

# OPEN PLATFORM BASED CLINICAL DECISION SUP- PORT

the possibilities of openEHR technology as part of  
health information systems renewal in Finland

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Field of Study Social Sciences, Business and Administration	
Degree Programme Master's Degree Programme in Digital Health	
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Title of Thesis Open platform based clinical decision support – the possibilities of openEHR technology as part of health information systems renewal in Finland	
Date 25.5.2022	Pages/Appendices 151/10
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<p>Abstract</p> <p>Finland's health and social services are under significant pressure for change, and digitalization has been emphasized in closing the sustainability gap. Challenges have been identified in health information systems and their development that are hampering change. The development of decision support systems has been identified as one of the most important future trends and possible solutions to the identified problems. There is a need to find out how the principle of an open platform and openEHR technology could help develop information management and decision support systems in Finland.</p> <p>The need was addressed through qualitative research using the Grounded Theory analysis method. Thematic interviews and a qualitative survey were used as data collection methods. The data collection was carried out using two different data collection methods and targeted two different target groups to implement two-level triangulation.</p> <p>Through the study, it was possible to understand what open platform-based clinical decision support means and how openEHR is related to it, and the reform of health information systems in Finland. Decision support systems can be implemented in stages in an open platform, involving professionals in development and leveraging extensive knowledge capital in a vendor and technology-neutral environment. The utilization of openEHR technology would enable the implementation of a multi-level modeling environment and the development of data persistence at the national level. However, the application of openEHR in the Finnish information management environment is not entirely problem-free. Further research would be needed in the practical application of the technology, for example, through a pilot project and its positioning to Finland's current information management guidance.</p>	
<p>Keywords</p> <p>openEHR, open platform, health information systems, interoperability, decision support systems, CDS, CDSS</p>	

Koulutusala Yhteiskuntatieteiden, liiketalouden ja hallinnon ala			
Tutkinto-ohjelma Digital Health tutkinto-ohjelma			
Työn tekijä(t) Henri Huttunen			
Työn nimi Avoimeen alustaan pohjautuva kliininen päätöksenteon tuki – openEHR-tekniologian mahdollisuudet osana terveystietojärjestelmien uudistamista Suomessa			
Päiväys	25.5.2022	Sivumäärä/Liitteet	151/10
Toimeksiantaja/Yhteistyökumppani(t) UNA Oy, Juha Rannanheimo Rosaldo Oy, Hanna Pohjonen			
<p>Tiivistelmä</p> <p>Suomen terveys ja sosiaalipalvelut merkittävien muutospainoiden alla ja digitalisaation merkitys on korostunut kestävyysvajeen kiinnikuomisessa. Terveystietojärjestelmissä ja niiden kehittämisessä on tunnistettu monia haasteita, jotka haittaavat muutosta. Päätöksentekijärjestelmien kehittäminen on tunnistettu yhdeksi tärkeimmistä tulevaisuuden trendeistä ja mahdollisista ratkaisuista havaittuihin ongelmiin. On syntynyt tarve selvittää miten avoimen alustan periaate ja openEHR-tekniologia voisi auttaa kehittämään tiedonhallintaa sekä päätöksenteon tukijärjestelmiä Suomessa.</p> <p>Tarpeeseen lähdettiin hakemaan ratkaisua laadullisen tutkimuksen avulla, jossa sovellettiin Grounded Theory -analyysimenetelmää. Tiedonkeruutapoina sovellettiin teemahaastatteluita sekä laadullista kyselyä. Tutkimuksessa tiedonkeruu toteutettiin kahdella eri tiedonkeruu metodilla ja kahdelle eri kohderyhmälle kohdistettuna kaksitasoisen triangulaation toteuttamiseksi.</p> <p>Opinnäytetyön kautta pystyttiin luomaan ymmärrys siitä mitä avoimeen alustaan pohjautuva kliininen päätöksenteon tuki tarkoittaa ja miten openEHR liittyy siihen ja ylipäättään terveyden tietojärjestelmien uudistamiseen Suomessa. Avoimessa alustassa päätöksenteon tukiratkaisut voidaan toteuttaa vaiheittain, osallistaen ammattilaiset mukaan kehittämiseen ja hyödyntäen laajaa tietopääomaa toimittaja- ja teknologianeutraalissa ympäristössä. OpenEHR-tekniologian hyödyntäminen mahdollistaisi monitasoisen mallinnusympäristön toteuttamisen ja tiedon pysyvyyden kehittämisen kansallisella tasolla. Täysin ongelmatonta openEHR:n soveltaminen Suomen tiedonhallintaympäristössä ei kuitenkaan ole. Lisätutkimusta tarvittaisiin tekniologian käytännön soveltamisessa esimerkiksi pilotti projektin kautta sekä sen asemoinnissa suhteessa nykyiseen tiedonhallinnan ohjaukseen suomessa.</p>			
<p>Avainsanat</p> <p>openEHR, avoin alusta, asiakas- ja potilastietojärjestelmät, yhteentoimivuus, päätöksenteon tuki, päätöksenteon tukijärjestelmä</p>			

## PREFACE

The implementation of this thesis proved to be a very burdensome and lengthy process in the current world situation. When the work was launched in late 2020, it could never have been imagined that the Coronavirus pandemic would continue for so long and contribute to burdening the researcher in so many ways. On the other hand, the process can be considered very instructive. It has opened up a whole new world for the researcher; information management and interoperability of health and social services.

I sincerely thank all those who participated in the interviews and responded to the qualitative survey. On behalf of Savonia University of Applied Sciences, I would like to thank my thesis supervisors for their support and encouragement to get the job done.

Special thanks go to the customer organization of this work, UNA Oy, and to the content supervisors Juha Rannanheimo (UNA Oy) and Hanna Pohjonen (Rosaldo Oy). Thank you for all your support, encouragement, and guidance in this exciting and challenging world and for opening the doors to the development community.

In the end, the enormous thanks go to my wife and children for coping through the process and ultimately for making the thesis possible. Without you, this would never have been possible.

Siilinjärvi 15.5.2022

Henri Huttunen

Many abbreviations are used in the concepts discussed in the thesis, although their use has been deliberately avoided. However, the abbreviations that have been used are summarized in the glossary below. The aim is to provide a clear definition of terminology and a structured overview to make it easier to read and understand. The abbreviations are arranged alphabetically.

Glossary: Abbreviations of terminology that occurred in concepts discussed in the thesis

API: Application Programming Interface

AQL: Archetype Query Language

CDA: Clinical Document Architecture

CDDS: Clinical Decision Support System

CDS: Clinical Decision Support

CEN: European Committee for Standardization

CIC: Community Interest Company

CKM: Clinical Knowledge Manager

CKR: Clinical Knowledge Resources

DICOM: Digital Imaging and Communications in Medicine  
DSM: Digital Single Market  
DSS: Decision Support System  
EHDS: European Health Data Space  
EHR: Electronic Health Record  
EIF: European Interoperability Framework  
EIRA: European Interoperability Reference Architecture  
ETL: Extract, Transform, Load  
EU: European Union  
FAIR: Findable, Accessible, Interoperable, and Reusable  
FHIR: Fast Healthcare Interoperability Resources  
GDPR: General Data Protection Regulation  
GDL: Guideline Definition Language  
HL7: Health Level Seven  
ICD: The International Statistical Classification of Diseases and Related Health Problems  
ICPC-2: International Classification of Primary Care, 2nd Edition  
ICT: Information and Communications Technology  
IHE: Integrating the Healthcare Enterprise  
ISO: International Organization for Standardization  
JSON: JavaScript Object Notation  
Kela: Social Insurance Institution of Finland  
LOINC: Logical Observation Identifiers Names and Codes  
MDR: Medical Device Regulation  
OMOP: Observational Medical Outcomes Partnership  
REST: Representational State Transfer  
RIM: Reference Information Model  
RM: Reference Model  
RxNorm: A Standardized Nomenclature for clinical drugs  
SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms  
SOAP: Simple Object Access Protocol  
STM: The Ministry of Social Affairs and Health  
THL: The Finnish Institute for Health and Welfare  
TRL: Technology Readiness Level  
XDS: Cross-Enterprise Document Sharing  
XML: Extensible Markup Language

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# 1 INTRODUCTION

Finnish healthcare and social welfare organizations are under significant pressure for change. The entire service system will change when the organization of public healthcare, social welfare, and rescue services in Finland are reformed from 2023 onwards. (Government proposal 241/2020). In addition to the administrative change, the reform has also been described as the most significant information system reform in Finnish history (Kajaste 2021). One of the key objectives of the reform is to harmonize services and make digital services accessible to citizens. As part of the reform, the harmonization and modernization of information systems used to process customer and patient data (in the future, an abbreviation health information system will be used to describe in general the information systems used by health and social care actors to process customer and patient data) at the regional level have been seen essential (Sote-uudistus 2020).

Europe's progress towards the digital age continues and remains a priority. A Digital Single Market is being built to support the health and social services, where data is opened and brought to the forefront of information security alongside people orientation. Progress will enable the digital transformation to realize new opportunities for citizens and the market. (European Commission 2022e.) This change also concretizes the direction of development at the national level and accelerates the application of various new technologies and standards to support change. (Ministry of Finance 2022).

Over the years, national development strategies have sought to influence the business environment of the future, creating opportunities for the development of health information systems. The goal has been to promote a functioning, vibrant, and evolving network around the evolving ecosystem of health information systems. In such an ecosystem, information is an essential resource that is freely available and promotes interoperability. Standardization and openness enable the agile development of solutions and the integration of innovations into the ecosystem. These goals affect current relationships between organizations and stakeholders, systems development and delivery practices, and, more broadly, the current operating environment for health information system vendors. (STM 2014.)

Information management at the national level has been seen as such an essential matter that a comprehensive reform of social and health information management legislation was launched in 2021. The current legislation has been described as fragmented and partly obsolete. In addition, problems have arisen in applying and harmonizing different laws. (VN/2037/2021. Hallituksen esitys eduskunnalle laiksi sosiaali- ja terveydenhuollon asiakastietojen käsittelystä sekä eräiksi siihen liittyviksi laeiksi.) New opportunities brought by technological developments and the need to combine health and social services customer data have also highlighted new regulatory needs (Laitinen, Pekkarinen, Reipas & Rantala 2021). The reform aims to form a unified legal basis for processing social and healthcare customer data, which would support the development of the service system and services and the integration of health and social services (STM 2021).

The development of decision support systems has been seen as one of the most important future trends and potential solutions to the problems identified in the current healthcare and social welfare environment. Decision support systems are entering a new era with technological advances reached

(Middleton, Sittig & Wright 2016). For example, the feasibility of artificial intelligence-assisted clinical decision support systems is one of the global trends in public health (WHO 2022, 7). Effective use of decision support can take the operational activities of healthcare and social welfare organizations to a new level and support closing the sustainability gap. There are still many ethical and legal challenges to decision support, but these are currently being actively addressed at the European Union and the Finnish level (European Commission 2022d; Finnish Government 2018; Ministry of Justice 2020).

Healthcare and social welfare organizations are currently extensively modernizing health information systems with the described forces and trends of change. In addition to the development needs of administrative reform, the so-called development dept has also accumulated in health information systems due to national guidance, the development of national information system services, and legislative changes. Regional development activities have not led to a large-scale modernization of organizations' health information systems but mainly implement the necessary interface features and other capabilities to integrate them into national information system services. Implementing integrations into national information system services has been found to be costly, complex to implement, and difficult for individual organizations to manage. (VN/2037/2021.)

In general, there is a widespread need to develop the capabilities of health information systems. New operating models and hospital constructions require modern technology to support the change and close the productivity gap. Current health information systems need a technological overhaul, as they are, in several cases, based on technology from a decade ago. They do not enable the promotion of digitalization in the broader context. Furthermore, for example, developing decision support systems and artificial intelligence is not possible as part of the current health information systems. The current health information systems are also not flexible enough for the reformation in terms of technology or contract structures, making system development expensive and time-consuming. (Ukkola & Vainio 2019, 20-25.)

User dissatisfaction is also familiar with current health information systems. The poor usability, lack of flexibility for change, and the clumsiness of implementing integrations cause problems and deficiencies almost daily (Vehko et al. 2018). One of the current situations and future development problems is the current system vendors' strong position, thereby threatening vendor lock-in, which poses challenges and cost challenges to development work (Ukkola & Vainio 2019, 20-25). Furthermore, the situation does not seem to be improving (Lepistö & Ukkola 2020, 7-8).

When health information systems are inevitably being developed, it is worth considering which direction to steer development and what we want to enable through development. Traditionally, the implementation of health information systems in Finland has been based on the so-called monolithic health information systems, mainly developed and supplied by the limited group of system vendors operating in Finland. This implementation model has led to many challenges identified in the current health information system ecosystem (Ukkola & Vainio 2019, 20). The effects of modernizing health information systems based solely on the monolithic solutions of international system vendors are

also increasing. Several projects have sought new types of development models for health information systems. However, the projects that have finally been realized have nevertheless ended up with very similar solutions to those currently in use. Therefore, it is unclear whether there are other ways to implement development in practice and, if so, what changes are needed to the current market and the direction of development. In other words, the realistic applicability of development models has remained unclear. (Sote-uudistus 2020, 16-17.)

We will have to ask if we want to rely in the future on monolithic solution models or promote a different kind of development, for example, to make the health information systems ecosystem more open and flexible? The development path could mean that Finland's health information systems development and the market rely on international system vendors (Lepistö & Ukkola 2020, 21-23). From the Finnish market point of view, this scenario could be worrying. It does not necessarily contribute to maintaining development expertise in Finland and improving national development strategic goals and principles (Pentikäinen et al. 2019, 28-29). It is good to remember that as the development of health information systems moves towards concrete measures, such as procurement and implementation, the measures aim to influence and challenge the way the market implements health information systems in Finland. Therefore, from a market perspective, it is essential that the development is determined, long-term, and implemented in the broadest possible cooperation. The small size of the Finnish market affects the willingness of international players to offer solutions and develop them for Finland's needs unless the direction of development is unambiguous and the broad community behind it. (Government proposal 241/2020, 181-183.)

In addition to these market, ecosystem, and interoperability aspects, decision-making and commitment are other significant challenges in developing health information systems. The development of decision support systems and health information systems is complex, both technologically and operationally. Development is also expensive, so the persuasiveness of development must be fully justified, preferably through operational benefits. The information systems are unlikely to deliver the desired costs and other benefits directly. The role of information systems is to support more efficient operations and more efficient services that will ultimately achieve the desired benefits. Therefore, organizations' commitment to a strategy for developing health information systems is an important decision for management, especially if the development strategy involves a pioneering spirit and resilience to uncertainty.

By developing and modernizing health information systems, health and social services can be provided more cost-effectively, significant benefits can be achieved in information management, and digital transformation can be supported (Ukkola 2020). However, what does the development and modernization of health information systems mean in practice? The development of health information systems can be implemented in many different ways and based on different development principles. Is it self-evident that the modernization of health information systems will lead to these benefits, or are certain principles needed for development?

Solving or even partially answering the problems considered is not a simple task. Efforts have been made to find answers through various cooperation networks and consortia, one example of which is

the network formed by UNA Oy. This cooperation network promotes the development of health information systems in broad regional cooperation. The development aims to modernize the information systems in use in the regions in practice. (UNA 2022.)

Development projects, such as those implemented by UNA seek new ways to develop health information systems to be more open, flexible, and efficient. The projects have raised concrete needs to define new ways to structure the development of health information systems as a counterweight to monolithic solutions. In particular, projects have explored the role of open ecosystems and open technologies' potential to develop health information systems and related business planning and enterprise resource planning solutions. (Rannanheimo 2019.)

In recent years, the reformation of health information systems globally has highlighted models in which modernization is based on open platform ecosystems and the utilization of openEHR technology. Such a reformation path has been seen in many studies and in practice in many European and Nordic countries as an opportunity to meet the challenges identified and to help advance national development goals. The importance of OpenEHR has even been seen in some estimates as revolutionizing healthcare by enabling the acceleration of digital change by shifting the history of the implementation model of interoperability based on integrations and data transfer and putting knowledge at the center. Thus, openEHR enables the transition from an application-centric to a data-centric architecture, eliminating data silos, eliminating point-to-point integrations between applications, and creating a modular architecture that accelerates development. (Allen 2022.)

The implementation model of open platform-based decision support systems supported by OpenEHR technology has also been seen to address the identified development challenges. Through the tools and specifications in OpenEHR, especially the Guideline Definition Language (GDL), a development model can be built in which future modular and archetype-based solutions and Legacy systems can work together to develop capabilities to build decision support systems in a vendor and technology-neutral manner (Anani et al. 2017, 4).

According to many international examples, an implementation model based on an open platform and openEHR technology could provide a reasonable basis, or part of it, for the modernization of information systems and the development of decision support systems in Finland. However, understanding the meaning of the concepts of an open platform and openEHR and positioning them in the Finnish health and social information management environment still requires clarification. It is also unclear whether this is the only realistic option for implementing an open platform and how openEHR technology relates to other healthcare interoperability standards and technologies in Finland.

Therefore, there is a fundamental need to determine the role and potential benefits of openEHR technology in Finland, considering the existing information management infrastructure. Justification is needed, in particular, when seeking a commitment to a long-term and innovative way of developing and building concrete development models that do not overly challenge existing delivery models and are therefore realistically feasible.

## 2 RESEARCH DESIGN

As stated in the introduction, the development of health information systems, including decision support systems, involves many concrete challenges and needs for which there are no simple solutions. For this reason, this thesis aims to deepen the understanding of the most critical areas for development and the possibilities of openEHR technology to support the development and formation of an open platform. Through this deepened understanding, the aim is to outline the concrete opportunities or benefits that could be achieved by applying openEHR technology and thus promote the development of decision support systems in Finland. More generally, the aim is to discover the role and application possibilities of the open platform and openEHR concepts in the Finnish health and social services information management environment.

The delimitation of the research area has been considered necessary due to its potentially large scope and to enable the feasibility of the work (Eco, Farina & Farina 2015, 18). In practice, delimitation is concretized through decision support systems and the Finnish information management environment. Focusing research on the role of concepts, especially in decision support systems, has been considered appropriate due to a large amount of previous research on decision support compared to a situation where research would focus directly and only on the concept of an open platform or openEHR.

At the national level, information management environments' key development goal is to promote measures that will enable healthcare and social welfare organizations to lead and improve their operations and services and make better decisions based on accurate and timely information (VN/2037/2021, 23). For this reason, it is not enough to explore the positioning and potential of open platform or openEHR technology from the perspective of information management or technology alone, but also to include perspectives that open up concepts to different stakeholders. From the perspective of senior management, the benefits and opportunities must be concretized to allow for commitment to the development strategy of alternative development models. Furthermore, on the other hand, for healthcare and social welfare professionals, opportunities need to be able to communicate understandably. Evaluation through decision support has been seen as an excellent way to concretize concepts and the potential benefits of technology. At least through it, it is possible to form a more holistic view of the research subject than just comparing the characteristics of development models and technologies.

The research results of the thesis are aimed at being realized on two levels. Increased understanding of the potential and importance of openEHR technology and the open platform concept is at a lower level and easier to achieve. The result mainly brings value to the actors developing health information systems or their national guidance. Achieving higher and more challenging results will help identify the benefits and opportunities for openEHR technology and open platform development in the context of decision support. Higher-level benefits could bring added value to healthcare and social welfare organizations. On the other hand, the development of decision support is a topical issue in Finland and internationally and brings operational significance to research.

Against this background, the research aimed to discover **how openEHR technology and the open platform concept could help develop decision support systems in Finland.**

The aim narrowed slightly from the preliminary form of the research plan, but this is characteristic of qualitative research, especially when applying the Grounded Theory analysis method.

In addition to this primary research aim, the study examines the answers to the following research questions:

1. What are the operational needs for developing decision support systems and their development models?
2. How do openEHR fit into the existing Finnish health and social services information management environment?

## 2.1 Research methods

The research part of the thesis is carried out as qualitative research supported by systematic information retrieval, which materializes into a theoretical framework of the thesis.

The theoretical framework of the thesis examines the conceptual background of the research and how the thesis relates to existing research through systematic information retrieval. It is used to map out what information exists about the research area and clarify gaps in the earlier research that should be specifically targeted. Systematic information retrieval also helps keep the scope of the thesis under control. (Hirsjärvi, Remes & Sajavaara 2009, 121.)

The thesis's actual research part is qualitative research because a literature review and the application of a quantitative research method are not recommended research methods to use in a situation where only a few previous theories and research explain the research problem (Kananen 2015, 66). According to several sources (Kananen 2015, 70-71; Pope, Mays & Allen 2020, 4-5; Creswell & Guetterman 2021, 40), qualitative, unlike quantitative, studies do not seek statistical generalizations but seek to interpret a particular phenomenon and make it understandable. Especially in situations where the study is based on a small number of cases, or there is no prior knowledge on the subject. Thus, qualitative research serves the purpose of the thesis as described in the definition of the method.

### 2.1.1 Data collection

Qualitative research material can be collected in various ways, the most traditional of which are observations, interviews, and the utilization of existing material. It was decided to collect the material for the thesis through interviews. In the interview, the researcher and the interviewee systematically discuss issues related to the research topic. Typically, qualitative interview methods are divided into three types; structured, semi-structured, and open interview. (Kananen 2015, 144.)

According to Merriam & Grenier (2019), it is also recommended to use several data collection methods to ensure the validity of the findings. For this reason, triangulation was applied to data collection in two different ways; in the form of data collection methods and the target group from the whom the data was collected. The aim was to make available two different data sets that could be

analyzed to see if the results would lead to a similar conclusion. (Leedy, Ormrod & Johnson 2021, 129.)

Data collection was divided into two parts to implement the principle of triangulation; the thematic interviews to identify operational development needs for decision support systems and structured interviews seeking the benefits of openEHR in developing decision support systems. The first part of the data collection was aimed at clinicians and developers of health information systems in Finland, and the second part at actors already utilizing openEHR technology worldwide.

In qualitative research, interview material is collected from individuals involved in the phenomenon under study (Kananen 2015, 145-146). Therefore, those with experience and knowledge of the phenomenon under study will be selected for the interviews. The information-oriented interviewees are not typically selected in large numbers, and the results of the interviews are thoroughly examined, in which case the quality of the information is essential (Brinkmann 2013, 57-58). It is ideal that the interviewees voluntarily participate in the study, which is essential for research ethics (King, Horrocks & Brooks 2018, 36).

The interviewees were carefully selected and evaluated by the thesis supervisors, who also acted as gatekeepers to reach the proper interviewees (King, Horrocks & Brooks 2018, 59). Following Salana's (2011, 34) recommendation, the aim was to select persons who were barely familiar with the researcher for interviews so that previously unknown perspectives would emerge in the interviews. The number of interviewees was not fixed before the interviews because it was impossible to estimate when saturation would be reached (Taylor, Bogdan & DeVault 2016, 106-107).

The thematic interviews were carefully prepared according to the recommendations (Holloway 2017, 88-89; Brinkman 2013, 46-49; Leedy et al. 2021, 274-279). The implementation, structure, and themes of the interviews were planned as described in Appendix 1. The interview structure was based on previous research (Sutton, Pincock & Baumgart 2020; Castillo & Kelemen 2013) to ensure a link to the research topic and the second part of data collection.

Unfortunately, all the interviews had to be conducted with electronic conferencing tools due to the ongoing situation with Coronavirus. Although this greatly facilitated the recording of the interviews. The recordings were used to transcribe the interviews, which were carried out at the basic level, where unnecessary repetitions and fill-in words were removed. Basic transcription was possible because the implementation of baseline spelling was adequate and appropriate for the qualitative analysis methods applied to the data (Pope et al. 2020, 51 & 112 & 135-141).

The interviews were conducted between May 2021 and August 2021. Pre-interview material (Appendix 1) was sent to the interviewees to orientate themselves in advance. However, it was emphasized to the interviewees that the interview situations were intended to be informal and conversational. Among the interviewees were experts from different healthcare and social welfare sectors who somehow were involved in developing health information systems or decision support systems. TA-

BLE 1 describes the interviewees' identifier, employer role, areas of expertise, and the interview duration. All interviews were conducted as individual interviews.

TABLE 1. Information of the participants of the thematic interviews

Identifier	Employer	Areas of expertise	Duration (min:sec)
Int_1	Development company	Drug supply and drug delivery Information management	48:50
Int_2	Social and Health Care District	Social welfare Interoperability	64:30
Int_3	Development company	Healthcare Information management	59:31
Int_4	Healthcare organization	Healthcare Information management	45:03
Int_5	University Hospital	Specialised health care Business development	39:49
Int_6	Social and Health Care District	Social welfare Information management	54:35
Int_7	University Hospital	Specialized health care and nursing Information management	51:20

After seven thematic interviews, it was assessed that the required saturation level had been reached. No new findings emerged significantly, and therefore no need for further interviews was seen. The results and analysis of the thematic interviews are described in Chapter 3.

The second part of the data collection focused on mapping the ideas and experiences of those already using openEHR technology about the benefits of the technology in developing decision support systems. Data collection was conducted as a qualitative survey that mimicked the features of structured and semi-structured interviews (Braun, Clarke, Boulton, Davey & McEvoy 2021). The aim was to seek the opinions of the interviewees on the pre-selected themes and make it possible to highlight issues that the researcher had not taken into account in advance. The main goal in choosing the data collection method was to minimize the researcher's influence in the actual interview and, on the other hand, to reach appropriate interviewees from outside the researcher's stakeholders. (Puusa, Juuti & Aaltio 2020, 107.)

Jansen (2010, 17-18) labeled the concept of qualitative survey and described it as a simple qualitative research method that is most often linked to Grounded Theory analysis. This analysis method is also applicable in this study. The use of questionnaires as part of qualitative research is not unequivocally accepted in a methodological sense, as Kananen (2015, 152) states, for example. However, it has been seen that qualitative research methods should be developed and adapted to serve modern research opportunities (Braun et al. 2021). The chosen data collection method is also partly justified



by the effort to carry out multi-method research, as the research seeks to explain and describe a new and demanding area of research (Puusa et al. 2020, 299).

Preparations were made for the implementation of data collection utilizing a qualitative survey, applying the same operating model as for the implementation of interviews following qualitative research methodology. The content of the qualitative survey was carefully designed, and the structure relied on Sutton et al. (2020) and Castillo & Kelemen (2013) previous studies on the target area. The survey structure (Appendix 2) and the survey invitation were evaluated concerning the research questions with the thesis' supervisors.

The target group for data collection was selected from providers of health information systems and healthcare and social welfare organizations across Europe that already use openEHR technology. The existing contacts of the thesis supervisor, Finland's openEHR ambassador Hanna Pohjonen, were utilized to contact the openEHR market participants and organizations applying the technology. In addition, a request to respond to a qualitative survey was posted on the researcher's LinkedIn account and on the openEHR community forum, where the research was also the subject of discussion (Appendix 3).

The qualitative survey was conducted between June 8, 2021, and June 30, 2021. Seven responses to the survey were received, which corresponded well to the number of respondents in the first part of data collection and were quite typical for a qualitative study where the subject of the study is demanding and relevant to a limited target group. TABLE 2 describes the respondent's identifier, employer's, and respondent's role.

TABLE 2. Information of respondents to the qualitative survey

Identifier	The role of the respondent's organization	The role of the respondent
Qs_1	Customer or user organization System vendor	Manager
Qs_2	Customer or user organization	Manager
Qs_3	Customer or user organization	Specialist in health or social care;
Qs_4	System vendor Developer or consulting Community	Manager Specialist in health or social care Specialist in business and administration Specialist in information and communication technology
Qs_5	Developer or consulting System vendor	Manager Specialist in information and communication technology Specialist in health or social care;
Qs_6	Community	Manager
Qs_7	System vendor Community	Specialist in information and communication technology

### 2.1.2 Data analysis

The collected research material was analyzed using the Grounded Theory analysis method. Grounded Theory is a data-driven method that seeks to structure a theoretical explanation for a phenomenon based on research data. In the method, the research material is thoroughly coded according to different topics, concepts, or categories and compared with each other in stages, generalizing the level of abstraction into a categorization that forms the basis of the explanation of the phenomenon (Goulding 2022, 48). Grounded Theory analysis is a kind of dialogue with the material, and it seeks to outline what the material tells us (Puusa et al. 2020, 239-240). In the method, the researcher thus synthesizes the significance of the research data into a practical theoretical integration using codes and concepts (De Chesnay & Banner 2015, 23).

The different categories start to form in the Grounded Theory method as the coding progresses. The Grounded Theory method has at least two steps; open coding, in which the material is reviewed, for example, line by line, and selective coding, the purpose of which is to form relationships and identify repetitive themes between the initial coding of the material. Finally, the codes are compiled into categories that describe the phenomenon under study. It is as if the material is first disassembled and then reassembled according to the themes found. (De Chesnay & Banner 2015, 21-23.)

The progress of the research data analysis using the Grounded Theory method is described in Chapter 3. The analysis proceeded as a step-by-step process in which the understanding of the subject of the study became more and more structured. The analysis sought to identify the theory or theories describing the topic. The implementation of the theoretical framework of the thesis was delayed because, as Eronen, Syrjäläinen & Värri (2007, 99) state, at the purest, the analysis of the material

should be completed first, and only then should be examined what research literature says about it. Thus, the theory created in the analysis phase settles into the research field, dealing with the topic through a theoretical framework.

## 2.2 Ensuring reliability and validity

Ensuring the reliability of research is a complex issue and is not unambiguous in qualitative research, which poses challenges to examining quality. Particular emphasis should be addressed on systematic and consistent work throughout the process and the quality of the material used in the research (Kananen 2015, 343-344). Nor should the researcher's influence on the research be underestimated. Therefore, the material should be handled consistently without preconceived notions and high source criticism (Vilkka 2021, 132).

The study's reliability can be examined based on the trustworthiness criteria defined by Lincoln and Guba (1985): credibility, transferability, dependability, and confirmability. Credibility looks at whether participants find the results credible. Transferability assesses whether the same conclusions can be drawn from other research settings. Dependability refers to whether the findings are consistent and reproducible based on existing data. Lastly, confirmability means whether other researchers can confirm the study's findings and that the researcher has not been convinced of the results. (Jason & Glenwick 2016, 39.)

In addition to these trustworthiness criteria, Whittemore, Chase & Mandle (2001, 534) have structured four validity criteria, credibility, authenticity, criticality, and integrity, to ensure the validity of a qualitative study. The defined validity criteria refine the review of reliability by ensuring the quality of the results rather than focusing on improving the technical reliability of the research. For this reason, criteria defined by Whitmore et al. (2001, 534) have been used to ensure the reliability and validity of this thesis.

Credibility is based on whether research findings credibly describe participants' experiences or context (Jason & Glenwick 2016, 39). The work's credibility is also affected by the researcher's in-depth acquaintance with the topic and the creation of a red thread to be followed in the research, as Kananen (2008, 39-40) states. Triangulation has also been used to strengthen the credibility of research and to support the perception of the phenomenon under study from different perspectives using different research methods and data (Kylmä & Juvakka 2007, 128). As pointed out by Roulston (2019, 31), the use of two datasets and a structured interview and the thematic interviews alongside, reduces the potential impact of the researcher on the outcome.

In addition to utilizing triangulation, the researcher has invested in developing expertise in the research area in addition to developing a theoretical framework by participating in the openEHR 2020 Digital Event (24.11.2020), HiGHmed SYMPOSIUM event (14.10.2021, Berlin, Germany), and the Scandinavian openEHR Collaboration Online Meetings (7.10.2021, 9.12.2021, and 15.2.2022) during the research period. By participating in the events, the researcher broadened his view of the research area and its relationship to other phenomena as part of empirical research, as suggested by

Kananen (2015, 157–158). Participation in events also contributed to implementing the scoping review recommended by Ikonen, Isojärvi & Malmivaara (2009, 3209) to refine the research questions and approaches.

Authenticity is based on whether all different perspectives have been taken into account. Authenticity has been defined to have different aspects; fairness, ontological, educational, catalytic, and tactical authenticity. The most important of these is fairness, which is how different perspectives have been considered in collecting and analyzing research data. (Amin et al. 2020.)

Efforts have been made to ensure the authenticity of the research by utilizing triangulation and collecting information from as many different sources as possible. Proponents of completely external theories or, in principle, those who have a negative attitude towards the study have not been deliberately selected for an interview. Obtaining completely external insights into research has not been seen as relevant to the scope of the study and the research questions. The interviewees have been told realistically and openly about the purpose of the interviews and the research itself. The researcher has consciously encouraged the interviewees to narrate their perspectives on the subject. The researcher has also tried to avoid directing the interviewees by all means. If the possibility of influencing has been notified, these answers have been ignored in the final data analysis.

Criticality examines whether the research process demonstrates evidence of critical appraisal. Criticism manifests itself in the research process through the researcher's self-criticism and the effort to look for alternative hypotheses and identify preconceptions (Whittmore et al. 2001, 531). The study has tried to be critical of all research results. In order to identify biases in the second phase of data collection, for example, the responses of different groups of respondents have been compared. The researcher has also sought to challenge the interpretations and observations made and seek confirmation from the research material and the theoretical frame of reference. It has been relatively easy for the researcher to be critical without preconceived notions about the research subject, as the researcher has no previous experience.

Integrity assesses whether the study continuously validates quality and conclusions and whether the findings are presented based on the data collected. Ultimately, integrity describes honesty in conducting qualitative research and supports ethical practice at all data collection and analysis stages. The realization of integrity is characterized by the researcher's openness, transparency, and objectivity and can be understood as a kind of moral honesty towards research. (Watts 2008.)

The researcher has sought to achieve integrity by describing the stages of the research process as accurately as possible and distributing the research materials as comprehensively as possible without compromising the privacy of those involved in the research. The Grounded Theory method applied in the data analysis also contributes to ensuring integrity, as the method is characterized by the construction of theories in stages based on research data.

### 3 RESEARCH RESULTS

The chapter presents the data collected in the research and the step-by-step progress of the data analysis process. First, the analysis process according to the Grounded Theory method and the categories formed during the process are reviewed. Preliminary theories formed based on the analysis are also presented. After that, thematic interview results and a description of conclusions drawn from the findings are presented. The results of the qualitative survey are then presented in a separate chapter.

Except for coded transcripts of the interviews, raw data from the study are presented in Appendices 4, 5, and 7. The study does not include raw data from the qualitative survey because the results have been carefully opened in Chapter 3.2.

In the study, the materials obtained by the different data collection parts were first processed separately, and after the preliminary coding of the research data, the data were combined. The data from the first part of data collection, discussions of the thematic interviews, were first coded in a spreadsheet to group similar reflections and answers into blocks (Appendix 4).

The interviews were conducted to discuss three different topics (see Appendix 1) and led to a straightforward first classification of the interviews; Needs, benefits, challenges, and lessons learned. In addition to these, the preliminary classification identified subjects classified as perspectives, motivations, observations, enablers, and the nature of the solution. From this, research progressed step-by-step towards categorizing the results and started to outline the first observations supporting the formation of the theory from the results of the interviews. As described by Eronen, Syrjäläinen & Värri (2007, 98-99), the process proceeded in stages, refining as is characteristic of the method. Gradually, the categories began to form, and the constraints that supported the formation of the theory alongside them were identified. A total of five categories were subtracted from the data; Cost control, Customer orientation, Development methods and models, Knowledge capital, and Operational support

Under these categories, it was possible to structure all the findings that emerged in the actual themes of the interviews. In addition, three additional categories were identified to classify the ancillary findings; Information management, Changing operating environment, and Principles and characteristics. However, these were not included in the actual categorization because no observations on the actual themes were identified below them.

The service area, development focus, and nature of the solution were identified as constraints. Constraint values have been described in TABLE 3. All categories and their relations between constraints can be examined in Appendix 5. Each observation was also highlighted according to how many interviews the same observation was made. In addition, the researcher noted individual observations that seemed particularly significant to support further processing and the formation of

theories.

TABLE 3. Constraints and values

Constraint	Value
Development focus	Information management Information systems Business/operations development
The nature of the solution	General Decision Support Clinical Decision Support
Service area	Healthcare Specialized healthcare Social welfare

In connection with the analysis of the first part data, the following preliminary theories were formed.

The development needs of decision support are primarily focused on the development of operations by supporting the success of professionals and involving patients or clients more closely in care. With the development, the quality of information will improve, and efficiency and cost savings can be achieved by developing the timeliness and coverage of care.

Development is hampered by complexity and thus by the long-term nature of development. Therefore, the benefits should be realized in stages by involving professionals in the development and relying on the re-use of information and technologies used in other industries.

Knowledge capital needs to be developed in particular to improve reliability and interpretability.

The data from the second part of data collection, the qualitative survey results (Appendix 6), were analyzed using the categories built in the first data analysis phase. The results were also loosely visualized using quantitative research methods, but actual quantitative research analysis methods were not applied to the data. The main goal was to detect possible dependencies and correlations, gain confirmation of the theories formed in the first phase, and increase the understanding of the strengths of openEHR technology in developing decision support systems. The aim was also to identify and prioritize the concepts included in the thesis' theoretical framework.

The implementation of the qualitative survey caused some discussion during the implementation due to its inaccuracy and scope, which is characteristic of qualitative research. The researcher encouraged the Nordic openEHR community to respond to the survey. In this context, openEHR board member Mikael Nyström (Mikael 23.6.2021) commented that it would be easier to receive relevant answers if the investigations were conducted as oral interviews than a survey. The finding was, in the researcher's view, relevant and expected. The researcher commented that, for his part, the survey was intentionally left a bit inaccurate because the questions were not too intended to guide respondents in approaching the topic. The survey simulated a structured interview that could not be conducted orally due to excessive workload. The chosen data collection method may be justified

because it provides experience in applying qualitative research as part of other data collection methods and enables data triangulation.

The categorization was re-examined in the second phase of data collection. Of the main categories identified, all others were highlighted and were particularly relevant in developing decision support systems based on openEHR technology except cost control. Perhaps cost control is more of a benefit or result than the main category worth carrying out in the study, so it was decided not to use it at this stage. The benefits and development needs linked under the cost control category were grouped under the category of operational support to which they naturally fit. Thus, the final categories that structured the research area were **customer orientation, development methods and models, knowledge capital, and operational support**.

Preliminary theories based on development needs were updated to consider the results of the second data analysis phase. In this way, a preliminary theory to answer the research aim was formulated:

OpenEHR technology in decision support systems emphasizes the standardization and harmonization of knowledge capital. A harmonized knowledge capital, combined with the principles of modularity, openness, and ready-made tools for platform technology, will help create a phased development ecosystem where professionals can be involved in development. In such an ecosystem, benefits can be realized in stages, patient-centered solutions can be implemented, and knowledge capital and data platform management can be held under the organization's control.

### 3.1 Results of the thematic interviews

The following subchapters present the results of the thematic interviews. The thematic interviews have been conducted in Finnish, and the researcher has translated the quotations presented in the following chapters. According to the original spelling, the interviewees' expressions are summarized in Appendix 6.

#### 3.1.1 Development needs

The development needs that emerged in the interviews were generally relatively consistent. The needs related to the development of operations were emphasized in the interviews across service areas. In particular, it was emphasized that information systems should be able to support professionals in carrying out service processes. As part of this, the need for automatic notifications that consider the customer's overall situation was emphasized. Notifications could be made, for example, for various rare diseases, dangerous combinations of medication, risk factors for social care, and other matters defined nationally, regionally, by a service provider, or even by a professional.

Nevertheless, such decision-making support would be needed, which would look at the patient's overall medication, for example, and perhaps, more broadly, the overall situation. And then, it would also help the doctor move forward in the process, for example, so that if there is no time to look at something at this stage, it will leave reports for review at a later stage in the treatment process. (Int\_1-1)

After all, decision-making also supported the fact that the system could tell the professional which direction to proceed. (Int\_2-1)

The need to evaluate the effects at different timespans was emphasized in the social services.

We should be able to bring to the perspective that it is worth investing even a hundred euros in a customer now, and then it will start to bring savings later. In which case, only a few tens of euros will be spent on customer service at a later stage. Sometimes it is worth investing more in the top so that the benefits will be there over the years and decades. Furthermore, those options should be able to show that if you invest a little more now, what will it affect in the long run. (Int\_2-2)

Diversity and the need for human judgment are characteristic of social services, as the impact of actions is much more challenging to assess than in healthcare services. The range of factors influencing the situation and its development is much more diverse than perhaps in the healthcare services.

If we take, for example, the fact that we have two people with substance abuse problems who would seem to be in a very similar situation. So if we give them the same interventions, the result can still be completely different. It has so many variables in its customer's life and different mechanisms that affect it. (Int\_6-1)

The potential of clinical decision support in diagnosis was similarly emphasized in the healthcare services. However, there was also a need to develop more general decision support.

When it is possible to treat patients in a more targeted way when decision-support guides the activities of the professional. Yes, there is potential for development. For example, in maternity and child health services, our maternity and child health clinics are still largely based on the operation model where all clients go through the same process, after which the professionals evaluate the situation. Benefits could be found for both patients and clients, doing things more targeted and then saving time and resources. (Int\_5-1)

Development needs were summarized in four different categories. **Cost Control;** The cost-effectiveness of measures and decisions must be made visible. **Customer orientation;** The customer must be involved in their care and provide information for the use of the service system. **Knowledge capital;** All information in the service system must be available, and it must be able to be combined. **Operational support;** Health information systems must support the professional in carrying out the processes, presenting notifications considering the customer's situation, and information systems should support professionals in entering data and observing the effects in different timespans.



### 3.1.2 Benefits

There were no exact weightings between the different service areas, development focuses, and the solution's natures in the benefits of decision support. In general, the opportunity to streamline operations at both the professional and organizational levels was emphasized as a benefit. Furthermore, the cost benefits of this development as the timeliness and breadth of care and operations are improved.

For example, if solutions were used so that the actors were better aware of each other and did not overlap and that things were done at the optimal time. (Int\_4-1)

And, of course, operations can be organized efficiently in a tightening staffing situation, supported by decision support systems. (Int\_7-1)

The cost aspects will be taken into account, not only in terms of reduced visits but also in terms of success in holistic medication. (Int\_1-2)

In addition, one of the particularly significant benefits of decision support was the potential to improve data quality. Decision support could help professionals record better quality data in many ways, such as automatically filling in data that can be inferred and automatically structuring the data in the background, and providing the professional situation-relevant options to choose from when possible.

In terms of improving documentation, I would emphasize support for decision-making, but perhaps different from what is currently being addressed. Therefore, registering structured data is not a shortcut to better data. If you keep everything registered structured and you are offered a list of five options, then probably none of them is correct. However, you may still be reading those five options and choosing the least wrong one. On the other hand, if you are offered a list of fifteen options that already contain more choices, you will probably never read all the options but choose the first one that is a bit out there. Increasing the registration of structured data does not improve the quality of data in principle and automatically. But decision support instead can. (Int\_3-1)

The benefits were summarized in four different categories. **Cost Control**; Effectiveness and cost savings through timeliness and pervasiveness. **Customer orientation**; Provide individual treatment for the client. **Knowledge capital**; Decision support can improve data quality, for example, by assisting a professional in recording information. **Operational support**; Decision support helps develop the organization's operations and personalize services and helps to create a holistic view of the customer's situation and ability to share tacit knowledge.

### 3.1.3 Challenges

In terms of challenges, there was significantly more variation than in the previous themes, and the findings were somewhat contradictory. For example, user resistance was relevant in social and primary healthcare services.

Much less among nurses, but to some extent, there is still a view in the medical profession that medicine is not only science but also art. (Int\_4-2)

And many times, these healthcare examples will come to mind where the robot reads the fundus images faster than humans will ever be able to do, so it may seem like the decision is being taken away. (Int\_2-3)

However, in the specialized healthcare services, the possibilities for decision support were seen as almost entirely positive. The situation can, of course, be explained by the potential misunderstanding of the role of social welfare professionals in decision support and the potential of current technology.

Certainly not exactly familiar with this concept [decision support] per se. (Int\_6-2)

Much good technology has been made in healthcare, and it should be utilized. Furthermore, of course, the fact that social welfare professionals would also be familiar with those solutions in order to be able to express those aspirations in the development of social care solutions. Professionals should dare to trust that these new technological or decision support systems will not take away individual decision-making power but speed up and support professionals. (Int\_2-4)

Although challenges were also identified on the information capital side, perhaps the major common challenge identified in the interviews was the complexity and comprehensiveness of development and the challenges of decision-making through the communication and realization of benefits.

The challenge currently facing development is that the development cycle is so slow. When the tangible benefits come only in the long run. (Int\_5-2)

Then another thing, even then, when that development work is done, it is slow. (Int\_7\_2)

The most important point about this is the lack of understanding among decision-makers. It follows that there is no funding. (Int\_3-2)

What is presented is a good perspective, but I think it lacks the most important thing. That is the shortcomings of our development management. About the way we do development work. It is perceived as part of the whole and how those things are developed to the end. (Int\_5-3)

Concerning knowledge capital, it was contradictory that, on the side of the findings, it was stated by several interviewees that knowledge capital is generally in good condition and that inference rules for clinical decision support exist and are available. The implementation of clinical decision support was characterized as low-hanging fruit.

Thanks to national information system services and architectural specifications, the interoperability of the information are in pretty

good condition. There are the same measurements, laboratory results, and descriptions regardless of the organization. The terms are also pretty similar. (Int\_4-c3)

We have procedure cards for certain procedures, which define what is needed for the procedure, which will then help the operating room prepare for that procedure. (Int\_7-c3)

For example, interactions, i.e., seeing which medications are not compatible with each other. (Int\_1-c3)

As for these rules and the like, algorithms are already starting to be worldwide for many different uses. Let us think about the simplest things related to image recognition, i.e., radiology and digital pathology, in the context of specialist care. (Int\_5-c3)

So clinical decision support is straightforward. Alternatively, it is not simple, but it is kind of invented. Meaning it is a significant thing and that its implementation is flawed. However, it requires nothing more than utilizing existing data and minor services that can infer things from the data. (Int\_3-c3)

At this point, the difference arises from the nature of the solution based on the analysis. When implementing clinical decision support systems, the knowledge capital is generally in good condition, and inference rules are available. However, the situation is not the same when implementing more general decision support systems. Implementing more general decision support is characterized by that data must be combined from many different sources. Different data must also be combined and interpreted, which is currently impossible due to shortcomings in standard data models and terminologies and data fragmentation. It follows that the information is not reliable and that it is only possible for a professional to justify the meaning of the information.

Medical research, despite all its shortcomings, is an old tradition. The amount of data is so huge that it does not seem to cause you to sigh because the content is that big deal, so it exists, and the source data is at a sufficient level to be utilized. But with the help of professionals. A medical professional must always interpret results because the data is not unambiguous. (Int\_3-c4)

... and then we come to the next point, i.e., data interoperability and comparability are big problems. Certainly, the biggest challenge is not understanding the significance of structured data registration and the co-dimensionality of information in taking the next steps in utilizing information. (Int\_5-c4)

The challenges were summarized in four different categories. **Development methods and models;** Development requires perseverance, and the entities are complex, and it is not easy to develop existing systems. Sectoral development should be eliminated, and good practices, solutions, and technologies can be introduced across industry boundaries. The ability of decision-makers and organizations to perceive the effects of development and commitment to development should be developed. **Knowledge capital;** We cannot register everything that is known. The data is not reliable, aggregation is not possible, and the significance of the data cannot be inferred because of the lack of consistent and shared data models and terminology and the fragmentation of data across various registries. **Operational support;** It is not easy to develop solutions based on operational

needs. It is not always possible to agree on operating models, at least in extensive cooperation. Solutions often remain detached from operations and increase the workload of professionals.

#### 3.1.4 Enablers, observations, and lessons learned

Although the interviews themselves aimed to identify the development needs, benefits, challenges, and lessons learned related to the development of decision support; the interviews produced enablers and observations as a by-product. These ancillary outputs are relevant in the context of the development of decision support systems, but they are of particular interest to the main research aim of the thesis. The researcher summarized the enablers and findings based directly on the interviewees' comments.

Several enablers were identified, with the support of which decision support systems can be promoted and, more generally, enable the development of health information systems. There was no attempt to identify enablers in the interviews, but they were chosen to be considered as they appeared. As a critical enabler, the assessment emerged that knowledge capital is generally in good condition and that inference rules for clinical decision support exist and are available to implement clinical decision support systems, as previously highlighted. This finding was well illustrated by the idea that existing information should be utilized in a new way in several interviews.

And then, if we have openEHR in the background or any other supporting technology, data can also be combined and imported for use in our repositories. (Int\_2-c5)

Furthermore, now, for years, I have been trying to get this kind of data analysis done. We have data on the patient's medication, and we know what the data should look at, and then we have databases to which the data should be compared. (Int\_1-c4)

The principle of phasing in benefits and involving professionals in development also emerged as enablers at the general level. Regarding enablers, the role of national services and the application of new and existing technology in other sectors were also emphasized in social welfare services. This finding is likely to be explained by the active development of social welfare information management and the introduction of a national customer data archive soon. Social care is characterized by a solid administrative and document management culture, and as a result, the industry has lagged in technological development concerning healthcare, albeit unnecessarily.

Then another, which I find inconvenient from system vendors as they market systems for health care or nursing services. Elderly services are a theme that gets money for development. Many good technologies for the elderly would work just as well for families with children. (Int\_2-c7)

In total, enablers were summarized in three different categories. **Development methods and models;** The benefits must be realized in stages, involving professionals in developing and relying on new and existing technology in other industries. **Information management;** Existing information needs to be re-utilized with the support of national information system services.

**Knowledge capital;** Knowledge capital is generally in good condition, and inference rules for clinical decision support are available.

All the key observations identified in the interviews are presented as they may be relevant, even if the finding emerged in only one interview. Common observation for service areas highlighted the growing role and progress of national information system services and the contribution of this development at the regional level to improving the utilization of information capital.

I am not a very technical person, but I could imagine that when data is stored in national information system services on a collaborative scale, it will also make it easier to utilize and process information locally. For example, in development and reporting. (Int\_6-3)

Observing the significance of the moment of data storage for the quality and further usability of the data is also essential for the research target area.

However, the main thing is that the moment of recording is a critical moment in the further utilization of the data because then it is defined what that data means. Which is also the most difficult point in its decision support. (Int\_3-c5)

Because the quality is formed when the data is registered for the first time. What is entered into the information system is output from it. Furthermore, it is also a reason why data can be used to support decision-making. (Int\_7-c4)

The ethics of decision support systems also came up in a very stopping way in one interview. The interviewee pointed out that it cannot be the case that decision support systems are developed by individual actors and are available only to some service providers. From the point of view of customer equality, it is not possible to end up in a situation where another service provider has a more advanced ability to detect, for example, rare diseases in the treatment and diagnosis history or to carry out higher-quality diagnosis or medication. Decision support must be accessible to all, and it would be justified to implement at least the criteria, rules of reasoning, and even solutions at the national level.

I think it is weird that it is not self-evident that decision support should be done on the same principle for everyone who encounters a client. Nor is it that the customer's service would somehow depend on whether the organization where he receives the service could afford to obtain that decision-making support. (Int\_3-c6)

In total, the observations were summarized in four different categories. **Changing operating environment;** The role of the professional is changing – decision support is not a threat but an opportunity. Simple decision support can even complicate work if it generates too much information and notifications. The importance of national services has been emphasized, and development has progressed. Through the development of national services, regional knowledge capital can also be developed. **Development methods and models;** The development partnership with the system provider enables the long-term development of complex entities. In developing large and complex

entities, apply an experimental culture and agile development to realize the benefits in stages. It is necessary to find a typical 80% functionality for the solutions and implement it across industry boundaries and in a nationally uniform way. The remaining part can be implemented by industry or organization. **Information management;** The moment of data storage is essential for data quality and further utilization. Conceptual modeling, shared data structures, and the creation of a common language are essential when developing in cooperation. **Principles and characteristics;** All actors should have equal access to decision support systems. In clinical decision support, the question set and the knowledge capital required for reasoning are more limited than in general decision support. Good leadership can overcome other challenges.

A few things were emphasized above all others and familiar to all service areas about the lessons learned. The importance of concretizing the benefits and phasing them out from both decision-making and commitment to development was emphasized, as was the involvement of users to ensure commitment to development and reduce resistance.

The knowledge about the development work and utilization of the data should be returned to the employees. For example, that decision support system may be in place at the management level, but this will not become known to data registrants, reducing the motivation to collect quality data. Solutions like this will be expensive. Somehow it feels like what has been developing here itself, so whenever employees are involved, then we have achieved better results. (Int\_6-4)

There are many types of clinics, but there are certainly those users who want to be involved in doing and developing. For example, decision-making could involve the possibility of involving professionals at different levels. There could be a version of this for a novice professional and then a version for a more advanced professional that would bring things up differently and allow for inclusion. (Int\_4-c4)

Integrating new solutions as a natural part of business processes and existing information systems was also a key lesson. The central spirit of the lessons learned was the phrase, "Let us do things in a nationally unified way."

The good thing is that it certainly makes sense to do joint and uniform information management in social welfare in a country the size of Finland. The development will provide comparable information and develop that knowledge base for social care development. That is certainly a great thing. Furthermore, neither will you be able to develop it further. If we now think of Kanta services, OmaKanta will come to social care and enable customers to see their information. That is great progress. (Int\_6-c5)

Lessons were recorded in three different categories. **Development methods and models;** The benefits must be able to be concretized and realized while involving users in the development. **Operational support;** Solutions must be integrated as a natural part of the existing operation. **Principles and characteristics;** Simple reasoning and decision support are already possible, and ethics is challenging to consider.

### 3.2 Qualitative survey results

As noted earlier, the responses to the qualitative survey were lightly analyzed using visualizations and calculations characteristic of quantitative research. However, the response rates were so small that no actual conclusions or significant factors could be deduced. The conclusions are the researcher's observations, which have only been structured using different research methods.

For the first three questions, which were single-answer multiple-choice questions, the means and standard deviations and the minimum, median, and maximum values were calculated to identify possible deviations. In addition, respondents were divided into two groups: customers & user organizations and system vendors, and group-specific means were calculated for the responses to identify possible differences. This breakdown was necessary because it was seen as a risk that system vendors could assess the positive impact of openEHR technology as more effective than it is. The remaining questions in the survey were open-ended, and their responses were treated as qualitative research data in the first analysis phase.

The first analyzed question of the qualitative survey was used to map respondents' thoughts on the role of openEHR in realizing the potential benefits identified in a previous study of decision support systems (Sutton et al. 2020). In particular, the question sought to outline whether the role of openEHR is significant in realizing some of the benefits to others. The answers to the question are analyzed in TABLE 4.

TABLE 4. Analysis of the answers to question 4

<b>Question 4 - Assess the role of openEHR in achieving the benefits of DSS</b>	<b>The role of the respondents organization</b>		<b>Comparative figures</b>				
<b>Answer options</b>	<b>User organizations Avg.</b>	<b>System vendors Avg.</b>	<b>Avg.</b>	<b>SD</b>	<b>Min</b>	<b>Med</b>	<b>Max</b>
1. Patient Safety	2,67	3,50	3,14	0,90	2	3	4
2. Clinical management	3,33	3,75	3,57	0,79	2	4	4
3. Cost containment	2,33	3,00	2,71	0,76	2	3	4
4. Administrative function / automation	2,33	3,50	3,00	1,00	2	3	4
5. Diagnostics Support	2,67	3,75	3,29	0,95	2	4	4
6. Diagnostics Support: Imaging, Laboratory, and Pathology	3,00	2,50	2,71	0,95	2	2	4
7. Patient decision Support	3,67	3,75	3,71	0,49	3	4	4
8. Better Documentation	3,00	3,75	3,43	0,53	3	3	4
9. Workflow improvement	3,00	3,50	3,29	0,76	2	3	4

Through the responses, a picture emerged that respondents felt that openEHR had a broadly positive impact on realizing the benefits of decision support systems. However, the impact was not seen as significant for customers and user organizations as for system vendors (see Figure 1). Finally, three of the answers to the question rose to the most significant role when evaluating the positive

impact of OpenEHR on the development of decision support systems is evaluated through means and medians of responses; clinical management, patient decision support, and better documentation. The lowest impact was assessed in diagnostic support for imaging, laboratory, and pathology.

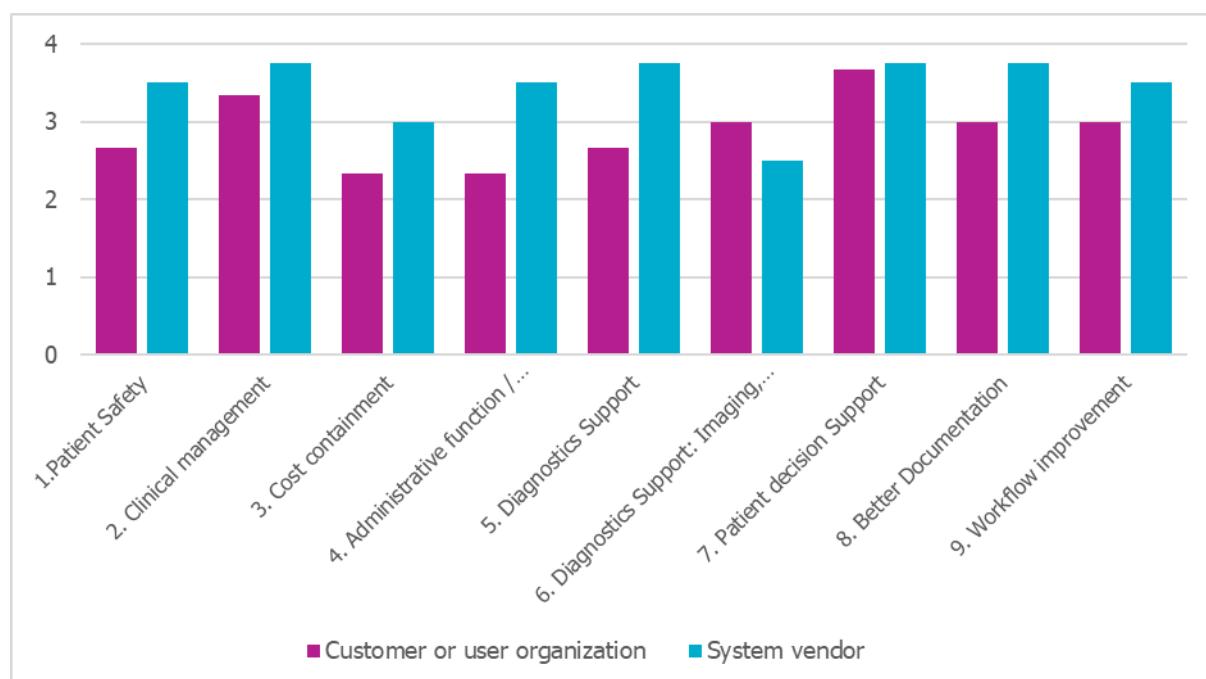


FIGURE 1, qualitative survey question 4 results per respondent group

The next question examined respondents' views on the role of openEHR in implementing decision support systems. The theme is essential because, as Castillo & Kelemen (2013) point out in their study, many aspects must be considered when implementing decision support systems. Without proper preparation and planning, implementation can fail very quickly. It is crucial to remember that the system must be integrated into existing workflows and health information systems to achieve successful implementation. The answer options used in the question were the twelve success factors of the successful decision support system structured by Castillon & Kelemen (2013). The question was undoubtedly somewhat challenging and would have yielded better results in the form of an interview. However, as shown in TABLE 5 for the five success factors, the role of openEHR was seen as relevant by respondents; User involvement, DSS specificity, DSS integration into current Workflow, Minimal DSS data entry, and Incorporation of DSS into existing systems. The averages were above the positive level in these response options, and the responses' variance based on the standard deviation was the lowest.



TABLE 5. Analysis of the answers to question 5

Question 5 - Assess the role of openEHR in the implementation of the DSS	The role of the respondent's organization		Comparative figures				
	User organizations Avg.	System vendors Avg.	Avg.	SD	Min	Med	Max
1. Incorporation of DSS into existing systems	2,67	3,50	3,14	0,69	2	3	4
2. DSS integration into current workflow	3,00	3,50	3,29	0,76	2	3	4
3. DSS specificity	3,00	3,75	3,43	0,79	2	4	4
4. User Involvement	3,67	3,75	3,71	0,49	3	4	4
5. DSS education and training	2,33	2,00	2,14	1,35	1	2	4
6. DSS Support	1,67	2,25	2,00	1,29	1	1	4
7. Automated DSS prompts	2,33	3,00	2,71	1,38	1	3	4
8. Straightforward Alerts	2,33	2,50	2,43	0,98	1	2	4
9. Simple DSS displays	3,00	2,00	2,43	1,27	1	2	4
10. Prompt Acknowledgement	2,00	2,00	2,00	1,15	1	2	4
11. Minimal DSS data entry	2,67	3,75	3,29	0,95	2	4	4
12. Evaluation and Monitoring	3,00	2,25	2,57	1,27	1	3	4

The responses of user organizations and system vendors differed, as in the previous question, with system vendors appreciating the importance of openEHR. However, the divergence between the question as a whole and the individual answers was considerable (see Figure 2).

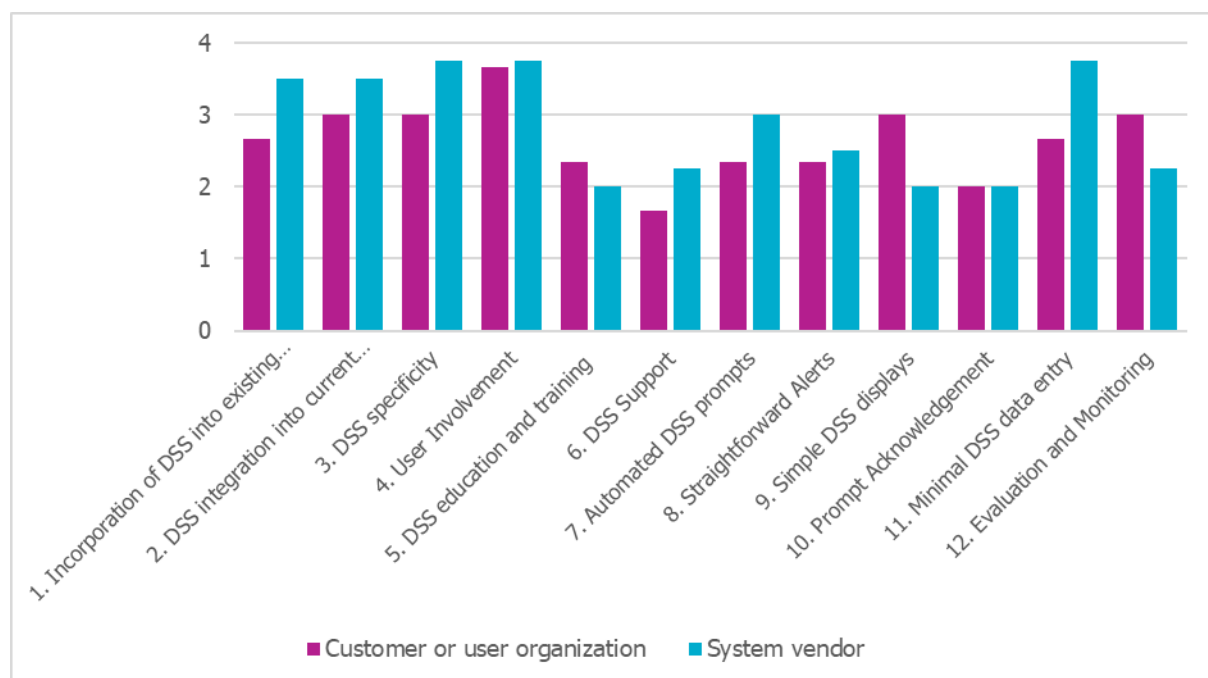


FIGURE 2, qualitative survey question 5 results per respondent group

The third and final multiple-choice question surveyed respondents' thoughts on various preconditions or requirements for developing decision support systems. The questions' answers

were compiled with the thesis supervisors through their perspectives and partly based on the ideas and preconceptions raised by the researcher. However, the answers cannot be based on specific research but are more like the researcher's open-ended questions. Based on the responses, there is a relatively unified perception that the issues at stake are relevant from the perspective of openEHR technology and positively impact almost all of them. A few observations relevant for further research could be formed based on the responses. According to TABLE 6, it is possible to observe that openEHR technology does not provide comprehensive testing tools. On the other hand, when looking at responses where the median is at the enabler level (4), an image is conveyed in which openEHR technology can play the role of enabler in the following development needs. These response options (2, 3, 4, 7, 8, 11) are considered necessary to take into account in the qualitative analysis and construction of the theoretical framework.

TABLE 6. Analysis of the answers to question 6

<b>Question 6 - Assess the role of openEHR in meeting the pre-conditions and/or requirements for developing DSS</b>	<b>The role of the respondent's organization</b>		<b>Comparative figures</b>				
	User organizations Avg.	System vendors Avg.	Avg.	SD	Min	Med	Max
1. Comprehensive testing protocols are in place	2,00	2,25	2,14	1,07	1	2	4
2. Decision Support guidelines can be defined by a professionals behalf easy to use interface	3,00	3,75	3,43	0,79	2	4	4
3. Decision Support guidelines are stored in machine-readable form	3,33	3,75	3,57	0,53	3	4	4
4. Decision Support guidelines can be widely reused through out DSS and even user community	3,00	3,75	3,43	0,79	2	4	4
5. Users can be shown on what material and reasoning rules the inference made by the DSS is based	3,00	3,25	3,14	0,90	2	3	4
6. DSS is a flexible and enables agile development	3,00	3,50	3,29	0,76	2	3	4
7. DSS is modular and supplier-independent implementation	3,00	3,75	3,43	0,79	2	4	4
8. Supports real-time and structured input and storage of Electronic Patient Records	3,67	3,50	3,57	0,53	3	4	4
9. Supports the integration of external standards, codes, and terminologies as well as open data sharing with other health information systems	3,00	3,75	3,43	0,53	3	3	4
10. The quality of data for DSS is consistent in context and does not vary in quality according to the source	2,67	3,25	3,00	1,00	2	3	4
11. The maximal amount of relevant data should be available	3,67	3,50	3,57	0,79	2	4	4
12. The data should be detailed enough	3,00	3,33	3,17	0,75	2	3	4

The answers differed similarly between user organizations and system vendors for this question, but perhaps the dispersion was slightly lower (see Figure 3).

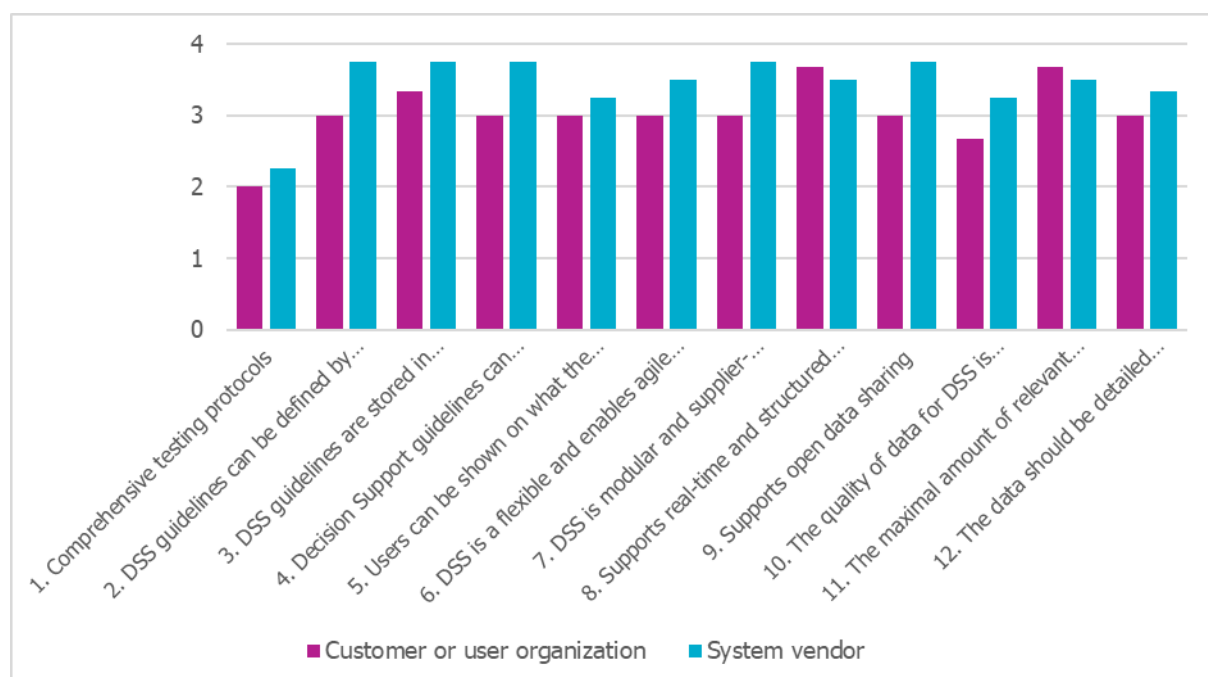


FIGURE 3, qualitative survey question 6 results per respondent group

Question seven sought to identify respondents' thoughts on which stakeholder or target group would benefit most from using openEHR technology as a basis for developing decision support systems. Respondents were asked to rank the five players according to whom they think will benefit most from the technology. The preliminarily identified potential beneficiaries in the question were health or social care organization managers, health or social care professionals, national interoperability authorities, information and communication technology professionals, and system vendors.

In addition, the first response option on the form was asked to move to the end of the list. The purpose was to identify responses in which the defendant did not answer on potential beneficiaries. Most respondents felt that the primary beneficiaries of applying openEHR technology would be healthcare and social welfare professionals and then managers (see Figure 4).

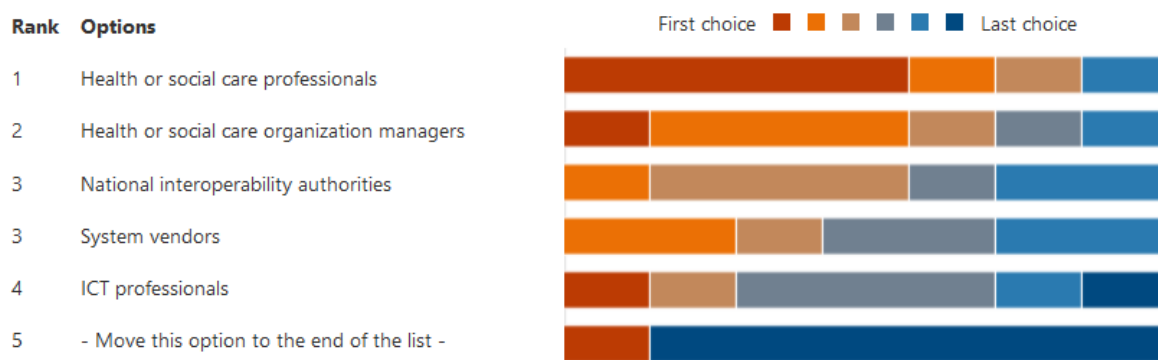


FIGURE 4, qualitative survey question 7 results

The result is supplemented by the open-ended answers to question 11 of the survey. Respondents were asked to briefly describe why or how the first-placed stakeholder or target group will benefit from openEHR technology. The responses conveyed the strengths of the technology in supporting the work of clinicians and enabling collaboration in general.

-- Clinicians, developers and vendors benefit from a good collaboration on a domain driven approach: GDL provides a flexible framework and Archetype allow for expert driven modelling. This way, clinicians can actively engage and vendors can provide scalable and extensible software.

-- Clinicians may have the benefit from better documentation practices.

-- All kinds of development must primarily be for the users.

On the other hand, the positive impact of openEHR technology on health information systems was highlighted beyond the development of decision support systems. The defendant also recalled that other interoperability standards, not just openEHR, have a similar positive effect on developing decision support systems.

-- It's important to keep in mind, openEHR is not the only informatics standard that will benefit CDS/CDSS development. In general, any major informatics standards in EHR (openEHR or HL7 FHIR) and terminology standards such as ICD-10, ATC, SNOMED CT will have positive effects on adoption of CDSS. For instance, CDS-hooks/Smart APP launch framework are widely adopted and implemented by major EHR vendors, thus will significantly reduce the integration barriers for CDSS applications in the market.

In addition, the survey included three open-ended questions that asked respondents to evaluate the key benefits and features of openEHR technology that support the development of decision support systems and describe the optimal path for developing a decision support system. According to the responses, a key benefit was retrieving standardized harmonized data made available through

openEHR technology, which improves the accessibility and usability of patient information in decision support systems. The responses also highlighted the opportunities offered by the openness and modular architecture of openEHR technology for the agile and multi-vendor development of solutions and the decision support features of the technology that support the development of solutions. As key features supporting the development of decision support systems, respondents cited the open data model and its archetypes and reference models and the Guideline Definition Language (GDL), a formal language for expressing decision support logic. One of the respondents summarized well the core features that technology brings:

-- There are specifications of how to build the semantics in the health record and decision support rules.

The complete answers to the open questions can be found in Appendix 7.

## 4 THEORETICAL FRAMEWORK

The theoretical framework defines the basic research concepts and deepens the understanding of the research area. The theoretical part focuses on outlining the particularly little-studied aspects of the research area and thus increasing the importance of research, as Kananen (2015, 32) recommends. The aim is to establish a close connection between research and existing knowledge by using comprehensive and recent sources.

The theoretical part inevitably becomes quite broad because the research area is vast. Before answering the actual research questions, the significance and definitions of several different core concepts must be outlined. The implementation of the theoretical part is also essential for research questions. The research area regarding an openEHR technology and open platform has been very little studied from the Finnish social welfare and healthcare sector's perspective, so it is necessary to define core concepts. The theoretical framework will so help to answer the research questions.

The thesis' core concepts are openEHR technology and open platform concept, clinical decision support, and Finnish health and social services information management environment, including legislative, development strategic, interoperability, and development ecosystem aspects.

Understanding OpenEHR technology and its relation to the open platform concept is a prerequisite for looking at the research aim and questions as a whole. The study of the decision support is included in the theoretical part to ensure that the operational connection according to the research approach in assessing the possibilities of the open platform and openEHR technology can be realized, and the concept itself can be understood.

Describing Finland's health and social services information management environments is key to assessing the significance of the study's findings and conclusions concerning the concrete environment. The study of interoperability standards aims to structure the environment for implementing health information systems interoperability. A review of the standards is necessary to position the openEHR technology concerning other standards and outline its role as part of the whole. Research into the development ecosystems of health information systems opens up what models currently are and can be used to implement modern information systems. Modular and monolithic architecture models will be considered based on the preliminary plan. The main focus will be on modular models, most relevant to research.

The theoretical part is implemented mainly based on literature, previous research, theses, and other Internet publications focused on core concepts. The lack of reference materials posed some problems in creating the theoretical basis for the concepts under consideration, especially in the Finnish context of health care and social care. There were also very few non-Internet sources available for openEHR technology. Efforts were made to reduce the risk by relying on research data from other industries and international research, especially in the Nordic countries. However, the unique features of Finnish social care are partially ignored in this analysis.

## 4.1 OpenEHR

OpenEHR is an e-health technology consisting of open platform specifications, clinical models and modeling, and software that works together to develop health information systems in an open and modular way (openEHR 2022a).

OpenEHR's vision is a world where healthcare routinely benefits from ICT through lifelong and interoperable Electronic Health Records (EHR), computational health data, and a reliable balance of data protection. To realize its vision, openEHR aims to promote the development and standardization of an open and vendor-neutral platform for EHRs and interoperable clinical data. (openEHR 2022b.) In other words, OpenEHR seeks to develop an open technological ecosystem in which different stakeholders can influence the development of technology and, on the other hand, benefit from the environment created by the ecosystem (HiGHmed 2018).

The technological entity formed by OpenEHR has been visualized by openEHR International (see Figure 5). The figure shows the linkage of technology to the operations and product solutions of the healthcare industry and the core competencies of the technology (clinical modeling, specifications, software, and education), and the ecosystem management model.

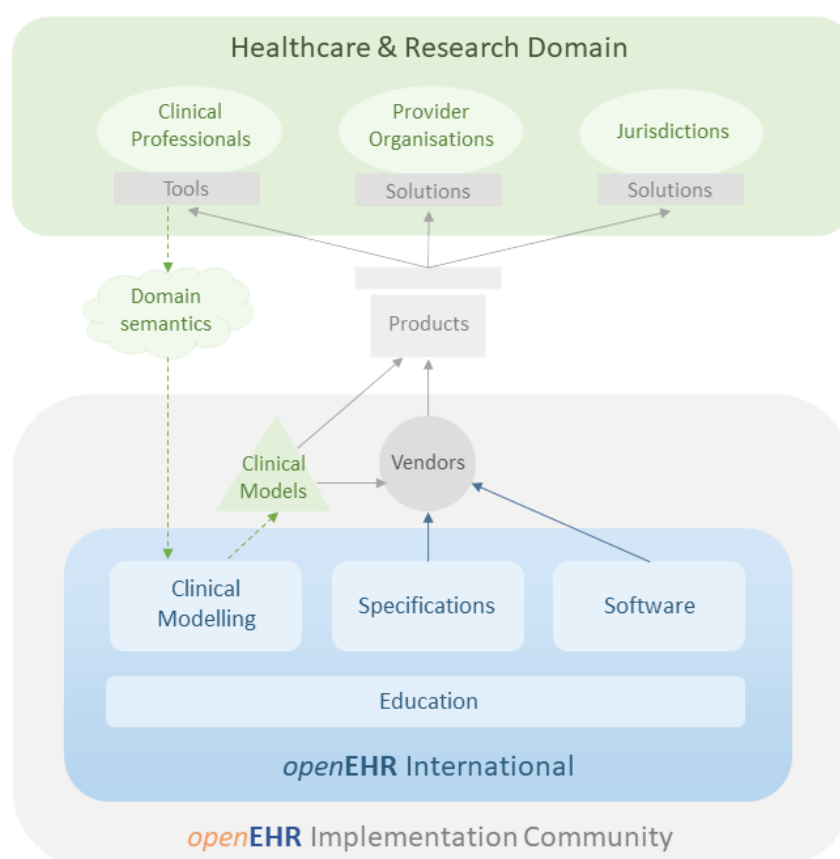


FIGURE 5, openEHR technology ecosystem (openEHR 2022d)

OpenEHR seeks to address challenges in the development ecosystems of health technologies, such as the complexity of knowledge and processes, the need for real-time utilization of information across the service system, and the ever-increasing pace of change in technology and the operating environment. The features (see Figure 6) in answering the challenges are a multi-level modeling

framework, an open platform architecture, and data management tools. The multi-level modeling framework separates the presentation of the data from the data itself. It allows experts in different fields to focus on issues that are important and topical to them in building solutions by forming a multi-professional development network. An open platform architecture can be used to manage health information and make it accessible to ecosystem actors while maintaining control and ownership of the information. Data tools concretely support the formalization of data modeling and the interoperability and usability of data. (openEHR 2022a.)

However, as Atalag et al. (2018, 13) state, openEHR solves only part of the overall problem and is intended to be integrated with other healthcare standards. OpenEHR relies on other standards, especially in implementing terminologies and coarse or very fine-grained distribution services. According to Min, Tian, Lu & Duan (2018, 2), OpenEHR is a terminology-neutral technology that supports the use of external terminologies such as SNOMED CT, ICD, and LOINC.

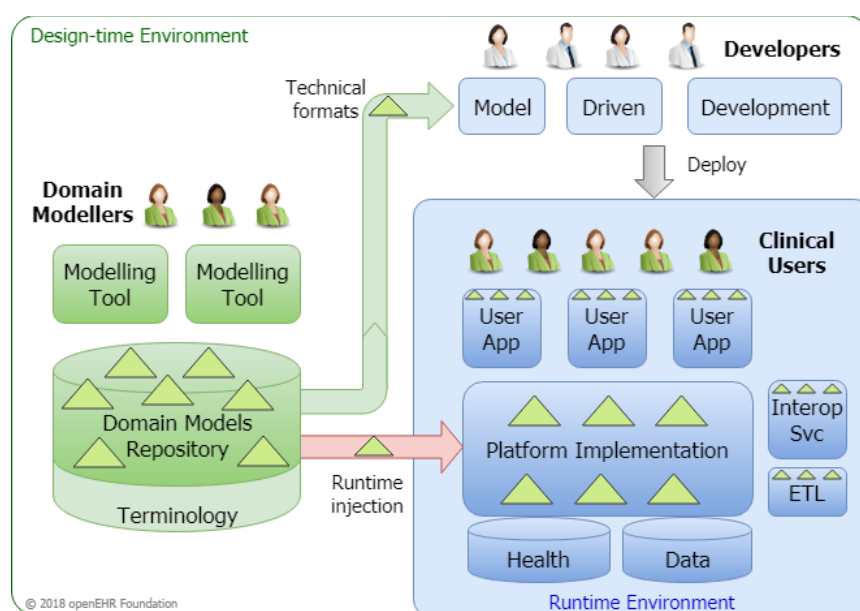


FIGURE 6, openEHR multi-level modeling framework (openEHR 2022a)

The openEHR community is ultimately responsible for developing and managing openEHR in practice through four programs; specification, clinical modeling, software, and education. The specification program defines the formal models and languages that allow the creation of the openEHR technological ecosystem, including the data model, the query language, the archetype language, and the specifications for openEHR services and Application Programming Interfaces (API). Clinical professionals and health informatics experts define archetypes as international standards for reusable clinical content in the clinical modeling program. The software program is responsible for developing open-source implementations of both tools and healthcare information system components. Lastly, bringing the technical outputs of other programs to the real world is the job of the education program. The development of technology by the community brings many benefits. It enables the genuine and transparent development of health technologies to enhance the value of clinical healthcare,



public health, and secondary information. In particular, community-based development has the advantage of healthcare organizations, system vendors, and professionals working together to solve common problems (openEHR 2022a).

There are seven national affiliates as part of the OpenEHR community; openEHR Netherlands, openEHR Germany, openEHR Sweden, openEHR Japan, openEHR China, openEHR Brasil and openEHR Spain. The role of these national actors is to promote and implement the development of openEHR at the national level, among other things, by implementing extensions to international clinical models due to national legislation or policies. A separate openEHR Finland working group was established in Finland in the spring of 2022 to promote openEHR modeling work in Finland (HL7 Finland 2022a, 2). The working group operates under the auspices of HL7 Finland and is at least not yet an official affiliate of openEHR International.

In order to manage this quite extensive development properly and efficiently, the openEHR Foundation has been supporting the openEHR community since 2010. In 2019, in addition to the foundation, OpenEHR Community Interest Company (CIC) non-profit company was established, which operates under the name "openEHR International". In connection with the company's establishment, the operational management of openEHR has been entrusted from the foundation to openEHR International (see Figure 7). (openEHR 2022c.)

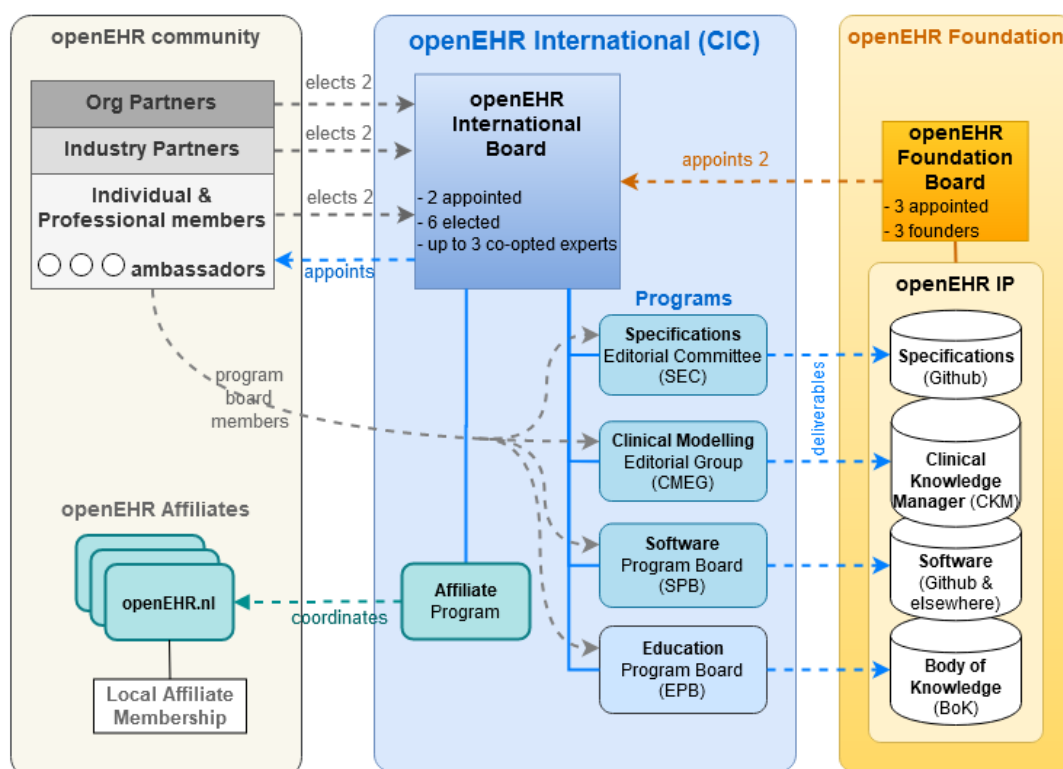


FIGURE 7, openEHR governance and organizational structure (openEHR 2022c)

Although openEHR itself meets the characteristics of a standard, as a whole, it cannot be considered a de jure standard (Allwell-Brown 2016, 13), and the openEHR community consciously does not attempt to be such (Atalag et al. 2016, 9). The decision has been made because, as Atalag et al. (2016, 9) state, the need to promote and ensure the interoperability and interaction of different

standards and enable the continuous development of openEHR by the community. However, because openEHR is applied in the healthcare sector, efforts have been made to keep it close to de jure standards. OpenEHR is committed to applying and implementing the CEN 13606 standard, adopted as a European ISO standard to guide EHR interoperability. Part 2 of the standard, ISO 13606-2: 2019 Health Informatics - Electronic health record communication - Part 2: Archetype interchange Specification, is a snapshot of the archetype specifications in openEHR (OpenEHR 2022b). In addition, the OpenEHR Foundation has worked closely with standardization organizations to ensure interoperability in openEHR and other EHR-related and clinical modeling standards (Atalag et al. 2016, 9).

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The following chapters describe the most relevant programs in openEHR technology for this thesis; Specifications and clinical modeling. Based on the preliminary conclusions of the study described in Chapter 3, the importance of software and education programs for the conclusions of the work is considered to be so minor that there is no need to focus on them.

#### 4.1.1 openEHR Specification

The specifications related to OpenEHR are developed under the specification program, and the role of the program in realizing the goals of openEHR is central. The program's objectives are to improve the quality of health data, support the use and development of commonly used technologies, promote integration with de jure standards, and manage the effects of changes in development. (openEHR 2022e.)

The OpenEHR specifications consist roughly of data models, query language, archetype formalism, decision support guidelines and task planning tools, and an open API specification. The specifications are divided into three categories; abstract specifications, implementation technology specifications, and conformance specification (see Figure 8). These categories have separate components, each containing specifications for a specific topic. In addition, to understand the relationships and dependencies of the components, the components are grouped thematically according to Figure 8. (openEHR Specification 2022a.)

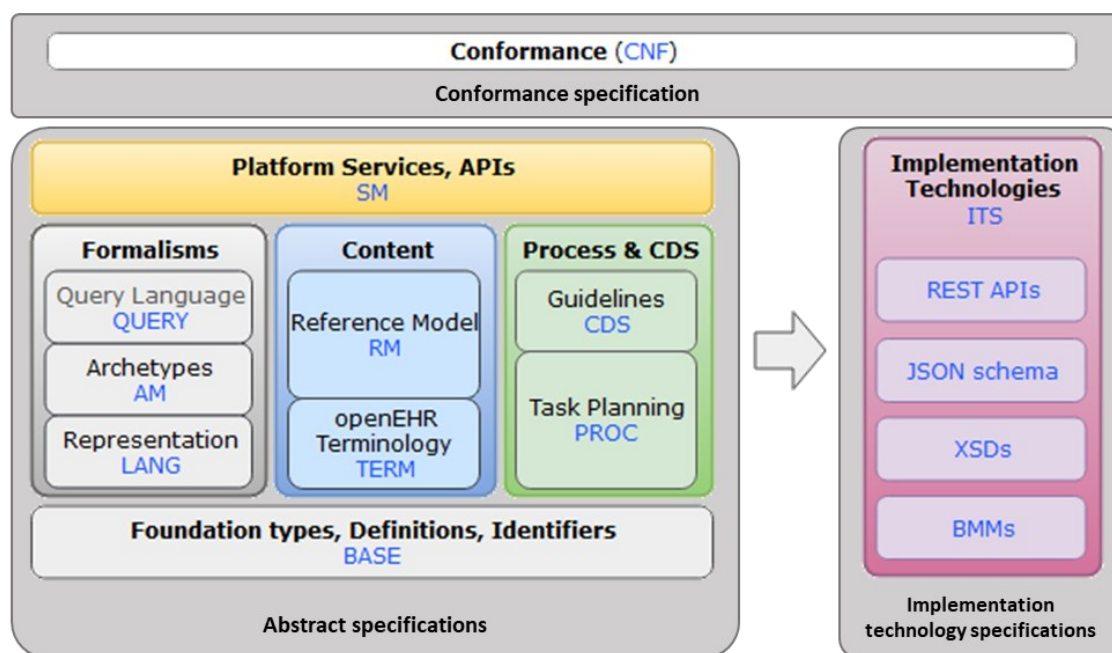


FIGURE 8, openEHR specification components (openEHR Specification 2022a)

Descriptions of the openEHR specification components can be found in a structured and comprehensive form on the openEHR Specification Program website (openEHR Specification 2022b) and are not considered necessary to explain in detail in the context of this thesis. Instead, the importance of the specifications from an architectural perspective is sought to be opened in the following paragraphs. The aim is to create an understanding of the potential of openEHR and its role in resolving research questions.

At the heart of the OpenEHR architecture is the multi-level modeling approach in a service-centric software architecture, where the models built by different domain experts operate on their separate layers (Atalag 2018, 9-10). The OpenEHR approach uses multi-level modeling that divides responsibility for software development and semantic definition of data. Because the openEHR approach is archetype-driven, the data storage and interface structure can be created using archetypes and templates. Archetypes are computable, which means they can be created and reused in an automated way. As a result, industry experts can participate in developing systems by defining archetypes and linking appropriate terminology. (Min et al. 2018, 2)

According to Arikan (2016, 53-54), a fundamental feature of OpenEHR is archetypes, expressed through the archetype definition language. The use of archetypes explicitly allows for multi-level modeling. Min et al. (2018, 1-2) specify that the OpenEHR approach has three main components supporting modeling; Reference Model (RM), Archetypes (AM), and Terminology (TERM).

The Reference Model focuses on defining a stable and formal data model to describe the logical structures of EHRs. In addition, the reference model defines the basic structures and attributes required to express EHR instances (openEHR Specification 2022c).

The Archetype component defines how archetypes and templates are generated in openEHR. According to the ISO 13606 standard, an archetype contains metadata and terms, rules, and constraints that describe how archetypes are used to create a clinically relevant data structure as Reference Model compliant building blocks. An archetype can be considered to describe all aspects of a particular clinical concept, such as blood glucose measurement or bodyweight measurement, forming a so-called maximum data set (Sundvall 2013, 27). The purpose of the templates is to enable the combination of archetypes to form data processing in larger clinical entities and, on the other hand, to enable the specialization and reuse of archetypes (Arikan 2016, 56).

The Terminology component defines how terminologies are used in openEHR. Archetypes themselves effectively define the meaning of clinical and related information and link information to external terminologies and vocabularies used in healthcare. In addition, the component describes how openEHR's internal terminology works in defining Reference Model attributes and, if necessary, in defining internal terminology for archetypes. (openEHR Specification 2022d.) Understanding the relationship between a multi-level modeling environment and its key components can be significantly supported by visualizing the whole (see Figure 9). It is easy to see how modeling in different ways serves and connects to support the realization of the technology ecosystem. Thus, the OpenEHR architecture implements ontological separation using multi-level modeling and archetypes, in which data models, domain content models, and terminology are separated. The separation of different semantic areas has been seen as allowing for precise and limited definitions and less reliance on different semantic areas (openEHR Specification 2022d).

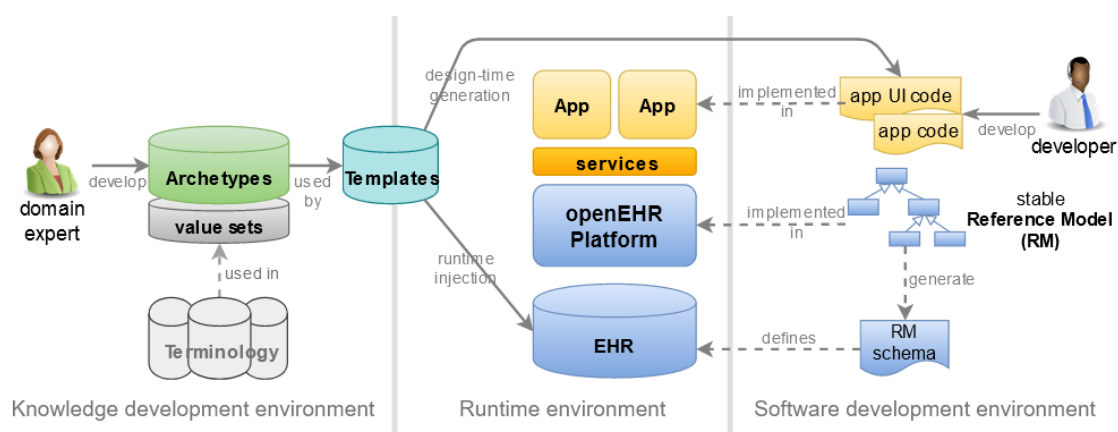


FIGURE 9, Multi-level Modelling and Software Engineering (openEHR Specification 2022a)

In addition to the multi-level modeling paradigm and archetype-based data architecture, the capabilities supporting the implementation and participatory development of solutions are of interest in the openEHR architecture. It is favorable for applying specific technology if it supports the implementation of findability, accessibility, interoperability, and reusability principles. According to Frexia et al. (2021, 117) the implementation of these so-called FAIR principles is built into openEHR. These principles are implemented using the platform services and technologies provided by the open platform architecture of the openEHR specification. According to Pazos (2015, 48), the core services provided by the platform architecture allow developers to focus on creating applications without having to start from scratch and solve the same problems repeatedly. In addition, they access standardized

data through de facto communication protocols and syntaxes, such as REST, SOAP, JSON, and XML, without the hassle of implementing these standards separately. These principles enable the creation of interoperable applications and vendor independence and ensure that the customer can manage the construction of the ecosystem (Atalag et al. 2016, 13).

A critical aspect of the capabilities that support participatory development is the tools included in openEHR. The most relevant tools for this study are Archetype Query Language (AQL) and Guideline Definition Language (GDL). AQL is a semantic, vendor-, and product-independent query language that enables information retrieval from an archetype-based data repository (Gök 2008, 13; openEHR Specification 2022e). Through the AQL language, openEHR provides a solid technical foundation for utilizing the necessary information in healthcare organizations and by system vendors (Highmed 2018, 9). Queries can be expressed using centrally managed models and performing high-performance searches by a professional in a human-readable format (Allwell-Brown 2016, 53).

GDL, on the other hand, enables the use of information on the openEHR platform to support decision-making natively. The purpose of the GDL is to express clinical logic and inference as machine-readable rules. Separate GDL rules can be combined into building blocks to support individual decision-making and more complex, concatenated decision-making processes (openEHR Specification 2022f). The open sharing of decision support logic and modules has long been an objective, albeit challenging to solve. The GDL finally makes it possible to express clinical logic that is truly agnostic to clinical industries, natural languages, and reference terminologies (Atalag et al. 2016, 13; Anani et al. 2017, 4). The unique feature of GDL is that it is fully technology-independent, so it can be implemented with different rule engines (openEHR Specification 2022f) and can also be used in technology environments other than using the openEHR and archetype approaches. GDL also brings advantages in, for example, FHIR Resource-based environments, i.e., the use of GDL is not limited to certain types of data sources (Laleci et al. 2018, 752).

#### 4.1.2 openEHR Clinical models

The OpenEHR community has a separate Clinical Modeling Program that develops archetypes, templates, and terminology to support clinical work. The program aims to harmonize the clinical data models used in virtually every health information system. Although physicians, nurses, and other healthcare professionals share many clinical concepts and can communicate these concepts effectively, health information systems have not had a standardized and comprehensive presentation of clinical information. The models developed in the program are intended for use in an international environment, and the outputs are freely available. (openEHR 2022)

Thus, the program defines Clinical Knowledge Resources (CKR) in practice, which describes clinical concepts in a formal model. Defining CKRs is very time-consuming and cumbersome, as noted by Garde (2013, 271). In addition, it is appropriate that each resource is defined only once. The characteristic of the resources is that in many cases, they are universal, for example, blood pressure. Furthermore, it is appropriate that CKRs be managed centrally, and openEHR has responded to this challenge by introducing the Clinical Knowledge Manager (CKM) (openEHR Clinical Knowledge Manager 2022).

OpenEHR CKM and its content are openly available, and anyone can also participate in the development of CKRs through the service. OpenEHR CKM is estimated to be the world's most complete CKR repository (Moner 2021, 62). In March 2022, the service had 2,767 registered users from 104 different countries, and 1156 archetypes were modeled in the service (see Figures 10 and 11). Most archetypes are still in the draft state ( $n = 440$ , 38%), while only 143 archetypes (12%) are in the published state (see Figure 11). However, the importance and contribution of CKM to it can be considered particularly significant, as Moner Cano (2021, 64) states.

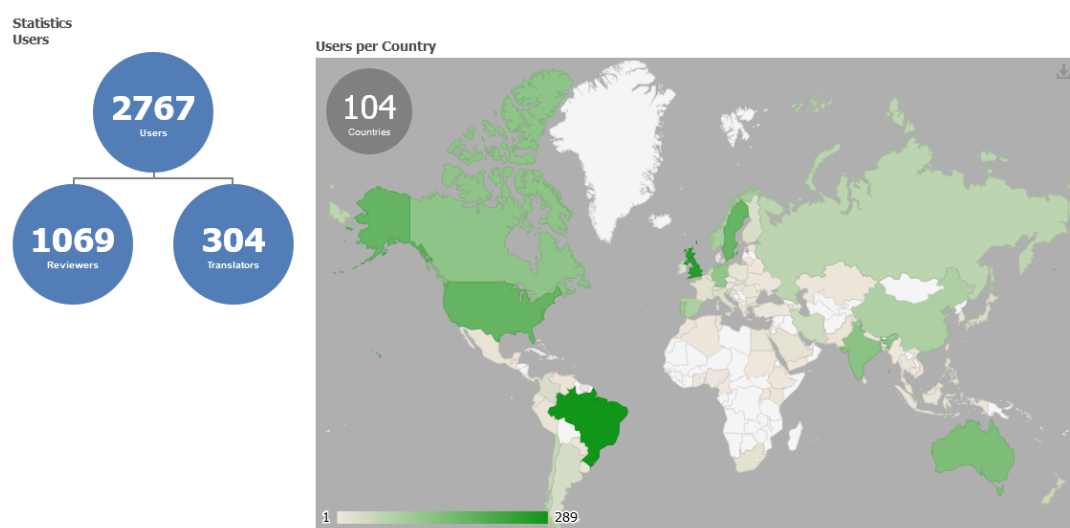


FIGURE 10, openEHR Clinical Knowledge Manager users March 2022 (openEHR CKM 2022)

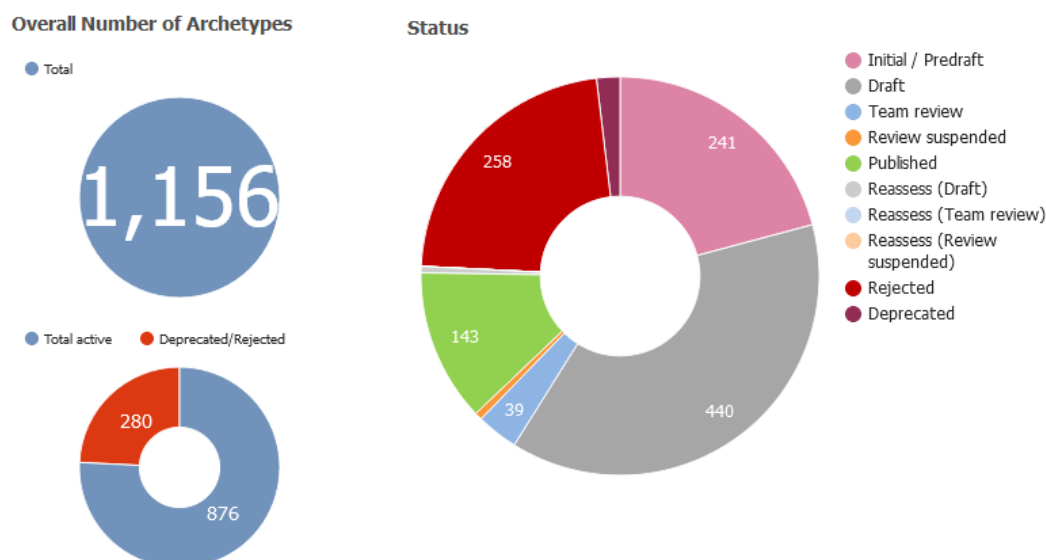


FIGURE 11, openEHR Clinical Knowledge Manager users March 2022 (openEHR CKM 2022)

In the OpenEHR CKM, each modeling object is described in the manner and accuracy defined by the openEHR Specifications. For example, for archetypes, the data, status, events, and protocols associated with the clinical concept always describe the archetype and additional description and attribution information. In addition, each data element is described with more detailed properties, including links to the external terminologies used, for example, for systolic data (see Figure 12).

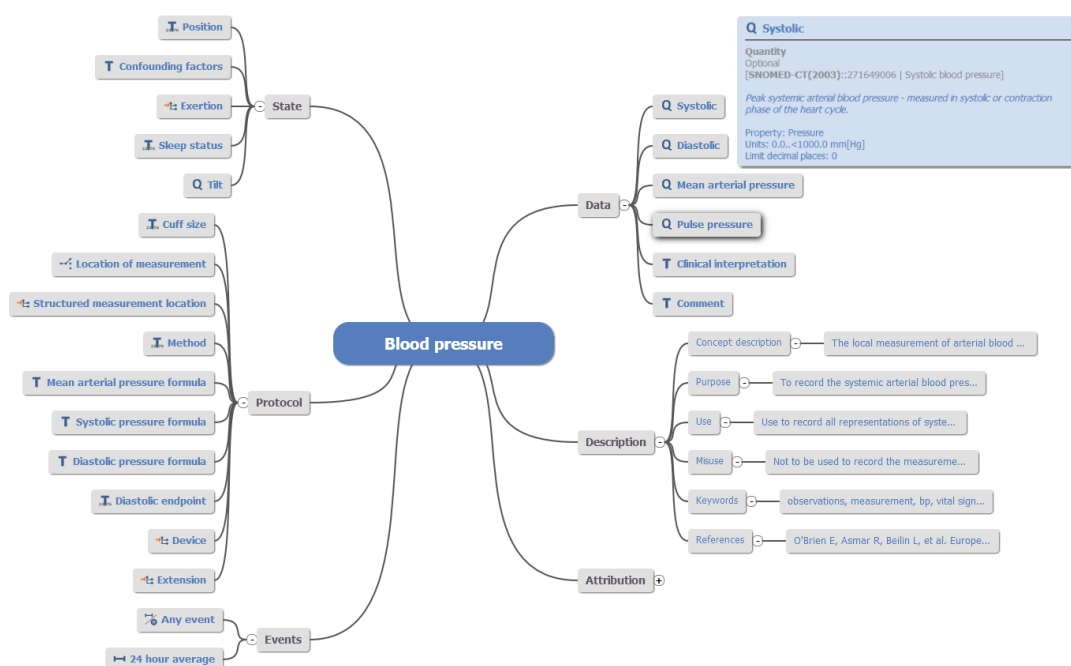


FIGURE 12, mind map of blood pressure archetype (openEHR Clinical Knowledge Manager 2022)

OpenEHR participates in the separation of clinical modeling and other development with the help of CKM from its principle of ontological separation. This multi-level modeling method has been found to allow the reusability and applicability of the model by industry professionals. Finding has been concretely stated in Oliveira et al. (2021, 1115), in which the openEHR modeling approach was utilized as a part of the COVID-19 activities in Portugal.

#### 4.1.3 openEHR maturity assessment

Understanding openEHR's maturity is critical when considering the technology's suitability for use in the environment, such as the Finnish health information management environment. Although new technologies have proven to be an effective way to increase existing capabilities, there is also a risk involved, as Rodriguez, Nicolás, Rio-Belver & Rodriguez-Andara (2019, 104) realize in their study. As new technological components intertwine with others in an integrated whole, the probability of failure increases geometrically. The current life cycle of the technology determines how much the technology is still evolving or changing. Thus, to reduce risks, the maturity of the technology for its use must be carefully assessed (Rodriguez et al. 2019, 104). In the field covered by this study, the applicable technologies' requirements are critical due to the health and social services regulations.

The maturity of openEHR technology can be assessed through the stage of completion and development of specifications and the projects and implementations that apply them, and through the activity of archetype modeling and software products that apply the technology. The maturity of the specifications is easy to assess through the description of component release information. The core parts of the specifications, the Reference Model, the Archetype Model, and the Base Model, were first published in December 2008. Since then, other component specifications have been published stepwise and further developed, as described in Table 7. Development has been relatively active with the three-level release numbering used by openEHR. Only one of the published components is

still in its first release version. The others have published at least the minor changes described by the third numbering position. Few components have also received major new releases described by the first numbering position. In addition to published components, a few components are still under development without any released versions. (openEHR Specification 2022g.)

TABLE 7. openEHR Releases (openEHR Specification 2022g)

Category	Group	Component	Release
Conformance		CNF: Conformance Specifications	Development
Implementation Technology Specifications		ITS-REST: REST API specifications	1.0.2 (Apr 2021)
		ITS-JSON: JSON Schemas	Development
		ITS-XML: XML Schemas	2.0.0 (Apr 2021)
		ITS-BMM: BMM Schemas	Development
Abstract Specifications		SM: Service Model	Development
	Process & CDS	PROC: Process Model	1.6.0 (Jun 2021)
		CDS: Clinical Decision Support	Development
	Content	RM: Reference Model	1.1.0 (Sep 2020)
		TERM: openEHR Terminology	2.1.0 (Nov 2017)
	Formalisms	QUERY: Query Languages	1.1.0 (May 2021)
		AM: Archetype Model	2.2.0 (Jun 2019)
		LANG: Generic Languages	1.0.0 (May 2020)
	Foundation	BASE: Base Model	1.2.0 (Apr 2021)

For CDS, one of the key components of this study, the description in Table 7 is somewhat misleading. The component is developed in two different entities in the form of GDL and GDL2 specifications, and of these, the GDL specification is in a stable state in the main version 2.0.0. A version of the GDL2 specification, defined for Trial status, has also been released in May 2019. According to the openEHR governance model, the specification in Trial status is very close to Stable status, and the specification is already formally managed. (openEHR Specification 2022b.) The specification was originally developed by Cambio Healthcare Systems and was approved by the openEHR Foundation as part of the openEHR technology in 2015 (De Bruin, Chen, Rappelsberger & Adlassnig 2020, 188). The maturity of the specification is also underlined by a total of 656 published clinical decision support applications in dozens of different medical fields built using the GDL specification (openEHR International 2022).

OpenEHR-based solutions have been implemented and put into production since 2010. Currently, there are more than 70 openEHR solutions in use in 14 different countries, according to the description of the openEHR community (openEHR 2022h). Furthermore, the listing certainly does not cover all actual deployments. For example, China is completely missing from the list. However, extensive modeling of archetypes has been done in China, and many solutions have been deployed based on openEHR technology. Unfortunately, only little public information is available on these. However, based on openEHR research and other information received from China, the importance of openEHR



can be estimated to be at least reasonable (Min, Wang, Lu & Duan 2015; Min et al. 2018; GitHub 2020).

Most recently, preparations for the deployment of openEHR technology have been promoted in the Catalonia region in Spain and the London area in the UK. Catalonia is promoting a new data-driven digital healthcare strategy in the region. Its crucial element is the longitudinal EHR that enables the management of lifelong health information (Jiménez, Rodríguez & Pérez 2020, 158-160). This modern EHR is the backbone of Catalonia's new information system model, the development of which has begun during the so-called second phase of the digital transformation of Catalonia's health sector. Open standards provide a new basis for development, and transparency has also opened up new opportunities for Catalonia's technology sector.

For this reason, it has been decided to base the new EHR in Catalonia on the openEHR specification (Generalitat de Catalunya 2021). The development of a new openEHR-based EHR has now started. The first steps have been to launch a preliminary market consultation for an openEHR-compliant clinical data management platform (Generalitat de Catalunya 2022a) and a market study for an electronic prescription and medicines management solution (Generalitat de Catalunya 2022b). On the other hand, in London's case, it was recently announced that a £ 3.1 million contract to implement a Shared Care Planning solution had been made to support One London's digital development. With this development, the London area will have an open, openEHR-based data platform that will enable healthcare professionals to participate in the design of care pathways and is a step toward an interoperable electronic Integrated Care Record (ECHAlliance 2022).

As noted in the previous chapter, the community involved in archetype modeling work can be considered very active and extensive. The community has also grown steadily over the years, with around 200 new modelers registered yearly since 2009. At the beginning of 2022, there were 2708 registered users in the service. (OpenEHR Clinical Knowledge Manager 2022.)

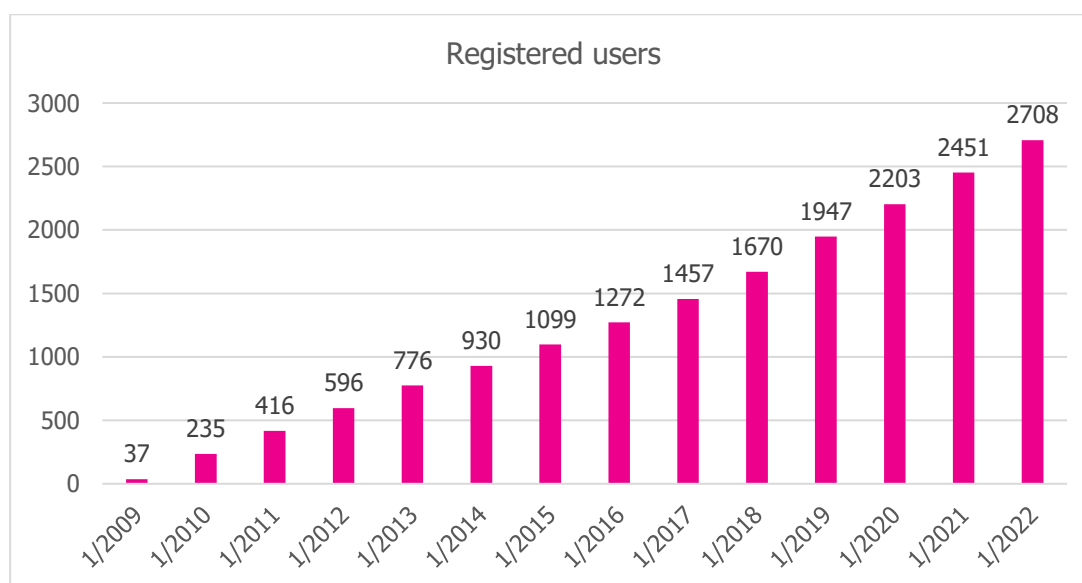


FIGURE 13, CKM registered users (openEHR Clinical Knowledge Manager 2022)

However, it should be noted that these figures provide only an indication of the community involved in modeling archetypes for the openEHR International CKM. In addition, internationally significant modeling work on archetypes is being carried out in several national modeling projects, exemplified by Leslie (2021) of Nasjonal IKT CKM in Norway, HiGHmed CKM in Germany, Apperta CKM in the UK, and Slovenian CKM. In addition to these, the archetype modeling work in China, which takes place in its own Healthcare Modeling Collaboration CKM environment, is noteworthy.

Products based on OpenEHR technology can already be found on the market and openly developed by the community to a significant extent. In particular, openEHR platform solutions and various products utilizing openEHR technology are widely available. Twenty industry partners in the openEHR community also reflect markets' interest in the technology (openEHR 2022g). The Products & Tools section of the [Openehr.org](https://openehr.org) website contains a very comprehensive list of tools, platforms, and applications that support the openEHR approach. In addition, a corresponding comprehensive listing of the market supply is maintained on the website implemented by Rosaldo Oy (Rosaldo 2022). These two sources make it possible to form a comprehensive picture of the market's maturity.

## 4.2 Clinical Decision Support

Health and social services are characterized by a wide range of different, complex decision-making problems that need to be addressed by professionals on an ongoing basis as part of care and care planning. Although medical professionals can mainly cope with the complexity of these knowledge-intensive tasks, decision-making is increasingly challenged by high time pressure, many parallel tasks, and interruptions. The professionals' expertise and the implicit information are bound to the individual and are not available to all professionals. These factors can lead to qualitatively weaker and more varied decisions than desired. The quality of decision-making depends mainly on the availability of a broad knowledge base that includes domain, explicit, factual, and tacit information. (Wulff et al. 2018, 10-11; Ozcan & Linhart 2017, 85.)

In order to understand the decision-making environment, it is essential to take into account the characteristics that distinguish health and social services from other industries in general. These characteristics are structured through five groups by Fitzsimmons & Fitzsimmons (2011, 18-21); customer participation, simultaneity, perishability, intangibility, and heterogeneity. The organization and the customer or patient interact throughout the service provision, which is a profound difference from many other industries regarding customer participation. Simultaneity manifests itself in services as the simultaneous production and consumption of services, challenging quality, and efficiency management. The service cannot be inspected and repaired in advance, and a process that has ended up in poor care can only be revised in future processes. Organizations plan their services to serve at a specific capacity for a particular time, exposing service capacity to perishability. If the planned capacity is not used during that period, the investment in capacity will be lost, and the output and planned treatment will have to be carried out later with the new capacity. With a few exceptions, the service output is intangible, making it difficult to assess the quality of the output. Patients' opinions about the quality of their care are formed over time, and one patient's experience

may not be the same as that of another receiving the same service. On the other hand, heterogeneity manifests itself in the fact that while some routine tasks can be automated, many tasks require high judgment and specialization, personal interaction, and individual adjustments. (Fitzsimmons & Fitzsimmons 2011, 18-21.)

Alongside these distinguishing factors, the data intensity of the decision-making environment needs to be understood. Health and social services generate a great deal of information that flows through the service system and is managed through various information systems. Much of this information is processed as EHRs, managed by a health information system. In addition to this clinical information, a large amount of other information generated in the service system, such as administrative and financial information and other information from external data sources, is also needed in decision-making. (Ozcan & Linhart 2017, 7-8)

Activities to support health decision-makers with identified challenges and characteristics have been called Clinical Decision Support (CDS). Therefore, the term refers to an activity or service that describes clinical information structured and supports professionals in healthcare decision-making. (Hak, Guimarães, Abelha & Santos 2020, 486.) However, the term used and its contribution to clinical work can be challenging. There is a significant need for decision support for non-clinical tasks and non-clinical users such as administrative staff and patients. These non-clinical decision support needs have also been seen to increase significantly in the future. Research studies have shown that the availability of decision support can enable patients to participate more actively in the treatment process, leading to better medical outcomes and improving the quality of healthcare decisions and outcomes (Berner, Eta & Andersen 2016, 9 & 163-165).

#### 4.2.1 Decision support systems

When planning care and making decisions, healthcare and social welfare professionals need to consider many issues in a potentially stressful situation through inadequate baseline data (Castillo & Kelemen 2013, 1-3). Over the years, computer-aided decision support systems, known as Clinical Decision Support Systems (CDSS), have been developed to meet this challenge. The CDSS is intended to improve service delivery by improving medical decisions with targeted clinical data, patient and client data, and other health data (Sutton et al. 2020, 1). Thus, through the pooling of data, the CDSS aims to improve the safety and quality of patient care, improve patient care and outcomes, reduce memory dependence, reduce error rates, and shorten response times (Castillo & Kelemen 2013, 1-3).

These systems often operate in conjunction with health information systems used to manage EHRs. The CDSS extracts patient status information from an EHR, combines it with medical information, and makes treatment proposals after screening a vast amount of digital data. In addition, such a system can provide its user with various reminders, warnings about drug interactions, and links to appropriate treatment instructions. (Varonen, Kaila, Kunnamo, Komulainen & Mäntyranta 2006, 1175-1176)

Studies on computer-aided decision support in medicine began in the early 1970s. They inspired several experimental systems that faced challenges in implementing integrations between systems and interpreting knowledge capital. Ethical and legal issues also came to the fore in the early years. (Sutton et al. 2020, 1) Over the years, it was observed that the essential part of the system was its medical knowledge base, and this was used as a basis in many subsequent decision support systems. Over the years, the ability to implement CDSS has developed dramatically with the technological development of health information systems, interoperability standards, and the improved availability of knowledge capital and data warehouse development. Furthermore, the pace of CDSS development and utilization is certainly not slowing down as the healthcare industry embarrasses other industries to take advantage of digitalization in the coming years. (Middleton et al. 2016, 105-106.)

Understanding how CDSS works can be supported by describing where they are used and how they are typically classified. The classification of a CDSS can be based on the operating logic of the system, the support delivery model, the communication method, or the underlying decision-making process or model (Wasylewicz & Scheepers-Hoeks 2018, 154-155). The different nature and application of CDSSs are well illustrated by the two examples described by Alther & Reddy (2015, 635-638) in their study, supporting order entry and diagnosis. In the first example, the decision support system helps fill in the order information, validate the information, take patient-specific features, and optimize care in order entry. In this way, order entry can improve clinical productivity and positively impact patient care. In the second example, support of diagnosis, the aim is to replicate the diagnostic process using information technology. Thus, based on the inputs provided and the available supplementary information, an attempt is made to identify a hypothetical diagnosis or a set of possible diagnoses. Based on this summary, the patient or professional can then initiate the necessary actions depending on the subject of the service. CDSS is utilized in both applications but has an entirely different role. (Alther & Reddy 2015, 635-638.)

Today, the most common classification model for CDSS systems is to divide them into knowledge-based and non-knowledge-based systems (Berner et al. 2016, 3; Castillo & Kelemen 2013; Sutton et al. 2020, 1). Knowledge-based CDSSs date back to the 1970s and have included diagnostic systems and systems designed to help the clinician make his or her own decisions. Most knowledge-based CDSSs have three parts; knowledge base, inference machine, and mechanism to communicate with the user (Alther & Reddy 2015, 630). The knowledge base typically consists of rules that can be developed using literature-based, practice-based, or patient-guided evidence (Sutton et al. 2020, 1). The inference machine compares these rules to the input it receives, for example, patient data, and the output of the inference is returned to the user via the user interface (Berner et al. 2016, 3-4). Non-knowledge-based CDSS systems differ from knowledge-based ones. They do not define ex-ante rules for making reasoning but use artificial analysis, machine learning, or statistical pattern recognition to implement reasoning (Sutton et al. 2020, 1). According to Alther & Reddy (2015, 634), there are two popular implementation principles for non-knowledge-based CDSS reasoning; artificial neural networks and genetic algorithms.

In addition, it is good to understand what benefits CDSS has been found to enable concretely. Previous studies have identified a wide range of potential to improve patient care. CDSS can help reduce

medical errors and side effects, ensure holistic care, encourage adherence, and shorten the patient time within the service. Through these benefits, the quality of patient care is improved, and organizational costs can also be reduced. (Castillo & Kelemen 2013.) The following table describes the benefits of CDSS in more detail.

TABLE 8. CDSS benefits (extracted from Sutton et al. 2020, 3-5)

<b>Benefit</b>	<b>Description</b>
Patient Safety	Reducing the incidence of medication/prescribing errors and adverse events.
Clinical management	Adherence to clinical guidelines, follow-up and treatment reminders, etc.
Cost containment	Reducing test and order duplication, suggesting cheaper medication or treatment options, automating tedious steps to reduce provider workload, etc.
Administrative function/automation	Diagnostic code selection, automated documentation, and note auto-fill.
Diagnostics support	Providing diagnostic suggestions based on patient data, automating output from test results.
Diagnostics Support: Imaging, Laboratory, and Pathology	Augmenting the extraction, visualization, and interpretation of medical images and laboratory test results.
Patient decision support	Decision support is administered directly to patients through personal health records (PHR) and other systems.
Better Documentation	Description of experts' tacit knowledge, practices, and inference rules to the knowledge base serves as documentation
Workflow improvement	CDSS can improve and expedite an existing clinical workflow in an EHR with better data retrieval and presentation.

Despite its relatively long history and undeniable potential, the exploitation and development of CDSSs have not been without problems. One might think that it is only now that a situation is being reached in which the realization of the valuable potential of CDSSs is achievable. Systems can be integrated into the work of professionals as a result of technological advances achieved, as envisioned by Middleton et al. (2016, 110-111).

The challenges of CDSS have been significantly studied over the years. These challenges must be considered in future developments so that the same problems do not have to be identified and addressed more than once. Alther & Reddy (2015, 639-651) have made a very comprehensive compilation of the challenges, focusing on Sittig et al. (2008) outlined the ten grand challenges of decision support and the critical and inadequate challenges of decision support described by Engle (1992). The challenges identified in these and a few other studies are summarized in TABLE 9 below. More detailed analysis and descriptions of the challenges and references to the sources can be found in Appendix 8.

TABLE 9. CDSS challenges (extracted from Appendix 8)

Challenge category	Challenge
<b>Utilization of CDSS</b>	Human-computer interface
	CDSS usability
	The CDSS system supports solving wrong issues
	User distrust of CDSS
	Excessive reliance on CDSS
<b>CDSS development</b>	CDSS development and deployment take time and is expensive
	CDSS development and deployment are complex
	Creating new CDSS interventions and algorithms is difficult
	CDSS maintenance
	Competition between clinicians
	Lack of expertise
<b>Architecture and technical Design</b>	Reliability of computers
	There is no common architecture to develop and share CDS modules and services
	Specialized CDSSs
	Lack of structured medical knowledge
	Formal diversity of knowledge
	Technology focus
	Integration with health information systems and clinical workflow
<b>Reasoning and complexity</b>	Inability to explain recommendations and learn from experience
	As knowledge capital expands, reasoning becomes more difficult
	It is not easy to understand the effects of time
	Summarizing patient-level data
	Filtering and prioritizing recommendations
	Consideration of co-morbidities
	Utilizing free text in clinical decision support
<b>Regulation</b>	Fragmentation of regulation
	Liability issues
<b>Ethics</b>	Acceptability of the use of CDSS
	CDSS misuse
	The role of CDSS in the care relationship
	Best practices are not openly shared
	Inference rules for clinical decision support are not available to everyone

Based on the study, complexity is highlighted as perhaps the critical challenge in CDSS utilization and implementation. Solutions have no understanding of human physiology, cannot recognize temporal concepts, and cannot learn and infer new facts. As a result of this complexity, solutions have been implemented in limited operational areas, making it challenging to utilize CDSS on a large scale in health and social services. Of course, the challenges of understanding the relevance of knowledge capital and ethics also seem to be very relevant based on the information gathered. Based on the compilation, it is easy to agree with Alther & Reddy's (2015, 653) conclusion on the key challenges of CDSS. While a computer-based decision system may indeed be helpful in clinical decision-making,

it is not a substitute for human interaction in an environment of complex symptoms and social factors. CDSSs are also prone to error, and the availability of systems is not at a level that would best support a vulnerable professional-patient decision-making relationship.

#### 4.2.2 Decision support systems in Finland

Solutions for clinical decision support have long been developed and utilized in Finland. An integrated healthcare system, extensive collections of care recommendations, and EHRs create good preconditions for developing decision support systems in Finland. The Finnish Medical Association Duodecim has been responsible for developing the decision support system and has prepared a wide range of treatment recommendations, care recommendations, and the Medical Databases service for healthcare professionals (Miettinen 2006, 17).

As early as 1989, Duodecim began considering a clinical decision support system that would provide appropriate guidance to the healthcare professional based on information about the patient's condition. The definition of a concrete solution started in 2002 with the technical definition of decision support, when the definition of a national electronic medical record was completed. The first results of the technical definition of decision support were published in 2004. The development of the actual CDSS took place from 2006 to 2008. It was part of the project where Duodecim's partners were the Medical Care Development Center ROHTO, the Technology Development Center, hospital districts, and information systems vendors. The CDSS created as a result of the development work was renamed EBMEDS, and since the beginning of 2009, it has been part of Kustannus Oy Duodecim's operations. (Kenkimäki 2019, 4-5.)

EBMEDS is not a national information system service such as KANTA services despite national development cooperation. Therefore, introducing the service and participation in its development requires each healthcare organization's decision to use the service. From a technological point of view, EBMEDS is already integrated into virtually all patient information systems in use in Finland (Kustannus Oy Duodecim 2022a). Actual statistics of the use of the service are not publicly available, but it is estimated that up to half of the Finnish medical profession already uses it (APOTTI 2022; Korkiatupa 2018). In Finland, however, the importance of the service has remained relatively small, as shown by the interviews conducted in the data collection. Internationally, however, EBMEDS has received significant attention, and the most recent indication of this is the victory in the Estonian state digital services competition 2021 (Kustannus Oy Duodecim 2022b). There is no precise information on using other CDSS systems in Finland, but the international UpToDate service is known to be used based on interviews.

In addition to clinical decision support systems, Finland has also developed extensive services that support diagnosis and self-diagnosis, also called CDSS. Omaolo is a nationally implemented service that brings together electronic symptom assessments, health check-ups, and service assessments for citizens to help them make their own decisions (Omaolo 2022). Another national service is Terveyskylä, a public online service provided by university hospital districts that make health care services accessible to everyone, regardless of where they live, thus increasing citizens' equality (Terveyskylä 2022). The services complement traditional hospital care and also include decision support

supports related features. The third service worth noting is Terveysportti, implemented by Kustannus Oy Duodecim, which gathers the medical information needed for practical work in one place and provides thus the information and services needed for decision-making (Duodecim 2022).

Research related to clinical decision support systems is new in Finland, and scientific research is scarce, as Miettinen (2006, 1) states in her thesis. Perception is confirmed by the literature review carried out by Ampio (2020, 15), in which only one source in Finnish was accepted for review. However, the situation may change when, for example, the Nursing Research Foundation (Hotus) has launched an "Electronic decision support for nursing" project in 2020, which aims to review and develop the use of electronic decision support in nursing (Hotus 2022).

### 4.3 Finnish health and social services information management environment

This chapter describes the Finnish health and social services information management environment and its key aspects; legislation, strategic development objectives, interoperability environment, and information system development ecosystems. Understanding these aspects is essential to put the study's results in context and seek answers to the research questions. Otherwise, the study results may be relevant, but they are not valid in Finland due to national characteristics or exceptions.

#### 4.3.1 Legislative environment

The legal framework governing the information management environment in Finnish health and social services is comprehensive and consists of legislation governing electronic information management and substance legislation. The processing of health and social services customer data, data protection, document processing, national information system services, and information management guidance are regulated at the legislative level. Legislation is currently enacted through 15 separate laws, briefly described to support the perception of the overall picture in Appendix 9. (Pentikäinen et al. 2019, 18-19.)

In 2021, the Ministry of Social Affairs and Health launched work to modernize information management legislation. The aim is to create a unified law on health and social services information management. With the reform, the legal framework for information management would form a clear, coherent, and comprehensive package that meets the requirements of the Constitution and the European General Data Protection Regulation (GDPR) and supports the development and integration of health and social services and information systems. (STM 2021.) The need for legislative reform is obvious and contributes positively to legislative guidance in the health and social services information management environment. The interpretation is also supported by the arguments entered in the Government's proposal to Parliament on the law on the processing of social and health care customer data and certain related laws (VN/2037/2021).

The need to reform and harmonize health and social services information management legislation has long been recognized. Legislation is currently fragmented into several different laws and has been promoted at different times. Some of the regulations are suitable for all health and social services, while some are only suitable for the electronic processing of customer data. Therefore, the legal basis is inconsistent and does not fully comply with the requirements of, for example, the



GDBR for the processing of personal data. Thus, the practical application of fragmented legislation in health and social services has proved challenging and complex, and the Constitutional Law Committee has also drawn attention to this (PeVL 4/2021 vp. Hallituksen esitys eduskunnalle laiksi sosiaali- ja terveydenhuollon asiakastietojen sähköisestä käsittelystä sekä eräiksi siihen liittyviksi laeiksi, 13§). Uniform and up-to-date legislation is a prerequisite for effective data management and data utilization, for example, in secondary use, which the legislative reform aims to enable (VN/2037/2021, 11).

The legislation also sets the framework for managing health and social services information management. A relatively wide range of actors is involved in steering and managing. The Ministry of Social Affairs and Health (STM) is responsible for general planning, guidance, and supervision of information management and financing of major national projects. The Finnish Institute for Health and Welfare (THL) is responsible for planning, directing, and monitoring the electronic processing of customer data and related data management and the use and implementation of national information system services and common data resources. The ongoing legislative reform proposes (VN/2037/2021, 32) clarifications and additions to THL's control and management tasks concerning the coordination of data structures used in data repositories and national information system services. Findata, an independent permit authority operating in conjunction with the THL, grants permits for secondary use of data and monitors compliance with the conditions attached to its permits. The National Supervisory Authority for Welfare and Health (Valvira) maintains registers of social and health care information systems, welfare applications, and their professional rights and monitors the compliance of customer and patient information systems. Finnish Medicines Agency (Fimea) monitors the pharmaceutical industry and its safety. Social Insurance Institution of Finland (Kela) is responsible for implementing Kanta services and the data security of the data stored. The ongoing legislative reform (VN/2037/2021, 33) introduces new responsibilities to the Kela related to information security and strengthens its role as a critical player in providing archiving services. DigiFinland Oy is a state-owned company entrusted with an assignment to develop and support the productivity and effectiveness of social and health care, rescue, and other industries through digitalization (STM 2022.)

National information system services are defined at the legislative level. All public and private health and social services providers are obliged to utilize, thus creating a nationwide technological basis for health and social services information management. Nationwide information system services refer to the services under Kela's responsibility, so-called Kanta services, specified in the Customer Information Act. Kanta services focus on solving customer data storage and processing needs; archiving customer data and log registers, processing of prescriptions and medication database, management and interface to citizen's data, data management service for secondary use of data, management of expressions of intent, and transmission of information between authorities. In addition, the law regulates the certification task under the responsibility of the Digital and Population Information Agency and THL's task in connection with the national coding service. (Customer Information Act 2021/784, 6-7§)

Concerning automated or electronic decision support, no harmonized legislation is available in Finland to support the development and utilization of CDSS. Different general and substantive legislation are currently applied in implementing and utilizing solutions (Kenkimäki 2019). The primary laws to be considered are the Administrative Act 2003/434, the Data Management Act 2019/906, the Customer Data Act 2021/784, and in particular, the General European Data Protection Regulation and the legislation governing its national application (Office of the Data Protection Ombudsman 2022). However, the situation is evolving as the Ministry of Justice has launched preparations to develop legislation on automatic decision-making in public administration. The legislation is currently in its second statement, and the law is due to enter into force in early 2023 (Ministry of Justice 2020).

In addition to the legislation described above, the ongoing health and social services reform significantly impacts the social and health information management environment. The reform is one of the most significant administrative reforms in Finnish history. From the beginning of 2023, the responsibility for organizing healthcare, social welfare, and rescue services will be transferred from municipalities and associations of municipalities to 21 wellbeing services counties and the city of Helsinki. (Sote-uudistus 2022.)

The reform has also been described as the most significant information system reform in Finnish history (Kajaste 2021). One of the key objectives of the reform is to harmonize services and make digital services accessible to citizens. Currently, the use of customer and patient information systems is fragmented nationwide. For this reason, health information systems are under intense pressure to change, with outdated technology and poor usability. As part of the reform, the harmonization and modernization of health information systems at the regional level are essential. (Sote-uudistus 2020.)

#### 4.3.2 Development strategic environment

Over the years, Finland has invested heavily in promoting eHealth, information management, and digitalization in line with the European Commission's actions and strategies. The European Commission's regulatory and health policies and actions for the development of eHealth have focused on supporting the modernization of health infrastructure and improving the efficiency of health systems. The EU has prioritized the development of eHealth quite aggressively in recent years, with € 2.2 billion funded in 2014-2018 for projects related to the reform of health systems and the deployment of eHealth and digital solutions. (Directorate-General for Health and Food Safety 2019.)

Increasing the use of digital technologies by creating the Digital Single Market (DSM) is one of the European Commission's top priorities. DSM aims to open up digital opportunities for people and businesses and bring the European Union's internal market into the digital age. Health is one of the areas on this agenda, given the potential benefits that digital services can bring to citizens and businesses in this area. The emergence of the digital market has been promoted by adopting directives on the free flow of non-personal data, cybersecurity, open data, and data protection. (European Commission 2022a.)

In Finland, in the previous strategy period, the Ministry of Social Affairs and Health guided development through eHealth and eSocial Strategy 2020 (STM 2015). The strategy describes the stages of the service system development vision, from organization-centered development to the service ecosystem development, and describes the measures needed to implement the change. The strategy also identified six key objectives for prioritizing development; Citizens as service users - Doing it yourself, Professionals - smart systems for capable users, Service system - effective utilization of limited resources, Refinement of information and knowledge management - knowledge-based management, Steering and co-operation in information management - from soloists to Harmony, and Infostructure - ensuring a solid foundation (STM 2015.)

The strategy promoted the formation of clear cooperation structures at the national and regional levels to guide health and social services information management. Measures in line with the strategy were promoted in the form of strategic programs following government programs, flagship projects, and the establishment of ICT development companies, and at the regional level by intensifying specific catchment areas cooperation as, for example, AKUSTI and UNA cooperation. In line with the strategy, the measures aim to achieve a situation where health and social services produce nationally consistent data, and health information systems are regionally integrated and nationally interoperable. It has also been seen as essential that new electronic services and regional health information systems be developed and procured to take advantage of the national service architecture and respect the principle of modularity. (Seppälä & Puranen 2019, 13-22 & 55.)

In 2021, a new strategy period was launched at both EU and Finnish levels, and the goals for the period can be seen as a direct continuation of the previous strategy period. No significant changes have been made in the direction of the development goals. However, the emphasis has been clarified in some respects, as Seppälä & Puranen (2019, 48) recommend in their mid-term strategy review.

In the strategy period 2021-2027, the EU will continue to invest in the development of healthcare. The aim is for health information systems to be further developed to support health promotion and disease prevention in the transition from hospital and institutional care to a community or home care and health and social care integration. These changes require various infrastructure investments, for which EU funding is targeted. For the Member States, this requires the design of long-term investment strategies to consider the needs of infrastructure, innovative technologies, and new therapies in developing health information systems. (Directorate-General for Health and Food Safety 2019.)

The implementation of the DSM will be continued by the European Data Strategy, which is developing a European data-driven society. Through the strategy, the EU aims to create an internal market for data, with information flowing freely between countries and sectors of government. Such a market would benefit businesses, researchers, public administrations, and EU citizens. (European Commission 2022b.)

The Digital Strategy for Europe promotes the digitalization of services and business and supports the green transition to a European climate-neutral one by 2050, bringing to the fore a topic of great

interest to the thesis (European Commission 2022c). Artificial intelligence has been identified as a priority for digitalization development in the European context. Data and artificial intelligence can be used to solve many societal problems, including health care, which requires building trust and reliability (European Commission 2022d). In support of these objectives, a regulation on artificial intelligence is being prepared to enable the development and deployment of artificial intelligence in the EU, ensuring that artificial intelligence works for the benefit of humans (Regulation 2021/0106 (COD), 17-18).

In addition to the above strategies and legislative preparation, the development of the European Health Data Space (EHDS) should be considered, especially in the health sector, which clarifies strategic objectives and promotes the development of legislation for data sharing and exploitation across Europe as part of the internal market. The measures will promote a robust data management system and data exchange rules, data quality, and strong infrastructure and interoperability. (European Commission 2022e.)

At the Finnish level, the development is guided in the current strategy period through the goals of Prime Minister Sanna Marin's government programme 2019; Inclusive and competent Finland (Finnish Government 2019). The government programme has several goals for the digitalization and information management of health and social services, which will be promoted through the general development of the public sector as part of the reform of health, social, and rescue services and separate projects such as the Toivo-program. Appendix 10 summarizes the core measures recorded in the government program, grouped according to objectives and strategic themes. Above all, the goals emphasize promoting and developing cooperation at the EU level, between countries, and at the national level. The goals also emphasize the development of interoperability by promoting the principles of data-centricity, customer-centricity, and openness.

In addition to the Government Program and its policies, the General Strategy for Public Administration (Ministry of Finance 2020) and the Strategy of the Ministry of Social Affairs and Health, and the Growth Strategy for Health Research and Innovation 2020-2023 (Finnish Government 2021) will promote its policies for the current 2030 strategy period. These strategies focus on the general and industry-specific development of digitalization and information management and the implementation of national and international development work in legislative preparation and guidance. A particularly prominent theme in the strategies is technology and knowledge intensity or, more specifically, improving the utilization of technology and knowledge capital, through which a large part of the strategic goals can be supported (Ministry of Finance 2020, 6-13; Finnish Government 2021, 13-15; Ministry of Social Affairs and Health 2022).

The importance of technology and information intensity has been emphasized that the Finnish Government approved a decision-in-principle on technology policy in March 2022. Technology policy aims to improve the development and utilization of technologies and the operating environment and knowledge base for companies and civil society. The goal of the technology policy is to make Finland the most successful and well-known country in the world in 2030 that produces well-being from the research, development, and utilization of technology. (Ministry of Finance 2022.) The way to

define technology policy has been paved in a report on information policy and artificial intelligence carried out during the last government term, which examines the necessary conditions, value base, ethical principles, and economic impact from the perspective of information management and utilization (Finnish Government 2018).

Concerning the development of knowledge capital, the role of the previously mentioned Toivo-program should also be taken into account. The program promotes measures to renew and develop the national and wellbeing services county-level knowledge base for health and social services. Visualization (see Figure 14) of how this knowledge base is constructed and how actors are involved in expanding the knowledge base helps to understand the information flow.

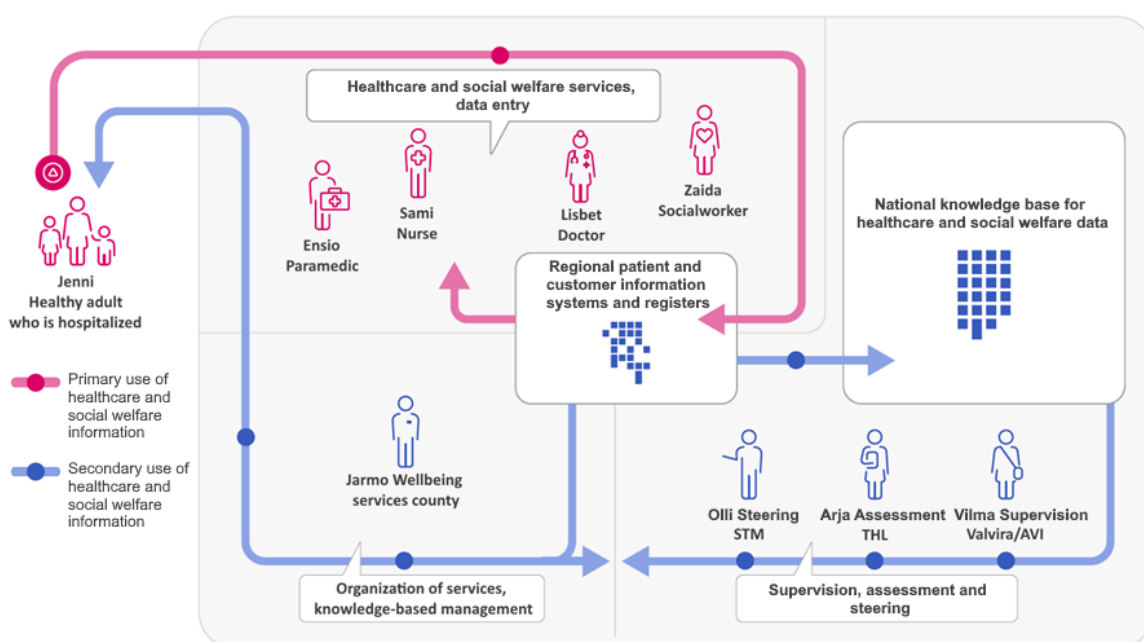


FIGURE 14, Construction of national knowledge base (Toivo-ohjelma 2022, 1)

#### 4.3.3 Health information systems interoperability

Interoperability is a key concept in enabling the use of information generated by health information systems and in implementing information management more generally. Interoperability refers to the ability of information systems, devices, and applications to exchange, integrate and exploit information in a coordinated manner (HIMMS 2022). The management and standardization of the interoperability of the information management environment of Finnish health information systems are based on the European Interoperability Framework (EIF), which is a set of guidelines for the development of public services. The EIF defines interoperability as:

The ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems. (European Commission 2022f.)

The levels of interoperability defined by EIF are legal, organizational, semantic, and technical (see Figure 15). Each level should be given special attention when implementing interoperable services.

In addition, EIF refines the cross-cutting theme of integrated management of public services and the background layer of interoperability governance. (European Commission 2022g.)

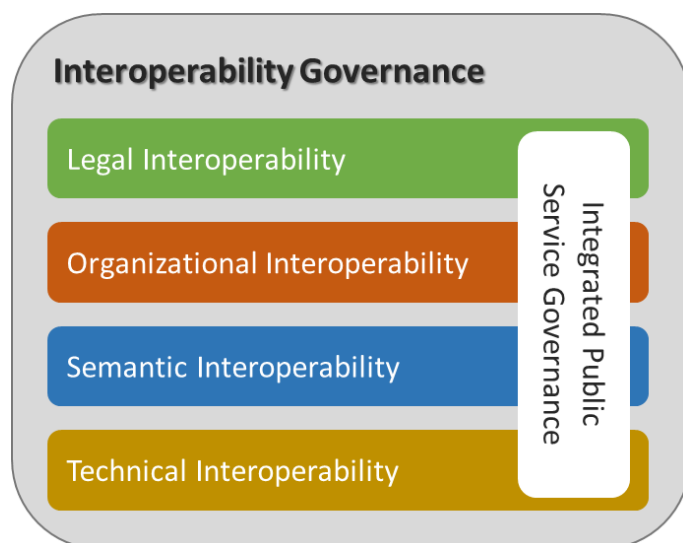


FIGURE 15, The revised EIF Conceptual Model (ISA² 2022a)

The background level for interoperability governance refers to decisions on interoperability frameworks, institutional arrangements, organizational structures, roles and responsibilities, policies, agreements, and other aspects of ensuring and monitoring interoperability at the national and EU level. The cross-cutting theme of integrated management of public services aims at defining governance, a collaborative model, and requirements for the provision of public services in an integrated and coherent way, serving the needs of end-users. Legal interoperability ensures that organizations operating under different legal frameworks, policies, and strategies can work together. Organizational interoperability means documenting and integrating or harmonizing business processes and exchanging information. Semantic interoperability ensures that the meaning and exact form of the information exchanged are preserved and understood during the exchange of information between the parties. Technical interoperability includes interface specifications, interconnection services, data integration services, presentation and exchange, and secure communication protocols. (European Commission 2022g.) The content of the interoperability levels is generally described in the EIF infographics (ISA² 2022b).

This chapter focuses on standards related to the implementation of semantic interoperability. As Benson (2010, 25) points out, semantic interoperability is at the core of what we usually mean by healthcare interoperability. Examining the methods for promoting and implementing legal, organizational, and technical interoperability has such a marginal effect on research issues that there is no need to study them in more depth. At the level of semantic interoperability, the implementation of the information management environment is guided, which is the main focus of this study.

In Finland, the national level's target state and the starting point is that customer and patient data processing occurs in regionally audited health information systems. Data transfer between service providers is primarily executed through the national information system services, i.e., Kanta ser-

vices. (Sote-uudistus 2020, 9) Kanta services can be considered the core of Finland's health and social services semantic interoperability, the development and mandatory use of which guide the implementation of interoperability at the national level (KANTA 2022).

The primary standards and specifications used in Finland related to health and social services semantic interoperability are described in TABLE 11 below. The application and development of standards are promoted in Finland mainly by HL7 Finland. HL7 Finland is an association founded in 1995, aiming to promote the preconditions for implementing integrations and the use of healthcare information system standards. HL7 Finland is a member of the international organization HL7 International. (HL7 Finland 2022b.)

TABLE 10. Social and health interoperability standards in Finland (KANTA 2022)

Standard	Type	Description
<b>DICOM</b>	Content and transport standard	Regional imaging solutions.
<b>HL7 CDA R2</b>	Content standard	Metadata and data contents of the Patient Data and Social Care Customer Data Archives and the Prescription Center.
<b>HL7 FHIR</b>	Transport standard	Content profiles and interfaces of the personal data repository and interfaces of some regional systems.
<b>HL7 V2</b>	Transport standard	Image archive demographic updates, regional imaging, and laboratory messages.
<b>HL7 V3 Medical Records</b>	Transport standard	Interfaces between the Patient Data and Social Care Customer Data Archives and the Prescription Center.
<b>IHE ITI-I</b>	Operating Models, Content Specifications, Communication Specifications, Guidelines for Applying Standards	Technical specifications related to the archiving of image materials and regional imaging solutions.
<b>ISO IDMP (ISO 11238, ISO 11239, ISO 11240, ISO 11616, ISO 11615)</b>	Pharmaceutical standards	ISO IDMP standards apply to pharmacovigilance activities and the classification, retrieval, presentation, risk-benefit assessment, electronic exchange, and reporting of information on medicinal products.
<b>ISO 27001 ISO 8000-8</b>	Quality standards	Ensuring the quality of service production and data quality.

Alongside the utilization of standards, Finland has a very long tradition in vocabulary and terminology work supporting health and social services information management. In addition, work has been carried out to define data structures in social welfare, and this work is expanding to the healthcare sector (Virkkunen 2022). The work has been somewhat sector-specific and punctual. However, in recent years significant efforts have been made to develop the governance model and operating methods, as described in Kalliokuusi & Eerola (2021). The relationship between the primary and secondary use of information and vocabulary, terminology and data structure work has also been addressed and guided by the Data Production Model Handbook, produced as part of the National Valtava Project. The handbook aims to harmonize practices and open up the different work stages of information production and the issues to be considered (Luoma et al. 2021).

Standards play an essential role in implementing semantic interoperability. Standards provide a common language and principles that enable interoperability between systems or devices. In order to seamlessly utilize customer or patient-related information and improve the overall coordination and implementation of services, the standards allow different parties to share information consistently, regardless of application or provider (HIMMS 2022).

Some interoperability standards are referred to as base standards because of their well-established use. Drawing conclusions from the standardization environment has become very challenging in practice as the development of standards has expanded, and a single standard can be applied to many different use cases. As a result, overlapping of standards has also increased, making it challenging to choose which standards to use. (MedTech Europe & COCIR 2021, 10.) Classification is thought to facilitate the identification of applicable standards for different use cases. Interoperability standards are typically classified according to their nature or purpose, such as messaging, terminology, document, and conceptual standards (HIQA 2013, 14-15). Other ways of classifying standards are also used, such as the classification used by HIMMS (2022) vocabulary/terminology, content, transport, privacy and security, and identifier standards.

It is essential to outline that utilizing a single standard does not yet enable interoperability, especially when implementing semantic interoperability of a comprehensive set of health information systems. However, standards describing the structure and meaning of information are essential for semantic interoperability. These standards ensure that information is usable and retains its relevance when used, stored, and transferred. The following subsections focus on a general description of such standards under vocabulary/terminology, content, and transport categories.

#### 4.3.3.1 Vocabulary/Terminology Standards

The category includes different vocabulary, code set, and terminology standards (hereafter classification systems) designed to define the meaning of information. As Cano (2021, 48) states, they are a crucial part of data documentation because they provide a coded and controlled way to unambiguously describe different concepts of medicine and, more importantly, the meaning of data.

Classification systems thus give a unique code or value, for example, to a specific disease, based on which, when transferring or further utilizing information, one can be sure of a uniform interpretation of the information. Some classification systems are hierarchical or even ontological, making it possible to perceive the relationships between concepts. (HIQA 2013, 14.) Different classification systems have been standardized for many different target areas in the healthcare industry. Therefore, it is inherent in the use of classification systems that several of them are usually used to allow interoperability simultaneously. For this reason, cross-mappings have been implemented between classification systems that link different classification systems (HIQA 2013, 29).

The following are examples of commonly used classification systems. **SNOMED CT** provides a comprehensive healthcare terminology that includes more than 311,000 actively evolving concepts, with unique meanings and formal logic-based definitions organized into hierarchies (Virtue & Rainey 2015, 15). **LOINC** is a reference terminology used to record health measurements, observations,



and documents. It uses concepts classified using six major attributes (component/analyte, property, time, system, scale, method) and four minor attributes (challenge, adjustments, time modifier, super-system) (Nikiema, Griffier, Jouhet & Mougin 2021, 2). **ICD-10** contains approximately 14,400 codes for injuries, illnesses, conditions, and causes of death. The implementation of the next version of the classification (ICD-11) is about to begin in 2022 and will contain about 55,000 codes. (Pihlava 2018). **ICPC-2** describes the causes and health problems in primary health care that led to visits (Kvist & Savolainen 2010, 12-13). **RxNorm** provides a concept-based model for describing clinical drugs and links concepts to pharmacy management systems and drug vocabularies (Bona, Brochhausen & Hogan 2019, 3).

#### 4.3.3.2 Content Standards

Content standards focus on defining information structures to implement information exchange (HIMMS 2022) or, more broadly, to maintain longitudinal EHRs relevant to electronic systems. In practice, standards often define the structure of the content of an EHR, message, or document. They can also define common data models that can be used to describe and store health data independently of the information system. The use of content standards to build health information systems solves interoperability issues related to information exchange and sharing. (Gamal, Barakat & Rezk 2021, 1).

Content standards thus enable the collection and sharing of patient data in a standardized format and enable the addition of clinical knowledge to the data (Blobel, Hvannberg & Gunnarsdóttir, Valgeður 2010, 96). Standards do this by supporting adaptability and defining common data models loosely linked to complementary concepts and data structures in the health sector. Standards also support the complete presentation of contextual information. Contextual information describes how the clinical data was recorded or other aspects that affect clinical information interpretation. (Cano 2022, 42.)

According to Cano (2021, 21), semantic interoperability can be based on a reference model, a clinical information model, and common clinical terminology. This method of structuring data based on a reference model and a clinical information model is often referred to as two-level modeling. The reference model describes a collection of shared data structures, and the clinical information model gives the data a logical and semantic meaning (Gamal et al. 2021, 1-2). The contribution of clinical terminology as a whole is to define the vocabulary used to describe the data (Cano 2021, 41). The figure below (see Figure 16) illustrates this two-level modeling approach and the role of the supporting clinical terminologies. The figure also summarizes the most commonly used reference models and the clinical information model used by each.

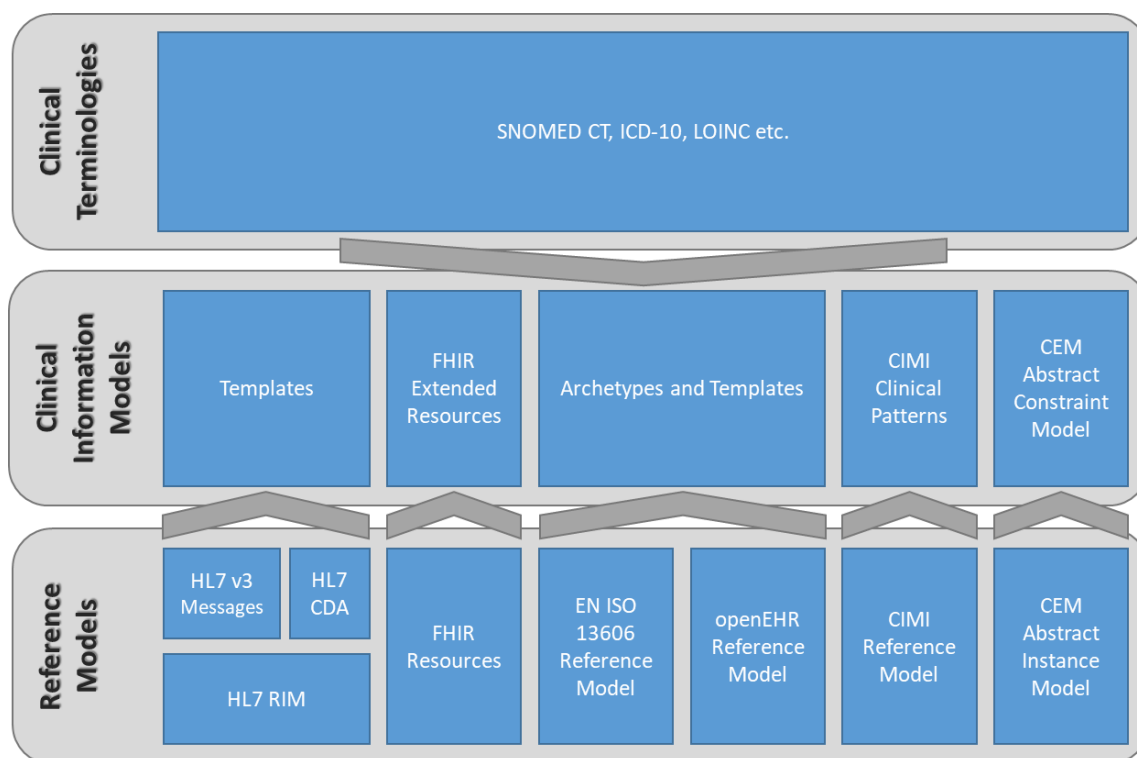


FIGURE 16, Summary of Reference Models, their Clinical Information Model representations, and Clinical Terminologies (according to Cano 2021, 46-49)

The following are examples of commonly used Content Standards. **HL7 CDA** is a document markup standard that defines the structure and semantics of clinical documents based on the HL7 reference model, following characteristics of persistence, stewardship, the potential for authentication, context, wholeness, and human readability (Dolin et al. 2010, 553). **HL7 version 3** provides a model-based methodology for building a set of clinical messages, data types, and terminologies based on the HL7 reference model (HL7 2022a). **HL7 RIM** is a data model that covers all aspects of healthcare information and defines a series of classes and subclasses, attributes, data types, and value domains related to medical functions, thus providing a basis for data interoperability (Yang et al. 2022, 2). **FHIR Resources** are definitions of common and reusable clinical data models based on an HL7 reference information model that can be combined or extended to describe data in health information systems (Saripalle, Runyan & Russell 2019, 3-4). **EN ISO 13606** (Electronic health record communication - Part 1: Reference model) describes an approach that enables the interoperable exchange of health information using a reference model and archetypes to form a two-level data architecture (Blobel et al. 2010, 96). **OpenEHR** see Chapter 4.1. **OMOP** has been developed to support the secondary use of health data in research by providing a common data model, terminology, and an ETL process for data processing (Li & Tsui 2020, 4).

#### 4.3.3.3 Exchange Standards

Exchange standards support the exchange of information between information systems by specifying the format of the messages to be exchanged, the document architecture, the clinical models, the user interface, and the linking of patient data. As a method of exchanging health information, the standards mainly use "push" and "pull" communication methods to meet different communication

needs (HIMMS 2022). In the push method, the sender initiates the data transfer, and the receiver stores the data for use in the information system. An example of a push method is delivering laboratory results to a doctor automatically when the results are complete. In the pull method, the user searching for data must actively use the system and query the relevant data. For example, if a doctor retrieves patient information from the patient record archive. (Campion et al. 2012, 77.)

Exchange standards contain some features of technical and content standards. However, the object of applying the standards, i.e., support for the exchange of health information, can be considered a distinguishing factor. The exchange standards also include various implementation specifications and profiles to describe how data transfer between information systems is implemented in specific use cases or certain health domains (ONC 2022, 194-196; HIMMS 2022). The most extensive example of profiles is the so-called IHE profiles developed by the Integrating Healthcare Enterprise (IHE) community. Thus, the community does not define standards but defines standards-based profiles for integrating health information systems and organizes activities supporting them (HIQA 2013, 17). The development of IHE profiles has started in imaging and radiology, but profiles have now been developed to support the exchange of information in the operation of many other domains (MedTech Europe & COCIR 2021, 6).

The following are examples of commonly used Exchange Standards. **DICOM** is used to exchange image data between the archiving and communication system and other systems (Payne 2015, 35-36). **Direct** defines a simple, secure, scalable, and standards-based direct mechanism for sending authenticated, encrypted health information to known trusted recipients over the Internet (The Direct Standard 2019). **HL7 version 2** (and v3) is the de-facto standard for electronic data interchange in the clinical field and probably the most widely used standard in healthcare worldwide, enabling the exchange of clinical information between information systems (HL7 2022b). **FHIR** utilizes the HL7 RIM, lightweight web services, and modern development principles to enable modular resource-based health information exchange (Saripalle et al. 2019, 3). **IHE Profiles** provide a common language and a clear deployment path to implement integrations, reducing the complexity, cost, and anxiety of implementing interoperable systems (IHE 2022).

#### 4.3.4 Health Information Systems Development Ecosystems

The Finnish health and social services information management environment is influenced by the visions of the market and the authorities regarding the development of health information systems and the formation of ecosystems, guided by legislation, development principles, and standardization. To this day, public healthcare and social welfare organizations have, in practice, relied on vendor-driven information systems based on the monolithic architecture in implementing health information systems, as Lepistö & Ukkola (2020, 10) describe in their study.

A monolithic architecture combines different components of an information system, such as user interface, business logic, and user management, into a single program from a single platform. Such an information system is a very tightly integrated entity for all its functions, and each function is highly platform-dependent (Gos & Zabierowski 2020, 1). The implementation of monolithic information systems has been justified and understandably promoted by the level of maturity of the

technology, clear manageability and responsibility, and the ability of the model to produce immediate performance. In contrast, the dependence on the ability of one information system vendor to develop an information system and the challenge of development when the parts of the whole are closely interconnected have been identified as significant challenges for monolithic information systems. (Tiwana 2014, 96-103.) Monolithic architecture can be considered as one of the most significant root causes of the risks associated with the development of existing health information systems described by the Association of Finnish Municipalities (2019, 20); slowness and high cost of development, lack of resources, and market concentration.

As a counterweight to monolithic architecture, the world has begun to envision, develop, and implement models for developing health information systems that have sought to meet the challenges of monolithic information systems. In general, the principle of modularity is applied in these development models. Roughly speaking, modularity refers to implementing different functions of an information system by independent subsystems, which can be called functional modules (Rogozov et al. 2020, 1). Functional modules can be thought of as lego blocks that can be combined to form a whole (Seidel, Grisold & Berente 2020, 5748). When discussing modularity, it is necessary to outline the relationship of the principle to the concepts of application architecture, platform architecture, and ecosystem architecture (see Figure 17).

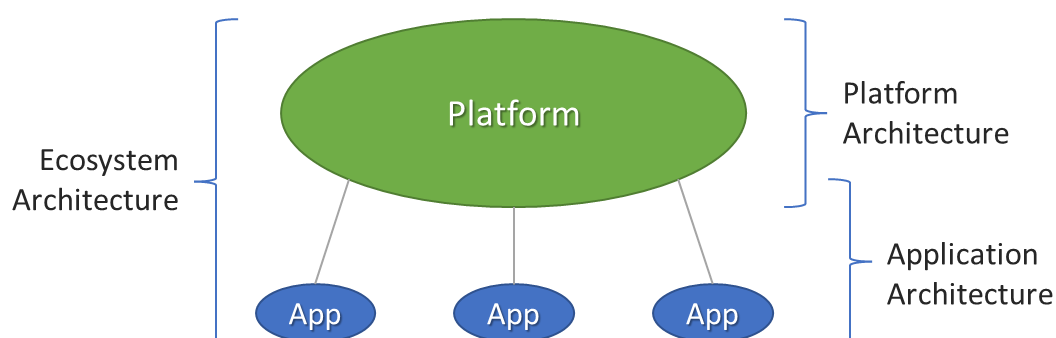


FIGURE 17, Formation of Ecosystem Architecture and related concepts (Tiwana 2014, 85)

Ecosystem architecture builds on platform architecture and application architectures. The role of ecosystem architecture is to define how these different levels of architecture work together. The platform architecture tells what the platform does and how. On the other hand, the application architecture explains how the application works and communicates with the platform and how the user interface, application logic, data management, and storage are implemented. (Tiwana 2014, 84-86.)

When applying modular development models, it is ultimately a question of what kind of ecosystem architecture exists or is desired to be built and how it is managed, on what standards interoperability in the ecosystem is built, and what is the division of responsibilities between platform and applications (Seidel et al. 2020, 5749-5750). The figure below (see Figure 18) illustrates how these architecture and ecosystem concepts form the conceptual whole of the platform ecosystem.

## Environment

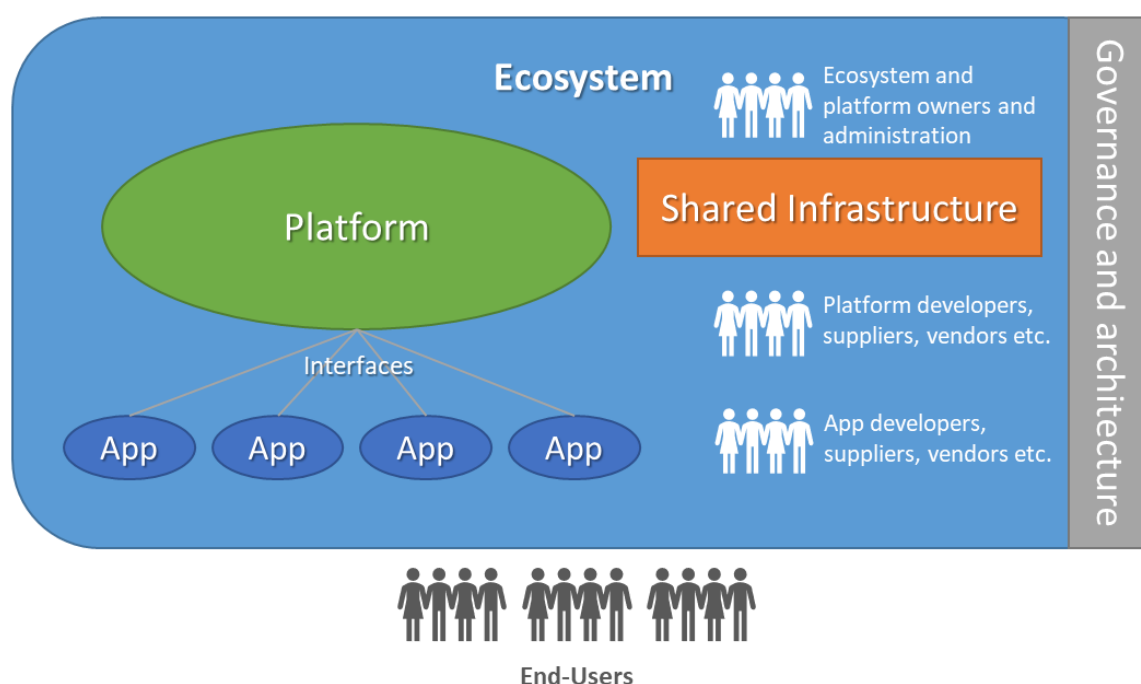


FIGURE 18, Elements of Platform ecosystem (Tiwana 2014, 6)

As described by Seidel (2020, 5748), the role and significance of Platform Ecosystems in our current operating environment are easy to outline through concrete examples. Good examples of such Platform Ecosystems in our everyday operating environment are operating systems (iOS, Windows), web browsers (Firefox, Edge), and social networks (Twitter, Facebook).

Currently, modular development models emphasize openness and data-centricity in response to future trends and challenges (Aue, Biesdorf & Henke 2016, Apperta Foundation 2017; Batra, Betts & Davis 2019; WHO 2020; Vermeulen 2021; Hoorne 2022; Ward 2022; WHO 2022). The proposal on adopting a European eHealth Reference Architecture (eHAction 2021, 17-18) supports this interpretation through its guiding principles of Security and Privacy, Transparency, Preservation of Information, Openness & Reusability, and Interoperability Standards.

The paradigm assumes that the customer must be brought to the center. All information related to citizens must be openly utilized to build an open data platform that feeds innovation development, market opening, and interaction between markets and healthcare organizations (Aue et al. 2016, 1-2). Such a data platform could also, according to Aue et al. (2016, 2), revolutionize the nature of health services and help reduce the cost of health information systems, paving the way for composable healthcare envisioned by Gartner analysts (Cribbs, Jones, Craft, Shanler & Bishop 2020).

Deloitte analysts (Batra, Betts & Davis 2019, 7) also envision that data and platforms will be among the fundamental archetypes that will be the backbone of tomorrow's healthcare ecosystem. They also emphasize that the future of healthcare requires that an increasing amount of data from different sources be collected and imported to enable new ways of delivering services and thereby ensure the organization's success. Vermeulen (2021, 2-3) describes that organizations need to break down data silos to move into the era of the Smart Health Ecosystem. Smart Health Ecosystem refers to an

environment where integrated patient-centered care is implemented to break down silos between care settings. Thus, thinking is moving to a new level away from the age of digitization, point-to-point integrations, and organizational focus, where many healthcare organizations are today.

Moreover, data and platforms are at the heart of this transition (Vermeulen 2021, 9). The EY report describes this paradigm shift from the current state of multi-systems and limited interoperability to a unified data-centric technology stack that provides a unified and real-time experience for clinicians, professionals, and patients (Roberts et al. 2020, 13).

Data, platforms, and openness have come to the fore, but why is this in practice? The reason is well illustrated by Ward (2022). He states that the complex structures of the healthcare services have been tested as patient expectations evolve with the development of other industries' capabilities and because of the forces for change like the COVID-19 pandemic. Unprecedented changes are at hand, requiring rapid changes in the front of healthcare technology and access to and use of information. It has been found that the available data are not up-to-date and comprehensive and do not allow insights to be drawn from them. Digital Health Platforms enable information to be gathered from the broader ecosystem using open, non-proprietary technologies with the services and tools they provide (see Figure 19). They thus create an aggregation point that facilitates the derivation of insights and the rapid realization of benefits. (Ward 2022.)

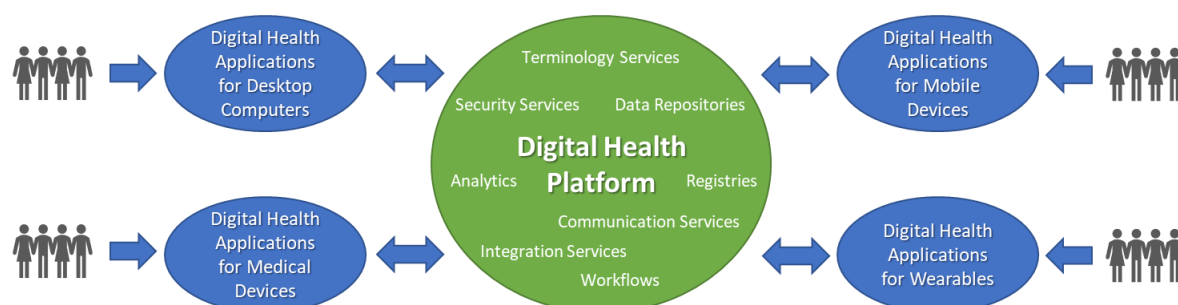


FIGURE 19, Digital Health Platform composition and interaction (WHO 2020, 12)

The figure above visualizes the concept and interaction model of the Digital Health Platform with external applications and users and the composition of the platform's core services. The Apperta Foundation (2017, 7-8) has taken the thinking of the Digital Health Platform to perhaps the most concrete level by defining the Open Platform concept, which aims to free up data and applications, making them portable and interoperable across platforms. The concept determines the principles on which an open ecosystem of health information systems can be created, where there will be no lock-in of vendors or technology. According to the concept, the Open Platform adheres to the following eight principles described in TABLE 12.

TABLE 11. Open Platform principles, according to The Apperta Foundation (2017, 16)

Principle	Description
Open Standards-Based	implementation should be comprehensively based on agile open standards
Shared Common Information Models	all open platform services should use common information models
Supporting Application Portability	Applications implemented on one platform should be able to run on another independently developed platform with little or no modification
Federatable	Open platforms must be interconnected to share information and workflows
Vendor and Technology Neutral	An open platform should not depend on a particular technology or require components from certain vendors
Supporting Open Data	Data must be provided for use in an open, shareable, computable format in near real-time
Providing Open APIs	A complete specification of programming interfaces should be freely available
Operability (as in DevOps)	The platform should support the principles of operability

According to the concept, the architecture of an open platform implementation can vary significantly. However, the architecture is similar to the figure (see Figure 20) below at a high conceptual level.

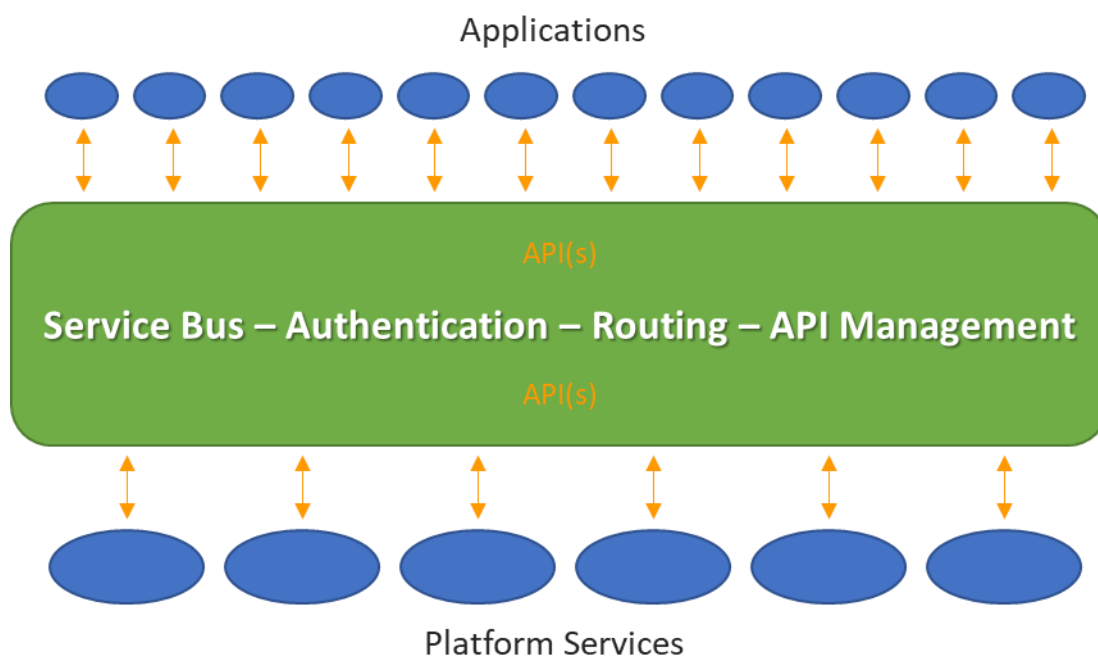


FIGURE 20, Open Platform Architecture (Apperta Foundation 2017, 17)

An open platform provides the facilities needed to build interoperable health and social services applications and services that developers cannot or do not want to do through platform services. These platform services can be implemented modularly. However, at least a service bus is provided

centrally that implements authentication, routing, and API management through a single primary platform vendor. Through the service bus, applications can securely access a broader range of services, such as data repositories, provided by platform service providers through secure and robust APIs and services provided by other federated platforms. (Apperta Foundation 2017, 17-18.)

The role of standards and data management implementation models applied in the Open Platform has been described in many more detailed studies. Meredith, Whitehead, & Dacey (2021) have defined a FOXS stack that can be used to ensure that data is findable, accessible, interoperable, and reusable according to FAIR principles. The FOXS stack is assembled from the four parts, each with its precise role. FHIR is the technical and syntactic interoperability standard for the stack. OpenEHR is a specification that acts as a persistence layer for core data. XDS allows sharing of documents and images. SNOMED CT acts as a hierarchical clinical vocabulary linked to other code systems and data structures. (Meredith et al. 2021, 134-135.)

In his reflection, Hoorne (2022) has come to a similar conclusion about implementing a modern health data platform. He emphasizes that since the data will be used in a single platform, it is crucial that the use of terminology, classification, and coding standards, such as SNOMED CT, LOINC, and ICD-10, has been defined. The application of FHIR and openEHR makes sense to Hoorne (2022) to manage and store clinical patient data. FHIR is needed to ensure interoperability, data availability, and openEHR to store data. As such, openEHR alone would be sufficient for data management, but the maturity and broader application of FHIR currently support its use as an intermediate layer through which data is utilized and converted for storage (see Figure 21).

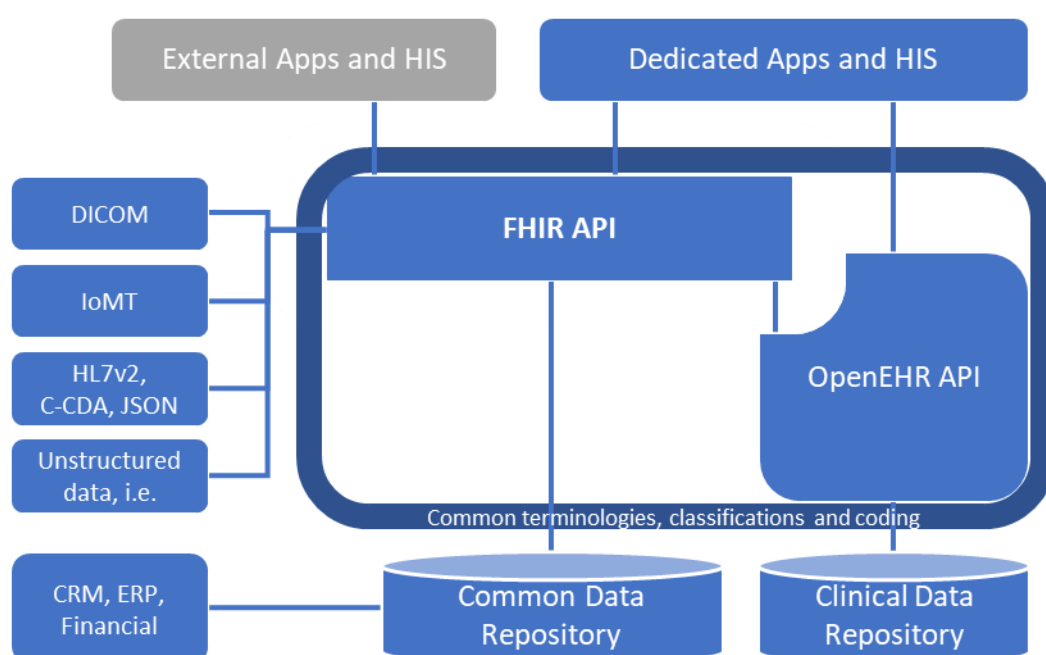


FIGURE 21, Application of standards to different data sources (Hoorne 2022)



## 5 DISCUSSION AND CONCLUSION

The study examined a broad and complex entity of health information systems development, limited to the positioning and possible utilization of openEHR technology in the Finnish health and social services information management environment, with particular emphasis on decision support systems. The study consisted of a research part in which the needs for developing decision support systems and the advantages of openEHR technology in their development were investigated through qualitative research. After the research phase, a theoretical framework was compiled. The aim was to identify and open up the fundamental concepts of the research area and form an idea of what the previous research literature has to say about the research subject.

This chapter discusses the results presented in the research and theoretical framework and summarizes the findings. Also, an evaluation of the limitations and reliability of this study is presented. Finally, the conclusions are stated, and possible targets for further research and measures to be promoted are considered.

### 5.1 Answering the research questions and aim

This chapter combines the research results with a theoretical framework, assesses the research results' significance, and finally forms answers to the research questions. The dismantling of the results and findings is initiated through research questions, making it possible to evaluate the research results and answer the primary research aim.

#### 5.1.1 Operational needs for developing DSSs and their development models

Answers to the question "What are the operational needs for developing decision support systems and their development models?" were sought through the first data collection phase in the study, which was carried out as thematic interviews. Data analysis was performed using the Grounded Theory method as described in Chapters 2.1.2 and 3.

Based on the data collection and analysis, a unified and clear picture of the operational needs for developing decision support systems and supportive development models was structured through five categories; Cost control, Customer Orientation, Development methods and models, Knowledge capital, and Operational Support. The categories and the observations under them made it possible to structure the preliminary theory to answer the research question. The emphasis on customer orientation, operational support, and knowledge capital was identified as key development needs themes.

Based on the study, customer orientation must manifest itself as the customer's involvement more closely in the services and the production of information for the use of the service system. The role of decision support systems regarding customer orientation can be twofold. Decision support systems can be implemented directly for the customer in the form of various symptom assessments and other digital services and for a professional to support the interpretation of the information produced by the customer and the execution of processes. Finland has a long history of implementing

such decision support systems for customers, and solutions have been comprehensively implemented at the national level. It is apparent that comprehensive services for citizens should be implemented in a nationally uniform way to maintain citizens' equality.

Operational support, in particular, means that health information systems should, in the future, support professionals in carrying out processes and entering information, assessing the client's situation, and observing the effects of interventions at different timespans. The cost-effectiveness of measures and decisions must also be visible regarding operational support. The development of decision support systems has a key role to play in meeting these needs and implementing operational support.

Another essential development theme identified was the need to develop knowledge capital. It was stated that a lot of information is available in many respects, which allows many kinds of development, but there are still significant challenges to solve. Perhaps the most important thing is understanding the meaning of information when disconnected from the primary context of use and the availability of ancillary information throughout the service system. Due to the challenge, it is also difficult to combine the information, and therefore, it is not possible to further utilize the information to the desired extent. Perhaps the most significant single observation in the theme was the importance of the moment of data recording. At the recording moment, the extent to which the information can be further utilized in decision support systems, for example, is determined. Therefore, it is essential to pay attention to the fact that the data is stored as comprehensively as possible, considering the information describing the context in which the data was created.

These findings illustrate the nature of the need to develop decision support in Finland. Finland has a relatively long history of processing EHRs, and patient data has long been archived in national information system services. In addition, current care guidelines and solutions that support symptom assessments and diagnoses have been in use for a long time. As a result, when implementing clinical decision support systems, the knowledge capital is generally in good condition, and reasoning rules are available.

However, the situation is not the same when implementing more general decision support systems. Implementing more general decision support is characterized by the need to combine data from several different sources. Different data also need to be combined and interpreted, which is currently impossible due to shortcomings in standard data models and terminology and data fragmentation. It follows that the information is unreliable and that only a professional can assess its significance.

Through these conclusions, the answer to the research question was structured.

The development needs of decision support are primarily focused on general decision support systems that help develop operations to support the success of professionals and involve patients or clients more closely in care.

Knowledge capital needs to be developed in particular to improve reliability and interpretability.

At the end of the research question, a position was also taken on development models. The interviews provided answers to the development needs related to the development models through challenges. The challenges highlighted that development requires perseverance and that the entities are complex and that developing existing systems is not easy. In addition, the ability of decision-makers and organizations to perceive the effects of development was emphasized to enable commitment to development. The solution to the challenges was to apply an experimental culture and agile development to realize the benefits in stages. Development cooperation with the system vendors was also seen as an option to enable the long-term development of complex entities. In general, the importance of development cooperation was significantly emphasized, even though the development of decision support systems was seen as a matter that should be implemented in a nationally coherent way. Typical 80% functionality must be found for the solutions and implemented across industry boundaries and in a nationally uniform manner. The rest can be done by the industry or organization independently. These findings were summarized in the following characterization.

Development is hampered by complexity and thus by the long-term nature of development. Therefore, the benefits should be realized in stages by involving professionals in the development and relying on the re-use of information and technologies used in other industries.

Addressing development needs and developing decision support systems were considered very important. To some extent, direct and point-to-point benefits were identified. However, decision support systems were primarily identified as enablers of the development of general health and social services challenges. Enabling is therefore very characteristic of promoting digitalization and the modern development of information systems.

With the development, the quality of information will improve, and efficiency and cost savings can be achieved by developing the timeliness and coverage of care.

The findings are very consistent when looking at the identified development needs and other findings concerning the description of decision support features in Chapter 4.2 of the theoretical framework. The impacts' complexity, lengthy review periods, and the importance of knowledge capital emerge as critical factors. Previous studies highlight clinical decision support systems that support diagnosis, which, in the light of the interviews conducted, are not as interesting in Finland as systems that support more general decision support. Of course, this trend was also evident in a study by Berner et al. (2016, 9 & 163-165), where the need for non-clinical decision support has also been seen to increase significantly in the future. The interviewees' visions of the current situation were also, in many respects, parallel to Middleton's, Sittig & Wright's (2016, 110-111) interpretations of the current situation. We are reaching technological and operational maturity, where decision support systems can be concretely implemented and integrated into the work of a professional.

On the other hand, if the identified development needs are examined from the perspective of the development of Finnish health and social services information management legislation and develop-

ment strategic guidance, the needs are well in line. At the heart of legislative and development strategic guidance are actions to improve the opening up and accessibility of knowledge capital (Ministry of Finance 2020, 6-13; Finnish Government 2021, 13-15; Ministry of Social Affairs and Health 2022) and to provide citizens with better control over their information and opportunity to improve the working conditions of professionals. Perhaps the development needs identified can be thought to be broader than just developing decision support systems. The challenges of developing existing information systems and the fragmented health information system environment, due to which the implementation of decision support solutions based on the existing knowledge capital has not progressed, certainly play a background. The situation is rather strange in the sense that although pioneering work has been done in Finland in developing decision support systems (Kustannus Oy Duodecim 2022a) and developing various symptom assessments and self-diagnosis solutions (Omaolo 2022; Terveyskylä 2022), their utilization has remained fragmented.

### 5.1.2 Positioning of openEHR technology in the Finnish information management environment

Answers to the question "How do openEHR and the open platform concept fit into the existing Finnish health and social services information management environment?" were mainly sought through Chapters 4.1 and 4.3 of the Theoretical Framework. The second phase of data collection in the research part, the qualitative survey, also sought to build a second perspective on which the interpretation of openEHR technology from written sources could be reflected. As the work progressed, the importance of this thinking was emphasized, as the construction of the theoretical framework had to rely quite heavily on Internet publications due to the lack of actual book-based sources.

The positioning of OpenEHR technology in the information management environment of Finnish health and social services is a rather diverse question, and this chapter seeks to examine the answers to the question from many different perspectives. The review has been carried out through the maturity of the technology and key aspects of Finland's existing information management environment; legislation, strategic development objectives, interoperability environment, and information systems development ecosystems.

Based on Chapter 4.1.3, it can be estimated that the maturity of openEHR is at a reasonable level. It is not a technology taking its first steps in its development. Based on the study, it can be estimated that openEHR technology has reached the latest level 9 on the widely used Technology Readiness Level (TRL) scale defined by NASA (Mankins 1995). The technology has been proven to work in practice, and its use is expanding in the market (Rodriguez et al. 2019, 106-107). The technology has thus reached a level of maturity that does not call into question its application as part of the Finnish health and social services information management environment in its intended use.

However, this raises the challenge of defining what the intended use of the openEHR technology is? In terms of thesis conclusions and research positioning, understanding and positioning openEHR concerning other health interoperability standards is one of the key objectives of the work and is surprisingly challenging (Leslie 2010). This challenge is mainly due to the nature of openEHR, which is not limited to the standardization of health data interoperability and modeling, as in many cases, openEHR studies are limited (Min et al. 2018; Allwell-Brown 2016, 15). Defining openEHR as a

standard is a point of view highlighted in previous research related to openEHR. Sometimes the term openEHR standard refers to openEHR in its entirety (Frexia et al. 2021, 114) and sometimes only to the parts of data modeling that it specifies (Arikan 2016, 53-54). Although openEHR itself meets the characteristics of a standard, as a whole, it cannot be considered a *de jure* standard (Allwell-Brown 2016, 13), as described in Chapter 4.1.

OpenEHR is a much larger initiative and entity (Arikan 2012; Frexia et al. 2021) than a mere standard for a particular need. Thus, from a researcher's perspective, the discussion and understanding of the role and content of openEHR would be significantly facilitated if the use of the standard term were avoided. When referring to OpenEHR as a whole, one could speak of a technology or approach, and the individual components would be referred to as specifications; at least, this principle is applied in openEHR International's communications.

Perhaps the most worrying feature about the maturity and application of OpenEHR is that there are no stable releases of either of the Conformance, Service Model, and parts of Implementation Technology components yet. These components are crucial when developing an open platform ecosystem built through openEHR technology, which is a fundamental goal of openEHR technology, as stated in Chapter 4.1.1. The lack of releases leaves some uncertainty about how the specifications should be applied in implementing an open platform. This lack may require a more substantial role for system vendors in building platform capabilities, which can be contrary to openEHR's, and open platform concepts' vendor-neutrality principle.

In conclusion, it is conceivable that the application of the technology should be initiated through clinical modeling and, in terms of specifications, through aspects related to archetype formalism and content definition. This interpretation is supported by a qualitative survey, which emphasized the role of OpenEHR technology in the implementation of standardization and harmonization of knowledge capital. The responses also stated that it is worthwhile to proceed with implementing the technology through the definition of archetypes. A pattern of progress along this line is also identifiable in the reference implementations most recently in Catalonia (Generalitat de Catalunya 2021). Archetypes are at the heart of technology, and it is impossible to exploit the full benefits of the technology unless the information in the form of archetypes is first available.

From a legal and development strategic point of view, there are no apparent obstacles to applying openEHR technology to develop decision support systems or health information systems in Finland. At the legislative level, the archiving of health and social services customer data in national information system services is defined, and standards are applied to transfer data between regional and national services (see TABLE 11). Data structures of transferred data are based on defined basic data types in HL7 V3 messages and CDA R2 documents. The definitions have not been taken to a level that would allow data to be stored in clinical data repositories to allow data to be used directly in decision support systems. Thus, the standardization of information management in Finnish health and social services currently focuses in practice on terminology and transmission, but not on the storage of maximum information content.

A very extensive and deserving vocabulary and terminology work is being done in Finland. In recent years, efforts have been made to compile data models, especially in information management in social welfare services. Work is also underway to define data models for health services. These definitions are implemented in practice to the Sosmeta and Termeta services. The definition does not directly rely on any single standard focusing on the definition of data contents or models. The form of the definitions is the result of national work. Although the definitions and schemes of the structures are published openly on the Internet, one might think that in light of the objectives of the European Union's Digital Single Market, Interoperability Framework, and national development strategies, it would be advisable to base the definitions on an international standard. From the interoperability point of view, applying an international standard would create a safe soil for the development and thus enable the outputs of other users of the standard to be used as part of the national specification work. In addition, market actors in Finland could build their solutions to be more compatible in the international market, and solutions from international vendors would be more compatible in the Finnish market without separate adaptation work. An archetype-based way to define data structures would be a possible way to meet this challenge.

The archetype work required by an individual actor or even a consortium developing health information systems with openEHR technology can become too much work to implement. Thus, to promote the practical application of the technology, it would be essential to establish cooperation at the national level to define archetypes or even guidance at the national level for the use of common archetypes. Finland is already taking the first steps in this direction when, in April 2022, an openEHR Finland working group was established under HL7 Finland to promote the definition of national archetypes (HL7 Finland 2022a, 2). The ongoing drafting of the law is assigning new responsibilities to THL regarding the coordination of the data structures of the national information system services (VN/2037/2021, 32). It might be worth considering whether openEHR technology should be used to define and describe interoperable data models in Finland. Other Nordic countries and several other European countries are already moving towards defining data content and models as archetypes (see Chapter 4.1.3), so now would be an excellent time to embark on this development path.

This measure would also concretely guide and encourage wellbeing service counties to move towards developing health information systems in a more open and modular way. In any case, health information systems will have to be developed, renewed, and even acquired through tenders, so now there would be a momentum in which the direction of the development of information systems could be concretely influenced. The risk is that if counties alone and independently have to decide on the direction of health information systems development, it may, in many cases, mean the path of the slightest possible change or even the postponement of development in the current economic situation.

From the point of view of the prevailing interoperability environment, openEHR cannot be seen to revolutionize or challenge the situation dramatically. The healthcare industry has a wide range of standards for different uses. Furthermore, this is perhaps one of the factors currently hampering the implementation of interoperability. Even the goal of standardization is quite the opposite. Standards are often intended only for a particular healthcare service or specialty, and end-to-end standards are

virtually non-existent in the healthcare industry (MedTech Europe & COCIR 2021, 4-5). The situation is well illustrated by the more than 260-page advisory publication on interoperability standards (ONC 2022) published by the U.S. Office of the National Coordinator for Health Information Technology. The publication describes how health interoperability is implemented in the United States. From the perspective of interoperability standardization, openEHR technology is located in an area with apparent gaps in the applicable standards. At the heart of OpenEHR is a focus on the fine-grained definition of information content relying on existing vocabularies and terminologies. In addition, it seeks to standardize things and bring tools to areas where there are not many options available such as task planning and decision support guidelines. A positive feature of openEHR is its comprehensiveness, but still a clear distinction between, for example, base standards focusing on data exchange such as HL7 version 2 and 3 and HL7 FHIR. Comprehensiveness is represented by the implementation technology specifications included in the technology and based on de-facto standards, which are intended to support the practical application of the technology. OpenEHR has found its niche area in which it does not over-challenge existing standards but takes advantage of them and fills in the gaps. Furthermore, enabling the formation of a comprehensive and future-proof set of standards for health information systems interoperability, as described by Meredith et al. (2021, 134-135).

The interpretation is also supported by the open comment returned in the qualitative survey:

-- It is important to keep in mind, openEHR is not the only Informatics standard that will benefit CDS / CDSS development. In general, any major Informatics standards in EHR (openEHR or HL7 FHIR) and terminology standards such as ICD-10, ATC, SNOMED CT will have positive effects on the adoption of CDSS.

Although the commentator refers to the role of openEHR in developing decision support systems, the comment more broadly describes the situation in the semantic interoperability of health and social services. One standard cannot solve all problems, but based on the use case, it is necessary to determine which standards apply to which needs consciously. As the defendant points out, it is essential to remember that relying on one standard or technology is not the only or even the right solution to a particular problem or need. By interpreting the answer, it can be argued that perhaps the most important thing is to apply the most appropriate standard or technique to solve a particular problem or need and to consciously define their relationship and role as part of a larger whole. Based on this reflection, it is possible to validate the layout of the primary research aim of the thesis. It seems valid because the study aims to position openEHR technology in the existing Finnish health and social services information management environment.

The last aspect in positioning openEHR technology in the Finnish health and social services information management environment is positioning the technology concerning developing health information systems ecosystems. Doing this positioning is relatively straightforward because, as described by openEHR international technology, OpenEHR is an eHealth technology consisting of open platform specifications, clinical models and modeling, and software that develops health information systems in an open and modular way (openEHR 2022a). Therefore, the OpenEHR technology is well suited for implementing the Digital Health Platform described in Chapter 4.3.4. The role of OpenEHR in such a platform would appear to be to implement a clinical data modeling environment, support

the persistence of maximum data content, and ensure vendor neutrality (Hoorne 2022; Sundvall 2013, 27; Meredith et al. 2021, 134-135). OpenEHR would help ensure that the emerging Digital Health Platform is transparent, technology-neutral, and vendor-neutral.

Although, in principle, the application of openEHR technology can be thought of as related to modular architecture models, it can also be applied quite well as part of monolithic architecture models. Through the application, monolithic or single-vendor solutions can be built with an open data management layer that improves data utilization and accessibility. Thus, the application of OpenEHR could promote the openness and interface capabilities of a monolithic solution, blurring the line between monolithic and modular solutions. Of course, from the perspective of existing solutions, the transition to utilizing openEHR for data persistence may not be straightforward to implement, so one might think that the transition will take place as part of developing new products.

There are already concrete signs of the growing importance of openEHR in the Finnish information management environment. The establishment of the OpenEHR Finland working group under HL7 Finland is a concrete statement of Finland's interest and investment in openEHR. In addition, Finland has actively participated in openEHR Nordic collaboration, promoting cooperation and information sharing between the Nordic countries to advance the utilization and development of openEHR technology.

One of the development steps that has changed Finland's health and social services information management environment and development ecosystems has been UNA Core, implemented in cooperation with the UNA community. UNA Core is an integration and information management solution designed to receive and retrieve information from various sources, including Kanta and local health information systems, and integrate this information. The implementation of UNA Core has applied the modeling and data management approach provided by openEHR technology to harmonize data content from various data sources into a common data model before making the data available through open interfaces. (Rannanheimo 2020.) The existing market for health information systems has also seen openEHR as a technology worth investing in. For example, TietoEvy has started developing and updating its products to apply the openEHR approach (TietoEVRY 2022).

Through this rather long and divergent reflection, the answer to the second research question emerges:

There is a clear place and even a need for openEHR technology in the information management environment of Finnish health and social services. OpenEHR technology would be most naturally positioned in data modeling and sustainability development, alongside other interoperability standards, to ensure that data remains relevant for further use. The application can be seen as beneficial from the point of view of market participants developing health information systems used by enablers of health and social services and those implementing national information management guidance in promoting transparency and interoperability.



### 5.1.3 OpenEHR technology as part of the development of Finnish decision support systems

The last and most important part of the work is to examine the answer to the actual research aim of the thesis - **How could openEHR technology and the open platform concept help develop decision support systems in Finland**. The answers to the research aim use the findings of all sections of the work and the summaries and conclusions formed in answering the research questions.

Through research questions, it emerged that the development needs of decision support are particularly relevant to the development of solutions that support the work of professionals and, to enable this, to the development of the quality of knowledge capital. The review also showed that openEHR technology has a place in the information management environment of Finnish health and social services, especially in developing a multi-level modeling environment and data persistence. On this basis, based on a preliminary theory structured in connection with qualitative survey data analysis of the role of openEHR in the development of decision support systems, the answer to the research aim can be formed:

OpenEHR technology in decision support systems emphasizes the standardization and harmonization of knowledge capital. A harmonized knowledge capital, combined with the principles of modularity, openness, and ready-made tools for platform technology, will help create a phased development Ecosystem where professionals can be involved in development. In such an Ecosystem, benefits can be realized in stages, patient-centered solutions can be implemented, and knowledge capital and data platform management can be held under the organization's control.

OpenEHR could be used to gradually create an environment for developing decision support systems that apply the principles of the open platform. Key enablers in openEHR technology would be a multi-level modeling paradigm, archetype-based data architecture, and GDL specification.

In particular, using the GDL specification would play an essential role in developing decision support systems based on the answers to the qualitative survey question. Utilizing it can allow professionals to participate in the development of solutions by defining decision support guidelines through an easy-to-use interface, storing the instructions in a machine-readable format, and enabling the reusability of the guidelines even beyond organizational boundaries. The importance of involving professionals alone in development has been seen as a prerequisite for success, and inclusion can also significantly reduce end-user resistance to solutions, as observed in the analysis of the thematic interviews.

Qualitative research, particularly its seventh question, produced an exciting result in terms of the involvement of the professionals. The question sought to identify respondents' thoughts on which stakeholder or target group would benefit most from using openEHR technology as a basis for developing decision support systems. The majority of respondents felt that applying openEHR technology would primarily benefit healthcare and social welfare professionals. The result was completely different from the researcher's expectations and was unexpected because many of the respondents

were system vendors. The researcher presumed that the exploitation of the technology would specifically benefit system vendors and national interoperability authorities through the harmonization of implementations and data models.

In addition to the GDL specification, the involvement of professionals in development is supported by the multi-level modeling paradigm of openEHR technology. The modeling approach allows the substance professionals and technical persons to develop the same entity simultaneously in a context and ways specific and relevant to each party (see Figure 9). As a result, industry professionals can participate in developing systems by defining archetypes and linking appropriate terminology (Min et al. 2018, 2). The collaborative development environment also supports the emergence of a common language and understanding. It is also possible to close the gap between operations and ICT in development, which some of the interviewees saw as a significant challenge in current development models and cooperation with vendors. In such development cooperation and environment, it is also likely that the solutions implemented serve the real needs of users and can be developed based on needs and benefits.

The development of decision support systems must consider that they involve many ethical issues and are, in many cases, subject to the EU's regulation of medical devices (MDR). The regulation of medical devices requires documentation of the development and operation of the solution and life cycle management in order for the solution to be found to meet its intended purpose. Utilizing the OpenEHR approach in the development of decision support systems provides a clear framework for managing the development and supports the documentation of implementation, helping to meet the requirements of the MDR. The use of open and vendor- and technology-neutral inference rules, i.e., the use of GDL, can also address ethical challenges when the inference rules are structured, machine-readable, and openly achievable. In this way, one of the interviewees' reflections that health and social care actors cannot be in an unequal position in the utilization of decision support systems could also be answered.

As a broader but more difficult advantage, the openEHR approach can support real-time and structured input and storage of EHRs so that maximum data content and relevant contextual information can also be stored. If this situation were addressed nationally and at the level of health information system ecosystems, the logic and dynamics of the development of all decision support solutions would change from the current way of implementing decision support systems.

As described in Section 4.2.1, decision support systems consist of three different parts; knowledge base, inference machine, and mechanism to communicate with the user, i.e., user interface. At present, there are generally two ways to implement decision support systems. A monolithic model in which all three components are implemented as part of a health information system. Furthermore, an almost monolithic model in which the knowledge base and inference machine are implemented in a separate application and the user interface is differentiated as in the implementation of EBMEDS, for example (EBMEDS 2022). The first model involves challenges generally described in this study as the challenges of monolithic systems. However, the benefit of the implementation model is that data transfer and conversion do not need to be implemented. While more modular in nature, the latter

model faces significant challenges in implementing integrations and interpreting the meaning of knowledge (Alther & Reddy 2015, 653). In addition, implementations easily become complex and fault-prone.

The comprehensive application of the OpenEHR approach would change the situation so that the strengths of both implementation models can be realized. In the approach, the decision support system could be implemented close to the health information system ecosystem seamlessly into other applications. However, a way that the knowledge base and inference machine form separate vendor- and technology-neutral application, or they can be separate applications if needed. The application may also include a user interface, or it may be implemented with the tools of a health information system, or both. In this approach, the application would have direct and comprehensive access to an archetype-based knowledge base, which would allow the implementation and testing of inference rules in real-time. Other knowledge sources can also be utilized, as described earlier.

Although the emphasis in the previous section is on the extensive use of openEHR technology, development can be promoted, and benefits can be achieved in stages. The implementation of the development path based on OpenEHR technology was questioned in the context of a qualitative survey. Respondents emphasize the development of knowledge capital and, based on this work, develop agile and step-by-step solutions to specific operational needs in collaboration with clinicians. The way of thinking is very positive in practical application and identified development needs, as the responses emphasize both step-by-step development and the rapid realization of benefits.

If the knowledge capital were to be maintained in a fundamentally uniform way, it would be possible to abandon the interoperability of data transfer and the implementation of mappings between different standards and classification systems and focus on the exploitation of data, the development of inference rules and guidelines. Archetypes themselves effectively define the meaning of clinical and related information and link information to external terminologies and vocabularies used in healthcare (openEHR Specification 2022d). Thus, openEHR technology would influence the quality of knowledge capital and ensure that the importance of information and the necessary contextual information is also retrieved. As stated in the interviews, the moment of recording the data is critical because then it is also determined how the data can be further utilized.

The change would also enable decision support systems to be implemented and deployed, if necessary, directly on the open platform formed by the health information system in a technology- and vendor-neutral manner. Nevertheless, it is still worth emphasizing that openEHR technology would appear to address one of the critical challenges in CDSS development "There is no common architecture to develop and share CDS modules and services" (see Table 9). There have been no standardized practices for the distribution and development of CDSS modules, and the format and interface standards of the knowledge base used by CDSS vary from industry to industry (Engle 1992; Sittig et al. 2008; Castillo & Kelemen 2013; Berner et al. 2016; Sutton et al. 2020). At the heart of OpenEHR technology is addressing these described challenges while also enabling the sharing and reuse of knowledge capital and decision support reasoning logic.

Based on the responses to the qualitative survey, it is fascinating to note that openEHR technology seems to provide tools and potential solutions to several development needs and challenges that emerged in the thematic interviews. Involving professionals in development, creating a common language, and the opportunity to improve documentation directly correlate with the classifications and theory of the first phase of research. OpenEHR technology would appear to respond very well to the challenges and structured categories identified in the study; it is customer-driven, contributes to the creation of a new model for the development of health information systems, develops knowledge capital, and brings operational support.

## 5.2 Reliability and limitations

All the sources used in the thesis have been reported openly and comprehensively following Savonia University of Applied Sciences' written report instructions. In addition, all the materials created in the study have been included in the appendices of the work. The distribution of research results and materials during the research process has been used to support the formation of work reliability and validity in addition to triangulation, as in Chapter 2.2. has been described.

The research work has been approached critically, and no researcher's own opinions have been added to the research or the theoretical framework. The conclusions have been based on the research part of the work, the theoretical framework, or both and are ultimately the researcher's conclusions.

Research ethics is an essential factor in the credibility of the research. Ethics are involved throughout the research work, from the design of the research process to its publication. During the whole thesis process, emphasis was placed on research ethics, which meant paying attention to the research material protection and protecting the persons involved in the research (Kuula 2006, 25). The research material was protected throughout the process, and only the researcher had access to it. The identities of those involved in the study remained anonymous throughout the study.

The aim was to keep ethics and the rights of the respondents clear throughout the process by communicating openly and, for example, entirely omitting information from the qualitative survey that would have allowed the respondents to make units. The interviewees selected for the theme interviews participated in the study voluntarily, which is desirable, as King et al. (2018, 36) state. Some of the interviewees were already familiar with the researcher, but some were not, and this was intended to ensure that previously unknown perspectives could emerge in the interviews (Salana 2011, 34). Virtually everyone to whom the invitation to the interview was sent participated in the interview because the interviewees found the topic topical and exciting.

The research aim was specified, and the research questions were limited a few times during the thesis process. The extent of the study area was somewhat surprising, although special attention was paid to the delineation of the site during the study design. In practice, the delineation was done by leaving the concept of an open platform to a minor role in research, and the role of openEHR technology was increased. The decision was made in practice because openEHR and the open platform can be seen as parallel concepts. OpenEHR technology allows the formation of an open platform, so

there was no need to treat the concepts in isolation. This finding also challenged the thesis's title to some extent, but it was not changed during the process. However, the red thread of the work is the potential of openEHR technology in developing open platform-based clinical decision support as part of the reform of health information systems in Finland.

In the name of honesty, the reliability of the work is, to some extent, challenged by the small sample sizes data collection in the research part. However, this is characteristic of qualitative research, especially in areas already studied to a limited extent. For thematic interviews, the small sample size may not seem problematic, as the subject area of the interviews was limited, and saturation was felt to be achievable. However, obtaining slightly more responses for a qualitative survey would have been particularly desirable. Perhaps the number of responses was influenced by the complexity of the survey as part of a qualitative study. If executed as actual interviews, more answers might have been obtained, but on the other hand, using a qualitative survey as part of the study was a conscious choice in terms of scope and application of the method. In the end, it should be noted that the concern is probably futile, as the theoretical framework in practice supported and confirmed the results achieved in the qualitative survey.

Regarding the thesis process, completing the research part first and only then the theoretical framework proved to be an excellent choice, albeit quite laborious. The procedure gradually opened up the concepts to the researcher and allowed the research phase to openly guide the researcher to structure the research subject without unnecessary presuppositions. The method became complicated because the concepts began to open up at the end of the process, and the connection became apparent. The process led to a reorganization of the work and a reassessment of the conclusions.

### 5.3 Conclusions and suggestions for further action

Through the research part of the thesis and the theoretical framework, the idea of what open platform-based clinical decision support means and how openEHR technology could help develop solutions, as the title of the thesis suggests, emerges. Through the work, it is also possible to outline how openEHR and concepts, in general, are positioned concerning the reform of health information systems in Finland.

An open platform is a concept of a vendor and a technology-neutral open ecosystem where data and applications are portable, reusable, and interoperable (The Apperta Foundation 2017, 16). In an open platform, clinical decision support systems can be implemented on a demand-driven basis, utilizing existing solutions or inference rules, involving industry professionals in development, and leveraging extensive knowledge capital. Utilizing OpenEHR technology to create an open platform would enable the implementation of a multi-level modeling environment and data persistence and support the implementation of decision support systems through the tools and specifications provided by the technology. By creating an open platform, information can be kept in possession of the organization or the customer, and the community enables joint development and the utilization of best practices.

From the perspective of developing decision support systems in Finland, the need for developing general decision support systems is especially emphasized. Clinical decision support is seen as a low-hanging fruit waiting to be picked. Development should be able to develop the capabilities of health and social services professionals to provide quality and timely care and to make effective and cost-conscious decisions. It must also be possible to develop customers' operating conditions and the opportunity to participate in the production of information. In order to meet the needs, all the knowledge capital available in the service system must be made available, and the quality of the data must be improved to improve reliability and interpretability.

The information management environment for health and social services in Finland has focused on promoting interoperability and implementing information management supported by national information system services. Although extensive terminology and vocabulary work has been advanced, nationally uniform data models for clinical data have not been implemented. Responsibilities related to the definition of data models are being clarified due to the ongoing legislative work (VN/2037/2021), and the work is being promoted through Sosmeta and Termeta services. The use of OpenEHR technology could bring benefits at the national level to data modeling and persistence development alongside other interoperability standards. The application of global and growing technology can also be seen as a positive thing for the market, promoting transparency, interoperability, and the creation of a European Digital Single Market. The Finnish market is so small that without reliance on international standards, we will not be able to develop the market.

Although the benefits of openEHR technology seem apparent and its application as a part of developing health information systems in Finland and more broadly in the Finnish health and social services information management environment seems possible, it is worth considering whether this is the case. Are there other options for solving the problems, and is openEHR a so-called silver bullet to solve the problems that have hindered the development of health information systems for years?

This thesis aimed to investigate the positioning and role of openEHR technology in the research area, so no alternative solutions have been consciously investigated. However, during the development of the theoretical framework, the researcher developed the perception that competing solutions are not available to a significant extent. At least such was not encountered in systematic information retrieval.

It can be said that openEHR technology does not provide a solution to all identified problems, and many risks are associated with the application of openEHR. As stated in the qualitative survey and confirmed in the theoretical framework, using a single standard does not yet lead to interoperability.

Although the specifications and tools in openEHR technology can be applied in many ways and in a wide variety of environments, the approach will ultimately be realized, and the full benefits will only be realized when archetype-based knowledge capital is available. At a minimum, this means that national archetypes must be defined and accessible from a centralized CKM. It would be even better if the clinical data were also stored in clinical data repositories in an archetypal format, allowing the data to be exploited without data conversions and mapping between different data formats.

Defining national archetypes is a big job, although general archetype descriptions produced by the international community are available. The definition cannot be carried out by a single actor or even a consortium, but the broadest possible community must be harnessed. An openEHR Finland working group has been set up to solve the problem and advance archetype definition. It seems promising that the definition work will proceed and that nationally common archetypes will be formed in Finland in due course. The work would be significantly supported and accelerated if a national level owner could be defined for the definition work and the application of openEHR as part of the Finnish health and social services information management environment.

The owner would naturally also be responsible for managing the national CKM. It would be logical to introduce CKM among other national information system services to make its accessibility and the obligation to use it on an equal footing with other national information system services. The implementation of the national CKM should be able to take into account the existing vocabulary, code, and Sosmeta and Termeta services involved in the definition of the national data capital. On the other hand, the role of existing definitions and services can also be seen as an opportunity. The document structures and data components defined in the services could be converted into archetypes and templates on a case-by-case and need-to-use basis. The openEHR modeling work would link the existing definitions thereby more tightly together. Reaching this level would require changes at the legislative level, so step-by-step and more agile models need to be found for development and application.

In addition to the need to define archetypes, it is also worth noting that Finland has an existing and comprehensive information management environment where many interoperability standards are already applied. In addition, the national basic FHIR profiling will start in 2022 (HL7 Finland 2022a, 1). Although the standards do not overlap but are mutually supportive, the situation will inevitably necessitate mapping between standards. The implementation of mappings contributes to the workload of implementing the new standard and potentially complicates the information management environment.

Developing an open platform requires significant investment in ecosystem management and governance, as is the case with any ecosystem construction (Tiwana 2014, 84-86). The risk has been identified, and it emerged in interviews that there are challenges in the ability of organizations to make decisions and commit to long-term development in the current situation. Thus, the ability to manage should be significantly developed from the current one if the open platform development model were to be pursued. Of course, the capability can rely on the help of the market, but in this case, there is a risk that a vendor lock-in will form somewhere in the open platform. Especially in the case of openEHR, this can be considered a significant risk, as the maturity of the technology platform service, implementation, and compliance with the specifications raise questions. Therefore, the guidance should ensure the transparency and independence of the open platform's core services, as recommended by the Apperta Foundation (2017, 17-18).

Through the implementation of the thesis, at least two proposals for further actions have been identified that could promote the understanding and practical application of openEHR technology and open platform decision support systems.

The application of the archetype-based and multi-level modeling method offered by OpenEHR technology as part of the Finnish health and social services information management environment would require more detailed research in order to gain a deep understanding of the potential benefits and the relationship with current modeling methods and practices. In particular, integrating the application of the openEHR approach into Sosmeta and Termeta services would be of particular interest. In this way, the usability of the results of the significant work promoted over the years, the guiding role of the national information management environment, and the international relevance could be further developed. Building the national archetype CKM alongside or in connection with these services could also be an interesting topic for consideration.

In order to promote the development of open platform decision support systems, it would be advisable to launch a concrete pilot project by a wellbeing service county organization, development company, or through a thesis. The project would be implemented through a limited use case to implement a solution in collaboration with clinicians for a specific need. The archetypes required for the use case and the inference rules for decision support would be defined with GDL2 tools to implement the solution. The solution would aim to bring the health information system into trial use in a real environment to assess its relevance and effectiveness. Of course, the trial operation could also be implemented in a simulated environment. These qualitative survey steps outlined by the respondent would provide concrete insights into the potential of an open platform and openEHR technology to help develop decision support systems, increase understanding of what incremental development means, and how development affects clinicians. If the pilot were to succeed, it could be put into production with relatively little effort, taking into account the requirement of the Medical Device Regulation.

The information management environment for health and social services in Finland is changing. Health information systems are being developed or consolidated as part of health and social services reform, and changes in the development of health information systems are underway globally. We are at a crossroads. Do we want to change the way we support the development of decision support systems and, more broadly, health information systems in the future? Or will we continue on the same path as before? The decision or failure to do so will guide the long-term development of the health information systems in wellbeing services counties and the development of the market and will have far-reaching implications for the use of resources. Whatever the decision and direction, one would like to find a spirit similar to that encouraged by one of the interviewees in the study: "Let us do things in a nationally unified way."

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## APPENDIX 1: THEMATIC INTERVIEW PLAN AND MATERIAL

# Decision support based on an open platform

Possibilities of the openEHR approach as part of the reform of health information systems in  
Finland

## Background

- Institution and degree program
  - Savonia UAS Master's programme in Digital Health
- Client of the thesis
  - UNA Oy
  - Supervisors: Arto Toppinen (Savonia), Juha Rannanheimo (UNA Oy) and Hanna Pohjonen (Rosaldo)
- Researcher
  - Henri Huttunen
  - Employer Istekki Oy

## Decision-support background

- Electronic decision support or decision support is by nature a support system for information management .
  - Decision support aims to improve practices or prevent treatment errors, for example,
  - acts as a memory aid and helps to manage the flood of information by highlighting the most important issues in each situation,
  - can also promote professional experiential learning and simplify work processes .
- In the interview, the possibilities of decision support can be assessed very freely from the perspective of one's own substance.
  - Assessing the potential of a clinical decision support system where a professional interacts with the system to make a diagnosis or receive treatment on the basis of input data (system under the Medical Devices Directive), or
  - a model in which the professional is more likely to receive suggestions, observations and stimuli for examination and evaluation (not a system covered by the Medical Devices Directive);
- The potential of the two main types of decision support schemes can also be assessed
  - Knowledgebased decision support
    - Reasoning is made on the basis of predefined rules
  - Non-informed decision support
    - Does not contain a predefined knowledge base, but reasoning is made by artificial intelligence and machine learning
    - However the systems are unable to explain the reasons for their conclusions

## Research questions

How could an open platform concept and openEHR technology help develop decision support systems in Finland, and does openEHR offer particular advantages compared to other implementation models?

In addition to this primary research question, the study examines the answers to the following secondary research questions:

1. What is the operational need to develop implementation models for decision support?
2. How do the open platform concept and openEHR fit into the existing Finnish social welfare and health information management environment?



## Implementation of the study

In this thesis, the research part of the study is conducted by qualitative research, divided into two parts

1. Identification of operational development needs on decision support (behalf **this** theme interview) and
2. Exploration of possible benefits that openEHR can offer to achieve operational development needs (separate structured interview).

## Introduction to the thematic interview

- About 1-hour interview around presented themes to map the operational development needs of decision support
- The target groups of the interview are social welfare and health care professionals and developers of health information systems in Finland
- The researcher records the interview to implement the transcription afterward
  - The researcher only uses the recording to transcribe the conversation
  - The recording is stored confidently
  - The researcher destroys the recording after transcription is finished and approved by the interviewee

## The course of the thematic interview

- Introduction of the interviewee
- Topics
  - Identified needs for decision support development Opportunities and benefits that development could create
  - Challenges in previous development of decision support solutions and bottlenecks that hinder development
  - Successes achieved in the previous development of decision support solutions and lessons to be taken into account in the development
- Summary and next steps

## Starting the interview

- Introduction of the interviewee
  - Name
  - Role / employer
  - Relation to the context of decision support
  - Previous experience in the subject

## Theme 1:

Identified needs for decision support development;  
Opportunities and benefits that development could create

- Perspectives

- Involving the patient or client and improving the flow of the treatment path
- Streamlining the clinical or administrative processes
- Cost control
- Diagnostic support
- Improving documentation

## Theme 2:

Challenges in previous development of decision support solutions and bottlenecks that hinder development

- Perspectives

- User resistance or lack of expertise
- Lack of information and research evidence to support decision support
- Lack of data interoperability and consistency
- Inflexibility of systems
- Lack of expertise or resistance from suppliers to develop products
- Funding

### Theme 3:

Successes achieved in the previous development of decision support solutions and lessons to be taken into account in the development

- Perspectives
  - Findings on the solutions implemented
  - Particularly impressive implementations

### Summary and next steps

- Accepting the transcription of the interview
- Permission for any additional questions or interviews

## APPENDIX 2: QUALITATIVE SURVEY

### OPENEHR BASED DECISION SUPPORT

#### Information about the survey

This survey is related to the Master's thesis, which examines how the openEHR approach can help reform decision support systems (later DSS) in Finland and what specific benefits the openEHR approach brings compared to other development models.

The survey is targeted at the openEHR community. The survey aims to identify areas where the openEHR approach supports realizing the benefits, implementation, and development of a successful DSS.

It takes about 10 to 20 minutes to complete the survey. The survey consists of four sections; this presentation, survey respondent information, multiple-choice questions, and a couple of free text questions.

The survey does not include questions that allow the respondent to be identified, and thereby the survey does not process personal information. Only the role represented by the respondent is highlighted in connection with the thesis. Respondents' organization is used only for quality assurance purposes. If you want to be informed about completing the thesis or allow the researcher to ask additional questions, please contact the researcher by free-form e-mail.

The information collected in the survey and the research results derived from it will be treated confidentially by following good information management practices required by data protection legislation. The survey data will not be disclosed outside the study or combined with any other data. The data of the survey is processed only by the researcher. At the end of the study, the survey data will be destroyed. Participation in the survey does not incur any costs for the subjects, and no compensation is paid for participating in the survey.

The thesis is implemented in The Master's Degree in Digital Health degree program at Savonia University of Applied Sciences (<https://www.savonia.fi/en/study-with-us/degree-studies/masters-in-english/digital-health/>), and the client of the thesis is UNA Oy (<https://unaoy.fi/briefly-in-english/>). Henri Huttunen ([henri.huttunen2@edu.savonia.fi](mailto:henri.huttunen2@edu.savonia.fi)) is responsible for the implementation of the thesis.

\* Required

## Survey respondent information

### 1. the role of the respondent's organization

\* 

- ☐ System vendor
- ☐ Developer or consulting
- ☐ Customer or user organization
- ☐ Community
- ☐ Other

### 2. The role of the respondent

\*

- ☐ Manager
- ☐ Specialist in health or social care
- ☐ Specialist in business and administration
- ☐ Specialist in information and communication technology
- ☐ Other

### 3. Organization

Enter your answer

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## How openEHR helps reform decision support

The answer options for multiple-choice questions can be interpreted as follows:

- No effect - The openEHR approach is unrelated or has no impact on the benefit, success factor, or precondition in question
- Support - The openEHR approach supports the achievement of a benefit, success factor, or precondition
- Positive - The openEHR approach can have a positive impact on achieving a benefit, success factor or precondition
- Enabler - The openEHR approach allows a benefit, success factor, or precondition to be achieved

### 4. Assess the role of openEHR in achieving the benefits of DSS?

DSS in previous studies has been identified to allow for a variety of benefits. Evaluate the role of openEHR in achieving the following benefits.

Source: Sutton, R.T., Pincock, D., Baumgart, D.C. et al. An overview of clinical decision support systems: benefits, risks, and strategies for success. *npj Digit. Med.* 3, 17 (2020).

<https://doi.org/10.1038/s41746-020-0221-y>

	No effect	Support	Positive	Enabler
<b>Patient Safety</b> Reducing incidence of medication/prescribing errors and adverse events.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Clinical management</b> Adherence to clinical guidelines, follow-up and treatment reminders, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Cost containment</b> Reducing test and order duplication, suggesting cheaper medication or treatment options, automating tedious steps to reduce provider workload, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Administrative function/automation</b> Diagnostic code selection, automated documentation and note auto-fill.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Diagnostics support</b> Providing diagnostic suggestions based on patient data, automating output from test results.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<b>Diagnostics Support: Imaging, Laboratory, and Pathology</b> Augmenting the extraction, visualization, and interpretation of medical images and laboratory test results.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Patient decision support</b> Decision support administered directly to patients through personal health records (PHR) and other systems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Better Documentation</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Workflow improvement</b> DSS can improve and expedite an existing clinical workflow in an EHR with better retrieval and presentation of data.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 5. Assess the role of openEHR in the implementation of the DSS?

In order to implement an effective DSS, several critical success factors have been identified in previous studies. Evaluate the role of openEHR in implementing the following success factors.

Source: CASTILLO, RANIELLE S. MSN, RN, CPN; KELEMEN, ARPAD PhD Considerations for a Successful Clinical Decision Support System, CIN: Computers, Informatics, Nursing: July 2013 - Volume 31 - Issue 7 - p 319-326  
 doi: 10.1097/NXN.0b013e3182997a9c

	No effect	Support	Positive	Enabler
<b>Incorporation of DSS into existing systems</b> Many successful dssS are those incorporated into existing EHRs and computerized physician order entry systems and have the advantage of using the available data within those systems to effectively generate prompts.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>DSS integration into current workflow</b> Users are more willing to utilize a DSS if the system does not disrupt their usual workflow, and the prompts are presented when the user is in the process of making the decision.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



**DSS specificity**

DSS that are customized to a specific specialty area and provide broad spectra of various interventions are more inclined to be utilized properly.

**User Involvement**

User involvement in the planning, development, design, and implementation of the DSS is beneficial to the final acceptance and efficient utilization of the DSS.

**DSS education and training**

Users who are thoroughly trained in the use of a DSS are more likely to effectively use the system.

**DSS support**

The presence of administrative assistance and designated DSS unit experts is vital so that they are readily available to help users utilize the DSS correctly and effectively.

**Automated DSS prompts**

The generation of automatic prompts with suggestions provided to the user increases DSS efficiency.

**Straightforward Alerts**

Decision support system alerts that are developed should be unambiguous and easy to understand so that the user is clear on the circumstances at hand and understands what actions are needed.

**Simple DSS displays**

Basic guideline information should be presented as simply as possible on a single screen window so that users can get important relevant information quickly and easily.



<b>Prompt Acknowledgement</b> Prompts should be made so that users must acknowledge them before continuing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Minimal DSS data entry</b> Additional traits of a CDSS that improve efficacy include allowing a minimal amount of user-entered data.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Evaluation and Monitoring</b> The override rate of newly implemented DSS rules should be evaluated as well as whether the targeted quality measure shows improvement.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## 6. Assess the role of openEHR in meeting the preconditions and/or requirements for developing DSS?

Previous research and practical experience have identified a number of preconditions to support the implementation of DSS. Evaluate the role of openEHR in fulfilling the following preconditions and objectives.

	No effect	Support	Positive	Enabler
Comprehensive testing protocols are in place	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Decision support guidelines can be defined by a professionals behalf easy to use interface	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Decision support guidelines are stored in machine-readable form	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Decision support guidelines can be widely reused through out DSS and even user community	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Users can be shown on what material and reasoning rules the inference made by the DSS is based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DSS is a flexible and enables agile development	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DSS is modular and supplier-independent implementation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Supports real-time and structured input and storage of Electronic Patient Records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Supports the integration of external standards, codes and terminologies as well as open data sharing with other health information systems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The quality of data for DSS is consistent, in context and not vary in quality according to the source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The maximal amount of relevant data should be available	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The data should be detailed enough	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. Assess which actors will benefit most from the use of openEHR in the development of decision support?

- Move this option to the end of the list -

Health or social care organization managers

Health or social care professionals

National interoperability authorities

Information and communication technology professionals (programmers, developers architects)

System vendors

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## Open questions

8. Evaluate the key benefits of openEHR in developing DSS?

Enter your answer

9. Highlight key features or functions of openEHR that support DSS development?

Enter your answer

10. Describe shortly the optimal development path of openEHR-based DSS?

Enter your answer

11. If you answered to question 8 (Assess which Actors will benefit most from the use of openEHR in the development of decision support?), briefly describe why / how the actor you placed first benefits from openEHR?

Enter your answer

12. What solutions, applications, or other services do you offer or have in place to implement openEHR-based decision support?

Enter your answer

13. Suggest reading tips, studies, or publications related to the topic

Enter your answer

14. Comments or remarks to the researcher. Word is free.

Enter your answer

You can print a copy of your answer after you submit

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Submit

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## APPENDIX 3: POST ON OPENEHR FORUM

See: <https://discourse.openehr.org/t/participate-in-the-thesis-survey/1657>

## Master's degree thesis on openEHR-based decision support - Participate in a research survey

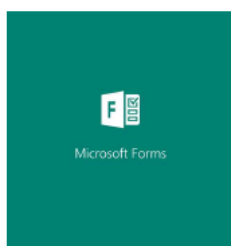
Henri\_Huttunen

Jun '21

Dear openEHR community,

My name is Henri Huttunen, and I am implementing a master's thesis related to openEHR-based decision support. The purpose of the thesis is to examine how an open platform and an openEHR approach could help reform decision support systems in a user-oriented way in Finland and what specific benefits the openEHR approach brings compared to other development models?

To identify areas where the openEHR approach supports the realization of the benefits, implementation, and development of a successful decision support system, I'm asking openEHR community's help by participating in [a survey](#) available at:



Microsoft Forms

It takes about 10 to 20 minutes to complete the survey, and it is open until June 30, 2021.

Many thanks in advance to everyone who took part in the survey.

If you have any questions regarding the thesis or the survey, you can contact me by e-mail at [henri.huttunen2@edu.savonia.fi](mailto:henri.huttunen2@edu.savonia.fi).

Yours sincerely,  
Henri Huttunen

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[🔗 Participate in the thesis survey](#)

thomas.beale  SEC member

Jun '21

Hi Henri,

I have just been looking through the rather comprehensive survey. One thing you might want to clarify is what release of openEHR you want to refer to. Today's running systems have some support for CDS and related things - via Instruction / Action tracking, **GDL** and generically, via AQL, which enables high quality semantic querying.

However in the medium term future, the use of the **Task Planning, Decision Language** and **Subject Proxy** architecture are likely to add a lot to the CDS capabilities - but of course they are still in development, and we don't know exactly what they will look like in practice.

So I think you may want to think about whether you want respondents to indicate 'how things are right now', i.e. in real, already-deployed systems, or whether you want them to indicate 'potential'.

Today, many of your DSS questions could be answered with reference to GDL, which in theory might be answerable only by those who have seen GDL running (might a smallish number); if we consider say a 3 year horizon, the same questions could be answered with reference to both GDL and TP/DL (mentioned above).

So it might be useful to be a bit clearer on whether you want respondents to answer speculatively (what they think will be supported, going by the specs, and/or deployments they have heard about) or just concretely right now.

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Henri\_Huttunen

Jun '21

Hi Mr. Beale,

Thank you for your comment and for highlighting the relevant perspective.

In principle, the survey does not intentionally refer to any particular openEHR version or functionality. It contributes to the openEHR community's views on the features that respondents feel will contribute to developing decision support systems in particular.

You are, of course, right that it may be of great importance to the respondents whether the answers are limited to the features already in production or whether they also take into account features under development or visions for the future.

Perhaps I would clarify this so that the answers can take into account, in addition to the existing features, the development of openEHR in the near future. The ultimate goal of the research is to deepen the understanding of the benefits and possibilities of the openEHR approach in the development of decision support systems in Finland, so the research will not go to an exact level, and features still in development can be taken into account. Of course, building development on a very speculative future is not possible, so the 3-year horizon you mentioned is appropriate.

I hope this answer clarified the matter. I will update the introduction to the survey on this topic as soon as possible. Thank you also for your excellent insight into openEHR's current and near future capabilities to support the development of decision support solutions 😊



---

**Henri\_Huttunen****Jun '21**

Hi,

Thanks to everyone who has already responded to the survey. A good number of responses have already been submitted, but a few more would be needed.

Please answer the survey if you want to help understand the benefits of the openEHR approach and position it to develop decision support systems and, more generally, health information systems in Finland.

## APPENDIX 4: THEMATIC INTERVIEW CODING

ID	Coding	Value	Comment
Int_1-1	Perspective	Information management	
Int_1-2	Perspective	Drug supply and drug delivery	
Int_1-3	Perspective	Specialist in specialty care	
Int_1-4	Motivation	Comprehensiveness	Small actions can have a big impact on the whole
Int_1-5	Motivation	Complexity	Must be able to control and consider many different variables in decision-making.
Int_1-6	Motivation	Complexity	Memorable operation is not possible
Int_1-7	Development need	Managing the overall situation with decision support	
Int_1-8	Enabler	Utilizing existing information in a new way	
Int_1-9	Development need	Supporting the professional in completing the process	
Int_1-10	Development need	Stimulants	
Int_1-11	Benefit	Visits are declining	
Int_1-12	Benefit	The customer's pharmaceutical costs are reduced	
Int_1-13	Benefit	Individual care / Personalization of the service	
Int_1-14	Benefit	The effectiveness of the treatment is improved, and through this, the costs are also reduced	
Int_1-15	Benefit	Effectiveness and cost savings through timeliness	
Int_1-16	Development need	Involving the client in their care	
Int_1-17	Challenge	Application of client-generated information as part of the care	
Int_1-18	Benefit	Patient safety is improved	
Int_1-19	Challenge	Uniform concepts and vocabulary	
Int_1-20	Challenge	Lack of uniform terminology	
Int_1-21	Challenge	Lack of uniform data models	The significance of the information cannot be inferred
Int_1-22	Challenge	It is not possible to display/utilize the information	
Int_1-23	Challenge	Developing current systems is difficult	
Int_1-24	Enabler	Utilization of information in a new solution	Existing knowledge will be further utilized in a new and more capable solution
Int_1-25	Challenge	Existing information and its significance cannot always be relied upon	The level of recording and the application of guidelines vary
Int_1-26	Challenge	Lack of coherence at the national level and between information systems	
Int_1-27	Challenge	Lack of development partners / Stakeholder engagement in development	
Int_1-28	Challenge	Difficulty of development	It is challenging to devise a solution to a complex problem
Int_1-29	Enabler	Decision support reasoning rules exist and are available	
Int_1-30	Enabler	Knowledge capital is generally in good condition	Related information and actual substance data are mainly in a structured form.
Int_1-31	The nature of the solution	Decision Support Professional Support / No Medical Device	

Int_1-32	The nature of the solution	Clinical Decision Support / Medical Device	
Int_1-33	Challenge	The ability of suppliers to develop/understand needs	
Int_1-34	Challenge	The ability of one's organization to develop a challenging whole	
Int_1-35	Lessons learned	Invested in digitization in recent years	
Int_1-36	Lessons learned	The ability of stakeholders to develop has improved	
Int_1-37	Lessons learned	The importance of national services has been emphasized, and development has progressed	
Int_1-38	Lessons learned	Due to the lack of sustainability, investing in large-scale development	
Int_1-39	Enabler	Efforts have been made to model operations	
Int_1-40	Observation	The development partnership enables the long-term development of complex entities	
Int_1-41	Lessons learned	The need for action as a starting point for the development	
Int_1-42	Observation	Focus on the basics and solving the challenges of knowledge capital	
Int_1-43	Challenge	Solutions must be integrated as a natural part of the operation	No separate solutions
Int_1-44	Challenge	Operational processes have not been described	It is difficult to implement support services
Int_2-1	Perspective	Social welfare	
Int_2-2	Perspective	Specialist medical care	Coordination of social and health information systems
Int_2-3	Perspective	Information systems	
Int_2-4	Motivation	Individual care / Personalization of the service	
Int_2-5	Challenge	The potential of the technology is unknown	
Int_2-6	Challenge	Take away decision-making power or individual discretion from a professional	
Int_2-7	Challenge	User resistance	Consequence of Int_2-6 and Int_2-5
Int_2-8	Development need	Supporting the professional in completing the process	
Int_2-9	Development need	Stimulants	
Int_2-10	The nature of the solution	Decision Support Professional Support / No Medical Device	
Int_2-11	Enabler	Knowledge capital is generally in good condition	And data models/structures defined
Int_2-12	Enabler	National services support access to information	
Int_2-13	Development need	Managing the overall situation with decision support	It can also be related to perceiving the network of work.
Int_2-14	Benefit	Effectiveness and cost savings through timeliness	
Int_2-15	Benefit	Findings across industry boundaries / Comprehensive review of customer relationships	
Int_2-16	Benefit	Business development	
Int_2-17	Development need	Ability to combine information produced in different industries and in different ways	
Int_2-18	Enabler	Utilizing existing information in a new way	Also, for new uses automatically

Int_2-19	Development need	Observation of effects in different periods	If € 100 is now invested in the customer base, what will be the effect in the long run. Alternatively, if you invest in the service now, it can help prevent some of the more significant problems from materializing.
Int_2-20	Challenge	Impact assessment is complex because there are many influencing factors and long periods	
Int_2-21	Challenge	It is not possible to combine data	Legislation / Interoperability Challenges
Int_2-22	Development need	Observation of dependencies and consequences	Related to Int_2-13
Int_2-23	Motivation	Complexity	
Int_2-24	Development need	Involving the client in their care / providing the service	
Int_2-25	Development need	Documentation of the customer's situation	
Int_2-26	Enabler	Application of new technology already used in other industries	
Int_2-27	Benefit	Orientation / Tacit sharing	
Int_2-28	Benefit	Improving quality and ensuring consistency	
Int_2-29	Challenge	The ability of suppliers to develop/understand needs/skills gaps	
Int_2-30	Challenge	Challenges for financing	Increase in cost level relative to Int_2-12
Int_2-31	Challenge	The need to raise the level	Digital jump
Int_2-32	Challenge	Suppliers do not proactively develop or raise awareness of the potential of new technology	
Int_2-33	Challenge	Developing current systems is difficult	Inflexibility of systems
Int_2-34	Challenge	Industry/service specificity of solutions	It is the result of Int_2-29
Int_2-35	Observation	You need to find it common 80% and implement it in a consistent way and the rest by industry	
Int_2-36	Enabler	Let us do things in a nationally unified way	
Int_2-37	Observation	The importance of national services has been emphasized, and development has progressed	
Int_2-38	Enabler	Through piloting, professionals are aware of the potential of technology	
Int_2-39	Challenge	Communicating the benefits	
Int_2-40	Enabler	The broader whole allows for investment in development	
Int_2-41	Challenge	Data fragmentation	Information is in many different places, and it is impossible to combine and interpret it simultaneously.
Int_2-42	Challenge	Reasoning logic for decision support is not available	Cost-effectiveness e.g.
Int_2-43	Lessons learned	The lessons of other industries should be utilized	
Int_2-44	Lessons learned	You need to be able to realize the benefits	
Int_2-45	Lessons learned	Involving users in the development	
Int_2-46	Lessons learned	Operation and process guidance and control in the system	Various separate manuals or process descriptions, etc.
Int_2-47	Lessons learned	Dissemination of one's innovations internationally	
Int_3-1	Perspective	Information systems	
Int_3-2	Perspective	Information management	

Int_3-3	Perspective	Health care	
Int_3-4	Enabler	Activity-based development	
Int_3-5	Challenge	The ideal world is very far away	
Int_3-6	Motivation	The systems should revolve around the client and not the professional	
Int_3-7	Challenge	It is not possible to make further use of the available information, but the relevance must be assessed by a professional	The result is Int_3-8 and Int_3-9
Int_3-8	Challenge	Data is not reliable	The significance of the information cannot be inferred
Int_3-9	Challenge	The knowledge base is not sufficient	Some of the information is not in a structured form
Int_3-10	Development need	Customer care guidance / Service guidance	
Int_3-11	Lessons learned	The simple reasoning is already possible	
Int_3-12	Challenge	Solutions must be integrated as a natural part of the operation	Implementation is deficient
Int_3-13	Enabler	Utilizing existing information in a new way	Or making information available
Int_3-14	The nature of the solution	Decision Support Professional Support / No Medical Device	More challenging to implement requires work to improve data quality
Int_3-15	The nature of the solution	Clinical Decision Support / Medical Device	Feasible / Low-hanging fruit, Another cost-benefit if rare exceptions could be identified from the mass
Int_3-16	Enabler	Decision support reasoning rules exist and are available	
Int_3-17	Enabler	Knowledge capital is generally in good condition	
Int_3-18	Challenge	Implementing solutions is expensive and resource-intensive	It is worth implementing centrally
Int_3-19	Lessons learned	Clinical decision support systems already exist	
Int_3-20	Challenge	Lack of development resources and will	
Int_3-21	Development need	Supporting the professional in completing the process	With the help of automation
Int_3-22	Development need	Managing the overall situation with decision support	
Int_3-23	Challenge	It is difficult to agree on common approaches	
Int_3-24	Development need	Stimulants	
Int_3-25	Development need	Cost information displayed	
Int_3-26	Benefit	Effectiveness and cost savings through timeliness	
Int_3-27	Benefit	Decision support can improve the quality of data (storage)	
Int_3-28	Lessons learned	Semantic interpretation of text and meanings	
Int_3-29	Development need	Utilization of the meaning of information and metadata related to information	
Int_3-30	Challenge	Systems cannot record what is known	
Int_3-31	Observation	An open data model is a crucial factor in improving the quality of data	
Int_3-32	Challenge	Consideration of the needs for primary and secondary use of data in data storage	
Int_3-33	Observation	The moment of recording is essential for the further utilization of the data	

Int_3-34	Challenge	Application of different data models for different uses	Flashing
Int_3-35	Observation	Everyone should have equal access to decision-making support	Inequality this is not an organization-specific issue. Associated with Int_3-18
Int_3-36	Challenge	Lack of understanding by decision-makers	Development requires perseverance, and the entities are complex
Int_3-37	Challenge	Ability to place good orders	
Int_3-38	Enabler	Professionals want to be involved in the development	
Int_3-39	Observation	The role of the professional is changing. Decision support is not a threat but an opportunity	
Int_3-40	Benefit	Individual care / Personalization of the service	
Int_3-41	Enabler	Experimental culture and phased development	Let us learn what you learn
Int_3-42	Lessons learned	Solutions must be integrated as a natural part of the operation	
Int_3-43	Lessons learned	You need to be able to realize the benefits	For the target group and the language they use
Int_4-1	Perspective	Health care	
Int_4-2	Perspective	Information systems	
Int_4-3	Lessons learned	Duodecim decision support	
Int_4-4	Lessons learned	A local solution can develop into a national entity	
Int_4-5	Development need	Involving the client in their care	To provide information for the use of the service system
Int_4-6	Challenge	The solutions are fragmented	
Int_4-7	Challenge	Information is not available	
Int_4-8	Lessons learned	The simple reasoning is already possible	
Int_4-9	Development need	Customer care guidance / Service guidance	Long-term review
Int_4-10	Lessons learned	Solutions must be integrated as a natural part of the operation	
Int_4-11	Challenge	Screening is not possible	
Int_4-12	Observation	Incentives and simple decision support can even make things harder when there are too many stimuli	Logic must involve reasoning/intelligence
Int_4-13	Development need	Personalization/configuration of solutions organization or even per user	
Int_4-14	Development need	Supporting the professional in completing the process	Step automation
Int_4-15	Development need	Managing the overall situation with decision support	
Int_4-16	Benefit	Effectiveness and cost savings through timeliness	
Int_4-17	Lessons learned	Clinical decision support systems already exist	
Int_4-18	Challenge	Opposition by users if it feels that decision-making power or individual discretion is being taken away from a professional	The possibility of human encounters and professional judgment must be maintained
Int_4-19	Challenge	The knowledge base is not sufficient	Some information is not available in the form, and solutions are operator-specific. Not all information is available
Int_4-20	Enabler	Decision support reasoning rules exist and are available	
Int_4-21	Enabler	Knowledge capital is generally in good condition	
Int_4-22	Enabler	The importance of national services has been emphasized, and development has progressed	
Int_4-23	Challenge	Developing current systems is difficult	Inflexibility

Int_4-24	Challenge	Implementing solutions is expensive and resource-intensive	It is worth implementing centrally
Int_4-25	Enabler	Professionals want to be involved in the development	Offering different levels of opportunities to participate, not everyone wants to code
Int_4-26	Lessons learned	Share outputs, codes, and logic openly with others	
Int_4-27	Challenge	Liability issues, e.g., from the point of view of the Medical Devices Directive	
Int_4-28	Development need	From one-way and straightforward solutions to comprehensive value-added services	Links to, e.g. Int_3-14
Int_4-29	Development need	Managing the overall situation with decision support	Information for the entire service system to use and utilize
Int_5-1	Perspective	Specialist medical care	University-level specialist nursing
Int_5-2	Perspective	Health care	
Int_5-3	Perspective	Business development	
Int_5-4	Motivation	Involving customers in development / Customer needs guides development	
Int_5-5	Challenge	Development requires perseverance, and the entities are complex	You need to be able to realize the benefits
Int_5-6	Observation	Experimental culture and phased development	You need to be able to realize the benefits
Int_5-7	Benefit	Effectiveness and cost savings through timeliness	
Int_5-8	Development need	Managing the overall situation with decision support	No need to do away
Int_5-9	Enabler	Utilizing existing information in a new way	Or recovery at all
Int_5-10	Development need	Supporting the professional in completing the process	Step automation
Int_5-11	Development need	Stimulants	
Int_5-12	Benefit	Decision support could help accomplish several things during the same visit	
Int_5-13	Benefit	Decision support can help develop operations	
Int_5-14	Enabler	Decision support reasoning rules exist and are available	
Int_5-15	Enabler	Knowledge capital is generally in good condition	
Int_5-16	The nature of the solution	Decision Support Professional Support / No Medical Device	More challenging to implement requires work to improve data quality
Int_5-17	The nature of the solution	Clinical Decision Support / Medical Device	Feasible / Low-hanging fruit, Another cost-benefit if rare exceptions could be identified from the mass
Int_5-18	The nature of the solution	In clinical decision support, the setting of the question and the knowledge capital required for reasoning are more limited	
Int_5-19	Challenge	Development requires perseverance, and the entities are complex	PTH / non-clinical decision support
Int_5-20	Observation	Modeling complex problems difficult Modeling languages are poorly supported	
Int_5-21	Challenge	Lack of understanding by decision-makers	Managing development requires perseverance and comprehensiveness.
Int_5-22	Enabler	Gradual development, continuous improvement, and LEAN	
Int_5-23	Observation	Good leadership can overcome other challenges	

Int_5-24	Enabler	Decision support reasoning rules exist and are available	
Int_5-25	Enabler	Knowledge capital is generally in good condition	
Int_5-26	Challenge	The meaning of information is not understood, e.g., the need for structured recording or the implications for the use of the information	
Int_5-27	Challenge	Supplier Management	Ability to order and manage the information system ecosystem as a whole in collaboration with other customers
Int_5-28	Challenge	Cost containment does not happen through the ICT	You need to be able to realize the benefits
Int_5-29	Observation	The benefits are realized through changes in operations	
Int_5-30	Observation	User resistance is not a relevant aspect of clinical decision support because the masses of data covered are extensive and provide support for managing particularly demanding situations.	User opposition is more relevant than the administrative side, and the so-called On the side of lighter decision support
Int_5-31	Lessons learned	Industry-specific decision support systems have realized the potential of technology	Combining artificial and machine learning with decision support
Int_5-32	Lessons learned	Ethics is a challenging issue	Currently, the responsibility is for the professional, but what if the decision support has not brought all the options for the professional to evaluate?
Int_5-33	Observation	It is very challenging for a computer to assess personal factors and so-called soft values	The knowledge base is entirely inadequate for such reasoning
Int_6-1	Perspective	Social welfare	
Int_6-2	Perspective	Information systems	
Int_6-3	Motivation	Development of systems to apply national specifications and to allow further use of information	
Int_6-4	Enabler	The importance of national services has been emphasized, and development has progressed	
Int_6-5	Development need	Streamlining the administrative process	
Int_6-6	Development need	Supporting the professional in completing the process	Made possible by Int_6-4, visibility to the service system, and suggestions for applicable services/service paths
Int_6-7	Observation	User resistance is not necessarily a relevant issue	Things are complex, and the process is regulated. Helping a professional succeed
Int_6-8	Development need	Stimulants	Remind the professional to act on time and consider related issues
Int_6-9	Observation	Decision support is not known as a concept, and the possibilities may not be known	
Int_6-10	Challenge	Impact assessment is complex because there are many influencing factors and long periods	
Int_6-11	Challenge	Individual care / Personalization of the service	The need to face the customer as an individual
Int_6-12	The nature of the solution	Decision Support Professional Support / No Medical Device	
Int_6-13	Development need	Involving the client in their care	Service referral and service need assessment. Generating information during the service and



			monitoring the impact. Stimulants and indicators.
Int_6-14	Observation	Customer involvement would improve the transparency of the service	
Int_6-15	Development need	Information systems support data logging	All necessary (and only necessary) information is entered correctly and on time
Int_6-16	Challenge	Data fragmentation	Moreover, the difference in practices, although Int_6-4 will fix the situation shortly.
Int_6-17	Challenge	Lack of a common data model	Int_6-4 fixes the situation
Int_6-18	Challenge	Recording of information not in a structured form	
Int_6-19	Challenge	User opposition to the use of common data models	Requires intelligent information systems to support so that only the necessary information needs to be recorded
Int_6-20	Enabler	Training in new practices and unlocking benefits	
Int_6-21	Benefit	Assisting a professional in recording information	
Int_6-22	Observation	The progress of national development has also increased suppliers' understanding of the Information interoperability	
Int_6-23	Observation	Through the development of national services, regional knowledge capital can also be developed	
Int_6-24	Enabler	Through national development requirements and the strategic development needs of organizations, we are ready to invest in the development	In other words, entities that support decision-making, such as information management, etc.
Int_6-25	Lessons learned	Involving users in the development	Thus, for actual end-users, it helps to realize and perceive the benefits
Int_6-26	Lessons learned	You need to be able to realize the benefits	For the target group and the language they use
Int_6-27	Lessons learned	Let us do things in a nationally unified way	Finland is a small country!
Int_6-28	Challenge	It is difficult to agree on common approaches	
Int_6-29	Challenge	Development requires perseverance, and the entities are complex	The benefits must be able to be realized in stages
Int_6-30	Observation	Conceptual modeling and the creation of a common language are essential when developing across industry boundaries	
Int_7-1	Perspective	Specialist medical care	University-level specialist nursing
Int_7-2	Perspective	Health care	
Int_7-3	Perspective	Information management	
Int_7-4	Observation	Professionals are trained	
Int_7-5	Development need	The crucial role of information systems is to support the professional in performing the task	
Int_7-6	Development need	The operating methods must be uniform, as well as the production of information	
Int_7-7	Observation	The moment of recording is essential for the further utilization of the data	The context is then known
Int_7-8	Development need	All service system information is available	And the opportunity to take advantage of and combine this information
Int_7-9	Development need	Managing the overall situation with decision support	Based on all available information

Int_7-10	Development need	Supporting the professional in completing the process	On many different levels; Diagnosis, treatment plan, and, e.g., visualization of the situation in the department.
Int_7-11	Development need	Stimulants	Focusing the professional on the essentials
Int_7-12	Benefit	Decision support could help organize work	
Int_7-13	Enabler	Decision support reasoning rules exist and are available	Action cards
Int_7-14	Benefit	Monitoring the effectiveness of treatment on a rapid cycle	
Int_7-15	Challenge	Lack of uniform data models	Although the information is there and it is very challenging to use it
Int_7-16	Development need	The data should be stored in a fine-grained manner and based on a variety of vocabulary and terminology	
Int_7-17	Benefit	The data stored with a unified data model would enable further utilization and, e.g., research	
Int_7-18	Development need	Involving the client in their care	and data production
Int_7-19	Challenge	The solutions are fragmented	Information from the national or local transaction service is not available to the service system
Int_7-20	Benefit	Decision support could also provide support to the customer	
Int_7-21	Challenge	Data cannot be combined to form an overall picture	
Int_7-22	Benefit	Decision support could help streamline materials management and thereby reduce costs	
Int_7-23	Benefit	Business development	Harmonization of policies
Int_7-24	Benefit	Personalization of the service	Consideration of the needs of a professional, e.g., material orders
Int_7-25	Development need	Cost information displayed	
Int_7-26	Development need	Emphasis on critical factors	Strongly related to Int_7-10 and Int_7-11
Int_7-27	Enabler	Professionals want to be involved in the development	
Int_7-28	Observation	Conceptual modeling and the creation of a common language are essential when developing	
Int_7-29	Challenge	Development requires professionals so that the result meets the need, but professionals do not have the time to develop	
Int_7-30	Observation	Consensus-building is needed	80/20
Int_7-31	Challenge	They do not know how to use the systems	There is no training or no training
Int_7-32	Enabler	Agreeing on and committing to practices	Nationally and regionally
Int_7-33	Challenge	Development requires perseverance, and the entities are complex	
Int_7-34	Enabler	Gradual development, continuous improvement, and LEAN	
Int_7-35	Enabler	The broader whole allows for investment in development	
Int_7-36	Enabler	Sufficient simplicity	Too complicated not to use
Int_7-37	Enabler	Knowledge capital is generally in good condition	
Int_7-38	Development need	Information systems support data logging	All necessary (and only necessary) information is entered correctly and on time

Int_7-39	Lessons learned	The indicators used in nursing are an excellent example of professional support	Even if they were given intelligence, it would serve even better
Int_7-40	Development need	Managing the overall situation with decision support	
Int_7-41	Lessons learned	Development needs to be completed	Focus on realizing the benefits
Int_7-42	Lessons learned	You need to be able to realize the benefits	Lack of understanding among decision-makers Development requires perseverance, and the entities are complex
Int_7-43	Lessons learned	Industry-specific solutions will be introduced	
Int_7-44	Lessons learned	Cost information displayed	To motivate in recording information and, e.g., to complete the process
Int_7-45	Lessons learned	Through reporting, monitoring, and control	

## APPENDIX 5: DATA ANALYSIS CATEGORIES

Theme	Service area	Development focus	The nature of the solution	Category	Weight	Important	Value
Benefits	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Cost control	5		Effectiveness and cost savings through timeliness
Benefits	Specialized healthcare;	Information systems;	Clinical Decision Support	Cost control	1		The effectiveness of the treatment is improved, and through this, the costs are also reduced
Benefits	Specialized healthcare;	Information systems;	General Decision Support; Clinical Decision Support	Cost control	2		Decision support could help accomplish several things during the same visit
Benefits	Specialized healthcare; Healthcare;	Information management; Information systems;	General Decision Support; Clinical Decision Support	Customer orientation	2		Individual treatment for the client
Benefits	Specialized healthcare;	Information systems; Business/operations development	Clinical Decision Support	Operational support	2		A holistic view of the customer's situation
Benefits	Social welfare	Information management; Information systems;	General Decision Support;	Knowledge capital	1		Supporting induction and sharing tacit knowledge
Benefits	Healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Knowledge capital	3	x	Decision support can improve data quality, for example, by assisting a professional in recording information
Benefits	Specialized healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	3		Decision support helps to develop the organization's operations
Benefits	Specialized healthcare;	Information systems;	General Decision Support; Clinical Decision Support	Operational support	1		Decision support could help organize work
Benefits	Specialized healthcare;	Information systems;	General Decision Support; Clinical Decision Support	Operational support	1		Decision support could help streamline materials management
Benefits	Specialized healthcare;	Information systems;	Clinical Decision Support	Operational support	1		Patient safety is improved
Benefits	Specialized healthcare; Healthcare;	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	3	x	Personalization of the service
Challenges	Specialized healthcare;	Information systems;	Clinical Decision Support	Customer orientation	1		Utilization of customer-generated information as part of the care

Challenges	Healthcare; Social welfare	Information management; Information systems;	General Decision Support;	Development methods and models	3	x	User resistance
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Development methods and models	5		Development requires perseverance, and the entities are complex
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Development methods and models	3		Developing current systems is difficult
Challenges	Specialized healthcare; Healthcare;	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Development methods and models	3		The ability of decision-makers and organizations to perceive the impact of development and to commit to the development
Challenges	Specialized healthcare; Healthcare;	Information management; Information systems;	General Decision Support; Clinical Decision Support	Development methods and models	2		Implementing solutions is expensive and resource-intensive
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Development methods and models	3	x	Industry/service specificity of solutions
Challenges	Social welfare	Information systems;	General Decision Support;	Development methods and models	2	x	Impact assessment is complex because there are so many influencing factors and long periods
Challenges	Specialized healthcare;	Information systems;	Clinical Decision Support	Development methods and models	1		Professionals are needed to get involved in the development, but they do not have time for that
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Knowledge capital	3	x	Cannot record everything that is known
Challenges	Specialized healthcare; Healthcare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Knowledge capital	2		The data is not reliable, and the significance of the data cannot be inferred

Challenges	Social welfare	Information management; Information systems;	General Decision Support;	Knowledge capital	2	x	Data fragmentation
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Knowledge capital	3		Data aggregation is not possible (legislation, capabilities)
Challenges	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Knowledge capital	4		Lack of consistent and shared data models and terminology
Challenges	Specialized healthcare; Healthcare;	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	2		Solutions do not succeed in integrating into the natural part of the operation
Challenges	Specialized healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	2		The ability of suppliers to develop solutions based on operational needs
Challenges	Healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	2		It is difficult to agree on common approaches
Development needs	Specialized healthcare; Healthcare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Cost control	2	x	The cost-effectiveness of measures and decisions must be made visible
Development needs	Specialized healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support;	Customer orientation	5		The customer must be involved in their care and provide information for the use of the service system
Development needs	Specialized healthcare; Healthcare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Knowledge capital	2	x	All information in the service system must be available, and it must be able to be combined
Development needs	Specialized healthcare; Social welfare	Information systems;	General Decision Support; Clinical Decision Support	Operational support	2		Information systems should support professionals in entering data
Development needs	Social welfare	Information systems;	General Decision Support;	Operational support	2		It must be possible to observe the effects in different periods
Development needs	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Operational support	7		Supporting the professional in carrying out the processes

Development needs	Healthcare;	Information management; Information systems;	General Decision Support;	Operational support	2		It must be possible to support the guidance of the customer's care and services
Development needs	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Operational support	6		Notifications
Development needs	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Operational support	6		Management of the customer's overall situation with decision support
Enabler	Specialized healthcare; Healthcare	Information management; Information systems;	Clinical Decision Support	Development methods and models	3		Social and Healthcare Professionals want to be involved in the development
Enabler	Social welfare	Information systems;	General Decision Support;	Development methods and models	1	x	Through national development requirements and the needs of the strategic development of organizations, we are ready to invest in the development of decision support systems.
Enabler	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Development methods and models	3		The benefits must be realized in stages
Enabler	Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Development methods and models	1	x	Utilization of new and existing technology in other industries in the development of social and health care information management
Enabler	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Information management	4		Utilizing existing information in a new way
Enabler	Social welfare	Information systems;	General Decision Support;	Information management	1	x	National information system services support access to information
Enabler	Specialized healthcare; Healthcare	Information management; Information systems; Business/operations development	Clinical Decision Support	Knowledge capital	5		Inference rules for clinical decision support exist and are available

Enabler	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Knowledge capital	6		Knowledge capital is generally in good condition
Lessons learned	Specialized healthcare; Healthcare; Social welfare	Information management; Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Development methods and models	4		The benefits must be able to be concretized and realized
Lessons learned	Specialized healthcare; Social welfare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Development methods and models	3		Involving users in the development
Lessons learned	Specialized healthcare; Healthcare	Information management; Information systems;	General Decision Support; Clinical Decision Support	Operational support	2	x	Solutions must be integrated as a natural part of the operation
Lessons learned	Specialized healthcare;	Information systems; Business/operations development	General Decision Support; Clinical Decision Support	Principles and characteristics	1	x	Ethics is a challenging issue when developing decision support systems
Lessons learned	Healthcare;	Information systems;	Clinical Decision Support	Principles and characteristics	1		Sharing one's innovations and outputs freely with others brings added value
Lessons learned	Social welfare	Information systems;	General Decision Support;	Principles and characteristics	1	x	Let us do things in a nationally unified way
Lessons learned	Healthcare;	Information systems;	Clinical Decision Support	Principles and characteristics	3		Simple reasoning and decision support are already possible
Motivation							Comprehensiveness
Motivation							Complexity
Motivation							Individual treatment
Motivation							Customer orientation
Observation	Healthcare;	Information management; Information systems;	General Decision Support; Clinical Decision Support	Changing operating environment	3		The role of the professional is changing. Decision support is not a threat but an opportunity
Observation	Healthcare;	Information systems;	General Decision Support; Clinical Decision Support	Changing operating environment	1		Simple decision-support can even complicate work when there is too much information and notifications



[illegible]

Perspective							Information systems
Perspective							Business development
The nature of the solution							Supporting a professional in decision making and observation / Non-medical device
The nature of the solution							Clinical Decision Support / Medical Device

## APPENDIX 6: ORIGINAL INTERVIEW CITATIONS IN FINNISH

Int\_1-c1

Mutta sitten esimerkiksi semmoista päätöksenteon tukea kaivattaisiin, joka katsoisi esimerkiksi potilaan kokonaislääkityksen ja ehkä jollakin tavalla laajemmin sitä tilannetta. Ja sitten myös ne auttaisi lääkäriä prosessissa eteenpäin esimerkiksi niin, että jos tässä vaiheessa ei ehditä katsoa jotain asiaa, lähtisi siitä herätteitä tarkistettavaksi myöhemmässä vaiheessa hoitoprosessia.

Int\_2-c1

Kyllähän se päätöksen tuki on myöskin sitä, että järjestelmä osaisi kertoa mihin suuntaan pitää edetä.

Int\_2-c2

Meillä pitäisi pystyä tuomaan sitä näkökulmaa, että kannattaako nyt panostaa vaikka 100 € asiakkaaseen niin sitten se rupeaa tuomaan säästöjä myöhemmin. Jolloin ei enää menekään kuin joitain kymmeniä euroja asiakkaan palveluun myöhemmässä vaiheessa. Joskus kannattaa alkuun sijoittaa enemmän, jotta se hyöty tulee siellä vuosien ja vuosikymmenten aikana.

Ja niitä vaihtoehtoja pitäisi pystyä tuomaan näkyville, että jos nyt sijoitetaan vähän enemmän niin mitä se vaikuttaa pitkässä tähtäimessä.

Int\_6-c1

Jos nyt otetaan vaikka esimerkiksi, että meillä on vaikka kaksi päihdeongelmaisista henkilöä, joilla ulkoisesti näyttäisi, että tilanne on hyvin samankaltainen. Niin jos me annetaan heille täsmälleen samat interventiot, niin silti lopputulos voi olla täysin eri. Siinä on niin monta muuttujaa sen asiakkaan elämässä ja erilaisia mekanismeja, jotka vaikuttaa siihen.

Int\_5-c1

Kun kohdennetummin pystytään hoitamaan potilaita sen kautta, että päätöksentuki ohjaa ammattilaisen toimintaa. ... Siihen tai sitten niinku neuvolatoiminnassa esimerkiksi, että nythän meidän neuvolat aika pitkälti vielä perustuu siihen, että kaikki käy saman seulan läpi. Jonka jälkeen ammatillaiset arvioi sitten asiaa, niin siinäkin voitaisiin löytää hyötyjä sekä niille potilaille ja asiakkaille, että kohdennetummin tehtäisiin asioita ja se sitten säästäisi kaikkien ihmisten aikaa ja resursseja.

Int\_7-c1

Ja tietenkin kiristyvässä henkilöstö tilanteessa on tärkeä asia, että työtä voitaisiin organisoida tehokkaalla tavalla päätöksentuen ratkaisujen tukemana.

Int\_4-c1

Esimerkiksi niin, että jos hyödynnettäisiin ratkaisuja siten, että toimijat olisivat paremmin tietoisia toinen toisistaan ja ei tehtäisi päällekkäisiä asioita ja että asioita tehtäisiin optimaaliseen aikaan.

Int\_1-c2

Elikkä monelta kantilta kustannusnäkökulmat tulee huomioidavaksi ei pelkästään se että käynnit vähenee vaan sitten myös, että kokonaisvaltaisessa lääkityksessä onnistuttaisiin.

Int\_4-c2

Niin tuota hoitajien piirissä vähemmän, mutta lääkärikunnassa on jossain määrin vielä edelleenkin olemassa tämmöistä näkemystä, että lääketiede ei ole vain tiedettävä vaan aika paljon myös taidetta.

Int\_2-c3

Ja varmaan tulee monta kertaa nämä terveydenhuollon esimerkit mieleen missä robotti lukee silmäpohjakuvia nopeammin kuin ihmiset koskaan, niin voihan se tuntua että viedään päätösvalta pois.

Int\_6-c2

Ei varmastikaan juuri tunneta tätä käsitettä sinänsä (päätöksentuki)

Int\_2-c4

Terveydenhuollossa on tehty paljon hyvää teknologiaa ja sitä kannattaisi hyödyntää. Ja tietysti se, että sosiaalihuollon ammattilaiset myös tutustuisi niihin ratkaisuihin, jotta voisi esittää niitä toiveita sosiaalihuollon ratkaisujen kehittämisessä. Ja pitäisi uskaltaa ehkä luottaakin siihen, että nämä uudet teknologiset tai päätöksentuen ratkaisut ei vie sitä tiettyä yksilökohtaista päätösvaltaa pois vaan ratkaisut tehostaa ja tukee ammattilaisia.

Int\_5-c2

Tai se haastehan mikä tällä hetkellä kehittämiseen kohdistuu on, että kehittämisen sykli on sen verran hidas. Kun konkreettiset hyödyt tulee vasta pitkällä aikavälillä.

Int\_7\_c2

Sitten toinen asia vielä sitten kun tehdään sitä kehitystyötä, niin se on valtavan hidasta.

Int\_3-c2

Joo, minusta tästä puuttuu kaiken tärkein kohta eli päätöksentekijöiden ymmärryksen puute. Siitä seuraa ettei ole rahoitusta.

Int\_5-c3

No esitetyt on ihan hyviä näkökulmia, mutta siitä puuttuu kyllä minun mielestä kaikkein tärkein. Se on meidän kehittämisen johtamisen puutteet. Siitä, että millä tavalla meillä kehitystyötä tehdään. Millä tavalla se hahmotetaan osaksi kokonaisuutta ja miten ne asiat kehitetään loppuun saakka.

Int\_4-c3

Tämä tiedon yhteentoimivuus ja yhteismitallisuus on, kiitos valtakunnallisten tietojärjestelmäpalveluiden ja kansallisten arkkitehtuurimääritysten puolesta aika hyvässä tilanteessa. On samoja mittauksia, laboratoriotuloksia ja kuvauksia organisaatiosta riippumatta. Termit ovat myös aika yhteneväisiä.

Int\_7-c3

Meillä on tietyissä toimenpiteissä tämmöiset toimenpidekortit, johon määritellään mitä toimenpiteessä tarvitaan, joka auttaa sitten leikkaussalissa valmistautumaan siihen toimenpiteeseen.

Int\_1-c3

Esimerkiksi interaktiot eli näkee mitkä lääkitykset eivät sovi keskenänsä.

Int\_5-c3

Mitä tulee näihin pohja-aineistoihin ja vastaaviin niin algoritmejähän alkaa olla maailmalla jo paljon erilaisiin käyttötarkoituksiin. Mietitään vaikka nyt ihan yksinkertaisimpia kuvatunnistukseen liittyviä asioita, siis radiologiaa ja digitaalista patologiaa, erikoissairaanhoidon kontekstissa.

Int\_3-c3

Siis kliininen päätöksenteon tuki niin se on, miten mä nyt sanoisin, yksinkertaista. Tai siis se ei ole yksinkertaista, mutta se on tavallaan keksitty. Eli että se on merkittävä asia ja sitä, että sen implementaatio on vajavaista, mutta se itse asiana se ei vaadi mitään muuta kuin olemassa olevan datan hyödyntämistä ja sitten vähän palveluita, jotka osaa päätellä asioita datasta.

Int\_3-c4

Lääketieteellinen tutkimus on kaikista vajavaisuuksistaan huolimatta vanha perinne. Dataa on niin valtavasti, että se ei ikään kuin aiheuta tarvetta huokailla, koska se sisältö, joka on se iso juttu niin se on olemassa ja myös lähdedata on riittävällä tasolla, että niitä voisi hyödyntää. Mutta siis ihmisen avustuksella. Eli aina sitä tulosta pitää tulkita viime kädessä vielä lääketieteen ammattihenkilön. Näin on siksi, että kuitenkin data ei ole yksiselitteistä.

Int\_5\_c4

Tämä on tietyllä tavalla standardi toimintaa ja sitten tullaankin seuraavaan kohtaan eli tiedon yhteentoimivuus ja yhteismitallisuus on iso ongelma. Ja lähinnä tässä varmastikin on tällä hetkellä se kaikkein suuri haaste siinä, että ei ymmärretä mikä rakenteisen kirjaamisen ja tiedon yhteismitallisuuden merkitys on siinä, että pystytään ottamaan seuraavia askeleita tiedon hyödyntämisessä.

Int\_2-c5

Ja silloin jos meillä on openEHR siellä taustalla tai mitä muuta tahansa tukevaa teknologiaa, niin myös saadaan omissa tietovarastoissa tietoja yhdistettyä ja tuotua hyötykäyttöön.

Int\_1-c4

Ja nyt sitten olen vuosia yrittänyt niin, että me saatais tämmöistä data-analyysia tehtyä. Meillä on dataa potilaan lääkityksestä, me tiedetään mitä datasta pitäisi katsoa ja sitten meillä on tietokantoja mihin dataa pitäisi verrata.

Int\_2-c6

Sitten toinen, mikä minun mielestä on hankalaa järjestelmätoimittajilta niin he markkinoi järjestelmiä terveydenhuoltoa tai vanhusten palveluita varten. Ikääntyvien palvelut ovat teema, joka saa rahaa kehittämiseen. Monet vanhuksille suunnatut hyvät teknologiat toimisi ihan yhtähyvin lapsiperheidenkin käyttöön.

Int\_6-c3

En nyt ole itse kauheen tekninen ihminen, mutta voisin kuvitella, että kun tieto tullaan tallentamaan valtakunnallisiin tietojärjestelmäpalveluihin yhteismitallisesti niin siinä samalla helpottuu myös paikallistasolla tiedon hyödyntäminen ja käsitteleminen. Esimerkiksi kehittämisessä ja raportoinnissa.

Int\_3-c5

Mutta se on pääasia, että se tallennus hetki on kriittinen hetki datan jatko hyödyntämisessä koska silloin määritellään mitä se tieto tarkoittaa. Joka myös on sen päätöksenteon tuen se kaikkein vaikein kohta.

Int\_7-c4

Koska se laatuhan muodostuu kun tieto rekisteröidään ensimmäisen kerran Se mitä sinne tietojärjestelmään syötetään niin sitähan sieltä saadaan ulos. Ja se on oikeastaan myöskin peruste sille, että tai itse ajattelen näin, että se on myöskin peruste sille, että niitä tietoja voidaan käyttää tämmöisen päätöksenteon tukena.

Int\_3-c6

Minusta se on erikoinen ajatus, ettei se ole itsestään selvää, että kaikki päätöksenteon tuki pitäisi mennä samalla periaatteella kaikille asiakkaan kohtaaville. Eikä niin että asiakkaan palvelu jotenkin riippuisi siitä, että onko sillä organisaatiolla, missä hän juuri saa palvelua, ollut varaa hankkia sitä päätöksenteon tukea.

Int\_6-c4

Ja sitten se, että kun sitä kehitystyötä tehdään niin se tieto kehittämisestä ja datan hyödyntämisestä palautuu myös työntekijöille. Esimerkiksi se päätöksenteon tukijärjestelmä voi olla johtoportaan käytössä, mutta tästä ei tule tietoa tiedon rekisteröijille, jolloin motivaatio laadukkaan datan keräämiseen saattaa laskea. Tämmöiset ratkaisut tulee hyvin kalliiksi. Jotenkin tuntuu, että se mitä tässä on itse ollut kehittämässä, niin aina kun on työntekijät mukana, niin silloin ollaan päästy parempiin tuloksiin.

Int\_4-c4

Kliinikoita on monenlaisia, mutta on varmasti niitä käyttäjiä, jotka haluavat olla mukana tekemässä ja kehittämässä. Esimerkiksi päätöksenteontuessa niin tuota siinä voisi olla mukana mahdollisuus osallistaa ammattilaisia tekemiseen eri tasoilla. Voisi olla tämmönen aloittelevan ammattilaisen versio ja sitten kehittyneemmän ammattilaisen versio, jotka toisi asioita eri tavalla esille ja mahdollistaisi osallistamisen.

Int\_6-c5

No hyvänä puolena ilman muuta se, että Suomen kokoisessa maassa on varmasti järkevää tehdä yhteistä ja yhdenmukaista tiedohallintaa sosiaalihuollossa. Näin saadaan vertailtavaa tietoa ja saadaan sitä tietopohjaa kehitettyä sosiaalihuollon kehittämiseksi ja niin edelleen.

Se on ilman muuta tosi hieno asia. Ja myös et, että pystytään kehittämään myös sitä edelleen. Jos nyt ajatellaan Kanta-palveluja niin sosiaalihuoltoon tulee OmaKanta, että asiakkaat pääsee myös itse näkemään omia sosiaalihuollon tietojaan. Se on todella hienoa edistystä.

## APPENDIX 7: QUALITATIVE SURVEY OPEN-ENDED ANSWERS TO QUESTIONS 8, 9, 10 AND 11

### 8. Evaluate the key benefits of openEHR in developing DSS?

- Rich domain models that solve the "curly braces" problem of clinical decision support and data availability and standardization through an open platform
- OpenEHR has the opportunity to provide unambiguous standardized harmonized data to be used by a CDSS
- the clinical models and query language. Independent from clinical units, easily scalable and flexible.
- Standardize data models in archetypes/templates as well as terminology bindings 2. Provide formal language such GDL/GDL2 to express clinical rules and practice guidelines 3. Encourage standard-based platform approach and plug-n-play style of integration instead of monolithic solutions
- The ability to find the appropriate information in the patient's health record.

### 9. Highlight key features or functions of openEHR that support DSS development?

- Guideline Definition Language, Archetype Query Language, Archetypes and Reference Model
- The Archetypes are understandable and relatively easy to explain and discuss with clinicians.
- Guideline related tools, query language
- GDL/GDL2 design specifications for DSS development, as well as its implementation documented here, <https://cds-apps.com/guides-and-tutorials/> 2. 597 published open source clinical models, <https://github.com/gdl-lang/common-clinical-models> 3. Community activities, <https://cds-apps.com/cds-app-challenge-2020/>
- There are specifications of how to build the semantics in the health record and decision support rules.

### 10. Describe shortly the optimal development path of openEHR-based DSS?

- Starting with implementing archetypes as widely as possible while providing a few good examples on how the data can be reused for cdss, research, quality registries etc
- Find a good use case that's clinically relevant, with existing national/international guidelines, with participation from clinical users 2. Implement the CDS with existing design/tools such as GDL2 tools, deploy it along side with a GP/EHR system as a pilot to evaluate the result 3. Measure the outcome in terms of time saving, user satisfaction, and even clinical outcomes (clinical trials settings) 4. Roll out the CDS application and start post-market surveillance process (required by EU MDR) 5. Start from no.1 and repeat the process
- It depends on the local prerequisites.

### 11. If you answered to question 8 (Assess which Actors will benefit most from the use of openEHR in the development of decision support?), briefly describe why / how the actor you placed first benefits from openEHR?



-- Clinicians, developers and vendors benefit from a good collaboration on a domain driven approach: GDL provides a flexible framework and Archetype allow for expert driven modelling. This way, clinicians can actively engage and vendors can provide scalable and extensible software.

-- Clinicians may have the benefit from better documentation practices.

-- DSS is most relevant for clinicians as current day's guidelines are changing and newer protocols being developed.

-- It's important to keep in mind, openEHR is not the only informatics standard that will benefit CDS/CDSS development. In general, any major informatics standards in EHR (openEHR or HL7 FHIR) and terminology standards such as ICD-10, ATC, SNOMED CT will have positive effects on adoption of CDSS. For instance, CDS-hooks/Smart APP launch framework are widely adopted and implemented by major EHR vendors, thus will significantly reduce the integration barriers for CDSS applications in the market.

-- All kinds of development must primarily be for the users.

## APPENDIX 8: CDSS CHALLENGES

Challenge category	Challenge	Description
<b>Utilization of CDSS</b>	Human-computer interface	The human-computer interface must not interfere with the performance of the clinical workflow with excessive alarms or inactivity. However, it must be able to highlight the essentials and issues that require attention. [3, 5, 6, 7]
	CDSS usability	CDSSs can be complex to use, and there is no time to learn how to use them, leading to systems being considered inefficient and unnecessary. [1, 3, 6, 7]
	The CDSS system supports solving wrong issues	CDSSs more often focus on limiting the number of diagnostic hypotheses than helping professionals with diagnosis and care planning where support would be needed. [1]
	User distrust of CDSS	CDSS can result in incorrect recommendations or warnings due to incorrect inputs or programming errors. This causes mistrust in the system and can lead to treatment errors.[1, 3, 7]
	Excessive reliance on CDSS	Users may become overly dependent on alerts and reminders generated by CDSS that they neglect to use their critical thinking skills and sound clinical judgment. [1, 3, 6, 7]
<b>CDSS development</b>	CDSS development and deployment are time-consuming and expensive	The solution must be developed consistently to a sufficient level in terms of knowledge capital and reasoning rules to make the whole useful from a clinician's perspective. Often, this development is slow and requires gradual and prioritized progress to realize the benefits. It is worth investing in developing knowledge capital and knowledge base so that the benefits of development can be realized independently of technology. [1, 5, 6]
	CDSS development and deployment are complex	The development of CDSS requires the parallel development of knowledge and technologies. [1, 4]
	Creating new CDSS interventions and algorithms is difficult	Large data sets are needed to create new interventions and algorithms, and it must be possible to infer or learn through the extraction of these. There are also many technical and social challenges associated with extensive data. [1, 5]
	CDSS maintenance	Maintaining the technological base and knowledge base of CDSS is an essential but often neglected part of the CDSS life cycle as technology, and medical practices evolve. [2, 6, 7]
	Competition between clinicians	While some competition between clinicians in developing clinical decision support may be beneficial, too much competition can severely hamper development and lead to poor relationships between clinicians. [4]
	Lack of expertise	The lack of competence is manifested in the substantive competence of system designers in health care, which may manifest as an inability to define comprehensive reasoning rules. Ignorance of clinical work professionals may also occur, primarily because there is no unified medical theory available. [1]
<b>Architecture and technical Design</b>	Reliability of computers	Computers, like all technology, can sometimes fail, posing a risk to CDSS availability. [4]
	There is no common architecture to develop and share CDS modules and services	There are no standardized policies or architectures for distributing CDSS modules and developing services. The definitions of the data capital (data models) required by the CDSS and the interface standards also vary from industry to industry. [2, 3, 4, 5, 6]
	Specialized CDSSs	Most CDSSs often specialize in a particular field of medicine, which may require the use of multiple differentiated CDSSs. This also limits the applicability of the solutions in supporting more comprehensive care settings. [1, 4, 6]
	Lack of structured medical knowledge	For a CDSS to work correctly, it must understand the significance of its processing information. [1, 2, 3]
	Formal diversity of knowledge	The information generated in social and health care is diverse in data types and representation formats. The significance of the information generated in the different service areas of the industry may not be inferred according to the same logic. [1, 2]

	Technology focus	CDSS development is very technology-intensive, leading to an excessive focus on technological issues instead of solving user problems. [1, 4]
	Integration with health information systems and clinical workflow	CDSS systems are often designed as stand-alone systems, in some cases, even without interfaces to electronic health records. For this reason, redundant data collection or user interface transitions are required, which may interfere with the routine use of CDSS. [1, 2, 6, 8]
<b>Reasoning and complexity</b>	Inability to explain recommendations and learn from experience	CDSS cannot justify things, and it can be difficult for a professional to check why and how a particular conclusion has been reached. Systems are also typically unable to learn or develop inference rules automatically. [1, 4]
	As knowledge capital expands, reasoning becomes more difficult	As the amount of data and sources processed by CDSS expands, performance deteriorates significantly. The ability of the solution to identify relevant information is also significantly hampered. [1, 6]
	It is difficult to understand the effects of time	The ability of CDSS to understand the effects of time on disease processes is complicated. [1, 5]
	Summarizing patient-level data	The CDSS must be able to provide an intelligent and rapid summary of a patient's treatment history and current situation, allowing for a more detailed analysis based on professional decisions. [5]
	Filtering and prioritizing recommendations	Computer systems cannot solve or even identify their inability to solve a problem outside their knowledge base. The CDSS should be able to provide helpful information to the current patient, taking into account available and inferred information, without causing alert fatigue to the professional. [5]
	Consideration of co-morbidities	The CDSS must be able to address co-morbidities and medications by eliminating recommendations that are either unnecessary or disruptive to the patient's overall care. [2, 5]
	Utilizing free text in clinical decision support	Even today, much of the patient data is free text, and this text can contain very relevant information that is difficult or even impossible to utilize in CDSS. [5]
<b>Regulation</b>	Fragmentation of regulation	The CDSS legal framework is challenging because it is affected by medical and IT regulations and no uniform international law is applicable. [1]
	Liability issues	Liability issues in the case of CDSS are very challenging because of the nature of the CDSS (service or product). Defining the responsibilities of a CDSS manufacturer, the organization that utilizes it, and a professional can also be challenging from a regulatory perspective. [1, 7]
<b>Ethics</b>	Acceptability of the use of CDSS	The crucial ethical question is whether the use of CDSS is acceptable in the midst of scientific uncertainty. It is not always clear whether a better diagnosis improves the quality of care and, on the other hand, whether the use of CDSS reduces the risk of error. [1, 2]
	CDSS misuse	CDSS can be misused for purposes other than those for which it was intended, or it can be used without adequate training. This can lead to many problems. CDSS cannot wholly replace people in decision-making. [1, 2, 7]
	The role of CDSS in the care relationship	The relationship between the professional and the patient is personal and confidential. The CDSS changes this relationship and raises the question of who and at what stage the conclusions generated by the CDSS should be made available. In addition, the role of CDSS in joint decision-making may become too important, especially as patient support decision-making services develop. [1, 2, 3]
	Best practices are not openly shared	Although many successes have been achieved in designing, developing, and implementing clinical decision support, best practices are generally not widely available. Sharing best practices would greatly benefit the further research and development of CDSS. [2, 5]
	Inference rules for clinical decision support are not available to everyone	All the rules for reasoning in support of a decision must be freely and formally available to all so that healthcare organizations and professionals do not have to reinvent their own rules and that there is no inequality of care. [2, 5]

1) Alther & Reddy 2015. 2) Berner et al. 2016. 3) Castillo & Kelemen 2013. 4) Engle 1992. 5) Sittig et al. 2008. 6) Sutton et al. 2020. 7) Varonen et al. 2006. 8) Wulff et al. 2018.

## APPENDIX 9: LEGISLATION ON ELECTRONIC DATA MANAGEMENT

TABLE 1. Title (Pentikäinen et al. 2019, 75-77)

Law / Degree	Description
Data Protection Act 2018/1050	The Data Protection Act complements the EU's general data protection regulation.
General Data Protection Regulation	Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on protecting individuals concerning personal data processing and the free movement of such data and repealing Directive 95/46 / EC (General Data Protection Regulation).
Act on the Electronic Processing of Social and Health Care Customer Data 2021/784	The Act promotes and enables the secure processing of customer data produced by social and health care organizations and well-being data produced by the customer to organize and provide health and social services. It also promotes the customer's access to information about the processing of their customer data.
Decree of the Ministry of Social Affairs and Health on national health information system services 2015/1257	Regulates the patient data stored in the national archive service and other critical patient health and medical data to be stored.
Act on Electronic Services and Communication in the Public Sector 2003/13	The Act regulates the originality and integrity of electronically archived documents and the rights, obligations, and responsibilities of the authorities and their customers in electronic transactions. The law aims to increase the flow of transactions and information security by promoting electronic data transmission methods.
Act on Social Welfare Customer Documents 2015/254	Regulates the recording and processing of social care customer data. The purpose of the law is to implement uniform procedures for processing information about a social care client and thus promote the performance of social care tasks.
Act on Electronic Prescription 2007/61	Regulates the processing of electronic prescriptions and the patient's right to information. The law provides for a nationwide recipe center and archive maintained by Kela.
Decree of the Ministry of Social Affairs and Health on the electronic prescription 2008/485	Regulates the criteria to be taken into account when prescribing medicines and the content and form of the prescription.
Act on Strong Electronic Identification and Electronic Trust Services 617/2009	The Act regulates electronic identification and signatures and the provision of related services.
Act on National Personal Registers of Health Care 556/1989	The Act regulates the confidentiality of personal data stored in national health care registers.
Act on Joint Administration Support Services for Electronic Transactions 571/2016	The Act regulates the common administrative support services for electronic transactions and their requirements.
Decree on the Openness of Government Activities and on Good Practice in Information Management 1030/1999	The decree defines the reports necessary to implement reasonable information management practice, the implementation and promotion of information access rights, and the state administration's communication.
Act on Information Management in Public Administration 906/2019	The Act regulates the uniform and high-quality management and secure processing of public authorities' data. In addition, it enables the safe and efficient utilization of data and promotes the interoperability of information systems and data resources.

Decree of the Ministry of Social Affairs and Health on patient records 298/2009	The Act regulates the patient records, care information, patient document and log entries, and their processing and retention times.
Act on the Secondary Use of Social and Health Information 552/2019	The Act regulates the efficient and secure processing and combination of social and health care customer data in secondary use.
Act on the Provision of Digital Services 306/2019	The purpose of the law is to promote the availability, security, and accessibility of digital services. The law implements the Accessibility Directive (EU) 2016/2102 set by the European Parliament and the Council.

## APPENDIX 10: DEVELOPMENT GOALS OF A HEALTH AND SOCIAL SERVICES INFORMATION MANAGEMENT ENVIRONMENT

TABLE 1. The main goals of Prime Minister Sanna Marin's government program to develop a health and social information management environment (Finnish Government 2019)

Theme	Objective	Measures
Globally influential Finland	An economically sustainable EU as the world's most competitive economic area	Finland will promote a digitalization policy for the EU that will regulate transnational platform services.
		Finland will contribute to drafting an ethically, economically, and socially sustainable regulatory framework for data and AI policy.
Safe and secure Finland built on the rule of law	Equality, non-discrimination, and equal implementation of rights to be strengthened	We will improve the accessibility of e-services.
	Democracy, participation, and trust in the institutions of society to be strengthened	The Government will monitor the social equality impacts of artificial intelligence.
		The preservation and reliability of information stored in digital format will be ensured.
Dynamic and thriving Finland	Finland, relying on its value-centric image, will provide solutions to global development challenges	Flexible and extensive use of healthcare and social welfare data will be encouraged while guaranteeing data protection rights.
		Information policy and efforts to further the use of digital services and technologies will also consider SMEs' scope to seize new opportunities via open interfaces.
	Finland will be known as a front runner in technological advances, innovative procurement, and the culture of experimentation	A programme will be put together to promote digitalization and a requirement for public services to be available digitally to individuals and businesses by 2023.
		A strategy and an action plan will be prepared to open up and utilize public sector data, considering the impact of data protection regulations and any legislative needs.
		Data sharing between companies and entrepreneurs within ecosystems will be promoted.
		The scope for individuals to manage personal information on themselves held in public services will be secured following the MyData principles.
		Digital systems will be developed together with partner countries such as the other Nordic countries and Estonia.
		Experiments and test platforms will be consistently promoted in collaboration with municipalities.
Fair, equal, and inclusive Finland	Improving healthcare and social welfare services	The development of multi-professional Health and social services centres will take advantage of digitalization.
		Services will be made more client-centered by increasing the availability of services on behalf of digital and mobile service solutions.
		We will ensure more efficient use of information resources and further develop information systems.
	Restructuring of health and social services	We will need well-functioning information systems and data management systems, a comprehensive knowledge base, and a uniform reporting system to restructure health and social services.
		To develop and improve the quality of services, we will harmonize the knowledge base in healthcare and social welfare.

Governance	Best public administration in the world	The Government will add depth to the management of information policy. The openness of public information will become the overarching principle of information policy, prioritizing open source software and laying down an obligation to utilize open interfaces.
		The Government will continue resolutely the earlier efforts to open up public information resources.
		The citizens' rights to digital data and privacy protection will be strengthened.