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An Analysis of the Data Composition of the Estonian National Health Information System and Recommendations for the Implementation of the HL7 FHIR standard

Master's thesis

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Tervise infosüsteemi andmekoosseisu analüüs ja soovitused HL7 FHIR standardi rakendamiseks

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: The Estonian National Health Information System (ENHIS) is crucial for exchanging patient health information among healthcare practitioners, enhancing patient care, and ensuring data transparency. However, reliance on outdated standards like HL7 v3 and CDA limits efficient data management. To address these limitations, Estonia is transitioning to the HL7 FHIR standard, which supports more flexible and near-real-time data exchange. This strategic shift is embodied in the New Generation Health Information System (upTIS) project, aiming to upgrade the ENHIS for greater sustainability and adaptability, thus better meeting the future needs of Estonia's healthcare sector. **The aim of the thesis** is to propose recommendations for planning the implementation of the FHIR standard in Estonia's healthcare system by providing guidelines for determining and prioritising data sections and addressing key considerations of the transition process. **Methods:** A qualitative descriptive case study was conducted, involving document and content analysis to identify common and overlapping data sections within ENHIS documents. Data sections were then mapped to corresponding FHIR resources using a migration methodology by Bossenko et al., and the FHIR specification was analysed to examine key implementation considerations. **Results:** The analysis covered 28 ENHIS document compositions, identifying 77 unique data sections, 38 of which overlap. Out of 77 data sections examined, 50 were mapped to FHIR resources, 27 sections did not receive results. Key considerations for FHIR implementation were analysed and described. Based on the results of the study, recommendations were proposed for implementing the FHIR standard in Estonia. **Conclusions:** The transitioning to the HL7 FHIR standard offers a significant opportunity to enhance interoperability, streamline data management, and improve healthcare delivery in Estonia. This study's findings and recommendations provide a strategic roadmap for implementing the FHIR standard in Estonia.

This thesis is written in English and is 49 pages long, including 6 chapters, 5 figures and 3 tables.

Annotatsioon

Tervise infosüsteemi andmekoosseisu analüüs ja soovitused HL7 FHIR standardi rakendamiseks

Taust: Tervise infosüsteem (TIS) on patsiendi terviseandmete vahetamiseks tervishoiutöötajate vahel oluline, parandades patsiendi ravi ja tagades andmete läbipaistvuse. Sõltuvus vananenud standarditest nagu HL7 v3 ja CDA piirab tõhusat andmehaldust. Nende takistuste ületamiseks liigub Eesti üle HL7 FHIR standardile, mis toetab paindlikumat ja peaaegu reaalajas andmevahetust. Seda strateegilist muutust kehastab Uue Põlvkonna Tervise infosüsteemi (upTIS) projekt, mille eesmärk on uuendada TIS suurema jätkusuutlikkuse ja kohanemisvõime saavutamiseks, et paremini vastata Eesti tervishoiusektori tulevikuvajadustele. **Lõputöö eesmärk** on teha ettepanekuid FHIR standardi rakendamise planeerimiseks Eesti tervishoiusüsteemis, pakkudes juhiseid andmesektsioonide määramiseks ja prioriseerimiseks ning käsitledes ülemineku protsessi peamisi kaalutlusi. **Metoodika**: Viidi läbi kvalitatiivne kirjeldav juhtumiuuring, mis hõlmas dokumentide ja sisuanalüüsi, et tuvastada TIS dokumentides levinud ja kattuvad andmesektsioonid. Seejärel vastendati andmesektsioonid vastavate FHIR ressurssidega, kasutades Bossenko jt. migratsioonimetoodikat, ning analüüsiti FHIR spetsifikatsiooni, et uurida peamisi rakendamise kaalutlusi. **Tulemused**: Analüüs hõlmas 28 TIS dokumendi andmekoosseisu, tuvastades 77 unikaalset andmesektsiooni, millest 38 kattuvad. 77-st uuritud andmeosast vastendati 50 FHIR ressursiga, 27 sektsioonile ei saadud tulemusi. FHIR rakendamise peamised kaalutlused analüüsiti ja kirjeldati. Uuringu tulemuste põhjal tehti ettepanekuid FHIR standardi rakendamiseks Eestis. **Järeldused**: Üleminek HL7 FHIR standardile pakub olulist võimalust parandada koostalitlusvõimet, muuta sujuvamaks andmehaldust ja parandada tervishoiuteenuste osutamist Eestis. Selle uuringu tulemused ja soovitused pakuvad strateegilist teekaarti FHIR standardi rakendamiseks Eestis.

Lõputöö on kirjutatud Inglise keeles ning sisaldab teksti 49 leheküljel, 6 peatükki, 5 joonist, 3 tabelit.

List of abbreviations and terms

API	Application Programming Interfaces
AI	Artificial intelligence
CDA	Clinical Document Architecture
DCM	Detailed Clinical Model
EHDS	European Health Data Space
EHR	Electronic Health Record
EIF	European Interoperability Framework
EU	European Union
ENHIS	Estonian National Health Information System
FHIR	Fast Healthcare Interoperability Resources
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
HTTP	Hypertext Transfer Protocol
IG	Implementation Guide
MMD	Multilevel Model-Driven
PKI	Public Key Infrastructure
RDF	Resource Description Framework
REST	Representational State Transfer
SOA	Service-Oriented Architecture
SOAP	Simple Object Access Protocol
WSDL	Web-Service Description Language
TEHIK	Health and Welfare Information Systems Centre
upTIS	New Generation Health Information System (*uue põlvkonna tervise infosüsteem*)

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1 Introduction

The Estonian National Health Information System (ENHIS), launched in 2008 and managed by the Health and Welfare Information Systems Centre (TEHIK) on behalf of the Ministry of Social Affairs and Estonian Health Insurance Fund, is a cornerstone of Estonia's healthcare infrastructure. This centralised database significantly enhances healthcare practitioners' interoperability, enabling patient health information exchange. It enables healthcare providers to access comprehensive health data histories and allows patients to oversee their data access through a dedicated portal. This infrastructure plays a crucial role in optimising patient care and ensuring data transparency within the Estonian healthcare ecosystem [1].

The reliance on outdated paper-based processes and the use of traditional standards like HL7 (Health Level Seven) v3 messages and the Clinical Document Architecture (CDA) has led to a system where a significant amount of the health data, being unstructured and in free text, offers limited reuse value. The current document-centric nature of the ENHIS struggles to meet the modern healthcare system's needs for structural flexibility and rapid data exchange [1], [2], [3].

Recognising these challenges, a strategic decision has been made in the evolution of the health information system to transition from document-based data exchange to a more flexible, near-real-time data exchange. This change aims to ensure that health data are readily available to relevant parties when needed, enhancing efficiency. The decision has been made to adopt the HL7 FHIR (Fast Healthcare Interoperability Resources) data exchange standard. This standard is well-suited for meeting the expectations set for the data exchange of future services due to its structure [2].

In response to these evolving demands, the New Generation Health Information System (upTIS, *uue põlvkonna tervise infosüsteem*) project was initiated in 2021, marking the commencement of efforts to upgrade the ENHIS. This transition not only aims to foster more sustainable healthcare operations but also to integrate innovative solutions through

a new data exchange platform, ensuring the ENHIS's adaptability and effectiveness in meeting the future needs of Estonia's healthcare sector [3].

Problem statement: The transition from the outdated HL7 v3 and CDA standards to the more flexible and modern HL7 FHIR standard requires a strategic plan to ensure seamless data integration when shifting from document-based to data-based exchange [3].

Aim: This study aims to propose recommendations for planning the implementation of the FHIR standard in Estonia's healthcare system by providing guidelines for determining and prioritising data sections and addressing key considerations of the transition process.

Objectives:

- Examine the common data sections within the documents of the ENHIS.
- Map and analyse the alignment of data sections with corresponding FHIR resources.
- Propose recommendations for implementing the FHIR standard in Estonia's healthcare setting.

Research questions:

1. What CDA documents are sent to the ENHIS?
2. What data sections does the ENHIS consist of, and which data sections overlap within the documents of the ENHIS?
3. Which FHIR resources conform to the data sections identified in the ENHIS?
4. What essential relations between FHIR resources need consideration to ensure seamless integration of the FHIR standard?

2 Background

This chapter presents a comprehensive overview of the ENHIS and the strategic vision for transitioning to an event-based data exchange model. It further elaborates on the concept of interoperability, underscoring its essential role in facilitating the effective exchange of health data across healthcare systems. Additionally, this gives an overview of previous studies regarding mappings from the CDA standard to the FHIR standard.

2.1 The Estonian National Health Information System (ENHIS)

Electronic Health Records (EHR) are comprehensive, cross-institutional, and longitudinal collections of a patient's health and healthcare data, including information relevant to medical treatment and overall health [4]. EHRs allow seamless communication and collaboration between healthcare providers, improving the quality and efficiency of healthcare delivery by providing accurate and up-to-date information. EHRs are supported by data standards and quality measures to ensure consistency and accuracy of the information [5].

The ENHIS is a standardised central repository for the health data of Estonian residents from birth to death. Integrating seamlessly with other public IT services enhances convenience for users ranging from citizens to healthcare professionals. Through the ENHIS, a wide range of actions such as data entry, appointment booking, and patient information retrieval are facilitated [6].

The content and functionalities of the ENHIS are defined by statutory law, and messages are processed according to regulated validation and security requirements [6]. The essential components of the ENHIS are the X-Road, a government-operated data exchange platform, and the e-identity system with its Public Key Infrastructure (PKI). X-Road ensures secure data transfers between information systems by encrypting and digitally signing outgoing data while authenticating and logging incoming data. It is built on standard Service-Oriented Architecture (SOA) principles, employing Simple Object

Access Protocol (SOAP) messages and Web-Service Description Language (WSDL) for secure and efficient data exchange [7].

The ENHIS is governed by four key regulations: the “Health Services Organisation Act” (*Tervishoiuteenuste korraldamise seadus*) [8], the “Health Information System Statute” (*Tervise infosüsteemi põhimäärus*) [9], the “Conditions and procedure for documenting the provision of health care services” (*Tervishoiuteenuse osutamise dokumenteerimise tingimused ja kord*) [10], and Regulation No. 53 issued by the Minister of Social Affairs, “Data composition of the documents to be transmitted to the health information system and the conditions and procedure for their submission” (*Tervise infosüsteemi edastatavate dokumentide andmekoosseisud ning nende esitamise tingimused ja kord*) [11].

According to the regulations [8], [9], the ENHIS serves multiple purposes, such as facilitating the execution and management of healthcare service contracts, ensuring the quality of health services and patients' rights, protecting public health, maintaining health registers, organising health statistics, and overseeing healthcare management. The Ministry of Social Affairs and the Estonian Health Insurance Fund jointly control the ENHIS, with its foundation and statutes being determined by Estonian government regulation, the “Health Information System Statute” [9]. This regulation outlines the responsibilities of co-controllers and processors, data management procedures, access protocols, and organisational matters.

The ENHIS processes a wide variety of data, including patient demographics, employment and insurance information, medical records, and data processing logs, ensuring long-term preservation and strict access controls. The regulation mandates healthcare providers to submit specific information to enhance care delivery and allows patients’ rights to input data for better service provision [8]. Healthcare providers must document the provision of healthcare services, including services delivered through communication technologies, and send the data to the ENHIS [10]. The data composition of the documents to be transmitted to the health information system and the conditions and procedures for their submission are established by regulation [11]. The ENHIS exchanges digital health documents in a standardised way, using international standards such as HL7 v3 and CDA [3], [7]. TEHIK, serving as a critical processor for the ENHIS, is responsible for ensuring the management and maintenance of the database by the requirements laid out in legal acts. This includes overseeing technical administration,

such as maintaining and publishing classifications, code systems, and data exchange standards [9].

2.1.1 The New Generation Health Information System

The ENHIS is rooted in outdated legacy paper-based workflows, making it challenging to offer the modern, intuitive solutions that Estonian patients and healthcare professionals anticipate. The inflexibility and complex modification requirements for specific data formats contribute to considerable hurdles and disproportionately high expenses in evolving healthcare services. Moreover, the ENHIS relies on the HL7 v3 messages and CDA document standard for exchanging health data; a considerable amount of this data is unstructured and recorded in free text, significantly reducing its reuse potential. This setup not only hinders the system's efficiency but also limits the innovation and adaptability needed to meet Estonia's e-health ambitions [2], [3].

The vision of the New Generation Health Information System (upTIS, *uue põlvkonna tervise infosüsteem*) project aims to transform the ENHIS into a flexible, interoperable, and user-focused ecosystem that supports the health and well-being of Estonian residents throughout their lives. This ecosystem aims to provide patients with better oversight and control over their health through smart solutions that ensure continuity of care, improve clinical processes, save time for health professionals, and allow for quick and informed decisions through high-quality and accessible health data [3].

The goal to make the ENHIS collaborative and interoperable involves establishing centrally managed and universally applied terminology based on international standards to ensure uniform terminology usage across the health system. This central management is essential for avoiding confusion and ensuring data can be effectively shared and used, both domestically and internationally. Simultaneously, adopting internationally recognised data exchange standards, like HL7 FHIR, and developing information models that accommodate the specifics of Estonia and adhere to international terminologies are essential. These measures aim to enhance the flexibility of data exchange, specifying the maximum data set for collection while ensuring interoperability [3].

2.2 Healthcare interoperability

Healthcare interoperability encompasses the dynamic and multifaceted ability of diverse healthcare information systems, applications, and devices to access seamlessly and efficiently, exchange, integrate, and cooperatively utilise data. This essential capability underpins the collaborative workings of these systems within and across organisational boundaries to enhance healthcare delivery to individuals and communities. By enabling the effective sharing and maintaining of data's clinical or operational integrity, purpose, security, and confidentiality throughout its exchange process, healthcare interoperability supports the provision of effective healthcare services and the sharing of knowledge through established business processes [12], [13].

The Healthcare Information and Management Systems Society (HIMSS) Integration and Interoperability Steering Committee emphasises that systems must interoperate in various dimensions to support healthcare processes effectively. These dimensions include ensuring data moves uniformly without alteration, data is presented consistently to different stakeholders, user controls are uniform across systems, data security and integrity are safeguarded, patient confidentiality is protected, and a common degree of system service quality is maintained. Achieving interoperability is essential for the healthcare industry's goal to advance the effective delivery of healthcare [13].

The European Commission has introduced The New European Interoperability Framework (EIF), which provides guidance on achieving interoperability, ensuring that public services across Europe can interact seamlessly. The EIF outlines principles, models, and recommendations for achieving interoperability across different layers: legal, organisational, semantic, and technical. It aims to support the digital single market by improving the interoperability of European public services and enhancing their efficiency, accessibility, and effectiveness across the European Union (EU) [12]. In addition, the European Commission has proposed establishing the European Health Data Space (EHDS). The EHDS will create a health-specific ecosystem with defined rules, common standards, practices, infrastructures, and a governance framework. It focuses on giving individuals greater digital access and control over their electronic health data both nationally and EU-wide, promoting free movement, and supporting a unified market for electronic health record systems, related medical devices, and high-risk Artificial

intelligence (AI) systems. Additionally, it seeks to establish a reliable and efficient framework for using health data in research, innovation, and policymaking [14].

2.3 Healthcare data exchange

Interoperability in healthcare is currently an unreached goal due to the development of independent and heterogeneous electronic health information systems within healthcare organisations. This results in many proprietary models for representing and recording patients' information, hindering the seamless exchange of information across healthcare systems. Lack of interoperability among healthcare systems leads to information silos, increased healthcare costs, declining quality of patient care, and the inability to integrate patients' information across systems [15]. The critical need for uniform terminologies and data standards in healthcare is increasingly recognised. As the exchange of electronic health records becomes more prevalent and health information exchanges grow, the urgency for standardised data protocols continues to surge. If these data standards are established and implemented, interoperability could be achieved more swiftly. It is becoming widely understood that health information technology can positively influence healthcare reform, with data standardisation and interoperability playing key roles in facilitating this progress [16].

The ENHIS is currently exchanging health data with the HL7 v3 messages and CDA document standard [7]. The decision has been made to transform from a document-based approach to an event-based approach adopt the HL7 FHIR standard [2]. FHIR was created by HL7 International). It combines features of HL7 v2, HL7 v3, and CDA standard, utilising Hypertext Transfer Protocol (HTTP) based Representational State Transfer (REST) Application Programming Interfaces (API) for accessing and handling patient health data at a granular level [17]. FHIR solutions are built from modular components called resources, which can be easily assembled into working systems to solve real-world clinical and administrative problems. FHIR resources cover a wide range of concepts, including administrative concepts (e.g., patient, provider, organisation, device) and clinical concepts (e.g., problems, medications, diagnostics, care plans) [18]. A FHIR Implementation Guide (IG) defines how to use FHIR resources to address specific interoperability issues. It includes profiles, extensions, value sets, and examples to standardise FHIR implementations [19].

HL7 International and Firely conducted a study [20], representing a significant effort to understand the global adoption and use of the FHIR standard. Gathering insights from 24 countries, the survey illustrates a worldwide interest in FHIR, with EHR vendors, app developers, and care providers being the primary adopters. The main motivations behind adopting the FHIR standard include innovation, regulatory influence, grants, and the potential for improved care, with significant achievements being enhanced access to information, lower costs, and better healthcare outcomes. However, the survey also identifies major challenges, such as a general lack of knowledge about the FHIR standard, unclear regulations, high investment costs, and uncertain benefits, which must be addressed to expand the adoption of the FHIR standard further globally.

2.3.1 Previous studies on mappings of CDA to FHIR

Several studies have been conducted on migrating from the other standards to the FHIR standard. In the context of Estonia, significant research has been conducted by Bossenko et al. [21]. This study analysed the CDA-based data, including patients' socioeconomic status in Estonia's Infectious Disease Information System. As a result of the study, a migration methodology of CDA documents and their components was developed. The methodology involves analysing each element and list critically, creating a comprehensive list of search keywords, checking both the FHIR site and Registry for matching profiles, reusing profiles where possible, searching openEHR for suitable archetypes and SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) and LOINC (Logical Observation Identifiers Names and Codes) for matching terminology, and finally developing, adapting, or adopting appropriate profiles and terminology.

An Austrian study proposed transforming HL7 CDA documents into FHIR resources using a JSON mapping strategy. Leveraging Java and the HAPI-FHIR framework, the method aligns with FHIR standards, enabling the reuse of existing infrastructure and providing granular access to CDA documents [22]. In Italy, a study introduces an innovative architectural model for extracting FHIR resources from CDA documents, focusing on the Italian Patient Summary. The model has four components: an interface for selecting FHIR resources, an extraction component for locating sections in CDA documents, mapping schemas for conversion, and a building component for compiling FHIR resources [23]. A Dutch study compared CDA and FHIR representations of

Detailed Clinical Models (DCMs) for interconvertibility and consistency. While most aspects were adequately represented, issues arose with restrictions, coded values, narrative structures, and attribute meanings. These issues could lead to a loss of meaning and interoperability challenges, highlighting the importance of choosing the right standard for DCM implementation [24]. The work of Luz et al. [25] demonstrated the conversion of FHIR schemas into an operational, semantically interoperable framework, employing the Multilevel Model-Driven (MMD) approach. By incorporating Resource Description Framework (RDF) triples into XML Schema Domain Models, this methodology bridges FHIR with the Semantic Web, enhancing healthcare information's semantic expressiveness. This work underscores the potential of integrating FHIR with semantic technologies to achieve comprehensive interoperability in healthcare informatics.

In conclusion, various studies highlight the diverse approaches to migrating and transforming CDA documents to the FHIR standard. These efforts encompass a range of methodologies, from the critical analysis of data elements and keyword searches to the development of JSON mapping strategies and innovative architectural models.

3 Methodology

This chapter outlines the research methodology adopted for this thesis, which aims to propose recommendations for implementing the FHIR standard in Estonia's healthcare setting. This involves analysing the data compositions managed by the ENHIS, mapping data sections to FHIR resources, and analysing key factors for FHIR implementation. The Data analysis subchapter presents a detailed examination of the methodologies employed to achieve the study's objectives and address the research questions.

3.1 Study design

The study utilises a qualitative descriptive case study design. The choice of this study design is grounded in the need to examine the data composition of the ENHIS and to map data sections to FHIR. Case studies are tailored to fit the case and research question [26], serving to understand a complex problem deeply and comprehensively within its actual environment. This research strategy can be articulated through multiple definitions, all emphasising the importance of thoroughly investigating an occurrence or phenomenon in its genuine setting [27]. The ENHIS provides a unique case due to its advanced digital health infrastructure and its integral contribution to the national healthcare system. Analysing the data composition of the ENHIS's documents within this specific system offers valuable insights into the challenges and opportunities of transitioning to the FHIR standard.

The descriptive component of this study is crucial for answering the research questions. It allows for a systematic analysis of the documents, identifying specific data sections, and mapping these sections to FHIR resources. This approach aligns with the goals of descriptive research to describe a phenomenon, situation, or condition accurately and systematically [28]. This study combines the qualitative descriptive method with the work of Bossenko et al. [21], which proposes a migration methodology of CDA documents to FHIR. It involves analysing CDA documents, compiling a list of search keywords, and

examining the FHIR specification' search [29] and FHIR Registry [30] for matching resources. Bossenko et al.'s methodology was chosen as it aligns best with the thesis objectives. This approach facilitates mappings at a semantic level, while other methodologies described in previous chapter utilised more technical mappings, making Bossenko et al.'s method the most appropriate for achieving the objectives.

The data analysis was structured into two phases based on the objectives of this study and the migration methodology proposed by Bossenko et al. [21]. The initial phase focused on collecting and analysing data compositions of documents sent to the ENHIS, informing the subsequent phase of mapping these data sections to FHIR resources. This included a document analysis to examine the data compositions of the documents sent to the ENHIS, followed by a content analysis to pinpoint specific overlapping data sections. These sections served as the basis for the second phase, utilising comparative analysis to match data sections to FHIR resources. The process culminated in thoroughly examining the FHIR specification [31] to identify critical interconnections between FHIR resources, facilitating transition to the FHIR standard.

3.2 Data collection

The collection of data for this study involved a detailed examination of data compositions of documents submitted to the ENHIS. To acquire a comprehensive understanding of the data sets of the ENHIS, this study drew upon three primary sources. The first source was Regulation No. 53 of the Minister of Social Affairs: "Data composition of the documents to be transmitted to the health information system and the conditions and procedure for their submission" [11] and it provides foundational guidelines on the content requirements for documents sent to the ENHIS. This regulation was enacted in 2008 and in this study the currently valid regulation, which came into force May 26, 2023, is analysed.

List of data compositions of the ENHIS documents from the regulation of the Minister of Social Affairs [11]:

1. Data composition of outpatient case summary *(Ambulatoorne epikriisi andmekoosseis)* [32]*;*
2. Data composition of inpatient and daycare discharge summary *(Statsionaarne ja päevaravi epikriisi andmekoosseis)* [33]*;*

3. Data composition of referral for examination, procedure, and analysis *(Uuringu, protseduuri ja analüüsi saatekirja andmekoosseis)* [34]*;*
4. Data composition of reply to referral *(Saatekirja vastuse andmekoosseis)* [35]*;*
5. Data composition of notice of outpatient case opening *(Ambulatoorse haigusjuhtumi avamise teatise andmekoosseis)* [36]*;*
6. Data composition of notice of inpatient case opening *(Statsionaarse haigusjuhtumi avamise teatise andmekoosseis)* [37]*;*
7. Data composition of notice of outpatient case closing *(Ambulatoorse haigusjuhtumi lõpetamise teatise andmekoosseis)* [38]*;*
8. Data composition of notice of inpatient case closing *(Statsionaarse haigusjuhtumi lõpetamise teatise andmekoosseis)* [39]*;*
9. Data composition of notice of development assessment *(Arengu hindamise teatise andmekoosseis)* [40]*;*
10. Data composition of notice of immunisation *(Immuniseerimise teatise andmekoosseis)* [41]*;*
11. Data composition of notice of examination *(Läbivaatuse teatise andmekoosseis)* [42]*;*
12. Data composition of notice of counselling *(Nõustamise teatise andmekoosseis)* [43]*;*
13. Data composition of notice of growth *(Kasvamise teatise andmekoosseis)* [44]*;*
14. Data composition of ambulance card *(Kiirabikaardi andmekoosseis)* [45]*;*
15. Dental card *(Hambaravikaart)* [46]*;*
16. Health declaration *(Tervisdeklaratsioon)* [47]*;*
17. Health certificate *(Tervisetõend)* [48]*;*
18. Data composition of referral for outpatient service, including e-consultation *(Ambulatoorse teenuse, sealhulgas e-konsultatsiooni saatekirja andmekoosseis)* [49]*;*
19. Data composition of notice of death *(Surmateatise andmekoosseis)* [50]*;*
20. Data composition of notice of cause of death (*Surma põhjuse teatise andmekoosseis)* [51]*;*
21. Data composition of notice of perinatal death cause *(Perinataalsurma põhjuse teatise andmekoosseis)* [52]*;*

22. Data composition of referral for independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse saatekirja andmekoosseis)* [53]*;*
23. Data composition of referral for inpatient and daycare services *(Statsionaarse ja päevaraviteenuse saatekirja andmekoosseis)* [54]*;*
24. Data composition of case summary of independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse õendusepikriisi andmekoosseis)* [55]*;*
25. Data composition of birth summary *(Sünniepikriisi andmekoosseis)* [56]*;*
26. Data composition of notice of suspected infectious disease *(Nakkushaiguse kahtluse teatise andmekoosseis)* [57]*;*
27. Data composition of notice of infectious disease *(Nakkushaiguse kahtluse teatise andmekoosseis)* [58]*;*
28. Data composition of notice of HIV *(HIV teatise andmekoosseis)* [59].

In addition to the regulation of the Minister of Social Affairs, two other sources were used in the analysis process. Firstly, the CDA templates which are technical and structured formats of documents sent to the ENHIS were examined. These templates are available in the data exchange management software of TEHIK's Information Centre [60]. The data compositions of the ENHIS's documents in the regulation are based on the CDA templates. The data compositions in the annex of the regulation are simplified, non-technical presentations of the CDA document data sets. Secondly, the instructions for filling out the documents sent to the ENHIS, which are published in the Publishing Centre of TEHIK, were studied [61]. These instructions serve as a practical guide for healthcare providers, ensuring that the submitted documents are both complete and compliant with established standards.

For the analysis of the FHIR standard, this study reviewed the FHIR standard specification [28] along with the FHIR Registry [30]. The specification [29] provides a detailed overview of the structural and functional requirements of FHIR resources, providing guidance for comparing and mapping the data compositions of the ENHIS's data sections. The FHIR Registry [30] provides additional context and resources, supporting a deeper understanding of FHIR's implementation and potential alignments with existing data sections.

3.3 Data analysis

Based on the research questions of this study and the migration methodology proposed by Bossenko et al. [21], the data analysis was separated into two phases. The first phase focused on collecting and analysing the ENHIS documents' data compositions and was an input for the second phase of the study. The second phase focused on mapping data sections to FHIR resources and analysing interconnections between FHIR resources.

3.3.1 The analysis of documents managed by the ENHIS

To answer the first two research questions, "What CDA documents are sent to the ENHIS?" and "What data sections does the ENHIS consist of, and which data sections overlap within the documents of the ENHIS?", a document analysis and a content analysis were conducted.

Document analysis is a valuable data source in qualitative research. Document analysis is particularly applicable to qualitative case studies, providing rich descriptions of a single phenomenon, event, organisation, or program. It can uncover meaning, develop understanding, and discover insights relevant to the research problem [62]. Document analysis laid the foundation for the broader goals of this thesis. A thorough understanding of the data compositions of the documents submitted to the ENHIS was important before identifying overlaps and mapping data sections to the FHIR standard.

The data compositions of the documents that are sent to the ENHIS were collected from Regulation No. 53 of the Minister of Social Affairs: "Data composition of the documents to be transmitted to the health information system and the conditions and procedure for their submission" [11]. The initial phase of document analysis involved a thorough examination of the data compositions of each document type. The aim of this analysis was to understand the structure and specific content of each document. The goal was to identify content patterns and similarities that would allow for logical grouping, simplifying further analysis. This review led to the organisation of the documents into four main categories based on content similarities: "Case summaries", "Referrals", "Notices", and "Other" for documents that did not fit into the first three categories (Table 1). The thorough classification and comprehensive study of these document types laid the groundwork for the next research stage, content analysis.

Table 1 List and categorisation of documents sent to the ENHIS

Category	Documents sent to the ENHIS
Case summaries	Outpatient case summary *(Ambulatoorne epikriis)*
	Inpatient and daycare discharge summary *(Statsionaarne ja päevaravi epikriis)*
	Birth summary *(Sünniepikriis)*
	Case summary of independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse õendusepikriis)*
Referrals	Referral for examination, procedure, and analysis *(Uuringu, protseduuri ja analüüsi saatekiri)*
	Referral for outpatient service, including e-consultation *(Ambulatoorse teenuse, sealhulgas e-konsultatsiooni saatekiri)*
	Referral for inpatient and daycare services *(statsionaarse ja päevaraviteenuse saatekiri)*
	Referral for independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse saatekiri)*
Notices	Notice of outpatient case opening *(Ambulatoorse haigusjuhtumi avamise teatis)*
	Notice of inpatient case opening *(Statsionaarse haigusjuhtumi avamise teatis)*
	Notice of outpatient case closing *(Ambulatoorse haigusjuhtumi lõpetamise teatis)*
	Notice of inpatient case closing *(Statsionaarse haigusjuhtumi lõpetamise teatis)*
	Notice of development assessment *(Arengu hindamise teatis)*
	Notice of examination *(Läbivaatuse teatis)*
	Notice of counselling *(Nõustamise teatis)*
	Notice of growth *(Kasvamise teatis)*
	Notice of immunisation *(Immuniseerimise teatis)*
	Notice of death *(Surmateatis)*

	Notice of cause of death *(Surma põhjuse teatis)*
	Notice of perinatal death cause *(Perinataalsurma põhjuse teatis)*
	Notice of suspected infectious disease *(Nakkushaiguse kahtluse teatis)*
	Notice of infectious disease *(Nakkushaiguse kahtluse teatis)*
	Notice of HIV *(HIV teatis)*
Other	Reply to referral *(Saatekirja vastus)*
	Ambulance card *(Kiirabikaart)*
	Dental card *(Hambaravikaart)*
	Health declaration *(Tervisde tervisetõend klaratsioon)*
	Health certificate *(Tervisetõend)*

A content analysis was performed to identify overlapping data sections in the documents' data compositions sent to the ENHIS. Content analysis is a method frequently utilised in qualitative research for examining words or phrases within textual documents [63]. This study uses an inductive approach, meaning the codes were derived from the data itself, not from the previous research or pre-existing theories [64]. Content analysis was pursued by comparing sections of the data compositions of the ENHIS's documents, which are described in Regulation No. 53 of the Minister of Social Affairs [11]. Additionally, the CDA templates of the ENHIS documents and the instructions for healthcare professionals to fill out the documents were studied. Both sources enabled a more granular and substantive comparison of the data elements contained in the documents. The list of instructions for filling out the documents used in the content analysis can be found in Appendix 1.

Microsoft Excel was used to create a cross-tabulation matrix to systematically examine and identify overlapping sections across the different ENHIS documents. This matrix was structured with the document types arrayed across the top row, serving as column headers, and the titles of the data sections listed vertically in the leftmost column. This arrangement provided a clear and accessible framework for mapping out the presence or absence of data section overlap among the documents.

In the cross-tabulation matrix, two symbols were used to mark the overlap between data sections: an "X" symbol was used to indicate a complete overlap, where most of a data section's content was found to be duplicated across documents. A "V" symbol was employed to signify a partial overlap, where only some portions of the data section were found to be replicated across documents. To enhance the utility and precision of the analysis, cells marked with a "V" were further annotated with comments. These comments provided detailed insights into the specific elements of the data sections that were partially overlapping, thus offering a nuanced view of the data composition within the documents.

The content analysis began by focusing on the case summaries, starting with the Outpatient case summary's data composition. For each document of data composition analysed, the section titles contained within the document were catalogued in the left column of the matrix, establishing a baseline for comparison. The following analyses of other documents' data compositions involved the identification of overlapping sections marked by "X" symbols in the corresponding rows. Sections not overlapping with previously analysed documents were listed anew in the left column, thereby progressively building a comprehensive list of document sections. An example of the content analysis of the data compositions of Outpatient case summary, Inpatient and daycare discharge summary and Birth summary is presented in Table 2.

Table 2 Content analysis of the data compositions of Outpatient case summary, Inpatient and daycare discharge summary and Birth summary

Document section	**Outpatient case summary**	**Inpatient and daycare discharge summary**	**Birth summary**
Medical document data	X	X	X
Document author	X	X	X
Patient data	X	X	X
Referral data	X	X	X
Case data	X	X	X
Diagnosis	X	X	X
Anamnesis	X	X	

Objective findings	X		
Allergies	X	X	
Observations/procedures	X	X	
Radiological examination	X	X	
Surgical operations	X	X	
Laboratory analysis	X	X	X
Pathology examination	X	X	
Endoscopy examination	X	X	
Immunisations	X	X	X
Patient treatment summary	X	X	X
Condition upon discharge from hospital		X	X
Regimen and treatment (including rehabilitation) recommendations	X	X	
Work organisation or environment modification	X	X	V
Administrated medications	X	X	X
Prescribed medications	X	X	X
Issued documents	X	X	X
Data on outpatient visit	X	X	

The list of overlapping sections identified in the content analysis is crucial input for the second phase, being the search words for matching data sections to the FHIR standard, as developing a list of all possible search keywords is a key step in the migration methodology of Bossenko et al. [21]. TEHIK experts who manage CDA templates of the ENHIS documents evaluated the finalised list of overlapping document sections.

3.3.2 Mapping the ENHIS's data sections to FHIR

To answer the third research question, "Which FHIR resources conform to the data sections identified in the ENHIS?" comparative analysis was performed using the steps proposed by Bossenko et al. [21], which was checking the FHIR specification's search [29] and the FHIR Registry [30] for resources matching the search keywords. The list of overlapping sections identified in the content analysis was used as the search words. The goal was to identify FHIR resources that align closely with the data sections and documentation practices currently in place within the ENHIS. By systematically mapping the coded data sections to corresponding FHIR resources, the study laid a foundation for understanding the challenges and opportunities in transitioning from the CDA standard to the FHIR standard in the Estonian healthcare ecosystem.

Finally, to answer the fourth research question, "What essential relations between FHIR resources need consideration to ensure a seamless integration of the FHIR standard?" FHIR specification [31] was thoroughly analysed. This included examining the interrelationships and dependencies of the various FHIR resources. This step was crucial for identifying any dependencies or relationships that play a central role in maintaining data integrity and ensuring a seamless integration process. By determining how these FHIR resources link together, recommendations could be defined for implementing the FHIR standard in Estonia.

4 Results

This chapter presents the results of the study, giving an overview of the outcomes of the analyses conducted on the data compositions of documents dent to the ENHIS, the results of the mappings of data sections to the FHIR standard, as well as evaluation of key factors for FHIR implementation. This chapter aims to address the research questions posed in this study. The data analysis was separated into two phases based on the research questions. The first phase focused on collecting and analysing the ENHIS documents' data compositions and was an input for the study's second phase. The second phase focused on mapping the ENHIS's data sections to FHIR resources and identifying critical interconnections between FHIR resources.

4.1 Overview of the data composition of the ENHIS

A document analysis and a content analysis were conducted to give answers to two first research questions: "What CDA documents are sent to the ENHIS?" and "What data sections does the ENHIS consist of, and which data sections overlap within the documents of the ENHIS?". The list of overlapping sections identified in the content analysis was crucial input for the second phase, being the search words for matching data sections to the FHIR standard.

4.1.1 Documents managed by the ENHIS

Document analysis included a detailed examination of the content of documents sent to the ENHIS described in the Minister of Social Affairs regulation [11]. The regulation lists the data compositions of 28 documents that are submitted to the ENHIS:

1. Outpatient case summary *(Ambulatoorne epikriis);*
2. Inpatient and daycare discharge summary *(Statsionaarne ja päevaravi epikriis);*
3. Birth summary *(Sünniepikriis);*
4. Case summary of independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse õendusepikriis);*

5. Referral for examination, procedure, and analysis *(Uuringu, protseduuri ja analüüsi saatekiri);*
6. Referral for outpatient service, including e-consultation *(Ambulatoorse teenuse, sealhulgas e-konsultatsiooni saatekiri);*
7. Referral for inpatient and day care services *(statsionaarse ja päevaraviteenuse saatekiri);*
8. Referral for independent inpatient nursing service and home nursing service *(Iseseisva statsionaarse õendusabiteenuse ja koduõendusteenuse saatekiri);*
9. Notice of outpatient case opening *(Ambulatoorse haigusjuhtumi avamise teatis);*
10. Notice of inpatient case opening *(Statsionaarse haigusjuhtumi avamise teatis);*
11. Notice of outpatient case closing *(Ambulatoorse haigusjuhtumi lõpetamise teatis);*
12. Notice of inpatient case closing *(Statsionaarse haigusjuhtumi lõpetamise teatis)*
13. Notice of development assessment *(Arengu hindamise teatis);*
14. Notice of examination *(Läbivaatuse teatis);*
15. Notice of counselling *(Nõustamise teatis);*
16. Notice of growth *(Kasvamise teatis);*
17. Notice of immunisation *(Immuniseerimise teatis);*
18. Notice of death *(Surmateatis);*
19. Notice of cause of death *(Surma põhjuse teatis);*
20. Notice of perinatal death cause *(Perinataalsurma põhjuse teatis);*
21. Notice of suspected infectious disease *(Nakkushaiguse kahtluse teatis);*
22. Notice of infectious disease *(Nakkushaiguse teatis);*
23. Notice of HIV *(HIV teatis);*
24. Reply to referral *(Saatekirja vastus);*
25. Ambulance card *(Kiirabikaart);*
26. Dental card *(Hambaravikaart);*
27. Health declaration *(Tervisedeklaratsioon);*
28. Health certificate *(Tervisetõend)*.

The CDA documents can be divided into categories based on content similarities: “Case summaries”, “Referrals”, and “Notices”. In addition, documents that do not fit the above categories are sent to the information system: Reply to referral, Ambulance card, Dental card, Health declaration and Health certificate. The categorisation is presented in Table

1, “List and categorisation of documents sent to the ENHIS,” in the Data Analysis subsection of the Methodology chapter.

Case summaries

A case summary is a conclusion of a patient's medical case, reflecting the case's dynamics based on the relevant information available to the physician [65].

- **An Outpatient case summary** is completed for each outpatient case after its conclusion. An outpatient case involves patient examination and treatment procedures within a healthcare facility focused on a specific speciality in outpatient care. It includes initial visits (including home visits), follow-up appointments, and other treatment-related activities like examinations and procedures. The outpatient case starts with a referral or a voluntary patient visit and concludes with the physician's decision to close the case. An outpatient case lasts no longer than 3 months [65]. Outpatient case summary must be submitted to the ENHIS within 1 working day after the health worker has approved the document [9].

- **An Inpatient discharge summary** includes a patient's examinations and treatment at a healthcare facility from hospitalisation to discharge. Inpatient care is a health service requiring 24-hour hospitalisation [66]. An Inpatient discharge summary must be submitted to the ENHIS within 5 working days after the health worker has approved the document [9]. A **Daycare discharge summary** involves patient examinations and treatment procedures at a healthcare facility within a specific speciality in outpatient daycare [67].

- **A Case summary of independent inpatient nursing service and home nursing service** is prepared by the nurse based on available information and includes a summary of the nursing case and recommendations for follow-up [68].

- **A Birth summary** is a summary of the newborn's developmental history, including information on the mother's pregnancy and labour, the newborn's health status, and the developmental dynamics of the neonatal period. A birth summary is prepared for every live-born newborn [69].

Referrals

A referral is a document or data set created based on a healthcare professional's decision during healthcare service provision. It provides a basis for referring patients for examinations, procedures, autopsies, or to receive outpatient or inpatient healthcare services. Additionally, it facilitates the transfer of patient sample materials for testing or analysis and the sharing of patient health data for e-consultation. An e-referral is a digital document compliant with the national referral standard [10], [70].

Notices

Notices can be categorised as follows: Case notices, Health check notices, Death notices, Infectious disease notices, and Immunisation notice.

- **Case notices** are structured technical documents used to document the beginning and end of both outpatient and inpatient treatments [36], [37], [38], [39].

- **Health check notices** document data collected during health checks of patients up to 18 years old, covering development [40], growth [44], [71], counselling [43] or examination [42], [72].

- **Death notices** are issued for all deaths occurring within Estonian territory. A death notice can be either a separate document or part of a medical document (such as an ambulance card), providing the deceased's identity, the time and place of death, and confirmation of death by the healthcare provider. This information serves as the basis for automatically registering the death in the population register [73]. After determining the cause of death, the doctor, forensic doctor, or pathologist who identifies the cause of death issues a cause of death notice [74]. A perinatal death notice is a document reflecting the cause of death of a stillborn or a child who died between 0-6 days of age (but was born alive) [75].

- **Infectious disease notices** are submitted by healthcare providers diagnosing a patient with a disease listed in the Republic Government Regulation No. 134 §2. The infectious disease must be laboratory-confirmed, except for tetanus, scarlet fever, Creutzfeldt-Jakob disease, chickenpox, and acute upper respiratory tract infections. Notices are submitted to register infectious disease cases for

prevention purposes and to analyse their spread trends [76]. Notices of suspected infectious diseases are submitted by healthcare providers when a patient is suspected of having an infectious disease [77]. Notices of HIV are filed by healthcare providers diagnosing a patient with HIV disease (AIDS) or HIV infection [78].

- **A Notice of immunisation**, transmitted digitally to the health information system, provides a record of all immunisations given to a patient. Healthcare providers document these immunisations either electronically or on paper [79].

Other documents sent to the ENHIS

A Reply to referral is created based on a referral after conducting examinations, analyses, or consultations for a patient. Its structure aligns with the data templates used in case summaries, promoting standardised documentation for those performing tests, analyses, and more [80].

An Ambulance card is a document prepared by the leading member of the ambulance team detailing the procedures performed during healthcare service. The digital ambulance card is a standardised data set that consists of information partly provided by the Emergency Response Centre, collected by the ambulance team during the response, as well as time-critical information about the patient available in the ENHIS, along with logistical information related to data entry and usage [81].

A Dental card details a patient's dental treatment, treatment plan, and general oral health history. The electronic dental record is a digital document created for every patient receiving dental care and verified by the treating dentist. Entries in the dental record reflect procedures conducted during the visit. The dental record contains three types of information: general patient information, visit data (including medical history), and dental status data [82].

A Health declaration is a document the patient completes about their health status. The technical solution ensures that the health declaration is pre-populated with relevant health data provided by healthcare service providers through the ENHIS [83].

A Health certificate is a document prepared by a healthcare provider to certify the applicant's health status based on a medical examination and the conditions of the

intended use. The certificate confirms that the applicant's health status meets the criteria outlined for that specific field and ensures the absence of health issues that could hinder activities or increase the risk of illness-related accidents, reducing potential harm [84].

4.1.2 Data sections of documents managed by the ENHIS

The data sections of documents sent to the ENHIS are described in Regulation No. 53 of the Minister of Social Affairs: “Data composition of the documents to be transmitted to the health information system and the conditions and procedure for their submission” [11]. There are a total of 301 data sections within the documents managed by the ENHIS. A more detailed overview of how many data sections are in the different documents is shown in Figure 1.

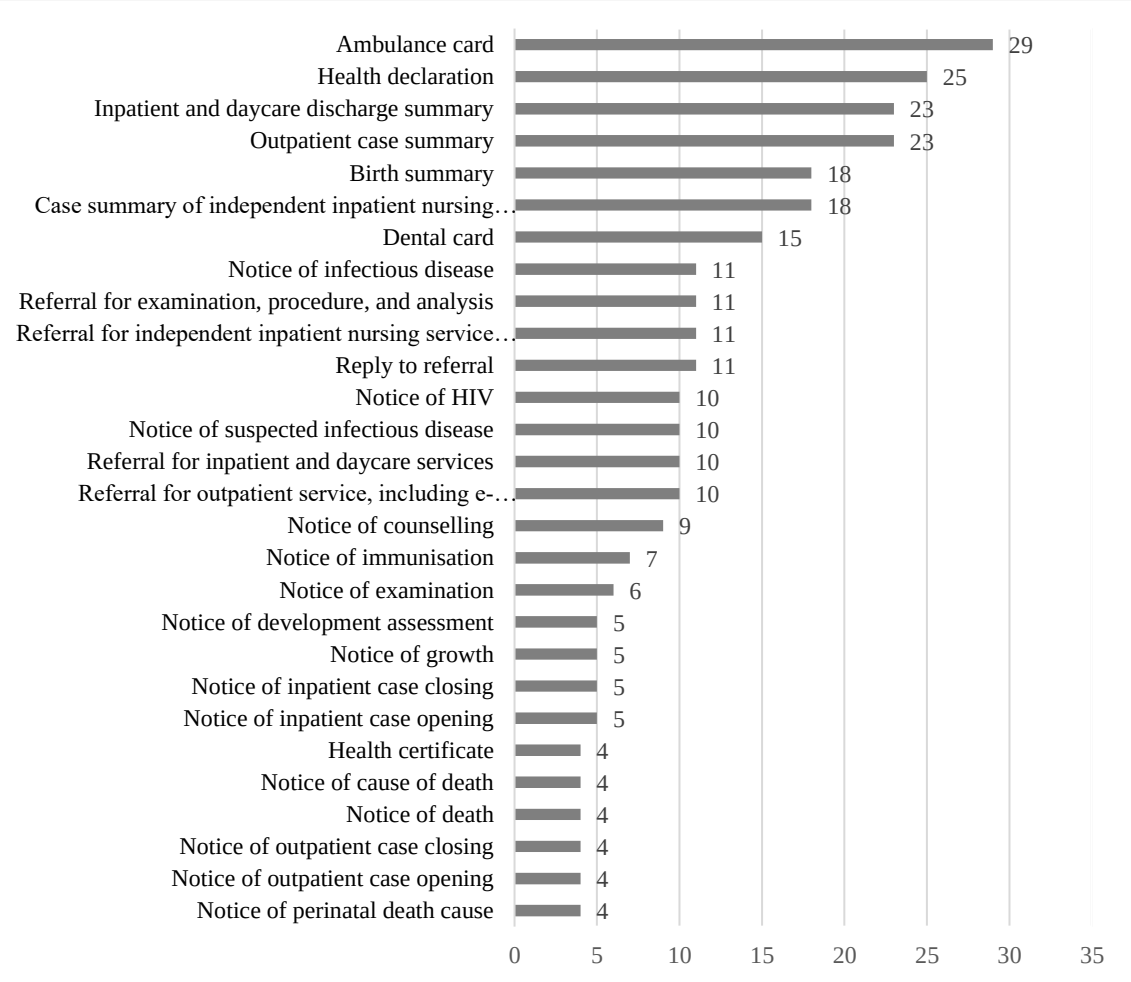

Figure 1 Number of data sections in the documents managed by the ENHIS

A content analysis was performed to identify overlapping data sections in the documents' data compositions sent to the ENHIS. Microsoft Excel was used to create a cross-tabulation matrix to examine and identify overlapping sections across different CDA documents systematically. The table of results of the content analysis is added to Appendix 2.

The data compositions of the ENHIS documents were analysed in two rounds. In the first round, the analysis was based on the titles of the data sections, which resulted in identifying 103 unique data sections across the initial set of documents. In the second round, the data sections were compared again, but this time, the instructions for filling out the documents sent to the ENHIS and CDA templates were studied to gather more detailed information about the data sections of the documents. As a result, some data sections could be combined, and a total of 77 data sections within the ENHIS documents were listed, including 38 overlapping data sections and 39 data sections that appeared only once within the documents. The document with the greatest number of unique data sections that do not appear in other documents is the Ambulance card, which has 16 unique data sections.

4.1.2.1 Common data sections in the ENHIS

38 overlapping data sections within the documents submitted to the ENHIS exist. Seven sections that were represented in more than 10 documents were: "Document author" (28 documents), "Patient data" (28 documents), “Medical document data” (24 documents), “Diagnosis” (16 documents), “Anamnesis” (13 documents), “Referral data” (12 documents), and “Notes” (10 documents):

- **“Medical document data”** includes essential information such as the document number, its confidentiality status, the time of approval, and its validity's start and end dates. This data is not described in the data compositions of case notices.

- **"Document author"** includes healthcare professionals’ first and last names, registration codes, speciality, and contact details. Additionally, it contains the healthcare institution's name, business registry code, contact information, and address (or the specific practice location).

- **"Patient data"** includes the patient's identification number, first and last names, gender, birth date, actual residence, and contact details. Furthermore, it identifies

other relevant parties, such as guardians or parents, providing their personal identification codes, names, and a relationship to the patient. The contact information of individuals related to the patient is also documented.

- **“Diagnosis”** section provides comprehensive information on the patient's diagnosed conditions. For malignant tumours, additional data is included, whether it's a primary or comorbid disease. Pathomorphological diagnoses and supplementary information are also recorded. Diagnosis code and name are determined according to the ICD-10 (International Classification of Diseases, 10th Revision). Diagnosis data can be described in case summaries, referrals, infectious disease notices, Reply to referral, Dental card, Ambulance card, and Immunisation notice. In Health declaration, data about diagnoses concerning different functionalities is queried from the ENHIS.

- **“Anamnesis”** describes anamnesis and complaints and can also include information about diagnosis justification and disease progression. In some documents, data on patient's allergies, medication history, and side effects are gathered. Anamnesis can be described in Outpatient case summary, Inpatient and daycare discharge summary, referrals, Dental card, Ambulance card, Notice of immunisation, and health check notices.

- **“Referral data”** includes information about the referring healthcare provider, the referral document, and the service to which the patient was referred. The onward referral data is described if the patient is transferred to another healthcare facility during an inpatient treatment. Referral data is recorded in case summaries, referrals, Reply to referral, Dental card, Ambulance card, and Notice of inpatient case closing.

- **“Notes”** are recorded in free text and can include data which cannot be described in other parts of the document. This section could include instructions to the patient, on how to prepare for the appointment, etc. “Notes” section is present in referrals, Reply to referral, Dental card, Notice of immunisation, and health check notices.

While data sections such as "Document author", "Patient data", “Medical document data”, and “Referral data” include administrative data, there are several clinical data sections

that overlap within the documents of the ENHIS. In addition to “Diagnosis” and “Anamnesis”, there are sections that can present structured clinical information like “Objective findings”, “Allergies”, “Laboratory examinations” or other procedures (e.g. radiology, surgical, pathology, endoscopy), and “Immunisations”.

4.2 Mappings of ENHIS data sections to FHIR resources

To answer the third research question: “Which FHIR resources conform to the data sections identified in the ENHIS?” a migration methodology proposed by Bossenko et al. [21] was used, examining the FHIR specification’s search [29] and FHIR Registry [30] for matching the ENHIS data sections to FHIR resources. The list of overlapping sections (77 sections) identified in the content analysis was used as the search words.

4.2.1 Mapping outcomes

This section gives an overview of mappings between ENHIS’s data sections and FHIR resources. The mapping is crucial for adopting FHIR, as it identifies direct alignments while highlighting areas that require further customisation to meet local requirements. The aim was to map each data section to one or more corresponding FHIR resources based on their semantic and functional similarities. For 77 data sections, FHIR mappings were searched. Out of 77 data sections, for 50 data sections, mappings to FHIR resources were returned, of which 39 data sections got results from both sources, but 11 data sections got results from one source (either from FHIR specifications or FHIR Registry), and 27 data sections did not get a result. The results of the mappings are added to Appendix 3. An example of the mappings between ENHIS’s data sections and FHIR resources based on the data sections of the Outpatient case summary is shown in Table 3.

Tabel 3 Mappings of data sections of Outpatient case summary to FHIR resources

Data section	**FHIR specification**	**FHIR Registry**
Medical document data	DocumentReference	DocumentReference
Document author	DocumentReference	DocumentReference
Patient data	Patient	Patient
Referral data	ReferralRequest, HealthcareService	Task, ServiceRequest
Case data		EpisodeofCare
Diagnosis	Condition	Condition
Anamnesis	Questionnaire	Questionnaire
Objective findings	Goal, Observation	Goal, Observation

Allergies	AllergyIntolerance	AllergyIntolerance
Examination/procedures	Procedure	Procedure
Radiology examination	ImagingStudy, DiagnosticReport, Observation	Observation, ImagingStudy, DiagnosticReprot
Surgical operations	Procedure	Procedure
Laboratory examination	Observation, DiagnosticReport	Observation, DiagnosticReport
Pathology examination	DiagnosticReport, ImagingStudy	DiagnosticReport, Observation
Endoscopy examination	Procedure	Procedure
Immunisations	Immunization	Immunization
Patient treatment summary		
Administrated medications	MedicationAdministration	MedicationAdministration
Prescribed medications	MedicationRequest	
Regimen and treatment (including rehabilitation) recommendations	CarePlan	Observation, Goal
Work organisation or environment modification		
Issued documents		
Outpatient visit	Encounter	
Overview of consultations		

Mappings from ENHIS's document sections to FHIR resources

FHIR specification and FHIR Registry presented Encounter [85] and EpisodeofCare [86] resources as a result of the ENHIS data sections that describe information on visits and cases. Observation [87] and Condition [88] resources as possible mapping options for data sections that describe the patient's conditions and objective findings. For different procedures, a Procedure [89] resource was returned as a result of sources. Some examples of possible options for mapping data sections to FHIR resources are presented below.

"Medical document data" and "Document author" mappings to FHIR resources

For "Medical document data" and "Document author" both FHIR Search and Registry returned DocumentReference resource [90] as a result, which is used to index a document, clinical note, and other objects such as a photo, video, or audio recording. Based on the examination of the FHIR resource and the ENHIS data sections, this resource is not a good match for these data sections.

In the ENHIS documents, “Medical document data” section includes information such as the document number and its confidentiality status, which are described in the FHIR standard with metadata elements which are concluded in all FHIR resources [91]. The time of approval can be marked with authoredOn [92] data element, and the validity's start and end dates can be marked with Effective Period extension [93].

“Document author” includes the healthcare professional’s name, registration codes, specialities, and the healthcare institution's contact information. In FHIR, this information is described with three different resources: Practitioner [94], PractitionerRole [95], and Organization [96]. While Practitioner resource describes the individual provider’s personal and professional details, PractitionerRole focuses on the relationship between a practitioner and their roles, affiliations, services, and locations in an organisation. Organization resource concludes information about the entity responsible for delivering healthcare services or supporting administrative functions.

Direct mappings to FHIR resources:

- For „Patient data“, both FHIR Search and FHIR Registry returned Patient resource [97] as a result, which represents an individual receiving or receiving healthcare services. It stores key demographic and administrative information necessary for identifying and managing a patient's healthcare records.

- For „Referral data“, FHIR Search returned ReferralRequest and HealthcareService as a result, and FHIR Registry returned Task and ServiceRequest. Based on the analysis of semantic and functional similarities of the ENHIS section and FHIR resources returned the best match for „Referral data“ is the ServiceRequest resource [98], which represents a healthcare provider's request for a procedure, diagnostic test, or another clinical service for a patient.

- For “Anamnesis”, both FHIR Search and Registry returned Questionnare resource [99] as a result. Based on the description of the Questionnare resource, it can be used to capture raw data and then convert the resulting QuestionnaireResponse [100] instances into other FHIR resources – Observations [88], MedicationStatements [101], FamilyMemberHistories [102] and others.

- For „Objective findings“, both sources returned Goal and Observation as a result. Based on the analysis of semantic and functional similarities of the ENHIS data section and FHIR resources returned, the best match for „Objective findings“ is Observation resource [87]. It represents a measurement, assessment, or evaluation made about a patient's health status. It is commonly used to capture vital signs, lab results, clinical assessments, and any other health-related information. The FHIR specification has standardised profiles based on Observation resource that can be used to measure vital signs, such as Body Mass Index (BMI), body height, temperature, blood pressure, heart rate and others [103].

- For „Diagnosis“, both sources returned Condition resource [88] as a result, representing a clinical condition, problem, diagnosis, or other medical issue affecting a patient. It is used by healthcare professionals to record and share important health information that will influence patient care.

- For „Allergies“, both sources returned the AllergyIntolerance resource [104] result, which represents allergic reactions and intolerances that a patient has experienced or is at risk of experiencing.

- For „Immunisations“, both sources returned the Immunization resource [105], which records and shares information about a patient's immunisations, such as vaccines they've received. It provides details about the type of vaccine, administration dates, and other relevant information.

Mappings of different procedures data:

- For „Examination/procedures“, „Surgical operations“, and „Endoscopy examination“, both sources returned Procedure resource [89] as a result for each data section. Procedure resource represents clinical procedures performed on a patient. A procedure could be surgical, therapeutic, diagnostic, or other actions undertaken for a patient's health.

- For „Radiology examination“, both sources returned ImagingStudy [106], DiagnosticReport [107], and Observation [87] resources as a result. All these resources offer a structured, detailed framework for capturing and exchanging radiology examination data.

- For „Laboratory examination“, both sources returned Observation resource [87] and DiagnosticReport resource [107]. Both resources complement each other and can be used together to represent laboratory results.

Mappings of medication data:

- For „Administrated medications“, both sources returned MedicationAdministration resource [108], which represents the administration of a medication to a patient. It tracks details of the event, such as the specific medication given, the dosage, the timing, and who administered it.

- For „Prescribed medications“, FHIR Search returned MedicationRequest resource, but the FHIR Registry did not return FHIR resource that could be mapped to this data section. MedicationRequest resource [109] represents a request for a patient to receive a specific medication. It is primarily used for recording prescriptions or medication orders by healthcare providers.

Data sections mappings to FHIR resources with no match

While mapping the ENHIS data sections to FHIR resources, many data sections could not be mapped to FHIR resources. In some cases, the data sections in the ENHIS's documents are too specific. Therefore, this data is not represented with the FHIR resource itself but rather with the data element or datatype of an FHIR resource. If the resource does not have the necessary data element, it is possible to create an extension [110]. The document with the most data sections that could not be mapped to the FHIR resource was the Ambulance Card. The sections that could be mapped to the data element of the FHIR resource or need an extension are for example "Additional assistance usage", "Transportation method", "Patient refuses further help", "Assisted another ambulance crew", and "Call priority according to the brigade's assessment".

4.3 Key relations and integration considerations for FHIR implementation

To answers the fourth research question: "What essential relations between FHIR resources need consideration to ensure a seamless integration of the FHIR standard?", the FHIR specification [31] was thoroughly analysed. The review examined the

interrelationships and dependencies of various FHIR resources. This step was crucial for highlighting dependencies that are central to maintaining data integrity and ensuring a seamless integration process. Understanding how these FHIR resources link together allows defining potential recommendations for implementing the FHIR standard in Estonia.

4.3.1 Key relations of FHIR resources

In the FHIR specification, resources and specifications are organised into several logical groupings and layers that reflect different aspects of healthcare data exchange [111]:

- Level 1 Basic framework on which the specification is built;
- Level 2 Supporting implementation and binding to external specifications;
- Level 3 Linking to real-world concepts in the healthcare system;
- Level 4 Record-keeping and Data Exchange for the healthcare process;
- Level 5 Providing the ability to reason about the healthcare process.

In this section of the study, Level 3 and Level 4 are analysed. Level 3 focuses on the Administration Module, and Level 3 describes healthcare process modules, such as Clinical, Diagnostics, Medications, Workflow and Financial. The financial module is not in the scope of this study.

4.3.1.1 Administration Module

The Administrative Module encompasses the foundational data that is subsequently connected to other modules containing clinical content. Prior to documenting any clinical information, the fundamental details of the patient must be recorded, along with, in many cases, the basis of the interaction, like an encounter [112].

Patient data is represented in the FHIR standard using the Patient resource. Furthermore, related individuals' details are crucial and captured through the RelatedPerson resource in the FHIR standard [112]. Within the ENHIS, the Master Patient Index *(Patsiendi üldandmete teenus)* [113] has been developed based on the FHIR standard. It provides comprehensive patient information such as education, guardianship, legal custody, disability, and work incapacity, collecting data from various registries.

Information about a patient visit is gathered with the Encounter resource, which represents an interaction between a patient and a healthcare provider(s) during which healthcare services are provided. It serves as a central point of reference for managing clinical and administrative data about each patient-provider interaction. The FHIR resource used to describe cases is the EpisodeOfCare resource, which represents a period during which a healthcare provider is actively involved in providing care to a patient. It encompasses a series of healthcare services related to a particular issue or treatment plan. EpisodeOfCare is the container that can link a series of Encounters together [112]. The relation between the Patient resource and Encounter and EpisodeOfCare resources is shown in Figure 2.

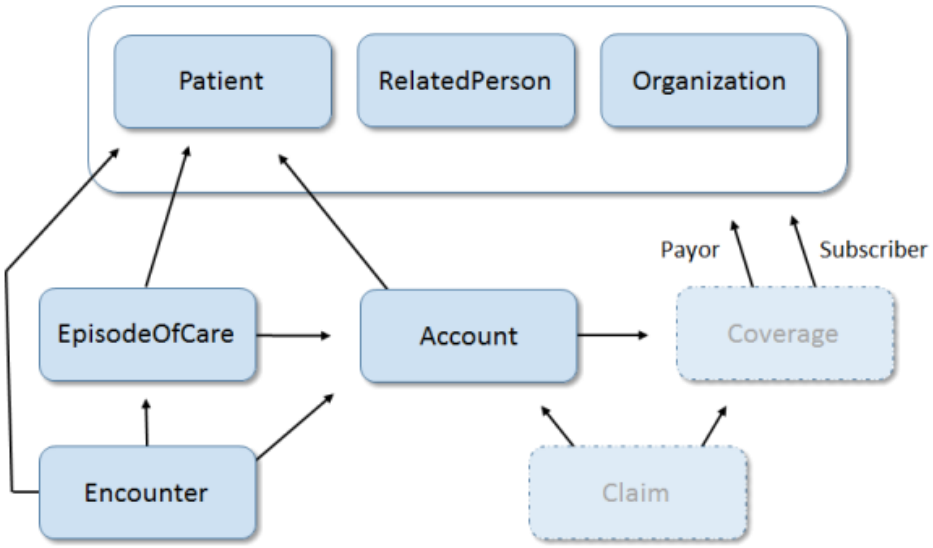

Figure 2 Clinical Categorization Resources [114]

Healthcare provides' data is described in FHIR standard with Practitioner, PractitionerRole and Organization resources. Details of provided healthcare service can be described with HealthcareService resource, and Location resource can be used for information about a place where services are provided [115].

The scheduling and appointment resources enable the planning of encounters and subsequent clinical activities. When scheduling resources need to specify the activity or service being arranged, either a HealthcareService resource or a coding system can be used to represent that activity. Appointments are scheduled encounters, while the Encounter resource tracks the actual visit. Appointments usually lead to Encounters,

which are created at the start of service, not upon patient arrival. Encounter resources can be created before the actual patient visit to convey pre-admission details like planned dates and locations, using a "planned" status. In emergency contexts, Encounter is created directly instead of using an Appointment resource [116]. Resources included in the scheduling process are shown in Figure 3.

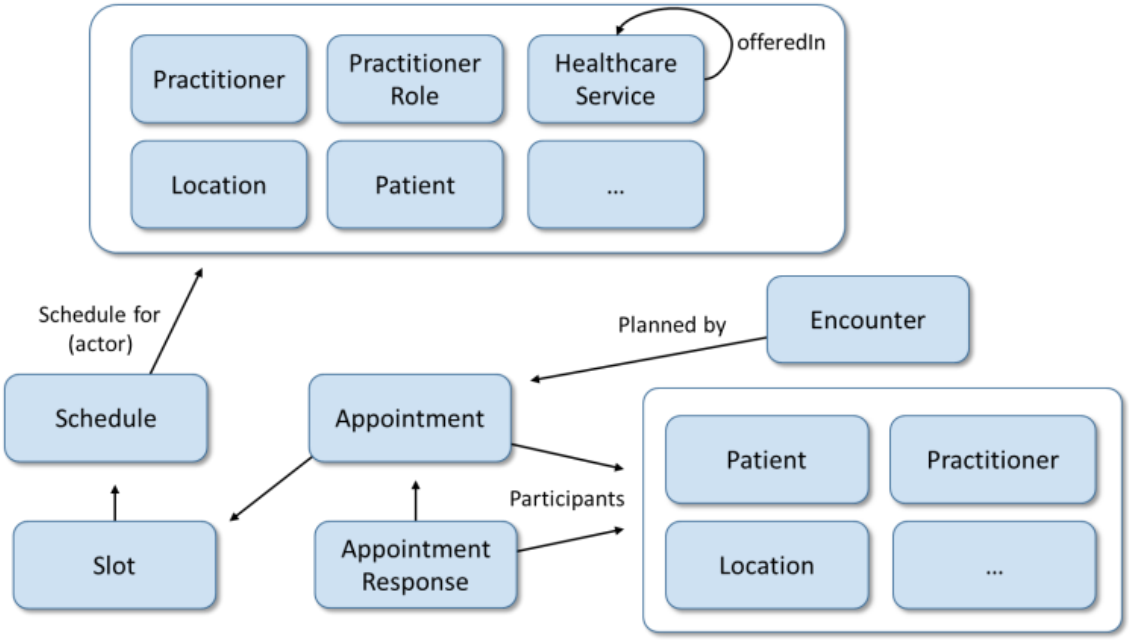

Figure 3 Scheduling and Appointments [116]

4.3.1.2 Clinical Module

The Clinical Module is centred on FHIR resources that include core clinical information about a patient. These resources, frequently documented, created, or retrieved during clinical care, address various aspects of patient health and interactions. Key resources in this module include those dealing with allergies, medical conditions, procedures, family medical histories, and care plans, among others. Each resource is designed to be focused on a small set of data, which, when combined, form a comprehensive clinical record. The Clinical module also provides use cases that illustrate common scenarios in which the resources might be applied, such as documenting patient conditions or managing care plans [117].

4.3.1.3 Diagnostic Module

The Diagnostics Module is primarily focused on organising and detailing resources that are used for ordering, documenting, and reporting on various clinical diagnostics such as laboratory tests, imaging studies, and genomic data. It covers a range of resources,

including Observation, DiagnosticReport, and ServiceRequest, which link together to represent the complex relationships and workflows in diagnostic medicine (Figure 4) [118].

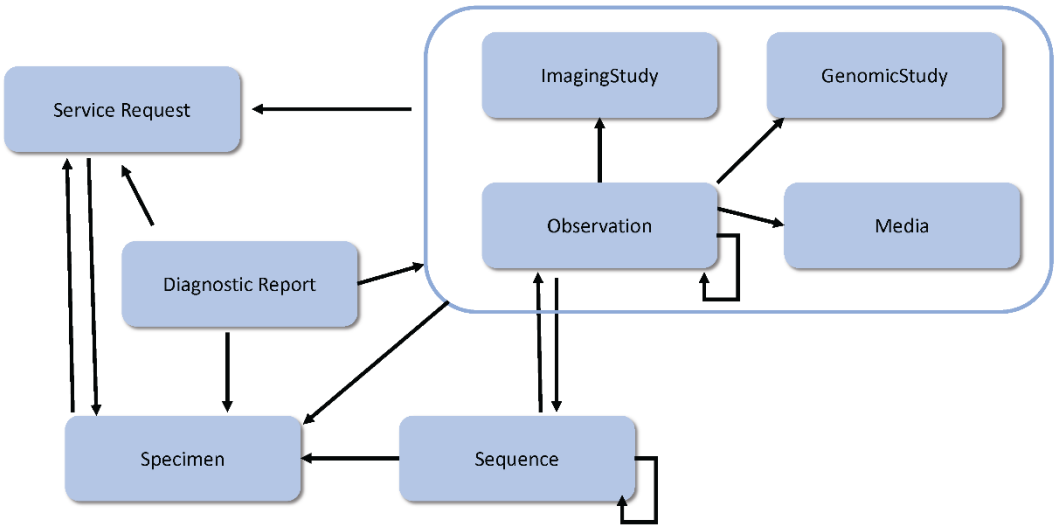

Figure 4 Relations of diagnostic resources [118]

4.3.1.4 Medication Module

The Medications Module in FHIR addresses the management of medication-related processes such as ordering, dispensing, administering, and documenting medication use, including immunisations. It ensures integration across healthcare settings by focusing on standardising how medication information is requested, recorded, and communicated [119].

4.3.1.5 Workflow Module

The Workflow Module describes the common patterns in workflow management and resource interactions across healthcare processes. Many FHIR resources describe different activities within workflows, categorised into definitions (what can be done), requests (desired actions), and events (completed actions) (Figure 5). Some resources pair naturally, like SupplyRequest with SupplyDelivery, while others, such as ServiceRequest, might be responded to by resources like Encounter, DiagnosticReport or Procedure. Similarly, a Procedure might be triggered by a ServiceRequest [120].

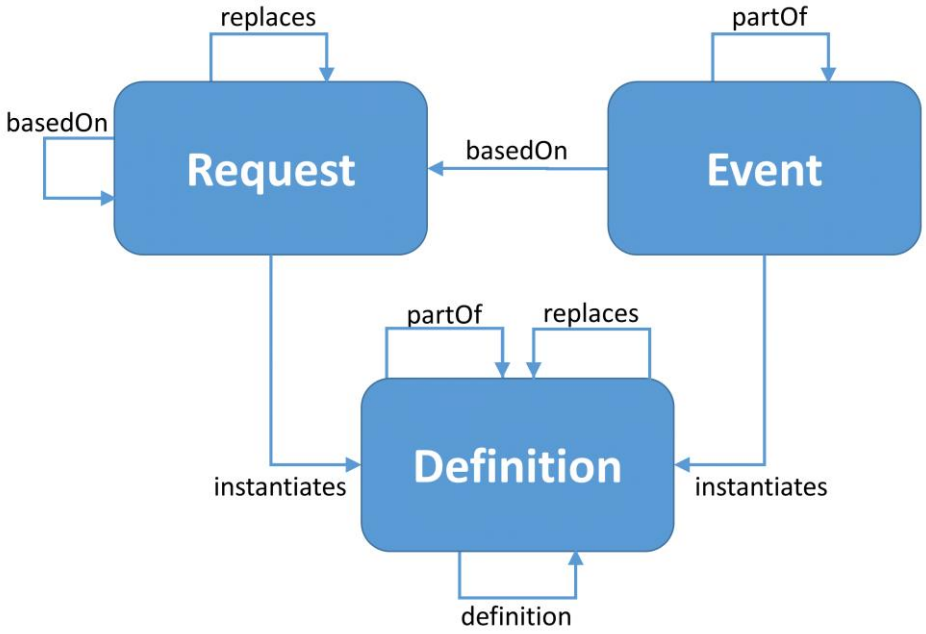

Figure 5 Relationships of Request, Event and Definition [121]

4.4 Conclusion of the results of the study

The results chapter of this study presented a detailed analysis of the data compositions of documents sent to the ENHIS and the mapping of these data sections to the FHIR resources. To effectively address the research questions, the study was separated to two phases. In the first phase, a document analysis was performed on data compositions of the ENHIS documents. Content analysis identified 77 data sections, which were used as input for the second phase of the study. Out of the 77 data sections, 38 sections overlapped.

The second phase focused on mapping the 77 data sections to FHIR resources. 50 data sections were mapped to FHIR resources, with 39 sections getting results from both FHIR specifications and the FHIR Registry. The mapping process identified direct alignments and areas needing customisation, crucial for adopting FHIR in Estonia. Furthermore, the study highlighted essential relations and integration considerations for FHIR implementation, ensuring data integrity and seamless integration of the FHIR standard.

Although the analysis focused on the Estonian context, the results are applicable on an international scale. The results of this study provide valuable insights for other countries aiming to implement the FHIR standard in their health information systems. Identifying

common data sections and document structures, can help reduce redundancy in the health systems in other countries and offer guidance for mapping data sections to the FHIR standard. The approach to mapping data sections to FHIR resources can be replicated, ensuring compatibility with FHIR standards. In addition, understanding relationships between FHIR resource helps in designing integrated health information systems.

In conclusion, this chapter provided a thorough analysis of ENHIS data compositions and their mapping to FHIR resources, offering valuable insights for adopting the FHIR standard in Estonia's health information system. The findings support the alignment of local data requirements with international interoperability standards, facilitating improved healthcare data exchange and management.

5 Discussion

This chapter interprets and contextualises the results obtained from analysing the documents managed by the ENHIS and mapping data sections to the FHIR standard. The study was divided into two phases: the first phase involved collecting and analysing the data compositions of the ENHIS's documents, while the second phase focused on mapping the ENHIS's data sections to FHIR resources and analysing the key relationships within the FHIR standard. This chapter discusses these results and proposes recommendations for implementing the FHIR standard in Estonian healthcare ecosystem.

5.1 The current data exchange within the ENHIS

The ENHIS serves as a comprehensive and centralised digital repository that manages the health data of Estonian residents from birth to death. It seamlessly integrates with other public IT systems, enhancing user convenience for both citizens and healthcare professionals. The system supports a range of functionalities, including data entry, appointment booking, and patient information retrieval [6]. The reliance on HL7 v3 messages and CDA documents has led to significant challenges to offer the modern, intuitive solutions that Estonian patients and healthcare professionals anticipate [3]. The findings from this study confirm that while the ENHIS successfully centralises patient information, the document-centric approach limits the efficiency and flexibility needed for modern healthcare data exchange.

The data compositions of documents managed by the ENHIS are regulated by the Minister of Social Affairs' Regulation No. 53 [11]. This regulation provides a comprehensive framework for the data composition of documents transmitted to the ENHIS and outlines the conditions and procedures for their submission. The regulation ensures that all necessary patient and clinical information is accurately captured and standardised across various healthcare documents.

This document analysis identified 28 data compositions of documents sent to the ENHIS, which can be categorised into three primary groups based on content similarities: Case summaries, Referrals, and Notices. Several documents did not fit into these categories, however, are still crucial for comprehensive health information management. This categorisation provided a structured approach to analysing the data compositions, ensuring easier data retrieval and analysis.

Case summaries serve as comprehensive records of a patient's medical case, summarising the case dynamics and relevant clinical information available to the healthcare professional. The detailed and structured content of case summaries ensures comprehensive patient care documentation, facilitating continuity of care and informed clinical decision-making.

Referrals are crucial in the healthcare process, enabling the transfer of patients for various medical services or examinations. These documents are created based on the decisions of healthcare professionals and support multiple functions. The e-referral, compliant with national standards, promotes efficient and secure data exchange, enhancing the overall coordination of patient care.

Notices encompass a wide array of documents, each serving specific administrative and clinical functions. A total of 15 notices can be sent to the ENHIS. Notices can be categorised into 5 groups. Case notices record the beginning and end of both outpatient and inpatient treatments. Health check notices include data from health checks for patients up to 18 years old, including development, growth, counselling, and examination results. Death notices include essential details about the deceased and are crucial for automatic death registration and cause of death documentation. Infectious disease notices are used to register and analyse infectious disease cases, and these notices support public health monitoring and prevention efforts. Notice of immunisation keeps a record of all immunisations administered to a patient, ensuring accurate immunisation tracking and reporting.

Reply to referral consolidates examination, analysis, or consultation data, enabling direct integration into central systems. Ambulance card, prepared by the ambulance team, includes procedural and logistical details. Dental card, maintained by dentists, document treatment and oral health history, categorised into general information, visit data, and

dental status. Health declaration, completed by patients, are pre-populated with relevant data from healthcare providers. Health certificate, issued by healthcare providers, certify an applicant's health status based on specific criteria, ensuring safety and reducing health-related risks.

By aligning documentation with standardised data templates and national standards, these documents support interoperability within the Estonian healthcare system. This ensures that data can be easily shared and understood across different healthcare entities, promoting consistent continuity of care. Structured and standardised documentation ensures that all aspects of patient care are thoroughly documented.

After the document analysis, a two-round content analysis was conducted to identify and analyse overlapping data sections within the documents managed by the ENHIS. In the first round, the analysis focused on the titles of data sections, identifying 103 unique sections. In the second round, instructions for filling out the documents were further reviewed, resulting in integrating some sections and identifying 77 unique data sections.

The analysis identified 38 overlapping data sections across the documents sent to the ENHIS, with seven sections appearing in more than ten documents. Administrative sections such as "Document author" and "Patient data" are included in all the documents, as well as “Medical document data” section, except for case notices. From the clinical data, “Diagnosis” (16 documents), “Anamnesis” (13 documents) and “Referral data” (12 documents) are presented the most in the documents. While these common data sections are crucial for ensuring consistency and interoperability across different healthcare records, the presence of overlapping data sections across multiple documents suggests potential redundancy. While necessary for comprehensive documentation, it also presents an opportunity to streamline data entry processes, reduce administrative burden, and minimise the risk of errors. Automated data integration and pre-population of common sections can lead to more efficient use of healthcare resources and better patient outcomes.

The “Notes” section was found in 10 documents. This section allows for free-text entries that include instructions or additional information not covered elsewhere in the document. In addition to the data section intended for free-text entries, there are other data sections in the CDA documents where information can be captured in free text. For example, the

“Anamnesis” section is described in free text, as well as the “Patient treatment summary”, which includes, for example, data on administrated medications and procedures that are not specified in the procedure data section. While free text sections provide valuable flexibility, they also pose data analysis and interoperability challenges. Unstructured data is more difficult to analyse systematically and may hinder the seamless exchange of information between different health information systems.

Based on the results of the first part of the study, it is reasonable to begin developing the new services based on the FHIR standard by focusing on the clinical data sections that overlapped the most. It is crucial to consider that when a dataset is migrated to the FHIR standard, this data should be exchanged with FHIR resources. Therefore, the corresponding section should be removed from the CDA documents if the CDA standard allows it, or the mappings must be provided. The table from the content analysis (Appendix 2) can be used to identify which documents need to be modified when migrating data sections from CDA to FHIR.

5.2 Transitioning from the CDA standard to the FHIR standard

The broader goal of the ENHIS is to transform the system into a flexible, interoperable, and user-focused ecosystem. The upTIS project envisions a system where health data is readily accessible, promoting continuity of care and enabling informed decision-making through high-quality, accessible health data. This vision aligns with the broader goals of enhancing patient care, improving clinical processes, and fostering innovation within Estonia's healthcare sector [3]. The upTIS project is closely aligned with the European Commission's EIF and EHDS initiatives, which aim to enhance interoperability. Adopting international standards like HL7 FHIR supports the technical and semantic interoperability goals outlined in the EIF [12], [14]. By ensuring that health data is exchanged in a structured and standardised manner, the upTIS project facilitates seamless communication between healthcare systems within Estonia and across European borders.

Mapping ENHIS’s data sections to FHIR resources

Several studies have been conducted on migrating from the other standards to the FHIR standard. In Estonia, significant study has been conducted by Bossenko et al. [21] and the migration methodology proposed by the authors was employed in this study to map the

data sections of the ENHIS's documents to corresponding FHIR resources. The aim of the mapping process was to identify FHIR resources that align with the data sections in the ENHIS documents based on semantic and functional similarities. Mapping the ENHIS's data sections to FHIR resources revealed a high degree of compatibility, with most data sections having corresponding FHIR resources. Out of 77 data sections examined, 50 were mapped to FHIR resources, and 27 sections did not receive results.

The mapping process identified that 50 out of 77 ENHIS's data sections had direct FHIR resource mappings. Data sections that describe information on visits and cases can be mapped to Encounter and EpisodeofCare resources. Sections that describe the patient's conditions and objective findings can be described with Observation and Condition resources. To present information about different procedures, a Procedure resource can be used. Several data sections were directly mapped to FHIR resources: "Patient data" to Patient resource, "Referral data" to ServiceRequest resource, "Anamnesis" to Questionnaire resource, "Objective findings" to Observation resource, "Diagnosis" to Condition resource, "Allergy" to AllergyIntolerance resource, and "Immunisation" to Immunization resource. These mappings demonstrate that the FHIR standard can conform to a substantial amount of the existing CDA data sections.

Analysing certain data sections required more nuanced approach, resulting in partial mappings. For instance, "Medical document data" initially matched to the DocumentReference resource. However, further examination revealed that metadata elements within all FHIR resources could better capture these details, such as document number, confidentiality status, approval time, and validity dates. Similarly, "Document author" section was matched to DocumentReference resource. This section includes information about healthcare professionals and institutions and can be best described with multiple FHIR resources: Practitioner, PractitionerRole, and Organization. Careful consideration and analysis are required to determine the most suitable approach for these mappings.

Several challenges were noted, particularly in the areas of data granularity. Many data sections were too specific to be directly mapped to existing FHIR resources. In such cases, the required information can be represented by data elements or datatypes within a FHIR resource and in some cases, the creation of custom extensions is needed. While the FHIR standard provides a robust framework for health information exchange, the need for

customisation through extensions highlights the balance between standardisation and flexibility. Custom extensions are essential for accommodating specific local requirements and ensuring that all necessary information is accurately captured. However, it is also important to be cautious with local extensions, as maintaining interoperability between systems is crucial. The challenge lies in achieving a balance where local adaptations do not compromise the seamless exchange of information across different healthcare systems.

The process of mapping existing data sections to FHIR resources revealed both high compatibility and gaps, with 50 out of 77 data sections successfully mapped. This indicates a need for continuous evaluation and potential adaptation of both ENHIS and FHIR frameworks to address the unmapped sections and ensure comprehensive data integration. Future work should focus on addressing the remaining data sections, enhancing the mapping process, and ensuring that the system remains adaptable to standards and technologies.

5.2.1 Key considerations for FHIR implementation

The integration from the CDA standard to the FHIR standard involves not just technical mappings but also strategic considerations regarding the relationships between data elements and their roles within the larger healthcare information system. Identifying the key relationships between FHIR resources is critical for maintaining the integrity and utility of healthcare data.

In the FHIR specification [31], FHIR resources are organised into modules and layers, which enhance interoperability by providing a standardised framework for capturing and exchanging healthcare data. This standardisation facilitates seamless data exchange between different health information systems, promoting coordinated and efficient patient care. Comprehensive clinical documentation is vital for maintaining detailed and accurate patient records. Transitioning to the FHIR standard can facilitate more structured and interoperable clinical documentation.

In the current documentation practices, different case summaries, referrals, notices, and other documents based on the CDA standard are sent to the ENHIS. In the FHIR standard, resources are used to document healthcare processes, including scheduling, appointments, clinical procedures, and care plan management. During the implementation of the FHIR

standard in the ENHIS, the documentation processes must be carefully analysed and agreed upon.

The Administrative Module captures essential patient and interaction data and highlights the importance of accurate and comprehensive patient information. This data is the cornerstone for all subsequent clinical documentation, ensuring that clinical and administrative records are linked and cohesive. The patient data, typically captured through the Patient resource, and the details of interactions, often represented by the Encounter resource, are critical for creating a unified patient record. This relationship supports continuity of care and effective patient management. By encompassing a series of encounters, the EpisodeOfCare resource allows healthcare providers to track the progression of a patient's condition over time and adjust treatment plans accordingly. This structured documentation is essential for managing chronic conditions, coordinating multidisciplinary care, and ensuring that all aspects of a patient’s health are addressed comprehensively. In the context of the ENHIS, it is important to establish clear definitions and uses for the Encounter and EpisodeOfCare resources. Agreeing on how these resources will document the care process is critical. Defining the parameters for what constitutes an encounter versus an episode of care can standardise documentation practices across the healthcare system. This standardisation is necessary to maintain the integrity of patient records and to facilitate seamless data exchange between different healthcare providers. Properly defining and integrating these resources can streamline administrative tasks, reduce redundant data entry, and enhance the accuracy of patient records. This, in turn, can lead to better patient outcomes, as healthcare providers will have access to more reliable and comprehensive data when making clinical decisions.

The Practitioner, PractitionerRole, and Organization resources capture detailed information about healthcare professionals and institutions. These resources ensure that data about the providers involved in a patient's care is accurately recorded and easily accessible. The HealthcareService and Location resources complement this data by providing details about the services offered and the locations where these services are provided. These resources facilitate the logistical and operational aspects of healthcare delivery, enabling efficient scheduling, resource allocation, and service planning. To effectively implement these resources in the ENHIS, it is essential to develop a comprehensive strategy to standardise the data related to healthcare providers and organisations. This includes defining the fields for capturing provider credentials,

specialisations, roles, and affiliations. Integrating service provider directories within the ENHIS will help maintain up-to-date and accurate information about healthcare professionals and institutions. Additionally, implementing automated processes for updating provider information will reduce manual entry errors and ensure data consistency. Furthermore, linking provider and organisation data with HealthcareService and Location resources will streamline service planning, scheduling, and resource allocation.

The Clinical, Diagnostics, and Medications Modules collectively ensure that all aspects of patient health and medical interactions are comprehensively documented. This holistic approach supports detailed and accurate patient records, which are crucial for clinical decision-making and continuity of care. The Workflow Module's focus on managing healthcare processes and resource interactions supports efficient workflow management. These modules ensure that healthcare processes are streamlined and well-coordinated by standardising how activities are defined, requested, and recorded. To implement these modules effectively in the ENHIS, it is important to create standardised protocols for documenting clinical interactions, diagnostic procedures, and medication management using FHIR resources. This includes defining specific workflows for common clinical scenarios. Ensuring that the Clinical, Diagnostics, and Medications modules are fully interoperable will facilitate seamless data exchange and improve clinical decision-making.

Implementation challenges

Despite the promising potential of FHIR, its adoption is accompanied by significant challenges. The HL7 International and Firely survey [20] illustrates a strong and growing interest in FHIR across various healthcare sectors, driven by its potential to foster innovation, comply with regulations, and secure grant funding. Despite the acknowledged successes in improving access to healthcare information, cost reduction, and healthcare outcomes, the path to wider adoption is hindered by challenges that need to be systematically addressed. Enhancing FHIR knowledge, clarifying regulations, managing investment costs, and articulating benefits more clearly are crucial steps toward leveraging FHIR's full potential for advancing global healthcare interoperability.

Another effective way to address implementation challenges is through international collaboration by leveraging collective expertise and experiences. The FHIR community, which includes implementers from around the world, is a crucial resource for Estonia. Working with other countries that are also implementing FHIR, Estonia can learn from others' experiences, and avoid common pitfalls. This collaboration can facilitate the exchange of technical insights, regulatory strategies, and practical solutions to implementation challenges. The role of implementation guides plays a significant role in the successful adoption of FHIR. Prior to developing local services, it is essential to thoroughly review existing implementation guides from other countries to understand best practices and lessons learned.

5.3 Limitations

One limitation of this study is the subjective nature of the analysis process, including identifying overlapping data sections. In the content analysis, an inductive approach was used to create a list of the overlapping data sections by the author of this study. Although the process was documented, multiple sources were used, and the results were reviewed by peers, the subjective nature of the analysis remains a limitation. Another limitation is that the scope of this study was limited to the analysis of data compositions managed by the ENHIS and the mapping of these data sections to FHIR resources. While the study focused on analysing and mapping data sections, it does not cover the technical requirements to implement the FHIR standard.

5.4 Future research

Future research should conduct a more detailed analysis of healthcare processes in Estonia. This involves examining specific workflows within healthcare settings and identifying how these processes can be documented with the FHIR standard to ensure an efficient data exchange in Estonian healthcare system. Research should also explore the mapping of data elements at a granular level. This detailed mapping is essential for comprehensive data integration, ensuring that every element of health information is accurately represented and exchanged between systems. It is important to note that this study focused on documents sent to the ENHIS. Future research should also analyse the documents generated by the ENHIS to provide a more comprehensive understanding of

the entire data exchange ecosystem. The successful adoption of FHIR requires significant changes not only in technology but also in organisational practices and human factors. Future studies should investigate strategies for effective change management, including training programs for healthcare professionals and IT staff. These programs should enhance knowledge and skills related to FHIR.

5.5 Conclusion

The transition from the HL7 CDA standard to the HL7 FHIR standard within the ENHIS presents a significant opportunity to enhance interoperability, streamline data management, and improve healthcare delivery. This study, structured into two phases, analysed the current data compositions of the ENHIS documents and mapped data sections to FHIR resources, and identified the key relationships and implementation challenges.

Based on the results of this study, the following recommendations can be proposed:

1. New services based on the FHIR standard should be developed by first focusing on clinical data sections with the most overlap.

2. Documentation processes should be analysed and agreed upon when transitioning from CDA-based documents to FHIR resources for healthcare processes such as scheduling, appointments, clinical procedures, and care plan management.

3. Clear definitions and uses for the Encounter and EpisodeOfCare resources within the ENHIS should be established. Documentation practices should be standardised to maintain patient record integrity and facilitate seamless data exchange.

4. A comprehensive strategy should be implemented to standardise data related to healthcare providers and organisations, including defining fields for provider credentials, specialisations, roles, and affiliations. Service provider directories should be integrated, and automated processes for updating provider information should be implemented to ensure data consistency.

5. Standardised protocols should be created for documenting clinical interactions, diagnostic procedures, and medication management using FHIR resources.

Specific workflows for common clinical scenarios should be defined, and the interoperability of the Clinical, Diagnostics, and Medications modules should be ensured to facilitate seamless data exchange and improve clinical decision-making.

6. FHIR knowledge should be enhanced, regulations clarified, investment costs managed, and benefits articulated to leverage FHIR's full potential for advancing global healthcare interoperability. Training programs should be developed, clear regulatory guidelines provided, funding secured.

7. International collaboration should be pursued to address implementation challenges by leveraging collective expertise and experiences. Engaging with the global FHIR community can help Estonia learn from others' experiences and avoid common pitfalls.

8. Reviewing existing implementation guides from other countries before developing local services is essential to understanding best practices and lessons learned.

The growing popularity of the FHIR standard underscores its potential impact on global healthcare interoperability. The findings of this study can serve as a valuable resource for other countries in the process of implementing the FHIR standard. The analysis and results presented here offer practical insights and strategies that can be adapted and applied in various healthcare systems.

6 Summary

The aim of the study was to propose recommendations for planning the implementation of the FHIR standard in Estonia's healthcare system by providing guidelines for determining and prioritising data sections and addressing key considerations of the transition process. To achieve the aim, the study was structured into two phases.

In the first phase, a document analysis and content analysis were conducted. This involved a thorough examination of the ENHIS documents' data compositions as defined in Regulation No. 53 of the Minister of Social Affairs. The document analysis identified 28 data compositions of documents sent to the ENHIS. The content analysis resulted in identifying 77 unique data sections, of which 38 sections overlap.

In the second phase, the study utilised the migration methodology proposed by Bossenko et al., involving the analysis of FHIR specifications and the FHIR Registry. Each data section identified in the content analysis was mapped to one or more corresponding FHIR resources based on semantic and functional similarities. The analysis revealed that out of 77 data sections examined, 50 were mapped to FHIR resources, and 27 sections did not receive results. In addition, the FHIR specification was analysed to examine the key relations and integration considerations for FHIR implementation. Finally, based on the results of the study, recommendations were proposed for implementing the FHIR standard in Estonia.

In conclusion, the transition to the HL7 FHIR standard presents a significant opportunity to enhance interoperability, streamline data management, and improve healthcare delivery in Estonia. This study's findings and recommendations provide a strategic roadmap for implementing the FHIR standard, ensuring the ENHIS's adaptability and effectiveness in meeting future healthcare needs. The analysis and results offer practical insights that can serve as a valuable resource for other countries in the process of adopting the FHIR standard.

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Appendix 1 – The list of instructions for filling out the CDA documents used in the content analysis

1. Instructions for filling out an outpatient case summary *(Ambulatoorse epikriisi täitmise juhend)* [65]*;*
2. Instructions for filling out a referral for hospital treatment *(Haiglaravile suunamise saatekirja täitmise juhend)* [70];
3. Instructions for filling out a dentaal card *(Hambaravikaardi täitmise juhend)* [82]*;*
4. Instructions for filling out an immunisation notice *(Immuniseerimise teatise täitmise juhend)* [79];
5. Instructions for filling out a growth notice *(Kasvamise teatise täitmise juhend* [71]*;*
6. Instructions for filling out a home and independent stationary nursing case summary *(Kodu- ja iseseisva statsionaarse õenduse epikriisi täitmise juhend)* [68]*;*
7. Instructions for filling out an ambulance card *(Kiirabikaardi täitmise juhend)* [81]*;*
8. Instructions for filling out a notice of an infectious patient *(Nakkushaige teatiste täitmise juhend)* [76]*;*
9. Instructions for filling out a notice of suspicion of an infectious patient *(Nakkushaige kahtluse teatiste täitmise juhend)* [77]*;*
10. Instructions for filling out a notice of HIV *(HIV teatiste täitmise juhend)* [78]*;*
11. Instructions for filling out an examination notice *(Läbivaatuse teatise täitmise juhend)* [72]*;*

12. Instructions for filling out a daycare case summary *(Päevaravi epikriisi täitmise juhend)* [67]*;*

13. Instructions for filling out a referral for outpatient service and e-consultation *(Ambulatoorsele vastuvõtule, e-konsultatsioonile suunamise saatekirja täitmise juhend)* [122]*;*

14. Instructions for filling out a referral reply *(Saatekirja vastuse täitmise juhend)* [80]*;*

15. Instructions for filling out an inpatient case summary *(Statsionaarse epikriisi täitmise juhend)* [66]*;*

16. Instructions for filling out a cause of death notice *(Surma põhjuse teatise täitmise juhend)* [74]*;*

17. Instructions for filling out a death notice *(Surmateatise täitmise juhend)* [73]*;*

18. Instructions for filling out a birth summary *(Sünniepikriisi täitmise juhend)* [69]*;*

19. Instructions for filling out a perinatal death cause notice *(Perinataalsurma põhjuse teatise täitmise juhend)* [75]*;*

20. Instructions for filling out a health declaration *(Tervisedeklaratsiooni täitmise juhend)* [83]*;*

21. Instructions for filling out a health certificate *(Tervisetõendi täitmise juhend)* [84]*;*

22. Instructions for filling out a referral for nursing care services *(Õendusabiteenusele suunamise saatekirja täitmise juhend)* [123]*;*

Appendix 2 – Analysis of data sections of CDA documents submitted to the ENHIS

CDA data section	Outpatient case summary	Inpatient and daycare discharge summary	Birth summary	Case summary of independent inpatient nursing service and home	Reply to referral	Referral for examination, procedure, and analysis	Referral for outpatient service, including e-consultation	Referral for inpatient and daycare services	Referral for independent inpatient nursing service and home nursing service	Dental card	Ambulance card	Notice of immunisation	Notice of suspected infectious disease	Notice of infectious disease	Notice of HIV	Notice of death	Notice of cause of death	Notice of perinatal death cause	Notice of development assessment	Notice of examination	Notice of counselling	Notice of growth	Notice of outpatient case opening	Notice of inpatient case opening	Notice of outpatient case closing	Notice of inpatient case closing	Health declaration	Health certificate	Total
Medical document data	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	24
Document author	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	V	V	V	V	X	X	28
Patient data	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	V	V	V	X	X	X	X	X	X	X	X	X	X	28
Referral data	X	X	X	X	X	X	X	X	X	X	V															V			12
Case data	X	X	X	X																			V	V	V	V			8
Diagnosis	X	X	X	X	X	X	X	X	X	X	X	V	V	V	V												X		16
Anamnesis	X	X				X	X	X	X	V	V	X							X	X	X	X							13
Objective findings	X			V			X	X	X		V											V					X		8
Patient health status overview				X					V																		X		3
Infectious diseases				X			X	X	V		V																X		6
Invasive device				X					X																				2
Nursing care activities provided to the patient				X					X																				2
Allergies	X	X		X			X	X	X		X																X		8
Examination/procedures	X	X			X	X	X	X	X		V									V									9

Radiology examination	X	X			X		X	X	X																				6
Surgical operations	X	X					X	X																			X		5
Laboratory examination	X	X	X		X	X	X	X	X																				8
Pathology examination	X	X			X		X	X																					5
Endoscopy examination	X	X			X		X	X																					5
Immunisations	X	X	X									X		X															5
Patient treatment summary	X	X	X							X	V																		5
Administrated medications	X	X	X	X						X	X	V																	7
Prescribed medications	X	X	X				X	X	X																		X		7
Condition upon discharge from hospital		X	X	X																									3
Regimen and treatment (including rehabilitation) recommendations	X	X		X						X																			4
Work organisation or environment modification	X	X	V																										3
Issued documents	X	X	X							X																			4
Outpatient visit	X	X								V																			3
Notes					X		X	X	X	X		X							X	X	X	X							10
Registration data													X	X															2
Illness data													X	X	X														3
Inpatient treatment													X	X															2
Staying abroad													X	X															2
Animal bites and tick attacks													X	X															2
Death data																X	X	X											3
Age section																			X	X	X	X							4
Overview of consultations	X			X	V						V																		2

Pregnancy and childbirth			X								V			V	V			V									X		6
Newborn birth			X																										1
Newborn health assessment			X																										1
Falls resulting in injury				X																									1
Safety measures usage				X																									1
Examination, procedure, analysis						X																							1
Nursing care needs assessment									X																				1
Patient's oral and dental history										X																			1
Dental visit										X																			1
Clinical dental observation										X																			1
Ambulance crew general data											X																		1
Ambulance crew members' data											X																		1
Incident data received from the emergency response centre											X																		1
Emergency call and dispatch and response data											X																		1
Patient assistance prior to ambulance arrival											X																		1
Time-critical patient data from the Health Information System											X																		1
Resuscitation											X																		1
Trauma											X																		1
Poisoning											X																		1
Additional assistance usage											X																		1

Transportation method											X																		1
Visit outcome											X																		1
Patient refuses further help											X																		1
Assisted another ambulance crew											X																		1
Reference to another document related to the same patient case											X																		1
Call priority according to the brigade's assessment											X																		1
Tuberculin/mantoux test												X																	1
Reason for testing															X														1
Infection spread data															X														1
Suspected place and time of infection															X														1
Aids indicator diseases															X														1
Development assessment section																			X										1
Examination section																				X									1
Counselling section																					X								1
Family situation section																					X								1
Health habits section																					X								1
Psychosocial background and development section																					X								1
Mental background and development section																					X								1
Patient's work environment																											X		1
Health certificate decision																												X	1

Appendix 3 – Data sections of CDA documents mapped to FHIR resources

Data section	FHIR SPECIFICATION	FHIR REGISTRY
Medical document data	DocumentReference	DocumentReference
Document author	DocumentReference	DocumentReference
Patient data	Patient	Patient
Referral data	ReferralRequest, HealthcareService	Task, ServiceRequest
Case data		EpisodeofCare
Diagnosis	Condition	Condition
Anamnesis	Questionnaire	Questionnaire
Objective findings	Goal, Observation	Goal, Observation
Patient health status overview	Encounter, Condition	Observation
Infectious diseases	Condition	Observation, Bundle
Invasive device	Device, Procedure	Device, Observation
Nursing care activities provided to the patient	CarePlan, HealthcareService, Procedure	Observation, Procedure, CarePlan, CareTeam
Allergies	AllergyIntolerance	AllergyIntolerance
Examination/procedures	Procedure	Procedure
Radiology examination	ImagingStudy, DiagnosticReport, Observation	Observation, ImagingStudy, DiagnosticReprot
Surgical operations	Procedure	Procedure
Laboratory examination	Observation or DiagnosticReport	Observation or DiagnosticReport
Pathology examination	DiagnosticReport, ImagingStudy	DiagnosticReport, Observation
Endoscopy examination	Procedure	Procedure
Immunisations	Immunization	Immunization
Patient treatment summary		
Administrated medications	MedicationAdministration	MedicationAdministration
Prescribed medications	MedicationRequest	
Condition upon discharge from hospital	Condition, DischargeSummary	Condition
Regimen and treatment (including rehabilitation) recommendations	CarePlan	Observation, Goal
Work organisation or environment modification		
Issued documents		
Outpatient visit	Encounter	
Notes		
Registration data		
Illness data	Condition	Observation, Condition
Inpatient treatment	Encounter, Procedure	Encounter, Observation
Staying abroad		
Animal bites and tick attacks		
Death data		Observation, Location, Procedure
Age section	DataType, Patient	
Overview of consultations		
Pregnancy and childbirth	Observation	Observation, Condition
Newborn birth	Encounter	Encounter, Procedure

Newborn health assessment	Observation, Condition	Observation, RiskAssesment
Falls resulting in injury	AdverseEvent, Condition, CarePlan	Observation
Safety measures usage		
Examination, procedure, analysis		
Nursing care needs assessment	Observation, ClinicalImpression, CarePlan, EpisodeOfCare	RiskAssesmnet, CarePlan, EpisodeOfCare
Patient's oral and dental history	Condition	Observation
Dental visit		
Clinical dental observation	Observation	Observation, Condition
Ambulance crew general data	Location,	Location, Encounter, Communication, Bundle
Ambulance crew members' data	Organization, Location, Encounter, Person	
Incident data received from the emergency response centre		
Emergency call and dispatch and response data		
Patient assistance prior to ambulance arrival		
Time-critical patient data from the Health Information System		
Resuscitation		Procedure
Trauma	Condition, CareTeam	Observation
Poisoning	AllergyInolerance	
Additional assistance usage		
Transportation method		
Visit outcome	Appointmenr, Encounter	
Patient refuses further help		
Assisted another ambulance crew		
Reference to another document related to the same patient case	DocumentReference	DocumentReference
Call priority according to the brigade's assessment		
Tuberculin/mantoux test	DiagnosticReport	
Reason for testing		
Infection spread data		
Suspected place and time of infection		
Aids indicator diseases		
Development assessment section	Observation	Observation
Examination section	Observation	Observation, DiagnosticReport
Counselling section	Procedure	
Family situation section	FamilyMemberHistory, Observation, Condition	Observation, Condition, FamilyMemberHistory
Health habits section		
Psychosocial background and development section		
Mental background and development section		Observation
Patient's work environment	Person	Observation
Health certificate decision		

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