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eSanté
EFES

Report WP10-1

Concept paper on a national EHR

eSanté team

Version **1.1**

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Customer

Project	Analyses et études de faisabilité pour l'eSanté – eSanté-EFES	
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CR SANTEC

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Objective of the Document

This document analyzes the EHR concepts and relative standards and provides some recommendations for the eSanté platform.

Change History

Version	Date	Author	Modification
0.01	09/08/2010	Fwi	Initial Document
0.02	27/09/2010	Fwi	TOC
0.14	11/11/2010	Fwi	Review of MDS comments
0.20	26/11/2010	Fwi	Version for first external review
0.23	07/01/2011	Fwi	Version for second external review
0.95	14/01/2011	RK	Draft diffusion to health professional
0.96	18/01/2011	Fwi	Review
0.97	21/01/2011	FWI	Optic analogy
0.98	03/03/2011	DMa	Gramatical review
1.0	20/04/2011	FWI	Integration of comment of RK, JCD and FB
1.1	27/04/2011	FWI	Some figures were missing

Table of content

Figures and Tables

1. EXECUTIVE SUMMARY

The aim of this document is to regroup, analyze and infer information related to EHR needs that have been identified during the first phase of the eSanté-EFES project. This work allows us to recommend the content, concept, technical architecture and major standards for an EHR hosted on the eHealth platform in Luxembourg.

In the context of the continuity of care, the eSanté team considers that Luxembourg should focus on an integrated Care EHR managed by a special health provider (e.g. a family doctor) and monitored by the patient.
The creation of the "**médecin référent**" is a good opportunity to assign responsibility for managing this EHR. The goal is to provide on one hand a shared environment between health providers (physicians, pharmacist, labs, long-term care …) authorized by the patient and on the other hand, in a sub part, a PHR to give the opportunity to the patient to supply the EHR with his own data. The patient provides access and rights to his record for his health providers or, if he wants, he can delegate these actions to his "médecin référent" or to a trusted third person (parents, children ...). If the patient does not specify special rights to his EHR, health providers' rights are those defined by default in a **habilitation matrix**.

This EHR will be longitudinal with data from various institutions and health providers, focused only on a set of data useful for the continuity of care. Based on (1) a list of current health related documents exchanged between health care providers, (2) the needs of exchange currently not covered and (3) the forecast of future active participation of the patient in the management of his health, the eSante team has proposed a list of document types that will help define the EHR content.

This list is a starting point for a dialog with user stakeholder groups (Physician, nurse, pharmacist …). The content of the EHR will evolve in time based on the needs of users in order to improve it. The generation, semi-automatically, of a Patient Summary will provide to all health providers the essential information needed for health care coordination, both for expected as well as unexpected, care. Its generation is an extract of document types selected and organized into a standardized backbone based on the "médecin référent". The added value of the "médecin référent" in this approach is to provide a medical sense to this data accumulation. He can, for example, link exams to a problem or determine which problems are active or passive. In order to get a holistic view of the patient's health, it is essential that all health providers participate and feed the EHR by sending their reports to the platform.

The selected EHR architecture for the platform should enable the EHR system of health providers to display three EHR views - time-oriented, problem-oriented, source-oriented - and enable a role based display according to the categorie of HCP, like a special for the médecin referent or for cancer patients[1].. The EuroRec Institute developed functional quality criteria that could be used to build a functional specification report for the EHR of the platform. The criteria of the EuroRec Seal in addition with national specific requirements could be used to certify the EHR systems of healthcare provider.

For the implementation of an EHR standard, the eSante team suggest the pragmatic approach outlined in the IHE integration profiles, and specifically the use of "Cross Entreprise Document Sharing" (XDS) in combination with the document standard Clinical Document Architecture (CDA) from the HL7 International, which shows the most impressive adoption in Europe and USA. Before creating a comprehensive EHR, it is recommended to continue the stepwise approach of eSanté with medical based projects in addition to the

[1] For instance in the French region Franche-Comté, the "Dossier communicant de cancerologie" is implemented as a special view on the patient record. This view is only accessible for specific HCPs.

current functional projects CARA and LABO. The content of each document can be based on the work of the IHE and adapted to national needs in the framework of a user stakeholder group.

2. GLOSSARY OF TERM

Wherever hyperlinks are provided in the text you can jump directly to the glossary entry with a simple click in the PDF document, or using Control + LeftClick in MS-Word. Alt + ← brings you back to the starting position.

Term	Description
Accreditation	Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks
American Health Information Management Association	The American Health Information Management Association (AHIMA) is the premier association of health information management (HIM) professionals. AHIMA's more than 61,000 members are dedicated to the effective management of personal health information required to deliver quality healthcare to the public. Founded in 1928 to improve the quality of medical records, AHIMA is committed to advancing the HIM profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning.
American Society for Testing and Materials	ASTM was founded in 1898 and chartered in 1902 as a scientific and technical organization for the development of standards on characteristics and performance of materials. ASTM is the largest non-government source of standards in the USA comprised of over 130 committees that publishe 10,000 standards annually.
Archetype model	information model of the metadata to represent the domain-specific characteristics of electronic health record entries by specifying values or value constraints for classes and attributes in the electronic health record reference model
Certification	Procedure by which a third party gives assurance that all or part of a data processing system conforms to specific requirements
Clinical Document Architecture	The CDA is a document markup standard that specifies the structure and semantics of clinical documents. A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content.
Cross Entreprise Document Sharing	IHE integration profile XDS "Cross Enterprise Document Sharing" - registers and shares electronic health record documents between healthcare enterprises, ranging from physician offices to clinics to acute care in-patient facilities
Digital Agenda	The Digital Agenda is Europe's strategy for a flourishing digital economy by 2020. It outlines policies and actions to maximise the benefit of the Digital Revolution for all.
eSanté platform	The overall IT system that delivers the services and functions described in this series of use cases. Its main purpose is to store medical data related to patients in the Luxemburgish health care system, and to facilitate the secure and controlled exchange of data among its different actors.
EuroRec Institute	The EUROREC Institute (EuroRec) is an independent not-for-profit organisation, promoting in Europe the use of high quality Electronic Health Record systems (EHRs). One of its main missions is to support,

Term	Description
	as the European certification body, EHRs quality labelling and defining functional and other criteria.
EuroRec Seal	EuroRec also defined, using a consistent cross-border approach, minimal quality criteria to be met by each application handling patient and care related data: the EuroRec Seals.
Habilitation matrix	a structure that defines basic health care provider access rights based on the categories of profession
Health Care Provider (HCP)	Professionals that are working in the health care sector, such as doctors, nurses, medical assistants, Samu, etc. Depending on the role they play in a use case they are sometimes referred to as "Médecin référent", prescriber, laboratory, specialist, data consumers, data receivers, etc.
HL7 International	A standards developing organization based in the United States of America.
IHE integration profiles	IHE Integration Profiles describe the solution to a specific integration problem, and document the system roles (Actors), standards and design details for implementers to develop systems that cooperate to address that problem. IHE Profiles are a convenient way for implementers and users to be sure they're talking about the same solution without having to restate the many technical details that ensure actual interoperability.
Meaningful use	The meaningful use is set of performance requirements implemented in USA by to benefit Medicare and Medicaid EHR Incentives
Médecin référent	A physician who has a special trust relationship with a patient. In the eSanté platform the reference doctor has special privileges and functions in respect with his patients' medical data such as: • having a privileged access to his patient's medical data record • sharing his patient's medical data with other HCPs in agreement with the patient He also happens to be the principal prescriber of most of the patient's tests.
Object-oriented representation	The basic concept in this approach is that of objects, which consist of data structures encapsulated with a set of routines, often called "methods" which operate on the data. Operations on the data must be performed via these methods, which are common to all instances of objects of a particular class. Thus, the interface to objects is well defined, and allows the code implementing the methods to be changed so long as the interface remains the same
Reference Information Model	The HL7 information model from which all other information models and messages are derived.
XML	XML (Extensible Mark-up Language) is a mark-up language for structuring arbitrary data based on element tags and attributes.
XSL transformations	Stylesheet Language that can be used for displaying XML documents. XSL Transformation (XSLT) is used to transform the XML document.

3. INTRODUCTION

At the end of 2006, the Luxembourgish government had adopted a national eHealth plan, elaborated by a working group with stakeholders from the health sector. The action plan recommends the realization of a telematic platform with different applications to favor the exchange and sharing of health related data.
In order to implement the eHealth plan, the Ministry of Health created the eSanté program. The objectives of the eSanté program are to:

- Improve the quality and the performance of health care by providing health providers with better access to medical data;
- Propose features to allow the exchange or sharing of medical data between healthcare professionals;
- Promote the transparency of healthcare services, by offering the necessary information to patients and to healthcare professionals;
- Assure the interoperability of the health system with those of other European countries in order to guarantee better care for mobile patients and to facilitate the mutual exchange of medical expertise.

As part of the eSanté program, the eSanté-EFES project has been implemented in two phases: The analysis of the current state and the identification of healthcare professionals' needs; the proposition of concepts to satisfy these needs. The first phase of the eSanté-EFES project has:

- analyzed the current situation of the healthcare sector in order to get knowledge about the current use of IT in the sector,
- determined the existing relationships between the different actors,
- Identified the current exchange of data between the actors,
- Identified further needs with respect to the exchange and sharing of health related data.

The results carried out in the first phase of the project are publically available in http://www.santec.lu/project/esante/efes/start

These results have been used in the second phase for specifying an EHR architecture, and for defining potential exchanges between health providers, healthcare institutions, governmental departments and others services providers. New solutions will be proposed to facilitate the exchange and sharing of medical data and to reduce administrative procedures and costs.

The eSanté platform is the technical and organizational infrastructure which will be put in place by the Luxemburgish healthcare authorities in order to support the secure exchange and sharing of health data in Luxembourg.
Two communication services are developed in the platform for the exchange of heath data:

- The "exchange of heath data service" is a kind of messaging services between health providers and it is used when an intended recipient of a information is clearly and unambiguously known. The service is receiver centric in the sense that the receiver gets first a list of documents send to him. The data will be deleted from the platform after consultation, unless they are used as well for the sharing service.
- The "sharing of heath data service" where by a patient accepts to have some of his data stored in the platform in order to share this data with health providers, which will facilitate the continuity of care. This service is patient centric in a sense that the user first sees the data available for a certain patient.

This document focus only on this second service: the sharing of heath data service in an EHR[2].

[2] Documents concerning the exchange of laboratory report and medical image report are available respectively on: http://www.santec.lu/project/esante/labo/start and http://www.santec.lu/project/esante/cara/start

4. GOALS

The goal of this document is to regroup, analyze and infer information related to EHR needs, which were identified during the first phase of the eSanté-EFES project. A literature review is presented to complement our analysis and to describe various concepts of EHR. Then, based on the *matrix of document exchange*, we list medical information needs, by categories of actor, and then propose a list of information to be considered during the definition of the EHR content. Finally, some recommendations related to the EHR structure and standards are presented.

5. LITERATURE OVERVIEW ON THE BENEFITS, COSTS, NEEDS AND USERS OF AN EHR

5.1. EHR COST-BENEFIT SHORT REVIEW OF THE LITERATURE

Before introducing an EHR in detail, it is useful to quickly remind the reader of the benefits of having an EHR.

Recent reviews of the literature find a set of high quality studies showing that Health Informatic Technology and specifically EHR systems improves the quality of care by increasing adherence to guidelines, enhancing disease surveillance, and decreasing medication errors[3]. Balfour[4] observed most absolute increases concerning improvements in the quality of care range from 12% to 20%. Coordination of care is one of the main benefits proposed by EHRs, particularly for individuals with chronic conditions or with multiple comorbidities. Enhanced primary and secondary preventive health care delivery has been examined in studies by Chaudhry[5], like influenza vaccination (12 to 18%), pneumococcal vaccinations (20 to 33%) and fecal occult blood testing (12 to 33%). EHR technology also enables better patient education, legal and regulatory compliance, decreases in adverse drug events, and provides a better ability to conduct research and business relationships.

The implementation of an EHR system requires substantial capital investments and organizational change. Costs identified include initial and ongoing costs for hardware, software, licensing, information systems staffing, external contractor services, installation, workflow process redesign, training and support of users, temporary reduction in staff productivity, and telecommunications. One 2001 study[6] estimates the ambulatory setting average of $10–$20K per provider for an EHR installation.

Among limited empirical studies measuring cost data, these reviews found some positive economic values for broadly functional EHR Systems. Money is saved by improvement such as a decrease in billing errors, increases in the productivity, reducing transcription and paper supply costs, transport of information costs, lower space requirements and enhancing revenue from higher payments for increased levels of coding for visits and health maintenance reminders. Thanks to less paper burden, the use of EHR reduced office visit times by 13%, creating additional time during the patient encounter to deliver care or to see another patient[7]. Another positive value is the decreased rates of health services utilization, specifically radiology tests and laboratory measurements[8]. According to the studies examined by Balfour[9], benefits provided by an EHR system overcome initial and ongoing costs in an average time of 2.5 years with a profit realized soon after.

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[3] Shekelle PG, Morton SC, Keeler EB. Costs and benefits of health information technology. Evidence Report/Technology Assessment (Full Rep). 2006 Apr;(132):1-71.
[4] Balfour, D.C. et al. Health information technology - results from a roundtable discussion. *Journal of managed care pharmacy JMCP* 15, 10-17 (2009).
[5] Chaudhry B et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med. 2006 May 16;144(10):742-52. Epub 2006 Apr 11.
[6] Carter, J., Electronic Health Records: A guide for Clinicians and Administrators, Philadelphia, PA,American College of Physicians, 2001.
[7] Menachemi N, Brooks RG. Reviewing the benefits and costs of electronic health records and associated patient safety technologies. Journal of Medical Systems 2006 Jun;30(3):159-68.
[8] Balfour, D.C. et al. Health information technology - results from a roundtable discussion. *Journal of managed care pharmacy JMCP* 15, 10-17 (2009).
[9] Balfour, D.C. et al. Health information technology - results from a roundtable discussion. *Journal of managed care pharmacy JMCP* 15, 10-17 (2009).

5.2. Overview of needs and expectations from the Health Professionals

Existing studies examined end user needs and expectations of the EHR system. The Professionals and Citizens Network for Integrated Care (PICNIC) project[10] listed its general features:

- Around-the-clock availability;
- Provision of fast responses even at high workload periods;
- Restricted access to information;
- Maintainability;
- Low usage cost;
- Role-based access to information;
- Secure communication of information;
- Activity monitoring;
- Access to reliable and up-to-date information;
- Support for native user interface;
- Support direct access to multimedia clinical data communication;
- Scalability;
- Support for standardized reference vocabularies;
- Functional and customizable user interfaces;
- High availability.

5.3. Users of the EHR system

However, the usage of an EHR system is not the same for all users. Each category of user has his own view of the EHR; they do not look at the same set of data and they may use different functionalities for visualization or usage of the EHR.

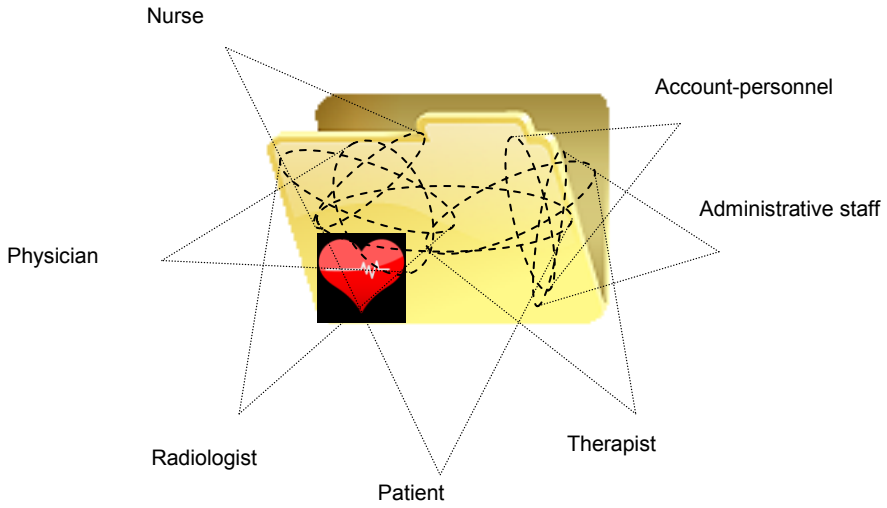

Figure 1 : View of the EHR by each category of player

[10] Professionals and Citizens Network for Integrated Care, Regional Health Economies and ICT Services: The PICNIC Experience. N. Saranummi, D. Piggott, D. G. Katehakis, M. Tsiknakis, and K. Bernstein, eds. Amsterdam, The Netherlands:IOS Press, August 2005

Häyrinen[11] examined the usage of EHR components by various healthcare professional categories and administrative staff. The Table 1 introduces the results of this study.

User	Component of EHR
Nurse	Daily charting; medication administration; physical assessment; admission nursing note; nursing care plan
Physician	Referral; present complaint, e.g. symptoms; past medical history; life style; physical examination; diagnoses; tests; procedures; treatment; medication; discharge
Patient	History ; diaries ; test
Parents	History
Secretarial staff	Procedures; problems diagnoses; findings; immunization
Pharmacists	Medication
Multiprofessional: physician, nurse, radiology staff, laboratory staff, healthcare professional, clerk or administrative staff	Referral; present complaint, e.g. symptoms; past medical; history; life style; physical examination; diagnoses; tests; procedures; treatment; medication; discharge; admission nursing note; daily charting
Pharmacy personnel	Administration of medication ;

Table 1 : Users of EHR systems and data components studied (Source: Häyrinen, 2008)

[11] Häyrinen K. et al, Definition, structure, content, use and impacts of electronic health records: A review of the research literature, international journal of medical informatics 77 (2008) 291–304

6. NEEDS AND USES OF AN EHR IN LUXEMBOURG

Currently there is no implementation of an integrated EHR in Luxembourg. The usage of EHR is limited to EMR in liberal practice, in hospitals and long-term facilities.

6.1. CURRENT USAGES OF THE EHR IN LUXEMBOURG

The eSanté team established in 2009 (as presented in the report 1.2 of the eSanté-EFES project) the usage of EHR systems in liberal practice by the physician. The most used features of practice software are to read and store encounter notes, to display lab tests and medical images, to edit and encode diagnostics in prescription and reports, and to write their letters. The Figure 2 shows the usage of this EHR system by the administrative and the medical staff of a general practitioner office in Luxembourg in 2009.

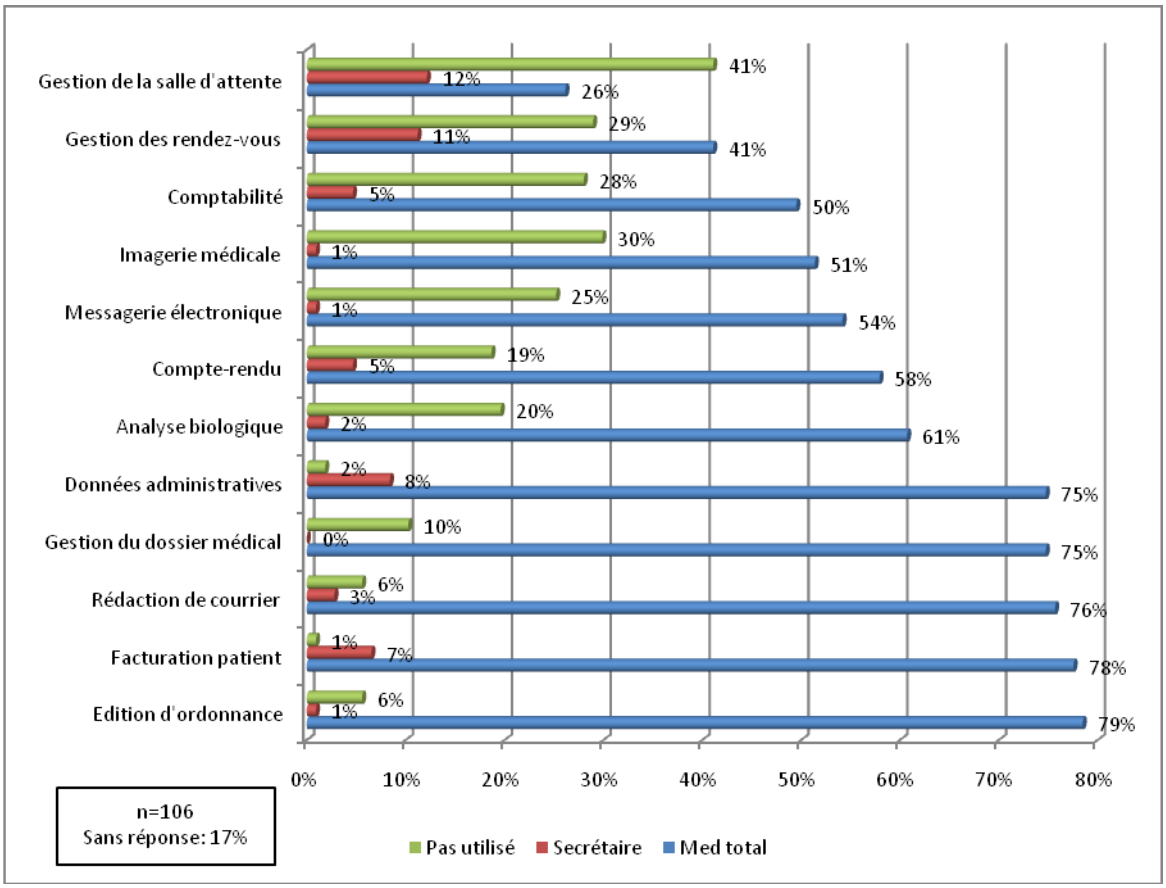

Figure 2 : Features used by the staff of a general practitioner's office in 2009 (eSanté-EFES)

This work was continued with the analysis of the needs for exchanging medical data in Luxembourg (presented in the report 3.3 of the study eSanté-EFES). The eSanté team interviewed representatives of actors (physician, pharmacist, physiotherapist, long-term care sector…). All actors were asked to:

- Share medical data in a patient summary
- Use secured e-mails
- Check affiliation of the patient with the Caisse Nationale de Santé

Physicians have been more precise and asked to share medical data on:

- Allergy medication
- Prescribed medicines
- Medical images and their reports
- Discharge letters from hospitals

- Lab tests and reports

As a fundamental principle, the continuity of care requires that health professionals share work paths and exchange information about and with patients at appropriate points in the care or treatment process. Report 3.2 of the eSanté-EFES project analyzed the current exchange of medical data in Luxembourg, and delivered a matrix of documents exchanged. This matrix, presented in Table 2 has been slightly modified to add the interaction of the patient and data from labs and pharmacies. Home care and long-term care facilities have been also merged together. Doctors' specialists and GPs are also merged.

	First line care				**Second line care**	**Third line care**	**Patient**
	Doctor	Pharmacy	Labo	SAMU	Hospital	Home care & long-term care	
Doctor	Full CPR[12],	DGTP	DGTP	Letter if on place	DGTP	Filling of the medical file of the Long stay establishment	Prescription, Admission letter Medical letter Medical report Care prescription Medical report for the care team
Pharmacy	-	-	-	-	-	-	-
Labo	Lab report	-	Lab report	-	-	-	Lab report (if claim)
SAMU	-	-	-	-	Transfer sheet	-	-
Hôpital	DGTP	DGTP	DGTP	N/A	Transfer sheet, Medical letter	Transfer sheet, Medical letter for the care team, Care prescription	Prescription Discharge letter, Encounter notes, Operation report, examen report
Home care & long-term care	Nurse care demand, Health status evolution information, Access on place to the nurse care record	Prescription	Prescription	Access on place to the nurse care record, Transfer sheet	Transfer sheet	Transfer sheet	-
Patient	Medical letter, Medical report , Discharge letter, Encounter notes, Operation report, Examen report	Prescription	Prescription	-	Prescription, Admission letter	Care prescription Medical report for the care team	-

DGTP: Documents given to the patient

Table 2 : Matrix of current document exchanged (the sender is in the first column)

6.2. POTENTIAL CONTENT FOR AN EHR IN LUXEMBOURG

In the framework of the continuity of care, we examine now this matrix in order to list current exchanges that could be part of our national EHR (Table 3). In addition, based on the needs expressed by health professionals, we add in green to this table exchanges not currently exchanged but expected to be included in the national EHR. The patient is currently considered as an indirect source of information. With the setting up of the eSanté platform, the role of patients may change and an active participation to the management or completeness of their medical data may be possible through specific services developed for them (e.g., patient consent, data visualization, data export/import, etc.).

[12] In case of doctor change (retirement, moving …)

Categories of actors	Potential document **electronically transferred** trough the eSanté platform	Potential documents **shared** in the national EHR of the eSanté platform
Doctor	Prescription, Admission letter, Medical letter, Medical report, Care prescription, Medical report for the care team	Allergies
Pharmacy	-	Delivered medication
Labo	-	Lab reports
Physiotherapist	-	Report (Bilan)
Hôpital	Prescription, Transfer sheet, Medical letter for the care team, Care prescription,	Discharge letter, Encounter notes, Operation report, Exam report, Dispensed medication
Home care & long-term care facilities	Prescription, Transfer sheet	-
Patient	-	Computerized diaries (Medication, auto medication, small diseases, food intake…), End of life wish, Organ donation declaration

Table 3: Set of document types potentially exchanged through the platform or stored in the national EHR by each category of actor in Luxembourg

This base for EHR, also illustrated in Figure 3, needs to be reviewed with a user stakeholder group (Physician, nurse, pharmacist …) in order to work on the specific content in the context of the continuity of care. The **content of the EHR will evolve in time** based on the needs of users in order to improve it.

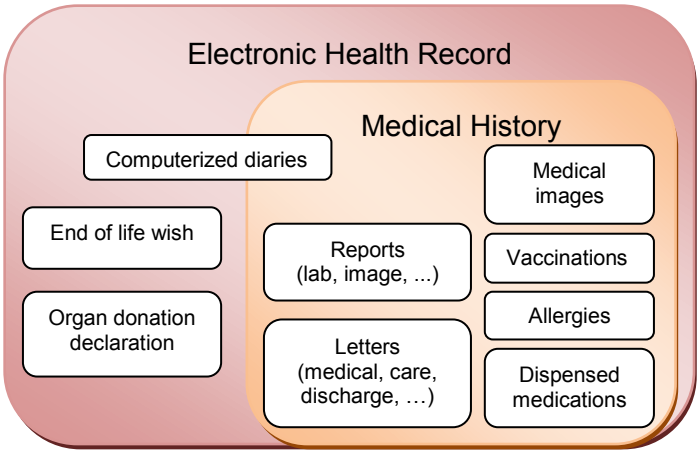

Figure 3: Document types stored in the national EHR

The AHIMA (American Health Information Management Association) worked on the precise content of EHR[13]. For information, a copy of their work is available in ANNEX 1. The ASTM (American Society for Testing and Materials) has even made a standard[14]: the Standard Practice for Content and Structure of the Electronic Health Record (EHR) - ASTM E1384 – 07.

The eSanté team did not investigate at this level; a working group of users is needed to elaborate this data list. Nevertheless, we can at least remind one result of the eSanté-EFES report 2.2 concerning the medication part contained in an EHR.

The minimum dataset for a medication description in the EHR should be:

- Date of the prescription
- Name of the medicine, dose and form
- Route of administration
- Dose per intake and for a period (24h)
- Rhythm or the schedules of the administration;
- Duration of treatment, when known in advance or fixed by regulations.
- For the injectable, the modalities of dilution, the speed and the duration of infusion
- For the inpatient prescriptions, the identification of the care unit.

The EHR has to be linked to the national medicine database (or other scientific medicine database) in order to provide information on the medicine to health providers.

Note: IHE started in 2009 the pharmacy domain and defined five integration profiles in trial for prescription and dispensation. The vendors are asked to test these profiles for the connecthaton of Pisa in 2011.

At the European level, the Digital Agenda[15], as part of the “EU2020” approach and strategy, proposes in Key Action 14 a recommendation defining a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012. This minimum common set of patient data is expected to be a patient summary (See 7.2.1).

[13] http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_034460.hcsp?dDocName=bok1_034460
[14] http://www.astm.org/Standards/E1384.htm
15 European Commission: A Digital Agenda for Europe. Brussels, 19.05.2010, COM(2010), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0245:EN:NOT

7. ELECTRONIC HEALTH RECORD - EHR

7.1. PURPOSE OF A HEALTH RECORD

Before defining the various concepts of the electronic version of the health record, it is useful to remind the reader of the general purpose of having available information about patients.

7.1.1. **Continuity of care**

Health record is one means to communicate the health information of a patient between health professionals and is considered the pillar of the coordination of care. It is also specifically useful in the absence of a regular health provider or for unplanned care. The findings of each professional must be available for others to perform their work efficiently, especially the doctor responsible for the patient who must make the final diagnosis and order treatment on the basis of all the documented findings.

7.1.2. **Medical-legal**

In the case of court action in civil or penal trial, health records represent a collection of time stamped evidence of a patient's condition, history and diagnosis. The content of the health record protects the legal interests of the patient, hospital, and health professional. It is used by both to assess the extent of injury in accident cases and to establish (or not) negligence by the health professional or hospital in the treatment of a patient.

7.1.3. **Statistical**

Statistics are collected for public health or epidemiology and in order to plan activities. A shared EHR can also be used by providers to self-assess their professional practices.

7.1.4. **Research and education**

Demographic and epidemiological data inside health records are useful in medical research and for training healthcare professionals.

7.1.5. **Historical**

The record acts as an archive of the type of care and method of treatment used at a particular point in time.

The scope of this document is to cover the needs of continuity of care, but the results reached can also be useful for the others purposes.

7.2. SYNTHESIS OF VARIOUS ELECTRONIC HEALTH RECORD (EHR) CONCEPTS

The IOM[16] declared the computer-based record as “essential technology for healthcare” in 1991. The results of a 2009 survey conducted by the CR SANTEC for the eSanté team showed in 2008 that in Luxemvebourg 86% of physicians outside hospitals use EHR. The term Electronic Health Record (EHR) became the most used “generic term”, but in the literature, EHR has various definitions and related terms and acronyms.

The scope of the EHR depends on its scale of usage: record of healthcare entities; regional health information organization; personal health records, and population databases.

[16] Institute of Medicine. The computer-based electronic medical record: An essential technology for healthcare. NAP, Washington, DC, 1991(revised 1997).

Haas[17] suggested a formal classification in 5-dimensions to define the purpose of an EHR.

1. Purpose of using electronic medical records
    - Primary purpose: for patient care and treatment.
    - Secondary purpose: For reasons given by governmental law such as billing, reporting and quality management.
    - Tertiary purpose: For research and teaching, health monitoring and clinical epidemiology, statistics.

2. The subject area covers two aspects, the institutional and the medical case leading to options:
    - Integrated patient centered record of a medical case of all involved institutions, for example the german "eFallakte"
    - Integrated patient centered record of a medical case in one institution: a new EMR is open each medical case.
    - Integrated patient centered record of all his medical cases in one institution: Health care domentation are added in the same EHR.
    - Integrated patient centered record of all his medical cases of all involved institutions: typically for a regional / national EHR

3. The level of digitalization and standardization: (content based)
    - Patient data and medical case data with a reference to paper based record (automated patient medical record).
    - Patient data and medical case data but with scanned medical documents (computerized patient medical record).
    - All patient and health care related content in structured and formalized form (electronic medical record).

4. The disease related content:
    - Information for one disease of the patient (make only sens for a national disease program, like cancer).
    - Information for all the disease of the patient.

5. The question of who moderates the record leads to the two options:
    - The institution (GP or hospital)
    - The patient himself

The ISO 20514 and Waegeman[18] incorporate several existing EHR concepts and related acronyms and gave a formal definition for each of them. Table 1 gives an overview of these definitions. This ISO standard also offers 2 levels of EHR definition; one generic, in order to be compliant with all kinds of EHR concepts, and another one more precise.

[17] Haas: Medizinische Informations systeme und Elektronische Krankenakten, Springer Verlag
[18] C. Peter Waegemann, Status Report 2002: Electronic Health Records,

- **The basic–generic EHR**

The basic–generic definition for the EHR is a repository of information regarding the health status of a subject of care, in computer processable form.

- **The Integrated Care EHR (ICEHR)**

The Integrated Care EHR (ICEHR) is defined as a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorized users. It has a standardized or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective.

Source: ISO/TR 20514 - Health informatics - Electronic health record - Definition, scope, and context

Acronym	Name	Definition
EMR	Electronic medical record	Special case of the EHR, restricted in scope to the medical domain or at least very much medically focused.
	Departmental EMR	Contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy)
	Inter-departmental EMR	Contains a patient's medical information from two or more hospital departments
	Hospital EMR	Contains all or most of a patient's clinical information from a particular hospital
	Inter-hospital EMR	Contains a patient's medical information from two or more hospitals
EPR	Electronic patient record	Electronic record of periodic health care of a single individual, provided mainly by one institution
CPR	Computerised patient record	Computer-based patient record, the term CPR is used mainly in the USA and seems to have a wide range of meanings which may encompass the EMR or EPR.
EHR	Electronic health record	Longitudinal collection of personal health information from all sources
EHCR	Electronic health care record	Previously used in europe, it is a synonymous with the EHR
ECR	Electronic client record	Scope is defined by the non-medical health professional group utilizing the record within their health discipline (e.g. physiotherapist, chiropractor, social worker)
VEHR	Virtual EHR	No authoritative definition. Concept referring to EHR which is assembled 'on the fly' through a process of federation of two or more EHR nodes
PHR	Personal health record	Controlled by the patient and contains information at least partly entered by the patient The PHR can then be considered in at least four different forms: a) a self-contained EHR, maintained and controlled by the patient/consumer, b) the same as a), but maintained by a third party such as a web service provider, c) a component of an ICEHR maintained by a health provider (e.g. a GP) and controlled at least partially (i.e. the PHR component as a minimum) by the patient/consumer, or d) the same as c), but maintained and controlled completely by the patient/consumer.
DMR	Digital medical record	A web-based record maintained by a healthcare provider or health plan. The DMR can have the functionality of the EMR, EPR, or EHR
CDR[19]	Clinical data repository	An operational data store that holds and manages clinical data collected from service encounters at point of service locations (e.g. hospitals, clinics). Data from a CDR can be fed to the EHR for that client, in that sense the CDR is recognized as a source system for the EHR." (Infoway:2003).

[19] not considered to be patient-centric EHRs

Acronym	Name	Definition
CMR[20]	Computerised medical record	A computerised record created by image scanning or optical character recognition (OCR) of a paper-based healthcare record (Waegemann:2002).
PopHR[21]	Population health record	Contains aggregated and usually de-identified data. It may be obtained directly from EHRs or created de novo from other electronic repositories. It is used for public health and other epidemiological purposes, research, health statistics, policy development, and health service management.

Table 4 : Common types of health records (from ISO/TR 20514)

The Medical Records Institute classified EHR concepts in five levels of sophistication. The Figure 4 displays them from the lowest to the highest level: Automated Medical Record (AMR), Computerized Medical Record (CMR), Electronic Medical Record (EMR), Electronic Patient Records (EPR), and Electronic Health Records (EHR).

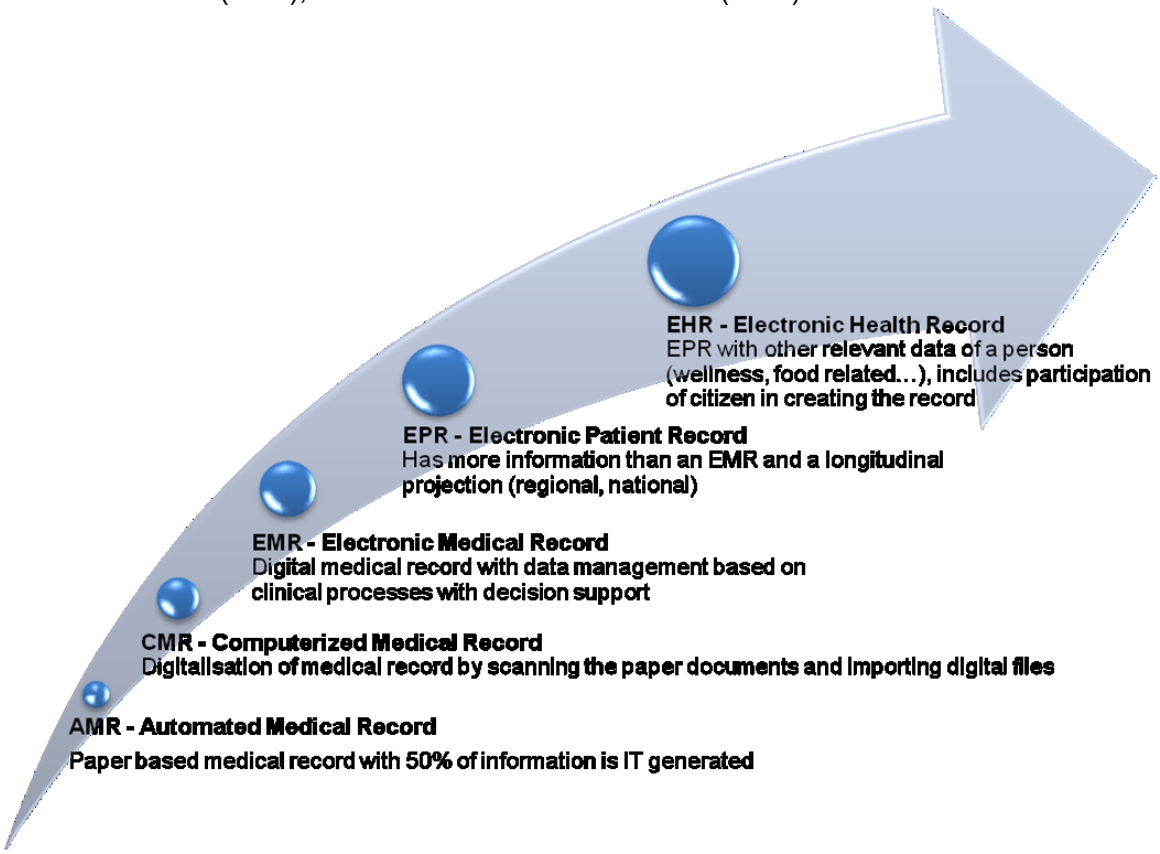

Figure 4 : EHR concepts in five levels from the lowest of sophistication to the highest level (adapted from Blobel[22])

Before recommending a concept for Luxembourg, we want to underline some sub-parts of the EHR that are very interesting to have such as a patient summary and a PHR with diaries.

7.2.1. **Patient Summary - PS**

The European large scale pilot, named epSOS[23], for the exchange of patient summary (PS) and electronic prescription data between European Member States, defined the PS as "*a concise clinical document that provides an electronic patient health data set applicable both for unexpected, as well as expected, health care contact. A PS provides an HCP with essential information needed for health care coordination and, in case of an unexpected*

[20] partially compliant to the basic-generic EHR definition since scanned paper records but no data structures to underpin any significant decision support
[21] not comply with the ISO EHR definitions
[22] Blobel - Architecture and Tools for Open, Interoperable and Portable EHRs, in Integration of Health Telematics into Medical Practice, IOS Press.
[23] www.epsos.eu

need, for the continuity of care, or when the patient consults an HCP other than his regular contact person (e.g. the general practitioner he/she is registered with).”

Healthcare provider creates PS at the end of an encounter or at the end of an episode of care and the PS is used for transfers, referrals, and discharges to be shared between both clinicians and the patient[24]. This sub-part of an EHR is a kind of cumulative report from all relevant information for the continuity of care. Häyrinen[25] reviewed the research literature on EHR, and declared that a patient summary typically contains:

- Patient history (of illness),
- Allergies,
- Active problems,
- Test results,
- Medications.

In some literature, patient summary (PS) is also badly called the Continuity of Care Record (CCR) or the Continuity of Care Document (CCD). In fact, CCR and CCD are competitive standards for PS, we will come back to this in the standard section.

7.2.2. **Computerized diaries**

Patients will be more and more involved in the medical documentation process; they can have electronic interviews concerning their medical history or enter information concerning a chronic disease like diabetes. The computerized diaries are one way for a patient to provide currently inaccessible data to their doctor.

Häyrinen[26] found that patients could use it to:

- control their medication
- control their urinary voiding
- control their food intake
- control the parameter of their disease: glycemia for diabetic people, period of allergen stress ...
- assess their pain intensity
- report on small diseases treated by auto medication; date, symptom, treatment, duration...

New trends in the web 2.0 show that people are used to going to social network websites. In medicine, the controversial initiative of www.patientslikeme.com demonstrates that patients like to compare themselves to other patients, even without a confidentiality framework. The eSanté platform could offer a patient a portal to enter their data in a secure way and to compare it to a national baseline built upon the data entered by other patients. Good practices could also be suggested to the patient in order to help him to reach their goal.

7.2.3. **Personal Health record - PHR**

The personal Health record (PHR) is an EHR **managed by the patient himself** in contrast to the health provider’s record of the patient that is managed by the health provider and/or the healthcare institution. The patient can **enter and access his health** data through such systems. The PHR includes all relevant data over the lifetime, from multiple sources, including health care facilities as well as the individual. The Table 5 lists a sample of PHR data type and potential sources made by a panel of experts[27].

[24] Dimitrios G. Katehakis Electronic health record
[25] Häyrinen K. et al, Definition, structure, content, use and impacts of electronic health records: A review of the research literature, international journal of medical informatics 77 (2008) 291–304
[26] Häyrinen K. et al, Definition, structure, content, use and impacts of electronic health records: A review of the research literature, international journal of medical informatics 77 (2008) 291–304
[27] Paul C. TANG,Personal Health Records: Definitions, benefits, and strategies for Overcoming barriers to Adoption, Journal of

Data type	Source
Problem list	Patient, EHR
Procedures	Patient, EHR, or claims
Major illnesses	Patient, EHR, or claims
Provider list, potentially linked to problems	Patient, EHR
Allergy data	Patient, EHR
Home-monitored data (e.g., BP, glucose, peak flow)	Patient, automated interface with equipment
Family history	Patient, EHR
Social history and lifestyle	Patient, EHR
Immunizations	Patient, EHR, immunization registries
Medications	Patient, EHR, claims history (partial data)
Laboratory tests	Patient, EHR, commercial laboratories

Table 5 : Sample PHR Data Types and potential sources (Paul C. TANG)

Like an EHR, a PHR can be standalone on smart cards, USB drives and CDs; it has the advantage to offer an individual control over access to the data contained in the PHR.
However, most benefits of PHRs are obtained when PHRs are integrated with EHRs:

- Data need not be reentered by the patient
- Health providers can access both EHR data and patient entered data in one single tool
- Additional functionality, such as allowing the patient to request appointments and prescription renewals and providing a communication channel to clinicians

A recurring issue is the reliability of patient-entered data; experts[28] claim that it depends on the nature of the information. Symptoms and easily measured objective parameters, such as height, weight, and temperature by thermometer, are usually reliable information.

Data within PHRs can be subjective or objective. The Table 6 shows objective and subjective PHR data types by their potential source(s).

Data Source	Data type	
	Subjective	Objective
Patient	Manual entry or results of online data capture (e.g., symptoms scores, qualitative descriptions)	Manual entry (e.g., blood pressure, weight)
Home instrumentation	N/A	Automated interfaces (e.g., blood pressure from interfaced home blood pressure monitor)
Clinicians	Automated interface with medical records	Automated interface with medical records
Claims databases	N/A	Automated interfaces

N/A: not applicable.

Table 6 : Objective and Subjective PHR Data Types by Source (Paul C. TANG)

In order to provide benefit for the patient, an adaptation of terminology, data presentation and accompanying tools is necessary in order to enable the patient to understand and to act on the information contained in the record.

the American Medical Informatics Association, Volume 13 Number 2 (2006)

[28] Paul C. TANG, Personal Health Records: Definitions, benefits, and strategies for Overcoming barriers to Adoption, Journal of the American Medical Informatics Association, Volume 13 Number 2 (2006)

7.2.4. **Recommendation for a national EHR for Luxembourg**

In Luxembourg, we have currently a highly fragmented source of unreachable health data. In general, health providers rarely know important health data for a patient contained in the EMR of other health providers. The current situation of information silos is not adapted to the management of the continuity of care.

In the context of the continuity of care, the eSanté team considers that Luxembourg should focus on an **integrated Care EHR managed by a special health provider** (e.g. a family doctor) **and monitored by the patient**. The creation of the "médecin référent" is a good opportunity to assign the responsibility to manage this EHR. The goal is to provide on the one hand a **shared environment between health providers authorized by the patient** (physicians, pharmacist, labs, long-term care …) and on the other hand in a sub part a PHR to give the patient the opportunity to supply the EHR with his own data. The technologies can support the patient in his first role of **maintaining his health status**, by providing tools to monitor his health status, guidelines dedicated to the patient, and tools to communicate with his health providers. Both **terminology** and **data presentation** of the patient interface is **adapted for his understanding**.

The patient provides **access and assigns rights** to his record to his health providers or, if he wants, he can delegate these actions to his "médecin référent" or to a trusted third person (parents, children ...). If the patient does not specify special rights on his EHR, health providers' rights are those defined by default in a **habilitation matrix** (RBAC model: role-based access control). Health providers are categorized into **structural roles** and **functional roles**[29] (See example in Table 7)**.** The structural roles detail the competences for actions (his position) and the functional roles detail the realization of acts (his mandate in the context of the patient care, e.g. médecin référent). Therefore, in function of his **resulting rights**, the EHR systems should be able to display information that is relevant to the health provider in the context or in the purpose of use (e.g. current problem of the patient). The EHR system should be transparent to the health provider; he should not be disturbed by the burden of locating, retrieving and accessing the relevant information. One challenge will be to enumerate a class of user and a class of virtual EHR (sub part of the EHR visible in a specific context) to represent all **access policies**[30].

Structural roles of healthcare professionals	Functional roles of healthcare professionals
Medical director; Director of clinic; Head of the department; Senior physician; Resident physician; Physician; Medical assistant; Trainee; Head nurse; Nurse; Medical student.	Caring doctor (responsible doctor); Member of diagnostic team; Member of therapeutic team; Consulting doctor; Admitting doctor; Family doctor; Function-specific nurse.

Table 7: Example of structural roles and functional roles (Source: ISO TS 22600-2)

In the end, thanks to an ongoing connection between patient and health provider, we should shift encounters from episodic to continuous. It will help to prevent some diseases or reduce the time to address arising problems.

This **longitudinal** record (with data from various institutions and health providers) does not

[29] ISO TS 22600-2, Privilege management and access control - Part 2: Formal models
[30] *Helma van der Linden,* Inter-organizational future proof EHR systems - A review of the security and privacy related issues, international journal of medical informatics 78 (2009) 141–160

cover the whole EMR of each health provider; it focuses only on a set of data useful for the continuity of care as illustrated in the Figure 5.

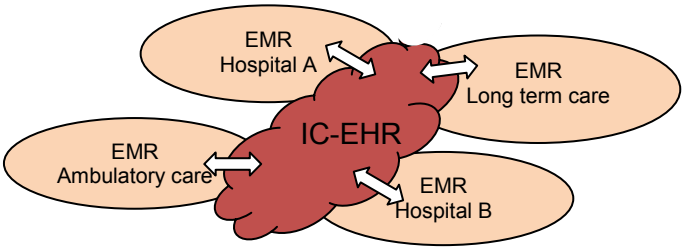

Figure 5: Multi source representation of a longitudinal record

There is a possible analogy with an optical system, the Integrated Care EHR (IC EHR) is consider as the visible part of the light specter and part of the EMR of health provider not covered by the IC EHR are in the range of the ultraviolet or infrared. As a chromatic (color) bandwidth filter enables to see only specific light radiations of the light specter (see Figure 6), the EHR system can display to the health provider only relevant information for him in his context (structural and functional role, patient consent, disease oriented, etc.).

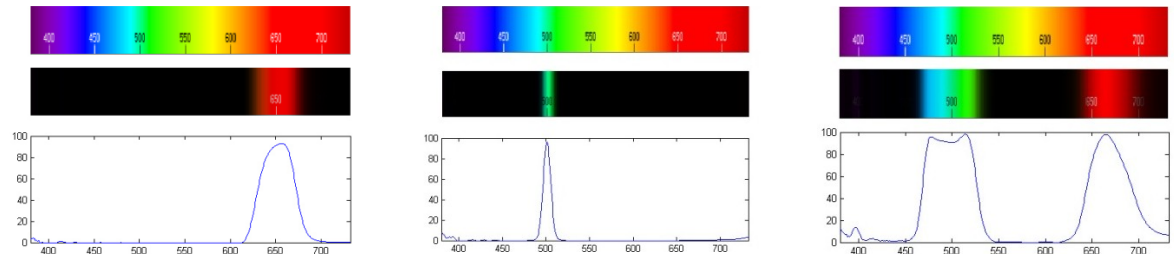

Figure 6: Example of three chromatic (color) bandwidth filters

As seen in the section 6.2, the continuity of care is currently ensured by document exchange between health providers. The Table 3 introduced the documents that could be send to the national EHR. Based on these documents, we suggest to **generate semi-automatically** a **Patient Summary validated by the "médecin référent**". This document provide to all health provider (owning enough access right) with the essential information needed for health care coordination both for unexpected, as well as expected care. Its generation is an extract of document types selected and organized into a standardized backbone by the "médecin référent". The added value of **the "médecin référent"** in this approach is to **provide a medical sense to this data accumulation**. He can by example link exam to a problem or determine which problem are active or passive.

To **get this holistic view** of the patient health, it is **essential that all health providers participate** and feed the EHR by sending their report to the platform.

*According to the classification of EHR suggested by Haas[31] in 5-dimensions, the **integrated Care EHR** can be defined:*

1. *Purpose of using electronic medical records: for patient care and treatment and later for research and teaching, health monitoring and clinical epidemiology, statistics.*
2. *Integrated patient centered record of all his treatments of all involved institutions extended with paramedical information and personal notes of the patient himself, the electronic health record.*
3. *All patient and h*ealth care related content in structured and formalized form (electronic medical record).
4. For all health information of this patient (not specific to one disease)
5. The moderator can be the patient himself and the “médecin de référence”

[31] Haas: Medizinische Informationssysteme und Elektronische Krankenakten, Springer Verlag

7.3. EHR SYSTEMS

EHR can be considered in two parts: the EHR itself, the repositories of medical information; and the EHR system[32], which operates the EHR providing the functionalities for creating, using, storing, and retrieving an EHR. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities.

The institute of Medicine listed in 2003 the eight key EHR system capabilities[33] (detailed in a table in ANNEX 2):

- Health Information and Data
- Results Management
- Order Entry/Management
- Decision Support
- Electronic Communication & Connectivity
- Patient Support
- Administrative Processes
- Reporting and Population Health Management

EHRs and EHR systems are required to be based on an EHR architecture characterizing a model of generic properties needed for every EHR to be communicable, comprehensive, useful, effective, and ethically-legally binding, retaining its integrity independent of the technology used to implement the EHR system and eHealth platforms as well as current organization structures over time[34].

7.3.1. **Electronic health record architecture (EHRA)**

The ISO/TS 18308 provides a principal definition of an electronic health record architecture (EHRA): “the generic structural components from which all EHRs are built, defined in terms of an information model”.

The EU-CEN: 1997[35] provides a more descriptive definition:
“a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care, and may retain integrity across systems, countries, and time. The Architecture does not prescribe or dictate what anyone stores in their healthcare records. Nor does it prescribe or dictate how any electronic healthcare record system is implemented. ... [It] places no restrictions on the types of data which can appear in the record, including those which have no counterpart in paper records. ... Details like “field sizes”, coming from the world of physical databases, are not relevant to the electronic healthcare record Architecture.”

In his analyses of various EHR approaches[36], Blobel[37] estimated that in order to have a sustainable-shared longitudinal EHR with characteristics found in Table 8, it is necessary that the architectural paradigms presented in Table 8 have to be met.

[32] Adapted from IOM:1991, Dick R., Steen E. *The Computer-Based Patient Record: An Essential Technology for Health Care*. US National Academy of Sciences, Institute of Medicine, 1991.
[33] IOM, Key Capabilities of an Electronic Health Record, Letter Report, 2003
[34] ISO/TS 18308 and Analysis and Evaluation of EHR Approaches - B. Blobel
[35] European Committee for Standardisation (CEN). Proceedings of the second EU-CEN workshop on the electronic healthcare record. CEN, 1997.
[36] HL7 standards, CCR, EN/ISO 13606, open EHR, IHE XDS, and DICOM SR were analyzed.
[37] Blobel B, Analysis and Evaluation of EHR Approaches, Methods Inf Med 2009; 48: 162–169

EHR characteristics	Architectural paradigms
Open Scalable Flexible Portable Distributed Standard-conformant Interoperable at an appropriate level Service-oriented User-accepted Applicable to any media Trustworthy Lawful	Distribution Component-orientation A model-driven and service-oriented design taking into account concepts, context, and knowledge Comprehensive business modeling Separation of computation-independent, platform-independent, and platform-specific modeling (thus separating the functional and the logical from the technological view) Agreed reference terminologies and ontologies A unified development process, and advanced security and privacy services embedded in the architecture

Table 8 : Architectural paradigms to fulfill the characteristics of an advanced and sustainable EHR (Source: Blobel 2009)

The ISO/TS 18308 defines eight frameworks that define an EHR architecture. We recommend considering this standard for the EHR requirements. For information, the Table 9 and Table 10 describe the content of these 8 frameworks without the context that can be found in the ISO/TS 18308.

STRUCTURE	PROCESS	COMMUNICATION	PRIVACY AND SECURITY
Record organisation; • *Sections* • *EHR format* • *Portability* • *Secondary uses* • *Archiving* Data organisation; • *Structured data* • *Non-structured data* • *Clinical Data* • *Administrative data* Type and form of data; • *Data types* • *Support for different types of data* • *Reference data* • *Contextual data* • *Links* Supporting health concept representation; • *Support for multiple coding systems* • *Unique representation of information* • *Representation of text*	Clinical processes; • *Support for clinical processes* • *Problems/issues and health status* • *Clinical reasoning* • *Decision support, guidelines, and protocols* • *Care Planning* • *Orders & service processes* • *Integrated care* • *Quality assurance* Record processes • *Data capture* • *Retrieval / query / views of data* • *Presentation of data* • *Scalability*	Messaging; Record exchange;	Privacy and confidentiality; Consent; Access control; Data integrity; Auditability of access;

Table 9 : Eight frameworks to define an EHR architecture - part 1 /2 - (Source: ISO/TS 18308)

MEDICO-LEGAL	ETHICAL	CONSUMER/ CULTURAL	EVOLUTION
Support for legal requirements; Actors; • *Subject of healthcare* • *Patient identification* • *User Identification* • *Clinician identification* • *Author responsibility* • *Attestation of entries* Clinical competence / governance; Faithfulness; Preservation of context; Permanence; Version control;	Support for ethical justification COC ;	Consumer issues; • *Support for consumer issues* Cultural issues; • *Support for cultural*	Support for EHR architecture and EHR system evolution *issues;*

Table 10: Eight frameworks to define an EHR architecture - part 2 /2 - (Source: ISO/TS 18308)

7.3.2. **Electronic health record representation**

EHRs can be presented in three different manners[38]: time-oriented, problem-oriented and source-oriented EHRs.

- In the **time-oriented** EHR, the data is showed in chronological order.
- In the **problem-oriented medical record (POMR)**, information is assigned to a problem (disease) of the patient, and each problem is described according to the method of documentation subjective, objective, assessments and plan (SOAP).
    - Subjective: any information provided by the patient (history of present illness, past medical history, etc)
    - Objective: any data of a physical finding during your exam, or lab results
    - Assessment: diagnose
    - Plan: treatment, response to the diagnose
- In the **source-oriented record**, data are sorted out according to the method by which the information was obtained (e.g. notes of visits, X-ray reports and blood tests) and reported in each section in a chronological order.

A national EHR can also provide a role base display to give a view at glance to each HCP categories of the relevant information types that they need to care the patient. The display of a physiotherapist should differ from the display of the Dossier Médical Général (DMG). In some regions in France the “dossier communicant de cancerologie” was implemented as a special view (subset of data available for certain users) of the patient record. To give an idea of a potential display of patient summary, we found the display of the national EHR in Sweden[39] (NPÖ). It contains 16 core information types:

- Patient Demographics
- Encounter
- Allergies and Alerts
- Care Plan (Primary, Secondary)
- Community Healthcare Service
- Activities of Daily Life
- Disability
- Diagnoses
- Clinical Document
- Prescribed Medication
- Dispensed Medication (Pharmacy)
- Clinical Chemistry
- Microbiology
- ECG
- Medical Imaging
- Other Examination

The representation of this data is source-oriented with a timeline on the top of the page to give a quick an outlook of the medical event during the last 5 years. Each medical type contains in the first page only 5 items. An arrow indicates if there is other data.

[38] Häyrinen K. et al, Definition, structure, content, use and impacts of electronic health records: A review of the research literature, international journal of medical informatics 77 (2008) 291–304
[39] http://www.intersystems.fr/media/media_manager/pdf/1827.pdf

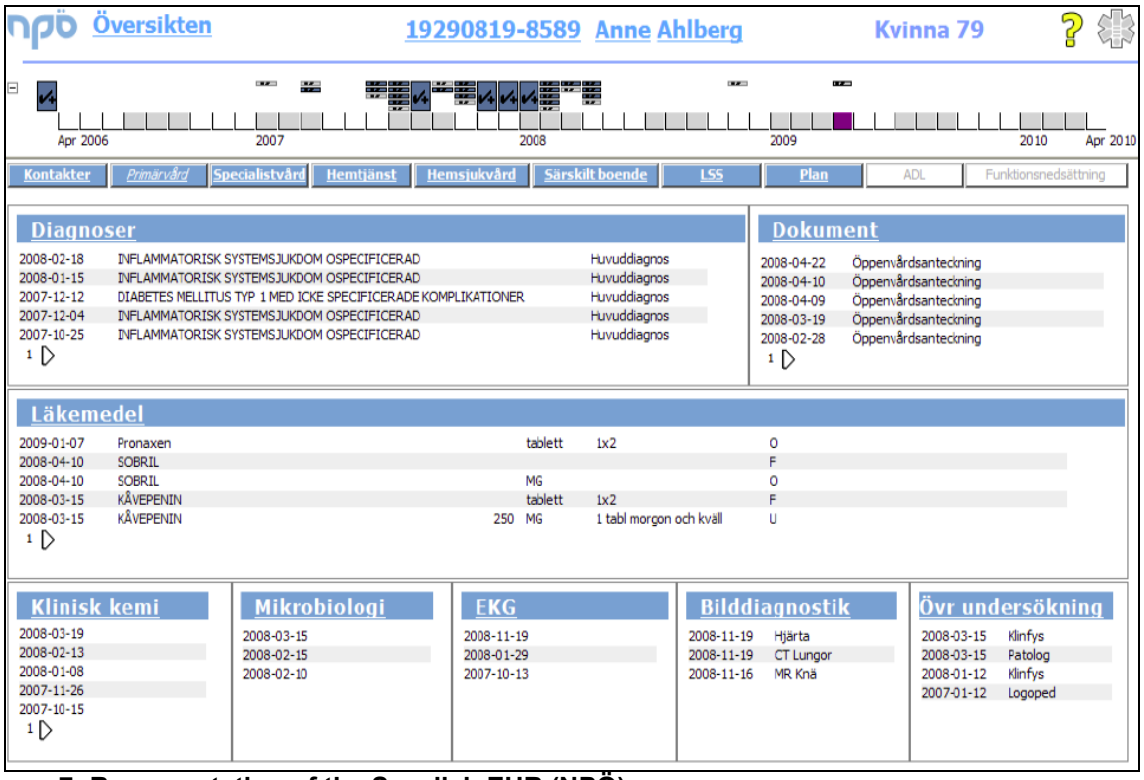

Figure 7: Representation of the Swedish EHR (NPÖ)

France has recently launched their own national EHR. It offers a view similar of a documentation timeline, but provide also some services like the prescription of medication.

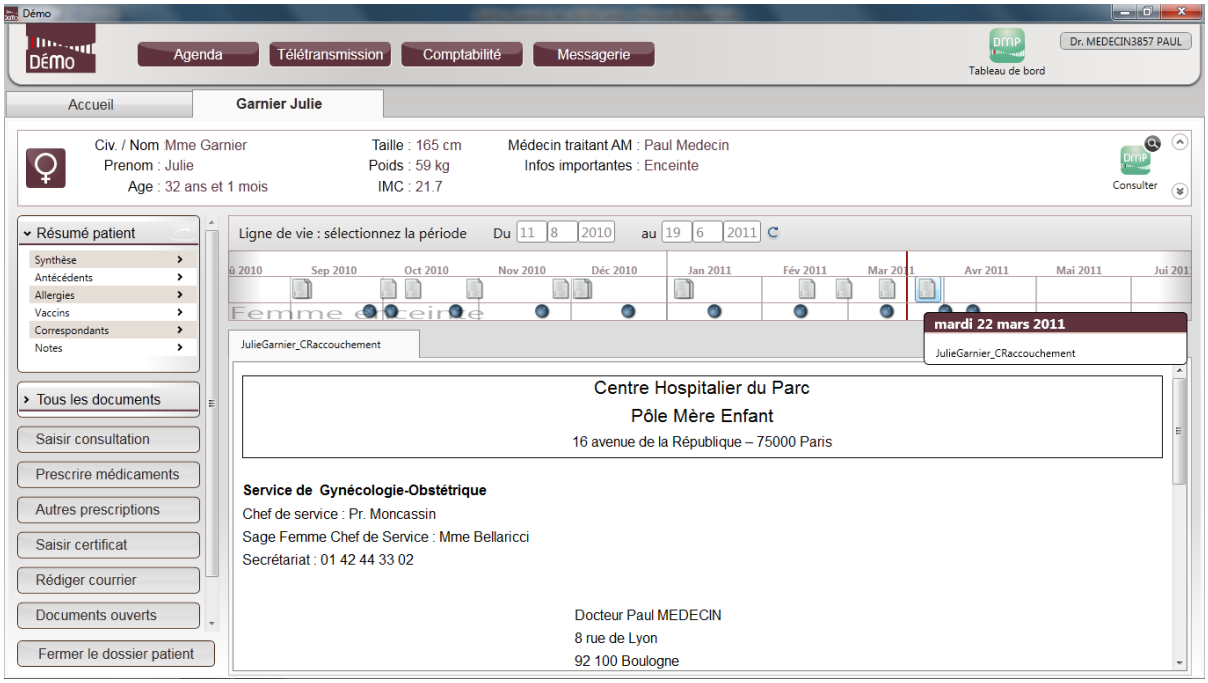

Figure 8: Representation of the French EHR (DMP)

7.3.2.1. Data Maturity

National EHR collects data from multiple different sources. To prevent the aggregation of redundant (maybe even superfluous) data into the EHR, it is necessary to provide filtering and selection features protecting future health providers from masses of data containing limited sets of real information.

Heidenreich[40] described the attribute of EHR maturity in the life cycle of health-care data as:

a) *chronological collection, that has not yet been consolidated or reduced ("chronological", machine-generated or entered without release/signature)*

b) *longitudinal, encounter-related collection of clinical information ("encounter-based", signed and released in a local context)*

c) *"eternal", redundancy-free, consistent diagnoses and procedures ("valid", condensed, long term information which has been selected and validated in the context of all previous EHR entries)*

Author added, "*this scheme allows for any unauthorized sources, like external entities, devices, non-medical staff and patients to enter data into the EHR, which would however describe this as "maturity level a)". Only after review by medical professionals - possibly eliminating redundant data - such entries would be promoted to b) and only after global review placed to level c)".*

7.3.3. **Recommendations for the architecture of the EHR**

In order to obtain the EHR characteristics presented in the Table 8 and to fulfill the expectations of users listed in the section 5.2, the functional specifications of the EHR system should follow the architectural paradigms proposed by Blobel (Table 8). The eight EHR architecture frameworks defined by ISO/TS 18308 can be a guide to drafting the EHR architecture requirement.

The selected EHR architecture of the platform should enable the EHR system of the health provider to display these three types: time-oriented, problem-oriented, and source-oriented.

The consistency of the EHR as seen in 7.2.3 (level c) must be ensured by a health professional. This responsibility of validating the EHR could be given to the "médecin référent".

[40] Dr Georg Heidenreich , Dr. Pantelis Angelidis, Six Steps to Electronic Health Records Interoperability, European Journal of ePractice · Nº 8 · December 2009 · ISSN: 1988-625X

7.4. EHR STANDARDS

It is necessary to use recognized standards to achieve interoperable data exchange inside and outside a country. In the specific case of a small country like Luxembourg, it is even more important. IT vendors are generally international companies and they do not want to develop one specific standard for each country. Therefore, to open the market to a maximum of IT vendors, Luxembourg has to choose proven standards used by a maximum number of users while at the same time considering only those that match or are close to its needs. This is in opposition to bigger countries that made their selection of standards depending on several criteria with more freedom, for instance in Australia[41]: features, ease of implementation and community support.

The purpose of the following sub-section is not to provide an overview of all standard possibilities or the capacities of all kinds of EHRs seen in this document. We try to offer a brief analysis of standards adapted to our vision of the Luxembourgish longitudinal integrated EHR as discussed in the previous section. European initiatives, like Q-REC project[42] or the joint project "eHealth-INTEROP" (also called mandate 403 or M/403)[43], have already delivered an inventory of relevant standards for EHR systems.

7.4.1. HL7 – Health Level Seven and RIM

HL7 (Health Level Seven) is the mostly used communication standard in health care. Health Level Seven International is the non-for-profit organization, which develop standards for the exchange of messages and documents for both clinical medical and administrative data in the field of health care. HL7 is very common in hospitals, where it is often used for communication between in-house software components (e.g. HIS, radiology system, telephone systems, catering systems, etc.), whereas it is not so widely used for doctor's medical software.

The RIM - Reference Information Model - was introduced with HL7 Version 3. It provides an explicit, object-oriented representation of the semantic and the lexical connections that exist between the data elements of a message. At the top level, the model consists only of five distinct objects and their relationships. The novelty of version 3 is the addition of a persistent document in time that can be stored (see CDA), in opposite to a message between two systems that disappears after the communication.

The HL7 EHR System Functional Model is a Draft Standard for Trial Use (DSTU). It provides a reference list of functions to be met in an Electronic Health Record System (EHR-S). The EHR-S Functional Model is narrative description composed of a functional outline (which is divided into three sections, direct care, supportive and information infrastructure), functional profiles (which overlay the outlined functions) and assigned priorities for the functions in the profile (see Table 11). Functional profiles can be used to constrain the functions to an intended use.

[41] NEHTA, Standard for e-health Interoperability, 2007
[42] http://www.eurorec.org/services/standards/Q-REC-Eurorec_Overview%20on%20EHR%20Standards%2001.pdf
[43] http://www.ehealth-interop.nen.nl/

Direct Care	DC.1 Care Management
	DC.2 Clinical Decision Support
	DC.3 Operations Management and Communication
Supportive	S.1 Clinical Support
	S.2 Measurement, Analysis, Research and Reports
	S.3 Administrative and Financial
Information Infrastructure	IN.1 Security
	IN.2 Health Record Information and Management
	IN.3 Registry and Directory Services
	IN.4 Standard Terminologies & Terminology Services
	IN.5 Standards-based Interoperability
	IN.6 Business Rules Management
	IN.7 Workflow Management

Table 11: Functional profiles of the HL7 EHR System Functional Model

In many countries, there are different national HL7 representations (so called affiliates). Luxembourg has created its own representation at the end of 2010.

7.4.2. ISO/CEN EN 13606 Health Informatics - Electronic Health Record Communication

The European predecessor version CEN ENV 13606 of the international EHR standard (ISO/CEN EN13606) has only been used by some school hospitals and the research world. According the CEN rule, each ENV norm has to be evaluated after 3 years to cancel it, to adopt it or revise it. The new version has been strongly revised to adopt to a **dual model approach** with a **reference model representing only information (very general)** and an **archetype model representing only knowledge** (specialize the generic data structure to the clinical content such as blood pressure, lab result etc.). This approach has the advantage of not mixing generic and domain-specific knowledge concepts and facilitates management issues.

This standard is organized into five parts:

1. ISO 13606-1:2008: Reference model
2. ISO 13606-2:2008: Archetype interchange specification
3. ISO 13606-3:2009: Reference archetypes and term lists
4. ISO 13606-4:2009: Security
5. ISO 13606-5:2010: Interface specification

Recently more national and regional projects look seriously to this standard for their EHR-infrastructure such as Sweden, United Kingdom, Slovakia and Brazil (State Minas Gerais)[44].A new consortium[45] is currently setting up in order to work collectively and secure joint IP. Announced country members are the UK, Sweden, Spain, Slovakia, Australia, Germany, Norway, Ireland, USA, Netherlands, Brazil, New Zealand, Serbia, USA and Singapore.

This standard is also used in European pilot epSOS[46] at two pilot sites.

[44] http://www.eurorec.org/files/filesPublic/20100708-EN13606-inaugural_implementers_workshop_Madrid.pdf
[45] http://www.en13606.org
[46] http://www.epsos.eu/uploads/tx_epsosfileshare/D3.5.2_Appendix_G_EN13606_Implementation.pdf

7.4.3. **Open-EHR**

OpenEHR is an international not-for-profit Foundation, working towards making the interoperable, lifelong electronic health record a reality, and improving health care in the information society. It does this by developing open specifications, open source software and knowledge resources, engaging in clinical implementation projects, participating in international standards development, supporting health informatics education.

OpenEHR is considered to have the similar specifications that the EN 13606, by using archetypes, but the IP of OpenEHR is mostly owned by Ocean Informatics. Besides this, the use of EN 13606 intellectual propriety is free.

7.4.4. **IHE – XDS**

IHE (Integrating the Healthcare Enterprise) is an industrial initiative to create an integration profile. Its approach is not to create new standard but use a set of existing standards in which integration options are constraints to enable the interoperability between systems. Today, all healthcare companies support this way of work and participate to the definition of integration profiles and its testing in a special event, the connecthaton. All companies that successfully pass the test receive an "Integration statement" proving that their product is able to operate within this profile. This approach is also supported by some governments; for instance, Austria writes all of its calls for tender using IHE integration profiles. The large-scale pilot epSOS reused the IHE test method to test their pilot site.

Cross-Enterprise Document Sharing (XDS) is the main integration profile developed by IHE. It defines infrastructure and protocols for the interchange of health care documents between health care providers over a wide area network. The main difference to other approaches is that in XDS the logical and physically separation of the information where documents are stored (indexing) and the document itself.

IHE XDS is part of the technical framework domain. IHE also works on other frameworks like the useful IHE Patient Care Coordination (PCC) domain, a suggested specification that IHE developed for health documents in CDA.

7.4.5. **CDA**

The clinical document architecture (CDA) is a standard for information exchange and storage of clinical documents and it is based on XML and the structure of the HL7 V3 RIM. CDA documents are always divided into a CDA header, which carries structured meta-information (documented, patient information, etc.) and a CDA body, which contains the actual medical data. The CDA R2 standard allows an incremental approach with the three possible levels of structuring for the body of the document:

- **Level 1**: Not structured and readable for the user. The contents are in a non-XML form, (PDF/A-1, txt, rtf, JPEG or tiff), encapsulated in 64 base in the body.
- **Level 2:** Structured for the reader and displayable for the user via style sheets: The text of the document is formatted in XML in the body, organized in a hierarchical list of sections (element section). Inside each section, the text appears in a narrative block (element text), which can be organized using structures such as paragraphs, tables, notes, figures, references etc. The sections announce their contents using a code of section associated with the wording and optionally with a title. The sections can if necessary encase the ones in the others.
- **Level 3: Structured** for the reader and the Health Information system. The body of the document is organized in sections as in level 2. Moreover, each

section can comprise one or more entries (element entry) embarking the data of the HIS producer. The narrative text inside the sections of level 2 is derived from the entries of level 3. The vocation of an entry is to provide the content in a coded and structured, importable and integrable form in the database of the Information system of Health (SIS) of the health professional who consults the document.

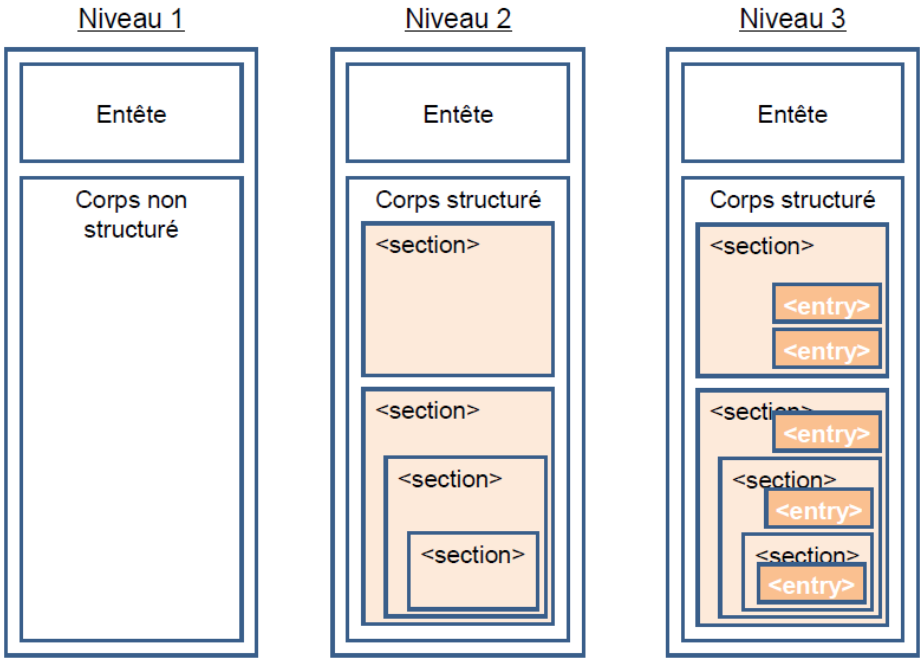

Figure 9: Three levels of the CDA format

The CDA document is stored in XML format, so it is human readable and can be transformed to other visual representations by using appropriate XSL transformations (level 1 and level 2). HL7 CDA can be used for all kinds of documentation. Moreover, CDA can support the electronic signature and the lifecycle of a document.

IHE is heavily relying on CDA for all kinds of documents, the so-called content-modules. A wiki[47] hosted by IHE, centralizes these document specifications, for instance:

- Discharge Summary Specification
- Medical Documents Specification
- Referral Summary Specification
- Discharge Summary Specification
- History and Physical
- PHR Extract Specification
- PHR Update Specification
- …

Note: CDA has been selected for epSOS, but small adaptations have been required.

7.4.6. **CCR, CCD and XDS-MS**

For patient summary, ASTM specified the Continuity of Care Record (CCR), which has been transposed by HL7 in CDA to create the Continuity of Care Document (CCD). Today, these two standards are in competition, CCD seems to be the most used.

[47] http://wiki.ihe.net/index.php?title=CDA_Release_2.0_Content_Modules

IHE developed the Medical Summaries (XDS-MS[48]) profile in order to exchange medical summaries between healthcare organisations (discharge summary, admission letter…). XDS-MS uses a CDA form.

7.5. CODING SYSTEMS AND TERMINOLOGIES OF AN EHR

This section describes the main coding systems used in healthcare. An extended list can be seen at this web site: http://inhcc.com/Standarization/coding_systems.htm.

7.5.1. ICPM

International Classification of Procedures published by the WHO in 1978. The classification should give transparency to the invoicing of medical treatments. It was extended and adopted by several countries. Support was frozen by WHO in 1989 because of a lack of resources. Different countries have built their own subversions/extensions on ICPM e.g. OPS-301 in Germany or ICPM-DE in the Netherlands.

7.5.2. ICD-10

The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use. ICD-10 is used in Luxembourg but only until the three digits.

7.5.3. ICF

The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health related domains.

7.5.4. ATC

The Anatomical Therapeutic Chemical classification system (ATC) is an international classification from the WHO. Its main purpose is the classification of therapeutic drugs. The drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified into five different levels. ATC is used in Luxembourg in the CEFIP list.

7.5.5. ICPC-2

ICPC-2 is based on the episodic approach and allows both diagnoses / findings to be coded as the reason for the consultation (RFE = Reason For Encounter) to capture and record even arranged procedures. ICPC-2 however, has only about 300 different codes (compared to about 14,000 of ICD-10). The WHO[49] is currently working in next version of the terminology: the ICPC-3. The AMMD has proposed to use ICPC in future version of the DMG[50].

7.5.6. SNOMED CT

The synonym SNOMED CT stands for Systemized Nomenclature of Medicine-Clinical Terms. SNOMED is a systematically organized computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, pharmaceuticals, etc. It allows a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps

[48] http://wiki.ihe.net/index.php?title=Medical_Summaries_Profile
[49] World Health Organisation
[50] Dossier Médical Général

organizing the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research.

7.5.7. **LOINC**

LOINC (Logical Observation Identifiers Names and Codes) was developed to provide a definitive standard for identifying clinical information in electronic reports. The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results in the context of existing HL7, ASTM E1238, and CEN TC251 observation report messages. One of the main goals of LOINC is to facilitate the exchange and pooling of results for clinical care, outcomes management, and research. LOINC codes are intended to identify the test result or clinical observation. LOINC is foreseen to be used in some labs in Luxembourg.

7.6. DISCUSSION ON STANDARDS FOR EHR

7.6.1. Overview of EHR standard use in Europe

In 2010, the CR SANTEC made an analysis of the state of the art of EHR systems in European countries. Table 12 makes a synthesis of the standard found in this study. This list is not exhaustive as it reflects only publicly available information at the time of the study.

Country	Architecture	Message or document based	Data transport	Semantics
Austria	IHE-XDS, central registry, distributed repository	HL7 V3, CDA R2	IHE: XDS, PIX, XUA, PCC, XCA, XDS-SD, BPPC[51]	ICD-10, SNOMED-CT, LOINC
Belgium	Planned to implement: IHE-XDS like architecture with so called central Meta-Hub (like Registry) and distributed repositories	Sumehr (Summarized Electronic Health Record) an XML message for Kmehr used for the exchange of medical information.	Kmehr (Kind messages *for* electronic healthcare record). A mapping will be done with HL7 and EHRcom, later on planned using webservices.	ICD-10 and ICPC-2. LOINC for laboratory results ATC for medicines.
Canada	IHE-XDS like	HL7 v3, HL7 v3 RIM, DICOM	HL7 v3	Pan Canadian Laboratory Observation Code Database (pCLOCD) based on Loinc, SNOMED-CT
Denmark	IHE-XDS (regional)	EDIFACT or XML-based messages	EDIFACT or XML-based messages	SNOMED-CT
Estonia	X-road (secure national data exchange layer)	HL-7, XML, DICOM	Webservices on X-road	SNOMED, LOINC, DICOM, ICD-10
Finland	National health information system with centralized services.	HL7 CDA R2,	HL7 V2/V3	LOINC, CCAM
France	IHE-XDS	HL7 CDA R2, DICOM.	Web services, SOAP, Presto, IHE-XDS	LOINC
Germany	No common infrastructure on national level. Region based implementations.	HL7 CDA, DICOM	HL7 V2/V3,	LOINC
Italy	IHE-XDS Registry, Repository shared at regional level	HL7 CDA	IHE: XDS, PIX	planned SNOMED CT, LOINC
Netherlands	Amsterdam wide XDS-I based radiology network and XDS like on broader range	HL7 V2 mostly used in hospitals, new developments will use HL7 V3.	IHE: XDS-I, XDS, National Switch Point (LSP)	SNOMED CT
Norway	IHE-XDS like, using ebXML Registries, XDR like reliable messaging	HL7 CDA, HL7 v3 RIM, DICOM	e.g., ebXML messages over SMTP	ICD 10, ICF, ATC, ICPC-2, SNOMED
Spain	IHE-XDS (regional)	HL7, DICOM	IHE	SNOMED
Sweden	EN 13606-x	EN 13606-x, OpenEHR RIM	XML and Edifact are used for ePrescribing	SNOMED CT, ICD ,ICF
Switzerland	IHE-XDS	HL7 CDA R2, DICOM	IHE: XDS, XUA, PIX/PDQ	n/a

Table 12: List of health standards used in European countries

This short analysis shows that there are two EHR structure standard alternatives; HL7 RIM with CDA and the EN 13606. LOINC or SNOMED CT are generally intended to be used for coding of laboratory results. Data transport standards used are IHE-XDS and the EN 13606.

[51] **IHE Integration profiles used**

XDS: Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records.
PIX: The Patient Identifier Cross Referencing Integration Profile supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains
XUA: Cross-Enterprise User Assertion Profile provides a means to communicate claims about the identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross-enterprise transactions there is a need to identify the requesting principal in a way that enables the receiver to make access decisions and generate the proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication
PCC: Patient Care Coordination domain deals with integration issues that cross providers, patient problems or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other specialty domains. XCA: The Cross Community Access profile supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/enterprises that have agreed to work together using a common set of policies for sharing health information.
XDS-SD: Cross Enterprise Sharing of Scanned Documents associates structured, healthcare metadata with non-healthcare specific document formats to maintain the integrity of the patient health record as managed by the source system
BPPC: Basic Patient Privacy Consents profile provide mechanisms to record the patient privacy consent(s) and enforce the privacy consent appropriate to the use.
PDQ: The Patient Demographics Query Integration Profile lets applications query a central patient information server and retrieve a patient's demographic and visit information
XDR: Cross-Enterprise Document Reliable Interchange provides document interchange using a reliable messaging system. This permits direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.

These various standards address different interoperability layers, some are in competition and some are complementary.

- CDA and the EN 13606 manage the content layer.
- XDS transaction and the EN 13606 message handle the communication and the security layer.
- XDS and the EN 13606 deal also with the organization of the data (architecture)

This shows that the combination of **CDA and XDS** is in competition with the **EN 13606**.

According to the view of experts in architecture, the dual model (reference information model and archetype for specialization) has some advantage over the one model (reference information model only). Kalra[52] declared that the combination of the reference model and the use of archetypes, like the ISO/EN 13606 helps to ensure that clinical shared care can be delivered safely, underpinned by complete and unambiguous information. In addition, Blobel[53] confirmed that the one-model approach reveals some weaknesses and problems related to technical, complexity, and management issues such as the size of the model (management of a large amount of concepts with detailed aspects). Besides these weakness, Blobel[54] added nevertheless that the HL7 V3 offers a very advanced approach geared towards semantically interoperable health information system architecture that provides sufficiently features and quality for an EHR.

Hopefully, the standard organizations make progress on the convergence of the interoperability of their EHR systems. We can observe some convergence between standards. Today the EN 13606 standard is able to create CDA and communicate with IHE XDS profiles. It could be even possible to see one day a version 4 of HL7 based on the dual model of the EN 13606…

7.6.2. **Recommendation for EHR standard in Luxembourg**

Nevertheless, the success of standards, i.e. its general adoption, is generally not due to its quality criteria, but thanks to its large scale adoption. For this reason we suggest the consideration of a **pragmatic approach of the IHE integration profiles and specifically XDS in combination with CDA**, which shows the most impressive adoption. The industry is not mature enough with the standard EN 13606 to have a comparative adoption rate. Additionally, IHE published on a Google map site of the location of adoption of XDS with HL7 CDA: http://tinyurl.com/wwxds

The current Luxembourgish information system does not use XDS and HL7 CDA, current exchanges are managed with HL7 V2. It is recommended that stakeholders continue the stepwise approach of eSanté with specific projects like CARA and LABO, before creating a comprehensive EHR. This gradual approach offers the possibility to switch new projects to other standards if the international or European situation changes. For the moment, the European large-scale pilot epSOS on ePrescription and Patient Summary has also selected the IHE XD series with CDA.

The content of each document can be based on the work of IHE, and slightly adapted to national needs in the framework of a user stakeholder group (Physician, nurse, pharmacist…). In order to have an adoption of the tool, users have to be solicited in the creation of the document type.

A national consensus has to be find to use the same coding systems and terminologies to enable a semantic interoperability and better reuse of data for statistical or epidemiological studies.

[52] Kalra D, Electronic Health Record Standards, IMIA Yearbook of Medical Informatics 2006
[53] Blobel B, Analysis and Evaluation of EHR Approaches, Methods Inf Med 2009; 48: 162–169
[54] Blobel B, Analysis and Evaluation of EHR Approaches, Methods Inf Med 2009; 48: 162–169

8. EHR CERTIFICATION

Many countries have established a certification process for the **EHR of a health provider**. The EHR certification is necessary for a minimum of quality of data by defining rules that ensure that information is consistently and securely captured, transferred, stored, organized, transformed and managed. It is also a powerful lever for a better piloting of any national health care system in order to:

- Secure professional secrets and the privacy of the patient
- Improve efficiency
- Manage cost
- Quality and comparability of health data.

Certification can also prove that the **EHR of a health provider** is compliant with the requirement of the national platform and follows all national constraints (terminology, interoperability with the platform or billing). It is necessary to share reliable data for the patient and for secondary usage.

For instance in Belgium[55], doctors using certified EHRs could ask annually their social security system for a financial contribution. In 2009, the contribution for physicians for expenses related to the use of a certified EHR was worth 787,66 EUR.
In the United States, the concept of "meaningful use" is used to incentivize use of health IT, with payments attached to the testable achievement of specific goals.

Three kinds of compliance testing exist. When the test is organized by a legal authority, it is a certification[56]. If it is another other "institute" or "organisation", it is labelling. And then if the testing is performed by a stakeholder group (like physicians), it is an accreditation.

The European project HITCH[57] made an overview of quality labeling and certification in 2010. Countries listed for the EHR scope are Belgium, Canada, Denmark, Ireland, Norway (EHR messaging), Serbia, Slovenia and USA. This project team[58] recorded the benefits and impacts of certification / quality labeling claimed in these countries:

- General
  - Improve the quality, safety, efficiency of health
  - Reduce health disparities
  - Ensure adequate privacy and security protections for personal health information
  - To promote the conformity to the clinical regulation
  - To decrease the treatment cost for the same level of quality

- Functional
  - Enhanced functionalities, harmonization of systems
  - Improved vendor reliability
  - To support the end-user (e.g. prescriber)
  - Improve quality of "content" and "output"

- Interoperability
  - Improvement of interoperability (implementation of standards
  - Conformity with regulation
  - Zero paper (electronic reimbursement document/ Healthcare information)

[55] https://www.ehealth.fgov.be/fr/page/website/home/platform/approval.html
Law of the 6th February 2003: https://www.ehealth.fgov.be/binaries/website/fr/pdf/AR-6-f-vrier-2003.pdf
[56] Référentiel de certification par essai de type des logiciels d'aide à la prescription en médecine ambulatoire : http://www.has-sante.fr/portail/jcms/c_576417/referentiel-de-certification-par-essai-de-type-des-logiciels-daide-a-la-prescription-en-medecine-ambulatoire

[57] http://www.hitch-project.eu
[58] Deliverable 4.1 "State of the art on interoperability certification and labelling", HITCH project

- Reduce the delay of reimbursement/ Healthcare information to the right person

- Financial
  - Receive financial incentives (users)

8.1. EUROREC

EuroRec is a European not for profit organization promoting in Europe the use of high quality Electronic Health Record systems (EHRs). One of its main missions is to support, as a European certification body, EHRs quality labeling and defining functional (and other) criteria.
For this purpose, EuroRec developed more than 1700 functional quality criteria contained in the EuroRec Repository. Each of these criteria is categorized and translated to up to 19 European languages.

EHR quality criteria were extracted from various countries' specifications with a certification process and added to a repository, refined and indexed:

- Belgium (1999-2006-2010)
- CCHIT
- Alberta (Canada)
- Irlande
- France (LAP)
- Danemark
- Meaningful use
- Clinical research

Since 2008, EuroRec works on the EuroRec EHR Quality Seal for the harmonization between EHR systems, favoring in Europe cross-border interoperability of those systems. The content of the EuroRec Seal evolves over time and encompass other criteria as well (e.g. functional ones and content-related ones). There are two levels of the EuroRec EHR Quality Seal:

- Level 1 is for granting cross border certificates based on a mainly generic and minimal (20) set of quality criteria for EHR systems. This level of the EuroRec Seal focuses on the trustworthiness of the clinical data.
- Level 2 encompasses 50 functional quality criteria, addressing various essential functions of the EHR: access and security management of the systems, basic functional requirements on medication, clinical data management and the generic statements focusing on trustworthiness of the clinical data already included in the Level 1 Seal.

In 2010, a workshop, organized in the framework of EHR-Q^{TN} project (Thematic Network on Quality Labeling and Certification of EHR Systems), validated the EuroRec Seal Level 1 in French by Luxembourgish and Belgium actors.

The HL7 EHR System Functional Model provides statements similar to EuroRec, but the approach of EuroRec is broader. The EuroRec functional quality criteria can be used to **build a functional specification report** (documentation or procurement) for the EHR of the platform and the **EuroRec Seal in addition with national specific requirements**, which could be used **to certify the EHR of any health provider.**

9. CONCLUSION

This report started with a short review of literature concerning EHRs and shows its cost benefit in the mid term. Next, Luxembourgish needs were analyzed to determine the type of document that should be found in the national EHR. A user stakeholder group (Physician, nurse, pharmacist …) should work on this base in order to define the specific content in the context of the continuity of care. After the examination of various concepts of EHRs, the eSanté team suggests to focus on an **integrated Care EHR manage by a special health provider** (e.g. a family doctor) **and monitored by the patient**. The creation of the "médecin référent" is a good opportunity to assign the responsibility to manage this EHR. The goal is to provide, on the one hand, a **shared environment between health providers authorized by the patient** (physicians, pharmacist, labs, long-term care …) and on the other hand - in a sub part - a PHR to give the opportunity to the patient to supply the EHR with his own data. Based on the documents shared, eSanté proposes to generate semi-automatically a **Patient Summary** validated by the "médecin référent". After that, the eSanté team has provided advice on some architectural paradigms for the EHR architecture. Finally, the eSanté project analyzed current EHR standards used in Europe and recommend the adoption of the IHE XDS approach in combination with CDA. The content of each document can be based on the work of IHE, and slightly adapted to national needs in the framework of a user stakeholder group (Physician, nurse, pharmacist…).

An Executive summary is placed on page 6.

10. ANNEXES

10.1. ANNEX I - DATA ELEMENTS FOR EHR DOCUMENTATION

This ANNEX is a copy of the web extra created to be used in conjunction with the AHIMA Practice Brief, "Data Content for EHR Documentation" found in: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_034460.hcsp?dDocName=bok1_034460

10.1.1. Document Headers

Section	Subsection	Data Element	Description
Header	N/A	Patient name Previously registered name/maiden name Individual identifier/medical record number Universal patient health number Gender Race Address Telephone number Date of birth Organization Admission date Discharge date Legal authenticator Authentication date Transcriptionist/data enterer Transcription date	The header provides the general demographic information.

10.1.2. History and Physical Report

Section	Subsection	Data Element	Description
Reason for visit/chief complaint	N/A	Chief complaint Reason for visit	The reason for the visit in the patient's own words (or those of the patient's representative); the principal reason the patient is seeking care. Local policy determines whether the information is divided into two sections or recorded in one section serving both purposes.
History of present illness	N/A	Symptom(s) Onset of symptom(s) Duration of symptom(s) Over-the-counter (OTC) treatment	This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.
Past medical history	Conditions	Condition type Date diagnosed Age of onset Treatment Condition status	The past medical history for the patient, including illnesses that might have an impact on the patient's current condition.
Medications	N/A	Drug Dosage Route Quantity number Quantity form Frequency Start date Stop date Prescribed by Prescription date Prescription number	The patient's current medications and pertinent medication history. The section may also include a patient's prescription history and enables the determination of the source of a medication list (e.g., from a pharmacy system versus from the patient, spouse, etc.).

		Pharmacy Allergic reaction Source of medication list	
Allergies		Allergy or sensitivity type Reaction Severity Date last occurred Treatment	This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum, current and any relevant historical allergies and adverse reactions should be listed.
Social history		Marital status Occupation Home environment Daily routine Dietary patterns Sleep patterns Exercise patterns Coffee consumption Tobacco use Alcohol use Drug use	This section contains data defining the patient's occupational, personal (i.e., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity, and religious affiliation. Social history can have significant influence on a patient's physical, psychological, and emotional health and well being, so it should be considered in the development of a complete record.
Family history	N/A	Child health history Adult health history Hereditary diseases Mother health status Mother age of death Mother cause of death Father health status Father age of death Father cause of death Sibling(s) health status Sibling(s) age of death Sibling(s) cause of death	This section contains data defining the patient's genetic relatives in terms of relevant health risk factors that have a potential impact on the patient's healthcare profile.
Review of systems	N/A	General Skin Head Eyes Ears Nose and sinuses Mouth and throat Neck Breasts Respiratory Cardiac Gastrointestinal Genitourinary Gynecologic Musculoskeletal Peripheral vascular Neurologic Hematologic Endocrine Psychiatric	A review of systems is the physician's summary of a patient's main and general body systems for basic functioning purposes. The physician will identify any problem areas in the respective sections if needed.
Physical examination	Vital signs	Pulse Respiratory rate Systolic blood pressure Diastolic blood pressure Body temperature Height Weight Body mass index Head circumference Crown-to-rump length	Vital signs are the indicators of a patient's general physical condition. It identifies a patient's level of physical functions based on elements such as heart rate, pulse, blood pressure, and body temperature.

		Pulse oximetry	
	General appearance	Appearance Body build Demeanor Hygiene	The general appearance section describes general observations and readily observable attributes of the patient, including affect and demeanor, apparent age compared to actual age, ethnicity, body build and habitus (e.g., muscular, cachectic, obese), developmental or other deformities, gait and mobility, personal hygiene, evidence of distress, voice quality, and speech.
	Physical findings	Skin Head Eyes Ears Nose and sinus Mouth and throat Neck Thorax, anterior, and posterior Breasts Lungs Cardiovascular Abdomen Male genitourinary Female reproductive organs Ano-rectal Musculoskeletal system Extremities Lymphatics Peripheral vascular Neurologic Mental status	The physical findings section describes direct observations made by the clinician, divided by organ system.
Diagnostic findings	Laboratory Pathology Imaging Cardiovascular	Test Result/finding Result/finding date Interpretation	This section contains the results of observations generated by laboratories, imaging procedures, and any other procedures that aid in defining treatment.
Assessment and plan	Assessment	Diagnoses Disposition	A history and physical contains either discrete sections for assessment and plan or a single section combining the two. The assessment (also dictated impression or diagnoses) represents the physician's conclusions and working assumptions that will guide treatment of the patient. The assessment is used to formulate a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.
	Plan	Treatment goals Procedures	The plan section contains all active, incomplete, or pending orders, appointments, referrals, procedures, and services. Any other pending events of clinical significance to the current and ongoing care of the patient should be listed unless constrained due to issues of privacy. The plan section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention and management, patient safety, and healthcare quality improvements, including widely accepted performance measures.
Procedure history (optional)	N/A	Procedure Date Physician Institution/location Result	This section is optional and will include any past procedures or surgeries that the patient has had to include information such as what was done, where it was done, by whom it was done, and the results of it.
Immunizations (optional)	Childhood immunizations	Vaccine Vaccine type	The immunizations section defines a patient's current immunization status and pertinent immunization history.

		Dose Age administered Date administered Lot number Physician	
	Adult immunizations	Vaccine Vaccine type Dose Date administered Lot number Physician	
Problems (optional)	N/A	Problem Date of onset	This section lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed.
Payers (optional)	N/A	Source of payment	The entity responsible for the financial aspects of the patient's care.

10.1.3. **Consultation Report**

Section	**Subsection**	**Data Element**	**Description**
Request for consultation	N/A	Requesting provider Consulting provider Reason for consultation	This section identifies to the consulting provider the focal point of the reason for the consultation request.
Chief complaint	N/A	Chief complaint	The reason for the visit in the patient's own words (or those of the patient's representative); the principal reason the patient is seeking care. Local policy determines whether the information is divided into two sections or recorded in one section serving both purposes.
History of present illness	N/A	Symptom(s) Onset of symptom(s) Duration of symptom(s) Over-the-counter (OTC) treatment	This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.
Past medical history	Conditions	Condition type Date diagnosed Age of onset Treatment Condition status	The past medical history for the patient, including illnesses that might have an impact on the patient's current condition.
Medications	N/A	Drug Dosage Route Quantity number Quantity form Frequency Start date Stop date Prescribed by Prescription date Prescription number Pharmacy Allergic reaction Source of medication list	The patient's current medications and pertinent medication history. The section may also include a patient's prescription history and enables the determination of the source of a medication list (e.g., from a pharmacy system versus from the patient, spouse, etc.).
Allergies		Allergy or sensitivity type Reaction Severity	This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum,

		Date last occurred Treatment	current and any relevant historical allergies and adverse reactions should be listed.
Social history		Marital status Occupation Home environment Daily routine Dietary patterns Sleep patterns Exercise patterns Coffee consumption Tobacco use Alcohol use Drug use	This section contains data defining the patient's occupational, personal (i.e., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity, and religious affiliation. Social history can have significant influence on a patient's physical, psychological, and emotional health and well being, so it should be considered in the development of a complete record.
Family history	N/A	Child health history Adult health history Hereditary diseases Mother health status Mother age of death Mother cause of death Father health status Father age of death Father cause of death Sibling(s) health status Sibling(s) age of death Sibling(s) cause of death	This section contains data defining the patient's genetic relatives in terms of relevant health risk factors that have a potential impact on the patient's healthcare profile.
Review of systems	N/A	General Skin Head Eyes Ears Nose and sinuses Mouth and throat Neck Breasts Respiratory Cardiac Gastrointestinal Genitourinary Gynecologic Musculoskeletal Peripheral vascular Neurologic Hematologic Endocrine Psychiatric	A review of systems is the physician's summary of a patient's main and general body systems for basic functioning purposes. The physician will identify any problem areas in the respective sections if needed.
Physical examination	Vital signs	Pulse Respiratory rate Systolic blood pressure Diastolic blood pressure Body temperature Height Weight Body mass index Head circumference Crown-to-rump length Pulse oximetry	Vital signs are the indicators of a patient's general physical condition. It identifies a patient's level of physical functions based on elements such as heart rate, pulse, blood pressure, and body temperature.
	General appearance	Appearance Body build Demeanor Hygiene	The general appearance section describes general observations and readily observable attributes of the patient, including affect and demeanor, apparent age compared to actual age, ethnicity, body build and habitus (e.g., muscular, cachectic, obese), developmental or other

			deformities, gait and mobility, personal hygiene, evidence of distress, voice quality, and speech.
	Physical findings	Skin Head Eyes Ears Nose and sinus Mouth and throat Neck Thorax, anterior, and posterior Breasts Lungs Cardiovascular Abdomen Male genitourinary Female reproductive organs Ano-rectal Musculoskeletal system Extremities Lymphatics Peripheral vascular Neurologic Mental status	The physical findings section describes direct observations made by the clinician, divided by organ system.
Procedure history (optional)	N/A	Procedure Date Physician Institution/location Result	This section is optional and will include any past procedures or surgeries that the patient has had to include information such as what was done, where it was done, by whom it was done, and the results of it.
Diagnostic findings	Laboratory Pathology Imaging Cardiovascular	Test Result/finding Result/finding date Interpretation	This section contains the results of observations generated by laboratories, imaging procedures, and any other procedures that aid in defining treatment.
Assessment and plan	Assessment	Diagnoses Disposition	A history and physical contains either discrete sections for assessment and plan or a single section combining the two. The assessment (also dictated impression or diagnoses) represents the physician's conclusions and working assumptions that will guide treatment of the patient. The assessment is used to formulate a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.
	Plan	Treatment goals Procedures	The plan section contains all active, incomplete, or pending orders, appointments, referrals, procedures, and services. Any other pending events of clinical significance to the current and ongoing care of the patient should be listed unless constrained due to issues of privacy. The plan section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention and management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

10.1.4. **Discharge Summary**

Section	Subsection	Data Element	Description
Reason for visit	N/A	Admitting diagnosis Other diagnoses Principal operation/procedure	This section describes why the patient presented for treatment

History of present illness	N/A	Symptom(s) Onset of symptom(s) Duration of symptom(s) Over-the-counter (OTC) treatment	This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.
Diagnostic findings	Laboratory Pathology Imaging Cardiovascular	Result/finding Result/finding date	This section contains significant findings and observations generated by laboratories, imaging procedures, and other procedures.
Procedures	N/A	Procedures performed Date procedure performed Physician Institution/location Result	This sections lists all procedures that were preformed on the patient, the date they were performed, by who, and where. This section will also provide a summary of those findings.
Medications at discharge	N/A	Drug Dosage Route Quantity number Quantity form Frequency Start date Stop date Prescribed by Prescription date Prescription number Pharmacy	This section is a detailed section of the medications a patient is going to be discharged with including prescription instructions. This section may or may not include pharmacy information and prescription number.
Patient's condition on discharge	N/A	Final diagnosis Condition on discharge Reason for discharge	This section provides the status of the patient before leaving the facility or practice. This section will also identify final diagnosis and why the patient is ready for discharge.
Discharge instructions	N/A	Disposition patient instructions Follow-up action Follow-up target date	This section is usually a listing of instructions to the patient for a healthy recovery or ongoing treatment beyond the facility. A follow-up date or action must be included.

10.1.5. **Operative Report**

Section	**Subsection**	**Data Element**	**Description**
Operative staff	N/A	Surgeon Assistant Anesthesiologist	This section identifies the clinicians who were present for the procedure such as who performed the surgery and who assisted.
Operative diagnoses	N/A	Preoperative diagnoses Postoperative diagnoses	This section provides the diagnoses of the patient prior to the surgery and can include the diagnoses after the surgery.
Operation	N/A	Operation/procedures performed Operation description Findings Sedation/anesthesia Complications Drains Estimated blood loss Packs Sutures	This section describes in detail how the surgery was performed, what equipment was used/implanted including bandages and sutures, and what was concluded about patient diagnoses based on findings. This section will also identify and complications during surgery.
Patient condition	N/A	Patient condition Discharge from recovery care	This section describes the patient's status after surgery and any precautions that need to be taken for recovery.

10.2. ANNEX II - EHR SYSTEM CAPABILITIES[59]

1. Health Information and Data	2. Results Management	3. Order Entry/Management	4. Decision Support
Key data (using standardized code sets where available) Problem list Procedures Diagnoses Medication list Allergies Demographics Diagnostic test results Radiology results Health maintenance Advance directives Disposition Level of service Minimum dataset (MDS) for nursing homes Defined MDS for nursing homes Expanded/refined MDS Note Narrative (clinical and patient narrative) Free text Template-based Deriving structure from unstructured text Natural Language Processing Structured and coded Signs and Symptoms - Diagnoses Procedures Level of service Treatment plan Single discipline Interdisciplinary Patient acuity/severity of illness/risk adjustment Nursing workload Severity adjustment Capture of identifiers People and roles Products/devices Places (including directions)	Results Reporting Laboratory Microbiology Pathology Radiology Reports Consults Results Notification Multiple views of data / Presentation Multimedia support Images Waveforms Scanned documents Patient consents Pictures Sounds	Computerized provider order entry Electronic prescribing Laboratory Microbiology Pathology XR Ancillary Nursing Supplies Consults	Access to knowledge sources Domain knowledge Patient education Drug alerts Drug dose defaults Drug dose checking Allergy checking Drug interaction checking Drug-lab checking Drug-condition checking Drug-diet checking Other rule-based alerts (e.g. significant lab trends, lab test because of drug) Reminders Preventive services Clinical guidelines and pathways Passive Context-sensitive passive Integrated Chronic disease management Clinician work list Incorporation of patient and/or family preferences Diagnostic decision support Use of epidemiologic data Automated real-time surveillance Detect adverse events and near misses Detect disease outbreaks Detect bioterrorism

[59] IOM, Key Capabilities of an Electronic Health Record, Letter Report, 2003

5. Electronic Communication & Connectivity	6. Patient Support	7. Administrative Processes	8. Reporting and Population Health Management
Provider-provider Team coordination Patient-provider E-mail Secure web messaging Medical devices Trading partners (external) Outside pharmacy Insurer Laboratory Radiology Integrated medical record Within setting Cross-setting Inpatient-outpatient Other cross-setting Cross-organizational	Patient education Access to patient education materials Custom patient education Tracking Family and informal health provider education Data entered by patient, family, and/or informal health provider Home monitoring Questionnaires	Scheduling management Appointments Admissions Surgery/procedure schedule Eligibility determination Insurance eligibility Clinical trial recruitment Drug recall Chronic disease management	Patient safety and quality reporting Clinical dashboards External accountability reporting Ad hoc reporting Public health reporting Reportable diseases Immunization Deidentifying data NA Disease registries

10.3. ANNEX III - SCORES OF IMPORTANCE GIVEN TO THE EUROREC SEAL 2010-2011 STATEMENTS DURING THE EHRQ TN WORKSHOP IN LUXEMBOURG.

EuroRec ID	Statement	Average importance 0 - 5
GS001512.1	The system enables to link a role to a user.	4,6
GS001519.4	The system shall include the information necessary to identify each patient, including the first name, surname, gender and date of birth.	5,0
GS001523.3	The system enables the capture of all patient demographic data necessary to meet legislative and regulatory requirements.	5,0
GS001531.2	The system displays all current health problems associated with a patient.	4,8
GS001537.3	Each version of a health item has a date and time of data entry.	4,1
GS001538.2	Each version of a health item identifies the actor who has actually entered the data.	4,3
GS001539.2	Each update of a health item results in a new version of that health item.	3,1
GS001544.4	The system supports the use of clinical coding systems, where appropriate, for data entry of health items.	3,8
GS001550.6	The system presents a current medication list associated with a patient.	4,4
GS001559.2	The system presents a medication history associated with a patient.	4,2
GS001573.2	The current medication list can be printed.	3,2
GS001577.3	The system provides a catalogue of medicinal products.	4,4
GS001579.2	Each version of a health item has a status of activity, e.g. active or current, inactive, history or past, completed, discontinued, archived.	2,5
GS001590.2	The systems presents a list of allergens with an active status.	3,6
GS001593.2	Deletion of a health item results in a new version of that health item with a status "deleted".	3,4
GS001594.2	Each version of a health item has a person responsible for the content of that version. The person responsible for the content can be a user or a third party.	4,0
GS001595.1	Each change of status of a health issue results in a new version of that health issue.	3,2
GS001598.2	A complete history of the versions of a health item can be presented.	2,8
GS001610.3	The system enables to document a patient contact.	4,3
GS001611.1	The system is able to present for one patient contact all the documentation associated with that patient.	4,3
GS001638.1	The system presents a history of the results for discrete lab tests.	4,2
GS001901.2	Each version of a health item has a date of validity.	2,8
GS001932.1	The system supports concurrent use.	5,0
GS001947.2	The system makes confidential information only accessible by appropriately authorised users.	4,8
GS002175.2	The system enables the implementation of a privilege and access management policy.	4,6
GS002182.1	The audit log contains the registration of users logging in or out.	3,4

EuroRec ID	Statement	Average importance 0 - 5
GS002184.1	The audit log contains the registration of security administration events.	2,8
GS002198.2	Audit logs cannot be changed after recording.	3,6
GS002211.1	The system enables a user to change his password.	4,8
GS002243.1	Security service issues and operation of the system are well documented.	4,3
GS002265.1	Each health item is uniquely and persistently associated with an identified patient.	5,0
GS002266.1	Each version of a health item is uniquely and persistently identified.	3,8
GS002268.1	Each user is uniquely and persistently identified.	4,8
GS002269.1	The system enables to assign different access rights to a health item (read, write...) considering the degree of confidentiality.	3,2
GS002281.1	All patient data can be accessed directly from the patient record.	4,4
GS002287.2	The system distinguishes administrators, privileged users and common users. Administrators assign privileges and/or access rights to privileged and common users. Privileged users assign privileges and/or access rights to common users.	3,8
GS002300.2	The system is available in the languages required by the regulatory authorities.	4,0
GS002307.2	Each patient and his EHR is uniquely and persistently identified within the system.	4,6
GS002312.1	The system is able to make a distinction between patients with same name, first name, gender and date of birth.	4,0
GS002415.4	The system takes the access rights into account when granting access to health items, considering the role of the care provider towards the patient.	3,0
GS002437.4	The system offers to all the users nationally approved coding lists to assist the structured and coded registration of health items.	3,2
GS002489.2	Data entry is only done once. Entered health items are available everywhere required.	4,6
GS002497.3	The system displays patient identification (name, first name, age and sex) on each data entry interface.	4,0
GS002582.2	The system displays, when prescribing a medicinal product, known allergies of the patient, if it does not alert the user for a specific allergen.	3,5
GS002625.1	The system enables the user to modify patient's administrative data.	4,8
GS002638.1	The system distinguishes actual or active medication items from past medication items when including and displaying medication items in lists or in a journal.	3,4
GS002639.1	The system enables the user to modify health items, if legally admitted.	2,5
GS002655.2	The system has a timeout function, terminating a session after a configurable period of inactivity.	3,2
GS003787.1	The system has a consistent way to present clinical alerts, e.g. red colour for abnormally and/or high lab results.	3,6
GS004729.2	A medication list presents at least the following elements: identification of the medicinal product (package), starting date, date of the latest prescription, dosing instructions (structured or as a textual expression)	4,2