



X-eHealth

Exchanging Electronic Health Records
in a common framework

D5.5 – Hospital Discharge Reports guideline and functional specifications

WP5 – DEFINITION OF EHRXF FUNCTIONAL SPECIFICATIONS

30-08-2021

Version 1.6

Status: Final

Abstract

Hospital discharge reports serve as the primary documents communicating a patient's episode of care related to hospitalisation. The aim of this document is to provide the necessary legal, organisational, and technical requirements for the structured definition for a common approach to an EU hospital discharge report. It gives added value to the existing Patient Summary, however, with the focus on extending the scope of cross-border data exchange services in healthcare to a standardised hospital discharge report that is interoperable across the EU Member States. This aim is supported by an information model for a common approach to a European hospital discharge report that is based on the European Electronic Health Record exchange format (EHRx). This information model is used to represent the concepts commonly used in hospital discharge reports and the relationships, constraints, rules, and operations to specify data semantics for a common approach to hospital discharge reporting in the EU. Furthermore, the document makes a detailed description of all relevant use cases and actors for the future hospital discharge report service, as well as listing functional and non-functional requirements for its implementation.

Key Words: Hospital Discharge Report; EHRx

DOCUMENT CONTROL	
Document name	D5.5 – Hospital Discharge Reports guideline and functional specifications
Work Package	WP5 – Definition of EHRxF Functional Specification
Dissemination level	PU
Revision	1.6
Status	Final
Authors	Vanja Pajić, Klára Jiráková, Hynek Kružík, Katre Pruul, Juan Antonio De Los Cobos, Sara Russo, Caitriona Wray, Jiří Keller, Pavla Doležalová
Reviewers	David Rodríguez Cocinero, Marcello Melgara, Giorgio Cangilioli, Andries Nelissen, Gergely Héja, Manne Anderson, Vincent van Pelt
Beneficiary(ies)	Kraj Vysočina, SPMS, FPS, HL7, MZCR, MSAE, AEEK, SAM, NICTIZ, NCZI, TIC Salut, DOH

Dissemination level: PU = Public, for wide dissemination (public deliverables shall be of a professional standard in a form suitable for print or electronic publication) or CO = Confidential, limited to project participants and European Commission.

REVISION HISTORY				
Revision	Date	Author	Organisation	Description
1.0	2021-09-08	Vanja Pajić, Hynek Kružík, Klára Jiráková	Vysočina reg.	First mature version produced for informal EC review
1.1	2022-01-05	Vanja Pajić, Hynek Kružík, Klára Jiráková, Katre Pruul, Sara Russo, Pavla Doležalová, Jiří Keller, Caitriona Wray	Vysočina reg., NCEZ (MoH CZ), MSAE, TICSALUT, SPMS, FPS Public Health, DOH	Update of the logical model
1.2	2022-01-31	Vanja Pajić, Hynek Kružík, Klára Jiráková, Katre Pruul, Sara Russo, Pavla Doležalová, Jiří Keller, Caitriona Wray, Gergely Héja	Vysočina reg., NCEZ (MoH CZ), MSAE, TICSALUT, SPMS, FPS Public Health, DOH	2nd intermediate deliverable
1.3	2022-05-30	Vanja Pajić, Hynek Kružík, Klára Jiráková, Katre Pruul, Sara Russo, Pavla Doležalová, Jiří Keller, Caitriona Wray, Gergely Héja	Vysočina reg., NCEZ (MoH CZ), MSAE, TICSALUT, SPMS, FPS Public Health, DOH	3rd intermediate deliverable

REVISION HISTORY				
Revision	Date	Author	Organisation	Description
1.4		Vanja Pajić, Katre Pruul, Caitriona Wray	Vysočina reg., MSAE, DOH	Pre-final revision of the document, consolidation of comments from previous stages of work
1.5		Vanja Pajić	Vysočina reg.	Final revision of the document before submission to Project Coordinator
1.6		Vanja Pajić, Hynek Kružík	Vysočina reg., NCEZ (MoH CZ),	Final document for submission to Project Coordinator

Ref. n.	Document
	X-eHealth Grant Agreement n. 951938
	Annex I – X-eHealth Proposal
	Commission Recommendation on EHRxP

Disclaimer and statement of originality

The content of this deliverable represents the views of the authors only and is their sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use of its contents. This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Statement of confidentiality

This statement of confidentiality applies to all personal identifiable information, whether written, computerized or audio record. The X-eHealth project hereby states that the personal data and any related personal information used to frame the content of this document is held in trust and strict confidence, by a secure and certified platform, and it shall be used only for the purposes required to fulfil this document specific end, and shall not be used for any other purpose, or disclosed to any third party.

Table of Contents

Terms and Abbreviations	2
List of Figures	3
List of Tables.....	3
1 Scope and Interdependencies.....	4
1.1 In scope	4
1.2 Out of scope	4
1.3 Interdependencies.....	4
2 INTRODUCTION	6
2.1 DESCRIPTION OF THE DOMAIN	6
2.2 CHALLENGES AND OPPORTUNITIES	6
2.3 OVERALL AMBITION	7
3 OBJECTIVES AND PRINCIPLES	8
3.1 PURPOSE	8
4 METHODOLOGY.....	9
4.1 STEPS PERFORMED	9
4.2 CONSIDERATIONS.....	10
4.2.1 Legal and regulatory considerations	10
4.2.2 Policy considerations.....	10
4.2.3 Terminology considerations	10
4.2.4 Other semantic considerations	11
4.3 LEGAL BASIS OF THIS DOCUMENT.....	13
4.4 PROCESS OF DEVELOPING THE GUIDELINES	14
4.4.1 Analysis of the existing material.....	14
4.5 INTRODUCTION TO EU HOSPITAL DISCHARGE REPORT LOGICAL MODELLING	17
4.5.1 Understanding Containers, Data and Code lists	18
4.5.2 Understanding Class Diagrams and Elements Lists	18
4.5.3 Understanding Cardinality.....	19
5 EU HOSPITAL DISCHARGE REPORT INFORMATION MODEL SPECIFICATIONS	20
5.1 List of EU hospital discharge report information building blocks/modules to be used for implementation purposes	20
5.1.1 Administration Module	20
5.1.2 Admission Evaluation Module	20
5.1.3 Patient History Module	21
5.1.4 Hospital Stay (Detailed In-patient Episode of Care) Module.....	23
5.1.5 Encounter (Summary of In-patient Episode of Care) Module	25
5.1.6 Discharge details.....	25

5.2	HOSPITAL DISCHARGE REPORT: A LOGICAL MODEL	26
6	<i>EU HOSPITAL DISCHARGE REPORT USE CASES AND IMPLEMENTATION SCENARIOS</i>	33
6.1	USE CASE IDENTIFICATION	33
6.2	USER ROLES' IDENTIFICATION AND DESCRIPTION	34
6.3	USE CASE DESCRIPTION	35
6.4	ACTORS' IDENTIFICATION AND DESCRIPTION	41
6.4.1	Human Actors	41
6.4.2	Institutional Actors	42
6.4.3	Information System (IS) Actors	42
7	<i>FUNCTIONAL AND NON-FUNCTIONAL REQUIREMENTS FOR THE EU HOSPITAL DISCHARGE REPORT.....</i>	44
7.1	REQUIREMENTS IDENTIFICATION AND DESCRIPTION	44
7.1.1	General requirements for a common EU hospital discharge report	44
7.2	REQUIREMENTS' DESCRIPTION	44
7.2.1	Functional Requirements	44
7.2.2	Non-Functional Requirements	52
8	CONCLUSION	62
9	REFERENCES	63

Terms and Abbreviations

Term	Description
Hospital Discharge Report	Primary clinical documents communicating a patient's episode of care during a hospital stay care to healthcare professionals. They typically include a patient's medical history, a summary of the hospital stays, and care plan for the post-hospital care team, other medical specialists or general practitioners / family doctors.
Episode of care	A health-related period during which healthcare activities are performed to address one health issue as identified by the healthcare professional.
Hospital encounter	An event or a series of events typically linked to a specific episode of care performed and completed within a single hospital setting.

Acronym	Description
HDR	Hospital Discharge Report
CDA	Clinical Document Architecture
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
EHRx/EEHRx/EEHRx	Electronic Health Record Exchange Format / (used interchangeably with) European Electronic Health Record Exchange Format
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
HP/HCP	Health Care Professional
HPO	Human Phenotype Ontology
ICD	International Classification of Diseases
IHE	Integrating the Healthcare Enterprise
LOINC	Logical Observation Identifiers Names and Codes
MVC	Master Value Sets Catalogue
NCP/NCPeH	National Contact Point
ORPHANet	a database dedicated to providing information on rare diseases and orphan drugs
PHR/PCHR	Personal Health Record / Personally Controlled Health Record
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms

List of Figures

<i>Figure 1: A building-block approach to modelling the common EU hospital discharge report that follows a typical hospital discharge workflow from admission to discharge from the hospital.</i>	<i>27</i>
<i>Figure 2: A logical model of the common EU hospital discharge report.....</i>	<i>28</i>

List of Tables

<i>Table 1: Hospital Discharge Report information models. Figure 1: A building-block approach to modelling the common EU hospital discharge report that follows a typical hospital discharge workflow from admission to discharge from the hospital.</i>	<i>29</i>
<i>Table 2: List of Hospital discharge Report use cases for cross-border EHRxF.....</i>	<i>33</i>
<i>Table 3: Use case descriptions for the Hospital Discharge Report domain, for the continuity of care ("Push") scenario.....</i>	<i>36</i>
<i>Table 4: Use case descriptions for the Hospital Discharge Report domain, for the patient/legal representative.</i>	<i>38</i>
<i>Table 5: Use case descriptions for the Hospital Discharge Report domain, for the "Pull" scenario.</i>	<i>40</i>
<i>Table 6: Functional Requirement 01: Healthcare Professional Identification, authentication and authorisation.</i>	<i>45</i>
<i>Table 7: Functional Requirement 02: Patient identification.</i>	<i>46</i>
<i>Table 8: Functional Requirement 03: Patient's legal representative identification and authentication. ...</i>	<i>47</i>
<i>Table 9: Functional Requirement 04: Structured Information.....</i>	<i>48</i>
<i>Table 10: Functional Requirement 05: Equivalent Information.....</i>	<i>48</i>
<i>Table 11: Functional Requirement 06: Information Understandability.....</i>	<i>49</i>
<i>Table 12: Functional Requirement 07: Information Traceability.....</i>	<i>50</i>
<i>Table 13: Functional Requirement 08: Storing of the Hospital Discharge Report as part of the patient Electronic Hospital Record / Electronic Medical Record.</i>	<i>51</i>
<i>Table 14: Non-functional Requirement 01: Service availability.....</i>	<i>52</i>
<i>Table 15: Non-functional Requirement 02: Communications.....</i>	<i>53</i>
<i>Table 16: Non-functional Requirement 03: Response time.</i>	<i>54</i>
<i>Table 17: Non-functional Requirement 04: Confidentiality.</i>	<i>55</i>
<i>Table 18: Non-functional Requirement 05: Access Control.</i>	<i>56</i>
<i>Table 19: Non-functional Requirement 06: Audit Control.</i>	<i>56</i>
<i>Table 20: Non-functional Requirement 07: Integrity.....</i>	<i>58</i>
<i>Table 21: Non-functional Requirement 08: Non-repudiation.....</i>	<i>59</i>
<i>Table 22: Non-functional Requirement 09: Guaranteed delivery.....</i>	<i>59</i>
<i>Table 23: Non-functional Requirement 10: Supervision services.....</i>	<i>60</i>
<i>Table 24: Non-functional Requirement 11: Timely completion and release of the documentation of inpatient stay.....</i>	<i>60</i>

1 Scope and Interdependencies

1.1 In scope

This document will cover all aspects of hospital discharge reports pertaining to the continuity of care between national and cross-border settings, including inpatient care in the following scenarios:

- Discharges from all inpatient care settings, including general hospitals, mental health hospitals, and other specialised hospitals or healthcare institutions which produce a document that can be considered as a hospital discharge report (e.g., nursing homes in some Member States).
- Emergency cases and urgent admissions when they resulted in an overnight stay and formal admission.
- Inpatient cases (an inpatient discharge is the release of a patient who was formally admitted into a hospital for treatment and/or care and who stayed for a minimum of one day/night).
- Special types of an inpatient cases, e.g., a case of nursing care.

1.2 Out of scope

This document will not cover scenarios not included in the previous list, e.g., outpatient/ambulatory care, emergency care that doesn't result in an inpatient hospital stay, and/or day care. Such scenarios might be added at a later date to a future version of this document, when and if needed.

1.3 Interdependencies

- D4.2.1 – Information paper on the current challenges in legal aspects of cross-border exchange of personal data
- D4.2.2 – Recommendation paper on legislative enablers for cross-border personal data interoperability
- D4.3.2 – Policy recommendation for EU level actions to achieve digital health data trust in the cyber space
- D5.1 - X-eHealth use cases driven methodology
- D5.2 - EEHRxF and its relationship with clinical guidelines
- D5.3 - Laboratory Requests and Reports guideline and functional specifications
- D5.4 - Medical Imaging and Reports guideline and functional specifications

- D5.6 - Refine PS functional specifications to account for eHN Guidelines and rare diseases
- D5.7 -Final Conclusions and Recommendations
- D6.1 - X-eHealth Services Specification
- D6.3 - X-eHealth Implementation Guide
- ID6.3 - X-eHealth Implementation Guide: Hospital Discharge Report
- D7.1 - EEHRxF architecture specifications
- D7.3 - Possible upgrades of eHDSI core and generic services
- D7.4 - Proposal guidelines to implement EEHRxF in National Services

2 INTRODUCTION

2.1 DESCRIPTION OF THE DOMAIN

A hospital discharge is the formal release of a patient from a hospital after a procedure or course of treatment. Hospital discharge reports are individualised instructions provided to the patient as they move from the hospital to home or instructions provided to subsequent healthcare providers as they move to a care facility while also providing information on the relevant diagnosis or treatment given while patient was in hospital (1).

An inpatient is a patient who is formally admitted (i.e., hospitalised) to an institution for treatment and/or care and stays for a minimum of one night or more than 24 hours in the hospital or other institution providing inpatient care. An inpatient case involves examination and treatment of a patient in one healthcare provider organisation from hospitalisation to discharge (i.e., patient was discharged from a hospital, referred to another hospital or died).

A hospital discharge occurs whenever a patient leaves the hospital after e.g., the finalisation of a treatment, a transfer to another health care institution or upon the death of the patient. Therefore, a hospital discharge report is a summary of a patient's medical case during hospital treatment, which reflects the dynamics of a given treatment episode based on the information available to the doctor. As such, the hospital discharge summary of a hospital encounter is compiled at the end of an inpatient case for the patient. The number of discharges is the most used measure of the utilisation of hospital services. Discharges, rather than admissions, are used because hospital abstracts for inpatient care are based on information gathered at the time of discharge. Diagnostic chapters (using principal diagnosis) have been defined according to the International Classification of Diseases (ICD) (2).

2.2 CHALLENGES AND OPPORTUNITIES

The political drive for cross border care within the European Union (EU) and an increasing focus on integrated care both have implications for Electronic Health Records (EHRs). The hospital discharge summary is a critical component to ensure quality and continuity of care and an electronic version is of particular benefit in a cross-border setting. However, due to the complexity of national healthcare systems across the EU and the lack of uniformity in the discharge information among the Member States, the safe and accurate exchange of cross-border exchange of planned hospital care information between EU treatment settings remains both a challenge and an opportunity. Significant progress has been made in recent years towards the implementation of cross-border solutions in healthcare, however, the achievement of a European level interoperable discharge summary is a goal yet to be achieved (3).

The aim of this document is to provide the necessary legal, organisational, and technical requirements for the structured definition for a **common European approach to a hospital discharge report**. It will provide additional information to the existing European Patient

Summary (4), however, with the focus on extending the scope of cross-border data exchange services in healthcare (5) to a standardised hospital discharge report that is interoperable across the EU Member States.

Note that the current scope of the Hospital discharge report service is intended for the healthcare professionals to have access to the patients' data (i.e., as an "extension" to the cross-border Patient Summary service already provided within the MyHealth@EU) and not the patient (which would be the so called "evolution" of the service thus extending its functionality to other applications and uses).

2.3 OVERALL AMBITION

While there are many benefits to implementing a common EU hospital discharge report, ultimately, the main beneficiary is the European citizen as a patient. A hospital discharge report plays a crucial role in keeping patients safe after leaving a hospital. With a growing number of European citizens working and living in other Member States, it is increasingly important to achieve a way of exchanging hospital discharge information across the EU in a way that keeps the confidentiality, integrity, and availability of patient information. Other benefits include reduced costs of treatment, ease of access to patient data for healthcare professionals, reduction of unnecessary laboratory tests etc.

Furthermore, the expected benefit of implementing such a standardised hospital discharge report across the EU is to add value to the role of healthcare professionals in Member States, by ensuring a safe and reliable way of accessing patient information, even for patients coming from different countries.

Additionally, the foreseen use for this common EU hospital discharge report is to support the Member State in healthcare policy formation, healthcare system performance monitoring, performing medical research, and managing patient privacy. In the future, the common hospital discharge report may be used to provide statistical information, reports and analyses about the trends in the delivery of hospitalisation services both nationally and on a provider basis, across a series of medical specialisations, as well as reimbursement purposes.

3 OBJECTIVES AND PRINCIPLES

3.1 PURPOSE

Hospital discharge reports serve as the primary documents communicating a patient's episode of care related to hospitalisation (6). Often, the hospital discharge report is the only form of communication that accompanies the patient to the next setting of care. High-quality discharge reports are generally thought to be essential for promoting patient safety during transitions between care settings, particularly during the initial post-hospital period (7). Additionally, hospital discharge reports also provide information intended for the patients themselves, informing them about their health status and the following steps related to care (e.g., recommendations from the medical specialist) (8).

The purpose of this document is to propose a set of functional requirements for the creation of the European hospital discharge report, as an extension to the current scope of the Patient Summary in the context of the eHealth Digital Service Infrastructure (eHDSI). Furthermore, it will provide an information model for a common approach to a European hospital discharge report that is aligned with the European Electronic Health Record exchange format (EHRXF) (9). The proposed Hospital Discharge Report is based on an information model which reflects the business requirements coming from healthcare providers in EU Member States. This information model is used to represent the concepts commonly used in hospital discharge reports and the relationships, constraints, rules, and operations to specify data semantics for a common approach to hospital discharge reporting in the EU.

4 METHODOLOGY

The hospital discharge report described in this document is based on existing international standards, best practices from EU Member States, current eHDSI documents used in cross-border exchange of patient data and work done in the scope of the X-eHealth project.

In this document, use cases for the implementation of a common EU hospital discharge report are extensively defined. Additionally, an information model of a typical hospital discharge report is provided to reflect the specific business requirements of the future implementations in Member States and within the scope of eHDSI. Also, functional and non-functional requirements for the hospital discharge report are listed and elaborated on in the appropriate sections below.

4.1 STEPS PERFORMED

The main objective of this task is to provide a guideline for the implementation of a common EU hospital discharge report, in such a way that it enables an interoperable patient data exchange across the Member States' borders and between healthcare providers within one or more EU Member States.

The specific steps performed in this task include the following:

A. DEFINING a common EU hospital discharge report

Performing a literature search on hospital discharge reports, focusing on the EU Member States;

Consulting with various healthcare, policy and academic institutions in EU Member States and collecting information on typical hospital discharge reports;

B. MAPPING and ANALYSING the use cases for the cross-border exchange of hospital discharge reports across the EU

Collecting relevant business requirements for the use and exchange of hospital discharge report data in the EU Member States;

C. CREATING an information model document for a common EU hospital discharge report based on EEHRxF

Defining the data elements of a typical hospital discharge report;

Defining relevant standards, medical ontologies and terminologies used in the definition of typical data elements in hospital discharge reports.

4.2 CONSIDERATIONS

4.2.1 Legal and regulatory considerations

Preconditional aspects include relevant EU and Member States' laws and regulations.

4.2.2 Policy considerations

Organisational requirements include various non-binding instruments and preconditions set in various policy documents (e.g., eHealth Network's recommendations and guidelines), as well as a body of relevant implementation documentation (e.g., eHDSI documentation) (10).

4.2.3 Terminology considerations

A hospital discharge report is generally created using the native language of the country where the healthcare provider is located (in combination with medical Latin). If this language is different from the patient's native one and the future care is transferred to the patient's country of affiliation, then relevant sections should be, at a minimum, provided in English and ideally in both the languages of the patient and the official language used by the healthcare provider.

This document will not go into much detail regarding differences in medical terminology used in Member States. However, several overarching terms need will be explained below to distinguish a hospital discharge report from other clinical documents.

4.2.3.1 *Episode of Care*

An "episode of care" is defined as a health-related period during which healthcare activities are performed to address one health issue as identified by the healthcare professional (11). These typically account for all the services provided to a patient with a medical problem, within a specific period across a continuum of care in an integrated system. Therefore, an episode of care encompasses all healthcare activities (such as diagnostic tests, treatment, and medication given to the patient) related to the same health issue. An episode of care starts with the very first contact with a healthcare provider for a health issue and it ends after the completion of all healthcare activities related to the last contact with that healthcare provider for the same health issue. For practical reasons (e.g., the need to state start and end dates of an episode of care) and because it relates specifically to a health issue defined by a given healthcare professional, an episode of care does not necessarily coincide with an "episode of illness" (or of disease, or of any other kind of health issue). During a mandated period of care several health issues may be

handled and as such be linked to several episodes of care. These episodes of care are said to be “concurrent”. Examples include an episode of urinary tract infection, an episode of cholecystectomy.

4.2.3.2 *Hospital encounter*

A “hospital encounter” may be considered as a one single event or a series of events typically linked to a specific episode of care performed and completed within a single hospital setting, e.g., starting as a referral from an emergency department to which the patient was initially admitted, the moving of the patient to an inpatient acute department for surgery, and finally accounting for the patient’s discharge from the hospital. In this document, the hospital discharge report is encompassing all treatment events during a hospital encounter usually manifesting as a hospital admission, stay and discharge.

4.2.3.3 *Clinical finding vs. observation*

Clinical finding and clinical observation are sometimes used interchangeably. However, we have opted for defining a clinical finding as a direct result of a clinical research or an investigation while we refer to a clinical observation as the act of observing (the patient), and the fact of being observed.

4.2.3.4 *Other terms used*

Note that other medical and miscellaneous technical terms were used in the definition of a logical model for hospital discharge reports. These terms and their explanations can be found in the Appendix, under the appropriate model.

4.2.4 Other semantic considerations

4.2.4.1 *Lexical semantics considerations*

Lexical semantics cover the wide area of the meaning of the text. This includes individual terms (terminology) and their combination in sentences (syntax). Typical disease features (description) and events (disease evolution, diagnostic and therapeutic actions) often have a traditional way how they are expressed. This “tradition” has been transcribed into medical terminologies, clinical classifications and nomenclatures as well as various ontologies (e.g., Human Phenotype Ontology, HPO, for rare disease description).

4.2.4.2 *Computational semantics considerations*

Computational semantics overlaps with lexical semantics as it processes abovementioned terminologies, nomenclatures and ontologies into a computerised interoperable format.

4.2.4.3 *Information considerations*

This document considers the existing traditional medical reporting that is generally shared by European healthcare professional community and offers a common logical structure, content and potential format/coding of individual information elements and relationships between them by defining the (a) data structures, (b) data elements, (c) terminology bindings.

The assumption here is that most European healthcare professionals are currently not closely familiar with standard nomenclatures/coding systems neither in creating or receiving healthcare-related documents such as the hospital discharge report. To allow implementation of interoperable hospital discharge reports across the EU in the future it is necessary to accept use of the narrative/free text in the way that is currently applied in various examples of European HDRs.

Therefore, this proposal uses generic units (“modules” and “resources”) of healthcare information, some of them being used in standards like HL7 CDA (12) or FHIR (13) and IHE (14) to allow for future integration of these structures as well as for the use of standard terminologies (e.g., LOINC and SNOMED-CT) (15, 16) once they are widely accepted and deployed.

Generic units could be seen as independent elements (building blocks) which may be used for various types of information needs, e.g., for the hospital discharge report use case (in scope of this project) or for other related projects (e.g., extensions to the European Patient Summary) (17).

4.2.4.4 *Conceptual semantic considerations*

The concept of a hospital discharge report as a clinical document defines properties that make it compatible with its use cases and that reflects relevant business requirements on which the use cases are based. For a hospital discharge report this means the truthful description of one concrete healthcare event, which is an episode of care during hospital stay. In broader meaning, a hospital discharge report must cover the following main types of information about the patient:

- **Demographic information:** Demographic/personal details of the patient and his/her caregivers as well as healthcare professionals involved in the current inpatient as well as related outpatient care
- **Past events/history (before current hospital stay):**

- Events that have led to the admission (relevant previous history)
 - Other health-related information (full personal, family, social history)
- **Current events (during hospital stay):**
 - Clinical description of the inpatient episode course from admission to discharge
 - Investigation results, procedures, diagnostic evaluation and treatments
- **Future events (after hospital stay):**
 - Instructions for management after discharge.

The extent of information (granularity) provided should be high enough to capture all information that may be potentially relevant to any healthcare services the patient may need in the future. As this cannot be fully anticipated by the information model, the granularity must be judged by the treating physician in relation to the type and degree of complexity of the case. In this respect emergency hospitalisation in an orthopaedic department for sport fracture will differ in its granularity from an inpatient stay for a fracture complicated by infection in a patient with a rare immunopathological condition.

4.2.4.5 Structural semantic considerations

Structure of the hospital discharge report as a clinical document is very closely related to its legibility as it allows better orientation and readability of the document, better understanding of the overall context and saves the time needed for retrieving the relevant patient data. Pieces of information should be presented in a logically sequenced well-defined categories / sections that are subdivided into subcategories / subsections that allow variable degree of granularity in the information model. Several rules should apply:

- Categories should include logically homogeneous information. E.g., when disease affecting multiple organs, systems are described (in a disease course section) by organ system involvement rather than combining all in a time-related manner. Another example goes for therapies – past, current, and future therapies should be summarised in one section, even if medication is mentioned in the disease course section as well. Certain degree of duplication therefore cannot be avoided.
- Hierarchical structure of the document.
- Meaningful sequence of sections and subsections within the document.

4.3 LEGAL BASIS OF THIS DOCUMENT

According to the primary responsibility of the Member States in the field of healthcare provision, as laid down in Article 168 (7) of the Treaty on the Functioning of the European Union (TFEU), these guidelines are legally non-binding.

The term “guideline” should therefore be interpreted as a set of non-binding recommendations. It is up to the willingness of each Member State to adopt this guideline and hence ensure that its national hospital discharge reports become suitable for both cross-border and national use.

This guideline should be reviewed in the light of its impact on the ongoing implementation of eHDSI. Additionally, it is recommended that the implementation of a common EU hospital discharge report should avoid interfering in the functioning and organisation of each Member State.

Furthermore, each Member State is ultimately responsible for the content of a common EU hospital discharge report. This means that it is left to the responsibility of every Member State when and how the hospital discharge report is created internally.

4.4 PROCESS OF DEVELOPING THE GUIDELINES

The guidelines have been developed in line with the process agreed by the X-eHealth project coordination.

To ensure monitoring and evaluation of cross-border services and related interoperability provisions and systems, Member States should consider setting up a facility as well as relevant policy, legal, organisational and technical mechanisms to enable progress on organisational, technical and semantic aspects for their successful implementation.

4.4.1 Analysis of the existing material

This section of the document will provide an overview of already available materials regarding existing protocols, guidelines and specifications, existing standards, profiles and terminologies, existing implementation examples for hospital discharge reports in the EU Member States.

4.4.1.1 Background information: Existing protocols, guidelines and specifications

4.4.1.1.1 National implementation Guides for electronic health records and hospital discharge reports

The implementation guides are documents that specify a set of rules of how a particular interoperability or standards problem can be solved using associated documentation to support and clarify the usage. In this way it can be reduced the ambiguity in the specification of an interoperability scenario. Various national implementation guides related to hospital discharge letters served as a resource of inspiration for the work on these functional specifications, namely

the discharge letters from Germany¹, Austria², Switzerland³, Italy⁴, Catalonia/Spain⁵, the Netherlands⁶, as well as different hospital discharge report examples from Estonia, Portugal, United Kingdom and Australia.

¹ The hospital discharge report under the name “Arztbrief 2014” was published as a new Implementation Guide for clinical discharge letters was balloted by HL7 Germany. The specification is actually an updated version of a previous German CDA R2 implementation guide published already in 2006. Due to the common language, this implementation guide has many similarities with the versions of the IG published as part of the ELGA project by the Switzerland and Austria. The specification was completely developed using ART-DECOR as a tool for templates, specification of value sets, and vocabulary binding.

² For the project ELGA, an implementation guideline for hospital discharge letters was specified using HL7 CDA R2 standard. The content requirements and the structure of the ELGA findings were developed together with numerous experts from the medical profession, nursing, hospitals, research as well as with representatives of the Austrian Medical Associations, standardisation organisations and software manufacturers and adopted as the national HL7 standard.

³ HL7 Switzerland has developed several implementation guides that can be found in the official webpage of the national HL7 organisation. CDA-CH 2020 V2.1 is intended to serve as an instrument to increase interoperability between service providers in the Swiss healthcare system and ensures that CDA-CH V2 documents can be optimally integrated into processes relating to the electronic patient record. In the section 5.2.9 of the CDA-CH 2020 V2.1 publication, it can be found the link to the implementation guide.

⁴ HL7 Italy published an implementation guide for the CDA, according to the HL7 CDA 2 standard of the hospital discharge letter.

⁵ In Catalonia, Spain, web services were defined for the publishing of clinical documents to HC3 - a shared Medical History of Catalonia database, from a patient generated at healthcare centre. An implementation guide was defined for each service web, including the CDA implementation guide for the hospital discharge report. HL7 Spain also defined an implementation guide for clinical documents following the CDA standard.

⁶ In the Netherlands, a national domain information model is developed to support information exchange via electronic patient records, and to support the adoption of the electronic patient record exchange format in Dutch healthcare practice. This model was used as the main source of inspiration for the EU hospital discharge report detailed in this document.

4.4.1.1.2 Existing standards and standardisation initiatives for electronic health records and hospital discharge reports

Additionally, different standards and healthcare standardisation initiatives were used to support the logical modelling and value set definitions of the EU hospital discharge report, namely: HL7 CDA Release 2⁷, HL7 V2.x⁸, HL7 FHIR⁹, IHE¹⁰.

⁷ HL7 CDA R2 is the basic standard for document interchange that provides an architecture, coding, semantic framework and markup language for the creation of clinical documents, using the HL7 information model (RIM), the HL7 V3 methodology and controlled or local vocabularies (SNOMED CT, ICD, LOINC, etc.). HL7 CDA documents are encoded in XML (Extensible Markup Language). CDA can support any kind of clinical information that can be included in a patient's medical record, like a discharge summary, prescriptions, history and physical examination, specialist reports, laboratory reports, diagnostics, immunisations, or discharge letters, among many other possibilities. CDA can be used as simple or complex as required, from sending a document with minimal contextual information, to fully encoded and referenced. A typical CDA consists of the header (CDA Header) and the body (CDA Body). The header identifies and classifies the document, and contains elements such as authentication, the encounter, the patient or the provider, while the body contains the clinical report (which can be structured or unstructured). The structured body is divided into sections that can be nested, and every section contains zero or more CDA entries. The entries represent structured components (derived from RIM classes), such as Act, Encounter, Observation, Procedure or Substance administration.

⁸ HL7 version 2.x is the messaging standard for the electronic interchange of health data from HL7 International most widely used internationally in the health field.

Some of its advantages are:

- It is compatible with most of the common interfaces used in the healthcare industry worldwide.
- Provides a framework for negotiations.
- Reduces implementation costs.
- Generally backward compatible with the standard.

The HL7 messages are generated and sent from one system to another when a trigger event occurred. A trigger event is the situation or circumstance that occurs in real life to generate the corresponding notification through a message, from a system A to a system B. For example, a trigger event occurs when there is an admission of a patient to a hospital and it is necessary that their data be sent to other systems.

The standard defines a wide variety of trigger events classified in different chapters. Every chapter treats different domains, like orders, queries, admissions, observations, etc. Specifically in chapter 3, the admission domain, it can be found the specification of the message Discharge/End Visit (Event A03, message type ADT).

The message ADT^A03 can be used to notify the end of a patient's stay in a healthcare facility. It signals that the patient's status has changed to "discharged" and that a discharge date has been recorded, therefore, in this type of message it can be attached (in HL7 CDA format codified on Base64) a hospital discharge report.

⁹ FHIR (Fast Healthcare Interoperability Resources) is the standard created by HL7 that combines the best features of messaging HL7 v2.x, H7 V3 and HL7 CDA. The standard is designed to enable the exchange of healthcare-related information, like clinical data as well as healthcare-related administrative, public health and research data. It can be used in a wide variety of contexts, including inpatient, ambulatory care, acute care, long-term care, community care, allied health, etc.

FHIR defines a set of "Resources" that represent granular clinical concepts, which can be managed in isolation or aggregated into complex documents.

Technically, FHIR is designed for the web, and it is quick to design and implement. The resources are based on simple XML or JSON structures, with an http-based RESTful protocol where each resource has a predictable URL.

FHIR not only define the "forms" for data exchange (Resources), but also defines a set of interfaces by which systems actually share that information through four primary mechanisms or "paradigms" supported by FHIR:

- via a REST interface,
- by exchanging Documents,
- by sending and receiving Messages
- by exposing and invoking Services.

The documents paradigms are a familiar mechanism for sharing information in the healthcare space. They're similar to HL7 CDA documents, as it can preserve the six main characteristics of clinical documents defined by CDA

4.5 INTRODUCTION TO EU HOSPITAL DISCHARGE REPORT LOGICAL MODELLING

This document contains a conceptual information model in which semantic information is included, representing the relevant concepts and the relationships, constraints, rules, and operations to specify data semantics for the common EU hospital discharge report. The models used here are logical data models that are used to define the structure of the data elements and set the relationships between them.

The information model for the common EU hospital discharge report is essentially a non-exhaustive list of key hospital discharge report components or modules organised into a hierarchical structure that reflects the varying relationships between them. It is based on models found by researching relevant European and international literature, and existing hospital discharge reports from EU Member States.

The hospital discharge report model used in this document was reviewed in the light of its:

- Accuracy, i.e., how well does it represent the required/needed/expected components of its chosen domain and its business/clinical needs. Special attention is made to the relationships between the models' elements as they should be able to accurately express the clinical reality.
- Completeness, i.e., does it include all of the required components of its chosen domain or does it lack something important; here special attention needs to be made to the class objects ("containers" or "boxes" in the model) and whether they are creating a "full picture" of what one (usually a clinician) would expect to see in his/her daily practice.
- Relevance, i.e., whether the model provides relevant information about its chosen domain or - in more general terms - does it fulfil its practical "purpose"; here special attention must be made on the model as a whole - when taken as a "blueprint" of the entire domain, e.g., does it represent something that is usable and makes sense in the real clinical setting.

(Persistence, Stewardship, Potential for authentication, Context, Wholeness and Human readability), but FHIR Documents can be also more flexible due to it can be about any subject and not only centered in patient like the CDA Documents. Examples of document-like things in healthcare include discharge summaries and lab reports.

¹⁰ IHE (Integrating the Healthcare Enterprise) is an initiative of healthcare professionals and industry to improve the way healthcare information systems share information. It promotes the coordinated use of established standards such as DICOM or HL7 to achieve optimal patient care. IHE improves healthcare by providing specifications, tools, and services for interoperability, and engages clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions to vital health information needs. All the profiles are classified in different domains (technical frameworks) like Cardiology, Patient Care Device or Laboratory, among others. In the technical framework for Patient Care Coordination, the use case of a Discharge Summary was specified, described fully in the XDS-MS profile, where it involves an episodic transfer of care in the form of a patient discharge from a hospital. The specification makes use of the standards HL7 CDA R2, CRS (HL7 Care Record Summary) and CCD (ASTM/HL7 Continuity of Care Document).

4.5.1 Understanding Containers, Data and Code lists

The HDR model is composed of “containers” which are the main structural unit produced to represent the logical hierarchy of an information system, from which all other components are derived.

Relationships may exist between two or more containers indicating that at least one is a sub-component of the other (e.g., the “Address” container may be associated with the “Patient” container, as the patient is always associated with some address).

Furthermore, Containers are usually composed of Data, which is a term used to describe smaller logical components that are associated with a higher structure and involve a range of values which is ascribed to them (e.g., “Hospital Discharge Report” is a container for a “Document ID” which is considered as data that has a specific numerical value that is given to it).

Finally, code lists define a range of possible values that a data element may have. A code list (value set) is a constraint on a coded value. Sometimes, when code lists are not necessary and e.g., free text is used as an alternative type of data in an HDR. Oftentimes however, especially in medicine, code lists enable a structured approach to handling data in a given document and are here considered to be the best approach, when possible. Although not widely used in this model, also note that “constraints” are objects which add a restriction to different elements of the model.

4.5.2 Understanding Class Diagrams and Elements Lists

The class diagram is used to visually represent the logical structure of the system – i.e., different classes of objects (containers, data and code lists) in all their relationships. In our static model, the different class diagrams describe what “exists” and what attributes it has, rather than demonstrating how something is done.

The class diagram (like any other diagram) can be viewed as an element List, which is a table representation of the class diagram. Unlike its graphical counterpart, the Elements List shows all the containers, data and code list elements in a “flat” manner of rows and columns, describing them as Types, Concepts, Cardinality and Descriptions:

- “Type” column represents the type of the object such as Container or Data.
- “Concept” is the actual name of the object in the model (e.g., the container for the date of approval of the Hospital Discharge report is called “ApprovalDateTime”).
- “Cardinality” is used to denote the cardinality order of elements.
- “Description” is used as a narrative description of the object in question and is self-explanatory.

4.5.3 Understanding Cardinality

The Cardinality is used to define the multiplicity of source and target elements in relationships. This is the range of instances of the role that can be active in the relationship, e.g., the “Patient” class can only be assigned to a single “Date of birth” class (see examples below) but can have multiple classes denoting e.g., a Physical Exam Report.

The Cardinality Values may have the following formats:

Relationship	Example	Left	Right	Description
One-to-one	person ↔ birth certificate	1	1	A person must have its own birth certificate
One-to-one (optional on one side)	person ↔ insurance card	1	0..1	A person may have an insurance card (but there’s always that one specific license which belongs to a specific person)
Many-to-one	person ↔ birthplace	1..*	1	Many people can be born at the <u>same</u> place
Many-to-many (optional on both sides)	person ↔ diagnoses	0..*	0..*	A person may have <u>many</u> diagnoses
One-to-many	prescription ↔ medication	1	1..*	A prescription contains <i>at least</i> one medication
Many-to-many	Therapy ↔ patient	1..*	1..*	One patient may be given <u>many</u> therapies

5 EU HOSPITAL DISCHARGE REPORT INFORMATION MODEL SPECIFICATIONS

5.1 List of EU hospital discharge report information building blocks/modules to be used for implementation purposes

Below are the individual building-blocks or modules that are contained in a typical hospital discharge report. These modules reflect the business/clinical needs for creating and maintaining a hospital discharge report and use the information module components of a common EU hospital discharge report detailed in the next chapters. The clinical need for implementing a specific module is identified as being either *mandatory* or *recommended*.

5.1.1 Administration Module

This is the first section of the HDR as it aims to identify the subjects involved in the episode of inpatient care as well as closely related subjects. Therefore, most of the data elements are mandatory. Standard coding is available (same as for e.g., disease registries), no free text fields. This module corresponds with the “Administrative Information” under 3.3 and “Patient administrative data” section of the Patient Summary document.

1. Patient demographics *Mandatory*

i. Identification (national healthcare ID), personal information (Full name, titles, date of birth, gender), Contact information: Patient (address, cell phone and email contact), preferred health professional to contact (name, role, organisation, phone and email), contact person/legal guardian (role, relationship level, name, phone, email), insurance number

ii. Insurance number

2. Contact information:

i. Patient information (address, cell phone and email contact),

ii. Preferred health professional to contact information (name, role, organisation, phone and email)

iii. Other health professional information (name, role, organisation, phone and email) *Recommended*

iv. Contact person/legal guardian information (role, relationship level, name, phone, email)

5.1.2 Admission Evaluation Module

This section is logically the first one to be presented as it is also the first piece of information gathered about the patient at the time of hospital admission. This section could potentially serve for an update of the Patient Summary document.

1. **Type of admission** *Mandatory*
 - i. Emergency
 - ii. Planned care
2. **Origin of referral** *Mandatory*
 - i. Referring physician and institution details
 - ii. Self-referral
3. **Dates of admission and discharge (efficient time)** *Mandatory*
4. **Reason for admission** *Mandatory*
 - i. History and the nature of the current problem described system by system
 - ii. List of the main symptoms
5. **Patient condition on admission** (ICD-11, SNOMED-CT, HPO) *Mandatory*
 - i. Vital signs
 - ii. Objective findings (Physical exam)
 - iii. Functional status
6. **Admission (working) diagnosis** (ICD-10, ICD-11, ORPHA) *Mandatory*
7. **Other relevant (secondary) diagnoses**
8. **Discharge mode** *Mandatory*
 - i. Home
 - ii. Transfer to another healthcare facility
 - iii. Transfer to a social care facility

5.1.3 Patient History Module

This module comes just after the administrative dataset. Such an order may be relevant mainly in paediatric setting

A. Family History

Family history is a heterogeneous category that covers subsections that may be relevant in some situations, e.g., detailed family history in case of yet undiagnosed, potentially heritable disorder. On the other hand, family history would not be essential in case of an acute abdomen for appendicitis requiring immediate surgery. Therefore, relevance to the underlying condition and expected outcome of the inpatient stay (e.g., differential diagnosis of a complex condition versus straightforward therapeutic intervention like antibiotic course for pneumonia) should inform the necessity of providing certain types of information. Family history needs to be complete in paediatric patients. Nevertheless, this should apply under the condition that the full patient history is maintained and regularly updated in appropriate detail as a part of the Patient Summary document. If this is not guaranteed a higher level of information granularity is recommended. For many data elements coding is available.

1. **Presence of specific conditions to be listed (risk factors in the family, heritable disorders etc).** These are the specific “conditions of interest” that carry risk of familial occurrence should be provided as options. *Mandatory*
2. **Detailed family history** *Recommended*
 - i. Parents: age, educational level, occupation (*Mandatory in paediatric patients*), health problems, age of death, reason for death
 - ii. Siblings: age, educational level, occupation (*Mandatory in paediatric patients*), health problems, age of death, reason for death
 - iii. Other relatives (relevant)

B. **Social history**

Patient’s cognition/intellectual capacity is an important factor of an HDR legibility and understanding. Educational level and occupation reflect it indirectly. Other information may be important in relation to certain types of health problems (e.g., sporting for musculoskeletal disorders and injuries, type of accommodation for disability). Corresponds partly with the “Social history” section of the Patient Summary document.

1. Patient education and occupation *Mandatory*
2. sporting and free-time activities (sports level – recreational, competitive) *Recommended*
3. Type of accommodation *Recommended*

C. **General medical history (Personal history) / Patient clinical data**

This history (anamnestic) subsection relates to health data only. It summarises all relevant health issues the admitted patient has had that are not in direct relation to the condition for which he or she is being admitted and likely do not require any specific action during the hospitalisation. Previous health problems bring an inventory of the past (resolved) conditions (e.g., infections, healed traumas etc) and ongoing stable conditions either chronic, requiring stable treatment and follow-up or just follow-up without treatment (e.g., hypercholesterolaemia, hypertension, diabetes type 2). This section overlaps grossly with the section “Patient clinical data” of the Patient Summary document.

1. **Allergies, intolerances, previous medication adverse effects** *Mandatory*

This subsection corresponds with the "Patient clinical data" / "Alerts" / "Allergy" section of the Patient Summary document.

2. **History of previous health problems incl. major traumas, surgeries** *Mandatory*

- i. Past (i.e., resolved) episodes of care

Corresponds with the "Medical history" / "List of resolved, closed or inactive problems" section of the Patient Summary document.

2. Ongoing stable incl. medical devices and implants and other procedures/surgeries

Corresponds with the “Medical alert information” section (other alerts not included in allergies) and “Medical problems” / “Medical devices and implants” and “Procedure” sections of the Patient Summary document.

3. Vaccinations

Corresponds with the “Medical history” / “Vaccination/prophylaxis” section of the Patient Summary document.

- i. Routine vaccinations (common parts of vaccination scheme across EU)
Mandatory
- ii. Additional vaccinations *Recommended*

4. Epidemiological history *Mandatory*

Corresponds with the “Patient provided data” / “Travel history” section of the Patient Summary document.

- i. Infectious disease contacts
- ii. Travel history

5. Gynaecological-obstetric history *Mandatory*

Corresponds partly with the “Pregnancy history” section of the Patient Summary document.

5.1.4 Hospital Stay (Detailed In-patient Episode of Care) Module

This section relates exclusively to what has been happening throughout the hospitalisation. The order of sections has logical sequence from diagnostic procedures to therapeutic interventions. In case of multiple repetitions of one test (e.g., blood count, ionogram) only the results that helped the diagnostic process or reflected the change in the condition should be included with their date.

Corresponds partly with the Results section of the Patient Summary

1. Diagnostics *Mandatory*

- i. Observation-based
 - a. Diagnostic observations (e.g., typical disease presentations fulfilling diagnostic criteria) (descriptive codes e.g., ICD-11, SNOMED-CT, HPO)
- ii. Laboratory test results
 - a. Blood: Haematology, biochemistry, serology, immunology, genetics, other
 - b. Urine: Biochemistry, microscopy, serology, microbiology, other

- c. Other specimen (cerebrospinal fluid, pleural or other effusion, BAL, bone marrow aspirate etc): Biochemistry, microscopy, serology, microbiology, other
- iii. Histopathology
 - a. Specimen (site): optic microscopy, immunohistochemistry, electronic microscopy, other
- iv. Imaging studies
 - a. Ultrasound, X-ray, CT, MR, scintigraphy, functional imaging studies
- v. Electrophysiology
 - a. ECG, EEG, EMG, evoked potentials etc
- vi. Outcomes of specialist consultations
 - a. Medical specialty/subspecialty, name of consultant
 - i. Relevant summary of the consultation
 - b. Allied health profession (e.g., psychology, physiotherapy, social worker etc.), name of consultant
 - i. Relevant summary of consultation

2. Procedures *Mandatory*

- i. Diagnostic and therapeutic interventions
 - a. Needle aspiration
 - b. Endoscopy
 - c. Biopsy
 - d. Other intervention (e.g., physiotherapy, rehabilitation, psychotherapy)
- ii. Surgery (operation)
 - a. Site, type of surgery
 - b. Surgery outcome/complications

3. Pharmacotherapy (daily dose, route of administration) *Mandatory*

- i. New medications added during inpatient stay
 - a. Date when added
- ii. Ongoing medications (received prior to admission and continued)
- iii. Withheld medications (received prior to admission and discontinued)
 - a. Date when withheld

- b. Medication adverse effects
 - i. Date
 - ii. Management

5.1.5 Encounter (Summary of In-patient Episode of Care) Module

The aim of this section is to briefly summarise the in-patient episode of care during the hospital stay including the main relevant information that lead to the diagnosis as well as therapeutic interventions and a clinical response to them. It should be written in the language legible to the lay person (patient or a patient's legal representative), and all medical terms and abbreviations should ideally be explained in the free text subsection. In case of a complex, multisystem condition, the disease course should be described in detail – i.e., one body system after another.

This section could serve as an extension to the Patient Summary document.

1. **Structured clinical narrative by individual systems/problems supported by relevant investigation results** *Mandatory*
2. **Active problems at discharge, prognosis** (narrative, SNOMED Clinical Terms, ICD-11) *Mandatory*
3. **Patient clinical condition and functional status at discharge** *Mandatory*
4. **Main discharge diagnosis** (ICD-10, ICD-11, ORPHA) *Mandatory*
5. **Secondary discharge diagnoses** (ICD-10, ICD-11, ORPHA) *Mandatory*

5.1.6 Discharge details

This section is the most important for the patient to understand, therefore it must be provided in the appropriate language and wording.

1. **Future management plan/discharge instructions** *Mandatory*

Corresponds partly with the Plan of care section of the Patient Summary document.

1. **Recommended pharmacotherapy**
 - i. Name of the drug, posology, dose and dosing frequency
2. **Other recommended therapies**
3. **Regime recommendations**
 - i. Dietary recommendation
 - ii. Physical activity / sports / working ability / incapacity recommendation
 - iii. Other regime measures
2. **Follow-up arrangements** *Mandatory*
 - i. Follow-up Appointments
 - a. Type of appointment (investigational, therapeutic)
 - b. Specialty/subspecialty, hospital/physician/therapist contacts
 - ii. Legal information

- a. Legal information/documents, financial agreements/documents, consents, power of attorney

3. Details of the person/persons completing and responsible for the HDR *Mandatory*

5.2 HOSPITAL DISCHARGE REPORT: A LOGICAL MODEL

This section of the document contains all the mandatory common elements to be included in the EU hospital discharge report document.

These typical data elements are organised into “modules” which account for the different “packages of patient information” that should be provided by the issuing party (i.e., healthcare provider or NCPeH) in the appropriate use-cases.

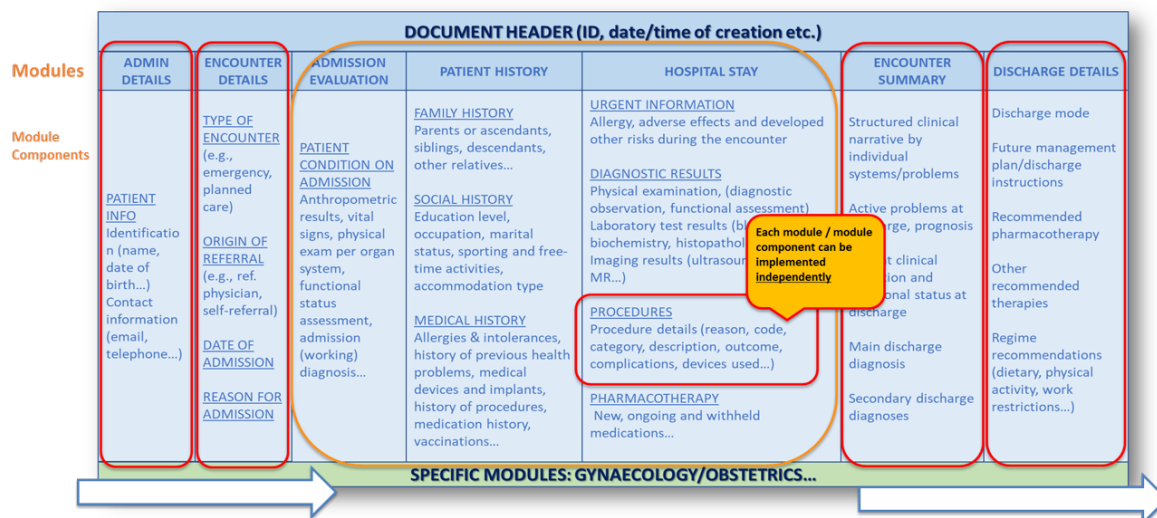
The second reason for organising the common data elements into modules is to underline the “building blocks” strategy used in developing a common EU hospital discharge report, which includes independent implementation components, which may be implemented separately depending on the medical needs of the healthcare institutions as well as data availability, both as a single hospital discharge report or as an addition to a patient summary or electronic health record.

The following is a representation of the logical model for a common EU hospital discharge report. It is composed of several “Modules” or sections which follow the common structure of hospital discharge reports internationally. These modules are represented as separate logical models embedded in the overarching model in a building block fashion. Each module can be implemented independently of the others. The main modules are important as they follow a typical workflow of a hospital-based episode of care, i.e., from admission to discharge. The modules represented in the common EU hospital discharge report are:

- a) Admission and Evaluation,
- b) Patient History / Anamnesis,
- c) Hospital Stay,
- d) Encounter and
- e) Discharge Details (see Figure 1).

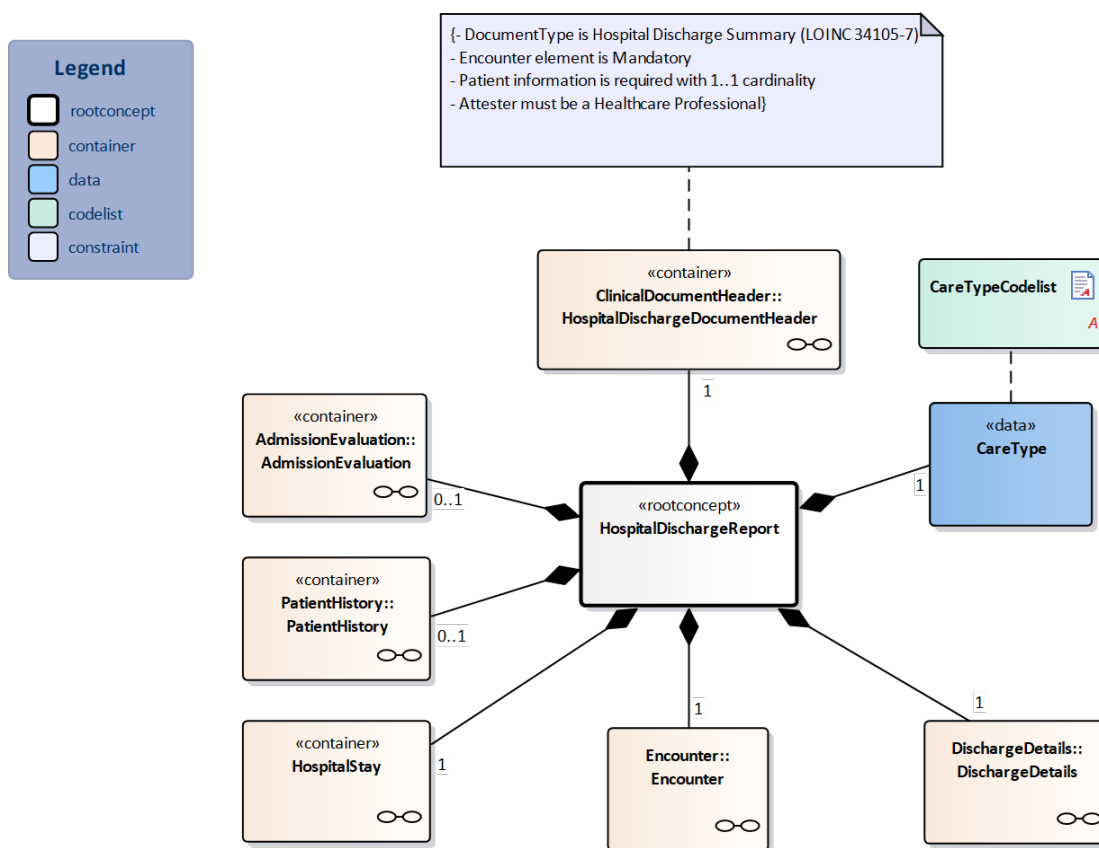
Each module is then fragmented into additional sub-models, all of which can be implemented as an extension to the Patient Summary document. The detailed descriptions of each model to the level of proposed value sets are presented in the Appendix.

Figure 1: A building-block approach to modelling the common EU hospital discharge report that follows a typical hospital discharge workflow from admission to discharge from the hospital.








An overarching logical model for a common EU hospital discharge report is shown in Figure 2. The model reflects the business requirements of a typical hospital stay – from admission to the collection of relevant information about the patient, the encounter itself, the hospital stay and the discharge summary.













Figure 2: A logical model of the common EU hospital discharge report.

















In Table 1. all relevant (sub)components that are needed for the implementation of a hospital discharge report are listed in alphabetical order, under the main Hospital Discharge (HDR) Information Model. Each structural unit called a “module” is comprised of several smaller logical models which supports this “building block” approach, meaning that it allows for single components to be implemented without the need to implement everything at the same time. It also means that different components of the overall model can be re-used and shared with other types of clinical documents already supported by eHDSI such as Patient Summary and ePrescription. Note also that each individual information model under the main Hospital Discharge Report Information Model is typically shared by several modules, depending on the business/clinical need. This approach should make it easier to update the current architecture of the eHDSI with new components, when and if needed.

Table 1: Hospital Discharge Report information models. Figure 1: A building-block approach to modelling the common EU hospital discharge report that follows a typical hospital discharge workflow from admission to discharge from the hospital.

Logical Model	Link to model	Embedded model
HOSPITAL DISCHARGE REPORT INFORMATION MODEL (Main Component)	HDR Information Model.docx	 HDR Information Model.docx
Alert Information Model	Alert Information Model.docx	 Alert Information Model.docx
Alerts And Risks Information Model	Alerts And Risks Information Model.docx	 Alerts And Risks Information Model.doc
Appointment Information Model	Appointment Information Model.docx	 Appointment Information Model.doc
Attachment Information Model	Attachment Information Model.docx	 Attachment Information Model.doc
Care Plan Information Model	Care Plan Information Model.docx	 Care Plan Information Model.doc
Care Team Information Model	Care Team Information Model.docx	 Care Team Information Model.doc
Clinical Document Information Model	Clinical Document Information Model.docx	 Clinical Document Information Model.doc
Clinical Impression Information Model	Clinical Impression Information Model.docx	 Clinical Impression Information Model.doc
Conclusion Information Model	Conclusion Information Model.docx	 Conclusion Information Model.doc

Condition Information Model	Condition Information Model.docx	 Condition Information Model.doc
Contact Information Model	Contact Information Model.docx	 Contact Information Model.docx
Contact Person Information Model	Contact Person Information Model.docx	 Contact Person Information Model.doc
Device Information Model	Device Information Model.docx	 Device Information Model.docx
Drug Use Information Model	Drug Use Information Model.docx	 Drug Use Information Model.doc
Education Information Model	Education Information Model.docx	 Education Information Model.doc
Encounter Information Model	Encounter Information Model.docx	 Encounter Information Model.doc
Family Situation Information Model	Family Situation Information Model.docx	 Family Situation Information Model.doc
Goal Information Model	Goal Information Model.docx	 Goal Information Model.docx
Infectious Contact Information Model	Infectious Contact Information Model.docx	 Infectious Contact Information Model.doc
Legal Situation Information Model	Legal Situation Information Model.docx	 Legal Situation Information Model.doc
Living Situation Information Model	Living Situation Information Model.docx	 Living Situation Information Model.doc

Marital Status Information Model	Marital Status Information Model.docx	 Marital Status Information Model.doc
Medication Administration Information Model	Medication Administration Information Model.docx	 Medication Administration Informr
Medication Request Information Model	Medication Request Information Model.docx	 Medication Request Information Model.doc
Medication Use Information Model	Medication Use Information Model.docx	 Medication Use Information Model.doc
Medication Use Instructions Information Model	Medication Use Instructions Information Model.docx	 Medication Use Instructions Informati
Nutrition Order Information Model	Nutrition Order Information Model.docx	 Nutrition Order Information Model.doc
Observation Information Model	Observation Information Model.docx	 Observation Information Model.doc
Participation In Society Information Model	Participation In Society Information Model.docx	 Participation In Society Information Iv
Pharmaceutical Product Information Model	Pharmaceutical Product Information Model.docx	 Pharmaceutical Product Information M
Physical Examination Information Model	Physical Examination Information Model.docx	 Physical Examination Information Model.doc
Pregnancy Information Model	Pregnancy Information Model.docx	 Pregnancy Information Model.doc
Procedure Information Model	Procedure Information Model.docx	 Procedure Information Model.doc

Range Information Model	Range Information Model.docx	 Range Information Model.docx
Task Information Model	Task Information Model.docx	 Task Information Model.docx
Tobacco Use Information Model	Tobacco Use Information Model.docx	 Tobacco Use Information Model.doc
Travel History Information Model	Travel History Information Model.docx	 Travel History Information Model.dc
Vaccination Information Model	Vaccination Information Model.docx	 Vaccination Information Model.dc

6 EU HOSPITAL DISCHARGE REPORT USE CASES AND IMPLEMENTATION SCENARIOS

6.1 USE CASE IDENTIFICATION

High level Hospital Discharge Report use cases identified for cross-border EHRxF are summarised in the table below.

Use cases were classified from the project scope point of view and working priority was assigned.

Table 2: List of Hospital discharge Report use cases for cross-border EHRxF.

Use case number	Use case name	Comment	Project scope
UC5.5.1	Hospital Discharge Report for continuity of care	<p>Hospital Discharge Report serves as source of information for continuity of care for:</p> <ul style="list-style-type: none"> • Registering general practitioner/assigned family medicine specialist if such exist • Healthcare professional which referred the patient to the hospital • Healthcare provider to whom the patient is referred after discharge from the hospital • Other healthcare providers of all types • Patient himself (or guardian), to document regimen instructions, dietary and lifestyle recommendations, self-treatment, and other health related information <p>In terms of versioning, a hospital discharge report could be preliminary,</p>	In-scope (Extension)

Use case number	Use case name	Comment	Project scope
		final, or amended (replaced with a new version).	
UC5.5.2	Hospital Discharge Report for the patient / patient's legal representative	Though patient (represented by him/herself or by another person acting as a legal representative) is one of the main actors of the general HDR use case (UC5.5.1), it might be seen also as a separate use case. This separation will be useful to identify and discuss specific functional requirements.	In-scope (Evolution)
UC5.5.3	Query for Hospital Discharge Report	Query EHR system for a hospital discharge report based on combination of query parameters.	In-scope (Extension)
UC5.5.4	Secondary use of HDR	<ul style="list-style-type: none"> • Reimbursement of care • Healthcare statistics • Healthcare research 	Out-of-scope (Evolution)
UC5.5.5	Referral Report	A report requesting of hospitalisation in an inpatient care setting, including the transfer of relevant medical information.	Out-of-scope (Evolution)

6.2 USER ROLES' IDENTIFICATION AND DESCRIPTION

This section deals with the roles involved in a typical hospital discharge report.

The roles identified in the requirements may be categorised as follows:

- **HDR author:** this role could be fulfilled by any healthcare professional authorised to prepare content of the hospital discharge report. In most cases this role requires medical education and relation to the subject of care, e.g., could be played by attending physician.

- **HDR validator:** this role is usually played by medical head of the hospital department or other senior medical staff responsible for clinical content of the report. In some standards (CDA), this role is called Legal authenticator.
- **HDR sender:** Hospital discharge report, once created and validated needs to be handed over to its receiver, which is either known at the time of discharge or unknown. In some EU countries, hospital discharge reports must be automatically sent to the GP or family physician that treats the patient on a regular basis or to a referring physician, or to the patient himself. In some countries a national EHR system where the hospital discharge report should be automatically stored may exist while other countries allow its storage in the different PHR/PCHR systems. HDR sender is a human or information system responsible for directing validated HDR into its recipient or target from which other authorised actors could pull it when they need.
- **HDR receiver:** Usually a primary care physician (GP) or other medical role equivalent that receives the HDR once it is sent from the HDR sender to a particular Healthcare Service Provider.
- **HDR subject:** The patient or the patient's legal representative or other legal equivalent which is the ultimate recipient of the Hospital Discharge Report, as well as (in the case of the patient) the data subject of the Hospital Discharge Report, i.e., the person whose data is being processed during the episode of care and exchanged in the Hospital Discharge Report Use-cases. Special attention needs to be paid to people that are represented by a legal representative or other legal equivalent, as well as and children and young adults under the legal age as they might not own personal identification means (e.g., an ID card).

6.3 USE CASE DESCRIPTION

The following section contains a detailed description of identified use cases for the implementation of a common EU hospital discharge report which were identified as being in scope of this document and future implementation of the hospital discharge report service in MyHealth@EU. The main implementable use cases for the Hospital Discharge Domain are based on either the “push” or “pull” scenarios, denoting that the clinical document is either sent or retrieved to and from the hospital / healthcare provider.

Table 3: Use case descriptions for the Hospital Discharge Report domain, for the continuity of care (“Push”) scenario.

Title	UC5.5.1 Hospital Discharge Report for continuity of care (“PUSH”)
Purpose	Summary of an episode of inpatient care to a healthcare professional, including the transfer of relevant medical information to ensure continuity of care that is “pushed” (i.e., sent) to the patient’s physician and/or another requested recipient after a hospital encounter discharge.
Relevance	Safe and reliable healthcare depends on access to, and use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. Ensuring that information can be shared efficiently and effectively, and, in a manner, which protects the privacy and confidentiality of patients is critical. To ensure continuity of care during the transition between different types of care, within a country or cross border, effective communication between healthcare professionals is required. Timely access to complete documentation regarding an inpatient stay can lead to improved quality of care after discharge. The hospital discharge report (HDR) generated at the end of an inpatient stay provides the basis for communication between healthcare professionals in different healthcare settings. For the HDR to be effective it must be a complete, accurate and relevant record of the inpatient stay and must be released in a timely manner. Additionally, the HDR may be stored as a part of the patient electronic hospital record (EHR) to ensure continuity of care in case of subsequent hospital admissions to the same or another care setting.
Domain	Referral and Discharge Reporting
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational
Context	At the end of the inpatient stay the patient is discharged. Episode-based patient summary information (with a focus on the episode of inpatient care) is prepared by the attending physician in the hospital. If appropriate, the information is transferred to the primary care physician and medical specialists and to the patient/legal representative. HDR should contain both human- and machine-readable content.

Information	<p>HDR should include following main parts (sections):</p> <ul style="list-style-type: none"> • Patient attributes - Patient details, caregiver/legal representative details • Contact details - Primary healthcare professional details, details of other physicians involved in the care • Condition on admission • Details of the episode (discharge mode, episode ID, efficient time) • Outcome of the episode (patient status at discharge) • Reason for admission – definition of the current health problem • Allergy reactions and other alerts and risks information • Previous medical history • Investigation and specialist consultation results (relevant) • Operations and procedures • Relevant treatments • Hospital course summary (structured by individual systems/problems, active problems at discharge) • Diagnoses, functional status, prognosis • Medication on discharge, medications stopped or withheld • Future management plan/follow-up arrangements • Details of the person/persons completing and responsible for the HDR
Participants	<ul style="list-style-type: none"> • Physician completing the HDR (HDR author), • Physician responsible for HDR validation (legal authenticator), • Primary care physician (GP), • Referring physician • A physician/healthcare professional or healthcare provider to whom is the patient referred for a consecutive care • EHR system • HDR sender
Preconditions	<p>Main interoperability/semantic issues sorted: standard structure of the HDR used, code systems used are interoperable, for areas where coding has not yet been generally accepted the free text will have to be allowed. Narrative parts should have a pre-defined structure and content (e.g., parts of the medical history) as well as a list of obligatory data under each section.</p>

Functional process flow	<p>Depending on the member state legislation and practice the HDR is provided to the patient upon discharge, sent directly to the relevant primary care physician, to the referring physician or other relevant healthcare practitioners or to the central or distributed EHR system. The process flow includes following steps:</p> <ol style="list-style-type: none"> 1. HDR author (attending physician) creates discharge report and stores it in his EHR system 2. Responsible physician validates the HDR 3. HDR sender sends HDR to identified HDR receivers.
-------------------------	---

Table 4: Use case descriptions for the Hospital Discharge Report domain, for the patient/legal representative.

Title	UC5.5.2 Hospital Discharge Report for patient/legal representative information
Purpose	A document prepared by the physician responsible for an inpatient care that summarises all relevant information related to the episode of inpatient care including patient or caregiver specific information about the hospital encounter, for ensuring the continuity of care, such as regimen instructions, dietary and lifestyle recommendations, self-treatment information, and other relevant information needed.
Relevance	The patient (or care giver) needs timely access to the relevant information on outcomes of hospitalisation, especially those related to recommendations (for continuing/discontinuing therapies after discharge and/or completion of other investigations) are inevitable.
Domain	Referral and Discharge Reporting
Scale	<ul style="list-style-type: none"> • Citizens at home and on the move
Context	Describes relevant aspects and influencing factors on the non-technical level that needs to be understandable to the different actors in the workflow (e.g., physicians and other healthcare workers, involved in the hospital

	encounter and the treatment of the patient, the patient and the patient's representatives etc.).
Information	<p>Sections of HDR that are mostly relevant to this UC are:</p> <ul style="list-style-type: none"> • Patient details • Primary healthcare professional details • Hospital course summary (structured by individual systems/problems) • Diagnoses, functional status • Medication on discharge, medications stopped or withheld • Future management plan • Details of the person/persons completing and responsible for the HDR
Participants	<ul style="list-style-type: none"> • Physician completing the HDR (HDR author), • Physician responsible for HDR validation (legal authenticator), • Patient (legal representative, caregiver)
Preconditions	<p>Main interoperability/semantic issues sorted: standard structure of the HDR used, code systems used are interoperable, for areas where coding has not yet been generally accepted the free text will have to be allowed. Narrative parts should have a pre-defined structure and content (e.g., parts of the medical history) as well as a list of obligatory data under each section.</p> <p>N.B.: As part of the eHDSI evolution, a service needs to be enabled that will allow the patient to receive the data directly.</p>
Functional process flow	<p>Depending on the Member State's legislation and practice the HDR is retrieved by the patient's primary physician (or other identified HDR receivers) upon request, after hospital discharge:</p> <ol style="list-style-type: none"> 1. HDR author (attending physician) creates discharge report and stores it in his EHR system 2. Responsible physician validates the HDR 3. HDR sender sends HDR to identified HDR receivers.

Table 5: Use case descriptions for the Hospital Discharge Report domain, for the "Pull" scenario.

Title	UC5.5.3 Query for Hospital Discharge Report ("PULL")
Purpose	Summary of an episode of inpatient care to a healthcare professional, including the transfer of relevant medical information to ensure continuity of care that is "pulled" (i.e., retrieved) by the patient's physician and/or another requested recipient after a hospital encounter discharge.
Relevance	Safe and reliable healthcare depends on access to, and use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. Ensuring that information can be shared efficiently and effectively, and, in a manner, which protects the privacy and confidentiality of patients is critical. To ensure continuity of care during the transition between different types of care, within a country or cross border, effective communication between healthcare professionals is required. Timely access to complete documentation regarding an inpatient stay can lead to improved quality of care after discharge. The hospital discharge report (HDR) generated at the end of an inpatient stay provides the basis for communication between healthcare professionals in different healthcare settings. For the HDR to be effective it must be a complete, accurate and relevant record of the inpatient stay and must be released in a timely manner. Additionally, the HDR may be stored as a part of the patient electronic hospital record (EHR) to ensure continuity of care in case of subsequent hospital admissions to the same or another care setting.
Domain	Referral and Discharge Reporting
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational • Citizens at home and on the move
Context	Describes relevant aspects and influencing factors on the non-technical level that needs to be understandable to the different actors in the workflow (e.g., physicians and other healthcare workers, involved in the hospital encounter and the treatment of the patient, the patient and the patient's representatives etc.)
Information	Sections of HDR that are mostly relevant to this UC are:

	<ul style="list-style-type: none"> • Patient details • Primary healthcare professional details • Hospital course summary (structured by individual systems/problems) • Diagnoses, functional status • Medication on discharge, medications stopped or withheld • Future management plan • Details of the person/persons completing and responsible for the HDR
Participants	<ul style="list-style-type: none"> • HDR sender: The hospital EHR systems / National Contact Point for eHealth (NCPeH) • HDR receiver (physician or other relevant healthcare professional based on the Member State's legal requirements) • HDR subject: Typically, the patient (or the patient's legal representative, caregiver)
Preconditions	<p>Future management plan and other sections intended to provide information for patient, must be provided in the way that is fully understandable to the patient language-wise (patient's preferred language or in English) and medical terminology-wise (patient friendly).</p>
Functional process flow	<ol style="list-style-type: none"> 1. Attending physician creates discharge report and stores it in his EHR system 2. Responsible physician validates the HDR 3. The HDR is provided to the patient or legal representative upon discharge.

6.4 ACTORS' IDENTIFICATION AND DESCRIPTION

This section deals with the actors typically involved in the creation and exchange of a hospital discharge report. The actors can "fulfil" a particular user role and may participate in the implementation of the use cases in the following ways.

6.4.1 Human Actors

- **Patient**
 - The data subject of a specific Hospital Discharge Report.

- Typical user role: HDR subject.
- **Patient's Legal Representative**
 - The data subject's legal representative.
 - Typical user role: HDR subject.
- **Healthcare Professional**
 - The professional that provides healthcare treatment to the patient identified as such by the national healthcare system, i.e., every healthcare professional must be assigned to at least one healthcare provider and registered with an official health authority belonging to the Member State. (N.B.: Each Member State must have a system to check the attributes (right for accessing to the information) of the end user who requests the Hospital Discharge Report information).
 - Typical user role: HDR author, HDR validator, HDR receiver.

6.4.2 Institutional Actors

- **Healthcare Provider**
 - As the name suggests, this is the organisation that provides healthcare services to the patient. A healthcare professional “belongs” to a specific healthcare service provider that can provide proof of his/her occupation as a healthcare professional, also enabling the identification and authentication of the healthcare professional.
 - Typical user role: HDR sender, HDR receiver.
- **Health Authorities Institutions**
 - Public health institutions that are mandated by law to provide governance of healthcare services within a given territory, within the Member State's jurisdiction (e.g., province/region/country level). These institutions assign and assure the status, the function, and can provide the authentication of the healthcare professional.
 - Typical user role: HDR sender, HDR receiver.

6.4.3 Information System (IS) Actors

- **Healthcare providers' EHR systems**
 - Information System or Information Technology Provider that is responsible for the exchange of patient information across hospital systems.
 - Responsible for the identification of patients (and patient's legal representatives), and the identification, authentication and authorisation of healthcare professionals.
 - Typical user role: HDR sender, HDR receiver.
- **Member States' National Contact Point for eHealth (NCPeH)**
 - Responsible for the external (i.e., EU-level) and internal (i.e., national) communication (exchange of information) and the semantic mapping between information on either side (e.g., between Healthcare Service Providers or Country A or Country B, in the case of cross-border patient data exchange).

- Responsible for securing that the necessary information exchange processes are properly implemented, and that the exchanged information is understandable, at the level of each of the Member States' information networks.
- Typical user role: HDR sender, HDR receiver.

Real-world actors are key for understanding the implementational aspects of the hospital discharge domain and will contribute to a better provision of functional and non-functional requirements.

7 FUNCTIONAL AND NON-FUNCTIONAL REQUIREMENTS FOR THE EU HOSPITAL DISCHARGE REPORT

7.1 REQUIREMENTS IDENTIFICATION AND DESCRIPTION

In this chapter the objective is to describe the agreed Use Cases, to identify the functional requirements and to summarise the responsibilities and actions that are needed per each actor (technical and human) in the eHealth DSI.

7.1.1 General requirements for a common EU hospital discharge report

- The information exchanged between Healthcare Providers must be understandable as service providers involved in the interaction.
- Ensure the comprehensibility of the information to the person who receives it (patient or healthcare professional, or any other relevant party involved).
- The above requirement must take priority over the completeness/exhaustiveness of the provided information.
- Unambiguous identification of the patient must be assured.
- The protection of personal data, privacy and confidentiality of both the patient, healthcare professional or any other relevant party involved must be assured.

7.2 REQUIREMENTS' DESCRIPTION

7.2.1 Functional Requirements

A detailed list of non-functional requirements for the EU hospital discharge report is provided below:

- FR01 Healthcare Professional Identification, authentication and authorisation
- FR02 Patient identification
- FR03 Patient's legal representative identification and authentication
- FR04 Structured Information
- FR05 Equivalent Information
- FR06 Information Understandable
- FR07 Information Traceability
- FR08 Hospital Discharge Report(s) from country B sent for continuity of care
- FR09 HDR(s) for patient available in country of affiliation
- FR10 Determining the patients GP or other HP to whom the HDR from Country B will be sent
- FR11 Timely completion and release of the documentation of inpatient stay

- FR12 Storing of the Hospital Discharge Report as part of the patient Electronic Hospital Record

Table 6: Functional Requirement 01: Healthcare Professional Identification, authentication and authorisation.

Requirement FR01	Healthcare Professional identification, authentication and authorisation
Description	The Healthcare Professional must be unequivocally identified, authenticated and authorised in his/her national healthcare system and must be identified according to the healthcare professional's role/profile.
Associated goals	<p>To ensure security in the information exchange and treatment process.</p> <p>To ensure that the Healthcare Professional is legally allowed to perform the functionalities described in this document.</p> <p>Prevention of creation-modification of information by unauthorised personnel.</p> <p>Prevention of any information disclosure to unauthorised persons or parties.</p>
Actors	<p>Healthcare Professional</p> <p>Healthcare Service Provider / Health Authorities Institutions</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

Table 7: Functional Requirement 02: Patient identification.

Requirement FR02	Patient identification
Description	<p>The patient first needs to be univocally identified in a reliable way (unique and unequivocal ID) to allow the healthcare professional to process his/her personal data, and to allow the patient to access the Hospital Discharge Reports.</p> <p>For functional and security purposes in the information usage, the univocal identification of the patient is highly relevant and one-to-one and unmistakable identification of the patient must be assured.</p> <p>The process of identification (positive or negative) must be recorded in the system.</p>
Associated goals	<p>To enable the exchange of information between countries.</p> <p>To have certainty over the identity of the patient.</p>
Actors	<p>Healthcare Professional</p> <p>Patient</p> <p>Health Authorities Institutions</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

Table 8: Functional Requirement 03: Patient’s legal representative identification and authentication.

Requirement FR03	Patient’s legal representative identification and authentication
Description	<p>The patient’s legal representative needs to be univocally identified and authenticated in his/her national system to allow the transfer of the Hospital Discharge Report of the patient to him/her if appropriate. The association between the patient and his/her representative shall be made by the country of affiliation of the patient.</p>
Associated goals	<p>To ensure security in the information exchange process.</p> <p>To ensure that the representative is legally allowed to access the information about the patient.</p> <p>Prevention of any information disclosure to unauthorised persons or parties.</p>
Actors	<p>Healthcare Professional</p> <p>Patient’s Legal Representative</p> <p>Health Authorities Institutions</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

Table 9: Functional Requirement 04: Structured Information.

Requirement FR04	Structured Information
Description	<p>The information that is exchanged between different Member States shall be structured in modular data groups (i.e., sorted under the appropriate nesting headlines) each of them containing related items of information with a unified meaning of fields (e.g., field ‘Current Problems/Diagnosis’ is properly identified in Country A and translated to Country B).</p> <p>Ideally, the information that is sent from Country A to Country B should be represented in the Country B as it is usually done (or otherwise expected by the Healthcare Professional), for ease of use.</p>
Associated goals	To guarantee that the Healthcare Professional understands the meaning of the received patient information contained in the Hospital Discharge Report to provide the proper healthcare treatment to the patient.
Actors	EHR systems / National Contact Point for eHealth (NCPeH)

Table 10: Functional Requirement 05: Equivalent Information.

Requirement FR05	Equivalent Information
Description	The information sent to another country must be equivalent in their meaning, i.e., a unified meaning of the information must be coherent with that system (e.g., the field

	'Admission Diagnosis' means the same in both countries).
Associated goals	<p>To guarantee that the Healthcare Professional understands the meaning of the received patient information contained in the Hospital Discharge Report to provide the proper healthcare treatment to the patient.</p> <p>To provide the patient/patient's legal representative with the necessary information in regard to the outcomes of hospitalisation.</p> <p>To facilitate the future processing of the information to assure its comprehension through semantic tools, systems of codification or of translation according to how it will be established elsewhere or later within the scope of eHDSI.</p>
Actors	<p>Healthcare Professional</p> <p>Patient/patient's legal representative</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

Table 11: Functional Requirement 06: Information Understandability.

Requirement FR06	Information Understandability
Description	The information sent to another country must be presented in an understandable way (i.e., by being properly translated in the appropriate language used universally – e.g., English, and/or used in that Member State) to the human actors that will make use of it.

Associated goals	<p>To guarantee that the Healthcare Professional understands the meaning of the received patient information contained in the Hospital Discharge Report to provide the proper healthcare treatment to the patient.</p> <p>To facilitate the future processing of the information to assure its comprehension through semantic tools, systems of codification or of translation according to how it will be established elsewhere or later within the scope of eHDSI.</p>
Actors	<p>Healthcare Professional with rights for accessing the HDR</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

Table 12: Functional Requirement 07: Information Traceability

Requirement FR07	Information Traceability
Description	All the information describing the process and the data involved in the process must be able to be properly traced.
Associated goals	<p>To facilitate the future processing of the information to assure its comprehension through semantic tools, systems of codification or of translation according to how it will be established elsewhere or later within the scope of eHDSI.</p> <p>To provide the necessary elements for any foreseen and unforeseen legal mitigation or action.</p>

Actors	<p>Healthcare Professional</p> <p>Patient / Patient's Legal Representative</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>
--------	--

Table 13: Functional Requirement 08: Storing of the Hospital Discharge Report as part of the patient Electronic Hospital Record / Electronic Medical Record.

Requirement FR12	Storing of the Hospital Discharge Report as part of the patient Electronic Hospital Record
Description	The HDR is stored as a part of the patient electronic hospital record or electronic medical record to ensure continuity of care in case of subsequent hospital admissions to the same or another care setting
Associated goals	To ensure continuity of care during the transition between different types of care cross border, timely communication between healthcare professionals is required.
Actors	<p>Healthcare Professional</p> <p>EHR systems / National Contact Point for eHealth (NCPeH)</p>

7.2.2 Non-Functional Requirements

A detailed list of non-functional requirements for the EU hospital discharge report is provided below:

- NFR01 Service availability
- NFR02 Communications
- NFR03 Response time
- NFR04 Confidentiality
- NFR05 Access control
- NFR06 Audit Trail
- NFR07 Integrity
- NFR08 Nonrepudiation
- NFR09 Guaranteed delivery
- NFR10 Supervision services

Table 14: Non-functional Requirement 01: Service availability.

Requirement NFR01	Service availability
Description	<p>Availability is the property of the service being accessible and usable upon demand by an authorised entity (see ISO 7498-2:1989).</p> <p>There are different causes for technical unavailability within the eHDSI:</p> <ul style="list-style-type: none"> - service failure - unplanned stop (bug, random error) - partial planned stop (non-optimal running) - planned stop (maintenance, update) <p>Each unpredictable service interruption should be detected as soon as possible.</p> <p>The origin of the failure must be explained and documented and involved Healthcare</p>

	<p>Service Providers must be notified of any such failure.</p> <p>The procedure to follow will be specified to come back to a normal service mode.</p> <p>In case of failure, the service should always be degraded, whenever possible, instead of having complete unavailability. The service shall provide degraded services (“graceful degradation”).</p> <p>In case of failure, suitable alerts and the procedures to follow will need to be defined.</p>
Associated goals	<p>The Hospital Discharge Report service must be continuously available without interruptions or service failures.</p>

Table 15: Non-functional Requirement 02: Communications.

Requirement NFR02	Communications
Description	<p>The Hospital Discharge Report service requires secure communications between different national systems, situated across the Healthcare Service Providers.</p> <p>The information exchanged between Healthcare Service Providers must be protected from random errors as well as snooping or hacking attacks.</p> <p>This means:</p> <ul style="list-style-type: none"> - That the parties participating to the communication must be properly identified in both countries.

	<ul style="list-style-type: none"> - The information exchanged must be protected. - The integrity of all information exchanged during the performance of any of the use cases must be guaranteed. - The session and the information exchanged must be associated with secured data allowing verification.
Associated goals	To have fast and reliable response times between Healthcare Service Providers.

Table 16: Non-functional Requirement 03: Response time.

Requirement NFR03	Response time
Description	<p>As the information must travel from one Healthcare Service Provider to another it has to be accessible and available within reasonable response times.</p> <p>The system shall provide an end-to-end response time (as experienced by the receiving Healthcare Professional) within the shortest time possible (e.g., a few seconds).</p> <p>The response times should be tested continually by the system to give the users some idea of what to expect.</p> <p>N.B.: An acceptable response time not only applies to the exchange of the medical information, but also to the identification and authentication details of the Healthcare Professional and the Patient.</p>

Associated goals	To have fast and reliable response times between Healthcare Service Providers.
------------------	--

Table 17: Non-functional Requirement 04: Confidentiality.

Requirement NFR04	Confidentiality
Description	<p>Confidentiality of the data must be enforced and safeguarded by the Hospital Discharge Report service (i.e., by all actors involved) whenever identifiable personal and medical data is being processed.</p> <p>All processing of identifiable data must be performed in a way that prohibits any unwanted disclosure of medical data to any third party.</p> <p>Furthermore, the Hospital Discharge Report service must enforce that any data access is only possible over safeguarded, well-defined interfaces.</p> <p>Any unwanted or unlawful disclosure of the exchanged data to an unauthorised party must also be always prohibited.</p>
Associated goals	<p>Manifesting the legal foundation for a lawful data processing.</p> <p>Protecting and safe-guarding the patients' and healthcare professionals' personal information.</p> <p>Ensuring that the involved healthcare professionals' to be compliant with their professional code.</p>

Table 18: Non-functional Requirement 05: Access Control.

Requirement NFR05	Access Control
Description	<p>Each system must assure that only authorised persons and systems are able to access protected data.</p> <p>As authorisations may involve the existence of a treatment context inside a Healthcare Service Provider, these treatment relationships must be justifiable on demand.</p> <p>The communication points need to be known to each other with prior positive verification that all involved partners are authentic: security features to be provided by the means of an identity (subjects, actors, and objects) and access management.</p>
Associated goals	<p>For traceability reasons.</p> <p>For security reasons.</p> <p>For confidentiality and integrity of medical data reasons.</p> <p>To align with the European Data Protection Regulations as applied to healthcare.</p>

Table 19: Non-functional Requirement 06: Audit Control.

Requirement NFR06	Audit Control
Description	<p>Any data access or attempt to access medical data through the Hospital Discharge Report service, must be fully transparent and traceable and reproducible e.g., by logging of</p>

	<p>“who” accessed “which” medical data from “where” at “what” time under “whose” authority.</p> <p>When all audit data is available, a supervision authority must be able to fully recover and reconstruct an access attempt and access path to verify its regulatory compliance.</p> <p>The collected data must be available and suitable for scheduled and unscheduled security audits. Extraordinary and/or emergency accesses must be specially marked to facilitate the local management of those.</p> <p>All data gathered by the audit services may contain identifiable personal data and must be protected accordingly.</p> <p>Furthermore, since the audit trail may be considered as evidence/proof in potential investigations, all protocols must be fully safeguarded in integrity and confidentiality. Access to the audit trail must be restricted and only be granted to authorised persons with concrete access necessities.</p> <p>The audit services of the Hospital Discharge Report service should collect a pre- defined set of operational data provide an adequate quality- and capacity-assessment.</p> <p>These services shall only be used for continuous service delivery and/or service improvement and must not leave the Hospital Discharge Report service context.</p>
Associated goals	Enabling a transparent and reconstructible system operation.

	<p>Documenting compliance and legitimacy of data accesses.</p> <p>Making the Hospital Discharge Report service auditable.</p>
--	---

Table 20: Non-functional Requirement 07: Integrity.

Requirement NFR07	Integrity
Description	<p>The integrity of the transmitted information must be guaranteed.</p> <p>This requirement guarantees that all transmitted data for the Patient arrives at the assessing Healthcare Professional without any alteration from the NCPeH.</p> <p>It must be ensured that the transmitted data has not been damaged, reduced or altered in any way.</p> <p>Any loss of integrity of the transmitted data must be made recognisable to the information's recipient.</p>
Associated goals	<p>For safety reasons.</p> <p>To transmit the Hospital Discharge Report unaltered.</p> <p>To enable detection of any damage, reduction or alteration of the Hospital Discharge Report.</p>

Table 21: Non-functional Requirement 08: Non-repudiation.

Requirement NFR08	Non-repudiation
Description	<p>The issuer of the transmitted information must be held accountable.</p> <p>This requirement guarantees that medical data from the Patient at the assessing Healthcare Professional is supported by the necessary assurance about the issuer of the information.</p> <p>It must remove the possibility that the issuer of information denies that the sending has taken place covering also the content.</p>
Associated goals	To guarantee that the issuer of the information agreed in this deliverable to be exchanged cannot refuse that the issuance has taken place.

Table 22: Non-functional Requirement 09: Guaranteed delivery.

Requirement NFR09	Guaranteed delivery
Description	When information is sent from one Healthcare Service Provider to another, it must be assured that the information has been properly received by the end user.
Associated goals	To check that the Hospital Discharge Report service has been properly completed.

Table 23: Non-functional Requirement 10: Supervision services.

Requirement NFR10	Supervision services
Description	A service must be put in place to detect all the technical exceptions and to check and monitor the performance of the service (time response, communications...) and to alert so that appropriate measures can be performed to solve these exceptions.
Associated goals	<p>To assure that the system is technically working properly.</p> <p>To assure the availability and to avoid degradation of the service, if necessary.</p>

Table 24: Non-functional Requirement 11: Timely completion and release of the documentation of inpatient stay.

Requirement FR11	Timely completion and release of the documentation of inpatient stay
Description	For the HDR to be effective it must be a complete, accurate and relevant record of the inpatient stay and must be released in a timely manner.
Associated goals	To enable the exchange of information between countries. To ensure continuity of care during the transition between different types of care cross border, timely communication between healthcare professionals is required.

Actors	Healthcare Professional EHR systems
--------	--

8 CONCLUSION

The opportunity for leveraging the power and capabilities of the current eHealth Digital Services Infrastructure (eHDSI) for advancing the Patient Summary service and extending it to the hospital discharge reports is both an opportunity and a challenge. The implementation of cross-border hospital discharge reports in the EU requires both an extension and an evolution of the current services and is foreseen to provide an added value to both the healthcare professional and the patient. The functional and non-functional requirements, use cases and relevant logical models included in this document hopefully ensure that this next step in connecting European citizens is done in a meaningful and efficient manner.

9 REFERENCES

- (1) Patel PR, Bechmann S. Discharge Planning. [Updated 2022 Apr 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK557819/>
- (2) Discharges from Hospitals, 2020. Eurostat. [Internet]. Accessed on 12.12.2020. Available from: <https://ec.europa.eu/eurostat/web/products-datasets/-/tps00048>.
- (3) Döring, Nora & Doupi, Persephone & Glonti, Ketil & Gil, Joan & Winkelmann, Juliane & Warren, Emily & McKee, Martin & Knai, Cécile. (2014). Electronic discharge summaries in cross-border care in the European Union: How close are we to making it happen. International Journal of Care Coordination. 17. 10.1177/2053435414540614.
- (4) Berler A, Tagaris A, Chronaki C. European Patient Summary Guideline: Focus on Greece. Stud Health Technol Inform. 2016;224:1-6. PMID: 27225544.
- (5) eHealth Digital Health and Care. European Commission. [Internet]. Accessed on 01.06.2022. Available from: https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en.
- (6) Tulloch AJ, Fowler GH, McMullan JJ, Spence JM. Hospital discharge reports: content and design. Br Med J. 1975;4(5994):443-446. doi:10.1136/bmj.4.5994.443
- (7) Branger PJ, van der Wouden JC, Schudel BR, Verboog E, Duisterhout JS, van der Lei J, van Bommel JH. Electronic communication between providers of primary and secondary care. BMJ. 1992 Oct 31;305(6861):1068-70. doi: 10.1136/bmj.305.6861.1068. PMID: 1467688; PMCID: PMC1883575.
- (8) Rasmussen HH, Pedersen B, Sørensen HT, Freund KS. Epikrisen fra en medicinsk gastroenterologisk afdeling [Epicrisis from a department of medical gastroenterology]. Ugeskr Laeger. 1991 Jun 24;153(26):1868-70. Danish. PMID: 1862571.
- (9) Available from: <https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format>
- (10) eHealth Network. European Commission. [Internet]. Accessed on 01.06.2022. Available from: https://ec.europa.eu/health/ehealth/policy/network_en
- (11) ISO 13606-1:2019(en) Health informatics — Electronic health record communication. ISO (Consys/ISO13940): 10.2.6 Episode of care. International Standards Organization. [Internet]. Accessed on 01.03.2022. Available from: <https://www.iso.org/obp/ui/#iso:std:iso:13606:-1:ed-2:v1:en>.

(12) CDA® Release 2. Health Level 7. [Internet]. Accessed on: 31.10.2020. Available from: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7.

(13) FHIR. Health Level 7. [Internet]. Accessed on: 01.02.2021. Available from: <https://www.hl7.org/fhir/>.

(14) International: Integrating the Healthcare Enterprise (IHE). [Internet]. Accessed on: 01.02.2021. Available from: <https://www.ihe.net/>.

(15) The international standard for identifying health measurements, observations, and documents. LOINC. [Internet]. Accessed on: 01.02.2021. Available from: <https://loinc.org/>.

(16) SNOMED-CT- SNOMED International. [Internet]. Accessed on: 01.02.2021. Available from: <https://www.snomed.org/>.

(17) EU Digital Strategy – European Standardized Digital Patient Summary. European Commission [Internet]. Accessed on: 01.02.2021. Available from: <https://digital-strategy.ec.europa.eu/en/news/european-standard-digital-patient-summary-has-been-approved>.