GUIDELINES ON MINIMUM/NON-EXHAUSTIVE PATIENT SUMMARY DATASET FOR ELECTRONIC EXCHANGE IN ACCORDANCE WITH THE CROSS-BORDER DIRECTIVE 2011/24/EU

RELEASE 1

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TABLE OF CONTENTS

1. INTRODUCTION 3
1.1. Purpose 3
1.2. Scope 3
1.3. Legal basis of the guidelines 3
1.4. Process of developing the guidelines 3
1.5. Evolving document 4
2. CONTEXT 5
2.1. Directive on patients' rights in cross-border healthcare 5
2.2. eHealth Network 5
2.3. Use cases 6
3. GUIDELINES FOR PATIENT DATASET 8
4. SUPPORTING INFORMATION 17
ANNEX A – LIST OF ABBREVIATIONS 33
ANNEX B – EPSOS REPORT ON CHOICE OF CODING SCHEMES 34
ANNEX C – EXAMPLE STANDARDS AND PROTOCOLS 35
References 35

1. INTRODUCTION

1.1. Purpose

The third meeting of the eHealth Network in May 2013 supported the use of basic and extended Patient Summary (PS) datasets and agreed to draw up guidelines on data that can be exchanged electronically across borders. This paper provides the first draft of the guidelines and should be seen as a living document which will be enhanced over time.

1.2. Scope

The primary focus of the guidelines is to support the objective of continuity of care and patient safety across borders, as stated in Article 14 (2) (b) (i) of the Directive on patients' rights in cross-border healthcare. The guidelines focus on emergency or unplanned care in a cross-border context (section 2.3 provides illustrative use cases).

The secondary focus of the guidelines is for reference use at national level. More advanced and elaborate Patient Summaries exist in some Member States (MS), but the eHealth Network agreed that the guidelines could serve as a common baseline for Patient Summaries at national level.

The aim is to enable Member States to understand not only what data is to be included in the PS but also to assess the implications of adopting such a PS in practice, especially in terms of organizational, technical and semantic requirements. The desired outcome is that Member States commit to implementing the dataset in their national systems. To achieve this, they must be able to assess the implications of making their own commitment.

1.3. Legal basis of the guidelines

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 (TFEU), these guidelines are non-binding. The term 'guidelines' should therefore be interpreted as a set of recommendations. It is up to the willingness of each Member State to adopt the guidelines and hence ensure that its national Patient Summary becomes suitable for both cross-border and national use.

1.4. Process of developing the guidelines

The guidelines have been developed in line with the process agreed by the eHGI Executive Committee. The outline structure was agreed in June 2013 and the first full draft was discussed at a workshop in Munich on 10 September 2013. This led to a revised draft being issued to all Member States in late September 2013, prior to the version 1.0 being presented at the eHealth Network meeting on 19 November 2013.

This document comprises three parts: section 2 – introductory text, section 3 – the guidelines ("what to do") and section 4 – explanatory text (advice on "how to" implement). The content structure of the guidelines is shown in Table 1 overleaf.

In order to ensure monitoring and evaluation of cross-border services and related interoperability provisions and systems, Member States should consider setting up a facility to review progress on organizational, technical and semantic aspects for their successful implementation.

1.5. Evolving document

This first release of the guidelines presents the basic elements for the electronic exchange of Patient Summaries across borders in support of emergency or unplanned care. The document indicates areas where further work is required, notably in the review and agreement of terminological schemes to be used as a basis for each data field in the dataset. This review will need to ensure that clinical need and patient safety requirements are taken into account, and hence it is important that representatives of the health professions are involved. This ongoing work will lead to Release 2 of the guidelines.

The guidelines will be further revised and updated on the basis of technical developments and feedback from users (Member States and other stakeholders) and in response to other use cases. The European Commission, at the request of the eHealth Network, will be responsible for setting up the appropriate structures and will coordinate the work on revising and updating the guidelines.

Table 1: Structure of the guidelines

Chapter I	General provisions
Article 1	Concept
Article 2	Definitions
Article 3	Legal basis of the guidelines
Chapter II	Intended use
Article 4	For cross-border patient care
Article 5	As a reference for Patient Summaries at national level
Chapter III	Specification of the dataset
Article 6	Basic dataset
Article 7	Extended dataset
Chapter IV	Organizational, technical and legal prerequisites
Article 8	Terminologies/terminology standards
Article 9	Use of master catalogue
Article 10	Quality standards and validation
Article 11	Technical standards and format
Article 12	Interoperability testing
Article 13	Authorization, authentication and identification
Article 14	Legal framework/enablers for the implementation process
Article 15	Education, training and awareness raising
Article 16	Amendments to the guidelines

2. CONTEXT

2.1. Directive on patients' rights in cross-border healthcare

Directive 2011/24/EU provides rules for facilitating access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, taking full account of national competencies in organizing and delivering healthcare. Article 14 states:

"1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network."

2.2. eHealth Network

The resulting eHealth Network has agreed a Multiannual Work Programme 2012-2014 that builds on these strategic aims, reflects Member States' priorities and takes into account European and national projects and initiatives. The Work Programme includes the specific objective to:

- adopt guidelines on a Patient Summary set of data for cross-border electronic exchange in accordance with the Directive on patients' rights in cross-border healthcare.

The aims of implementing the Patient Summary dataset are:

- to ensure access to safe and high-quality healthcare;
- to achieve a high level of trust and security;
- to enhance the continuity of care for individual patients.

The measures proposed are not legally binding and shall take full account of the responsibilities of the Member States for the organization and delivery of health services and medical care.

2.3. Use cases

The use cases addressed by these guidelines relate to emergency or unplanned care. The "Guidance for commissioning integrated urgent and emergency care" published by the Royal College of General Practitioners in London in August 2011 notes that terms such as "unscheduled care", "unplanned care" and "emergency care and urgent care" are often used interchangeably, and quotes the following definition: "Urgent and emergency care is the range of healthcare services available to people who need medical advice, diagnosis and/or treatment quickly and unexpectedly." [February 2011, UK Department of Health]

The Patient Summary can be useful in any clinical encounter and access will not be restricted to a particular situation. However, the Patient Summary is most useful when the health professional and patient do not share the same language and where, as an unplanned encounter, no information has been previously requested. Within this unplanned scenario, the assistance needed can be emergency or non-emergency care. The human actors (individuals) are as follows:

Patient: individual from a country ("country of origin" – country A) requesting healthcare in another country ("country of treatment" – country B).

Health professional: the health professional who provides healthcare. The health professional must be registered with at least one professional healthcare organization or health authority belonging to the country in order to identify him or her unequivocally. Each Member State will need a system to check the attributes (e.g. rights to access the information via eID) of the end user who requests the PS information.

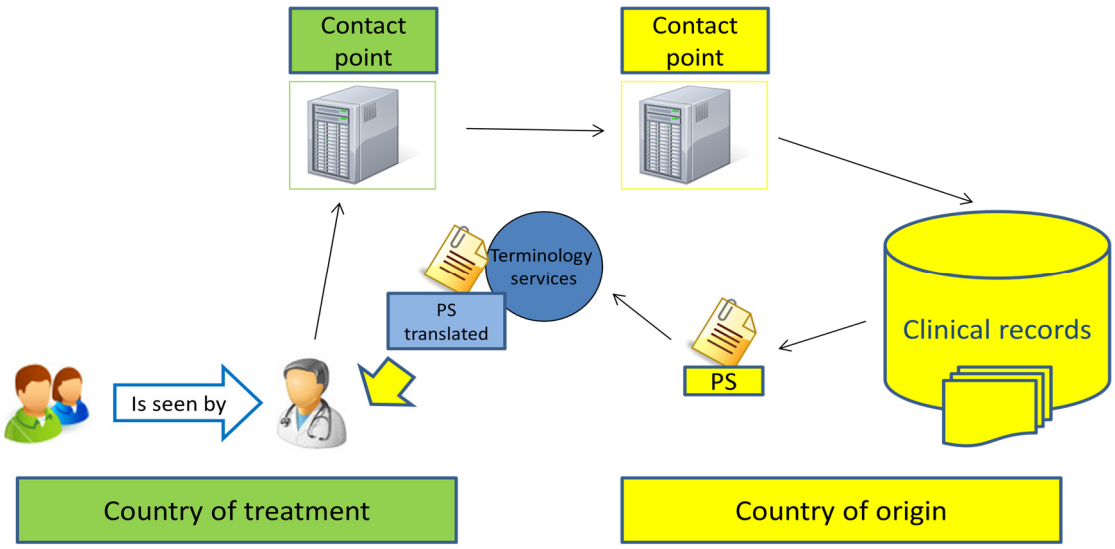
Two use cases are outlined below; in these, the health professional is the actor requesting access to the PS of a patient.

These use cases are provided here for illustrative purposes and as context for the guidelines which follow. Both use cases 1 and 2 can each represent emergency or non-emergency care.

The patient is in the physical presence of the professional and is the individual seeking healthcare. The differences between use case 1 and 2 are based on the situation of the patient and described below.

USE CASE 1: The patient is an occasional visitor to the country of treatment, for example someone on holiday or attending a business meeting. The distinguishing characteristic is that this type of visit is irregular, infrequent and may not be repeated. This is a type of incidental encounter where the health professional will not normally have a previous record of the person seeking care and where the health professional does not know the patient.

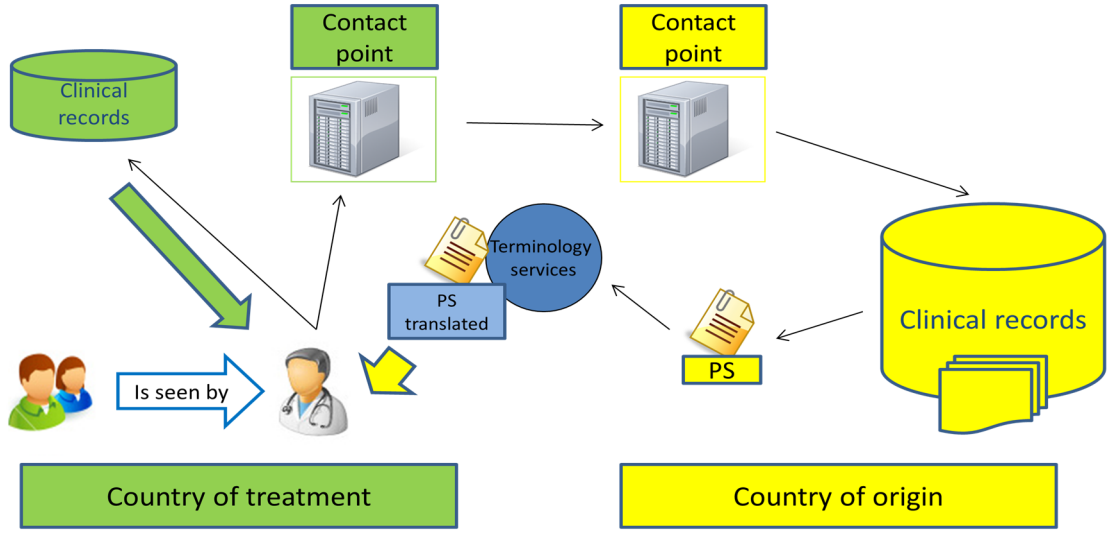
Figure 1: Use case 1



The patient feels sick and seeks healthcare in a country that is not his/her country of origin. The most frequent situation is that the health professional has no prior clinical information about that patient and it is not expected that his visit will be repeated. They will not normally have a language in common.

USE CASE 2: The patient is a regular visitor to another country from his or her country of origin, for example someone who lives in one country but works in another. The distinguishing characteristic is that this type of visit is regular, frequent and the person seeking care may be accustomed to using services in the country where he or she works as a matter of personal convenience. In this situation, the health professional may have some information available from previous encounters; the patient may therefore have a patient record locally stored in country B and possibly also a PS in country A, and both sources of information could be consulted.

Figure 2: Use case 2



The patient feels sick and seeks healthcare in a country that is not his/her country of origin. As he/she frequently visits that country the health professional may have some clinical information about that patient in his/her own records. They will not normally have a language in common.

3. GUIDELINES FOR PATIENT DATASET

THE MEMBER STATES in the eHealth Network,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 thereof,

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, and in particular Article 14 thereof,

WHEREAS:

(1) According to Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities;

(2) Based on Articles 114 and 168 of the TFEU, the Union adopted Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare;

(3) Article 14 (2) (b) (i) of Directive 2011/24/EU identifies an objective of the eHealth Network as being to draw up guidelines on a non-exhaustive list of data that is to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders;

(4) The Member States have been playing an active role in the development of these guidelines, in particular by providing their knowledge and experience;

(5) Preliminary work in the field of eHealth, in particular the European Large Scale Pilot "European Patients' Smart Open Services" (epSOS), the CALLIOPE Network and the eHealth Governance Initiative (eHGI), shall provide a solid and reliable foundation for these guidelines;

(6) As Patient Summary services take place in the field of public health and in accordance with Article 14, the goal must be to use open standards wherever possible;

(7) The provisions of Directive 95/46/EC on the protection of personal data and free movement of such data are the legal basis for using personal health data. According to Article 8 of the Directive, the legal foundations for using personal data will be the explicit consent to the processing of data (Article 8 (2) (a)), vital interests (Article 8 (2) c, i.e. medical emergencies (Article 8 (2) (c)) or the necessity for healthcare purposes (Article 8 (3) (b)),

HAVE ADOPTED THESE GUIDELINES:

CHAPTER I: GENERAL PROVISIONS

Article 1: Concept

1. These guidelines, as adopted by the eHealth Network, are non-binding, 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 TFEU, 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 Patient Summary datasets interoperable, both technically and semantically.

Article 2: Definitions

1. For the purpose of these guidelines, the definitions of the directives cited within the recitals of these guidelines and the following definitions shall apply:

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

b) The basic dataset *is defined as a set of essential health information that needs to be sent from a clinical point of view in order to be able to deliver safe care to the patient (focused in unscheduled care). The information of the basic dataset must always be available*.

c) The extended dataset *is defined as the minimum amount of recommended health information from a clinical point of view that needs to be exchanged between Member States. These fields should be completed whenever possible.*

Article 3: Legal basis of the guidelines

1. These guidelines are non-binding and Member States may:

(a) have the right to choose freely the way in which they implement Patient Summary data systems;

(b) use open standards for public health activities;

(c) decide freely whether they want to adopt such requirements in local legislation;

(d) bear in mind these guidelines when adapting their legislation.

2. The implementation of these guidelines is in line with Directive 95/46/EC on the protection of personal data and free movement of such data.

Chapter II: Intended use

Article 4: For cross-border patient care

1. The aim of the dataset is to help support safe, high-quality cross-border care for emergency or unplanned care events.

Article 5: As a reference for electronic Patient Summaries at national level

1. The ability to populate this dataset implies the existence of a local electronic Patient Summary. 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 these guidelines for reference purposes for national implementation.

Chapter III: Specification of the dataset

Article 6: Basic and extended dataset

1. The content of the Patient Summary dataset is shown in the following tables. The Patient Summary data comprises patient administrative data and patient clinical data.

2. The final column in the table identifies those fields that form part of the basic and extended datasets.

Table 2: Patient Summary dataset

PATIENT ADMINISTRATIVE DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/ EXTENDED (Ext) DATASET**
Identification [1]	National healthcare patient ID	National healthcare patient ID	Country ID, unique to the patient in that country. Example: ID for United Kingdom patient	Basic
Personal information	Full name	Given name	The first name of the patient (example: John). This field can contain more than one element.	Basic
		Family name/surname	This field can contain more than one element. Example: Español Smith Note: some countries require surnames to be the birth name [to avoid potential problems with married women's surnames).	Basic
	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	Basic
	Gender	Gender code	This field must contain a recognized valid value.	Basic
Contact information	Address[2]	Street	Example: Oxford Street	Ext
		House number	Example: 221	Ext
		City	Example: London	Ext
		Post code	Example: W1W 8LG	Ext
		State or province	Example: London	Ext
		Country	Example: UK	Ext
	Telephone no.	Telephone no.	Example: +45 20 7025 6161	Ext
	e-mail	e-mail	Example: jens@hotmail.com	Ext
	Preferred HP/HPO to contact[3]	Name of the HP/HPO	Name of the HP/ HPO that has been treating the patient. If this is an HP, the structure of the name will be the same as described in 'Full name' (given name, family name/surname).	Basic
		Telephone no.	Example: +45 20 7025 6161	Basic
		e-mail	e-mail of the HP/legal organization	Basic
	Contact person/ legal guardian (if available)	Role of that person	Legal guardian or contact person	Ext
		Given name	The first name of the contact person/guardian (example: Peter). This field can contain more than one element.	Ext
		Family name/surname	This field can contain more than one element. Example: Español Smith	Ext
		Telephone no.	Example: +45 20 7025 6161	Ext
		e-mail	e-mail of the contact person/legal guardian	Ext
Insurance information	Insurance number	Insurance number	Example: QQ 12 34 56 A	Ext

[1] Dataset that enables the univocal identification of the patient

[2] May vary by country

[3] A health professional in country A may need a contact (health professional/healthcare provider) who knows the patient.

PATIENT CLINICAL DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/ EXTENDED (Ext) DATASET**
Alerts	Allergy	Allergy description	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)	Basic
		Allergy description ID code	Normalized identifier	Basic
		Onset date	Date of the observation of the reaction	Ext
		Agent	Describes the agent (drug, food, chemical agent, etc.) that is responsible for the adverse reaction	Basic
		Agent ID code	Normalized identifier	Basic
	Medical alert information (other alerts not included in allergies)	Healthcare alert description	Medical alert information: any other clinical information that is essential 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 cannot tolerate it because of persistent cough).	Basic
		Healthcare alert ID code	Normalized identifier	Basic
Medical history	Vaccinations	Vaccinations	Contains each disease against which the patient has been immunized	Ext
		Brand name		Ext
		Vaccination ID code	Normalized identifier	Ext
		Vaccination date	Date when the immunization was given	Ext
	List of resolved, closed or inactive problems	Problem description	Problems or diagnoses not included in the definition of "current problems or diagnosis". Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem, which is therefore a closed problem)	Ext
		Problem ID code	Normalized identifier	Ext
		Onset time	Date of onset of problem	Ext
		End date	Problem resolution date	Ext
		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).	Ext
	Surgical procedures prior to the past six months	Procedure description	Describes the type of procedure	Basic
		Procedure ID (code)	Normalized identifier	Basic
		Procedure date	Date when procedure was performed	Basic

PATIENT CLINICAL DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/ EXTENDED (Ext) DATASET**
Medical problems	List of current problems/diagnoses	Problem/diagnosis description	Problems/diagnoses that fit these conditions: conditions that may have a chronic or relapsing course (e.g. exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g. diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g. dyspepsia, migraine and asthma)	Basic
		Problem ID (code)	Normalized identifier	Basic
		Onset time	Date of onset of problem	Basic
	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 fibrillators, prostheses, ferromagnetic bone implants, etc. of which the HP needs to be aware.	Basic
		Device ID code	Normalized identifier	Basic
		Implant date	Date when procedure was performed	Basic
	Major surgical procedures in the past six months	Procedure description	Describes the type of procedure	Basic
		Procedure ID (code)	Normalized identifier	Basic
		Procedure date	Date when procedure was performed	Basic
	Treatment recommendations	Description of recommendations	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	Basic
		Recommendation ID (code)	Normalized identifier	Basic
	Autonomy/invalidity	Description	Need for the patient to be continuously assessed by third parties; invalidity status may influence decisions about how to administer treatments	Basic
		Invalidity ID code	Normalized invalidity identifier (if any, otherwise free text)	Basic
Medication summary	List of current medicines (All prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not)	Active ingredient Exemption: brand name	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: "paracetamol" Brand name if a biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU)	Basic
		Active ingredient ID code	Code that identifies the active ingredient	Basic
		Strength	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	Basic
		Pharmaceutical dose form	Form in which a pharmaceutical product is presented in the medicinal product packaging (e.g. tablet, syrup)	Basic
		Number of units per intake	Number of units per intake that the patient is taking. Example: 1 tablet	Basic
		Frequency of intakes	Frequency of intakes per hour/day/week/month. Example: every 24 hours	Basic
		Duration of treatment	Example: 14 days	Basic
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	Basic

Variable (nesting level 1)	Variables (nesting level 2)	Variables (nesting level 3)	DEFINITION AND COMMENTS	BASIC (Basic)/ EXTENDED (Ext) DATASET
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	Ext
		Reference date range	Example: from 1974 to 2004	Ext
Pregnancy history	Expected date of delivery	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).	Ext
Physical findings	Vital signs observations	Blood pressure	One blood pressure value, which includes systolic blood pressure and diastolic blood pressure	Ext
		Date when blood pressure was measured	Date when blood pressure was measured	Ext
Diagnostic tests	Blood group	Result of blood group	Result of blood group test performed on the patient	Ext
		Date	Date on which the blood group test was performed. This field may contain only the year if the day and month are not available (e.g. 01/01/2009).	Ext

PATIENT ADMINISTRATIVE DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/ EXTENDED (Ext) DATASET**
Country	Country	Country	Name of country A	Basic
Patient Summary	Date created	Date created	Date on which PS was generated	Basic
	Date of last update	Date of last update	Date on which PS was updated (date of most recent version)	Basic
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	Basic
Author organization	Author organization	Author organization	At least one author organization (HCP) shall be listed. If there is no HCP, at least one HP shall be listed.	Basic

Chapter IV: Organizational, technical and legal prerequisites

Note: The Articles in this chapter are by definition not part of the specification of the Patient Summary dataset in these guidelines. Their purpose is to describe the most important organizational, technical and legal prerequisites necessary to enable cross-border exchange of Patient Summaries or health data in general. The content of each of these Articles is therefore a brief description of the scope and not the final wording nor the specification for implementation. Member States will need to agree the details of implementation of these prerequisites in different settings and outside these guidelines.

Article 8: Terminologies/terminology standards

1. Emergency or unplanned care situations require an ability to convey both meaning and context in the Patient Summary to enable safe, high-quality care. It is agreed that to achieve this in a cross-border setting, it is necessary to have structured and coded data for identified fields.

2. Member States wishing to engage in cross-border communication may perform mapping, transcoding and translation activities to support such activity or may wish to use the coding schemes as described in the example set out in Appendix B.

3. Further work is needed to review the code schemes described in Appendix B. The assessment of each field will be undertaken according to an agreed set of criteria and by groups including professional representative bodies. The proposed criteria are that a chosen scheme should:
    - Be internationally used
    - Be in use in some Member States
    - Have translations in a number of different languages
    - Have a maintenance process
    - Have a number of transcoding systems/services, e.g. mapping facilities
    - Be easy to implement
    - Take account of the cost of licences, implementation and maintenance.

Article 9: Use of master catalogue

1. Agreement on a set of coding schemes as set out in Article 8 will require a master catalogue at EU level which can be used by all Member States for sharing value sets, allowing each Member State to translate and transcode them, if required, to their national equivalents.

Article 10: Quality standards and validation

1. Each Member State should apply commonly agreed quality and safety standards in the process of coding the information into patient records.
2. Similarly, Member States should apply commonly agreed rules for quality and safety when creating catalogue entries.

Article 11: Technical standards and format

1. 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 should be based on agreed international standards and profiles. An example set is described in Annex C. Further work will be needed to review these.
2. Member States shall ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures.
3. Member States shall ensure that cross-border transactions are logged and make logs available for legal purposes, e.g. a health professional request for a Patient Summary; this is an important feature.

Article 12: Interoperability testing

1. Member States will need to establish testing mechanisms that demonstrate compliance with agreed standards. For cross-border purposes, a Europe-wide testing process will also be required, including validation of data fields against defined criteria (e.g. dates in valid date format). Further work is needed on proposals for clinical validation.

Article 13: Authorization, authentication and identification

1. Implementation of the patient dataset implies that each Member State has considered enabling activities such as:
    a) Providing an official ID health number for each citizen (with national federation of IDs if numerous regional systems are available). For cross-border purposes, a unique patient identifier is a necessary requirement so that each individual patient can be linked to the patient record in the country of affiliation.
    b) Maintaining electronic registers of health professionals
    c) Agreed levels of authentication of citizens and health professionals

Article 14: Legal framework/enablers for the implementation process

1. EU and national laws create the legal basis for interoperability. The EU and national legal frameworks define the conditions under which health data may be shared, making provisions for specific safeguards that need to be in place without, however, being prescriptive of such safeguards. Member States should ensure they have measures in place to assure and evaluate their own compliance.
2. All data contained in Patient Summaries is “sensitive personal data” and Member States will therefore need to ensure that processing and storage are in line with legal and data protection requirements. In particular, Member States will need to implement consent management for the processing and storing of data and subsequent authorized access.

Article 15: Education, training and awareness raising

1. In terms of education, training and awareness raising, Member States should:
    a) undertake activities towards increasing awareness of the benefits of and need for interoperability and related standards and specifications for electronic cross-border patient data exchange;

b) pay particular attention to education, training and dissemination of good practices in electronically recording, storing and processing patient information as well as in gaining the informed consent of the patient and lawfully sharing the patient's personal data;

c) initiate appropriate, easy to understand information and awareness raising measures for all individuals, in particular patients.

d) provide education and training for promoting a culture of high levels of security and privacy.

Article 16: Amendments to the guidelines

1. The eHealth Network will include in its Multi-Annual Work Programme the necessary activities for:

   - Collecting information on the approaches of Member States to implementing the guidelines
   - Updating the guidelines on a regular basis to reflect the evolution of the EU legal framework, technological advances and lessons learned from their use by the Member States.

The guidelines are addressed to the Member States.

4. 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 guidelines themselves.

Some of the material is taken from the experiences of the epSOS project. Other examples have been provided by individual Member States.

Chapter I: General provisions

Article 1: Concept

The focus on emergency or unplanned care is deliberate in that it requires agreement on those data items needed when a patient previously unknown to the health professional (HP) needs treatment. For planned care, additional referral information will typically be provided and hence is not covered by the scope of this release [Release 1] of the guidelines.

The epSOS project started with 12 participating nations that defined and agreed the initial functional design (Austria, Czech Republic, Denmark, France, Germany, Greece, Italy, the Netherlands, Slovakia, Spain, Sweden and the United Kingdom). Subsequently, 14 more countries (Belgium, Croatia, Estonia, Finland, Hungary, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Slovenia, Switzerland and Turkey) joined the consortium and were requested to review and analyse the selected use cases. On two occasions the project performed a country analysis of the preconditions in the participating nations (PNs). This information has been supplemented by the survey carried out through the eHGI of all Member States.

The epSOS working group, including clinical experts, defined the functional service related to the Patient Summary. A Patient Summary was defined as a "*dataset of essential and understandable health informatio*n" that is made available "*at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in unscheduled care";* it can also be defined at high level as: *"the minimum set of information needed to assure healthcare coordination and the continuity of care*".

Due to the unscheduled care scenario and the potential added value in emergency situations, the epSOS Patient Summary use case introduced the clinical concept of a "maximum" set of information that may be sent for the specific epSOS purpose. The intention was to highlight the fact that there is a balance between the usefulness of having more clinical information and the usefulness of having it summarized so that the professional can quickly understand the relevant conditions. The Patient Summary should therefore give the professional a summary of the most relevant information that can be consulted "at a glance". Because of this situation, it was agreed that fields not belonging to the basic or extended agreed PS dataset will not be exchanged even if they are available in some countries.[3]

Each field in the dataset was defined while *"keeping in mind the medical perspective and the clinical purpose"*.

During the epSOS project, consultation with the Calliope thematic network (http://www.calliope-network.eu/) and the STORK project (https://www.eid-stork.eu/) resulted in recommendations for future development.

Other European projects have found the dataset and terminologies chosen to be useful. Example projects include **ELECTRONIC HEALTH RECORD FOR CLINICAL RESEARCH -** EHR4CR (http://www.ehr4cr.eu/) and Translational Research and Patient Safety in Europe – TRANSFoRm (http://www.transformproject.eu/).

More recently, the dataset has been reviewed by US stakeholders as part of the work following the EU-US roadmap and MoU collaboration agreement.

Article 2: Definitions

Each field in the dataset has its own definition and functional purpose. The epSOS clinical team carried out their work while *"keeping in mind the medical perspective and the clinical purpose"* as well as the available information and the needs of the participating Member States as the aim was to describe a real pilot.

Because of the need to create a balance between the clinical purpose and the actual information available, the dataset has been divided into sections based on the "*degree of relevance of the information for the Patient Summary Service*".

The Patient Summary questionnaire showed that, as of 2010, important data (included in the basic dataset) was not yet available in some of the countries (not coded, could not be recovered, etc.). The decision was taken that it was necessary to allow *"Null flavour values"* even if the section has to be added to the dataset to be exchanged. The expectation was that countries will focus on having that information ready to be exchanged.

Article 3: Legal basis of the guidelines

The contents of these guidelines are seen as advice that will help each Member State to make progress in terms of their own agenda.

Chapter II: Intended use

Article 4: For cross-border patient care

These guidelines focus on the content issues and the description of possible ways of producing this content for cross-border exchange, taking into consideration existing national implementations.

The fundamental requirement for the exchange of information is the use of a structured approach to the recording of information. The fields in the datasets were selected according to the following criteria:

- **Relevance to the scope:** Elements were selected from the European Emergency Health Card, the Czech and Slovak proposal for an Emergency Dataset (EDS), the ISO 21549-3 (Patient Health Card Data – Limited Clinical Data), the Hospital Data Project dataset, the HL7 Terminology and the IHE Recommendations. These data elements define the basic categories of terms in use. However, they were too loosely defined to be used as specifications for data exchange. These data elements should be used as a representation of the data elements, and all the concepts must have a clear

relation to the specific domain that they are representing and should be used in its context.

- **Presence in clinical data:** The relevance of the terms was evaluated with respect to the following criteria.
- **Information sufficient for clinical decision:** Health terminology is very complex and covers a large area of knowledge requiring a great deal of effort to organize part of this terminology for a specific purpose. It is hard to decide what level of detail should be used, especially when use cases cannot be precisely specified. However, in the basic use case of a HP taking care of a citizen from a foreign country (possibly in an emergency situation), one should always think about what information really needs to be obtained about given conditions. Sometimes merely presence or absence needs to be known (e.g. whether the patient has been immunized against tetanus), in other cases more specific attributes are necessary (e.g. type of pacemaker, date of last examination, clinical course). These various levels of information and granularity were addressed in choosing the syntax and the value set that accompany the respective value sets syntax. Each coded element was studied as a group, within the health professionals in the semantic group, resulting in the Reference Terminology.
- **Information systems in use:** When creating a Value Set Catalogue, its main purpose has to be kept in mind – it can be used to represent communication between information systems (e.g. NCP, national systems). The content and representation should follow constraints given by their implementations – semantic services and communication standards. Moreover, current local systems may introduce a number of additional constraints to be faced. The approved technical specification of semantic services needs to be revised.
- **Frequency of use:** Even within one domain, delimited by scope documents, the number of possible concepts may exceed realization possibilities.
- **Severity (consequences):** If the absence of a particular, even very rare fact can lead to the patient's health conditions being placed at serious risk, it should be incorporated even if this means that less important information will have to be omitted.
- **Content evaluation and acceptance:** The process of choosing concepts is relatively arduous and time-consuming. However, it has to be executed properly and the evaluation needs to be included.
- **Reconcilability:** Special emphasis should be placed on the reconcilability of a concept's meaning through the chosen term. Generally, self-explanatory terms are to be preferred. At an international level, higher priority should be given to terms incorporating Latin or Greek elements.
- **Non-ambiguity:** The meaning of the concept should be as clearly understandable as possible from the term and, moreover, for professionals from all medical specialities.
- **Clinical acceptability:** As with concept selection, it is crucial to follow clinicians' preferences. Qualification and acceptance in practice play a major role.

- **Consistency and systematic order:** Decisions about which terms to choose have to be consistent within the framework of the entire terminological system. If it is decided to follow certain morphological or syntactic rules for a specific category of concepts, they have to be applied to all terms from this category and any exceptions should be well justified. The same set of criteria applies to the translation of terms into the languages of participating countries.

Article 5: As a reference for Patient Summaries at national level

The aim of the dataset is to support cross-border care. However, the ability to populate this dataset requires national activity. More advanced and elaborate Patient Summaries exist in some Member States (MS), but the eHealth Network agreed that the guidelines could serve as a common baseline of Patient Summaries at national level.

The guidelines could also be used by Member States to help them address their own circumstances, such as:

- I have a national PS that has already been implemented: what do I need to do to make it compatible with the EU specification?
    - My national system is based on the EN13606 standard; what do I need to do to enable data to be exchanged across borders?
- I have no plans for a national PS – any requests for access will be routed to the local healthcare provider(s) who maintain the PS for the patient, so
    - How do I ensure consistency of structure and content?
    - I am expecting to construct a Patient Summary "on the fly" from multiple inputs, so how do I (a) ensure this is practical (e.g. response times) and (b) assure the content?
- What if the information available in my national PS is more granular (e.g. problem coded in SNOMED-CT) than in the EU PS? Would the granularity of the information be lost or should this information be kept separate from the minimal information requested (3-digit ICD)?
- What happens if I do not have a licence for any of the mandatory terminology resources?

Chapter III: Specification of the dataset

Article 6: Basic dataset

The epSOS pilot operated on the twin principles of building on what is available and not interfering with the internal systems in a Member State. The need to maintain consistency with existing developments added more constraints to the initial clinical definitions. These constraints were considered necessary by clinicians and technicians within the project to allow the real pilot to be carried out. Whilst the aim is to be able to have a service definition that can actually be piloted in the real world, this is not always the best situation from a clinical viewpoint. Increased quality and quantity could and should be added as the systems gain more maturity at all levels (regional, national, European, etc.).

Article 7: Extended dataset

Many countries build their Patient Summary information from multiple sources, which complicates the update of cross-border PS information. Very few are currently able to incorporate information from external sources both in terms of capabilities of information systems and procedures. Furthermore, few are able to send the data to the incumbent information systems.

The dataset description includes details on which fields are mandatory (very few). However, each Member State will need to consider which of the fields they might populate. There are, of course, occasions, when a field is blank precisely because there is no relevant information in the patient record.

From a clinical perspective, information about the blood group would not be used as a basis for a blood transfusion unless it is confirmed by further medical tests.

Some of the fields in the extended dataset may be of little use for emergency and/or unplanned care, e.g. fields concerning treatment recommendations that do not include drugs (diet, physical activity, etc.), the social history of the patient, or even blood pressure information (which can change from day to day). It is recommended that the review process should involve health professionals who will use this dataset in order to test the usefulness of the fields when treating a patient in an emergency or unplanned context. The results of this review could be reflected in Release 2 of the guideline.

Chapter IV: Organizational, technical and legal prerequisites

Article 8: Terminologies/terminology standards

Semantic interoperability requires the meaning of clinical information to be represented in standardized ways that allow both humans and computers to understand clinical information. An underlying principle is that exchange mechanisms convey both meaning and context in the Patient Summary in order to enable safe, high-quality care. It is agreed that to achieve this in a cross-border setting, it is necessary to have structured and coded data for identified fields.

It requires the effective use of standards to support accurate and complete clinical documentation that is faithful to the patient's situation, and electronic health record (EHR) data to be transferred and structurally mapped into a receiving repository in a way that enables its clinical content to be interpreted with a meaning that is commonly understood – by computers as well as by people.

Since code systems such as SNOMED-CT and ICD-10 (to name but two) contain a large number of terms, it is not possible to use them in their entirety within the European context, where some Member States might use different code systems that they will have to cross-reference and/or translate. Certain criteria were used to choose between the most significant terms and arrive at a reasonable manageable content. For example, ICD-10 is a classification consisting of 22 chapters divided into categories having a 3-digit code. Each category is also divided into several sub-categories that provide a more granular level of information about the pathology coded.

Each coded element has a value belonging to a value set or in some cases even an entire code system. For example the data element ‘List of current problems/diagnoses’ is mapped onto the CDA content module section *Active Problems* within the entry *Problem Concern*. The coded element within the *Problem* entry, in theory, may have values from one or more code systems since different countries may have different code systems. For example, a term such as *chronic ischemic heart disease* may be expressed using different terms originating from different code systems:

- 414 Other forms of chronic ischemic heart disease (ICD9CM)
- I25 Chronic ischemic heart disease (WHOICD10)

- 413838009 Chronic ischemic heart disease (disorder) (SNOMED-CT).

However, the value set for a particular coded field is chosen from only one code system based on the criteria below, and the Member States are responsible for the translation/verification of each of the terms employed.

The different code systems were chosen according to the following criteria:

- **Internationally used:** An international code system such as those released by ISO or WHO, for example, has the advantage of having been elaborated by experts with vast experience of terminology implementation and application. Internationally used code systems have implementation guidelines that are used at a national level as well as maintenance guidelines. The code system used in the Value Sets Catalogue must be internationally recognized. Its suitability should be evaluated by experts in the field, both medical and non-medical.
- **In use:** The second most important criterion when selecting the code system is its use in the Member States. A survey was conducted among the experts working on the epSOS Value Sets Master Catalogue in order to obtain an accurate representation of the code systems used in each country.
- **Existence of translations into different languages:** The existence of translations into different languages is another key element to be evaluated, since this will dramatically reduce the activity of translating the Value Sets Catalogue terms into the local (national) language. If a code system exists in the local (national) version, it is likely that existing translations have been already validated/certified and aligned when newer versions are released.
- **Has a maintenance process:** A code system that has an official maintenance process is highly desirable. The release of new versions should be taken into account during the decision-making process. The maintenance process should include specifications for distribution and support.
- **Existence of transcoding systems/services:** The existence of officially defined or at least consolidated systems/services to perform transcoding from one code system to another is a desirable element in order to reduce costs and risks. However, most standard organization bodies are known to be struggling with this important issue. Nevertheless, it is considered to be very useful whenever official attempts exist to map one code system to another as it provides guidance for mapping.
- **Cost of licences, implementation and maintenance:** Although most of the code system licences are provided free of charge for research purposes, the costs might prove to be prohibitive. In addition to the cost of the licences, the costs of implementation and maintenance need to be considered.
- **The code system must be easy to implement:** The code system must be easy to implement based on a sound methodology that takes into account both the syntactic and vocabulary aspects.

The selection made in epSOS represented the position at a point in time and reflected the (relatively poor) levels of maturity of coding in Member States at that time. A number of concerns have been raised about some of the epSOS proposals (e.g. the use of 3-digit ICD codes, presently under reconsideration by the Semantic Team) and a desire for the list to be reviewed. Similar issues were raised at the workshop on 10

September 2013. A report was commissioned by the epSOS team inviting proposals on what might be done differently. The conclusions of "THE EXPERIENCE OF SELECTING THE CODE SYSTEMS FOR THE DEVELOPMENT OF THE EPSOS MASTER VALUE CATALOGUE (MVC)" are as follows:

"The Semantic Team in epSOS has gone through an enormous journey in developing the Master Value Set Catalogue for the epSOS project. It has not been easy but was definitely a learning process that the team value very much. Many reflections can be made and again there will probably be many opinions but five general recommendations are to be given to future similar work based on the experience of this work:

Selection criteria: *The Semantic Team will definitely recommend that any work similar to this draws up a set of selection criteria. They have been used several times in this semantic development as the majority vote when a decision needed to be taken.*

IP and licence: *Developing semantics will rely on work owned by SDOs. Our recommendation is therefore that agreement with the SDOs should be made prior to the development of the semantic work. This is for two reasons: (i) not to delay the work licence to use the (relevant part of the) code system during a project period and (ii) to dismiss any discussions about who may use the developed work afterwards in order to ensure the sustainability of the semantic work. Many decisions in epSOS would probably have been easier if there had been an agreement with the SDO that the value sets/datasets developed in the project were to be used for free after the project had ended.*

Tooling: *Creating and storing the code system and the value sets first started out in epSOS with the use of spreadsheets. This very quickly resulted in errors, especially around the versioning part; it was also difficult to obtain full traceability of the approval workflow and good change logs in a work of this scale. The epSOS project therefore decided to implement a terminology server and tooling. The recommendation is therefore to ensure that there is tooling support in similar work to this for an improved code system overview for clinicians when they need to understand what a code system contains. Dataset selection tools with versioning control to obtain the full change log and traceability are also needed, as is a central repository so that everyone can access the selected code systems.*

Common import formats for code systems: *It is recommended that the SDOs adopt a minimum common import format of the code systems, based on international standards such as HL7 CTS2, in order to allow projects like this to import and access their code system in a repository more easily. It took the project many hours to collect and re-format the many different formats that the code systems were delivered in.*

Value set meta-information: *It is recommended that the SDOs generate a minimum amount of meta-information containing the most important information for a value set, including information about how the value set was created. This would have helped the epSOS project to function as a log of the semantic work, which can then be easily passed on to future projects for adoption."*

It is therefore necessary to conduct a review of the coding schemes to be used and for this to be documented in the next release of the guidelines.

Article 9: Use of a master catalogue

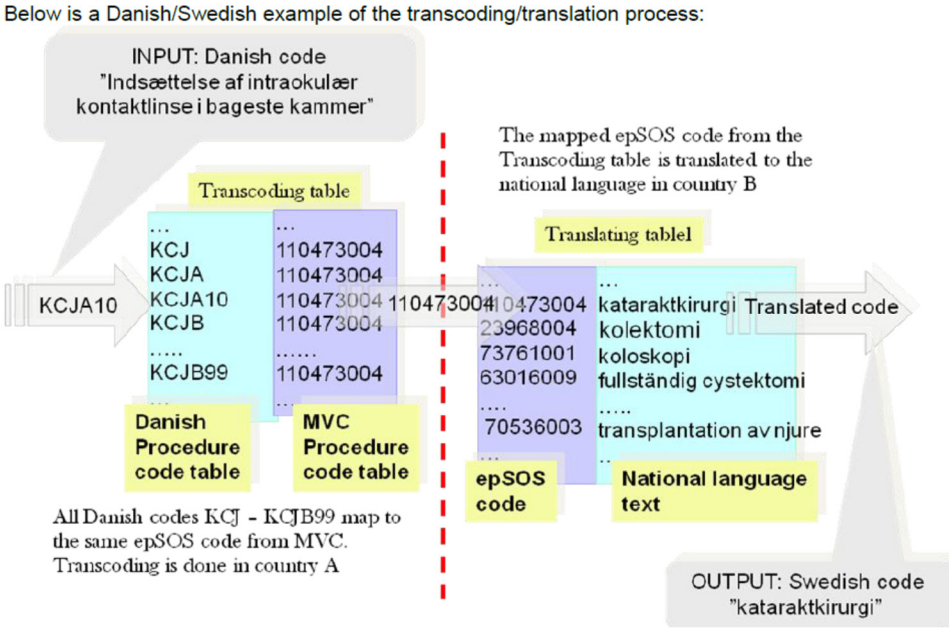
Across Europe, there are different languages, different standards and different coding schemes. In epSOS, this was addressed by the use of two master files: the Master Value Sets Catalogue (MVC), which applies across all Member States, and the Master Translation/Transcoding Catalogue (MTC).

Only one code system was chosen per coded element. No official mapping between code systems exists; therefore only one code system is chosen per coded field. Since transcoding at a Member State level or translation is expected, the number of terms in the value sets must be limited while providing the broadest medical coverage possible. Thus, each coded element has only one code system associated with it and its display name is in English only. These terms were compiled in an Excel file named the Master Value Sets Catalogue (MVC), which provides the basis for data exchange.

The content of the MVC is in English; the terms are based on criteria defined by the use cases. Each nation is then required to translate the terms and transcode them into their national coding system, thus creating the Master Translation/Transcoding Catalogue (MTC).

The MVC and MTC are supported by an EU-wide Central Reference Terminology Server; each Member State needs its own local terminology repository as a copy of its MTC. If an update is made to the Central Reference Terminology Server, the local terminology repositories are notified and updated.

Figure 3: Translation and transcoding



A number of characteristics are required to support the evolution of the MVC, which is the basis for the ontology over time. It must be noted that these considerations are fairly general and they are typical of any international code system.

- **Context-free identifiers:** Concept identifiers such as codes shall not be tied to a hierarchical position or other contexts; their format shall not carry any meaning (non-semantic identifiers).
- **Persistence of identifiers:** Codes shall not be reused when a concept is obsolete or superseded.

- **Version control:** Updates and modifications to the value sets shall point to consistent version identifiers (OIDs). Usage in patient records should carry this version information as the interpretation of coded patient data is a function of the terminology used at a point in time. This version information should also be recorded in all audit data stored.
- **Editorial information:** New and revised terms, concepts and synonyms shall have information about their date of entry or effect in the terminological system associated with them, along with pointers to their source and/or authority.
- **Obsolete marking:** Superseded terminological entries shall be so marked, together with their preferred successor. Data may still exist in historical patient records using obsolete terms; their future interpretation and aggregation are dependent upon that term being carried and cross-referenced to subsequent terms.
- **Identification and registration:** Terminologies that are intended to be used for the purpose of information interchange in health shall have a unique, permanent terminology identifier (OID) registered with an appropriate organization. HL7 Version 3 messages and CDA use OIDs (object identifiers) to identify terminological systems. prEN 1068-1 (superseded) proposes a Registration Authority to maintain a register of health coding systems in Europe.
- **Interoperability:** Healthcare terminologies shall conform to international terminological standards and the relationship between the terminology and relevant messaging/information standards shall be explicitly recognized. If there is need to extend the content of the terms, this shall be addressed in the maintenance and implementation process.

Article 10: Quality standards and validation

The semantic transformation is performed according to the translation, mapping and transcoding carried out by designated competent legal entities in each Member State. The responsibility for the *accuracy* and integrity of the process is with each national designated competent legal entity responsible for such semantic processing. The issue of liability for errors in the semantic mapping will need to be considered further, but is likely to be shared between the respective Member States.

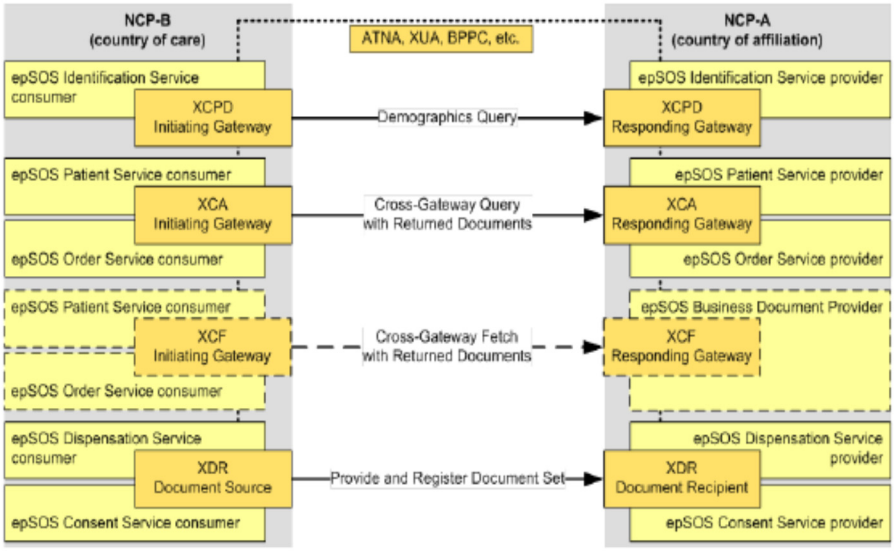
Article 11: Technical standards and format

Following the clinical rationale that drove the definition of the datasets, the semantic group chose the standards to provide the transport mechanism for the data. The diagram below illustrates the IHE profiles recommended to support interoperability.

Internally Member States might base their national implementations on international standards such as EN13606. For the exchange of data across borders, a shared document structure is needed.

As described in Annex C, one approach to this would be to adopt a structure compliant to HL7 Clinical Document Architecture (CDA) Version 2, level 3 with the additional constraints of the HL7 Continuity of Care Document (CCD) and IHE Patient Care Coordination (IHE PCC).

Figure 4: IHE profiles



Any of these documents is made up of a header (or the part defining the document, and its identifying information about the patient such as the health professional and the document type) and a body, or the part containing the clinical content.

A high level of IT security is necessary in order to fully comply with the security principles of the Directive and the specific risks related to the processing of personal data in cross-border healthcare:

- All staff implementing the project should be provided with clear, written instructions on how to use the cross-border system appropriately in order to prevent security risks and breaches;
- Suitable arrangements should be made in using the Patient Summary and prescription storage and archiving systems to protect the data from unauthorized access, theft and/or partial/total loss of storage media;
- For data exchanges, secure communication protocols and end-to-end-security must be adopted;
- Special attention must be paid to adopting a reliable and effective electronic identification system that provides the appropriate level of assurance (of both participating staff and patients) in compliance with EHN decisions;
- The system must be capable of correctly recording and tracking the individual operations that make up the overall data processing in an auditable way;
- Unauthorized data access and/or changes should be prevented when the back-up data is transferred and/or stored;
- In emergency situations, any access should be logged and subject to audit.

For security purposes, logging of transactions, e.g. a health professional request for a Patient Summary, is an important feature. Unauthorized access to private medical data can be detected or prevented by having a transactions log. Logged information in most cases consists of:

- Who has accessed information,
- When information has been accessed, and

- What information was requested.

In most Member States, a tool is used to identify suspicious behaviour or other anomalies based on available logging data. Misuse of private medical data could be detected or even prevented using this functionality.

Article 12: Interoperability testing

Member States will need to implement software to support cross-border exchange. One option would be to re-use the open source components developed in epSOS and released for all in the "JoinUp" EC-supported Open Source Community. These components can be adopted by participating nations and system integrators in order to develop their own NCP solution.

In epSOS, regardless of the adopted solution, it was mandatory for all the participating nations to follow the testing strategies, which involved:

- The demonstration of compliance with the adopted normative standards (e.g. IHE, HL7) by an independent third party (or parties) (in epSOS, IHE International through the Gazelle Test Tools and Connectathon interoperability testing events).
- The establishment (at least in the epSOS LSP) of two environments:
    - The pre-production (PPT) environment for technical interoperability testing and clinical end-2-end validation and quality improvement
    - The operation environment, where real patients' data is exchanged.

To assure high-quality, safe and secure cross-border implementation, it will be necessary for Member States to agree on testing strategies, possibly with a Europe-wide testing facility.

Article 13: Authorization, authentication and identification

Each Member State would be expected to have a National Contact Point (NCP), which is the technical and organizational element that ensures interoperability across national borders towards other Member States and decouples the national infrastructure from other Member States.

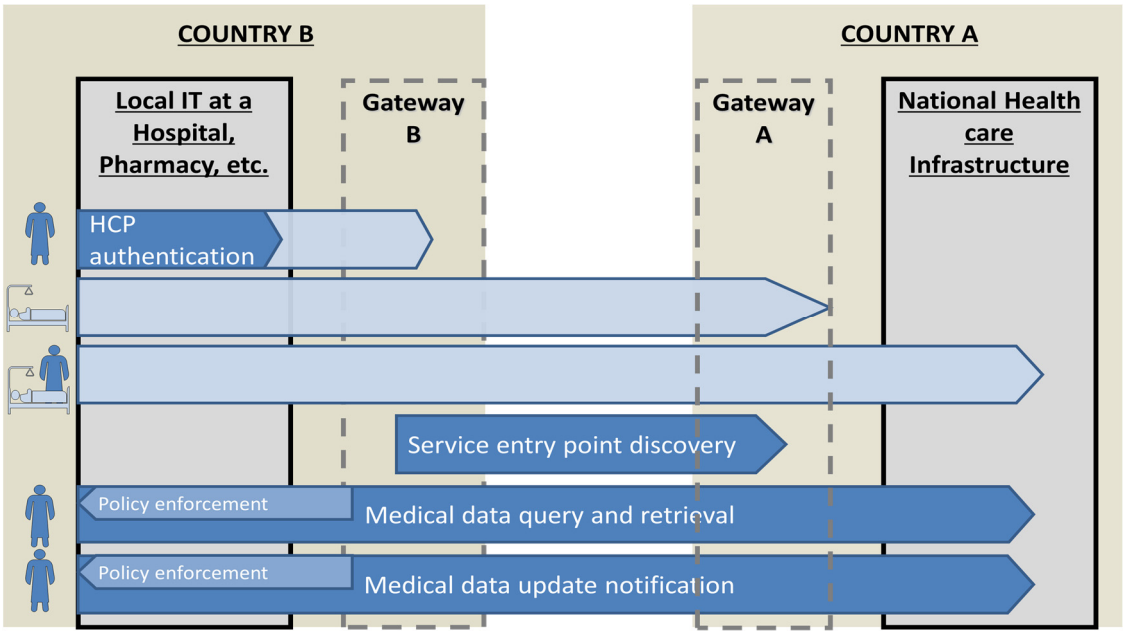
The first consequence is that the external interface is standardized, with specifications of protocols, procedures and exchanged documents.

The interface towards the national infrastructure is specified at a conceptual level, but each Member State is free to adopt the most suitable solution for interfacing the NCP with their national infrastructure.

The NCP performs the basic functional activities related to security management, health professional authentication, patient identification, consent management, document exchange, audit logging and, most relevantly, document semantic transformation between national structure, adopted coding systems and language and the document interchange format of the "pivot document".

To be able 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 so that each individual patient can 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.

Figure 5: NCP roles



In Austria, Spain and the UK, regional and national patient identification numbers are in co-existence with each other. In order to find a patient successfully, it is important to map the regional numbers with the national numbers, which is done in Spain. This mapping is relevant in order to ensure that all existing patient information can be located if requested in a cross-border setting.

Official documents, such as passports, ID cards and driving licences, seem to be accepted across the PNs for authentication. In cases where a patient does not have (access to) a national patient ID or identification document, different kinds of personal information elements, such as last name and date of birth, are used to create a unique (temporary) form of identification.

Medical information exchange has always been a sensitive subject due to the highly confidential nature of this information. Besides having means to identify a patient, facilities to identify a health professional or healthcare provider organization are a prerequisite for maintaining a high level of confidentiality of medical information when it is exchanged in a secure manner between other health professionals/healthcare provider organizations. The health professional/healthcare provider organization identifier is coupled to a digital identity, which is issued by a certified authority. This identifier provides a base to create a trust circle between health professionals/healthcare provider organizations and is also a precondition for electronic signing by the health professional/healthcare provider organization.

Almost all Member States have unique identification for health professionals/healthcare provider organizations. Most have a central Trusted Third Party (TTP) which has the task of maintaining and/or providing a registry for identification information purposes. This registry is available electronically to its users.

The digital IDs of health professionals/healthcare provider organizations are also used for authentication purposes by the majority of Member States. Similarly, the majority make use of digital signing for health professionals/healthcare provider organizations in their country. In some countries a prescription is not valid without the (electronic) signature of the health professional.

For most Member States, the digital identity of the health professional is coupled to the health professional role, and authorization for accessing patient information is based on the role, e.g. GP or pharmacist, of the health professional. This is the case in most of the PNs, based on the *digital* identity of the health professional. In the majority of Member States, the health professional prescribing role or health professional medication dispensing role can be inferred from the digital identity of the health professional.

Generally, authorized access to patient information takes place at the level of events (health care encounters), role with current care and characteristics of data (e.g. only medication information).

Article 14: Legal framework/enablers for the implementation process

The main challenge faced by epSOS was the great diversity in the implementation of the Data Protection Directive across Member States. It was necessary to establish a "trusted domain" governed by a number of privacy, security and safety policies adopted by national health authorities.

The processing of healthcare data must have a clear legal basis. In the absence of other legitimate grounds, this can be the data subject's two-step explicit consent (first for participation in general and then at the time of the subsequent encounter).

Where the country of affiliation (A) requests and the country of treatment (B) can make it feasible, it is possible to allow patients to give also their first consent in country B, for instance in a secure way over the Internet.

The processing of personal data must be strictly limited to the minimum required for the fulfilment of cross-border purposes, which must be specified, explicit and legitimate.

In exceptional circumstances, the processing of personal and sensitive data can be justified without second consent in country B (e.g. if, in the emergency situation, the data subject is physically or legally incapable of giving his or her consent). In such a case, however, a full audit trail should be maintained. Furthermore, the patient or person acting on behalf of the patient should be informed about the override of consent upon leaving the Point of Care, including details of access, OR the patient should be provided with access to audit trails.

Data in the log files is to be stored for the purposes of the pilot and for litigation purposes for up to a maximum of 10 years.

Each query about the personal data available across borders should be for a real need of access to specific information related to the care or treatment to be provided or the medicine to be prescribed or dispensed in a particular case.

All data controllers handling cross-border data must notify the competent supervisory authority in accordance with national legislation, regardless of whether the data subjects are nationals or residents of another Member State and irrespective of whether the data handled originates from data controllers in other Member States.

A data subject should be able to address questions about access and requests for rectification/erasure/blocking to any of the controllers as well as to any other body involved in the cross-border exchange of information. A request to access or rectify/erase/block data that is given to a cross-border partner who does not handle data about the data subject should be forwarded to the data controller in charge within

the cross-border system, even if the relevant controller is established in another Member State.

A common cross-border website should provide information on the specific rights of data subjects according to the different legislations of all the participating Member States. The information on the website should clearly specify the rights, conditions and practicalities according to the national legislation of each Member State.

The semantic transformation is performed according to the translation, mapping and transcoding carried out by designated competent legal entities in the cross-border countries in which:

- the responsibility for the *accuracy* and integrity of the process is with each national designated competent legal entity responsible for such semantic processing
- liability for errors in the semantic mapping is a shared cross-border responsibility between the respective Member States and is managed at cross-border level and as part of its trust-building framework.

Agreement on the Data Protection Regulation will provide both clarity and consistency, but is likely to require local action and agreed cross-border arrangements to ensure compliance.

Article 15: Education, training and awareness raising

Member States should take steps to engage in education, training and awareness raising. Such an approach would promote the more effective use of health information as patients move between a variety of healthcare providers, along the continuum of care, and receive treatment and care wherever they are in the Union.

Article 16: Amendments to the guidelines

Each Member State is represented by a National Contact Point (NCP). An NCP is an organization legally mandated by the appropriate authority of each PN to act as a bidirectional technical, organizational and legal interface between the existing different national functions and infrastructures.

The NCP is legally competent to contract with other organizations in order to provide the necessary services, which are needed to fulfil the cross-border use cases. The NCP is identifiable in both the cross-border domain and in its national domain. It acts as a communication gateway and also as a mediator for legal and regulatory aspects of delivering cross-border services. As such, an NCP is an active part of the cross-border environment if it is compliant to normative cross-border interfaces in terms of structure, behaviour and security policy compliance.

Similar recommendations were made by the Article 29 Data Protection Working Party, which subsequently reviewed the cross-border approach and issued a working document on cross-border issues; while the Party verified the appropriateness of the adopted measures, it made specific recommendations for sustainability and for reinforcing patient control and transparency.

The proposed General Data Protection Regulation and its subsequent Delegated and Implementation Acts aim to improve consistency and reduce diversity in data protection and rights, including access to personal data and deletion or suppression of sensitive information. As such, it could in future abolish the need for specific agreements relating

to data protection and, with the transposition of Directive 2011/24/EU, significantly reduce the scope of such (interoperability) agreements.

The organizational setup and procedures for operating the NCP are based on ITIL. The selected service and support processes have been deemed to be the minimal requirement for operating the NCPs in a coherent way. It is up to Member States to decide on the actual operating management framework implemented, provided that the functions described are established and implemented for cooperation between the PNs.

Each Member State must have its own national support organization in place and publish information about the responsible persons. There should be a central service desk for managing incidents, problems and changes and an interface between the national and central service desks should be arranged.

All Member States must have ***incident management*** in place, including a service desk function. This service desk function may differ from country to country. Incident management is important for the individual Member State as well as across borders; Member States should be able to contact each other in the event of technical or organizational problems.

Problem management aims to resolve the root causes of incidents, and thus to minimize the adverse impact of incidents and problems on business that are caused by errors within the IT infrastructure, and to prevent the recurrence of incidents related to these errors. Member States must have organized ways to solve problems.

Change management aims to ensure that standardized methods and procedures are used for efficient handling of all changes in the technical setup, in the organizational setup or in practical matters in a Member State. Each Member State must have a documented process for implementing changes of technical, organizational and practical kinds. The change process must include proper planning and ensure that sufficient information has been disseminated to other Member States.

In order to ensure monitoring and evaluation of cross-border services and related interoperability provisions and systems, Member States should:

- consider setting up a monitoring facility for cross-border services to monitor, benchmark and assess progress on technical and semantic interoperability for their successful implementation;
- undertake assessment activities, such as measuring the quantitative and qualitative eventual benefits and risks (including economic benefits and cost-effectiveness) of services.

ANNEX A – LIST OF ABBREVIATIONS

Acronym	Name
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
eHGI	eHealth Governance Initiative
eHN	eHealth Network
eP	ePrescription
epSOS	European Patient Smart Open Services
HCP	Healthcare provider (i.e. an organization)
HL7	Health Level 7
HP	Healthcare professional (i.e. an individual)
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology SDO
ISO	International Standards Organization
LSP	Large Scale Pilot
MoU	Memorandum of Understanding
MS	Member States
MTC	Master Translation Transcoding Catalogue
MVC	Master Value Sets Catalogue
MWP	Multiannual Work Programme
NCP	National Contact Point
OID	Object Identifier
PCC	Patient Care Coordination
PN	Participating Nations
PoC	Point of Care
PPT	Pre-production test environment
PS	Patient Summary
SDO	Standards Developing Organization
STORK	Secure idenTity across-borders linKed
TFEU	Treaty on the Functioning of the European Union
Transform	Translational Research and Patient Safety in Europe
TTP	Trusted Third Party
WHO	World Health Organisation

THE EXPERIENCE OF SELECTING THE CODE SYSTEMS FOR THE DEVELOPMENT OF THE EPSOS MASTER VALUE CATALOGUE (MVC)

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ANNEX C – EXAMPLE STANDARDS AND PROTOCOLS

This Annex provides reference information on the technical specifications used in the epSOS project.

The epSOS Patient Summary Specification [1a&1b] is based on HL7 Clinical Document Architecture (CDA) Version 2 [2] and the IHE Patient Care Coordination Technical Framework [3].

The exchange specification is based on the epSOS Common Components Specifications [4] using IHE profiles XCPD [5], XCA [6], XDR [7] and optionally XCF [8].

References

[1a] Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines
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[6] IHE IT Infrastructure Technical Framework Supplement – Cross-Community Access (XCA) http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf

[7] IHE IT Infrastructure Technical Framework – Cross-Enterprise Document Reliable Interchange (XDR)
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf

[8] IHE IT Infrastructure Technical Framework Supplement – Cross-Community Fetch (XCF) http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XCF_Rev1-1_TI_2011-08-19.pdf