Democratizing health data semantics
A commons-based technology-enhanced activity space to support productive work with health data semantics

by
Mate Bestek

B.Sc., Faculty of Computer Science, University of Ljubljana, 2007

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Abstract in English
This work has two main objectives: (1) to improve the understanding of semantic interoperability issues in healthcare and (2) to find possible solutions to these issues. Several research projects focusing on semantic interoperability support the work to achieve these goals. Semantic interoperability problems are caused by value conflicts between different stakeholders in the health care system over semantic resources that define the meaning of data. These conflicting values cause containment, which is the dominant business model in healthcare. For this purpose, data is not available where it is needed. In turn, this results in a significant power asymmetry with regard to semantic resources that are locked up in different systems. Furthermore, this power asymmetry causes problems in the management of health data.

This thesis proposes a solution for this chain of effects of semantic interoperability in the form of a work practice for productive work on semantic resources. Ideas from participatory design and co-design support the work practice—specifically, technology-enhanced activity spaces as an approach to solving different value concepts of the participants. In addition, the work practice uses OpenEHR's detailed clinical modelling approach to create semantic resources. The theory from the Commons studies supports a governance model of the work practice that is independent of state and the market. The specification of such a work practice is considered a formalization innovation.

This work leads to an interesting innovation that has the potential to help solve semantic interoperability problems or at least provide enough knowledge to improve their understanding. Thus, both goals of the work have been achieved.

Abstract in Danish
Dette arbejde har to hovedmål: (1) at forbedre forståelsen af semantiske interoperabilitetsproblemer i sundhedsvæsenet og (2) at finde mulige løsninger på disse spørgsmål.

Flere forskningsprojekter med fokus på semantisk interoperabilitet understøtter arbejdet med at nå disse mål. Semantiske interoperabilitetsproblemer er forårsaget af værdikonflikter mellem forskellige interessenter i sundhedssystemet over semantiske ressourcer, der definerer betydningen af data. Disse modstridende værdier forårsager inde slutning, som er den dominerende forretningsmodel inden for sundhedsvæsenet. Til dette formål er data ikke tilgængelige, hvor det er nødvendigt. Til gengæld resulterer dette i en betydelig magtasymetri med hensyn til semantiske ressourcer, der er låst i forskellige systemer. Desuden forårsager denne magtasymetri problemer i styringen af sundhedsdata.

Denne afhandling foreslår en løsning på denne kæde af effekter af semantisk interoperabilitet i form af en arbejdspraksis for produktivt arbejde med semantiske ressourcer. Ideer fra deltagende design og co-design understøtter arbejdspraksis — specifikt teknologiforbedrede aktivitetsrum som en tilgang til løsning af deltagernes forskellige værdikoncepter. Derudover bruger arbejdspraksis OpenEHRs detaljerede kliniske modelleringsmetode til at skabe semantiske ressourcer. Teorien fra Commons-studierne understøtter en styringsmodel for arbejdspraksis, der er uafhængig af stat og marked. Specifikationen af en sådan arbejdspraksis betragtes som en formalisering innovation.

Dette arbejde fører til en interessant innovation, der har potentialet til at hjælpe med at løse semantiske interoperabilitetsproblemer i kæden af effekter eller i det mindste give tilstrækkelig viden til at forbedre deres forståelse. Således opnås begge mål for arbejdet.
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## Abbreviations

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<td>ADR</td>
<td>Action Design Research</td>
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<tr>
<td>AI</td>
<td>Artificial intelligence</td>
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<td>AQL</td>
<td>Archetypes Query Language</td>
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<td>AR</td>
<td>Action Research</td>
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<td>BCT</td>
<td>Behaviour Change Techniques</td>
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<td>BPMN2</td>
<td>Business Process Management Notation version 2</td>
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<td>BPR</td>
<td>Business Process Redesign</td>
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<td>CAS</td>
<td>Complex Adaptive System</td>
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<td>CBPP</td>
<td>Commons-based peer production</td>
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<tr>
<td>CDA</td>
<td>HL7 Clinical Document Architecture Standard</td>
</tr>
<tr>
<td>CINDI</td>
<td>Countrywide Integrated Noncommunicable Diseases Intervention</td>
</tr>
<tr>
<td>CND</td>
<td>Chronic non-communicable diseases</td>
</tr>
<tr>
<td>DCM</td>
<td>Detailed Clinical Modelling</td>
</tr>
<tr>
<td>DHI</td>
<td>Digital Health Intervention</td>
</tr>
<tr>
<td>DSR</td>
<td>Design Science Research</td>
</tr>
<tr>
<td>EC</td>
<td>The European Commission</td>
</tr>
<tr>
<td>eHDSI</td>
<td>European Commission eHealth Digital Service Infrastructure</td>
</tr>
<tr>
<td>eHealth</td>
<td>Electronic Health</td>
</tr>
<tr>
<td>eHMSEG</td>
<td>Member States eHealth Expert Group</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>EPR</td>
<td>Electronic Patient Record</td>
</tr>
<tr>
<td>EU28</td>
<td>28 Countries that are used as a sample in different policy proposal research</td>
</tr>
<tr>
<td>GST</td>
<td>General Systems Theory</td>
</tr>
<tr>
<td>HCI</td>
<td>Human-Computer Interaction</td>
</tr>
<tr>
<td>HIS</td>
<td>Hospital information system</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level 7</td>
</tr>
<tr>
<td>HL7 RIM</td>
<td>HL7 Reference Information Model</td>
</tr>
<tr>
<td>ICD</td>
<td>International Classification of Diseases is used by healthcare organizations to code diseases. This is usually needed for the purpose of billing.</td>
</tr>
<tr>
<td>ICT</td>
<td>Information Communication Technology</td>
</tr>
<tr>
<td>ID</td>
<td>Interaction Design</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating the Healthcare Environment</td>
</tr>
<tr>
<td>IoM</td>
<td>US Institute of Medicine</td>
</tr>
<tr>
<td>IoT</td>
<td>Internet of things</td>
</tr>
<tr>
<td>KE</td>
<td>Knowledge Engineering</td>
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<tr>
<td>KLC</td>
<td>Knowledge life cycle theory</td>
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<tr>
<td>LHS</td>
<td>Learning Health System</td>
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<tr>
<td>LoHS</td>
<td>Levels of Health Systems</td>
</tr>
<tr>
<td>LTER</td>
<td>Long term ecological research</td>
</tr>
<tr>
<td>mHealth</td>
<td>Mobile health</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NHIF</td>
<td>National Health Insurance Fund</td>
</tr>
<tr>
<td>NIPH</td>
<td>National Institute of Public Health</td>
</tr>
<tr>
<td>OCDR</td>
<td>OpenEHR-based clinical data repository</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>OSI</td>
<td>Open Systems Interconnect</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Clinical Trial</td>
</tr>
<tr>
<td>SECO</td>
<td>Software ecosystem</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>SNOMED</td>
<td>Originally defined as Systematized Nomenclature of Medicine but today seen as a brand name rather than an acronym</td>
</tr>
<tr>
<td>SNOMED CT</td>
<td>SNOMED Clinical Terms</td>
</tr>
<tr>
<td>TDS</td>
<td>Technology development stages of the typical healthcare innovation process.</td>
</tr>
<tr>
<td>TEAS</td>
<td>Technology Enhanced Activity Space</td>
</tr>
<tr>
<td>UCD</td>
<td>User-Centred Design</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>XML</td>
<td>eXtensible Markup Language</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Action Design Research</td>
<td>A method proposed in [1] as research done by performing inseparable intertwined activities in order to design an artifact, intervene in the organization, and evaluate the artifact at the same time.</td>
</tr>
<tr>
<td>Big Data</td>
<td>A concept depicting vast amount of data that is mostly unstructured in nature to suggest learning from such data by means of machine learning and AI methods.</td>
</tr>
<tr>
<td>Complex Adaptive Systems</td>
<td>Weichert, Guedria and Nauder in [2] define them as systems that consist of networks of interacting agents that gather, process, and provide information needed to support smart decision making.</td>
</tr>
<tr>
<td>Digital Health</td>
<td>Defined by WHO and used in e.g. [3]: the use of digital, mobile and wireless technologies to support the achievement of health objectives. Digital health describes the general use of ICT for health and is inclusive of both mHealth and eHealth.</td>
</tr>
<tr>
<td>Digital transformation</td>
<td>See in [4] as an examination on how the public sector uses ICTs to enhance service delivery, change organizational processes and culture, as well as its impact on value creation.</td>
</tr>
<tr>
<td>Distributed organizational knowledge base</td>
<td>Contains all the knowledge available in an organization. It includes both technology and people as sources. Information systems support access to such databases.</td>
</tr>
<tr>
<td>Electronic Health Record</td>
<td>The life-long medical record of a patient that spans healthcare providers, regions and even countries</td>
</tr>
<tr>
<td>Electronic Patient Record</td>
<td>Defined by Hanseth et al. in [5] as systems used to specify, routinize, and uniformize the type and format of clinical information to be collected, and support coordination and cooperation between departments, professions, medical specialties and hospitals.</td>
</tr>
<tr>
<td>General Systems Theory</td>
<td>Represents the basis of system science. It is based on the observation and modelling of biological systems and provides a general framework facilitating communication between disciplines.</td>
</tr>
<tr>
<td>Healthcare delivery process</td>
<td>The core process in healthcare that is in charge of treating patients. It is often described as care delivery.</td>
</tr>
<tr>
<td>Interoperability</td>
<td>Interoperability can be supported only by “gaining a more concrete understanding of process, rules, objects, software systems, cultural, knowledge, service, social networks, electronic identity, cloud, and ecosystems interoperability issues.”[6]</td>
</tr>
<tr>
<td>Knowledge life cycle theory</td>
<td>Based on CAS and supports knowledge management and organizational learning as</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Learning Health System</td>
<td>Represents an alignment of science, informatics, incentives, and culture</td>
</tr>
<tr>
<td></td>
<td>“for continuous improvement and innovation, with best practices</td>
</tr>
<tr>
<td></td>
<td>seamlessly embedded in the care process, patients and families active</td>
</tr>
<tr>
<td></td>
<td>participants in all elements, and new knowledge captured as an</td>
</tr>
<tr>
<td></td>
<td>integral by-product of the care experience” [7].</td>
</tr>
<tr>
<td>Mobile technologies</td>
<td>In healthcare known also as mHealth.</td>
</tr>
<tr>
<td>Patchwork</td>
<td>A term used by Ellingsen and Monteiro in [8] to depict a continuous set</td>
</tr>
<tr>
<td></td>
<td>of independent incremental changes of interdependent and heterogenous</td>
</tr>
<tr>
<td></td>
<td>health information systems.</td>
</tr>
<tr>
<td>Platform</td>
<td>In this thesis the platform means digital platforms, technological</td>
</tr>
<tr>
<td></td>
<td>platforms, software platforms or any other synonym that revolves around</td>
</tr>
<tr>
<td></td>
<td>a central technical product that enables extension from the third parties.</td>
</tr>
<tr>
<td>Socio-technical systems</td>
<td>Systems that include technology and people.</td>
</tr>
</tbody>
</table>
1. Introduction

The focus of this thesis is on interoperability in health care. However, as interoperability can only be supported by "a more concrete understanding of the interoperability of processes, rules, objects, software systems, culture, knowledge, services, social networks, electronic identity, clouds and ecosystems" as proposed by Graham, Jacques, Ford and Colombi, this seems to be a very complex undertaking. Nevertheless, I have attempted to address this complexity through action, research and learning in the context of healthcare.

This work is an accumulation of knowledge and experience from ten years during which I have participated in many projects in Slovenia and abroad - both as a designer of artefacts (e.g., digital health interventions, software platforms) and as a researcher. In these roles, I have acted and researched in specific contexts ranging from a small GP practise to the national and international ecosystems of electronic health (eHealth) enabled by technological platforms. This research can therefore be placed in the Action Design Research (ADR) tradition.

Furthermore, the gradual evolution towards ecosystems supported by technological platforms led me to consider the concept of software ecosystems (SECO) to better understand the organisation of software development projects in which I myself have been involved and to conceive of the whole research as a SECO development. In this context, it seemed important to me to learn more about evolution, platforms and institutions of the health system in order to (1) better understand my research and (2) draw lessons for the future.

To talk about SECO evolution, I use terminology for evolving artefacts introduced in Section 3.2.1. Technological platforms, which are considered as enablers of SECOs in this thesis, are such artefacts that play an important role in the overall SECO evolution and can be used to better understand SECO evolution by highlighting several general requirements for successful artefact evolution within SECOs. In addition, the lens of evolving artefacts is also used in this thesis to draw lessons in the form of informed recommendations about SECO evolution in Section 12.2.1 that may be useful for future use.

Within SECO evolution, another process related to technological platforms is important in this work. It is the process that supports the long-term establishment of platforms, known as generative entrenchment which is presented in Section 3.2.3. Its application additionally helps to understand the evolution of technological platforms and the general evolution of SECO by highlighting some of the prerequisites for the successful establishment of platforms. Such analysis additionally contributes to the informed recommendations on the development of SECOs in Section 12.2.1.

SECOs can be seen as an approach to developing software within ecosystems that encompass many different stakeholders. In this thesis, the ecosystem considered is the Slovenian health system and health systems as ecosystems in general. Health systems traditionally include many different stakeholders and are often controlled by the state and its institutions. In order to better understand the influence of these institutions on innovation in the health system and thus on the development of SECO, where innovation takes place, I use the institutional theory presented in Section 3.2.2. This analysis also contributes to the informed recommendations about SECO's development in Section 12.2.1.

Within this health ecosystem development supported by the technological platform, I have focused on interoperability. The main reason for my interest in healthcare
interoperability was triggered in 2009 when I learned first-hand how far behind the healthcare sector was in digital transformation. Despite all the advice not to get into healthcare and the inherent complexity of interoperability [6], my intrinsic motivation was much stronger. Perhaps I was naïve, but I saw healthcare as the only industry where my work with technology could have a positive impact on people's health.

I see this work as an important step towards a better understanding of healthcare, healthcare interoperability and semantic interoperability within the emergent process of SECO evolution. To this end, I have tried to use concepts and theories from different scientific fields to explain, learn and potentially address the different complexities. Some concepts are seen as primary, others only as supportive. It all started with health systems and their sustainability problems.

1.1 Health systems sustainability issues and the digital transformation

Changing demographics, increasing demand, fragmentation of services, lack of resources and inefficient management have resulted in current health systems being unsustainable [9]. The global coronavirus pandemic shows what the collapse of health systems means. When demand grows too fast, no health system can cope. Beds and other medical equipment become a scarce resource. Despite all the progress that has been made in the world, no health system is yet prepared for a pandemic. However, as we learn in Section 2, the efficiency and effectiveness of health systems are far from optimal even without pandemics. Various strategies from international bodies such as the OECD [10] and EC [11] were all presented well before the pandemic and share the common goal of helping countries address sustainability problems in their health systems. Although the health sector invests many resources in innovative technologies, it is also one of the last industries to focus on improving its efficiency and effectiveness through the adoption of digital technologies. This transformation process is known as the digital transformation of healthcare. It is recognised by the World Economic Forum as a global phenomenon that includes digital technologies such as artificial intelligence (AI), mobile technologies (mHealth), big data and the Internet of Things (IoT) [12]. These technologies are being used in various innovations to support digital health interventions (DHI) that address different healthcare needs.

1.2 Need for guidelines on DHI design, evaluation and implementation

The introduction and use of DHI is not happening as planned. The lack of guidelines on how this should be done is perhaps part of the problem. For example, in 2019, Kowatsch et al. proposed an approach that can help with design and evaluation [13]. However, several problems related to the design, evaluation and implementation of DHI have been reported in the literature.

Incomplete design of DHI is the first problem that contributes to the low uptake and implementation of DHI in practise. To illustrate this, I use an example of DHI for ageing in place from Hillcoat-Nalletamby et al [14]. The focus of ageing-in-place DHI is on supporting older patients at home. Such DHIs can affect not only the patient or care provider, but also local, regional, national and in some cases global concerns, as raised by Grönvall and Lundberg [15]. They point out that the introduction of DHI into patients' homes may in some cases require improvements in the reliability of services from electricity, water, internet and other providers [15]. In addition, having patients undergo medical procedures at home may have implications for sawing and waste disposal, which is not adequate as in hospitals. It is then clear that the environment can be negatively affected. This requires a change in regulation at national and global levels, which then mandates changed regulatory frameworks and standards. Therefore, the
impact of DHI can be seen as a complex chain of effects through which the impact spreads in the environment where DHI is adopted and used. The most important point here is that we should consider such chains of effects already in the design and development of DHI.

With regard to the evaluation of DHI, Guo, Ashrafian, Ghafur et al. have recently called for new approaches to the evaluation of DHI to provide credible evidence that is critical for the adoption and implementation of DHI [16]. What credible evidence this might be is nicely illustrated by Murray et al. using several research questions that a DHI evaluation should answer [17]. These include questions such as the definition of the problem and the likely benefits of the DHI, the likely reach and acceptability of the intervention, the causal model that describes how the intervention achieves the intended benefits, the key components of the DHI and how they interact with each other, and the estimation of the overall benefits in terms of effectiveness, cost-effectiveness and harm. The evaluation of DHI has already been identified as problematic by Moxey et al [18], O'Sullivan et al. [19] and Shaw et al. [20]. Existing evaluation approaches do not seem to support the "fail fast, fail often" mantra of the start-up world, which perhaps helps to understand why start-ups are not so keen to work in the health system, as Szijarto suggested using Austria as an example [21].

In addition to the problems in designing and evaluating DHI, some barriers to implementation should also be considered. These have been divided, for example, into person-related, process-related and object-related barriers [21].

- **Person-related barriers** include barriers for patients (social support, social interaction, individual characteristics, personal resources, ease of use, patient expectations), healthcare providers (social interaction, individual characteristics, negative associations with technology use, ease of use and individual resources), cultural and disease-related barriers (e.g. culturally inappropriate communication, special requirements for group therapy).
- **Process-related barriers** include healthcare barriers (integration into existing workflows, workforce), standards and guidelines, legal barriers (regulatory issues, responsibilities), financial barriers (funding, costs, reimbursement, benefits), organisational barriers (accessibility, workforce, collaboration, planning) and methodological barriers (lack of clinical evaluation, evidence of cost-effectiveness, lack of reliability).
- **Object-related barriers** include technological barriers (outcome expectations - lack of functionality, usability, interoperability, human technical support, regional infrastructure), as non-interoperable and difficult-to-use technologies hinder the development and implementation of a DHI, in this case a telemedicine DHI [21].

To better understand how to plan for the implementation of DHI, we need to consider health systems as complex adaptive systems (CAS). CAS suggest that it is inherently difficult to predict the behaviour of CAS systems because they consist of a large number of actors - or stakeholders - with an even larger number of different collaborations between them. As the many actors constantly adapt to cope with reality, new collaborations and behaviours emerge. These characteristics are part of all these systems, which we call ecosystems in reference to nature. In context of implementing DHI, agents of such health ecosystems could, we argue, become more involved if DHI development would be organized differently – as SECOs. As we already noted, SECOs
can be seen as an approach to developing software within ecosystems that encompass many different stakeholders.

Health systems generally function at three levels - the micro, meso and macro levels of health systems (LoHS), as introduced by Valentijn [22]. The micro level is where patient care takes place. The meso level represents the different health organisations and their collaboration, and the macro level represents the regional or national decision-making organisations and activities.

Designing DHI without being aware of the context in which a DHI is to be implemented means that little attention is paid to the culture in the health systems and how the culture can support the transformation so that it can adapt and implement DHI. For clarity, we see a culture where internal chains of action occur, which depend on people's values, beliefs and attitudes.

In addressing the external chains of impact that are evident in the case of age-related DHI, systems thinking can help, while design thinking and design research methods can help in adapting to the existing culture (see also the methods Section 6). In my view, digital transformation encompasses a variety of DHI. Therefore, it is crucial to see digital transformation as a cultural transformation that needs to take into account all the different and often contradictory values, beliefs and attitudes of the many actors in healthcare. An example of such contradictions is evaluation as an evidence-gathering activity, which is not part of the traditional technology start-up mentality but is crucial for the adoption and implementation of DHI. Another example is semantic interoperability in healthcare, where software companies and healthcare professionals have inherently different value systems, beliefs and attitudes towards data sharing. In order to address such issues with value systems, this thesis considers technology-enhanced activity spaces (TEAS) that together with SECOs represent two main components of the main result of this thesis.

1.3 Semantic interoperability effect chain and the Research Questions

This thesis is also concerned with the design, development, evaluation and implementation of DHI. The entire research began with the design and development of a DHI to support people with depression. We observed positive clinical outcomes for patients and were also able to consider such a service to be economically sustainable. Our next goal was therefore to design and develop a platform that would support multiple such DHIs. As we considered healthcare as an ecosystem, we wanted DHIs to be able to become part of an ecosystem where data, information and knowledge flow to where they are needed and when they are needed. To achieve this, we were motivated to create DHIs that were interoperable by design. At the time, it was clear that most new DHIs, which deal with many different health-related issues, were not designed to be interoperable. Instead, they were and are built to create more and more isolated solutions that work on the basis of information and data locks and therefore do not promote exchange - also known as data liquidity. With the plethora of solutions from the last century, such as electronic patient records (EPR) and hospital information systems (HIS), which already cause significant problems in the health sector because they are not interoperable, the same mistakes are repeated again and again.

This is understandable to a certain extent, because interoperability in general and semantic interoperability in particular are so-called cross-cutting issues. This means that they are not usually dealt with in time-limited projects or programmes - or in focused products like the DHI. However, semantic interoperability is a crucial issue that needs to be addressed globally if the digital transformation of healthcare is to be considered a real option [12].
In this thesis I explore impact chains associated with semantic interoperability while working on the design, development, evaluation and implementation of DHI. As we have learned, interoperability is one of the hurdles in the DHI implementation process. To overcome this obstacle, I have focused on interoperability in the DHI design phase of all projects. This focus is embodied in the principle of ‘interoperability by design’. In order to always have clarity about the DHI lifecycle stage, I use established terminology from the field of healthcare innovation. In particular, Technology Development Stages (TDS) presents such lifecycle stages from design to broad implementation. Throughout the research process, I followed the principle of interoperability by design, which allowed me to (1) improve my understanding of semantic interoperability issues in healthcare and (2) search for possible solutions to the problems encountered. In pursuing these goals, I have tried to find a way to influence and change the chain of effects of semantic interoperability that leads to the current situation of interoperability in healthcare.

The impact chain of semantic interoperability in the health sector
The impact chain of semantic interoperability I am interested in begins with the conflicting values of healthcare stakeholders that prevent overarching concerns such as semantic interoperability from being achieved. Health professionals need data at the point of care. Patients bring data with them when they are treated using different applications and other technologies. Most data today is stored in data repositories provided by different private companies within different healthcare information systems. The companies do not disclose how they encode and store the data, suggesting hidden definitions of the meaning of the data. These definitions are referred to here as semantic resources (for examples, see paper 5 in Section 11). Data without the semantic resources that define the meaning of the data makes the data inherently useless and lost. We can see this in EPRs and other systems in healthcare. In these systems, the data and its semantics are locked into these systems and only the company can understand it. Moreover, data sharing is not supported in a sustainable way. The cost of integration is not sustainable and often not even fully possible because the data structures and other semantic artefacts are not harmonised and interoperable. Such integrations represent small incremental changes to different subsystems that are not well coordinated. The result is a highly complex information infrastructure (information infrastructure as the shared resources that make all the work possible), also called patchwork by Ellingsen, that is difficult to change and even more difficult to replace because the installed base, as we call this patchwork, becomes a force in its own right and consolidates its position [8].

We say that companies have values that are at odds with the values of health professionals, patients and many other stakeholders in the health system. Companies strive for profit, while doctors and patients strive for health. These different values of healthcare stakeholders are a major reason why interoperability in healthcare is still not sufficiently addressed. Data is not available when it is needed and it does not flow where it should [23]. User-centred data is not available anytime, anywhere [24]. Conflicting stakeholder values about semantic resources lead to an asymmetry of power at the administrative level. Every time data needs to be retrieved, the company has to prepare the data. Unfortunately, such business models based on lock-in or information blocking are prevalent in the health sector.
Since healthcare stakeholders are highly dependent on companies, this results in their power over the data being less than the companies' power over the data, which is constantly increasing due to the nature of the data. The more complex the data, the more connected and dependent the healthcare actors are on the companies. Because healthcare data is highly complex and becoming more complex every day, companies are difficult to replace. From the perspective of healthcare professionals, these companies become a weak installed base of the overall healthcare information infrastructure. On the contrary, the companies see themselves as successful in securing long-term revenue streams. Figure 1 shows a schematic representation of the described basic principles of semantic interoperability on which this thesis is based.

![Figure 1: A schematic depiction of the rationale about semantic interoperability behind this thesis.](image)

Based on the scheme in Figure 1, I have extracted the focus of this work. It is shown in Figure 2 as the semantic interoperability chain of effects, which I tried to understand and ultimately change.
To achieve the main objectives of this thesis within the chain of effects shown in Figure 2, I consider (1) several previous projects in which I participated between 2009 and 2019, (2) my published research, particularly that contained in this thesis, and (3) the literature. With these sources, I attempt to substantiate the answers to my research questions. It is important to note here that the research questions were never defined in advance. Rather, my research began with a project called eCare, where I focused on the specific DHI design, development, evaluation and implementation. The DHI implementation was to be supported by a software platform, as this is known to support the creation of ecosystems where different providers can offer solutions to different end-users. Chapter 6 provides more details on the overall research process and methods used. Here we summarise the research questions that have developed over the different action design research cycles and focus on finding a work practice for productive work on semantic interoperability in healthcare. I consider this work practise to be the main outcome of this work. It represents a solution for semantic interoperability that focuses not only on the technical aspects of semantic interoperability, but more importantly on the organisational and social aspects that need to be considered for continuous work on semantic interoperability. In this thesis, literature on commons and commoning is explored in connection to these aspects.

I now present the research questions that help guide and understand the quest for the work practise.

**RQ1: What kind of new practice could support productive work on semantic interoperability in healthcare?**

I was particularly interested in how work on semantic interoperability issues could be supported in the development of DHI. A promising new approach in 2009 was OpenEHR as an approach to semantic interoperability in healthcare. It promised to
separate concerns between technical and clinical aspects of semantic interoperability. To explore OpenEHR in more detail, I define a sub-question of RQ1 as follows:

RQ1.1 Is OpenEHR a suitable approach for productive work on semantic interoperability in the health care sector?

In this thesis, we follow OpenEHR through a series of projects that together constitute a process described in the literature and presented in Section 2.3 using various concepts such as socio-technical transitions, infrastructuring, platformisation, software ecosystem evolution, spanning embedding process and perhaps others. In these projects, OpenEHR has been used for both bottom-up infrastructuring and top-down infrastructuring. The former include projects that focused on the technical development of DHI and the latter include projects that were national or international top-down activities focusing on standards. The crucial aspect is that both groups of projects aim to create ecosystems to foster the well-known network effects that support ecosystems and thus improve the adoption and use of DHI in the health sector. I use the concept of SECOs as a lens to view these projects from the technical, organisational and business perspectives of SECOs, all of which are represented in my research. Furthermore, I can view both sets of projects as a common SECO development, where two platforms are connected and support a common SECO or even an information infrastructure.

As OpenEHR is a completely different and new approach to infrastructuring in healthcare and thus to SECO evolution, my second research question seeks to capture the impact of OpenEHR on established practises within SECO evolution. The second research question is therefore defined as follows:

RQ2: What are the effects of such a new work practice on existing practices?

In the context of the development of SECO, I can only answer this research question to a limited extent. This is because I have only been able to focus on a few technical, organisational and business/administrative elements of SECO’s development. These include the use of OpenEHR in conjunction with the development of AI algorithms, DHI, software platforms (one focusing on the use of DHI and one focusing on national eHealth) and the ecosystems that support the platforms and which are discussed in the papers included in this thesis. These five elements also represent the main socio-technical transitions in the development of SECO. They represent the changes in the context in which one sociotechnical artefact is embedded in another broader artefact until they evolve into ecosystems. The second research question is therefore supported by the following sub-questions:

RQ2.1: How does OpenEHR influence the design and development of AI algorithms in healthcare?
RQ2.2: How does OpenEHR influence the design and development of digital health interventions?
RQ2.3: What influence does OpenEHR have on the design and development of software platforms?
RQ2.4: What impact does OpenEHR have on the design and development of national government-owned eHealth platforms and their ecosystems?
By pursuing the answer to RQ2, I can provide evidence of OpenEHR-based SECO evolution. As I have learned from working on the projects and consulting the relevant literature, OpenEHR has problems in doing so. The key point is that we have not been able to deliver on the promise of OpenEHR, which is to separate the technical and clinical aspects of technology development. I have learned that it is critical to create a multi-level governance structure to support OpenEHR's modelling activities - productive work on semantic interoperability. However, in my experience and also in the literature, it is difficult to create such organisations and to achieve participation and collaboration between medical and technical professionals.

To address this problem, I came across the literature on design approaches of participatory design and co-design. These approaches are closely coupled with what is called infrastructuring - the process of building information infrastructures - the shared resources that make any work possible. SECOs are also such resources. As I have observed in practise and learned from the literature, the governance of OpenEHR semantic resources has not been successful because neither the government nor the market has been able to create such governance structures to support the OpenEHR approach to semantic interoperability. I found a possible solution in the literature on the political theory of commons. Commons are a third approach to governance in which neither the market nor government play a central role. Commons have been successfully established and sustained in the past for different types of resources. To learn how commons might contribute to semantic interoperability, I posed the third research question to explore what impact commons might have on productive work on semantic interoperability. I defined the third research question as follows:

**RQ3: What are the implications of Commons theory when applied to the governance of semantic resources in the new work practice?**

By answering RQ3, I was able to complete the definition of the new work practice for productive work on semantic resources from an organisational and governance perspective.

The process of answering the three research questions is illustrated in Figure 3. As we can see, RQ1 is answered in parallel with RQ2 and RQ3, which are answered sequentially. We can also see how the published research findings and the informative context of the projects influence the three research questions. The reader should also take into consideration that the results in the bottom of Figure 3 are partially constructed in Section 12 based on the results from the papers included in the thesis. More details on this process is available in the methods Section 6.
Figure 3 How the published research papers (yellow rectangular shapes) and the informative context of the different projects (blue rectangular shapes) help support answering the three research questions.
In order to develop the answers to the above research questions, I have structured this thesis as follows:

In Section 2, we first deal with background information in order to get an overview of the current literature. In Section 2.1, we first learn about the complexity of the healthcare system, which is a constant source of implementation barriers to healthcare innovation. Then, in Section 2.2, we learn about DHIs as a specific type of healthcare innovation that plays a central role in this thesis. Several DHI development projects support this thesis. Finally, we focus on the core point of the thesis - the semantic interoperability effect chain. Several concepts are explored here, but many only play a supporting role in understanding how the chain of effects is related.

In Section 3, we learn about the main theoretical perspectives and concepts that are used in this work either for a better understanding of the context or as support for the results and answers to the research questions.

Section 4 introduces the context of this thesis. This includes an introduction to the Slovenian health system and the crucial problems it faces (Section 4.1). I then expand on the significance of these problems by presenting Europe-wide health system problems in Section 4.2. This makes my work accessible to a wider audience and improves its generalisability. In Section 4.3, I present the projects in which I have participated and which provide the micro-context of my research. This is where I gained my experience of impact chains in relation to OpenEHR and semantic interoperability.

Further on, Section 5 provides the interpretive context that cannot be directly observed in the published research, but which helps to better understand how the different projects and published research contribute to providing answers to the research questions.

Section 6 summarises the different methods used in this research and the overall process that led to the results of this thesis.

Sections 7, 8, 9, 10 and 11 are the published research included in this thesis.

In Section 12.1 I first present the results from the papers. Based on these I then develop key findings and results of the thesis in Section 12.2.

I conclude the thesis with Section 13 where I (1) answer the research questions, (2) discuss practical, methodological and theoretical implications of my findings, and (3) conclude the thesis and point to potential future work.

In this explorative process of searching for answers to the research questions, I was able to achieve both objectives of this thesis - to improve understanding of semantic interoperability issues, and to find solutions for some of these issues.
2. Background

In this chapter, we first learn about the complexities of the health system, as this is the context in which all the research was conducted. Since this thesis is based on several DHI development projects, here we learn more about DHI and the way they are characterised in this thesis. Finally, we focus on exploring the impact chain of semantic interoperability, as we need to learn more about it in order to try to change it and reap the benefits within healthcare SECOs.

2.1 The complexities of innovating in healthcare

Innovation in healthcare is a subfield of technology and innovation management that deals with healthcare services, management and innovation issues [25]. Innovation in health differs from its parent research area in that health is a highly complex and fast-moving field, with huge differences in the way health systems are organised, the challenges they face and the resources available to them. All health systems need innovation to provide the best possible care for as many people as possible with the resources available [25]. However, innovation in health differs from other sectors of the economy for several reasons, as illustrated in Figure 4: (1) the healthcare product is poorly defined, (2) the outcome of care is uncertain, (3) large parts of the industry are dominated by non-profit providers, (4) payments are made by third parties such as governments and private insurers [25]. All of these factors are also present in other industries, but they are not present in any other industry at the same time [25]. It is the interplay of these factors that makes healthcare so unique.
Figure 4 Crucial factors that make innovating in healthcare different and far more complex than in any other industry.

Further on, the core elements, depicted in Figure 5, that define a typical health system are (1) context, (2) values, (3) principles, (4) population, (5) service delivery, (6) resources, (7) leadership, (8) governance, (9) outcomes, and (10) goals, as defined by Van Olmen in his Health System Dynamics framework [26].
Figure 5 Health System Dynamics Framework [26] depicts the core elements of a typical health system and the relationships between them that form dynamic complexity and complex adaptive systems.

These core elements of a typical health system also function on three different levels, defined by Valentijn as micro, meso and macro [22]. At the micro level, everything revolves around the provision of health services. That is, this level is about healthcare professionals providing care. The meso level describes the organisational collaboration of professionals across the continuum of care. The macro level is about putting the needs of the population at the centre. The way in which micro, meso and macro levels are linked to ensure connectivity between the three levels is functional and normative integration [22], which is illustrated in Figure 6.
Micro, meso and macro levels [22] of a health system need to integrate through functional and normative integration.

Functional integration is about linking funding, information and management modalities to add the most value to the system [22]. Normative integration is about developing and maintaining a common frame of reference between organisations, professional groups and individuals [22]. Common frames of reference can be a shared mission, vision, values and culture.

Looking again at the core elements of health systems, as shown in Figure 5, and the three levels of a typical health system, as shown in Figure 6, we can see that there are a variety of relationships that interact with contextual factors, characteristics of health systems, institutions and the introducing bodies within those institutions to influence how receptive a health system is to innovation, as well as the speed and extent of adoption and diffusion [27], as shown in Figure 7.

Figure 6 Micro, meso and macro levels [22] of a health system need to integrate through functional and normative integration.

Figure 7 Core elements of health systems collectively communicate on and between different levels of health systems and with this influence how well a health system is receptive to innovations and the speed and scale of adoption and diffusion of innovations.
As such interactions cause dynamic complexity and form a complex adaptive system, systems thinking becomes essential for planning and introduction or implementation of innovations into health systems. Inadequately considered interventions often upset the equilibrium within complex systems to resist such interventions, leading to policy resistance [27].

Concerning DHIs implementation in such complex adaptive systems, several barriers have been identified in the literature. A review by Ross et al. [28] identified several such factors that have been categorised to established constructs in implementation science as follows:

- **innovation characteristics:**
  a. *adaptability* – DHIs that are more adaptable to fit the local context better seem to be better accepted and adopted. A crucial aspect of adaptability is interoperability. Many research reviewed in [28] presents a sound evidence base for the need of DHIs to be able to interface with other IT systems and exchange information. Lack of data standards is seen as a significant bottleneck, for example, in implementing EHRs.
  b. *complexity* – slow performance of systems, their problematic usage, many software modifications, articulation work needed to transfer records between systems, lack of real-time access, data handling, reliability, slow speed, unplanned downtime, and connectivity issues all influence implementation efforts and its success. Also, the review in [28] reports on issues with health professionals not being able to master the technology at hand. This suggests DHIs vendors need to design these systems to be user friendly by involving the users in the design and development of DHIs, provide guides for the use of DHIs and offer technical assistance.
  c. *cost* – cost related to purchasing and implementation of DHIs has been found in [28] as a problem in the majority of the reviewed studies. In some cases, financial incentives from governments and insurers have helped overcome the problem. However, the suggested strategy for overcoming cost issues are new business models and incentives.

- **outer setting:**
  a. *external policy and incentives* – inadequate legislation and policies, together with liability concerns, are seen as a barrier both for healthcare organisations and health professionals. Also, standards for provisioning DHIs would help reduce concerns about patient data safety and professional liability, and also help with the exchange of electronic health information between systems and organisations while maintaining data integrity. Strategies for overcoming these issues include incentives from the government and other external stakeholders. Financial incentives include initial funds to cover initial costs, financial sponsorship, reimbursement for adoption, and pay for performance initiatives [28].

- **inner setting** – implementation climate:
  a. *implementation climate* is the general *compatibility* of the DHIs with organisations. This mostly means how well the new DHIs fit existing workflows. Many times, DHIs do not fit with existing work practices or daily clinical work, and this then negatively influences the implementation of DHIs. Therefore, DHIs must not disrupt workflows
and how clinical care is practised. Instead, DHIs should positively influence work practice efficiency. For this, analysis of work practices should happen in the DHI design phase. By integrating the DHI into existing work/care practice, offering user-friendly DHIs, and by minimising workflow disruption in the implementation phase, we can achieve work practice efficiency. If a DHI brings new roles, responsibilities and working styles, this can also cause resistance as such changes can bring fear, dissatisfaction, and uncertainty to health professionals over such changes. Strategies to address these issues include careful project management that is aware of the effects of a DHI will have in the workflows, additional training, the adaptability of technology, and technical support.

b. In addition to compatibility, leadership engagement, that is, management support is needed for successful implementation efforts.

c. Also important is the availability of resources that support the implementation process such as electricity, internet, computers, and mobile phones. Also, enabling a grace period in which new and old ways can co-exist can help with a more successful implementation.

d. Access to knowledge and information about the benefits of DHIs are important factors also.

- individual characteristics:
  a. knowledge and beliefs – positive attitudes towards DHIs help the implementation succeed. These include beliefs that the new systems would benefit patients, interest in the technologies, and perceived usefulness and motivation in working with the systems. Strategies to overcome negative attitudes and beliefs foster a culture of communication and cooperation, involving users in design, development, and implementation, leadership, friendly and context-aware user interfaces, better education, clear communication of benefits, and realistic expectations for the DHIs. Also, attitude od colleagues and patients influenced staff attitudes regarding DHI acceptance. In general, the most reported issues for adopting and implementing DHIs are generally the fear over loss of autonomy, concerns about liability, patient privacy and security, and perceived threats to patient and health professional relationships.

- process:
  a. planning the implementation is needed, and this includes a clear definition of roles and responsibilities, securing time for system selection and procurement, evaluating policy and process change, needs assessment and analysis, development of a business plan, early identification and engagement of champions, involving end-users, establishing a guiding philosophy, development of incentive and innovation structures, communication of the strategy to all staff, development of protocols for using the system and for provision of training. Incremental implementation strategies where features are made available in small steps are preferred over all-at once top-down approaches within complex organisations. Also recognised was the need for additional effort after the initial go-live that happens in the maintenance phase of implementation.

- engaging:
a. designation of champions is considered a success factor for implementation
b. engagement of key stakeholders is crucial for the success of implementation through fostering a sense of ownership, confidence, acceptance, enjoyment and self-pride towards the DHI and increasing buy-in.

- reflecting and evaluating:
  a. evaluation is seen as essential to ensure system benefits, to increase health professional acceptance through demonstration of benefits and to secure ongoing funding, whereas a lack of evaluation and evidence may act as a barrier to implementation

Figure 8 summarises the recommendations on what to consider when planning DHI implementation in healthcare.

![Figure 8](image)

**Figure 8 What needs to be taken into consideration when implementing DHIs, based on a review by Ross et al. [28].**

The factors presented above represent the complexity of implementing DHIs of different types, for example, including ones that focus on chronic disease patients [29], routine healthcare [30], telemedicine [31] and EHRs [32]. The relationship between the different implementation strategies, implementation outcomes and degree of implementation success is, however, still a matter of active research, e.g. [29]. Despite the evident complexity of healthcare, matters have lately become even more complex due to the global coronavirus pandemic. It causes even more pressure on health systems globally by introducing new needs for patients with covid19 [33]. Also, the pandemic clearly shows many of the system-level problems typical health systems have that were not in the centre of attention of policymakers. Digital technology usage has now actually become crucial in many cases, e.g. patient-physician relationship has forcefully become remote [34]. Unfortunately, the actual consequences of the pandemic will be seen in years to come as health systems cannot operate as usually do. In such a
context, the resilience of health systems takes on an even more complex role and is undoubtedly to be even more in the spotlight of global activities.

2.2 Digital Health Interventions

Digital health interventions are a specific type of innovations or interventions that facilitate change and are supported by technology. Often, we label them with terms like digital health, connected health, ehealth, mhealth, telehealth and many more. I use a standard label for this class of interventions as is proposed by the World Health Organization (WHO) [35], namely, the digital health interventions. The DHIs are new services established by the interactions between a new tool, a team of, e.g. health care providers and other stakeholders, and newly established routines of service delivery [19]. DHIs, evolve through the intervention maturity lifecycle, as defined by WHO [3], from pre-pilot phase to, e.g. national implementation. In this thesis, I chose to use the more generic healthcare innovation evolution process – the TDSs.

As reported in this thesis, our past focus was on several patient conditions or diseases, that require behaviour change in order to achieve a better quality of care and life for the patient. Intervention protocols are a form of DHIs and are patient-centred protocols designed for digital interventions focusing on home care. Where the physician may not have direct access to the patient, the use of patient-centred protocols to monitor and empower the patient in their care process is critical [36]. Continuous control of disease involves the patient and the physician in a very coupled, dynamic and iterative flow in which the decisions of physicians and the responses of patients seem to be as crucial as the biomedical data gathered in the care process [36]. In this flow, personalisation, usability, and engagement are essential. Informing such protocols with behaviour change theory could yield better outcomes.

With ubiquitous computing supported environments, behaviour change can be induced by following two main approaches: top-down and bottom-up [37]. The top-down approach can be persuasive systems with carefully designed persuasive messages as the basis for inducing behaviour change. The bottom-up approach uses large-scale analysis of human behaviour. It can lead to engineered contexts for affecting behaviour at different resolutions ranging from the individual level (e.g., mobile platforms or smart homes) to urban level (e.g., carefully planned smart cities). These techniques become part of Information Communication Technologies (ICT) solutions through the process of mapping behaviour change techniques to technology. These mappings are frameworks and recommendations for adapting the techniques to computing specifics [38]. [39]–[45] provide examples of such frameworks. We can look at such approaches as theory nexus – using multiple theories in order to obtain a new artefact [46].

When we think of behaviour change and technology, many different research strands exist, e.g. captology [47], persuasive design, and behaviour change support systems [48]. Common to all is the transformation or mapping of behaviour change theories or other psychological knowledge into technology. A term to describe such technology is the behavioural intervention technology [49] and Mohr et al. [38] present an integrated conceptual and technological framework for DHIs where we can see an example of such a mapping.

In general, behaviour change interventions (seen here as being digital health interventions) have traditionally not been digital. However, as presented by Moller et al. [50], they are moving from analogue to digital. To support multiple digital
interventions, digital platforms are lately more and more considered as a viable approach. However, there are many identified challenges towards creating such a digital platform. Several such challenges for digital platforms that would support digital behaviour change interventions, are brought forward by Moller et al. [50].

First, the multi-component health interventions (digital and traditional) are complex, as these components include behaviour change techniques (BCTs; the potentially active ingredients of intervention) and different modes of delivery (e.g., design features of, e.g. smartphone apps or communication skills in face-to-face delivery). A challenge is also to learn about the interactions among these components in terms of identifying (1) which techniques are contributing to any effects observed and (2) the mechanisms of action of techniques contributing to the effects.

Second, the lack of evidence-based theories and technique specification applied to behaviour change interventions. There is a need for better specification of BCTs and underlying theory-based mechanisms. Suppose we do not know what the intervention consisted of. In that case, we are unable to investigate its mechanisms of action (i.e., theory defined concepts) and hence explain the effect and further improve the intervention. Even when interventions are well specified in terms of BCTs, the hypothesised mechanisms of action of those BCTs are frequently not stated.

Theory Coding Scheme [51] has been used to analyse existing interventions for their usage of theory derived concepts - mechanisms of action. However, an additional issue is that names of evidence-based theories, theory-derived mechanisms of action, and BCTs may be specified, but inappropriately operationalised.

Also, when using digital health platforms to support behaviour change interventions, Mohr, Cuijpers and Lehman have posited that self-monitoring and other BCTs may be more effective with the addition of particular forms of social support, specifically, when participants receive support from a coach who is trustworthy, benevolent, and has expertise (i.e., supportive accountability) [52]. The interventions presented in this thesis do also include such support.

Ahern assesses that “unfortunately, few studies provide sufficient information to ascertain the specific conceptual or theoretical bases for specific components of the programs” [53], but they cite only one study, namely [54].

In overall, there is evidence available that gives positive arguments in favour of including BCTs in the design phase of behaviour change DHIs in spite the shortage of prescriptive knowledge about how to exactly do the mapping between the mechanisms of action and the designed features of some digital solution.

The idea of using systems for motivating using user models is not new. Examples can be found from the 1980s onward as also presented [55]. Three known research fields develop complex cognitive models of users which include emotions, beliefs, motivation, and argumentation. Persuasive technology [56]–[58] – Human-Computer Interaction (HCI), Affective Computing focuses on the use, understanding, and modelling of emotions and affect in computer systems [59], and Argument and Computation which is interested in computational models and theories of argumentation and persuasion coming from Philosophy and Artificial Intelligence [60]. Further examples of work in these fields can be found in [61]–[64].
2.3 Semantic interoperability effect chain

Information sharing is part of information management, a critical element of the healthcare delivery process [65] or as Heard et al: "Healthcare is one of the very few areas where information sharing is the norm rather than the exception" [66]. Different information systems support the management of information in health care. By using information systems, organizations can access the distributed organizational knowledge bases that include not only technology but also people. Unfortunately, as Murdoch and Detsky point out, data managed in different information systems has traditionally been considered a by-product of service delivery [67]. This complicates access to the distributed knowledge base and influences the suboptimal efficiency of the care provided. Instead, data should become a core asset. However, in order to benefit from the use of data as a means of accessing the available knowledge and thus improve clinical decision making, clinical data must be structured. Unfortunately, as Murdoch and Detsky report, this is a major problem, as about 80% of healthcare data is unstructured [74].

To understand the relationships between (1) information systems and their support for (2) access to distributed knowledge bases, we will first explain the role of these two concepts. We will focus on one type of information system in particular, known as EHR or more broadly EPR. As far as access to the distributed organizational knowledge base is concerned, we will focus in detail on (3) interoperability as a prerequisite for such access. Interoperability, in particular (4) semantic interoperability, is also at the heart of this work, which we hope to achieve by using OpenEHR as an approach to structuring clinical data.

2.3.1 Electronic health/patient records

Although the health care system is highly dependent on information systems to carry out core processes such as the provision of care services, the reality is unfortunately very far from the ideal. As Ellingsen and Monteiro noted [8], the information systems that support health care can be seen as a patchwork – a series of interdependent and heterogeneous health information systems which are each the result of modular, incremental changes, without anyone being "responsible" for the whole [68]. Østerlund et al. give an even broader overview of the current situation with information systems which, in their view, are not only a patchwork of systems but also a patchwork of practices that are interrelated and intertwined [69].

In general, according to Hannah, Ball and Edwards, the information systems in healthcare environments fall into three main categories [65]. The first type is systems that are limited in objective and scope. Examples of such systems are laboratory, radiology or dietary information systems. The second type includes hospital information systems that consist of a communication network, a clinical component and a financial and administrative component. Such systems often focus on acute care and are organized around departmental functions.

The third type of information systems in healthcare environments are enterprise health information systems. Such enterprise health information systems have evolved into EHRs that are being established in many countries on a regional or national level and are also becoming cross-border systems between many countries. Such systems capture patient information across the entire continuum of care in health organizations that are using integrated healthcare delivery models. EHRs are focused on patients that receive
care in different integrated care settings and have one typical organizational structure – they are seen as single enterprises [65]. Based on the ISO definition of an integrated EHR, Garde et al. explicate four main characteristics of EHRs [70]. EHRs should be (1) patient-centred (one EHR relates to one patient), (2) longitudinal (birth to death record), (3) comprehensive (all care events are captured), and (4) prospective (EHRs include not only past events but also instructions, plans, and goals). The main benefits of EHRs depicted by Adel et al. are fast access to patient’s data, reduction of medical errors, enhancing healthcare quality, and chronic disease management [71]. In literature, EHRs are also described as large-scale EPRs [72]. Hanseth et al. see EPRs as systems used to specify, routinize, and uniformize the type and format of clinical information to be collected, and support coordination and cooperation between departments, professions, medical specialities and hospitals. EPRs can, therefore, be used by individual doctors, as a standard system in a clinical department, or as a shared and common system in an entire hospital or even among several hospitals [5]. Therefore, EPR and EHR are used interchangeably in this thesis, but the meaning is the one of EHRs – the life-long medical record of a patient that spans healthcare providers, regions and even countries but depends on obtaining information from the patchwork. EHRs as organizations can be understood better using theoretical underpinnings of systems science, particularly the general systems’ theory (GST) and CAS.

2.3.1.1 Systems view on EHRs
Enterprises are defined according to the GST as enterprise systems [73]. GST originates from works of von Bertalanffy and represents the basis of the systems science. GST is based on the observation and modelling of biological systems and provides a general framework facilitating communication between disciplines. In general, enterprise systems are independent but need to be able to collaborate at the same time functionally. Enterprise systems are defined as socio-technical systems where agents interact and are seen as a network of information gathering, information processing, and information providing systems supporting smart decision making [2]. Such networks of agents exhibit properties of CAS. Weichart, Guedria and Nauder describe CAS properties such as (1) active and independent agents that communicate between each other, (2) attractors as a means of indirect influence on other agents; for this, agents may be unpredictable, (3) non-linear relationships and feedback loops as agents are influenced by their environment, but at the same time they influence their environment which leads to time dependence and feedback loops, and (4) dynamism, co-evolution and emergence – agents evolve independently through time which leads to co-evolution; the non-linear and unpredictable relationships between agents can mean that the future state of the overall system may not be predicted – but is still not random [2]. It is said that the future state emerges through time. EHRs and EPRs [5] are an example of such CAS systems, and so are healthcare environments in general [74]–[76].

2.3.2 Accessing the distributed knowledge base
In healthcare and organizations in general, learning is seen as a prime way of enterprise networks to use information in order to evolve and meet their business demands [2]. The US Institute of Medicine defined a vision for future healthcare systems that is based on learning. The learning health system (LHS) represents an alignment of science, informatics, incentives, and culture “for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active
participants in all elements, and new knowledge captured as an integral by-product of the care experience” [7].

The knowledge life cycle theory (KLC) is based on CAS and supports knowledge management and organizational learning as crucial elements of the evolution of today’s organizations [2]. It provides management concepts and a framework for handling distributed knowledge and dynamic business environments [2]. As Weichart, Guedria and Nauder explain [2], the KLC suggests three main components of learning and management of knowledge that is stored in a distributed organizational knowledge base:

(1) the distributed Enterprise Information System - also suggests non-digital information,

(2) the business processing environment - local environment of agents where they perform their everyday tasks by observing their environment directly or using the data available in the information system. The agents then check if there is a match between the information and his beliefs (expected information). Then the agent can make decisions that lead to implementing actions in the environment, which can be observed again. In case an agent finds a mismatch between the expected information and information observed, then it can and often does find a local solution that aligns expected and observed information. Such small changes are known as single-loop learning which suggests learning is a routine task;

(3) the knowledge processing environment – becomes vital in more exceptional mismatches between observed and expected information. In such situations, the whole organization system is influenced, which includes several sub-systems. The whole organizational system or enterprise can become unstable due to the observed information being different from what the organizational system beliefs or expected information are. In order to tackle such problems, multiple perspectives are needed to find the underlying problem and find a solution. This is done in the knowledge-processing environment through the double-loop (suggest a focus on elements that are seen as stable in single-loop learning) learning process that changes knowledge in the distributed organizational knowledge base.

2.3.2.1 Interoperability as the basis for access to distributed organizational knowledge bases

The term distributed organizational knowledge base suggests that information and knowledge are held in many different systems, not a single system. In order to access such knowledge bases, the different information systems need to become interoperable. This means that both the minds of agents and all technical system elements that form the distributed organizational knowledge base need to be interoperable. This further means that information needs to be accessed and changed in both the business and knowledge processing environments, which suggests that data needs to be exchanged through interfaces between different system elements. As Brauenstein states, a learning health system requires interoperability [77]. Figure 9 summarizes the so far mentioned relationships and the central role of interoperability.
Figure 9 Interoperability as the core prerequisite to enable the future vision of learning health systems.

The approach towards creating interoperability solutions based on the CAS view, suggests bottom-up creation of interoperability solutions. For this, a robust technical infrastructure is needed to facilitate bottom-up engineering of interoperability solutions. The infrastructure needs to allow and support the creation of interoperability solutions within and between technical systems exchanging data, and organizational systems that are part of a typical business process.

There are many approaches to interoperability between technical systems, and also between social/organizational and technical systems [2]. Enterprise integration, interoperability and networking are disciplines studying collaborative, communicative enterprise systems [73]. Enterprise Modelling Techniques, Next Generation Computing Architectures and Socio-technical Platforms along with Semantic Interoperability approaches are essential pillars supporting the achievement of sustainable enterprise systems [73].

We will now present a more in-depth explanation of the concept of interoperability in order to understand it better and to be able to articulate different approaches to interoperability in a more precise way in order to specify the main focus of this thesis within interoperability more precisely.
2.3.3 Interoperability

Interoperability is positioned on a continuum between compatible systems and integrated systems. Interoperability refers to coexistence, autonomy and federated environments, whereas integration refers to the concepts of coordination and coherency [73]. For this, interoperability suggests more loose coupling in comparison to integration that suggests tightly coupled systems that are also functionally dependent. Functional collaboration between systems can primarily be supported through interoperability as here there is no functional dependency between systems. Compatible systems are even less coupled than interoperable systems.

Interoperability has been studied for several decades, mostly in the context of the enterprise, military, and software [78]. Ford et al. have surveyed the field of interoperability and have identified 34 different definitions of interoperability and 64 different interoperability types [79].

As previously note, interoperability can be supported only by “gaining a more concrete understanding of process, rules, objects, software systems, cultural, knowledge, service, social networks, electronic identity, cloud, and ecosystems interoperability issues” [6].

Weber and Kuziemsky discuss a very narrow definition of interoperability seeing it as a very technical one stating it as the ability of two or more systems or components to exchange information and to use the information that has been exchanged [80]. In such a view, interoperability involves standards, protocols, and integration and adaptation of interfaces to enable effective, efficient communication between systems [81].

Interoperability is a complex concept that can be defined in a broad sense as a pursuit of improving organizational and societal interactions between organizations, groups of users (citizens or businesses), municipalities, regions, or even nation-states [82]. Weber and Kuziemsky see interoperability in eHealth in the broad sense as a dynamically evolving socio-technical processes [80].

In the whole continuum of interoperability definition ranging from the narrow to very broad, it is essential to understand the different views of interoperability as presented by Rothenberg et al. [82].

These different views of interoperability include (1) dimensions, (2) layers, (3) scope, (4) targets, and (5) perspectives.

*Dimensions* view of interoperability includes Enterprise, Organizational, Semantic, Technical and Legal dimensions of interoperability [82]:

- **Enterprise Interoperability** denotes the alignment of missions, policies, and business processes.
- **Organizational Interoperability** denotes the ability of two or more organizations to interact with each other.
- **Semantic Interoperability** denotes the ability of entities to share information meaningfully and to engage in meaningful collaborative activities in order to perform collaborative business processes.
- **Technical Interoperability** denotes the ability of systems to exchange data, perform collaborative processing, synchronize transactions, and coordinate their interactions; the technical interoperability is often expressed as syntactic
or foundational interoperability (represents the data exchange format) and structural interoperability (agreed models of domain-specific concepts),

- Legal interoperability provides the legislative foundation for interoperability, for example, by providing compatible regulations concerning privacy and access control.

Although these dimensions interact with each other, the mechanisms that are appropriate to fostering interoperability in each dimension are quite different. Enterprise interoperability involves the ways that the missions, policies, and business processes of an enterprise interact with those of other enterprises. Organizational interoperability is a matter of organizational structure, culture, and procedure, which may be affected by oversight, legislation, reorganization, and inter-agency agreements. Semantic interoperability requires that business processes are analysed and potentially re-engineered to be consistent and compatible, that terminology and ontologies are harmonized, and that metadata is created. Technical interoperability requires that communication and interaction protocols are standardized, that processing and transaction mechanisms are implemented consistently across systems, and that wrappers or “adapters” are created to transform data and translate among different electronic service interfaces. Finally, legal interoperability involves the promotion of consistent legal policies and the possible creation of legislation to enable appropriate interoperation among organizations and enterprises.

The layers view on interoperability has been one of the first to emerge and includes the Open Systems Interconnect (OSI) model that defines seven layers: physical, data link, network, transport, session, presentation and application layer. These do map well to the different dimensions above. Crucial for the layers view on interoperability is that in order to talk about interoperability, each of the layers needs to be interoperable in order for the next layer also to be interoperable. This is also in line with the bottom-up approach to interoperability solutions in CAS environments such as healthcare [2], in order to achieve more than just data interoperability (service, process, business).

There are several known scopes in which interoperability may become required and include:

- G2G – Government-to-Government
- G2C – Government-to-Citizen
- G2B – Government-to-Business
- B2B – Business-to-Business
- B2C – Business-to-Citizen
- C2C – Citizen-to-Citizen

Each of these scopes suggests different requirements for interoperability. For example, the C2C scope interoperability suggests interoperability in the collaboration between citizens, e.g. patients, but that does not mean that it is also required to support interoperability between, e.g. hospitals. For this to happen, the scope should be B2B.

The target of an interoperability effort may be a specific nation, a group of nations (such as the EU), or organizations within a given sector (health, education, law enforcement). These different targets may have different functional needs, vocabularies, ontologies, and languages even within a given scope (such as G2C). Different targets have different interoperability implications in terms of linguistics, culture, and semantics.
Interoperability can be viewed from the perspective of various stakeholders, each of whom is likely to interpret interoperability quite differently.

As we can see, interoperability is a multi-dimensional concept which is usually out of the scope of particular projects. We say that interoperability is a cross-cutting concern that involves interaction with other projects and programs that are outside of the boundary of the given effort. Therefore, interoperability should be motivated with mechanisms that transcend normal project boundaries.

In order to interoperate meaningfully, organizations must have compatible data definitions and interpretations, terminology, business processes, organizational cultures, and policies concerning privacy, access, transparency, and accountability. Achieving true interoperability, therefore, requires the alignment of these semantics across all interacting organizations and their systems. Such alignment requires each organization, sector, and community of interest to define and codify its own semantics and to establish appropriate correspondences with the semantics of any other such entities with which it interacts. This, in turn, requires cross-organizational, cross-sector, and cross-community interaction and negotiation. Because this process is labour intensive and involves significant intellectual effort, it requires considerable lead time and so should be started as early as possible.

Interoperability being a cross-cutting concern means that it cuts across system boundaries and other considerations and for this, interoperability must therefore be [82]:

- Embodied in the conceptual design
- Reflected in system architecture
- Supported by infrastructure
- Designed-in to actual systems and components
- Considered in the context of:
  a. The purpose of, e.g. eGovernment and eServices
  b. Coordination of service provision
  c. Business process redesign (BPR)
  d. Governance
  e. Policy (openness, multilingualism)
  f. Security and information assurance
  g. Privacy and confidentiality
  h. Other cross-cutting concerns, including the quality of service “-ilities”
     (usability, reusability, reliability, scalability, flexibility, extensibility, accessibility)

The above requirements for interoperability make it clear that interoperability cannot be just added to systems after they are built but should be thought about in design-time.

Up until now, we have learned about the nature of healthcare environments as socio-technical CAS systems. In such environments, learning is seen as a prime way of enterprise networks to use information in order to evolve and meet their business demands. The KLC helps us understand how learning happens. Both CAS and KLC help us understand the importance of interoperability as a prerequisite to a distributed organizational knowledge database which suggests sharing of information is a prerequisite in order to be able to meet business demand. In healthcare, this is even
more true, as put nicely by Heard et al. [66] “Healthcare is one of the very few domains where sharing information is the norm, rather than the exception”.

Therefore, in order to be able to support sharing of information as part of information management in the health care delivery process, different systems that support access to the distributed organizational knowledge base, need to become interoperable.

We learned about the multiple views on interoperability like dimensions, layers, scopes, targets and user perspectives and have seen it is a cross-cutting concern that spans the boundaries of traditional projects or programs and for this requires a different kind of motivation. In addition, interoperability needs to be tackled early on, in design-time. Otherwise, it is not possible to just add it when systems are already implemented. This is crucial to consider when building new systems.

2.3.3.1 Articulation work, Data work

As we have already noted, the healthcare environments are typically supported by many different information systems like EPRs. Not only that these systems are not interoperable, but they also appear to be designed to mimic paper forms and provide little support for the cognitive tasks of clinicians or the workflow of the people who must actually use the systems, as noted by Braunstein [77]. As a consequence, multiple integrations are implemented between different information systems. This has resulted in a state of play depicted nicely by Ellingsen and Monteiro as a patchwork [8]. Ellingsen and Monteiro stress an essential point that integrations are not always seamless; they are not adding value [8]. In some cases, integrating different professional groups brings more work for them. The different professional groups should be allowed to have different perspectives in order to support communication, collaboration, and coordination [8]. The work of Ash et al. brought forward the errors which occur because such different perspectives and the nature of work are not considered enough while designing information systems in healthcare [83]. Ash et al. categorize these errors into two groups, namely, (1) errors that occur during the process of entering and retrieving information, and (2) errors that occur in the communication and coordination process that information systems should support. These errors occur because information technologies are not fit well to medical work practices and so their generative power, as brought forward by Berg, is worse than expected [84]. The generative power of information technology that is embedded in work practices suggests more freedom for nurses and doctors in the way they interact so that they do not need to focus on how to work around the technology but rather use it. In line with maximizing the generative power of information technology, Ellingsen and Monteiro define a design principle for the integration of different systems [8]. It suggests that integration in healthcare environments is a balance between overemphasizing the potential of technology and doing nothing, as changing anything could interrupt a delicate interplay. Bjornstad and Ellingsen offer a different understanding of such balancing [85]. With this balance in mind, Ellingsen and Monteiro suggest, that the integration of healthcare information systems should be seen as an ambiguous yet powerful vision that can help negotiations with stakeholders instead of seeing it as a purely technical matter [86]. Looking at integration as only technical tasks is an oversimplification as such work does not take into account implicated administrative work associated with integrations. In hospital environments, such work is done when patients are admitted to the hospital, and at the time of discharge from the hospital. This implies large amounts of articulation work. Articulation work is “work that gets things back ‘on track’ in the face of the unexpected, and modifies action to accommodate unanticipated contingencies. The important thing about articulation work is that it is invisible to rationalized models of work” [85].
Ignoring articulation work could lead to systems not being used – that is, their generative power would be lower. As no work practice standard can anticipate all the possible actions, articulation work is always present to deal with unintended contingencies that arise. We can see that integration is a socio-technical engagement that requires effort to keep running [85]. Bossen and Grönvall discuss challenges of such efforts that they conceptualize as collaboration in-between - theoretically linked to the theory of symbolic interaction [87].

Therefore, when implementing new technology, a deep understanding of clinical practices is needed and also of the articulation work that is part of clinical practices in order to maximize the generative power of information technology.

Bossen et al. see articulation as part of data work in which different artefacts such as lists, tables, plans, paper, computer screens, and whiteboards are used to organize complex cooperation of distributed actors and see them as coordinating artefacts that reduce the complexity of articulating and coordinating actions [88]. As new technologies emerge, such data work becomes ever more challenging as it becomes even harder to link, integrate, and reuse information on a much larger scale [88] [89]. Crucial for this thesis is an understanding of data and data work, as brought forward by Bossen et al. [88]. They see data work as production and reuse of data in three different orders that are all interconnected. The first order data production and reuse start in medical records that contain clinical documentation. This data is used in the second-order data reuse as administrative data where coding happens and also other administrative data production. In the third-order data reuse, it is about quality measurement and reports where data analytics happens, and indicators are tracked.

Such different orders of data work that help data circulate in different contexts do not only happen at one site but at all different clinical sites forming an information ecosystem. Gansel et al. provide an example where they consider Bossen et al. [88] orders of data production as part of the primary usage of medical data to be distinguished from the secondary usage of medical data such as national shared EHRs, medical and clinical research, and public health surveillance systems [90]. Especially in the secondary usage of medical data, semantics become even more critical as queries, preferably semantic queries, need to be supported such as ones presented by Zhang et al. in order to be able to access relevant data needed for research [91].

Looking back at interoperability in CAS systems like healthcare it is clear that it is not just a robust technical infrastructure that is needed to support the circulation of data, and that integration and interoperability are not mere technicalities, but require constant local effort and collaboration from doctors, nurses, and computer scientists to ensure the correctness of data [88]. All these actor-networks take part in socio-technical information infrastructure.

### 2.3.3.2 Information infrastructure

Information infrastructure is a shared resource between heterogeneous groups of users that all the work depends on [92]. Ulriksen, Pedersen and Ellingsen summarize [93] that information infrastructure has previously been used to study the design (innovation), implementation (adoption), and use of large-scale information systems (scaling) [94]–[96], as well as the development of standards for supporting the free flow of information [97], [98]. As explained by Baker, Karasti and Millerand, there are three main facets of information infrastructure, namely technical, organizational and social, which are all connected [99]. Baker et al. bring forward the distinction between local and global information infrastructure where local infrastructure is grown bottom-up while global infrastructure is designed top-down (e.g. through the use of standards).
The tensions between local needs and global standardization are a central research discussion theme. The extra articulation or data work in the context of information infrastructure calls for new roles such as mediation, as discussed by Baker, Karasti and Millerand. Mediation represents work across boundaries of traditional arenas. The mediation work in healthcare is bridging local and global arenas of infrastructure all the time. Mediation role is a prerequisite for an information infrastructure to expand. Such boundary work is not permanent and frequent negotiation is necessary. Boundary work is needed to distinguish the responsibility areas of the different governance units in the fragmented governance organization.

A lot of mediation work is needed for EHRs to become a reality. Unfortunately, it is often the case that EHRs as an information infrastructure are often designed in a top-down approach while it would be more successful if a bottom-up growing would be supported. Prominent examples of such top-down approaches include the National Program for Information Technology attempted by the National Health Service in the UK, which spent up to 20 billion GBP before the program was terminated. Lately, Denmark seems to have repeated similar mistakes with its large scale implementation of the Sundhedsplatformen (a national digital health platform), where even the most optimistic users are becoming increasingly frustrated. In Norway, plans for a large scale EHR implementation are uncertain, especially after the UK and Denmark provided evidence of obstacles to implementation challenges.

Matthiesen and Björn explore this problem of failed projects and identify several issues that they suggest can be explained with (1) work needed on tracing back to knowledge about law and technical specifications, and also (2) the dynamic evolution of the information infrastructure over time. Unfortunately, as depicted by Ellingsen and Monteiro, this dynamic evolution often involves multiple gradual integrations between individual subsystems, which in general would be the right solution, if only coordinated as part of a bigger picture and would also consider the negative impacts, called reverse synergy by Langhoff et al., of such gradual increments in order to attain positive inertia of the information infrastructure. The generative mechanisms of this evolution have been identified as innovation, adoption and scaling. As explained by Hanseth and Lyttinen, infrastructure complexity grows with the number of elements over time, where the installed base of interconnected systems and established routines become a force in itself, which is difficult to change. In order to tackle this complexity, architecture and governance are seen by Tiwana as crucial mechanisms – usually considered within research on ecosystems and SECO in particular. SECO is further introduced in Section 3.2 as I use SECO aspects to understand better the context of this thesis (the set of projects) and also to specify results.

The issues explained in the previous paragraph seem to support the idea that it is perhaps better to consider smaller and less complicated systems that can be more effective and efficient than larger ones. Berg notes that up to 75% of large scale implementations are considered as operating failures. The crucial problem is that such top-down approaches try to enforce a monolithic and standards-based EPR culture that is contradicting the multiple local cultures (nursing, medical and administrative work) that exist within healthcare organizations. Bygstad et al. call such smaller and less complicated systems as configurable lightweight IT that enables incremental design and implementation.
The design process through which information infrastructure is created and highlights participation and co-construction, as well as the complex relationships between the long-term, data, participants, collaborations, information systems, and infrastructure, is defined by Baker as infrastructuring [111]. Karasti brings forward multiple temporalities in order to differentiate between project time which is usually 3 to 4 years and infrastructure time which takes considerably longer [112]. Connecting to interoperability as a cross-cutting concern that is not dealt with within a project, we can see how infrastructuring interoperability is an ongoing long-term process.
Interoperability is not just technical infrastructure but also includes a constant local effort – data work. All this forms an information infrastructure obtained through the process of infrastructuring. The main aspects of information infrastructures, namely, technical, organizational and social, are all connected. For this, achieving interoperability is a connected effort of the technical, organizational and social.

A future vision for health systems
This is also one of the crucial reasons for the lack of interoperability in healthcare, which is related to funding or better said, the lack of it. Lack of focus on interoperability negatively impacts the overall information infrastructure in healthcare that is researched from aspects of fundamental, organizational and work practice complexities as depicted by Ellingsen and Bjørn [113]. Fürstenaet et al identify three processes through which a system becomes embedded in such infrastructures [114]. The parallel process suggests an independent evolution of different systems that leads to highly fragmented siloed systems. The competitive process happens where there is overlap in functionalities of different systems that share resources. In such a context, one system is chosen over the other, which results in the so-called regenerated infrastructure. Particularly noteworthy is the third process that enables interoperability, namely, the spanning process that results in a unified digital infrastructure. The spanning process uses integrative technologies to connect the different systems.

At this point, we can grasp how data circulation within and with the information infrastructure requires additional work to be usable in all the different contexts of use. This extra work is also known as the law of medical information defined by Berg and Goorman as: “the further information has to be able to circulate (i.e. the more diverse contexts it has to be usable in), the more work is required to disentangle the information from the context of its production. The question that then becomes pertinent is; who has to do this work, and who reaps the benefits” [115]?

2.3.3.3 Dynamic evolution of information infrastructure lacks focus on the cross-cutting concern of interoperability

In the patchwork planet view of integration and cooperation in healthcare, as brought forward by Ellingsen [8], every integration between two sources of data require additional work for the integration to actually be of use. As we have noted already, such gradual integration is part of the dynamic evolution of information infrastructure, which in healthcare lacks focus on cross-cutting concerns like interoperability. Each integration is often seen as a single project. The patchwork planet is thus the result which suggests a highly fragmented and poorly connected information infrastructure. To tackle the apparent problem, a more coordinated alignment and integration of existing highly distributed sources of data are needed, and also a common vision of an interoperable healthcare information infrastructure. Interoperability cannot be provided by one organization. It is a collective effort of all the stakeholders in healthcare that is being attempted for decades through many projects and initiatives. In Europe, a lot of these efforts are state-run. This includes projects like epSOS [116], SemanticHealthNet [117], EXPAND [118], PARENT [119], SALUS [120], Trillium [121], Trillium II [122], EHR4CR [123], Antilope [124], TRANSFoRm [125], and eStandards [126]. However, despite the extensive investment of resources, Europe has not been able to achieve a unified, interoperable healthcare environment [127]. According to a recent review article [128], a similar reality exists in the US. Crucial complexities that seem to prevent achieving such goals in Europe as described by Kautsch et al. include legal regulation differs by country, patient consent procedures, rights to access and change medical data, data confidentiality and types of EHRs, and data protection principles must all be reconciled in order to talk about interoperable national e-health systems [129].

In this thesis, the focus is on how to improve the focus on interoperability in the dynamic evolution of information infrastructure. We have learned about the different, but connected views on interoperability, namely dimensions, layers, scope, targets and
perspectives, that help understand the complex socio-technical concept of interoperability. However, my focus is not on all the dimensions of interoperability but preferably on the most challenging dimension, namely, semantic interoperability as part of healthcare interoperability.

2.3.3.4 Healthcare Interoperability

In her PhD thesis, Ducrou has reviewed standards like HL7 and OpenEHR, terminologies like SNOMED, process models such as BPMN, and proposed an approach to achieve the complete interoperability in healthcare, suggesting technical, semantic and process interoperability are all achievable with available knowhow [130]. Kuziemsky nicely explains technical interoperability as being about moving data between systems which is addressed by distributed computing approaches like Java, CORBA, DCOM, XML, web services, and SOA, without considering the meaning of transferred data [131]. The concepts and vocabulary that defines the meaning of the data are handled by semantic interoperability [131]. It also includes information models that can represent domain information. Examples of such information models are the HL7 Reference Information Model, and also OpenEHR.

Process interoperability relates to work processes and people who interact with technology and is about understanding the context within which the exchanged data is to be used [131]. As noted by Avison and Young, interoperability research cannot just be transferred to healthcare due to the inherent complexities of healthcare delivery and the processes within it [132]. What can be transferred is the need for processes to be the drivers of interoperability. Avison and Young identify three types of process interoperability, namely, knowledge (clinical practice guidelines as a potential solution), clinical (order entry systems need to interoperate with decision support systems and all other systems also) and collaborative (supporting asynchronous collaboration between teams) [132]. Also, it is essential to understand that non-technical factors like data ownership, distributed IT governance and cyber-security are crucial for understanding the lack of interoperability. Enactment model presented by Yang et al. can enable interoperability to be engaged effectively and efficiently, thereby addressing the data ownership concern in healthcare systems [133].

2.3.4 Semantic Interoperability

Semantic interoperability is the ability of different systems to communicate and share semantically compatible information, perform compatible transactions, and interact in ways that support compatible business processes to enable their users to perform the desired tasks [82]. Gaynor et al. define semantic interoperability as the capability of application components to exchange structurally defined data with contextual meaning [134]. This entails two leading technologies, namely, a data encoding layer and a semantic meaning layer. The former is often the eXtensible Markup Language (XML). As XML needs domain-specific vocabularies to express what the different XML tags mean, the semantic meaning layer is essential. The semantic meaning layer in healthcare consists of many different data dictionaries and even ontologies. Examples include the International Classification of Diseases (ICD) and SNOMED.

When talking about semantic interoperability, it is of value to distinguish between the internal and external semantic interoperability, as brought forward by Gaynor [134]. The internal semantic interoperability is limited to, e.g. single organizations like hospitals and the exchange of data between the many systems that exist there. To achieve such semantic interoperability is not particularly hard, and large Health
Information System providers excel in doing this as they become even more embedded into the organizations and even harder to replace. This is possible because the vendors are not obliged to conform to any exchange standards. My interest is, therefore, mostly in achieving external interoperability which suggests an exchange of data between many different organizations. Such semantic interoperability is much harder to achieve [135]. Ashrafi et al. note that practices of information blocking by HIS providers and HCPs [136], is just one problem that is still not appropriately solved [137].

Coming back to the Berg and Goorman’s law of medical information [115], in order to be able to reuse clinical data in as many contexts as possible, it should be possible to separate the data from the context within which the data has been captured. Such work is often done locally, at the data source. Such separation work is seen as site-based data curation work in the context of long term ecological research (LTER) of Karasti [138]. Such work traditionally entails mapping between different information models before transforming data into the prescribed exchange data format. This mapping between models is about aligning the semantics – the meaning of data. In the context of LTER, standard vocabularies have traditionally been used to tackle semantic issues. Lately, ontologies are being used as intermediary information models. Different data source models are then mapped to these intermediary models. This approach to interoperability is also known as semantic mediation which falls into the ontology-based approaches to semantic interoperability. Such an approach to semantic interoperability is also considered as design-time interoperability in contrast to the run-time interoperability. The former is supported by upfront design and use of service-oriented architecture where web services are designed upfront. The run-time interoperability is supported by event-based architectures that presume semantic mediation in run-time without the need to design all the data exchanges upfront. Remembering here the notion of the generative power of information technology, we can say that run-time interoperability should support more freedom for nurses and medical doctors in how they interact.

### 2.3.4.1 Semantic interoperability of clinical data as the crucial problem

As noted in the context of EHRs or EPRs by Ashrafi et al. recent work [136], the most challenging problem of interoperability is semantic interoperability of clinical data. It is considered a global problem [139], as noted by Tapuria [140] “There is widespread recognition globally that a formalized and scalable means of defining and sharing clinical data structures is needed to achieve the value of investment in e-Health.” Adel et al. see health domain data types as a prerequisite for EHR interoperability [71]. It is so because, in order to solve it, one needs to either find a way to translate the natural language of medicine to computer codes or change how doctors communicate their clinical observations - both approaches are still far from completion [136]. In this thesis the focus is on the former - the translation of the natural language of medicine to computer codes that Tapuria et al. summarize as (1) the definition and sharing of applicable data structure definitions, and (2) binding of the data structures to terminology [140]. In order to achieve both of these requirements, technical and clinical competencies are needed [140].

As clinical data is highly dynamic and changes often, it is hard to standardize it. One of the main reasons for the dynamic nature of clinical data is that medicine is probably one of the most complex and continuously changing domains. In fact, according to an
estimate by Densen, the medical knowledge doubles in quantity every 73 days in the year 2020 [141]. For a comparison, doubling time for medical knowledge in 1950 was 50 years, in 1980 it was seven years, and in 2010 it was 3.5 years.

All this continually changing medical knowledge brings constant changes in the distributed knowledge database in healthcare. A direct consequence of this expansion of knowledge is that the clinical picture for diseases gets new definitions, and new interventions are introduced after their validation [142]. In order to access and use this knowledge, the multiple and ideally interoperable information systems supporting access, need to change also – as we have already noted when introducing the knowledge life-cycle theory. There we learned that there is also a third component of knowledge management in organizations, namely, the business processing environment where clinical practice is conducted daily and represents an additional source of change as the care processes are often ad-hoc and hard to standardize. Such complexity brings forward the “inescapable semantic difference between business (clinical) considerations and technical considerations” as noted by Benaben et al. [143]. Therefore, any standardization process results become obsolete to soon and make an effort futile. Lewis et al. note that standardization in healthcare in terms of choosing the latest clinical data standard is not enough as such a standard “does not take into account clinical workflows and operational contexts that differ across point-of-care systems and have a large effect on how accurately clinicians interpret data” [144]. In spite that, it is still essential to find a suitable standard for clinical data, not only for achieving semantic interoperability but also to support clinical decision support. This is noted by Gonzales-Ferer and Peleg [145] and studied in-depth in a systematic review by Marco-Ruiz et al. [146].

2.3.4.2 Approaches to semantic interoperability of clinical data

In the context of EHRs, there are many known standardization initiatives led by international standardization organizations such as the ones listed in Table 1.

<table>
<thead>
<tr>
<th>Standardization Organization Name</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>The OpenEHR Foundation</td>
<td><a href="http://www.openehr.org">http://www.openehr.org</a></td>
</tr>
<tr>
<td>Consolidated Health Informatics Initiative</td>
<td><a href="https://www.cms.gov/">https://www.cms.gov/</a></td>
</tr>
<tr>
<td>Certification Commission for Healthcare Information Technology</td>
<td><a href="https://www.cchit.org/">https://www.cchit.org/</a></td>
</tr>
<tr>
<td>Healthcare Information and Management Systems Society</td>
<td><a href="https://www.himss.org/">https://www.himss.org/</a></td>
</tr>
<tr>
<td>International Organisation for Standardisation</td>
<td><a href="http://www.iso.org">http://www.iso.org</a></td>
</tr>
<tr>
<td>American National Standards Institute</td>
<td><a href="https://www.ansi.org/">https://www.ansi.org/</a></td>
</tr>
<tr>
<td>Canada Health Infoway</td>
<td><a href="https://www.infoway-inforoute.ca/en/">https://www.infoway-inforoute.ca/en/</a></td>
</tr>
<tr>
<td>European Committee for standardisation</td>
<td><a href="http://www.cen.eu">http://www.cen.eu</a></td>
</tr>
<tr>
<td>The European Institute for Health Records</td>
<td><a href="https://www.eurorec.org/">https://www.eurorec.org/</a></td>
</tr>
<tr>
<td>Clinical Information Modelling Initiative</td>
<td><a href="http://informatics.mayo.edu/">http://informatics.mayo.edu/</a></td>
</tr>
</tbody>
</table>

Table 1 International standardization organizations

All these initiatives strive to achieve semantic interoperability between EHRs through the top-down standardization – which is undoubtedly a gap in healthcare [93] as is also interoperability in healthcare [147]–[149]. It seems that a common denominator of all the different approaches, as noted by Moreno-Conde et al., is the separation of definitions of clinical information models from the actual representation and persistence of the data values [150].
In this thesis, the focus is on the so-called dual modelling approaches with a specific focus on one such approach called OpenEHR. In its essence, OpenEHR promotes how to build new systems that would be interoperable by design.

### 2.3.4.3 The role of dual-level modelling in achieving semantic interoperability

Traditionally, as Beale puts it [151], information systems are developed in a way in which domain concepts that are to be processed by the information system, are hard-coded into the software and database models of the information systems. Similarly, different systems are usually integrated in a peer-to-peer fashion, which only adds costs and complexity but not solve interoperability. The main disadvantage of this approach is that with the frequent expansion of medical knowledge, the software becomes unsuitable and outdated, as also noted by Sachdeva and Bhalla [139].

To tackle this challenge, one idea is to separate the domain concepts from the technical implementation, or put differently by Beale [151], to add degrees of freedom to clinical concept models. By doing so, the domain concepts can be freely changed or added. Somewhat promising approaches to achieving semantic interoperability in healthcare by separating the domain concept from the technical implementation, are the so-called dual model [152] approaches where an information level is separated from knowledge level.

A reference information model represents the information level, and the knowledge is represented with archetypes – special data structures that hold medical knowledge [153]. This separation guarantees not only semantic interoperability between systems but also system maintenance and sustainability over time [152]. In this way, the well-known causes of data interoperability issues as brought forward by Renner [154] can be adequately addressed.

### 2.3.4.4 OpenEHR as a dual model approach

OpenEHR is one such dual model approach, one of several known care process models presented by Beale and Heard as an ontology that later served as the basis for the information and knowledge models [155]. As standardization in healthcare is a difficult undertaking, as also noted by Silsand and Ellingsen [156], usually a top-down endeavour in which users and their work practice are not indeed considered, alternative standardization strategies have been put forward. One such alternative strategy is to focus on standardizing the content of the EPRs. OpenEHR is one such approach that is generally known as detailed clinical modelling (DCM). In order for such user-driven standardization of semantic interoperable EPR systems to succeed, the efforts need to be supported by a multi-level organisational infrastructure, in addition to governance organisations that make decisions and monitor results and performances at different healthcare levels [156].

Despite the separation, the reference model and archetypes are interdependent of each other in constituting semantically interoperable EHR or EPR systems as brought forward by Silsand and Ellingsen [156]. In this view on clinical data, archetypes are primarily modelled by clinicians. Silsand and Ellingsen see archetypes as information infrastructure that materializes in a continuous process of design and evolution in order to cope with the ever-changing health knowledge. Silsand and Ellingsen also use the concept of do-cracy as a way to go about modelling archetypes based on local clinical needs in which clinicians and other health workers participate, which is strongly connected to the concepts of universal locality and collective capability that have been
used to describe similar work on terminologies, which have also been considered as information infrastructure [157].

OpenEHR is considered as a more practical alternative to modelling complex terminologies like SNOMED as has been established, e.g. on the case of nursing by Hovenga, Heard and Garde [158]. OpenEHR is also considered more pragmatic than the ontology-based approaches to semantic interoperability as these approaches are very complex and more suitable for engineers. OpenEHR is seen as an integrative approach that can also map data elements to terminologies or even ontologies, which has been nicely presented by Garde et al. [70]. Also, OpenEHR seems to address the core issues of clinical decision support systems, namely, a standard underlying model, as stated by Garde et al. [159]. OpenEHR has been extended with a query mechanism as described by Ma et al. [160] which is where the semantics usually becomes essential [66]. Querying becomes a crucial way of supporting the secondary usage of healthcare data, as we have already noted while introducing data work.

To exemplify good designs for interoperable EHR systems through open source components, and to validate and refine these through practical clinical demonstrators, the not-for-profit OpenEHR Foundation [161] was established. Since then, OpenEHR has been used in many different scopes ranging from small local projects to large national and even international endeavours. OpenEHR itself has become a standard, the ISO 13606-2:2019. OpenEHR supports a concept-based exchange of healthcare information, also addressed by Maldonado et al. [162]. The upper of the dual models is focused on concepts and represents the basis for domain knowledge governance. This knowledge represents a consensus among the broadest possible group of healthcare professionals and is therefore independent of particular implementations of EHRs, EPRs or any other system. The governance process should be done on national and international levels, and it should be timely in order to achieve semantic interoperability. However, as we will learn in the next section, in spite of having OpenEHR, there are open issues that prevent achieving semantic interoperability in healthcare.

2.3.4.5 OpenEHR Use

OpenEHR can be used and reused together with mappings to ontologies and terminologies in different use cases on local, national and global levels as noted by Pederson and Ellingsen [163]. Experiences include primary healthcare [164], exchange of data between secondary and primary healthcare [165], research [166], patient registries [167], regional eHealth [168], and national eHealth [169], among others. Interestingly, OpenEHR has also been used as the basis for semantic interoperability between the Internet of Things or Internet of Medical Things, and EHRs as presented by Rubi and Gondim [170] - an example of mapping between different models that have been tackled by Maldonado et al. with the development of technical tooling that supports the mediation process between the different models [162]. Maldonado et al. developed the LinkEHR tool that enables the design-time definition of mappings between different models [162]. To contrast, the run-time approach to such mappings is known as schema matching algorithms that are based on calculating similarities between different schemas such as the one presented by Naveed et al. [171]. In this thesis, we do not deal with mappings between models, the semantic mediation, nor do we focus on run-time schema matching. The focus here is on increasing the focus on interoperability of the dynamic evolution of information infrastructures by defining
new work practices, and new ways of governing OpenEHR artefacts that would yield a higher level of participation from the main stakeholders, namely, medical professionals as this seems one of the crucial problems to solve. Before uncovering how exactly this thesis tries to help do this, we first need to learn what consequences of using OpenEHR have been observed that serve as further motivation for the work in this thesis.

2.3.4.6 The impact of using OpenEHR
As nicely put by Sachdeva and Bhalla, OpenEHR enables taking into account clinical workflows and operational contexts and by this, ensures interoperability across enterprises [172]. We have learned about cases where OpenEHR has been used. However, there are still interesting open questions to address. As noted by Ulriksen, the promise of OpenEHR on the separation of technical and clinical concerns, do not really happen in practice [101].

An exciting and complex consequence of the dual model approach like OpenEHR, as explained by Ulriksen, is a new way of establishing an information infrastructure within healthcare [101]. This entails ICT governance that needs to be established on a regional or national level. It also entails establishing close collaboration between clinical and technical ICT governance organizations. In such collaborations, system developers are linked with healthcare personnel in doing cross-disciplinary or boundary work which is further explained in Section 3.5. They do so by using boundary objects. All this accumulates to support an organizationally challenging clinical standardization.

Establishing archetypes and archetype governance demands for a close collaboration between technical and clinical resources. Archetype governance is a new concept including both how to model the archetypes, and how to use them for clinical practice [101]. This means, as nicely stated by Christensen and Ellingsen, that modelling of OpenEHR archetypes and templates can be seen as a complex standardization process that influences both the actual modelling and healthcare practice itself [173]. Archetypes need to be tried in a system to see how they work in clinical practice. Having an organization to support such work certainly makes a success factor for the implementation of EHRs or EPRs and their infrastructuring process [101].

However, as already noted, engaging clinicians to become involved in such work with technical models remains a challenge today as it was ten years ago [174]. As stated by Malm-Nicolaisen and Ellingsen, the OpenEHR approach suffers from a lack of involvement and commitment from users as well as from failure to fulfil the original ambition of user-controlled local tailoring [175].

Christensen and Ellingsen see such work as being too complicated and that it attracts only specially focused people worldwide rather than being practised locally [173]. For this, it became clear that this modelling work or also data work happens across different clinical sites as part of an ecosystem which requires consideration of a broad range of socio-technical issues to understand the processes of implementation and use [173]. These issues have been examined by Ulriksen in his thesis [176]. Ulriksen brings forward several interesting conclusions including (1) recognizing the need for the closer interrelation between archetype standards and the EPR systems than the dual model presents; (2) a need to find a balance between user involvement and the efficiency of the development process; (3) it is crucial to decide on how to include enough end-users for such standardisation processes to be successful and to consider the power relations
between the actors in the standardisation process and how this influences the outcome of the work. Ulriksen concludes that one of the most critical overall findings of his thesis is the need for the close interrelation between the information and communication technology system, local practice, and the users in the infrastructuring process of developing and approving national archetypes. This contradicts a fundamental belief in the openEHR architecture – namely, separating technical and clinical work.
3. Theoretical perspectives and concepts

I present here the main theoretical perspectives and concepts more in-depth. I first introduce TDSs and SECOs in Sections 3.1 and 3.2 respectively. TDSs serve as a reference point for all the research projects with respect to their achievement of particular innovation goals. SECOs are used as a frame for understanding the whole research under one umbrella – a SECO evolution. By applying three theoretical lenses introduced in sections 3.2.1, 3.2.2, and 3.2.3, I am able to construct the second research result of this thesis.

I introduce the TEAS in Section 3.3. TEASs help design solutions to support the co-existence of contradictory values of different stakeholders. In this thesis, I conceptualize the new work practice for productive work on semantic resources studied within RQ1 as a TEAS which represents the first result of this thesis. The process of making the new work practice for productive work on semantic resources more explicit is in this thesis represented through the lens of formalization innovation. I introduce it in Section 3.4.

The productive work on semantic resources includes cooperation between several disciplines such as medicine and computer science. Such work is known as crossing each discipline’s boundaries and is called boundary practice. Within such work, different boundary objects are created and used, such as semantic resources. Section 3.5 introduces boundary practice and objects. Section 3.6 introduces concepts from political theory known as commons that help address the governance aspects of the new work practice.

3.1 Innovation process and technology development stages

The TDSs typically consist of (1) laboratory research, (2) applied methods, (3) product/service development, (4) field testing, (5) regulatory approval, (6) in-use evaluations, and, (7) widespread deployment. TDS have been used in healthcare by, e.g., Hardisty as part of the multi-path mapping exercise for stimulating future innovation chains, introduced previously by Robinson in [177], as possible development paths of the telehealth technology used for telemonitoring of chronic disease [178]. In general, multi-path mapping is a strategy development tool used by many research funding agencies [178]. The TDSs support the innovation process goals of development, evaluation and implementation of interventions in the field of healthcare. In this thesis, I use the innovation process goals and the TDSs as a frame to depict our past research concerning the TDS phases. I do so to show where in the TDSs, the different past projects fit in. This is important for this thesis as we searched for solutions for the semantic interoperability problems. By supporting the proposed solutions with research results from all of the TDSs which suggests variability (meaning the projects cover all the DHI life cycle stages), I hope to have a stronger argument in favour of the proposed solutions.

3.2 Software ecosystems (SECOs)

Suominen, Hyrynsalmi, and Seppäläinen explain that the SECO literature draws its theoretical background from different disciplines [179], namely:

- technical,
- research methodology,
- business,
- management, and
- strategy.
The term ecosystem has its conceptual roots in the 1930s in the context of biological ecosystems and re-established and reinforced by Moore as business ecosystems in 1990s [179]. Suominen, Hyrynsalmi, and Seppäläinen identified sub-types of ecosystems, such as business ecosystem, industrial ecosystem, innovation ecosystem, knowledge ecosystem, mobile ecosystems, SECOs, and digital ecosystems [179]. However, the relationship or boundaries between different types of ecosystems are not clear. I chose SECOs in order to look at the overall research through the lens of SECO evolution.

Concerning SECOs, Jansen, Finkelstein and Brinkkemper set forward a research agenda on SECOs in which software vendors need to consider three different perspectives in order to function and survive within SECOs [180]. On the software ecosystem level, firms decide on their behaviour within SECOs in order to maximise profit. One level below is the software supply network level where strategies are determined on their immediate buyers and suppliers. The third level is the software vendor level, where firms establish the influence of SECOs on their product and service portfolio, knowledge management and relationship management [180].

Dittrich sees the SECO concept as a future for software engineering based on the recognition that software is changing and is becoming a more and more customisable and configurable product [181]. For this, the concept of projects as a primary way of organising work in software engineering/product development is to be replaced by SECOs in which continuous innovation is possible even across multiple ecosystems. In such way of organising, Dittrich has observed some commonalities that are important for such work as, e.g. the distribution of design, more complex technical design, and development taking place in cycles within cycles. Dittrich also sees two main research topics, one on the evolution of software product lines to becoming software ecosystems, and the other on the interaction between actors in the ecosystem [181].

Manikas and Hansen define SECOs as the interaction of a set of actors on top of a common technological platform that results in several software solutions or services [182]. In this thesis, we use several other names for technological platforms like digital platforms, eHealth platforms, and software-based platforms but always mean technological platforms.

Sadi, Dai, and Yu see analysing and designing SECOs as a recent and multi-faceted issue [183]. To reduce the complexity of the problems raised in the design of SECOs, existing efforts mostly advise to separate business, organisational, social, and technical concerns, and address each of these concerns independently. Most of the research focuses on one dimension! That is mostly the technical dimension.

Very little attention has been given to (a) analysing the interrelationships between technical, business, social and organisational factors in the design of SECOs; and (b) aligning these dimensions with each other. Garcia-Holgado and Garcia-Penaivo in their systematic mapping of SECOs reviews come to a similar conclusion, that is, »the research in software ecosystems is in its infancy« [184].

Christensen, Hansen, Kyng, and Manikas separate three main structures or aspects important in SECOs [185]: (1) organisational structure of SECO participants, (2) software structure, and (3) business structure. Manikas brings forward organisational structure with a focus on decision making [186]. Accordingly, four main types of organising are explicated: (1) monarchy – one actor orchestrates the ecosystem, (2) federal – a set of representative actors orchestrate the ecosystem, (3) collective – all the
actors are involved through, e.g. voting, and (4) anarchy – each actor acts alone without any specific coordination.

Manikas sees business structures as a means of value creation in the ecosystem. Accordingly, we can characterise ecosystems as (1) proprietary – contributions are proprietary and such ecosystems are protected by intellectual property and value relates to money, (2) open-source – contributions are available to the rest of actors or are public; values are not monetary but rather knowledge, experience or need satisfaction, and (3) hybrid – this kind of ecosystem supports both proprietary and open source contributions [186].

Manikas sees software structure as four possibilities: (1) platform – contributions extend a common software platform, (2) protocol – for achieving software interaction, (3) standard – software interaction is achieved based on compliance to one or more standards, and (4) infrastructure – here the interaction between software and actors occurs mostly in development time, e.g. GitHub [186].

In order to foster a common language in research on SECOs, the recent SECO meta-model is a good step forward. The SECO meta-model was proposed by Wouters et al. as “a unified context description schema for SECO research” [187]. The meta-model consists of five main topics: (1) actors and roles (individuals or organisations), (2) products and platforms (e.g. standards, APIs, architecture, intellectual property), (3) boundaries (e.g. legal framework, ecosystem type, market), (4) ecosystem health (e.g. maturity, niche creation, growth) and (5) strategy (e.g. ecosystem openness, platform strategy). The main result of Wouters et al. is the separation of the topics into business segment topics (strategy, ecosystem health, and boundaries) and technical segment topics (actors, roles, and products and platforms). The business segment is considered as strategic, whereas, the technical segment is considered operational. One needs to model both of these aspects of SECOs in order to offer a complete model.

Concerning SECOs in healthcare, there is generally a lack of studies on SECOs as brought forward by Christensen, Hansen, Kyng, and Manikas [185], and lately also by Marcos-Pablos and García-Peñalvo [188]. A review of technological ecosystems in the health sector by García-Holgado, Marcos-Pablos, Therón-Sánchez, and García-Peñalvo bases on the mapping of several European projects [189]. It reveals that more or less, projects use traditional technologies (web, sensors, mobiles, cloud). Also, most projects focus on healthcare and independent living and are mostly research and development in nature. Interestingly, Italian organisations are by far the most involved in the projects. The projects focus mostly on older people, formal carers and software providers. Also, most solutions are platform-centric. More interestingly, sensors and other devices are more in line with regulatory compliance as medical devices. Lastly, the article suggests a growing interest in technological ecosystems in the health sector.

SECOs are used in this thesis because of their utility to show the overall research process as a SECO evolution. In this process, I have worked on projects and produced results that fall in the technical, organisational and business aspects of SECOs. Also, I use SECOs in the results to make explicit the SECO evolution observed in this research. To learn about the properties of such a SECO evolution, I use three theoretical lenses that I now shortly introduce.
3.2.1 Evolutionary mechanisms of digital artifacts

The evolutionary mechanisms of digital artefacts have been proposed by Schlieter et al. [190]. They recognise four basic evolutionary mechanisms, namely: (1) mutation and (2) migration, which introduce variation, and (3) natural selection and (4) genetic drift, which transmit variation.

Mutation evolutionary mechanism leads to a genetic variation within a population. Migration evolutionary mechanism allows the transfer of variation to further populations. This implies that design artefacts can be transferred to a different context, thus giving way to a separate evolutionary line of the artefact. Mutation and migration are enablers for two more evolutionary mechanism known as natural selection and gene drift. Natural selection influences variation by non-random sorting. Gene drift also acts on variation with the difference that here the sorting is random.

3.2.2 Institutional theory niche, regime and landscape levels

The niche, regime and landscape levels are socio-technical transitions which involve people, organisations and technology [191]. Innovation-producing activities at the niche level include the niche environments of innovation and acceleration programmes. Development carried out in niche environments can be seen as experimenting with new reconfigurations of service systems, including the design of new value propositions that connect the service system internally and externally. However, such niche activities usually involve small groups of actors working on joint projects or in newly established temporary start-up organisations. It is obvious that the aim is to help these niche innovations to break out of the niche level and to move to the regime level.

Traditionally, innovation at the regime level has been constrained by different institutionalised rules that prevent the adoption and diffusion of innovations that are not in line with the existing institutionalised pattern. Previous research [191] suggests two possible approaches for this break from the niche to the regime level. First, regime adjustment takes place when innovations that bring about gradual institutional change are accepted by the regime. Second, regime transformation, where many innovations accumulate and cause a significant shift in institutional arrangements at the regime level.

3.2.3 Platformization and generative entrenchment

The platformization process represents a gradual formation and development of software platforms. It is defined as a gradual accumulation of additional layers that extend the functionality and scope of existing systems while strengthening their entrenchment [192]. This means that social (governance) and technical (architecture) elements become the basis for the generation of new initiatives. As a feedback mechanism, these new initiatives increase the stability of the same social and technical elements. Rodon uses the concept of generative entrenchment [192] to theorise the idea that:

- platforms grow from an installed base, which has downstream enabling and restricting consequences for new platforms. These new platforms in turn have a feedback to the same installed base;
- the installed base has parts with wider and more pervasive effects, so that the elements of the installed base are preserved differently;
- the dependencies of the new platforms on the installed base change over time.
3.3 Technology-enhanced activity spaces (TEAS)

Interaction design (ID) is an umbrella term for all the different approaches to understanding the interaction between people and digital technology [193]. Winograd has seen ID as a separate research field that should focus on designing spaces for human communication and interaction [193]. However, ID primarily focused on designing interactive products and use-related characteristics of digital artefacts using user-centred design (UCD) instead of following the vision of Winograd [193]. Looking back on how these concepts developed further, we can see that focus of attention has shifted from designing interactive products to designing habitats and ecologies – also called the ecological turn in ID [193]. The term ecological turn in ID, therefore means that digital technologies have become an organic part of the natural environment and should be understood and further developed as such [193].

This meant that ID became important not only for the design of new artefacts but was also there to help people create better environments for their work and other activities. This new way of thinking about ID was needed in order to support the understanding of the internal transformation of work practices. The concept of TEAS was introduced to place technology in the set of possibilities for doing action in particular work settings [193]. It is a result of new technologies like smart environments, open-source hardware and software platforms which enable people to become designers of their homes and work practices, and by doing so, enable the intrinsic practice transformation.

The interaction of artefacts design and practice development can be depicted by the task-artefact cycle model [193]. The model assumes continuous cycles of technology and user task coevolution. Each cycle involves design, implementation and appropriation of the new artefact. As such new artefacts create a new use situation, this means new requirements that then influence the next iteration. The model is depicted in Figure 11 as a continuation of design, implementation, appropriation of artefacts and practices as a relationship between tasks and artefacts in which tasks or practices produce requirements for the artefacts and then these, in turn, create new opportunities for the tasks or practices that then propel the next iteration of requirements.

![Figure 11 Continuous design, implementation and appropriation of artefacts and practices.](image)

External introduction of technology is the motivating force of the task-artefact cycle. Therefore, it sets designers in the centre, and they are the ones who know what the user needs are within given practices. However, the workers within work practices find solutions to the emerging work practice problems in a special innovation process called ephemeral innovation. Such innovation is an intrinsic influence on changing work practices and is a contrast to extrinsic technology and design-driven improvement of
practices. Engestroms’ 1987 [194] model of expansive transformation of activity systems, as cited in [193], describes the intrinsic transformations of practices. The important thing about the intrinsic and extrinsic transformation of practices is the fact that these represent two perspectives of technology-enabled practice transformation. Innovative technologies should fit the needs, expectations, and strategies of people who are changing their practices (intrinsic practice transformation). At the same time, innovative technologies increase the number of available resources for people to use, which then facilitate the intrinsic transformation of practices. There are several vital differences between intrinsic and extrinsic transformations of practices. As these are important to understanding technology-enhanced activity spaces and why they were conceptualised, we look at these differences in Table 2.

<table>
<thead>
<tr>
<th>Intrinsic Practice Transformation</th>
<th>Description</th>
<th>Extrinsic Practice Transformation</th>
<th>Description</th>
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<tbody>
<tr>
<td>Continuous</td>
<td>There is a rapid progression between old and new practices.</td>
<td>Discontinuous</td>
<td>The designed artefact is mostly not implemented in practice studied. Also, as design and implementation can take years, once it becomes ready, it does not fit the practice which changed. There is no rapid progression between the two practices.</td>
</tr>
<tr>
<td>Direct</td>
<td>A new solution used by the practice itself immediately impacts the practice.</td>
<td>Indirect</td>
<td>The user-centred design affects the artefact and not the practice immediately.</td>
</tr>
<tr>
<td>Situated</td>
<td>The solution is appropriate for the task at hand.</td>
<td>Generic</td>
<td>Solutions applied through user-centred design are generic as they can fit many different contexts.</td>
</tr>
<tr>
<td>Relative novelty</td>
<td>It is enough for the solution to solve specific problems and does not have to be useful anywhere else.</td>
<td>Absolute</td>
<td>The user-centred design produces solutions that are novel in an absolute sense. New designs are a result.</td>
</tr>
<tr>
<td>Multiple technologies can be used in a specific context.</td>
<td>Users in a specific context are not bound to specific technologies and can use multiple.</td>
<td>Giving shape to a specific product</td>
<td>Bound to one specific technology that is being designed.</td>
</tr>
</tbody>
</table>

Table 2 Differences between intrinsic and extrinsic transformations of practices.

ID needed to expand to account for both intrinsic and extrinsic transformation of practices. It must include the transformation of practices and habitats that involve intrinsic, continuous transformation of practices through deployment and appropriation of digital technologies [193]. This is important because people are perhaps not so interested in the artefacts and their novelty but are somewhat concerned about how to use all existing resources, including interactive technologies to improve their practice and their environment. The ecological turn of ID should not only help with providing
new and novel artefacts but also help people to create better environments for their daily life. Several approaches within human-computer interaction are known for trying to address the lack of focus on intrinsic practice transformation, namely, participatory design, end-user design, meta-design and design for appropriation.

The participatory design makes users equal partners in design. Therefore, it addresses one aspect of intrinsic practice transformation; that is, it recognises users as the ones who drive design and not solely designers. However, the case often is that extrinsic practice gets more focus as designers use end-users as a means to achieve their cause – design of a novel artefact.

With the ecological turn, the object of design expanded from product innovation to design of environments and habitats. The object of design in the case of intrinsic technology-enabled practice transformation is technology-enhanced activity space seen as a spatially and temporally organised configuration of resources, including digital technologies, which enable an individual or a group to carry out one activity or several coordinated activities [193]. This implies that ID should explore strategies for employing interactive technologies in order to augment support for human action in a specific environment [193]. Activity spaces refer to the possibilities for action provided by the environment.

When dealing with TEAS, the following aspects are essential:

- **designability** – designing the user is a notion often present in ID where user experience and activities are »designed«; however, these are unique, situated and emergent phenomena that cannot be given shape to. Similarly goes for designing complex natural environments called contexts, places, ecologies, or habitats. Such environments are transformed by actors and evolve instead of changing according to a plan. So context, place, ecology, and habitat are not fully designable. TEAS is an attempt to focus on designable aspects of environments for human action. It is not about designing human activities but rather about providing resources for them. »Creating technology-enhanced activity spaces through introducing, modifying, developing, or coordinating digital tools and materials means setting up preconditions and creating possibilities for human action— which possibilities may or may not actually be realised « [193].

- **integration of the physical, social and the virtual** is done around activities as people focus on achieving a goal, they switch between physical, social and virtual which represent one interconnected world rather than three different ones;

- **variable scope** – as activities are hierarchically organised into several levels that can have multiple sub-levels, the TEAS can also be defined at different embedded levels

- **diverse interaction designers** – with TEAS the designer means a collective designer, meaning many categories of actors and not a single designer actor. As many of the collective designers are not professionals, they need tools and methods to support them in the design efforts. Designer as the hero is becoming past as collective design kicks in.
With relation to intrinsic practice transformation, the work presented in [195], [196] revolves around the concept of community artefact ecologies as a way of understanding the constellation of technologies a community owns, has access to and uses in their practices and in which members of communities are designers. In such communities, the decisions around technologies are made democratically. However, specific skills and understanding are a prerequisite to be able to decide on a technology. For this, decisions are often left to those who understand technology better. As this thesis focuses on healthcare where it is usually not the case that, e.g. medical professionals create IT tools or introduce new ones on their own. That is, medical professionals do not act as a designer within their communities, and that our focus is on designable things, technology-enhanced activity spaces that separate extrinsic and intrinsic transformation of work practices is a more important concept for this thesis. TEAS are used to support the answer to the RQ1.

3.3.1 The role of values
Differing values of stakeholders can be supported using TEASs. The crucial thing to know is that values are not considered as universal values but rather as values specific to the design situation and the participating stakeholders. In such design situations, values are discovered and acknowledged in the design process [197]. In this thesis, the differences in values of stakeholders in healthcare are seen as the reason for power asymmetries over health data and their semantics. I consider TEASs as a possible approach to alleviating the value differences to support productive work on semantic resources.

3.4 Formalisation innovation
Innovation is a process in which the product, be it a good or a service, changes [198]. This view is possible in the integrative characteristics-based definition of products [198]. Here, products are described as a set of vectors that include both tangible and intangible technical characteristics of the production process, and competencies of both clients and providers [199]. The final service characteristics is thus also a vector that links with all the other vectors. This service characteristic represents or relays the value to the client or user [199].
Based on such representation of products, different models of innovation have been identified that are results of the dynamics of their characteristics. Essential for this thesis is the formalisation innovation model which occurs when one or more characteristics are formatted or standardised, which in case of services, add materiality to the service provided [198]. As suggested in the literature [198], this can happen when a new technological system is introduced, or the intangible production and delivery process is changed and how it is organised.
Further on, we can describe services not only using these vectors but use perhaps more operationalised approaches [198]. Here service is referred to as an assembled service, e.g. a hospital is seen as a complex activity defined as (1) one constituent services composed of functions or groups of operations that add up to the assembled service, (2) the functions are associated with targets like material objects, information, knowledge or individuals and therefore these operations are material, informational, methodological and relational, (3) the service characteristics desired, and (4) competences of the service providers.
In this thesis, I use the formalisation innovation model of innovation to describe the results of research on RQ1.
3.5 Boundary practice and objects

Practices such as social skills, shared technology patterns, networks, knowledge, coordination, and collaboration abilities are ongoing production which emerges through everyday actions at work [200]. Such a definition of practice allows for multiple practices within a particular setting, and many practices can intertwine with each other. The concept of boundaries originates in Wengers (1998) communities of practice and helps understand what happens when two practices meet. Boundaries can include organisational, social and cultural distances among different stakeholder groups or practices in a collaborative setting [200] and come from having different backgrounds and diverse ways of communication.

As practitioners start collaborating with other types of professionals, they cross boundaries and establish bridges across boundaries within communities of practice. This bridging of boundaries constitutes two intertwined parts, namely, boundary objects and brokering as activities and situations. In the long term, the point of bridging boundaries is to develop connections between different practices. Such new practices that function as bridges are called boundary practices and can be co-created by the members of the groups that participate in it.

Boundary practices are interesting to this thesis. First, as a way of looking at digital platforms owned by the government, as platforms also support spanning boundaries between different stakeholders. Second, and more important for this thesis, the work practice for productive work on semantic resources is such a boundary practice in itself that connects professional with different backgrounds and ways of communication.

Such boundary practices can also form to cross the existing knowledge boundaries of different collaborating expert groups by introducing a common understanding and shared language. Then shared boundary objects can be created and used for representing different expertise.

In this thesis, semantic resources are such boundary objects. The OpenEHR methodology and different terminologies used in the domain of healthcare, ensure shared understanding and common language.

3.6 Commons and Commoning

Elinor Ostrom’s studies in natural resources usage such as fisheries or pastures have shown that successful local governance of shared resources was possible [201]. Marttila, Botero and Saad-Sulonen summarise the evolution of commons [202]. Commons as natural resources were followed by new commons [203] where data, information and knowledge were essential resources. From the activist’s point of view, we can understand commons as a movement for social change and democracy. This movement focuses on creating and governing commons through the creation of partnerships and the education of people in order for them to participate in patterns and practices within commons. These patterns and practices support commons-based peer production (CBPP), also known as social production that is a characteristic, particularly of knowledge commons.

Benkler’s definition of peer production includes openness of its outputs and a decentralised, participant-driven method of working [204]. Accordingly, CBPP means peer production based on commons resources and goods that are jointly developed and maintained by a community and shared according to community-defined rules.

Kostakis and Bauwens [205] see CBPP as a new pattern of value creation for digital production which means that the work of the community orients to use-value creation,
not exchange value. Benkler sees commons-based working as a more optimal way of elicitation of non-monetary motivations, both intrinsic and extrinsic – social (e.g. status) in comparison to traditional firms monetary approaches [206]. The free and open-source software has shown us that indeed material incentives can be replaced in the core of innovation by intrinsic and social motivation into a combination of hedonic gain and indirect appropriation: (1) the playful joy of creation, (2) reputation, (3) social-psychological rewards, and (4) increases in human capital, as reported by Papadimitropoulos [207].

The term commoning refers to the process and activities of creating, maintaining and nurturing commons.

Studies on the commons predict that if a robust governance structure is created, the commons-based way of self-organising gives participants incentives to contribute to a common based pool resource while dampening collective action problems, as pointed out by Ostrom [201] thus avoiding depletion of the resources. As commons governance confronts various obstacles towards achieving robust governance and sustainable sharing and cooperation, communities can and often do overcome obstacles through constructed as well as emergent commons [208]. Creation of new commons is a natural approach towards a robust governance structure. Lately, as theorised by Briassoulis [209], robustness can be improved by giving emotions a crucial role in the institutional arrangements that becomes more and more aligned with the existing culture.

Commoning, which is the process of designing a common, entails social processes of maintenance and governance of a commons. Teli has expanded the notion of commons from the institutional arrangements related to the management of a specific resource, to the ensemble of the material and symbolic elements that tie human beings together [210]. In this view, value is extracted out of the collaborative capabilities of people. This means that participatory design, for example, can help make social practices and social groups that nourish the common, more robust, and help identify essential allies and practical means [210].

In this thesis, commons and commoning through participatory design are crucial in the RQ3 where we look at the potential benefits to the governance of semantic resources.
4. Context

The main motivation for this thesis lies in the sustainability issues of health care systems, due to which digital technology is used in various DHI to support the digital transformation process. In order to better understand these different issues that the different projects tried to solve, I will first present Health System of Slovenia in Section 4.1. Then I extend the scope of by presenting European-wide problems of health care systems in Section 4.2. With this I try to draw a picture for a wider audience and to improve the impact of my work. In Section 4.3 I present the series of projects I have participated in and present the micro-context of my research, in which I have gained experience with impact chains regarding OpenEHR and semantic interoperability. Finally, in Section 4.4 I present the different roles in which I worked on the different projects.

4.1 Health System in Slovenia

The health system in Slovenia lags behind the 28 European countries (EU28) average in most aspects [211]. This is partly explained by Böhm who still considers Slovenia's Health System to be in transition [212]. This means that we cannot attribute it to any of the five types of health system (national health service, national health insurance, social health insurance, private health system and statutory social health insurance) that Böhm identified as viable [212]. It seems that in the almost three decades since Slovenia's independence there has not been enough time to complete the transition. The closest type and probably the most viable option where the transition should end is the same type of health care system that exists in countries such as Austria, Switzerland, Germany and Luxembourg, i.e. the health care system type of social health insurance. The main difference between the above-mentioned health systems and the health system in Slovenia is at the level of care provided by service providers, which are still part of the public sector. In Slovenia, the majority of health care providers are state-owned. In contrast, the health care providers in the other countries mentioned are private organizations.

A typical health care system provides twenty or more different services such as acute care, hospitals, emergency departments, physician practices, assisted living, home care, behavioural medicine and care management, to name but a few [213]. We can divide these services into seven different categories: extended care, acute hospital care, ambulatory care, home care, outreach work, wellness and housing. The reality is that health services are becoming increasingly fragmented due to the increasing specialization of health professionals and that the range of services offered by a typical health care system is growing.

In addition to the fragmentation of services, chronic non-communicable diseases (CNDs) represent a constant and growing burden on health systems. The most common CNDs are mostly preventable or at least can be delayed until an older age. In Slovenia, CNDs accounted for about 80% of all deaths in 2003. In terms of total mortality rate in 2005 (similar rates apply in 2018), 40.7% of deaths were due to cardiovascular diseases, 27.6% to cancer (these two rates are close to the EU-28 average), 7.4% to respiratory diseases, 5.7% to gastrointestinal diseases, 7% to injuries and poisoning and 10% to other diseases [214].

On average, Slovenians live seven years with a chronic disease or with some kind of reduced capacity or disability. These seven years account for 9% of total life expectancy.
Regarding the costs associated with CNDs, we see that 80% of the costs are associated with CNDs, while only 3% are related to prevention [11]. Demographic changes are an additional burden on health care systems. In 2060, about 30% of the population will be over 65 and 12.1% over 85 years old [215]. In addition to increasing fragmentation of services, the growing prevalence of chronic diseases and demographic change, the additional burden on health systems is due to increased health literacy, as people increasingly want the best possible care (and are aware of what this means). For the sake of clarity, these causal relationships are shown in Figure 12.

As a result, the demand for health services has risen rapidly, causing costs and utilization to rise so much that we speak of an unsustainable health care system [9]. Such an increase in demand, on the one hand, and the lack of resilience of health systems to cope with such demand, on the other, means that patients' health needs cannot be met. Unsatisfied patient needs mean that the health system cannot achieve its outcomes and goals. Unfortunately, Slovenia is not the only country that is struggling with these undesirable causal relationships that are driving its health system towards unsustainability. The following subsection presents the problems on a broader European level.

### 4.2 Health Systems in Europe – the problems and suggested solutions

A look at the 27 European countries shows that they spent an average of 5.9% of GDP in 1990 and 7.2% of GDP in 2010 on financing health care [215]. Projections indicate that spending on financing health systems is expected to continue to increase to 8.5% in 2060 [215].

Let's take a look at the Eurostat statistics of January 2018 on various unmet needs in the health sector [216]. We see that one in four European inhabitants has been unable to meet their health care needs due to cost, distance or timeliness (waiting lines). This percentage ranges from 9.4% in Cyprus to 41.8% in Latvia. Long waiting lines seem to be the most common reason for unmet care needs in 15 EU countries and Iceland. The share of the corresponding countries was above 25% in Denmark (25.1%), Poland (26.2%), Malta (26.5%), Ireland (27.2%), Italy (29.9%) and Luxembourg (31%). In Slovakia, Hungary, Romania, Bulgaria, Spain, Greece, Portugal, Estonia, Latvia and Ireland, as well as in Norway and Turkey, too expensive was the most frequently cited reason for unmet health care needs. The highest rates were recorded in Estonia, Ireland and Latvia (30% or higher). Of the three reasons considered, distance or transport was the least common factor affecting unmet health care needs in all countries. The
proportion ranged from 1.3 % in Slovakia to 9.1 % in Italy, with Cyprus reporting a value below this range (0.1 %). The corresponding share in Turkey was the highest of all reporting countries included, reaching 13.3%.
Figure 13 illustrates these causal relationships resulting from the low resilience of health systems.

![Figure 13 Causal links that arise from the low resilience of health systems, leading to patients’ needs not being met, but also to health systems not achieving their outcomes and objectives.](image)

The question is how to simultaneously meet the health needs of the population and increase the resilience of health systems. Both European Commission and the OECD try to provide guidance on this in their publications, and we now want to take a brief look at the proposed approaches to solving the inherent problems in the member states.

In its call for a digital transformation in the health care system [11], European Commission attempts to address this question by proposing a focus:

- Patients at the heart of healthcare - to improve patient outcomes and reduce wasteful healthcare spending - there is a strong focus on better health data as a basis for policy and practise,
- Health promotion and disease prevention as the way to a more effective and efficient health system - 80% of costs are due to non-communicable chronic diseases, but only 3% are spent on prevention,
- Healthy primary care guides patients through the health system and helps to avoid wasteful spending - 27% of patients visit the emergency room for inadequate primary care; 14 countries need a referral to primary care to consult a specialist; 9 more countries have financial incentives for referrals,
- Better planning of the health workforce to make health systems resilient to future developments - Europe has 18 million health workers whose potential must be unlocked.
• Integrated care as a way to tackle the problems of fragmentation of care through which patients must move.

The OECD also stresses the need for more resilient health systems in addition to the need for more effective and accessible health systems [10]. Effective in reducing the number of people who die prematurely and increasing healthy life expectancy. Despite increasing life expectancy, Europe has lost 1.2 million people in 2013 alone due to various communicable and non-communicable diseases and other injuries that could be prevented. Non-communicable diseases alone cause the premature death of 550,000 people in European countries every year. High standards of care could undoubtedly help to reduce this number. In terms of cost, the OECD estimates that 3.4 million potentially productive years of life are lost, which is 115 billion for the EU economies [10]. An acceptable public health policy is urgently needed to address these problems. In terms of accessibility, the OECD targets the problems of people who are unable to get the care they need because of long waiting times or high costs, especially for poor people [10]. This includes health systems with universal health care. The lack of resilience of health care systems is reflected in the way an increase in demand causes undesirable effects such as long queues for care. The OECD therefore advocates that the focus should be on improving primary care to support more integrated and patient-oriented care.

Figure 14 summarises the proposed solutions that should help to improve the low resilience of health systems while reducing the burden on health systems to achieve sustainability.

The solution scheme shown in Figure 14 represents generic system-level interventions that serve as a basis for more granular interventions, which always depend on the specific context. Each country must define its health system-specific interventions to include its culture; otherwise, implementation problems arise that can seriously affect the success of the interventions. It is widely recognised that new interventions often involve digital technologies. Although the health care system invests many resources in innovative technologies, it is also one of the last industries to focus on improving its efficiency and effectiveness through the introduction of more and more digital technology. This overall process, which involves changes induced by various interventions, is a global phenomenon known as the digital transformation of the health care system. This includes digital technologies such as artificial intelligence, mobile technologies, large amounts of data and the Internet of Things. These technologies are used in various DHI that address different health care needs.
However, adoption and actual use do not take place, i.e. the epic disruption of health care by Christians [217] does not take place because health care is a much more complex context in which innovation and implementation of DHIs are necessary. The reader can gain a better understanding of health care as a complex context for innovation and implementation in Section 2.1.

We will now look at the various projects that have been planned as interventions to contribute to the transformation of the Slovenian health care system, and also present the micro-contexts in which I have tried to find, learn and follow up on research questions for over ten years. Each of the projects described also provides a brief description that relates to some of the problems of the Slovenian health system (which are also present in other European countries) and attempts to support the possible solutions to the problems as defined by European Commission (EC) and the Organisation for Economic Cooperation and Development (OECD).

4.3 The micro-contexts of the thesis - a set of projects

This section tries to provide short summaries of the different projects that were important in the overall process of this thesis. Each project description states the period in which I was participating in a particular project. Also, the subsections explain how the particular projects connect to the healthcare problems and proposed solutions that I present in the previous Section 4.2.

4.3.1 E-Depression (2008-2010)

In an application-oriented project called E-Depression, we developed an ICT environment to support the process of depression treatment. To support this process, we set out to transfer the innovative concept of business process management, which was confirmed by a study, to the health care system. Since the process was designed as a DHI, we identified the main elements that could improve mental health care and that should be supported in the new care process as follows:

- integrated, multidisciplinary patient records,
- access to these records in real time from different locations,
- content and time planning and monitoring of health care and
- simple multimodal and multi-channel communication.

The DHI "E-Depression" dealt with the problem of depression, which is particularly problematic in Slovenia. Depression in particular can lead to suicide. In 2019, according to our statistical office, we recorded 394 suicides [214]. We can state that our suicide rate is high, and according to [218] Slovenia is one of the twenty leading countries in the world (in 2020 Slovenia was in 13th place).

In addition, the E-Depression DHI supports several of the solutions proposed by the OECD and EC to improve the resilience of health systems:

- more integrated care for patients diagnosed with depression to hide the problems of fragmentation of care; the process of depression treatment coordinates healthcare professionals and patients when patients are at home,
- patients in order to reduce wasteful expenditure, improve health data for policy and practise, and improve health outcomes for patients; improved clinical outcomes of the E-Depression intervention were reported [219],
- improved depression management through the use of digital technology supports more effective and efficient health care; a report on the economic cost-effectiveness of such a service is available [220].
In my earlier technical research [221], [222] I focused on new technologies that bridge the worlds of the Internet and telecommunications and enable so-called convergent services. Such services support a consistent user experience for end users, whether they use their phone or online applications. This work has influenced my contribution to the E-Depression project [223] and has strongly influenced my work on the eCare project that I present in the following section.

4.3.2 The E-health care (eCare) process support research project (2011-2014)

From a technical and organizational point of view, the eCare project [224] builds on earlier work in the area of health process support and the E-Depression. The eCare research project is one of the largest research projects in Slovenia, which led to a common platform on which we evaluated several DHIs on the basis of clinical studies. In this project, we set out to model business processes or care processes that extend from healthcare organizations to patients' homes. For this purpose we chose Business Process Management version 2 (BPMN2). A crucial aspect of this project regarding care processes was the evaluation in the form of randomized clinical trials. The aim was to collect evidence on the effectiveness and efficiency of care processes spanning healthcare organizations and patient homes. By building such evidence, we wanted to increase confidence in the care processes themselves, but also in the overall platform that would only support clinically evaluated care processes. Such care processes included tasks that were supported by ICT, but also tasks that were performed manually either by healthcare professionals or by patients at home. These clinically evaluated care processes helped to improve control and treatment outcomes. We published positive results for asthma [225] and diabetes [226].

Since our focus was on interoperability from the beginning, we also chose the OpenEHR approach to model clinical data that is part of the care processes. We modelled all forms, tasks, or any other part of the user experience offered to patients and healthcare professionals. This enabled us to develop a platform that is highly configurable and interoperable in terms of both the care processes supported and the clinical data. Together with the supporting OpenEHR models, new care processes could be added to the platform. Further details on the architecture of the platform can be found in our publication [227], where standardisation approaches such as Integrating the Healthcare Environment (IHE), BPMN2, and OpenEHR are the core methodologies to support interoperability, especially technical, semantic, and organisational.

Another important aspect of this project is related to the design of DHI. As we learned about the main elements of a DHI that can improve mental health care in the E-Depression project (Section 4.3.1), we wanted to use this knowledge in our design in the eCare project. To this end, I enrolled in a PhD-level psychology course at University Ljubljana, where I worked with a clinical psychologist to better understand the theoretical background of behavioural change. Behavioural change is the primary goal of DHIs or the care processes we have designed, developed and evaluated in clinical trials.

My main focus was on the question of how this knowledge can be applied to the design of ICT-supported care processes. It turned out that a lot of research exists on this topic. However, my main focus was to stay connected to the medical field, so I studied the work on BCTs which is in domain of health psychology. Although this knowledge was not yet mature enough to be structured in a, e.g. ontology that could be used in ICT, I
tried several different approaches to bring such knowledge into our DHI design phase. One of these approaches is the work in which we, together with a health psychologist, described a mapping between BCTs and characteristics of our DHIs [228]. Since this mapping was defined based on the knowledge of the health psychologist who is actively researching the design of DHI for health care, I was interested in perhaps finding a way to model such knowledge. The closest I came was using a conceptual model to define health interventions. I then mapped such models to clinically evaluated care process models. We reported on this work [229] and I included it in this thesis in Section 7.

In the eCare project we wanted to support several clinical contents in a similar way as we supported depression in the project E-Depression. These included asthma, diabetes, obesity, schizophrenia and physical activity, which we will now briefly introduce.

4.3.2.1 The eAsthma DHI
The problem in general is actually a social problem of patients with the chronic asthma disease, who have several problems and needs that need to be met and which lead to a worse quality of life for them. The involvement of asthma patients in drug treatment or other medical interventions is surprisingly low. Overall, asthma patients receive only 20% of the prescribed dose of preventive medication. Lack of treatment is one of the most important reasons for poorly managed asthma [230]. Asthma patients also neglect other factors such as smoking cessation, flu shots and various allergy interventions, all of which contribute to poor asthma management. Patients are not aware that they are managing their asthma badly, or they do not understand that asthma symptoms can be reduced, if not eliminated, through treatment and prevention. They often do not recognise the early onset of the disease or are unfamiliar with self-management measures for asthma [231].

These are the reasons why many asthma patients have a significantly lower quality of life and are unable to perform many physical activities that they would otherwise be able to do if their asthma was properly treated. In addition, the ability of a patient to work decreases. Some asthma patients die during an asthma worsening. A large number of deaths are attributed to low commitment to treatment with preventive anti-inflammatory drugs. Familiarity with the treatments that can increase commitment to such treatment is therefore crucial [232].

In this DHI, our main clinical partners were the lung disease specialists from Golnik Clinic in Slovenia, who participated in the role of the leading clinical research institution at the secondary level of the health care system. The most important artefact, the eAsthma DHI, was to be accessible to multiple user groups within or outside of typical care environments, including patients at home. This led to the need for a digital platform that would support not only this intervention for multiple user groups but also all other interventions. The kernel theory used for the digital platform is that of the multi-page platform theory on which our design was based. In particular, we derived design questions from this theory.

With the aim of achieving equal or improved health outcomes, we focused on theories of behavioural change and in particular on techniques for changing behaviour to influence the design of digital health interventions themselves. We wanted to design
theory-based digital health interventions that target behavioural changes in asthma patients. In this way, the care process supported by eHealth digital health interventions would be enriched with knowledge from health psychology, so that the intervention leads more effectively to equal or better health outcomes.

The process model for asthma treatment was implemented and used on a digital platform. Further details of the process are available [227]. The intervention initially involved informing health professionals about the changed care process and their role in this process. They were also taught how to use the provided digital eAsthma health intervention to implement the changed care process as effectively as possible.

4.3.2.2 The eDiabetes DHI

The eDiabetes DHI is similar to the eAsthma. The main differences were the following:

- the healthcare setting was different as here we collaborated with a network of primary care physicians as with eAsthma we focused on one hospital that represents the secondary care of the health system.
- We conducted the initial design with a small group of physicians led by the Family Medicine cathedra of the Medical Faculty.
- We piloted the intervention in twenty different practices.
- The clinical trial was executed in twenty different primary care practices.

We have also managed to show positive health outcomes with eDiabetes DHI [226].

Concerning the formalization of learning, continuing from the eAsthma DHI, the abstract care process model that we developed for the eAsthma, has now been refactored. As we designed the abstract eDiabetes care process model, we identified common reusable sub-processes that became building blocks for both abstract care process models. With this, we have created a new layer of process models that are even more abstract than both eAsthma and eDiabetes care process models. Therefore, some patterns emerged here as we were able to find common elements in both care process models that we could extract into the higher abstraction level process model. The connection between the two levels of abstract care process models was inheritance.

4.3.2.3 The case of eObesity Digital Health Intervention

The WHO is trying to find answers leading to the more efficient management of CNDs. In the last 25 years, WHO's program for the prevention and management of CND, called CINDI (Countrywide Integrated Noncommunicable Diseases Intervention) acquired an extensive base of knowledge, research-based evidence, experience and acceptable practices [233], [234]. CINDI's actions direct towards the prevention of all known risk factors. Its broad approach combines different implementation strategies, including policy formulation, capacity building, establishing partnerships, as well as information support for all levels and cross-sectorial activities to exert influence on health determinants.

Currently, the National program for primary prevention of cardiovascular diseases (CVD) or other CNDs is run by family physicians in primary health care service [233]. It consists of screening for people with high risks, men between 35 and 65 years of age and women between 45 and 70 years of age. Also running is the Health Counselling
Programme (workshops on healthy nutrition, physical activity, healthy dieting, and quit smoking) in Health Education Units within health centres. The program has proven efficient [234]. However, it turned out that the attendance “compliance” of people threatened with high risks for cardio-vascular diseases and other chronic diseases at workshops in health education units was insufficient, especially regarding risk groups that were employed. There is a need for the development and availability of more advance types of adequate DHIs leading towards lifestyle changes.

With the e Obesity DHI, we had a more difficult task at hand since we had issues with streamlining existing obesity-oriented care processes. Here, these were special events organized for obese patients, where they are taught about how to lose weight. The new care process model that we were designing was to replace these events.

4.3.2.4 The case of eSports Digital Health Intervention
Lifestyle change could reduce up to 90% of diabetes mellitus type 2, 80% of coronary heart disease and more than a third of all cancer cases. Physical activity for health and physical exercise, healthy eating habits, and physical activity create synergic health-related effects and significantly contribute to disease prevention, reduce early mortality and disability and improve lifestyle quality for the population in Slovenia [235]. Regular physical activity positively influences reduced incidences of cardiovascular disease, Osteoporosis, diabetes type 2, certain cancer types and obesity – in so doing increasing life expectancy [236]. Regular physical activity also reduces stress, depression, and anxiety, improving self-perception and enhancing social engagement. Evidence suggests that regular physical activity in children and adolescents improves learning, self-image and reduces the intake of alcoholic beverages and other drugs [237]. In Slovenia, 50% of the population is physically inactive, resulting in increased health care services utilization and increased health care cost [238]. An overall estimate for Slovenia, based on an Australian calculation is that 800 deaths and more than €80 million EUR spent yearly are the consequences of inactivity [239]. Similar results have been shown in the UK and elsewhere [240]. Jones and Eaton have shown that a saving of US$4,3000M would result if all inactive population became physically active [241]. The World Health Organization describes 2% to 7% of total health care cost as the consequence of physical inactivity and a sedentary lifestyle [242]. With the help of innovative web and mobile-based services for the management of the regular physical activity, we wish to increase the share of the physically active population, measure the effect of the intervention on psychosocial status, and demonstrate improved overall physical fitness.

4.3.2.5 The case of the e Shizophrenia Digital Health Intervention
The primary focus of this content was anxiety disorders. However, we later switched to schizophrenia as we were not able to ensure the participation of the stakeholders from the anxiety disorder field. However, I do provide here a short rationale for the anxiety disorders and then also a short rationale for the schizophrenia condition.

Anxiety disorders are the most critical mental health condition in the developed world besides depression, with an overall prevalence of 5 to 18%. It includes social anxiety, generalized anxiety, obsessive-compulsive disorder, post-traumatic stress disorder,
panic, agoraphobia and other phobias. Anxiety disorders are common both in the adult population and with children. Research shows that eHealth and emerging ICT tools are essential for improving the recognition and treatment of anxiety disorder. Further research and development of these tools are necessary. For example, online cognitive behavioural therapy has already been shown effective. An integrated approach to anxiety management with the addition of adapted physical exercise has been shown efficient.

Summary of the work on the eCare project
With the work on the eCare project, we tried:

- to provide new ways for the patients to be more in charge of their chronic diseases – to become more empowered and put in the centre, and at the same time decrease the workload of nurses and other medical professionals and with this reduce wasteful spending – and by this support more resilient health system in the future,
- to help DHI designers with a way to bring their designs into practice as e.g. health psychologists often are not able to go beyond evaluating their designs.
- to increase the trust of medical professionals towards the clinical processes that were the basis for the digitally supported interventions,
- to help bring new DHIs into clinical practice through the use of the digital platform that supports interoperability by design through the use of OpenEHR.

At the end of the eCare project, it became clear that we would not be able to implement such a digital platform within the healthcare system and with this not be able to bring new DHIs into clinical practice. There are several reasons for such a conclusion, such as lack of funding. However, more importantly, there is a highly complex institutional context that does not support such changes to happen quickly or happen at all. Therefore, I was motivated to learn more about digital platforms, and the ecosystems the platforms enable and support. This led me to the concept of open platforms which forms one of the core concepts of all the following projects.

All of the following projects thus introduce digital platforms as a means to support two-sided exchange between different providers and consumers of the platform. Such exchanges could be, for example, our past E-Depression intervention or any of the eCare project interventions. Digital platforms thus represent this next step of embedding digital interventions in order for them to become available to a broader pool of end-users, and also providers. My focus in these projects was on digital platforms where public institutions and not private companies take the roles of sponsorship and ownership.

Digital platforms can support several of the solutions to the low resilience of the health systems as promoted by the European Commission and OECD:

- more integrated care for the patients,
- patients in the centre of health care to achieve less wasteful spending, improved patient outcomes, and better health data for policy and practice,
- new interventions on the platform can support health promotion and disease prevention, and
- support healthier primary care by enabling many different DHIs to alleviate the burden on medical professionals.
A number of documented and published results are available as part of the project legacy, including:

- a paper on ubiquitous ICT to support chronic disease management [243],
- empowering patients with DHIs for specific chronic conditions [244],
- DHIs for behaviour change [245] [246],
- interoperability by design of the eCare platform that supported the different DHIs was described in [227] and also in a local health informatics publication [247],
- in [228] I present the design of DHIs consisting of semantics, processes and behaviour change techniques,
- we identified the focus on behaviour change as something that would need to be organized differently within the health system of Slovenia [248],
- we also addressed the secondary usage of real-world data obtained during the clinical trials by applying advanced methods of machine learning [249].

4.3.3 The Italy-Slovenia eHealth Project (2010-2013)

The project focused on the cross-border exchange of administrative and clinical patient data utilizing an information infrastructure that would support interoperability between healthcare providers from both countries. Many different stakeholders from both countries participated in the project ranging from local government, health care providers, universities and the industry. The project tried to support more integrated care for patients in the border regions of the two countries. To put the patient in the centre and provide quality data exchange between physicians in both countries was the goal. Improved health outcomes for the patients, reduction of wasteful spending, and more effective and efficient health systems were the expected outcomes of the project. Concerning the projects’ connection to this thesis, it was the first cross-border exchange of health data type of project where I participated in the design of the overall architecture. We utilized the IHE approach to standardization in healthcare. For this, this project is a top-down approach to infrastructuring through the use of standards. Part of this project was also an analysis of the state of ICT in six of Slovene hospitals. With this analysis, we wanted to establish a baseline for the health data exchange. We did not publish the results of this study, but they provided valuable insights into insufficient levels of maturity of ICT in Slovene hospitals.

Interestingly, almost ten years later, after performing a similar study in Slovene hospitals, I learned that the Slovene healthcare does not have the capabilities to participate in the digital transformation. For this, it is heavily dependent on private companies. The main result is power asymmetry over ICT, interoperability, and data. These results have heavily influenced the commons approach to governance as a different way forward that does not depend on the state or market.

4.3.4 Smart Open Services for European Patients (epSOS) (2012-2014)

The epSOS project lasted between 2008 and 2014. The funding available was some 38 MIO EUR, and 25 member states of the EU participated. The goal of the project was to pilot the cross-border exchange of patient health data, namely, patient summary and prescriptions. A patient summary is considered a basic set of patient health data needed to save a patients' life. Prescriptions contain all the information needed for dispensing medications. Slovenia participated in the project from 2012 to 2014 and successfully piloted the national implementation of the technological and organizational artefacts
that supported the cross-border exchange of patient data. I participated in the role of an architect and led the development of the technical solution that passed all the formal requirements of IHE specifications. This work required integration towards the Slovene national eHealth platform on one side and supported the cross-border workflows between all the EU member states on the other side. The project was highly complex and tackled cross-border interoperability issues on all levels of the European eHealth Interoperability Framework including technical, semantic, organizational, process and legal levels [250]. All the work resulted in a vast number of documents specifying how to solve interoperability issues at each level. In order to show that it is possible to implement a real solution, the piloting took place which was successfully finished. The positive results of the epSOS project were the basic building blocks for implementing production-ready solutions, also called eHealth Digital Service Infrastructure (eHDSI). The project is still an ongoing activity which we describe in the next section.

4.3.5 EU eHealth Digital Service Infrastructure (EU eHealth DSI) (2017-2019)

The European Commission funds the eHealth Digital Service Infrastructure, and each member state can obtain funding for implementing national solutions that enable cross-border exchange of health data. Slovenia applied for the funding in 2016 and started the project in 2017. It should end in 2022. However, I participated in the project up to the end of 2019. During this time, I was in charge of the extension of the national eHealth platform architecture that was to support the cross-border use cases. I was also a member of the Member States eHealth Expert Group (eHMSEG), where I participated in decision-making about allowing countries to enter production environment. I have successfully overseen change implementation on the national eHealth platform that would enable the cross-border exchange of the patient summary. However, we postponed the prescription use case for a new round of funding. The OpenEHR is officially not used in the project, but Slovenia used it to define the Patient Summary document. This made Slovenia one of the first countries to have a structured patient summary document available. Also, as the national eHealth platform is based on IHE and OpenEHR, the patient summaries are available in the national OpenEHR Clinical Data Repository from where it is ready for transport across borders. The national eHealth platform evolved in the national eHealth project, which is presented next.

Particular publications have not been creating that would focus mainly on this project. However, it serves as part of the context as it provided requirements for the further evolution of the national eHealth platform that was becoming more and more part of a common European eHealth platform or information infrastructure.

The European Commission has been financing many different projects during the last decade that have and still focus on achieving the digital single market. New regulation on data privacy, European electronic identification, and cross-border eHealth use cases have slowly been developing during the years. These projects focus on opening the national health systems to communicate in a cross-border manner and with this support mobility of people and their health data. Slovenia has participated in these projects that have had a substantial influence on the national eHealth platform architecture. Notably, the legislation needed to change, new organizations needed to be established and interoperable information systems needed to work together across national borders. Here, the targeted solutions suggested by the European Commission and the OECD are similar to those identified at the national eHealth in Slovenia project. The main difference is the cross-border nature. In spite some of the countries having achieved production environment for services like the ePrescription it was quickly evident, that
we are still far from having a proper cross-border exchange of data due to the complexities we have described at the beginning of this chapter. Each health system is specific and integrating them just makes these differences more visible and becomes a constant source of future change.

Concerning OpenEHR, this platform has not adopted it. As a consequence, huge problems arose at the point when two countries would start the cross-border exchange of health data. Only then it became visible, that the semantics and processes are different and that by establishing a technical infrastructure without having a mutual understanding of the content and the process in which the content is created, would not yield cross-border interoperability. With OpenEHR, it would perhaps take a longer time to model the semantic artefacts in a collaborative effort between member states. However, it would provide standard semantics of the data.

This project is therefore vital for this thesis as it represents some of the consequences of not focusing on interoperability at design time, specifically, not focusing on the semantics enough and ensuring policy support in order to achieve it.

4.3.6 Cross Border Patient Registries Initiative (PARENT) (2013-2014)

This project was funded by the European Commission and had a goal of establishing a methodology for design, development and implementation of registries in Europe. I participated in the project for my experience with other European cross-border projects. OpenEHR is defined as one of the methods used in designing interoperable registries in Europe. Mainly, OpenEHR is to be used for modelling the content of the registries. By having common data elements, the future registries would become interoperable, which now is unfortunately not the case.

4.3.7 The national eHealth Project in Slovenia (eHealth) (2011-2019)

The goal of the national eHealth project was to establish an information infrastructure that would support the integration of different healthcare providers vertically and horizontally. It consists of central services that are complemented by many solution providers. Some of the core services include eReferral, ePrescription, the Electronic Health Record, and Teleradiology. In essence, it is a platform governed by the government and not a private company. Concerning the solutions suggested by the European Commission and OECD for tackling low resilience of health systems, such a platform tries to put the patient in the centre, support a more integrated care experience for the patient, reduce waiting times for services, and provide better data for improved policy and practice. The data such a platform generates can be used for a more proactive workforce planning and forecasting.

This project is, in addition to the eCare project, a crucial project supporting the results of this thesis. Here is where different approaches to semantic interoperability have been used in a complementary way. This includes IHE, OpenEHR, SNOMED and even Continua (an approach to standardization similar to IHE but focused on sensors and other measuring devices). The overall architecture of the eHealth platform is very similar to the eCare platform architecture – at least at the level of the infrastructure based on standards. The DHIs are here certainly different and focus on solving mostly administrative problems in healthcare, for example, prescriptions and referrals.

In this project, we established a national OpenEHR clinical data repository and modelled a national document called Patient Summary, which has lately become an international ISO standard. There is also a European version of the Patient Summary that serves as the basis of the European eHealth platform cross-border exchange use cases where the Patient Summary is one of the most complex ones and still far from
reality. In overall, the national eHealth platform supports non-structured documents, half-structured documents, and the fully structured OpenEHR-based documents. With this, a generic infrastructure has been established that is future proof and supports the gradual transition from non-structured to fully structured documents being exchanged in the health system.

Concerning publications, the work on this project resulted in several published materials, including:

- a combination of behaviour change as part of the design of DHIs, and open eHealth platforms (the national eHealth) served as the basis for one of the publications [229] – this is where we tried to bring the DHIs from the eCare platform to the national eHealth platform and by this support further embedding of our DHIs into everyday work practices.
- Interoperability by design on the national eHealth platform has been presented [169], and
- the ecosystem perspective of the national eHealth platform was presented on the case of the cervical cancer network in Slovenia [251],
- we used existing design principles for eHealth platforms in order to assess how open the national eHealth platform was in practice [252]; we presented the open eHealth platform design principles in a form of a questionnaire for our self assessment and were somewhat surprised by the results; the national eHealth platform was not really open in spite being funded by public resources; it seems lock-in was established even in the case where the government was in the role of the sponsor and platform owner,
- we stressed the importance of an open eHealth platform for digital health innovation and proposed a different organizational approach to tackle the lack of openness, the lack of digital health capabilities in the health system, and the lack of an overall vision and strategy for the future infrastructuring [253]; we proposed an extension to the agency that focused on behavior change [248]. We proposed a competence centre for digital health that would be a public agency with members coming from the government, healthcare organizations, industry and academia.
- As it became clear that such a competence centre that would also focus on interoperability was far from becoming a reality, our focus on attention became somewhat away from both the government and the industry; this is how we started to focus on the values of commons and commoning and presented our views on how these concepts and the vastly available experience help tackle semantic interoperability. Our view is available in Section 11.
- As the first step towards commons and commoning, we started a collaboration with the local Medical Chamber. We posted a call for action to all the 11.000 medical professionals who are members of the Medical Chamber [254] that was motivated by the von Hippels’ democratization of innovation – a democratic processes of innovation in healthcare [255].

4.3.8 The EkoSmart Smart City Project (EkoSmart) (2016-2019)
The EkoSmart project was a multi-domain programme that included not only healthcare but also domains like traffic. The goal was to establish a smart city platform that would enable the publication of different application interfaces through which new services
would be possible that would use data from different domains. One of the sources of data was also the national eHealth platform. This project served as a source of requirements for the national eHealth architecture and governance changes towards becoming part of smart city platforms to support new services that span different industries. Unfortunately, most of these ideas have only been demonstrated in the proof of concept type solutions due to the highly complex nature of healthcare.

In this project, the focus was on new DHIs for specific diseases like heart failure. There was also a digital platform established that integrated with the national eHealth platform. The exchange of data between the two platforms has been modelled with OpenEHR. There are no specific publications related to this project but serves the purpose of the thesis as OpenEHR has been used here also.

4.3.9 The National Cancer Prevention Programme (NCPP) (2017-2019)

As cancer is a significant cause of mortality in Slovenia, we have the national cancer prevention programme in place in order to lower mortality and improve the quality of life of surviving patients. The latest program accepted is a five-year program that ends in 2021. The significant development in this program was the realization of healthcare professionals about the importance of information technology. Even so, healthcare professionals have given it the highest priority among all the goals related to diagnosing and treating cancer.

In this context, I have worked in a team of health professionals that worked on improving the information system of the cervical cancer prevention network of providers. My special interest was in expanding the national eHealth platform ecosystem with this network of providers in order to use existing resources more optimally. This included some changes to the national eHealth but also on the side of the cervical cancer network of providers. This project is still an ongoing activity but represents an essential step in the process of the national eHealth infrastructuring.

Awareness of OpenEHR has been high here, and the cervical cancer networks' information system that was in the process of implementation, was based on OpenEHR. Also, the integration between the cervical cancer network and the national eHealth platform was partially to be supported by OpenEHR.

The work on this project has been presented at the European Public Health Conference, together with cervical cancer network lead [251].

4.4 Main Researchers’ role in the projects

My roles differed within the research projects. Nevertheless, in all projects, my role was dual in its core. I was both a designer and a researcher.

The eCare project was my primary research project where I wore the most different hats. At the kick-off meeting of the project I was nominated as the operational project manager. It was the first time I was named into such a position. In addition to overseeing the project, I also participated in all the activities involving design with the stakeholders, leading the architectural choices as the main architect, lead software development, and participated in the intervention and clinical trial planning with the partnering organizations.

The software development was mostly done by a team of developers who were employed by the project. However, we did outsource the eSports digital health intervention to an external software development company in order to evaluate a
research hypothesis about the resource consumption of designing and developing a new
digital health intervention.
In the collaboration with the primary health care providers, secondary healthcare
providers and tertiary healthcare providers, I played the role of an assistant in the parts
connected to the medical domain as we had a colleague on board that was closer to the
medical domain with his education and experience. This was how we were able to
empathize more with the healthcare professionals and were consequently able to have
them participate with us in more long-term way.
Part of the eCare project was also design and development of front-end web
applications for the end users, and also design and development of a mobile application.
I participated in the role of the information architect but did not participate as a
developer as I was mostly focusing on the overall digital platform. I also participated
as a researcher and a supervisor to a student who used the mobile application
development for his bachelor thesis. He focused on using the boundary resources of the
digital platform on a mobile phone and found it feasible and useful.
On the Italy-Slovenia cross-border eHealth project, I participated in the role of an
architect focusing on the cross-border exchange of medical administrative and clinical
patient data. Before working on the architecture specification, I performed an analysis
of the state of ICT in six hospitals in Slovenia with the goal to identify the potential for
integrating the hospitals in a cross-border scenario. I was able to reuse the basic
architectural principles that I used in other projects.
I started participating on the national eHealth project during the eCare project. I was
hired by the Ministry of Health to become the lead of the standards group. My main
result during this assignment was to prepare a conceptual architecture of the national
eHealth with special focus on interoperability and international standards. I defined the
main architectural principles that were to ensure long term interoperability and with
this sustainability of the national eHealth. I also defined such requirements for all the
planned national eHealth services like the eReferral, ePrescription, Teleradiology etc.
These results were then used as the basis for the public procurement process at the
Ministry of Health. Therefore, my role at this point was an architect and an external
consultant. However, I was able to apply several architectural principles from my eCare
primary research project. Sometime later, I accepted a position at the Ministry of
Health, so I became a full-time employee of the Ministry. My role was that of a
secretary or a senior official at the main regulator of the health system. I managed the
national EHR project the basis of which I defined as a consultant a few years earlier. I
was able to ensure that the important architectural principles were followed through the
procurement process and later also through the national implementation process. At this
position I had the roles of a government official and was able to influence national
decisions, the role of a project manager in charge of national eHealth projects, and the
role of an architect as I oversaw the overall architecture of the national eHealth but were
unable to influence all the architectural principles to be in line with the requirements I
specified for the different eHealth services. The procurement process is a dynamic and
rather unpredictable process that can also be influenced by the politics. Therefore, the
purchased solutions did not all comply with the specified requirements.

On the EkoSmart Smart city project I represented the National Institute of Public Health
My role on the project was a project manager and was in charge of several work
packages focusing on legislation, interoperability and technology. In addition, I was in
the role of the national eHealth architect and participated in the activities of extending
the overall eHealth architecture for it to become part of the smart city platform which
in addition to healthcare included also domains like traffic etc. I also played the role of a strategist towards the different stakeholders. Particularly, I was part of the design thinking activities with the stakeholders where I was making sure that several architectural principles of the national eHealth were applied and used in order to assure interoperability and long-term sustainability and prevent lock-in. I also used some design principles from the eCare project – namely the ones focusing on designing clinical care protocols.

On the European eHealth platform related projects, I participate in several roles. One is being a project manager for Slovenia and represent Slovenia in the European Commission project consortiums. I also participate as the national eHealth architect and strategist towards the European Commission in order to ensure the requirements of Slovenia are taken into consideration. I also focus on cross-border interoperability principles and align these with the national eHealth platform. In the past, I also defined the architecture of a platform for cross-border registries. In overall, the main projects from this group are the Joint Action Parent project, the large-scale ePSOS project, the latest and also the last eHealth Joint Action project, the project for establishing the cross-border integration for the ePrescription and Patient Summary scenarios, and the EIDAS regulation-based project that focuses on establishing the infostructure for a common electronic identity in Europe.

On the epSOS project, I worked in the role of the integration architect and also implemented the integration as a software developer. The project was a pilot project where all the European Union countries participated with the goal of preparing specifications of a joint European eHealth platform that would support cross-border exchange of patient data and with this support the digital single market concept. These specifications are the basis for the current project of integrating the national eHealth with the European eHealth platform.

In the EIDAS project I participated as the national eHealth architect and worked on specifying the extension points in the architecture in order to support a cross-border electronic identification.

The national cancer prevention programme is a five-year program focusing on improving all the aspects of cancer care in Slovenia. I was nominated by the Ministry of Health to become the lead of the group focusing on IT. It is important since medical professionals have given IT a primer priority. This means that the awareness of the importance of having the right information at the right moment has, at least in the oncology medical sub-domain, reached the highest level of importance. For this purpose, I also played the role of the national eHealth architect in order to plan for changes in the architecture in order to support all the needs of cancer care in Slovenia in order to integrate all parts of the cancer care continuum into an integrated information system – vertically and horizontally. I participate also as a member of the experts governing body of the national program being the only non-medical professional.

A specific task within the program was to use the national eHealth platform core services to support the new information system of the cervical cancer health providers network. As such networks are an important part of the national eHealth ecosystem, I see myself as being in the national eHealth ecosystem architect [256] as I focus on speeding up implementation, unlocking new resources, increasing the value of the national eHealth core services, increase attractiveness for new users, decrease total cost of ownership for platform functionalities etc. and also in general, to decrease resource consumption within healthcare. In terms of the evolutionary stages of ecosystems I see my role in the specific case to be part of the expansion (expansion of the national ecosystems).
eHealth platform) and leadership (encouraging health providers and suppliers to work together) stages. In general, an ecosystem architect participates in all the phases of the platform ecosystem evolution, namely: birth, expansion, leadership, and self-renewal [256]. Table 3 provides an overview of all the roles I had on different projects. There are four main roles I have over all projects, namely, a designer, researcher, project manager, and architect.
<table>
<thead>
<tr>
<th>Role/Project</th>
<th>E-Depression</th>
<th>eCare</th>
<th>Italy-Slovenia eHealth</th>
<th>epSOS</th>
<th>EU eHealth DSI</th>
<th>PARENT</th>
<th>National eHealth</th>
<th>EkoSmart</th>
<th>NCPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designer</td>
<td></td>
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<tr>
<td>Researcher</td>
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<tr>
<td>Project Manager</td>
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<tr>
<td>Architect</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Lead Software Developer and</td>
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<tr>
<td>Team Lead</td>
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<tr>
<td>Consultant</td>
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<tr>
<td>Standards Lead</td>
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<tr>
<td>Government official</td>
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<td></td>
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<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Strategist</td>
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<td>X X X</td>
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<tr>
<td>Ministry of Health</td>
<td>X</td>
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<tr>
<td>Workgroup Lead</td>
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<tr>
<td>Expert Governing Body Member</td>
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<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Ecosystem Architect</td>
<td></td>
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<td>X X X</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3 Overview of the roles I had in different projects**
I would like to mention, that I did not participate as a researcher in the medical domain. This means that clinical trial and especially the dissemination of results was entirely independently performed and published. Therefore, I only cite those results. Not being part of the clinical results dissemination is in my opinion just another way of empathizing with the medical professionals that increases the overall trust towards me and the other non-medical colleagues, and the research project.
5. The informative context of the main projects

This chapter has two main objectives. The first is to clarify the relationship between projects, papers and research questions, and the second is to show how the results of published research support the answers to the research questions presented in Section 12. We begin with an overview of the relationships in Table 4, which are described in more detail in the following text. Then we provide additional information from the two main projects (eCare and eHealth) in subsections 5.1 and 5.2, which are maybe not directly mentioned in the published research, but play an important role in supporting the answers to the research questions. The information in Sections 5.1 and 5.2 is referred throughout this paper as the informative context.

<table>
<thead>
<tr>
<th>Published research paper included in the thesis</th>
<th>RQ1</th>
<th>RQ2</th>
<th>RQ3</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper 1: Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge</td>
<td>X</td>
<td></td>
<td></td>
<td>eCare, eHealth</td>
</tr>
<tr>
<td>Paper 2: Modelling Time-series of Glucose Measurements from Diabetes Patients using Predictive Clustering Trees</td>
<td>X</td>
<td>X</td>
<td></td>
<td>eCare, eHealth</td>
</tr>
<tr>
<td>Paper 3: Special Topic Interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national eHealth</td>
<td>X</td>
<td>X</td>
<td></td>
<td>eHealth</td>
</tr>
<tr>
<td>Paper 4: Is national eHealth in Slovenia on Track to be an Open eHealth Platform?</td>
<td>X</td>
<td>X</td>
<td></td>
<td>eCare, eHealth</td>
</tr>
<tr>
<td>Paper 5: Commoning Semantic Interoperability</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4 Connection between research papers included in this thesis, the main projects, and the research questions they support.

RQ1 focuses on finding a work practise that enables productive work with semantic resources. In RQ2 I investigate how the work practise affects the current work methods. In RQ3 I look for a solution to problems that hinder productive work with semantic resources. The new work practise should support productive work in the early phases of TDSs, the technical, organisational and governance aspects of SECOs and at the micro, meso and macro levels of health systems. Therefore, the new work practise should be able to link the innovation process in health care with software ecosystems in order to organise projects in a way that they can support productive work on semantic resources at micro, meso and macro levels of health systems.

Figure 15 presents the overall research as a SECO evolution in which several socio-technical transitions took place - starting with an algorithm for machine learning, which is embedded in DHIs at the next socio-technical transition. Next, the DHIs will be embedded in a software platform to become part of the offer. The next step is the national governmental eHealth platform, in which the DHIs and the supporting platform will be embedded. Such a national platform supports the ecosystem of the national eHealth platform, which represents the final socio-technical transition. These transitions are further elaborated in the results in Section 12.
The socio-technical transitions observed in this thesis that can also be seen as the SECO evolution.

The socio-technical transitions took place in various projects. To better understand their role, we can look at Figure 16. Here we see all projects categorised by TDS and the main topics are explicitly shown on the left. Reference is made to interoperability approaches such as OpenEHR, IHE, and Continua, which represent approaches to interoperability in healthcare. These interoperability approaches are also discussed in several papers and are part of the results of this thesis. All these topics are explicitly addressed in the following text and linked to the research papers and research questions.

On the right side of Figure 16 we can see the micro, meso and macro levels of health systems as tags for each of the projects, indicating the levels at which particular projects were present with their activities and outcomes. Thus, the interpretive context contains information that is relevant to the research questions, since productive work on semantic resources is required at all these levels. By presenting the various projects and providing information about the work on semantic resources, it is therefore implicitly clear which levels of LoHS were involved in the work.
The main themes, interoperability approaches and levels of health systems that the various projects address in the overall SECO evolution. The projects are categorised according to their position within the TDS of a typical innovation process in the health sector. The work practise of RQ1 is influenced by the experience of productive work on semantic resources in all phases of TDS covered by the different projects. The experiences from the projects described here as an informative context together with the research work contribute to the design of the work practise of RQ1 and at the same time support the answer to RQ2.

Despite the many projects that are presented as an informative context for answering research questions, there are specific interdependencies between projects that are important and are shown in Figure 17.
It should be clear that there are two main projects which have been influenced by all other projects: the eCare and the national eHealth projects. To this end, I will focus on these two projects and provide an interpretive context in which I will explain all relationships with other projects. This interpretive context, together with the papers and their results, will form the basis for answering the research questions.

In Table 5, a timeline shows a categorization of all publications according to the two main projects. This links the projects with the research work. The work on RQ3 with Commons is seen as an activity separate from the projects but influenced by them. Furthermore, each of the published papers is categorized into one or more SECO aspects, the technical (T), organisational (O) and governance aspects (G). This suggests that we can classify the results into these aspects of SECO's which is important because the entire research flow is a SECO evolution – starting with technical development (the level of software providers [180]), continuing with the introduction of relationships with organisations (hospitals, health professionals, etc.), which is part of the software supply network level [180], and finally participation at the software ecosystem level [180], where the provider has to open interfaces and exchange knowledge. The SECO in focus is the national eHealth SECO. Within this SECO evolution, the papers included in this thesis address some of the identified problems that fall under technical, organisational or governance aspects of SECOs and are presented in results in Section 12.
<table>
<thead>
<tr>
<th>Year</th>
<th>Title of the published research</th>
<th>Research context</th>
<th>SECO aspects</th>
<th>Part of thesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Opensource SDP architecture for building convergent services for remote care [221]</td>
<td>Prior technical research</td>
<td>T</td>
<td>G</td>
</tr>
<tr>
<td></td>
<td>Using open source based convergent services in the field of healthcare [222]</td>
<td>Prior technical research</td>
<td>T</td>
<td>X</td>
</tr>
<tr>
<td>2010</td>
<td>Depression treatment with the help of open source convergent services [223]</td>
<td>eCare</td>
<td>T</td>
<td>X</td>
</tr>
<tr>
<td>2011</td>
<td>Ubiquitous ICT supported care of chronic diseases</td>
<td>eCare</td>
<td>T</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Conceptualization of an interoperable backbone for the national eHealth [257]</td>
<td>eHealth</td>
<td>T</td>
<td>O</td>
</tr>
<tr>
<td></td>
<td>Empowering Patients with Chronic Diseases [244]</td>
<td>eCare</td>
<td>T</td>
<td>O</td>
</tr>
<tr>
<td>2012</td>
<td>E-Health Approach to Chronic Disease Management for Self-Management and Behaviour Change [245]</td>
<td>eCare</td>
<td>T</td>
<td>X</td>
</tr>
<tr>
<td>2013</td>
<td>Comparing the Success of ECare Interventions for Chronic Disease Management and Disease Prevention [246]</td>
<td>eCare</td>
<td>X</td>
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</tr>
<tr>
<td>2014</td>
<td>Interoperability and mHealth – precondition for successful eCare [227]</td>
<td>eCare</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Design and Deployment of eHealth Interventions using Behavior Change Techniques, BPMN2 and OpenEHR [228]</td>
<td>eCare</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>Establishing a National Agency for eHealth and mHealth as Interventions for Behavior Change [248]</td>
<td>eCare</td>
<td>X</td>
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<tr>
<td></td>
<td>Preconditions for successful eCare [247]</td>
<td>eCare</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>Modelling time-series of glucose measurements from diabetes patients using predictive clustering trees [249]</td>
<td>eCare</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national ehealth [169]</td>
<td>eHealth</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge [229]</td>
<td>eHealth</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fifteen years of Slovenian cervical cancer screening programme ZORA. A change in a registry concept [251]</td>
<td>eHealth</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>Is National Ehealth in Slovenia on Track To Be an Open Ehealth Platform ? [252]</td>
<td>eHealth</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Digital health innovation based on the national eHealth platform [253]</td>
<td>eHealth</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td>Commoning Semantic Interoperability</td>
<td>Commons</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Democratization of Digital Health Innovation Design – a call for action [254]</td>
<td>Commons</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Table 5 A timeline of the published work. The research context is mostly the eCare and eHealth projects. Focus on commons was not part of a particular project. Each paper contains information about the SECO aspects it focuses on. SECO aspects are depicted as T for technical, O for organisational and G for governance. Papers 1 to 5 are included in the thesis.
5.1 The informative context of the eCare project

The eCare project was first presented in Section 4.3.2, where we learned that the focus is on three main concepts: (1) to bring the clinically validated concept of business process management into healthcare, (2) to design interventions grounded in behaviour theory, and (3) to focus on interoperability during the DHI design phase in order to design interoperable DHIs. This is illustrated in Figure 18, where we can also see the three primary expected outcomes of implementing the three concepts, namely inducing behavioural changes, optimising care processes, and enabling data liquidity.

![Diagram of DHI concepts and outcomes]

**Figure 18** The three main concepts of the DHIs in the eCare project DHIs together with the expected outcomes of implementing the three concepts

Bringing the clinically validated concept of business process management to the healthcare sector began with our earlier work in the E-Depression project described in Section 2.3.1. This means that we have redesigned existing processes or created new processes. These can be seen as process innovations and represent changes in the work processes of health care organisations that are part of the healthcare system. We refer to such innovations as DHIs, and the literature reports an apparent lack of DHIs that reduce symptoms, promote comfort, and ensure that patients are well at home, work, or school [258].

In accordance with the objectives of the innovation process, as shown in Figure 16 above, we were able to design and develop the DHIs and evaluate them in randomised control studies, even start implementation. However, we did not complete it and therefore did not achieve the embedding of the DHIs in clinical practise. In order to better understand each of the objectives of the innovation process, we will now look at each of these objectives individually and then explain why this text is essential for this thesis and the research questions.

**DHI Design and Development**

The design and development of the DHI was carried out in a multidisciplinary and participatory manner. Perhaps such approaches are standard in the Scandinavian
countries but are unfortunately often ignored in other parts of the world, including Slovenia. Here, the separation between developers and users in the health care sector is expected [259], and a gap between the collection of technical requirements and more user-oriented, design thinking based techniques with a focus on health care [260], [261] is obvious.

The focus was on creating more optimal care processes to replace or improve existing working practices. As we have learnt in the literature and also presented in Section 2.2, various findings - namely theories - should be carefully considered when designing the DHI. The goals of the DHI were to improve outcomes for patients while at the same time optimising work processes for medical staff. The patient outcomes to be improved or at least to be maintained were both clinical and behavioural. Patients had to develop more self-confidence and have better managed conditions or at least the same as without the DHI. In order to achieve this, the patient's behaviour must be changed to provide the basis for improved behavioural outcomes.

Coping with this problem was difficult, but necessary, because we learned from the literature that behaviour theory informed DHI lead to better results - although it is not entirely clear why exactly. So, the promise was to use behavioural theory in our DHI design phase to reduce the risks associated with achieving adverse clinical and behavioural outcomes for patients. This led to collaboration with health psychologists and clinical psychologists. In [228] we present our work in which we mapped behavioural change techniques to our DHI characteristics. The participating health psychologist validated the mapping.

In the following I wanted to go one step further and model behavioural theory so that it could be used in the software. I came closest to this goal by first researching the available literature together with a clinical psychologist during a PhD course at the Faculty of Psychology and putting such a modelling into practise. In particular, I used a conceptual framework for adaptive preventive interventions [262] to highlight the main components of behavioural interventions in general (decision points, intervention options, adaptation variables, and decision rules) and to provide specific components that we implemented in our case study intervention, and to show what behavioural knowledge we used and how it was applied. I used the conceptual framework to model the behavioural change knowledge and then implemented a mapping of these models to the DHI care process models. This work was published in [229] and is also included in Section 7.

It is also worth noting that the work included in Section 7 was presented at a conference attended by international health psychologists, clinical psychologists, medical doctors, prospective nurses, and many other health care students and professionals. I see my participation in this conference as part of empathising with the existing health culture to better understand it and to help implement changes supported by innovative DHI. Many of my publications have been published in venues that might not be on the radar for a typical academic. In my case, such venues were usually relatively new and very interdisciplinary, where I could best test my ideas while building trust with the many health professionals. This is part of the reasoning behind using action design research tradition as the core method of this thesis and is also part of the view that the digital transformation is primarily a cultural transformation.

Therefore, the DHI we design should be based on behavioural theory. In the literature, a clear lack of such DHI is reported [50], [178], [263], [264]. If we had ignored this knowledge, the behavioural change abilities of our DHIs would be completely random
and a result of pure luck, as reported in the literature and as presented in our work in Section 7 and also in Section 2.2, where I introduce DHIs.

**DHI Evaluation**
The decisive reason for evaluating such new care processes with the help of randomised clinical studies was twofold. Firstly, to gain the confidence of healthcare professionals in DHIs, and secondly, to gain confidence in the software platform we built to support many such DHIs. The lack of such platforms is evident from the literature [50], [264], [265]. Such a platform would therefore only support clinically validated DHIs that could evolve over time to become even more optimal. The platform would support a constant trial-based evaluation in real clinical environments.

**DHI Implementation**
The implementation was started, as the DHIs were already used in clinical practise during the evaluation period. However, we were not able to complete the implementation mainly due to unclear business aspects. In Section 2.1 we learned about the critical factors that influence the success of the implementation. In our case, there was little financial or legislative support. There were no funds available for either the eCare project or the service providers. It was expected that the Ministry of Health would finance the implementation and future maintenance. These expectations were based on the fact that the Ministry of Health was a co-financing partner of the project together with the Slovenian Research Agency. This never happened, mainly due to the monopolistic behaviour of the existing vendors in healthcare. At that time, I became fascinated by the organisational infrastructure in the health care system and continued my research in this direction. I hoped that through a better understanding of both the institutional theory and the functioning of these key players in the health care system, I would be able to create a more robust DHI implementation plan. The lack of such a plan was the second missing implementation success factor that we learned about in Section 2.1.

**Importance for the thesis**
Although the main research questions do not focus on behavioural change aspects of DHI design, I have included a paper (Section 7) in this thesis to emphasise the importance of knowledge engineering (KE). KE was necessary for behavioural knowledge, but even more critical for Semantic Resources Engineering. KE falls under the SECO technical aspect. In addition to the KE, I also wanted to provide information about DHI design based on behavioural theory, since one result of this work was a proposed organisational change in our health care system which falls under the SECO organizational and governance aspects. I described the need and the proposed solution - a new national agency focusing on behavioural change and health psychology [248]. In my opinion, at the time of writing I saw the need to organise such work at national level in order to achieve a more optimal use of resources and better results for the users of DHI. The problem was that health psychology was not yet recognised as a specialisation in Slovenia and that we only train clinical psychologists. This presents significant organisational and management barriers, so an agency would be able to recruit foreign experts and perhaps carry out a transfer of knowledge. Such a service would therefore be offered at national level and become part of the national eHealth platform and the SECO it supports, where various companies would design and develop new theory informed DHI as complements of the platform.
In this thesis, the behavioural aspects of designing DHI can be considered complex and require specific knowledge and KE. We can see that the design of DHI for behaviour change consists of technical, organisational and business/governance aspects of SECO. As far as the work on national eHealth is concerned, I saw an agency focusing on DHIs for behaviour change as a necessary core service offering of the whole national eHealth platform. It would support valid DHIs as an extension of the platform's core offering. This would allow the eHealth platform ecosystem to expand. The main reason is that such theory-based and clinically evaluated DHIs would be more trusted by healthcare professionals. This would make the DHI implementation plan more optimal. In addition, as mentioned above, I have considered such coded behavioural knowledge to be freely available. This is important for my RQ3, in which I discuss Commons for semantic resources.

These ideas had a positive influence on my later research, because I encountered similar technical, organisational and governance problems with semantic resources as with behavioural knowledge. However, based on my experience with national stakeholders such as the MoH, NIPH and NHIF, I realised that organising and governing at the national level is not possible, just as one cannot count on industry, since both can be considered as the ones that caused interoperability problems in the first place. These considerations formed the basis for the political theory from which the well-examined Commons concept helped me to design a potentially independent solution for the management of semantic resources, but also for knowledge engineering in health care in general. RQ3 is mainly concerned with Commons based governance, so a DHI design based on behavioural theory is essential, as it led my considerations to a solution of the governance problems that are at the core of RQ3. If we look through the lens of SECO governance, we can see a development that has taken place in my way of thinking about governance. In particular, proposing national agencies has not contributed to semantic interoperability. Something else was needed there. Commons seemed to be a plausible answer. In paper 5, available in Section 11, I discuss the implications of Commons theory for productive work with semantic resources.

The third concept shown in Figure 18, which I considered to be crucial for DHIs to achieve the desired results, was interoperability. Adding interoperability at the design stage certainly makes the design process much more complicated, but necessary. Otherwise we will not see a successful digital transformation in the future. As we learned in Section 2.3.4.1, semantic interoperability of clinical data is one of the most complicated goals to achieve. However, it must be achieved, or the medical profession must invent a new way of communicating their results.

Our goal was to integrate DHI into different areas of health care. In order for this to happen without the traditional information blocking problems, interoperability as an enabler of data liquidity was given a very high priority. We looked at interoperability from the technical, semantic, and organisational aspects presented in [227], but I am bringing in the crucial information from this work at this point.

The technical aspects included a general service-oriented architecture of the platform with several health care specifics. Since the eCare platform, on which all DHIs were deployed and which provided the runtime environment for the DHIs, needed to be interoperable with the existing systems and work processes, our approach to the technical, semantic and organisational aspects was based on several interoperability approaches:
• using OpenEHR to model all of the DHI’s data requirements and also using established terminologies such as the ICD; 70% of the models were reused from publicly available OpenEHR repositories - this forms the basis of the semantic interoperability
• doctors as co-designers of the user experience, care process models and semantic resources
• storage of structured patient data in an OpenEHR repository for clinical data, which we developed for the needs of the project, as there were not many options available at that time
• interfaces based on IHE and HL7, which allow data to be either obtained from external systems or sent from our platform to external systems; we have demonstrated such functionality by integrating with the national eHealth platform and with the cross-border exchange platform - we see this as the basis for technical interoperability
• the DHIs themselves were supposed to become process standards in health organisations supported by a common eCare platform - so we see them as the basis for organisational interoperability; in fact, such DHIs were process models used on the eCare platform, which was accessible via an API. This meant that any vendor could use such process models within their solution that might have a different user experience but the same underlying clinically evaluated care process model.

I will present some of the research findings from the eCare project later in this thesis in Section 12. At this point I would like to highlight some of the tensions related to interoperability and OpenEHR that I have observed in this project and that are particularly relevant to the research questions in this thesis. These tensions also contribute to a better understanding of the various socio-technical transitions that have occurred throughout the research reported in this thesis.

OpenEHR was the chosen approach for the creation of semantic resources, which is vendor-independent and allows a high degree of reusability because the clinical concepts that model them are universal. Our greatest excitement was the fundamental promise of OpenEHR to separate clinical knowledge from software development. We received a lot of support for using OpenEHR, but, as it turned out, only as vague political statements. In practise, we were the ones who still had to listen to the doctors, carefully model clinical concepts, validate them with the doctors, model nursing processes, validate those with the doctors and nurses, and then use the results as input for the software development process. This failure to achieve the separation of clinical and technical was the first tension we experienced.

Software developers were not used to developing solutions in such a way which brings us to our second observed tension. Software developers were used to developing new software solutions in the traditional way - those that usually include a database where tables and columns are created for all data elements used in the applications. With the introduction of OpenEHR, such a database was no longer used. Instead, it was seen as the OpenEHR repository for clinical data, capable of storing OpenEHR data structures along with the data values themselves. There were also the care process models that were mapped as BPMN2 process models. These were provided directly on a BPMN2-native process engine that was capable of performing all steps - activities defined in such process models. This means that the software developers did not have to develop their own business logic, as they traditionally did. Therefore, the way web applications and even mobile applications were developed in this project was different from the
tradition. It also brought more complexity because the software platform consisted of a loosely coupled set of components orchestrated by the BPMN2 care process models. The software developers had to change their way of working significantly to promote OpenEHR.

Fortunately, the software developers adapted, but the physicians did not - at least not in the part where they were supposed to model the clinical concepts.

In the context of these participatory modelling and validation activities, we observed the third tension with OpenEHR. OpenEHR is based on the premise that each clinical concept is modelled as an archetype representing the complete data set that is considered significant by as many different medical professionals as possible. Only such an approach for a maximum data set can capture all possible data points that are important for all different medical subspecialties. The tension we observed was that our focus was not on achieving such a maximum data set. Instead, we focused only on the local needs of specific medical professionals. This means that the 30% of archetypes we explicitly modelled for this project are very project-specific and therefore cannot be directly used elsewhere - perhaps only as a basis for further modelling at a global or international level. Nor have any of the archetypes we have created undergone the cheques and balances that are now part of the governance mechanisms of OpenEHR. As a result, our DHIs have become only about 70% interoperable.

These three central tensions that we experienced in connection with OpenEHR support RQ1 and RQ2, since despite the tensions productive work on the semantic resources was achieved, but with slightly different roles as originally planned. The latter was part of the motivation for the work on RQ3.

Not only did we have a method for modelling semantic resources and mapping them to existing terminology, but we also had a lot of already available semantic resources that we could freely reuse. The key sacrifice in supporting these two key benefits of OpenEHR was the change process for both the overall architecture of the software platform and the way the software developers developed the final DHI solutions. These change processes form the basis for responding to RQ2, as these are some of the implications of the OpenEHR-based work practise for productive work on semantic resources on existing working practises.

The third tension also shows that this project was more of a bottom-up infrastructuring process than a top-down process. For this, there was no clear management structure to motivate us to better follow how OpenEHR's semantic resources should be managed. Nevertheless, our archetypes, which are tailored to local needs, could still be used to support semantic interoperability if they were publicly published and adopted by all "compliant" OpenEHR systems. Unfortunately, even today there are still a minimal number of such systems. However, the question of a motivational governance for OpenEHR's semantic resources is still relevant and provides the additional motivation to work on a solution for RQ3. OpenEHR introduced the need for a better governance approach that would encompass different levels of health care but at the same time is not part of a government or industry initiative.

We can see here that semantic resources KE also means SECO technical, organisational and business/governance aspects. The three main research questions correspond to all three SECO aspects of semantic resources KE: the work practise of RQ1, the technical elements and software development methods used in and affected by the RQ1 work practise (RQ2), and the governance of semantic resources (RQ3). Going back to the
paper on behavioural knowledge KE I should stress, that it helped increase awareness of the different SECO aspects that reappeared in the work on semantic resources.

It is at this point that we must present the next research that was carried out under this project. It is specifically linked to artificial intelligence and machine learning. After evaluating DHI in randomised clinical trials, we wanted to add new functions to our DHI. In line with behavioural theories, we wanted to provide patients with powerful feedback mechanisms to bring about meaningful behavioural change. With the eDiabetes DHI, for example, we wanted to help patients better manage diabetes and achieve better clinical outcomes.

We set out to develop a predictive analytics feature that could give patients a prediction of what their health status might look like a year in advance if they continued to manage their diabetes as they did at that time. The algorithm itself and the exciting results that showed that such a thing is possible are presented in the second included paper in Section 8. Apart from being part of the behavioural aspects of the DHIs, this work is also related to the aspects of interoperability - in particular, the impact of the work practise of RQ1 on existing working practises, which in this research meant research and development of machine learning algorithms. This work is therefore essential for RQ2.

The algorithm itself uses OpenEHR as the primary data source from which the attributes of the data instances used for the learning part of the algorithm are extracted. The algorithm is generic enough to use any set of attributes derived from the OpenEHR clinical data repository. In our case, the data itself was obtained during the clinical trials. This means that we were able to teach our algorithm on real-world data from clinically validated DHIs. In addition, we were able to achieve very positive results because, despite a somewhat low number of data instances (about 75), we had a high number of attributes to describe each patient (one data instance). Normally algorithms are trained with a high number of data instances but with few available attributes. I believe that in healthcare, the rich context is far more important than the sheer number of available data instances.

This work is crucial to this thesis, not only as a basis for even more optimal DHIs that provide decision support to health professionals and feedback mechanisms to patients, but also for their relationship to OpenEHR. In order to use the OpenEHR clinical data repository of the eCare platform, we had to develop some tools. The main goal was to support Archetype Query Language as the basis for mapping data to attributes of the algorithm. This enabled the secondary use of the clinical data, which is also an important issue for national and international researchers, industry and health policy makers. The reason why this is important is due to Bossen et al. discussion on data work [88]. With OpenEHR, a lot of the data work required by physicians, nurses and computer scientists to prepare data correctly for use in different contexts can be greatly reduced. In our case, the work of doctors has been reduced to zero. This is possible because OpenEHR allows data to be collected together with the context in which that data was collected. For this purpose, the data can then be easily obtained without the context by means of semantic queries. Therefore, the work on the algorithm is considered important for RQ2 because it influences the data work required for the exchange of clinical data and also influences technical aspects of algorithm development. In both cases, OpenEHR helps by reducing the amount of work required to prepare the data for use in the respective context - whether for AI or for uploading into an EHR or other potential use-cases.
When the eCare project was completed in 2014, one thing was clear. We failed to implement the interventions at the point of care for the reasons already mentioned (lack of financial and legislative support and lack of planning for implementation). The software platform and all DHIs were put in a drawer - something we feared most. This happened despite all the positive evidence we had built in for the use of such DHIs at the point of care. However, there were many more obstacles to overcome before this was possible. These included the involvement of stakeholders such as the Ministry of Health (MoH), National Institute of Public Health (NIPH) and National Health Insurance Fund (NHIF) - the institutional context that needed to be changed - including legislation. I hoped that the national eHealth project, which started during our eCare project and involved stakeholders from the MoH, NIPH and NHIF, could help us better plan our DHI implementation, first on a pilot scale within a region and then at the national level. It was therefore important to learn how our DHIs could be embedded in the developing national eHealth information infrastructure.

5.2 The informative context of the National eHealth in Slovenia

The objective of the national eHealth in Slovenia was to design and develop a national health information infrastructure that would help to connect the micro, meso and macro levels of the health system into an integrated health care system. The information should be able to flow both horizontally and vertically.

I started working on this project based on my experience with software development, digital platforms and interoperability in the health care sector - all topics from the eCare project. My first task was to write a document that would conceptually define the core elements of the national eHealth information infrastructure. This was a simple top-down approach to infrastructuring that required some kind of infrastructure for the exchange of health information. A reasonable approach was to introduce IHE as an interoperability requirement. I gained experience with IHE in the eCare project, but mainly in two European projects in which I actively participated.

The first was the cross-border eHealth project Italy-Slovenia, presented in Section 4.3.3, where I helped define the overall architecture of the exchange infrastructure after an initial analysis of the state of IT in several of the participating hospitals. The architecture was based on IHE.

The second project in which I actively participated was the epSOS project, which was presented in Section 4.3.4 and in which IHE was also used as a basis for the cross-border exchange of health data between all EU member states. This was a pilot project that produced valuable results on how to address interoperability between countries. These results enabled the implementation of a production environment for cross-border exchange in Europe through the eHDSI project, which was presented in Section 4.3.5. The eHDSI project is not yet completed.

At that time, OpenEHR did not yet have vendors available to tackle such a complex information infrastructure, and OpenEHR was rather seen as a powerful complement to IHE standardisation in the health care sector. The goal was therefore to build a common national eHealth information infrastructure based on IHE and OpenEHR. The benefits and possibilities of such an approach were only recently, in 2020, examined by Wettstein [266], so the literature on the subject was and is scarce. OpenEHR would be used to define the content of messages to be exchanged within the IHE exchange infrastructure. Before we decided to use OpenEHR, we first tried HL7 v3, and it turned out that we faced the same problems described in the literature. Namely, that we lacked the technical skills to make good use of HL7 v3. Also, our working groups were unable to take advantage of this because medical professionals were the first to participate.
Therefore, it was decided to use OpenEHR to model the requirements set by healthcare professionals that would become national standards. As I had a lot of experience with OpenEHR, I was able to advocate and demonstrate its application in practise. This concept definition was published [257] as a work result and served as a basis for all public tenders, where several technical elements were procured in the following years. I was also responsible for the definition of standards in all planned national eHealth services to be implemented in addition to the core infrastructure. I wanted to ensure that semantic interoperability was supported by the design, as was the case in the eCare project. That was 2011, and as I did a lot of research and development for the eCare project, I did not continue the work on the national eHealth services until the eCare project was completed. At the end of 2014, I was offered a position at the MoH, where I was given the opportunity to lead the national implementation of the concept I had helped to create in 2011.

By then, the IHE exchange infrastructure was already in place, integrated with all eight different HIS providers. Unfortunately, OpenEHR was not used to define the content to be exchanged. In 2014, only unstructured pdf documents with some metadata were exchanged. The first national implementation I was responsible for was the OpenEHR infrastructure. I have gained significant experience not only through the eCare research project and the early stages of national eHealth, but also in another European project called PARENT, which was presented in Section 4.3.6. This project focused on the cross-border interoperability of patient registers. In this project, I helped with the European methodology for setting up patient registers, identifying OpenEHR as an essential method for modelling the content of the registers. I also contributed to the pilot implementation of the methodology in the case of an endoprostheses register in Slovenia. Part of the process was the establishment of an OpenEHR infrastructure to support the implementation of the national endoprostheses registry.

With this experience I started the national eHealth project, which aimed to upgrade the existing IHE infrastructure with the OpenEHR infrastructure. The first document modelled on OpenEHR, which served as the first implementation on the common IHE and OpenEHR infrastructure, was the national Patient Summary. Especially the dataset itself was first defined in the epSOS project and later refined in the eHDSI project. In addition, the Patient Summary dataset has evolved into a ISO standard.

So by focusing on the international Patient Summary as a guide, we prepared our national eHealth for cross-border exchange and at the same time provided a valuable resource for our citizens and medical professionals. The Patient Summary, together with several other documents, was made mandatory for both preparation and uploading to the national eHealth infrastructure and for use at the point of care. The implementation of Patient Summary was then - and to my knowledge still is - the first national Patient Summary implementation using OpenEHR. This certainly represents a valuable competitive advantage for Slovenia compared to all other EU countries participating in the eHDSI project, where the cross-border exchange of the Patient Summary data set is being established. However, there are still problems with this implementation today. Despite the legal obligation to send Patient Summary data sections to the national eHealth, this is not happening as planned. Many healthcare providers and their HIS providers are doing a poor job. Since the providers of HIS operate on the basis of an information lock that does not allow anyone to know anything about their semantic resources built into the HIS systems, they are able to have more power over both the semantic resources and the data itself. With this power they can block progress towards interoperability. In addition, the problem is often that they are not able to secure the right data that would be valid against the OpenEHR models. This
is because each HIS provider has a different approach to its semantic resources and data elements are not interoperable between the different HIS. This then indicates a lot of additional data work to satisfy all information needs of e.g. MoH, NIPH and NHIF.

Regarding the work with OpenEHR in the national eHealth and several other projects, I have observed several tensions. These tensions, similar to the tensions identified in the eCare project, will help answer the research questions. The first tension I identified has just been described and concerns the problems with information locks and lock-in-based business models of HIS providers.

The second tension was observed in the work on the concept of the national eHealth infrastructure. The tension concerned the role of OpenEHR for the IT standards in the health sector. As OpenEHR was only partially standardised at that time, it was not easy to decide on its use - especially at national level. I examined this issue of different approaches to interoperability in health care in a later paper, which is also included in this thesis in Section 9. At that time, however, there was a tension between OpenEHR and HL7 Clinical Document Architecture (CDA) R2 - a new standard published by HL7 based on the use of the HL7 reference information model (HL7 RIM). These two approaches seemed to be in competition with each other, although in reality they were and still are highly complementary. Nevertheless, much literature is available to compare the two approaches. In our case, both were chosen because we saw OpenEHR as something that medical professionals could use, and HL7 CDA R2 as something that could be used to exchange OpenEHR content via the IHE exchange infrastructure. OpenEHR should be used to model the body part of HL7 CDA R2 to avoid HL7 RIM, which has been discussed in the literature as ambiguous, and many other issues [267], [268] that inhibit rather than support interoperability. Medical professionals participated, at least initially, and saw OpenEHR as a way to better communicate their needs. This was possible thanks to the freely available tools that supported the generation of simple user interfaces based on OpenEHR models. In this way, physicians were able to visualise their requirements much better and change them if necessary. However, not all doctors found OpenEHR useful. For the most part, they still used simple documents to write down requirements. Then it was up to us to model the OpenEHR archetypes and templates. It was similar to the modelling process that was done in the eCare project, with one big difference. These models were to become national standards. This required a consensus among medical professionals. And this brings us to the third tension identified.

In medicine, it is incredibly difficult to reach a consensus on anything. There is no effective governance mechanism in place to ensure that an OpenEHR archetype or template is processed, and the result would be a structure that most would agree to. Such consensus was achieved for the Patient Summary OpenEHR model, but after the project was completed., At that point, it became clear that the aspirations for more sustainable management of the OpenEHR archetypes and templates did not survive.

The fourth tension observed concerns national eHealth services, which have been introduced gradually, starting with ePrescription and eReferral. It was not clear why OpenEHR should be used to define the content of these services. Somehow the various providers of HIS who participated in these projects saw the benefits of OpenEHR only in terms of the national exchange infrastructure. They saw it as a way to specify the interfaces between the systems. However, they did not see the need and did not have the possibilities to implement OpenEHR within their existing systems.
Making such a change would require huge investments of resources that they never really had. In addition, there was no governing body that would promote the use of OpenEHR, and OpenEHR was not even adopted by the MoH as an official approach to clinical content modelling. This lack of governance also allowed the low skills of health IT professionals to remain the norm, OpenEHR modelling never really took off at the national level, and there were no health care professionals engaged in OpenEHR modelling.

The *fifth and final tension* was observed in the work and research on national eHealth - especially in the work on the concept of open eHealth platforms that enable national eHealth ecosystems. A paper in which I evaluated the national eHealth platform against the organisational design principles for open eHealth platforms is included in this thesis in Section 10. Within this perspective, OpenEHR can be seen as the central service offering of the eHealth platform, which can lead to new additions to the eHealth platform that contribute to the expansion of the overall national eHealth ecosystem. However, I realised that national eHealth still needed a lot of work to achieve a reasonable level of openness that would help me to bring eCare DHIs to the national level without having to go through the many layers of government and policy makers. Nevertheless, OpenEHR has been used in two projects, briefly described in sections 4.3.8 and 4.3.9, to create new additions to the eHealth platform. In the first project it was a telemedicine platform that produced OpenEHR documents that were stored in the national eHealth. Therefore, OpenEHR was used as an integration approach. Here the telemedicine platform did not become a national solution to the same problems of openness as mentioned above.

The result was different in the second project, where OpenEHR was used as the basis for the external system and for integration with national eHealth. The main owner of this external system was a physician who sincerely believed in OpenEHR and worked to put it into practice in the field of oncology. This joint work was presented in [251]. The oncology system was already a national system, so the openness of the national eHealth platform was sufficient.

The openness of the eHealth Platform was thus the tension that prohibited new DHIs from being brought in at the national level, but only for initiatives by non-governmental organisations. So, the government created a state-owned platform which was strictly controlled and almost nobody was allowed to create additions to this platform. In essence, it is a self-contained platform. What would help to solve this problem would be a certification process that would help the government decide which DHIs should and which should not be included. Unfortunately, as discussed in Section 10, there are still many issues to be resolved before such a process would be possible. For example, the business model of the new DHI and the business models supported by the national eHealth platform.

The five tensions described in connection with OpenEHR support the answers to RQ1 and RQ2 and help to find the solution to RQ3. The work practice of RQ1 must help to eliminate or at least reduce the identified tensions. This means first and foremost winning over health professionals to work with OpenEHR and the consensus process, even if there is no funded project. It would indeed be helpful if the MoH officially accepted OpenEHR. However, this alone would not provide sufficient motivation for anyone to start working on OpenEHR. Due to the general lack of doctors in Slovenia, such participation is even further from becoming a reality. This was also the reason why I tried to increase the interest of professionals from other health sciences. My
cooperation with the Health Sciences Faculty resulted in my participation in their conferences, e.g. [253] and [229]. The latter is also included in this thesis in Section 7.

Despite all the tensions, we were able to use OpenEHR productively while working on various projects. However, it became increasingly clear that governance could not be resolved either at government or industry level.

RQ2 can be supported by all projects where technical elements were procured, implemented and used in real use cases, such as Patient Summary.

RQ3 can be supported or motivated by the identified governance-oriented tensions. Due to the observed information blockade, which could be observed both among the industry players who refused to implement OpenEHR in their systems and among the government platforms that prevent the addition of new DHIs, I felt motivated to research Commons from political theory, perhaps to find a solution for governance that is separate from the market and government. This work is presented in the final paper included in Section 11.

For the sake of clarity, all the tensions observed both on the eCare and eHealth projects and their use to support answers to the research questions are summarized in Table 6.

<table>
<thead>
<tr>
<th>ID</th>
<th>Project</th>
<th>Name</th>
<th>Description</th>
<th>RQ1</th>
<th>RQ2</th>
<th>RQ3</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>eCare</td>
<td>Separation of concerns</td>
<td>Failure to achieve the separation of technical and clinical aspects while working with OpenEHR due to the lack of interest for modelling by the medical professionals</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>eCare</td>
<td>Software development impact</td>
<td>Software development was impacted by the need to change the software architecture and the software development methods.</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T3</td>
<td>eCare</td>
<td>Focus on local needs</td>
<td>Failure to engage in global model review procedures.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T4</td>
<td>eHealth</td>
<td>Lock-in based business models work against OpenEHR</td>
<td>Poor adoption of OpenEHR by the vendors.</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>T5</td>
<td>eHealth</td>
<td>OpenEHR role in health IT standards</td>
<td>HL7 CDA R2 and OpenEHR are complementary, as are also OpenEHR and IHE. Due to lack of understanding the differences, comparisons in the literature raised false competition.</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>T6</td>
<td>eHealth</td>
<td>OpenEHR as a content standard</td>
<td>Achieving a national consensus on an OpenEHR model was hard or impossible to achieve.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T7</td>
<td>eHealth</td>
<td>OpenEHR as a core offering</td>
<td>OpenEHR was often seen only as a way to support information exchange.</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T8</td>
<td>eHealth</td>
<td>OpenEHR offering used in complements</td>
<td>Poor levels of national eHealth platform openness negatively impact the role of OpenEHR as part of the core offering of the platform.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Table 6 A summary of the tensions observed with OpenEHR on the eCare and eHealth projects and their influence on the research question.
In this chapter we learned how the various projects for which I have provided additional context are linked to research work and how both sets of information contribute to answering the research questions. The reader is now encouraged to read the next five chapters, which contain the published research papers, or continue with the results in Section 12, followed by the discussion and conclusions in Section 13.
6. Methods

As this research began with the exploratory design and development of several DHIs that lie at the intersection of biomedical, behavioural, computational and engineering research, methods from all of these disciplines were needed [269]. This work is therefore a multi-method research. All the research did not start with precise research questions, but explored research possibilities while working with specific contexts. In fact, I consider the writing process of the dissertation as research in its own right and as something normal within exploratory constructive design research that leads to the creation of new artefacts. While writing the dissertation, I searched for a suitable design for the dissertation that would connect all the dots (including the papers and the previous research). In an effort to find a research method that would support such diverse modes of data collection, where research often occurs in context, where doing and learning are the iteratively changing roles of the primary author, experimental design research and the action design research tradition [270] were identified as a potentially interesting option. In light of the recent call for more design research in healthcare [260], the evaluation of ADR in healthcare seems to be an interesting research in its own right.

Dresch, Lacerda and Miguel, in their comparison of three different research methods, namely the case study, action research (AR) and design science research (DSR), distinguish these methods by considering the case study as a method that enables a deeper understanding of certain phenomena, AR a direct interaction between researcher and research object and an intervention that supports both, and DSR as a method that enables the researcher not only to explore, describe or explain a phenomenon, but also to design or prescribe solutions to a given problem [271].

Due to the complementarity of AR and DSR and the complexity of implementing artefacts in real-world contexts, a new method integrating AR and DSR seemed necessary. ADR was proposed by Sein et al [1] as research in which inextricably linked activities are performed to design an artefact, intervene in the organisation and evaluate the artefact simultaneously. As Keijzer-Broers et al. point out, research activity is 'problem-inspired and combines thinking with doing' [272]. To support such research, ADR defines four main phases: (1) problem formulation, (2) building, intervention and evaluation (BIE), (3) reflection and learning, and (4) formulation of learning. The initial academic problem formulation changes to a real-world context in the BIE phase, where a solution to the problem is conceptualised, developed and evaluated in a specific organisational context. The reflection phase is an ongoing phase that spans the entire ADR project. The final phase should focus on viewing the problem solved in an organisational context as an instance of a class of problems. Such a conceptual step is outlined by (1) describing what accomplishments are realised in the IT artifact, and (2) describing the organisational outcomes [1]. Together, these descriptions constitute the formalisation of learning.

ADR considers the dynamics between the intended design and the context of use, which is an essential aspect of designing IT artefacts [273]. Furthermore, ADR focuses on the ongoing interaction between researchers, practitioners and end-users throughout the design process and is strongly collaborative, resulting in a more market-oriented end product [273]. As ADR evaluation is not a separate phase of the research process that
follows construction, but a continuous process, it lends itself to the development of IT artefacts as they are continuously shaped and adapted in an iterative process before being brought to market [273].

ADR's focus on supporting the development of new artefacts that influence the working practises of organisations where such artefacts are actually evaluated is particularly important in the context of healthcare. Medicine as a discipline focuses heavily on practise and is similar to design research in that it develops both (1) descriptive theories and models of how organisms (especially humans) and their health function, and (2) prescriptive methods and tools for improving (or destroying) the health of those organisms [274]. The use of a similar research method therefore allows for a better fit with the mental models of health professionals, and thus perhaps a more optimal collaboration during research in this context. Therefore, ADR may serve as a method for presenting this research, as ADR was not used in any of the research projects.

In this thesis, I use the elaborated version of the ADR process model proposed by Mullarkey and Hevner [273], based on Sein's original ADR process model [1]. In creating the elaborated ADR process model, they incorporated their first-hand experience with a complex project in an industrial setting, which allowed for a more realistic representation of the phases and activities that occur in such an environment. The elaborated ADR process model defines four main phases of ADR projects: (1) diagnosis, (2) design, (3) implementation and (4) evolution. The first two phases focus on understanding the problem and the solution, while the last two phases focus on the development of a new system and its upgrades during its lifetime in a specific organisational context.

I have chosen to use the elaborated ADR model because it has three interesting features. First, in each of the four phases of ADR projects, all five main ADR activities can be carried out in an iterative and co-creative manner: (1) problem formulation/action planning, (2) artefact creation, (3) evaluation, (4) reflection and (5) formalisation of learning. Each of these activities is based on one or more principles that capture the underlying assumptions, beliefs and values [1], as summarised in Table 7.

<table>
<thead>
<tr>
<th>Activities and principles</th>
<th>Principles Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Problem Formulation / Action planning</td>
<td></td>
</tr>
<tr>
<td>Principle 1: Practice inspired Research</td>
<td>Consider field problems as opportunities to create knowledge that can be applied to the class of problems that the specific problem exemplifies.</td>
</tr>
<tr>
<td>Principle 2: Theory-ingrained Artifact</td>
<td>Ensemble artefacts created and evaluated by ADR are informed by theories to (1) structure the problem, (2) identify possible solutions, and (3) guide design. Theoretical elements are inscribed in the ensemble artefact and manifest the theory in a socially recognisable form.</td>
</tr>
<tr>
<td>(2) Artefact creation</td>
<td></td>
</tr>
<tr>
<td>Principle 8: Abstraction</td>
<td>Generalisation of creation activity that informs research and practice by supporting the creation of different levels of abstraction of artefacts for the current state of research objectives in the problem environment before an information system is implemented in an organisational context.</td>
</tr>
<tr>
<td>(3) Evaluation</td>
<td></td>
</tr>
</tbody>
</table>
Principle 5: Authentic and Concurrent Evaluation
Evaluation of whether the overall artefact meets the requirements is carried out continuously with practitioners. Alpha versions are formative and improve the artefacts, while later beta versions are summative - they evaluate the value and usefulness of the results. It is not always possible to assess if the artefact is emerging.

(4) Reflection
Principle 6: Guided Emergence
Captures a key feature of ADR - the interplay between seemingly contradictory design (external deliberate intervention) and emergence (organic evolution). The ensemble artefact reflects both the preliminary design and its ongoing formation through organisational use, perspectives and participants, as well as through the results of authentic, concurrent evaluation.

(5) Formalization of Learning
Principle 7: Generalized Outcomes
The resulting ensemble artefact is a bundle of properties in different domains. It represents a solution that addresses a problem. Both can be generalised by moving from the specific and unique to the generic and abstract. This step can be taken at three levels: (1) generalising the problem instance as an instance of a class, (2) generalising the solution instance by reconceptualising the instance into a class of solutions, and (3) deriving design principles from the results of design research, which requires reconceptualising learning from the specific solution instance into design principles for a class of solutions that address a class of problems.

Table 7 Summary of principles from [1] (principles 1, 2, 5, 6 and 7) and [273] (principle 8) that capture the underlying assumptions, beliefs, and values of each of the ADR cycle activities

The above table intentionally omits Principles 3 and 4 as they support guided, emergent and iterative cycles of intervention (Principle 3: Reciprocal Shaping), which includes the five activities supporting co-creation between researchers and practitioners (Principle 4: Mutually Influencing Roles). Because of Principle 8, each ADR intervention cycle can produce an artefact at the level of abstraction that is possible in the current phase of project activities and goals [273]. This means that each iteration of the ADR intervention cycle described above can make valuable contributions to research and practise in each of the ADR project phases.

Second, the elaborated ADR process model recognises the need to start ADR projects at different entry points. ADR projects can start at the diagnostic phase, where a need for a new artefact is to be identified. This is called the problem-centred entry point. If the need for a new artefact is already clearly defined, the ADR project can start in the goal-oriented entry point. This happens in the design phase with the aim of improving an existing artefact. If a researcher wants to evaluate existing instantiations either in different organisational settings or by assessing the usefulness of an artefact, he/she can use the development-centred entry point in the implementation phase. If a researcher is considering the future evolution of an artefact instance after its implementation in a particular organisational context, the observation-centred entry point can be used to enter the evolution phase of the elaborated ADR.

Third, the elaborated ADR process model allows one to start from any stage and then work forward or backward through the different elaborated ADR stages. This means
that one can move freely between the different stages of the model. This supports an agile, sprint-based approach that aligns well with the goals of many organisational ADR projects [273].

This flexibility of the elaborated ADR process model helps me to represent past projects as ADR projects. The reason for this view is that all ADR projects together help to define the main outcomes of this thesis, as they all contribute to the same underlying problem addressed in this thesis - the semantic interoperability effect chain. This includes the writing of this thesis, which is considered an ADR project in its own right, where I played the dual role in the researcher-practitioner interventions. The writing of the thesis can therefore be considered as an ADR project that used the problem-oriented entry point to diagnose and design a conceptual solution to semantic chain of effects problems that may not have been explicitly addressed by other ADR projects but pointed to context-specific problems that need to be solved.

Table 8 lists the different past ADR projects, the elaborated stages of the projects' ADR process model, the entry points used as starting points for the research, and their knowledge contributions in the overall argumentation to the main findings of the thesis by presenting crucial artefacts (results). Although I focus mainly on two projects in Section 5, namely the eCare and eHealth projects, I divide them into several ADR projects here to present separate research activities. However, I keep eCare and eHealth as part of the naming convention I use to name the ADR projects to ensure traceability.

<table>
<thead>
<tr>
<th>ADR Project</th>
<th>ADR Intervention Cycle</th>
<th>Stages/Entrypoint</th>
<th>Knowledge Contributions as results</th>
<th>Semantic interoperability in healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>eCare ADR Project</td>
<td>Several cycles have been executed in all the stages</td>
<td>Diagnosis Design Implementation Evolution - Problem-centred</td>
<td>IT Solution Class: An interoperable platform to support care protocols for different target patient groups Problem Class: Develop a platform to support different care protocols Intervention Domain: Several patient groups and healthcare professionals. Artefact: eCare Software Platform (Section 12.1.2), Architecture Template, Functional Requirements, Non-functional Requirements, Project plan, Alpha version of the platform, Production version of the platform, Process Models, OpenEHR models</td>
<td>The eCare platform depicts the use of OpenEHR to implemented semantic interoperability by design in software platforms. It is also a source of challenges related to multi-disciplinary collaboration on OpenEHR and the lack of national OpenEHR governance.</td>
</tr>
<tr>
<td>eCare – eAsthma ADR Project</td>
<td>Several cycles have been executed in all the stages</td>
<td>Diagnosis Design Implementation Evolution - Problem-centred</td>
<td>IT Solution Class: An ICT supported asthma intervention – eAsthma DHI Problem Class: Develop and clinically evaluate an</td>
<td>Shows the use of OpenEHR in design and development of new web solutions that</td>
</tr>
<tr>
<td>eCare – eDiabetes ADR Project</td>
<td>Several cycles have been executed in all the stages</td>
<td>Diagnosis Design Implementation Evolution - Problem-centred</td>
<td>IT Solution Class: An ICT supported diabetes intervention – eDiabetes DHI</td>
<td>Problem Class: Develop and clinically evaluate a diabetes management solution as support for patient-clinician collaboration</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>eCare – eObesity ADR Project</td>
<td>Several cycles have been executed in all the stages</td>
<td>Diagnosis Design Implementation Evolution - Problem-centred</td>
<td>IT Solution Class: An ICT supported obesity intervention – eObesity DHI</td>
<td>Problem Class: Develop and clinically evaluate an obesity educational intervention as an obesity management solution</td>
</tr>
<tr>
<td>eCare - eSports ADR Project</td>
<td>Several cycles have been executed in all the stages</td>
<td>Diagnosis Design Implementation Evolution - Problem-centred</td>
<td>IT Solution Class: An ICT supported sports activity intervention – eSports DHI</td>
<td>Problem Class: Develop and clinically evaluate a</td>
</tr>
</tbody>
</table>
| eCare - Paper 1 ADR Project | Several cycles of both stages | Diagnosis - Problem-centred | IT Solution Class: Behavioural Knowledge Engineering  
Problem Class: Conceptual behavioural knowledge  
Model mapping to industry standards  
Intervention Domain: Knowledge modelling and Mapping eAsthma DHI  
Artifact: eAsthma behavioural model mapped to BPMN2 (Section 12.1.1) | Sports activity management solution to promote healthier lifestyle  
Intervention Domain: General population that should become more physically active  
Artifact: A new eSports application deployed on the eCare platform, a mobile application that uses the eCare platform resources such as the care process models  
Points to problems with multi-disciplinary collaboration with OpenEHR and technology development in general that ground the main result – the new work practice. |
| eCare - Paper 2 ADR Project | Several cycles of both stages | Diagnosis - Development-centred | IT Solution Class: AI Algorithm  
Problem Class: Design and develop a diabetes patient segmentation algorithm based on glucose measurements  
Intervention Domain: Patients with diabetes  
Artifact: Tools for OpenEHR-based data curation, Predictive clustering trees – based Algorithm implementation (Section 12.1.4) | Points to the use of OpenEHR in the field of AI that can help reduce data work with AI algorithm development due to supporting semantic interoperability. |
| eHealth - Paper 3 ADR Project | One cycle to evaluate interoperability approaches used, Two cycles in Design – one for interop. approaches and one for impl. success factors | Evolution - Observation-centred | IT Solution Class: Government-owned eHealth Platform  
Problem Class: The choice of interoperability approaches on national eHealth and support planning their implementation  
Intervention Domain: National Institute of Public Health (NIPH) as the governing body of the Slovenie eHealth platform | Points to problems with OpenEHR, particularly with governance, and technology development in general that help define the main result – the new work practice. |
<table>
<thead>
<tr>
<th>Paper</th>
<th>Project</th>
<th>Cycle Details</th>
<th>IT Solution Class</th>
<th>Problem Class</th>
<th>Intervention Domain</th>
<th>Artefact</th>
<th>Points to Problems</th>
<th>Points to Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>eHealth - Paper 4</td>
<td>ADR Project</td>
<td>One cycle with NIPH in Evolution to evaluate the platform, One cycle of design to propose future strategy for improving the platform</td>
<td>Government-owned eHealth Platform</td>
<td>Evaluation of Compliance with theoretical eHealth platform organizational design principles</td>
<td>National Institute of Public Health (NIPH) as the governing body of the Slovene eHealth Platform</td>
<td>A gap in compliance of Slovene eHealth platform against theoretical eHealth Platform organizational design principles influenced future Slovene eHealth Platform design</td>
<td>(Section 12.1.6)</td>
<td>Problems with multi-disciplinary collaboration – not only on OpenEHR but more generally.</td>
</tr>
<tr>
<td>Paper 5</td>
<td>ADR Project</td>
<td>Several cycles due to the emergent nature of the thesis ideas and bridging of two domains</td>
<td>Governance of semantic resources as a prerequisite to semantic interoperability</td>
<td>Multi-disciplinary collaboration on semantic resources in healthcare</td>
<td>Healthcare Ecosystems</td>
<td>Commoning as an approach to governing semantic resources</td>
<td>(Section 12.1.7)</td>
<td>Problems with OpenEHR governance and proposes a solution for the problem.</td>
</tr>
<tr>
<td>Thesis</td>
<td>ADR Project</td>
<td>Multiple failed cycles over several years, but seven are relevant</td>
<td>Work practice for productive work on semantic resources</td>
<td>Sustainable long-term semantic work as a prerequisite for semantic interoperability</td>
<td>Technology Development Principles</td>
<td>Three main challenges with semantic work in healthcare by proposing a solution – a work practice for productive work on semantic resources as a prerequisite for achieving semantic interoperability.</td>
<td>Addresses three main challenges with semantic work in healthcare by proposing a solution – a work practice for productive work on semantic resources as a prerequisite for achieving semantic interoperability.</td>
<td></td>
</tr>
</tbody>
</table>
Artefact: A new solution concept based on TEAS, SECOs and Commons on how to tackle semantic interoperability and technology development in general (Section 12.2.4)

Table 8 Depiction of past research activities as ADR projects. Each ADR project is described in terms of elaborated ADR process model stages, number of the ADR intervention cycles executed, entrypoints used, and knowledge contributions from which some represent results discussed in this thesis and are marked with pointers to the results sections where these results are discussed more in-depth. In addition, I provide information how each ADR project explores semantic interoperability issues that are the underlying problem addressed by this thesis.

To further illustrate how the various research findings, together with this thesis, constitute a series of ADR cycles for exploring semantic interoperability in healthcare, I present Figure 19.
Figure 19 (1) ADR Projects (2) exploring semantic interoperability related issues (yellow post-it notes) within one or more ADR intervention cycles that are (3) analyzed in different sections of the thesis. The timeline starts in 2009 at bottom left and depicts progression from technical infrastructures development to commons-based governance of semantic resources (2021) at the top right where the thesis (4) main result #8 is depicted. The grey timeline phases correspond to TDS stages and thesis writing.
It shows the thesis progress through the different ADR projects, starting at the bottom left and ending at the top right, where the main result of the work is shown. The main result was developed in the Thesis ADR project, where I iteratively carried out several ADR intervention cycles of ADR activities in the ADR phases of diagnosis and design. Several of these cycles did not improve the result/artifact (the work practise). In the following, I describe only the cycles that led to an improvement in the main outcome. I start first by describing the ADR diagnostic phase and the ADR intervention cycles that I carried out. In each of these cycles I used one of the outcomes from the published research described in sections 12.1.1-12.1.7. In total, then, I conducted seven ADR cycles. Within each cycle, I formulated the problem by reflecting on the specific paper and its results to extract the challenges of the specific paper that are related to the underlying problems of the semantic interoperability effect chain and link all the ADR projects listed as ADR projects in Table 8 Depiction of past research activities as ADR projects. Each ADR project is described in terms of elaborated ADR process model stages, number of the ADR intervention cycles executed, entrypoints used, and knowledge contributions from which some represent results discussed in this thesis and are marked with pointers to the results sections where these results are discussed more in-depth. In addition, I provide information how each ADR project explores semantic interoperability issues that are the underlying problem addressed by this thesis.

These challenges are based on existing practises in achieving semantic interoperability in healthcare and in healthcare technology development in general, and therefore align well with the practise-inspired research principle 1 in Table 7.

Next, I looked at the identified challenges of a particular paper and applied theory (new concepts) to better understand the challenges and highlight potential solutions by reinterpreting how the identified challenges would look different if theory were incorporated into the solution. In all seven cycles combined, I used SECOs, TEAS and commons as theory. Such use of theories fits well with the theory-anchored artefacts, Principle 2 in Table 7. The reinterpretation can also be aligned with Abstraction Principle 8 from Table 7, as I have shown the use of an abstract artefact (generalised solution) for identified challenges through the reinterpretation. The reinterpretation is also consistent with Evaluation Principle 5 in Table 7, as I evaluate whether the potential generalised solution can address the identified challenges. However, such an evaluation is only formative as the artefact is only at an alpha stage and it is difficult to evaluate it in a real organisational context. Such reinterpretation, seen as formative evaluation, helps to align with guided emergent principle 6 in Table 7, as the ensemble artefact of the future - the solution to the challenges identified in the paper - will reflect both the preliminary theory-based design and such ongoing design - perhaps once in the context of an organisational application, but here mainly through such formative evaluation results. Principle 7, focusing on generalisation of results, motivates the description of the ensemble artefact as a guide to solving similar problems, and with the transition from the instance to the abstract level to begin the discussion of solution classes. The identified particular problems are also generalised by moving from particular instances of identified challenges to classes of problems. The result of such formalisation of learning can be seen in Table 12 - three groups of challenges are classes of problems, while theory-based artefacts representing classes of solutions are represented by the main theory used, namely SECO, TEAS and Commons.
For clarity, I present the pattern described above and used in each of the ADR cycles in Figure 20 (it is also repeated as Figure 21 in Section 12.1 where the results are described in detail).

![Figure 20 Common pattern for describing each of the results that is used here to align with the ADR activities guiding principles and is used in Section 12.1 to develop the different findings and results of this thesis.](image)

Next, I moved on to the ADR design phase, where I also conducted several ADR intervention cycles, which are described in sections 12.2.1, 12.2.2, 12.2.3 and 12.2.4. There, I use all seven theory-based solutions to specific challenges identified from the results of the published papers (from the ADR diagnostic phase described above) to first develop TEAS, SECOs and commons-based conceptual solutions as solutions that address all challenges in a particular class (software development challenges, multidisciplinary collaboration challenges and multi-level governance challenges) - see Table 12 in Section 12.2. Further on, in Section 12.2.4, I use the three conceptual solutions for the three classes of problems and construct a new conceptual solution - the work practice - which is the main result of this thesis and is considered as a generalised solution class for a generalised problem class.

To summarize, the methods in this thesis include methods used in the different published research together with the overarching ADR. The methods used in this thesis are summarized in Table 9.

<table>
<thead>
<tr>
<th>ID</th>
<th>Method Name</th>
<th>Method description and use</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>Action Design Research</td>
<td>These methods are used to depict the whole research process which is considered as several ADR iterations in which different learning during action in different contexts happened. Descriptions of projects and the published papers provide additional information about the context, learning and action. The research did not start with defined research questions but was an exploratory design research in which the research questions emerged during writing of the thesis.</td>
</tr>
<tr>
<td>M2</td>
<td>Forward and backward snowballing</td>
<td>In order to obtain an overview of existing state of the art in different reported research and in this thesis, I used snowballing, both backward [275] and forward [276] as the main method. Publish or Perish in combination with Google Scholar were the tools mostly used in the process.</td>
</tr>
<tr>
<td>M3</td>
<td>Constructive design research</td>
<td>Method used in Paper 1: Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge. First, a theory nexus was constructed based on using behavioural theory that I mapped to a conceptual framework. Then the construct was implemented using a business process management standard known as BPMN2.</td>
</tr>
<tr>
<td>M4</td>
<td>Experimental design</td>
<td>Method used in Paper 2: Modelling Time-series of Glucose Measurements from Diabetes Patients using Predictive Clustering Trees included designing a method for predicting glucose measurements a year in advance. Predictive clustering trees are the specifics of how the experimental design was achieved and tested on a dataset obtained in the eCare project clinical trials.</td>
</tr>
<tr>
<td>M5</td>
<td>Interpretive case study and information extraction</td>
<td>Methods used in Paper 3: Special Topic Interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national eHealth. The work included both the real-life experience and literature as the main sources within the context of Slovene national eHealth project as the local context to which the case study adapted. In addition, these methods have also helped during writing of the thesis where I also combined my experience in the projects with the existing literature and my published papers as three main sources for answering the research questions from which I performed information extraction. However, the context of the thesis is not limited to only Slovenia as the problems I tried to address are recognized gaps in the literature.</td>
</tr>
<tr>
<td>M6</td>
<td>Experimental design and organizational design principles evaluation on a specific case.</td>
<td>These methods were used in the Paper 4: Is national eHealth in Slovenia on Track to be an Open eHealth Platform? Experimental design was used to construct a questionnaire based on design theory in the form of organizational design principles for eHealth platforms. The questionnaire design preserved the content but rather introduced a new type of visualization for the organizational design principles. However, the questionnaire was not additionally validated. I received only a positive feedback from the original author of the organizational design principles. I used the constructed questionnaire in an evaluation on the case of the national eHealth platform in Slovenia. With this, I was only able to show utility of the questionnaire in such evaluation projects. However, the results have been informally validated by experts from the national eHealth platform in Slovenia.</td>
</tr>
<tr>
<td>M7</td>
<td>Constructive design research and information extraction</td>
<td>These methods were used in Paper 5: Commoning Semantic Interoperability where a theoretical construct (the new semantic resources commons) was created based on information extraction from existing literature and my experience on different projects in Slovenia.</td>
</tr>
<tr>
<td>M8</td>
<td>Randomized clinical trial (RCT)</td>
<td>A method from the medical domain was used for evaluating the DHIs we designed and developed in the E-Depression, eCare and EkoSmart City projects.</td>
</tr>
<tr>
<td>M9</td>
<td>Standardized Usability Questionnaires translated to Slovenian language</td>
<td>For each of the DHIs we used questionnaires at the start of RCTs and after these ended. Our focus was to learn about the usability of the DHIs used by the patients and medical doctors and nurses.</td>
</tr>
</tbody>
</table>

**Table 9** Main methods used in the thesis together with methods used in specific research reported in the papers included in this thesis.
7. Paper 1: Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge

Mate BEŠTEK\textsuperscript{a,b} Peter EKLUND\textsuperscript{a}
\textsuperscript{a} IT University of Copenhagen, Denmark
\textsuperscript{b} National Institute of Public Health of Slovenia, Slovenia

Abstract

\textit{Introduction:} Open eHealth platforms can, by offering a core of seed services, become the basis for national eHealth initiatives by supporting communication between many networks that exist in a typical healthcare system. In order to achieve better engagement of end users, focus should be put on structured behavioral knowledge in different health interventions.

\textit{Methods:} A conceptual framework for defining adaptive preventive interventions is described and used to represent how this can be implemented with an industry standard – BPMN2. This is used as the basis for extending the national open eHealth platform with structured behavioral knowledge.

\textit{Results:} We depict the growing importance of behavioral knowledge in health interventions, delivered via Internet, and also identify different knowledge, based on using psychological theories, as a basis for designing new health interventions. In addition, the results of a case study are presented to demonstrate how such knowledge can be delivered as distributed care processes as an extension to the national open eHealth platform.

\textit{Discussion:} Since healthcare systems suffer sustainability issues due to demographic changes, distributed ICT supported health interventions outside of hospitals are prone to failure because they do not take into account knowledge of human behavior in the design phase. Addressing this issue holds the promise of increasing patient adherence with care plans, better communication with healthcare professionals and improved design of public health programs.

\textit{Keywords:} open eHealth platforms, health interventions, behavior change, distributed care processes

7.1 Introduction

Implementing national eHealth is a difficult to manage activity (Stroetmann, Artmann and ..., 2011; Informatics, 2017). Due to being high cost and time consuming, it is difficult to cooperate with resident practitioners. Treating the national eHealth as a ‘platform’ could allow more effective resource allocation. The primary role of platforms are to establish market functions for eHealth services and to overcome the traditional lock-in from solutions providers. In general, platforms can be defined as “products and services that bring together groups of users in two-sided networks” (Eisenmann, Parker and Alstyne, 2006). Open platforms suggest a structured component-based service architecture that encourage participation. Open platforms are believed to be enablers of the ‘platforms ecosystems concept’. Ecosystems in general are inter-organizational networks (Benedict, 2018). In the context of platforms, ecosystems represent the platform and all the applications specific to the platform (Tiwana, 2014).
The vision of a unified, interoperable eHealth infrastructure in Europe is still not realized (Informatics, 2017). The driving force for ICT in healthcare has been the trend toward a better coordination of care (Winter et al., 2011; Aanestad et al., 2017). As part of the digital transformation process, typical care processes are becoming more integrated, not only in healthcare but also other contexts, such as social care and the environment of the patient’s home. Further, such integrated care processes are becoming personalized adaptive care pathways (Gand and Schlieter, no date; Schrijvers, Hoorn and Huiskes, 2012; Schlieter et al., 2017).

Digital transformation can be seen as a cultural transformation of patients, doctors, and nurses. Changing human behavior is complex and a shift from solutions to interventions is needed, suggesting a switch from the traditional search for solutions for specific problems towards interventions - a continuous process of action. Over the past decades, psychology has accumulated an extensive toolbox of behavior change techniques and has accumulated evidence of their effectiveness (Abraham & Michie, 2008; Michie, van Stralen, & West, 2011; Peters, de Bruin, & Crutzen, 2015) as cited in (Raghallaigh and Adam, 2017). These techniques have been used to design theory based health interventions that were more optimal in terms of how well the patients were able to achieve desired behavioral and/or clinical outcomes (e.g. smoking cessation). As noted in (Holman, Lynch and Reeves, 2017), the only way to solve complex societal challenges is through interdisciplinary work, a deep interdisciplinary collaboration between health psychology, computer science, health informatics, cognitive science, and an educational methodology is needed in order to research interaction between different technology components, in order to use the potentials of information technology in behavior research (Catriona M. Kennedy et al., 2012). This points towards viewing information technology as supporting dynamic and adaptive information processing instead of viewing it as a traditional passive medium focused on efficient transmission of information and a positive user experience (Catriona M Kennedy et al., 2012). Interventions that support behavior change have lately been named Digitally Based Change Interventions (Raghallaigh and Adam, 2017) - automated, interactive, and personalized ‘just-in-time’ adaptive interventions – JITAls (Nahum-shani et al., 2014; Pavel et al., 2015; Nahum-Shani et al., 2016; Moller et al., 2017). JITAls are intervention protocols, labeled also as computerized behavioral protocols (Lenert et al., 2005) that could represent reusable components (interventions). Authors in (Lenert et al., 2005) have formally defined such a protocol and computerized it by using an ontology and define a ‘protocol’ as a behavior change program that may be implemented in clinical, worksite, home or school settings that combines multiple modes for changing behavior. Behavioral knowledge has been used for supporting behavior change with patients (Curtis, Lahiri and Brown, 2015; Curtis, Atkins and Brown, 2017), for addressing the issue of communicating to healthcare professionals (Perkins et al., 2007), and to deploy more effective public health programs (Glanz and Bishop, 2010). Computerizing behavior knowledge is also the basis of the behavior change support systems (Oinas-Kukkonen, 2012) and is a term coined for the purpose of describing software systems that implement behavioral knowledge. An example of using structured behavioral knowledge in the form of a medical ontology has been used in (Bickmore, Schulman and Sidner, 2011) to support a health counseling dialogue system.

In this article, we present a case study where business process models were used for representing different care protocols (e.g. asthma care protocol) that were evaluated in a clinical trial. The clinical trial was conducted during the eCare (University of Primorska, Slovenian Research Agency, 2010) project. The clinical trial lasted for a
year and included patients at home, and medical professionals at Golnik Clinic for Respiratory Disease in Slovenia. These models could be added to the national eHealth platform as core components that could be approved by the health technology acceptance process. Different ecosystem participants could use the validated core processes as the basis for creating new integrated care solutions in which these validated protocols could play a role in gaining knowledge about how to achieve better engagement and lower fatigue in different interventions.

7.2 Methods
We present and use the conceptual framework for adaptive preventive interventions (Nahum-Shani et al., 2016) in order to highlight the main components of behavioural interventions in general (decision points, interventions options, tailoring variables, and decision rules) and provide specific components that were implemented in our case study intervention and also show what behavioural knowledge we used and how was it used. Through this, we show how the conceptual framework can be implemented in order to become part of the extendable core services of the national eHealth platform.

7.3 Results
Our case study project focused on patients with different conditions (asthma, diabetes and obesity). Greater details about the project and the developed system together with the results of the clinical trial focused on patients with type 2 diabetes are described in previous publications (Beštek and Brodnik, 2014; Beštek, Curtis and Brodnik, 2015; Iljaž et al., 2017). In addition, we want to present the eAsthma use case that was also supported in this project.

The selected case of the eCare project was to support the process of care for patients while they were at home. The care process thus includes patients, doctors and nurses who played the role of care managers. The care process represents a protocol that precisely defines the flow of actions together with participating roles. This includes actions like performing measurements at home, completing questionnaires, or sending the patient to a laboratory to do some tests. Such process models were then used directly in an information-communication system that was able to execute the process as defined. The execution of these processes is the enactment of the protocol. Figure 1 shows a simple process model that depicts the main steps of the process and how these are connected.
Figure 1 A process model depicting notifications of patients, doctors and nurses (Care managers – CM) in the process of creating a new PEF measurement of Asthma patients.

The conceptual framework as defined in (Collins, Murphy and Bierman, 2004), and cited in (Nahum-Shani et al., 2016), defines four main components of interventions. (1) Decision points, (2) Interventions options, (3) Tailoring variables, and (4) Decision rules.

Decision point represents the time when an intervention decision is made. Time can be either a predefined time interval, a specific time of the day, or after random prompts. An example decision point would be immediately after a patient is, for example, shown a questionnaire. Depending on the answers, a different intervention can be enacted. The process shown in Picture 1 contains several decision points that are depicted in a BPMN2 syntax (e.g. the process starts when a predefined time trigger occurs).

Intervention options represent a set of treatments or actions that can be enacted at any decision point. In our process, intervention options include reminders over SMS and email, phone calls, and tailored feedback.

Tailoring variables are information about an individual that is used to decide when to provide an intervention and which to provide. Our use case process is focused on peak flow measurements of asthma patients which in turn represents the main tailoring variable.

Decision rules operationalize the adaptation (personalization) by defining which intervention option to offer, for whom and when. Each decision point has a decision rule defined, which in turn connects intervention options with tailoring variables. Our
process uses BPMN2 syntax to define all the decision rules by connecting tailoring variables with intervention options to be used at certain decision points. Generally, interventions are designed for the purpose of achieving two types of goals. The ultimate intervention goals e.g. smoking cessation, are defined as distal outcomes. In our case, managed asthma is a long-term distal outcome. The other type of goals is defined as proximal outcomes and represent smaller steps that are needed in order to reach the ultimate goal and can be behavioural, cognitive or affective. These address the issues of adherence. Design principles for intervention options target engagement.

7.4 Discussion
We have presented a conceptual framework for defining behavioural interventions. We used the eAsthma use case, specifically a BPMN2 based process model that described a specific set of intervention options of the eAsthma care protocol that focused on peak flow measurement in order to show that the conceptual framework can easily be mapped to an industry standard that could become the basis for extending the core services of the national eHealth platform. The models could represent, for example, clinically validated care protocols that could then be used by different applications provided by different providers. With this, structured behavioural knowledge could become part of the national eHealth open platform that would enable the creation of behavioural theory grounded applications that would represent targeted interventions both for individual patients as well as patient populations. Such approaches promise not only a higher level of adherence but also reduced costs – both direct (more users means less per user costs) and indirect (healthier patients mean less costs for the healthcare system). Such approaches are lately being tested (Larsen et al., 2016; Michie et al., 2017) in order to create an ontology of behaviour change techniques that could then serve the purpose mentioned in this paper.

7.5 Conclusion
During the time of the design phase of our project, a taxonomy of behaviour change techniques represented the structured behavioural knowledge that was available (Abraham and Michie, 2008). Lately, there has been more progress in this field so that now one can use more sophisticated and highly expressive ontologies (Larsen et al., 2017). Such structured behavioural knowledge brings a higher level of semantics that allow computer programs to become more effective and efficient. Incorporating artificial intelligence and machine learning algorithms into the process of ontology development can support a learning system that creates new knowledge based on evidence (Michie et al., 2017).

In this article, we presented a case study where business process models were used for representing different care protocols (e.g. asthma care protocol) that were evaluated in a clinical trial. These models could be added to the national eHealth platform as core components that could be validated in clinical trials and approved by the health technology acceptance process. Different ecosystem participants could use the validated core processes as the basis for creating new integrated care solutions in which these validated protocols could provide knowledge about how to achieve higher adherence and better engagement in different interventions focused on patients, in communicating with healthcare professionals, and designing more effective public health programs.
7.6 References


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8. Paper 2: Modelling Time-series of Glucose Measurements from Diabetes Patients using Predictive Clustering Trees

Mate Bestek\textsuperscript{1}, Dragi Kocev\textsuperscript{2}, Saso Dzeroski\textsuperscript{2}, and Rade Iljaz\textsuperscript{3}

\textsuperscript{1}National Institute of Public Health, Trubarjeva 2, Slovenia, mate.bestek@nijz.si
\textsuperscript{2}Jozef Stefan Institute, Jamova cesta 39, 1000 Ljubljana, Slovenia, dragi.kocev@ijs.si, saso.dzeroski@ijs.si
\textsuperscript{3}Faculty of Medicine, Vrazov trg 2, 1104 Ljubljana, Slovenia, rade.iljaz@guest.arnes.si

Abstract
In this paper, we presented the results of data analysis of 1 year measurements from diabetes patients within the Slovenian health-care project eCare. We focused on looking for groups/clusters of patients with similar time profile of the glucose values and describe those patients with their clinical status. We treated in a similar way the WONCA scores (i.e., patients’ functional status). Considering the complexity of the data at hand (time series with different number of measurements and different time intervals), we used predictive clustering trees with dynamic time warping as distance between time series. The obtained PCTs identified several groups of patients that exhibit similar behaviour. More specifically, we described groups of patients that are able to keep under control their disease, and groups that are less successful in that. Further-more, we identified and described groups of patients that have similar functional status.

\textbf{Keywords}: eCare, Diabetes patients, Time series prediction, Predictive clustering, WONCA scores

\textsuperscript{1}Article was published before the official start of enrollment
8.1 Introduction

In healthcare, clinical trials represent an accepted method for validation of new drugs, procedures etc. that need to be executed before introduction to clinical practice. In addition, healthcare transformation is an ongoing process which requires creation of new business models for healthcare systems. Connected to this transformation is the use of information-communication technology which could support new business models in healthcare [13].

Predictive analytics is gaining a lot of traction lately in different industries, including healthcare. In [15], authors survey data mining approaches for prediction and diagnosis of diabetes. By supporting decisions about the future, backed with strong data and prediction methods, one can expect many positive outcomes. In healthcare, doctors could make more informed decisions about therapy when prediction models would be available to assist them. Patients could use such models to inform themselves of the consequences of their health related decisions. Feedback is one of the psychological behavior change techniques, that is also used in the field of healthcare service or intervention design[1]. When these models could predict structured output variables, such as time series of glucose measurements, one can expect even more informed patients and doctors.

Diabetes is a chronic condition that represents a major health care problem both on households and society [17]. Hypoglycemia prevention is one of the major challenges in diabetes research and it has been shown that predicted rather than measured continuous glucose measurements (CGM) allow a significant reduction of the number of the hypoglycemic events. This stimulates further research on the generation of preventive hypoglycemic alerts that are based on using glucose prediction methods [19]. In general, there are two approaches to blood glucose prediction. The first approach is based on mathematical models, while the second is based on data-driven models. The data-driven models can be further divided into time series based methods and one-step look ahead prediction [8]. The former methods aim to model the time course profiles of the values of the glucose of the patients, while the latter are concerned with predicting just the next value of the glucose of the patients.

In addition to blood glucose prediction and hypoglycaemia prevention, there are also many activities in predicting diabetes. Data based prediction approaches can be short-term and the long-term. Short-term predictions usually include CGM, and long-term predictions are more involved with long-term glucose control and the incidence of diabetic complications [9].

In this work, we use the data collected within the eCare project (or eOskrba in Slovenian, https://eoskrba.pint.upr/) [2]. It focused on the design of new interventions [12] for healthcare which were deployed and supported by an ICT platform. Since the goal of the project was to introduce new care protocols into clinical practice, several clinical trials were performed in order to show the validity and relevance of the project. More specifically, we use the data obtained in the trials performed within eCare in order to create decision models for assisting healthcare professionals. In addition, these methods could provide valuable insights for policy makers in the field of healthcare.

We focus on a specific part of the data collected within the project: the year long measurements of glucose levels of the patients and the answers to the questions from the WONCA (World Organisation of Family Doctors, http://www.globalfamilydoctor.com/) questionnaire. This means that the data at hand comprise of patients’ clinical status, on one hand and its yearly measurements of glucose and WONCA status on the other. Each of the time series data can contain up to 20 measurements. Moreover, each patient has a different number of measurements and
they are performed at different time points. The number of measurements and the intervals depend on the patients’ compliance with the prescribed care protocol. All in all, the goal is to model a time series based on the current patient data.

Considering the outlined complexities of the data at hand, we used predictive clustering trees (PCTs) [4, 11] to address the modelling task at hand. PCTs are generalization of decision trees able to predict structured output datatypes including time series data. Moreover, considering the fact that each patient has different number of measurements taken at different time intervals, we coupled the PCTs with the dynamic time warping (DTW) [14] to obtain the models. The result of this study are the discovery of groups/clusters of patients that exhibit similar dynamics of the glucose measurements and the WONCA scores and the description of these clusters with the patients’ clinical status.

The remainder of this paper is organized as follows. Section 2 presents the predictive clustering trees methodology. Next, Section 3 describes the data and the experimental design. Section 4 discusses the results of the study and Section 5 concludes and provides directions for further work.

8.2 Predictive clustering trees for time series modelling

Predictive Clustering Trees (PCTs) [4] generalize decision trees [5] and can be used for a variety of learning tasks, including different types of prediction and clustering. The PCT framework views a decision tree as a hierarchy of clusters (see Figs 3 and 4): the top-node of a PCT corresponds to one cluster (group) containing all data, which is recursively partitioned into smaller clusters while moving down the tree. The leaves represent the clusters at the lowest level of the hierarchy and each leaf is labeled with its clusters prototype (prediction). PCTs can be learned by the system CLUS available at http://clus.sourceforge.net.

PCTs are built with a greedy recursive top-down induction (TDI) algorithm, similar to that of C4.5 or CART [5]. The learning algorithm starts by selecting a test for the root node. Based on this test, the training set is partitioned into subsets according to the test outcome. This is recursively repeated to construct the subtrees. The partitioning process stops when a stopping criterion is satisfied (e.g., the number of records in the induced subsets is smaller than some predefined value; the length of the path from the root to the current subset exceeds some predefined value, etc.). In that case, the prototype is calculated and stored in a leaf.

One of the most important steps in the TDI algorithm is the test selection procedure. For each node, a test is selected by using a heuristic function computed on the training examples. The goal of the heuristic is to guide the algorithm towards small trees with good predictive performance. The heuristic used in this algorithm for selecting the attribute tests in the internal nodes is intra-cluster variation summed over the subsets induced by the test. Lower intra-subset variance results in more accurate predictions.

The cluster variance is calculated as the sum of the squared pairwise distances between the cluster elements, i.e.,

$$ Var(C) = \frac{1}{2|C|^2} \sum_{X \in C} \sum_{Y \in C} d^2(X, Y). $$

(1)

where C is the cluster, X and Y are examples from C and d is the distance measure. Note that, no cluster prototypes are required for the computation of variance in this case. The prototype c of a cluster of time series C is then calculated as
After building a tree (and a PCT), it is typical to prune it, in order to deal with noise and other types of imperfection in the data. We employ two pruning algorithms: MaxDepth pruning and MaxSize pruning. The MaxDepth pruning algorithm limits the depth of the leaves in a tree. Selecting a smaller value for this parameter yields a smaller tree. The MaxSize pruning algorithm [18] takes as input a given maximum tree size k and computes a subtree of the given tree of size at most k with minimum error. These pruning algorithms increase the interpretability of PCTs, while maintaining (or increasing) their predictive performance (on unseen cases).

The predictive clustering trees approach has a number of desirable properties. No prior assumptions are made on the probability distributions of the dependent and the independent variables. PCTs can handle discrete or continuous independent variables, as well as missing values. In addition, they are tolerant to redundant variables and noise. Furthermore, they are computationally inexpensive and are easily interpretable. Also, from a clustering point of view, the PCTs are unique in the sense that they provide cluster descriptions while constructing the clusters. All in all, PCTs are robust, efficient and interpretable models with satisfactory predictive performance.

Considering the guidelines given in [7], we used an extension of PCTs for modelling time series data described in detail in [16, 10, 6]. More specifically, we used PCTs that use dynamic time warping (DTW) [14] distance between time series to calculate the variance function needed for split selection. DTW can capture non-linear distortion along the time axis. It accomplishes this by assigning multiple values of one of the time series to a single value of the other. As a result, DTW is suitable to use if the time series are not properly synchronized, e.g., if one is delayed, or if the two time series are not of the same length.

\[ d_{DTW}(X, Y) = \arg \min_{q} \sum_{X \in C} d^2(X, q). \]  

DTW takes into account differences in scale and baseline of the values of the time series. If a given time series is identical to a second time series, but scaled by a certain factor or offset by some constant, then the two time series will be distant. For many applications, these differences are, however, not important and only the shape of the time series matters.

### 8.3 Data description and experimental design

The datasets consists of measurements for 120 subjects (diabetes patients). Each of the patient is described with three types of data [3]:

- **Clinical status:** described with 41 variables (simple numeric or nominal variables) such as age, gender, height, weight, frequency and amount of alcohol consumption, typical frequency of measurement of blood pressure, glucose and body weight, use of insulin, disease/diabetes status, blood glucose cholesterol (HDL and LDL), triglycerides, albumin, alcohol and creatinine.
- Glucose measurements: Yearly measurements of glucose that patients take at home (time series variable).
- WONCA scores: Assessment of one’s own functional status throughout a year. The scores represent a measuring instrument for physicians providing them with social and psychometric data about a patient. There are 8 categories (time series variables) describing different aspects of everyday life including physical fitness, feelings, daily activities, social activities, change in health, overall health, feeling of pain and overall weighted summary.

In Figures 1 and 2, we show some of the properties of the data at hand. More specifically, in Figure 1, we give a histograms of the age by gender and the glucose values as measured before entering the study and, in Figure 2, we show histograms of additional measurements taken before entering the study, namely the overall cholesterol and also both the LDL (low-density lipoprotein or the “bad” cholesterol) and HDL (high-density lipoprotein - the “good” cholesterol) types of cholesterol. Higher values of LDL and low levels of HDL increase your chance of heart disease while high levels of HDL decrease your chances of heart disease. HDL should be higher than 1 for male and 1.2 for female, and LDL should be lower then 3. These graphs show that the majority of patients are over 50 years old, have increased glucose levels (due to having diabetes), mostly have somewhat acceptable cholesterol levels or slightly increased with HDL distributed around the normal value of 1 and LDL mostly in acceptable levels. We

![Figure 1. Male age, female age and glucose distribution](image1.png)

![Figure 2. LDL, HDL and overall cholesterol](image2.png)

We can say that these patients are not at a high risk and seem to manage to keep their diabetes in control.
The clinical status of the patients was assessed in a physicians’ office (lab- oratory examinations) before the patients were admitted to the study: yearly measurements of glucose and the answering the WONCA questionnaires. After their examination the patients were released to go home and were required to complete different tasks on their own. These tasks included measuring the blood glucose, and filling out the WONCA questionnaires. The patients were suggested to perform these measurements 1 per month, but not all of them complied to this. The mean value of the number of measurements was 4.5 and 3 for glucose and WONCA, respectfully. We constructed two types of datasets representing the two tasks addressed here:

- Glucose time series: Consisting of the patients’ clinical status and the glucose measurements.
- WONCA time series: We constructed 8 datasets, each one targeting the different WONCA categories outlined above.

For analyzing all of the datasets, we used the CLUS system for learning predictive clustering trees. More specifically, we used the extension of PCTs that is able to predict time series [16]. Next, we selected dynamic time warping (DTW) as distance measure between the time series. We were bound to make this selection because the properties of the measurements at hand: time series with different number of measurements taken at different time intervals. Furthermore, we experimented with the two pruning algorithms described above: MaxDepth was set to 3 and MaxSize was set to 20.

1. Results

Prediction of yearly glucose measurements. In Figure 3, we show the obtained PCT with MaxDepth set to 3 on the glucose measurements. The model identified eight different clusters considering the time series profiles of the patients belonging to the leafs. The first attribute of the tree is the labalthcp which indicates levels of Alanine Aminotransferase (ALT) enzyme in blood. Levels of ALT can indicate liver damage or disease and as such represents a very important attribute. The next attributes over which the tree is split are the frequency of self measurement of blood pressure (pogostostsamomeritevkrvnitlak) where the values indicate frequency of at least 2 to 3 times a month, and diabetes status (stanjesladkornebolezni) where diabetes without complications is indicated. In the third level split, the additional important attributes identified are sex, frequency of measuring glucose levels (pogostostsamomeritevkrvnisladkor), and alcohol consumption frequency (alcoholfrequencyhcp). The cluster C1 indicates male patients that measure their blood pressure at least 2 to 3 times a month and have their ALT value higher then 0.37. It shows glucose measurements that fluctuate slightly on a few occasions but otherwise seem steady at around 7. This indicates a patient with a managed diabetes since not only that the glucose values do not indicate relapses but also the sheer number of measurements tells us, that this are patients who take measurements regularly. Similar conclusions can be drawn from the cluster C3 where even greater number of taken measurements by the patients are shown and in addition, the values of the measurements are lower at about 6.5 which indicates an even better managed diabetes. Comparing patients in C1 and C3 we can see that patients in C3 focus more on measuring their blood glucose levels as those in C1 that focus more on measuring their blood pressure. Both C1 and C3 present patients that are well aware of their health status and try their best in order to be healthy with those in C3 with slightly better results. In addition to C1 and C3, the C4 cluster...
shows a flat line which indicates a managed glucose level but low compliance to the therapy in terms of the number of glucose measurements taken. These patients do not measure often their blood pressure or glucose.

We now consider cluster C2. We can note that the measurements fluctuate even into very high glucose levels of more than 15. This indicates patients that do not have a well-managed diabetes. These fluctuations are a sign of quickly changing glucose levels which causes health deterioration in the long term and sooner or later come of diabetes complications. The patients in this group are often taking measurements of their blood glucose and are female.

Continuing with the analysis of the right side, the tree is first split on weather diabetes is without complications. For those patients that fall into this category, the frequency of alcohol consumption is considered next. Patients that consume one glass of alcohol per month or less show fluctuations in their glucose levels but the overall levels are never to high as is shown in C5. The cluster C6 exhibits similar behavior as cluster C5, but at even lower glucose levels which does indicate a managed diabetes. Finally, clusters C7 and C8 indicate patients that have diabetes with complications. C7 describes patients with only two measurements both of high values up to more than 13, while cluster C8 shows relapses and a poorly managed diabetes.

**Prediction of the WONCA scores.** We have constructed PCTs for each score separately and here we illustrate, in Figure 4, the obtained PCT with MaxDepth set to 3 on the overall WONCA scores. The tree identifies 8 clusters of patients with several of them showing only straight lines. This suggests little change through time, but we have different WONCA sum values at which such change is not occurring - four clusters show values at around 15 namely C1, C3, C4, and C6, while cluster C7 shows values around 12 and C5 shows values around 7. Cluster C2 is the only one showing fluctuations indicating change through time.

The tree is first split based on the age. For patients older than 42, the next attribute used to split the tree is the institution type. For the general practitioners (ambulnosed) the cholesterol level is used for further splitting the tree producing clusters C1 and C2, and for other types of institution, the attribute about usage of blood glucose measuring devices (uporabamerilakrvenasladko-jra) is used for splitting the tree further, producing clusters C3 and C4. Patients that are younger than 42 and do not measure their blood glucose (pogostost-samomeritekvrvenasladkor = at0017) have a rather bad WONCA sum of less than 8 (cluster C5). For the patients taking measurements and

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**Fig. 3.** Predictive clustering tree for modelling the glucose measurements obtained with MaxDepth set to 3.
visiting public health-care providers (publicInstitution = 1), have a rather high WONCA sum of 16 (cluster C6) in comparison to less than 12 for cluster C7 that indicates patients who visit private healthcare providers.

Finally, for example, we observe that younger patients that do not have a high cholesterol, tend to fluctuate more with their WONCA values. This suggests that these patients are not facing any complications in terms of a high cholesterol and are thus not well managed in terms of the WONCA results as shown in C2. We can also see that older people should measure their blood pressure levels otherwise their WONCA values will be very low which represents a basis for further complications of diabetes.

8.4 Conclusions

In this paper, we presented the results of data analysis of measurements from diabetes patients. The data used here were obtained from the Slovenian healthcare project eCare that monitored the status of several patients throughout a period.

![WONCA sum prediction tree with MaxDepth set to 3](image)

Fig. 4. WONCA sum prediction tree with MaxDepth set to 3 of 1 year. The main idea behind the work presented here is to provide stronger decision support for doctors that will handle future patients. More specifically, we focused on modelling yearly glucose measurements and WONCA scores using the patients’ clinical status. In other words, we opted to search for patients with similar time profile of the glucose values and describe those patients with their clinical status. We had the same goal for the functional status (WONCA scores).

Considering the complexity of the data at hand (time series with different number of measurements and different time intervals), we selected predictive clustering trees as modelling framework. The extension of the PCTs employed here uses dynamic time warping as distance between time series. The obtained PCTs identified several groups of patients that exhibit similar behaviour. More specifically, we described groups of patients that are able to keep their disease under control, and groups that are less successful. Furthermore, we identified and described groups of patients that have similar functional status.

We plan to extend this work along several direction. To begin with, we plan to improve the prognostic power of the methods by using ensembles of PCTs. Next, we will use feature ranking for structured data to elucidate the most important features that need to be monitored. Furthermore, we can analyze this data in the one-look-ahead approach: predict the next glucose value based on the clinical status and the previous
measurements of glucose. Finally, we will use the knowledge from the models to design a decision support system for helping the medical practitioners.

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9. Paper 3: Special Topic Interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national eHealth

Mate Beštek (mate.bestek@nijz.si)
National Institute of Public Health, Trubarjeva 2, 1000 Ljubljana, Slovenia
IT University of Copenhagen
Dalibor Stanimirović (dalibor.stanimirovic@nijz.si)
National Institute of Public Health, Trubarjeva 2, 1000 Ljubljana, Slovenia
University of Ljubljana

Abstract

Objectives
The main aims of the paper comprise the characterization and examination of the potential approaches regarding interoperability. This includes openEHR, SNOMED, IHE, and Continua as combined interoperability approaches, possibilities for their incorporation into the eHealth environment, and identification of the main success factors in the field, which are necessary for achieving required interoperability, and consequently, for the successful implementation of eHealth projects in general.

Methods
The paper represents an in-depth analysis regarding the potential application of openEHR, SNOMED, IHE and Continua approaches in the development and implementation process of eHealth in Slovenia. The research method used is both exploratory and deductive in nature. The methodological framework is grounded on information retrieval with a special focus on research and charting of existing experience in the field, and sources, both electronic and written, which include interoperability concepts and related implementation issues.

Results
The paper will try to answer the following inquiries that are complementing each other:
1. Scrutiny of the potential approaches, which could alleviate the pertinent interoperability issues in the Slovenian eHealth context.
2. Analyzing the possibilities (requirements) for their inclusion in the construction process for individual eHealth solutions.
3. Identification and charting the main success factors in the interoperability field that critically influence development and implementation of eHealth projects in an efficient manner.

Conclusions
Provided insights and identified success factors could serve as a constituent of the strategic starting points for continuous integration of interoperability principles into the healthcare domain. Moreover, the general implementation of the identified success factors could facilitate better penetration of ICT into the healthcare environment and enable the eHealth-based transformation of the health system especially in the countries which are still in an early phase of eHealth planning and development and are often confronted with differing interests, requirements, and contending strategies.

Keywords: Telemedicine, Common Data Elements, Knowledge Management, Electronic Health Records, Health information exchange
9.1 Background and Significance

The sustainability of the Slovenian healthcare system has been a major challenge since its inception [1]–[3]. The early reforms of the healthcare system have only been partly successful due to major political change and transitional social and economic circumstances [4]. Specific measures were planned to provide the means for its sustainable financing, efficient operation and long-term development. Nonetheless, the Slovenian healthcare system is still substantially underfinanced and continuously incapacitated in terms of healthcare resources [5]. The majority of parameters concerning human, physical and technological capabilities of the healthcare system still lag behind the Organisation for Economic Co-operation and Development (OECD) average [5]. Operating efficiency, increasing costs, and low throughput of services provided represent the major challenges and limitations [4], [6], [7]. Considerably underexploited is the application of information-communication technology (ICT) in the healthcare environment. Despite early partial digitalization of the healthcare system, Slovenia is still far from an accurate and interoperable information system (IS) which has been of strategic importance in developed countries for improving their health systems [8] and for increasing the social welfare [9] and economic growth [10], [11]. Existing ISs have been developed and used within individual healthcare organizations and are adapted to their business processes and needs. This subsequently entails a low degree of interoperability resulting in the fact that complete and timely information is not available. In 2005 Slovenia launched the national eHealth project with the vision of integrating all fragmented ISs and providing the foundation for patient-oriented care [12], [13], while the high-quality data should support effective planning, supervision and performance evaluation of individual healthcare organizations and the healthcare system in general [14], [15]. Ambitious eHealth strategy and goals have proven to be rather difficult to follow and attain in practice. Various obstacles have considerably hindered the development of eHealth, which caused the main gaps in the implementation schedule. Notwithstanding significant delays, the national eHealth project represents a systematic and comprehensive solution. It aims to provide benefits to all stakeholders [16], [17] and assist increasingly more critical evidence-based management of the healthcare system [18], [19].

In this context, interoperability issues represent obstacles and hindrances of high priority. Healthcare environments have evolved to become ever more specialized and distributed. Health ICT and especially Health Information Exchange (HIE) have enabled convergence by removing the boundaries between the activities, sources, and users of healthcare data and information [20]. This convergence, or better said, alignment can be outlined as a complex multi-level concept named interoperability. Despite the fact that interoperability has traditionally been understood as a very technical term – meaning the ability of different ICT systems to exchange data and to understand the exchanged data meaningfully – it is considered from other non-technical aspects as well. Furthermore, these aspects have become even more important, due to the complexity of healthcare environment, which makes interoperability one of the major burning issues. Successful implementation of interoperable solutions has to support the core idea regarding the accessibility of patient data at any time and place needed. Obviously, a simple solution would be to have one ICT system/source in place globally,
but this is very unlikely to happen. Therefore, we need to focus on many different aspects of aligning and integrating existing highly distributed sources of patient data. The core viewpoints or building blocks of this aligned and therefore interoperable health ICT are defined in [21] as: Core technical standards and functions, Certification to support adoption and optimization of health ICT products and services, Privacy and security protections for health information, Supportive business, clinical, cultural, and regulatory environments, and Rules of engagement and governance.

One approach to achieving such alignment is the construction of Enterprise Architecture (EA). Whereas, the alignment has to take place between business level processes and ICT, containing application and data layer. It defines different viewpoints of business and ICT that need to be connected and aligned.

In Europe, a set of specific viewpoints is defined as the European Interoperability Framework (EIF). It defines technical, semantic, organizational, and legal aspects of interoperability, which are supported by a political context [22]. In [23]. The EIF was applied to the domain of eHealth with the eHealth European Interoperability Framework (EEIF), by the addition of eHealth services into the EIF. The underlying fundamental assumptions of EIF are security and privacy, transparency, preservation of information, reusability, technological neutrality and adaptability, and openness. Also, the EEIF adds eHealth specific patient centricity and use case approach principles.

A special aspect of interoperability in healthcare, that is by itself a far more complex problem than in other domains, is the semantic interoperability [24]. The main activities at this level are standardization of different e.g. terminologies and clinical knowledge models, that represent the common vocabulary and meaning for the ICT systems in order to understand the exchanged data. Also, when talking about interoperability between countries, natural language processing also needs to be considered for the purpose of presenting data and information in different languages.

There have been many large projects in Europe that dealt with the issues of semantic interoperability. Their aim was to develop guidelines and artefacts that member states could reuse e.g. epSOS [25], SemanticHealthNet [26], EXPAND [27], PARENT [28], SALUS [29], Trillium [30], Trillium II [31], EHR4CR[32], Antilope [33], TRANSFoRm [34], and eStandards [35].

Interoperability of healthcare ISs supported by a strong and flexible health ICT ecosystem provides the support for transparency and decision-making, reduce redundancy, simplifies payment reform, and facilitates the transformation of care into a new paradigm promoting the concept of ubiquitous health [21]. An interoperable health ICT (IH-ICT) ecosystem makes the right data available to the right people at the right time across services/products and organizations in a way that can be relied upon and meaningfully used by recipients [21].

Conforming to the fundamental assumptions mentioned earlier (e.g. Patient centricity), it is also important to focus on bringing Consumer Health Informatics into the IH-ICT ecosystem [21], [36]. Integration frameworks [37], which precisely define functional requirements and implementation of core building blocks [38], support such inclusion.

Our previous work on defining an EA framework for IH-ICT in Slovenia is elaborated in detail in [39]. Work presented in [40], [41] includes an openEHR based project, and also a document that describes a conceptual plan for the national eHealth
in Slovenia based on Integrating the Healthcare Enterprise (IHE) [42]. This work has been the foundation for the core technical standards, functions and certification to support adoption and optimization of health ICT products and services on the national eHealth implementation level in Slovenia. As pointed out in [21], coordinated work on all the building blocks of IH-ICT is a continuous process, whereas the EA framework connects all the components and activities mentioned earlier.

9.2 Objectives

In this article, we present the results regarding IH-ICT elements in Slovenia, as the EHR (Electronic Health Record) introduces the components like the used standards and methodologies, and also provides solid evidence regarding our experience and statistics about the national usage. This includes the lessons learned, recognition and identification of the major obstacles, and elaboration of the strategy used to tackle the emerging challenges. This contains information for all the building blocks introduced earlier - we provide new evidence on technical, semantic, organizational, and legal aspects of interoperability regarding success factors, which were identified and presented in this article.

The main objectives of the paper comprise the characterization and investigation of the potential approaches in terms of interoperability. We focus on openEHR[43], Systematized Nomenclature of Medicine (SNOMED)[44], IHE and Continua Health Alliance (Continua) [45]. We evaluate possibilities for their incorporation into the eHealth environment, and identification of the main success factors in the field, which are necessary for achieving required interoperability, and consequently, for the successful implementation of eHealth projects in general. The paper will try to answer these inquiries that are complementing each other:

1. Scrutiny of the potential approaches, which could alleviate the pertinent interoperability issues in the Slovenian eHealth context.
2. Analyzing the possibilities (requirements) for their inclusion in the construction process for individual eHealth solutions.
3. Identification and charting the main success factors in the interoperability field that critically influence development and implementation of eHealth projects in an efficient manner.

9.3 Methods

The methodological framework was grounded on information retrieval focusing on research and charting of existing experience in the field, and various electronic and written sources covering interoperability concept and related implementation issues.

We performed the in-depth analysis concerning interoperability problems in the context of the Slovenian eHealth in the second half of 2016. The methodological framework consists of three stages, whereas in each stage we focus on a specific research objective. The first stage involved the investigation of interoperability concept regarding theoretical foundations and a study of the recent and relevant state of the art. Extensive investigation of online resources including strategies, reports, action plans and other forms containing interoperability-related contents were carried out. In the second, experientially oriented stage, our attention was focused on the scrutiny of the experience of previous years, the current situation, and the requirements that arise in related fields, trying to identify the opportunities and the conditions that would enable usage of these approaches in the context of the Slovenian eHealth. As HIE presents the
major component of the national eHealth, we considered all four main HIE categories as identified in [38]. Namely, the EHR-EHR data exchange within the same institution (EHR-EHR-SI), EHR-EHR cross-institutional exchange (EHR-EHR-CI), the EHR-PHR exchange (where PHR denotes Personal Health Records), and the EHR-Clinical Report Form (CRF) exchange (EHR-CRF).

The last stage, deriving from obtained investigation results of the previous two steps, is striving to integrate conceptual and practical aspects and enable identification and charting of the main success factors in the interoperability field, which are critical for the effective development and implementation of eHealth projects.

The in-depth qualitative analysis was conducted combining different techniques [46]. Research methods selection was adjusted to the research field [46], [47], given the idiosyncrasy of the interoperability concept and the extent of eHealth initiatives.

9.4 Results

The research results of the first stage of our methodological framework are in line with the main HIE categories identified earlier. They include short introductions to coexisting approaches to interoperability, as it will be illustrated by the experience in Slovenia. The approaches combined in national eHealth project in Slovenia, which is not all truly implemented yet, are the openEHR, SNOMED, IHE and Continua. Table I shows main evaluation points for each approach, while additional introductory notes and descriptions of each approach are provided in the following section.

9.4.1 Potential interoperability approaches

IHE represents a set of profiles, which define most common use cases that occur in the healthcare environment. Such use cases span from the core ICT profiles that define e.g. security, logging, and synchronized time, all the way to the content profiles, which focus on data sets. The IHE certifies solution providers for the available profiles. The main focus is thus on technical interoperability and only partly on semantic interoperability. Regarding the presented categories of HIE, it can be said that all the basic IHE certified solutions focus on enabling the transfer of data in organizations and between organizations or domains, and in a very limited set of profiles also the exchange between EHRs and PHRs. IHE defines profiles that consist of agents and transactions between them, which are implemented using existing standards like HL7.

Lack of proper structuring of the content that is being exchanged accounts as one of the major obstacles of IHE. In relevant literature, clinical modeling is discussed by different approaches [48], [49]. Main strengths of openEHR approach are mainly being open and free, while it can also be used as an applicable interface for existing models [50]. It enables opening of the clinical data models that are typically locked in siloed ICT systems. Such unlocking is the basis for achieving semantic interoperability by following the shared knowledge paradigm. openEHR tooling supports the modeling of core artifacts that are publicly available. As this enables ICT systems to share the definition of clinical concepts, a higher level of semantic interoperability can be expected. Lately, HL7 Fast Healthcare Interoperability Resources (FHIR) [51] has gained traction. It is based on the concept of resources, which are a library of models (openEHR models could as well become part of this library). Similarly, openEHR has archetypes and templates. Application of new resource in HL7 FHIR requires new software, whereas in openEHR no new software is needed since a common reference model has to be implemented only once and then new archetypes and templates can be formed or manipulated as they are created. HL7 FHIR uses XML schemas, which
require changes in the software, dependent upon their change. In addition to the mentioned usage of openEHR archetypes and templates as resources to HL7 FHIR, there is also a simple way of adding HL7 FHIR on top of openEHR by means of developing new application interfaces with HL7 FHIR, which then execute queries against openEHR data. We started using IHE and openEHR in 2010 when HL7 FHIR was not an option but rather the HL7 v3.

OpenEHR is focused mainly on the modeling of clinical data. These models reference clinical concepts and codes from standardized terminologies. The most comprehensive terminology available is the SNOMED. It consists of some 300,000 terms with millions of interconnections. In our case, openEHR and SNOMED are used together. Obviously, there are many more international terminologies being used, and also national and organization specific terminologies, which, by existing, additionally complicate the goal of achieving IH-ICT. We consider SNOMED as the central terminology to which we can map other existing terminologies because it is an ontology, which enables complex relationships between the terms. Also, in one of the notable projects, The European Commission [52], strongly recommended the use of SNOMED.

In theory, openEHR and SNOMED can be used to model clinical data that reference clinical concepts. From these, use case oriented datasets are defined (e.g. Discharge Letter). We can transform such datasets to standardized formats, which are used in the exchange over IHE. Using openEHR and SNOMED to semantically define clinical data, which can be used for exchange over IHE, is the basis for EHR-EHR exchange. Also, the EHR-CRF exchange works in a similar way.

To include the aspect of bringing data from consumer devices, we also evaluate the Continua. Continua is similar to IHE since it also defines profiles. Implementation of profiles uses different existing standards focused on end user devices (e.g. sensors, and measurement devices). The combination of IHE and Continua has previously been explored for the purpose of EHR-PHR exchange of data and was found suitable, despite identified gaps and limitations [53]. In Slovenia and lately also at the European level, Continua and IHE were chosen as the main approaches towards interoperability. In our case, we consider Continua at the national level for the national implementation of telecare. In this way, patients will take measurements at home; the data will be transferred to the national EHR using Continua and IHE. In the EHR, also the openEHR repository will be filled with structured data coming from devices.

In theory, one can expect to support all the categories of HIE by combining these four approaches and also achieving IH-ICT. In terms of interoperability viewpoints, IHE and Continua enable technical interoperability and to a small extent also the semantic interoperability. Adding openEHR and SNOMED to the overall stack is a major step towards semantic interoperability. Authors of [40] have also touched the topic of adding the adaptive clinical process layer and achieving the standardization of processes, which is an evident next step in the future work section.

9.4.2 Utilization of interoperability approaches in Slovenia – possibilities, and requirements

In 2012 Slovenia established the national IHE Technical Infrastructure (IHE TI), which consists of the main IHE profiles. Namely XDS (Cross Enterprise Document Sharing), XUA (Cross-Enterprise User Assertion), XDR (Cross-enterprise Document Reliable Interchange), PDQ (Patient Demographics Query), PIX (Patient Identifier Cross-Referencing), and ATNA (Audit Trail and Node Authentication). In spite having also several IHE content profiles supported in the solution, the first goal was to support only
the exchange of unstructured Discharge letters. The solution enabled the sharing of
documents, which could be processed only by humans. In 2015, Slovenia upgraded the
IHE TI with the goal of supporting semantic interoperability. The methodology used
was openEHR. Approaches like HL7 v3 have also been trialed out, but it has been
empirically confirmed that they require too many resources, not to mention the
ambiguity and other issues concerning the underlying HL7 Reference Information
Model [54], [55]. The IHE TI upgrade included an additional IHE certified solution that
manipulated openEHR data directly.

Following this openEHR approach, we started a project of establishing the
National Patient Summary (PS). We adopted the core dataset from the epSOS [56]
project, which is also a recommendation from the European eHealth Network. The PS
dataset was reviewed by a group of doctors in Slovenia during the epSOS project. This
review represents the much needed professional consensus on the dataset and as such
represented the basis for the national PS implementation.

The specification documents within the public call for tender for the
implementation of National PS dataset in 2015 required that datasets have to be
modeled using openEHR archetypes and templates. Archetypes are focused on
modeling clinical recording scenarios by using clinical concepts together with a
constrained information model, namely the openEHR Reference Model [57].
Constraints are introduced by using the Archetype Definition Language (ADL) to meet
the requirements of a specific clinical record – a template [58]. The platform can
automatically produce XML (Extensible Markup Language) Schema and technical
specifications that are traditionally used by software developers. It also provides a
REST (Representational state transfer)-based interface for more light web-oriented use
cases. For the purpose of modeling archetypes and templates, we used the tools
Archetype Editor and Template Designer (http://www.openehr.org/downloads/modellingtools).

Overall, eight software providers offer Electronic Medical Record Systems
(EMR) in Slovenia. We have contracted all of them to connect their systems to the
national PS. Since such integration has previously been implemented (for the purpose
of discharge letters), the main requirement was to support the transfer of new data.
These schemas are based on openEHR, and existing terminologies – both local and
international. Terminologies used were the Slovene version of ICD10, SNOMED-CT,
and LOINC among others. This project also represents the first national implementation
of SNOMED CT subset in Slovenia.

Figure 1 shows an activity diagram for a simple use case in which a patient uses
a device at home to perform a measurement. In addition to the activity steps and actors,
we depict different interoperability approaches and artifacts as they are used in order to
show how all the interoperability approaches are connected. We can see that Continua
profiles cover the transfer of data from devices to a cloud service, which will then
produce a Diagnostic Results Document (Results Doc) as an XML/JSON structured
document and send it over IHE profiles to the national eHealth (e.g. Electronic Health
Record). Here, the Results Doc is validated against the openEHR template, which
consists of one or more openEHR archetypes. Different data elements will have to
contain codes from various terminologies like LOINC, ICD10, and SNOMED. The
national eHealth then sends a notification to the patient's personal doctor that a new
measurement is available. He will then use his Electronic Medical Record (EMR) to
retrieve the Results Doc in XML/JSON format. This is possible since all the EMR
systems are integrated with the eHealth IHE infrastructure.
It is important to stress that we are still working on the introduction of Continua to support the EHR-PHR exchange. Also, we will extend our work towards concepts like ubiquitous health and smart cities with ongoing projects [59].

**Identified obstacles**

During this implementation, the major obstacles identified at the level of healthcare providers (HCP) include:

- obtaining a common data set for the PS where government bodies needed to act (time consumption and lack of engagement were identified as the main issues concerning this matter),
- obtaining consensus from doctors on the dataset, which is often very time-consuming and medical professionals very often require extra funding for such projects,
- the creation and usage of the PS influences existing business processes in the healthcare system, meaning it is necessary to get the support from the management at HCPs and MoH,
- the implementation had to use terminologies that were already in use – SNOMED-CT was in turn used on a much smaller scale to what was planned; also, the inclusion of existing terminology custodians in the process of common dataset preparation was a prerequisite,
- software providers had different data models in their systems, and they were not willing to change their solutions for the purpose of PS – obviously, also the user interface changes were connected to the changes of data models,
- another national implementation of a vaccination registry was conducted in parallel to the PS project. The PS contained the actual vaccination section as a subset; therefore any change in the vaccination dataset was manifested as a change in the PS project; this co-dependency between two national projects was another source of complexity with the PS implementation,
- integration with the hospitals and other HCPs was a part of the public call for tender in which we acquired and established the IHE-TI. Each of the software companies had implemented application interfaces to IHE-TI. Now, when a new set of data is defined, they only work on implementing new XML schema (generated from openEHR templates) for sending the data,
- in spite of having the technical integration established, hospitals and other providers did not just start sending documents. Slovenia in 2015 changed the Healthcare Databases Act that was expanded with eHealth (defined as the national healthcare information system) and all eHealth solutions have become national databases. Especially the Central registry of patient data (CRPD / EHR), became obligatory for the HCPs,
- Despite the Healthcare Databases Act from 2015 defined the usage of national EHR as obligatory, we still do not have all the HCPs sending and receiving documents. This is still an ongoing process.

**Requirements for inclusion of the interoperability approaches**

For the national PS like projects to succeed, they must meet several requirements. These include at least:

- a strong core healthcare informatics team that oversees all of the activities and is competent to participate and also takes custody of the subject matter including healthcare specific standards and methodologies is a prerequisite; this also includes a strong emphasis on clinical modeling and terminology management on a national level,
• a project specific or national board of healthcare professionals that take part in the consensus development, which can also include participation in clinical modeling and terminology governance,
• the support of the management of all the main stakeholders – HCPs management, MoH, health insurance fund,
• continuous presence in the media with the purpose of informing and education different user groups,
• strong technical standards based (IHE, Continua) infrastructure in place enables the standardized exchange of data between the various nodes in the healthcare system,
• quality contracts with private companies that are strategically important for the national eHealth,
• open public calls for tendering for the development of new solutions,
• certification of the solutions is highly needed and
• the internal organization needs to support such dynamic cooperation with different entities, so moving the organization to the more agile way of work is strongly suggested.

Following from these particular experience from the past years, we additionally reviewed existing literature to obtain more generalized success factors that influence the effectiveness of the eHealth implementation.

9.4.3 Identification of the main success factors in the interoperability field

In examining the possibilities and requirements for the inclusion of depicted approaches into the Slovenian eHealth context, we have identified several success factors with enough influence potential for the effective execution of interoperability principles and implementation of eHealth projects in general.

Success factors meaning appropriate and balanced dynamics between healthcare ecosystem conditions and elemental eHealth requirements were identified by primarily focusing on critical aspects of the development and implementation of eHealth projects.

Accordingly, and in compliance with existing frameworks; the political, regulatory, institutional, and technological areas where identified as having the most influence on eHealth. Depending on the recent experience in the eHealth development and implementation process, we mapped a list of success factors for each area. The effectiveness of the application of these factors is strongly connected with the general development level of eHealth projects and presents a highly likely mechanism for identifying successful countries in the digitalization of healthcare systems. In Table II, all the factors grouped into the four identified areas are presented. Evidence suggests that some of the identified success factors hold more influence regarding not only raising the overall success rate of eHealth projects but also alleviate the shortcomings of other success factors. It is clear that only versed operationalization and coordination of the success factors can support effective development and implementation of eHealth projects.

The chosen interoperability approaches have positively influenced the implementation of new national documents both for the government and for the ICT solutions providers in Slovenia. The development cycles have become shorter and agiler. This is clearly depicted in Figure 2 that shows the number of documents
available in the national eHealth in 2016. The number of records is the direct result of using the IHE, openEHR and SNOMED approaches to interoperability. In Figure 3 we see the number of distinct patients that have at least one document available in different eHealth solutions (eReferral, ePrescription, and the CRPD). Also, in Figure 4 we see how well a particular solution reaches the overall population (2 M). For the eReferral, we can see that it reaches 18% of the population while ePrescription and CRPD reach 79% and 48% of the population respectfully. In overall, more than 84% of the population has at least one document available in the national eHealth.

9.5 Discussion

Combining and applying different approaches to alleviate the interoperability issues is a very challenging undertaking. Lack of first-hand empirical studies that would systematically map and analyze different interoperability approaches and their prospective incorporation into the planning, development, and implementation of national eHealth projects intensifies the challenge even more. Furthermore, we can observe the limited focus of the majority of the relevant research efforts in the field that highlight only a small number of views on interoperability and their influence on the operation of specific ICT solutions or provision of distinct healthcare specific ICT services. This situation considerably impedes research on interoperability in healthcare ICTs. Also, it additionally complicates the formulation of a coherent platform, that would provide practical support in further efforts towards the innovative application of existing interoperability approaches (such as openEHR, SNOMED, IHE, and Continua) in the planning, development, and implementation of national eHealth projects.

Albeit precise outlining and characterisation of the applicability as well as final long-term effects of the interoperability approaches mentioned above are difficult, we can rather describe a few outcomes from an early stage. Based on the eHealth project structure and the solutions available thus far, the adequate use of proposed interoperability approaches is likely to have a positive effect on all main elements of the eHealth development and implementation. The effective application of interoperability approaches should consider the multitude of influences from the healthcare ecosystem that may adversely affect their integration into the healthcare IS. This situation calls for a new definition of the behavior of the principal agents in the healthcare system, and the new arrangement of the infrastructural, organizational, and technological elements that support the interoperability requirements.

Strategic sources of Slovenia [3], [60] focus on improved coordination of actors in the healthcare system, patient centeredness, quality of health services, financial sustainability and transparency, and standardization, simplification, and optimization of the healthcare processes. These attributes present the verification framework regarding the importance of interoperability principles, which should represent the foundation of the future health IS.

However, the whole transformation towards the interoperability has to be adequately arranged taking into consideration all the complexities. The successful introduction of interoperability principles clearly requires government incentive, engagement of all stakeholders, and their agreement on the various and often antagonistic issues within the healthcare system.

Despite sensitivity to subjectiveness and different interpretations, our in-depth analysis provides a valuable view of the interoperability concerns and their profound effects on the general success of eHealth projects development and implementation. The main limitations of the study probably concern the interoperability approaches that
we chose arbitrarily, as well as the fact that we defined their applicability on the basis of internal examination and sources investigation without experimental testing and validation of each interoperability approach in practice. Accordingly, the questions of interoperability approaches’ quality and suitability can be questioned, and the results of the conducted in-depth analysis may, therefore, be open to different interpretations. These concerns should be further addressed in future research and successive experiments following the main idea of defining a theory-based framework for the analysis of interoperability issues in the national and international context. Despite some potential methodological shortcomings and restricted resources, our in-depth analysis exposes critical dynamics of interoperability and its wide-ranging effects on the general success of eHealth projects. The identified success factors may be used as a practical starting point for the planning of project coordination, advance activities, required material and non-material resources as well as the amount of necessary managerial effort.

9.6 Conclusions
Pervasive penetration of ICT solutions into the healthcare processes in the last decades has made existing IS development practices being questioned. The presented research does not focus on providing a magic stick solution for the interoperability concerns related to planning, development, and implementation of eHealth projects, but attempts to establish a ground for addressing interoperability concerns, and identification of the most important success factors for their alleviation.

The obtained results could help identify the required actions and indicate the appropriate measures for the inclusion of the adequate interoperability approach into the whole eHealth project development and implementation cycle. Provided insights and identified success factors could become part of the strategic starting points for continuous integration of interoperability principles into the healthcare domain and more efficient ICTs inclusion, especially in the countries which are still in an early phase of eHealth planning and development. Also, issues discussed could support the much-needed change in the ISs development area and promote further steps towards the general interoperability in the national and international healthcare environment.

The presented research provides the comprehensive analysis of existing configurations and may serve as the grounds for further steps in this area. Despite system considerations and related difficulties, the introduction of interoperability approaches in the Slovenian eHealth project, and most likely elsewhere, represents a development opportunity. To secure improved utilization of healthcare resources and provide real public health benefits, it is of utmost importance to focus on coordination of eHealth with other ecosystem factors and pending structural reforms of the Slovenian healthcare system.

Questions

Q1: What is the optimal approach to national eHealth implementation?

1. An optimal approach to national eHealth implementation is based on identification and implementation of success factors on a national level.

2. The approach based on a technological interoperability framework is needed since technology is the main critical element of national eHealth implementation.
3. Focusing on appropriate implementation of ICT solutions and adequate funding is the best approach.
4. Since health professionals and citizens are the main users of eHealth solutions, it is best to focus on the promotion of eHealth and education of these two major end user groups.

Explanation of the correct answer to Question 1: answers 2, 3 and 4 represent only a partial set of factors that influence national eHealth implementation. It is of most importance to base the national eHealth implementation on the broad range of previously identified success factors. Therefore, the answer 1 is the correct reply to the first question.

Q2: What is openEHR in the context of interoperability?
1. OpenEHR supports the message based approach to interoperability where the focus is on specifying exactly defined data sets for specific use cases, where the main focus is on the data flow between systems without knowing anything about the internal workings of the affected systems.
2. OpenEHR is an ontology that consists of clinical concepts. Data elements in different messages are mapped to these concepts.
3. OpenEHR is based on the idea of resources. These are a library of different models that can be used to define different data structures for the exchange between systems.
4. OpenEHR supports the single source based approach to interoperability. This includes global models that are freely accessible.

Explanation of the correct answer to Question 2:
Answer 1 does not describe openEHR, but would better fit the message based approaches like HL7 v2 and v3 where the focus is on defining the data flow between systems without knowing anything about the internal workings of the systems. Answer 1 is not the correct option.
Answer 2 does not describe openEHR. Such description would fit a terminology like SNOMED better. Terminologies are definitions of clinical concepts which are used for giving meaning to data elements. Answer 2 is not the correct answer.
Answer 3 is a description of the latest HL7 FHIR approach to interoperability. OpenEHR models could become new resources – elements of the library of models available for different purposes. This answer is not the correct answer.
Answer 4 is the right answer since openEHR is an example of a single source based approach to interoperability where models are taken outside of existing systems and represent common artifacts that define the meaning of clinical data. As such, they can be used as the basis for transformation to any other of existing messaging formats.

Clinical Relevance Statement

The interoperable eHealth solutions enable higher quality care for patients, better-informed decision-making for doctors and evidence-based management of the individual healthcare institutions and health systems in general.

Conflict of Interest

The authors declare that they have no conflicts of interest in the research.

Protection of Human and Animal Subjects
The authors declare that human and/or animal subjects were not included in the project.

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9.7 References


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Table I Evaluation of interoperability approaches

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<thead>
<tr>
<th>Interoperability approach</th>
<th>Description</th>
<th>Pros</th>
<th>Cons</th>
</tr>
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<tbody>
<tr>
<td><strong>IHE</strong></td>
<td>IHE represents a set of profiles that define most common use cases that occur in the healthcare environment.</td>
<td>Standardized use-cases in the healthcare environment that consist of agents and transactions between them. A global approach to interoperability. Has become common off the shelf product. Supports adding new solutions. Promoted to the EU level.</td>
<td>Not all IHE profiles are in use. A long learning curve for existing solution providers. We needed a special interface between IHE infrastructure and existing solutions in the hospitals.</td>
</tr>
<tr>
<td><strong>Continua</strong></td>
<td>Similar to IHE but focused on smaller devices that enable remote measurements and conveying of data to e.g. EHR.</td>
<td>Enables standardization of use-cases focused on different devices used in healthcare. Connection with IHE supported. A global approach to devices interoperability. Promoted to the EU level.</td>
<td>Devices tend to be more expensive. A long learning curve. Support for non-Continua compliant devices are still needed due to their higher market share.</td>
</tr>
<tr>
<td><strong>SNOMED</strong></td>
<td>The largest terminology</td>
<td>As an ontology, it enables great concept definitions</td>
<td>More than 300,000 concepts represent</td>
</tr>
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</table>
available. It enables modeling clinical concepts that are used to define semantics.

regarding connections between concepts and supporting attributes.

Subsetting can be used to use parts of SNOMED for specific projects – thus supporting gradual national implementation.

Existing mappings of other terminologies to SNOMED – e.g. LOINC to SNOMED.

Great support for member countries from the International Health Terminology Standards Development Organization (IHTSDO).

a complex and expensive translation projects.

Terminology management solution is needed for more effective management.

<table>
<thead>
<tr>
<th>OpenEHR</th>
<th>An approach to modeling data that is created and used in the healthcare processes. Also, specifies an architecture for an EHR.</th>
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<tr>
<td></td>
<td>Supports concepts like open data and open standards.</td>
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<td>Data definitions are publicly available and used nationally.</td>
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<td>Interfaces to existing terminologies are supported.</td>
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<td>Empowers healthcare professionals, who can create new e.g. registries (without specific software development process)</td>
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<td></td>
<td>Enables semantic querying. The international community around the OpenEHR foundation supports the clinical modeling. The results are shared internationally.</td>
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<td>Healthcare professionals are not motivated to engage in clinical modeling for various reasons</td>
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<td>Establishing a national editorial board is both expensive and hard to achieve.</td>
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Table II Main success factors for effective development and implementation of eHealth projects

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<td>Inclusion of stakeholders and effective collaboration</td>
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<td>Realistic agenda and adequate budget</td>
<td>Adoption and implementation of the necessary regulations and code of practice</td>
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<td>Strong project management team</td>
<td>Harmonization of national regulation with international conventions and agreements</td>
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<td>Monitoring and control of project implementation and timely measures</td>
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<td>Evaluation frameworks and practice</td>
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<td>Promotional campaign, media presentations, and mobilization of public support</td>
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<tr>
<td>Regional cooperation and international integration</td>
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<td>Projections and vision for the future</td>
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<th>Institutional factors</th>
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<td>Business process and service standardization</td>
<td>Specialized ICT development team and adequate funding</td>
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<td>Intra- and interinstitutional agreements, cooperation, and joint public procurement</td>
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<td>Promoting the use of ICT, education, and training</td>
<td>Monitoring and technology watch</td>
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<td>Pilot projects</td>
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<td>Contingency plan</td>
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Figure 1 Mapping interoperability approaches to a simple use case

Figure 2 Number of documents available in the Central Registry of Patient Data (national EHR)
Figure 3 Distinct number of patients in different eHealth solutions and across all solutions

Figure 4 The share of population reached by the three national eHealth solutions and the proportion over all solutions

“This article is not an exact copy of the original published article in Applied Clinical Informatics. The definitive publisher-authenticated version of Special Topic Interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national eHealth is available online at: https://aci.schattauer.de/contents/archive/issue/2503/manuscript/27811.html ."
10. Paper 4: Is national eHealth in Slovenia on Track to be an Open eHealth Platform?

Mate Beštek\textsuperscript{2,3}, Peter Eklund\textsuperscript{1}
\textsuperscript{1}Deakin University, Australia
\textsuperscript{2}IT University of Copenhagen, Denmark
\textsuperscript{3}National Institute of Public Health, Slovenia

Abstract

Background
The driving force for information-communication technology in healthcare has been directed towards better-coordinated care but high cost and time consumption in addition to difficulties with cooperation with resident practitioners has hampered progress. Therefore, due to the underestimation of difficulties to manage national eHealth activities, the potential of eHealth in Europe is still to be realized.

Results
We have identified a gap that needs to be bridged in order for Slovenia to achieve all the benefits of an open eHealth platform that could become a strategic direction for the future. We constructed a questionnaire that is based on the open platform theory grounded design principles for open eHealth platforms which we used as a helping tool to perform the analysis.

Methods
An evaluation of the national eHealth in Slovenia grounded on open platform theory based organizational design principles for eHealth platforms has been conducted. We used a running use case of an eDiabetes digital health intervention as a potential new central service of the national eHealth platform. We discussed all the design principles and also constructed a questionnaire during the process to additionally help with the evaluation.

Conclusion
By evaluating the national eHealth in Slovenia against the open eHealth platform organizational design principles, we identified a gap that needs to be bridged to benefit from the positive effects of open eHealth platforms. Being open suggests participation, extension and growth both in terms of demand side users (e.g. patients and doctors) and supply side platform users (e.g. IT companies, HCPs etc.) Shortage of a business model is just one principle that still needs to be met in addition to several others. With this, Slovenia can ground its national eHealth vision and strategy on the results of this analysis.

Keywords: ehealth, platforms, open platforms, open ehealth platforms, evaluation, design principles, organizational design principles
10.1 Introduction

The eHealth Action Plan for 2012–2020 states that the promise of eHealth “remains largely unfulfilled” and the vision of a unified, interoperable eHealth Infrastructure in Europe is still not realized [1]. The driving force for ICT in health care has been the trend toward better coordination of care [2], [3]. Implementing national eHealth is an underestimated difficult to manage activity [1], [4] that is high cost and time-consuming. For these reasons it is difficult to cooperate with resident practitioners that are highly burdened due to an ever growing demand for their services. Due to this, an expectation gap occurs between the value of eHealth and the intention to adopt ICT in the healthcare sector [5].

Treating the national eHealth as a platform could allow more effective resource allocation. The primary role of platforms is to establish market functions for eHealth services and to overcome the traditional lock-in from solutions providers. Instead, a platform provides a component-based service architecture. As part of the digital transformation process, typical care processes are becoming ever more integrated including not only healthcare but also in different contexts, such as social care and the environment of the patient’s home. Further, such integrated care processes are becoming personalized adaptive care pathways in the healthcare sector [6]–[8] that we can describe as highly distributed, with adaptive integrated care processes spanning different domains (e.g., healthcare and social welfare domains).

To address the question of how to use the component-based services that comprise the national eHealth platform to develop new integrated care information systems, we look into design principles, as presented in [5], in order to address this question during eHealth platform construction.

These design principles are focused on the design of the organization that will offer the eHealth platform. Focusing on general information infrastructure design principles and more technical design principles are not the focus of this paper. Since design science research suggests we cannot obtain a generalized abstract artifact for eHealth platforms, design principles are an adequate means to create a theory in the field of eHealth platforms [5]. Following the ideas from [9] that suggest we can obtain design principles from initiated artifacts, we will use the national eHealth in Slovenia as a case setting in which we will see how well we can operationalize the design principles in this setting. By doing this, we will provide new evidence for supporting existing design principles or support the extension with new principles. We also provide a set of questions that we derived from the design principles and existing evidence to support the operationalization of the measurement of adherence to design principles. Also, we will consider implications of using the design principles as the basis for defining an eHealth strategy.

The focus of this article is, therefore, to revise the national eHealth of Slovenia as a platform, and, therefore, as an information infrastructure and to learn how the existing organization in charge of governance, fits the organizational design principles for establishing an eHealth platform. We intend to identify a gap between the implementation and the requirements. By addressing the gap, we will identify a main national strategy on eHealth that will also be a guide to understand better, plan and execute the overall digital transformation of our healthcare system since the national eHealth in Slovenia has been legally defined as the national health information system in Slovenia [10].

This article is structured as follows: in Section 2 we quickly present the main concepts of the eHealth platforms, in Section 3 we present the national eHealth in Slovenia. In Section 4 we show the organizational design principles and use these as a checklist for
10.2 Definition of concepts

We can define platforms as “products and services that bring together groups of users in two-sided networks” [11], where some groups of users represent the demand side and other user groups represent the service providers. In the case of search engines, web surfers (demand) are joined with advertisers (supply). The platform role model [12] describes four main roles of participants that can either be open, meaning structured to encourage participation or closed [11]. Selecting optimal levels of openness is crucial for firms that create and maintain platforms [13] since a platform that is too open is not always the best option [14]. Open platforms are believed to be enablers of the ‘platforms ecosystems concept’. Ecosystems in, general, are inter-organizational networks [15]. In the context of platforms, ecosystems represent the platform and all the applications specific to the platform [16]. The ecosystem metaphor suggests the following systemic behavior as outlined in [5]: (1) the open platform is a dynamic network-based system that supports inter-component interaction. Initiation or interruption of interactions can occur [17], [18]. A central instance does not coordinate the emergence of communications. (2) The ecosystem allows both competition and cooperation between participants at the same time [19], [20]. (3) Components of the platform ecosystem are developing independently from each other but influence one another mutually in their development. This principle can be called co-evolution [21]. The components of the ecosystem can be combined, analogous to the recombination in nature [22]. (4) Participants can principally accede to the ecosystem or leave the ecosystem [23]. Therefore, it is an open system. (5) It is a non-predictable system [21]. Future system characteristics and components and their dynamics can consequently not be foreseen. In line with the typology of ecosystems research presented in [15], we consider platform ecosystems as socio-technical systems – systems that comprise decision-making social entities like humans (or enterprises) as well as technical-components [24], [25], as cited in [15]. We look at the platform ecosystem as a type of ecosystem in information systems [15] that emerge around a central open platform [26]. A central open platform provides different IT components and rules that connect actors around and to the platform [21], [26] that, together with its boundary resources, play the dominant role when engineering ecosystems [19].

Open platforms as enablers of platform ecosystems can be an information infrastructure with only one platform [5]. Information infrastructure is defined as shared, open, heterogeneous and evolving socio-technical system of IT capabilities (recursive consist of information infrastructures, platforms, applications, and IT Capabilities) [27]. Distributed forms of control over information infrastructures often form the only way to coordinate their evolution and, therefore, they are never changed from above [28] - meaning there is no central coordinator that would be able to do a top-down control. Therefore, we cannot genuinely design them in a traditional sense as in conventional approaches a designer assumes control over the design space [29], [30] as cited in [27]. The blueprint to build a platform to enable ecosystem-effects is a platform strategy [31] that should be able to dynamically orchestrate the coordination, governance, and capabilities renewal processes – the three central processes of open innovation that is supported by platform-based ecosystems [32].
Open innovation was defined by [33] and is about opening the boundaries of organizations into a system of relations with different partners to support innovation. In such a context, platform-based ecosystems appear to be an effective way of managing a portfolio of contributions from varied and independent players for continuous innovation which has recently become a prime innovation approach [32]. Author of [34] presents the future of open innovation as going beyond technology to business models that will embrace both product and service innovation. However, achieving open innovation is not to be considered a trivial task [35]. Open innovation traditionally revolves around a central organization – the supplier that expands into a network in both inwards and outwards. Authors of [36] suggest the opposite view on open innovation, where customers are the focal point. Governments can act as customers and with their legislative power can be the drivers of open innovation. Customer co-creation is also one of the identified gaps in the open innovation literature [37]. By supporting such collaboration, the transformation of value creation and service delivery is possible [38].

Platform ecosystems evolve. We can describe evolution by different network effects, e.g. [39]. Hence, the design of a platform strategy must address the intended effects of an ecosystem [31]. The governance rules and architecture are the control instruments for the establishment of intended network effects in an ecosystem [21], [40]. To understand platform architecture, governance, and evolution, it is essential also to be aware of the concept of the platform lifecycle. The platform strategy, therefore, depends on the lifecycle stage in which a platform currently exists, which is explained concerning dominant design stage (pre- or post- identification of the dominant design), the stage along the S-curve (progression of technology from introduction, ascent, maturity, and decline phase), and the diffusion curve (share of users that have adopted) [41]. From the technical perspective, the platform should provide a basic set of “Seed”-services to initiate these effects [42]. We focus on platforms that exploit network effects by mediating transactions between platform users [11], [12], [43], [44]. A platform comprises of a set of components and rules that coordinate network participants activities [45] and include standards, protocols, policies, and contracts [12]. In a recent call to revise eHealth platforms from the perspective of organizational design, [5] propose seven design principles grounded in existing platform theories [5] that we can use as guidelines for establishing platforms – in addition to existing technical considerations [46] and general information infrastructure design principles [27]. The seven design principles are as follows:

1. Open and synergetic business model,
2. Avoiding high entry fees and entry risk,
3. User-oriented price model and risk management of the platform participation,
4. Identifiability of products and services,
5. Reduction of information and knowledge deficits for platform users,
6. Securing restrictions from platform utilization possibilities,
7. Differentiation between platform management and the care management.

10.3 National eHealth in Slovenia

The national health system in Slovenia is suffering from fragmentation and poor quality health information which affects the provision of healthcare services and the management of the healthcare system [47] and has been lagging behind the EU28 average in most aspects [48].
The national eHealth system primarily focuses on becoming the health information system. In [47], the Slovene health information system is presented concerning three main components: an eHealth Network, a health portal, and an electronic health record. We focus on providing a view on the national eHealth system that is based on existing platform theory and specific eHealth oriented organizational guidelines for assessing the national eHealth system concerning being an open platform and identifying the requirements and implementation gap with regards to the open dual-sided platform theory [11]. With this, we would like to focus the attention of the national eHealth system towards the platform thinking that would support the platform economy in the healthcare system and with this enable better utilization of resources and as a consequence a more sustainable healthcare system.

Figure 1 depicts the main components of national eHealth system and also the main domain applications that represent different networks, processes, and ecosystems that are supported.

The core components of the national eHealth system are supported by a set of technology solutions, standards, and methodologies that we now describe in more detail. Due to space limitations, we omit details about the different applications.

### 10.4 National eHealth system Core Components

Identity Management supports three essential services that are used by the national eHealth system core components and applications including the Identity Assurance Service that holds correct data about employees of the health system, and also holds identification data about patients, the two main user groups that access the national eHealth system. The data is obtained from different official national registries that are governed by different ministries. Technically, the Identity Assurance Service is used for authentication and authorization using the Security Assertions Markup Language (SAML) and OAuth2 (similar to SAML but focused more on the web applications) to enable federated identity.

Central Registry of Patient Data (CRPD) is the central component of the national eHealth system and is, in fact, an Electronic Health Record. It consists of an interoperable information infrastructure that supports the sharing of data between different healthcare providers (HCPs). It provides essential services like the Demographic service as well as services that support document repositories that can be both unstructured and structured (concerning, e.g., OpenEHR[49] archetypes and templates). Table 1 presents the main document types and their overall number and share as of September 2017, and also the number of patients for each document type. In overall, some 67% of citizens have at least one document in the CRPD.

#### 10.4.1 Knowledge sources

The national eHealth system supports different knowledge sources, namely terminologies, information models (OpenEHR [49] archetypes and templates), workflows (with limited scope), and also some decision support for the drugs related scenarios like contraindications and interactions. Terminologies like ICD-10 [50] and SNOMED [51], [52] are used by different applications and are deployed on the Terminology Server. To achieve interoperability that also enables the breaking of existing vendor lock-in-based business models, the national eHealth system is using OpenEHR as an approach towards modeling clinical data in the form of openly available archetypes and templates. Managing cross-organizational care pathways that are adaptive and also personalized, is becoming of utmost importance. The national
eHealth system has used Business Process Modeling Notation version 2 (BPMN2) as the basis only for some cases like the triage algorithm in eTriage, and a research project called eCare [53]. Decision support is, generally, not advanced in the national eHealth system and is in use only in the ePerscription where contraindications and interactions are presented to the prescribing doctor so that the best drug is selected and prescribed to the patient.

10.4.2 Boundary resources
The central components of the national eHealth system are available through different forms of application interfaces (APIs). The lifecycle of these APIs needs to be managed, and lately, the API Management architecture reference implementation that supports all stages of the lifecycle (implemented during the EkoSmart project [54]) is being adopted. The boundary resources will, therefore, be provided through this solution. This includes both technical and documentation specific for different user groups. Boundary resources are primarily used by all the networks that use the national eHealth system platform. They are represented as standard or lightweight web services and even web forms that are integrated into existing solutions.

10.4.3 IT infrastructure
The national eHealth system is running on two geographically different locations where one is called the primary and the other a recovery location. Data centers consist of typical server elements on top of which a virtualization layer is implemented. This is then used to run over 100 virtual appliances in the primary location that together support the system. The network (zNET) is a physically separate network consisting of about 130 physical routers that are distributed to the largest HCPs and pharmacies. To be able to access the services (except the patient portal), one needs to be included into the network, which does not run over the regular Internet. With this, the basic service availability can be efficiently supported.

10.5 National eHealth system Core Applications
The core set of applications that are supported include ePrescription, eReferral, eTriage, TeleStroke, TeleRadiology, Patient Portal, and National Registries (e.g., Patient Summary, National Vaccines Registry), and several small-scale applications.

10.6 Case Study for Design Principles for open eHealth platform

10.6.1 The eDiabetes intervention as a running use case
To have a running use case for this paper, we will use a use case of adding a new service to the national eHealth system that will support coordination of care, a platform in itself, and supports interventions targeting patients with conditions like asthma and diabetes, but also obesity, and those that are not sufficiently physically active. The platform would like to bring new services to the national eHealth and make them available to patients and many groups of professionals. We will focus specifically on the diabetes intervention (eDiabetes), described previously [55]. The primary process that eDiabetes intervention supports includes patients at home, nurses that perform the role of care
managers, and primary level physicians. A home care protocol has been defined for patients and defines the tasks and frequencies of the tasks. Care managers (nurses) were given tools to monitor the status of diabetes in their group of patients. The intervention was evaluated in a clinical trial that included a network of primary level healthcare providers [56].

10.6.2 Analysis of the inclusion process of eDiabetes to the national eHealth system

We now analyze the organizational design guidelines and refer to the eDiabetes use case and by doing so, analyze the national eHealth system concerning design principles for open eHealth platforms that are presented in [5]. The principles are focused on organizational design and not on the technical aspects [46], where authors present the concept of medical application platform and focus on device interoperability, interoperability standards, common components technical architectures, and also lack of regulation and lack of ecosystems for such medical applications; or the general information infrastructure aspects [27]. Table 2 specifies detailed questions we asked ourselves to understand all the seven design principles more precisely and to use them for evaluating an existing eHealth platform.

Firstly, following the [12] platform role model, we define each of the four roles as they exist in the national eHealth. The Ministry of Health (MoH) is the primary provider of funding and, therefore, plays the role of a platform sponsor. With new legislation passed in 2015 [10], the governance of the national eHealth has been transferred from the MoH to the Centre for Healthcare Informatics (CHI) at the National institute of Public Health. Contracted service providers support the activities. The role of the platform provider is, therefore, shared by the CHI and external private providers which could give rise to issues with mismatching goals of public and private organizations and require having an explicit agreement about each party’s goals [57]. The eHealth network of HCPs are connected to the core components through existing systems, e.g. medical record systems and laboratory information systems. The IT providers of central services play a role of supply-side users. The national Health insurance fund participates in the national eHealth platform in the role of a demand-side user since it obtains essential information from the platform.

The eHealth network consisting of all the HCPs are legally bound to using the national eHealth core services. Unfortunately, many factors influence the current incomplete inclusion of all the HCPs [58] that are in the role of the demand-side users together with the patients. In the eDiabetes use case, the service providers want to take on a role of a supply-side platform user.

10.6.3 Open and synergetic business models

Healthcare is an actively regulated industry, and generally, organizations that are part of the public network are not supposed to be competing with one another in the market but in reality they do. Most HCPs in the healthcare system are contracting with the national Health insurance fund – these represent the public healthcare network. The national eHealth is providing core services to all the HCPs, but only those in the public network are obliged to use them. Regulation, therefore, enforces the use of core services. The CHI is in charge of the process of identifying new potential services and bringing them on the national level. This means that an IT provider, the supply side
user, can create a new specialized application for a network of HCPs and can integrate with the existing core services of the national eHealth to provide the service to the demand side users. The integration is supported by the boundary resources [59] – namely the APIs. The CHI provides all the documents that specify how such inclusion can be executed together with all the technical documents of the core services to implement the integration. The necessary information is available on a special website, and the more specific documents can be obtained on demand if the new provider meets the preconditions of inclusion to the national eHealth. The preconditions primarily mean that there is a HCP that is requiring access to the national eHealth since HCPs have the legal grounds to do so. Companies therefore cannot become part of the national eHealth if they do not provide services for HCPs.

The financial aspects of the business model are unfortunately not transparent. The Health insurance fund is providing fixed monthly payments to the HCPs so that they can cover the IT costs in their organizations. Also, the MoH is financing the national eHealth which often includes upgrades to the solutions of all the IT providers of HCPs. Adding a new service to the national eHealth, therefore, means that there need to be more funds allocated by the Health insurance fund for the IT budget of all the HCPs. This is possible once a year through the general agreement contract that is signed by the Health insurance fund and all the HCPs.

To summarise, eDiabetes can be included in the national eHealth but due to an unclear business model, and several system level issues which in turn hinders innovation we can say, that the national eHealth business model is not open and certainly not synergetic. Table 2 provides all the responses and the overall score as the share of responses that were same as optimal responses for this design principle of 25%.

10.6.4 Avoiding high entry fees and entry risks

In the eDiabetes use case, doctors and patients would need to use an existing national eHealth Identity Provider to use the new services. This brings integration costs to eDiabetes. Also, the integration with the CRPD is also a cost since different health-related data would be stored in the CRPD in the form of a chronic disease summary document. Entry fees for a new supply-side user are in this case present. This design principle scored a 42.86% (Table 2).

10.6.5 User-oriented price model and risk management of the platform participation

Platform participation contracts are not underpinned with a transparent pricing model for participating in the platform. As has already been mentioned, the members of the eHealth network – namely the HCPs, need to fund participation in the national eHealth platform. In overall, financial aspects are very unclear and are the cause of many issues. Considering eDiabetes, the financial aspects are not apparent and are left to at least negotiation with each HCP which represents a considerable barrier for platform participation. A more viable approach would be to obtain a direct contract with the platform provider which is subject to public procurement. The overall score for this design principle as given in Table 2, is 0%. The main reason for such a result is that there is no pricing model for platform participants defined which in turn represents a barrier for platform participation and is also not aligned with usage scenarios.
10.6.6 Identifiability of products and services
All the core services and applications are described publicly on a special web page. With this, third parties can identify potentials of the platform. Also, documentation is also published (www.ezdrav.si) that focuses on technical aspects but also end users. In the eDiabetes case, the documentation should be included on the mentioned web page. Unfortunately, third party services are not yet described there. Currently, no rules exist about including information about third party services to the primary national eHealth web page. Table 2 overall score of 85.71% suggests the identifiability of products and services, but not for all cases.

10.6.7 Reduction of information and knowledge deficits for platform users
Design features of the platform are not clearly and sufficiently documented. Same holds for the platform ecosystem and knowledge transfer. The platform provider organizes only occasional meetings that only report the state of affairs. However, the national eHealth provides social resources that offer support with information exchange and knowledge transfer on demand for different user groups, namely HCPs, patients, and IT companies. For the eDiabetes case providers, this means high resource consumption to understand the platform and becoming a participant. Even if social resources are available, these are, generally, very few which represents a high risk for the eDiabetes providers. The national eHealth currently employees only nine people at the CHI which does not enable normal operation.
The Table 2 score for this design principle is 28.57% which does also suggest a poor transfer of knowledge.

10.6.8 Securing restrictions from platform utilization possibilities
Ensuring security compliance of the eDiabetes services would not be an issue after implementing the core authentication and authorization services of the national eHealth. The eDiabetes has obtained positive feedback from the Data Protection Officer during the design, development, and evaluation in a clinical setting that it is in line with the data protection regulation in Slovenia. However, this process would need to happen again before production use since now there will be no patient consents available as they were during evaluation. Obtaining a green light from the Data Protection Officer is a time-consuming process that can represent a high risk in case the eDiabetes providers are not competent enough with this legislation – not only in Slovenia but now also on EU level due to General Data Protection Regulation. Table 2 overall score of a 100% suggests high security focus.

10.6.9 Differentiation between platform management and the care management
Design and management of new healthcare networks can be done independently of the platform provider as long as the members of the network have the legal grounds for participating in the national eHealth.
In the case of eDiabetes, the healthcare network consists of primary level physicians who are involved in managing patients with Diabetes. Here we assume, that eDiabetes is not used as part of the MoH policy tools set and, therefore, the network is fully independent and agile in changing eDiabetes as needed. The national eHealth can keep
up with any smaller changes but otherwise focuses on providing core services that should not change too much. Tight coupling with the national eHealth is, therefore, not a right approach for eDiabetes. Support for the eDiabetes healthcare network managers would have to be done by the eDiabetes providers, most likely directly or through the already mentioned forum. Table 2 overall score for this design principle is 80% which still leaves room for improvement but shows a considerable maturity of this principle.

10.7 Conclusions and Future work
After analyzing the national eHealth from the perspective of organizational design guidelines by using the inclusion of eDiabetes services use case as the basis, we can see, that we were able to identify issues that inhibit the national eHealth to support the platform economy concept. The national eHealth can include new services, but the cost covering mechanisms are complex and represent a high entry barrier for services that are not introduced by the MoH.

We have used the detailed questionnaire depicted in Table 2 to evaluate all the served organizational design principles and also defined the optimal responses to give a numerical value or the score to the national eHealth concerning each organizational design principle. With the average score overall design principles of 51.46% and median value even lower at 42.86%, we could conclude, that the national eHealth is not compliant with the principles in a sufficient manner to be labelled an open eHealth platform - a basis for a platform economy. The national eHealth is fully compliant only with the sixth design principle on security and data protection. The identified requirements and implementation gap could be used as a basis for future governance strategy to at least reduce this gap, if not close it altogether. This would primarily include the definition of the business model (DP1) which is currently unclear and also the pricing model (DP3) for platform participation. This work needs to be a joint contribution of all the primary stakeholders of the national eHealth but mainly of MoH, National institute of Public Health, and the national Health insurance fund. The next step from here would be enabling continuous knowledge transfer (DP5) and lowering the platform entry costs (DP2).

To sum up, innovative and even clinically validated web-based support tools for patients with diabetes, cannot be included in the national eHealth. Moreover, since innovation is the foundation of a sustainable healthcare system together with its healthcare information system, our results can be used for increasing the importance of innovation in healthcare once again. One of the prime tasks is aligning the goals of public organizations and private companies for participation in the national eHealth since this mismatch hinders open innovation of platform-based ecosystems [57].

The work presented here is based on the idea of measuring the level of adherence to organizational design principles and questions are presented that could potentially help to operationalize the measurement. However, the discussion should be opened about other principles that could be added. Also, more specific questions may be necessary to analyse some principles. The set of questions used in this work was developed by the authors to clarify understanding of the applied design principles. Our future work would include using the questions in other settings – namely different similar organizations in other countries. By doing this, we could also provide newly identified design principles or refine existing ones.

The main contributions of this paper are (1) new evidence for supporting existing organizational design principles, (2) a detailed questionnaire that has the potential to be useful for measuring the adherence to the design principles, and (3) an example of
evaluating existing eHealth infrastructures concerning organizational design principles which can be used by other evaluators.

**Competing Interests**
No competing interests.

**Authors' Contributions**
Both authors contributed equally.

**Acknowledgments**

10.8 References


**Figures**

Figure 1 National eHealth Components

**Tables**

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Share of documents</th>
<th>Number of Documents</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory result</td>
<td>39,97%</td>
<td>3,113,062</td>
<td>880,404</td>
</tr>
<tr>
<td>eReferral</td>
<td>31,84%</td>
<td>2,480,123</td>
<td>939,826</td>
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<tr>
<td>Patient Summary</td>
<td>17,29%</td>
<td>1,346,958</td>
<td>576,012</td>
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<tr>
<td>Hospital Discharge Letter</td>
<td>6,30%</td>
<td>491,039</td>
<td>263,023</td>
</tr>
<tr>
<td>Paper Referral</td>
<td>4,58%</td>
<td>356,386</td>
<td>244,551</td>
</tr>
<tr>
<td>Privacy Statements</td>
<td>0,01%</td>
<td>1,037</td>
<td>965</td>
</tr>
<tr>
<td><strong>100%</strong></td>
<td></td>
<td><strong>7,788,605</strong></td>
<td><strong>1,390,194</strong> (# distinct patients)</td>
</tr>
</tbody>
</table>

*Table 1* Share and the number of different document types, and number of patients for different document types in the CRPD

<table>
<thead>
<tr>
<th>DESIGN PRINCIPLES</th>
<th>A</th>
<th>O</th>
<th>A==O</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. OPEN AND SYNERGETIC BUSINESS MODEL</td>
<td>6</td>
<td>2</td>
<td>6,00</td>
<td>23,08%</td>
</tr>
<tr>
<td>1.1 Is there a business model described for the national eHealth?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.2 Is it published online?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.3 Does it describe the concept of how a sustainable and economic business is provided?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.4 Has the platform provided specified how the return of investment will be provided?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.5 Is the platform commercialized so that platform provider and platform sponsor can increase revenue?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.6 Are key performance indicators defined?</td>
<td>1</td>
<td>1</td>
<td>1,00</td>
<td></td>
</tr>
<tr>
<td>1.7 Are they monitored?</td>
<td>1</td>
<td>1</td>
<td>1,00</td>
<td></td>
</tr>
<tr>
<td>1.8 Does the platform follow a business model?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>Does the business model follow the principles of complete openness?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.10</td>
<td>Does the model support synergies between platform users?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.11</td>
<td>Does the model support different usage?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.12</td>
<td>Does the model bring more benefits to the users than disadvantages?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
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<tr>
<td>1.13</td>
<td>Is a development strategy of the platform available?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.14</td>
<td>Are openness and transparency enacted?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.15</td>
<td>Are the impacts of joining the platform made explicit - is it published online?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
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<tr>
<td>1.16</td>
<td>Is innovation based on the platform encouraged?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.17</td>
<td>Are profit oriented participants accepted to the platform?</td>
<td>1</td>
<td>1</td>
<td>1,00</td>
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<tr>
<td>1.18</td>
<td>Is it allowed to commercialize solutions for the open platform?</td>
<td>1</td>
<td>1</td>
<td>1,00</td>
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<tr>
<td>1.19</td>
<td>Do the platform sponsor and provider prevent or interfere with the use and expansion of the platform?</td>
<td>1</td>
<td>0</td>
<td>0,00</td>
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<tr>
<td>1.20</td>
<td>Are control processess made explicit?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
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<tr>
<td>1.21</td>
<td>Does the platform sponsor respect the platform provider his determination on implementing the business model?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
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<tr>
<td>1.22</td>
<td>Is the platform provider a private company?</td>
<td>0</td>
<td>0</td>
<td>1,00</td>
</tr>
<tr>
<td>1.23</td>
<td>Do private companies provide software and technology.</td>
<td>1</td>
<td>1</td>
<td>1,00</td>
</tr>
<tr>
<td>1.24</td>
<td>Is the platform provider a neutral platform management company?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.25</td>
<td>Is the information on how the platform sponsor influences platform provider made public?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
<tr>
<td>1.26</td>
<td>Has neutrality of the business model been demonstrated by a third party, e.g. an information system expert?</td>
<td>0</td>
<td>1</td>
<td>0,00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A</th>
<th>O</th>
<th>A=O</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. AVOIDING HIGH ENTRY FEES AND ENTRY RISK</td>
<td>3</td>
<td>7</td>
<td>3,00</td>
</tr>
<tr>
<td>2.1</td>
<td>Can an independent healthcare network (demand and supply side) design integrated care scenarios?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2.2</td>
<td>Are the costs for these users too high so that they prevent market participation of the platform users?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2.3</td>
<td>Are there investment costs to be covered while accessing the platform (initially)?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2.4</td>
<td>Are there membership fees included at the time of first access to the platform?</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.5</td>
<td>Are direct entry costs formed at the time they arise or are they part of the initial access?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2.6</td>
<td>Is there a risk for the platform user that the platform provider will acquire their ideas and commercialize on their private platform?</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.7</td>
<td>Are there rules available that govern how intellectual property of the platform based solutions can be exploited - either to avoid or to control?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>O</td>
<td>A==O</td>
<td>Score</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>3. USER-ORIENTED PRICE MODEL AND RISK MANAGEMENT OF THE PLATFORM PARTICIPATION</td>
<td>1</td>
<td>3</td>
<td>0,00 %</td>
</tr>
<tr>
<td>3.1</td>
<td>Is there a pricing model for platform participants defined?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3.2</td>
<td>Does the pricing model represent a barrier for platform participation?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3.3</td>
<td>Is the pricing model aligned with usage scenarios? (e.g., A flat rate can be a risk for an integrated care use case if not enough patients can be acquired)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4. IDENTIFIABILITY OF PRODUCTS AND SERVICES</td>
<td>6</td>
<td>7</td>
<td>6,00</td>
</tr>
<tr>
<td>4.1</td>
<td>Are products and services identifiable on their own so that third parties can identify potential of platforms?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4.2</td>
<td>Are these products and services part of a standardized architecture of participation?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4.3</td>
<td>Do the products and services form the starting point for the targeted acquisition of platform resources?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4.4</td>
<td>Are products and services of third-parties also identifiable on their own?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4.5</td>
<td>Are information channels set up through which platform users can obtain information?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4.6</td>
<td>Is target group-oriented documentation available?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4.7</td>
<td>Is contact information available for the products and services?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5. REDUCTION OF INFORMATION AND KNOWLEDGE DEFICITS FOR PLATFORM USERS</td>
<td>2</td>
<td>7</td>
<td>2,00</td>
</tr>
<tr>
<td>5.1</td>
<td>Are design features of the eHealth platform sufficiently documented?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.2</td>
<td>Are design features of the eHealth ecosystem sufficiently documented?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.3</td>
<td>Is the knowledge transfer concept of the platform available or documented?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.4</td>
<td>Is the platform provider organizing information exchange (e.g., Forums, tutorials)?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.5</td>
<td>Is the platform provider organizing meetups to facilitate knowledge transfer?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.6</td>
<td>Are there not only technical resources available but also social resources? Is there somebody available for information exchange and knowledge transfer?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5.7</td>
<td>Is the knowledge transfer concept adapted for different groups of end users (e.g., SW companies, HCPs, patients,...) and identify individual knowledge requirements?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6. SECURING RESTRICTIONS FROM PLATFORM UTILIZATION POSSIBILITIES</td>
<td>6</td>
<td>6</td>
<td>6,00</td>
</tr>
<tr>
<td>6.1</td>
<td>Are governance and safeguard rules for platform use implemented?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Question</td>
<td>A</td>
<td>O</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>6.2</td>
<td>Does the platform provider utilize sanctions in the contracts with the platform users?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6.3</td>
<td>Are these mechanisms neutral concerning being open and nondiscriminant?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6.4</td>
<td>Is the eHealth platforms security in line with comprehensive security and data protection regulation?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6.5</td>
<td>Are access restrictions regarding security and data protection transparently presented?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6.6</td>
<td>Is there an independent organization available to assess how a potential platform user is in line with different security/data protection restrictions?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>DIFFERENTIATION BETWEEN PLATFORM MANAGEMENT AND THE CARE MANAGEMENT</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7.1</td>
<td>Is design and management of new healthcare networks independent of platform provider?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7.2</td>
<td>Do platform participants maintain their independence and agility with regards to market and business changes? What are the decision rights of the platform participants?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7.3</td>
<td>Does the eHealth platform as an IT infrastructure support agile response to changes in healthcare networks integrated care scenarios (their business models)?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7.4</td>
<td>Does the platform provider have technical support in place and administration that supports changes also for the healthcare network managers?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7.5</td>
<td>Can healthcare network management configure by itself the operations of their integrated care scenarios?</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2 Detailed questions that a platform evaluator should ask to ensure compliance with the design principles. Also, the authors’ responses are given (attribute A, 1 meaning yes and 0 meaning no) together with the number of responses that are the same as optimal (attribute O). The final score is also given for the core seven design principles. It is calculated as the share of optimal responses given of all the optimal responses. If we use the scores to calculate the average score over all seven design principles, we obtain the result 59,90%. The responses and optimal responses are obtained from cooperation with the National institute of Public Health - especially the CHI.

Additional files
11. Paper 5: Commoning Semantic Interoperability in Healthcare

Mate Bestek, mbes@itu.dk, IT University of Copenhagen, Rued Langgaards Vej 7, DK-2300 Copenhagen S, Denmark (The corresponding author)
Joanna Saad-Sulonen, jsaa@itu.dk, IT University of Copenhagen
Erik Grönvall, erig@itu.dk, IT University of Copenhagen

Abstract

Commons traditionally refer to shared natural resources that are at risk of being depleted or even destroyed. The rules established by commoners offer a way to manage such scarce resources. Through a series of projects on national eHealth platforms, we have identified another type of shared resource, called semantic resources that require commons-based governance. Semantic resources are standardised definitions of shareable health data that ensure that the data is always understood in the same way to prevent medical errors.

In this paper, we first use commons as a lens to observe and better understand shared semantic resources and their associated governance challenges. This leads to (1) a better understanding of shared semantic resources as global commons, (2) a clearer understanding of the relationship between the global and local levels of semantic resource governance, and (3) by observing traces of commoning at the local level, the role of commoning is identified as a suitable concept to apply in the context of semantic interoperability. Second, we use commons, and commoning in particular, to justify our proposal of the notion of semantic commons as a way to address the governance problems of semantic resources in a sustainable and long-term way.

Based on our findings, we not only provide a way to govern semantic resources in healthcare, but also contribute to the commons literature by (1) proposing a new area of research for commons scholars, (2) identifying semantic resources in healthcare as an interesting and important type of resource, (3) offering a new perspective on the dynamics of the relationship between global and local commons, and (4) point to a future in which commoning takes a central role in healthcare, not only with governance of semantic resources to enable health data sharing to where and when needed to help treat patients, but more generally.

Keywords: semantic interoperability; commoning; healthcare; local commons; semantic resources governance

2 Article has been submitted to a journal
11.1 Introduction

Commons traditionally refer to shared natural resources that are at risk of being depleted or even destroyed (e.g., agriculture (Araral, 2009; Premrl et al., 2015), fisheries (Cinner & McClanahan, 2006), water supply (Hasan et al., 2020) and global warming (Bonnéda, 2014)) due to collective action problems that arise in contexts where individuals choose actions to maximise their own, often material, benefits rather than working towards the achievement of common goals (Araral, 2009; Benfeldt et al., 2020; Ostrom, 2010). Ostrom has shown (Ostrom, 1990) that commons offer a viable alternative approach to solving collective action problems.

Ostrom's early work has been extended by broadening the focus of commons to include 'new commons' (Hess, 2008; Marttila et al., 2014b) where resources can include data, information, culture and knowledge (Desouza, 2008). Such resources are often digital and are thus called digital commons. Such digital commons cannot be depleted but rather the opposite - the more there are users of the resources, the more the resources become valuable (Potts, 2019). This is known as the tragedy of the anticommons (Heller, 2017, p. 201; Simcoe, 2014). New commons, like digital commons, focus on pooling/gathering of distributed and specialized data, information or knowledge (Potts, 2019). For example, electronic health records (EHR) are a collection of patient health data that are initially created in different medical practices but are gathered into lifelong electronic health records. As such, these gathered patient health records contain all available data of a patient and with this, enable more optimal treatment decisions of medical doctors. Such gathering of data is also a characteristic of Big Data in general that is nowadays being done by private companies that operate in different markets, and public entities like governments.

However, commons appear to be more efficient at gathering resources compared to corporations, markets or governments. This efficiency has been observed through the lens of polycentric governance (Ostrom, 1990), meaning that commons can use local information effectively if a community can establish and enforce its own governance rules (Potts, 2019).

As part of a series of projects on national eHealth platforms dealing with patient records in healthcare, we identified another type of resources, called semantic resources, which we assume should be brought together as part of a commons-based governance. Semantic resources are standardised definitions of shareable health data that ensure that the data is always understood in the same way, regardless of where, when and by whom the data is used to treat patients. To achieve standardised definitions and meanings of health data, it is necessary to bring together the currently dispersed definitions and meanings from physicians and other healthcare actors at a global level. Only then can the sharing of health data, which is being studied in the technical fields of science under the term semantic interoperability, be effectively made possible. One approach to achieve semantic interoperability in healthcare is called OpenEHR. OpenEHR "consists of open specifications, clinical models and software that can be used to create standards and build information and interoperability solutions for healthcare" - (OpenEHR.Org, 2021) and is currently being used in projects and health implementations worldwide. However, as has been observed in our empirical data and very recently in research by Min et al (2021), OpenEHR suffers from semantic resources governance problems at the local and national level, which hamper the achievement of high levels of semantic interoperability (Min et al., 2021).

In this paper, we approach and discuss semantic resources governance problems from a commons and commoning perspective. First, we use commons as a lens to observe and better understand shared semantic resources and the associated governance challenges in our
This leads to (1) a better understanding of shared semantic resources as a global commons, (2) a clearer understanding of the relationship between the global and local levels of semantic resource governance, and (3) by observing traces of commoning at the local level, the role of commoning is identified as a suitable concept for application in the context of semantic interoperability. Second, we use commons, and in particular commoning, to ground our proposal on how to address the governance problems of semantic resources in a sustainable and long-term way that can address issues put forward by Min et al. (2021).

Based on our findings, we not only provide a way to manage semantic resources in healthcare, but also contribute to the commons literature. First, we (1) propose a new research area for commons scholars, namely semantic interoperability in healthcare, which impacts the ability to deliver life-saving healthcare data where and when it is needed. To achieve this, (2) semantic resources in healthcare are becoming an important type of resource, enabling health data to be defined in an understandable way, regardless of where, when and by whom the health data is used to treat patients. Furthermore, we (3) offer a new perspective on the dynamics of the relationship between global and local commons. Finally, our work (4) points to a future in which commoning could take a central role in healthcare, not only in the management of semantic resources, but more generally.

The reining of this paper is structured as follows. In Related Work & Theory we introduce the existing commons theory that we use to support our claims in this paper. In Methods and data, we present our methods and data used. Then we introduce the empirical case of working with semantic interoperability in Slovenia as the source of our data. Next, we present our empirical results that were obtained by analysing available data. Based on these empirical results, we discuss the key findings and results of this paper in section 6. Based on these results, we approach challenges with semantic resources governance by discussing the potential for a new semantic commons in section 7. We conclude the paper in section 8, where we also point to possible future research.

11.2 Related work and theory
In this section we delineate our theoretical and conceptual framework within commons’ scholarship. As depicted in Figure 1, the positioning of our work lies at the intersection of several existing topics of interest within the new commons scholarship (Laerhoven et al., 2020) and recent reflections on commoning (Marttila et al., 2014a). This includes commons in healthcare, global and local commons, and design as commoning.
11.2.1 Commons in healthcare

The healthcare industry relies mainly on business plans where customer relationships are characterised by lock-in mechanisms and encapsulation (Mazzucato, 2018). Various software providers do not readily disclose information about how their data is stored, which prevents data sharing. The result is that once a system has been purchased, it becomes difficult to switch providers or connect systems from different vendors. The idea of building health infrastructures based on the commons is therefore anything but commonplace today. Nevertheless, there are examples of commons in healthcare, mostly in research and less in industrial applications. Lazo's work on the sustainability of health systems (Lazo, 2019) develops the concept of the health commons, which encompasses health and social care resources and aims to influence more optimal management of health resources. Commons have also been used to define different commons for medical data (e.g. commons for genomic data (Contreras & Knoppers, 2018; Evans, 2017) and sleep data commons (Zhang et al., 2018)), medical information commons (Bollinger et al., 2019) (e.g. (Bubela et al., 2019; Deverka et al., 2019; McGuire et al., 2019)) and medical knowledge commons (Marchetti et al., 2017) (e.g. (Abbott, 2017; Flowers, 2017; Larson & Chon, 2017; Mattioli, 2017; Oliveira et al., 2017; Strandburg & Bechtold, 2017; Strandburg & Frischmann, 2017)). Commons have also been used to ground digital applications (for example, virtual patient education (Ellaway et al., 2008)) as a way to ensure creation of a community of long-term users of the application in a sustainable way. Commons have also impacted research into EHRs, which are a core element of today's digitalization of health systems towards becoming learning health systems (of Medicine, 2013). In this context, Hall and Schulman have explored commons-based incentives for patients to obtain interoperable EHRs (Hall & Schulman, 2010). Although commons are used in many different healthcare contexts, we see an opportunity to expand knowledge about commons by focusing on issues of semantic interoperability and data sharing that highlight the need for improved local management of shared resources - in our case, semantic resources - to achieve a sustainable and long-term governing of semantic resources to enable semantic interoperability and data sharing in healthcare.
11.2.2 Global-local commons perspective

Commons can be divided into two categories: global and local. Solving challenges with shared resources management on a global scale requires international cooperation and participation. Examples of global commons are climate change (Cruz & Cruz, 1990; Ostrom, 2012) and freshwater and marine ecosystems (Ostrom et al., 1999). Examples of global new commons that are often not only of local importance but require global collaboration include learning commons (Price, 2013), new technologies (Stern, 2011), genetic commons (Geary & Bubela, 2019), and data commons (Shkabatur, 2018). Despite their importance, global commons are not well researched as there seems to be a lack of multidisciplinary or transnational collaboration (Laerhoven et al., 2020), which is a prerequisite for a sustainable global commons.

The term local commons is used to represent dependence on the local context and where case studies are the predominant research method (Laerhoven et al., 2020). Local commons are typically linked to specific microsites and can be exemplified by commons related to fisheries and agriculture.

Solutions to problems of managing shared resources are often sought at the local level, with the aim of later transferring the solutions found to the global level (Mcginnis & Ostrom, 1992). The approach of moving from the local to the global level seems to promise faster results (Stern, 2011) than the reverse approach of starting from a global problem and working down to the local level (Mcginnis & Ostrom, 1992). An example of a global problem rooted in inadequate local regulation was given by Cruz, who analysed poor local regulation in relation to deforestation and its impact on global climate change (Cruz & Cruz, 1990; Ostrom, 2012). In this case, it is crucial to understand that deforestation will continue to worsen until more effective institutional arrangements are achieved at the local level (Mcginnis & Ostrom, 1992). As Salazar and Cerna point out, binding agreements at the global level and governance of local commons are a prerequisite for sustainable commons (Salazar & Cerna, 2020).

11.2.3 Commoning

Commoning, a term coined by (Linebaugh, 2008), refers to commons as a verb and an activity. The term is also used by activist commoners, such as (Bollier & Helfrich, 2019), who define it as "the exploratory process by which people devise and enact situation-specific systems of provisioning and peer governance as part of a larger process of unfolding our humanity." (p.75). They continue the definition by referring to the creative agency of ordinary people "developing solutions that seem fair and effective to them" in sharing and managing commons.

This creative agency inherent in commoning, as well as a shared concern to understand and support collaborative action within an inherent democratic agenda, has attracted researchers in participatory design to the topic of commons and commoning (Marttila et al., 2014b). Marttila et al. (Marttila et al., 2014b) suggest that commoning is a form of 'design' (i.e., design work). This is a different way of connecting the concepts of design and commons than was originally found in the commons literature. Ostrom's design principles were not to be understood as recipes for creating new commons, but as essential elements or conditions for the success of commons-based institutional arrangements (Marttila et al., 2014a; Ostrom, 1990). Later, scholars such as Poblet and Sierra (Poblet & Sierra, 2020) have applied Ostrom's design principles as design guidelines - in their case to a digital tool designed to facilitate the creation and development of communities of mutual support. Ostrom's design principles were also used as a template for the development of a technical infrastructure to support self-organisation, self-management and pro-social behaviour (Pitt & Diaconescu, 2014) in Internet-based applications.
These examples illustrate the evolution from commons-based explorations to solutions supporting associations and organisations, as well as an interaction and communication (Laerhoven et al., 2020; Lohmann, 2016). Similarly, and returning to participatory design, Teli (Teli, 2015), in his work on computational commons, expanded the concept of commons from the institutional arrangements related to the management of a particular resource to the ensemble of material and symbolic elements that connect people. In Teli’s view, value is derived from people's collaborative capacities. This means, for example, that participatory design can help make social practices and social groups that nurture the common more reliable and identify essential allies and practical resources (Teli, 2015). Marttila et al. (Marttila et al., 2014b) also see commons such as social networks, digital platforms and shared resources on the internet as new opportunities for productive participation in commons-based peer production in online communities. The term commoning therefore refers to the process and activities of collaboratively creating, maintaining and nurturing commons. This is in line with Strandburg's (Strandburg et al., 2017) assertion that robust commons governance can often lead to the creation or emergence of new commons, thus we consider commoning as the crucial prerequisite for the creation or emergence of a sustainable and long-term commons.
11.3 Methods and data

The first author has participated in several projects and activities in the field of health care in Slovenia between 2010 and 2019 in various roles (see Table 1). An overview of the main findings from this period is presented in the next section, which analyses the specific empirical data used in this paper. Here the main methods are described and how they were used to obtain the empirical data.

Table 1 Overview of the roles held by the first author in several healthcare projects. For the purposes of writing this article, material from these projects have been analyzed.

<table>
<thead>
<tr>
<th>Role\Project</th>
<th>ECare\3</th>
<th>eHealth Slovenia-Italy\4</th>
<th>National eHealth\5</th>
<th>EkoSmart Smart City\6</th>
<th>European eHealth Platform\7</th>
<th>National Cancer Program\8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designer</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Researcher</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Project Manager</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>IT Architect</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Lead Software</td>
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<tr>
<td>Developer and Team</td>
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<tr>
<td>Lead</td>
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<tr>
<td>Standards Lead</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Government official</td>
<td>X</td>
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<tr>
<td>National Workgroup</td>
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<tr>
<td>Lead</td>
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<td>X</td>
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<tr>
<td>Medical Expert</td>
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<td>X</td>
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<tr>
<td>Governing Body</td>
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<tr>
<td>Member</td>
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<tr>
<td>Ecosystem Architect</td>
<td>X</td>
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<td></td>
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<td>X</td>
</tr>
</tbody>
</table>

The National eHealth project was composed of different sub-projects, including the Reference Outpatient Clinics (ROC), and the Registry of patients at risk of cardiovascular diseases. The common denominator of all activities is the attempt to harmonise the semantic resources used in the different projects. This means that data elements, their structures, mappings to

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3 Platform for multiple digital health interventions
4 Cross-border exchange of administrative and clinical patient data
5 National eHealth information infrastructure
6 Smart City platform
7 Cross-border exchange of health data between EU Member States
8 Extension of national eHealth platform and ecosystem
different terminologies and values were actively discussed and harmonised across the different activities. In the process, various observation notes, formal and informal documents, communication exchanges and face-to-face workshop reports were collected and are used here to support this paper. As presented in Table 2, the methods used to obtain the empirical data were information retrieval, think aloud testing, semi-structured questionnaires, informal interviews and analysis and comparison of code repositories.

Table 2: Methods used to obtain empirical data for this paper

<table>
<thead>
<tr>
<th>Method</th>
<th>Projects</th>
<th>Participants</th>
<th>Sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Think aloud testing</td>
<td>National eHealth eCare</td>
<td>Medical doctors</td>
<td>One session with a medical doctor who performed OpenEHR modeling</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>One session with a medical doctor who used an EMR system X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>One session with a medical doctor who used an EMR system Y</td>
</tr>
<tr>
<td>Information retrieval</td>
<td>National eHealth eCare</td>
<td>First author</td>
<td>A session to obtain information from existing documents</td>
</tr>
<tr>
<td></td>
<td>eHealth Slovenia-Italy</td>
<td></td>
<td>A session to obtain information from existing communication exchanges</td>
</tr>
<tr>
<td></td>
<td>European eHealth platform</td>
<td></td>
<td>A session to obtain information from existing workshop reports</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>A session to obtain information from existing informal interviews</td>
</tr>
<tr>
<td>Semi-structured questionnaires</td>
<td>National eHealth</td>
<td>Medical doctors</td>
<td>Several sessions during work on semantic resources.</td>
</tr>
<tr>
<td>Interviews</td>
<td>National eHealth</td>
<td>Medical doctors</td>
<td>Several sessions with different medical doctors on issues with existing EMR systems, ideas for improvements and visions for new projects</td>
</tr>
<tr>
<td>Code repository</td>
<td>National eHealth</td>
<td>First author</td>
<td>One session to obtain</td>
</tr>
</tbody>
</table>
In this section we describe the empirical case, including a summary of the first author’s experience with work on semantic interoperability in Slovenia between 2010 and 2019 during which a special approach to semantic interoperability has been used, namely, OpenEHR (see also Table 1 for an overview).

In 2019, the Slovenian Ministry of Health launched an initiative called Consolidation of Health Information Systems with the aim of unifying the segmented health information system. This can either mean replacing all the existing systems with one system, or more realistically, achieving semantic interoperability between all the systems as the problem of semantic interoperability has been addressed in many projects as the lack of semantic interoperability in healthcare is considered a global problem addressed by the World Health Organization (Sachdeva & Bhalla, 2010).

Previous studies on improving semantic interoperability have suggested two main strategies or approaches: 1) translating the natural language of medicine (physician medical notes and other written data) into technical code (data structures and mapping local terminology to international structured medical terminology) and 2) changing the way physicians communicate clinical observations. Both approaches are far from complete (Ashrafi et al., 2018). The former (i.e., translating the natural language of medicine) requires both medical and technical expertise. Medical professionals need to agree on a large number of data structures, which has not yet been achieved. Technical professionals can then use such standardized medical content models in various technical systems. As OpenEHR addresses both of these concerns, many of the project initiatives in Slovenia have tried to use OpenEHR as an approach to semantic interoperability.

OpenEHR "consists of open specifications, clinical models and software that can be used to create standards and build information and interoperability solutions for healthcare" - (OpenEHR.Org, 2021). OpenEHR provides methods and tools for medical professionals to create medical data models that map to international terminologies in order to provide structured and standardised medical content that can then be exchanged between systems and understood by the various receiving medical professionals. Such harmonised models can then be adopted by technical professionals and implemented in technical systems. In this way, OpenEHR empowers medical professionals to deal with medical semantics so that technical professionals do not have to. This is how OpenEHR enables the needed separation of medical and technical professionals in terms of semantics.

However, the practise of working with semantics (semantics work) using OpenEHR has not yet become part of the infrastructure. The low level of awareness of the problem and the low level of competencies of those working in the health sector certainly contribute to this state of affairs. Within the framework of the national eHealth initiative in Slovenia, many of the technological tools that support semantics work at the micro, meso and macro levels of the...
health system have been procured and implemented. As we will learn in this paper, there were even early positive examples of such semantics work to be observed. However, it seems that in Slovenia it is not possible to achieve a high level of participation in such semantics work, as the crucial actors mostly follow the political interests of the ruling parties and often do not cooperate at all. The best examples are the Ministry of Health (MoH) and the National Health Insurance Fund of Slovenia (NHIF). Medical professionals, especially doctors, are another important stakeholder, who see both the Ministry of Health and the NHIF as a huge overhead without much added value. The situation is similar with other stakeholders. We can say that there is a general lack of mutual respect and cooperation between these stakeholders, and the weakest stakeholders, namely the patients, suffer the consequences. In such a context, innovation is difficult or even impossible.

Furthermore, if we look at the IT sector in Slovenia, which supports different technical systems that together carry the health information system of the Slovenian health system, we see a strong segmentation. There are a similar number of IT companies providing these systems in a market with 2 MIO inhabitants as in a much larger market like the US. Yet the overall quality of these systems is very low and certainly does not support interoperability. For example, one hospital uses up to four different electronic medical record (EMR) vendors and it is common for two adjacent departments to be completely isolated due to the use of different EMR systems. Lock-in based business models are therefore the main approach to the way healthcare institutions operate IT.
11.5 Empirical results

As part of the national Slovenian eHealth programme, a multidisciplinary working group (WG) was established in 2011 to work on the semantic resources of the project ROC. The project ROC focused on setting up an information system to support the monitoring of the success of various initiatives to change primary health care. The participants of WG were representatives of the eCare project, the Ministry of Health (MoH), the national eHealth programme (eH) and several physicians representing primary health care institutions geographically spread all over Slovenia, ranging in size from small doctors' practises in the province to the largest in the capital.

The following text contains the results obtained from the analysis of the work of WG. The thematic grouping of the analysis results points to three main themes: semantic resources (SR), government support for the harmonisation of semantic resources (GOV), and commons and commoning (CC). The following text is divided into the three topics mentioned above. In addition, the three themes are numbered and highlighted by their acronyms throughout the text for further reference.

11.5.1 Harmonisation of semantic resources

Our analysis of previous work from the WG has revealed several types of semantic resources. The most common semantic resources covered by the WG were various data elements such as blood pressure measurement or blood glucose level. Blood pressure and blood glucose are clinical concepts (SR1) that are usually described by several additional data elements (SR2). For example, blood pressure might include an additional data element that explains the physical position the patient was in during the measurement. It is important to understand that these additional data elements that help describe a clinical concept may vary between medical specialties or even from doctor to doctor. A GP would not mind not seeing whether the patient was lying or sitting when their blood pressure was taken. However, for a doctor who specialises in hypertension, such additional information is crucial.

The OpenEHR approach to defining clinical concepts is designed so that different healthcare professionals from different medical subspecialties can have different perspectives on the same clinical concepts. The idea is to capture as many supporting data elements as possible for each clinical concept. Such structures are called archetypes in OpenEHR (SR3).

Each of the data elements that make up a clinical concept must define what type of data it captures (SR4). This can be a number, string or other typical data type. It can also be a code from a terminology (structured vocabulary). These may be defined locally (SR5), for example in a particular doctor's practise, or they may be defined globally (SR6), such as the International Classification of Diseases (ICD) or SNOMED. From our empirical data, we have learned that physicians tend to define their own terminologies that are unique to their medical practise. However, in order to achieve standardisation, there needed to be harmonisation for each code used in the different data elements. For example, harmonisation of a particular code used to identify smokers and non-smokers was requested by a doctor in a very respectful way: "I ask to reconsider the code used to identify a smoker/non-smoker. So far I have used code F17.1 to identify a smoker and Z000 to identify a non-smoker, but perhaps a better coding approach would be needed" (SR7).

In addition, different data elements and clinical concepts can be grouped together to represent more complex clinical concepts (SR8). A typical example is various questionnaires (SR9) used to assess the health status of patients. An example of a questionnaire discussed by the members
of WG was the questionnaire for assessing the asthma status of patients. Such questionnaires are considered medical tools used to optimally diagnose the condition of patients.

We also observed in our empirical data that the complexity of clinical concepts can be reduced. For example, a proposed data structure for a questionnaire was commented by a doctor: "Dividing the questionnaire into two parts would certainly be useful". In this way, a complex questionnaire was simplified, but the individual parts also became more generally applicable. The more complex a data structure is, the less likely it is to be used directly in another medical practise. OpenEHR provides a mechanism to support the creation of such more generally applicable data structures, which may not represent clinical concepts on their own, but only in interaction with some additional data structures. OpenEHR refers to such intermediate data structures (SR10) as clusters. Multiple data clusters can be linked together to create a new archetype representing a clinical concept. In this way, a higher degree of reusability of data elements can be achieved. In addition, OpenEHR provides another mechanism that allows full customisation of clinical concepts for specific use cases, which may even be specific to a particular clinical practise. This mechanism is called templates (SR11). Templates are created by combining one or more archetypes. However, as archetypes contain a maximum number of supporting data elements for each clinical concept, it is usually necessary to select only those data elements that are used in the particular scenario. Templates are therefore a constraining mechanism that supports such selection of data elements. Templates are in fact the final semantic resource used to hand over to software companies that implement them in the various systems. The key point about templates is that the data structures and their meaning are preserved because they draw on the archetypes, which are global and free.

During such a detail-oriented collaborative process, a very thoroughly defined set of semantic resources was iteratively developed.

11.5.2 Lack of semantic resources governance

In the empirical data on the work of WG, we have also observed some challenges experienced by the members of WG related to the management of semantic resources. The original aim of WG was to propose a standardised set of semantic resources needed in the ROC project (GOV1). However, as the MoH was familiar with ideas for harmonising semantic resources and even funded projects to test harmonisation approaches such as OpenEHR, one of the ideas that the MoH brought to WG was to establish collaboration with the different projects to identify the potential for harmonising different semantic resources across projects. The MoH even took the necessary steps to transfer the OpenEHR approach to Slovenia by organising multi-day workshops for different professional groups, or as the MoH representative put it: "Considering our previous discussions and your proposal, we plan to form two groups, one with clinicians/analysts and the other with technicians".

The reason for this consideration by the Ministry of Health was that the ROC project was part of the national eHealth programme, which focused on building a national collection of patient health data in a semantically interoperable way. This focus on semantic interoperability was expressed by eHealth representatives in the following words: "The vision of national eHealth is to enable interoperability between different healthcare information systems. For example, when different documents are exchanged between primary and secondary healthcare providers (e.g. referrals, discharge letters and different summaries), it is very important that the data set, the data structures and the values used in the documents are harmonised. The data needs of the ROC project are certainly such that harmonisation is necessary".
As the eCare project used OpenEHR to model patient health data and the dataset was similar to that of the ROC project, there was the prospect that a significant amount of OpenEHR-related semantic resources could be reused. This idea would then spread to many other projects. Not only could harmonisation of data elements be achieved, but also more optimal use of resources. The eCare-based approach to harmonisation was that of open and shareable semantic resources and OpenEHR was the approach that achieved both.

When the WG started its work on harmonisation, one of the first problems observed in our empirical data was brought forward in the above analysis of the different semantic resources. In the context of local and global terminologies, we found that doctors tend to define their own terminologies, which are then specific to their medical practise. This clearly points to a major bottleneck in achieving semantic interoperability and also a clear problem in managing terminologies. Terminologies are the fundamental elements of semantics and should therefore be harmonised at least nationally, if not internationally (GOV2).

Another problem encountered during the work on WG on the asthma questionnaire was nicely described by a doctor in the following words: "The questionnaires are protected and owned by the pharmaceutical company" (GOV3). From the doctor's words "I received the contract for the use of the questionnaires from their office abroad", it is clear that the task of ensuring the use of the questionnaires at the national level in Slovenia was taken over by this doctor himself. Another doctor's comment that such tasks should be carried out by "one of the institutions (MoH) and not by individuals" was one of the first indications of poor or non-existent management of semantic resources in Slovenia (GOV4).

The fact that a pharmaceutical company should be part of the WG collaboration was also not well received by some participants, as this would mean "bad publicity for the ROC project". This pointed to another governance problem - that of the MoH not collaborating with obvious stakeholders of the ROC project but not being involved (GOV5).

When WG finished the work by delivering the proposed specification of the data definitions needed to achieve the goals of the ROC project, it was clear that the goal of working with different projects to create a harmonised set of semantic resources based on OpenEHR had not been achieved. There are several reasons for this outcome. The work on ROC semantic resources took four months, from May 2011 to October 2011. If more medical professionals from other projects had been involved in the collaboration, the timeline of the project ROC would have been compromised (GOV6). This was clearly expressed by the Minister of the Ministry of Health who was "very sceptical about the timeliness of harmonisation between projects" and that "ROC cannot wait for a harmonised set of semantic resources as I need to move ROC forward as soon as possible". Furthermore, there were not enough resources available to fully engage in the OpenEHR modelling activities, so this was only partially achieved. Unfortunately, although the MoH was subsequently able to attract more staff to work on national eHealth measures, there was never much interest in introducing governance for semantic resources with or without OpenEHR - although OpenEHR was accepted by the various medical professionals (GOV7). This is evident from the reports of one of the workshops held as part of the ROC project on 31 May 2011, in which several decisions make clear the use of OpenEHR:

- Decision 2: "All present have become familiar with the OpenEHR approach to defining clinical content and are in agreement with its use. Future requirements specifications for software companies should be prepared using OpenEHR".
- Decision 4: "Using the OpenEHR approach, templates will be created based on archetypes."
This agreement and support for the harmonisation of semantic resources was not a problem for the medical professionals. However, they pointed to some past experiences that led them to believe that such national harmonisation may not be feasible. An example from one doctor: "We must not forget the vaccination programme, which was a monopoly on vaccination data because it was planned at national level. It failed ingloriously, but took a lot of effort and time. I wonder what will happen to the harmonised models if, for example, the government changes, the staff in the Ministry of Health changes, etc." The doctor continued, "It is not a problem to have harmonised terminology in Slovenia if someone introduces it and the medical profession is behind it." The doctor pointed out the low involvement of the Ministry of Health in harmonisation, which would reassure medical professionals that their efforts are not in vain (GOV8). The above example also shows that medical practitioners see national projects as a means of establishing monopolies on health data as it is defined nationally (GOV9). This suggests that they are unable to acquire additional data that may better serve their research ideas or another purpose. This also offers an explanation for why physicians prefer to define terminologies and other semantic resources within their medical practice. To have the freedom to meet data needs in their own way (GOV10). Such scenarios would be possible if the data is separated from the applications that use the data, which is a core idea of the OpenEHR approach.

11.5.3 Traces of Commoning

The idea of working with the different projects to identify the potential for cross-project harmonisation of the different semantic resources, which was brought to WG by the MoH, is seen here as an attempt in commoning semantic resources (CC1). The MoH even conducted a knowledge transfer on the use of OpenEHR in the form of a workshop lasting several days. The main motivation for the MoH was to tap into an existing culture where medical professionals often collaborated on various initiatives without asking for additional remuneration. In fact, they only required the MoH to do its part to ensure that their "time and effort" were not in vain (CC2).

Similarly, traces of commoning can be identified in the participation of doctors in WG activities. The WG collaborated in the development of several versions of the harmonised semantic resources, with the seventh version being the final version (CC3). During its work, the WG has overcome several challenges (CC4) in order to continue nurturing the semantic resources that is an essence of commoning. For example, the Asthma Questionnaire was the intellectual property of a pharmaceutical company but despite that, the WG found a way to still use it as part of the semantic resources.

More importantly, despite the many challenges, the WG has continued to collaborate productively in defining different semantic resources (CC5) in a highly respective way between health professionals (see, for example, the discussion on smoking status with SR7), but also between health professionals and non-medical members of WG (CC6) as was the case in the simplification of complex questionnaires where suggestions from non-medical WG members were accepted and used.

All the above examples can be considered commoning because they show a network of people who freely participated in the social process and activities of collaboratively creating, maintaining and nurturing free and open semantic resources in healthcare. We consider the above examples as traces of commoning because the WG work has ended only shortly after finalizing the semantic resources for the project ROC.
11.6 Results

In this section, we look at the results of our empirical analysis through the lens of commons and commoning to explain the first three findings of this paper: (1) we propose to understand semantic resources as global commons; (2) based on our examination of OpenEHR from a commons perspective, we expand the relationship between global and local commons; (3) based on the observation of traces of commoning at the local level, we suggest that commoning is a crucial aspect of sustainable global-local semantic resource commons.

11.6.1 Understanding of semantic resources as global commons

Table 3 summarizes semantic resources observed in the empirical analysis in section 4. We can learn what semantic resources are and what it means to work with semantic resources which is considered as semantic work in this paper.

Table 3: Summary of observed semantic resources

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SR1</td>
<td>Clinical Concepts</td>
<td>Data elements that represent some clinically important concept e.g. blood pressure</td>
</tr>
<tr>
<td>SR2</td>
<td>Supporting Data Elements</td>
<td>Data elements that are used to provide additional information about a clinical concept - different medical specialities can define different supporting data elements for the same clinical concepts</td>
</tr>
<tr>
<td>SR3</td>
<td>Archetypes</td>
<td>Data structures that represent clinical concepts using maximum possible number of supporting data elements (SR2)</td>
</tr>
<tr>
<td>SR4</td>
<td>Data Value Type</td>
<td>Each data element defines what kind of values it can capture. This can be a number, string, or a date, etc. It can also be a code from some terminology</td>
</tr>
<tr>
<td>SR5</td>
<td>Local Terminologies</td>
<td>Doctors tend to define their own terminologies that they use in their medical practices.</td>
</tr>
<tr>
<td>SR6</td>
<td>Global Terminologies</td>
<td>Some terminologies are defined globally and represent standardized terminologies. However, their use is scarce</td>
</tr>
<tr>
<td>SR7</td>
<td>Harmonised Terminology Codes</td>
<td>Medical doctors need to agree to use same codes and the corresponding terminologies if semantic interoperability is to be achieved</td>
</tr>
<tr>
<td>SR8</td>
<td>Complex Clinical Concepts</td>
<td>Grouping of data elements and concepts into higher order structures such as</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>SR9</strong></td>
<td><strong>Questionnaires</strong></td>
<td>Represent complex clinical concepts that are also considered to be medical instruments as they help doctors more optimally diagnose diseases. Often, they tend to be protected by intellectual property legislation and are owned by private companies such as pharmaceutical companies.</td>
</tr>
<tr>
<td><strong>SR10</strong></td>
<td><strong>Intermediate Data Elements</strong></td>
<td>Complex clinical concepts may be split into several parts in order to reduce the structure’s overall complexity. Several generic data structures can be obtained that do not represent clinical concepts, but can be reused in different definitions of clinical concepts.</td>
</tr>
<tr>
<td><strong>SR11</strong></td>
<td><strong>Templates</strong></td>
<td>Templates enable design of use-case specific data structures by combining one or more archetypes and eliminating data elements from archetypes that are not needed in specific use cases by means of introducing constraints on particular data elements. Example constraint that can be introduced is called exclusion. By applying it, a data element does not appear in the template even if it is defined in an archetype. Templates are handed to software engineers who use them to implement different functionalities of IT systems.</td>
</tr>
</tbody>
</table>

Based on the table above we see that the empirical analysis has revealed different types of semantic resources. But the more important learning is that if one wants to define semantic resources in such a way that they can also be used in other scenarios or contexts, one must be able to capture as many characteristics of these different contexts as possible when creating semantic resources. And not by asking all the doctors in the world for input but instead considering semantic resources as global semantic resources that through gradual evolution arrive at the level when they contain features of most contexts of use. In this way, semantic resources can become globally open and shared resources. In essence, OpenEHR was created to enable just that.

From the literature on commons, we learn that the management of such globally shareable resources rooted in a global problem of semantic interoperability are called global commons. Since OpenEHR is globally managed by the OpenEHR Foundation, which represents the institutional infrastructure and community that does the required semantic work, we consider OpenEHR semantic resources as global commons. As we also learn from the state of art on
commons, a sustainable commons requires also a sustainable local commons where global rules are adapted to local context. In our case, the local commons were initially linked to the global commons with the OpenEHR workshops that the MoH organised. However, the global-local relationship has since greatly deteriorated, causing issues with achieving semantic interoperability. Since such a relationship between local and global commons is a crucial aspect for achieving sustainable and long-term commons, it represents a valuable source of new learning.

11.6.2 A new perspective on the global-local commons relationship

Table 4 summarizes issues with the governance of semantic resources that we identified in our empirical analysis in section 4. Of crucial importance is the learning that the Ministry of Health in Slovenia should have played an important role but in reality, that was not the case.

Table 4: A summary of empirical results of the lack of semantic resources governance in Slovenia

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOV1</td>
<td>Project Specific Semantic Resources</td>
<td>The MoH tried to obtain semantic resources specifically for the ROC project.</td>
</tr>
<tr>
<td>GOV2</td>
<td>Lack of terminology management</td>
<td>Each medical doctor typically defines terminologies specific to their medical practice. To enable semantic interoperability, the MoH should nationally govern terminologies.</td>
</tr>
<tr>
<td>GOV3</td>
<td>Semantic resources are not Open and Shareable</td>
<td>The asthma questionnaire example shows that private companies can establish ownership rights on information artifacts that help diagnose patients.</td>
</tr>
<tr>
<td>GOV4</td>
<td>Semantic resources are not managed nationally</td>
<td>Example: MoH does not govern contracts for questionnaires that are used by doctors as instruments to treat patients.</td>
</tr>
<tr>
<td>GOV5</td>
<td>MoH does not involve all stakeholders</td>
<td>The inclusion of the pharma company - the owner of the asthma questionnaire - would be considered as bad publicity.</td>
</tr>
<tr>
<td>GOV6</td>
<td>Timelines of the MoH are more important than harmonisation</td>
<td>The MoH needed ROC focused results as soon as possible as this was part of a political agenda of the MoH. Harmonization of semantic resources was not.</td>
</tr>
<tr>
<td>GOV7</td>
<td>Official Adoption of OpenEHR</td>
<td>OpenEHR was endorsed by the medical professionals as the approach used, but not by the MoH. MoH officially adopting OpenEHR would be needed to motivate its more widespread use.</td>
</tr>
</tbody>
</table>
As we learn from our empirical analysis, the relationship to the global commons level was first established through the organisation of educational workshops in Slovenia by the Ministry of Health, in which OpenEHR and the semantic work it could support were presented. Workshop participants included people from different professional backgrounds such as medical professionals, software engineers and government officials.

However, as we can also learn from our empirical analysis, the global-local relationship has evolved in a different direction. What was first discussed as a lack of semantic resource governance (see Table 4) indicates a poor level of maintenance of the global-local commons relationship. In particular, the role of the Ministry of Health in semantic resource governance was described as poor by participants in the semantic work. As a result, the semantic resources were very project-specific and as such did not contribute to semantic interoperability at the global level. It can be deduced that the relationship between the global and local levels in the case of semantic resources is such that it needs to be constantly maintained. This suggests a different dynamic of the global-local relationship than is traditionally the case with similar relationships. For example, if we consider the example of climate change in Sweden (Bonnedahl, 2014), the global rules of the climate commons rules have been applied locally in Sweden in the form of legal rules. However, such rules by their nature do not change often, which makes them unsuitable for application to semantic resources. This emerges from our empirical analysis, as the initial actions to transfer the OpenEHR global commons approach and rules to Slovenia were not successful in ensuring sustainable and long-term cooperation on semantic resources. Such dynamics of the global-local relationship in the case of semantic resources may be based on the nature of the medical knowledge field itself. It is constantly changing and evolving. Therefore, semantic resources must also be constantly changing and evolving, and so the relationship between local and global commons must also be adapted to foster this dynamic.

As we have learned so far, Slovenia has failed to create a sustainable local OpenEHR-based semantic resource commons that promotes its relationship with the global OpenEHR commons. In order to understand and learn from the commons literature how to address this problem, we believe that commoning may play a crucial role.

### 11.6.3 The crucial role of commoning at the local level

Table 5 provides a list of traces of commoning that we observed in our empirical data. This entails a community of different professionals working on open and shared semantic resources.
However, this evidence is called traces because, unfortunately, it was short-lived and did not manage to establish a working relationship with the global work on open and shared semantic resources.

Table 5: A summary of empirical evidence pointing to commoning - traces of commoning.

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC1</td>
<td>Commoning attempt proposed by the MoH</td>
<td>Attempt of harmonization of semantic resources across several projects</td>
</tr>
<tr>
<td>CC2</td>
<td>Medical professionals are used to participating in community activities</td>
<td>Medical professionals often participate in collaborations on a pro-bono basis as they see value in the collaboration.</td>
</tr>
<tr>
<td>CC3</td>
<td>Iterative collaboration</td>
<td>The semantic resources are produced within several iterations until no new change proposals are observed.</td>
</tr>
<tr>
<td>CC4</td>
<td>Overcoming Challenges Collaboratively</td>
<td>WG participants elaborated on the best route forward for each identified challenge.</td>
</tr>
<tr>
<td>CC5</td>
<td>Productive collaboration</td>
<td>The WG overcame challenges and produced semantic resources.</td>
</tr>
<tr>
<td>CC6</td>
<td>Productive multidisciplinary collaboration</td>
<td>Comments and proposals from different professionals have been used to improve semantic resources</td>
</tr>
</tbody>
</table>

In spite of that, we have also learned that medical professionals are used to participating in community activities as long as their time and effort is not in vain. Such behavior has been observed in our empirical data - see CC3-CC6 in Table 5 above and can be assigned to the ethos of care and affect - a strong force that influences personal participation in commoning (Poderi, 2020).

We therefore believe that such commoning at the local level of OpenEHR's global-local relationship is necessary to achieve a sustainable and long-term commons. Especially so as it can recognize the medical professionals as commoners ready to participate in the commoning in order to create and nurture a semantic commons and with this, align with their existing needs, expectations and desires (Poderi, 2020) and point to a different kind of social values and priorities of our social order (Stavrides, 2016).

In the following section, we use the above three findings together with the literature on commons and commoning to propose the notion of a semantic commons, which is also the main outcome of this paper.

11.7 Towards a new semantic commons

Using the presented findings and the literature on commons and commoning in Related Work, we propose the notion of “semantic commons” to address the problem of poor local governance of semantic resources.
The semantic commons resources we encountered (Table 3) can help clarify what new semantic commons could consist of, such as a set of data structures, along with their definitions and mappings to the various terminologies in use. In this sense, new semantic commons are similar to the open source commons, where different software is produced, but is different from, for example, the innovation commons, where it is not known in advance what exactly the resource will be (Potts, 2019).

The new semantic commons would be created and maintained through the social process of commoning. Based on our observations of short-lived traces of commoning in past projects we propose that these identified traces of commoning, such as medical doctors participating in community activities, productive multidisciplinary collaboration and overcoming challenges, evolve towards sustainable and long-term commoning because such traces of commoning represent processes and activities of collaboratively creating, maintaining and nurturing commons. The more actors participate in the commoning, the more valuable the commons become. Similarly, Potts (Potts, 2019) shows how the innovation commons is created through the pooling of distributed information. The more information is available, the less uncertainty there is about starting a new innovation, and the more value is placed on information commons. In the new semantic commons, information is also pooled to create and maintain standardised semantic resources. This information represents data elements, their structure and the meaning associated with them, and is distributed with all medical professionals in the world. The need to pool such information stems from the World Health Organisation’s desire to create semantically interoperable health information systems and Electronic Health Records, which also clearly signals that semantic interoperability is recognised as a global challenge (Sachdeva & Bhalla, 2010). Global-local commoning in support of the semantic commons is, in our view, one way to implement semantic interoperability. However, sustainable commons require global-level agreements and the governance of local commons (Salazar & Cerna, 2020).

Our empirical findings suggest that stakeholders such as the MoH need to actively engage in the local commoning. It was during such engagement that initial traces of commoning emerged. These reflections on government involvement in the commons are in line with the recent evolutionary stage of commons research, in which more and more commons are moving from being an alternative to the government-market dichotomy to working with them to ensure long-term sustainability (Cumbers, 2015). However, we found that such commoning requires the government to become an active commoner.

11.8 Conclusion and future work

This article bridges two different research communities: the health community and the commons community. Based on our findings from combining current work in both research areas, we identify commoning as a crucial element for creating a new semantic commons - a potential way to manage semantic resources in healthcare. Commoning is seen as a social process that helps to create and maintain commons in a sustainable and long-term way. In particular, commoning can help manage semantic resources at the local level and maintain the relationship between global and local commons. In our study, however, we found that such commoning requires the government to become an active commoner. Without a national stakeholder such as the government taking on the role of active commoner, the relationship between global and local commons is difficult or impossible to maintain, which means that a high level of semantic interoperability cannot be achieved.

One could argue that the healthcare industry should also participate in commoning. In our projects, it would have been sufficient if we could have achieved harmonised semantic resources across several projects. These would then have served as requirements for the
different software companies, consisting of precise definitions of the data, its structure and the values used. The companies would then have to implement these in their systems, thus achieving the goal of open and shared semantic resources. This has always been a problem that has enabled the lock-in based business model of software companies in the first place.

We have also proposed a new area for Commons researchers to explore, namely semantic interoperability in healthcare. Semantic interoperability can directly impact the ability to deliver life-saving health data where and when it is needed. We also identify semantic resources in healthcare as an interesting and important type of open and shareable resource that allows health data to be defined in an understandable way, regardless of where, when and by whom the health data is used to treat patients. Furthermore, we propose a new perspective on the dynamic nature of the relationship between global and local commons. As research on this topic is sparse, we hope to develop interesting new research ideas. Moreover, the notion of a new semantic commons that we propose represents a contribution that can be useful not only for the health sector, but also for the commons community as a whole. Especially as it bridges the two communities and can stimulate interesting future research collaborations. Finally, we would like to use this research to point to a future where commoning takes a central role in healthcare. Not only in the management of semantic resources, but more generally, for example, in other governance issues in healthcare.


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12. Results

The results of this thesis are divided into two parts. The first part in Section 12.1 summarizes the results from the published papers and the supporting projects. Each of these results is additionally discussed in terms of its relevance to this thesis. This is important for two reasons. First, to understand that while the individual papers were being written, the thesis main ideas about contributions have not yet been established (see Section 6 where the writing of the thesis is presented as a separate ADR research cycle). Second, to identify important challenges and introduce new concepts that can help understand the challenges and point to possible solutions to the challenges.

The second set of results is obtained by applying new concepts to the challenges identified in the first set of results. These key findings and results are summarized in Table 16.

Both sets of results are used in the discussion in Section 13 to answer the research questions and outline the contributions of this thesis.

12.1 Results from the published papers

This section is structured into seven subsections. Five subsections correspond to the published papers included in this thesis, and the other two (sections 12.1.2 and 12.1.3) discuss two artefacts that resulted in the eCare project (see Section 5) and have been referred to and described in different publications (see Table 5 in Section 5) including the five that are included in this thesis.

Each of the results in all the subsections is described following a simple pattern depicted in Figure 21.

Figure 21 Common pattern for describing each of the results that is used in the text to identify paragraphs that contain each step of this pattern.

First, each result is shortly summarized. Second, the relevance to this thesis is discussed in which one or more challenges are identified. The challenges point to some aspect of the research in which a particular research result has been created but could be more optimal if the challenges would not have been there. Third, new concepts are introduced that have the potential to help understand and solve the identified challenges. Fourth, the result and its relevance to the thesis are reinterpreted using the new concepts to better understand the identified challenges through the lenses of the new concepts, and to picture how the new concepts could influence the primary result. Also, at the end of each subsection, a short summary is provided on how the subsection helps with answering the research questions this thesis poses.
12.1.1 Paper 1: Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge - results and relevance to this thesis

Results

Paper 1 [229] presents the value of using a conceptual framework to define adaptive preventive interventions to model DHIs [277]. The conceptual framework is based on behavioral theory, which recognizes the existence of what we call a "behavioral substance" that can influence behavior change in people. Behavioral substance are defined as behavior change techniques (BCTs) that represent potentially active components of interventions [278], [279]. These may need to be considered in real life as being spread over different DHIs that jointly support the wanted behaviour change (see [280] for interesting research on “lived informatics”).

Using the eAsthma DHI as an example, this paper shows that conceptual knowledge models developed by applying the conceptual framework of Collins et.al. [277] to the eAsthma DHI can, in this particular case, be mapped to process modeling industry standards as BMPN2⁹ to make them computable, i.e. they can be executed as computer programs. Such computable models represent structured behavioral knowledge that is theoretically associated with the ability to change behavior and thus improve user engagement when using the DHI. Such computable models can become part of the core offering of a software platform. Such computable models also represent a validated consensus of medical and behavioral experts and may become crucial resources for the future development of DHIs. However, as Slovenia is not yet training new Health Psychologists (only clinical psychologists) needed for the design of theory-based DHIs (see e.g. [228]), a useful next step could be the transfer of knowledge to Slovenia which we proposed in [248].

Relevance to this thesis

Paper 1 provides important research on the technical aspects of DHI design and development. It builds on earlier work in the eCare project (presented in Section 5), which took an OpenEHR-based approach to modeling medical knowledge - as described in [227]. Paper 1 addresses the behavioral aspects of designing clinically validated care protocols, which in this paper is a stand-alone outcome of the clinical validation of several DHIs within the eCare project (see Section 5).

Identified challenges: Similarly, just as the use of OpenEHR requires collaboration between medical professionals and computer and information scientists to address semantic interoperability issues, the development of theory-based DHI requires collaboration. This paper does not directly discuss this specific need due to the different contexts in which the paper was written. However, from a broader perspective, we can note that we have (1) collaborated with health psychologists [228] in the design of our DHIs to align our DHIs with behavioral theory, and (2) proposed the formation of a new national organization [248] that would support the transfer of knowledge in health psychology from, for example, United Kingdom to Slovenia and the future behavioral theory-based design and development of DHIs. This bigger picture, along with this paper, is a clear indication of the need for interdisciplinary collaboration with the behavioral sciences, and health psychologists in particular.

⁹ https://www.omg.org/spec/BPMN/2.0/
New concepts: Thus, if one wants to develop theory-based DHIs that can become part of clinical practice, collaboration among various professionals is required, including at least medical doctors, health psychologists, and computer and information scientists.

All these professionals/experts must be able to work together in a constructive way by participating in a shared activity space that takes into account their differences in knowledge, culture and value systems. This is important because these differences affect the trust that different professionals have in each other, a phenomenon described in [281] as bounded confidence. Therefore, it is important to establish activity spaces that take into account these differences between professionals and enable collaboration despite the inherent differences. To help design activity spaces where multidisciplinary collaboration in the design of theory-driven DHIs is possible, new concepts need to be considered.

In this thesis, we consider TEAS (see Section 3.3) as one such concept. In essence, TEAS can be viewed as a continuous task-artifact cycle in which artifacts and user tasks evolve together, enabling intrinsic transformation of practice (user tasks).

Reinterpretation of the results: given the findings of Paper 1, TEAS would support the continuous co-evolution of social and technical aspects of DHI design. In such a design, behavioral scientists would be able to collaborate with technical experts and medical professionals while using the artifact (early versions and later final versions of artifacts) to transform their existing work practices in an intrinsic way. In this way, they would also influence future changes to the artifacts. A healthcare professional would be able to constantly consider the new DHI in the context of their medical practice. In this way, the new DHI would be appropriated for use in medical practice. This constant appropriation within an existing medical practice has also been defined by Botero et al. as design in use [282]. Technical aspects of such appropriation are researched under the term End-User Development [283].

Influence on the answers to the research questions

Paper 1 and the above contextualization of its findings highlight the need to introduce new concepts (in this case TEAS) to address the challenges associated with the collaborative social and technical design of technologies such as DHIs. For this reason, both Paper 1 and the contextualisation of its findings partially support the answer to research question RQ1.1.

In addition, Paper 1 discusses clinically validated care protocols (see Section 12.1.3) in which OpenEHR plays an important role, so I believe Paper 1 also contributes to answering RQ2.2.

12.1.2 eCare Software Platform

Results

The eCare software platform (see Section 5) is based on the use of OpenEHR and BPMN2 as the foundation for DHI implementations on the platform. The methodology for design, development, and deployment of a new DHI on the eCare software platform is described in [227]. Each DHI is implemented as a set of BPMN2 process models supported by OpenEHR archetypes and templates. All data points that appear in the BPMN2 process models are modelled using OpenEHR archetypes and templates. At runtime, the process models are initiated on the platform and all data captured during the execution of the various instances of the process models are stored in OpenEHR format.

The development of the first DHI took about 6 months due to the concurrent development of the eCare software platform. The final DHI development was outsourced to a small IT company that had no previous experience with OpenEHR, BPMN2, or the content of the DHI.
It took the company about three weeks to implement the DHI. This was possible because the various artefacts that the eCare platform provided as core components were highly reusable. These included the BPMN2 process models and the OpenEHR semantic resources. We found these short time intervals for developing new DHIs critical to the eCare software platform's support for dynamic and agile DHI design, development, and deployment.

The platform is described in more detail in [227] and the source code of the platform is freely available online [284].

Relevance to this thesis
The eCare software platform result is important for this thesis as it shows the technical use of OpenEHR in the context of DHI and software platforms.

Identified challenges: In addition, the eCare platform was developed jointly with the DHIs. This means that the software developers who worked on the eCare software platform had to design the OpenEHR semantic resources with the medical professionals. However, this collaboration was never in line with how OpenEHR should be used. This led to the software developers modeling the semantic OpenEHR resources based on questionnaires they created for the healthcare professionals to capture as many use cases and data requirements of the use cases as possible, without any real collaboration on the development of the OpenEHR artifacts. This led to the creation of very specific OpenEHR archetypes and templates that could be used for the specific needs of the eCare project. The OpenEHR semantic resources therefore lacked a global perspective in which semantic resources are designed for global use, as this is the only way to achieve semantic interoperability. The main reason for this very localized design of semantic OpenEHR resources is that neither the Ministry of Health nor any other institutional healthcare stakeholder was involved in or cared about the governance of the OpenEHR semantic resources. For this reason, most projects in Slovenia that used OpenEHR did not really enable semantic interoperability, as the semantic resources were highly proprietary and focused on the needs of specific projects.

In summary, the above challenges (1) the lack of participation of healthcare professionals in the modeling of OpenEHR semantic resources and (2) the lack of national governance of OpenEHR semantic resources have led most engineers to create highly proprietary semantic resources that do not contribute to semantic interoperability in healthcare.

New concepts: To address the first challenge, we should consider creating new activity spaces that would better support collaboration between different professionals despite their differences in knowledge, culture, and value systems. In this thesis, we consider TEAS (see Section 3.3) as an approach to create such activity spaces. TEAS can be viewed as a continuous task-artifact cycle in which artifacts and user tasks co-evolve to enable intrinsic transformation of practice (user tasks).

The second challenge, the lack of national governance of OpenEHR semantic resources, prompted us to seek new concepts that could help achieve more optimal governance. In this thesis, commons and commoning are such concepts. Traditionally, commons are used as a governance approach over natural resources like forests, fisheries, and pastures. However, commons have also been successfully used to govern other types of resources including data, information, knowledge, and culture (see paper 5).

Reinterpretation of the results: In the case of the design and development of DHIs in the eCare project, a TEAS would need to enable physicians, Ministry of Health officials, and software developers to collaborate on semantic OpenEHR resources. This would mean that medical
professionals could participate in the design of DHI by not only modeling semantic OpenEHR resources, but also participating in DHI development which we have already shortly discussed in Section 12.1.1. Physicians would need to be able to suggest changes to specific DHI so that the DHI can help change the working practices of the physician's practice. At the same time, physicians would be able to test the DHI in their practice and suggest changes that would drive new versions of the DHI.

Regarding OpenEHR semantic resources within the eCare project (see Section 5) several tools were available for local design and development of OpenEHR semantic resources and their integration into the DHI. These tools could also be used by the Ministry of Health to better manage semantic resources. However, the management of the OpenEHR semantic resources was not properly implemented at the national level or by the industry involved in the eCare project.

Looking at our eCare project from the perspective of commons and commoning, the OpenEHR modeling of semantic resources would be done by a community of people who understand the Slovenian healthcare system. This includes medical professionals, software engineers, and representatives of the Ministry of Health. The state of the art of the commons (see paper 5) suggests that the future of the commons may not lie in being an alternative to government and industry focused semantic resource management, but rather in working with both government and industry to achieve a sustainable approach to OpenEHR semantic resource modeling.

**Influence on the answers to the research questions**

The eCare software platform represents technical use of OpenEHR for DHI and platform development. It can therefore be used to support answering RQ2.2 and RQ2.3, suggesting partial support for answering RQ2.

Research and development activities related to the eCare software platform support also answering of the RQ3, as they help identify challenges that can be addressed by commons (see paper 5 in Section 11). Answering RQ1 can also be supported as the challenges observed in design and development point to TEAS and commons. Both concepts support the definition of a new work practice for productive work on semantic resources which is part of answering RQ1.

### 12.1.3 eCare Clinically Validated Care Process Models

**Results**

The clinically validated care protocols are the result of several clinically evaluated DHI within the eCare project (see Section 5). The DHI were evaluated in randomized clinical trials and, from a technical point of view, are implemented as BPMN2 process models. We call this technical representation the clinically validated care process models [244]. The idea of developing such models was that they could be used on the eCare platform (based on OpenEHR) and become boundary resources (see Section 3.5) there. The care process models could then be used to define new products/services based on them. OpenEHR was used for the technical management of all data processed by the process models. The technical representations of the clinically validated care process models are freely available [284].


Relevance to this thesis

Identified challenges: I identify two main challenges related to this result. First, as the artifact is to become a boundary resource of a platform, which is different from traditional boundary resources such as APIs, it suggests a different view on software development projects. In this view, process models can be provided by one software company, while another can use the process models to define a new product. This new product can then be offered to health professionals. The challenge is therefore, how to organize software development to support such collaboration between software companies on different parts of products.

Second challenge is linked to the need to participate in multi-disciplinary activities to define new OpenEHR semantic resources needed for new process models, and to define the process models themselves. This suggests the need for collaboration within new activity spaces dedicated to multi-disciplinary work.

New concepts: In this thesis, SECO's view of software development allows to understand the first above-mentioned challenge. The second challenge can be addressed with a TEAS-based activity that has already been introduced in 12.1.2.

Reinterpretation of the results: SECOs enable different distribution of roles in development of a common artifact such as a process model. These can be co-created and used by many different SECO participants. Some SECO participants might specialize in the design, development, and evaluation of such care process models, while others might focus on user experience, for example, and create better experiences for end users in addition to existing care process models. Such a partial approach to product design and development involving many different stakeholders should also be well supported by software platforms that support a SECO. The eCare clinically validated care process models are an example of such partial design that is supported by the eCare software platform.

With respect to the second challenge and TEAS as a potential new concept to address the need of collaboration on the OpenEHR semantic resources we can say that, not only are such activity spaces needed for work on semantic resources (see also Section 12.1.1), but are also needed for work on other types of artefacts like process models, and DHI design and development in general (see also Section 12.1.1). This suggests that SECOs and TEAS need to be aligned to support the needed DHI design and development activities in which professionals from many domains can successfully collaborate. This strongly points towards co-evolution of social and technical aspects of technology/DHI design and development in the field of healthcare. We elaborate on this more in detail in Section 12.2.

Influence on the answers to the research questions

The use of OpenEHR to technically implement data management in care process models supports the answer to RQ2. Since OpenEHR was used for both the software platform development and the DHI design, this result can contribute to answering RQ2.2 and RQ2.3 where OpenEHR’s impact on DHIs and software platforms is the focus. This artefact also helps introduce new concepts, primarily TEAS and SECOs, that are needed to define the answer to RQ1 as both concepts represent core components of the work practice for productive work on semantic resources.
12.1.4 Paper 2: Modelling time-series of glucose measurements from diabetes patients using predictive clustering trees – results and relevance to this thesis

Results
The main result of paper 2 is a method for segmenting patients into several groups according to their diabetes stability. It has the potential to be used for informing patients of their prospects for the future, and for informing decisions made by healthcare professionals. As part of the results, there are tools available that allow interfacing with an OpenEHR repository of patient medical data. It can thus be used in different systems like the electronic medical records (medical records within specific medical providers) or even electronic health records (the life-long medical records of patients across many medical providers). The limitation of paper 2 is that the results have not been validated in a randomized clinical trial, meaning, that there has not been a separate clinical study conducted to test the results of the prediction algorithm in real clinical practice. Before such an algorithm could become part of clinical practice, the results should be validated on a much larger scale. However, that was far out of scope of the small research project.

Relevance to this thesis
Identified challenges: the algorithm is a component that could be included in our eDiabetes DHI (see Section 5), or could become a new add-on/extension of a software platform. Through becoming part of e.g., the national eHealth platform, the algorithm could in fact be used to build new products on top of it and offer those to end users such as patients and medical professionals. To support such partial software product development, new concepts are needed that allow software development to organize differently. In this thesis, SECOs are such a concept.

In addition, the process of implementing such an algorithm in clinical practice is very complex and requires time and a lot of collaboration between many stakeholders and different experts before it can be implemented in clinical practice. While developing the algorithm is not a trivial technical task, implementing it in clinical practice also requires much attention on the social aspects. For example, how are the predictions provided by the algorithm used in clinical practice? If these predictions can impact patient health, the algorithm needs to be certified as a medical device which can be a rather long and costly process that involves stakeholders from standards and quality assurance organizations. Further on, how do doctors explain their care related decisions that were supported by the suggestions an algorithm provided? These social aspects include people from different professional domains that need to participate in appropriation of the algorithm for it to be used in clinical practice. In this thesis, TEAS can help with such problems.

New concepts: SECOs are considered for the problem of organizing software development differently to support distributed software product development.

TEAS are seen as the new concept that can help design activity spaces in which different professionals can work together to design and develop socio-technical artefacts that represent the clinically implemented algorithms. This means that an AI algorithm that is deployed as a boundary resource on a software platform, could be appropriated in a socio-technical sense if a TEAS would be available.

Reinterpretation of the results: A SECO would enable distributed development of a clinically implemented algorithm. This means one software vendor could develop the algorithm, while
some other could use it as part of its product that would fit some needs of medical professionals better than the algorithm alone. This new product would be designed within a TEAS, where the algorithm within the product, and the clinical practice would co-evolve in a continuous cycle. The software platform would provide tooling to support such co-evolution towards an AI algorithm-based application that is implemented in clinical practice. This is made possible exactly by the intrinsic practice transformation that is supported within a TEAS.

Influence on the answers to the research questions
The paper is an example of using OpenEHR in the context of artificial intelligence and data science. For this, the results can be used to support answering RQ2.1 as this work can be seen as an example of the impact OpenEHR can have on ways of working within the context of artificial intelligence.

The pointers this paper provides toward the need for more inclusion of social aspects in technology (in this case, AI algorithms) development, helps with answering RQ1. First, the TEAS is considered to support co-design, design in use and appropriation of the AI algorithm to arrive at an application that is implemented in a clinical practice. TEAS is seen as a crucial component of the new work practice for productive work on semantic resources, searched for in RQ1.

12.1.5 Paper 3: Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national ehealth – results and relevance to this thesis

Results
First, the paper analyzes the different healthcare interoperability approaches (see Table I in Section 9) that could help with interoperability issues in the Slovenian eHealth context. Second, the paper presented several groups of success factors in the interoperability field (political, regulatory, institutional, and technological) that represent “appropriate and balanced dynamics between healthcare ecosystem conditions and elemental eHealth requirements” [169], and have a critical influence on the development and implementation of eHealth projects (see Table II in Section 9). The different interoperability principles can be used as a strategic starting point for continuous work towards achieving interoperability in healthcare.

Relevance to this thesis
Identified challenges: A direct result of this paper is a list of obstacles identified during the implementation of interoperability approaches, including OpenEHR, on the national level in Slovenia (see Section 9). The list points to the social aspect of working with semantic interoperability as the needed participation of the doctors, the government and software providers in the interoperability implementation was not there and so all the technical solutions were not optimally implemented. Particularly, in paper 3 the OpenEHR is showcased using the example of the national Patient Summary (initially developed within the epSOS project – see Section 4.3.4 – and defines critical health data definitions that are crucial in the process of saving a patient’s life; recently became the ISO 27269:2021 standard).
The patient summary example makes it clear that (1) there was not a proper multi-level governance in place that would support the (2) multi-disciplinary work of doctors and engineers with OpenEHR to achieve semantic interoperability, and that (3) there was no real collaboration between the different stakeholders (e.g., Ministry of Health, National Health Insurance Fund, National Institute of Public Health, Medical Doctors etc.). These findings are important for this thesis as they point out social challenges of working with OpenEHR such as multi-disciplinary and multi-level collaboration on OpenEHR artefacts.

New concepts: as already brought forward in previous subsections, new activity spaces are needed that would enable (3) multi-disciplinary work of doctors and engineers on OpenEHR. We look at TEAS (See Section 3.2) as a potential solution to this problem.
In addition, due to the identified issues with the (1) multi-level governance of OpenEHR that was not established successfully in Slovenia, and because both the government and the industry were not able to provide solutions but have rather been recognized as part of the problem (see paper 5 in Section 11), similarly as in Section 12.1.2, the need for new governance concepts has been identified. Particularly, there was a need to look at the similar existing collective action problems and bring new solution concepts into the field of semantic interoperability. Concepts of commons and commoning are considered in this thesis and have been examined as potential solutions for semantic interoperability (see also paper 5 in Section 11).
Finally, (2) the inability of the software providers to jointly work on achieving semantic interoperability calls for a new view on software development that is lately more and more evolving towards SECOs.

Reinterpretation of the results: In this case, TEAS would support collaboration between different professionals to enable intrinsic practice transformation. This means that doctors, government employees, and other stakeholders would be able to work on OpenEHR semantic resources in a way that would impact intrinsic change in their current work practices. Such constant task-artefact co-evolution cycles are in fact needed to bring OpenEHR to all the stakeholders that are needed to enable multi-disciplinary collaboration on OpenEHR semantic resources.

Interpreting the OpenEHR governance challenges of paper 3 through the lens of commons and commoning suggests that the stakeholders would participate in governing OpenEHR semantic resources in a way that would bring the government and the industry more closely together in pursuit of a common goal of achieving semantic interoperability.

Looking at paper 3 through the SECO lens we could say that if all the software providers together with other healthcare stakeholders, namely end users, would take part in a SECO, a different division of roles could be established in the SECO. Based on these roles, business models of the software companies could become more sustainable as they would be able to specialize more. Jointly, they would all be cooperating and working towards extending the SECO around a common software platform.

Influence on the answers to the research questions
Paper 3 represents a cornerstone for the thesis as it contributes to answering all three research questions. Its focus on OpenEHR partially helps answering RQ2 by providing information needed to answer RQ2.4 which focuses on OpenEHR’s impact on national eHealth platforms. By providing in-depth information on ways of working on national eHealth in Slovenia and gaps inherent in the field of semantic interoperability in healthcare, together with identified obstacles in the implementation process, the paper also support answering RQ1. The commons
as an approach to governance of resources helps understand the governance issues with OpenEHR artefacts on the national level in Slovenia and with this provides the needed argumentation for answering RQ3. The overall point of social aspects of technology development that includes TEAS, commons and SECOs, additionally help with answering RQ1 by providing arguments for the conceptualization of the work practice for productive work on semantic resources that supports answering RQ1.

12.1.6 Paper 4: Is National Ehealth in Slovenia on Track To Be an Open Ehealth Platform? – results and relevance to this thesis

Results
Paper 4 focuses on using organisational design principles that are grounded on existing platform theory (see [285]–[288]), and represent the state of art for organizational design principles related to eHealth platforms. The organizational design principles were used to evaluate the national eHealth platform in Slovenia from the perspective of how well it supports the open eHealth platform concept from an organizational aspect. By doing so, we identified a gap in the Slovene national eHealth platform in comparison to the theoretical organizational design principles for eHealth platforms. This suggests that the organizational design principles for eHealth platforms could be considered relevant as an analytical theory. The identified gap in the Slovene national eHealth platform can be used to strategically guide future evolution of the national eHealth platform in Slovenia. Paper 4 were able to not only provide additional evidence of the organizational design principles usefulness, but also presented these organizational design principles as important knowledge at an organizational level of platform governance.

Relevance to this thesis
Identified challenges: Paper 4 focus on a particular type of information infrastructures in healthcare, namely, platforms. Such platforms are software-based platforms that support SECOs. Christensen in [185] introduces three aspects of software ecosystems architecture, namely organization, business and software structure. Dittrich in [181] provides principles of sustainable software ecosystems as a future form of projects which certainly hold true more today than ever. In line with the software platforms terminology, paper 4 presents the core components and services it provides. More importantly, paper 4 used the eCare eDiabetes DHI in a hypothetical scenario of implementing the DHI on the national eHealth platform. Particularly, through this use case, the national eHealth platform is evaluated through the lens of organizational design theory for eHealth platforms. This analysis teaches what are the organizational prerequisites for successful socio-technical transition of the eDiabetes DHI to the national eHealth platforms. This basically means that in spite having OpenEHR technically available both in the eDiabetes DHI and on the national eHealth, there are aspects that fall into the social arena of technology development and implementation. Particularly, paper 4 presents all the crucial roles/stakeholders of the national eHealth and the result of the analysis suggests that the different stakeholders have not so far cooperated enough to establish the needed organizational prerequisites that would support bringing new solutions from the niche to regime level (see Institutional Theory in Section 3.2.2).
We have learned from paper 4 that (1) one of the technological success factors for successful implementation of national eHealth projects is also the Collaboration and testing of ICT solutions with stakeholders’, and (2) dynamic and agile cooperation with different entities is needed to successfully implement national eHealth projects. Also, (3) quality contracts with
private software development companies are strategically important. Such requirements are hard to achieve with existing public tendering and classical view on software development where a software product is provided by a single software company. In addition, the results of paper 4 also suggest that because of the inherent issues with the national eHealth platform, the ecosystem around it is not well established. One example of expanding the ecosystem around the national eHealth platform, has been described in the case of the national cervical cancer registry. Here, the national eHealth platform can be regarded as the enabler platform for a new concept for the cervical cancer registry in Slovenia that is based on OpenEHR and enables interoperable exchange of information between a few hundred gynecology medical specialists in Slovenia. However, the inherent organizational issues uncovered in paper 4 had made the expansion a hard and long process in which legislation needed to be changed and software providers barely collaborated.

New concepts: With the challenges of assuring organizational prerequisites of eHealth platforms, an approach to supporting improved future cooperation could be seen in new activity spaces that support collaboration between multiple stakeholders in spite the differences in their culture, knowledge, and values systems. To create such activity spaces, new concepts need to be considered. In this thesis, TEAS (see Section 3.3) is the concept considered.

To help with issues identified with respect to software development and collaboration with software companies, SECOs can be used.

Reinterpretation of the results: on the case of organizational design principles for eHealth platforms, the artefact is the national eHealth of Slovenia, and the task encapsulates different stakeholders work practices that can use the resources offered by the national eHealth platform in their everyday practice. Each stakeholder will thus be able to intrinsically transform (not just by being externally forced by technology providers) its own practice according to his needs which is an essence of why TEAS are important. Such a broad view on the task and artefact cycle is needed because, in a national eHealth platform, all the stakeholders of health systems need to collaborate for the national eHealth platform ecosystem to expand, and the resources offered by the national eHealth platform become implemented and used in everyday practices.

We can say that the goal of the national eHealth platform in Slovenia (can also be said more generally for other eHealth platforms) is to expand its ecosystem in a way that the resources offered by the national eHealth platform are used in the continuous task-artefact cycle in which existing practices intrinsically change and with this represent a source for new changes for the artefacts – the national eHealth platform resources.

In this thesis, we use SECOs (see Section 3.2, Section 12.1.3, and Section 12.1.5) as a different way of viewing software development that could fit better with the above-mentioned needs for quality collaboration with software companies on the national eHealth platform.

The national eHealth platform contains a set of resources – core components and applications as are presented in paper 4. Each of the components and applications changes through time and there are many dependencies between the components and applications. With the SECO way of thinking about software development to support the national eHealth platform, all the providers would need to collaborate on the SECO strategy, supply chain and software development levels and they would become more aware that they are in fact taking part in an ecosystem and cannot think of themselves as independent players. For this and backed by the literature (see Section 3.2) we can say that a SECO supports a more dynamic and agile collaboration between different stakeholders since the national eHealth platform can be considered as a product/service that is provided by many providers that are part of SECO.
Each provider provides support for a part of the overall product. Therefore, incorporating a SECO oriented thinking on technical, organizational, and business levels could potentially lead to more optimal collaboration on the national eHealth platform (see Section 3.2) and with this to a more expanded ecosystem around the national eHealth platform as the SECO will be able to react more promptly and in a more agile way to potential change requests.

**Influence on the answers to the research questions**

The analysis in this paper gives more information on the social part of the socio-technical transition of a DHI towards the national eHealth. Paper 4 identifies a need for more focus on the social aspects on the national eHealth in Slovenia and in the analysis above we considered both TEAS and SECOs to incorporate social aspects in the technology development on the case of the national eHealth platform in Slovenia.

The results of paper 4 highlighted above represent a path to establishing software ecosystems. Particularly, the focus here is on organizational principles of the software ecosystem overall architecture. This focus on information systems, namely platforms, and SECOs, support answering RQ1 as SECOs represent an important concept for the definition of a new work practice that is the main result of this thesis and is also used to answer RQ1.

In addition to SECOs, we have also considered TEAS in the results of paper 4 highlighted above. TEAS are seen as a concept that can guide the creation of activity spaces to support the multi-disciplinary and multi-level collaboration between healthcare system stakeholders to implement organizational design principles of eHealth platforms on the case of the national eHealth platform in Slovenia. TEAS are also considered as a crucial element of the main result of the thesis and are used to define it and support answering the RQ1. Both TEAS and SECOs acknowledge social aspects of technology development and enable the socio-technical co-design of technology. For this, both concepts are crucial for answering RQ1 and to support the main contributions of this thesis.

In addition, as part of the national eHealth platform are also knowledge resources like the OpenEHR models, and several software systems that represent the platform core services including the OpenEHR system, we use the paper to support answering our RQ2. The OpenEHR models require national collaboration on semantic resources and so this provides additional information on the impact of OpenEHR on software platforms (RQ2.3). The OpenEHR system that is one of the core components of the national eHealth platform in Slovenia also provides additional information on the influence of OpenEHR on software platforms (RQ2.3).

### 12.1.7 Paper 5: Commoning Semantic Interoperability in Healthcare – results and relevance to this thesis

**Results**

Paper 5 addresses semantic interoperability problems from a governance aspect by proposing semantic resources become managed using commons and particularly commoning (see Section 3.6). Based on existing commons theory, commons-based governance can be sustainable and can offer more intrinsic and social motivation to join working for the commons, in comparison to the usual mostly monetary motivation. Paper 5 develops commons-based governance idea in the domain of semantic interoperability. Particularly, paper 5 focuses on constant semantic work with OpenEHR that is needed in order to achieve interoperability in healthcare. With the commons based approach to governing semantic resources, it is possible to alleviate the power differences over semantic resources and data between different healthcare stakeholders.
With respect to commoning semantic interoperability, there has not been such an independent commons-based approach to semantic resources governance yet that would work in practice. However, we have seen the emergence of successful data commons, like the genomic data commons (see Section 3.6). However, even these new data commons struggle with data curation issues at the primary data sources that in healthcare are usually different electronic medical record system. Similarly, lock-in and data curation is a symptom of almost all data sources in healthcare. Having a semantic resources commons would help establish rules that would motivate collaborative work on semantic resources and at the same time solve existing data and semantics lock-in problems.

Relevance to this thesis

Identified challenges: as the semantic resources governance is mostly a social element of the activities towards achieving semantic interoperability in healthcare, paper 5 points to a rudimental need to look at technology design not only as a technical activity but rather as a holistic socio-technical co-design and co-evolution.

New concepts: This is mostly because the activity of commoning in the new semantic commons requires a new activity space for productive collaboration of different professionals. It points in the direction of bringing in new concepts that help with the creation of such activity spaces, namely TEAS. As the crucial role in achieving semantic interoperability is played by software providers, they also need to become active members of such activity spaces. This means that software products are to become collaboratively designed and developed by different stakeholders (one or more software companies, medical doctors, etc.). This means that software development should be viewed differently, more in line with the concept of SECOs (see Section 3.2) to allow cooperation of the software companies with stakeholders like medical professionals and other experts.

Reinterpretation of the results: A commons-based governance of OpenEHR semantic resources is described in paper 5 as pointing to a tighter collaboration between the government and the industry. Such a goal can be achieved if a TEAS is provided in which different professionals could collaborate in, in spite their differences in knowledge, culture, and value systems. In addition, TEAS would need to be aligned with the SECOs. This means that TEAS would include participants from SECOs taking part in commoning the semantic resources. But more importantly, such a TEAS would become a crucial element of the SECO governance that would enable future evolution of the SECO.

Influence on the answers to the research questions

Paper 5 deals with the problem of multi-level governance that is needed to successfully govern OpenEHR artefacts at the local Slovene level. By providing this information, it partially supports answering RQ2 as it shows additional impact of OpenEHR on existing DHI design and development approaches (RQ2.2). Also, paper 5 provides information that additionally helps understand the impact of OpenEHR on national eHealth platform in Slovenia (RQ2.3) and with this helps answering RQ2.

This paper supports answering the RQ3 by providing information on how commons can help with tackling governance problems with OpenEHR semantic resources that have been observed in different research that underpin this thesis (see Section 5 and OpenEHR-related results in Section 12.1). The above-mentioned social aspects of technology development that require new concepts like commons, TEAS and SECOs all jointly help construct the main result of this thesis, the new
work practice for productive work on semantic resources, and therefore support answering RQ1.
To summarize, paper 5 provides important insights that partially support answering all three research questions.

In Table 10 below I summarize the influences of all the results discussed in Section 12.1 to all the research questions.

<table>
<thead>
<tr>
<th>Subsection</th>
<th>RQ1</th>
<th>RQ1.1</th>
<th>RQ2.1</th>
<th>RQ2.2</th>
<th>RQ2.3</th>
<th>RQ2.4</th>
<th>RQ3</th>
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<td>12.1.7 Paper 5</td>
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Table 10 Summary of influences of the discussion about the results from papers on research questions answers.

A summary of all the results, identified new challenges, introduced new concepts and reinterpreted results is given in Table 11.

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Result</th>
<th>Result ID</th>
<th>Identified Challenges</th>
<th>Challenge ID</th>
<th>New concepts</th>
<th>Reinterpretation of results</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1.1 Paper 1:</td>
<td>Increasing patient engagement using an extensible open eHealth platform with structured behavioral knowledge - results and relevance to this thesis</td>
<td>PR1</td>
<td>Collaboration with health psychologists.</td>
<td>IC1</td>
<td>TEAS</td>
<td>DHI Design co-evolves, the DHIs and other artifacts are evaluated in the TEAS task-artefact cycles.</td>
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<tr>
<td>Section</td>
<td>Project</td>
<td>Description</td>
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<td>12.1.2</td>
<td>eCare Project</td>
<td>eCare Software platform</td>
<td>PR2</td>
<td>IC2 TEAS</td>
<td>DHI Design and development co-evolution of social and technical; OpenEHR modelling. Commoning jointly with the government and the industry.</td>
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<td>Lack of participation of healthcare professionals in the modeling of OpenEHR semantic resources. Lack of national governances of OpenEHR caused the lack of global perspective in OpenEHR semantic resources.</td>
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<td>12.1.3</td>
<td>eCare Project</td>
<td>Clinically validated care process models</td>
<td>PR3</td>
<td>IC4 SECO</td>
<td>The process models as partial products within SECOs jointly developed by many SECO participants.</td>
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<td>A new type of boundary resources that needs a different way of organizing software development. Need for collaboration on OpenEHR semantic resources.</td>
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<td>12.1.4</td>
<td>Paper 2: Modelling time-series of glucose measurements from diabetes patients using predictive clustering trees – results and relevance to this thesis</td>
<td>Predictive clustering trees for predicting based on segmentation of patients</td>
<td>PR4</td>
<td>IC6 TEAS</td>
<td>Co-evolution of AI algorithm and clinical practice.</td>
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<td>Experts from different domains need to participate in implementing AI algorithms in clinical practice. Using the algorithm as a platform extension to allow building new products on top of the algorithm.</td>
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<tr>
<td>12.1.5</td>
<td>Paper 3: Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and</td>
<td>Analysis of interoperability approaches in healthcare. Success factors for successful implementation</td>
<td>PR5</td>
<td>IC8 TEAS</td>
<td>Multi-disciplinary collaboration on OpenEHR and other approaches to interoperability in which all stakeholders participate and</td>
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<td>PR6</td>
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<td>National eHealth interoperability implementation requires collaboration of doctors, government,</td>
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219
Continua as approaches to interoperability on national eHealth – results and relevance to this thesis of interoperability approaches in the national eHealth.

and software providers, but it was not sufficient.

Lack of OpenEHR Multi-level governance.

Poor collaboration between software firms.

IC9 Commons perform commoning is enabled by TEAS.

Commons can help with governing resources that are often poorly governed by the government or the industry.

IC10 SECO Software firms collaborate within SECOs.

<table>
<thead>
<tr>
<th>12.1.6</th>
<th>Paper 4: Is National Ehealth in Slovenia on Track To Be an Open Ehealth Platform? – results and relevance to this thesis</th>
<th>Organizational design principles for eHealth platforms as a useful analytical tool, and important for platform governance.</th>
<th>PR7 Poor collaboration on establishing the needed organizational design principles.</th>
<th>IC11 TEAS National eHealth platform as an artifact that co-evolves with practices of different stakeholders in healthcare.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Poor collaboration with software firms and between software firms.</td>
<td>IC12 SECO</td>
<td>National eHealth as a SECO.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.1.7</th>
<th>Paper 5: Commoning Semantic Interoperability in Healthcare – results and relevance to this thesis</th>
<th>A new semantic commons for governing OpenEHR semantic resources.</th>
<th>PR8 Need to look at technology design as a holistic socio-technical co-design and co-evolution.</th>
<th>IC13 TEAS Commoning as an activity to nurture a commons is performed within TEAS.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Software companies need to organize differently to participate in TEAS.</td>
<td>IC14 SECO</td>
<td>Software providers need to organize as a SECO to be able to participate in co-design and co-evolution of the social and technical aspects of technology development.</td>
</tr>
</tbody>
</table>

Table 11 Summary of results from the papers together with identified challenges, new concepts that help understand and perhaps solve the challenges, and reinterpretation of results looking through the lenses of the new concepts.
12.2 From technical infrastructures to commons – key findings and results

The purpose of this section is to build on the findings presented in the previous Section 12.1 to develop the main contributions of this thesis. Summarising Section 12.1, we can categorize the identified challenges and proposed new concepts of TEAS, SECOs and commons into three groups:

1. software development challenges and the need for an evolution of software development towards SECOs to solve the challenges,
2. multidisciplinary collaboration and the need for TEAS in which different professionals can collaborate despite their differences in knowledge, values and culture, and
3. multi-level governance of semantic resources that can be approached from the aspects of commons and commoning in particular.

Based on the summaries of results from the papers presented in Table 11, the three above mentioned groups are depicted in Table 12 below. Each group is represented by a set of identified challenges from Table 11.

<table>
<thead>
<tr>
<th>Group</th>
<th>New Concept</th>
<th>Challenge</th>
<th>Challenge ID</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SECO</td>
<td>A new type of boundary resources that needs a different way of organizing software development</td>
<td>IC4</td>
<td>12.1.3 eCare Clinically Validated Care Process Models</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Using the algorithm as a platform extension to allow building new products on top of the algorithm.</td>
<td>IC7</td>
<td>12.1.4 Paper 2: Modelling time-series of glucose measurements from diabetes patients using predictive clustering trees – results and relevance to this thesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poor collaboration between software firms.</td>
<td>IC10</td>
<td>12.1.5 Paper 3: Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national ehealth – results and relevance to this thesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poor collaboration with software firms and between software firms.</td>
<td>IC12</td>
<td>12.1.6 Paper 4: Is National Ehealth in Slovenia on Track To Be an Open Ehealth Platform? – results and relevance to this thesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Software companies need to organize differently to participate in TEAS.</td>
<td>IC14</td>
<td>12.1.7 Paper 5: Commoning Semantic Interoperability in Healthcare – results and relevance to this thesis</td>
</tr>
<tr>
<td>2</td>
<td>TEAS</td>
<td>Collaboration with health psychologists.</td>
<td>IC1</td>
<td>12.1.1 Paper 1: Increasing patient engagement using an extensible open eHealth</td>
</tr>
<tr>
<td>IC2</td>
<td>Lack of participation of healthcare professionals in the modeling of OpenEHR semantic resources</td>
<td>12.1.2 eCare Software Platform</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC5</td>
<td>Need for collaboration on OpenEHR semantic resources</td>
<td>12.1.3 eCare Clinically Validated Care Process Models</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC6</td>
<td>Experts from different domains need to participate in implementing AI algorithms in clinical practice.</td>
<td>12.1.4 Paper 2: Modelling time-series of glucose measurements from diabetes patients using predictive clustering trees – results and relevance to this thesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC8</td>
<td>National eHealth interoperability implementation requires collaboration of doctors, government, and software providers, but it was not sufficient.</td>
<td>12.1.5 Paper 3: Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national ehealth – results and relevance to this thesis</td>
<td></td>
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</tr>
<tr>
<td>IC11</td>
<td>Poor collaboration on establishing the needed organizational design principles.</td>
<td>12.1.6 Paper 4: Is National Ehealth in Slovenia on Track To Be an Open Ehealth Platform? – results and relevance to this thesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC13</td>
<td>Need to look at technology design as a holistic socio-technical co-design and co-evolution</td>
<td>12.1.7 Paper 5: Commoning Semantic Interoperability in Healthcare – results and relevance to this thesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC3</td>
<td>Lack of national governances of OpenEHR caused the lack of global perspective in OpenEHR semantic resources.</td>
<td>12.1.2 eCare Software Platform</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC9</td>
<td>Lack of OpenEHR Multi-level governance.</td>
<td>12.1.5 Paper 3: Special topic interoperability and EHR: Combining openEHR, SNOMED, IHE, and Continua as approaches to interoperability on national ehealth – results and relevance to this thesis</td>
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</table>

Table 12 The proposed new concept-based groups of challenges they potentially help with in different subsections of 12.1
As we can learn from Table 12, the challenges are mostly connected to participation, collaboration, organization, and governance. These all fall into social aspects of technology development. We now elaborate more on each of the concepts from Table 12 to depict an evolution from technical infrastructures to commons that seems to be the underlying idea that connects all elements of this research. We start first in Section 12.2.1 with the needed transition of software development that is based on projects, to SECOs to show these can help resolve the SECO oriented challenges of Table 12. Then, in Section 12.2.2, we focus on the problems of multi-disciplinary collaboration where TEAS have been identified as potential help. Further on, in Section 12.2.3, we summarize the problem of multi-level governance of semantic resources with an approach based on commons and commoning. Finally, in Section 12.2.4, I describe the main result of this thesis, namely, the work practice for productive work on semantic resources in healthcare which is based on SECOs, TEAS and Commons.

### 12.2.1 From software development to SECOs

Much of the research reported in this thesis is based on technical developments ranging from the development of AI prediction algorithms to very comprehensive national eHealth infrastructures. A brief summary of the technical developments can be found in Table 13 below.

<table>
<thead>
<tr>
<th>Technical development</th>
<th>Referenced in section</th>
</tr>
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<tbody>
<tr>
<td>1 Development of AI algorithms</td>
<td>see paper 2 in Section 11 and a summary of results in Section 12.1.4</td>
</tr>
<tr>
<td>2 Clinically validated care process models</td>
<td>see Section 12.1.3</td>
</tr>
<tr>
<td>3 Development of DHI's</td>
<td>see Section 5 where the eCare project is described and papers 1 and 4 that discuss DHI's in Sections 7 and 10 respectively</td>
</tr>
<tr>
<td>4 OpenEHR-based software platform</td>
<td>see Section 12.1.2</td>
</tr>
<tr>
<td>5 National eHealth infrastructure</td>
<td>see description of the national eHealth project in Section 5, papers 3 and 4 that focus on national eHealth in Sections 9 and 10, and a summary of results involving national eHealth in Sections 12.1.5 and 12.1.6</td>
</tr>
</tbody>
</table>

*Table 13 A summary of technical development that underpins this thesis research*

A connection can be made between all artefacts to form an evolution. Each artefact can be seen as a component of the next artefact. Thus, the AI algorithm could become part of the clinically validated care process models, which in fact became part of the different DHI's in the eCare project. As the project progressed, each DHI was deployed on the OpenEHR-based software platform, which could become part of the national eHealth infrastructure. But along the way, several challenges, listed in Table 12, prevented the transitions from the AI algorithm to the national eHealth infrastructure from taking place.

In this section, we will first learn about the potential of SECOs to address the technical and social challenges identified in Section 12.1 and summarised in Table 12. Then we will try to gain new insights by looking at the whole research as a SECO evolution and viewing it through three different lenses.

As outlined in Section 12.1 and summarised in Table 12, the need for a transition from traditional project-based software development to the modern distributed SECO organisation of software development could perhaps help to overcome the challenges identified in Table 12.
Traditional software development is based on following methodologies that range from waterfall to agile but all primarily focus on the development within one organisation, whereas SECOs support co-innovation between multiple organisations [182], [289]. The challenges from Table 12 themselves are partly technical (IC4 and IC7) and partly social (IC10, IC12, and IC14). SECOs involve multiple perspectives, not only social and technical, but also communication, economy, business and law [289], [290]. According to Dittrich [181], the technical challenges fall under the first main research topic on SECOs - the evolution of software product lines into software ecosystems. The social challenges fall under the second main research topic on SECOs - the interaction between actors in the ecosystem.

We now use the AI algorithm as a starting point to first learn about complexity during their TDS lifecycle, and then try to learn how SECOs might help address the IC7 challenge – the AI algorithm as a platform extension. Then we go on to find out how SECOs could also help with IC4, IC10, IC12 and IC14.

The design and development of such algorithms requires specific expert knowledge. Jiang et al. describe in [291] a very active research community focusing on specific diseases, and for each disease many different AI methods are used to develop such algorithms. Alloghani et al. provide another overview of AI in healthcare in their recent systematic review of the field [292]. The development of AI algorithms therefore requires not only expert knowledge of AI methods and approaches, which is usually the domain of computer scientists, but also expert knowledge of specific medical conditions, which falls within the domain of medical sciences. Before an algorithm can be used in clinical practise, a clinical evaluation must be performed. Such evaluations, also known as prospective studies, seek to show how a particular algorithm performs on real data derived from real patients treated in clinical practise, as it is to be expected that the performance of AI algorithms will degrade in such real-world settings [293].

Moreover, it is quite a different challenge to implement or translate such algorithms in clinical practice [292], [294], [295]. The challenges of implementing an AI algorithm in clinical practise are nicely summarised by Davenport et al: "...AI systems must be approved by regulators, integrated with EHR systems, standardised to a sufficient degree that similar products work in a similar fashion, taught to clinicians, paid for by public or private payer organisations and updated over time in the field" [294]. These implementation challenges require collaboration between different disciplines at all levels of health systems. The success of such collaboration has a direct impact on how receptive a health system is to innovations such as AI algorithms, and how quickly and to what extent innovations are adopted and diffused (see Figure 7 in Section 2.1). It is therefore crucial to plan implementation projects with known considerations in mind (such as those illustrated in Figure 8 in Section 2.1).

Given the complexity of implementing AI algorithms into clinical practise, it is not surprising that there is limited evidence of successful implementations, as highlighted by Klumpp et al. in [296] and Kelly et al. in [293].

The use of AI algorithms by start-ups in novel business models seems to be approaching hype [297]. However, this is not the case for healthcare start-ups. Given the aforementioned complexity of implementing AI algorithms in clinical practise, it is highly unlikely that a small start-up company can survive long enough for its algorithm to be used in clinical practise. It is therefore not surprising that start-ups are not interested in operating in the healthcare sector, as Szijarto points out using Austria as an example [21]. In fact, even large companies like Epic, which may have the resources, find it difficult to implement. A prominent example of what has been called a failure is the low clinical utility of the Epic Sepsis Prediction Model [298], [299].
From the above overview of the complexity of implementing AI algorithms in healthcare, from the observation of Klumpp et al. in [296] that the implementation of AI algorithms is both a research and a management problem, and from my experience with the AI algorithm I reported in paper 2, we can learn that successful implementation of an AI algorithm in clinical practise is only possible if there is continuous collaboration between the different stakeholders - doctors, nurses, patients, authorities, software companies, etc., during all TDS phases, takes place. Stakeholders must be able to engage in the TDS lifecycle phases of the AI algorithm as needed. This means that an AI algorithm requires constant collaboration not only in the design and development phases, but also in the TDS phases of evaluation and implementation, suggesting Design in Use [282], also identified by Dittrich as a characteristic of SECOs [181].

In my research, I see software platforms as enablers of SECOs to support such a different organisation of software development, where projects are no longer the primary way of organising work [181]. In this particular focus on AI algorithms, SECOs enable a move away from a highly technical approach to the design and development of AI algorithms by viewing software development as a distributed activity that spans many stakeholders in one or more SECOs and where new stakeholders can always be added. Within SECOs, continuous innovation is even possible across multiple SECOs. Besides design in use, Dittrich observed other common features of SECO-oriented work, namely distributed design, more complex technical design and development that takes place in cycles within cycles [181].

These properties of SECOs can help us with our challenge with AI algorithms, which is to use the algorithm as a platform extension that allows new products to be built on top of the algorithm. The algorithm alone is only a partial design of the overall product, which will only become a complete product when many SECO members/software companies provide their partial designs. The design of the product based on the AI algorithm is thus distributed within one or more SECOs. Since the AI algorithm is considered as a stand-alone component deployed on a software platform, its technical design must be more complex (compared to the traditional approach of software product development by a single company) to enable its use as a component of a new software product. Finally, the development of the encapsulating software product is now mostly done within cycles as part of agile development approaches. But the development of the AI algorithm is also done within cycles. The hierarchical relationship between the encapsulating product and our AI algorithm also suggests their development in cycles within cycles. SECOs allow our algorithm to become a platform extension, even if it is not a full-fledged product that can be used by end users.

Looking back at the technical developments of this thesis, summarised in Table 13, the clinically valid care process models (challenge IC4 in Table 12) can encapsulate the AI algorithm, but are also considered as platform extensions or boundary resources of a software platform that can be used to define new products that encapsulate or embed the process models. So we can say that SECOs provide a way to solve the IC4 challenge by helping turn clinically validated care process models into platform extensions.

We can apply the same SECO reasoning for all the technical developments in Table 13. By organising the development of each of the technical artefacts in Table 12 in a SECO way, drawing on the SECO properties discussed above, the link between all the artefacts that we set out at the beginning of this subsection, where each artefact can be seen as a component of the next, could actually become a reality. Each of the artefacts would be developed by one or more
SECO members, and each SECO member would need to have a clear strategy for the three main SECO levels, according to Jansen et al [180]. At the SECO level, companies have to decide on their behaviour within SECOs in order to maximise their profit. The level below is the software supply network level, where buyers and suppliers are strategised. The third level is the software vendor level, where companies determine the influence of SECOs on their product and service portfolio, knowledge management and relationship management [180]. Christensen et al. have focused on three main SECO structures or aspects [185], namely the organisational structure of SECO participants, the structure of the software and the business structure. As was already pointed out in Section 3.2, Manikas [300] defines (1) four ways of organising SECOs (monarchy, federal, collective and anarchy) depending on how SECO actors are involved in decision-making, (2) three types of SECOs according to the value creation that the SECO business structure represents (proprietary, open source, hybrid), and (3) four options for the software structure (platform, protocol, standard and infrastructure).

If one were to try to define a SECO that would help address the challenges in Table 12, the optimal SECO software structure would be the shared platform. A shared platform would enable new types of boundary resources such as clinically validated care process models and AI algorithms. Furthermore, a shared platform would need to define its architecture based on open standards (e.g. OpenEHR).

In terms of business structure, a hybrid SECO design seems to be the best fit, as it allows both open source and proprietary software as the basis for value creation. In our case, the software platform based on OpenEHR is open source, while the national eHealth platform is mostly proprietary software, in some cases based on open standards. If software companies participate with purchasers in a SECO that is seen by all SECO participants as part of their strategies, one can imagine that the level of collaboration with software companies and between software companies (challenges IC10 and IC12 in Table 12) will improve. Furthermore, since SECOs are seen as strategic, any kind of participation (challenge IC14 in Table 12) needed to achieve their strategy at SECO level that allows companies to maximise their profit would not be a problem.

The organisational structure of our SECO seems to be the least clear. However, we can say that anarchy is not an option, as healthcare is a highly regulated and complex environment (see Section 2). Thus, a SECO for health could not organise itself without becoming part of this regulated and complex environment, where some stakeholders have more power in decision-making. It seems therefore that a federal SECO organisation could be the closest to reality, with the hope of achieving a collective organisation in the future.

Due to the lack of research on SECOs in health (see Section 3.2), we try to gain new insights by looking at all the research as a SECO evolution and viewing it through the three lenses we introduced in Section 1 and discussed in sections 3.2.1, 3.2.2 and 3.2.3, namely the evolutionary mechanisms of digital artefacts, the institutional theory niche, regime and landscape levels, and platformisation and generative entrenchment. These theoretical lenses help to define general strategic guidelines for SECO participants and in particular provide guidance on content and interoperability, as this is the main focus of this thesis.

**SECO Strategy Guidelines for more optimal SECO strategies**

We begin by presenting the projects and research findings of this thesis as a SECO evolution, as shown in Figure 22.
The figure above shows a line of socio-technical artefacts depicted as squares. Two artefacts are connected by sociotechnical transitions (SCT). The idea here is that the AI algorithm is first embedded into a DHI. For the embedding to happen, not only technical but also social enveloping occurs over the AI algorithm. Further on, the DHI is embedded into a local platform (the OpenEHR-based software platform) in a different SCT. Becoming an add-on to a platform, the DHI becomes available to a wider ecosystem of users and other providers that can perhaps improve it or use it in their own user base. This means that the DHI on the platform needs to go through additional SCT to become used in the local ecosystem. In this research, such a platform is the eCare OpenEHR-based software platform and the ecosystem is represented by the partners in the eCare project (Golnik Hospital for pulmonary diseases, Primary healthcare providers treating diabetes patients, National Institute of Public Health).

Further down the line of Figure 22, the national eHealth platform is depicted as the next artefact. The SCT towards it was in fact a great research inspiration that sparked interesting research.

The last artefact depicted on the right side of Figure 22 is the national healthcare ecosystem that represents the health system of Slovenia. The DHI should thus become available as an add-on to the national platform to be available to a wider health ecosystem. There are many obstacles to be handled before such a SCT can become possible in Slovenia such as the ones dealing with platform openness.

Extracting additional observation from the SECO evolution described above can perhaps help future DHI designers to plan their implementation projects in a more optimal way to achieve the goal of having medical professionals using their DHIs. We now proceed with the analysis using the three theoretical lenses.

**Evolutionary mechanisms analysis**

We can view the brief description of the evolution of our algorithm through the lens of the evolutionary mechanisms of digital artefacts as proposed by Schlieter et al [190]. They recognise four basic evolutionary mechanisms, namely: (1) mutation and (2) migration, which introduce variation, and (3) natural selection and (4) genetic drift, which pass on variation.

The algorithm evolution described above seems to best fit the migration mechanism, which allows design artefacts to be transferred to another context, creating their own evolutionary lineage [190]. This means that artefacts can evolve quite differently from what the original designers and developers imagined and produced. With digital products now at the core of many young businesses, created through constant adaptation to end-user needs, it may not be natural for products to naturally evolve into something different in the context of healthcare SECOs, where multiple stakeholders have a say in product development. This fits well with why in this study we have considered AI algorithms or perhaps clinically validated care processes as platform add-ons rather than whole solutions/applications as is traditionally the case. In healthcare, even such small components are complex to design, develop, evaluate and implement. But having an ecosystem available to create products from such components is perhaps an interesting idea. Therefore, to capture the relevance of evolutionary migration mechanisms within healthcare SECOs, we can extract our first SECO guideline that
summarises the above analysis. We refer to the SG -1 guideline as an acronym for SECO Guideline #1 and call it *Evolutionary migration mechanism* to illustrate the relevance of migration as a highly interesting and likely way in which an artefact evolves in its lifecycle within a healthcare SECO. The SG -1 is also summarised in Table 14.

In this evolutionary migration view, our algorithm starts a new evolutionary line each time it evolves in our description of Figure 22 and throughout the research. Therefore, in each of the evolutionary steps where the embedding of artefacts into another artefact occurs, a new evolutionary line begins, which is an evolution in its own right. Thus, the evolution of the algorithm at the starting point has a different evolutionary line than that embedded in other artefacts. In this view, some evolutionary lines may die off and those where the algorithm goes through the various required embeddings would prove to be the most appropriate. The crucial point here is to decide on the right embeddings. Such decisions are made at the SECO level [190] as part of a SECO strategy where the algorithm provider has to figure out its position in SECO and how it can benefit from being part of SECO. This constant positioning within a SECO is what we see as *SG-2 Monitor artefact position within SECO*, summarised in Table 14.

In terms of SECO strategy, the more successful SECO participants would be those who are able to predict the best line of development for their product/service. Since a provider cannot afford to try all options, it has to prioritise its choices. To address this need to predict/prioritise lines of development for products/services, we introduce the next guideline *SG3 Simulate/Discover lines of development* which is also summarized in Table 14.

The next guideline might give you some guidance on what to look for when predicting the best line of development for products/services. Some of the key aspects that need to be considered and are a critical focus in this thesis, are delivered content (DHI) and interoperability. We summarise these two crucial elements of this work, which are also crucial in healthcare more generally (see Section 2 for more details), under *SG4 Focus on content quality and interoperability*. The main results of this thesis focus either on the creation of high-quality content for DHIs (see e.g. Section 12.1.1 ) or on interoperability in healthcare (see e.g. Section 12.1.5). The fact that even the main result of this thesis focuses on how to achieve productive work on semantic interoperability (see Section 12.2) underlines the relevance of SG4 and its inclusion in Table 14. For this reason, SG4 is expanded into its own set of guidelines focusing on content quality and interoperability that could be useful for the SECO software vendor level, the lowest SECO level. We discuss these guidelines in more detail in Section 12.2.1. Now we turn our attention to the middle SECO level - the level of the SECO supply chain, which includes not only the providers but also, and more importantly, the buyers. In order to highlight some interesting findings at this middle SECO level, especially with regard to how buyers can be better supported, we now focus on extracting guidelines that include these findings.

*Analysis based on institutional theory and the role of platforms*

The problem of bringing our AI algorithm from Figure 22 into clinical practise can also be analysed through the lens of the three analytical levels of institutional theory that we briefly introduce in Section 3.2.2. This institutional theory provides an additional understanding of why it is so difficult to innovate in health systems, especially as the typical health system itself is also considered at three levels, namely the micro level (clinical), the meso level (organisational) and the macro level (regional or national) [301]. The development of an algorithm is typically an innovation-driven activity at the niche level. From this point of view, our AI algorithm from Figure 22 can move from the niche to the
regime - the national level - but only under certain conditions. These conditions were at least partially explored in Paper 4, where we tried to understand the design theory behind theoretically successful government-operated open eHealth platforms as a means of moving from the niche to the regime level, and used this theory to analyse the national eHealth platform in Slovenia. In our case, the national eHealth platform in Slovenia was not yet ready to support such leaps from the niche to the regime level, suggesting, however, that the transition from the niche to the regime level could indeed be supported by government-owned or government-operated open platforms. However, there is very little evidence of government software platforms in the health sector and their SECOs. See, for example, Christensen [185] and Marcos-Pablos [188].

This is despite their importance in the health sector, as Faggini [302] points out. He makes many arguments for digital platforms in the health sector and calls for the increased establishment of digital platforms to achieve the long-term sustainability of health systems. This view on government-owned platforms represents an important element for the sustainable implementation of DHI s in health, which brings us to the next SECO guideline in Table 14, SG-5 Consider government-owned open platforms to break from the niche to regime level.

Such government-managed health platforms are difficult to implement and scale, and do not yet represent exploited potential [302]. They become part of the institutional infrastructure and thus part of a highly regulated environment where achieving a sufficiently high level of openness is a problem (as also shown in Paper 4) that could lead to sustainability problems and platform closure in the long run.

Platform openness is a complex issue (see Setzke [303] for five aspects of platform openness) but the right level of platform openness is a crucial requirement for the government owned open platforms, which was also identified in this research. Unfortunately, the Slovenian national eHealth platform was nowhere near open enough (see Paper 4) to facilitate the transition of the AI algorithm or any of the DHI s to the regime level. Particularly problematic were the business aspects, which were unclear and non-existent. To illustrate this importance of platform openness, we add in Table 14 SG-6 Evaluate platform openness.

The difficulty in achieving openness in healthcare software platforms that are owned by the state is perhaps due to the fact that there are often a variety of laws that support the operation of these platforms, making the concept of open platforms difficult to achieve. Nevertheless, it may be possible to achieve partial platform openness by focusing on the interoperability potential of the platform.

Partial consideration of platform openness by focusing on the interoperability potential of the platform

The interoperability potential is also referred to as the extensibility of platforms, which is a crucial element for the openness of platforms to new solutions and communication cases [304]. In this thesis, we focused on OpenEHR, which allowed us to focus not on specific situational interoperability, which focuses on the ability to adapt an interface to similar communication events, but rather on platform interoperability potential - the ability of a system to respond to previously unknown interoperability requirements (previously unknown communication scenarios) [305]. Unfortunately, interoperability potential is difficult to measure, and this work has not focused on interoperability maturity models, e.g. ISO 11354.211, which we could use for this purpose [305]. However, as interoperability potential is an important step towards

platform openness, it is captured in Table 14 as the *SG-7 Assess platform interoperability potential*. The use of interoperability maturity models for measuring platform interoperability potential is captured in *SG-8 Use interoperability maturity models to measure interoperability potential*.

**Semantic interoperability a key element of SECO strategy leading to dominant designs**
In my research, the main research question focuses on semantic interoperability. In particular, the interoperability potential of platforms is increased if semantic interoperability is solved well enough. Therefore, I see work on semantic interoperability as the key prerequisite for SECOs to operate in the health sector in a way that supports focus on strategic lines of development of e.g. AI algorithms, instead of dealing with lack of interoperability and SECO mentality, as is the case in Slovenia. It seems therefore that SECO's would become more expansive if semantic interoperability was solved and this would open more opportunities for SECO participants. There would be no problem if several embedded solutions with similar functionalities were offered, as each of these embeddings would develop independently. Over time, some of these embeddings could become dominant designs. However, in such a future, the focus would not be on preconditions (e.g. interoperability) but on solving the real problems and supporting patients, health professionals and other stakeholders to achieve more effective and efficient health systems.

So far, we have learned about the evolutionary line that begins each time a new embedding of our AI algorithm is made. This embedding has been described as a socio-technical transition involving people, organisations and technology. What connects all of these are the SECOs. Indeed, a SECO consists of technical, organisational and business aspects and can therefore be used to better describe the socio-technical transitions as well as the evolution of the algorithm. I see the evolution of the algorithm towards an open platform used by third party developers that together form the software ecosystem as part of the research on the development of product lines into software ecosystems as presented by Dittrich [181]. Therefore, it is not sufficient to look at our algorithm from the perspective of software evolution, a well-researched area where the complexity of software evolution was observed several decades ago as laws of software evolution [306]–[308], to understand the overall evolution of the algorithm observed in this research.

In this evolution, there are specifics of the health system, such as evaluation in randomised clinical trials or classification as a medical device, the role of the government as a platform operator, and institutional theory.

The evolution observed in this thesis extends the traditional SECO evolution. In a healthcare environment the trust of healthcare professionals in the software and in our algorithm is crucial, so implementing future changes is a major challenge. The trust must be long-term. Because the algorithm in question can be used to predict the future health of patients, it falls into the category of medical devices, which are much more difficult to change compared to more traditional software products. Therefore, strict regulations can be a major burden for software related to healthcare. In terms of the evolutionary lineage of digital artefacts, the notion of 'fittest' suggests that those best suited to the existing values and culture are those most trusted by healthcare professionals. We summarise this as the next guideline in Table 14, namely, *SG-9 Trust as a metric*.

Such a view of the development of our algorithm further complicates the role of a SECO architect who has to take into account the typical technology development steps of the healthcare innovation process, as used in the introduction of the thesis. This is also the key reason for using TDSs in this thesis - to raise awareness of the need for a different view of
software development, which we capture in *SG-10 More than software development*. In addition to TDSs, such a different view is represented by DHIs, which consist of many embeddings (think of adding onion layers) of an algorithm to deal with the bounded confidence of medical professionals [281].

Algorithm evolution and generative entrenchment

The final view of observed algorithm development in is a process reconstruction for software platforms in the health sector. As pointed out by Fürstenau [309], such platforms are founded by start-ups or governments. This process of establishing platforms is also referred to as the platformisation process, which is defined as the gradual accumulation of additional layers that expand the functionality and scope of existing systems while reinforcing their entrenchment (anchoring), i.e. social and technical elements become the basis for new initiatives that in turn further stabilise these social and technical elements [192].

Generative entrenchment is good for OpenEHR, AI algorithms or any other element of a software platform because it helps establish it as an installed base from which platforms expand and grow. Installed bases change but are difficult to replace. That should be the goal of any government software platform, which is why its architecture is so much more important. We sum up this need for generative entrenchment in our next guideline, namely that without a proper architecture, not only the platform but also the ecosystem could lead to new types of lock-ins with government platforms. Indeed, we can learn from paper 4 that the national eHealth platform in Slovenia suffers from lock-in because it does not sufficiently fulfil the organisational design theory of eHealth platforms in terms of platform openness. We capture this importance of architecture and governance rules as two critical elements for platform success [107] in *SG-11 Consider platform architecture and governance rules*. The status of the national eHealth platform in Slovenia, as assessed in paper 4, requires improvement of the two crucial elements - the architecture and the governance rules. To capture this necessary continuous improvement of the crucial elements of platforms Table 14 provide the *SG-12 Plan for improving the platform architecture and governance*.

In my research, I also see generative entrenchment as a problem that is becoming more difficult to solve over time. It is the basis for the numerous lock-ins in the health system. Indeed, as my interest is focused on the problem of semantic interoperability and my research provides evidence and solutions to this problem, I am concerned with the need to achieve less dependence on the existing platform/information infrastructure in healthcare in Slovenia and in general. By working on commons and commoning, I conceive a way to gradually replace the existing installed base (proprietary formats and semantics of clinical data used differently by different software providers). To achieve this, the same generative entrenchment process is required for the new working practise for productive work on semantic resources to become installed base. Therefore, although generative entrenchment has enabled software vendors to arrive at the current lock-in based business models (I understand that companies want to achieve such lock-ins to create long-term business opportunities), it should also be seen as an opportunity to support a transformation where the focus is centrally on interoperability based on shared semantic resources. The *SG-13 Plan to achieve generative entrenchment - becoming part of the installed base of platforms* captures this relevance of generative entrenchment not only as a problem but also as a solution to achieving semantic interoperability in healthcare. Furthermore, generative entrenchment is also a process by which the products/services of individual software providers can become part of the installed base. However, the most important point is to consider SG-4 and focus on content and interoperability as crucial aspects to become a dominant product/service within a SECO. SECOs and SECO-based business
models offer viable alternatives to software vendor lock-in [310]. As suggested in the literature, SECOs can help to create alternative revenue streams [310]. For this, the development of a SECO mentality is of great importance, which is described in *SG-14 Implement a SECO mentality*.

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<thead>
<tr>
<th>ID</th>
<th>SECO Strategy Guideline Name</th>
<th>SECO Strategy Guideline Description</th>
<th>Grounding</th>
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<tbody>
<tr>
<td>SG-1</td>
<td>Evolutionary migration mechanisms</td>
<td>Use evolutionary migration mechanisms to plan the evolution of your product/service in a SECO as these allow transfer of design artifacts to a new context. With each such transfer, a new evolutionary line is started.</td>
<td>Schlieter et al. [190]</td>
</tr>
<tr>
<td>SG-2</td>
<td>Monitor artifact position in SECO</td>
<td>Constantly monitor the position of your artefact within a SECO to maximize its likelihood of becoming the fittest – a dominant design.</td>
<td>Schlieter et al. [190]</td>
</tr>
<tr>
<td>SG-3</td>
<td>Simulate/discover lines of development</td>
<td>To decide on best embeddings, simulate or discover different potential evolutionary lines based on how well each optimizes the artifact position within a SECO. The chance of trying all the possible evolutionary lines decreases as the size of the SECO increases.</td>
<td>Schlieter et al. [190]</td>
</tr>
<tr>
<td>SG-4</td>
<td>Focus on content quality and interoperability</td>
<td>Use the framework presented in the analysis above to identify embeddings that have the greatest impact on <em>SG-8 Trust as a metric</em> and can be used in <em>SG-3</em>. This means focus on content quality and interoperability are crucial – based on the results obtained in this thesis.</td>
<td></td>
</tr>
<tr>
<td>SG-5</td>
<td>Consider government-owned open platforms to break from the niche to regime level</td>
<td>Such platforms are seen as a way to support sustainable health systems. Their number is growing.</td>
<td>Faggini [302]</td>
</tr>
<tr>
<td>SG-6</td>
<td>Evaluate platform openness</td>
<td>Government-owned platforms are usually not fully open. Use organizational design principles used in paper</td>
<td>Setzke [303]</td>
</tr>
<tr>
<td>SG-7</td>
<td>Assess platform interoperability potential</td>
<td>Evaluate possibility to extend the platforms with the focus on semantic interoperability. OpenEHR improves the interoperability potential of platforms by improving semantic interoperability. Better interoperability potential means better adaptability to new unknown communication scenarios. This affects costs of embedding your artefact and with this the probability of your artefact becoming a dominant design. Better interoperability potential suggests better platform openness – SG-5.</td>
<td>Benedict [305], Tiwana [304], OpenEHR</td>
</tr>
<tr>
<td>SG-8</td>
<td>Use interoperability maturity models to measure interoperability potential</td>
<td>Such models are e.g. the ISO 11354.2. With this, you support SG-6.</td>
<td>Benedict [305]</td>
</tr>
<tr>
<td>SG-9</td>
<td>Trust as a metric</td>
<td>To measure the position of your artifact within a SECO, measure trust by the crucial stakeholders. In case of healthcare, these are e.g. doctors. With this, you maximize alignment to their culture and values and with this improve the probability for your artifact becoming a dominant design.</td>
<td></td>
</tr>
<tr>
<td>SG-10</td>
<td>More than software development</td>
<td>One should rather think of Technology Development Stages in healthcare instead of focusing solely on software development to be more aware of the complexities inherent</td>
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with software development in healthcare such as for example with our DHIs.

<table>
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<tr>
<th>SG-11</th>
<th>Consider platform architecture and governance rules</th>
<th>Platform architecture and governance impact possible new initiatives on platforms. Evaluating these two main mechanisms of platformization helps make more optimal decisions on embedding your artefact within the particular platform.</th>
<th>Tiwana [107], Paper 4 in Section 10.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SG-12</td>
<td>Plan for improving the platform architecture and governance</td>
<td>With this, you influence on reinforcing the architecture and governance and consequently influence platform stability. This increases the chance for your artifact to eventually become a dominant design.</td>
<td>Tiwana [107], Paper 4 in Section 10.</td>
</tr>
<tr>
<td>SG-13</td>
<td>Plan to achieve generative entrenchment - becoming part of the installed base of platforms</td>
<td>With this, you increase the likelihood of your artifact becoming a dominant design. Do not forget SG-4 and prevent new types of lock-ins or loose the buyers in the SECO supply chain.</td>
<td>Section 3.2.3</td>
</tr>
<tr>
<td>SG-14</td>
<td>Implement a SECO mentality</td>
<td>One part of the SECO mentality is seeing SECOs as sources of new income channels.</td>
<td>Section 3.2</td>
</tr>
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</table>

Table 14 SECO strategy guidelines extracted from the analysis of the SECO evolution through different views. Grounding refers to different literature and introductory sections of this thesis. Implicitly, grounding is also provided by the detailed analysis above.

Guidelines for content and interoperability in DHI design, development, evaluation and implementation

Based on the exploratory and emerging research reported in this dissertation, the design, development, evaluation and implementation of DHIs can be better planned if multiple guidelines are considered. The guidelines have been identified as important in 10 years of work in various health-related projects and are supported by the current literature. The guidelines presented in Table 15 are also considered as strategic guidelines (SG -4) within the SECO strategic guidelines, as presented in Table 14. In addition, they also represent the mid-level SECO findings focusing on the SECO supply chain where buyers/end-users are crucial actors. In the following, we will elaborate on each guideline based on our previous projects, published materials and literature.
In the introductory sections 1 and 2, I introduced DHIs as a particular type of healthcare innovation, presented the complexity of innovating in healthcare and pointed out the lack of guidelines that would help with the life cycle of DHIs, which starts with design and ends with implementation. From a purely technical perspective, the lifecycle of a DHI is usually somewhat simpler than when considering a broader healthcare perspective. In particular, the need to provide clinical evidence (see Section 1.2) for DHIs has meant that TDSs have had to be introduced to align all previous projects and research with this broader healthcare perspective (see Figure 16 in Section 5). The eCare project, but also projects such as the national eHealth in Slovenia (see Section 5 for more information on the projects), started primarily as very technically oriented projects. For this reason, many interesting solutions have not reached implementation in the clinical practise of the Slovenian healthcare system. Take for example the AI algorithm for glucose prediction from Paper 2. One of the main problems why such interesting solutions have not been adopted in the health system is the misconception of their life cycle. For example, the need for evaluation was not taken into account when planning eCare and other projects (the pharmaceutical and medtech industries are much more aware of this need). To capture the importance of understanding and knowing the correct life cycle of healthcare innovations such as DHIs, the first guideline in Table 15 was created and named GCI-1 Healthcare innovation process awareness in DHI design.

To take a further step towards the first phase of TDS, the design phase, this thesis shows research findings on various challenges in designing the content of DHIs. In Paper 1 and its results discussion, we learn about an attempt to capture structured behavioural knowledge that can be used computationally. The theoretical basis for such computational models is behavioural theory and BCTs. In Section 12.1.1. and in Paper 1, DHIs based on behavioural theory are referred to and referenced as theory-based DHIs. Such DHI represents a theory nexus. The relevance of theory underpinning DHIs is presented in Table 15 as GCI-2 Design of DHI content should represent a theory nexus. This is important because such theory-based DHIs have been shown in the literature to be more effective in supporting behaviour change needed to improve patient health outcomes (see e.g. [228], [248]).

As mentioned in Section 12.1.1, Slovenia lacked competent experts capable of developing theory-based DHIs. To solve the problem, the suggestion was made to establish a national organisation that would help with knowledge transfer from abroad [248]. This need for organisational support to achieve theory linkage in DHI design is captured in Table 15 as GCI-3 Ensure organizational support to achieve theory linkage in DHI design.

Besides pointing out the relevance of DHI content as a theory nexus, interoperability is the other crucial aspect of DHI design. The eCare and national eHealth projects (see Section 5) have been important venues for testing new approaches to semantic interoperability based mainly on OpenEHR and complementary approaches such as SNOMED, IHE and Continua (see, e.g. Paper 3). To reflect the need to focus not only on technical aspects of interoperability, but also on organisational and governance aspects, Table 15 introduces GCI-4 Focus on interoperability from technical aspects and GCI-5 Focus on interoperability from organisational and governance aspects.

Working on semantic interoperability is thus a complex task that requires multidisciplinary collaboration. Software vendors and other key stakeholders such as healthcare professionals need to be able to collaborate in a new way where lock-in-based business models are not viable, but SECO-oriented business models that enable multi-stakeholder collaboration and represent a different paradigm in the way software development takes place (see SECO focused discussion in 12.1). As software is no longer designed and developed as a product by a single vendor, but rather is a collaborative effort of many software vendors within a SECO, the need
to design DHIs to include participation in SECOs must be captured. To this end, Table 15 introduces **GCI-6 Design for participation in healthcare SECOs**.

In the introductory Section 1 and most recently in the above text we have pointed out the great need to understand evaluation as a crucial step in the DHI life cycle, where clinically valid evidence can be generated that is required for the use of DHIs in clinical practise. This need is captured in Table 15 as **GCI-7 Design DHIs to support healthcare evaluation methods**.

The final phase of the DHI lifecycle is implementation. This work explored the use of open platforms to support the DHI implementation phase. As suggested in the literature and most recently outlined in this thesis in Section 12, platforms are seen as enablers of SECOs and can thus help to achieve the multidisciplinary collaboration required to not only design, develop and evaluate DHIs, but also implement them in clinical practise. To capture the relevance of open platforms, Table 15 presents the **GCI-8 Plan DHI implementation using open platforms**. As also discussed in Section 12.1.3, this is necessary because DHIs can be designed and developed to complement a platform around which a SECO of providers could help create end-user solutions.

The discussion of the socio-technical transitions of our AI algorithm artefact in Section 12.2.1 goes on to say that each time an artefact is introduced into a new environment, embedding takes place. This means that the artefact can be adapted or appropriated to be usable in the given context, which includes not only technical but also social aspects. Therefore, it is important to capture the relevance of planning for such embedding. Table 15 presents the awareness of embedding in the **GCI-9 DHI implementation plan** for this purpose.

As much of this work focuses on semantic interoperability, **GCI-10 Semantic interoperability as a prerequisite for DHI implementation** in Table 15 captures the need to design semantically interoperable DHIs to support successful implementation in clinical practise in the future. As discussed in part in all the papers and then additionally in Section 12.1 on the findings, there is a need for technical and social co-development and co-evolution of the technology, particularly if semantic interoperability is to be achieved.

<table>
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<tr>
<th>ID</th>
<th>Guideline Name</th>
<th>Guideline Description</th>
<th>Grounding</th>
</tr>
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<tbody>
<tr>
<td>GCI-1</td>
<td>Healthcare innovation process awareness in DHI design</td>
<td>Be aware of the healthcare innovation process – particularly the TDSs when planning your project – budget accordingly or expect your DHI to fail.</td>
<td>Section 2.1, Section 1.2, Figure 16 in Section 5, Section 5, paper 2 in Section 8,</td>
</tr>
<tr>
<td>GCI-2</td>
<td>Design of DHI content should represent a theory nexus</td>
<td>The DHI design should be informed by behavioural theory; the methods used in this research can guide to better use of the behavioural knowledge in DHI design and development.</td>
<td>Section 7, Section 12.1.1, [228], [248]</td>
</tr>
<tr>
<td>GCI-3</td>
<td>Ensure organizational support to achieve theory linkage in DHI design</td>
<td>Designing theory informed DHIs requires organisational support</td>
<td>Section 12.1.1, [248]</td>
</tr>
<tr>
<td>GCI-4</td>
<td>Focus on interoperability from technical aspects</td>
<td>This includes at least model-driven development, a new layer in the software architecture, and a new way of storing data.</td>
<td>Section 5, Section 12.1.2, paper 2 in Section 8, paper 3 in Section 9, paper 4 in Sections 10, paper 5 in</td>
</tr>
<tr>
<td>GCI-5</td>
<td>Focus on interoperability from</td>
<td>This includes participating in the new work practice (RQ1) for productive work on semantic</td>
<td></td>
</tr>
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</table>

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<table>
<thead>
<tr>
<th>GCI-6</th>
<th>Design for participation in healthcare SECOs</th>
<th>Plan for participating in healthcare SECOs and even help others do so.</th>
<th>Sections 12.1.3, 12.1.5, 12.1.6, 12.1.7, and 12.2.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCI-7</td>
<td>Design DHIs to support healthcare evaluation methods</td>
<td>The capacity and functionality to support randomised clinical trials or other evaluation methods (see e.g. [311] for single case design or N-of-1) need to be built into DHIs to align with medical professional’s culture and existing work practices and to build the trust of the medical professionals.</td>
<td>Section 1</td>
</tr>
<tr>
<td>GCI-8</td>
<td>Plan DHI implementation using open platforms</td>
<td>Open platforms are a way to support a SECO of DHI providers.</td>
<td>Section 12, 12.1.3</td>
</tr>
<tr>
<td>GCI-9</td>
<td>DHI implementation plan</td>
<td>Strategically decide on how to embed your DHI when becoming part of a SECO.</td>
<td></td>
</tr>
<tr>
<td>GCI-10</td>
<td>Semantic interoperability as a prerequisite for DHI implementation</td>
<td>Semantic interoperability is crucial for successful DHI implementation.</td>
<td>Paper 1 in Section 7, paper 2 in Section 8, paper 3 in Section 9, paper 4 in Sections 10, paper 5 in Section 11, and Section 12.1</td>
</tr>
</tbody>
</table>

| Table 15 Guidelines for content and interoperability within DHI design, development, evaluation and implementation. Grounding refers to different literature and sections of this thesis. The above analysis is implicitly also grounding these learning. |

The above guidelines are related to the need for software companies to collaborate on OpenEHR semantic resources. Work on semantic resources should become part of all three levels of SECOs [290]. At the ecosystem level, where companies are trying to define their role in the SECO to maximise profit, it should be clear that those companies that participate in multi-stakeholder collaboration on semantic resources can make more profit. Our SECO strategy guidelines presented in Section 12.2.1 could potentially help at this level. This improved gain can be seen as achievable as the software supplier network, the second SECO level, involves suppliers and especially buyers who might need semantic interoperability based on shared semantic resources. Moreover, the buyers themselves should be actively involved in the multidisciplinary work on semantic resources. The third SECO level is the software vendor level. At this level, software vendors determine the impact of SECOs on their product and service portfolio. In terms of semantic resources, they should be used in the different products or services to meet the needs of the buyers. Our second set of guidelines, presented in Section 12.2.1, attempts to provide additional support at this level.

The analysis of our research in the SECO evolution has thus resulted in two sets of guidelines. The first set, which is discussed in Section 12.2.1, focuses on the SECO strategy level - the top SECO level. The second set of guidelines is discussed in Section 12.2.1 and focuses more on the lower SECO level - the software provider level, by providing our findings at the level of specific software products, namely our DHIs. The middle SECO level, the supplier network, which also includes the buyers or end-users of specific software products, is where we see the entry point for joint multidisciplinary productive work on semantic resources. As we have discussed in the various deliverables of this work and their relevance to this work, we have identified the need for new activity spaces known as TEAS as a new concept that can help establish this necessary multidisciplinary collaboration.
12.2.2 Multi-disciplinary collaboration and TEAS

The second challenge that emerges from the Section 12.1 results is the collaboration between different professionals. This challenge was brought forward in the work on OpenEHR semantic resources (challenges IC2 and IC5 in Table 12), as well as in other types of knowledge engineering tasks, such as behavioural knowledge capture (challenge IC1 in Table 12). In addition, collaboration between different professionals has been point out as a challenge in the AI algorithm design, development and implementation (challenge IC6 in Table 12), implementation of national health interoperability (challenge IC8 in Table 12), and organisational design principles for open eHealth platforms (challenge IC11 in Table 12). In its essence, collaboration is a social element of technology development. Due to this identification of social aspects of technology development as a challenge in all the technical developments of this thesis (see Table 13), it comes natural to consider technology design, development and implementation as holistic social and technical co-design and co-evolution that is identified as challenge IC13 in Table 12.

TEAS is a new concept introduced in this thesis as a possible answer to the challenges of inter-professional collaboration. A TEAS can be seen as a continuous task-artefact cycle in which artefacts are used in a particular user's task/practise to support intrinsic practise transformation [312]. As recently pointed out by Dittmar [313], this view on users being everyday designers in their own environments or activity spaces and causes intrinsic practice transformation is, unfortunately, rarely the focus of designer-user relationships. Mostly, artefacts that are to be appropriated to a particular practice are introduced from the outside causing extrinsic practice transformation [312], [313]. In this thesis, I consider intrinsic practice transformation as the design objective to be pursued, especially in the field of healthcare as medical doctors, for example, do not accept the role of being just appropriators of digital artifacts that somebody else introduced. Here we recall the complexity of innovating in healthcare that we introduced in the background discussion in Section 2. A health system is a complex adaptive system in which relationships between different actors on different levels of health systems influence how well a health system is receptive of some innovation. In our research, none of the digital artifacts have been successfully accepted into the health system which suggests low receptiveness of the health system for the different innovations, including the national eHealth platform. In my view, a major problem was in attempting to achieve extrinsic practice transformation by forcing new digital artifacts into the health system, when the focus and support should actually be directed towards achieving intrinsic practice transformation. In such a scenario, the intrinsic practise change would also influence the artefact, which also would need to change. Both the artefact and the practise influence each other until convergence is achieved, the artefact is sufficiently appropriated, and the practise can use it in its daily activities. I think that only by focusing on supporting the co-evolution of the social and the technical in the design, development and implementation of technologies, implementation of digital artifacts can actually happen in health care settings. The technology enhanced activity spaces are needed to enable a bridge between the differences in knowledge, culture and value systems of different professional groups (medical doctors, health psychologists, computer and information scientists, software developers and bioinformaticians).

Therefore, the co-evolution of the social and the technical where Dittmar’s [313] co-reflection of designers and users occurs is in my opinion necessary for productive work on semantic resources, for the design, development and implementation of DHI and for any other kind of
technology that may include information infrastructures (e.g. platforms, terminologies, OpenEHR,...) in healthcare. In this view, the experience of medical professionals is not something that can be designed but is something that is “personal, situated, emergent, mediated by shaped artifacts” and considers digital artifacts as a cultural phenomenon [313]. Such expansion of the viewpoints on users and their needs has evolved from purely focusing on functionality and usability towards including aesthetic, emotional and social aspects of interaction [313].

In order to be able to support such intrinsic practice transformation in which digital artifacts and work practices co-evolve and change each other, changes in software development needs to happen to support the development of such digital artifacts. Compliant with the ideas of TEAS but focused also on the software development is work on designing for appropriation by e.g. Tchounikine in [314].

According to the viewpoint of Tchounikine in [314] that is based on activity theory, a digital artifact/software is considered as instrument for users in the context of their activities only when it allows users to achieve a task that users consider in the way they consider them. Tchounikine thus suggests that the key notion in appropriation is not that of artifact but of an instrument [314]. This means that users try to turn software into their instruments. The way users create instruments from software is based in the way they perform their tasks in the first place. Therefore, each could in fact create a special version of the instrument. This focus on instruments is what differentiates users from designers. Designers are focused on artifacts that are appropriations of technology, while instruments are what users create. By doing so, users tackle their, as defined in [315], instrument-artifact tensions to create instruments that support interacting with their tasks.

Designing artifacts to enable the creation of instruments from the artifacts is the theoretical focus of Tchounikine in [314] that defines development of instruments as two sets of functionalities of an artifact. One set is designed by the designer and inherently enables the user to perform the needed task. The second set of functionalities are adaptation features. These adaptation features can be used either to change the existing system, or to interoperate with some other systems. An artifact designer can according to this view be seen as a meta designer as he designs an artefact to enable design in use by the users [314]. Another important outcome from [314] is that the adaptation of the artifact can be performed at an individual level, or at the community level. So an artifact like our AI algorithm should be able to support such appropriation on different levels. However, constructing such artefacts and especially the technical aspect of software development is considered an open research question (see e.g., [314] and [315]). An interesting example of multi-disciplinary collaborative design and development of software to support appropriation in the medical domain, known in the example as End-User Development, is presented by Costabile et al in [283].

Therefore, unless software design shifts towards design for appropriation, we will continue to witness interesting technical research, such as our AI algorithm, which will not end up being implemented in clinical practise, as clinical practise professionals will not be motivated/enabled to intrinsically change their work practices in which they can both influence the development of the AI algorithm and adapt their practise to accept the AI algorithm in their daily clinical practise, while not losing their knowledge, culture and value specifics that make them who they are [313].

12.2.3 Multi-level governance of semantic resources with commons and commoning
The third group of issues and new concepts identified in Section 12.1 is the multi-level governance of semantic resources with commons and commoning. We have touched OpenEHR in the TEAS focused text above where we mention how TEAS enables productive collaborative work on OpenEHR semantic resources. However, the multi-level governance has been found in this research only partially or not at all present not only at the national level in Slovenia, but also in other countries.

As discussed in different previous sections, multilevel governance must not only support collaboration between medical professionals and software engineers, but also involve many other actors in a typical health system, which can be roughly divided into three levels (as shown in the background in Section 2). At the micro level, it is the medical professionals who identify specific use cases in their clinical practise that are needed as input for modelling various semantic OpenEHR resource artefacts. At the meso level, we are talking about organisations such as hospitals that also need to participate - not only by engaging in semantic resource work, but also to manage potential procurement and alignment with other actors in the health system ecosystem. At the macro level, we typically see organisations like the Ministry of Health. They oversee legislation, but also important national projects and programmes. Their involvement in semantic resource work is particularly important, as only they have the ability to build national consensus around a particular semantic resource and thus broader adoption. As we have learned in our research (see e.g. papers 3 and 5), building such a multi-level governance organisation is difficult to achieve or is only achieved for a short period of time (e.g. during the lifetime of a project). However, working on semantic resources is an ongoing process that never really ends. This is because semantic interoperability is a cross-project concern and depends on the constant dynamics of medical knowledge production.

To address this, the concept of commons and commoning has proved to be a particularly interesting approach to the governance of OpenEHR semantic resources. This is discussed in detail in Paper 5. Commons and commoning are not only seen as an alternative to markets and governments. Recent trends in the commons literature show that more and more research on commons is focused on collaboration between market, state and commons through participation in commoning. On this basis, we see commons, and commoning in particular, as a necessary approach to achieving multi-level governance of semantic resources. It enables software companies, governments, medical providers and all other stakeholders in healthcare to create common semantic resources that are a prerequisite for semantic interoperability in healthcare.

12.2.4 A work practice based on SECOs, TEAS and Commons that supports co-creation and co-evolution of social and technical aspects of technology development

Epistemological analysis
In this thesis, I try to conceptualize a work practice for productive work on semantic interoperability. I do so by using three different concepts: SECOs, TEAS, and Commoning. We can link SECOs, TEAS and Commoning through a common epistemology. The practice theory can be used as such epistemological underpinning. Practice is focused on doing actions to change society [316]. All three above concepts therefore align with their focus on the social, and practice as what social entails in the real world. We now shortly define practice theory as the underlying connection between the three concepts.
SECOs are seen as the approach to achieve collaboration between different actors over a common technological platform the result of which are new software solutions or services. Example of such solutions are e.g., the AI algorithm or the several DHIs that resulted in the eCare project. Traditional software development approaches need to change to be able to function within a SECO context. A software practice-focused approach to achieving such change is given by e.g. Dittrich in [317]. Practice theory from social sciences is the underlying theory that enables seeing practice as the unit of analysis [318].

TEAS enable intrinsic practice transformation in which the task-artefact cycle introduces changes both to the artifact and the work practice. Activity spaces can be represented as collective activity systems [194] and provide an interpretation of a real-world situation that is comprehensive and clear. TEAS are based on the activity theory (the focus is on a single human activity) while TEAS support different activities and use of tools across activities. Activity theory (and with this TEAS) is considered a practice theory [319], [320].

Commons shift to commoning is seen as a continuous nurturing of the commons by means of shared practice [321]. Commoning has been conceptualized as social practice based on practice theory [322] by Euler in [323].

From the above analysis we see that practice theory enables seeing the TEAS, SECO and Commons concepts as being related and with this their joint use for defining the main result of this thesis scientifically acceptable.

All three of the newly introduced concepts, namely TEAS, commons and SECOs, strongly suggest a shift in the way technology is developed by pointing to a co-creation and co-evolution of both the social and technical aspects of technology development. This means that, for example, our clinically validated care process models would be developed in a multidisciplinary collaboration within a TEAS that also involves SECO participants in the collaboration and also involves commons-based working on OpenEHR semantic resources. TEAS and commons can therefore be seen as a way to bring multidisciplinary collaboration into SECOs, where participation in them becomes strategic for SECO and allows software vendors, buyers and suppliers of software products to actively participate in technology development. Otherwise, even the best technical solutions will not be implemented in healthcare ecosystems.

Table 16 below summarizes the key findings and results of this thesis. Each line of Table 16 represents a separate result that is labeled with its identifier (e.g., SR1), the new concept that is used in construction of the result, the section in which the result is constructed and the description of key finding and/or result.
<table>
<thead>
<tr>
<th>Result ID</th>
<th>New Concept</th>
<th>Subsection</th>
<th>Key findings and results</th>
</tr>
</thead>
<tbody>
<tr>
<td>SR1</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Conceptualization of a SECO-based solution to the identified technical (IC4, IC7) and social (IC10, IC12, IC14) SECO group of challenges from Section 12.1 and summarized in Table 12.</td>
</tr>
<tr>
<td>SR2</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Result: SECO Strategy Guidelines/informed recommendations for more optimal SECO strategies based on looking at the overall research through the lenses of evolutionary mechanisms of digital artifacts (SR3), institutional theory (SR4) and generative entrenchment (SR5)</td>
</tr>
<tr>
<td>SR3</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Analysis of the overall research as SECO evolution through the lens of evolutionary mechanisms</td>
</tr>
<tr>
<td>SR4</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Analysis of the overall research as SECO evolution through the lens of institutional theory</td>
</tr>
<tr>
<td>SR5</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Analysis of the AI algorithm evolution through the lens of generative entrenchment</td>
</tr>
<tr>
<td>SR6</td>
<td>SECO</td>
<td>12.2.1</td>
<td>Result: Guidelines/informed recommendations for content and interoperability in DHI design, development, evaluation and implementation</td>
</tr>
<tr>
<td>SR7</td>
<td>TEAS</td>
<td>12.2.2</td>
<td>Conceptualization of a TEAS-based solution for the problem of multi-disciplinary collaboration challenges (IC1, IC2, IC5, IC6, IC8, IC11, IC13) from Section 12.1 and summarized in Table 12</td>
</tr>
<tr>
<td>SR8</td>
<td>Commons</td>
<td>12.2.3</td>
<td>Conceptualization of a Commons-based solution to the identified social commons group of challenges (IC3, IC9) from Section 12.1 and summarized in Table 12</td>
</tr>
<tr>
<td>SR9</td>
<td>SECO, TEAS, Commons</td>
<td>12.2.4</td>
<td>Result: Conceptualization of a work practice based on SECOs, TEAS and Commons that supports co-creation and co-evolution of social and technical aspects of technology development.</td>
</tr>
</tbody>
</table>

Table 16 A summary of key findings and results supporting the evolution from technical infrastructures to commons

<table>
<thead>
<tr>
<th>Subsection</th>
<th>RQ1</th>
<th>RQ1</th>
<th>RQ2</th>
<th>RQ3</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1.1</td>
<td>Paper 1</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>12.1.2</td>
<td>eCare Project</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.1.3</td>
<td>eCare Project</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.1.4</td>
<td>Paper 2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.1.5</td>
<td>Paper 3</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.1.6</td>
<td>Paper 4</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.1.7</td>
<td>Paper 5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12.2.1</td>
<td>SECO</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.2.2</td>
<td>TEAS</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.2.3</td>
<td>Commons</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>12.2.4</td>
<td>Work practice</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 17 Impact of all key findings and results of this thesis on research questions. The table extends Table 11 with the key findings and results of this thesis.
13. Discussion and conclusion

The central focus of this thesis is the semantic interoperability of clinical data, which is the most complex challenge [136] that needs to be solved globally in the context of the more general discussion on semantic interoperability between organizations [139] [140]. The information blocking which is practiced by both HIS providers and healthcare professionals [136], is only one issue that still hinders successful semantic interoperability [137]. Since semantic interoperability is usually not available, data exchange is associated with additional data work. In this way, every required information exchange must be designed, which is certainly not an optimal way of using resources, especially since this work is often done by medical doctors, computer scientists and other professionals. The law of medical information suggests [115] that the more such data is to be reused in different contexts that represent the different orders of data reuse of Bossen et al. [88], the more data work is required to make the data usable in the new contexts. A solution for this expensive and time-consuming data work is seen in the realization of the principle of semantic interoperability at runtime. In practice, this principle means little or no additional data work, since the information systems support any future information exchange needs. This would give nurses, doctors and other health professionals the freedom to interact. Semantic interoperability requires that data be captured together with its context. This includes standardized data types from the health domain [71], which are mapped to different medical terminologies that share the meaning of data [140]. This must be achieved, otherwise physicians will have to find another way to communicate their clinical observations [136].

In this thesis, a unique approach that promises interoperability at runtime, called OpenEHR, is investigated. However, OpenEHR still has challenges. In this thesis I try to address these challenges, for example, the sub-optimal multi-level organizational infrastructure and governance required to support OpenEHR’s widespread adoption [156]. The research questions guided the search for solutions to the challenges. The research process arrived at several research findings and key results that are presented in Section 12.

In the following text I first answer the three main research questions in Section 13.1. Then, in Section 13.2, I present the practical, methodological and theoretical implications of this thesis findings and how the key findings help address existing open research questions that were identified in the initial sections of this thesis. I conclude this thesis with Section 12.3 where I also point to potential future work.
13.1 Answers to the research questions

The process of answering RQ1 is depicted in Figure 23. It entails using the (1) results Section 12, (2) informative context of the various projects described in Section 5, (3) the published papers included in this thesis (sections 7-11), (4) experiences and results published in various other publications [169], [227], [228], [251], and (5) answers to the research questions RQ1.1, RQ2 and RQ3, as the basis for the explicit description of the new work practice that represents the answer to RQ1. Therefore, answering RQ1 starts with answering RQ1.1, followed by answers to RQ2 and RQ3. Even though Figure 23 represents a somewhat sequential process of answering RQ1, it is in fact intertwined with the answers to RQ2 and RQ3.
Figure 23 The overall flow of answering the RQ1 includes first answering RQ2 and RQ3.
In the following text we therefore start with answering RQ1 and its sub question RQ1.1, continue with answering RQ2 and RQ3 and then return to answering RQ1 to finalize the answer to my main research question.

Towards an answer to RQ1
To recall, the RQ1 focuses on explicating a work practice for productive work on semantic resources and is defined as follows:

RQ1: What kind of new practice could support productive work on semantic interoperability in healthcare?

Our key finding presented in Section 12.2.4 is a work practice based on SECOs, TEAS and Commons that supports co-creation and co-evolution of social and technical aspects of technology development – which includes also work on semantic interoperability. The conceptualized work practice can thus be considered more general and not focusing only on semantic interoperability. To add this focus to the work practice, RQ1.1 helped guide this process. The RQ1.1 is defined as:

RQ1.1 Is OpenEHR a suitable approach for productive work on semantic interoperability in the health care sector?

In this thesis, I evaluated different experience with OpenEHR not only ones obtained in the projects in which I participated (see Section 5 and the published papers), but also those found in the state of the art (sections 2 and 3). I categorize these experiences into positive and negative. Positive claims support RQ1.1 by providing claims of OpenEHR enabling productive work on semantic interoperability in healthcare. Negative experiences work against supporting such claims about productivity of OpenEHR and with this do not work to support RQ1.1. Table 18 below presents the positive influences on RQ1.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Description of the positive influence on RQ1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 Informative Context, 12.1.2 eCare Platform, 12.1.6 Paper 4</td>
<td>OpenEHR was successfully used as a core service on software platforms.</td>
</tr>
<tr>
<td>2</td>
<td>12.1.5 Paper 3, 12.1.2 eCare Platform, 12.1.6 Paper 4</td>
<td>Successful implementations on top of OpenEHR-based platforms have been achieved in different levels, including the national level in Slovenia. For Example, the national Patient Summary was modelled using OpenEHR and successfully implemented.</td>
</tr>
<tr>
<td>3</td>
<td>5 Informative Context, 12.1.1 Paper 1, 12.1.3 eCare Process models</td>
<td>It has successfully been used to design several DHIs and the underlying care process models.</td>
</tr>
<tr>
<td>4</td>
<td>12.1.4 Paper 2</td>
<td>It was successfully used as a data source for AI algorithm development.</td>
</tr>
<tr>
<td>5</td>
<td>12.1.7 Paper 5</td>
<td>OpenEHR was confirmed by medical professionals to be used for modelling clinical content.</td>
</tr>
</tbody>
</table>

Table 18 Positive experiences with OpenEHR that work to support RQ1.1. Sections depict where the experience originates from to ensure traceability.

Following is Table 19 that presents experiences that work against RQ1.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Description of the negative influence on RQ1.1</th>
</tr>
</thead>
</table>
| 1 | 12.1.2 eCare Platform, 12.1.3 eCare Process models, | Separation of concerns has not been successfully established in any of the activities. OpenEHR-based modelling was not done by the
Based on the above two tables of statements about OpenEHR, we can say that we were able to use OpenEHR in a productive way to produce artifacts that are enabled by OpenEHR (archetypes, templates, software libraries, databases, algorithms data input, core platform services). However, we can also say that we were not able to achieve separation of concerns as medical professionals typically did not take part in modelling activities. The modelling was left to be done by the technical people, namely, software engineers. In addition, OpenEHR experiences have also pointed to the difficult governance of OpenEHR artifacts. This should have been an extension of the global governance rules set forward by the OpenEHR Foundation. However, in our case, OpenEHR was used in a project-focused way, leading to proprietary OpenEHR archetypes and templates that cannot really be used to achieve interoperability. Even with the national Patient Summary example from Table 18, the document is still a Slovene version of the Patient Summary that was originally defined by the epSOS project and later by ISO as the international patient summary ISO standard\(^\text{12}\). In spite that, it is still one of the rare examples of structured clinical content in Europe being implemented on the national level with so many data elements overlapping with international versions. The OpenEHR archetypes and templates of the Slovene patient summary are freely available online\(^\text{13}\). For this, it shows great potential of OpenEHR to address semantic interoperability in healthcare.

Trying to elicit an explicit answer to RQ1.1 based on the above analysis we can say that OpenEHR, as a set of technical mechanisms, can be productively used to create digital artifacts. However, such digital artifacts are not necessarily semantically interoperable. There are two main problems. First, OpenEHR still lacks guidelines on how to solve the problems of multi-disciplinary collaboration on modelling different semantic resources and second, the multi-level governance of the semantic resources. As these two main problems with OpenEHR are addressed at least partially by this thesis results pointing to potential ideas for future solutions, the answer to RQ1.1 can thus be a conditional answer in favor of using OpenEHR for productive work on semantic interoperability in healthcare. Therefore, I provide the answer to the RQ1.1 in Table 20 below.

<table>
<thead>
<tr>
<th>ID</th>
<th>Suitability of OpenEHR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OpenEHR can be used to support productive work on semantic interoperability under condition that the multi-disciplinary modelling and multi-level governance are addressed in a better way.</td>
</tr>
</tbody>
</table>

Table 20 Suitability of OpenEHR for productive work on semantic interoperability in healthcare as the answer to RQ1.1

**Answer to the RQ2**

The second research question is defined as follows:

**RQ2: What are the effects of such a new work practice on existing practices?**

---


\(^{13}\) http://ukz.ezdrav.si/ckm/templates/1075.91.3
The RQ consists of four sub questions that all align with published research papers included in this thesis. Therefore, I first answer each of the sub questions before completing the overall answer to the RQ2.

**RQ2.1: How does OpenEHR influence the design and development of AI algorithms in healthcare?**

Paper 2 in Section 8, together with the informative context of the projects from Section 5 where several tensions with using OpenEHR use in the eCare and national eHealth projects have been put forward, help answer RQ2.1 by providing the following description of the influence that OpenEHR has had on the design and development of an AI algorithm in healthcare:

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Description of the influence on RQ2.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8 Paper 2</td>
<td>(1) We used an OpenEHR-based clinical data repository (OCDR) as a source of clinical patient data. Access to the data was available through an application interface that is dynamic in nature. This means that the data structures used in different API methods can dynamically change to foster the extendibility of OpenEHR semantic resources. If a new archetype or template is deployed to OCDR, the API does not need to change. Example open-source solutions that have significantly developed since my work on the research are available at [324] and [325].</td>
</tr>
<tr>
<td>1</td>
<td>5 Informative Context</td>
<td>(2) I used the OpenEHR archetype and template structures and data as input to the predictive analytics machine-learning algorithm to help patients manage their diabetes.</td>
</tr>
<tr>
<td>1</td>
<td>12.1.4 Paper 2 results</td>
<td>(3) To support the data work needed to prepare the data for the algorithm (to separate the data from the context in which it was collected), it was necessary to prepare tools to help with this. Such tools support the functionalities of Archetype Query Language (AQL) - either directly or indirectly, as in our case. Once developed, the AQL interface is generic enough to support any future change of data structures within the OCDR. This means AQL queries can always include new archetypes as parameters. AQL is often implemented as part of the standardized API. See [324] and [325] for examples.</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>(4) The developed algorithm can therefore automatically work with any other OpenEHR repository of data if it contains the same set of archetypes and templates. Otherwise, the mapping between the AQL queries and the attributes that serve as input to the algorithm need to be changes. This means that the AQL queries represent the attributes that are used in the learning process of the algorithm.</td>
</tr>
</tbody>
</table>

**Table 21 OpenEHR influence on development of AI algorithms as support for answering RQ2.1.**

Based on the above description of using OpenEHR in the AI algorithm we can say that (1) OpenEHR introduces a special layer into AI work practises that allows OpenEHR semantic queries to feed the learning process of the algorithms. It therefore (2) influences the process of preparing data that are fed to algorithms by aligning it more with the medical domain that the OpenEHR represents. This may suggest (3) less time needed to work on data curation in healthcare scenarios. Also, due to the use of a standardized API to access data, (4) deployment of the AI algorithm into production could also be simplified. Based on the results Section 12, the OpenEHR-induced changes of AI algorithms development can be seen as needed in the future if one wants to consider (5) medical professionals to take part in appropriating these algorithms into their work practices and turn the algorithms into their instruments. OpenEHR can be seen as part of additional features needed to support such appropriation – something we shortly discussed results Section 12.2.2 on TEAS as the needed concept to help solve multi-disciplinary collaboration on, among other activities, AI algorithm
development. Medical professionals working within a TEAS could use the AI algorithms in the task-artefact change cycle in which (6) the algorithm could evolve to become an instrument that helps intrinsically change the medical professional’s work practice.

With the above depicted influences of OpenEHR on AI algorithm development, (7) the complexity inherent with AI algorithms development in healthcare (for example, see [326]), could be reduced in the future.

Table 22 summarizes above-mentioned influences of OpenEHR on AI algorithm development in healthcare and represents the answer to RQ2.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description of OpenEHR influence on RQ2.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Semantic queries as input to the algorithm.</td>
</tr>
<tr>
<td>2</td>
<td>Alignment of data curation with the medical domain.</td>
</tr>
<tr>
<td>3</td>
<td>Reduced time complexity of data curation in healthcare scenarios.</td>
</tr>
<tr>
<td>4</td>
<td>Simplified deployment of algorithms to production.</td>
</tr>
<tr>
<td>5</td>
<td>Medical professionals can appropriate algorithms to their work practices.</td>
</tr>
<tr>
<td>6</td>
<td>Supports conversion of AI algorithms into instruments used in medical practice change.</td>
</tr>
<tr>
<td>7</td>
<td>Reduction of complexity inherent with AI algorithm development.</td>
</tr>
</tbody>
</table>

Table 22: A summary of influences of OpenEHR on AI algorithm development in healthcare that represents the answer to RQ2.1. Points 5, 6 and 7 are separated with a line and in italic format to depict implications as potential for the future whereas the first four items summarize results observed in my past research.

RQ2.2: How does OpenEHR influence the design and development of digital health interventions?
The following Table 23 summarizes key findings and results from the results Section 12.1 that were identified as contributing to RQ2.2. The different influences on RQ2.2 are also described based on the discussion in particular sub-sections of Section 12.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Key findings and Results</th>
<th>Description of the influence on RQ2.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12.1.1</td>
<td>Conceptual knowledge models mapped to an industry standard</td>
<td>(1) OpenEHR is used to model data and information needs of the process models that were implemented using the industry standard. Such process models are components of the different DHIs. (2) OpenEHR helps achieve interoperable process models that can exchange data in a standardized way.</td>
</tr>
<tr>
<td>2</td>
<td>12.1.2</td>
<td>eCare Software platform</td>
<td>OpenEHR is implemented as a core service of the software platform. This increases the platforms interoperability potential as it is capable to support any new communication scenario for exchange of data without the need of programming. Improved interoperability potential suggests improved platform openness. With the OpenEHR core service, the platform supports development of interoperable DHIs that can be deployed on this OpenEHR-based eCare software</td>
</tr>
</tbody>
</table>
platform. OpenEHR thus influences DHI by directly enabling interoperability by design in the DHI. It also introduces changed design and development practices that require multi-disciplinary collaboration on OpenEHR semantic resources.

OpenEHR is used to implement data management in the process models and to implemented of the OpenEHR core service of the platform to which the process models can be deployed as boundary resources. OpenEHR makes such clinically validated care process models also interoperable by design.

The proposed commons-based governance of OpenEHR semantic resources influences DHI by injecting the need for participation and collaboration in the commoning activities on the OpenEHR semantic resources. With this, proprietary implementations of OpenEHR resources are preventable, and multi-level governance and multi-disciplinary collaboration ensured. All the OpenEHR technical, organizational and governance approaches motivate DHI designers to design semantically interoperable DHI.

Table 23 Key findings and results from Section 12.1 together with descriptions of how OpenEHR influences design and development of DHI. Each unique influence is marked with a number within parenthesis. In the above table, 6 such unique influences are depicted.

Further on, I extract all the unique influences of OpenEHR on design and development of DHI from Table 23 to form Table 24 below. Table 24 below represents the answer to the RQ2.2.

<table>
<thead>
<tr>
<th>ID</th>
<th>OpenEHR influence Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OpenEHR is used to model data and information needs of the process models that represent main components of the DHI.</td>
</tr>
<tr>
<td>2</td>
<td>OpenEHR helps achieve interoperable process models that can exchange data in a standardized way.</td>
</tr>
<tr>
<td>3</td>
<td>OpenEHR enables interoperability by design in the DHI.</td>
</tr>
<tr>
<td>4</td>
<td>OpenEHR introduces change to design and development practices by requiring multi-disciplinary collaboration on OpenEHR semantic resources.</td>
</tr>
<tr>
<td>5</td>
<td>The commons-based governance of OpenEHR semantic resources influences DHI by pointing to the need for participation and collaboration in the commoning activities on the OpenEHR semantic resources within the new semantic commons.</td>
</tr>
<tr>
<td>6</td>
<td>OpenEHR technical, organizational and governance approaches motivate DHI designers to design semantically interoperable DHI.</td>
</tr>
</tbody>
</table>

Table 24 A summary of influences of OpenEHR on design and development of DHI that represents the answer to RQ2.2. Points 5 and 6 represent implications as potential for the future and have not been observed.

RQ2.3: What influence does OpenEHR have on the design and development of software platforms?
Table 25 below summarizes key findings and results from the results Section 12.1 that were identified as contributing to RQ2.3. The different influences on RQ2.3 are also described based on the discussion in particular sub-sections of Section 12.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Key findings and Results</th>
<th>Description of the influence on RQ2.3</th>
</tr>
</thead>
</table>
| 1  | 12.1.2  | eCare Software platform  | (1) *OpenEHR impacts the software architecture* (see [227] and tension T2, Table 6 in Section 5) of the platform. OpenEHR is a crucial element of the software platform as the main clinical data storage service implements the OpenEHR reference information model. It can store any future data structure if it complies with the OpenEHR reference information model.  
(2) *Software development methods need to change* to foster OpenEHR-based separation of concerns (see tension T1, Table 6 in Section 5) and content modelling by the medical professionals (see [227] and Section 5).  
OpenEHR was perceived only as another information exchange approach (see tension T7, Table 6 in Section 5) which impacted its use on the national eHealth platform in Slovenia. This reduced the importance of OpenEHR between eCare and eHealth platforms.  
(3) *OpenEHR impacts the perception of Health IT standards landscape* in healthcare (e.g. IHE and HL7). Because OpenEHR was wrongly considered as a competing standard instead of complementary, software platforms combined different health IT standards even when that was not necessary (see tension T5, Table 6 in Section 5). |
| 2  | 12.1.3  | Clinically validated care process models | Such models are considered as becoming extensions of software platforms. For this, several impacts of the process models on software platforms regarding OpenEHR have been observed in this research.  
OpenEHR impacts the design of such models as all the data and information needs of the process models are modelled using OpenEHR. With this, the process models pose a requirement on the software platforms to which such models are to be deployed. (4) *Platforms need to implement an OpenEHR-based data management and offer an integration interface* that the process models integrate with.  
(5) *Software platform governance is impacted* because the OpenEHR models used in the process models need to become globally validated to enable interoperable exchange of data with different platforms. Thus, *focus from local to global OpenEHR semantic* |
resources is needed (see tension T3, Table 6 in Section 5).

The national eHealth platform discussed in the paper implements a national OpenEHR clinical data storage system which is the source of several impacts of OpenEHR on software platforms. (1) The paper shows its impact on the architecture of the platform, (3) how OpenEHR compares to other health IT standards, the use of OpenEHR to model the Patient Summary use case and the related issue of (5) OpenEHR modelled content needs to be nationally (globally) discussed and consensus reached. This is hard to achieve (see tension T6, Table 6 in Section 5).

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Table 25 Key findings and results from Section 12.1 together with descriptions of how OpenEHR influences design and development of software platforms. Each unique influence is marked with a number within parenthesis. In the above table, 6 such unique influences are depicted.

The Table 26 summarizes unique influences from Table 25 and represents the answer to RQ2.3.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Key findings and Results</th>
<th>Description of the influence on RQ2.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12.1.6</td>
<td>Organizational design principles for eHealth platforms as a useful analytical tool, and important for platform governance.</td>
<td>OpenEHR becomes part of the national Health IT standards landscape together with</td>
</tr>
<tr>
<td>2</td>
<td>12.1.7</td>
<td>A new semantic commons for governing OpenEHR semantic resources</td>
<td></td>
</tr>
</tbody>
</table>

Table 26 A summary of influences of OpenEHR on design and development of software platforms that represents the answer to RQ2.3.

RQ2.4: What impact does OpenEHR have on the design and development of national government-owned eHealth platforms and their ecosystems?

Table 27 below summarizes key findings and results from the results Section 12.1 that were identified as contributing to RQ2.4. The different influences on RQ2.4 are also described based on the discussion in particular sub-sections of Section 12.1.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Key findings and Results</th>
<th>Description of the influence on RQ2.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5, 12.1.6, Paper 3</td>
<td>Organizational design principles for eHealth platforms as a useful analytical tool, and important for platform governance.</td>
<td>(1) OpenEHR becomes part of the national Health IT standards landscape together with</td>
</tr>
</tbody>
</table>
tool, and important for platform governance.

IHE, Continua, and SNOMED (see also tension T5, Table 6 in Section 5). Once OpenEHR system is implemented, (2) no upgrades are needed when new communication scenarios are added. This can (3) reduce costs associated with ownership of a national eHealth platform.

(4) OpenEHR and SNOMED are used to semantically define clinical data while IHE and Continua are used for transporting the data between systems.

(5) OpenEHR influences public tendering required in governing the eHealth platform by providing datasets to be implemented in the OpenEHR form.

(6) OpenEHR requires special software to be implemented as part of the platform to enable work with OpenEHR semantic resources.

(7) OpenEHR is used for validating data coming from different systems.

(8) OpenEHR helps reduce length of development cycles on new communication cases and improves agility.

(9) OpenEHR, an interoperability approach, requires behaviour change of all healthcare ecosystem agents in order to change infrastructural, organizational, and technological elements that support the interoperability requirements.

(10) OpenEHR opens discussion on lock-in based business models as it is itself a free and open standard (see tension T4, Table 6 in Section 5). For this, software vendors were not eager to adopt it in Slovenia.

(11) OpenEHR requires a multi-level governance of semantic resources (see tension T6, Table 6 in Section 5)

(12) OpenEHR influences national eHealth platform interoperability potential that can be reduced by poor levels of platform openness (see tension T8, Table 6 in Section 5)

<table>
<thead>
<tr>
<th>ID</th>
<th>Description of OpenEHR influence on RQ2.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OpenEHR becomes part of the national Health IT standards landscape</td>
</tr>
<tr>
<td>2</td>
<td>New communication scenarios do not require upgrading OpenEHR-based systems</td>
</tr>
<tr>
<td>3</td>
<td>Reduced costs associated with ownership of the national eHealth platform</td>
</tr>
<tr>
<td>4</td>
<td>OpenEHR is complementary to other interoperability approaches</td>
</tr>
<tr>
<td>5</td>
<td>OpenEHR influences public tenders that are part of governance of national eHealth platforms</td>
</tr>
<tr>
<td>6</td>
<td>Special software needs to be added to the eHealth platform to support modelling with OpenEHR</td>
</tr>
<tr>
<td>7</td>
<td>OpenEHR is used for validating data from different systems</td>
</tr>
</tbody>
</table>

Table 27 Key findings and results from Section 12.1 together with descriptions of how OpenEHR influences design and development of national government-owned eHealth platforms and their ecosystems. Each unique influence is marked with a number within parenthesis. In the above table, 12 such unique influences are depicted.

The following Table 28 summarizes unique influences from the above Table 27 and represents the answer to RQ2.4.
Length of development cycles on new communication scenarios is reduced and agility improved.

Healthcare ecosystem agents need to change their behavior with the ecosystem to change infrastructural, organizational and technological elements in order to implement interoperability approaches such as OpenEHR.

OpenEHR promotes free and open semantic resources which works against existing lock-in based business models.

OpenEHR requires a multi-level governance of semantic resources.

OpenEHR improves platform interoperability potential.

Table 28 A summary of influences of OpenEHR on design and development of national government-owned eHealth platforms and their ecosystems that represents the answer to RQ2.4.

Table 29 below summarizes key findings and results from the results Section 12.1 that were identified as contributing to RQ3. The different influences on RQ3 are also described based on the discussion in particular Section 12.1.7.

Now that I provided answers to RQ2.1, RQ2.2, RQ2.3 and RQ2.4, I can also provide an answer to the RQ2. First, it should be clear that the answer provided for RQ2 is very much tied to the particular context of the thesis as each of the RQ2 sub questions focus on a specific research reported in the included papers. For this, the influence of the OpenEHR is studied because it is seen as an important method of the new work practice. Based on the answers to the RQ2 sub questions I can say that the influence of OpenEHR, being just one aspect of the new work practice, can be described with respect to the context within which it is used – as provided in above answers to the RQ2 sub questions. For this, the influence of the conceptualized new work practice on existing work practices cannot be really shown. However, what can be discussed are potential implications of the new work practice. I provide such an analysis in Section 13.2 where implications of the results are discussed. Here, the answer to RQ2 consists of a union of tables Table 22, Table 24, Table 26, and Table 28. Such is the influence of the OpenEHR aspect of the new work practice within the context of my research setting in Slovenia.

Answer to the RQ3

RQ3: What are the implications of Commons theory when applied to the governance of semantic resources in the new work practice?

Table 29 below summarizes key findings and results from the results Section 12.1 that were identified as contributing to RQ3. The different influences on RQ3 are also described based on the discussion in particular Section 12.1.7.

<table>
<thead>
<tr>
<th>ID</th>
<th>Section</th>
<th>Key findings and Results</th>
<th>Description of the influence on RQ3</th>
</tr>
</thead>
</table>
| 1  | 12.1.7  | A new semantic commons for governing OpenEHR semantic resources | (1) Commons have been successfully used for sustainable long-term governance of different resources.  
(2) Commons enable governance that involves not only a community but also the state and the market.  
(3) Commons theory provides evidence of intrinsic motivation to participate in a commons.  
(4) Commons local and global aspects help understand the problem of tackling OpenEHR modelling in a global way instead of focusing in local project needs. |
(5) Commoning as a process that enables the creation and nurturing of a commons helps define the way OpenEHR governance should be done in practice.

(6) Commons can help open existing semantic resources that are currently hidden in different technical solutions.

(7) Commons can help achieve a sustainable ongoing collaboration on semantic resources between different professionals.

(8) Commons can help achieve nurturing and maintenance of semantic resources especially on the Local level.

(9) Commons help understand existing local use of OpenEHR on different projects as traces of commoning.

Table 29 Key findings and results from Section 12.1 together with descriptions of how Commons theory influences governance of semantic resources. Each unique influence is marked with a number within parenthesis. Nine influences have been identified in the table.

The following Table 30 summarizes unique implications of commons theory on governance of semantic resources and represents the answer to RQ3.

<table>
<thead>
<tr>
<th>ID</th>
<th>Implications of Commons theory on governance of semantic resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Commons enable sustainable long-term governance of different resources.</td>
</tr>
<tr>
<td>2</td>
<td>Commons enable governance that involves not only a community but also the state and the market.</td>
</tr>
<tr>
<td>3</td>
<td>Commons theory provides evidence of intrinsic motivation to participate in a commons.</td>
</tr>
<tr>
<td>4</td>
<td>Commons local and global aspects help understand the problem of tackling OpenEHR modelling in a global way instead of focusing in local project needs.</td>
</tr>
<tr>
<td>5</td>
<td>Commoning as a process that enables the creation and nurturing of a commons helps define the OpenEHR governance approach.</td>
</tr>
<tr>
<td>6</td>
<td>Commons can help open up existing semantic resources that are currently hidden in different technical solutions.</td>
</tr>
<tr>
<td>7</td>
<td>Commons can help achieve a sustainable ongoing collaboration on semantic resources between different professionals.</td>
</tr>
<tr>
<td>8</td>
<td>Commons can help achieve nurturing and maintenance of semantic resources especially on the Local level.</td>
</tr>
<tr>
<td>9</td>
<td>Commons help understand existing local use of OpenEHR on different projects as traces of commoning.</td>
</tr>
</tbody>
</table>

Table 30 Implications of commons theory on governance of semantic resources. These implications represent the answer to the RQ3.

**Answer to the RQ1**

After answering RQ1.1, RQ2 and its sub questions RQ2.1, RQ2.2, RQ2.3 and RQ2.4, I am now ready to finalize an answer to the RQ1.

We have learned already that the new work practice is a conceptualization based on SECO, TEAS and commons concepts that support co-creation and co-evolution of social and technical aspects of technology development including work on semantic interoperability. As OpenEHR has been considered as an important approach to support the work on semantic interoperability, the exploration of OpenEHR was supported first by RQ1.1. and then with RQ2.1, RQ2.2, RQ2.3 and RQ2.4. The answers to these research questions provide positive evidence of using OpenEHR in different scenarios. Particularly RQ1.1 points to the need of solving OpenEHR issues with multi-disciplinary collaboration and multi-level governance of semantic resources. The later, the multi-level governance, is tackled in work guided by RQ3 where commons theory
is questioned to learn of potential use in the field of governing semantic resources. The multi-disciplinary collaboration is addressed in sections 12.1 and particularly 12.2 where TEAS and SECOs are identified as important concepts that can help solve this problem. As already mentioned, Section 12.2.4 provides the initial conceptualization of the new work practice as a combination of TEAS, SECOs and Commons. The influences of OpenEHR discussed in answers to RQ1.1 and the four sub questions of RQ2 point to important elements of the OpenEHR that is seen as part of the new work practice.

To answer RQ1, namely, what kind of new practice could support productive work on semantic interoperability in healthcare we can say that such a practice that will use (1) OpenEHR as a specific method to work on semantic interoperability within a (2) TEAS - technology-enhanced activity space that will enable task-artefact cycles in which different professionals will be able to collaborate and appropriate the different artifacts to their work practices. Further on, this collaboration will be considered as (3) commoning – process of creating and nurturing commons that will enable long term sustainable way of working on semantic interoperability in healthcare. In the commoning, participation of the government, the industry and a community will be supported and needed.

Further on, these TEAS and Commons related activities will be part of (4) SECOs – software ecosystems. This is needed because semantics is constantly changing and requires ongoing semantic work. Such work needs to become part of software development because such work requires multi-disciplinary collaboration at least between medical professionals and software engineers. SECOs help organize new ways of software development that is needed within the new work practice as software firms represent the industry that also need to take part in TEAS and Commons. SECOs strategy level particularly needs to put participation in the new work practice highly in the strategy of every software company as SECOs involve also end users – the buyers of new software solutions and provide the needed motivation for the software companies. Based on the above description, I depict the new work practice in Figure 24 below.
I now answer the RQ1 in terms of summarizing the above Figure 24. The new practice for productive work on semantic interoperability in healthcare supports multi-disciplinary collaboration of different actors that have different roles within the SECO (buyers, vendors, platform owners, etc.). They jointly represent the (3) Organizational Structure of SECO Participants at the bottom of Figure 24. The different SECO actors collaborate within a TEAS that provides technical and non-technical resources needed to productively do OpenEHR related activities such as modelling, or governance as depicted in Figure 24. TEAS enable multi-disciplinary collaboration within task-artefact cycles. In the task-artefact cycles on the case of OpenEHR modelling activity, OpenEHR is used to model semantic

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**Figure 24 Depiction of the new practice for productive work on semantic interoperability in healthcare as three structures of the software ecosystems.**

(1) SECO Software structure - OpenEHR as a standard

- Semantic Resources Commons

create and nurture

(2) Commoning as the SECO Business structure producing open source artifacts

Technology Enhanced Activity Spaces

- OpenEHR Modelling Tools
- OpenEHR Modelling Activity Space
- Task-artefact cycles
- OpenEHR Governance Activity Space
- Task-artefact cycles
- OpenEHR Governance Tools

collaborate in

(3) Organisational Structure of SECO Participants

- Medical Doctors
- Software Engineers
- MoH Employee
- MoH Employee
- Software Engineers
- Medical Doctors
resources. These are then used to appropriate existing software systems in the e.g. medical doctor’s practice. Vice versa, the practice influences OpenEHR semantic resources to change yet again because some part of the semantic resources has perhaps been found to not be sufficiently defined to be used in the medical doctor’s practice. This process continues until a convergence happens and no more changes to the semantic resources or the practice can be defined.

This process in which new semantic resources are created and tested in medical doctor’s practice, needs to be supported by a wider SECO community to constantly create semantic resources that enable semantic interoperability in order not to fall into the trap of creating project-specific semantic resources as was the case in many of the projects in which I participated. In this thesis, this SECO community is seen as the community participating in the process of commoning that, as we learned in paper 5, connects the local and global OpenEHR aspects on governance. In this commoning process, the SECO community that involves also the global OpenEHR community, the semantic resources commons are created and nurtured. This means that the semantic resources are openly available to all actors of the SECO suggesting values not being monetary but that of e.g. knowledge [300].

For the above-presented aspects, the business structure in Figure 24 is depicted as (2) Commoning as the SECO Business structure producing open-source artifacts. The above discussion also influences the top-level structure in Figure 24 depicting the (1) SECO Software structure as focused on the OpenEHR as a “standard” according to Manikas ‘s observed types of software structures in [300] where the focus is on achieving software interaction based on compliance to agreed one or more standards.

As such a new practice theoretically eliminates the issues found with OpenEHR (see also Table 6), namely that of multi-level governance and multi-disciplinary collaboration, I believe it can be a practice that supports productive work on semantic interoperability in healthcare. The above description of the new work practice together with the described perspectives of the new work practice, namely, OpenEHR, TEAS, and Commons in the following Section 13.2 can be considered as formalization innovation as I depicted tangible and intangible elements of the work practice either directly or indirectly (e.g. OpenEHR implies the use of several technical modeling tools).
The new work practice can be seen as a theory nexus, since we used existing theory of SECOs, TEAS and Commons as a basis for the conceptualization of the new work practice. This new work practice thus deals in theory with issues of the OpenEHR approach to managing semantic resources. If such a work practice were to be implemented in the real world, it would have several positive benefits.

The new work practice for productive work on semantic interoperability provides practical, methodological and theoretical implications. We now discuss implications of the main aspects of the new work practice, namely, (1) OpenEHR, (2) Commons, (3) TEAS and (4) SECOs.

OpenEHR aspect of the new work practice
With respect to the gaps identified in Section 2, the new work practice would primarily help to reduce the lack of structured data in the health care system. As outlined by Murdoch and Detsky [67], it is estimated that 80% of healthcare data is unstructured. OpenEHR is an approach to structuring health data. This should be done in the design phase of technology development to anticipate future semantic interoperability. Once the governance issues of the lack of multi-level organizational support involving medical and other professionals are adequately addressed, OpenEHR would move beyond the tipping point of the diffusion of innovation curve - from the early majority to the late majority - and eventually become mainstream. The main reason for such considerations is that there is no other approach that could better address semantic interoperability in healthcare by primarily focusing on storing data differently and not focusing primarily on data exchange as it is usually the case with other approaches.

As we have learned, most other approaches focus either on implementing messaging between different systems or on semantic mediation, where mappings between models are designed. OpenEHR can and has also been used for semantic mediation, especially in combination with legacy systems. However, the key advantage of the OpenEHR approach is its ability to capture data and the context in which data was captured and to store data in a different way. Later, such structured data can be easily separated from context using the provided semantic query mechanism known as AQL. In the sense of Bossen et al. [88], this separation of data from its context is crucial for the different orders of data reuse. This additional work or data work is optimized with OpenEHR. With regard to the law of medical information, one could say that the law does not necessarily apply so strongly anymore.

We learned about such data work and articulation work in Section 2. By using OpenEHR, we are able to create a technology that better fits medical work practices. This can significantly improve the generative power of the Bergs' technology from [84] by giving medical professionals more freedom in the way and timing of their interaction. This means that they can actually use the technology. Supporting the structuring of medical data from the perspective of physicians also contributes to reducing the probability of the two types of errors proposed by Ash et al. [83]: (1) errors that occur during the process of entering and retrieving information, and (2) errors that occur in the communication and coordination process that information systems should support. The OpenEHR-based work practice enables health care professionals to control such errors during the development period. By putting healthcare professionals in the role of designers, it also ensures that the delicate interplay between overemphasis on technology and inaction - a design principle for integrating different systems as proposed by Ellingsen and Monteiro [8] - is not broken. By participating in the OpenEHR-based work practice, physicians are actively involved in negotiations between different stakeholders - a vision proposed by Ellingsen and Monteiro [86].
Therefore, we can say that OpenEHR can help improve the current poor data circulation, also known as data liquidity in the health sector, which allows data and information to be made available when and where needed. This means that the information ecosystem in which this data must flow can function better, because interoperability is never just a technical issue. This can be achieved by supporting the event-driven architecture of systems where events are modelled with OpenEHR. This means that systems that support or implement the OpenEHR reference information model can always understand any ad-hoc events or messages received if they are modelled using the same OpenEHR reference information model. Such systems become future proof because they are ready to support any new future communication without the need to update exchange software. Such systems support runtime interoperability, which gives nurses, physicians and other healthcare professionals and patients greater freedom of interaction.

With OpenEHR-based systems, the dynamic development of the information infrastructure with a focus on semantic interoperability to support generative evolutionary mechanisms (innovation, adoption, scaling) is possible. This is due to both the architecture and the focus of governance on semantic interoperability, which is implicit in the results of this thesis. This has never happened before, as the healthcare environment is often seen as a patchwork of different systems. OpenEHR used within the new work practice supports the implementation of the unified digital infrastructure of Fürstenaet et al. [114].

**Commons aspect of the new work practice**
The new work practice with its Commons-based management of semantic resources can help with the complex and poorly addressed clinical standardisation of content. This has been identified before as a crucial problem to be solved and is an open research question [127] [128]. With the new work practice in place, OpenEHR can be used to drive such standardisation further.

In addition to the clinical standardisation of content, the new work practice, if implemented, could also help solve the problems with information blocking [136] [137]. Recalling the depiction of the new work practice in Figure 24 software companies are important actors in the overall SECO and participate in the OpenEHR activities not on monetary base but rather that of e.g. knowledge. This is possible to achieve in practice if the SECO buyers are then willing to purchase software solutions that comply with OpenEHR in this case.

The commons aspect of the new work practice also attempts to contribute to the discussion about more commons in healthcare [327]. This cause is additionally contributed by the artefacts that were produced in the eCare project and are all freely available. This includes the eCare software platform (contributes to the lack of platforms that support multiple DHIs [258] [328] [178]) source code, the AI algorithm implementation, the clinically validated care process models, all the DHIs (contribute to the gap in available DHIs in healthcare in general [258], and the lack of theory-based DHIs [50], [178], [263], [264]), and the OpenEHR semantic resources.

The commons aspect of the new work practice, by bridging semantic interoperability and commons fields, also contributes to the commons research. As has been brought forward in paper 5, we contribute with (1) a new area of semantic interoperability in healthcare for Commons researcher to explore, (2) identifying semantic resources as interesting and important as they enable health data sharing where and when needed to treat patients, (3) a new perspective on the relationship between local and global commons relationship where research on the subject is particularly scarce, and (5) we propose the notion of a new semantic commons that has the potential to spark interesting research between healthcare and commons researchers. In overall, the commons aspect of my research should also point to future...
healthcare where commoning takes on a central role. Not only in managing semantic resources
but also in other governance issues and with this help achieve more sustainable health systems.

**TEAS aspect of the new work practice**
In addition, the new work practise would be embedded in the existing working practises of
health professionals through TEAS. This promises to improve the level of participation of
health professionals in productive work on semantic resources. More generally, such
participation could also be possible on development of e.g. algorithms and DHI or any other
technology development. However, such development by end users (see End User
Development [283]), as discussed e.g. by Tchounikine in [314], is an open research problem
on its own [314] [315]and represents a fundamental shift in technology development.
Particularly so, if we consider [329] where Baxter et al put forward, that user-centered
development methods use, that enable end users to become the focus of technology
development (see worker-centered platform design for example [330]), is disappointing.

The establishment of such cooperation spaces, TEAS, would reduce the existing separation
gaps between developers and users [259], since such cooperation spaces support boundary
practices between different professional groups by means of boundary objects. The gap
between the collection of technical requirements and a more user-oriented design approach in
health care [260], [261] would also be reduced.

**SECO aspect of the new work practice**
SECOs help to understand the complexity of the information infrastructure. In addition, SECOs
helped to understand the entire research process as a SECO evolution. By analysing this
evolution, I was able to obtain guidelines for defining SECO's strategy that are considered as
informed guidelines for the future.

Work on extracting the guidelines provides an overview of SECO's development based on
OpenEHR - an example of SECO's development in the health sector. Overall, there is a lack of
studies on SECOs in the health sector, so this research is a new contribution [185] [188] as the
main result is represented as a SECO and relationships between the main SECO structures,
namely, organizational, business and software, are discussed in an integrated way – usually,
studies focus on one structure and often the software is the focus. This research also takes into
account technical, organisational and business/administrative SECO aspects, all of which are
interrelated when it comes to semantic interoperability – as depicted in Figure 24. In fact, the
three research questions deal with these different SECO aspects and therefore do not only focus
on the usual technical aspect [183]. We can say that all three SECO aspects must be well
coordinated in order to achieve productive work with semantic resources. This work thus
contributes a small step towards perhaps a better understanding of the interplay of the SECO
aspects - in the case of productive work on semantic resources.

Since this work has analysed a SECO evolution from a product - an algorithm - to its
development towards an embedding in a SECO, this work contributes to the discussion on the
development of software product lines for SECOs [181].

Looking at the main aspects of SECO, such as Christensen, Hansen, Kyng and Manikas [185],
the type of organisation in our SECO is collective. What contributes to this is the influence of
commons on the new work practice, where commoning is a collective effort involving
stakeholders from the industry, the government and different professional groups. Furthermore,
the way value is produced is best suited to open-source characteristics, or hybrid, including
some proprietary ways of adding value. For example, TEAS could be supported by a proprietary technology, but the results of the work done would be open source. As far as the technical or software aspect of SECO's work is concerned, our work implies contributions through the extension of a common software platform, because as such both the eCare and the eHealth projects were, and in terms of OpenEHR being a standard (see Figure 24 and its description in Section 13.1).

With regard to the SECO metamodel proposed by Wouters et al [187], our result - the SECO Strategic Guidelines - falls into the category of business area topics. The category of technical segment topics includes all platforms, AI algorithms and other technical elements.

In practise, the use of SECOs and the analysis of SECO development carried out are useful because they enable learning for improved future SECO strategies. For this, I see the guidelines as informed recommendations that can help in the future. The SECO guidelines can be used in practise by software providers when assessing their position, potential benefits and next steps within SECOs. Methodologically, the SECO guidelines were obtained by applying three theoretical lenses introduced in Sections 3.2.1, 3.2.2, and 3.2.3 on overall research. In the future, such a method of SECO evolutionary analysis can be further improved.

In a similar way, the DHI guidelines for content and interoperability can also be considered. The content and interoperability guidelines positioned within DHI design, development, evaluation and implementation represent informed recommendations that can perhaps be of future use. They support the bottom-up growth of Bygstad et al's lightweight IT incremental design and development [100] – enabled primarily by OpenEHR. The framework supports DHI life cycle phases that are consistent with existing values and health culture. They are in line with the existing values and culture because they do not force a monolithic top-down approach to the implementation stage of TDS. Such top-down approaches have usually led to operational errors (Berg cites 75% [109]). The guidelines also support a continuous process of design and evaluation to cope with changing knowledge in the health care system. The DHI guidelines and supporting sources can help DHI designers better understand all the TDS phases that a DHI must go through. The different stages of health care are also critical to better plan implementation. The implementation plan should also cover the software platforms and their SECOs. These are seen as an excellent opportunity for more effective and efficient health care.

Socio-technical focus of the new work practice

In this thesis, I introduced and discussed several technical artifacts that have been interesting to work on. However, what has been more interesting is to observe challenges during the technology development that were not concerned with technology, but rather with people. Primarily, how people from different professions can become better involved in technology development. Identifying challenges such as multi-disciplinary collaboration in the development of e.g. DHIs and algorithms helped to spark research into fields like participatory design and co-design. There, I was able to identify the concept of technology-enhanced activity spaces or TEAS that provided a vocabulary to talk about the problem of multi-disciplinary collaboration. In essence, TEAS is a concept that allows considering end users as appropriators of new technology within task-artefact cycles. These suggest that users work practices also change together with the changing technological artefact. Therefore, TEAS help introduce a strong social component into technology development. This social component is therefore also an important aspect of my main research result – the new work practice.
In addition to the problem of multi-disciplinary collaboration, I was also able to identify issues with multi-level governance of semantic resources in my work with OpenEHR. This problem is seen in this thesis as the main issue to be solved for OpenEHR to become mainstream. As OpenEHR is an approach to produce free and shared semantic resources that can be used in different communication scenarios to assure semantic interoperability, I became interested in how to govern such resources better in order to assure participation by the different levels of health systems, and the industry. Seemingly an impossible task that also focuses on people. Namely, in their ability to establish governance rules over resources that are not owned by anyone. The literature on commons and commoning was identified as a potential source of vocabulary to talk about the governance issues. Again, the social component seems crucial with governing semantic resources and through commons, the new work practice also focuses on the social. By bringing commons theory into semantic interoperability, new paths for solving semantic interoperability by focusing on the social, are opened. This transfer of commons to semantic interoperability is one of two main contributions of this thesis.

The third new concept introduced as the basis for the new work practice was the software ecosystems or the SECOs concept. As discussed in Section 12.1, the SECO concept can help organize software development in a way that collaboration between different stakeholders is better supported and that new stakeholders can always be added. In a similar manner to TEAS and Commons, SECOs also contain a strong social component.

The new work practice through the concepts of TEAS, Commons and SECOs thus joins three social components brought in by the three concepts. Interestingly, this points to a very important point. That is, the social aspects of technology development are crucial. This leads to thinking that technology development needs to be thoroughly changed to include such social aspects from design all the way to implementation of new technology. Especially so if we want to consider semantic interoperability in healthcare a serious option for the future in which sustainable health systems are the only available option that need semantic interoperability to be solved. The work practice with its integration of TEAS, Commons and SECOs represents the second main contribution of this thesis.

Looking back at the semantic interoperability effect chain that was put forward as motivation for this thesis in the introduction and considering the above mentioned two main contributions of this thesis, we can see the effect chain changing in the future. The effect chain is depicted in Figure 2 in the introduction section. The initial drive of the chain is represented by the differing values of different stakeholders in healthcare that prevent cross-cutting concerns such as semantic interoperability from being achieved. The new work practice would be able to help with such conflicting values.

TEAS as a crucial grounding for the new work practice has been developed as a potential answer to eliminate value differences between stakeholders. TEAS enable that to happen by providing activity spaces in which technology is used to support multi-disciplinary collaboration in spite conflicting values (for example, values of software companies and medical doctors over health data semantics differ considerably). The ability to collaborate on semantic resources within TEAS also help resolve the interoperability issues that are the second drive in the semantic interoperability effect chain. By eliminating the interoperability issues, there are would be no more power asymmetries over health data as the semantic resources that define the data would be publicly available.

The last drive of the semantic interoperability effect chain represents the governance issues that occur due to power asymmetries over health data. If the work practice would be put in
place, this problem would be at least less complicated but would not be based on poor level of semantic interoperability.
The new work practice thus could help solve the problems set forward by the semantic interoperability effect chain, primarily by addressing problems of governance of semantic resources and by proposing social aspects to become equal partners in the technology development.
13.3 Conclusion and future work

There were two main objectives in this work: (1) to understand the complexity of semantic interoperability, and (2) to find solutions to the problems.

The whole research had one central theme - OpenEHR. OpenEHR offers a different approach to achieving semantic interoperability in healthcare than e.g. HL7. OpenEHR requires a multilevel governance structure that includes the micro, meso and macro levels of health systems, while HL7 is very technical and typically not used by healthcare professionals. OpenEHR also has a significant impact on existing software development practises, but the reduced complexity of not having to deal with the constant expansion of medical knowledge should encourage software developers to change the way they work towards using OpenEHR. OpenEHR therefore served as an excellent subject through which I was able to learn about semantic interoperability in practical, methodological and theoretical terms. This interest led to the successful completion of several projects and the publication of papers on this topic, and the development of the main results of this thesis. I can thus say that I have achieved both main objectives of the thesis, although there are still more interests left for the future.

In order to implement the main result of the thesis (for a list of all key findings and results see Table 11 and Table 16), there is a need for action in context. I have already taken the first steps in this direction by joining forces with Slovene Medical Chamber. Together we have published a call for action [254] to the 11,000 members of Medical Chamber. The call was about the democratisation of innovation in healthcare, inspired by von Hippel [255]. In von Hippel's terms, we want to find lead users who not only participate in the productive work on semantic resources within the new work practise, but also in a broader sense, in innovations in the health care system.

The results of this thesis, particularly several available open source artifacts (open source as commons) and the commons-based governance approach to governing semantic resources, could perhaps provide additional motivation to lead the digital transformation of healthcare to a more successful future, in which medical professionals would be part of SECOs, not only as customers at the SECO supply chain level, but as an equivalent partner at the SECO vendor level and the overarching SECO level. Here, the SECO strategy guidelines, content and interoperability guidelines for DHI design, development, evaluation and implementation, and the set of commons would help as a starting point. With this, we would have achieved a much higher level of participation of medical professionals and healthcare organizations which would gradually improve health systems receptiveness of innovation, speed and scale of adoption of innovations, and speed and scale of diffusion of innovations.

It seems, that my initial motivation to work and learn within healthcare from 2009 when I realized how far behind healthcare in Slovenia was with its digital transformation, lead me to search for ways on how to help healthcare professionals to become lead users in this process and provide advice and tools to help them on the way. I see this thesis as my small contribution to help achieve positive impact on people’s health using technology – my intrinsic motivation through all the ups and downs. Therefore, I certainly do not underestimate such intrinsic motivation when proposing commons and commoning as a crucial component of the digital transformation in healthcare in the future, and more generally, social aspects to become equal partners in the technology development needed to support the digital transformation of healthcare towards sustainable learning health systems.
14. References


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