eHealth Network sub-group on Semantics

Common Semantic Strategy for Health in the European Union

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Acronyms

Acronym	Description
ATC	Anatomical Therapeutic Chemical medicines classification
CALLIOPE	CALL for InterOPErability (See: CALLIOPE - Progress Report)
CBeHIS	Cross-Border eHealth Information Services
CSA	Coordination and Support Action
CSS	Common Semantic Strategy
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
EC	European Commission
eD	eDispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	eHealth Digital Services Infrastructure
eHMSEG	eHealth Member States Expert Group
EHR	Electronic Health Record
eHN	eHealth Network
EHRxF	Electronic Health Record Exchange Format
EMA	European Medicines Agency
eP	ePrescription
epSOS	European Patients Smart Open Services
EQA	External Quality Assurance
EQALM	European Organisation for External Quality Assurance Providers in Laboratory Medicine
ERN	European Reference Networks
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable
HC	Healthcare
HL7	Health Level 7
HL7 FHIR	Health Level 7 Fast Healthcare Interoperability Resources Specification
HP	Health Professional
ICD-10	International Classification of Diseases – version 10
ICD-10-CM	International Classification of Diseases – version 10 – Clinical Modification
ICD-O	International Classification of Diseases for Oncology
ICT	Information and Communication Technology
ISO	International Organization for Standardization
JCP	Joint Coordination Process
JRC	Joint Research Centre
LOINC	Logical Observation Identifiers Names and Codes
MRI	Magnetic resonance imaging
MS	Member State
MS/C	Member States/Countries
NCPeH	National Contact Point for eHealth
NCSP	NOMESCO Classification of Surgical Procedures
NPU	Nomenclature for Properties and Units
PCS	Procedure Coding System
PS	Patient Summary
RMS	Referentials Management Services
SDO	Standards Development Organisation
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
STF	Semantic Task Force
WG	Working Group

Executive summary

The European Commission (EC) has acknowledged the need for eHealth interoperability for more than a decade. Considering this necessity, some projects have aimed to develop the interoperability of electronic health records within the European Union (EU). This has triggered initiatives such as epSOS and CALLIOPE, as well as a subsequent first Joint Action, the eHealth Governance Initiative (eHGI). These were some of the first steps to define and drive a way forward to achieve the best feasible scenario for EU eHealth integration.

In the collaborative project named CALLIOPE (2008-2010), various eHealth experts proposed an interoperability roadmap, which remains, for the most part, amazingly valid, especially with regards to semantic interoperability. Amongst the many useful recommendations in this document, there were also concrete possible steps suggested.

In May 2018 the eHealth Network (eHN) discussed the need for a common semantic approach towards standardised exchange of health information in the European Union. In November 2018, the eHN endorsed the work of the Working Group on Common Semantic Strategy (CSS) created within the eHAction Joint Action to come up with a solid proposal for a five-year strategy, that was discussed as a draft in June 2019 and to be approved in November 2019.

According to the recent EC Recommendation on European Electronic Health Record Exchange Format[1] (EHRxF, 6th Feb. 2019) the following healthcare information domains have been identified as a source of baseline requirements to establish EU semantic interoperability recommendations:

- Patient Summary
- ePrescription/eDispensation
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge reports

In addition to the above, the field of rare diseases has been identified as the one with a high demand for standardisation due to a specific nature of rare diseases, their devastating impact on patients and unique challenges associated with their treatment. Rare diseases are also one of the key domains of the European Reference Networks (ERN)[2].

To achieve a Common Semantic Strategy for health information capture, visualisation, portability, processing, storage, markup, annotation, retrieval, accessibility, exchange, secondary use, analytics, reporting, communications, knowledge representation, modelling, decision support and innovative information management, consideration should be given to all semantic requirements that are relevant for health data in the EU or globally. Initial focus should be on cross-border eHealth requirements, but including all other eHealth related subjects as necessary, to support national-level approaches when required and as needed.

It should be noted that the governance structure proposed in the document is the result of shared reflections of the CSS working group, the CSS workshops, the work of subgroups, Member States/Countries' (MS/C) internal work around the CSS, and the work of the Semantic Task Force (STF). This is still to be

[1] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format
[2] https://ec.europa.eu/health/ern/networks_en

aligned and streamlined with a global approach under the concept of the Joint Coordination Process[3] and other holistic governance efforts of the eHN and its subgroups, as well as other functional and already existing bodies, like the eHealth Member States Expert Group (eHMSEG) and its Semantic Task Force. The CSS proposal of interaction could be seen throughout the document, considering these groups and new ones.

This document intends to formally present to the eHN the work developed by the CSS Working Group, in the form of an elaborated CSS draft proposal to achieve semantic interoperability in selected use cases for healthcare and health management at the EU level in the coming years. The selected information domains represent what the group has considered reasonably feasible within 5 years. Some future domains will need a more precise definition before any strategic proposal can be formulated.

[3] The first debate between EC and the Member States was on the 6th May 2019, in an eHN subgroup meeting, and is still to be further debated in the eHN meeting in June. Please, see chapter 6 for more information.

1. Introduction

1.1. Background

The European Commission (EC) has acknowledged the need for eHealth interoperability for more than a decade. Considering this necessity, some projects are aimed at developing the interoperability of electronic health records within the European Union (EU). This has triggered initiatives such as epSOS and CALLIOPE, and a subsequent first Joint Action, the eHealth Governance Initiative (eHGI). These were some of the first steps to define and drive a way forward to achieve the best feasible scenario for EU eHealth integration.

The epSOS[4] project (2008-2014) was set out to develop, evaluate and pilot some cross-border eHealth services and elaborate recommendations for them. The focus of this initiative was to achieve high quality, secure and safe services for the exchange of Patient Summary and ePrescription/eDispensation data in a European cross-border context.

The European Commission expressed the need for enhanced cross-border interoperability of electronic health records through the publication of its Recommendations on 2nd July 2008 (2008/594/EC)[5]. The semantics topic was one of the main points to be improved and structured for this proposal. Ten years after this first initiative, the adoption and implementation of a European Electronic Health Record Exchange Format (EHRxF) and interoperability mechanisms is still a strong necessity to be achieved within the EU.

In the collaborative project named CALLIOPE[6] (2008-2010), various eHealth experts proposed an interoperability roadmap which remains, for the most part, amazingly valid, especially with regards to semantic interoperability. Amongst the many useful recommendations in this document, there were also concrete possible steps suggested.

The eHealth interoperability topic gained even more importance through the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU)[7] published on 9 March 2011. Within it, the legal foundation was created to set up the eHealth Network (art. 14) whose main objective is to "work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications […]". Furthermore, the European Commission came up with a detailed roadmap to empower patients and healthcare workers, to link up devices and technologies, and to invest in research towards personalised medicine for the future through the eHealth Action Plan 2012-2020[8]. With the Digital Single Market strategy[9], the Commission made eHealth interoperability part of its priorities in order to strengthen EU competitiveness.

According to the recent EC Recommendation on European Electronic Health Record Exchange Format (EHRxF[10], 6th Feb. 2019) the following healthcare domains have been identified as a source of baseline requirements for technical interoperability standardisation:

[4] https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved
[5] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008H0594
[6] http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5bCALLIOPE%20-%20published%20by%20DG%20INFSO%5d.pdf
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN
[8] https://ec.europa.eu/health/sites/health/files/ehealth/docs/com_2012_736_en.pdf
[9] https://ec.europa.eu/commission/priorities/digital-single-market_en
[10] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

- Patient Summary
- ePrescription
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

In addition to the above, the field of rare diseases has been identified as the one with specific needs and high priority for standardisation. Rare diseases may be debilitating or life threatening and can have devastating impact on patients and their families. Treatment is associated with challenges different and often more serious than from those associated with more prevalent diseases. Due to the unique nature of rare diseases, promising therapies can only be developed through international collaboration based on comprehensive collection and cross-border sharing of clinical data. Standardisation of rare diseases shall be aligned with the above-mentioned domains where appropriate (e.g. adding of rare disease in a Patient Summary record).

As things stand today regarding semantic interoperability, some Member States/Countries (MS/C) have set national-level semantic strategies in order to generate and provide data for cross-border patient care, as well as aggregate data from different sources for public health and health management applications.

Additionally, future semantic interoperability may request:

- Adoption of interoperability standards for biomedical research and other secondary uses, such as e.g.: ISO/DIS21393 "Health Informatics - Omics Mark-up Language (OML)[11];
- Standards and methodologies for promising new uses based on Real World Data, such as Artificial Intelligence and Big Data applications.

1.2. Current context

Achieving genuine interoperability in the EU is key to promoting an effective exchange of health information. Interoperability means the ability of health information systems to work together within and across organisational, regional and national boundaries in order to share information needed to provide healthcare services. In particular, semantic interoperability enables sharing and processing of healthcare data while keeping its relevant context and meaning. Semantic interoperability retains the ubiquity of the information travelling across clinicians, laboratories, hospitals, pharmacies and patients, regardless of the ICT systems applied. It is crucial to make data commonly available and interpretable across the whole healthcare and well-being pathway.

Information modelling and coding standards are the pillars on which technical, syntactic and semantic interoperability are supported. However, there should be uniform guidelines referring not only to the use of standards but also to information exchange formats. The uniformity of coded and structured data, travelling through standardised messages using standardised formats, will allow for the meaningful sharing of information between IT systems.

The overall aim is to facilitate the meaningful sharing of information both internally within a country and across borders. Thus, health information should flow for European citizens along their healthcare pathway, with minimum loss of meaning, or no loss at all.

[11] https://www.iso.org/standard/70855.html

To achieve this, a meaning-oriented strategy needs to be put in place, encompassing all kinds of health information, potentially including patient generated and owned data, as well as information used for health and social care, and research.

Cross-border standard specifications have a great potential for usage in national systems. The standardisation of the semantic approach should bring benefits for MS/C due to:

- Availability of knowledge for national semantic resources of MS/C;
- Common standards as a reference for specifications for other ICT related projects within MS/C;
- Use of common semantic standards for setting national standards, minimising burden on national resources;
- Higher acceptance among national users for adoption of a common EU standard (as the legitimacy of such standards would not be questioned by national stakeholders).

The adoption and use of semantic standards for health will bring benefits to all stakeholders: healthcare service providers, health professionals, healthcare service system vendors, citizens/patients, public institutions responsible for public healthcare, public payers and many others[12].

The use of the commonly adopted standards can therefore ensure better treatment for patients, regardless of their whereabouts, by ensuring the correct and unambiguous exchange of clinical data between MS/C and healthcare stakeholders. Additionally, the increase in exchange of health information could have secondary uses, relevant to public health programmes and clinical research, updating national and regional policies to improve citizens' life.

Some initiatives to improve eHealth semantic interoperability among MS/C are already being developed, such as the Semantic Task Force[13] working under eHMSEG responsibility. This group is focused on practical issues regarding the implementation of two cross-border services: Patient Summary (PS) and ePrescription / eDispensation (eP/eD). They have already made available some recommendations regarding these domains of healthcare. However, as this group is driven by the practical issues of only two of the five EHRxF information domains, a large part of EU semantic necessities is still unexplored and in need of a solid strategy on how to move forward within the sphere of semantic interoperability.

During the 13th eHN meeting held on 15th May 2018, eHealth interoperability and policy actions to improve semantic interoperability in the EU were discussed[14]. This was intended to initiate a constructive discussion among members of the eHN with the objective to further improve semantic interoperability in the EU. As a result of this discussion, it was noted by the participants that a Common Semantic Strategy (CSS) in the EU was needed. As such, a provisional working group was raised under the eHAction activities, to discuss the principles, scope and ambition of such a strategy. A formal invitation to all MS/C representatives was made, asking each one to nominate an expert for this working group.

This document is the result of the active participation of the nominated representatives from a set of MS/C in 14 teleconferences and three workshops: two held in Lisbon (1st & 2nd October 2018 and 18th & 19th March 2019) and one held in Brussels (2nd & 3rd September 2019).

The aim of the Working Group is to set a foundation for the development of a Common Semantic Strategy for Health in the EU, whilst addressing some of the relevant needs. It should describe possible steps to achieve a solid basis within 5 years, while noting that, for a solid semantic strategy, the work cannot stop

[12] https://www.euhealthsummit.eu/wp-content/uploads/Future-of-Health-recommendations-in-full-new.pdf
[13] https://ec.europa.eu/cefdigital/wiki/display/EHSEMANTIC/eHMSEG+Semantic+Task+Force+documents
[14] Cover Note by eHealth Network Secretariat:
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

there and planning for continuity needs to be included in further considerations. It was stated by the semantic experts that such a semantic strategy is a matter for at least 10 years and, once established, needs ongoing maintenance and evaluation. The mission and the vision of the resulting CSS should set and share a 10-year perspective.

1.3. Description of the challenge

Due to the lack of regulation on the adoption of semantic standards for health information at EU level, MS/C have addressed their needs through the adoption of national standards or divergent international standards. Therefore, the decision on which standard to adopt has been taken in MS/C according to their internal exchange and analysis needs, and not according to any alignment with any criteria from other European authorities. So far, MS/C have achieved different levels of adoption and implementation of modelling and semantic standards that enable semantic interoperability of health data. Many national-level decisions are trying to cope with internal interoperability issues, lack of national semantic resources and conflicting interests among national stakeholders. Existing standards-based solutions and systems may be aimed to address immediate priorities but often tend to have limited applicability outside each national environment and are not easily sustainable in the long term. This causes a situation of high heterogeneity of semantic standards adopted and in use in the EU, and consequently a low alignment between MS/C for the exchange of information.

To solve this, it may not be realistic to force MS/C to implement a retrospective adoption of standards, or to impose standards prospectively in the short term. This situation of **high heterogeneity** of semantic standards in use, and **low alignment** between MS/C represents a **challenge** that must be resolved to achieve **genuine semantic interoperability** among the MS/C of the EU. Evolving and maintain Semantic Assets and Capacity Building aligned with universities; Foster National Terminology/Semantic Centres.

2. Mission and Vision

2.1. Mission

Establish a Common Semantic Strategy for the adoption of standards facilitating large-scale exchange of health information in the European Union, by facilitating convergence on interoperability standards for all MS/C. This adoption should be based on sustainable EU policies, information exchange flows between countries, conditions of availability of data, and the national standards that countries have adopted in the absence of previous European regulations. The governance process for semantic interoperability efforts shall be interlinked with the governance of projects and services for eHealth in Europe, within the framework of the Joint Coordination Process.

2.2. Vision

The EU and its partners will achieve genuine semantic interoperability that allows the effective exchange and use of electronic health data.

3. Goals

In order to make it feasible to effectively align to the Common Semantic Strategy by 2025, three strategic goals are set for the upcoming period of 5 years:

G1 – Structure a common approach on health semantics in the European Union

Elaborate the framework, guidelines and recommendations to drive the basis for semantic standardisation at European level. These guidelines should be prescriptive at EU level but adopted and supported by policies at national level sources of information.

G2 – Provide guidance for EU level decisions on health semantics

Establish mechanisms for capacity building in countries for consideration and use of the Common Semantic Strategy, e.g. by fostering participation in the discussion and approval of EU semantic assets and projects.

G3 – Ensuring establishment and continuity on health semantics in the EU

Create sustainability to the eHN Semantic Subgroup and make the case for dynamics of the subgroup.

Table 1 - CSS Goals objectives and activities.

Goal	Description	Objective	Activity
G1	Structuring a common approach on health semantics in the EU	**O1.1** Realise a Common Semantic Strategy for Health in the EU	**A1.1.1** Communicate with and obtain support from the eHN for 5-year CSS
			A1.1.2 Analyse current and future data availability, standards and information exchange flows in MS/C
			A1.1.3 Structure a learning programme to assist capacity building in MS/C
			A1.1.4 Midterm evaluation and iterative review
			A.1.1.5 Ensure active MS/C participation
			A.1.1.6 Set up an operational plan to ensure the development and completion of the other domains.
		O1.2 Develop common semantic assets for PS, eP, laboratory results, medical imaging and reports, hospital discharge reports	**A1.2.1** Drive the development of common semantic assets for the Patient Summary
			A1.2.2 Drive the development of common semantic assets for the ePrescription/eDispensation
			A1.2.3 Drive the development of common semantic assets for the Laboratory Results
			A1.2.4 Drive the development of common semantic assets for the Medical Imaging and Reports
			A1.2.5 Drive the development of common semantic assets for the Hospital Discharge Reports
			A1.2.6 Set up common semantic assets: "Common European Health Semantic Services"
		O1.3 Provide guidelines for standards adoption	**A1.3.1** Study the current and future data availability and standards in use in the different MS/C
			A1.3.2 Access and refine common standards for the cross-border exchange of health information
		O1.4 Establish a solid relationship with key bodies of the EU and key technological partners	**A1.4.1** Liaison with key partners such as SDOs, technology developers etc. relevant to the CSS
			A1.4.2 Establish a collaboration routine and mechanisms with key bodies of the EU relevant to the CSS
G2	Providing guidance for EU level decisions on health semantics	**O2.1** Establish methodology to address alignment to CSS issues at an EU level.	**A2.1.1** Propose a mechanism to build capacity in MS/C to foster the use of EU semantic standards for healthcare
			A2.1.2 Influence EU deployment projects that use semantic standards
		O2.2 Ensure the alignment with the CSS launch of new initiatives related with semantic assets and projects	**A2.2.1** Propose to the eHN a mechanism to participate in the approval of EU semantic assets and projects
G3	Ensuring stability and continuity on health semantics in the EU	**O3.1** Sustainable semantics activity in EU	**A3.1.1** Make case for stable dynamics
			A3.1.2 Create sustainability plan
			A3.1.3 Draft new CSS for 2025-2030

4. Value Proposition

Following the EC recommendation on Electronic Health Record exchange format (EHRxF) published on 6th Feb. 2019, this chapter aims at presenting five value propositions to better describe and contextualise the need for the establishment of a Common Semantic Strategy for Health in the EU. These propositions relate to the information domain a set out in the EHRxF EC recommendation.

The definition of a Common Semantic Strategy is needed to support the adoption of national and cross-border technologies. Furthermore, not all EU countries have the technical possibility to receive electronic prescriptions from other EU countries, since countries are in different states of maturity of electronic systems development. The actual coding standards used by the MS/C can be seen in Annex 2.

4.1. Patient Summary Domain

Patient Summary Guidelines were first prepared by the epSOS project as a starting point for the development and pilot testing of a Patient Summary for citizens who are travelling abroad and need unplanned medical help[15]. Since then, the need to exchange essential clinical data across borders has become increasingly recognised. Citizens of the EU travel for work, study and leisure; and the number of persons seeking medical help abroad continues to grow. In the forthcoming years, even more people are expected to receive medical treatment in facilities located outside of their country of domicile.

The Patient Summary (PS) domain has been deployed in many MS/C. Being a concise clinical document, it is universally applicable, and its usability is not limited to emergency care. It is supportive in continuous care of chronic patients and can be used in conjunction with other sources of data.

Access to a PS increases patient safety and helps to optimise the outcome of medical treatment. Patients, health professionals and healthcare providers are increasingly aware of its value and national borders must not be barriers stopping its flow. While past solutions, before the adoption of CEF eHDSI, for getting medical information from another country were often unsafe, incomplete and non-standard, there is a reasonable expectation that the PS is accessible wherever emergency or planned treatment is taking place.

The PS dataset comprises patient administrative data and patient medical history. The patient clinical dataset is divided into several sections: Alerts, Allergies, Medical problems, Medication summary, Surgical procedures, Vaccinations, Implanted devices, Social history, Pregnancy history, Physical findings and Diagnostic tests.

The purpose is “sharing information about the medical background and history of a patient from one MS, “Country A” (the patient’s country of affiliation) with a health professional in another MS, “Country B” (the country of treatment). The use case is relevant for people requesting clinical assistance when travelling, working or living abroad.

The setting up of cross-border exchange of PS through the eHealth Digital Service Infrastructure (eHDSI), supported by the Connecting Europe Facility (CEF), is in progress. The following is the latest description of the PS that potentially will be in use in almost all MS/C in the not-too-distant future:

[15] https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved

A Patient Summary is an identifiable "data set of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care". It can also be defined at a high level as: "the minimum set of information needed to assure Health Care Coordination and the continuity of care".

4.1.1. Known used standards

The code systems that were used for Patient Summary in epSOS are listed in the Master Value Set Catalogue (MVC)[16], which has been subsequently updated in eHealth DSI by the eHMSEG Semantic Task Force. The Value Set Catalogue is a collection of the mostly used terms from different international code systems based on definite criteria presented in the methodology section. The MVC is the basis for the creation of the Master Translation/Transcoding Catalogue (MTC) by each deploying country. As use of code systems vary across MS/C, it is expected that translation between systems will be necessary. Continuous monitoring of systems used in MS/C will thus be important.

4.1.2. Semantic constraints and challenges

The sharing of data through mapping and translation of terminology codes (national and international) could generate loss of information. In many cases, full mapping is not possible between different coding systems, for example NOMESCO Classification of Surgical Procedures (NCSP) and SNOMED CT for surgical procedures.

In addition, for a Patient Summary to be considered valid, there is a minimum set of information to be provided in a structured and coded format. The minimum set of information was decided based on its relevance from a clinical point of view and declared readiness during the epSOS Project[17]. The issue raised by some countries is that they cannot provide the minimum set of information within the Patient Summary in a structured and coded format.

In the eHN's Release 2 of the PS Guidelines[18] it is also said: "*It is expected that the eHN will oversee the process by which code systems are kept under review and ensure that appropriate licensing arrangements are in place*". Based on a Change Proposal approved by EC (DG SANTE) and eHMSEG, the computable CDA Template specifications (based on ART-DECOR[19]) has allowed to improve the consistency and reliability of the exchange of PS data.

A gradual adoption of the CEN International Patient Summary (IPS)[20], based on the EU PS Guidelines and on HL7 IPS Implementation Guides will enforce the adoption of international standards and take advantage of the Patient Summary derived from epSOS, potentially extending its applicability to Planned Care.

Content and structure of the PS should be regularly evaluated and adapted as new use cases might create additional semantic requirements, e.g. inclusion of information about rare diseases, and new versions of terminology and coding systems might better reflect clinical needs of interoperable records. In all cases

[16] https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=35208905
[17] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Patient+Summary+Required+Sections+-+Clarifications+on+the+information+to+be+exchanged
[18] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[19] https://art-decor.org
[20] http://www.ehealth-standards.eu/results-of-the-international-patient-summary-project-2/

thorough feasibility and impact analysis should be done as implementation of new semantic features might have implications for the MS/C national infrastructure.

4.2. ePrescription/eDispensation Domain

An ePrescription is defined as the electronic document resulting from prescribing medicine using software, performed by a health professional legally authorised to do so, for dispensing, once it has been electronically transmitted to the pharmacy. ePrescribing consists in an electronic prescription of medicine by a health professional and its electronic transmission to a pharmacy where the medicine can then be dispensed.

eDispensation within the eHealth DSI is defined as the electronic document resulting from dispensing medicine using software, performed by a pharmacist legally authorised to do so, of an ePrescription transmitted to the pharmacy. eDispensing is defined as the electronic retrieval of a prescription and the dispensing of the medicine to the patient as indicated in the corresponding ePrescription.

4.2.1. Known used standards

The epSOS Semantic Work Group identified the code systems that were used for ePrescription and eDispensation in the first versions of the Master Value Set Catalogue (MVC), which was subsequently updated in EXPAND and also in eHealth DSI by the eHMSEG Semantic Task Force. (The MVC has been described in section 4.1).

The MVC includes various classifications relevant to ePrescriptions/eDispensations, for example ATC (Anatomic Therapeutic Chemical classification), EDQM (European Directorate for the Quality of Medicines) for Dose Form, Packages, Route of Administration, Display Labels, Health Professional Roles and Country. The use of international classifications based on ISO IDMP[21] (Identification of Medicinal Products), and other relevant code systems to support semantic interoperability within the EU could be considered in the future. Most countries have National Drug Code Systems, adjusted to their domestic situation, so the possibility of performing mappings between international standards and national code systems can be relevant.

4.2.2. Semantic constraints and challenges

Some technical and legal challenges have occurred in ePrescription and eDispensation.

One of the major constraints is the lack of a uniform classification system or an international standard regarding drugs that is universally accepted. ePrescription/eDispensation systems, when existent, are highly dependent on national code systems, turning semantic interoperability into a true challenge. The variability of the correspondence of drugs between countries (e.g. commercial names of the drugs, dosages, pharmaceutical form, etc.) makes this harmonisation even more difficult. The need for a European-wide univocal identification number or code for a medicinal product and its underlying pharmaceutical product(s) has been acknowledged for many years. The eHealth Network Guidelines on ePrescription[22] and Patient Summary[23] indicate the adoption of the ISO IDMP codes as a way to solve pharmaceutical/medicinal products identification issues.

[21] https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview
[22] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf

Ongoing and newly starting projects (such as the recently approved UNICOM[24] project), aim at solving the discrepancies and have to be considered further in the work of the CSS Working Group.

4.3. Laboratory Results Domain

Clinical laboratory requests and results play an important role in diagnosis, treatment and follow-up of patients.

Thus, requests and sharing of laboratory results in cross-border health information exchange is an expected and wanted further extension within the CEF eHDSI. Furthermore, exchange of laboratory test orders and result reports will support free movement of the services as one of the key principles of the EU (Commission Recommendation of 6th Feb. 2019 on a European Electronic Health Record exchange format).

It is important that laboratories produce high quality test results as they often are the basis for clinical decision making. Proper quality management is therefore essential. It is also important that requests sent to the laboratories are of sufficient quality to enable the laboratory to respond in an adequate way to the request, for example including sufficient medical background.

The Laboratory area is one of the most standardised areas of the medical industry, thanks to the extended use of automation (produced by global companies) while the situation is not without challenges, as well as to a long tradition in the organisation of external quality control programmes.

4.3.1. Known used standards

A recent study on comparison of terminologies for laboratory results shows that "there are still limitations in electronic transition of lab reports in complex treatment pathways that involve multiple laboratories. Medical laboratories do not only measure analysis, but also strive to make their results actionable for patient treatment. They ensure that the laboratory reports are correctly transmitted to the requesting physician with a short turnaround time. Laboratories also assist in the interpretation of their results by providing comments, statements regarding measurement uncertainty, reference intervals, medical decision limits, or other means"[25].

According to a quick survey between MS/C represented in the CSS working group, two main international laboratory terminology systems for test coding are being used: Logical Observation Identifiers Names and Codes (LOINC)[26] and Nomenclature for Properties and Units (NPU)[27]. Four countries reported use of LOINC based systems (Austria, Estonia, Portugal and the Netherlands) and four countries use NPU based systems (Sweden, Denmark, Norway and the Czech Republic); several countries are using other national

[23] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[24] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-09-2019
[25] https://www.researchgate.net/profile/Stefan_Schulz3/publication/328558872_NPU_LOINC_and_SNOMED_CT_a_comparison_of_terminologies_for_laboratory_results_reveals_individual_advantages_and_a_lack_of_possibilities_to_encode_interpretive_comments/links/5c10c8be299bf139c7524c1b/NPU-LOINC-and-SNOMED-CT-a-comparison-of-terminologies-for-laboratory-results-reveals-individual-advantages-and-a-lack-of-possibilities-to-encode-interpretive-comments.pdf?origin=publication_detail.
[26] https://loinc.org/
[27] http://www.npu-terminology.org

terminologies, a mix of different terminologies, or a defined laboratory terminology has not been decided upon (e.g. Germany, Slovakia, Poland, Slovenia).

It should also be noted that additional code systems are needed for coding of specimen types, anatomic specification, specimen collection, processing and test methods, containers, measurement units, and ordinal or nominal-scale test results.

Terminology-wise, requests are not as well standardised as reports, where requests more often reflect local ordering practices where national standardisation is lacking. Some laboratories use standard terminologies like LOINC and NPU also for ordering while others do not.

4.3.2. Semantic constraints and challenges

Exchange of laboratory orders and results is currently not an eHDSI-supported use case. EU countries with well-established electronic laboratory communication will not be likely to change their existing laboratory coding systems, thus transcoding to the selected pivot terminology represents one of the main challenges on the way to the semantic interoperability of the order/result cross-border communication.

Still, while laboratory medicine is relatively well standardised, comparison of results between different laboratories is a major challenge due to differences in methods, instruments, and lack of international calibrators which is certainly true for some areas of laboratory medicine, such as microbiology, immunology and histopathology.

4.4. Medical Imaging and Reports Domain

Medical imaging is an important diagnostic tool and is central in many diagnostic or treatment processes, like orthopaedic diagnostics and follow-up of cancer treatment. In the last decades many imaging areas such as radiology have undergone a shift from analogue to digital technology, allowing new ways of working with medical images. As an example, in teleradiology, the communication of images and reports enabled by digitalisation is now common practice. Cross-border communication of imaging data is also routine but typically through point-to-point communication using Digital Imaging and Communications in Medicine (DICOM) standards. In addition to reports, information provided in the request is important for interpretation of results and should also be elaborated on future EU projects.

4.4.1. Known used standards

DICOM is used worldwide as standard in the storage, exchange, and transmission of medical images. DICOM has been central to the development of modern radiological imaging: DICOM standards are used for imaging modalities such as radiography, ultrasonography, computed tomography (CT), magnetic resonance imaging (MRI), and radiation therapy. DICOM includes protocols for image exchange (e.g., via portable media such as DVDs), image compression, 3-D visualisation, image presentation, and results reporting.

The same basic format is used for all applications, including network and file usage, but when written to a file, usually a true "header" (containing copies of a few key attributes and details of the application which wrote it) is added.

4.4.2. Semantic constraints and challenges

One of the constraints regarding medical imaging and reports is that the results are mostly described with free text. In addition, national value sets are used to identify the medical imaging procedures for

reimbursement reasons and therefore mapping the national value sets to international ones can be complicated.

4.5. Hospital Discharge Reports Domain

The discharge report after a hospital stay is a well-established instrument of communication between the hospital and a physician responsible for the post-hospital care of a patient, independently of the setting in which this care is provided. In addition, it is a source of information for the patient and caregivers.

Use of discharge reports is not limited to inpatient episodes. Some health services may also provide discharge reports for emergency care and for ambulatory clinic processes of care.

Discharge reports originated as personal letters written from one doctor to another doctor to provide information on a defined situation during a period of time spent in a health environment; therefore, a discharge report is an important element of information about the patient, which has to respect pre-defined conditions to present a complete set of important information about the patient. This means it should be structured, if possible, containing also coded information, using defined catalogues and tools. The ambition is to have a communicable composition which is an integral part of a national electronic health record, which fits into international formats, and could to a certain extent be translated automatically using the epSOS/ eHDSI infrastructure and covers the requirement of having text which can be understood by physicians and patients.

In addition to information for the post-hospital phase, a hospital discharge report should contain: detailed medical findings during the stay, medication used, laboratory findings and radiology reports.

4.5.1. Known used standards

The intended EU strategy for interoperability of this information object could be informed by several specifications already developed by MS/C[28], and by European and international SDOs.

4.5.2. Semantic constraints and challenges

The differences in the requirements for the content of the discharge report from different types of episodes (from different medical specialties), together with historical tradition of structure and content of discharge reports by healthcare facilities, represent a major challenge for semantic standardisation. It should be taken into account that some national medical environments are less inclined to standardise in this area.

However, it is clear that discharge reports (as well as other types of comprehensive medical documents) should not only be understandable to a person, but also be machine-readable. This means that the document should include both a narrative part, intended only for human beings, and a part encoded for further machine processing with clear standardised sections and coded entries. The discharge letters could include, in the future, information provided by other health professionals.

[28] Some MS/C have established Hospital Discharge letters:
https://theprsb.org/wp-content/uploads/standards/5b98da94aa3ef80313a9e97c.xlsx
https://theprsb.org/standards/edischargesummary/
https://digital.nhs.uk/services/transfer-of-care-initiative/edischarge-summaries
https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=29950390

Standards for structure and coded entries need to be specified and agreed between MS/C based on common identified patterns.

Decisions on terminologies and other code systems used by national infrastructures should be made. Pre-defined structures of coded entries such as those of the PS (problems, medications, procedures, etc.) should be reused.

5. Common Semantic layers

This chapter aims at providing some insights on key aspects that need to be addressed in order to realise a common approach to health semantics in the EU, aiming at providing the reader with further context about the subject whilst also setting a path for future work by MS/C.

It is also important to clarify that some of the aspects presented in this chapter can be discussion items of other EU bodies and their conclusions must be made as part of the final common semantic strategy proposal.

The following figure describes the relationship between the five domains of EHRxF, and potential future domains with the five information domains and the layers of the Common Semantic Strategy (Figure 1). While standardising health information in the five domains listed here and in EHRxF is a goal, in order to guarantee the consistent and efficient development of semantic resources across the five domains, the strategy includes four layers which span the domains horizontally: processes, information, services (applications), technology and their impact on this strategy.

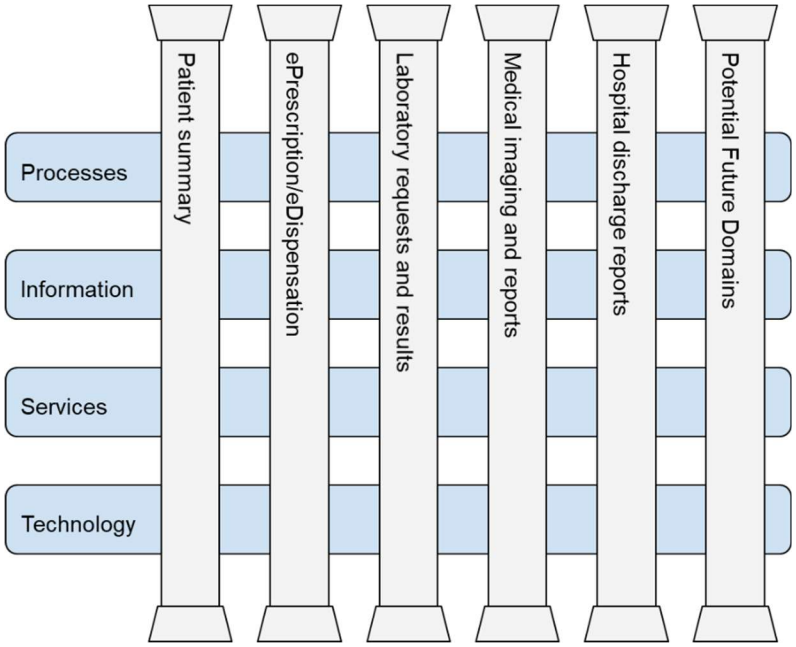

Figure 1 - Transversal health information domains among the semantic layers.

5.1. Processes

Core processes underpinning the semantic strategy need to be laid out, such as establishing a way to consult MS/C for their needs and inputs regarding semantic issues. In this regard, establishing a methodology to prioritise the roadmap leading to semantic interoperability is also required, as well as defining a maturity model to assess or keep track of the maturity of MS/C regarding health semantics.

Likewise, it is as important to establish a set of processes that allow the maintenance and update of EU level semantic assets and capacity building within the MS/Cs and NCPs.

5.2. Information

Central to the strategy is the capacity to share health information within MS/Cs and within Europe with the ability to use and re-use information in the receiving systems for both primary and secondary purposes.

This requires the establishment of standardised semantic assets such as information models and code systems.

The eHDSI laid the ground for semantic assets in the field of exchange of PS and eP/eD. These assets will be re-used and, when necessary, expanded in the context of laboratory medicine, medical imaging and hospital discharge reports, as well as future domains brought by EU projects and activities.

MS/C are constantly reviewing emerging trends in eHealth, in structured and unstructured formats, including for example adoption of new standards, information models and code systems; this requires monitoring on a strategic level.

5.3. Services

For successful realisation the strategy further depends on services being available for use by MS/C and EU projects. As the number of distinct services can be expected to be large, an ecosystem of services, both existing and newly developed, needs to be established. The strategy will be building upon services already established by, for example, eHDSI, the EU Rare Diseases Platform, EARS-Net, the European Medicines Agency's Referentials Management Services (RMS)[29] and other helpful services.

Examples of such services can be:

- Provision of a "Common European Network of Health Semantic Services" as a repository for standardised semantic assets
- Provision of testing tools and test plans, together with reference test data.

5.4. Technology

Technology is a key enabler of the semantic strategy, i.e. technology needs to be put in place which allows the results of the activities within the strategy to be implemented. Thus, lack of technology standards is also a barrier. Also, the constant development of new and improved technologies is a challenge for any long-term strategy. The strategy will be agile to adapt to emerging and developing technologies in eHealth.

Here, the strategy will build upon what has been established by the eHDSI and eHMSEG.

Particularly, the success of innovative technologies like Natural Language Processing, AI, and Big Data Analytics will have a dependency on the availability of standardised structured data, i.e. the realisation of this strategy.

Here, the strategy will build upon what has been established by the eHDSI and eHMSEG.

[29] https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/referentials-management-service-rms

6. Policy and Governance Structure description

The governance aspects proposed resulted from CSS Working Group reflections in the workshops and teleconference sessions, as well as considerations resulting from existing eHealth Network and eHDSI governance bodies. This is still to be finally aligned and streamlined with a global approach under the concept of the Joint Coordination Process played out in the EHRxF recommendation and formally approved by the eHealth Network. A concrete proposal making use of the new eHN Subgroup for Semantics (approved during the 15th eHN meeting, 11th-12th June 2019), as well as other functional and already existing formal/informal bodies, like the eHealth Member States Expert Group (eHMSEG) and its Semantic Task Force, is advanced.

6.1. Guiding Principles

A Common Semantic Strategy (CSS) should consider all semantic requirements that are relevant for healthcare in the EU, focussing initially on the eHealth domains addressed in this paper but progressively expanding on all health-related subjects, including research.

The realisation of a CSS must be guided by the needs of MS/C, as well as by "FAIR" principles: i.e. recommendations of semantic standards will acknowledge that they have to be Findable, Accessible, Interoperable, and Reusable. Implications such as licensing, maintenance or accessibility issues of the recommended standards will have to be considered before their adoption, and solutions to avoid any limitations of use for MS/C will have to be addressed.

A CSS will have to be future-oriented towards new developments in the field of standards to be included without the need for redevelopment of the resources and the technical infrastructure. Revisions of included standards (like ICD-10 to ICD-11) need to be addressed once available and a joint approach on the change to the newer version can be beneficial for all involved countries as the burden of evaluation and implementation needs can be shared (like education, technical support etc.).

The strategies elaborated by the eHN Semantic Subgroup will be presented as guidelines or recommendations at eHN meetings for endorsement. If endorsed, the recommendations should be structured as EU level guidelines.

6.1.1. Transparency

As the CSS Working Group is discussing topics relevant for international as well as national semantic strategy, all discussions and results should be made public. Even though meetings themselves will be limited in participation to nominated members – to achieve the most efficient outcome of the meetings – the minutes as well as the upcoming topics will have to be available publicly.

6.2. Need for a Common Semantic Governance Framework

To fully achieve the realisation of a Common Semantic Strategy within the EU, there is a need to expand beyond the scope of Patient Summary and e-Prescription/e-Dispensation domains, broadening it to encompass Laboratory Results, Medical Imaging and Results and Discharge Summary domains. This calls for a new approach that simultaneously builds upon the existing work so far realised and also aims to expand beyond it. On the other hand, it uses the new eHN Semantic Subgroup, for a robust and stable structure, responsible for overseeing all matters concerning its ongoing follow-up and ensuring as much as possible its adoption by MS/C.

The eHN Semantic Subgroup should have as its core attributes the ability to set up rules regarding common semantic artefacts at the EU level, whilst trying to better align them with the needs of each MS/C, operating as a steering body for overarching strategic and policy decisions aligned with eHN mandate.

It should likewise be the responsibility of the eHN Semantic Subgroup to keep track of related work regarding semantics being conducted by other working groups within the EU, thus assuring that efforts are not duplicated, and to create a unified channel for proposals to the eHN and downwards communication from the eHN towards more strategic, tactical and/or operational implementers.

This chapter aims at providing further insights on the responsibilities that should fall upon the eHN Semantic Subgroup, as well as to how the eHN Semantic Subgroup should operate within the context of the EU and the eHealth Network. It also explores and explains the links with eHMSEG Semantic Task Force, as well as other eventual related semantic efforts in temporary Coordination and Support Actions or projects and pilots.

6.3. Proposed Governance Framework

6.3.1. Existing semantic structures

eHMSEG Semantic Task Force (STF)

The STF is a group composed of experts on semantics inside the eHMSEG domain. This group's scope is so far limited to Patient Summary and ePrescription/eDispensation, although it could see its "mandate" expanded to the 3 new domains, as they will, eventually, be part of the eHDSI.

eHN Semantic Subgroup

During the 15th eHN meeting (11th-12th June 2019), the creation of an eHN Semantic Subgroup within the eHN scope was approved. This group will be composed of the representatives indicated by the eHN member of each MS/C, allowing the possibility that more semantic experts are incorporated in it in future. In an ideal scenario, each MS/C should have a representative on this group.

National Terminology/Semantic Centre

A national terminology/semantic centre is a body (organisation, group of organisations, or other national body) with the competence, capacity, authority and mandate to create, support and monitor the adoption of semantic solutions in a MS/C for health, or health and social care.

The representative to the eHN Semantic Subgroup, mandated by the MS/C, would be expected to be connected to this body.

6.3.2. Ongoing and future projects calls and projects (under 2020 and beyond)

UNICOM Up-scaling the Global Univocal Identification of Medicines – Horizon 2020[30]

The UNICOM project, submitted in response to the H2020-SC1-DTH-2019 call, was recently approved (Grant Agreement 875299) and will start in January 2020. This project aims to implement ISO IDMP

30 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-09-2019

standards, establishing definitions and concepts to describe data elements and their structural relationships of products that are required for the unique identification of:

- Regulated medicinal product information - ISO 11615
- Regulated pharmaceutical product information - ISO 11616
- Substances - ISO 11238
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
- Units of measurement - ISO 11240

ISO IDMP standards apply to both authorised and developmental medicinal products for human use.

Coordination and Support Action (CSA) – Horizon 2020 proposal to adopt EHRxF (X-eHealth Project)

A project to adopt the EHRxF EC recommendation will be proposed under the call "SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment". The information domains that have not yet been discussed will be the focus of this call (Laboratory Results; Medical Imaging and Reports; Hospital Discharge Reports). It is natural that there is a need to assemble new semantic assets for the three new domains, and that some of that work should be aligned with eHMSEG work, as well as under guidance of the eHN Semantic Subgroup.

6.3.3. Four-Level Approach

To ensure the fulfilment of a Common Semantic Strategy, the recently approved eHN Semantic Subgroup must be part of a robust and stable governance model. The correct layout of this governance model is key to assure overall coherence in the strategy and in semantic interoperability across the EU. Therefore, a governance structure which has strong steering elements addressing both policy and technical issues is needed. Also, given that the semantic strategy is intended to be laid out and carried out initially over the course of five years, that period should correspond to the duration of the Semantic Subgroup, after which need for a new, permanent governance structure should be addressed. Outlining that permanent governance model, after 2025, is outside the scope of this document but can be designed according to the ideas set out in this paper, if proven to be effective.

The proposed governance structure includes bodies aligned with:

- eHN Semantic Subgroup (with representatives from MS/C);
- Administrative functions (supported by EU and MS/C);
- Work groups: "expanded eHMSEG Semantic Task Force"; Work Groups creating and maintain semantic assets within EU Projects related to health, such as UNICOM, CSA for EHRxF, other EU funded projects;

It should be noted that this governance structure seeks not to set up new structures, but associate eHN Semantic Subgroup activities to existing bodies, to the extent possible, as presented schematically in Figure 2.

In order to allow for the widest reach possible within EU projects and planning, the eHN Semantic Subgroup should primarily report to the eHealth Network but should also be associated with other EU areas of health, e.g. as in the realm of DG SANTÉ, DG CONNECT and CHAFEA.

The eHN Semantic Subgroup should be composed of national representatives nominated by MS/C. Ideally these representatives should be experts in the field of semantics and belong to organisations that have a relevant national mandate or are working as expert or competence centres in this field.

The rules of procedure, as well as chairing and rapporteur functions, of the eHN Semantic Subgroup should be developed and approved in its first meeting and can be inspired by the Rules of Procedure of the

eHealth Network[31] as this has proven to be an effective setup. Once it is established, additional Terms of Reference can be set, if necessary.

In order to achieve best coverage on health topics, the group shall be open to inputs from all fields of health and must not be limited to eHealth applications. Therefore, mechanisms should be put in place to allow for input of discussion items (requirements) into the work stream of the group. Criteria need to be developed for what requirements the group will address, before deciding on a recommendation.

National requirements can be brought forward additionally to EU requirements if they have the potential to:

- Be of mutual interest
- Be beneficial for EU-wide digitalisation of health sector
- Fill gaps in cross-border communication that have been identified within that country

The eHN Semantic Subgroup will have to be managed at the EU level and a secretariat is needed to organise management practicalities. As an eHN subgroup the official administrative secretariat is provided by DG SANTE, the group will be co-chaired by the EC and one appointed MS/C. One additional MS/C will serve as rapporteur to the group. This will ensure continuity as well as some more capacity to the Subgroup. The above mentioned management arrangements shall be reviewed in 2 years time, to evaluate its fitness for purpose.

As the initial phase of the eHN Semantic Subgroup is set out to be five years, MS/C should nominate one expert for the group for this period of time and be prepared to set in place mechanisms to nationally consolidate input to the eHN Semantic Subgroup by the nominated representative.

Meetings should take place twice a year and meeting support (organisation, facilities, travel expenses, etc.) should be provided through the eHealth Network. It is expected that the national consolidation of feedback and the additional work of the experts outside the meeting will be covered by the national bodies seconding experts to this task. In between meetings regular exchange is encouraged but the schedule needs to be defined according to the work requirements.

[31] https://ec.europa.eu/health/sites/health/files/ehealth/docs/rules_procedures_ehealth_network_en.pdf

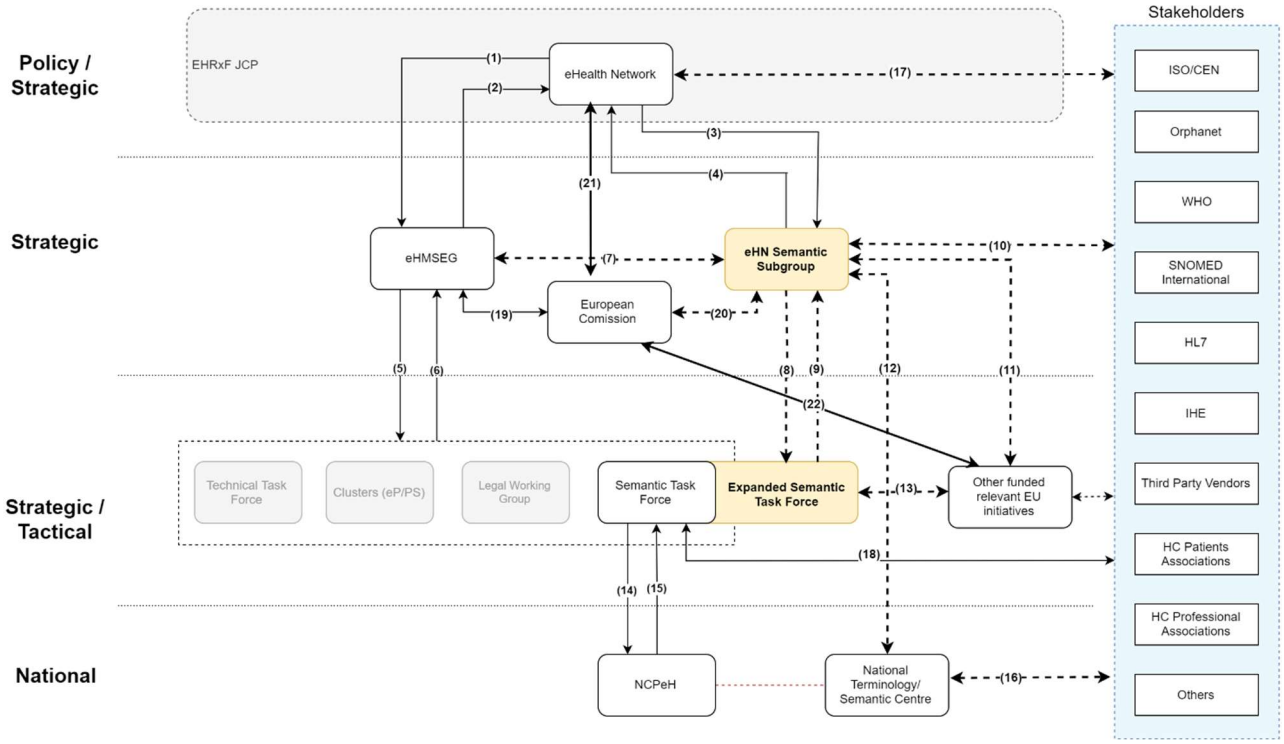

Figure 2 - Proposed revised governance framework for semantics in the eHN structure

This figure details the governance structure regarding semantics in the eHealth DSI cross-border services spectrum, which can be detailed as follows from the different interactions:

***Relations (1), (2), (5), (6), (11) and (12):** as described in the eHDSI Governance Model document[32];*

***Relations (3) and (4):** the eHN Semantic Subgroup should exert its functions under the eHN scope. The eHN Semantic Subgroup shall propose semantic guidance to the eHN for endorsement, in this way acting as a consulting body to the eHN, which in return shall take the eHN Semantic Subgroup's proposals and structure them as EU level guidelines;*

***Relation (7):** The eHN Semantic Subgroup and the eHMSEG should maintain a strategic collaboration, assuring that there is a convergent view regarding eHealth Semantics;*

***Relation (8) (9):** The eHN Semantic Subgroup should rely upon and expanded version of the Semantic Task Force to carry out strategic/tactical activities, that shall assure the execution of the proposed expanded semantic services/domains*

***Relation (10):** The eHN Semantic Subgroup should act as a liaison agent with key partners, within the EU and the private sector, such as SDOs, technology developers and others relevant to the CSS. From a strategic viewpoint, it is noted to be of particular importance to establish a relationship with the UNICOM project (recently approved large EU project dealing with medication coding (see chapter 6.3.1) and Orphanet, or other relevant large initiatives worthy of inclusion to be decided by the eHN Semantic Subgroup;*

***Relation (11):** The eHN Semantic Subgroup should have the capacity to ensure alignment of new EU funded initiatives' work on semantics with supporting assets that have been created and finalised in the realm of the CSS;*

***Relation (12):** The eHN Semantic Subgroup should act as a liaison agent to the existing National Terminology/Semantic Centres, assuring that there is a convergent view regarding semantic artefacts at a national level with the ones defined at an EU level;*

***Relation (13):** The Expanded Semantic Taskforce should collaborate closely with other relevant EU funded initiatives relating Health Semantics;*

[32] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Governance?preview=/35210447/41287688/ev_20161121_co06_en.pdf

Relation (16): *The National Terminology/Semantic Centres can collaborate with relevant stakeholders as necessary;*

Relation (17): *as described in the eHN Rules of Procedure document[33];*

Relation (18): *The Semantic Task Force has collaborated with stakeholders and will maintain this relationship after its extension.*

Relation (19): *The EC elaborates proposals to be considered by the eHMSEG.*

Relation (20): *The EC elaborates proposals to be considered by the eHN SG on Semantics.*

Relation (21): *The EC elaborates proposals to be considered by the eHN.*

Relation (22): *The EC may support EU level initiatives on semantic related matters.*

6.4. How to implement the Governance Structure

Currently, eHMSEG stands as the body responsible for the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF), currently specialising in ePrescription/eDispensation and Patient Summary services. Given the necessity to procure IT services regarding the maintenance and dissemination of semantic assets, resourcing to the eHDSI is a possibility to address this need, whilst also preventing the duplication of efforts and work within bodies of the EU.

While the eHMSEG Semantic Task Force has done terrific work in the fields of ePrescription/eDispensation and Patient Summary, there is a strongly-felt need to build upon that work and expand it to other relevant fields, such as laboratory results, medical imaging and reports, and hospital discharge reports.

As such, this Task Force should continue its work in the ePrescription/eDispensation and Patient Summary domains, to ensure the continuity of the work already in place.

Additionally, other domains such as Laboratory Results, Medical Imaging and Reports, and Hospital Discharge Reports should be picked up through new EU-funded projects and be streamlined with the existing work of the Semantic Task Force. This requires the existence of a strategic relationship and understanding between the eHMSEG and the eHN Semantic Subgroup, given that until the requirements to continue the work in an Expanded Semantic Task Force and equivalent bodies are met, the current task force should account for proposed use cases from the eHN Semantic Subgroup regarding Patient Summary and ePrescription/eDispensation.

It is thus proposed to build upon the work carried out by the eHMSEG Semantic Task Force in future developments and continue its work even after the end of the CEF-project. This continuation can be approved in the eHN meeting in November 2019, as part of the approval of this strategy and governance document. All work done at tactical/operational level should follow the strategy laid out by the subgroup.

Other semantic work streams within the EU may have developed other mechanisms (like the EMA for the implementation of ISO IDMP or the JRC for the development of EU-wide registers for patients with rare diseases). Stepwise these work streams should be addressed, lessons learnt should be considered, and a future joint work programme set, as a way to bring the different developments together. One such way for that is, for example, linking up work with UNICOM project in the case of ISO IDMP for real use in the eP/eD use case.

[33] https://ec.europa.eu/health/sites/health/files/ehealth/docs/rules_procedures_ehealth_network_en.pdf

6.4.1. eHN sub-group on Semantics

The eHN SG on Semantics, in alignment with the EHRxF Joint Coordination Process (JCP), has the following responsibilities among others:

- Provide input to policies regarding health semantics in the EU;
- Formulate recommendations on the use of certain standards, based on set criteria and guidelines for the acceptance of semantic assets as EU common semantic standards;
- Manage and maintain the "Common European Network of Health Semantic Services" as a repository for standardised semantic assets.
- Act as a liaison agent with key partners, within the EU and the private sector, such as SDOs, technology developers, patient associations, professionals' associations and others relevant to the CSS;
- Convey strategic decisions regarding the subject of semantics to the eHealth Network.

6.4.1.1. Final approval of eHN Semantic Subgroup's recommendations by the eHN

The strategies elaborated by the eHN Semantic Subgroup will be presented as guidelines or recommendations at eHN meetings for endorsement. If endorsed, the recommendations should be structured as EU level guidelines.

6.4.2. eHMSEG Semantic Task Force

In order to allow for a quick start of the work, the existing group within the eHDSI, the eHMSEG Semantic Task Force (STF), should continue its work to achieve results on Patient Summary and ePrescription/eDispensation in a reasonably short period of time. This means the current STF should account for proposed use cases from the eHN Semantic Subgroup regarding Patient Summary and ePrescription/eDispensation.

6.4.2.1. Additional work stream within EU-funded projects

Inclusion of new domains (Laboratory Results, Medical Imaging and Reports, and Hospital Discharge Reports) should follow shortly afterwards, ideally driven by EU-funded projects in the likes of an expanded STF or equivalent bodies. The initial period could include all information domains related to the EC recommendation about the EHRxF:

Present role of STF

- Patient Summary
- ePrescription/eDispensation

New roles proposed to be addressed by new EU-funded projects

- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

6.5. Adoption and Compliance Strategy

In order to achieve semantic interoperability across the EU, decisions carried out by the eHN Semantic Subgroup should be taken as prescriptive for common semantic standards as a tool for cross-border healthcare and EU databases, infrastructure and projects; whilst noting that some national semantic strategies of individual MS/C can refer to different standards than those set in the EU cross-border space,

therefore noting that an EU Semantic Strategy does not imply national adoption of the recommendation. Still, the recommendations of the eHN Semantic Subgroup should be addressed nationally and be considered whenever a national semantic strategy is to be set or revised.

6.6. Involvement with SDOs and Stakeholders

The creation of the eHN Semantic Subgroup presents an opportunity for bridging the gap between the work carried out by the eHN and the MS/C regarding semantics, and key partners both within the EU and the private sector. Thus, they are deemed as strategic partnerships, for example:

1. ISO/CEN “International Patient Summary”
2. Orphanet
3. World Health Organization
4. SNOMED International
5. Health Level 7
6. Integrating the Healthcare Enterprise
7. Multiple technology developers
8. Healthcare patient associations
9. Healthcare professionals’ associations
10. Others

It is important that high-level strategic and policy planning are done at the Subgroup level, with the involvement of relevant EC DGs. When strategies are sketched, the Semantic Task Force engages with these organisations to operationalize them through concrete work.

7. Roadmap

7.1. Roadmap to achieve the three main goals of a CSS

The three goals, as specified in chapter 4, will guide the roadmap of the work of the eHN Semantic Subgroup.

Goal 1: Structuring a common approach to health semantics in the EU, by realising a Common Semantic Strategy for Health in the EU, developing common semantic artefacts for the EU and by providing guidelines for standards adoption (capacity building) is a goal that can be addressed in the initial five years and can be expanded upon in the timespan afterwards as the horizon of the work stream of the eHN Semantic Subgroup widens. Especially capacity building in MS/C will have to be supported after the initial five years as the adoption of standards will require a substantial period of preparation.

Goals 2 and 3: Providing guidance to European level decisions on health semantics and ensuring stability and continuity on health semantics in the EU: these goals are oriented towards the working method of the eHN Semantic Subgroup, its embodiment in the overall work of the EU and MS/C and what can be achieved in the first five years. Still, in Year 5 a decision on continuity will have to be taken; this will present the final step in establishment of the eHN Semantic Subgroup, its roles and responsibilities and the way of communication within EU, towards and from MS/C and to third parties involved in standards generation and implementation.

In the next section, the work within the first five years is outlined. After this period, further topics will have to be addressed, and a regular cycle to update the decisions on sematic assets has to be established. To allow for maximum reliability for MS/C on the availability of CSS results, a favourable model would be to set up a continuous roadmap after the initial five years that will be permanent work within the EU. If such a decision cannot be taken based on the results of the first five years, a second period of five years with another evaluation can be proposed. After the second period it is recommended, though, that a final decision is taken, and a permanent group is established or the idea is discontinued and work on this topic stopped.

7.2. Roadmap for the first five years

For the first period of five years, a circumscribed program of work is feasible, with the options of additional items being brought forward for discussion if the need arises (Figure 3).

Work of the first year will encompass:

- Establishment of the eHN Semantic Subgroup with a clear governance scope (endorsed during the 15th eHN meeting – 11th-12th June 2019, Bucharest)
- Capacity building of the eHN Semantic Subgroup according to the common goals defined by this paper by consolidating Member State needs and status

In **Year 1** Patient Summary will be considered as the first example for a recommendation; work on this recommendation will serve as an exemplar for future work. Based on the first exemplar an operational plan must be drafted to ensure the development and completion of the other domains.

In **Year 1 to 5** ePrescription/eDispensation, Laboratory Results, Hospital Discharge Reports and Medical Imaging and Reports will be addressed consecutively and finalised in a stepwise approach, with each step recognising and reviewing previously defined semantic assets.

In **Year 5**, recommendations on all five domains will be available. An evaluation of the rationale, working method and effectiveness of the group will be prepared. The evaluation documentation will be provided early in the Year 5, in order to enable decisions on the continuity of the Subgroup after the initial five years by the eHN. Together with the evaluation documentation, a plan for next steps in the Common Semantic Strategy will be provided.

The work will have to note that, between the different tasks, overlap is possible (e.g. a hospital discharge report might contain laboratory results). In such cases the eHN Semantic Subgroup will have to address these issues once the problem arises and might need to deviate from the timeline indicated above.

Topics for discussion can be brought to the eHN Semantic Subgroup from EU-funded projects and national requirements at any time during the first five years and, if necessary, will be prioritised according to the overall strategy of the eHN.

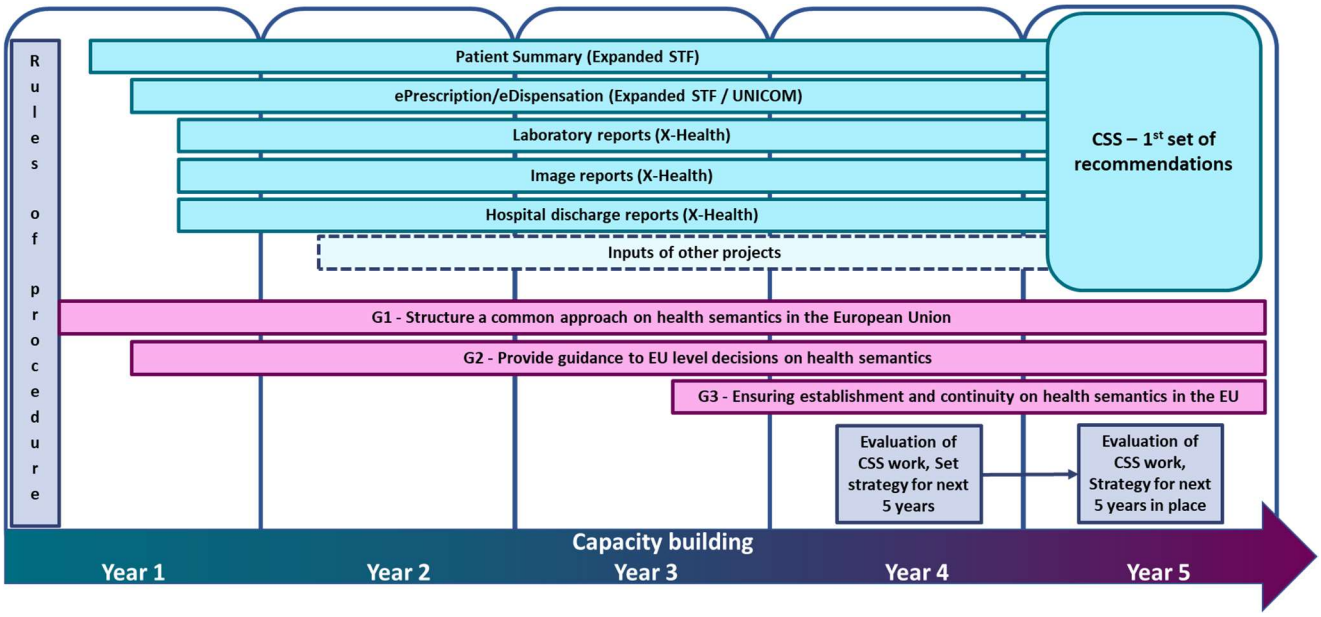

Figure 3 - Resumed roadmap.

For details regarding ongoing activities for the five years plan consult Chapter 3.

7.3. Capacity Building

Capacity building will be an activity that is ongoing over the five years and will have to be continued beyond this initial time frame. Whereas the focus in Year 1 will be on the capacity of the eHN Semantic Subgroup, capacity building beyond that year will have to address other international and especially national experts in order to be able to transfer the work and knowledge from the CSS to national groups and users. This will enable countries to fully consider benefits and inputs of recommendations and will hopefully foster the adoption of EU suggestions in MS/C.

It is encouraged that the EC engages activities in capacity building with the MS/C regarding semantics.

7.4. Resources to achieve a CSS

MS/C will have to recognise that a solid Common Semantic Strategy will require the continuous provision of resources for the different aspects of the work, namely:

1. Resources for participation in the eHN Semantic Subgroup;

2. Ongoing resources for capacity building on semantic assets in each MS/C;
3. Continuous resources for the national coordination of the development of the EU semantic assets in order to allow for fitness of purpose of the semantic asset for each country.

7.4.1. Participation in the eHN Semantic Subgroup

The work of the eHN Semantic Subgroup should be supported by the EU but will require countries to allocate a national expert to the work for a continuous period of time.

7.4.2. Capacity building

Whilst capacity building in the eHN Semantic Subgroup will be an initial effort, ongoing capacity building within the countries is necessary to enable successful use of the semantic assets in each MS/C. This can be supported by the EU but will require continuous measures taken by each MS/C as well.

7.4.3. National Coordination

In order to arrive at solid semantic assets a process for each MS/C needs to be in place to check the asset under development in the eHN Semantic Subgroup for its fitness for purpose and against national requirements. This might require setting up some national board for discussion of open questions and for discussion on how to integrate semantic assets into national strategies.

8. Annexes

8.1. Annex 1 - Relevant factors and processes for CSS development

To define and organise elements of the composition and roadmap for a stable semantic group in the EU, a mind map scheme has been developed. This scheme has been built in a collaborative way, including the contributions that each MS/C has made and reaching partial consensus. The diagram describes the vision on input, output, resources and standards.

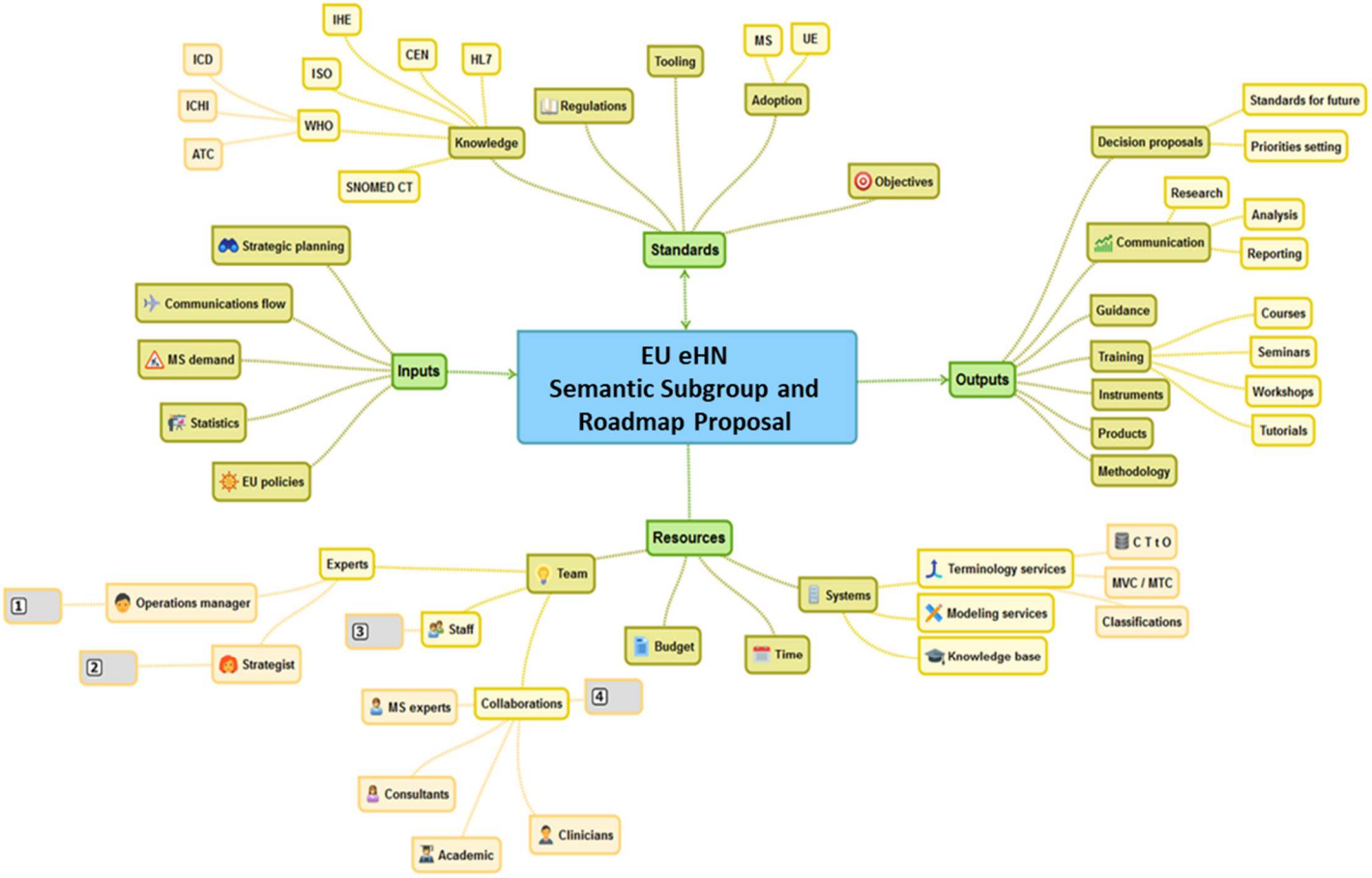

Figure 4 - A mind map describing relevant factors and processes for CSS development

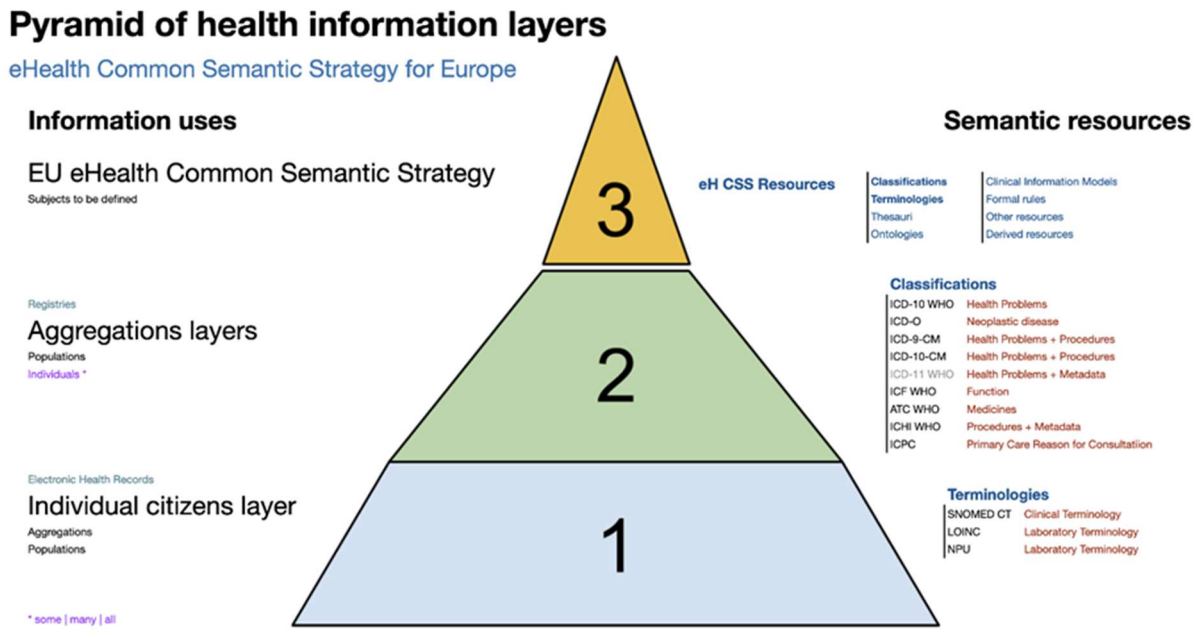

Figure 5 - Three-layer pyramid of health information uses, associated with semantic resources of choice

8.2. Annex 2 - Survey about coding standards used in EU MS/C.

Table 2 - Main terminology codes used on EU.

	Diagnosis	Cancer diagnosis	Procedures	Drugs		Laboratory	Disability			Primary care	Rare diseases
	ICD-10	ICD-O	ICD	ATC	SNOMED CT	LOINC	ICF	NPU	Pathology	ICPC-2	Orpha
Austria	X	X		X	X	X	Rare			Rare	
Belgium	X (BE: 1)	X	ICD-10-CM / ICD-10-PCS	X	Rare	X	X			X	X
Croatia	X			X							
Cyprus	X	X	ICD-9-CM	X	X		X				
Czech Rep.	X	X	ICD-TNM	X	X		X	X			
Denmark	X	X		X	X		X	X	X	X	
Estonia	X			X	X	X					
Finland	X	X	National Classification	X	X	FinLOINC	X		X	ICPC	X
Germany	X(DE:1)	X	OPS	X		UD	X				UD
Hungary	X	X		X		UD	X				
Ireland	X		ICD-10-AM 9th ed	X	X	X				X	
Italy	X		ICD-9-CM	X	UD	X	UD			X	
Latvia	X			X			X				X
Lithuania	X		ICD-10-AM	X	X					X	
Malta	X	X	ICD-9-CM	X	X					X	X
Netherlands	X	X	ICD-10-NL	X	X	X	X		Linked to SNOMED CT	ICPC-1	
Norway	X			X	X		X	X	X	X	
Poland	X	X	ICD-9-PL	X	X	X					
Portugal	X (PT:1)	X	ICD-9-CM	X	X	X				X	
Romania	X		ICD-10-AM	X			X				
Slovakia	X		ICD-10-SK	X	X	X					
Slovenia	X			X	X						
Spain	X (ES:1)	X (ES:2)	ICD-9-CM / ICD-10-CM (ES:3)	X (ES:4)	X	X	X			X	
Sweden	X	X		X	X		X	X			

This survey was answered by some of the CSS representatives and shows the terminology coding used most in these MS/C. It represents an image of the heterogeneity, as well a starting point for the work of the CSS. (The **X** means that this coding system is used in the MS/C; **UD** - Under consideration; BE:1, ES:1 and PT:1 Used for classifying causes of death; DE:1 ICD-10-GM used for morbidity coding; ES:2 ICD-O-3.1 Morphology used for hospital discharge classification; ES:3 Since 2016; ES:4 Used for adverse event classification.

8.3. Annex 3 - Methodology of document elaboration

Since the creation of the Common Semantic Strategy Working Group, that was endorsed by the 13th eHN meeting (May 2018), all the Member States of the eHN and eHAction were formally invited to name one representative from their country to take part in the CSS Working Group. Along the almost one year of intensive work to elaborate the D8.2.2 document, the MS/C that did not name a representative and the MS/C that, for any reason, the representative left the group, were re-invited to re-join the CSS group. Through these initiatives the group could be enlarged and obtain value contributors from the representatives to contribute to the global thinking about how achieve semantic interoperability among the EU MS.

The development of the work was aligned through regular teleconferences (14 in total); all representatives were invited to contribute, including representatives who were absent for a long time from the meetings. Similar invitations were made for the three workshops (held in Lisbon in Oct. 2018 and Mar. 2019 and in Brussels in Sep. 2019); the attendance of the meetings can be observed in Table 3. The costs for the workshops was supported by the eHAction budget, including the travel costs for the face-to-face meetings. In each meeting, the representatives discussed previous work, gave inputs and aligned thoughts to improve document content.

The CSS representatives were able to give all necessary inputs to improve the D8.2.2 document according to the general agreement, discussions at the meetings and exchange of communications via email, for the presented strategy.

Through this collective effort by the representatives, it was possible to construct the *Common Semantic Strategy for Health in the European Union* document, that summarises the general view on what should be done and how to achieve real semantic interoperability across the EU.

This initiative is a huge step to align European countries to establish semantic interoperability.

Table 3 - Number of participations in the CSS meetings

Country	1st CSS Workshop 1 & 2 Oct. 2018	1st Tcon (14 Jan)	2nd Tcon (28 Jan)	3rd Tcon (11 Feb)	4th Tcon (25 Feb)	5th Tcon (11 Mar)	2nd CSS Workshop 18 & 19 Mar. 2019	6th Tcon (25 Mar)	7th Tcon (01 Apr)	8th Tcon (8 Apr)	9th Tcon (27 May)	10th Tcon (18 Jun)	11th Tcon (15 Jul)	12th Tcon (29 Jul)	13th Tcon (19 Aug)	3rd CSS Workshop 2 & 3 Sep. 2019	14th Tcon (06 Sep)	Total of participations
Austria	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	N	Y	N	3
Belgium	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	3
Croatia	Slides	Y	N	Y	Y	Y	N	Y	Y	Y	Y	N	Y	N	N	N	N	9
Cyprus	N	N	N	N	Y	Y	N	Y	N	N	N	N	N	N	N	Y	Y	5
Czech Rep.	N	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	Y	Y	N	N	N	9
Denmark	N	Y	Y	N	Y	Y	N	N	Y	N	N	Y	N	N	Y	N	Y	8
Estonia	N	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	N	12
Finland	N	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	12
France	Y	N	N	N	N	N	N	N	Y	N	Y	Y	N	N	N	N	N	4
Germany	Slides	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	13
Hungary	N	Y	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	3
Ireland	Slides	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	14
Latvia	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	3
Lithuania	N	N	N	N	Y	N	N	Y	Y	Y	N	Y	N	N	N	N	N	5
Malta	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	3
Netherlands	Y	Y	N	N	N	N	Y	Y	N	N	N	Y	N	Y	Y	N	N	7
Norway	Y	Y	N	Y	N	Y	N	N	N	N	Y	Y	Y	N	Y	N	Y	9
Poland	N	N	Y	Y	N	N	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y	11
Portugal	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	17
Romania	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	2
Serbia	Y	N	Y	y	Y	N	N	Y	N	Y	Y	Y	N	N	N	N	N	8
Slovakia	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	2
Slovenia	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	Y	Y	12
Spain	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	12
Sweden	Slides	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	14
European Commission	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	2
Semantic Task force	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	Y	Y	4
Total MS/C	10	14	12	12	14	11	11	14	13	10	11	15	13	8	11	15	12	