanian Minister of Health dated 7 October 2011 Regarding Approval of the Data Safety Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[39] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[40] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

[41] Order No 180 of the Government of the Republic of Lithuania dated 27 February 2013 Regarding Approval of Procedures for the Establishment, Development, Modernization and Liquidation of State Information Systems.

Questions	Legal reference	Detailed description
		According to Article 30(2) of the Law on Management of State Information Resources when establishing State information systems the institution shall prepare the draft State information system regulations and draft State information system data protection regulations. Chapter II of the Order No 180 provides that for the establishment of the State's IS the legal act that approves safety regulations must be drafted and coordinated with the Information Society Development Committee under the Ministry of Internal Affairs and other authorised institutions. Therefore, these requirements are applicable both to the ESPBI IS and to establishment of internal IS of healthcare institutions.
In particular, is there any obligation to have the information included in EHRs encrypted?		The current legislation does not provide any obligation to have the information included in EHRs encrypted.
Are there any specific auditing requirements for institutions hosting and processing EHRs?	Law on Management of State Information Resources of the Republic of Lithuania Order No 180[42]	According to Article 14 of the Law on Management of State Information Resources the audit of information technologies shall be carried out at least once every three years when assessing the management and protection of the State information systems which process the institution's managed information important for the entire State and the main State registers, as well as State information systems and registers for the creation or modernization of which the amount of funding set by the Government or its authorized institution has been exceeded. The audit shall be carried out by certified information systems auditors of universally recognized international organizations. Article 1.2 of Order No 180 also provides that if more than 1 million LTL (EUR 289.620) of State's funds has been used for development or modernisation of State information system or modernization the audit of information technologies shall be carried out at least once every three years. In view of the above, we considered that due to the importance of the data stored and the usage of State's funding the auditing requirement would be applicable to the ESPBI IS.

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[42] Order No 180 of the Government of the Republic of Lithuania dated 27 February 2013 Regarding Approval of Procedures for the Establishment, Development, Modernization and Liquidation of State Information Systems.

2.3. Patient consent

2.3.1. Main findings

Lithuanian legal framework does not provide any specific national rules on consent from the patient to set-up EHRs. It seems[43] that in practice creation of EHR would be covered by the provision of Article 5(2)(8) of the Law on Data Protection under which it is not prohibited to process special categories of personal data (including information on a person's health) where it is a legal obligation of the data controller to process such data.

Therefore, it is expected that EHRs will be created and processed by health professionals without obtaining patient's consent for the creation and usage of the EHR. However, if additional information not required to be provided to the national ESPBI IS system's EHRs would be collected by the healthcare institution or shared with other subjects without a ground in legal acts, the consent of a patient would be required for processing of such information.

There are no specific national rules on consent of the patient to share data. However a patient whose data are processed in the ESPBI IS is entitled to hide some of the personal data. In such case the patient should be clearly warned about possible consequences of hiding of EHR data.

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[43] Interview with Chief Specialist of the State Data Protection Inspectorate on 26 February 2014.

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?	The Law on Data Protection of the Republic of Lithuania	The current legislation does not provide any specific rules on consent from the patient to set-up EHRs. Under the general provisions of Article 3(2) of the Law on Data Protection it shall be prohibited to process special categories of personal data, except where the data subject has given his consent. However, there is also an exception provided by Article 5(2)(8) of this law which states that it is not prohibited to process special categories of personal data if it is a legal obligation of the data controller to process such data. In addition Article 5(3) of the Law on Data Protection provides that data about a person's health may also be processed for the purposes and in the procedure laid down in Article 10 of the Law on Data Protection and other laws pertaining to healthcare. Accordingly Article 10(1) indicates that personal data on a person's health (its state, diagnosis, prognosis, treatment, etc) may be processed by an authorised healthcare professional. Therefore, it is considered[44] that EHRs would be properly created and processed by health professionals without obtaining patient's consent.
Is a materialised consent needed?	The Law on Data Protection of the Republic of Lithuania	The consent of a patient (neither material nor electronic) should not be required from the patient to set-up EHRs as the processing of such data would be obligatory under the law. Article 5(3) of the Law on Data Protection provides that data about a person's health may also be processed for the purposes and in the procedure laid down in Article 10 of the Law on Data Protection and other laws pertaining to healthcare. Accordingly Article 10(1) indicates that personal data on a person's health (its state, diagnosis, prognosis, treatment, etc) may be processed by an authorised healthcare professional.
Are there requirements to inform the		The current legislation does not provide requirements to inform the patient about

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[44] Interview with Chief Specialist of the State Data Protection Inspectorate on 26 February 2014.

Questions	Legal reference	Detailed description
patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?		the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs as the consent from the patient to set-up EHRs would not be required.
Are there specific national rules on consent from the patient to share data?	Order No 1057[45]	There are no specific national rules on consent from the patient to share data. Under Article 50 of Order No 1057 a patient whose data is processed in the ESPBI IS is entitled to hide some of the personal data in an EHR according to the rules provided by the manager of the ESPBI IS. Hiding data relating to contagious diseases, mental illness and other cases hazardous to the public might be performed only in accordance with the specific regulation of legal acts. The patient should be clearly warned about possible consequences of EHR data not appearing to be expressed and provide explicit consent for hiding of EHR data (Article 50.1 of the Order No 1057).
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?	The Law on Data Protection of the Republic of Lithuania	According to Article 10(1) of the Law on Data Protection personal data on a person's health (its state, diagnosis, prognosis, treatment, etc) may be processed by an authorised healthcare professional. Therefore, consent from a patient would not be required.
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?	Order No 1057[46]	The Lithuanian legal framework does not require consent to be expressed when data is being processed or shared. However, a patient may require certain information not to be reported (hidden) on his/her EHR (e.g. Order No 1057).
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?		National legislation does not provide any requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs.
Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the		Cross-border issues are not specifically regulated by the national legal framework as regards to the implementation of EHRs.

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[45] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[46] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
Member State (cross-border situations)?		The current EHR scheme is a national initiative. Therefore, only health professionals and health institutions of Lithuania would be allowed to access patient's EHR.

The national system is developed with the intention to be integrated in the EU network at some stage. However at the current stage the particular rules or procedures for cross-border sharing of patient's data have not been settled yet.[47]

However a patient would be allowed to consent to his EHRs being transferred to a health practitioner or health institution outside of the Member State under the general data protection rules provided by the Law on Data Protection, i.e. the data would be freely transferable within the EU. |
| *Are there specific rules on patient consent to share data on a cross-border situation?* | | Cross-border issues are not specifically regulated by the current legal framework. The data would be freely transferable within the EU under the general regulation of free movement of data.

It is expected that national system will be integrated in the EU network at later stage. At present the particular rules or procedures for cross-border sharing of patient's data have not been settled yet.[48] |

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[47] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[48] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

In general the Lithuanian EHR system is based on the concept that data of EHRs are the property of the patient. Therefore, the patient has a right to access all documents stored in his EHR. It appears that the content of EHR could be also downloaded, although it is not detailed in the legislation. As an exception sensitive documents can be hidden from the patient for instance specific cases when a patient has been diagnosed with cancer but still ignores it.

Concerning the patient's access to the EHR the patient will receive a specific login and password that should be used for connection to the ESPBI IS databases (it is planned that the login to the system would be performed through the authorisation of a person via internet banking system or ID authorisation card). The patient provided with login credentials would be allowed to access the EHR as well as other related data of ESPBI IS system via the special national internet portal.

The current rules provide patients only with the right to review their EHR (Article 6 of the Order No V-761 and Article 49.1 of the Order No 1057). Therefore, the right of a patient to update, modify and erase EHRs content has not been established. However patients would have a right to request modification, update or removal of information that is no longer correct or complete.

Health professionals need to be properly authenticated before acceding to EHRs. The law does not provide different categories of access for different health professionals. It is planned[49] that the authentication will be performed through the special internet portal, professional access or via internal IS of healthcare institution integrated with ESPBI IS.

According to Article 3 of Order No V-761[50] access to ESPBI IS will be granted for users of the system pursuant to the principle "*need to know*". Users of ESPBI IS will have access rights only to the data in the extent necessary for their direct activities.

Particular health professionals are allowed to access data of EHR even if a patient decides to hide such information[51]. The right to see all of the patient's EHR personal data is recognized to the patient's family physician, healthcare professionals providing primary medical care to the patient, health professionals who carry out the patient's medical examination (court, specialized, psychiatric, psychological or other) and providing findings on the risk of patient's working conditions, military medical experts when they are required for the patient military medical examination to be carried out.

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[49] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[50] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.
[51] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

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?	Law on Data Protection of the Republic of Lithuania	There are no specific national rules regarding who can create and where can EHRs be created. However under the general provision of Article 10(1) of the Law on Data Protection, personal data on a person's health (its state, diagnosis, prognosis, treatment, etc) may be processed by an authorised healthcare professional.
Are there specific national rules on access and update to EHRs?	Order No 1057[52] Order No V-761[53] Order No V-89[54]	The general requirements and rights of a patient to access EHRs are provided by Order No 1057, where Article 49.1 provides that a patient, who has been identified through the ESPBI IS or after the request provided to the processor of the data (in writing or personally by submitting the relevant identification document) shall have a right to obtain information on his/her personal data from EHRs. According to Article 3 of Order No V-761 access to the ESPBI IS is granted for users of the system pursuant to the principle "*need to know*". Users of the ESPBI IS have access rights only in the extent necessary for their direct activities. Article 6 of Order No V-761 also states that the ESPBI IS users (except for the patients) have the right to collect, process, transmit, store or otherwise use the ESPBI IS electronic information only in the course of their direct functions. As regards to internal IS of healthcare institutions integrated into the ESPBI IS, Article 27 of Order No V-89 provides that adequate protection of personal data must be ensured and that only as much data as necessary to provide quality services to patients should be processed.

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[52] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[53] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[54] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

Questions	Legal reference	Detailed description
Are there different categories of access for different health professionals?		The law does not provide different categories of access for different health professionals. The authentication will be performed through the special internet portal or via the internal IS of the healthcare institution integrated with the ESPBI IS. However the healthcare institutions should access only the data related to their activities and patients. Also the patient may exercise his/her right to restrict the access to some information.
Are patients entitled to access their EHRs?	Order No 1057[55]	According to Article 49.1 of Order No 1057 a patient, who has been identified through the ESPBI IS or after the request provided to the processor of the data (in writing or personally by submitting identification document) shall have a right to obtain information on his/her personal data from EHRs. The patient provided with login credentials will be allowed to access the EHR as well as other databases of the ESPBI IS via the special national internet portal.
Can patient have access to all of EHR content?		In general the Lithuanian EHR system is based on the conception that data from EHRs are the property of the patient. Therefore, the patient has a right to access all documents on his EHR.

In certain situations the information needs to be first disclosed to the patient in a meeting before being accessible on the EHR. This is for instance specific cases when a patient has been diagnosed with cancer but still ignores it[56]. |
| *Can patient download all or some of EHR content?* | | It is considered that content of EHRs could be downloaded[57]. This is however not detailed in the legislation. |
| *Can patient update their record, modify and erase EHR content?* | Order No V-761[58]
Order No 1057[59] | The Lithuanian law provides patients only with the right to review their EHR (Article 6 of Order No V-761 and Article 49.1 of Order No 1057). The right of a patient to update, modify and erase the content of his EHR is not established. |

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[55] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[56] Interview with Managing Director of Centro Out-patient Clinic on 19 February 2014.

[57] Interview with Managing Director of Centro Out-patient Clinic on 19 February 2014.

[58] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[59] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		According to Article 49.3 of Order No 1057 if the patient after being aware of his personal EHR data finds that his personal data is incorrect or inaccurate, he may immediately contact the healthcare institution that has processed the data. The healthcare institution must immediately check the indicated data and decide on the patient's request (in writing or personally by submitting the relevant identification document) whether to correct false or inaccurate data and (or) to stop processing of such data.
Do different types of health professionals have the same rights to update EHRs?	Order No V-761[60] Order No 1057[61]	The Lithuanian law does not specifically establish whether different types of health professionals have the same rights to update EHRs.

However, as regards to access rights of different types of health professionals Article 3 of Order No V-761 provides that access to the ESPBI IS is granted for users of the system pursuant to the principle "*need to know*". Users of the ESPBI IS have access rights only to the extent necessary for their direct activities.

Article 6 of Order No V-761 also states that the ESPBI IS users (except for the patients) have the right to collect, process, transmit, store or otherwise use the ESPBI IS electronic information only in the course of their direct functions.

In cases when a patient decides to hide any of the information of his EHR, only particular health professionals are allowed to access such data. Under Article 50.4 of Order No 1057 the right to see all of the patient's EHR personal data, including the hidden data is recognized to the patient's family physician, healthcare professionals providing primary medical care to the patient, health professionals who carry out the patient's medical examination (court, specialized, psychiatric, psychological or other) and providing |

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[60] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[61] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		findings on the risk of patient's working conditions, military medical expert when they are required for the patient military medical examination to be carried out. As regards to the internal IS of the healthcare institutions it is considered[62] that different categories of access would depend on the relation between the healthcare institution that is attempting to access the data and the patient. For instance the initial healthcare institution providing services for the patient would be allowed to access all of the data stored in their internal database. However other healthcare institutions would access only the data stored in the national the ESPBI IS EHRs database. Furthermore, the healthcare institutions will be allowed to access only the data of patients that are registered in a particular institution. Other healthcare institutions will be allowed to access such data of a patient after he/her would be brought to the institution for the provision of healthcare services[63].
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		The Lithuanian law does not provide any explicit occupational prohibitions as regards to data of EHRs.
Are there exceptions to the access requirements (e.g. in case of emergency)?	Order No 1057[64]	Article 50 of Order No 1057 states that the exclusive right to see all of the patient's EHR personal data, including the hidden data is recognized to: – patient's family physician; – healthcare professionals providing primary medical care to the patient; – health professionals who carry out the patient's medical examination (court, specialized, psychiatric, psychological or other); – health professionals providing findings on the risk of patient's working conditions; – military medical expert when they are required for the patient military medical examination to be carried out.

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[62] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

[63] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

[64] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		In cases of emergency data of patient's EHR will become accessible for the particular healthcare institution from the moment when the patient would be transferred therein.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*	Order No V-761[65]	National legal framework provides only aggregated rules on identification and authentication for healthcare professionals. For instance Article 21 of Order No V-761 provides that users of the ESPBI IS access the databases with the qualified digital certificate or other equivalent means of identification. In practise e-signature issued with ID authorisation card or authorization through banking system will be used[66].
Does the patient have the right to know who has accessed to his/her EHRs?	Order No 1057[67]	Article 49.2 of Order No 1057 provides that the patient after being identified in the system is allowed, through the portal of the ESPBI IS or by directly contacting the controller of the ESPBI IS (in writing or personally by submitting identification document), to obtain information from any sources from which the personal data of the EHR has been collected, the purpose for which such data is processed and what recipients have received the data within the period of 3 years.
Is there an obligation on health professionals to update EHRs?	Law on Data Protection of the Republic of Lithuania	The national legal framework does not provide any particular obligation on health professionals to update EHRs. However the general obligation to update information of EHRs is provided under Article 3 of the Law on Data Protection which states that the data controller must ensure that personal data is accurate and, where necessary, for purposes of personal data processing, kept up to date; inaccurate or incomplete data must be rectified, supplemented, erased or their further processing must be suspended; identical, adequate and not excessive in relation to the purposes for which they are collected and further processed.
Are there any provisions for accessing data on 'behalf of' and for request for		The law does not regulate whether accessing data on "behalf of" and for request for second opinion is allowed or subject to specific requirements.

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[65] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[66] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

[67] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
second opinion?		
		As regards to access of data for the second opinion, legal acts also do not provide particular regulation. However, based on legal framework we consider that a patient would be allowed to show data of his/her EHR to other persons for second opinion.
Is there in place an identification code system for cross-border healthcare purpose?	Order No V-1079[68]	Cross-border issues are not regulated by the current legal framework. However it is stated in Article 25 of Order No V-1079 that the exchange of patient's data, medical images and ePrescriptions with other European Union Member States shall be implemented by using epSOS and guidance and experience of other projects as well as statutory requirements of the EU law, including standards *HL7 v3, HL7 v3 CDA,* terminology *DICOM 3.0,* and classifiers *SNOMED CT, ICD-10-AM* and *LOINC.*
Are there any measures that consider access to EHRs from health professionals in another Member State?	Order No V-1079[69]	Cross-border issues are not regulated by the current legal framework. However it is stated in Article 25 of Order No V-1079 that the exchange of patient's data, medical images and ePrescriptions with other European Union Member States shall be implemented by using epSOS and guidance and experience of other projects as well as statutory requirements of the EU law, including standards *HL7 v3, HL7 v3 CDA,* terminology *DICOM 3.0,* and classifiers *SNOMED CT, ICD-10-AM* and *LOINC.*

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[68] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of HealthCare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.
[69] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of HealthCare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.

2.5. Liability

2.5.1. Main findings

The national legislation does not set specific liability requirements related to the use of EHRs. Therefore, the general rules on liability shall be applicable.

Under Article 3(1)(3) of the Law on Data Protection the data controller must ensure that personal data is accurate and, where necessary, for purposes of personal data processing, kept up to date; inaccurate or incomplete data must be rectified, supplemented, erased or their further processing must be suspended; personal data must be also identical, adequate and not excessive in relation to the purposes for which they are collected and further processed. Therefore, professionals could be held liable because of input errors or because they have erased data from the EHRs.

Moreover, input of information necessary for the coordination of healthcare provided to the patient in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered a professional fault subject to liability.

Hosting institutions might be held liable in cases of defect of their internal security/software systems. The national law also provides for the liability of the data processor (the MoH) and the data controllers (State Enterprise Centre of Registers and healthcare institutions) of the ESPBI IS in regard with the safety of the ESPBI IS data.

The national law provides patients only with the right to review their EHR (Article 6 of Order No V-761 and Article 49.1 of the Order No 1057). The right of a patient to update, modify and erase the content of his EHR has not been established. Therefore, a patient cannot be held liable for erasing key medical information in EHRs.

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?		The national legislation does not set specific medical liability requirements related to the use of EHRs. Therefore, the general rules on liability would be applicable.
Can patients be held liable for erasing key medical information in EHRs?	Order No V-761[70] Order No 1057[71]	The national legislation provides patients only with the right to review their EHR (Article 6 of Order No V-761 and Article 49.1 of Order No 1057). The right of a patient to update, modify and erase the content of his HER has not been established. Therefore, the patient cannot be held liable for erasing key medical information in EHRs.
Can physicians be held liable because of input errors?	The Civil Code of the Republic of Lithuania Law on Data Protection of the Republic of Lithuania	Under Article 3(3) of the Law on Data Protection the data controller must ensure that personal data is accurate and, where necessary, for purposes of personal data processing, kept up to date; inaccurate or incomplete data must be rectified, supplemented, erased or their further processing must be suspended; the data must also be identical, adequate and not excessive in relation to the purposes for which they are collected and further processed. Therefore, it appears that health physicians could be held liable because of input errors in EHRs. Input of information necessary for the coordination of healthcare provided to the patient in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered a professional fault subject to liability. For instance, Article 6.732 of the Civil Code provides that in the pursuit of his activities the provider of personal healthcare services must ensure such a degree of care which may be expected from an honest provider of personal healthcare services. Such activities must be based on responsibility stipulated by the relevant laws, other legal acts and professional standards of providers of healthcare services.

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[70] Order No V-761 of Lithuanian Minister of Health dated 8 August 2012 Regarding Approval of the Legal Acts Implementing Safety Policy of the State Electronic Health Services and Cooperation Infrastructure Information System.

[71] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		Therefore, it should be considered that physicians could be held liable under non-contractual (delictual) liability because of input errors if it would be considered as breach of, for instance, required degree of care.
Can physicians be held liable because they have erased data from the EHRs?	Law on Data Protection of the Republic of Lithuania Law on the Rights of Patients and Compensation for Health Damage of the Republic of Lithuania.	According to the current legislation physicians could be held liable because they have erased data from the EHRs. Erase of the data (whether it was negligent, reckless, or intentional) could be considered a professional fault subject to liability. Erasing is also considered as data processing; therefore, the particular liability would be established under the general provisions of the Law on Data Protection.
Are hosting institutions liable in case of defect of their security/software systems?	Order No 1057[72]	Article 56 of Order No 1057 states that the data processor (the MoH) and the data controllers (State Enterprise Centre of Registers and healthcare institutions) of the ESPBI IS are held liable under the laws in regard with the safety of the data of ESPBI IS.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		The national legislation does not provide specific measures limiting the liability risks for health professionals.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Order No 1057[73] Law on the Rights of Patients and Compensation for Health Damage of the Republic of Lithuania	The national legislation does not provide liability rules related to the breach of access to EHRs. Only general requirements of data protection should be applicable in such case. Article 56 of Order No 1057 states that the data processor (the MoH) and tge data controllers (State Enterprise Centre of Registers and healthcare institutions) of the ESPBI IS are held liable under the laws in regard with the safety of the data of ESPBI IS. Moreover Article 9(2) of the Law on the Rights of Patients and Compensation for Health Damage states that the liability is provided by laws for the illegal collection and use of confidential information about the patient.

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[72] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.
[73] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		The national legislation does not provide an obligation on health professionals to access EHRs prior to take a decision involving the patient.
Are there liability rules related to the misuse of secondary use of health data?	Law on Data Protection of the Republic of Lithuania Law on the Rights of Patients and Compensation for Health Damage of the Republic of Lithuania.	Under Lithuanian legislation there are no specific rules in regard with misuse of secondary use of health data. Article 53 of the Law on Data Protection provides the general rule that persons in violation of this law shall be held liable under the law. Moreover Article 9(2) of the Law on the Rights of Patients and Compensation for Health Damage states that the liability is provided by laws for the illegal collection and use of confidential information about the patient. According to Article 54 of the Law on Data Protection any person who has sustained damage as a result of unlawful processing of personal data or any other acts (omissions) by the data controller, the data processor or other persons violating the provisions of this law shall be entitled to claim compensation for pecuniary and non-pecuniary damage caused to him.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The national legislation ensures that the patient's EHR personal data is kept in the ESPBI IS database throughout the life of the patient and for 3 years after his death. At the end of this period the patient's personal data is automatically transferred to the archive of the ESPBI IS.

Personal data is stored in the archive of the ESPBI IS for the 75 years after the moment of the transfer of such data from the ESPBI IS database.

The regulation also ensures that health data might be used for secondary purposes (e.g. scientific research or statistics) under specific conditions.

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?	Order No 1057[74]	Article 47 of Order No 1057 states that the patient's EHR personal data is kept in the ESPBI IS database throughout the life of the patient and for 3 years after his death. At the end of this period the patient's personal data is automatically transferred to the archive of the ESPBI IS. Personal data of health professional is kept in ESPBI IS database as long as EHRs processed by this particular professional are kept in the database. After this period, personal data of health professional is automatically transferred to the archive of ESPBI IS. According to Article 48 of Order No 1057 personal data is stored in the archive of the ESPBI IS for 75 years after the moment of the transfer of such from ESPBI IS database. Requirements of other legal acts may also be applicable to some extent (e.g. The Law on Documents and Archives of the Republic of Lithuania).
Are there different archiving rules for different providers and institutions?	The Law on Documents and Archives of the Republic of Lithuania	The rules related to the archiving durations of EHR data are general and applicable to all providers and institutions similarly.
Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?	Order No 1057[75]	The law provides for an obligation to destroy data at the end of the archiving duration under certain conditions. However it does not provide for an obligation to destroy data in case of closure of the EHR. According to Article 48 of Order No 1057 in cases when the period of 75 years for archiving of data has passed and the data becomes obsolete for the objectives of the ESPBI IS or in other cases provided by legal acts of the Republic of Lithuania, the data stored in the archive of the ESPBI IS shall be destroyed or transferred to the state archives or other IS of the MoH under the decision of the board composed by the the ESPBI IS controller.

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[74] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[75] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
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?	Order No 1057[76] The Law on Documents and Archives of the Republic of Lithuania	As regards to the case of closure of the EHR Article 48 of Order No 1057 provides that the ESPBI IS archive could be destroyed or transferred to the State Archives under the provisions of the Law on Documents and Archives of the Republic of Lithuania and other legal acts. Article 16(2) of the Law on Documents and Archives of the Republic of Lithuania provides that documents subject to liquidation, the retention period of which has not expired, shall be transferred to the successor to the functions of the institution, agency or enterprise subject to liquidation and in the absence of the above-mentioned successor – to the institution executing the institution executing the owner's rights and duties or an agency authorised by it, or if the institution executing the rights and duties of the owner of the state institution, agency or enterprise is the Seimas of the Republic of Lithuania or the Government of the Republic of Lithuania – to the municipality within the territory of which the registered office of the state institution, agency or enterprise was located.
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Law on Data Protection of the Republic of Lithuania Order No 1057[77]	The general rules on the secondary use of health data are set under the Law on Data Protection of the Republic of Lithuania. Article 3(2) of the Law on Data Protection provides that personal data collected for other purposes may be processed for statistical, historical or scientific research purposes only in the cases laid down in laws, provided that adequate data protection measures are met. Article 13 of the Law on Data Protection provides that personal data collected for other than statistical purposes may be used in the cases laid down by law for the preparation of official statistical information. The general provision related to the secondary use of health data is also stated in Article 51 of the Order No V-89 under which the internal IS of healthcare

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[76] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

[77] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		institutions must ensure the availability of impersonated financial and statistical data analysis.
		As regards to special provisions applicable to the ESPBI IS system Article 26.3 of Order No 1057[78] provides the right of the Institute of Hygiene to receive impersonated data of EHR databases for performance of statistical calculations. For the needs of States Register of Patient's Death and its Reasons the Institute of Hygiene receives among other information sensitive data of a patient (provided health services (statistical accounting forms), summaries of outpatient treatment or hospitalization (visit status, diaries, summaries, extracts, etc), codes of diagnosis or condition, treatment methods, performed procedures and operations (intervention) and long-term follow-up data).
Are there health data that cannot be used for secondary use?		The national law does not provide for any particular health data not to be used for secondary use.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	Law on Data Protection of the Republic of Lithuania	As regards to general legislation, Article 13(3) of the Law on Data Protection indicates that special categories of personal data (ie data concerning racial or ethnic origin of a natural person, his political opinions or religious, philosophical or other beliefs, membership in trade unions, and his health, sexual life and criminal convictions) shall be collected for statistical purposes solely in the form which does not permit direct or indirect identification of the data subject, except in the cases laid down by law.

Article 10(2) of the Law on Data Protection provides that personal data processing for scientific medical research purposes shall be carried out in accordance with this and other laws. However there are no special provisions regarding health data. General requirements will be therefore applicable, for instance personal data which have been used for the purposes of scientific research must be altered immediately in a manner which makes it impossible to identify the data subject.

Under Article 10(3) of the Law on Data Protection personal data on a person's |

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[78] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		health may be processed by automatic means, also for scientific medical research purposes, only after having notified the State Data Protection Inspectorate. In this case, the State Data Protection Inspectorate must carry out a prior checking.
Does the law say who will be entitled to use and access this data?	Law on Data Protection of the Republic of Lithuania	As regards to the use and access of the health data the national law does not say who will be entitled to use and access such data. Article 10(1) of the Law on Data Protection provides only that personal data on a person's health (its state, diagnosis, prognosis, treatment, etc.) may be processed by an authorised healthcare professional. For scientific research in some cases a permit or authorization may be needed.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?	Law on Data Protection of the Republic of Lithuania	As regards to general provisions, Article 12 of the Law on Data Protection states that personal data may be processed for the purposes of scientific research on condition that the data subject has given his consent. Without the data subject's consent, personal data may be processed for the purposes of scientific research only upon notifying the State Data Protection Inspectorate. In this case, the State Data Protection Inspectorate must carry out a prior checking.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

Currently there is no common EHR architecture available on national level in Lithuania. However, the ESPBI IS system is planned to be implemented as a one centralised data base. The legislation provides that the exchange of data between the internal IS of healthcare institutions and the ESPBI IS shall be carried out by using indicated standards and data protocols.

The initiatives related to the development of the interoperability standards of EHRs have established under the eHealth Strategy policy. In this stage no form of conformity testing or accreditation scheme for eHealth systems and applications are available in Lithuania. Only minimal requirements for the IS of healthcare institutions are provided by the MoH. Other possibilities are only under the consideration at the moment.

As regards to specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others, there is only a regulation applicable for internal IS of healthcare institutions, which provides the list of recommended EHR and clinical data structure standards. In addition, other legal acts identify the standards and data protocols required for the exchange of data between the local healthcare institutions IS and ESPBI IS. Other general legal requirements are related to material (paper) files of a patient.

Cross-border issues are not regulated by the national legal framework. Therefore, only health professionals and health institutions of Lithuania will have access to the patient's EHR by using the ESPBI IS. According to MoH ESPBI IS will be developed with an aim to ensure the ability to exchange patients' EHRs with the healthcare professionals and institutions of other Member States of the European Union. However, at the current stage of implementation of ESPBI IS, there are no particular regulations related to the cross-border sharing of patient's EHRs and the particular rules or procedures for cross-border sharing of patient's data have not been settled yet.[79].

The current legal framework provides only general principles for the exchange suof patient data, medical images and ePrescriptions with other EU Member States. They will be implemented by using epSOS and guidance and experience of other projects as well as statutory requirements of the EU law, including HL7 v3, HL7 v3 CDA and DICOM 3.0 standards and SNOMED CT terminology, ICD-10-AM, LOINC classifications.

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[79] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

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?	Order No V-1079[80]	Article 5 of Order No V-1079 provides that the exchange of data between the internal IS of healthcare institutions and the ESPBI IS shall be carried out by using provided (indicated therein) standards and data protocols.
Are there any specific rules/standards on the interoperability of EHR?	Order No V-1079[81] Order No V-89[82]	Order No V-89 applicable for internal IS of healthcare institutions provides the list of recommended EHR and clinical data structure standards (*HL7 CDA, HL7 EHR, IHE XDS*) interoperability and data exchange in healthcare standards (*HL7 v3, HL7 RIM, HL7 CMET, DICOM*), classifiers and standards glossaries (*ICPC, LOINC, SNOMED CT, ICD, HL7 CTS*), standards governing the field of e-health information technology tools (*TCP/IPv4, IEEE 802, XML 1.0, ebXML, SOA 1.0, ISO/IEC 9075, SHA-1, FIPS 180-1, MIME, UTF-8, ISO/IEC, RFC 3987*) and other standards (*UCUM*).

Article 5 of Order No V-1079 provides that the exchange of data between the internal IS of healthcare institutions and the ESPBI IS shall be carried out by using provided (indicated therein) standards and data protocols.

Order No V-89 applicable for internal IS of healthcare institutions provides the list of recommended EHR and clinical data structure standards (*HL7 CDA, HL7 EHR, IHE XDS*) interoperability and data exchange in healthcare standards (*HL7 v3, HL7 RIM, HL7 CMET, DICOM*), classifiers and standards glossaries (*ICPC, LOINC, SNOMED CT, ICD, HL7 CTS*), standards governing the field of e-health information technology tools (*TCP/IPv4, IEEE 802, XML 1.0, ebXML, SOA 1.0, ISO/IEC 9075, SHA-1, FIPS 180-1, MIME, UTF-8, ISO/IEC, RFC 3987*) and other standards (*UCUM*). |
| *Does the law consider or refer to interoperability issues with other Member States systems?* | | Cross-border issues are not regulated by the current legal framework.

However it is stated by Article 25 of Order No V-1079 that the exchange of |

[80] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of Healthcare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.
[81] Order No V-1079 of Lithuanian Minister of Health dated 17 December 2010 Regarding Approval of Requirements and Technical Specifications for Integration of Healthcare Information Systems into the State Electronic Health Services and Cooperation Infrastructure Information System.
[82] Order No V-89 of Lithuanian Minister of Health dated 28 January 2011 Regarding Requirements for Information System of Healthcare Institutions.

Questions	Legal reference	Detailed description
		patient data, medical images and ePrescriptions with other European Union Member States shall be implemented by using epSOS and guidance and experience of other projects as well as statutory requirements of the EU law, including standards *HL7 v3, HL7 v3 CDA,* terminology *DICOM 3.0*, and classifiers *SNOMED CT, ICD-10-AM* and *LOINC*.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

Based on the current legislation EHRs and ePrescription are designed as separate databases of the ESPBI IS. However they will be inter-connected, e.g. in the ePrescription database the EHR data about healthcare professional or pharmacy technician that prescribed medicine or compensatory medical care device will be included. It is planned that they will be part of one IS[83].

The database of EHRs will be used as a measure of control, i.e. it will record information about issued prescription medicines etc. Therefore, doctors, writing the ePrescription would have access to the EHR of the patient. In order to issue an ePrescription particular data (eg entering information on patient's visit) would be required to be included into patient's EHRs[84].

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[83] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[84] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

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?	Order No 1057[85]	The existence of EHR will be a precondition for the ePrescription system..
Can an ePrescription be prescribed to a patient who does not have an EHR?		Although at the moment ePrescription and EHRs systems are being developed separately as different databases of the national ESPBI IS, after the implementation of the ESPBI IS ePrescriptions could not be prescribed to a patient who does not have an EHR[86]. The database of EHRs will be used as a measure of control, ie it would record information about issued prescription medicines and medical care devices, etc. In order to issue an ePrescription particular data (eg entering information on patient's visit) would be required to be included into patient's EHRs[87].

- *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?	Order No 1057[88]	Doctors, hospital doctors, dentists and pharmacists writing the ePrescription will be allowed to access to the EHR of the patient. According to Article 22 of Order No 1057 a reference to the EHR data about the healthcare professional who prescribed medicine or compensatory medical care device would be processed and stored in the ePrescription database. For instance, under Article 26.1.2 of Order No 1057 pharmacies will be allowed

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[85] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.
[86] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[87] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[88] Order No 1057 of the Government of the Republic of Lithuania dated 7 September 2011 Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System.

Questions	Legal reference	Detailed description
		to receive the following general patient data (personal identification number, name(s), surname(s), special health-related patient data (prescribed medicines and medical products, names and codes of diagnosed allergic reactions, adverse reactions, bad habits), healthcare professionals data (name(s), surname(s), number of health specialist stamp), data of prescribed medicinal products and medical devices, data of methodological assistance relating to clinical information of medicinal products. As regards to the internal IS of healthcare institutions they must ensure adequate protection of personal data and provision of only as much data as necessary to provide quality services to patients. For instance, in order to issue an ePrescription particular data (e.g. entering information on patient's visit) would be required to be included into patient's EHRs. Therefore, it would be accessible to persons issuing the ePrescription.
Can those health professionals write ePrescriptions without having access to EHRs?		Although at the moment ePrescription and EHRs systems are being developed separately as different databases of the national ESPBI IS after the implementation of the ESPBI IS health professionals would not be allowed to write ePrescriptions without entering information on patient visit, i.e. having access to EHR[89]. The database of EHRs would be used as a measure of control, i.e. it would record information about issued prescription medicines and medical care devices, etc.[90].

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[89] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.
[90] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.

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

- *Good practices for the development of EHRs in Lithuania*

The use of EHRs in Lithuania has been initiated by the strategy document "eHealth Strategy for 2007-2015". However development of EHRs as well as the whole ESPBI IS is only in the initial stage of implementation. Currently there is no unified database of patient's medical records and only the largest healthcare institutions have their internal IS for the collection and administration of the patients' data.

Therefore, it is too early assess whether there are any good practices for the development of EHRs in Lithuania, because the system has not been launched yet. However it should be noted that based on the current legal framework it could be concluded that the system of ESPBI IS would be highly unified within the national level, i.e. will efficiently integrate internal IS of healthcare institutions and ensure high level of uniformity of the stored data on national level..

- *Potential legal barriers for the development of EHRs in Lithuania*

While it is expected that the EHR system would be completely interoperable throughout Lithuania, it is not yet clear how the interoperability in cross-border cases would be ensured. The main issue raised by the stakeholders is the unification of the language and classifiers used in the national systems of the Member States. Furthermore it is not clear what standards and requirements will be established for the national EHRs systems for their integration into EU level.

The national legislation does not set specific medical liability requirement related to the use of the EHR. As a result the general rules on medical liability shall apply which in some cases might cause difficulties for their application to the use of EHR.

If e-signature will be used to authorize every entry, the institutions should ensure compliance with the requirements of the Law on Electronic Signature of the Republic of Lithuania and other legal acts related to the signed data authenticity, availability and the validity of the electronic signature. However such requirements would demand a considerable amount of time from the health professional in order to access and to sign each patient's EHR with e-signature. Therefore, alternative procedures are currently being held under consideration.[91]

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[91] Interview with Head of eHealth Coordination and Implementation Division of the MoH on 20 February 2014.