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D8.2.2 Common Semantic Strategy for Health in the European Union

WP8 Integration in National Policies and Sustainability

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Acronyms

Acronym	Description
ATC	Anatomical Therapeutic Chemical
CALLIOPE	CALL for InterOPErability
CBeHIS	Cross-Border eHealth Information Services
CSS	Common Semantic Strategy
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
EC	European Commission
eD	eDispensation
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Expert Group
EHR	Electronic Health Record
EHRxF	Electronic Health Record Exchange Format
eP	ePrescription
epSOS	European Patients Smart Open Services
EQA	External Quality Assurance
EQALM	European Organisation for External Quality Assurance Providers in Laboratory Medicine
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable
HC	Healthcare
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
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
SDO	Standards Development Organization
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
WG	Working Group

Executive summary

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

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

In May 2018 the eHealth Network (eHN) discussed the need for a common semantic approach, and in November 2018 it endorsed the work of the Working Group on Common Semantic Strategy (CSS) created in the eHAction joint action to come up with a solid proposal for a five-year strategy to be discussed as a draft in May/June 2019 and approved in November 2019.

According to the EC recommendation on European Electronic Health Record exchange format (EHRxF) published on 6 February 2019, the following healthcare domains have been identified as a baseline for standardisation: Patient Summary, ePrescription, Laboratory Requests and Results, Medical Imaging and Reports and Hospital Discharge reports.

To achieve a Common Semantic Strategy, consideration should be given to all semantic requirements that are relevant for healthcare in the EU, focussing initially on cross-border eHealth requirements but including all other eHealth related subjects as necessary, to support national-level approaches when and as needed.

This document intends to 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 at the EU level in the coming years.

Note on Governance

The governance structure proposed in the document is that which resulted from the CSS working group reflection, the CSS workshops and the general work around the CSS. It is perhaps too detailed and may need to be simplified in its description. This is still to be aligned and streamlined with a global approach under the concept of the Joint Coordination Process (which saw its first debate between EC and Member States on the 6th May 2019, in a eHN subgroup meeting, and is still to be further debated in the eHN meeting in June) and other holistic governance of the eHN and its Sub-Groups, other functional and already existing formal/informal bodies, like the eHealth Member States Expert Group (eHMSEG) and its Semantic Task Force.

1. Introduction

1.1. Background

The European Commission has acknowledged the need for eHealth interoperability for more than a decade. Besides this necessity, some projects aimed to develop the interoperability of electronic health record systems within the European Union (EU). This triggered initiatives such as epSOS and CALLIOPE, as well as later the first Joint Action: the eHealth Governance Initiative (eHGI)[1]. These were the first steps to define and drive a way forward to achieve the best scenario of EU eHealth integration.

The epSOS[2] project (2008-2014) 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 data in a European cross-border context.

The European Commission expressed the need for enhanced cross-border interoperability of electronic health record systems through the publication of its Recommendations on 2 July 2008 (2008/594/EC)[3]. The semantic topic was one of the main points to be improved and structured for this proposal. Ten years after this first initiative, the implementation of a European Electronic Health Record Exchange Format (EHRxF)[4] and interoperability mechanisms is still a strong necessity to be achieved within the EU.

In the collaborative project CALLIOPE[5] (2010), various eHealth experts proposed an interoperability roadmap, the context of which remains, for the most part, amazingly still valid, especially with regards to semantic interoperability. Amongst the many useful recommendations in this document, there were also concrete possible steps, suggested as recommendations, outlined from that project.

The eHealth interoperability topic gained even more importance through the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU)[6] 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 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[7]. Now, with the Digital Single Market strategy[8], the Commission has made eHealth interoperability part of its priority in order to strengthen EU competitiveness.

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

According to the EC recommendation on EHRxF published on 6 February 2019, the following healthcare domains have been identified as a baseline for standardisation: Patient Summary, ePrescription, Laboratory Requests and Results, Medical Imaging and Reports and Hospital Discharge reports.

As things stand, regarding semantic interoperability, some Member States/Countries (MS/C) have set 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.

Regardless of this, future semantic interoperability will require:

- Interoperability for biomedical research and other secondary uses;
- 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. Modelling and coding standards are the pillars on which technical, syntactic and semantic interoperability rests. 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 minimal loss of meaning, or no loss at all.

To achieve this, a meaningful 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:

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

The standardisation of health semantics 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.

The use of the common standards can, therefore, ensure better treatment for patients, regardless of where they might be, by ensuring the safe 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 programs 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"[9] that works under eHMSEG responsibility. This group is focused on practical issues regarding the implementation of two cross-border services: Patient Summary (PS) and ePrescription (eP). 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[10]. This was intended to initiate a constructive discussion in 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 scope, 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 representatives of each MS/C in 8 teleconferences and two workshops held in Lisbon (1st & 2nd October 2018 and 18th & 19th March 2019).

It aims to set a foundation for the development of a Common Semantic Strategy for Health in the EU, whilst addressing some of the needs to be sorted out, and possible steps to achieve a solid basis within 5 years, noting that for a solid semantic strategy the work cannot stop there and planning for continuity needs to be included in further considerations. It was stated by the semantic experts that the semantic strategy is a matter for at least 10 years and, once established, needs ongoing maintenance and evaluation.

1.3. Description of the challenge

- Due to the lack of regulations on the adoption of semantic standards for health information at EU level, MS/C have addressed their needs through the adoption of national standards. Therefore, the decision on which norm to adopt has been taken in MS/C according to their exchange and analysis needs, and not according to any alignment with other European authorities.

- So far, MS/C have achieved different levels of semantic standardisation. Many are coping with internal interoperability issues, lack of national semantic resources and conflicting interests of national stakeholders. Existing solutions may be aimed to address immediate priorities but have limited applicability and are not sustainable in the long term.

- This causes a high heterogeneity of semantic standards in use in the EU, and 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 standardisation or to standardise prospectively in the short term.

9 https://ec.europa.eu/cefdigital/wiki/display/EHSEMANTIC/eHMSEG+Semantic+Task+Force+documents
10 Cover Note by eHealth Network Secretariat: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

- 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.

2. Mission and Vision

2.1. Mission

Establish a Common Semantic Strategy for the standardised exchange of health information in the European Union, facilitating convergence of interoperability standards. This adoption should be based on EU policies, exchange flows between countries, conditions of availability of data, and the national standards that countries have adopted in the absence of European regulation. The governance process for semantic efforts is interlinked with the governance of projects and services in 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 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 supporting at national level.

G2 – Provide guidance to EU level decisions on health semantics

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

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

Establish a Common Semantic Strategy Committee under the eHN mandate and gather one representative from each MS/C to participate in all CSS decisions.

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** Propose a 5-year CSS to the eHN
			A1.1.2 Analyse data availability, standards in use and information exchange flows in MS/C.
			A1.1.3 Structure a learning programme to assist capacity building in MS/C
		O1.2 Develop common semantic artefacts for PS, eP, lab requests and results, medical imaging and reports, hospital discharge reports	**A1.2.1** Publish common semantic artefacts for the chosen semantic domains
			A1.2.2 Setup common semantic resources: "Common European Healthcare Semantic Server"
		O1.3 Provide guidelines for the standards adoption	**A1.3.1** Study the data availability and standards in use in the different MS/C
			A1.3.2 Define a set of 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 routine exchange format with key bodies of the EU relevant to the CSS
G2	Providing guidance for EU level decisions on health semantics	**O2.1** Establish mechanism/ methodology to audit conformance 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 cross-border healthcare
		O2.2 Establish a mechanism to participate in the approval of EU semantic artefacts and projects	**A2.2.1** Propose a mechanism to participate in the approval of EU semantic artefacts and projects to the eHN
G3	Ensuring stability and continuity on health semantics in the EU	**O3.1** Establish a CSS Committee	**A3.1.1** Get a mandate from the eHN
			A3.1.2 Get representatives from each MS/C to join the Committee

4. Value Proposition

Following the EC recommendation on Electronic Health Record exchange format (EHRxF)[11] published on 6 February 2019, this chapter aims at presenting five use cases (value propositions) to better describe and contextualise the need for the establishment of a Common Semantic Strategy for Health in the EU. Each use case relates to each information domain set in EHRxF EC recommendation.

4.1. Patient Summary – Use case

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 medical help (unplanned)[12]. 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) use case 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 current solutions for getting medical information from another country are often unsafe, incomplete and non-standard, there is a reasonable expectation that the PS is accessible wherever the accidental or planned treatment is taking place.

The PS clinical dataset includes medical history, medical problems and medication summary. The PS dataset comprises patient administrative data and patient clinical data. The patient clinical dataset is divided into several sections: Alerts, Medical history, Medical problems, Medication summary, Social history, Pregnancy history, Physical findings and Diagnostic tests.

The purpose is “sharing information about the medical background and history of a patient from 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 eHealth Digital Service Infrastructure (eHDSI)– Connecting Europe Facility (CEF) cross-border exchange of PS is in progress; here is the latest description of the PS that potentially will be in use in almost all MS in the not-too-distant future.

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]

[11] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format
[12] https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved

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), which have 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.

The code systems used are: ICD-10, ICD-O, ICD-10-CM/PCS, SNOMED CT, ATC, UCUM, EDQM[13].

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[14]. 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[15] 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". There is approved by EC (DG SANTE) and eHMSEG a change proposal for the adoption of computable CDA Template specifications, so it could improve the consistency and reliability of the exchange of PS data.

4.2. ePrescription/eDispensation – Use case

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

[13] According to a survey conducted by this working group. For further details, please consider Annex 2 - Survey about the EU used coding standards.

[14] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Patient+Summary+Required+Sections+-+Clarifications+on+the+information+to+be+exchanged

[15] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

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, for example ATC (Anatomic Therapeutic Chemical classification), EDQM (for dose form), Packages, Route of Administration, Display Labels, Health Professional Roles and Country. The CSS could suggest the use of international classifications, such as ATC, SNOMED CT and other relevant classifications to support semantic interoperability within the EU. 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 systems, when existent, are highly dependent on national code systems, turning semantic interoperability into a true challenge. On the other hand, the variability of the association of drugs between countries makes this harmonisation 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[16] and Patient Summary[17] indicate the adoption of the ISO IDMP codes as a way to solve pharmaceutical/medicinal products identification issues.

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. Ongoing and newly starting projects (such as, potentially, the currently proposed UNICOM project), aim at solving the discrepancies and have to be considered further in the work of the CSS Working Group.

4.3. Laboratory Requests and Results – Use case

Clinical laboratory 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 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 6.2.2019 on a European Electronic Health Record exchange format).

[16] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf
[17] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

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 a 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), as well as to a long tradition in the organisation of external quality control programmes. Medical laboratories have internal quality control procedures and participate in national and/or international external quality assessment (EQA) programs. The European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM) was founded in 1996 and currently has members from 29 European countries and 6 countries from outside the EU.

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"[18].

According to a quick survey between MS 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) and Nomenclature for Properties and Units (NPU). Four countries reported use of LOINC based systems (Austria, Estonia, Portugal and Netherlands) and four countries use NPU based systems (Sweden, Denmark, Norway and the Czech Republic); several countries are using other national terminologies, a mix of different terminologies (Poland), 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 a supported use-case by the eHDSI infrastructure. EU countries with well-established electronic laboratory communication will not change their existing laboratory coding systems, e.g. NPU and LOINC, thus transcoding to the selected pivot terminology

[18] Bietenbeck, Andreas & Boeker, Martin & Schulz, Stefan. (2018). NPU, LOINC, and SNOMED CT: a comparison of terminologies for laboratory results reveals individual advantages and a lack of possibilities to encode interpretive comments. LaboratoriumsMedizin. 10.1515/labmed-2018-0103.

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 highly standardised, comparison of results between different laboratories is a major challenge due to differences in methods, instruments, and lack of international calibrators.

4.4. Medical Imaging and Reports – Use case

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.

4.4.1. Known used standards

DICOM is used worldwide to store, exchange, and transmit medical images. DICOM has been central to the development of modern radiological imaging: DICOM incorporates standards 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 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 – Use case

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

highly structured, if possible, containing also coded information, using defined catalogues and tools defined in the Master Value Set Catalogue or reusing some of the Patient Summary and ePrescription definitions. The ambition is to have a communicable composition which is an integrative part of a national electronic health record, which fits into international formats, and could to a certain extent be translated automatically using the epSOS/CEF/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 inspired by several specifications already developed by MS, 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 standardisation. It should be remembered 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 be not only 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.

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

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

5. Semantic Strategy

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.

It should be noted that this chapter does not intend to address these aspects in an operational manner, nor is it intended to draw out a strategy in itself. It aims at providing the reader with further context and 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 the five information domains and the layers of the Common Semantic Strategy (Figure 01).

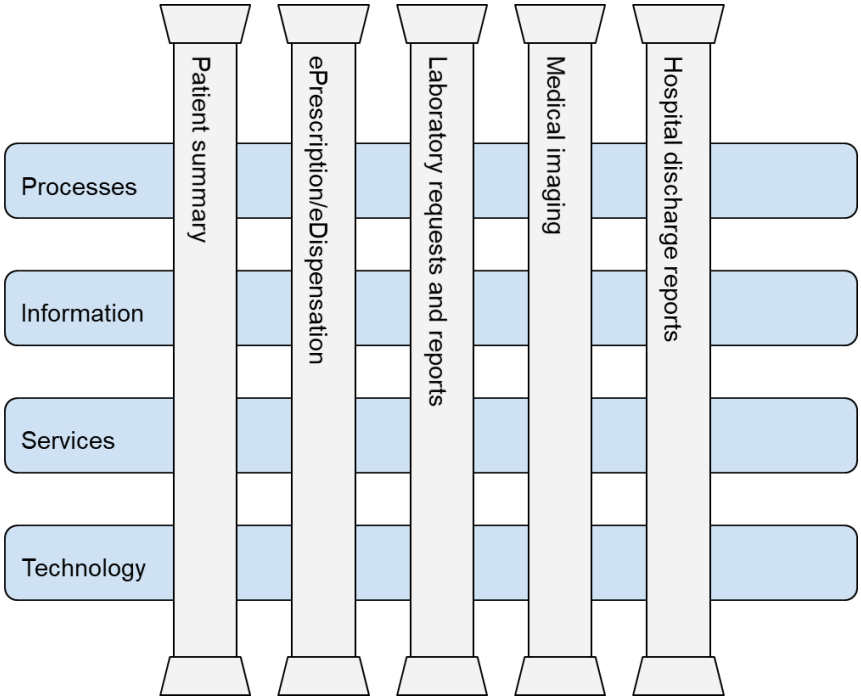

Figure 1: Transversal health information domains among the semantic components.

5.1. Semantic Components

An interoperable information lifecycle consists of several major steps of creation, communication, transformation and consumption of data and information; and similarly, we can classify interoperability standards. Information is being created as a result of processes of care and documentation/recording of the care process; data can be transferred between data sources and consumers through information flows which might include translation, transcoding and other transformation processes in order to be available without significant loss of information and meaning. All these steps must be supported by ICT services as the enabler of sharing of interoperable information.

Similar layers could be found in the semantic interoperability area itself; CSS will have to address interoperable semantic assets at European level as well as processes necessary to manage those assets and services allowing use of the semantic assets in the information solutions, both at EU level and M/S level.

In order to realise the CSS, there are four main architectural domains that need to be addressed: processes, information, services (applications), technology and their impact on this strategy.

The architecture domains and recommended standards ensure that communication and semantic interoperability can be performed in a simple and efficient way that facilitates quality and efficiency of services within healthcare providers in the European eHealth environment. This subchapter aims at discriminating some key aspects regarding each of these four domains.

5.1.1. Processes

To achieve a common approach to health semantics interoperability in the EU, technical aspects also need to be considered. Processes need to be established in order to manage semantic queries from members.

There will be a requirement for a roadmap and a maturity model that will inform semantic interoperability and track its adoption.

In that sense, some core processes 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 artefacts.

From a population perspective, it is essential to invest both in education and capabilities building. Semantics start at the health professional's site, in any given appointment or contact with a patient. So, investing in the training and education of health professionals and into national capacity building will be essential to build this strategy.

Finally, addressing technological stakeholders and how they commit to the strategy is a key component to its success. Whilst in some domains there is a high diversity of technological partners providing services to the health community, in other domains, such as in medical imaging, the number of stakeholders is much more contained. Collaboration is required with technology stakeholders in order to fully realise this strategy.

5.1.2. Information

It is essential that the individual citizen's data is standardised with respect to its original meaning; without this, no higher-level semantic interoperability is possible. In the same way, it is necessary to have common standard data models that will be required to develop formats for secondary use of data. Lastly, it is also required to develop standardised formats for secondary use of data, to allow for a communicable and accessible representation using artefacts such as dashboards and infographics.

The eHDSI project laid the ground for semantic assets in the field of exchange of PS and eP/eD. These assets will need to be expanded in the context of laboratory, imaging and discharge summary. Common ontology should play a significant role in the mutual understanding of key concepts in EU wide information sharing.

Numerous attempts have been made to systematise and identify uses of healthcare information. This document proposes a vision based on three levels: 1) individual citizens' health information, 2) groups or populations' health information, and 3) mixed data, information, knowledge, models and rules (Figure 02).

For health information from individuals, the semantic resources of choice are the clinical terminologies. These resources support the highest level of precision and details for numerous or all axes of clinical information. However, the implementation of these kinds of resources can be a significant challenge for a health system.

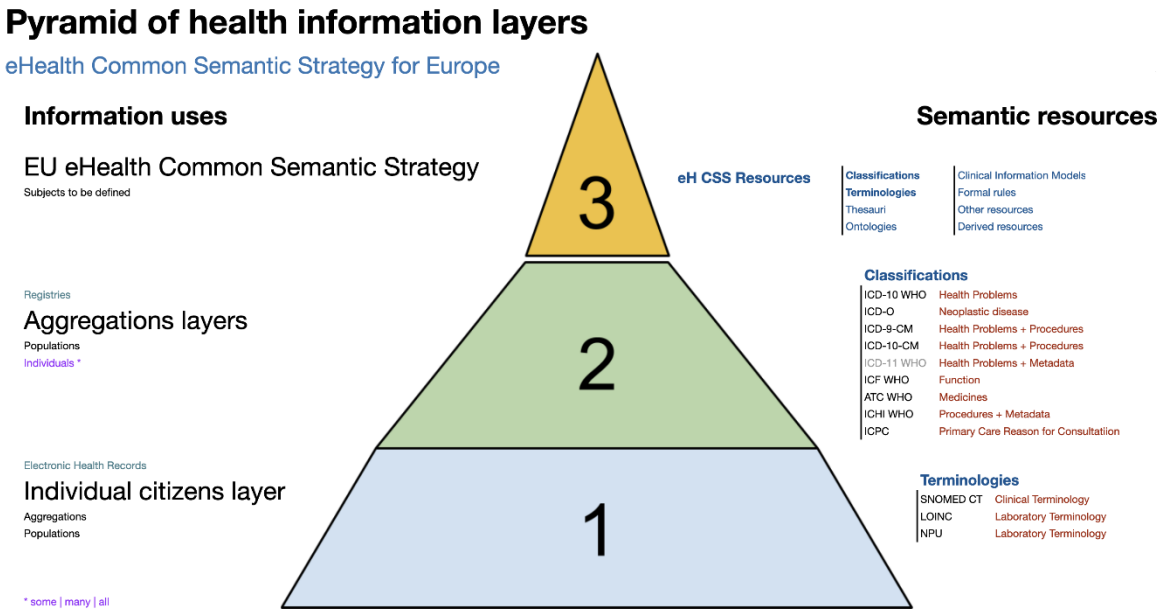

Figure 2: Three-layer pyramid of health information uses, associated to semantic resources of choice.

For health information from populations, numerous types of classifications have been developed by international or national organisations and have been providing excellent services for years. These resources were originally designed for statistical analysis, although more precision and detail exist on newer generation classification systems. They cover a limited range of information axes (health problems, procedures, medicines, etc.) and are able to support case count for epidemiology and management. However, they tend to generate miscellaneous and non-specific classes as a means to avoid the effect of double counting. This may limit precision when used for individual patients or citizens. Version control and data migration may be a challenge, and training on the rules of classification can be a difficult obstacle as well.

In a holistic vision, natural language (words and sentences), classifications (classes), terminologies (terms associated to concepts and relationships among concepts), and ontologies (collections of axioms) will be able to coexist and facilitate synergies for health information management in classical or innovative uses.

Resources should be intelligently associated to information models to maximise their power for representation of meaning. With all these elements in place, healthcare business rules may be applicable to assist us in clinical decision making and innovative uses of information.

Our schema has been represented using a diagram / infographic. Information uses are organised by levels on the left side, including an EU eHealth Common Semantics “family of information uses” still to be defined. On the right, we list some representative semantic resources (only a selection of actual resources is represented). The main features of each resource are described in red (scope, additions). While uses of the resources may overlap between individuals and populations; there are certain requirements that are better met by specific resources. However, full implementation and wide accessibility of these resources in computable form is always a prerequisite for data and information standardisation

5.1.3. Services

The Services Architecture provides a framework focused on developing and/or implementing applications to fulfil the systems' requirements to achieve the quality necessary to meet the needs of semantic interoperability.

Services that need to be established/reused/modified:

- Providing a universal Application Programming Interface (API) to communicate with an EU terminology server.
- Provision of an agreed EU terminology server as repository for standards (e.g. like the server for the MVC in the eHDSI; eHDSI services could be used as a basis for future expansion of EU wide semantic services.
- Semantic standardisation within the infrastructure of other existing EU wide projects (for example EURODIS, EU RD Platform, EARS-Net) should be aligned and a single infrastructure for semantic standardisation should be created and used.

5.1.4. Technology

The Technology Architecture provides the foundation that supports the applications, data and processes identified on the needed services. The Technology Architecture identifies and plans the computing services that form the technical infrastructure for the use of semantic standards.

Technology is a key aspect in semantics. In order to achieve semantic interoperability, there is a need for an EU terminology server solution in which semantic artefacts, such as terminology catalogues, can be maintained. Evolution of terminology servers should be in line with exchange ambitions of countries and practical uses of information being deployed. Ontology servers should also be able to respond to growing demands of structured knowledge, machine readable truth, diversification of semantic resources and meanings.

Natural Language Processing is considered important as a possible future additional asset to the semantic strategy to be adopted. The creation of algorithms, capable of identifying the most used codes in a given country, would help in minimising the use time and/or mapping with less used or unused codes at all. The same scenario applies when we think of the automatic identification, through an algorithm, of a code that best suits a particular situation.

6. Policy and Governance Structure description

Note on Governance

The governance structure/considerations proposed in the document is that which resulted from the CSS working group reflection, the CSS workshops and the general work around the CSS. It is perhaps too detailed and may need to be simplified in its description. This is still to be aligned and streamlined with a global approach under the concept of the Joint Coordination Process (which saw its first debate between EC and Member States on the 6th May 2019, in a eHN subgroup meeting, and is still to be further debated in the eHN meeting in June) and other holistic governance of the eHN and its Sub-Groups, other functional and already existing formal/informal bodies, like the eHealth Member States Expert Group (eHMSEG) and its Semantic Task Force, which has been contacted to provide comments.

6.1. Guiding Principles

A Common Semantic Strategy should consider all semantic requirements that are relevant for healthcare in the EU, focussing initially on eHealth requirements but including all other health related subjects as necessary.

The realisation of a CSS must be guided by the needs of MS, 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 will have to be addressed.

The CSS will have to be future-oriented to enable new developments in the field of standards to be included without the need for redevelopment of the resources and the technical infrastructure.

6.2. Need for a Common Semantic Strategic Committee

To fully achieve a Common Semantic Strategy within the EU, there is a need for a Committee of experts, with a robust and stable structure, responsible for overseeing all matters concerning its definition, and adoption by MS/C.

This Committee should have in its core competencies the ability to set up rules regarding common semantic artefacts at an EU level, whilst trying to better align them with the needs of MS/C.

It should likewise fall upon the responsibilities of this Committee to keep track of related work regarding semantics being conducted by other working groups within the EU, this way assuring that efforts are not duplicated.

This sub-chapter aims at providing further insights on the need for a Common Semantic Strategy Committee (CSS Committee), as well as to how that Committee should operate within the context of the EU and the eHealth Network.

6.2.1. Roles and Responsibilities

The CSS Committee should initially obtain a five-year mandate from the eHealth Network as to ensure it can oversee all activities regarding the realisation and maintenance of a CSS in the EU. After five years the mandate can be renewed, if the Committee has proven to be effective in achieving the goal of a CSS.

It should therefore be the responsibility of the Committee, but not limited to:

- Issue policies regarding health semantics in the EU;
- Serve as decision making body in case of competing standards;
- Set rules and guidelines for the acceptance of semantic artefacts as EU common semantic standards;
- Manage and maintain EU level semantic artefacts;
- Evaluate new standards for their fitness for purpose to serve as a new artefact within the set of standards.

6.2.2. CSS Committee Governance Structure

To ensure the fulfilment of all the responsibilities established in the previous section, the CSS Committee needs a robust governance model. The correct layout of this governance model is key to assure an 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 CSS is intended to be laid out and carried out initially over the course of five years, that period should correspond to the probation period of this Committee, after which a new, permanent governance structure should be addressed. The permanent governance model is outside the scope of this document.

The CSS Committee should present itself with a governance structure formed by bodies dealing with:

- CSS Board (with representatives from MS/C);
- Administrative functions;
- Work groups;

It should be noted that this governance structure seeks not to set up new structures, but associate the CSS Committee activities to existing bodies, to the extent possible.

In order to allow for the widest reach possible within EU projects and planning, the CSS Committee 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 CSS Committee should be composed of national representatives nominated by MS. Ideally these representatives should be experts in the field of semantics and belong to organisations that have a national mandate or are working as expert centres in this field (Figure 3).

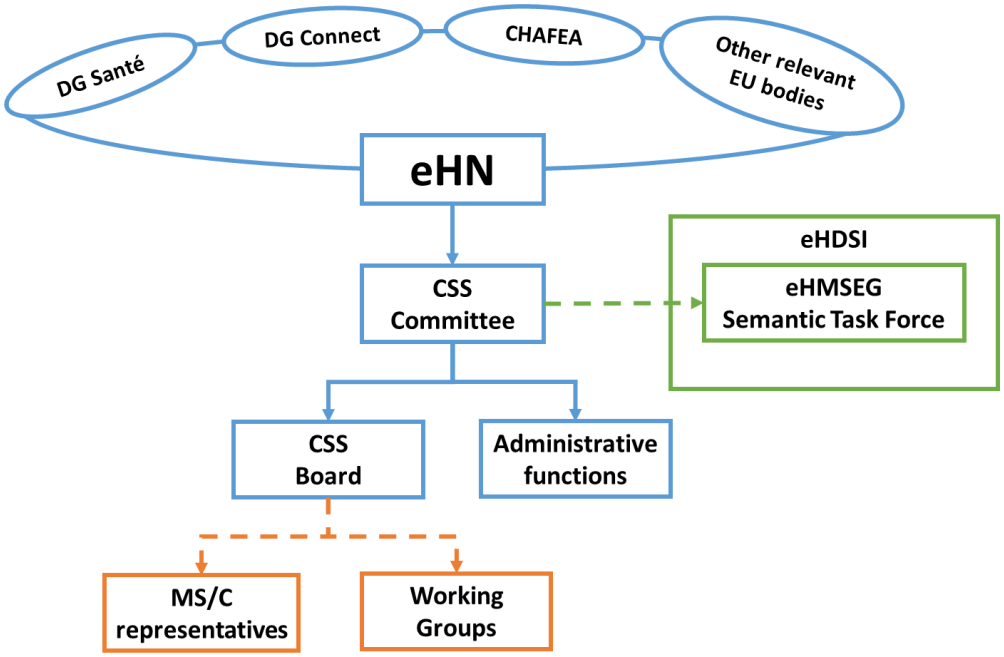

Figure 3: The CSS Committee and its setting in the EU structure

The governance model of the CSS Committee should be developed under the model of the Rules of Procedures of the eHealth Network[19] as this has proven to be an effective setup. Once the Committee 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 CSS Committee will have to be managed at the EU level and a secretariat is needed to organise management practicalities. The secretariat could either be provided by Member States, rotating every year to another member state, or it could be set by the eHealth Network or its administrative bodies.

As the initial phase of the CSS Committee is set out to be five years, Member States 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 CSS Committee 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

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

and the additional work of the experts outside the meeting will be covered by the national bodies seconding the expert to this task.

Portugal, as chair of the CSS working group, has added some final lines on governance to keep it open for alignment with other governance changes underway.

Final and critical note: this governance structure is the proposed result of the workshop and the work of the CSS it is perhaps too detailed and may need to be simplified in its description; it is still to be aligned and streamlined with a global approach under the concept of the Joint Coordination Process and other holistic governance of the eHealth Network and its Sub-Groups and other functional and already existing formal/informal bodies, like the eHMSEG and the Semantic Task Force.

6.2.3. Temporary sub-groups

The CSS Committee can form sub-groups and invite experts to participate in the sub-groups e.g. if:

- Specific topics require intensive preparation and evaluation before they can be put up for decision
- Specific requirements of the CSS have to be evaluated, like licensing issues, administrative and data protection issues or other issues of similar content.

Sub-groups will be formed for a maximum of one to two years and will be given a date as to when to report back to the Committee.

6.2.4. 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 most efficient outcome of the meetings – the minutes as well as the upcoming topics will have to be available publicly.

6.3. Stewardship

Albeit the CSS Committee should be the central EU body overseeing all activities related to the EU Common Semantic Strategy, it is worth noting the existence of other EU level bodies relevant to semantics, such as the eHMSEG Semantic Task Force.

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 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 and Patient Summary, there is a strong feeling on the 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, to name a few.

As such, a strong collaboration with this Task Force is advised, as to ensure the continuity of the work already in place regarding ePrescription and Patient Summary, as well as building on the recommendations

laid out by this group. In the future it is desirable to merge the eHMSEG Semantic Task Force into a working group under the CSS Committee or to combine the expertise from both groups into one. It is not envisaged that both groups exist on a permanent parallel work stream as this will duplicate the effort for countries. Rather the CSS work can learn from the established eHMSEG Semantic Task Force and build upon it in future developments.

6.4. Compliance Strategy

In order to achieve semantic interoperability across the EU, decisions carried out by the CSS Committee should be taken as prescriptive for common semantic standards as the 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 EU cross-border space, therefore noting that an EU Semantic Strategy does not imply national adoption of the recommendation. Still, recommendations of the CSS Committee should be addressed nationally and be considered whenever a national semantic strategy is to be set or revised.

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 CSS Committee.

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 CSS Committee 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 Committee, 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 CSS Committee, 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 a 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 to be established or the idea is discontinued and work on this topic stopped.

7.2. Roadmap for the first five years

The roadmap laid out in this chapter focusses on an initial phase of five years, recognising that a semantic strategy is a process that will have to be continued afterwards and planning beyond five years' time seems to be of great importance.

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 04).

To achieve clear governance, the work of the first year will focus on:

- Establishment of the CSS Committee with a clear governance scope
- Creating common goals (capacity building) by consolidating Member State needs and status
- Discharge Reports will be considered as the first example for a recommendation; work on this recommendation will serve as exemplar for future work

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 CSS Committee, 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.

In Year 2, Laboratory Reports will be addressed and the work on the Discharge Reports will continue.

In Year 3, Image Reports will be addressed and work on Laboratory Reports will continue. Discharge Reports will be finalised, and a recommendation is expected to be available in Year 3.

In Year 4, Laboratory Reports will be finalised, and a recommendation is expected; work on Image Reports will continue; and evaluation documentation on the rationale, working method and effectiveness of the group will be started.

In Year 5, recommendations on Discharge, Laboratory and Image Reports will be available, as well as an evaluation of the rationale, working method and effectiveness of the group. The evaluation documentation will be provided early in the Year 5, in order to decide on the continuity of the group after the initial five years. Together with the evaluation documentation, a plan for next steps in the Common Semantic Strategy will be provided.

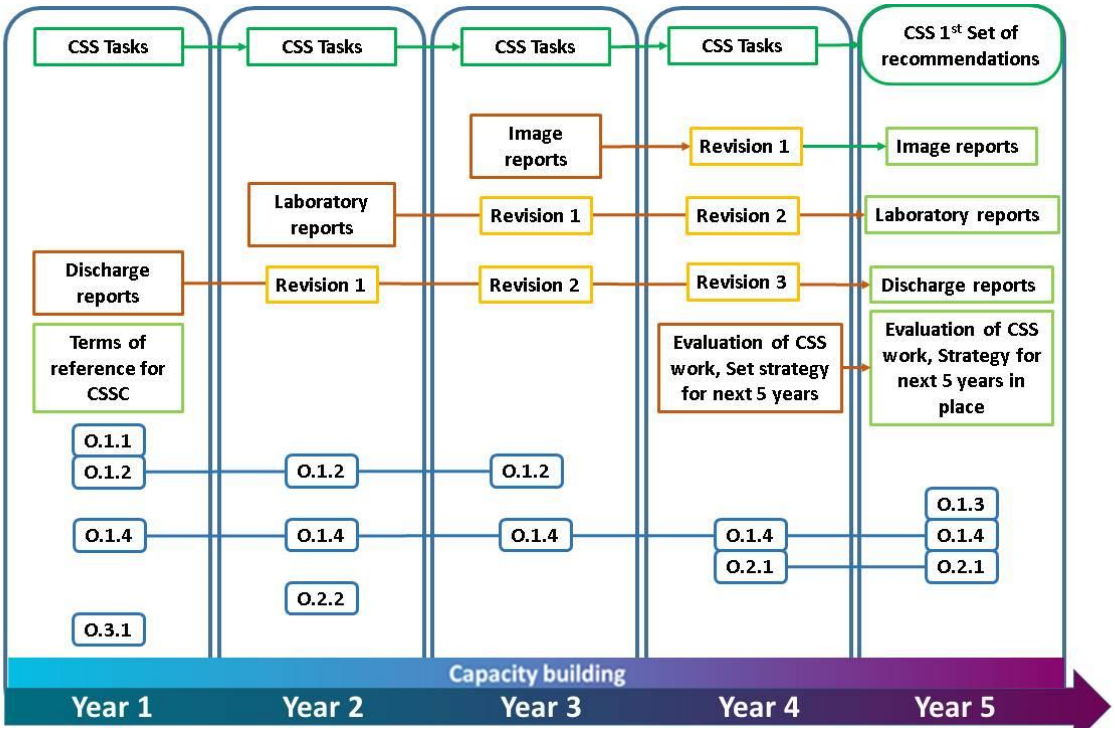

Figure 4: Roadmap for the development of information domains and objectives during the first five years of the CSS

Annexes

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 5: A mind map describing relevant factors and processes for CSS development

Annex 2 - Survey about the EU used coding standards

Table 2: Main terminology codes used on EU.

	ICD-10	ICD-O	ICD -X	ATC	SNOMED CT	LOINC	ICF	NPU	Pathology	ICPC-2
Austria										
Croatia										
Cyprus			ICD-9-CM							
Czech Rep.			ICD-TNM							
Denmark										
Estonia										
Finland						FinLOINC				ICPC
Germany			ICD-10-GM			**UD**				
Hungary						**UD**				
Ireland			ICD-10-AM 9th ed							
Lithuania			ICD-10-AM							
Netherlands			ICD-10-NL						Linked to SNOMED CT	ICPC-1
Norway										
Poland			ICD-9-PL							
Portugal	*		ICD-9-CM							
Slovenia										
Spain			ICD-X-CM							
Sweden										

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 **green** colour means that this coding is used in the MS/C; **UD** - Under consideration; ***** is used only for coding of causes of death).