eHealth Network

GUIDELINE

on

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

Release 2

Patient Summary for unscheduled care

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. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by consensus by the eHealth Network, Brussels, 21 November 2016

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TABLE OF CONTENTS

1. USE CASE DESCRIPTION

1.1. Cross-border Patient Summary for Unscheduled Care

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.

Use Case description:

Title	Patient Summary sharing on a cross-border scale
Purpose	Sharing information about the medical background and history of a patient from Country A (the patient's country of affiliation) with a healthcare professional in another Member State Country B (the country of treatment)
Relevance	Many people request medical help when travelling, working or living abroad. Medical information from the country of origin should be available to all citizens in Europe (in their native language). The current solutions (if any) for obtaining medical information from another country are often cumbersome, unsafe, incomplete and non-standard. The treatment of patients without proper medical background information 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. This Use Case proposes a way towards solving this problem.
Domain	Patient Summary
Situation	Cross-border
Context	The definition of a Patient Summary was laid down by the epSOS project as a starting point for the development and pilot testing of a Patient Summary for citizens who are travelling abroad and need medical help (unplanned). Challenges are related to the level of data required and the quality of information relevant to support patient treatment effectively across different participating European countries. Different countries operate different health care systems, support their own culture for healthcare provision, and may use a different (or several different) language(s). A Patient Summary provides background 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 (HP) 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. 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 HP may have some information available from previous encounters in this type of occasional situation. 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.
Information	Patient Summary (in patient's language and country B language) Patient consent
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 patient is identified (identity confirmed by country A) The health professional is identified, authenticated and authorised The patient may have given consent before travelling to country B or in country B to the health professional (except for emergency cases) In the latter case, the health professional will then register this confirmation The Patient Summary is electronically transferred from the patient's country of origin to the health professional in the country that s/he is visiting (the "visiting country") in a secure way. The health professional retrieves the Patient Summary and uses it for the consultation. The PS is received in both the language of the patient (PDF of original PS) and as a translated version for the health professional.

Table 1: Patient Summary Use Case description

2. GUIDELINES FOR PATIENT DATASET

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 unscheduled care.

Chapter I – General Considerations

Article 1: Objectives and scope

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 shall therefore engage in taking appropriate measures to make their respective information systems interoperable, both technically and semantically, for this Use Case.

Article 2: Definitions

1. For the purpose of this guideline, the definitions of the directives cited within the recitals of this guideline 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 the unscheduled care";* it can also be defined at a high level as: *"the minimum set of information needed to assure Health Care Coordination and the continuity of care*".

Article 3: Concept and intended use

1. The provisions in the general guidelines apply.

2. The aim of the Use Case is to help support safe, high-quality cross-border care for emergency or unplanned 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.

Chapter II – Legal and Regulatory Considerations

Article 4: Data protection

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 5: Authorisation, authentication and identification

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

a) Providing an official ID health number for each citizen (with a national federation of IDs if numerous regional systems are available). 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) Maintaining electronic registers of health professionals

c) Agreed levels of authentication of citizens and health professionals

Article 6: Patient safety

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter III – Organisational and Policy Considerations

Article 7: Enablers for implementation

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 this guideline for reference for national implementation.

Article 8: Quality standards and validation

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 9: Education, training and awareness

1. Effective sharing of Patient Summary data is dependent on the recording health professional and the health professional retrieving the Patient Summary being able to share the understanding of the patient's condition. MS should therefore take care to ensure appropriate awareness and training for all.
2. For instance, the presence of a rare disease code might indicate that specific action should be taken; health professionals need to be aware of this.

Chapter IV – Semantic Considerations

Article 10: Data

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. It is the responsibility of the MS to provide data in compliance with these guidelines. Certain fields may be empty because there is no data for a given patient.

Article 11: Terminology

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.

2. Member States wishing to engage in cross-border communication will need to use the coding schemes as described in the dataset in section 4.

Article 12: Master Catalogue

1. There is a particular issue regarding the identification of medicinal products. It is expected that the coding schemes currently included within the dataset will be replaced by identifiers developed using the IDMP set of standards. The European Medicines Agency is leading work on this; further details will be provided in due course.

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 should be based on standards and profiles as agreed by the eHN. The cross-border specification is described in section 5, which also refers to supporting requirements and other relevant documentation.

Article 14: Security

Member States shall assure logging of cross-border transactions and make logs available for legal purposes, e.g. a health professional request for a Patient Summary is important.

Article 15: Testing and audit

Member States wishing to engage in cross-border communication will need to demonstrate their compliance to the specification in section 5.

Article 16: Amendments to the guidelines

The eHealth Network is responsible for updating the guidelines, which are addressed to Member States.

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 material in this supporting document has built on earlier epSOS experiences, but cites follow-on work in EXPAND, in the relevant Horizon 2020 projects and the joint EU/US Trillium Bridge project.

Chapter I - General Considerations

Article 1: Objectives and scope

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 within the scope of this release [Release 2] of the guideline.

More recently, the dataset has been reviewed by US stakeholders as part of the Trillium Bridge project, in line with the EU-US roadmap and MoU collaboration agreement.

Article 2: Definitions

The definitions section has been extended to include a number of relevant definitions relating to Patient Summaries.

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 systems.

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 dataset may be used to hold additional information, such as information about rare diseases, using current data fields.

Chapter II – Legal and Regulatory Considerations

Article 4: Data protection

Each query about the personal data available through cross-border exchange should be for a real need of access to specific information related to the care or treatment to be provided.

Article 5: Authorisation, authentication and identification

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 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 and date of birth, are used to create a unique (temporary) form of identification.

Article 6: Patient safety

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter III – Organisational and Policy Considerations

Article 7: Enablers for implementation

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 has agreed that the guideline could serve as a common baseline for Patient Summaries at national level.

Article 8: Quality standards and validation

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 9: Education, training and awareness

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: Data

Many countries build their Patient Summary information from multiple sources, which complicates the update of cross-border Patient Summary information. The content of the dataset is version controlled, subject to change control through the eHMSEG. A number of proposals have been made for amendments or additions to the dataset (e.g. a proposal from ValueHealth to expand the "Vital signs" section); these would need to be assessed for impact through the Change Control process for inclusion.

Article 11: Terminology

Successful sharing of information requires the effective use of standards to support accurate and complete clinical documentation that is faithful to the patient's situation, and for 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 persons.

Since code systems such as SNOMED-CT and ICD-10 (to name but two) contain a large number of terms, it is not practical to use them in their entirety within the European context, where some Member States might use different code systems which 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. It is expected that the eHN will oversee the process by which code systems are kept under review and ensure that appropriate licensing arrangements are in place.

Article 12: Master Catalogue

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter V – Technical Considerations

Article 13: Technical requirements

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 14: Security

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 15: Testing and audit

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

4. PATIENT SUMMARY DATASET

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 United Kingdom patient	
Personal information	Full name	Given name	The patient's first name (example: John). This field can contain more than one element.	
		Family name/surname	This field can contain more than one element. Example: Español Smith 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	
Contact information	Address[2]	Street	Example: Oxford Street	
		House number	Example: 221	
		City	Example: London	
		Post code	Example: W1W 8LG	
		State or province	Example: London	
		Country	Example: UK	
	Telephone no.	Telephone no.	Example: +45 20 7025 6161	
	Email	Email	Example: jens@hotmail.com	
	Preferred HP to contact[3]	Name of the HP	Name of the HP 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)]	
		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	
		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	

Table 2: Patient Summary dataset for patient administrative data

[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**	
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)	
		Allergy description ID code	Normalised identifier	
		Onset date	Date of the observation of the reaction	
		Agent	Describes the agent (drug, food, chemical agent, etc.) that is responsible for the adverse reaction	
		Agent ID code	Normalised identifier	
	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)	
		Healthcare alert ID code	Normalised identifier	
Medical history	Vaccinations	Vaccinations	Contains each disease against which the patient has been immunised	
		Brand name		
		Vaccinations ID code	Normalised identifier	
		Vaccination date	The date when the immunisation was given	
	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 and the problem is therefore closed)	
		Problem ID code	Normalised identifier	
		Onset time	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).	
	Surgical procedures prior to the past six months	Procedure description	Describes the type of procedure	
		Procedure ID (code)	Normalised identifier	
		Procedure date	Date when procedure was performed	

PATIENT CLINICAL DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	
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. irritable bowel syndrome, otitis media), 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)	
		Problem ID (code)	Normalised identifier	
		Onset time	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.	
		Device ID code	Normalised identifier	
		Implant date	Date when procedure was performed	
	Major surgical procedures in the past six months	Procedure description	Describes the type of procedure	
		Procedure ID (code)	Normalised identifier	
		Procedure date	Date when procedure was performed	
	Treatment recommendations	Recommendations description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	
		Recommendation ID (code)	Normalised identifier	
	Autonomy/invalidity	Description	Need for the patient to be continuously assessed by third parties; invalidity status may influence decisions about how to administer treatments	
		Invalidity ID code	Normalised invalidity identifier (if any, otherwise free text)	
Medication summary	List of current medicines (Relevant prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not)	Active ingredient lists 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)	
		Active ingredient ID code	Code that identifies the active ingredient	
		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	
		Pharmaceutical dose form	The form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablet, syrup)	
		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	
		Duration of treatment	Example: 14 days	
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	

Variable (nesting level 1)	Variables (nesting level 2)	Variables (nesting level 3)	DEFINITION AND COMMENTS	
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	
		Reference date range	Example: from 1974 to 2004	
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).	
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).	

Table 3: Patient Summary dataset for patient clinical data

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	

Table 4: Patient Summary dataset for metadata

5. STANDARDS AND PROTOCOLS

Reference is made to three classes of material:

Background requirements and explanatory material

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

Formal technical and semantic specifications

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

Formal terminology bindings

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