eHealth Network

GUIDELINE

on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Patient Summary

Release 3, November 2020

eHealth Network

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU.

It provides a platform of Member States' competent authorities dealing with eHealth.

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1 USE CASE DESCRIPTION

This Use Case represents a high level of consensus on what constitutes European eHealth services, as this Use Case was described by Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Title	**Patient Summary sharing on a cross-border scale**
Purpose	Sharing information about the medical background and history of a patient from his country of affiliation (*Country A*) with a healthcare professional the country of treatment (*Country B*). As information sharing is not limited to the cross-border use case, Member States could also use these guidelines for National and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.
Relevance	Many people request medical help when travelling, working or living abroad. Information about the medical background and history of a patient (health data) from the country of affiliation should be available to all citizens and healthcare professionals in Europe (in their native language). The treatment of patients without proper medical background information on medical background and history is hazardous and should be avoided. Benefits can be gained from increased quality of care (e.g. patient safety) (both medical and economical) and from a decrease in the effort of gathering/exchanging health information and provide healthcare professionals with most up to date information to treat a patient. This Use Case proposes a way towards solving this problem.
Domain	Patient Summary
Situation	Cross-border
Context	Countries operate different health care systems, support their own culture for healthcare provision, and may use different (or several different) language(s) and possibly different clinical vocabularies. This raises challenges (e.g. in semantic interoperability) for the support of cross-border exchange of health data and may result in limitations in the use of patient's medical information during patient treatment in different European countries. A Patient Summary provides health information on important aspects such as allergies, current medication, previous illnesses and surgeries, etc. These are necessary for the proper treatment of a patient abroad, especially when there is a language barrier between the healthcare professional and the patient. Two Use Cases are possible with regard to the Patient Summary (PS). The first

	is the one in which an occasional visitor needs his/her PS in country B for emergency or planned care. The second is the one in which the person is a regular visitor in country B (i.e. someone who lives in one country but works in another country). The distinguishing characteristic is that the healthcare professional may have some information available from previous encounters in this type of regular visitor. Both a PS from country A and one from country B need to be consulted. In this Use Case, the Use Case of the occasional visitor is described. eHN PS Guidelines Release 2 covered the Unplanned Care. This was defined by Emergency Health Professionals and GPs as a synthetic document. Data elements were selected to be concise and easily implementable, providing acceptable coverage of the cases to be addressed. In Release 3 of this guideline additions were made to fill in existing gaps (e.g. increased support for the treatment of patients with rare conditions) as well as the extension to the planned care context that requires a wider range of information that can be presented to the healthcare professional in country B. This can e.g. include some elements for the continuity of care (and care plans) for most common pathologies as well as specific information for specialist encounters. Planned Care documents call for completeness and higher granularity, to transfer all the relevant information for the specific pathology, which necessitates a wider range of detail for already specified elements from Release 2, like laboratory findings and results. Lessons learned from the experience of the Covid-19 Pandemic show that in case of health care emergencies immediate collection of data on patients is key to monitor the emergency and to identifying possible solutions. Having a visible and comprehensive Patient summary definition on European level can serve as the starting point for data collection standardised on European level. Moreover, it may foster compliant implementations at national and regional level. Therefore, consensus on the Patient Summary should be promoted and the visibility of the Patient Summary should be enhanced.
Information	Patient Summary (in patient's language and country B language) Patient Information Notices
Participants	Patient Health professional in patient's country of origin/affiliation (country A) Health professional in country of treatment (country B)
Functional process steps	(With the reservation that preconditions are met) The patient consults a health professional in country B The health professional is identified, authenticated and authorised The patient is identified (identity confirmed by country A)

	Health professional provides information to the patient on how personal health data in the Patient Summary will be collected and processed. The Patient Summary is electronically transferred from the patient's country of affiliation to the health professional in the country that s/he is visiting (the "country of treatment") in a secure way. The health professional retrieves the Patient Summary and uses to provide health care service. The Patient Summary should be presented to the healthcare professional in an understandable way, namely regarding language, structure and vocabularies.

2 GUIDELINES FOR PATIENT SUMMARY DATA SETS

The Member States in the eHealth Network have adopted these supplementary clauses to the general guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU to support the exchange of Patient Summary data for cross border care.

Chapter I - General Considerations

Article 1: Objectives, scope and maintenance

1. These guidelines, as adopted by the eHealth Network, are addressed to the Member States of the European Union and apply to the implementation of a patient dataset for cross-border exchange.
2. According to the primary responsibility of the Member States in the field of healthcare provision, as laid down in Article 168 (7) of the Treaty on the Functioning of the European Union, these guidelines are non-binding. In a cross-border context, interoperability is essential to the provision of high quality care. Member States should therefore engage in taking appropriate measures to make their respective information systems interoperable, both technically and semantically, for this Use Case.
3. These guidelines could serve as a guiding principle for the development and implementation of national implementations for Patient summary datasets.
4. The patient summary facilitates the free movement of patients accross borders, as well as national interoperability, avoiding repeated costs, savings for patients and healthcare systems. It also allows for the portability of data, which is one of the rights embedded in several legislative acts, such as GDPR.
5. The eHealth Network is responsible for updating the guidelines, which are addressed to Member States.

Article 2: Definitions

1. For the purpose of this guideline, the definitions of the directive (Patients rights cross-border directive 2011/24/EU) and the following definitions shall apply:
   a) A Patient Summary is an identifiable dataset of essential and understandable health information that includes the most important clinical facts required to ensure safe and secure healthcare. This summarised version of the patient's medical data gives health professionals the essential information they need to provide care. Although this dataset is intended to aid health professionals in providing unscheduled care, it can also be used to provide planned medical care (e.g. in the case of citizens movements or cross-organisational care paths).
2. For the purpose of this guidelines, the following definitions apply:
   a) A code system is a collection of unique codes that have associated designations and meaning, which represent concepts (single meaning ideas in the healthcare domain). A code system usually contains unique identifiers (codes) that when

combined with the identifier of the code system, it creates an identifier that is unique within the healthcare domain.

b) A data set is a structured compilation of elements that refer to the various aspects of the information being grouped.
c) A value set is a compilation of concept identifiers from one or more Code Systems applicable as possible values for a specific data element.

Article 3: Concept and intended use

1. The provisions in the "eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines" apply.
2. The aim of the Use Case is to help support safe, high-quality cross-border care for emergency, unplanned and planned care events. This does not preclude the Patient Summary being used for other purposes.
3. The Patient Summary may, by agreement, be used to share information such as that on rare diseases or may be extended on specific sections with additional information, e.g. like on selected communicable diseases (like covid-19).

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

Data contained in patient summaries are a special category of personal data within the meaning of Art. 9 of the General Data Protection Regulation[1] and therefore Member States will need to ensure processing and storage are in line with applicable data protection requirements.

Article 5: Authorisation, authentication and identification

Implementation of the patient dataset implies that each Member State has addressed enabling activities such as:

a) Providing an official health ID number for each citizen. For cross-border purposes, a unique patient identifier is a necessary requirement for each individual patient to be linked to the patient record in the country of affiliation
b) Maintain electronic registers of healthcare professionals
c) Agree levels of authentication for citizens and healthcare professionals
d) Agree on levels of authorisation for certain healthcare roles

[1] Regulation (EU) 2016/679: **General Data Protection Regulation**, https://eur-lex.europa.eu/eli/reg/2016/679/oj

Article 6: Patient safety

There being no specific additional requirements, reference is made to the provisions defined in the "eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines".

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

1. The essential information contained in a Patient Summary dataset makes it highly valuable for unscheduled care where the health professionals have no previous knowledge about the patient. Even so, it can also provide a complementary source of information in planned care by supporting health professionals to connect to the stream of information generated along the patient continuity of care.
   a) Taking in consideration the nature of the information contained in the Patient Summary dataset, it is up to each Member State, healthcare provider or initiative to identify the clinical procedures that can benefit from its availability and possible updates.
   b) The ability to populate the dataset relies on a coordinated and integrated approach to patients electronic health records. It is up to each Member State, healthcare provider or initiative to establish the necessary policies to ensure that the Patient Summary is available, used in the aimed clinical processes as well as updated appropriately.

Article 8: Quality standards and validation

1. The Patient Summary guidelines introduces the concept of "preferred code systems" for some of the data elements in the dataset.
   a) The purpose of such guideline is to promote convergence towards code systems internationally used, officially maintained, available in several languages as well as possible to transcode to other relevant code systems. Therefore in this context the word preferred should be understood as a guiding principle and not as an obligation.
   b) The convergent use of code systems should contribute to ensure clear understanding and preserve the meaning of the information present in the Patient Summary documents, by tackling the variability of coding practices.
   c) The convergent use of code systems should also contribute to the increase of quality of health data collection as well as facilitate benchmarking and evaluation initiatives.
   d) When convergent use of standards is not achievable in practice, solutions should be found to enable the exchange of existing information without undermining patient safety.
2. The above provisions shall ultimately contribute to reinforce patient safety and increase the overall quality of the continuity of care process.

Article 9: Education, training and awareness

1. The added value of the Patient Summary relies on its use under the right conditions. One essential condition is the education and training of health professionals to streamline the access to the Patient Summary without adding additional burden when compared to the access of other health information.
2. Taking in consideration the essential nature of the information present in a Patient Summary, it is important to train health professionals in the use of key pieces of information available. For instance, the presence of a rare disease code might indicate that specific action should be taken.
3. It is also crucial to raise health professionals awareness that the Patient Summary contains health data emanating from several healthcare events that took place at different providers and collected by several health professionals. The diversity healthcare cultures, recording practices, staff roles in the context of creation of the Patient Summary may introduce variations on how information is collected and recorded. Health professionals should be educated and trained to be able to detect and cope with such variations.
4. Along the Patient Continuity of Care, several health professionals will interact with the Patient. Each of these health professionals should be educated and trained about the key information that should be included into the Patient Summary.

Chapter IV - Semantic Considerations

Article 10: Selection of data elements

1. The content of the Patient Summary dataset is shown in section 4. The Patient Summary data comprises Patient Administrative Data and Patient Clinical Data.
2. Clinical information in the Patient Summary will comprise narrative text along with coded data, the latter will allow an unambiguous way of communicating the same information between the country of affiliation and the country of treatment.

3. It is the responsibility of the Member State to provide data in compliance with these guidelines. Member States are encouraged to align their future considerations on a national Patient Summary dataset according to the Dataset structure given in section 4. For a given patient, some of the elements might be empty as no data would be applicable or available; such situations should be communicated differently.
4. The content of the Patient Summary dataset is received by the health professional in two languages, Country A language and a translation to Country B language. If Country B language is unavailable for translation, English can be used.
5. When the available coded information in one Member State cannot be transcoded into the selected preferred code system currently, the information should, as an interim solution, be transferred encoded and/or narrative form, in an agreed language (e.g. English).

Article 11: Terminology

1. The Use Cases require the ability to convey both meaning and context in the Patient Summary to enable safe, high-quality care. For that purpose, along with the data set structure, preferred code systems provide concepts that will be understood by both the provider and the receiver of the Patient Summary.
2. Different code systems are used by Member States. The strategic long-term goal is to gradually reduce fragmentation and converge on the use of international code systems across Europe also considering, in the future, the expected wider use of new and emerging international standards such as the International Classification for Diseases 11th Revision (ICD-11) or SNOMED CT Global Patient Summary Set (SNOMED GPS).
3. "Terminology set out in the ISO Identification of Medicinal Products (IDMP) suite of standards" is binding for regulatory purposes for "Member States, marketing authorisation holders and the European Medicines Agency (EMA)" (Regulation (EU) No 520/2012 on Pharmacovigilance), IDMP suite of standards should be used for medicinal identification, as soon as made available by the EMA and National Competent Authorities joint SPOR (Substances, Products, Organisations, Referentials) Project.
4. Member States wishing to engage in cross-border health information services will need to use the preferred code systems as described in the dataset section.

Article 12: Controlled Lists (Valueset Catalogues)

1. An agreed selection of sets of concepts from the preferred code systems is necessary to facilitate the understanding of the information exchanged in the Patient Summary by the Health Professionals receiving it.
2. That selection of concepts and its designations, organised into sets, form the Valueset Catalogues, which will be based on international code systems whenever possible.
3. It is considered essential to evaluate on a regular basis the selection of concepts and the code systems used. For historical health data preservation, ValueSet Catalogues should maintain previous versions of the code systems.
4. A suggested general policy is to adopt the latest version of a code. If this is not possible, at a minimum the adoption of critical concepts should be considered (e.g. the new concepts released for the COVID pandemic).
5. There might be one or multiple ValueSet Catalogues depending on the scope of each specific implementation. Relevant ValueSet Catalogues should be easily available for implementers. Ideally ValueSet Catalogues should create a network of EU ValueSet Catalogues accessible and interoperable across Europe with a harmonised maintenance process.

Chapter V - Technical Considerations

Article 13: Technical requirements

Member States are free to choose the technical implementation of their Patient Summary dataset. Nonetheless, for cross-border exchange the format of the document for exchange

shall be based on standards and profiles as agreed by the eHealth Network for the particular technical infrastructure. The cross-border specifications are described in section 4, which also refers to supporting requirements and other relevant documentation.

Article 14: Security

Member States shall ensure that they are fully compliant with the cross-border Security Policy.

Article 15: Testing and audit

1. Implementers of this Patient Summary guidelines should consider testing and audit trails provisions, manly:
   a) Demonstrate compliance with technical interoperability specifications in the scope of the implementation project.
   b) Perform end-to-end testing with health professionals to ensure the correctness and comprehensibility of Patient Summary data.
   c) Ensure that audit trails are recorded to support the monitoring and verification of events related with Patient Summary information (e.g. access, transfer).

3 SUPPORTING INFORMATION

This chapter provides supporting information and explanatory text to aid understanding of the guidelines, and the rationale behind the proposals. It therefore follows the same structure as the general guidelines.

The basic reference are the CEF eHDSI requirements and specifications, being the main goal of these Guidelines, the setting up of cross-border services. They can be taken as an inspiration for Member States for National or local implementation of Patient Summary services.

The material in this supporting document has built on earlier epSOS experiences, but cites follow-on work in EXPAND, in the relevant Horizon 2020 projects like OpenMedicine, eStandards, VALUeHEALTH, and the joint EU/US Trillium Bridge and Trillium II projects. The H2020 project UNICOM is defining, implementing and piloting the initial adoption of ISO IDMP for medicinal product identification.

CEF HEALTHeID specified and demonstrated the patient identification in the CEF eHDSI context by exploiting eIDAS procedures and infrastructures. H2020 X-eHealth project is specifying and demonstrating the cross-border services for Laboratory Results, Images, Discharge Letters and Patient Summary for specific pathologies, in particular Rare Diseases.

Chapter I - General Considerations

Article 1: Objectives and scope

The objective in this Release of the PS Guideline is to retain the concept of a controlled Patient Summary but to extend the application to include datasets relevant for planned care. The dataset is non-exhaustive, providing a robust, well-defined core set of data items.

CEN International Patient Summary (IPS) Guidelines were taken as reference for the extension of the data sets in eHealth Network Guidelines Release 3.

Article 2: Definitions

The definitions section has been amended to reflect the revised scope.

Article 3: Concept and intended use

These guidelines are non-binding and Member States are considered to have the right to choose freely their way of implementing Patient Summary data sets. The Patient Summary guidelines focus on the content issues and the description of possible ways to produce this content for cross-border exchange, taking existing national implementations into consideration.

The selection of data elements comprising the Patient Summary may be extended to hold additional information, such as information about emerging health care conditions or project specific extensions.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

Pursuant to GDPR Art 9, 4 Member states may introduce further conditions/limitations.

Article 5: Authorisation, authentication and identification

In order to link patients with their patient records, the existence of a patient identifier is necessary. For cross-border purposes, a unique patient identifier is also a necessary requirement for each individual patient to be linked to the patient record in the country of origin. Analysis of data shows that most Member States already have a national patient identification number available. In some cases, Member States have a regional patient identification number.

Official documents, such as a passport, ID card or driver's licence, seem to be accepted across MS for authentication. In cases where a patient does not have (access to) a national patient ID or an identification document, different kinds of personal information elements, such as the patient's last name, given name and date of birth, are used to create a unique (temporary) form of identification.

Article 6: Patient safety

The Patient Summary is a clinical document to support the Health Professional during an encounter. For the patient safety it is important the Health Professional is aware the PS can be not exhaustive, but the provided data must be reliable, coherent both when it is declared the presence or the noted absence of specific clinical conditions.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

Even if the primary goal of the Patient Summary dataset is to support cross-border care, some Member States have implemented, or are in the course of implementing, national or regional Patient Summaries. Some Member States already have more detailed summaries from which this summary data can be extracted. Other Member States may use this guideline for reference for national implementation.

However, the ability to populate this dataset always requires national activity. More advanced and elaborated Patient Summaries exist in some Member States (MS), but the eHealth Network has agreed that the guideline could serve as a common baseline for Patient Summaries at national level. Agreement on the Patient Summary Dataset on European level and widespread implementation of it will assist Member States in the implementation of interoperable solutions for health care emergencies such as a pandemic event. Using the Patient Summary guideline as the guiding principle for all kind of EU-projects and

implementations (such as registries and research projects) can foster the use of Patient Summary data within the European Health Data Space.

Article 8: Quality standards and validation

Member States should work together to build a convergent use of code systems. Mappings should be done as shared activities when more MS are affected. Also licensing activities with SDO partners should be done together. This will reduce the burden of the workload, support capacity building and also foster the EU pathway towards a harmonised way forward. This may be facilitated by EU commission.

Article 9: Education, training and awareness

Member States may have different national policies while creating and updating the PS: these differences should be made evident to the Health Professional both in the Country of Affiliation and the Country of Treatment, through appropriate training.

The use of the Patient Summary to record rare disease information has to be a clinical decision, with leadership and direction from health professional organisations.

Chapter IV - Semantic Considerations

Article 10: Selection of data elements

The Patient Summary can be created and signed by a health professional or be automatically generated by a system. The different approaches should be made evident to the health professional at the point of care, together with the Entity responsible for the provided contents and their traceability.

In both cases, either manually or automatically generated Patient Summaries, information may be derived from multiple sources using different semantic standards and data sets, which complicates the exchange of cross-border Patient Summary information. Therefore, a selection of data elements for Cross border care was compiled to serve as exchange format throughout Europe. This data set can provide countries with a guideline to orient future evolutions of their national patient summary accordingly. The content of the dataset is version controlled, subject to change through a change control process.

International standards shall be adopted to convey Patient Summary contents in a structured and coded way, understandable by Health Professional at national and cross-border level. The CEF eHDSI interoperability infrastructure has currently adopted HL7 CDA Level 3 and Level 1 as standard for document exchange. Member States are free to adopt at National level the same HL7 standard or other international or national standard to create and exchange the Patient Summary (e.g. HL7 FHIR or other standards).

The identification of medicinal products is posing important challenges for the exchange of information in the Patient Summary. It is expected that the coding schemes currently included within the dataset will be complemented by datasets and identifiers developed during the

implementation of the ISO IDMP set of standards. The European Medicines Agency is leading the work on this implementation in Europe in coordination with the National Competent Authorities in Member States. Three Datasets of the Patient Summary make reference to medicines: the Medication Summary, the Vaccinations, and the Allergies. The health professional creating the Patient Summary or generating the source of information used for the creation, should carefully decide if it is relevant to make reference to the Substance, to the generic pharmaceutical product with its attributes (strength, dose form) or to the specific medicinal products with its excipients, selecting the appropriate ISO IDMP identifiers and/or their attributes. Member States may decide if, in the Medication Summary, the generic pharmaceutical product (PhPID) or the specific medicinal product (MPID) shall be identified. The choice of identifying the medicinal product might be related to a specific need of the patient (demonstrated efficacy or known allergies). In the case of the Vaccination, the decision of identifying the vaccine as a pharmaceutical product or a specific medicinal product is normally related to the national policies of tracing vaccinations. The choice for the Allergies is more related to the patient's condition: the health professional should express either the allergy to a substance or generic product, or a specific allergy to a specific medicinal product and its excipients.

Article 11: Terminology

Successful sharing of information requires the effective use of standards to support accurate and complete clinical documentation that is true and accurate reflection to the patient's situation.

The use of code systems allows the unambiguous exchange of clinical information in the Patient Summary. Both the Member State providing the information and the Member State receiving it need to understand the clinical content code, therefore it is necessary to use preferred code systems as presented in section 4.

It is up to the eHealth Network to oversee the process by which code systems are kept under review and facilitate licensing arrangements.

Article 12: Controlled Lists (Valueset Catalogue)

Since some code systems such as SNOMED CT, LOINC and ICD (to name but three) contain a large number of concepts, it might not always be practical to use them in their entirety within the European context, where some Member States might use internally different code systems that they will have to cross-reference and/or translate. Additionally, some code systems, such as SNOMED CT, are restricted in use. In these cases, Priority should be given to the available unrestricted subsets from these code systems should be considered, for example, the content of the SNOMED CT Global Patient Summary Set (GPS).

A clear set of criteria should be used to select the most significant concepts and arrive at a reasonable manageable content.

Member States may adopt different international standard code systems, which include concepts not suitable for mapping. In those cases, together with the preferred code system,

alternate code systems can be used in Patient Summary enabling its exchange in an agreed language.

Chapter V - Technical Considerations

Article 13: Technical requirements

There is no specific support information.

Article 14: Security

There is no specific support information.

Article 15: Testing and audit

There is no specific support information.

4 PATIENT SUMMARY DATA SETS

The data sets indicated in the following tables are considered relevant for patient safety and the provision of adequate level of care both at cross-border and national level. It is up to each implementation project to decide on the conformance and cardinality (i.e. data elements required or optional and number of repetitions).

The indicated "Preferred Code Systems" are inspired by the eHealth Digital Service Infrastructure implementation and HL7 IPS implementation.

4.1. PATIENT ADMINISTRATIVE DATA

Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**
Identification 1	National healthcare patient ID	National healthcare patient ID	Country ID, unique to the patient in that country. Example: ID for Portuguese patient
Personal information	Full name	Given name	The patient's first name (example: João). This field can contain more than one element.
		Family name/surname	This field can contain more than one element. Example: Rodrigues dos Santos Note: some countries require the surname to be the birth name [to avoid potential problems with married women's surnames).
	Date of birth	Date of birth	This field may contain only the year if the day and month are not available, e.g.: 01/01 /2009

	Gender	Gender code	This field must contain a recognised valid value for "*administrative gender*". If different, "*physiological gender"* should be communicated elsewhere.
Contact information	Address	Street	Example: Rua dos Campeões
		House number	Example: 246
		City	Example: Porto
		Post code	Example: 4500
		State or province	Example: Santa Maria de Lamas
		Country	Example: PT
	Telephone no.	Telephone no.	Example: +351 20 7025 6161
	Email	Email	Example: joao@bigsmile.eu
	Preferred HP to contact	Name of the HP	Name of the Health Professional that has been treating the patient. [the structure of the name will be the same as described in 'Full name' (given name, family name / surname)]
		Role of the HP	Healthcare professional role in the relation to the patient.

		Telephone no.	Example: +45 20 7025 6161
		Email	Email of the HP/legal organisation
	Contact person/ legal guardian	Role of that person	Legal guardian or contact person
		Relationship level	Relationship type with the patient (e.g. father, wife, daughter)
		Given name	The first name of the contact person/guardian (example: Peter). This field can contain more than one element.
		Family name/surname	This field can contain more than one element. Example: Español Smith
		Telephone no.	Example: +45 20 7025 6161
		Email	Email of the contact person/legal guardian
Insurance information	Insurance number	Insurance number	Example: QQ 12 34 56 A

4.2. PATIENT CLINICAL DATA

Variable (nesting level 1)	Variables (nesting level 2)	Variables (nesting level 3)	DEFINITION AND COMMENTS	Preferred Code System
Alerts	Allergy	Allergy description	Textual description of the allergy or intolerance	
		Type of propensity	This element describes whether this condition refers to an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance)	SNOMED CT
		Allergy ~~description~~ manifestation	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	SNOMED CT
		Severity	Severity of the clinical manifestation of the allergic reaction.	SNOMED CT
		Criticality	Potential risk for future life-threatening adverse reactions when exposed to a substance known to cause an adverse reaction.	
		Onset date	Date of the observation of the reaction	

		End Date	Date of resolution of the allergy (e.g. when the clinician deemed there is no longer any need to track the underlying condition)	
		Status	Current status of the allergy or intolerance, for example, whether it is active, in remission, resolved, and so on ...	
		Certainty	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and/or clinical evidence of condition.	
		Agent or Allergen	A specific allergen or other agent/substance (drug, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.	SNOMED CT or ATC (IDMP, when available)

	Medical alert information (other alerts not included in allergies)	Healthcare alert description	Medical alert information: any other clinical information that is imperative to know so that the life or health of the patient does not come under threat. - ▪ Example 1: intolerance to aspirin due to gastrointestinal bleeding. ▪ Example 2: intolerance to captopril because of cough (the patient is not allergic but can't tolerate it because of persistent cough) ▪ Example 3: the patient has a rare disease that requires special treatment ▪ Example 4: Airway Alert / Difficult Intubation ▪ Example 5: Diagnoses such as malignant hyperthermia, porphyria, and bleeding disorders; special treatments like anticoagulants or immunosuppressants; implanted devices. ▪ Example 6: transplanted organs illustrate other information that has to be taken into account in a healthcare contact.	
Medical history	Vaccinations	Vaccination~~s~~	Information related to vaccine and its administration	SNOMED CT or ATC (IDMP, when available)
		~~Brand name~~		

		Product administered	Medicinal product administered; this may include Local product code; lot number; etc. At least the brand name should be provided if nothing else is available.	
		Position of Vaccination	Sequence number of vaccination in a series	
		Target diseases	List of target diseases (contains each disease against which the patient has been vaccinated)	ICD-10, ICD-11
		Vaccination date	The date when the vaccination was administered	
		Planned vaccination date	The date when the vaccination is planned to be given/repeated (e.g. next dose)	
	List of resolved, closed or inactive problems	Problem description	List of problems or diagnoses that the patient suffered in the past, and which have been resolved, closed or declared as inactive (not included in "current problems or diagnosis") Example: hepatic cyst (the patient has been treated with a hepatic cystectomy that solved the problem and the problem is therefore closed)	ICD-10, in the future ICD-11
		Onset ~~time~~ date	Date of problem onset	
		End date	Problem resolution date	

		Resolution circumstances	Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.). This field includes "free text" if the resolution circumstances are not already included in other fields such as surgical procedure, medical device, etc., e.g. hepatic cystectomy (this will be the resolution circumstances for the problem "hepatic cyst" and will be included in surgical procedures).	
Medical problems	List of current problems~~/ diagnoses~~	Problem / diagnosis description	Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter.	ICD-10, in the future ICD-11. Together with Orphacode if rare disease is diagnosed
		Onset ~~time~~ date	Date of problem onset	
	Medical devices and implants	Device and implant description	Describes the patient's implanted and external medical devices and equipment upon which their health status depends. Includes devices such as cardiac pacemakers, implantable fibrillator, prosthesis, ferromagnetic bone implants, etc. of which the HP needs to be aware.	SNOMED CT EMDN
		Device ID	Normalised identifier of the device instance	

		~~Device Type ID (code)~~	~~Normalised code~~	~~SNOMED CT~~
		Implant date	Date when procedure was performed	
		End date	Date when the device was explanted from the patient or the external device was no longer in use; likewise when the device is planned to be explanted	
	Major surgical procedures	Procedure description	Describes the type of procedure NOTE: major surgery has been defined in relation to the preexisting comorbidities of the patient, the extent and the complexity of the procedure, its pathophysiological consequences and the subsequent clinical outcome	SNOMED CT [ICHI in the future]
		Body site	Procedure target body site	SNOMED CT [ICHI in the future]
		Procedure date	Date when procedure was performed	
	Treatment recommendations	Recommendations description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	

	~~Autonomy/ invalidity~~ Functional status	Description	Need for the patient to be continuously assessed by third parties; ~~invalidity~~ functional status may influence decisions about how to plan and administer treatments	ICF?
		Onset Date	Onset date of a condition	
		Functional assessment description	Description of the functional assessment	ADL, FIM?
		Functional assessment date	Date of the functional assessment	
		~~Functional assessment type ID code~~	~~Functional assessment type code~~	~~ADL, FIM?~~
		Functional assessment result	Functional assessment result value	
Medication summary	List of current and relevant past medicines (Relevant prescribed medicines whose	Medication reason	The reason why the medication is or was prescribed, or used	ICD-10, in the future ICD-11
		Brand name	Brand name if biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU)	

	period of time indicated for the treatment has not yet expired whether it has been dispensed or not, or medicines that influence current health status or are relevant to a clinical decision) Note: Medication summary section might need to be revised to reflect outcomes of the UNICOM project.	Active ingredient lists	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: "paracetamol"	ATC (IDMP identifier, when available)
		Strength	The content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	UCUM / EDQM
		Pharmaceutical dose form	The form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablet, syrup)	EDQM Standard Terms
		Number of units per intake	The number of units per intake that the patient is taking. Example: 1 tablet	
		Frequency of intakes	Frequency of intakes per hour/day/week/month. Example: every 24 hours	
		Route of administration	Path by which the pharmaceutical product is taken into or makes contact with the body.	EDQM Standard Terms
		Duration of treatment	Example: 14 days	
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	

Social history	Social history observations	Social history observations related to smoking, alcohol and diet	Health related "lifestyle factors" or "lifestyle observations" Example: cigarette smoker, alcohol consumption	SNOMED CT
		Reference date range	Example: from 1974 to 2004	
Pregnancy history	Current pregnancy status Expected date of delivery	Date of observation	Date on which the observation of the pregnancy state was made	
		Status	Provides the woman's current state at the date the observation was made: e.g. pregnant, not pregnant, unknown	LOINC
		Expected date of delivery	Date on which the woman is due to give birth. Year, month and day are required (e.g. 01/01/2014).	
	History of previous pregnancies	Previous pregnancies status	Information on the woman's previous pregnancies: ▪ Yes, previous pregnancies; ▪ No, previous pregnancies; ▪ Unknown	LOINC
		Previous pregnancies description (list)		

		• Outcome date	Date referred to the previous pregnancies outcome	
		• Outcome	Outcome of the previous pregnancies: e.g. safe delivery; termination; stillborn; miscarriage;	LOINC
		• Number of children	Number of children/fetus in this specific pregnancy	
~~Physical findings~~	~~Vital signs observations~~	~~Blood pressure~~	~~One blood pressure value which includes: systolic blood pressure and diastolic blood pressure~~	
		~~Date when blood pressure was measured~~	~~Date when blood pressure was measured~~	
~~Diagnostic tests~~	~~Blood group~~	~~Result of blood group~~	~~Result of blood group test performed on the patient~~	
		~~Date~~	~~Date on which the blood group was performed. This field may contain only the year if day and month are not available (e.g. 01/01/2009).~~	
Results		Date	Date and time of the observation	

	Result observations (A list of observation results pertaining to the subject of care's health condition and which might have impact on future treatments) Note: Results section might need to be revised to reflect outcomes of the X-eHealth project.	Observation type	Observation results types that may be measurements, laboratory results, anatomic pathology results, radiology results or other imaging or clinical results. Examples: • Diagnostic results (Blood group, Laboratory Observations, Imaging results etc.) • Physical findings (Vital signs observations)	
		Result description	Narrative representation of the observation result and findings.	
		Observation details	Observation details including code that identifies observation, specification of the observed body structure or specimen, date and time of the specimen collection.	LOINC SNOMED CT NPU
		Observation results	Result of the observation including numeric and coded results of the measurement, details about how the tests were done to get the result values, information about referential ranges and result interpretation. Content of the observation result will vary according to the type of the observation.	
		Performer	Identifies the originator/author and provides provenance information about the source of the results data that may have not originated with the source of the whole PS document.	

4.3. METADATA

Variable (nesting level 1)	Variables (nesting level 2)	Variables (nesting level 3)	DEFINITION AND COMMENTS
Country	Country	Country	Name of country A
Patient Summary	Date created	Date created	Date on which PS was generated
	Date of last update	Date of last update	Date on which PS was updated (date of most recent version)
Nature of the PS	Nature of the PS	Nature of the PS	Defines the context in which it was generated. Distinguishes between three methodological approaches for generating the PS: direct human intervention by an HP, automatically generated approach and mixed approach
Author organisation	Author organisation	Author organisation	At least one author organisation (HCP) shall be listed. In the event that there is no HCP, at least one HP shall be listed
Legal authenticator			Legal entity (Health Professional or Health Care Provider who authenticated the Patient Summary

5 REFERENCES AND EXAMPLES

5.1 eHealth Digital Service Infrastructure (eHDSI)

- eHDSI CDA IG, MVC;

Formal technical and semantic specifications

{+} https://ec.europa.eu/cefdigital/wiki/x/30QZAg+

Formal terminology bindings

{+} https://ec.europa.eu/cefdigital/wiki/x/30QZAg+

5.2. European Electronic Health Record exchange format

- To be further developed

5.3. International Patient Summary

- IPS and HL7 FHIR and CDA IG)

5.4. Rare Diseases Action

http://www.rd-action.eu/wp-content/uploads/2017/05/D5.2_Standard-procedure-and-guide_final.pdf, Guideline 6