eHealth Network

GUIDELINE

on

Electronic exchange of health data under the Cross-border Directive 2011/24/EU

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, Amsterdam, 7 June 2016

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
eHGI	eHealth Governance Initiative
eHN	eHealth Network
EMA	European Medicines Agency
eP	ePrescription
epSOS	European Patient Smart Open Services
HCP	Health Care 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
MLA	Multi-Lateral Agreement
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
NCPeH	National Contact Point for eHealth
OFW	Organisational Framework
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

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1. Introduction

1.1. Purpose

The 4th meeting of the eHealth Network in November 2013 adopted release 1 of the Patient Summary guidelines. At the 6th meeting in November 2014, release 1 of the guidelines for ePrescription was also adopted. In each case it was agreed that the guidelines would be subject to review, and the updates have been included as task 5.3 under the Joint Action (JAseHN) initiative.

This document introduces a new approach, in which a core set of guidelines be developed, to be accompanied by annexes for each use case, starting with Patient Summary followed by ePrescription and then others as required.

1.2. Background: Directive on patients' rights in cross-border healthcare

Directive 2011/24/EU provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising 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.

The eHealth Network agreed a new Multiannual Work Programme 2015–2018, adopted by the eHealth Network at the meeting on 13 May 2014. The resulting Joint Action 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 task 5.3, which expressly provides that the adopted guidelines shall be revised and updated.

1.3. Rationale and review of the guidelines

The aims of implementing the guidelines are in line with the principles of cross-border care, namely:

- to achieve a high level of trust and security;

- to enhance the continuity of care for individual patients;
- to ensure access to safe and high-quality healthcare.

The guidelines and the measures proposed within them are not legally binding and were designed to respect fully the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Whilst the primary focus of the guidelines is to support care across borders, as stated in Article 14 (2) (b) (i) of the Directive, there is a secondary focus of the guidelines as a reference for use at national level. More advanced and elaborate systems exist in some Member States (MSs), but the eHealth Network agreed that the guidelines could serve as a common baseline for ehealth at national level.

As one of the early tasks in JAseHN, T6.1 Implementation of eHealth guidelinesconducted a review of the status of implementation of the Patient Summary guidelines across Member States. The findings were as follows:

"The questionnaire results indicate that in most EU countries the Patient Summary guidelines' implementation is at an early stage. Although some countries already have in place many of the components necessary for supporting the Patient Summary guidelines' implementation, in most Member States the implementation of the recommended interoperable public services has not yet been finished. Although most Member States actively participated in cross-border interoperability projects such as epSOS, PARENT, EXPAND, eSENS and others, testing the national infrastructure and preparing the interoperability framework for cross-border data exchange, there remains the problem of the full deployment of all services envisioned by the Patient Summary guidelines. Member State feedback suggests that the prioritisation of other national projects in healthcare is one of the main obstacles to [progress] as, at this point, the cross-border data exchange is perceived as a secondary issue for most Member States.

Barriers to the implementation of the Patient Summary guidelines were identified by all Member State representatives; these relate to legal issues, implementation mechanisms (organisational and technical), tracking and coordination, possible internalisation problems and stakeholder engagement. Member States' responses show some level of indirect investment in cross-border interoperability, mainly in terms of education and raising awareness.

Most Member States have an established legal basis for personal data exchange relating to the care of individual patients. What is less clear are the arrangements for safeguarding the re-use of data for other purposes.

Most Member States have established institutional data controllers to provide information to interested parties (e.g. patients).

Member States expressed interest in implementing the eHealth guidelines that would lead to the creation of the Cross-Border eHealth Information Services (CBeHIS), but there is still the need for some additional steps towards achieving the European Union's Single Market goals for healthcare. The technical and semantic uptake of the guidelines has been progressing steadily after the epSOS project, but there are some nontechnical burdens to be negotiated before their full implementation. The updated guidelines should probably more seriously take into account the legal and organisational aspects of cross-border data exchange. Flexible but permanent legal arrangements and organisational changes aimed at interoperability should ensure the long-term sustainability of these efforts.

After epSOS, Member States reported that no mechanism for regional Patient Summary consolidation has been implemented beyond proof-of-concept. There has been neither enough harmonisation nor shared encoding of value sets. As these are prerequisites for a cross-border

healthcare data exchange environment, which should guarantee integrity of information and avoid or document redundant registers, the recommendations on how to achieve this on the organisational level should be explained in more detail in the future.

Member States showed a high degree of awareness regarding the benefits of enabling cross-border data exchange, and they expressed their motivation to provide public information via National Contact Points. However, the provision of information can only go so far if the organisational support of the Member States' governing authorities does not recognise the need for organisational continuity and legal uptake.

The crucially important next step in the eHealth guidelines' implementation is to find the best way to involve a wider community of experts and official authorities that would provide information dissemination and continuity. The updated guidelines could include recommendations on how to include other interest groups that already have access to information on cross-border healthcare. They would then participate in organisational and legal changes towards an improved EU-wide cooperation on raising healthcare standards or improving access to cross-border data. Empowering stakeholders after gaining their trust could be a bottom-up approach to organisational and legal changes.

The next step in building a more robust environment providing cross-border healthcare data is the adoption of the more complete eHealth guidelines which would advance from the technical and semantic aspects of interoperability towards legal and organisational ones. What is also needed is the strengthening of the eHealth NCP role in Member States, which should provide continuity and sustainability to all future eHealth implementations." [DN: social care in or out of scope ?]

1.4. Organisational Framework

As noted above, D5.1.1 of JAseHN proposes the Organisational Framework for the implementation of Cross Border eHealth Information Services (CBeHIS). The main architectural element of the Organisational Framework (OFW) is the National Contact Point for eHealth (NCPeH). Under the eHealth Digital Services Infrastructure (eHDSI) terminology, the provision of generic services in the Member State means the preparation, setting-up, deployment and operations of the National Contact Point for eHealth (NCPeH) for the Cross Border eHealth Information Services (CBeHIS).

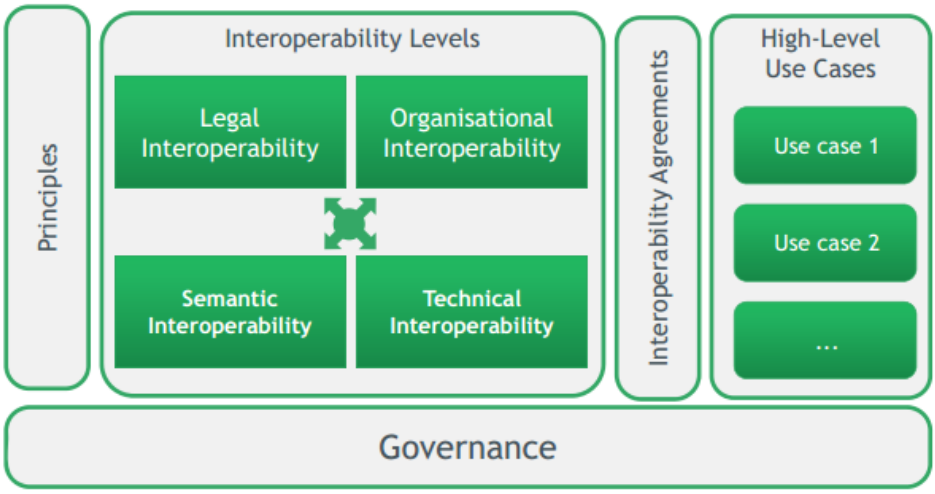


Figure 1 – Resulting eHealth EIF structure

The core services, to be provided by the European Commission, refer to those services that are necessary at EU level for the CBeHIS. This proposal for an OFW-NCPeH was designed on the basis

of the European Interoperability Framework for eHealth (eEIF). Future updates and revisions will take into consideration the ReEIF (Refined eHealth European Interoperability Framework).

The OFW-NCPeH focuses as much as possible on the organisational principles and requirements and is in alignment with several other important arrangements that have been prepared by other projects (e.g. Antilope, EXPAND, epSOS, eHN LSG).

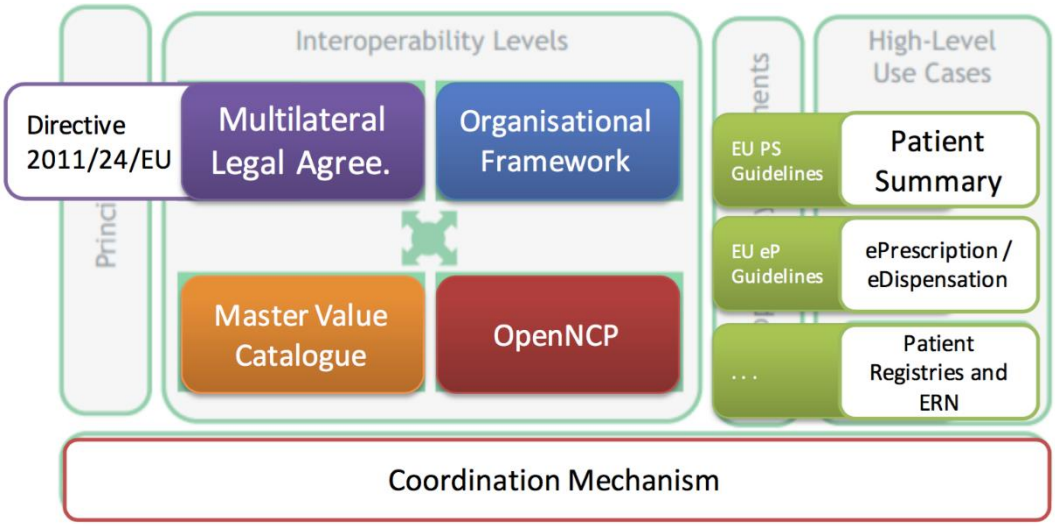


Figure 2 – OFW-NCPeH alignment with related instruments

Figure 2 provides a better understanding of how the OFW-NCPeH suits the eHealth EIF and how it interacts with several other arrangements taking place.

1.5. National Contact Point for eHealth

The National Contact Point for cross-border eHealth (NCPeH) is different from the National Contact Point described in Article 6 of Directive 2011/24/EU (e.g. different mission/goal, diverse services provided, different entity, different governance, and different requirements). There is some overlap in the obligation for provision of information to patients about the processing of their personal data (Patient Information Notice) in line with their rights under the Data Protection Directive.

Each MS needs to organise/set up one NCPeH to act as a communication gateway with other MS and also as a mediator for delivering services. As such, an NCPeH should be identifiable in both the EU domain and its national domain, and remain an active part of the CBeHIS environment if compliant with the legal, organisational, semantic and technical requirements. The NCPeH must act as the interface with existing national infrastructures.

1.6. Process for update

The first release of the guidelines presented the basic elements for the electronic exchange of patient summaries and ePrescriptions across borders. The documents indicated areas where further work would be required, notably in the review and agreement of terminological schemes to be used as a basis for each data field in the dataset. These guidelines have been developed as follows:

- The input documents are Release 1 of the Patient Summary Guidelines (2013) and the ePrescription Guidelines (2014)
- Initiation of the JAseHN Task 5.3 liaising with Task 6.1 assessing the experiences to date of Member States in implementing the guidelines

- Building on Task 5.1.1, the Organisational Framework and Task 6.2 on the Multi-Lateral Agreement
- Liaison with the current projects and initiatives exploring pertinent issues, such as Horizon 2020 projects OpenMedicine, AssessCT and eStandards, the Trillium Bridge project and the EXPAND thematic network
- Input from key stakeholders.

1.7. Timescales

The JAseHN plan was that the revised PS guidelines would be approved in November 2015, with eP in November 2016 and Patient Registers in November 2017. The PS update was postponed, as other JAseHN work packages were underway and the revision is now scheduled for adoption in June 2016. The JAseHN D5.1.1 (OFW), adopted in November gives a good starting point that focuses on the organisational readiness activities and allows restructuring of the core text. This approach should allow alignment of the CEF and JAseHN, with the application responses for the CEF call due in March 2016 focussing on organisational readiness, with a later focus on the semantic content during the CEF negotiation phase. Deliverable 5.3.1 would therefore be aimed at the June 2016 eHN meeting as an item for adoption.

The proposed timeline indicates the importance of consultation with a wide range of stakeholders and, in particular, the early activity to secure feedback on the revised structure proposed here. The dates are designed to be consistent with the timeline provided by the Project Co-ordinator. There are some important dependencies, notably clarification over the Multi-Lateral Agreement and confirmation over the updates to the specification. The aim for eP would be that the core text remains unchanged, and that the development focuses on the production of a second annex, relating to ePrescription, to be submitted to the eHN in November 2016.

1.8. Proposed Structure for the Guidelines

The structure of these guidelines builds on the lessons learned by eHN through the preparation of Release 1. The guidelines have been restructured to align with the interoperability framework dimensions (legal, organisational, semantic and technical, to allow for a more generic structure in future releases. The content structure of the guidelines is shown in Table 1 below.

Table 1: Structure of the Guideline

Chapter I - General Considerations
Article 1: Object and scope / context
Article 2: Definitions including Interoperability
Article 3: Concepts
Chapter II – Legal Considerations
Article 4: Data protection
Article 5: Authorisation, authentication and identification
Article 6: Patient safety issues specific to these guidelines
Chapter III – Organisational Considerations
Article 7: Enablers for implementation
Article 8: Quality standards and validation
Article 9: Education, training and awareness
Chapter IV - Semantic Considerations
Article 10: Intended use
Article 11: Data requirements
Article 12: Terminology standards
Article 13: Master Catalogue
Chapter V – Technical Considerations
Article 14: Technical standards
Article 15: Security
Article 16: Interoperability testing , audit and compliance model
Chapter VI
Article 17: Amendments to the guidelines
For each Annex
Annex X.1: Use Case Description
Annex X.2: Guidelines
Annex X.3: Supporting Information

2. Guidelines for electronic exchange of health data

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 the Articles 114 and 168 of the TFEU, the Union adopted the 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) Art 14 (2) (b) (i) of the Directive 2011/24/EU identifies an objective of the eHealth Network to draw up guideline on 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.

(4) The Member States have adopted Release 1 of the Patient Summary Guidelines in November 2013, Release 1 of the ePrescription Guidelines in November 2014 and Release 1 of the Organisational Readiness Guidelines in November 2015.

(5) The Member States have been playing an active role in the revision of the guidelines, in particular by providing their knowledge and experience.

(6) Preliminary work in the field of eHealth, in particular of 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 this guideline.

(7) 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.

(8) 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 Considerations

Article 1: Object and scope

1. These guidelines, as adopted by the eHealth Network, are non-binding and are addressed to the Member States of the European Union and applies to the implementation of a patient dataset for cross-border exchange.
2. These guidelines are addressed to the Member States of the European Union and apply to the implementation of interoperable electronic prescription services across Member States, in order to facilitate the recognition and delivery of prescriptions issued in another Member State.

3. 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 at national level. 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. This serves the purposes of the internal market according to Article 114 of the Treaty on the Functioning of the European Union.

4. These guidelines aim at supporting the Member States to achieve a minimum level of interoperability, taking considerations of patient safety and data protection into account, by defining minimum requirements for communication between National Contact Points for eHealth (as defined in Article 2) and for interfaces between national and European levels.

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) 'Health care professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC[1], or another professional exercising activities in the healthcare sector, which are restricted to a regulated profession as defined in Article 3 (1) (a) of Directive 2005/36/EC, or a person considered to be a *health professional* according to the legislation of the Member State of treatment.

b) 'Interoperability', within the context of European public service delivery, is the ability of disparate and diverse organisations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organisations, through the business processes they support, by means of the exchange of data between their respective ICT systems (European Interoperability Framework)

c) 'National Contact Point for eHealth' refers to the unique entity on a national level authorised by a Member State to provide an interface between the national and European aspects of exchanging Patient Summaries[2].

Article 3: Concepts

1. This guideline is non-binding at MS level and Member States are considered to:

(b) use open standards for public health activities;
(c) decide freely whether they want to adopt such requirements into local legislation;

(d) bear in mind this guideline, 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.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:en:PDF
[2] Each Member State may establish one or more of these entities (at regional/local level) depending on the respective National Health Service model.

Chapter II – Legal Considerations

Article 4: Data protection

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. Data provided for the purposes of healthcare are "sensitive personal data" and therefore Member States will need to ensure 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 5: Authorization, authentication and identification

1. The NCPeH must enforce the validation and authentication of foreign patients.
2. The NCPeH shall take all reasonable steps to ensure data security (including data confidentiality, integrity, authenticity, availability and non-repudiation).
3. The NCPeH must ensure that CBeHIS data is not transmitted to MS not belonging or allowed into the CBeHIS environment.
4. The NCPeH shall adopt a national OFW-NCPeH on CBeHIS that comprise commonly adopted policies, processes and audit mechanisms.

Article 6: Patient safety issues specific to these guidelines

1. Health professionals, patients and National Contact Points for eHealth may rely upon the information released by the National Contact Points for eHealth of other Member States.
2. In the event of semantic transformation, both the transformed and the original documents shall for safety and audit reasons be available to all persons who are authorised to use this data.
3. Liability for errors in the semantic transformation will be described in the MLA.

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

1. The application of these guidelines should at all times take place according to the provisions of relevant European and national legislation. Where such provisions do not exist or are not in force, Member States are expected to implement, monitor and audit common policies, safeguards and measures representing agreements of the eHealth Network, as foreseen in its Multiannual Work Programme (MWP).
2. Such agreements will apply to the exchange of health related data across borders in a generic way and they will include but are not limited to agreements on duties and responsibilities of the eHealth NCPeHs and on common identification authentication and authorisation measures.
3. MS participating in the CBeHIS should set up an NCPeH compliant with the OFW-NCPeH. This should be unique to each MS in its relationship with other MS, i.e. a single

NCPeH communication gateway should be responsible for interaction with other MS NCPeH communication gateways for cross-border services.

4. The entry into operation of an NCPeH requires the explicit approval of the coordination mechanism established for the CBeHIS environment.
5. Participating MS should establish NCPeH adequate monitoring procedures.
6. The NCPeH must establish the connection with the national infrastructure, ensuring that appropriate processes and procedures are in place (security measures, safeguards etc.).
7. The NCPeH must provide a gateway service, a request port and a semantic transformation service in order to enable it to execute the core steps in the CBeHIS (e.g. Patient Summary, ePrescription).

Article 9: 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. In order to assure safe implementation, particularly patient safety and data protection and further development of cross-Union eHealth services, Member States should:
   a) consider setting up a facility for cross-border services to quality assure, benchmark and assess progress on legal, organisational, technical and semantic interoperability for their successful implementation;
   b) undertake assessment activities, such as measuring the quantitative and qualitative possible benefits and risks (including economic benefits, risks and cost-effectiveness) of cross-border services.

Article 8: Education, Training and Awareness

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; including awareness of the need to foster the interoperability of technical systems among producers and vendors of information and communication technologies, health care providers, public health institutions, insurers and other stakeholders

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 informed consent of the patient and lawfully sharing patient's personal data;

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

d) consider recommendations for education and awareness raising measures targeting health policymakers and health professionals.

Chapter IV - Semantic Considerations

Article 10: Intended Use

1. Each Annex describes use cases relating to the intended application.

Article 11: Data Requirements

1. The responsibility for the content, accuracy and integrity of the data is with each national designated competent entity for such semantic processing.
2. The NCPeH must maintain the national versions of the controlled vocabularies used in semantic transformation.

Article 12: Terminology standards

1. Safe and secure cross-border care requires an ability to convey both meaning and context in data exchange. It is agreed that to achieve this, 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 in Appendix B.
3. Further work is needed to review the code schemes used for cross-border scenarios. The assessment of each field will be undertaken according to an agreed set of criteria and by groups including professional representative bodies.

Article 13: Master Catalogue

1. Agreement on a set of coding schemes as in Article 12 will require a master catalogue at EU level which can be used by all Member States to share value sets, allowing each Member State to translate and transcode schemes, if required, to their national equivalents.

Chapter V – Technical Considerations

Article 14: Technical standards

1. Member States shall ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures.
2. The NCPeH must ensure that semantic transformation (e.g. translation and mapping), which is needed for the cross-border information exchange, is performed.
3. 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 an important feature.
4. The NCPeH shall guarantee that all CBeHIS agreed service requirements and specifications (legal, organisational, semantic and technical) are fulfilled.
5. The NCPeH must ensure the appropriate interface with the core services set up at EU level.

Article 15: Data security

1. The NCPeH Security Policy Baseline creates a general security and data protection baseline adapted to CBeHIS needs.
2. The NCPeH Security Policy Baseline addresses all elements of data flows in the CBeHIS, including national and cross-border data flows.
3. MS shall ensure that they are fully compliant with the CBeHIS Security Policy.
4. The MS must ensure that the NCPeH for the CBeHIS has clearly identified the responsible data controller and data processor in accordance with the provisions of Directive 95/46 EU.
5. The NCPeH shall establish appropriate security and data protection systems to conform to the CBeHIS Security Policy.
6. Member States shall ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures.

Article 16: 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).
2. [DN: intro ?] to CBeHIS requirements as well as all applicable national requirements.
3. The NCPeH shall establish an appropriate system of audit trail, allowing authorised official bodies to duly inspect the established mechanisms for data collection, processing, translation and transmitting.
4. Non-EU countries may operate in line with the CBeHIS with the explicit approval eHealth Network.
5. The NCPeH shall establish and maintain an incident management solution to support Health Professionals, Healthcare Providers and citizens in its territory.
6. The NCPeH must ensure the security (confidentiality, integrity, availability, non-repudiation, authenticity and auditability) of data processed on their territory.
7. The NCPeH must ensure an auditing mechanism for legal, organisational, semantic and technical requirements.
8. The NCPeH shall enforce identity validation of Health Professionals that use CBeHIS.

Article 17: Amendments to the guidelines

1. The eHealth Network will include in its Multiannual 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, functional and technological advances and lessons learned from their use by the Member States.
- The NCPeH shall collaborate actively on the harmonisation of guidelines and appropriate practices to facilitate the establishment of the CBeHIS environment.

The Guideline is 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 guidelines themselves.

The material in this supporting document has built on earlier projects such as epSOS, but cites follow-on work in EXPAND, in the relevant Horizon 2020 projects, in particular Assess CT and OpenMedicine for the medication related aspects, and the joint EU/US Trillium Bridge project. Other examples have been provided by individual Member States, with information from the survey carried out as part of JAseHN Task 6.1. However, most of these activities are still underway, and hence there have been few content changes to the guidelines themselves.

Chapter I - General Considerations
Article 1: Object and Scope

The primary purpose of the guidelines is, at this stage, to underpin cross-border services supported through the CEF programme.

Article 2: Definitions

The definitions section focuses on concepts which are common to cross-border health.

Article 3: Concept

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

Chapter II – Legal Considerations
Article 4: Data protection

The main challenge faced by the epSOS pilot 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 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 suppressions of sensitive information. As such, it could in the future abolish the need for specific Agreements for Data Protection and together with the transposition of Directive 2011/24EU, reduce significantly the scope of such (Interoperability) agreements.

Agreement on the Data Protection Regulation is likely to require local actions and agreed cross-border arrangements to ensure compliance

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

A data subject should be able to address questions about access and demands for rectification/erasure/blocking to any of the controllers as well as to any other body involved in the exchange of information within cross-border. A demand to access or for the rectification/erasure/blocking of data which 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 this relevant controller is established in another Member State.

A common cross-border website should inform 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.

Article 5: Authorization, authentication and identification

Issues of identification, authentication and authorisation of patients and healthcare professionals involved in cross-border care relationships are crucial elements and should be addressed in a cross-cutting approach, building on the core service platform of the Connecting Europe Facility (CEF).

To be able to link patients with their patient records, the existence of a patient identifier is necessary.

Medical information exchange always has been a sensitive subject due to the highly confidential nature of this information. 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. pharmacists can get from the Patient Summary only medication information included in the "Medication Related Overview" (MRO) document).

Besides having means to identify a patient, facilities to identify and authenticate a health professional or health care provider organization are a requisite for maintaining high confidentiality of medical information when exchanged in a secure manner between other health professionals / health care provider organizations. The health professional/ health care 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/ health care provider organizations and is also a precondition for electronic signing by the health professional/ health care provider organization.

Member States may wish to consider the content of a register of health professionals who are entitled to prescribe and dispense. Further details may be provided in the Annexes, but fields might include:

(a) the name and profession,

(b) a personal identification number, including the ISO 3166 country code,

(c) the current address of the health care provider organisation with which the health professional is affiliated or the address of his or her private practice,

(d) the date of issue of the healthcare professional's licence to practice,

(e) the speciality might be recorded as the prescribing of some medicinal products may be restricted.

Member States will need to consider their approach to implementing digital signature services at the eGovernment or eHealth service level in the light of the electronic identification and trust services (eIDAS[3]) regulation adopted in July 2014.

The identification of the health professional will need to be linked to access the data (i.e. confirmation of patient consent) and the authorisations to prescribe. Datasets to enable this are

[3] http://ec.europa.eu/digital-agenda/en/trust-services-and-eid

available from some Member State competent authorities, but wider linkages are required for professional bodies to support cross-border ePrescribing.

Furthermore, the guidelines should provide (easy) access to the health providers to obtain access to information including the (trusted source) supporting schemes for checking the identity, professional role and local rights of the health professional.

The digital ID of health professional and/or health care provider organisation is also used for authentication purposes by a majority of Member States. Similarly, a majority make use of digital signing for health professional/health care provider organisations 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 authorisation for accessing patient information is based on the role, e.g. GP or pharmacist, of the health professional. In most of these Member States, this is 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.

Article 6: Patient safety issues specific to these guidelines

The semantic transformation is performed according to the translation, mapping and transcoding performed 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 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 the level of cross-border and as part of its trust building framework.

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

Each Member State would be expected to have one "National Contact Point for eHealth" (NCPeH), which is the technical and organisational entity that ensures interoperability across national borders with other Member States and decouples the national infrastructure from other Member States.

The first consequence is that the external interface is standardised, with specifications of protocols, procedures and exchanged documents. The interface with the national infrastructure is specified at a conceptual level, but each Member State remains free to adopt the most suitable solution to interface the NCPeH with their national infrastructure.

The NCPeHs as developed in the context of the epSOS large scale pilot will provide transformation services by semantically transforming health data created according to national rules and by electronically signed confirmation by the National Contact Points that both documents are of identical content (currently by a cyclic redundancy check (CRC).

The NCPeH 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".

The organizational setup and procedures for operating the NCPeH is based on ITIL. The selected service and support processes have been deemed minimal requirement for operating the NCPeHs in a coherent way. It is for Member States to decide the actual implemented

operating management framework, as long as the described functions are established and implemented for cooperation between PN.

"Regional replicas" of both the technological and organisational arrangements of a typical NCPeH, which would constitute a Regional Contact Point (RCPeH), are possible and, in principle, follow the same requirements.

If a MS has two or more Regional Contact Points, it needs to nominate one to act as an NCPeH, to act as the national gateway vis-à-vis other MS.

Participating MS should make adequate arrangements to ensure NCPeH readiness for operation of CBeHIS and level of service sustainability (by following the compliance establishment process described in article 15).

Each Member State must have the own national Support Organization in place and publish information about the responsible persons. The Central Service Desk for managing the Incidents, Problems and Changes should be acquainted with and the interface between National and Central Service desk should 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 cross-border; Member States should be able to contact each other in case of technical or organizational problems.

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

Change Management aims to ensure that standardised 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, like measuring the quantitative and qualitative eventual benefits and risks (including economic benefits and cost-effectiveness) of services.

Article 8: Education, Training and Awareness

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.

It is recommended that national training materials and activities be provided to support CBeHIS operation, including description of the national infrastructure with the purpose of interfacing (e.g. services available, data sources).

It is recommended that participating MS engage Health Professionals in specification updates and other clinical concerns related to the operation of services.

It is recommended that participating MS inform citizens about CBeHIS provisions.

Article 9: Quality standards and validation

Chapter IV - Semantic Considerations

Article 10: Intended Use

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, an approach to this would be adopting a structure compliant to HL7 Clinical Document Architecture (CDA) Version 2, level 3 with the additional constraints defined by the epSOS and updated by the EXPAND project based where applicable on the HL7 Continuity of Care Document (CCD) and IHE Patient Care Coordination (IHE PCC) content modules.

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 care professional, the document type), and the body, or the part containing the clinical content.

Article 11: 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.

Article 12: Terminology standards

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

The European Commission has initiated three projects under Horizon 2020 to look at aspects of this: eStandards, OpenMedicine and AssessCT, but the outcome of these will not be known for some months. The Commission is also engaged in discussions with relevant SDOs regarding licensing arrangements. Some changes in the way of describing pharmaceutical and medicinal products are reflected in Annex B to the guidelines. The semantic group in EXPAND reviewed specific elements and made some changes, which are also reflected in Annex B to the guidelines.

Article 13: Master Catalogue

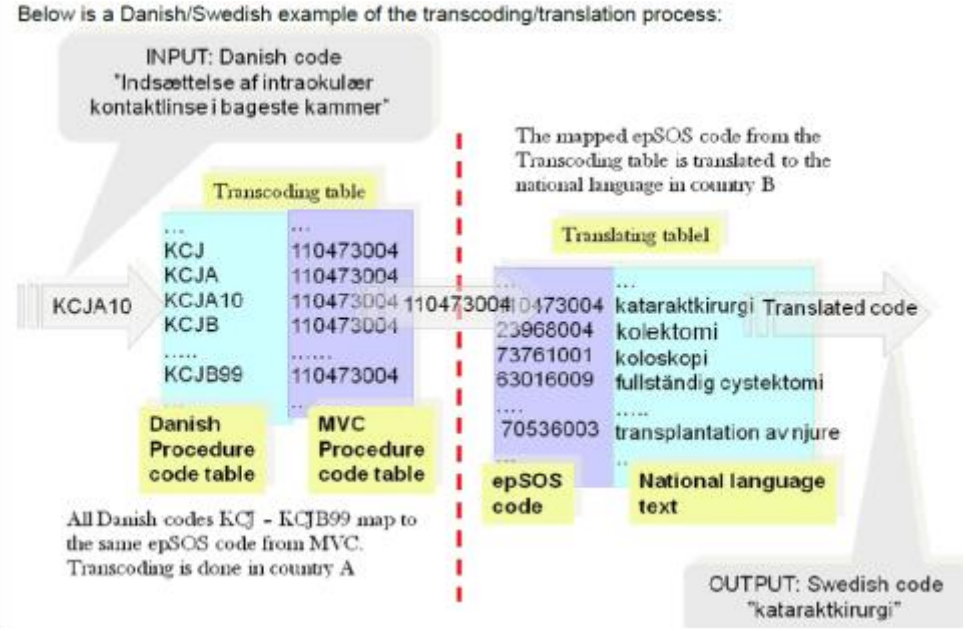
Across Europe, there are different languages, different standards and different coding schemes. In epSOS, this was addressed by the use of two master files: the Master Value Sets Catalogue (MVC), which applies across all Member States, and the Master Translation / Transcoding Catalogue (MTC).

Only one code system was chosen for each coded element. This is because there are few official mappings between code systems. Since transcoding and / or translation is expected at a Member State level, he number of terms in the value sets should be limited, while providing the largest medical coverage possible. Thus, each coded element has only one code system associated with it, with its display name in English only. These terms were compiled into an excel file named the Master Value Sets Catalogue (MVC) that provides the basis for data exchange.

These terms were loaded, edited, validated and approved in the Central Terminology Server. The exported excel file, after the MVC approval, provides an easily handled document for Value Sets dissemination.

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 their national coding system into them, thus creating the Master Translation / Transcoding Catalogue (MTC).

Figure 3: Translation and Transcoding



Work within EXPAND has been developing the MVC further and, for the purposes of the CEF call, will be using MVC 2.0.

The MVC and MTC are supported by an EU-wide Central Reference Terminology Server which will be operated by DG Sante. 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.

Chapter V – Technical Considerations

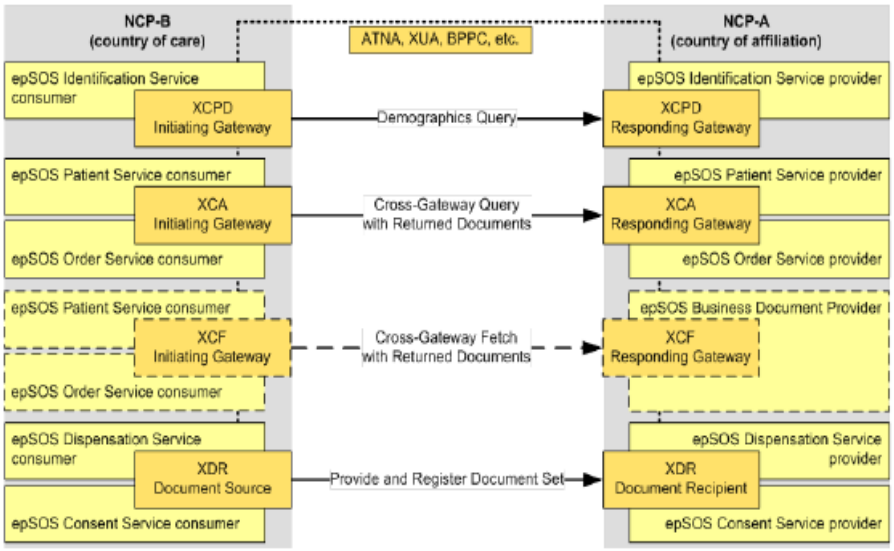
Article 14: Technical standards

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.

As described in Annex C, an approach to this would be adopting 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). The original document in PDF format is always transferred embedded in a HL7 CDA V2 Level 1 document.

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 care professional, the document type), and the body, or the part containing the clinical content.

Figure 4: IHE Profiles



The work in epSOS was based on the following technical components:

(a) For encoding of text the international encoding standard Unicode UTF-8 (UCS Transformation Format—8-bit) or higher
(b) Extensible Markup Language (XML) as an open and human as well as machine readable standard for exchanging data
(c) HL7 (Health level 7) CDA (Clinical Document Architecture) standards

Article 15: Data security

The diversity of national and regional healthcare systems, their structures, cultures and roles of health professionals are taken into account by a "common trust model", which provides the basis for interoperability via National Contact Points. These entities are designated by the Member States and serve on the one hand as interfaces between the national and European requirements for exchanging personal health data and on the other as guarantors regarding the origin and content of personal health data.

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.

A high level of IT-security is necessary in order to take full account of security principles which follow from the Directive and the specific risks related to the processing of personal data in cross-border:

- 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 against 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);

- The system must be capable to correctly record and track in an auditable way the individual operations that make-up the overall data processing;

- Unauthorized data access and/or changes should be prevented when the back-up data are 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. Unauthorised access to private medical data can be detected or prevented when 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 16: Interoperability testing

Member States will need to implement software to support cross-border exchange. One option would be to re-use the so called "OpenNCP", the Open Source components developed in epSOS and released for all in the "JoinUp" EC-supported Open Source Community. During EXPAND, the management of the OpenNCP toolkit was handed over to EC DG Santé who is currently managing its maintenance and provision.

These components can be adopted by Participating Nations, System Integrators, to build their own NCP solution.

In epSOS, regardless the adopted solution, it was MANDATORY for all the Participating Nation to follow the agreed Testing Strategy. The "testing shop" in EXPAND is reviewing the steps needed, and they will be as follows:

- *The demonstration of compliance with the adopted Normative Standards (e.g. IHE, HL7), by independent third party(ies) (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:*

o *The Pre-Production (PPT) environment for technical interoperability testing and clinical end-2-end validation and quality improvement*

o *The Operation environment, where real patients' data are exchanged.*

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

The following Member State Service Operation Audit process, describes a method for ensuring that NCPeH compliance can be established, maintained and reinforced through a pre-defined set of activities and responsibilities, namely

a) The eHDSI governance structure can establish a peer-to-peer process to validate organisational arrangements between MS and at EU level (core services);

b) Checking and endorsing NCPeH organisational readiness for starting operation of CBeHIS;

c) Following up and endorsing developments in the MS after the initial audit.

d) Ensuring a level of service of the NCPeH during operation in the CBeHIS environment.

One of the key building blocks for OFW-NCPeH is the procedure through which the coordination mechanism and the MS monitor progress regarding preparation, deployment and operation of cross-border care services.

Lessons learnt from previous Cross Border eHealth Information Services (CBeHIS) initiatives point to the following:

- There must be an accession process for MS into the CBeHIS environment, with clear role assignments, once all (Legal, Organizational, Semantic and Technical) requirements have been fulfilled and verified through interoperability testing, peer review and other appropriate methods.

- This process shall allow for the contractual agreements established at national level to be (peer) reviewed and assessed as compliant with MLA and OFW-NCPeH. This process should consider international, well established principles of certification.

- There must be a monitoring and support mechanism for ensuring continuing capacity (comply with principles and requirements and perform according to expected service level's) to be part of the CBeHIS environment.

The aim of the Service Operation Audit is to ensure that NCPeH compliance can be established, maintained and reinforced.

The eHealth Network has the broad mandate to (as stated in Article 14, 2011/24/EU):

"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".

The eHealth Network has a central role in coordinating eHealth-specific policy aspects within the more general EU level governance for interoperability.

The OFW-NCPeH requires that the coordination mechanism enforces the legal, organisational, semantic and technical principles and requirements underlying an entry into operation in the CBeHIS environment, the Coordination Function should be complemented by a Technical Committee that would support the necessary MS compliance assessment.

The coordination mechanism should consider a steering group composed by MS representatives.

The eHealth Network takes the decision on admitting an NCPeH to join the CBeHIS, based on the audit report.

4. Annexes

4.1 Annex A: Patient Summary

4.1.1 Use case description

4.1.1.1 Scenarios

The scenarios 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 GPs in London in August 2011 notes that terms such as "unscheduled care", "unplanned care", "emergency care and urgent care" are often used interchangeably, and quotes a definition as follows: "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].

Two use cases are described in outline below: in these, the healthcare professional is the actor requesting access to the PS of a patient. The patient is in the physical presence of the professional and is the one that is 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 in 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 might also include a patient who is unconscious.

USE CASE 2: The patient is a regular visitor to another country from their 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. This might also include patient-mediated access.

4.1.1.2 Use Cases for Patient Summary

The use cases addressed by these guidelines relate to unplanned or unscheduled care. Although the patient summary can be useful in any clinical encounter and the access will not be restricted depending on the type of situation, it has been considered that the maximum usefulness of a translated patient summary is that in which the healthcare professional and the patient don't share the language and in which being the situation unplanned no information has been possibly requested to the country of origin. Within the unplanned or unscheduled scenario the assistance needed can be emergency or non-emergency care.

The scenarios within the scope of this document are where:

Country A: This is the country where the patient can be univocally identified and his or her data may be accessed.

Country B: This is the country that the patient is visiting and in which information about the patient is needed in case he or she needs healthcare.

The human actors (individuals) are as follows:

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

Healthcare Professional: the health professional who provides the Health Care. The Healthcare Professional must be registered with at least one Healthcare Professional Organization or Health Authority belonging to the country, in order to identify him or her unequivocally. Each Member State

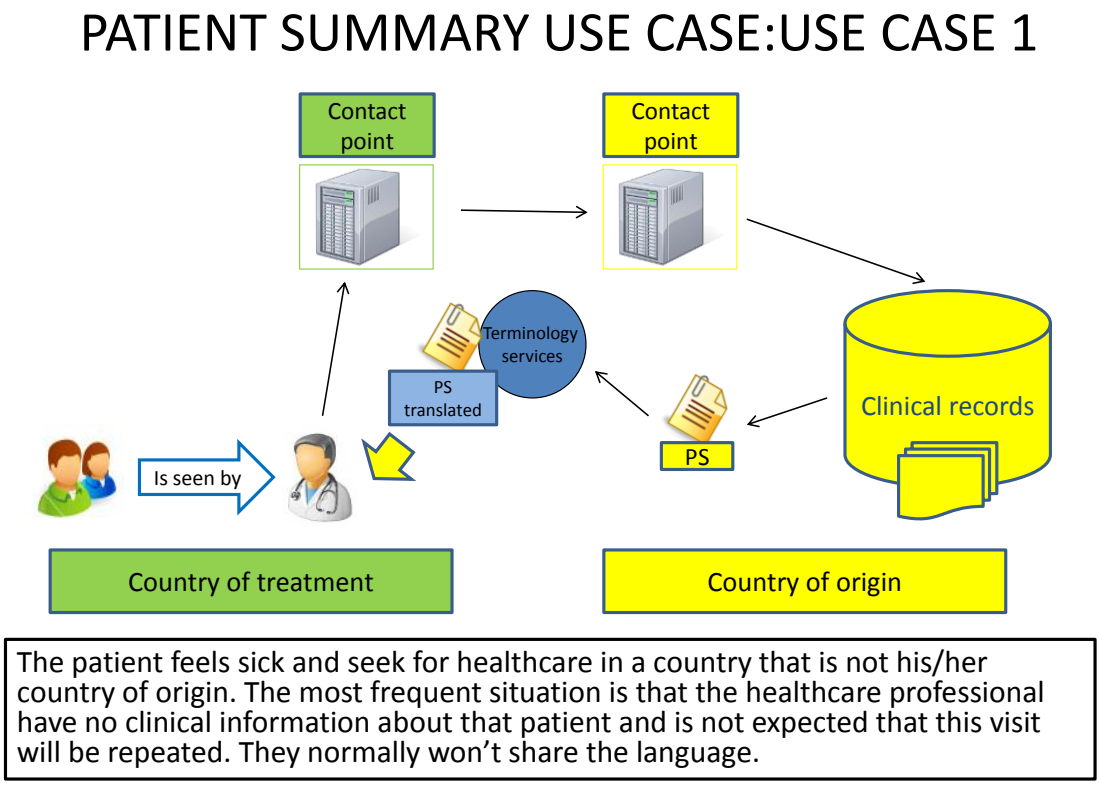
will need a system to check the attributes (e.g. rights to accessing to the information through eID) of the end user who requests the PS information.

In practice, the Emergency department may have a nurse admitting the patient and performing the triage, who identifies the patients, makes the initial assessment, sometimes checks medical documents and assigns priority – facilities in Country B would need to support this.

Two use cases have been considered

USE CASE 1:

The patient is an occasional visitor in 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 Care professional normally won't have a previous record of the person seeking care and where the healthcare professional does not know the patient.



Note:

In this picture, terminology services are within the Contact point; they are responsible not just for translating but also transforming the Patient Summary. There is no access for the Health Professional to the Terminology Services, which are in both NCPeH, but only to the Contact Point.

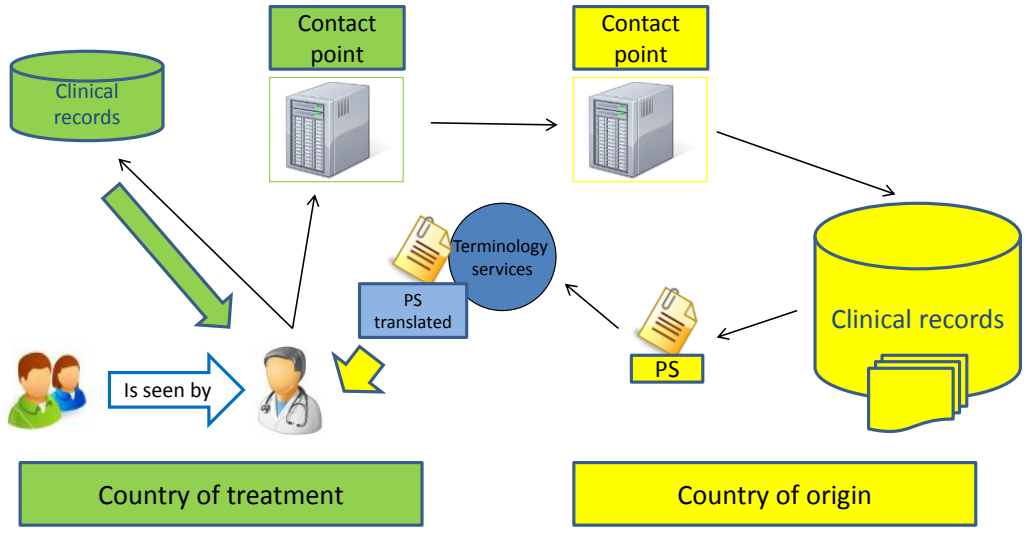
USE CASE 2:

The patient is a regular visitor to country the country of origin, for example someone who lives in one country but works in another country. 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. This is a type of occasional situation

where the Health Care professional may have some information available from previous encounters, therefore the patient could have a medical record locally stored in country B, and maybe a PS in country A also and both sources of information could be consulted.

Both use cases 1 and 2 can be emergency and non-emergency care, being both very similar, apart from the time dimension, whereby the emergency care scenario may require immediate action, even if necessary bypassing the process of securing patient consent.

PATIENT SUMMARY USE CASE:USE CASE 2



The patient feels sick and seek for healthcare in a country that is not his/her country of origin. As he/she frequently goes to that country the healthcare professional can have some clinical information about that patient in its own records. They normally won't share the language.

Three major actions are identified for the description of the use cases (UC1&2):

UC 1&2 Action list
A: Check Patient ID
B: Verify patient consent
C: Consult Patient Summary of Country A

In effect the distinction between the use cases is small, whereby the second allows consultation of a medical record locally stored in country B.

4.1.1.3 Sequence Diagram

The two UCs are analysed in the following sequence diagram and table description

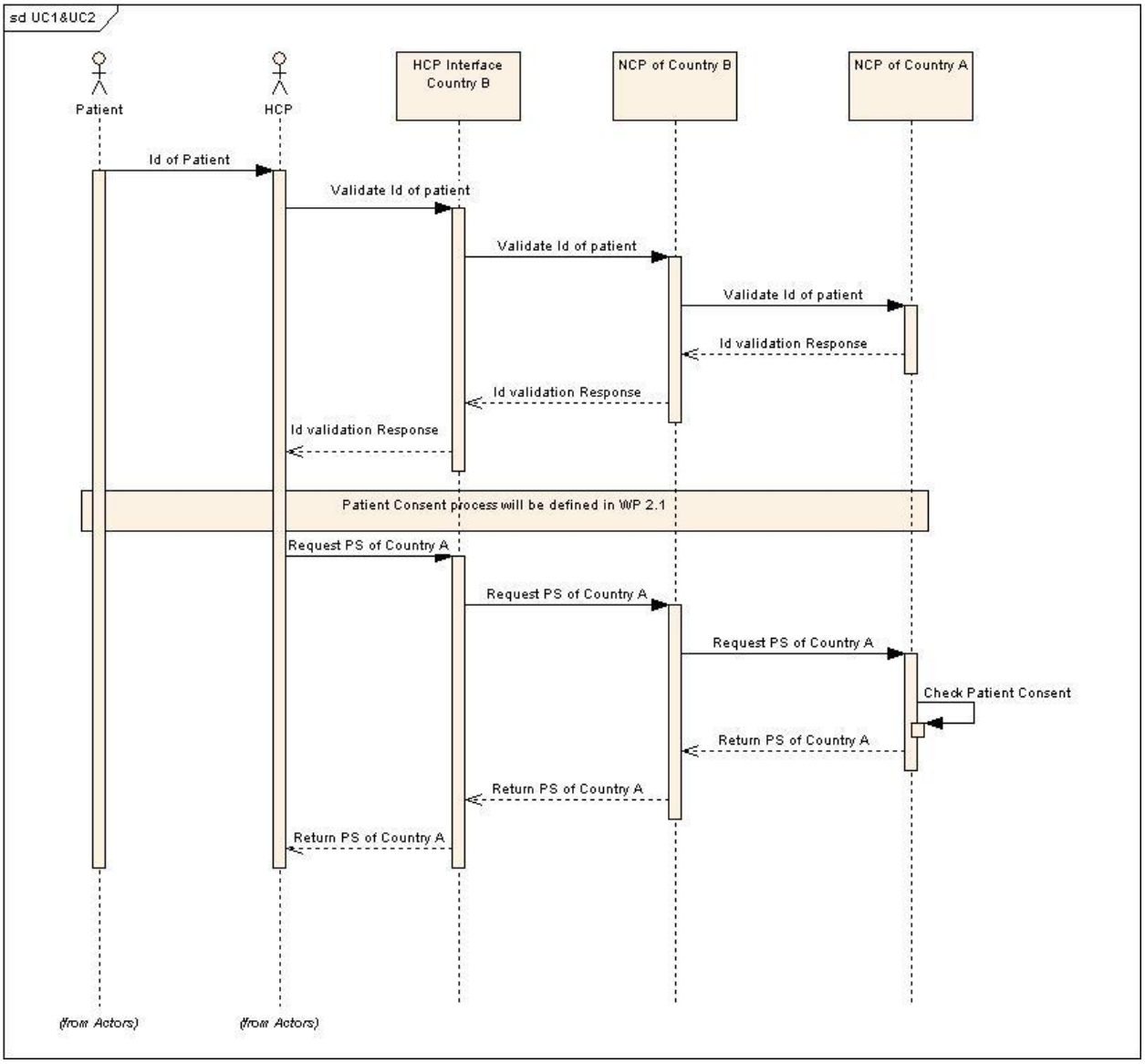


Figure 1. Sequence diagram Use Case 1&2: Patient summary occasional and regular visit

Note: The patient consent process has been explored further, including confirmation of the patient's consent to viewing of their record in country B. Further detail will be provided in the Multi-Lateral Agreement.

UC 1&2	**Patient summary occasional and regular visit**	
Goal	The goal of UC 1&2 is to allow the Health Professional of Country B to consult the Patient Summary of Country A of the patient seeking for healthcare either in occasional or in regular visit	
Functional Requirements to be fulfilled by Country A	FR02:[4] Trust between countries FR03- Patient identification FR04: Patient consent to access data FR05: Structured Information FR06: Equivalent Information FR07: Information Understandable FR18: Information Traceability FR19: Patient summary of Country A available	
Functional Requirements to be fulfilled by Country B	FR01: Health Professional Identification & authentication FR02: Trust between countries FR04: Patient consent to access data FR07: Information Understandable FR18: Information Traceability	
Actors	**Human and institutional actors**	**Technical actors**
	• Patient • Health Professional (HP) • Healthcare Provider Organisation (HCPO)	• NCPeH B • NCPeH A
Preconditions or requirements	1. Patient request for medical assistance in Country B to a HP 2. PS in Country A 3. The HP is a person legally authorised in Country B to provide health care and is identified and authenticated in Country B[5] (FR01) 4. A mechanism to validate the identity of the patient and to handle patient consent against Country A has to be available at the Point of Care 5. HP of Country B knows the identity of Country A 6. The Health Care Professional must be related to at least one HCPO or to a Health Authority. 7. Country B must provide, maintain and support a NCP supporting communication of information with Country A and vice versa (FR18) 8. There is a chain of trust between system actors in this process (FR02) 9. The HP must be able to access the "communication layout" that handles the PS in the European Countries 10. All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it (such as the identification of the HCP, the identification of the patient, the information contained in the PS…), all this information must be able to be traced and recovered (FR18)	
Post conditions	The HP-B gets access to the PS (of Country A) of the patient at the point of care The information exchanged must be understandable in both countries involved resolving semantic differences such as medication names and clinical terminologies. Syntactical interoperability and record of the access must be done.	
Normal sequence		
Step	**Actions (or description)**	
	A: Check Patient ID	**FRs fulfilled: FR 03**
1.	A patient from Country A visits a HP in Country B seeking Health Care assistance	
2.	Patient is identified	
3.	The HP requests the validation of the identity of the patient through the HP interface or using the patient eID card	
4.	The HP interface conveys this request to the NCP of Country B	
5.	The NCP of Country B conveys this request to the NCP of Country A	

[4] FRx: refer to the Functional Requirements included in epSOS deliverable D3.2.1: Patient Summary functional specifications

[5] It is important to emphasize that there might be different definitions of roles/attributes of the end user in each Country (e.g.: patient, physician, pharmacist) which is based on national law. This means that the rights for accessing the information based on the profile of the HCP could be different in each Country

6.	The NCP of Country A checks ID and provides to the NCP of Country B the (positive or negative) patient's identification confirmation.	
7.	The NCP of Country B provides the patient's identity confirmation to the HCP interface	
	B: Patient consent	**FRs fulfilled: FR 04**
8.	Once the identity of the patient is validated, the patient consent is verified, and confirmation of permission to retrieve documents Is requested to the patient [6]	
	C: Consult PS of Country A	**FRs fulfilled: FR 05, 06, 07, 19,**
9.	Once the identity of the patient is validated, the HP of Country B requests the PS of Country A that can be visualized by HP interface	
10.	The HP interface requests the PS of Country A to the NCP of Country B	
11.	The NCP of Country B requests PS of Country A to the NCP of Country A	
12.	The NCP of Country A, after checking if patient consent has been provided, gets and provides to the NCP of Country B the PS of Country A on the epSOS format.	
13.	The NCP of Country B conveys the PS of Country A to HP interface	
14.	The HP-B accesses to the Patient Summary of Country A	
15.	The use case is terminated	
Exceptions[7]		
The identity of the patient cannot be properly validated in Country A		
6	The NCP of Country A informs the NCP of Country B of the identification failure	
7	The NCP of Country B informs the HP interface of the identification failure	
8	The HP informs of this failure to the patient. The validation of the identification might be requested again many times[8] and if not possible the use case is terminated. Should the validation be successful, the use case is resumed at step 6	
Denial of Patient Consent		
8	If patient consent is not given by the patient or it cannot be recorded in Country B, the use case is terminated.	
8	If patient is unconscious, no confirmation can be provided: a specific flag has to be set, to track the event and to inform NCP-A the consent was not confirmed. Country A applies its policies on treatment of unconscious patients. Country A may terminate the use case.	
Patient consent cannot be checked		
12	If Country A cannot check that patient consent has been given, a notification is sent to Country B and the PS of Country A is not provided. The use case is terminated	
Patient Summary does not exist in Country A		
11	The HCP informs of this situation to the patient.. The use case is terminated.	
Patient Summary can't be retrieved from NCP A		
11	The HP informs of this failure to the patient. The solicitation to the PS might be requested again many times[8] and if not possible the use case is terminated. Should the validation be successful, the use case is resumed at step 12	
The communication is broken somewhere during the process (steps A,B,C)		
	The HP needs to be informed of the issue and the probable cause.	
	The HP informs the patient of this issue. The process can be repeated again many times[8] and if not possible the use case is terminated. This issue has to be logged and reported	

Table 1. Use case 1&2 description: Patient summary occasional and regular visit

[6] This point is subject to Legal aspects defined in epSOS WP2.1 and the different solutions to handle it are described in epSOS WP3.6. The eHN Legal group will have to align with the MLA and to address the situations when the patient is a child, a person under guardianship or is unable to give his consent (e.g.: unconscious) and there is a risk for the patient´s health.

[7] The numbers under "Exceptions" refer to the 'steps' numbers in the 'Normal sequence' section of this table.

[8] This issue is to be addressed within the JAseHN organisational framework groups (???)

4.1.2 Guidelines for patient dataset

THE MEMBER STATES in the eHealth Network HAVE ADOPTED THESE supplementary clauses to the Cross Border Guidelines to support Patient Summary data.

CHAPTER I – General Considerations

Article 1: Object and scope

5. These guidelines, as adopted by the eHealth Network, are non-binding and are addressed to the Member States of the European Union and applies to the implementation of a patient dataset for cross-border exchange.

Article 2: Definitions

2. 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 need to assure Health Care Coordination and the continuity of care*".

b) The Dataset *is defined as a set of essential health information that is required from the clinical point of view to be sent to deliver safe care to the patient (focused in unscheduled care). Where data content exists, the fields in the Basic Dataset must be populated for cross-border exchange.* When data content does not exist, or it is provided into a form that does not allow safe representation into HP-B language (e.g. free text for elements that are supposed to be valorized with coded information), it shall be provided the reason why that information has not been provided as expected (e.g. using the appropriate "null-flavour"[9]).

Article 3: Concepts

(no supplementary requirements)

Chapter II – Legal Considerations

Article 4: Data protection

(no supplementary requirements)

Article 5: 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 of each citizen (with national federation of IDs if numerous regional systems available). For cross-border purposes, a unique patient identifier is a necessary requirement for each single 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

[9] Null flavour: a set of coded value to express e.g. missing data, not known clinical situation, not applicable…

Article 6: Patient safety issues specific to these guidelines

(no supplementary requirements)

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

8. The application of these guidelines should at all times take place according to the provisions of relevant European and national legislation. Where such provisions do not exist or are not in force, Member States are expected to implement, monitor and audit common policies, safeguards and measures representing agreements of the eHealth Network, as foreseen in its Multiannual Work Programme (MWP).

9. Such agreements will apply to the exchange of health related data across borders in a generic way and they will include but are not limited to agreements on duties and responsibilities of the eHealth NCPeHs and on common identification authentication and authorisation measures.

Article 8: Education, Training and Awareness

(no supplementary requirements)

Article 9: Quality standards and validation

(no supplementary requirements)

Chapter IV - Semantic Considerations

Article 10: Intended Use

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

3. 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 11: Dataset

3. The content for the Patient Summary dataset is shown in Annex A.4. The Patient Summary data comprises Patient Administrative Data and Patient Clinical Data. The final column in the table identifies those fields which form part of the basic and extended dataset.

Article 12: 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.

2. Member States wishing to engage in cross-border communication will need to use the coding schemes as described in the dataset in Appendix A2

3. Further work is needed to review the code schemes described in Appendix A.2. The assessment of each field will be undertaken according to an agreed set of criteria and by groups including professional representative bodies.

Article 13: Master Catalogue

(no supplementary requirements)

Chapter V – Technical Considerations

Article 14: Technical standards

6. 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 A.5. Further work will be needed to review these.

Article 15: Data security

1. 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 16: Interoperability testing

(no supplementary requirements)

Article 17: Amendments to the guidelines

The Guideline is addressed to Member States.

4.1.3 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 guidelines themselves.

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: Object 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 in scope in this release [Release 2] of the guideline.

More recently, the dataset has been reviewed by USA 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 some relevant definitions relating to Patient Summaries.

Article 3: Concept

3. This guideline is non-binding and Member States are considered to:

(a) have the right to choose freely their way of implementing patient summary data systems

Chapter II – Legal Considerations

Article 4: Data protection

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 subsequent encounter). Where the country of affiliation requests (A) 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 which is necessary for the fulfillment of the 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 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 access to audit trails. Data in the log files is to be stored and for litigation purposes up to a maximum of 10 years.

Each query about the personal data available through cross-border 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.

Article 5: Authorization, 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.

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 to make sure all existing patient information can be located if requested from a cross-border setting.

Official documents, such as a passport, ID card or drivers licence seem to be accepted across MS 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 birth date may be used to create a unique (temporary) way of identification in line with national rules.

Article 6: Patient safety issues specific to these guidelines

(no supplementary requirements)

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

(no supplementary requirements)

Article 8: Education, Training and Awareness

(no supplementary requirements)

Article 9: Quality standards and validation

(no supplementary requirements)

Article 10: Intended Use

The Patient Summary guidelines focused on the content issues and the description of possible ways to produce this content for cross-border exchange considering already-existing national implementations. 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 guideline could serve as a common baseline of patient summaries at national level.

The Trillium Bridge study compared the epSOS specification together with US experience, as a result of which a number of recommendations have been made regarding the content of the dataset (see below).

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

- I have an already implemented national PS: what do I need 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 exchange of data across-borders? (This case was considered in epSOS. D3.5.2 includes as appendix an example of mapping 13606 archetypes into the epSOS).
- I have no plans for a national PS – any request for access will be routed to the local HealthCare Provider(s) that maintains the PS for the patient, so
    - How do I ensure consistency of structure and content?
- I'm expecting to construct a patient summary "on the fly" from multiple inputs, so how do I
    - ensure this is practical (e.g. response times) and
    - 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 info be kept aside from the minimal one requested (3 digits ICD)?
    - Original codes are conveyed together with the common epSOS ones. MVC 2.0 includes the full ICD-10, with all the hierarchical levels (from 2 to 4 digits)
- What if I do not have any license for any of the mandatory terminology resources?

Article 11: 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.

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, where a field is blank precisely because there is no relevant information in the patient record.

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

Some of the fields in the extended dataset may be of little use for emergency and/or unplanned care. In Release 1, it was recommended that the review process should include consideration by health professionals who will use this dataset, to test the usefulness of the fields when treating a patient in an emergency or unplanned context. Feedback has been sought through the survey of Member States and through the EXPAND and the Trillium Bridge project but at this stage it is too early to include these additional items in the guidelines themselves.

Article 12: Terminology standards

An underlying principle is that exchange mechanisms 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. It 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 contain a large number of terms, it is not likely that they would be used 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. The full ICD-10 set of values is used in MVC 2.0

Certain criteria were used to choose between the most significant terms and arrive to a reasonable manageable content. 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.

Release 1 noted that it was necessary to conduct a review of the coding schemes to be used, and for this to be documented in the next release of the guideline.

Article 13: Master Catalogue

(no supplementary requirements)

Chapter V – Technical Considerations

Article 14: Technical standards

(no supplementary requirements)

Article 15: Data security

(no supplementary requirements)

Article 16: Interoperability testing

(no supplementary requirements)

4.1.4 Annex: Patient Summary Dataset

PATIENT ADMINISTRATIVE DATA				
Variable (nesting level 1)	**Variables (nesting level 2)**	**Variables (nesting level 3)**	**DEFINITION AND COMMENTS**	
Identification[10]	National Health Care patient ID	National Health Care patient ID	Country ID, unique for the patient in that country. Example: ID for United Kingdom patient	
Personal information	Full Name	Given name	The Name of the patient (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 surname to be the birth name [to avoid potential problems with married women names).	
	Date of Birth	Date of Birth	This field may contain only the year if day and month are not available. E.g.: 01/01/2009	
	Gender	Gender Code	This field must contain a recognized valid value	
Contact information	Address[11]	Street	Example: Oxford	All the parts of the address are optional, but at least one shall be provided if the address is not null-flavored
		Number of Street	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	can be null
	Email	Email	Example: jens@hotmail.com	can be null
	Preferred HP/HPO to contact[12]	Name of the HP/HPO	Name of the HP/name of the HPO that has been treating the patient. If it is a HP, 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	can be null
		Email	Email of the HP/legal organization	can be null
	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	All those elements are required IF the contact person is provided
		Given name	The 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	
		E-mail	E-mail of the contact person/legal guardian	
Insurance information	Insurance Number	Insurance Number	Example: QQ 12 34 56 A	

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

[11] May vary by country

[12] 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)	If present, then need a text description or a code
		Allergy description id code	Normalized 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	Aim to use MPID
		Agent id code	Normalized identifier	
	Medical Alert Information (other alerts not included in allergies) ? rename ?	Health Care 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)	
		Health Care Alert id code	Normalized identifier	
Medical History	Vaccinations	Vaccinations	Contains each disease against which immunizations has been given	
		Product information		
		Vaccinations id code	Normalized identifier	
		Vaccination Date	the date when the immunization was received	
	List of resolved, closed or inactive problems	Problem description	Problems or diagnoses not included under the definition of "current problems or diagnosis". Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it's a closed problem)	
		Problem id code	Normalized identifier	
		On set time	Date of problem onset	
		End date	Problem resolution date	
		Resolution Circumstances	Describes the reason by which the problem changed the status 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 like 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)	To be clarified
	Surgical Procedures prior to the past six months	Procedure Description	Describes the type of procedure	To be sorted by date
		Procedure Id (code)	Normalized 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 under 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)	Normalized 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 that their health status depends on. Includes devices as cardiac pacemakers, implantable fibrillator, prosthesis, ferromagnetic bone implants, etc. that are important to be known by the HP	
		Device Id code	Normalized 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)	Normalized 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)	Normalized identifier	
	Autonomy / Invalidity	Description	Need of the patient to be continuously assessed by third parties, invalidity status may influence decisions about how to administer treatments	no value set defined for this field
		Invalidity Id code	Normalized invalidity identifier (if any, otherwise free text)	
Medication Summary	List of current medicines	Active ingredients list 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)	Many MS are reporting “Relevant” Medicine, not “All” medicine
		Active ingredient id code	Code that identifies the active ingredient	Reference to the use of PhPID and, if needed MPID should be made
	Prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not)	Strength	the content of the each 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) NB for PS drawn by GP’s it is more likely to find therapy for chronic diseases (e.g. hypertension) than antibiotics for 3-5 days treatment	
		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 each 24 hours	

PATIENT CLINICAL DATA				
		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, diet	Health related "life-style factors" or "life style observations" Example: cigarette smoker, alcohol consumption	
		Reference date range	Example: from 1974 thru 2004	
Pregnancy history	Expected date of delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, month day are required (e.g. 01/01/2014)	
Physical findings	Vital Signs Observations	Blood pressure	One value of blood pressure 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 made to the patient	
		Date	Date on which the blood group was done. This field may contain only the year if day and month are not available (e.g. 01/01/2009)	

PATIENT ADMINISTRATIVE DATA				
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	Define the context in which it was generated. Distinguish among three methodological approaches to build the PS: direct human intervention of an HP, automatically generated and mixed approach	Implied by type of author
Author organization	Author organization	Author organization	At least an author organization (HCP) shall be listed. In case there is no HCP, at least an HP shall be listed	

4.1.5 Annex: 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] was based on HL7 Clinical Document Architecture (CDA) Version 2 [2] and the IHE Patient Care Coordination Technical Framework [3]. The exchange specification was based on the epSOS Common Components Specifications [4] using IHE profiles XCPD [5], XCA [6], XDR [7] and optionally XCF [8].

References

[1a] EXPAND "epSOS Patient Summary, ePrescription eDispensation and Common Modules HL7 CDA R2 Implementation Guide."
https://service.projectplace.com/pp/pp.cgi/r1147714042

[1b] epSOS Patient Summary, ePrescription eDispensation and Common Modules HL7 CDA R2 Implementation Guide published on ART DECOR[13]:

https://art-decor.org/art-decor/decor-project--epsos-

[1c] Master Value Catalogue https://ecrtsppt.conet-services.de/ . An informal excel export of the MVC 2.0 is available on https://service.projectplace.com/pp/pp.cgi/r1193682804; An informal html version is accessible through the ART DECOR based specifications (https://art-decor.org/art-decor/decor-valuesets--epsos-)

[2] Clinical Document Architecture Release 2:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[3] IHE Patient Care Coordination Technical Framework
http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_TF_Vol2.pdf

[4] Work Package 3.4 - epSOS_Common_Components_Specification_01

http://www.epsos.eu/uploads/tx_epsosfileshare/D3.4.2_epSOS_Common_Components_Specification_01.pdf

[5] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Patient Discovery (XCPD) http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XCPD.pdf

[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

4.2 Annex B: ePrescriptions

4.2.1 Use case description

4.2.1.1 Scenario

The scenario within the scope of this document is that a patient from Country A has a prescription issued in Country A and dispensed in Country B, where:

Country A: This is the country where the patient can be univocally identified and his or her data may be accessed.

[13] the ART DECOR® representation is an informative release of the epSOS CDAs Implementation Guides.

Country B: This is the country that the patient is visiting and in which information about the patient is needed in case he or she needs healthcare.

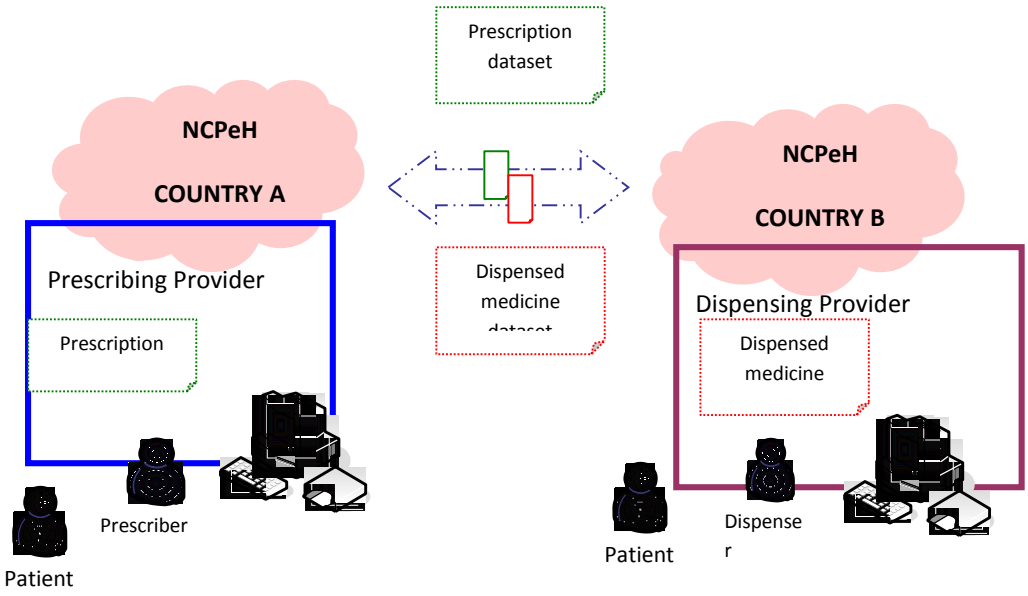


Figure 1: Scenario 1 of ePrescription Service

The actors may be categorised as:

Human actors (individuals):

- Patient: individual for whom the healthcare professional (HP) decides to prescribe a medicine or who requires dispensing of medicine(s) prescribed in country A
- Prescriber: legally authorised HP who prescribes medicine(s) to be dispensed to the patient by means of his/her prescription provider.
- Dispenser: legally authorised HP who dispenses medicine(s) to the patient fulfilling a prescription issued by a prescriber.

System actors (information system or provider such as those used to prescribe, dispense, process or convey information across borders):

- Prescribing provider: information provider used by the prescriber to identify himself or herself and to order prescriptions. This actor is a concept of a system that contains all health information and is not intended to match any physical or technical implementation as in each country these functions may be implemented in a different way.
- Dispensing provider: information provider used to identify the dispenser and to retrieve available and non-fulfilled prescriptions and to update information on the medicine(s) dispensed. This system is a logical entity and is not intended to match any physical implementation.
- National Contact Point or NCPeH. This entity deals with the following:
  - Semantics to solve the issues related to translation between different coding systems and different nomenclatures
  - Identification of patients and identification and authentication of HPs
  - Conveying information to and from prescribing and dispensing systems and logical nodes of other countries
  - Legal aspects

This actor is responsible for assuring the security, reliability and availability of information and for complying with national and international regulations and laws. All the information needed for the use cases is made interchangeable by means of the National Contact Points in both countries.

The following table outlines the direct interaction between human actors and technical actors in the ePrescription service:

Table 1 Human and technical relationships

System actor	Human actor
Prescribing provider	Prescriber
Dispensing provider	Dispenser
NCPeH	NA

Description of the use case and requirements

The objective of this section is to describe the use case and the requirements that will need to be fulfilled to ensure a secure interoperable scenario. This includes the knowledge required (not just data) and requirements about how to access and obtain information.

Use case: Medicine already prescribed in Country A

This use case describes the dispensing of medicine(s) in Country B when the medicine(s) has (have) been prescribed in a different country (Country A). In this case, Country A is also the country where the patient can be univocally identified.

In order for the use case to take place, several preconditions are needed:

- The patient has already been electronically prescribed medicine by a prescriber authorised to prescribe in Country A.
- In Country B, a mechanism to validate the identity of the patient has to be available at the pharmacy and the dispenser is a person legally authorised to dispense medicinal products.

In order to obtain the information required in Country B, the Prescribing Provider in Country A must make accessible the 'available' prescriptions to be sent or requested by another country. This implies that Country A is able to calculate the 'available' prescriptions (it has the necessary information or parameters to select the prescriptions that can be dispensed at that moment).

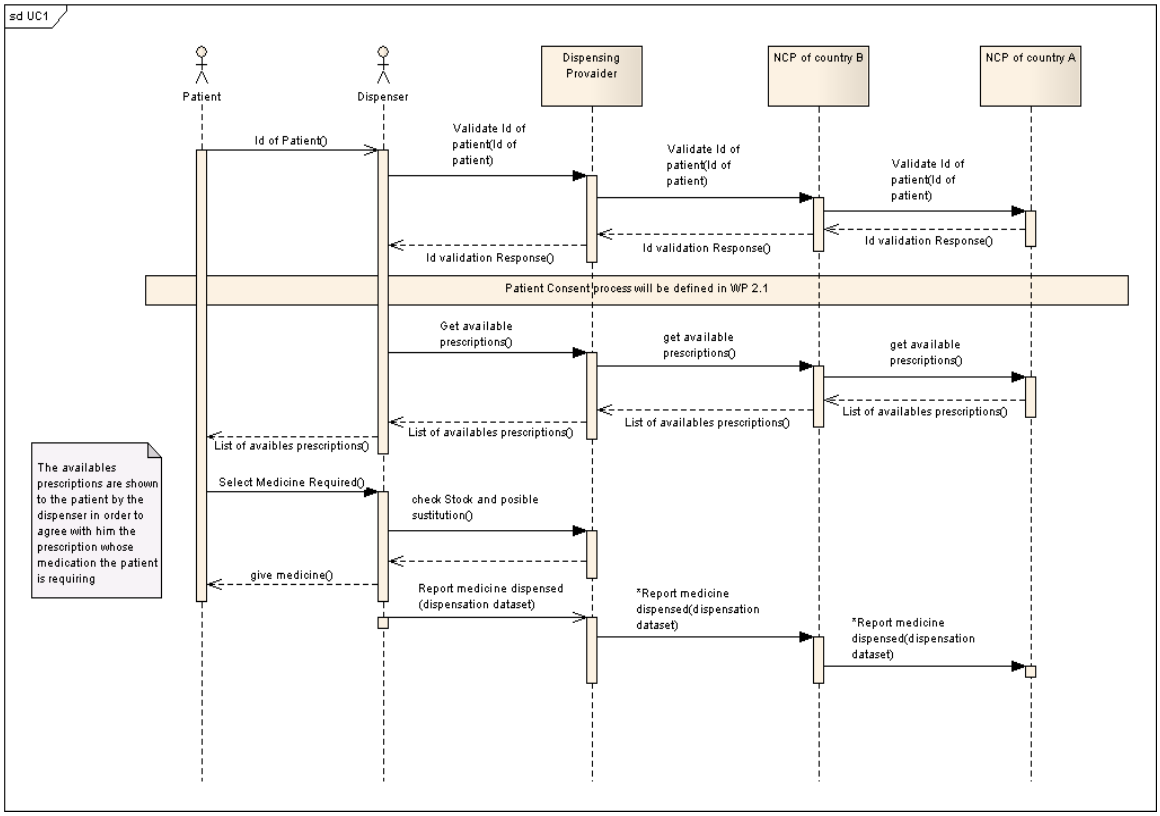


Figure 2: Sequence diagram use case (update)

As for PS Sequence Diagram, now WP2.1 is ambiguous. Suggestion is to apply here the same change of PS Sequence Diagram. "Check stock and possible substitution" is an optional action, or better a suggested good practice to maximise dispensations. The Prescription Provider is not included in the Sequence Diagram, not to interfere with National policies and strategies.

However, for symmetry it would be nice to make it evident. Country A must provide, maintain and support a logical country node (NCPeH) supporting communication of the information identified in this section with Country B and vice versa and there must be a chain of trust between system actors in this process.

The NCPeH – A should be connected to the Country A prescribing system, to identify the patient, retrieve the "available" prescription and mark as fulfilled the dispensed ones, to avoid patient safety risks. Furthermore, it is suggested that exactly the dispensed packaged medicinal product is reported, in order to be able to communicate to the pharmacovigilance systems, it in case of adverse drug events.

If these preconditions are met, the use case can take place and the first thing the patient needs to do is to identify himself or herself to the dispenser. The dispenser has to check if this identification is valid through his or her Dispensing Provider before accessing any data. In order to avoid legal issues, it is imperative that the patient is univocally identified so that his or her identity can be assured with certainty.

Once the patient has been identified, the dispenser needs to obtain the patient's consent confirmation before accessing any data during this specific encounter. After the encounter, the pharmacist will need to obtain new consent confirmation to access any data about the patient.

In order to select the prescription requested by the patient, the list of the 'available' (and thus, valid) prescriptions from Country A has to be presented to the dispenser and the patient. These prescriptions are provided by Country A according to the rules that apply in its health system,

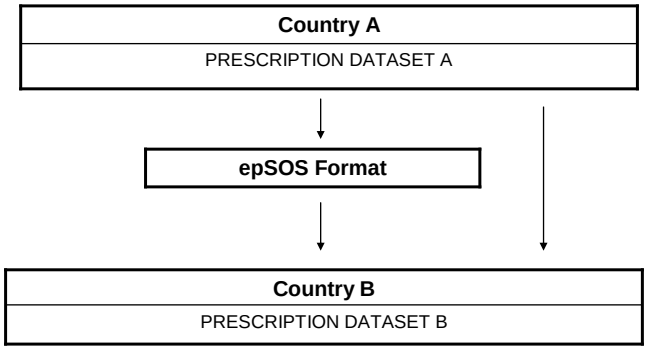
meaning that only a prescription that can be dispensed in Country A at that moment is available for dispensing in Country B.

The prescription has to be valid (time validity) and also be within the permitted slot of time to collect it from the pharmacy in Country A (in some countries, mainly with long term treatments, prescriptions can only be collected from the pharmacy on specific dates to help the patient to correctly administer the medicine(s)).

Apart from the 'available' prescriptions, Country A could also send, if allowed there, the current prescriptions (this information may be contained within the Medication Summary) to the dispenser in Country B to enable him or her to consult that information (e.g. to check possible interactions).

In order to allow the dispenser to understand the information, this must be intelligible to him or her (structured, equivalent meaning and understandable), presented in his or her system as it is normally presented and contain all the information required to select the right packaged medicinal product.

As the medicinal products are not the same in the different countries, they will need to be translated identifying the active ingredient (and not the brand name) as it is the common nomenclature. The following scenario is assumed in the process of sending the prescription dataset from Country A to Country B:



The information that Country A sends to Country B will be converted to a common format to be sent to Country B. Country B will then receive the prescription dataset of Country A in this common format. This format will then need to be translated to a single concept in Country B (if a single prescription is issued in Country A, it is not possible to issue several prescriptions for practical reasons in Country B and one of the medicinal product names should then be selected from all those available in Country B; the same applies to items within the prescription). As in most cases, if the same medicinal packaged product does not exist (this document covers different brand names and/or sizes of package) in both countries, Country B will translate its single code into a packaged medicinal product that exists there: (brand name (different from the original) + strength + pharmaceutical dose form + package size (that can be different from the original) + mode of administration (different from the original)) and that is different from the one prescribed in Country A. For safety reasons, Country B must also receive the prescription dataset A in Country A format so that the original prescription is available in Country B. This "copy" of the unchanged original prescription from Country A may be used for a manual safety and security check in Country B.

Safety: check the prescribed pharmaceutical or medicinal product and the patient; security: check the patient and the prescriber

Country A packaged medicinal product	Country A (Medicinal or pharmaceutical product)	epSOS format	Country B (medicinal product)	Country B packaged medicinal product

Termalgin 500mg 30 cap	Paracetamol 500mg 30 cap	xxx	Paracetamol 500mg 30 cap	Paracetamol Tesco 500mg 20 cap

A number of issues may arise when translating the medicine from Country A to Country B. The different possibilities are described:

- In Country B the Medicinal or pharmaceutical product exists, meaning that the exact same following elements are found: active ingredient+strength+pharmaceutical dose form+package size. The dispenser then dispenses the medicine.

- In Country B the medicine does exist but in a different package size. The dispenser might then dispense another size (smaller or bigger) according to Country B rules or legislation. The consequence of changing the package size affects the use case at different levels:

  - The patient receives less medicine than required

  - If Country A prescribes prescriptions for long term treatments, this will affect the update of the prescription (to calculate the new credit).

- In Country B the medicine does not exist, meaning the active ingredient or strength or pharmaceutical dose form is not the same. In this case, under epSOS LSP rules, the dispensing was not possible as substitution of any of these three elements. The Horison2020 PHC-34 project "openMedicine"[14] is defining new procedures for medicinal product selection or substitution. The dispenser has to see and be aware that it may happen there is an available prescription but that it cannot be translated into a medicinal product in Country B as the active ingredient or the strength or the pharmaceutical dose form is not the same.

Once the patient and the dispenser agree on the prescription (in order to do so, both have to understand the information), it is dispensed according to Country B legislation and the information about the medicine dispensed must be sent to Country A. This information must allow the relevant prescription to be identified so that it can be updated and must reflect factors such as package size substitution.

4.2.2 Guidelines for ePrescriptions

THE MEMBER STATES in the eHealth Network HAVE ADOPTED THESE supplementary clauses to the Cross Border Guidelines to support ePrescriptions.

Chapter I – Scope and Definitions

Article 1: Object and scope

1. These guidelines are addressed to the Member States of the European Union and apply to the implementation of interoperable electronic prescription services across Member States, in order to facilitate the recognition and delivery of prescriptions issued in another Member State.

4. In particular, while the non-exhaustive list of elements to be included in medical prescriptions has been fixed in Commission Implementing Directive 2012/52/EU, there is a need to define the electronic requirements applicable to the seamless identification of the patient, of the prescribing health professional and of the health product.

5. These guidelines do not cover medical devices; the guidelines do not cover non-pharmaceutical products.

[14] www.openmedicineproject.eu

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) eDispensing is defined as the act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format.[15]

b) 'Electronic medication data' means any electronically used data regarding medication of a patient, including but not limited to ePrescriptions and the electronic information about the dispensation of medication.

c) 'ePrescription' means a medicinal prescription, as defined by Article 1 (19) of Directive 2001/83/EC[16], issued and transmitted electronically, as elaborated in point 3 (f) of Commission Recommendation 2008/594/EC on cross-border interoperability of electronic health records.

d) 'Prescription' means a prescription for a medicinal product or a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued.

e) 'Medicinal prescription' means any medicinal prescription issued by a professional person qualified to do so.

f) 'Pharmaceutical product'[17] means a compound intended for human care, described in the ePrescription, in terms of active ingredient, strength, route of administration, dose form, unit of presentation, and other parameters defined in the relevant standards. It can be both a registered product and a magisterial preparation.

g) 'Medicinal product'[18] is pharmaceutical product registered by the producer to a National Medication Agency or to the European Medication Agency.

h) 'Medicinal product' means – check ISO

- any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- any substance or combination of substances, which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Article 3: Concepts

(no supplementary requirements)

[15] See supporting detail in Article 6; the aim is that the ePrescription can be updated before another dispensation can take place.

[16] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF

[17] Add the ISO spec reference

[18] Add the ISO spec reference

Chapter II – Legal Considerations

Article 4: Data protection

10. The application of these guidelines should at all times take place according to the provisions of relevant European and national legislation. Where such provisions do not exist or are not in force, Member States are expected to implement, monitor and audit common policies, safeguards and measures representing agreements of the eHealth Network, as foreseen in its Multiannual Work Programme (MWP).

11. Such agreements will apply to the exchange of health related data across borders in a generic way and they will include but are not limited to agreements on duties and responsibilities of the eHealth NCPeHs and on common identification authentication and authorisation measures.

Article 5: Authorisation, authentication and identification

1. Member States shall ensure that, for reasons of identification and authentication, information is available at national, regional or any other level:

(a) on the health professionals who are entitled to prescribe as well as

(b) on the health professionals/heath care providers who are entitled (according to national law) to dispense.

2. Member States of affiliation are responsible for ensuring that ePrescriptions are issued only by registered persons (or, where relevant, organisations).

3. The healthcare professional must be registered with at least one healthcare professional organisation 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 data.

4. The information according to paragraph 1 of this Article 5 is to be shared via the National Contact Points for eHealth, which are responsible for the proof of authenticity of origin and content of ePrescriptions. At European level National Contact Points for eHealth are responsible to their counterparts for the faithful representation of the information provided by them. To this end National Contact Points for eHealth shall implement audit trails.

Article 6: Patient safety issues specific to these guidelines

1. Health professionals, patients and National Contact Points for eHealth may rely upon the information released by the National Contact Points for eHealth of other Member States.

2. In the event of semantic transformation, both the transformed and the original documents shall for safety and audit reasons be available to all persons who are authorised to use this data.

Article 6: Substitution

1. The rules of the dispensing Member State shall apply; hence Member States are responsible for application of their rules regarding substitution.
2. It is acknowledged that the rules for substitution are outwith the remit of the eHealth Network. However, Member States will wish to ensure that agreements regarding substitution are reflected in the information flows to support cross-border ePrescriptions.

Article 6: Storage periods

1. National legislation applies to the rules regarding storage of ePrescriptions.

Article 6: Organisation of dispensation

1. Prescription drugs may not be dispensed without appropriate identification of the recipient, e.g. by inspection of the European Health Insurance Card of the citizen together with photo ID.

2. Member States of treatment shall be responsible for communicating details of items dispensed back to the originating country according to national laws. In the case of eDispensations, the following data should be sent to the prescriber via the relevant National Contact Point for eHealth for the respective recipient:

(a) identification number of the dispenser,

(b) name of dispenser,

(c) ISO 3166 country code of the dispenser,

(d) address of the dispenser,

(e) personal identification number of the patient, together with the ISO 3166 country code,

(f) identification number of the prescription,

(g) items dispensed.

Chapter III – Organisational Considerations

Article 7: Enablers for Implementation

(no supplementary requirements)

Article 8: Quality standards and validation

1. In order to assure safe implementation, particularly patient safety and data protection and further development of cross-Union eHealth services, in particular ePrescriptions, Member States should:

(a) consider setting up a facility for cross-border ePrescription services to quality assure, benchmark and assess progress on legal, organisational, technical and semantic interoperability for their successful implementation;

(b) undertake assessment activities, such as measuring the quantitative and qualitative possible benefits and risks (including economic benefits, risks and cost-effectiveness) of ePrescription services.

Article 9: Education, training and awareness

1. In terms of education, training and awareness raising, Member States should:

(a) undertake common activities towards increasing awareness of the benefits of and need for interoperability and related standards and specifications for ePrescription services, and for electronic patient data exchange in general, including awareness of the need to foster the interoperability of technical systems among producers and vendors of information and communication technologies, health care providers, public health institutions, insurers and other stakeholders;

(b) consider recommendations for education and awareness raising measures targeting health policymakers and health professionals;

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

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

Chapter IV –Semantic Considerations

Article 10: Intended Use

1. In addition to the dataset requirements, it is important to specify rules for conformance to these guidelines – i.e. demonstrating how logical and implementable models can be derived from this data set. A key issue is that of optionality where, for example, optional shall remain optional OR optional can be further constrained to Required or Mandatory. Minimum data set elements shall can be required so it can be used a model constrained approach therefore optional field can be made required or mandatory. Or the contrary, optional can remain optional OR optional could be required but never mandatory and so on

Article 11: Dataset for ePrescriptions

1. Table 2 shows fields for the dataset. The data elements are taken from Implementing Directive 2012/52/EU and Draft International Standard DIS 17523[19]. Reference is also made to other relevant standards, including the ISO Identification of Medicinal Products (IDMP) standards as referred to in the Implementing Directive. The data elements ticked in the second column are mandatory; other elements are optional. Annex B.4 provides supporting information on each data field; further details will be added in future releases of the guidelines.

2. ePrescriptions that contain data according to paragraph 1 of this Article 4, but that are not ready for semantic interpretation by machines, may be rejected on grounds of patient safety/national legislation.

3. For the eDispensation Dataset, it is fundamental to include the data of the dispenser and indicate, in the most precise as possible, which (packaged) medicinal product was dispensed. In this case the priority should be PCID, MPID and, PhPID. That will make easier both to document what was dispensed and get info for pharmacovigilance in case of Adverse Drug Events

Table 2: ePrescription Dataset

Data Field	ID
A.1 Core data elements	
A.1.1 Identification of the patient	
A.1.1.1 Surname [ISO TS 22220]	☐
A.1.1.2 Given name [ISO TS 22220]	☐
A.1.1.3 Date of birth [ISO TS 22220]	☐
A.1.1.4 Personal identifier	☐

[19] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59952

A.1.1.5 Gender	☐
A.1.2 Authentication of the prescription	
A.1.2.1 Prescription ID (not item id)	☐
A.1.2.2 Issue date (when authored)	☐
A.1.3 Identification of the prescribing health professional	
A.1.3.1 Surname	☐
A.1.3.2 Given name	☐
A.1.3.3 Professional qualifications (have profession (required) and specialty (optional from a functional point of view but not actually implemented since no value sets have been defined for that)	☐
A.1.3.4 Details of direct contact	☐
A.1.3.5 Work address	
A.1.3.6 (Digital or electronic) signature (clarify)	☐
A.1.3.7 Health care provider identifier (HCPI)	☐
A.1.4 Identification of the prescribed product[20] [list of active substances; associated reference strengths; PhPID; MPID;PCID]	
A.1.4.1 Name of the item [+ identifier as described in ISO IS 11615]	☐ ☐ with null flavour
A.1.4.2 Identifier of the item [with name and identifier as described in ISO IS 11616]	☐ ☐ with null flavour
A.1.4.3 Strength of the item [Article 1 of Directive 2001/83/EC]	☐
A.1.5 Prescription information [will need rules for compliance]	
A.1.5.1 Pharmaceutical dose form	☐
A.1.5.2 Quantity[21]	☐
A.1.5.3 Dose regimen[22]	☐
A.1.5.4 Duration of treatment (start and/or stop time)	
A.1.5.5 Directions for use (? Including route of admission)	
A.1.5.6 Pharmaceutical preparation description[23]	
A.2 Optional elements of prescription	
A.2.1 Identification of the patient	
A.2.1.1 Address details	
A.2.1.2 Native language [could be taken from the ISO language table (ISO 639.2 or ISO 639-3)]	
A.2.2 Patient characteristics [not in the current specification]	
A.2.2.1 Body weight	
A.2.2.2 Body height	
A.2.2.3 Drug allergies and drug sensitivities	
A.2.2.4 Patient conditions	
A.2.3 Prescription information [not currently implemented]	
A.2.3.1 Prescription expiry date	
A.2.3.2 Repeats/refills	
A.2.3.3 Minimum dispensing interval	
A.2.3.4 Reason for prescription	

[20] The term product includes pharmaceutical products (branded medicinal products, generic/scientific name medicinal products or pharmaceutical preparations [ISO 21549-7:2007]) or non-pharmaceutical products.
[21] See Appendix B A1.5.2
[22] See Appendix B A1.5.3
[23] This also includes extemporaneous preparation, compounded medication and magistral preparation.

A.2.3.5 Substitution handling	

2. There is a particular issue regarding the identification of medicinal products. The European Medicines Agency (EMA) has suggested the use of the inventory of medicines established under the legal obligations laid down in Article 57 (2) of Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("pharmacovigilance legislation of 2010")[24]: the so-called 'Article 57 database'. EMA has also suggested, in agreement with the National Regulatory Agencies, to start the aforementioned use when ISO IDMP adoption process will reach a significant completion. Member States will work with the EMA and the European Commission to explore this issue.
3.

Article 12: Terminology standards

(no supplementary requirements)

Article 13: Master Catalogue

(no supplementary requirements)

Chapter IV – Technical Provisions

Article 14: Minimum technical requirements for cross-border ePrescriptions

1. Member States are free to choose the implementation of their ePrescription dataset. 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 B.5. Further work will be needed to review these.

Article 15: Data security

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 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 16: Interoperability testing, audit and compliance model

(no supplementary requirements)

Article 17: Amendments to the guidelines

2. The eHealth Network will include in its Multiannual Work Programme the necessary activities for:

[24] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF

- 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, functional and technological advances and lessons learned from their use by the Member States.

These guidelines are addressed to Member States.

4.2.3 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 guidelines themselves.

Chapter I – Scope and Definitions

Article 1: Object and scope

The guidelines will take a gradual approach to solving the interoperability issues inherent to ePrescriptions, particularly at the semantic level (identification of drugs, information for patients, drug use instructions) and for issues of substitution as a number of important decisions are expected to be taken in the near future.

The following items within the scope of this first release of the guidelines:

- The scope of guidelines for interoperable ePrescriptions shall be limited to medicinal products.

- From the perspective of stakeholders, patient safety and ease of practice are essential. There is a need for greater clarification of the legal framework, especially in relation to data protection and liability issues.

- The guidelines should make sure that all data deemed compulsory can be made available by Member States given existing or planned registers.

The following items are outside the scope of this first release of the guidelines and will be discussed as part of the review process:

- A number of Member States have highlighted an interest in reimbursement. Although not within the scope of this release, the topic will be revisited by the eHN.

- The guidelines do not deal in detail with transversal generic issues and supporting services which are addressed elsewhere (such as identification, authentication and authorisation issues) but streamline essential dependencies. In this respect, alignment with Chapter IV of the patient summary guidelines has been performed.

- Aspects such as signature (NCPeH versus healthcare professionals) will be discussed further.

- The guidelines have sought to avoid architectural design which would be in contradiction with the principles established in certain Member States (e.g. decentralised or central storage of documents). Likewise, they seek to avoid referring to any specific cryptographic algorithms or national guidelines other than as examples.

Article 2: Definitions

Formal definitions are provided in Article 2 in section 3 of these guidelines. However, it is recognised that across Europe there are other terms for which different concepts apply; examples include "primary care prescribing" and "substitution" (e.g. therapeutic, economic).

Article 3: Concepts

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

Chapter II – Legal Considerations

Article 4: Data protection

(no supplementary requirements)

Article 5: Authorisation, authentication and identification

Member States may wish to consider the content of a register of health professionals who are entitled to prescribe and dispense, for instance:

(a) the name and profession,

(b) a personal identification number, including the ISO 3166 country code,

(c) the current address of the health care provider organisation with which the health professional is affiliated or the address of his or her private practice,

(d) the date of issue of the healthcare professional's licence to practice,

(e) the speciality might be recorded as the prescribing of some medicinal products may be restricted.

Member States will need to consider their approach to implementing digital signature services at the eGovernment or eHealth service level in the light of the electronic identification and trust services (eIDAS[25]) regulation adopted in July 2014.

In relation to the ePrescribing scenario, the identification of the health professional will need to be linked to access the data (i.e. confirmation of patient consent) and the authorisations to prescribe. Datasets to enable this are available from some Member State competent authorities, but wider linkages are required for professional bodies to support cross-border ePrescribing.

Furthermore, the guidelines should provide (easy) access to the health providers to obtain access to information including the (trusted source) supporting schemes for checking the identity, professional role and local prescribing rights of the health professional who has issued the ePrescription.

The digital ID of health professional and/or health care provider organisation is also used for authentication purposes by a majority of Member States. Similarly, a majority make use of digital signing for health professional/health care provider organisations 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 authorisation for accessing patient information is based on the

[25] http://ec.europa.eu/digital agenda/en/trust-services-and-eid

role, e.g. GP or pharmacist, of the health professional. In most of these Member States, this is 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.

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.

Article 6: Patient safety issues specific to these guidelines

(no supplementary requirements)

Article 6: Substitution

There is no common definition, process or set of rules across Europe regarding the substitution of medication. In order to aid discussion, the following definitions might be used:

- Generic substitution: occurs when a different formulation of the same drug is substituted. Usually, generic versions of a drug are considered by the licensing authority to be equivalent to each other and to the originator drug. [26]

- Therapeutic substitution: is the replacement of the originally prescribed drug with an alternative molecule with assumed equivalent therapeutic effect. The alternative drug may be within the same class or from another class with assumed therapeutic equivalence.[27]

For the purposes of these guidelines, it is recognised that the substitution is not within the scope of the eHN other than in enabling appropriate information exchange to support the agreed policy.

Within a Member State, national dispensing rules shall apply. Most Member States, but not all, allow generic substitution. For cross-border purposes, it is assumed that the rules of the country where the dispensation is made should be accepted by the prescribing country. This issue will be need to be worked out for clarification of the consequences for both sides and proposed in the next version of the guidelines. In formulating these guidelines, some guiding principles have been proposed. Member States may wish to consider these:

- *Therapeutic substitution is not allowed without formal prior consultation with the prescriber. As a consequence, it is not possible to substitute active ingredients; additionally, some MS do not allow substitution in this instance of dose, pharmaceutical form or route of administration.*

- *For the countries which do not allow generic substitution or for countries which have put specific limitations on generic prescriptions, it is thus advisable to allow for substitution of package size and/or brand name in these situations:*

- *in the event of shortages in the pharmacy, where the prescribed product is not available in the country,*

[26] Some exceptions might apply such as for biologics, biosimilars, drugs with a narrow therapeutic index and non-interchangeable modified release preparations.
[27] British Journal of Pharmacology, November 2011, 72(5), 727-730

- *urgency: if the product is available in the country but the pharmacist does not have it at that moment and the patient needs it urgently,*
- *if the brand name or size is not authorised or commercially available in country B, or*
- *if the rules of substitution in country B force the change to be made.*
- *In such cases, Country B will decide the brand name or package size to be dispensed according to their own rules of substitution*[28].

Article 6: Storage periods

There is no EU-wide agreement on minimum storage duration for ePrescription and dispensation records but the following proposals may be considered:

a) ePrescriptions and personal data concerning dispensation of these ePrescriptions shall be kept for a minimum period of 24 months.

b) Data according to point a) above shall not be kept for more than 10 years, unless demanded by patients or required by law, e.g. as part of a patient electronic record, in particular for the establishment, exercise or defence of legal claims.

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

Article 7: Organisation of dispensation

Most of the Member States allow ePrescriptions to accommodate multiple dispensations for multiple drugs.

Member States of treatment shall be responsible for communicating back dispensation in line with the fields identified in Article 5. These may be sent in the form of an XML message.

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

(no supplementary requirements)

Article 8: Evaluation and quality assurance

(no supplementary requirements)

Article 9: Education and awareness raising

(no supplementary requirements)

Chapter IV – Semantic Considerations

Article 10: Intended use

(no supplementary requirements)

Article 11: Dataset for ePrescriptions

[28] As footnote 18

Semantic interoperability requires representing the meaning of clinical information in standardised ways that allow both humans and computers to understand clinical information. An underlying principle is that exchange mechanisms convey both meaning and context.

The guidelines represent initial agreement on an EU-wide prescription and dispensation dataset, aligned with Implementing Directive (2012/52/EC). 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 ePrescriptions exist in some Member States, but the eHealth Network has agreed that the guidelines could serve as a common baseline for ePrescriptions at national level.

The dataset in these guidelines is based on Implementing Directive 2012/52/EU and ISO DIS 17523. Annex B.4 gives supporting descriptions of the data items together with a summary of lessons learned from epSOS pilot sites. DIS 17523 is currently under ballot and may be subject to change, but this could be reflected in the next release of these guidelines.

It will be necessary to reach agreement on an international standard to represent active ingredients in medications. The epSOS project used the Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs developed by the World Health Organization (WHO), but this was not appropriate for the requirements of cross-border exchange as it does not deliver non-ambiguous and sufficient information.

EXPAND improved the specifications, allowing to better distinguish between the pharmaceutical substance (the ATC code associated to a drug) and the active ingredients with their strengths. Waiting for global ingredient identifiers, likely the Global Ingredient Archival Service (GInAS) IDs, the ATC codes are for the time being still used for ingredients.

The European Medicines Agency (EMA) holds an inventory of all medicines authorised for human use in the EU and EEA established under the legal obligations laid down in Article 57 (2) of Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("pharmacovigilance legislation of 2010"): the so-called 'Article 57 database'.

The Article 57 database provides a European-wide reference and terminology for medicinal product(s) (including information about therapeutic indications, strength, pharmaceutical form and route of administration) that may support the identification and exchange of such information for cross-border ePrescriptions[29].

Member States will work with the EMA to explore the use of the Article 57 database to define implementation and integration strategy and to resolve possible legal and regulatory issues in close cooperation with the EU Commission. The Horizon 2020 project to explore this area may be able to assist with this study.

EMA and the National Regulatory Agencies have agreed a roadmap to adopt, starting from 2018, the ISO Identification of Medicinal Products (IDMP) standards as referred to in Implementing Directive 2012/52. ISO IDMP identifiers will be included in the new release of Article 57 database, together a procedure to qualify the medicinal registration data. Those actions will introduce additional benefits to cross-border ePrescription business cases.

[29] In view of the timelines for the Article 57 data maintenance submission and the data validation performed by the EMA, the Article 57 database is expected to be functional to support the business cases in Q1 2015 provided that pharmaceutical industry complies with the Article 57 legal obligation. The Agency will work closely with the eHealth Network to monitor compliance and introduce corrective actions.

Article 12: Terminology standards

(no supplementary requirements)

Article 13: Master Catalogue

(no supplementary requirements)

Chapter IV – Technical Provisions

Article 14: Minimum technical requirements for cross-border ePrescriptions

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

As electronic medication services take place in the field of public health and in accordance with Article 11 of Directive 2011/24/EU, the goal must be to use open standards wherever possible.

The fundamental requirement for exchange of information is to use a structured approach to the recording of information.

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 work in epSOS was based on the following technical components:

(a) For encoding of text the international encoding standard Unicode UTF-8 (UCS Transformation Format—8-bit) or higher
(b) Extensible Markup Language (XML) as an open and human as well as machine readable standard for exchanging data
(c) HL7 (Health level 7) CDA (Clinical Document Architecture) Release 2, Level 3 standards
(d) Medicinal products described using the current Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs (but note comments elsewhere on the limitations of this approach)
(e) The dose form, route of administration and packaging of the medication shall be described using European Directorate for the Quality of Medicines and Healthcare (EDQM) conventions.

Article 15: Data security

(no supplementary requirements)

Article 16: Interoperability testing, audit and compliance model

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, to build their own NCPeH solution.

In epSOS, regardless of the adopted solution, all participating nations were required to follow the testing strategies in which:

- The demonstration of compliance with the adopted normative standards (e.g. IHE, HL7) by independent third party(ies) (in epSOS, IHE International via the Gazelle Test Tools and Connectathon interoperability testing events).
- The establishment (at least in the epSOS LSP) of two environments:

- The Pre-Production Test (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.

4.2.4 Annex: ePrescription dataset

This Annex provides further information on the data items in the proposed dataset as well as a number of comments based on epSOS' experiences.

Fields	Field description	Notes
A.1 Core data elements		
A.1.1 Identification of the patient		
A.1.1.1 Surname	Surname of the patient. The part of a name a person usually has in common with some other members of his/her family, as distinguished from his/her given names [ISO TS 22220].	
A.1.1.2 Given name	Given name of the patient (also known as first name). The subject's identifying name(s) within the family group or by which the subject is uniquely socially identified [ISO TS 22220].	
A.1.1.3 Date of birth	The date of birth of the patient [ISO TS 22220]. Information regarding the age of the patient should be noted. This can either be the date of birth and/or the actual age of the patient. Since age affects drug ADMET (absorption, distribution, metabolism, excretion and toxicity) parameters, this is important for the choice of drug and drug dosage.	
A.1.1.4 Personal identifier	A machine-readable identifier of the patient that is unique within a defined scope	
A.1.1.5 Gender	Gender is the biological distinction between male and female [ISO TS 22220]. The gender of the patient may be noted on the prescription since this can be important for gender specific effects of drugs, contra-indications etc.	Should be mandatory
A.1.2 Authentication of the prescription		
A.1.2.1 Prescription ID	*A unique string generated by an EPS (Electronic Prescribing System) to uniquely identify a prescription. The prescription should receive a unique identifying code for traceability. It might additionally be used to register whether a prescription, and/or the maximum number of repeats, has already been dispensed to prevent patients from receiving medicines several times using the same prescription.*	In epSOS: - Prescription item ID: mandatory - To identify each prescribed medicinal product in the eP A specific process is set up in epSOS to deal with eP with multiple items, and multiple and single eD
A.1.2.2 Issue date	The date and optionally the time the prescription was issued by the prescriber. The date and time should be known in order to be able to conduct checks on medication safety as well as reimbursement of the prescribed drug(s) and whether the prescription is still valid to trigger a dispensing event.	
A.1.3 Identification of the prescribing health professional		
A.1.3.1 Surname	The prescription should state the family name/surname/last name of the prescriber. This enables the prescriber to be traced in the event of questions or emergencies.	

A.1.3.2 Given name	The prescription should state the given name/first name of the prescriber. This enables the prescriber to be traced in the event of questions or emergencies.	[AT] In some cases only the name of the medical organisation will be used instead of the name of the health professional.
A.1.3.3 Professional qualifications	The professional title of the prescribing health professional which may be used to prove the authority of the prescriber. Note: in some countries, a nurse or midwife might not possess a professional title, but may still be entitled to prescribe (certain) drugs.	Profession: compulsory, speciality: optional
A.1.3.4 Details of direct contact	Details of direct contact could be an address and/or phone/fax number of the prescriber in order for the dispenser and/or patient to contact the prescriber. This might be necessary if problems arise with dosage, allergies, reimbursement etc.	This is optional in epSOS: hard to contact a GP in another country in real time
A.1.3.5 Work address	This is the address of the hospital or the private practice where the health professional normally works, meets patients and prescribes medication.	This is optional
A.1.3.6 (Digital or electronic) signature	Most countries require by law either a handwritten signature or a digital token as proof of the authenticity of the prescriber. A digital signature is an approved authentication token necessary to comply with national laws on prescribing medicines. A prescribing message or document without this signature can only be regarded as a notice of the actual (paper) prescription.	Not supported by epSOS: it should at least be optional Business process issue – time consuming – user acceptance
A.1.3.7 Health care provider identifier (HCPI)	A unique number or code issued for the purpose of identifying a health care provider [ISO/TS 27527:2010]. A unique identification code that can be used to trace the prescriber at all times. This may be a licence or registration number that can be used to uniquely identify the prescriber. This can be used to check whether a drug was prescribed by the right person according to the law.	
A.1.4 Identification of the prescribed product **active ingredients, PhP, MP, PC**		
A.1.4.1 Name of the item	An identification of the medicinal product [i.e. any substance or combination of substances that may be administered to human beings for treating or preventing disease, with a view to making a medical diagnosis or to restore, correct or modify physiological functions] that is prescribed to the patient. In addition, information may be included regarding the possibility to replace the prescribed product with an alternative equivalent product. Note: the term product includes pharmaceutical products (branded medicinal products, generic/scientific name medicinal products or pharmaceutical preparations [ISO 21549-7:2007]) or non-pharmaceutical products.	Ref to IDMP
A.1.4.2 Identifier of the item	Medicinal product manufactured in a pharmacy or pharmacy department, which is based on a recipe and is intended to be used for one and only one subject of care [ISO 21549-7:2007]. Note 1: a magistral/extemporaneous medicinal product is also a pharmaceutical product. Note 2: the term extemporaneous medicinal product is not to be used, as it is more appropriate for describing a medicine processed during the administration of a medicinal product, especially when a mixture is made just before, for example, intravenous administration. Information about the constituent ingredients if the prescription concerns an extemporaneous preparation or compound medicine.	

A.1.4.3 Strength of the item	The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form. [Article 1 of Directive 2001/83/EC] Note: strength of the medicinal product may also be derived from the element 'dose regimen'. If for example the prescription contains a statement such as 'take 10mg 3x daily for 9 days' the strength can be derived from this. In such circumstances, strength may not be provided separately.	It cannot be expressed separately from A.1.4.1 because the strength/dilution as a ratio should be provided for each active ingredient in compounds.
A.1.5 Prescription information		
A.1.5.1 Pharmaceutical formulation	The formula in which the prescribed medicinal product is/will be administered (e.g. Tablet, solution, ointment)	
A.1.5.2 Quantity	Total quantity or volume of the medicinal product that is prescribed Note 1: in some cases quantity might be derived from element 1.5.3 Dose regimen. In this case, the quantity does not need to be stated separately. Note 2: depending on national legislation, this quantity may or may not be dispensed in one dispensation.	This is a complex concept: simple in the case of pills, more complex for liquids. Very various and complex for packs of packages (e.g. 10 syringes of 1 ml).
A.1.5.3 Dose regimen	The regimen governing the dose quantity per single administration, the dose frequency, the route of administration and/or speed of administration (in the event of intravenous administration). Note: this information may be used by the dispenser to calculate the quantity to be dispensed.	Few MS have it. Even less as coded element: optional in epSOS
A.1.5.4 Duration of treatment	Start and/or stop time of treatment	
A.1.5.5 Directions for use	Details about the directions for use of the prescribed medicinal product, such as 'with food' or 'before a meal') and any cautionary advice for correct use of the prescribed drug by the patient	Nearly none has this as a coded concept Since several data elements are not specified in the implementation guide, nor ValueSets are defined, a roadmap for their specification and the identification of the entities in charge of that, should be defined.
A.1.5.6 Pharmaceutical preparation description	This also includes extemporaneous preparation, compounded medication and magistral preparation.	
A.2 Optional elements of prescription		
A.2.1 Identification of the patient		
A.2.1.1 Address details	The address details of the patient. In some countries (e.g. Germany) it is sometimes required that the patient's address details are included on the prescription.	
A.2.1.2 Native language [could be taken from the ISO language table (ISO 639.2 or ISO 639-3)]	The native language of the patient. This may be important for the information that is given to the patient regarding use of the prescribed product [N1228 ISO NP TS 17251]. This could be taken from the ISO language table (ISO 639.2 or ISO 639-3 for three character list of languages) or another language specification code system.	Native language of whom? The patient? The prescriber? Country of origin of the eP is mandatory, not optional

A.2.2 Patient characteristics		
A.2.2.1 Body weight	The weight of the patient. This can be important for calculating the BMI used for dosage calculation, e.g. oncology medication, or also body surface for other specific medications; this will need to specify units of measure.	
A.2.2.2 Body height	The height of the patient. This can be important for calculating the BMI used for dosage calculation, e.g. oncology medication; this will need to specify units of measure.	
A.2.2.3 Drug allergies and drug sensitivities	Information regarding allergies and sensitivities to medicinal products (e.g. certain antibiotics), drug groups and both active and non-active ingredients may be noted.	
A.2.2.4 Patient conditions	Conditions that affect the use of medicinal products, such as renal/hepatic failure, pregnancy and pharmacogenetic profile. Some medicinal products may alter fertility, harm an unborn child or affect a child via breastfeeding. This may result in another (type of) medicinal product being dispensed and/or modification of the dosage regimen. This may also be important when the person is intending to become pregnant. Note 1: in some countries a change of the medicinal product or modification of the dosage regimen does not lie within the competence of the dispenser. Note 2: in some cases the effect on fertility or pregnancy has not yet been scientifically established.	
A.2.3 Prescription information		
A.2.3.1 Starting date of therapy	The time and date on which it is agreed that therapy will start	End of the therapy is also an optional item of data in epSOS
A.2.3.2 Prescription expiry date	*The date and optionally time when the prescription is considered to have expired. This might be dependent on local or national policy or legislation, in accordance with the treatment plan or because the therapeutic need for the prescribed medicine has expired. In some countries (e.g. Germany) legislation is so clear that it is not necessary to include it in the prescription.*	Not implemented
A.2.3.3 Repeats	Whether an issued prescription allows for several repeating dispensations [5]. In some countries, when medicinal products are dispensed for the first time, the patient may only receive medication for a short period of time. When a patient starts taking medication for a chronic illness, the prescriber can issue a prescription for a longer period that is now separated by repeats. In addition, the maximum quantity (A.1.5.2) of the prescribed product that may be dispensed in one dispensation may be stated here.	Not implemented
A.2.3.4 Minimum dispensing interval	If an issued prescription allows for several repeating dispensations (A.2.3.3) the minimum time interval between dispensations should be stated here [e.g. 5]. This can be important in the case of medicinal products of which patients are prone to take overdoses, e.g. opioids.	Not implemented
A.2.3.5 Reason for prescription	The reason why the medicine is being prescribed, including the option to mention that the medicinal product is being prescribed for 'off label' use. The reason for the prescription gives the dispenser the opportunity to review the prescription for medication safety issues. Note: in some countries it is obligatory to state the reason for prescription on the prescription itself for some or all medicinal products. An example of this in the Netherlands is the	Not implemented

	prescription of methotrexate, since the indication for which it is used in the Netherlands (chemotherapy or rheumatoid arthritis) greatly impacts both strength and dose interval of the medication.	
A2.3.6 Substitution	Substitution handling can be recorded as a code (not a flag!) to indicate whether and to what extent substitution is allowed by the prescriber.	

4.2.5 Example profiles

This Annex provides reference information on standards and profiles.

ISO Identification of Medicinal Products (IDMP) standards

- ISO 11615:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55034)
- ISO 11238:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55031)
- ISO 11616:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55035)
- ISO 11239:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55032)
- ISO 11240:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55033)

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 (May need to be validated)

[1a] EXPAND "epSOS Patient Summary, ePrescription eDispensation and Common Modules HL7 CDA R2 Implementation Guide."
https://service.projectplace.com/pp/pp.cgi/r1147714042

[1b] epSOS Patient Summary, ePrescription eDispensation and Common Modules HL7 CDA R2 Implementation Guide published on ART DECOR[30]:

https://art-decor.org/art-decor/decor-project--epsos-

[1c] Master Value Catalogue https://ecrtsppt.conet-services.de/ . An informal excel export of the MVC 2.0 is available on https://service.projectplace.com/pp/pp.cgi/r1193682804; An informal html version is accessible through the ART DECOR based specifications (https://art-decor.org/art-decor/decor-valuesets--epsos-)

[2] Clinical Document Architecture Release 2:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[3] IHE Patient Care Coordination Technical Framework
http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_TF_Vol2.pdf

[4] Work Package 3.4 - epSOS_Common_Components_Specification_01

http://www.epsos.eu/uploads/tx_epsosfileshare/D3.4.2_epSOS_Common_Components_Specification_01.pdf

[30] At the time of publication of this document the ART DECOR® representation is an informative release of the epSOS CDAs Implementation Guides.

[5] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Patient Discovery (XCPD) http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XCPD.pdf

[6] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Access (XCA) http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf