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

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

National Report for Luxembourg

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Executive Summary

1. Stage of development of EHRs in Luxembourg

In October 2006 the Government of Luxembourg adopted an eHealth action plan. The objectives of this plan were to develop the exchange or sharing of health information between health professionals, to improve the quality and performance of health care and to better control the evolution of health expenditure. This plan recommended the implementation of a common platform to support such sharing and exchange of medical information. As a follow-up to this plan, the Government consolidated and modernized a previous electronic platform of exchange and sharing of health data called HealthNet created in the nineties[1]. Since 2012 this HealthNet is under the control of the National Agency of shared information in the domain of health. This platform provides access to the Record of Shared Care (*le Dossier de Soins Partagé*) (RSC) which is the main national Electronic health Record initiative in Luxembourg. The RSC will be tested by a limited group of patients starting end 2014. The full implementation of the system is foreseen in 2016 through an opt-out approach for citizens of Luxembourg and an opt-in approach for foreign workers in Luxembourg.

The main legal framework for the RSC is the Law on the reform of the health system adopted in 2010 which amends the Code of Social Security (Code de la Sécurité Sociale). This law only sets general principles on RSC. As mentioned below Article 60 quarter of the Code of Social Security as amended, following the opinion of the National Commission for data protection requires the adoption of a Grand-Ducal Regulation to further define the rules applying to RSC. This Grand-Ducal Regulation has not yet been adopted. Luxembourg, after the approval of the national Commission for data protection, decided to implement a pilot system first and then to adopt the legal requirements based on the outcomes of the pilot phase. At the time of writing this report, the National Agency of shared information in the domain of health and the National Commission for data protection are carrying out a privacy impact assessment of the RSC.

2. Summary of legal requirements applying to EHRs

Requirements on health data to be included in EHRS

RSCs may include information about the patient relevant and useful in order to promote safety, continuity of care, coordination of care as well as an efficient use of health care services. It must contain medical data in form of medical reports, test results, reports of diagnostic investigations, medical prescriptions, medical imaging or any document related to the health or therapeutic treatment of a patient, prescriptions made in the field of bio-medical analysis, medical imaging and eventually the related results, the history and records of the care of certain health care services. This law allows the patient to include information or declaration in the RSC and administrative information on the patient. The law does not contain requirements on the use of common terminology or coding systems. A Regulation must specify the conditions of level access taking into account the different categories of health professionals and the different categories of health data. However such Regulation has not yet been adopted

Requirement on institutions hosting EHRs data

Specific rules on the hosting and management of data from EHRs do not exist in Luxembourg. A European Public tender was launched in January to designate the company in charge of hosting data from the RSC but also to design the e-health platform in Luxembourg

[1]HealthNet was at the beginning a secured network for health and social care created in the nineties as a research project. It was in fact a secured national network but had not many shared common services. The existing info structure has been consolidated and modernized under the umbrella of the HealthNet GIE.

Patient consent

At the time of writing the legislation of Luxembourg does not contain any requirement on patient consent. Luxembourg however decided to adopt an opt-out consent approach for the creation of RSC and the processing of related health data. However each time a patient is in a therapeutic relationship *'relation therapeutique'* with a health professional he/she must consent on the access by this health professional to his/her RSC by giving a 'presence password' that ensures that the patient is with the health professional and accepted the access.

Creation, access to and update of EHR

Since Luxembourg decided to apply an opt-out approach for the creation of the RSC, these e-health records will be created for all citizens of Luxembourg by the e-health agency of Luxembourg. The current legislation does not set detailed legal requirements on access and update to the RSC. The law on the reform of the health system only mentions that each patient has a right to access his/her RSC and that in respect of confidentiality the RSC is accessible only by the medical consultant, the regular doctor and other health professionals. Article 60 quarter of the Code of Social Security as amended by the Law on the reform of the health system provides that a Grand-Ducal Regulation must specify the procedure and conditions of access to RSCs.

According to the website of the eHealth Agency and interviewees there will be different categories of access for different health professionals. The medical consultant (*médecin referent*) will have access to all information in the RSC. Other health professionals will have access to restricted information in relation to their domain of expertise (e.g. pharmacists will have access to information related to medication; kinesitherapists will have access to medical imaging). The patient will be able to block access to the RSC to certain health professionals and hide documents to certain health professionals. Patients will have access to all RSC content with the exception of documents submitted prior to the announcement of a diagnostic. Luxembourg is also planning to allow patients to download RSC. Patient will not be able to modify and erase RSC content. In case of emergency and only in hospitals, RSC will be accessed without the prior consent of the patient. The patient can however decide to reject this 'by default' exception. The patient and the consultant medical will be able to trace all actions and access to the RSCs as foreseen under Article 60 quarter paragraph 4. There is no identification code system for cross-border healthcare purposes and no measures exist to consider access to EHRs from health professionals in another Member State. However Luxembourg is starting to cooperate with neighbouring regions to develop exchange of health data in order to ensure continuity of care of patients that evolve in a cross-border area. Furthermore Luxembourg has joined epSOS and is actively piloting the patient summary use case

Liability

General medical liability rules or the sanctioning regime set under the law on the protection of personal data apply to RSCs. Luxembourg is not planning to adopt specific rules for EHRs. The general sanction regime related to personal data under the law on data protection applies in case hosting institutions of health data do not set the adequate technical measures to ensure the security and confidentiality of these data. There are no specific liability rules concerning the breach of access to RSCs. However, the law on data protection sets some sanctions in case of infringement to the provisions related to the right of access to personal data, and the Criminal Code contains criminal sanctions for the infringement of the non-disclosure of information obligation from health professionals (Article 458) and for the offence of intrusion in an IT system (Article 509-1 to 7).

Secondary uses and archiving durations

On archiving duration Luxembourg is planning to set a 10 years archiving duration from the closure of RSC. Concerning the secondary use of health data from RSCs, the e-Health Agency, the Health

Ministry, the National Health Laboratory, the General Inspectorate of Social Security and the National Health Fund, are entitled to exchange using automatic procedures or not, anonymised information for statistical or epidemiological purposes. There is no opt-in/opt-out patient consent requirement for the secondary uses of health data included in RSCs

Requirements on interoperability of EHRs

There is no obligation in the law to develop interoperability of EHRs. Luxembourg is providing support to health professionals to update their software to be interoperable with the e-Health Agency Platform. The Law on the reform of the health system requires that a Grand-Ducal Regulation should develop the conditions for the cooperation and cross-border transfer of data to the relevant authorities in another Member State of the EU or part of the EEA.

Links between EHRs and E-prescriptions

The legislation in Luxembourg does not include any references to ePrescriptions and to the links between ePrescriptions and RSCs. However Luxembourg plans to integrate or use the RSC to develop ePrescriptions. Health professionals when granted access by the patient will be entitled to include prescriptions (drugs, tests, images) in the RSC. Pharmacists or other health professionals entitled by the patient will access to the prescription through the RSC.

3. Good practices

They all considered that the opt-out consent approach for the creation of EHRs was the best manner to deploy EHR systems but it should be accompanied by a strong and widespread information campaign for patients and doctors.

They all considered as a good practice to implement a pilot system first in order to test what would be the adequate rules for an efficient functioning of the system and then to adopt the legal requirements based on the outcomes of the pilot phase.

All interviewees stressed that the State semestrial remuneration of the medical consultant (*médecin referent*) for updating the RSC is a good financial incentive to involve doctors in the new system and to ensure their participation. The representative of the eHealth Agency however flagged that an efficient system that improves the situation of health professionals does not the remuneration of physicians.

The representative of the Health Ministry considered that the adoption of specific liability rules for EHRs was not needed. He justified that the general principles of medical liability did not have to be changed each time there was a technical progress.

All interviewees underlined that in order to enhance the confidence of patients on the system, they should be empowered to control access EHRs like in the RSC system. However the representative of the e-Health Agency flagged that if too many rights are given to the patient this may lead to the lack of confidence of health professionals to use and update EHRs. He stressed that health professionals should remain the main actors of EHRs.

The representative of the Ministry of Health underlined that a key for the success of the development of EHRs systems is to involve all partners at the start of the project (e.g. industry, doctors, patients, hospitals). He also stressed that the RSC should only be seen as a complementary tool that would not replace the health records in hospitals and in doctor offices.

On health data to be included in RSC the representative of the doctors association stressed that the patient consumption of medicines should appear in the RSC only for patient health benefit but not with

the purpose to trace the patient consumption in view of limiting the cost of health care or any other goal not related to the patient.

The representative of the doctor association underlined that in order to give confidence to patients they should be informed on the secondary use of health data.

All interviewees highlighted the need to achieve as a prerequisite the uniformisation of medical terminology standards prior to developing cross-border transfer of health data.

4. Legal barriers

The representative of the eHealth Agency mentioned that a legislation that sets too detailed requirements related to the content of EHRs is counterproductive as it may then not be comprehensive enough. He suggested that the law should remain quite vague and that the definition of health data should be done through practice in a more flexible manner.

The representative of doctors association highlighted that the opt-in approach for the creation of EHRs would put too much administrative burden on doctors.

He stressed that currently in Luxembourg research institutes use health data that are not anonymised and that they only have the obligation to render this data anonymised when they publish their results. He suggested that health data should be anonymised by a trusted third party prior to being used by research institutes.

With regard to the cross-border transfer of health data the representative of the eHealth Agency mentioned that the lack of harmonised rules on the identification of patients and identification of health professionals in a cross border situation was the main barrier to the cross-border transfer of health data within the EU.

Contents

List of abbreviations

EHRs	Electronic Health Records
RSC	Records of Shared Care (*Dossiers de Soins Partagé*)

1. General context

1.1. EHR systems in place

In October 2006 the Government of Luxembourg adopted an eHealth action plan (*plan d'action santé*) developed by a working group of stakeholders in the healthcare sector in Luxembourg. The objectives of this plan were to develop the exchange or sharing of health information between health professionals, to improve the quality and performance of health care and to better control the evolution of health expenditure. The aim of the plan was also to develop better empowerment of patients with regard to their medical care through appropriate management of personal health information. This plan recommended the implementation of a common platform to support such sharing and exchange of medical information. As a follow-up to this plan, the Government consolidated and modernized a previous electronic platform of exchange and sharing of health data called HealthNet created in the nineties[2]. Since 2012 this HealthNet is under the control of the National Agency of shared information in the domain of health (*Agence National des informations partagees dans le domaine de la santé*) (e-Health Agency). This platform provides access to the Records of Shared Care (*les Dossiers de Soins Partagé*) (RSC) which is the main national Electronic health Record initiative in Luxembourg and to other health related services (e.g. register of health professionals, Epsos). Note that the RSC is still being tested by voluntary patients and is not yet deployed to all patients in Luxembourg. The full implementation of the system is foreseen in 2015 through an opt-out approach for citizens of Luxembourg and an opt-in approach for foreign workers in Luxembourg. Luxembourg is also active for the cross-border transfer of health data and started discussions with neighbouring regions (e.g. Lorraine in France) in order to allow the cross-border exchange of health data and the continuity of care for patients due to the proximity with France, Belgium and Germany are more likely to consult health professionals in different countries.

1.2. Institutional setting

- *E-Health Agency*

In September 2010, the Government decided to establish an e-Health Agency. Article 60ter of the Law on the reform of the health system[3] sets the legal basis for the creation of this Agency that was effectively set-up in October 2011. This Article also defines the competences of the e-Health Agency.

The e-Health Agency is in charge of the implementation, deployment, operation, and administrative and technical management of a national electronic platform of electronic exchange and sharing of health data, as well as related health applications and systems such as the RSC and other national wide IT projects to facilitate the exchange, sharing or better use of health data. It is also in charge of the communication of data with similar platforms in other Member States[4].

The other main competence of the e-Health Agency is the promotion of interoperability and security in the implementation of health information systems through:

- the production and promotion of standards leading to interoperability and security of health information systems,

[2]HealthNet was at the beginning a secured network for health and social care created in the nineties as a research project. It was in fact a secured national network but had not many shared common services. The existing info structure has been consolidated and modernized under the umbrella of the HealthNet GIE.

[3] *Loi du 17 décembre 2010 portant réforme du système de soins de santé et modifiant: 1. le Code de la sécurité sociale; 2. la loi modifiée du 28 août 1998 sur les établissements hospitaliers.*

[4] Note that for the moment there is no such exchange apart from the Epsos project.

- the implementation of a convergence of health information systems through the implementation of interoperability standards.
- the monitoring of standards of health information systems
- the collaboration with international organisations in charge of standardisation.

- *The national Commission for data protection (la Commission nationale pour la protection des données)*

The national Commission for data protection is in charge of enforcing the law on the treatment of personal data of 2 August 2002 as amended[5] and its implementing regulations in particular those relating to the confidentiality and security of data processing. The Commission is also competent to provide opinions on any proposals of law and any related implementing measures that entail the processing of personal data. In November 2010 the Commission adopted an opinion (*avis*) on the proposal of law on the reform of the health system. This opinion mainly focused on the legal requirements to be applied to the RSC. In this opinion the National Commission for data protection requested that a Grand-Ducal Regulation in addition to what was already mentioned in the draft law should further specify the different levels of access with regards to particular categories of data.

1.3. Legal setting and future legal development

The main legal framework for the RSC is the Law on the reform of the health system adopted in 2010 which amends the Code of Social Security. As mentioned above Article 60 quarter of the Code of Security requires the adoption of a Grand-Ducal Regulation to further define the following rules applying to RSC:

- Creation and deletion of RSCs
- Access conditions to the RSCs by the patient and health professionals
- Patient access to the traces of access by health professionals to the RSCs
- The determination of different levels of access taking into account the responsibilities of different categories of providers and different categories of data
- The necessary measures to ensure a particularly high level of security of the national platform on electronic exchange and sharing of health data
- The procedures, standardized nomenclatures and methodologies and other norms and technical modalities related to the transfer of information and electronic documents to the RSCs
- The timeframe within which the health providers, the national health fund (caisse nationale de santé) and any other actor detaining information must transfer information to the RSCs.
- The creation of RSC for beneficiaries of health care in Luxembourg but are not residents
- Cooperation modalities and cross-border transfer with other Member State authorities

This Grand-Ducal Regulation has not yet been adopted.

The law on the treatment of personal data of 2 August 2002 as amended sets general requirements that also apply to RSCs.

[5] *Texte coordonné de la loi du 2 août 2002 relative à la protection des personnes à l'égard du traitement des données à caractère personnel modifiée par la loi du 31 juillet 2006, la loi du 22 décembre 2006, la loi du 27 juillet 2007.*

2. Legal requirements applying to EHRs in Luxembourg

2.1. Health data to be included in EHRs

2.1.1. Main findings

The law on the reform of the health system provides that RSCs must include relevant and useful information about the patient in order to promote safety, continuity of care, coordination of care as well as an efficient use of health care services. It must contain medical data in form of medical reports, test results, reports of diagnostic investigations, medical prescriptions, medical imaging or any document related to the health or therapeutic treatment of a patient, prescriptions made in the field of bio-medical analysis, medical imaging and eventually the related results, the history and records of the care of certain health care services. These are quite open categories. At the implementation phase Luxembourg plans to set more specific categories of health data in the system. This law allows the patient to include information or declaration in the RSC (e.g. whether or not they are willing to donate their organs) and administrative information on the patient. The law does not contain requirements on the use of common terminology or coding systems. Luxembourg is however working on that for the implementation phase.

A Regulation must specify the conditions of level access taking into account the different categories of health professionals and the different categories of health data. However such Regulation has not yet been adopted. Luxembourg plans to set different access rules for the different health professionals. These rules are today under review by the National Commission for data protection under a Privacy Impact Assessment. Once validated, they will be deployed and may be adapted as a result of the testing phase and be the basis of the future Regulation.

Concerning the identification of patients, in Luxembourg there is one common unique identifier for identification of natural persons that are residents or have another link with Luxembourg public services. This unique identifier is identical to the social security number and is therefore also used in the healthcare domain. According to the law, the Agence eSanté is allowed to use that identifier within a national master patient index. The use of this identifier is governed by a specific law.

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?)	Code of Social Security as amended by Law on the reform of the health system 17 December 2010 Art. 60 quarter	The Law on the reform of the health system provides that the record of shared care (RSC) must include information about the patient relevant and useful in order to promote safety, continuity of care, coordination of care as well as an efficient use of health care services. It must contain: - Medical data in form of medical reports, test results, reports of diagnostic investigations, medical prescriptions, medical imaging or any document related to the health or therapeutic treatment of a patient - Prescriptions made in the field of bio-medical analysis, medical imaging and eventually the related results - The history and records of the care of certain health care services - Information or declarations made by the patient him/herself The information leaflet prepared by the eHealth agency stresses that the RSC will contain: - the reports of radiology, - radiological images that permit the diagnosis and meaningful images to proofread by another health professional if necessary, - the results of laboratory tests, - the minutes of surgeries already performed, - endoscopies already made, - drug prescriptions - history of disease, - information on chronic disease you are suffering such as diabetes, - information about allergies, - information on vaccinations,

Questions	Legal reference	Detailed description
		- administrative patient data, - the personal expression of the patient.[6]
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	Same as above	The law allows the patient to include information or declaration in the RSC (e.g. whether or not they are willing to donate their organs) and administrative information on the patient. According to one interviewee of the Ministry of Health in Luxembourg they plan to add other type of information than purely restricted health data in the second or third phase of implementation, but this is still uncertain.
Is there a definition of EHR or patient's summary provided in the national legislation?		The legislation does not set such a generic definition of EHRS but only defines the RSC.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?	*Same as above*	The law sets an exhaustive list of types of information that can be included in the RSC: - Medical data in form of medical reports, test results, reports of diagnostic investigations, medical prescriptions, medical imaging or any document related to the health or therapeutic treatment of a patient - Prescriptions made in the field of bio-medical analysis, medical imaging and drugs and eventually the related results - The history and records of the care of certain health care services - Information or declarations made by the patient him/herself These are quite open categories. At the implementation phase Luxembourg plans to set more specific categories of health data in the system. .
Are there any specific rules on the use of a common terminology or coding system to identify diseases,		The law does not contain requirements on the use of common terminology or coding systems. Luxembourg is however working on that for the implementation phase.

[6] Le Dossier Soins Partagé un outil pour la qualité de vos soins, Minstere de la Sante et Ministère de la Sécurité Sociale sur la reforme de la sante, published 17 December 2010. Available February 2014 at : http://www.sante.public.lu/fr/dossiers/2010/reforme-sante/030-dossier-soins-partage/

Questions	Legal reference	Detailed description
disorders, symptoms and others?		
Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?		According to Article 60 quarter of the Law on the reform of the health system a Regulation must specify the conditions of level access taking into account the different categories of health professionals and the different categories of health data. However such Regulation has not yet been adopted in Luxembourg. According to the information leaflet, Luxembourg will set different access rule s for the different health professionals (e.g. pharmacists will mainly have access to medication issues)
Are there any specific rules on identification of patients in EHRs?		There are for the moment no specific rules on the identification of patients. Patient will have a card with a number and they will have to enter this number as a password. It is quite similar to a banking system.
Is there is a specific identification number for eHealth purposes?		There is one common unique identifier for identification of natural persons that are residents or have another link with Luxembourg public services. This unique identifier is identical to the social security number and is therefore also used in the healthcare domain. According to the law, the Agence eSanté is allowed to use that identifier within a national master patient index.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

Specific rules on the hosting and management of data from EHRs do not exist in Luxembourg. A European Public tender was launched in January to designate the company in charge of hosting data from the RSC but also to design the e-health platform in Luxembourg. It was won by a consortium of companies (Henri Tudor, l'éditeur de logiciel SQLI, Accenture Luxembourg, LuxTrust, Regify et ebrc). The consortium is applying the following security norms : Certifications ISO 27001 ISO 20000 (best practices on management of IT operations), and also PCI-DSS Level 1 (Payment Card Industry Data Security Standard), from the financial world to the medical sector.

A legal obligation to encrypt data is not yet mentioned in the legislation of Luxembourg but according to the e-health platform website the health data are encrypted when they are transmitted through electronic means from health professionals to the RSC.

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?		Such specific rules do not exist in Luxembourg. A European Public tender was launched in January to designate the company in charge of hosting data from the RSC but also to design the e-health platform in Luxembourg. It was won by a consortium of companies (Henri Tudor, l'éditeur de logiciel SQLI, Accenture Luxembourg, LuxTrust, Regify et ebrc). The consortium is applying the following security norms : Certifications ISO 27001 ISO 20000 (best practices on management of IT operations), and also PCI-DSS Level 1 (Payment Card Industry Data Security Standard), from the financial world to the medical sector. Note that the general rules from the transposing provisions of the Directive on data protection under the law on the treatment of personal data require the person in charge of the processing of data to set all adequate security measures to ensure the protection of data.
Is there a need for a specific authorisation or licence to host and process data from EHRs?		See above
Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?		See above
In particular, is there any obligation to have the information included in EHRs encrypted?		Such obligation is not yet mentioned in the legislation of Luxembourg but according to the e-health platform website the health data will be encrypted when they will be transmitted through electronic means from health professionals to the RSC.
Are there any specific auditing requirements for institutions hosting and processing EHRs?		No

2.3. Patient consent

2.3.1. Main findings

At the time of writing the legislation of Luxembourg does not contain any requirement on patient consent. Luxembourg however decided to adopt an opt-out consent approach for the creation of RSC and the processing of related health data. During the pilot phase, the consent from patients is needed to create a RSC. After the pilot phase a RSC will be created for all patients and patients will have the opportunity to opt-out. The decision to opt-out will need to be materialised (e.g. on a piece of paper). Patients will receive information about the RSC and its consequences.

The patient will be entitled to decide which health professionals can have access to the RSC. Furthermore each time a patient is in a therapeutic relationship *'relation therapeutique'* with a health professional he/she must consent on the access by this health professional to his/her RSC by giving a 'presence password' that ensures that the patient is with the health professional and accepted the access. No rules are envisaged related to the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member States. According to interviewees the patient can still give his/her password to a health practitioner or health institution outside of Luxembourg.

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?		Luxembourg decided to adopt an opt-out consent approach for the creation of RSC and processing of related health data but it is not yet reflected in the legislation of Luxembourg. During the pilot phase, the consent from patients is needed to create a RSC. After the pilot phase a RSC will be created for all patients and patients will have the opportunity to opt-out.
Is a materialised consent needed?		Only the decision to opt-out will need to be materialised (e.g. on a piece of paper)
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?		The current legislation in Luxembourg does not contain such information requirements. However, according to interviewees and the e-health platform website, patients will receive information about the RSC and its consequences.
Are there specific national rules on consent from the patient to share data?		The current legislation does not set such requirement. This will be further defined by the Regulation to be adopted under Article 60 quarter on the Law on the reform of the health system. According to interviewees and the e-health platform website the patient will be entitled to decide which health professionals can have access to the RSC. Furthermore each time a patient is in a therapeutic relationship *'relation therapeutique'* with a health professional he/she must consent on the access by this health professional to his/her RSC by giving a 'presence password' that ensures that the patient is with the health professional and accepted the access.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?	Code of Social Security as amended by Law on the reform of the health system 17 December 2010 Art. 60 quarter	Luxembourg decided to adopt an opt-out approach for the creation and processing of RSC as reflected in Article 60 quater of the Code of Social Security.
Are there any opt-in/opt-out rules for patient consent with regard to		Luxembourg decided to apply an opt-in approach for the patient consent with regard to the sharing of information from RSCs. The Patient must

Questions	Legal reference	Detailed description
sharing of EHRs?		consent each time he/she is in a therapeutic relationship with a health professional on the access to the EHRs by providing a 'presence password'. Such consent will also include the right by the health professional to update the RSC.
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?		The current legislation does not set such requirement. This may be further defined by the Regulation to be adopted under Article 60 quarter on the Law on the reform of the health system.
Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-border situations)?		The current legislation does not set such requirements. According to interviewees, in practice, the patient can give his/her password to a health practitioner or health institution outside of Luxembourg and by that, enabling him to access his file.
Are there specific rules on patient consent to share data on a cross-border situation?		The current legislation does not set such requirements. According to interviewees this could be clarified within the future Regulation after the pilot phase. There is currently a specific consent as required by epSOS framework agreement on the EU level. It has not been decided yet, whether or not to keep opt-in for cross-border.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

Since Luxembourg decided to apply an opt-out approach for the creation of the RSC, these e-health records will be created for all citizens of Luxembourg by the e-health agency of Luxembourg. The current legislation does not set detailed legal requirements on access and update to the RSC. The law on the reform of the health system only mentions that each patient has a right to access his/her RSC and that in respect of confidentiality the RSC is accessible only by the medical consultant, the regular doctor and other health professionals. Article 60 quarter of the Law on the reform of the health system provides that a Grand-Ducal Regulation must specify the procedure and conditions of access to RSCs.

According to the website of the eHealth Agency and interviewees there will be different categories of access for different health professionals. The medical consultant (*médecin referent*) will have access to all information in the RSC. Other health professionals will have access to restricted information in relation to their domain of expertise (e.g. pharmacists will have access to information related to medication, kinesitherapists will have access to medical imaging). The patient will be able to block access to the RSC to certain health professionals and hide documents to certain health professionals. Patients will have access to all RSC content with the exception of documents submitted prior to the announcement of a diagnostic. Luxembourg is also planning to allow patients to download RSC. Patient will be able to hide information from the RSC, but will not be able to modify and erase RSC content. In case of emergency and only in hospitals, RSC will be accessed without the prior consent of the patient. The patient can however decide to reject this 'by default' exception. The patient and the consultant medical will be able to trace all actions and access to the RSCs. Such right is not yet included in the legislation.

There is no identification code system for cross-border healthcare purposes and no measures exist to consider access to EHRs from health professionals in another Member State. However Luxembourg is starting to cooperate with neighbouring regions to develop exchange of health data in order to ensure continuity of care

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?		Since Luxembourg decided to apply an opt-out approach for the creation of the RSC, these e-health records will be created for all citizens of Luxembourg by the e-health agency of Luxembourg. Therefore such question is not relevant for Luxembourg.
Are there specific national rules on access and update to EHRs?		The current legislation does not set such requirement. This will be further defined by the Regulation to be adopted under Article 60 quarter on the Law on the reform of the health system that must specify the procedure and conditions of access to RSCs.
Are there different categories of access for different health professionals?		According to the website of the eHealth Agency and interviewees there will be different categories of access for different health professionals. - The medical consultant (*médecin referent*) will have access to all information in the RSC - Other health professionals will have access to restricted information in relation to their domain of expertise (e.g. pharmacists will have access to information related to medication, kinesitherapists will have access to medical imaging) Note that the patient can block access to the RSC to certain health professionals and can hide documents to certain health professionals.
Are patients entitled to access their EHRs?	Law on the reform of the health system 17 December 2010 Art. 60 quarter point 4	The law on the reform of the health systems provides that each patient has a right to access his/her RSC.
Can patient have access to all of EHR content?		According to the website of the eHealth Agency and interviewees patient have access to all RSC content with the exception of documents submitted prior to the announcement of a diagnostic.
Can patient download all or some of EHR content?		Such requirement is not yet mentioned in the law but Luxembourg is planning to allow patient to download EHR content.
Can patient update their record, modify and erase EHR content?		Patient will be able to hide information from the RSC, but will not be able to modify and erase EHR content.
Do different types of health		Health professional have the same right to update EHRs

Questions	Legal reference	Detailed description
professionals have the same rights to update EHRs?		
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		The law on the reform of the health systems provides that in respect of confidentiality the RSC is accessible only by the medical consultant, the regular doctor and other health professionals. Therefore insurance companies will not have access to the RSC. According to the eHealth Agency website, the occupational doctors will not have access to the RSC nor insurance companies since access is restricted to health professionals
Are there exceptions to the access requirements (e.g. in case of emergency)?		In case of emergency and only in hospitals, RSC can be accessed without the prior consent of the patient. The patient can however decide to reject this 'by default' exception.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		This is being discussed at the moment. They should be identified through the national register of health professionals.
Does the patient have the right to know who has accessed to his/her EHRs?		According to the eHealth Agency website the patient and the consultant medical will be able to trace all actions and access on the RSCs. Such right is not yet included in the legislation.
Is there an obligation on health professionals to update EHRs?		Luxembourg plans not to set obligation on health professionals to update EHRs
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?		In practice clerks will access the RSC on behalf of doctors but doctors will still be responsible for this access. At hospitals this is not clearly decided yet.
Is there in place an identification code system for cross-border healthcare purpose?		No
Are there any measures that consider access to EHRs from health professionals in another Member State?		No

2.5. Liability

2.5.1. Main findings

General medical liability rules or the sanctioning regime set under the law on the protection of personal data (e.g. secondary use of health data, technical measures to secure data protection) apply to RSCs. Luxembourg is not planning to adopt specific rules for EHRs. The general sanction regime related to personal data under the law on data protection applies in case hosting institutions of health data do not set the adequate technical measures to ensure the security and confidentiality of these data. There are no specific liability rules concerning the breach of access to RSCs. However, the law on data protection sets some sanctions in case of infringement to the provisions related to the right of access to personal data (e.g. by using fake names).

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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 general liability rules apply in the case of EHRs. Luxembourg is not planning to adopt specific rules for EHRs.
Can patients be held liable for erasing key medical information in EHRs?		There is no such reference in the law. According to interviewees it is not foreseen in the future legal framework as the RSC should be seen as a complementary tool that will not replace EHRs.
Can physicians be held liable because of input errors?		According to interviewees the general principles of medical liability apply.
Can physicians be held liable because they have erased data from the EHRs?		According to interviewees the general principles of medical liability apply.
Are hosting institutions liable in case of defect of their security/software systems?	Law on data protection as amended in July 2007 Art.25	According to the law on data protection persons in charge of the treatment of personal data can be held liable if they do not set adequate technical measures to protect personal data. Such infringement can lead to the following criminal sanctions: Fines from 251 EUR to 125 000 EUR and/or imprisonment from eight days to sixth months and the prohibition to process these data.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		No
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Law on data protection as amended in July 2007 Art.28(7) Criminal Code	No there are no specific liability rules concerning the breach of access to RSCs. However, according to the law on data protection whosoever breaches provisions related to the right of access to personal data (e.g. by using fake names) can be imposed the following criminal sanctions: Fines from 251 EUR to 125 000 EUR and/or imprisonment from eight days to sixth months and the prohibition to process these data. The Criminal Code contains criminal sanctions for the infringement of

Questions	Legal reference	Detailed description
	Art.458 and Art 509-1 to 509-7	the non-disclosure of information obligation from health professionals and for the offence of intrusion in an IT system.
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		No
Are there liability rules related to the misuse of secondary use of health data?	Law on data protection as amended in July 2007 Art.7	The law on data protection set some rules on the processing of health data for secondary purposes in general but not specifically to electronic health records. The infringement to the rules setting conditions to the secondary use of health data can lead to the following sanctions: Fines from 251 EUR to 125 000 EUR and/or imprisonment from eight days to sixth months and the prohibition to process these data.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

On archiving duration Luxembourg is planning to set a 10 years archiving duration from the closure of RSC. However discussions are on-going with regard to the prescription period in case of medical accidents. Based on information gathered through interviews the RSCs after the archiving duration would be destroyed.

Concerning the secondary use of health data from RSCs, the e-Health Agency, the Health Ministry, the National Health Laboratory, the General Inspectorate of Social Security and the National Health Fund, are entitled to exchange using automatic procedures or not, anonymised information for statistical or epidemiological purposes. There is no opt-in/opt-out patient consent requirement for the secondary uses of health data included in RSCs.

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?		This is not yet decided but Luxembourg is planning to set a 10 years archiving duration from the closure of RSC. However discussions are on-going with regard to the prescription period in case of medical accidents.
Are there different archiving rules for different providers and institutions?		No
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?		Based on information gathered through interviews the EHRs after the archiving duration would be destroyed. This is not yet decided.
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?		No
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Law on the reform of the health system 17 December 2010 Art. 60 quarter point 5	The e-Health Agency, the Health Ministry, the National Health Laboratory, the General Inspectorate of Social Security and the National Health Fund, exchange using automatic procedures or not, anonymised information for statistical or epidemiological purposes. Not that the law on the protection of personal data sets also some general rules on the secondary use of health data:
Are there health data that cannot be used for secondary use?		No
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 the reform of the health system 17 December 2010 Art. 60 quarter point 5	The exchange of information must be anonymised.
Does the law say who will be entitled to use and access this data?	Law on the reform of the health system 17 December 2010 Art. 60 quarter point 5	The e-Health Agency, the Health Ministry , the National Health Laboratory, the General Inspectorate of Social Security and the National Health Fund are entitled to exchange using automatic procedures or not, anonymised information from RSCs for statistical or epidemiological

Questions	Legal reference	Detailed description
		purposes.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?		No

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

There is no obligation in the law to develop interoperability of EHRs. Luxembourg is providing support to health professionals to update their software to be interoperable with the e-Health Agency Platform. They decided to set a unique national RSC to avoid interoperability issues. The Law on the reform of the health system requires that a Grand-Ducal Regulation should develop the conditions for the cooperation and cross-border transfer of data to the relevant authorities in another Member State of the EU or part of the EEA.

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?		Note that Luxembourg is providing support to health professionals to update their software to be interoperable with the e-Health Agency Plateform. They decided to set a unique national RSC to avoid interoperability issues.
Are there any specific rules/standards on the interoperability of EHR?		The law does not refer to any specific standards for interoperability
Does the law consider or refer to interoperability issues with other Member States systems?	Law on the reform of the health system 17 December 2010 Art. 60 quarter point 2	The Law on the reform of the health system requires that a Grand-Ducal Regulation should develop the conditions for the cooperation and cross-border transfer of data to the relevant authorities in another Member State of the EU or part of the EEA.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The legislation in Luxembourg does not include any references to ePrescriptions and to the links between ePrescriptions and RSCs. However Luxembourg plans to integrate or use the RSC to develop ePrescriptions. Health professionals when granted access by the patient will be entitled to include prescriptions (drugs, tests, images) in the RSC. Pharmacists or other health professionals entitled by the patient will access to the prescription through the RSC.

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?		The ePrescription will be a service included in the RSC
Can an ePrescription be prescribed to a patient who does not have an EHR?		It will be necessary to have an RSC.

- ***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?		It will be a prerequisite to have access to the RSC to do the ePrescription
Can those health professionals write ePrescriptions without having access to EHRs?		It will be a prerequisite to have access to the RSC to do the ePrescription

2.9. Other requirements

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

All interviewees outlined that it is difficult to identify legal barriers and good practices in Luxembourg, since the system is only being tested and detailed legal requirements on EHRs have not yet been adopted.

- *Good practices*

They all considered that the opt-out consent approach for the creation of EHRs was the best manner to deploy EHR systems but it should be accompanied by a strong and widespread information campaign for patients and doctors.

They all considered as a good practice to implement a pilot system first in order to test what would be the adequate rules for an efficient functioning of the system and then to adopt the legal requirements based on the outcomes of the pilot phase.

All interviewees stressed that the State semestrial remuneration of the medical consultant (*médecin referent*) for updating the RSC is a good financial incentive to involve doctors in the new system and to ensure their participation[7]. The representative of the eHealth Agency[8] however flagged that an efficient system that improves the situation of health professionals does not the remuneration of physicians.

The representative of the Health Ministry[9] considered that the adoption of specific liability rules for EHRs was not needed. He justified that the general principles of medical liability did not have to be changed each time there was a technical progress.

All interviewees underlined that in order to enhance the confidence of patients on the system, they should be empowered to control access EHRs like in the RSC system. However the representative of the e-Health Agency flagged that if too many rights are given to the patient this may lead to the lack of confidence of health professionals to use and update EHRs. He stressed that health professionals should remain the main actors of EHRs.

The representative of the Ministry of Health underlined that a key for the success of the development of EHRs systems is to involve all partners at the start of the project (e.g. industry, doctors, patients, hospitals). He also stressed that the RSC should only be seen as a complementary tool that would not replace the health records in hospitals and in doctor offices.

On health data to be included in RSC the representative of the doctors association[10] stressed that the patient consumption of medicines should appear in the RSC only for patient health benefit but not with the purpose to trace the patient consumption in view of limiting the cost of health care or any other goal not related to the patient.

The representative of the doctor association underlined that in order to give confidence to patients they should be informed on the secondary use of health data.

All interviewees highlighted the need to achieve as a prerequisite the uniformisation of medical terminology standards prior to developing cross-border transfer of health data.

[7] Note that at the time of writing the semestrial remuneration only applies to the 'patient summary' that must be filled by the medical consultant (*médecin referent*)
[8] Interview was held on 27 March 2014.
[9] Interview was held on 19 February 2014
[10] Interview was held on 6 March 2014

- *Legal barriers*

The representative of the eHealth Agency mentioned that a legislation that sets too detailed requirements related to the content of EHRs is counterproductive as it may then not be comprehensive enough. He suggested that the law should remain quite vague and that the definition of health data should be done through practice in a more flexible manner.

The representative of doctors association highlighted that the opt-in approach for the creation of EHRs would put too much administrative burden on doctors.

He stressed that currently in Luxembourg research institutes use health data that are not anonymised and that they only have the obligation to render this data anonymised when they publish their results. He suggested that health data should be anonymised by a trusted third party prior to being used by research institutes.

With regard to the cross-border transfer of health data the representative of the eHealth Agency mentioned that the lack of harmonised rules on the identification of patients and identification of health professionals in a cross border situation was the main barrier to the cross-border transfer of health data within the EU.