

Evolutionary Design of Electronic Medical Record Systems

Submitted in part fulfilment of
the requirements for the degree of
Doctor of Philosophy in Informatics of
the Graduate School of Informatics,
Kyoto University

by
Samar El Helou
Kyoto University, Japan

Supervisor: Prof. Tomohiro Kuroda

Copyright © 2019 by Samar El Helou
Kyoto University, Japan
All rights reserved.

Abstract

Evolutionary Design of Electronic Medical Record Systems

Samar El Helou

Kyoto University, Japan, 2019

Electronic Medical Records (EMRs) are digital versions of traditional paper-based patient records. EMR systems are computer systems used to record, retrieve, and manipulate information inside EMRs. If EMR systems are widely adopted and effectively used, the efficiency and effectiveness of our healthcare systems could potentially improve. Two major barriers for the adoption and effective use of EMR systems are their cost of implementation and maintenance and their low level of usefulness and usability. In the last three decades, significant effort was dedicated to address these barriers; however, major EMR design issues persist.

Indeed, designing EMR systems is a complex task due to the systems' complex nature. EMR systems are asynchronous, specialized, critical, and non-trivial systems involving multiple stakeholders with different and sometimes conflicting priorities. Traditionally, EMR system designers followed the commonly known User-Centered Design (UCD) approach. Following this approach, the designers first analyzed their users' context and needs and drafted the systems' specifications accordingly. Based on these specifications, they designed the EMR systems and implemented them in their context of use. Once these systems were implemented, the designers would only make modifications based on the users' requests to fix bugs or add extra functionalities.

However, the main users of EMR systems – healthcare providers – are experts in their fields, and therefore their description of their work does not accurately and consistently represent how they actually perform it. Moreover, like other artifact users, the users of EMR systems may have needs that they are unaware of, or cannot articulate. In some cases, the users may even develop new needs due to the continuous change in healthcare practices. In this scheme, following the traditional UCD approach results in rigid systems that are built based on a partial understanding of the users' needs.

To address the limitations of the traditional UCD approach, this work proposes an evolutionary design approach for EMR systems. Following this approach, the designers view EMR systems as evolutionary systems, i.e., systems that must continuously evolve and adapt to the ever-changing needs of their users. Instead of only focusing on implementing

EMR systems that perfectly fit the users' requirements as they are initially understood, designers also have to focus on (i) designing EMR systems that are easily adaptable and (ii) continuously identifying the users' emerging needs and addressing them through redesign.

To support the designers in their evolutionary design of EMR systems, I first present a structured EMR design process that treats the EMR system as an evolutionary prototype that requires continuous adaptation to fit the contextual needs of its users. Afterwards, I propose a set of methods to facilitate the evolutionary design process of EMR systems.

To present the design methods, EMR systems are viewed in their simplest form as a combination of a database and an interface. The interface of the EMR system is its front-end: the part with which the users interact with the system in its context of use. The database of the EMR system is its back-end: the part in which the EMRs are stored. The interface of the EMR system presents designers with context specific requirements. These requirements need to be well understood and defined. Once they are defined, the designers need to prioritize them to decide which needs are the most important to address. On the other hand, the database of the EMR system presents designers with three universal requirements: high interoperability, high adaptability, and high performance. These three requirements have to be met if we aim to design systems that do not become obsolete after a short period of time. Accordingly, the proposed methods fall under two categories: (i) Methods for defining and prioritizing context specific EMR system requirements and (ii) Methods for implementing interoperable, adaptable, and performant EMR databases.

Methods for defining and prioritizing context specific EMR system requirements include:

- A method for understanding the unarticulated and emerging needs of the users by identifying the situated roles of the EMR system. The system's situated roles refer to the unintended ways in which the users relate to and engage with the system in its context of use.
- A method for understanding the wants and priorities of the users. Through this understanding, the designers can create user-centered redesign strategies by aligning their design activities with their users' preferences.
- A method for prioritizing the EMR features to redesign by taking into consideration (i) the priorities of the different user groups and (ii) the interdependency of the EMR system's features. The method ranks the features based on the overall effect of redesigning them and allows the designers to optimize their redesign activities by maximizing the positive effects and avoiding negative consequences.

Methods for implementing interoperable, adaptable, and performant EMR databases include:

- A method for data modeling the clinical concepts involved in an EMR system by reusing existing data models. The method allows the designers to increase the interoperability of their systems while decreasing their data modeling tasks.
- A method for implementing EMR databases following an EMR interoperability standard and using commercially available graph databases. The method results in interoperable, adaptable and performant EMR databases.

Throughout the dissertation, the methods are showcased in the Japanese antenatal care context. Antenatal care was chosen as a case study due to its importance in terms of aim and timing. Antenatal care is the care that a woman receives during her pregnancy. The aim of antenatal care is the prevention and early detection of diseases that might affect multiple entities: the pregnant woman and her fetus(es). Since we are collecting information about the health of the fetus, antenatal care would potentially be the first point of contact of an individual with their EMR. Thus, if we aim to have complete longitudinal EMRs, the effective adoption and use of EMR systems in antenatal care is required.

Following the proposed design approach and with the support of the proposed methods, EMR system designers can design adaptable and scalable EMR systems and continuously adapt them to increase their usefulness and usability for their users. Although the proposed methods address the particular requirements of EMR systems, they could also be applied for the evolutionary design of other complex socio-technical systems.

Contents

1	Introduction	1
2	EMR Systems: Complex Socio-Technical Systems in Need of Redesign	5
2.1	EMR Systems in the Examination Room	5
2.1.1	Healthcare Provider Attitudes towards EMR Systems	5
2.1.2	Patient Attitudes towards EMR Systems	6
2.1.3	Patient-Centered EMR Systems	7
2.2	Designing Information Systems	8
2.2.1	Information Systems Design Research	8
2.2.2	User Centered Design	9
2.2.3	Prototyping	10
2.3	Evolutionary Design Approach for EMR Systems	10
2.4	Choice of Antenatal Care as a Case Study	13
I	Methods for Defining and Prioritizing Context Specific EMR System Requirements	17
3	Extracting the Situated Roles of EMR Systems	19
3.1	Introduction	19
3.2	Background	21
3.3	Methods	22
3.3.1	Gathering Contextual Data	22
3.3.2	Extracting the Situated Roles	23
3.3.3	Case Study	23
3.4	Results	25
3.4.1	The Wingman	26
3.4.2	The Accomplice	27

3.4.3	The Third Wheel	28
3.4.4	The Bouncer	28
3.4.5	The Messenger	29
3.4.6	The Summarizer	30
3.4.7	The Assistant	30
3.4.8	The Gossip	31
3.4.9	The Alien	31
3.4.10	The Bureaucrat	32
3.5	Discussion	33
3.6	Conclusion	34
4	Understanding the Experiences, Wants, and Priorities of the Users of EMR Systems	35
4.1	Introduction	35
4.2	Methods	36
4.2.1	Survey Design	36
4.2.2	Survey Analysis	37
4.3	Results	38
4.3.1	Validation of the Situated Roles	38
4.3.2	Desired Frequency of the Situated Roles	39
4.3.3	Importance of the Situated Roles	39
4.4	Discussion	40
4.5	Conclusion	43
5	Prioritizing EMR Features to Redesign	45
5.1	Introduction	45
5.2	Methods	46
5.2.1	Identifying the Importance of Different EMR Features to the users	47
5.2.2	Identifying the Relationship between the EMR Features	48
5.2.3	Computing the Overall Effect of Modifying each Feature	49
5.2.4	Computing the Priority for Targeting each EMR Feature	49
5.2.5	Example to Illustrate the Method	50
5.3	Results	51
5.3.1	Importance of the Different EMR Features to the Users	51
5.3.2	Relationships between the EMR features	52
5.3.3	Priority for Targeting each EMR Feature	54
5.4	Discussion	55

5.4.1	Giving Weights to the Opinions of the Different User Groups	56
5.4.2	Dealing with the Missing Data	56
5.4.3	Analyzing the Relationships between the EMR Features	57
5.5	Conclusion	58

II Methods for Implementing Interoperable, Adaptable, and Performant EMR Databases 59

6 Modeling Clinical Concepts Using openEHR Archetypes 61

6.1	Introduction	61
6.2	Background	63
6.2.1	Traditional EMR Database Design	63
6.2.2	EMR Interoperability Standards	63
6.2.3	openEHR	64
6.3	Methods	64
6.3.1	Identifying Health concepts	65
6.3.2	Preparing Archetypes and Templates	66
6.3.3	Evaluation	68
6.4	Results	69
6.4.1	Domain Analysis Results	69
6.4.2	Evaluation of the Data Modeling Process	71
6.5	Discussion	73
6.6	Conclusion	73

7 Implementing EMR Databases using openEHR Specifications and Graph Databases 75

7.1	Introduction	75
7.2	Background	76
7.2.1	How the Database Implementation Can Affect EMR Systems	76
7.2.2	openEHR Database Implementations	77
7.2.3	Graph Databases	79
7.3	Methods	81
7.3.1	Graph Model of the openEHR RM	81
7.3.2	Storing Archetyped Data with Neo4j	83
7.3.3	Test Datasets Generation	83
7.3.4	Evaluation Setup	90

7.3.5	Labeling and Indexing	91
7.4	Results	92
7.4.1	Storage Space Requirement	92
7.4.2	Query Reponse Times	92
7.5	Discussion	94
7.6	Conclusion	96
8	Discussion	97
8.1	Defining the Requirements of EMR Systems	98
8.2	Person-Centered EMR Systems	98
8.3	Controlling Data in EMR Systems	99
8.4	EMR Systems as Agents of Change	100
9	Conclusion	101
9.1	Contributions	101
9.2	Future directions	102

List of Figures

1.1	Design methods for EMR systems.	3
1.2	The structure and flow of the dissertation.	4
2.1	Evolutionary design process EMR systems.	11
3.1	The conceptual approach.	20
3.2	The layout of the observed clinic.	26
5.1	Four steps to prioritize the EMR feature to (re)design.	47
5.2	The map of interdependencies between the EMR feature	53
6.1	The archetype modelling process and the tools used	68
6.2	The antenatal care process as described by the midwife	70
7.1	The openEHR Reference Model	78
7.2	The graph model	80
7.3	The graph model of the openEHR reference model	82
7.4	The dataset generation process	84
7.5	The high-level structure of the simulated records	85
7.6	The relational schema over which the data generation plans were executed .	86
7.7	The first set of data generation plans	87
7.8	The second set of data generation plans	88
7.9	The third set of data generation plans	88
7.10	The fourth set of data generation plans	89
7.11	The required storage space for each dataset	92
7.12	Comparison of the query response times for the two implementation ap- proaches with different size datasets	93
7.13	Comparison of the query response times for the two implementation ap- proaches with different queries	94

7.14 Effect of indexing on storage space requirements	95
---	----

List of Tables

3.1	The EMR system’s situated roles.	27
4.1	The extent to which the respondents experience the situated roles	39
4.2	The extent to which the respondents want to experience the situated roles	39
4.3	The importance of the different role-related experiences	40
5.1	The Importance of Different EMR Features to the Users	52
5.2	Final Ranking of EMR Features to Redesign	54
6.1	The health concepts that are included in the clinical check-up module	69
6.2	The health concepts that are included in the home monitoring module	71
6.3	The mapping of the health concepts to openEHR archetypes	72
7.1	Example of an extracted leaf node path	83

Acknowledgments

First, I would like to express my sincere gratitude and appreciation for my supervisor Prof. Tomohiro Kuroda for being a great mentor. He provided me with a supportive and free environment to learn and grow, and throughout my studies treated me with kindness, patience, and respect. He always asked me the hardest questions and pushed me to scrutinize my work, develop my thoughts, and never forget the big picture. I am very lucky that I had the chance to study under his supervision.

Second, I would like to express my gratitude to the Japanese taxpayers, who financially supported me during my graduate studies through the Ministry of Education, Culture, Sports, Science, and Technology (MEXT) of Japan.

I would also like to thank my thesis committee members, Prof. Masatoshi Yoshikawa, Prof. Katsuya Yamori, and Prof. Naohide Tomita for volunteering their precious time to review and provide feedback for this thesis. In addition, I want to thank Prof. Masatoshi Yoshikawa and Prof. Naohide Tomita for being my advisors in the doctoral course.

I am also very grateful to Dr. Goshiro Yamamoto, Dr. Naoto Kume, and Dr. Shinji Kobayashi for advising me during my graduate studies. Dr. Goshiro Yamamoto closely advised me through my PhD course and helped me figure out my plan and carry out my research activities. Dr. Naoto Kume taught me how to structure my thoughts and papers and always encouraged me to go beyond “scratching the surface.” Dr. Shinji Kobayashi introduced me to openEHR and taught me about interoperability and the design of EHR databases.

Conducting this research would not have been possible without the support of Prof. Hiroshi Tamura and Dr. Eiji Kondo. I am extremely grateful to you for giving me the opportunity to conduct research at Kyoto University Hospital and for providing the medical expertise and connections to supervise and conduct this research.

I would also like to extend my thanks to all the faculty of Medinfo including Prof. Masayuki Nambu, Dr. Kazuya Okamoto, Dr. Osamu Sugiyama, Dr. Shusuke Hiragi, and Dr. Purnomo Husnul Khotimah. Thank you for supporting me in this work and for always providing valuable feedback that both inspired me and pointed out aspects that I would not have otherwise considered.

My time at Medinfo would not have been as smooth and my life in Japan would not have been as easy without the invaluable support from Ms. Yoko Hara, Ms. Yuko Furusawa,

and Ms. Kaori Shiomi. You supported me with every little detail even when you were overwhelmed with work. You helped me with the process of moving to Japan, settling, managing my finances and my studies, and graduating. I cannot imagine how I could have done it without your kindness and I am forever grateful to you.

I am also grateful for all the students that I met in Medinfo including Tuukka Karvonen, Kensuke Morris, and Luciano Santos. It was a pleasure studying along you guys and seeing you ride your highs and your lows. And of course, I will always remember our beers and talks on the Kamogawa.

In addition to being part of Medinfo, I am extremely thankful for being part of the Design School of Kyoto University. Joining the Design School was one of the best decisions I ever made. The Collaborative Graduate Program in Design provided me with great learning opportunities and led me to change my whole research perspective. I am grateful for the whole Design School team including Prof. Toru Ishida, Prof. Kumiyo Nakakoji, Dr. Takushi Sogo, Dr. Yusuke Kita, and Dr. Yohei Murakami. I am also grateful to Ms. Eri Tsunokawa, Ms. Saki Hagihara, Ms. Fumika Akiyama, Ms. Yoko Kubota, Ms. Junko Maruyama, and Mr. Takeo Inoue for their continuous help and support throughout my journey in the Design School.

Finally, my deepest thanks and love for my family and friends. For my amazing parents Sonia and Said who dedicated their modest and honest lives for their children. For my siblings and guardians, Jihad, Jeanine, and Elie who supported me throughout my life whenever I needed their help. For Martha Knauf, who rode this roller-coaster, edited my articles, and made this whole process bearable, even enjoyable. For Victoria Abou-Khalil, my great friend and my favorite co-author who always reminds me of the important things in life. For Jad Touma, my great friend and my non-ending well of support and encouragement. I am eternally grateful for all of you.

Samar El Helou
Kyoto, 2019

Chapter 1

Introduction

A medical record is a document that contains information about the health of a patient. Usually, the information consists of the patient's medical history, medical encounters, orders and prescriptions, progress notes, and test results. Historically, medical records were paper-based and filled by healthcare providers. The widespread adoption of computers in the late 20th century led to the digitization of the medical record. In the 1990's, in a report titled 'The computer-based patient record,' the Institute of Medicine (IOM) promoted the development, implementation and widespread adoption of Computer-Based Patient Records (CPRs) [1]. The IOM highlighted the potential benefits of CPRs in terms of increasing the efficiency and effectiveness of healthcare provision. Today, the term Electronic Medical Record (EMR) refers to the same concept as a CPR: a digital record of an individual's health related information.

In this scheme, EMR systems are the computer systems used to record, retrieve, and manipulate information in EMRs. To yield the promised benefits of EMRs, EMR systems must be effectively used. Two major barriers for the effective use of EMR systems are their low level of usefulness and usability. In fact, healthcare providers who have adopted EMR systems continuously complain about these systems negatively affecting their communication with their patients, hindering their workflow, and adding unnecessary work to their already busy schedules [2–4]. In this sense, EMR systems commonly suffer from bad design, as they do not fulfill the needs of their users and do not fit into their use contexts.

The low levels of usefulness and usability of EMR systems is a widely known issue. Therefore, EMR system designers usually customize EMR systems with the aim of addressing the needs of the users and fitting the systems into their contexts of use. Yet, the issues with

the EMR systems' design persist. This implies that designing EMR systems is a complex, non-trivial task.

Indeed, EMR systems are complex socio-technical systems; they are asynchronous, specialized, critical, and non-trivial systems involving multiple stakeholders with different and sometimes conflicting priorities. EMR systems are used in healthcare settings where the clinical requirements and processes are prone to constant change. Their main users, healthcare providers, are experts in their fields, and therefore their description of their work does not accurately and consistently represent how they actually perform it. Moreover, like other artifact users, the users of EMR systems may have needs that they are unaware of or cannot articulate. Due to these considerations, designing EMR systems requires specific methods that can address the particularity of these artifacts.

In this dissertation, I view EMR systems as evolutionary systems, i.e., systems that must continuously evolve and adapt to the ever-changing needs of their users. Instead of only focusing on designing EMR systems that perfectly fit the users' requirements as they are currently understood, I believe that designers should also focus on (i) designing EMR systems that are easily adaptable and (ii) continuously identifying emerging needs and addressing them through redesign.

I also view EMR systems in their simplest form: as the combination of a database and an interface, as shown in Fig. 1.1. The interface of the EMR system is its front-end: the part with which the users interact with the system in its context of use. The database of the EMR system is its back-end: the part in which the EMRs are stored. The interface of the EMR system presents designers with context specific requirements. These requirements need to be well understood and defined. Once they are defined, the designers need to prioritize them to decide which needs are the most important to address. On the other hand, the database of the EMR system presents designers with universal requirements: high interoperability, high adaptability, and high performance. These three requirements have to be met if we aim to have scalable and adaptable EMR systems that do not become obsolete after a short period of time.

To support EMR system designers in their evolutionary design efforts, I propose a set of design methods for EMR systems. The proposed methods fall under two parts: (i) Methods for defining and prioritizing context specific EMR system requirements and (ii) Methods for implementing interoperable, adaptable, and performant EMR databases. Throughout the dissertation, I showcase the methods by applying them in Japanese antenatal care settings.

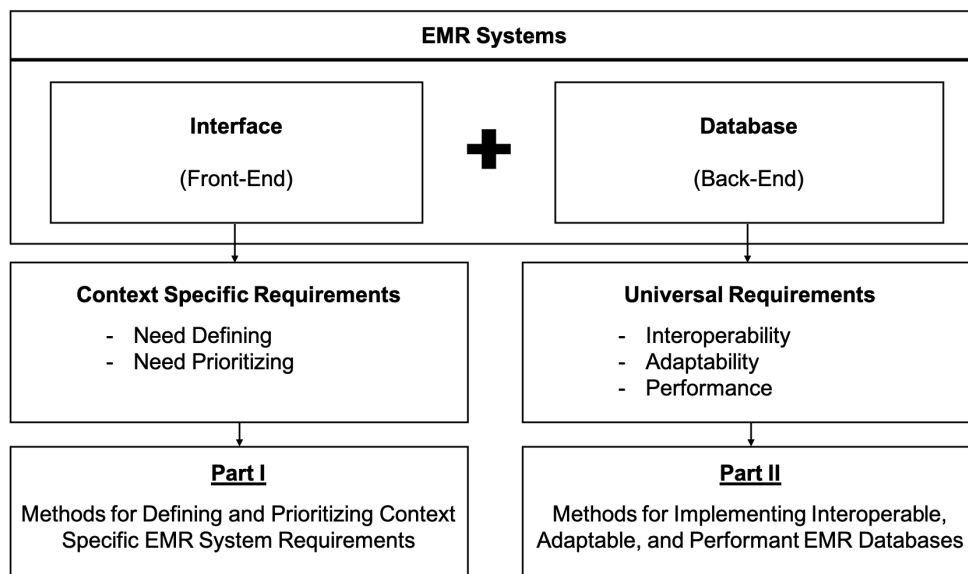


Fig. 1.1: Design methods for EMR systems.

To these ends, in Chapter 2, I look at the background of EMR systems and present the challenges faced by their designers. Then, I present a structured EMR design process that treats the EMR system as an evolutionary prototype. Finally, I describe the antenatal care context and explain my rationale for choosing it as a case study.

In Chapter 3, I present a novel method for identifying the unarticulated needs of the users by extracting the situated roles of an EMR system.

Chapter 4 builds on the results of Chapter 3 and provides a method for understanding the current experiences, wants, and priorities of the EMR system users.

Chapter 5 builds on the results of Chapter 4, and provides a novel method to prioritize EMR features to (re)design. The method takes into consideration the different priorities of the different user groups and the interdependency of the system's features.

In part II, I present methods for implementing interoperable, adaptable, and performant EMR databases. In Chapter 6, I explore the feasibility of modeling clinical concepts by reusing existing openEHR archetypes. Using these existing and validated data models would allow for higher levels of interoperability.

In Chapter 7, I propose a method for implementing EMR databases using openEHR specifications and graph databases. I evaluate the implementation method and show that it provides higher adaptability and performance levels.

In Chapter 8, I discuss the outcomes of the research, the limitations, the challenges that we faced, and the goals that we achieved.

Finally, in Chapter 9, I conclude by summarizing the main findings and highlighting future research directions.

The structure and flow of the dissertation are shown in Fig. 1.2.

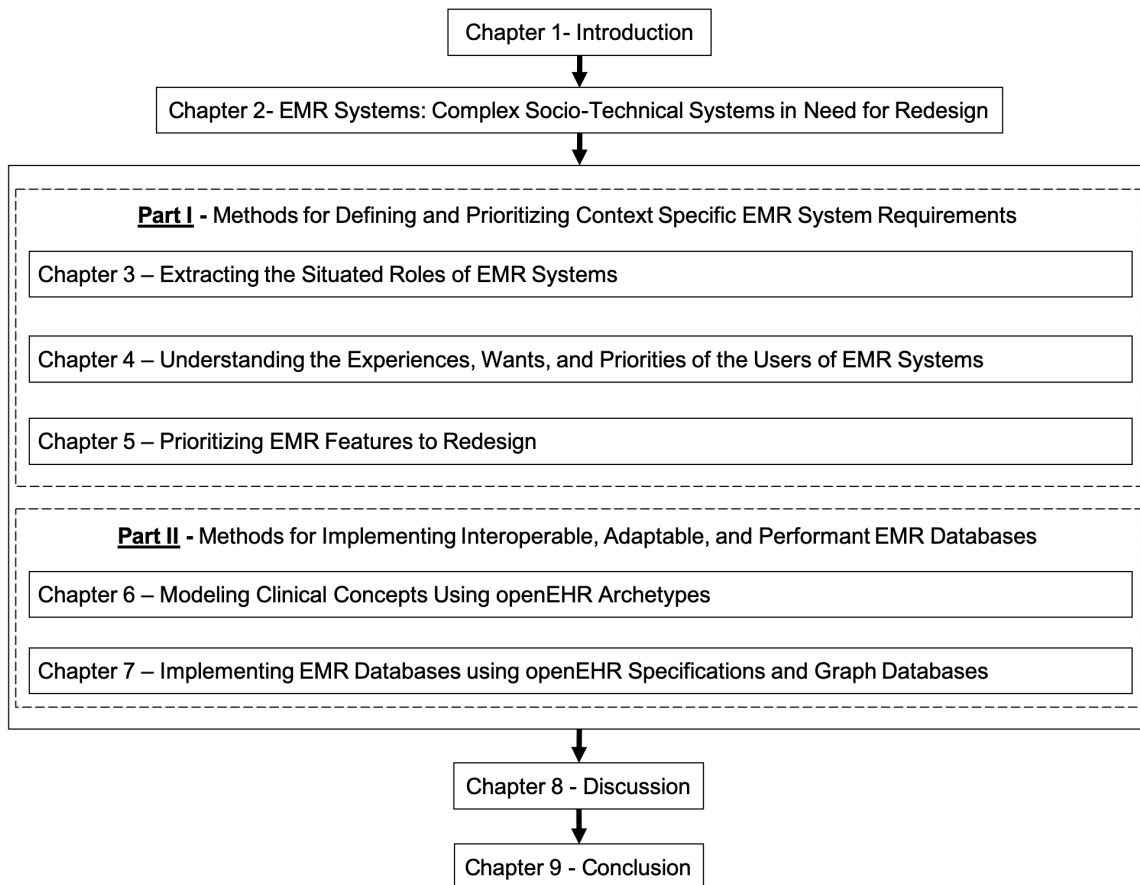


Fig. 1.2: The structure and flow of the dissertation.

Chapter 2

EMR Systems: Complex Socio-Technical Systems in Need of Redesign

2.1 EMR Systems in the Examination Room

In general, the healthcare sector has been slow at adopting EMR systems in examination rooms. Previous studies described multiple EMR adoption barriers, including usability issues, lack of fitness of EMR systems with existing clinical workflows, and concerns about computers negatively affecting the patient-provider relationship. To increase the adoption of EMR systems in healthcare, numerous studies have examined the needs of healthcare providers and the effects of computers on the patient-provider relationship.

2.1.1 Healthcare Provider Attitudes towards EMR Systems

Previous studies have shown that healthcare providers do not want EMR systems to disrupt their existing workflows and want them to integrate well into their work practices [5–7]. They want to easily navigate and find information in the EMRs [8–10] and need the EMR systems to support all of their formal [4, 11] and informal documentation and communication tasks [12]. The shortcomings of previous EMR systems could be attributed to the task-focused mindset of early system designers. Early EMR system implementations mostly aimed at allowing individual care providers to efficiently perform certain tasks.

Soon, it became clear that analyzing care processes and designing for healthcare teamwork was needed [13].

The presence of a computer in the examination room may also impact the patient-provider relationship and the satisfaction of the patient with the received care. Scott and Purves [14] noted the need to consider the patient, doctor, and computer in a triadic relationship when researching patient-provider relationships. Pearce et al. [15, 16] further highlighted this triadic relationship by showing that the computer influences the human actors during the examination. The computers may amplify existing communication behaviors of clinicians [17] due to a bottleneck effect where the clinicians lose the ability to multitask [18, 19]. This effect increases as the EMR tasks become more complex [19].

Factors external to the EMR systems could affect the way they are used, including: the doctor and patient characteristics [15, 16], the clinical room layout [20], and the content of the examination [21]. Chan et al. [21] found that doctors spent 50% less time using computers in examinations with psychological content. Als [22] found that clinicians appropriated the computers and used them in unintended ways, like using the computer as a magic box that allows them to present their abstractions as medical facts or conclusions while pointing at it. Als [22] also found that the clinicians resorted to the computer when they needed to take some rest or some “time out” to think.

2.1.2 Patient Attitudes towards EMR Systems

Multiple studies showed that the use of EMR systems negatively affects patient-provider communication [23–25]. However, there is currently no evidence that the use of a computer during the examination affects patient satisfaction or the patients perception of patient-provider communication [26, 27].

Patients characteristics may affect their attitudes towards the use of EMR systems during examinations. Strayer et al. [28] found differences between the attitudes of different patient groups towards the use of tablet computers in the examination room. Although patients had a generally positive attitude regarding their physicians using tablet computers, higher age and education levels were associated with a more negative attitude. People with high school or lower education were less worried about the safety of their health information and the mistakes that tablet computers are prone to. People from minority groups were more likely to state that the interaction became less personal because of the use of the tablet computer.

Previous studies also show that patients want to have the ability to access their EMRs [29–31]. When granted access to their EMRs, patients reported a feeling of autonomy and empowerment, and improved communication with their providers [32–34]. A recent study from Australia explored the attitudes of pregnant women regarding the electronic access of their pregnancy records. The women reported that the electronic system was a valuable tool for communicating information and managing their pregnancy [35].

On the other hand, providers are reluctant to expose all the EMR contents because they do not usually write their EMR notes with the intent of sharing them [36]. The notes are therefore complex and could contain the providers personal thoughts. Nevertheless, patients prefer having access to their EMRs even when the contents are inconsistent, derogatory or previously undisclosed [32].

In addition, patients were shown to want granular control over their EMRs and the ability to share them temporarily with different healthcare providers [37–40].

2.1.3 Patient-Centered EMR Systems

In 1998, a group of participants at a seminar in Salzburg, Austria, imagined the country of PeoplePower and designed the healthcare system of that country. In PeoplePower, the guiding principle of the healthcare system is nothing about me, without me. Patients in PeoplePower are well informed and actively participate in the decision-making process with their healthcare providers. In "PeoplePower" IT tools are widely adopted and used in the healthcare system [41].

Three years later, in 2001, the Institute of Medicine (IOM) proposed Patient-centered care as one of the main ways to improve the quality of Healthcare. Patient-centered care is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions [42]. Nowadays, the patient-centered care model is widely acclaimed. Nonetheless, its effective incorporation into the existing healthcare system is slow due to the lack of policies and tools facilitating the adoption of patient-centered activities [43]. Genuine patient-centered care requires informed and involved patients and families, along with receptive and responsive providers who in addition to focusing on treating diseases, concentrate on the individuality of their patient [44].

Although patient-centered care is acknowledged as a necessity [44], The designers of EMR systems rarely take into consideration the patients needs, preferences, and values [45]. They consider the healthcare providers as the main users and buyers of EMR systems. In

this scheme, implementing EMR systems inside clinical environments while facilitating the provision of patient-centered care remains an unresolved design challenge [46]. To tackle this challenge, the designers of EMR system need to understand the attitudes, preferences, and priorities of the patients and construct their design plans accordingly.

2.2 Designing Information Systems

Multiple definitions of “design” and “designers” exist. According to Simon’s often cited definition, “[t]o design is to devise courses of action aimed at changing existing situations into preferred ones.” Therefore, “[e]veryone designs who devises courses of action aimed at changing existing situations into preferred ones [47].” However, when applied to Information Systems (IS), design was traditionally seen as “the act of creating an explicitly applicable solution to a problem.” Therefore, the focus of Information Systems Design Research (ISDR) was about acquiring knowledge through the design and evaluation of artifacts [48]. In the next paragraphs, we present some background about ISDR and show how the field is moving towards a broader conceptualization, one that includes studying IS design processes.

2.2.1 Information Systems Design Research

Nowadays, design science is widely applied to IS. However its conceptualization is narrower than in non-IS areas [49]. McKay et al. describe the existence of two design science communities in IS: the mainstream community and the pluralistic community.

The mainstream community builds on the work of Hevner et al., [50] and adopts the widely accepted position that design science in IS is about designing ‘new and innovative artifacts’. McKay et al. [49] argue that this approach separates the “building and developing activities from the social, cultural and political aspects in organizational contexts.”

Conversely, the pluralistic community promotes a variety of perspectives around design [49] and expresses “concern that the pressure for (short-term) relevance and the understandable desire for definitional closure for the area are prematurely narrowing the perception of ISDR; focusing it exclusively on the constructivist methodology and on prescriptive design theories (models) for low level artifacts (IT mechanisms) rather than allowing it to have the breadth it has achieved in other design fields [51].”

McKay et al. [49] further show that the conceptualization of design science in IS is much

narrower than in non-IS areas. They expose the need for a more human-centered conceptualization of IS design, one that goes beyond design as Problem solving, Product, and Process, to include design as Intention, Planning, Communication, User experience, Value, Professional practice, and Service.

To widen the design construct in ISDR, McKay et al. [49] proposed a design research agenda that answers a number of questions including:

- “How do the intentions and requirements of the users become evident to IS designers?”
- “How well do emergent plans and models align with the intentions of IS designers and relevant stakeholders, and how might it be possible to achieve and ensure greater shared understanding and alignment of those models?”
- “How do support teams go about understanding the problems as experienced by users and their objectives in seeking resolutions so that the service desired by users can effectively be designed and delivered? How are on-going modifications and enhancements consonant with the original intentions of IS designers and stakeholders and with perceptions of the value associated with the IS implementation?”

2.2.2 User Centered Design

User Centered Design (UCD) or Human-centered design is an ISO standard providing a set of design principles and activities for the implementation of computer-based interactive systems [52]. For the improvement of the human-system interaction, UCD relies on the understanding of the users and the environments where they use the systems, and iteratively designing and testing the applications to achieve user performance goals.

UCD is usually a continuous cycle resulting in new releases of improved versions of the application. This cycle may prove beneficial when applied to EMR system development [53].

A core component of UCD is usability testing. The purpose of usability testing is to improve the application in terms of interactions, workflows, navigation among other criteria needed to address the users needs and requirements. Usability testing can be done with use of prototypes.

2.2.3 Prototyping

A prototype is a partial implementation of a system created to learn more about the requirements and the possible ways for satisfying them. Prototyping in the software industry is meant to lower the risk of developing software that does not correctly address the users' requirements.

There are two main approaches to prototyping [54]:

- Quick and sloppy creation of throwaway prototypes that will be discarded after the needed information is learned.
- Quality development of an evolutionary prototype that incrementally implements the new requirements after the needed information is learned.

Throwaway prototypes are good for experimenting with poorly understood requirements, which is when we know that the user needs something but we are not sure how a system would satisfy this need. This approach works well in isolation to verify small parts of the system. One drawback for this approach is that some poorly understood requirements make sense only in the context of a working system.

Evolutionary prototypes start off by the creation of a working system by implementing the critical and well understood functions. Later on, they allow the detection and implementation of new requirements as they arise. One drawback of evolutionary prototyping is the amount of time and human resources required to implement the new requirements.

2.3 Evolutionary Design Approach for EMR Systems

EMR systems are usually customized to fit the needs of their users. Therefore, we can assume that EMR designers follow a UCD approach where they (i) analyze the needs of the users, and (ii) build systems that answer to those needs. However, once EMR systems are implemented, they are not expected to go through any major changes. EMR designers offer the users after-sale services that usually includes fixing bugs and adding new functionalities as requested by the users. In this dissertation, we argue that this traditional EMR design approach is not optimal for answering the needs of EMR users and we propose an alternative design approach that can address these needs.

Traditionally, EMR designers focused on designing systems that perfectly fit the require-

ments of the users as they are understood in the initial design stages. However, it is important to note that EMR systems are used in healthcare settings where the clinical requirements and processes are prone to constant change. Their main users, healthcare providers, are experts in their fields, and therefore their description of their work does not accurately and consistently represent how they actually perform it. Moreover, like other artifact users, the users of EMR systems may have needs that they are unaware of or cannot articulate.

Due to the above-mentioned EMR particularities, following the traditional EMR design approach results in EMR systems that do not completely answer the users' needs and are difficult to adapt. By not understanding and adapting to the hidden, emerging, or changing needs of the users, EMR systems can quickly become outdated and may become obsolete. Therefore, a new design approach for EMR systems is needed; one that focuses on continuously redesigning EMR systems to answer the hidden, emerging, and changing needs of their users.

To this end, we view EMR systems as evolutionary systems that need to continuously evolve and adapt to the ever-changing needs of their users. We propose an evolutionary design process for EMR systems, as shown in Fig. 2.1. The design process is based on the UCD process but puts more emphasis on the redesign activities.

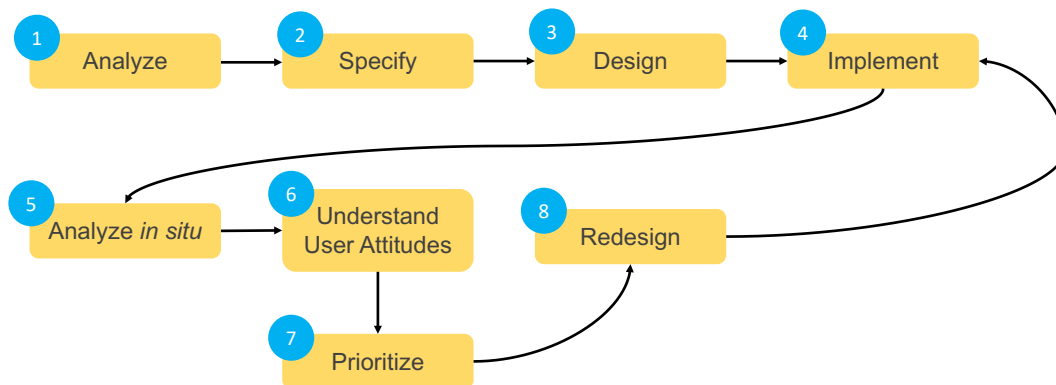


Fig. 2.1: Evolutionary design process EMR systems.

In steps 1, 2, 3, and 4 the designers follow the traditional EMR design process where they (1)

analyze the context of use and the users' processes and needs, (2) specify the requirements of the users, (3) produce and test system designs that satisfy those requirements, and (4) implement the system in its context of use. Once the EMR system is implemented in its context of use, the designers focus on continuously redesigning the system and adapting it to the users' needs.

In step 5, the designers analyze the EMR system in situ to identify the system's situated roles. These situated roles reflect how the system is appropriated by the users and allows the designers to identify the needs that the users are unaware of or cannot articulate.

In step 6, the designers gather feedback from the users to understand their attitudes regarding the situated roles of the EMR system. Through the feedback, the designers understand which roles are favorable, which ones are unfavorable, and which ones are the most important to the users.

In step 7, the designers prioritize the EMR features to redesign. This step is needed because system designers usually have limited resources that prevent them from addressing all the users' needs. When prioritizing the features to redesign, they use the feedback gathered in step 6 to align their design activities with the users' priorities.

Finally, in step 8, the designers produce and test system redesigns. Once the changes are implemented, the designers go back to step 5 and continuously repeat the redesign process described in steps 5, 6, 7, and 8.

When following this EMR design process, designers face multiple challenges including:

- The lack of design methods to support their activities in Steps 5, 6, and 7 where they need to define and prioritize context specific EMR system requirements.
- The technical difficulty of implementing interoperable, adaptable, and performant EMR databases.

To address these challenges, in this dissertation, we provide a set of methods that support the evolutionary design of EMR systems. The methods are split into two categories:

1. Methods for defining and prioritizing context specific EMR system requirements.
2. Methods for implementing interoperable, adaptable, and performant EMR databases.

2.4 Choice of Antenatal Care as a Case Study

Since the healthcare domain is highly specialized, we needed to select a specific setting to apply and evaluate our methods. We chose the antenatal care setting due to its unique goals, timing, and process. In this section, we explain our rationale for choosing antenatal care as the setting for our case studies.

Antenatal care is defined as the care a woman receives from healthcare professionals during her pregnancy. First introduced in 1902 by Scottish obstetrician J.W. Ballantyne with prevention as the primary purpose, antenatal care soon spread throughout Europe and is now an international routine medical practice [55]. Usually, the process involves the woman, her partner, her family, and multiple healthcare providers such as obstetricians, midwives, and nurses. For pregnant women, satisfactory antenatal care provides them with enough information about their pregnancy and addresses their concerns seriously [56].

In this work, we apply and evaluate our methods using a case study of EMR systems in Japanese antenatal care settings. In these settings, pregnant women rather than patients are taken care of, rather than being cured. The importance of studying EMR systems in antenatal care derives from the unique needs and aspirations of pregnant women, and the unique context of antenatal care in terms of timing, goals, processes, and outcomes.

First, pregnancy is a special time for women where joy and excitement are accompanied by fear, uncertainty, and anxiety about their pregnancy and future [57]. During their pregnancy, pregnant women are encouraged to be highly involved and actively exchange information with their care providers.

Seconds, it is common for the partners and family members of the pregnant women to be involved in the process and attend the routine antenatal care visits. In this sense, antenatal care settings are unique in that the care providers and receivers do not fall into the usual clinician-patient scheme. Moreover, most of the previous research about EMR systems was situated in a triadic relationship scheme. Since the pregnant women are usually accompanied by a partner or family member, the antenatal care setting targeted in this work does not perfectly fit into the triadic scheme.

Finally, unlike other care processes where the purpose is to cure one patient, antenatal care aims to prevent and early detect diseases that could affect the pregnant woman and her fetus(es). During antenatal care, health data is collected about the pregnant woman and her fetus(es) because health problems occurring during pregnancy could have lifetime

health effects on both of them. Therefore, antenatal care is the first point of contact humans have with their medical record. The effective use of EMR systems in antenatal care settings is necessary if we aim to have complete longitudinal health records and reduce future healthcare costs.

Antenatal Care in Japan

In 2016, Japan had approximately one million births [58]. Obstetrical practice in Japan is standardized by the Japan Society of Obstetrics and Gynecology (JSOG) and the Japan Association of Obstetricians and Gynecologists (JAOG) [59]. As of 2011, an estimated 99.7% of pregnant women in Japan undergo the recommended regular antenatal checkups [60]. Healthy women with uncomplicated pregnancies usually receive 14 checkups, starting before their eighth week of pregnancy and continuing until one week after childbirth [59]. In some cases, pregnant women in Japan do *satogaeri shussan* where they return to their natal home during the last stages of their pregnancy [61], a geographical move that entails a change of healthcare providers.

In addition to the antenatal care visits, the pregnant women are provided with the *Boshi Kenko Techo*, a paper-based Maternal and Child Health (MCH) handbook [60]. The MCH handbook is used by almost all pregnant and postpartum women in Japan. It consists of records of the woman's pregnancy, delivery, and child development and health. The handbook is also filled and reviewed by antenatal care providers at hospitals, clinics, or health centers [62]. Historically, the role of the MCH handbook changed with respect to public health needs and policies. The drastic decrease in newborns led to an emphasis on psychosocial support for childbearing and child rearing in recent versions of the handbook [61].

Japanese women can choose between obstetrician-led (OB-led) or midwife-led (MW-led) antenatal care. When comparing both types of antenatal care for low-risk pregnancies, Iida et al. [63] found that pregnant women in MW-led care had longer antenatal care visits, conversed more, and received more specific advice than women in the OB-led group. Moreover, women in the MW-led care group gave higher ratings to their satisfaction with care and their perception of woman-centered care. The authors suggest that these results highlight the different roles of the obstetricians and the midwives. The obstetricians role is to intervene when they find abnormal medical signs while the midwives role is to promote self-care and autonomy.

EMR Systems in Japanese Antenatal Care Settings

As of 2007, an estimated 93% of university hospitals, 71% of public hospitals, 33% of private hospitals, and 10% of clinics in Japan were using a form of computerized medical record or order entry system [64]. Since 2007, the adoption of EMR systems has been steadily increasing and is expected to reach 90% in general hospitals by 2020 ¹.

In addition, multiple web and mobile applications for pregnant women were announced in Japan in the last decade ². These proposed applications are digital versions of the MCH handbook with extra functionalities such as automatic chart generation and child immunization reminders. The number of pregnant women using these applications is increasing but their usage remains uncommon. Google Play shows less than half a million downloads for Ninpu-Techo, a pregnancy mobile app developed by Hakuhodo DY Media Partners, Tokyo, Japan and NTT DOCOMO Inc., Tokyo, Japan in 2013 ³. To our knowledge, pregnant women in Japan currently do not have online access to their official EMRs inside their providers systems. Even though EMR systems are commonly used in Japanese antenatal care settings, not much is known about their use or about the pregnant womens attitudes regarding them.

¹www.kantei.go.jp/jp/singi/keizaisaisei/kadaibetu/dai6/siryou1.pdf

²http://open_jicareport.jica.go.jp/pdf/12148631.pdf

³<https://play.google.com/store/apps/details?id=jp.co.hakuhodody.media.nimputecho>

Part I

Methods for Defining and Prioritizing Context Specific EMR System Requirements

Chapter 3

Extracting the Situated Roles of EMR Systems

In this chapter, we tackle the first challenge faced by designers when redesigning EMR systems: defining the context specific requirements for the EMR system. We propose an approach that views users as designers and considers their interactions with the system to be part of the design process. Instead of relying on the users' verbal input, the designers identify the users' needs by looking at their actions. Instead of focusing on the problems that the users encounter when using the system, the designers focus on all types of interactions that take place around the system. By taking this approach, designers can identify the unarticulated needs of the users and find design opportunities that improve the system's existing functions, and more importantly extend them to include new functions.

3.1 Introduction

To be accepted and effectively used by their users, Electronic Medical Record (EMR) systems have to be highly useful and usable [2, 3, 65]. To this end, multiple user and usability studies were previously conducted with the aim of refining the EMR systems' functional and non-functional specifications [4–10, 12, 66–69]. In these studies, researchers used multiple methods to identify the needs of EMR users and the issues they encounter when using the EMR systems. Previously used methods include surveys, focus groups, interviews, and/or observations and allow the designers to identify problems that users have when using the EMR system and functions that answer the articulated needs of the

users. However, previous methods do not allow the designers to identify the needs that the users are not aware of or cannot articulate. Moreover, when experts describe their work, their verbal descriptions are usually inconsistent with how they actually perform their work in the field [70].

To address the limitations of the previous methods, we propose an approach for understanding an EMR system in situ. Our approach is inspired and based on the idea of ‘redesign from appropriation’ and allows the designers to identify design opportunities for EMR systems [71]. We view and analyze EMR systems as artifacts that evolve with time and exhibit situated roles. Situated roles refer to the ways the EMR system is appropriated by its users, i.e., the unintended ways the users engage with, relate to, and perceive the system in its context of use. Our conceptual approach is shown in Fig. 3.1.

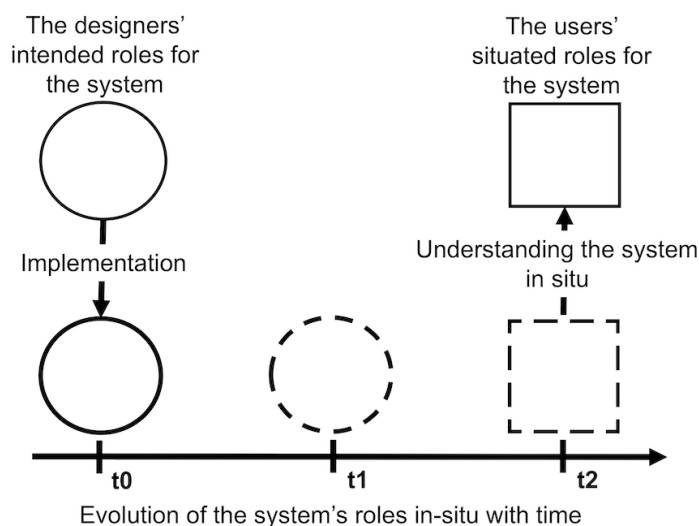


Fig. 3.1: The conceptual approach.

An EMR system can exhibit multiple situated roles; for example, a physician could use the system as a tool to communicate visual information to a patient during a consultation, or as an excuse to pause the conversation with the patient. These situated roles emerge with time as a response by the users to a contextual need or constraint. Therefore, the designers are usually unaware of the existence of these situated roles. In this scheme, understanding the situated roles of EMR systems could expose user-centered redesign opportunities.

3.2 Background

In his model for artifact study, Fleming discussed the function of an artifact as one of its five basic properties [72]. He noted that function encompasses both the uses (intended functions) and the roles (unintended functions) of the artifact in its culture. He also highlighted that, when designers conduct functional analysis, they need to involve the discussion of the human and their artifact associated behavior.

Similarly, various studies in Computer-Supported Cooperative Work (CSCW) discussed a system's unintended functions through the concept of appropriation. Once the artifacts or technologies are implemented in their contexts of use, they go through a process of appropriation by their users [73, 74]. Appropriation refers to the way a technology is adopted, adapted and incorporated into the users' working practice [75]. Dourish described the concept of technology appropriation as a broader view of the concept of customization; appropriation includes users utilizing technologies to serve new ends or for purposes beyond those for which they were originally designed. In this sense, Dourish noted that the appropriation of artifacts lies at the intersection of design studies and workplace studies, and that understanding how users appropriate technologies is critical to designing them.

Carroll [71] further argued that by appropriating a technology, the users play a crucial role in completing its design. Therefore, the appropriation of technologies could be considered as a part of their design process. Carroll also proposed improving the design of technologies by gathering the users' needs from their appropriation activities. By harvesting the requirements from the appropriated technology, the designer would 'design from appropriation.' By doing so, the designer turns the users into co-designers and they partake together in an evolutionary design approach.

In his work on the design of High Functionality Environments (HFE)s, Fischer [76] described the impossibility of complete coverage as one of the biggest design challenges for designing HFEs. To tackle this challenge, he proposed viewing the systems as open-ended artifacts that are continuously adapted by their users in their day-to-day work. Currently, various works in fields such as HCI [76], persuasive technology design [77], and Design Engineering [78] aim to understand how technologies are appropriated and use this understand to improve their design.

In this work, we propose an approach that allows designers to understand the ways EMR systems are appropriated, which we refer to as the 'situated roles' of the EMR system. The

term ‘situated role’ is inspired by the ‘situated action’ perspective introduced by Suchman [79]. Suchman [80] notes that ‘behavior can only be understood in its relations with real-world situations’ and that ‘actions are structured in relation to specific circumstances, and need to be understood in those terms.’ Similarly, we view the ways users appropriate EMR systems as structured in relation to specific circumstances, and believe they should be interpreted as such.

3.3 Methods

Our approach views the EMR system as an artifact that is appropriated by its users and exhibits situated roles. Situated roles refer to the unintended ways the users engage, perceive, and relate to the system. These situated roles emerge as a response by the users to a contextual need or constraint. The aim of our approach is to understand the system’s situated roles. Through this understanding, the designers harvest the users’ unarticulated needs and aspirations.

Our proposed method consists of two stages where the designer: (1) gathers contextual data regarding the use of system in situ and (2) analyzes the collected data to extract the situated roles.

3.3.1 Gathering Contextual Data

At this stage, the designer gathers information about the interactions of the users with the system in its context of use.

The situated roles emerge and evolve with time and are affected by organizational, professional, and personal cultures. Gathering contextual data is needed because there is no way for the system’s designers to predict the situated roles.

Different field research approaches could be applied at this stage. The designer can capture the data through direct observation or participant observation. Both approaches can offer the designer contextual data on the setting and the interactions. Direct observation requires the designer to be unobtrusive and detached from the setting, which can be difficult in private settings. Participant observation requires the designer to engage with the participants and become part of the setting, which entails a longer time investment and could affect the designer’s ability to differentiate between intended functions of the system

and its situated roles. The designer can collect this data using field notes, photographs, and/or video images.

3.3.2 Extracting the Situated Roles

At this stage, the designer looks for patterns in the collected data from stage 1. From these patterns, the designer extracts the situated roles. A situated role describes an unintended way in which the users engage, perceive, and relate to the system.

Extracting the situated roles provides the designer with a list of situated roles that will form be translated into design opportunities.

Multiple data analysis methods could be applied at this stage such as Thematic Analysis (TA) or Content Analysis, and different researchers might choose different methods [81]. TA is relatively simple, flexible, and could be applied by designers with little experience in qualitative data analysis. TA is used to identify patterns across the data. These patterns provide an answer to the research question at hand. In this case, the question is: ‘In what unintended ways do the users engage, perceive, and relate to the system?’ If TA is chosen, each identified theme would correspond to a situated role. For example, if the designer finds that ‘The EMR system is used to communicate information between the providers’ is a common theme in the data, they could assign a situated role named ‘the messenger’ to this theme. A common approach to TA consists of six phases: (1) familiarization with the data, (2) coding, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, (6) reporting the themes.

3.3.3 Case Study

To showcase the approach, we present a case study in which we apply the approach for an Electronic Medical Records (EMR) system in Japanese antenatal care settings. The work was a part of a research project aiming to improve antenatal care clinics. Before we started our work, we assumed that ‘In a smart clinic, Information Technology (IT) would be used to provide a better working environment for providers and better care for patients.’ Based on this assumption, we decided to focus on the situated roles of the EMR system in relation to the providers’ workflow and their communication with the patients. The research question central to this work was: ‘What situated roles does the EMR system play in regard to the clinical process and communication during the antenatal care visits?’

The following subsections describe our activities over a period of ten months and the results of each activity.

Gathering Contextual data

To rapidly gather a large corpus of knowledge and gain an initial understanding of the antenatal care process, we conducted a review targeting the existing literature on the antenatal care process and guidelines for obstetrical practices in Japan [82]. We validated our initial understanding of the process through the input of a practicing obstetrician in the antenatal care department. Then, we observed a team of obstetricians, midwives, and nurses providing antenatal care services at a Japanese university hospital. After obtaining the approval of three obstetricians to observe checkups during their shifts, one researcher visited the antenatal care outpatient clinics twice a week over a period of three weeks.

At the beginning of the check-ups, the obstetricians asked the pregnant women and their companions for their approval for the researcher to observe and take notes. The researcher directly observed the antenatal care routine check-ups and took detailed notes. During the observations, the researcher did not engage in conversations with the involved parties. After the pregnant women and their companions left the clinic, the researcher asked the clinical staff questions to gain a better understanding of ambiguous occurrences.

Extracting the Situated roles

After each observation, the field notes were transcribed and imported into QDA Miner, a qualitative data analysis tool. After the observations were completed, the data was analyzed by three researchers following the six phases of thematic analysis described by Braun et al [83]:

- Familiarization with the data: in the beginning of the analysis process, we read and discussed the data multiple times to familiarize ourselves with it.
- Coding the data: The coding process was conducted over three iterations in which the codes were extended and refined. The process went as follows:

While familiarizing ourselves with the data, we found that the interactions with the EMR system fall into four main categories: (i) interactions that support the communication, (ii) interactions that hinder the communication, (iii) interactions that support the clinical process, and (iv) interactions that hinder the clinical process.

These categories were mapped into four initial codes and were used in the first coding iteration.

After the first coding iteration, we noted more specifically how the EMR system supports/hinders the communication/process. These more detailed descriptions were used to code the data in the second coding iteration.

After the second coding iteration, we extended the codes to reflect aspects that could not be captured in the original codes and we merged codes together when their contents overlapped. Using these extended and refined codes, we did our third coding iteration.

- Searching for the themes: after the coding was completed, two researchers examined the codes to see which ones could fit together under one theme. A theme was considered to be any set of codes that captures a significant or interesting unintended way in which the parties interact with the EMR system.
- Reviewing the themes: in this step, we discussed which themes qualify as situated roles of the EMR system. A situated role of the EMR system would be any theme that reflects an unintended way that the users engage with, relate to, and perceive the system in its context of use. When deciding which themes to keep and which themes to discard, we answered the following questions:
 1. Does the theme really reflect an unintended way that the users engage with, relate to, and perceive the system?
 2. Does the theme make sense?
 3. Does the data that we collected support our conclusion?
- Defining and naming the themes: after reviewing the themes, we finally named and clearly defined them to reflect situated roles of the EMR system.
- Producing the report: the situated roles of the EMR system are presented in the results section.

3.4 Results

In total, we observed a team of three obstetricians, six midwives, and several nurses performing 37 antenatal care routine check-ups for 35 different pregnant women between their

eighth and their 33rd week of pregnancy. In the observed clinic, there were two desks with computer terminals. One desk was used by the obstetrician and the other by the midwife. The EMR is accessed via those terminals as depicted by the observing researcher in Fig. 3.2. The room layout, in this case, was ‘semi-inclusive patient controlled’ where the pregnant women could move their direction of gaze to see what the obstetrician is doing using the EMR system [84].

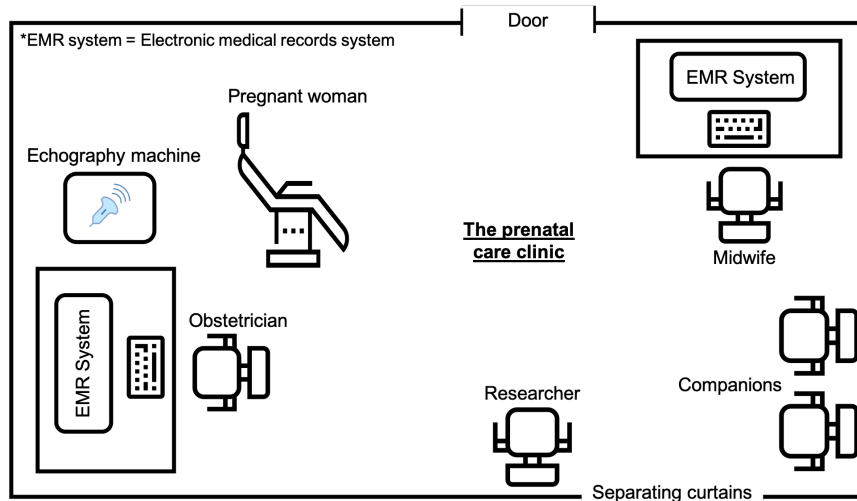


Fig. 3.2: The layout of the observed clinic.

The observed team relied on the EMR system and on manually recorded data (e.g., notes written by the team members, and notes written by the pregnant women in their Maternal and Child Health handbooks).

Following the thematic analysis, we were able to extract 10 distinct situated roles from the data. We found four situated roles relating to the communication between the providers, the pregnant women, and their companions, namely: (i) the wingman, (ii) the accomplice, (iii) the third wheel, and (iv) the bouncer. In regard to the clinical process, we found that the EMR system plays six different situated roles, namely: (i) the messenger, (ii) the summarizer, (iii) the assistant, (iv) the gossip, (v) the alien, and (vi) the bureaucrat [85,86]. Table 1 shows the situated roles and their definitions.

3.4.1 The Wingman

As a wingman, the EMR system supports the care providers in the explanation process.

During the checkups, the clinical staff verbally communicated clinical information to the

Table 3.1: The EMR system's situated roles.

Situated Role	Definition
The wingman	Supports the obstetricians in the explanation process.
The accomplice	Helps pause communication with the pregnant women.
The third wheel	Distracts the obstetricians from communicating with the women.
The bouncer	Excludes the pregnant women and their companions from the EMR.
The messenger	Enables the communication of information between the providers.
The summarizer	Provides a quick summary of the pregnancy's course.
The assistant	Facilitates the management and preparation of the check-ups.
The gossip	Is not completely trusted by the staff with sensitive information.
The alien	Hard to learn, requires recall, and doesn't support routine tasks.
The bureaucrat	Requires the providers to halt the clinical process to report data.

pregnant women and their companions. This communication helps the pregnant women and their companions understand the current state of the pregnancy and the logic behind clinical decisions. In the observations, the obstetricians used the EMR system as a support tool to provide clinical information and explanations. We observed the obstetricians pointing towards the screen while reading their EMR notes and explaining them. The obstetricians also used automatically generated charts and ultrasound images from their EMR notes to visually communicate information to the pregnant women and their companions.

However, the obstetricians did not always automatically employ this strategy. In one case, while the obstetrician was explaining, the pregnant woman started leaning towards the EMR systems screen to see the image that the obstetrician was looking at. Only after realizing that the pregnant woman was interested in seeing the image did the obstetrician rotate the monitor in her direction.

3.4.2 The Accomplice

As an accomplice, the EMR system helps pause communication with the pregnant women.

We found that the obstetricians used the EMR system as a tool to pause communication with the pregnant women, a strategy which proved particularly useful when their workload was high, or in highly emotional situations.

One of the obstetricians expressed the need for a moment to think in which they do not have to maintain a conversation with the pregnant women. In such cases, the EMR system served as a tool to pause the conversation and provide them with the needed moment to think.

Moreover, talking about pregnancies, especially complicated ones, could result in highly emotional situations. In this case, the EMR system provided the obstetricians with a bubble allowing them to distance themselves from the interaction. In one observed case, the obstetrician had to tell the pregnant woman that her pregnancy must be terminated. This woman had already experienced a pregnancy termination. After receiving the information, the pregnant woman started crying. At that moment, the obstetrician resorted to the EMR system to avoid looking at the pregnant woman and allow her to privately wipe her tears and stop herself from crying. When the obstetrician turned to the EMR system, the midwife left her desk and went towards the pregnant woman with a tissue box in hand. The midwife continued standing next to the pregnant woman while the obstetrician was working on the EMR system.

3.4.3 The Third Wheel

As a third wheel, the EMR system distracts the care providers from communicating with the pregnant women.

We found that the obstetricians spent a major part of the checkup time keyboarding and facing the EMR screen. During the obstetricians' data input time, the pregnant women waited silently in their chair, looked closely at the EMR screen to see what their obstetrician was typing, or tried to initiate a conversation with the obstetrician or their companions.

While inputting data, the obstetricians responded to the pregnant women in various ways. Most of the time, they responded by turning their heads slightly away from the screen towards the pregnant woman. When the pregnant woman continued to ask questions or tried to engage in conversation, the obstetricians either started to alternate quickly between the screen and her or stopped inputting data and turned their chair away from the desk to face and respond to her. In some cases, they fully rotated their chair, but in most cases, they turned it halfway between their desk and the pregnant woman.

3.4.4 The Bouncer

As a bouncer, the EMR system creates an exclusive environment by physically excluding the pregnant women and their companions.

On multiple occasions, we found that the pregnant women and their companions showed interest in looking at the EMR. However, the pregnant women had to actively get closer

to the screen while their companions' assigned chairs were placed too far from the screen, leading most of them to stop trying to look at the screen after a while.

On one occasion, the companion of the pregnant woman stood up to get a better view of the EMR screen. After standing up and realizing that he still cannot get a clear view, he tilted his head and body forward in the direction of the screen. When he realized that, even in this position, he cannot clearly see the contents of the EMR, he went back to his seat. After some time, he got up again, tilted forward towards the screen, and went back to his seat clearly feeling disappointed. A while later, he repeated the same sequence: he stood up, tilted forward, and sat down again. After sitting down, he gazed at the floor, bored and frustrated. Finally, he stood up, moved closer to the pregnant woman and to the EMR screen and remained standing there until the end of the checkup.

3.4.5 The Messenger

As a messenger, the EMR system enables the communication of information between the care providers.

In the case of the observed clinic, every pregnancy was cared for by multiple obstetricians and midwives. The rotation of the clinical staff required them to communicate the pregnant women's health data. The EMR system was the main tool for communicating clinical information to ensure continuity of care. The EMR system, in this case, provided seamless communication between the clinical staff over time and staff rotations.

On the other hand, when pregnant women were transferred from other clinics, the team only had access to the paper records that they had brought with them. In this case, the team created new EMRs for the women. However, the previous notes existing in the paper records were not transferred to the newly created EMRs.

Even though the pregnant women and their family members are involved in communicating health related information to the care providers, they did not have the ability to directly add information into the EMR. During the checkups, through conversations with the pregnant women and notes from the women's MCH handbooks, the providers gathered information and added them into EMR memos. However, what went into the EMR remained under the full control of the care providers.

In one examination, a pregnant woman, with a history of high blood pressure, brought along a paper containing a list of blood pressure measurements that she self-monitored

and recorded. The obstetrician reviewed the measurements and handed the paper back to the woman. Then, the obstetrician wrote a note in an EMR memo regarding the measurements. However, the full list of blood pressure measurements remained out of the woman's EMR.

3.4.6 The Summarizer

As a summarizer, the EMR system provides the care providers with a summary of the pregnancy's current state and care course.

The EMR system allows the antenatal care providers to have all the health information in one place. On multiple occasions, before calling a pregnant woman into the clinic, the obstetricians quickly navigated through the previous EMR notes to form a mental summary of her current course of pregnancy.

However, the EMR system did not allow for a quick understanding of the current state of the pregnancy. One obstetrician noted, we would like to see the course of care in one glance. With paper records, it was easier to do that. However, with this system, it takes a lot of clicking and scrolling to get the full image.

The staff needed the EMR system to act as a summarizer. To achieve that, the obstetricians employed a workaround. To give themselves and the other providers a quick understanding of the care course, the obstetricians emphasized certain parts of their EMR notes by changing the size, boldness, and color of the text.

3.4.7 The Assistant

As an assistant, the EMR system facilitates the management and preparation of the checkups.

At the beginning of their shift, using the EMR system, the obstetrician and the midwife viewed the list of scheduled checkups. Knowing the number of checkups, they could estimate the workload for the day. Based on that information, they adapted the speed of their work and the duration of checkups.

Moreover, using the scheduled checkups list, the obstetrician and midwife knew who they were examining next and had access to her records prior to the checkup. Before calling the woman in, they reviewed the previous notes and discussed the current state of the

woman's pregnancy. Using this information, they could form a picture of what care actions they needed to perform once the pregnant woman was called in. By allowing for prior preparation, the EMR system makes the checkups run more smoothly. It eliminates the need for the staff to orient themselves and for the pregnant woman to explain the reason for her visit at the beginning of her visit.

3.4.8 The Gossip

As a gossip, the EMR system is not completely trusted with sensitive information.

In our analysis, we found that the clinical staff hesitate to include highly sensitive information in the pregnant women's records due to privacy and legal concerns. In one of our discussions with the staff, one midwife stated, if we have concerns over some psychosocial issues such as domestic abuse, we note it indirectly in the record. We do not write it literally; we use codes to pass the message to the other clinical staff. Employing this sort of strategy to document sensitive information implies that the EMR system is not completely trusted by the staff with information that is usually considered private or could be used for legal purposes.

3.4.9 The Alien

As an alien, the EMR system: (i) has low learnability, (ii) requires a high level of recall, and (iii) has an interface that is not optimized for routine tasks.

The difficulty of learning how to use the EMR system was one of the problems noted by the obstetricians. One obstetrician mentioned that it took them at least one month to get used to the system. Moreover, during a checkup, a staff member walked into the clinic and asked the obstetrician a question regarding the use of the EMR system, which the obstetrician answered by guiding them through the interface.

Furthermore, the EMR system appeared to require a high level of memory recall. The obstetricians frequently paused and tried to recall in which tab a specific field, or note, was placed. The inconvenience of the manual data input was further amplified by an interface design that was not optimized for routine data input and data retrieval tasks.

In addition, the EMR system suffered from performance-related issues. In certain cases, the system would temporarily stop responding or have a slow response time. These issues

occurred particularly when the providers opened a new EMR. Even though 90% of the common database queries are usually cached, and the list of patients is previously compiled, opening a new EMR required more than ten seconds in certain observed cases. This poor performance resulted in obvious frustration and time loss. To counter this issue, some midwives employed a sort of manual caching where they anticipated the need to open the records, opened the records, and let them load before they actually needed them.

3.4.10 The Bureaucrat

As a bureaucrat, the EMR system requires the care providers to halt the care process to input data.

During the checkups, the providers continuously collect data from multiple sources and add it into the EMR. Those sources include conversations with the pregnant women and their family members, ultrasound imaging devices, and measuring devices such as blood pressure meters, weight scales, and measuring tapes. The lack of integration between the medical devices and the EMR system required the providers to manually input most of the data that they collect. To do so, they had to intermittently pause their clinical flow. Below are some examples of occurrences encountered during the observations.

Before entering the clinic, the pregnant women use a blood pressure meter and a weight scale located in the waiting room. The machines print the measurements on small paper receipts. Once they enter the clinic, the women hand the paper receipts and their MCH handbooks to the midwives. During the checkup, the midwives copy the measurements into the MCH handbook and then input them into the EMR. The process of copying the data could take up to three minutes. After they copy the measurements, the midwives throw the small paper receipts in a trash bin under their desks. On two different occasions, during ongoing checkups, the midwives had to look in the trash bin for receipts that they had previously thrown away. In one of those occasions, a nurse had to come in, put gloves on, and help the midwife look inside the trash bin.

In addition, the midwives routinely measure the belly circumference before the obstetricians start to conduct the ultrasound. Using a measurement tape, they measure the belly twice; vertically and then horizontally. After the second measurement, the midwives sometimes retake the first measurement, as that they might have forgotten the first measure. Once they finish measuring, some midwives prepare the women for the ultrasound, turn off the lights and then head back to their desks to input the measures. Since this increases the

risk of forgetting the measures, other midwives prefer to head fast to their desks, input the measures in the MCH handbook and the EMR, and then return to the woman to prepare her for the ultrasound.

As for the obstetricians, they routinely use two ultrasound devices to collect data. After they finish conducting the ultrasounds, they reflect on the results and summarize them inside free-text EMR notes. Then, they add the ultrasound images to the notes. To do so, they manually copy the information from the output of the ultrasound devices into the EMR. In addition, they use an image snipping tool to take screenshots of the ultrasound images and then they paste the images inside the EMR notes.

It is important to note that similarly to the Third Wheel, this role is manifested when the providers input data into the EMR system. However, as a Third Wheel, the EMR system hinders the communication between the providers and the pregnant women, while as a Bureaucrat, the EMR system hinders the clinical workflow.

3.5 Discussion

The presented case study described how we applied the proposed approach to understand the situated roles of an EMR system in Japanese antenatal care settings. Our aim was to find redesign opportunities to improve the usefulness and usability of the EMR system in regard to patient-provider communication and clinical process support. By describing our process and outcomes, we illustrated the proposed approach.

We were able to identify the situated roles of the EMR system. by doing so, we reached a new and deeper understanding of the system in situ. This understanding will be used in the consequent stages of the systems redesign.

Even though we reached a deeper understanding of the system in situ, it is still unclear how we can align our intentions and plans with the intentions and priorities of the relevant stakeholders. Therefore, in addition to extracting the systems situated roles, we have to understand the users perspectives regarding them. Until this stage, the situated roles are a result of solely observational input from our perspective. Even if accounted for and actively put aside, our biases still exist in the current outcomes. To form a user-centered redesign strategy we need to know: (1) if the situated role is experienced by the users and to what extent, (2) if the users want to reinforce the situated role or inhibit it, and (3) if the situated role is highly relevant to the users and should be prioritized as a design target.

Moreover, in its current state, the approach results in multiple situated roles of the EMR system. Therefore, the designers reach the end of the process with multiple possible directions for redesign. Within teams, perspectives could differ over what constitutes the best situated role to target in the next step. Moreover, even if the team agrees on a direction for redesign, the question of how a design solution emerges based on the situated roles remains unanswered. An extension of the method is needed to answer these questions.

In other respects, the extracted situated roles are not necessarily interdependent, as the alteration of one could create a cascade effect affecting the others. Further analysis of the dynamics of the situated roles could result in finding strategic design targets that result in a bigger overall effect. This would allow for the conception of redesign strategies that prioritize design targets based on their overall effects instead of solely relying on their levels of importance. Therefore, future work will aim to understand the dynamics of the situated roles and to exploit this understanding for the conception of redesign strategies.

3.6 Conclusion

To conclude, the proposed approach focuses on the system's situated roles, i.e., the unintended ways the users engage with, relate to, and perceive the system. Following this approach, the designers identify the ways the EMR system is appropriated by its users.

Instead of relying on the users' articulations of their usage habits and needs, the first stage employs field observations to gather contextual data. From this data, the situated roles are extracted using qualitative data analysis methods. Since the extraction of the situated roles is solely based on observational data, there is a need to emphasize that the field observations and the data analysis should be conducted in a thorough manner.

When conducting the observations and the data analysis stages, the designers' values and biases might affect the process. To counteract the designers' biases that could threaten the credibility and validity of the situated roles and the consequent redesign strategies, designers need to validate their findings. The validation could be done by gathering feedback from the users. In chapter 4, we propose a method to validate the results and further understand the wants and the priorities of the users.

Chapter 4

Understanding the Experiences, Wants, and Priorities of the Users of EMR Systems

4.1 Introduction

In Chapter 3, we proposed a method to understand the EMR system in situ. The method allows designers to identify the situated roles of EMR systems. These situated roles reflect the unintended ways the users of the system engage with it, relate to it, and perceive it. Through these situated roles, the designers gain insights on the unarticulated needs of the users. Even though these new insights are valuable for the designers, they are the result of their own observations and analysis. A user-centered design approach requires the designers to put the needs and wants of the users in the center of the design process. Therefore, it is important to gather user feedback and use it to guide design decisions.

Therefore, after extracting the situated roles, the designers must first validate their conclusions. Furthermore, knowing the situated roles of the EMR systems does not allow the designers to align their design activities with the wants and priorities of their users. To do so, the designers must understand the wants and priorities of the users regarding the situated roles.

To address these limitations, in this chapter, we propose a method that allows the designers to validate the situated roles of the EMR system and understand the wants and priorities

of the users regarding them.

Since this chapter builds on the previous chapter results, we apply our method in Japanese antenatal care. In our case study, we consider that the main stakeholders of the EMR system are the antenatal care providers and the pregnant women. This is based on our belief that the design of EMR systems should, first of all, respond to the needs of healthcare providers and receivers.

4.2 Methods

The end goal of this process is to provide the designers with information allowing them to align their design plans with the users needs, wants and aspirations.

So far, the designers have a list of EMR situated roles that they extracted by observing how the EMR system is appropriated by its users. To form a user-centered redesign strategy the designers need to know: (1) if the situated roles are experienced by the users and to what extent, (2) if the users want to reinforce the situated roles or inhibit them, and (3) which situated roles are highly relevant to the users and should be prioritized as design targets.

To gather this information, the designers can collect the users assessments through surveys or interviews. In our case study, we used paper-based surveys to collect information from the antenatal care staff and online surveys to collect information from pregnant Japanese women. In the following subsections, we present a detailed description of how we designed the survey questions and how we analyzed the survey responses.

4.2.1 Survey Design

To gather feedback from the users regarding the situated roles, we administered surveys to (i) antenatal care providers including obstetricians and midwives (ii) pregnant Japanese women. The surveys inquired about their current experiences, their optimal experiences, and their priorities.

For each role-related experience, we asked three questions:

1. Currently, how frequently do you experience [role-related experience]?

The purpose of this type of question was to validate the situated roles through the users current experiences. Answers to this type of question were reported using a 6-point Likert scale ranging from Very frequently (1) to Not at all (6).

2. Optimally, how frequently would you experience [role-related experience]?

The purpose of this type of question was to understand how frequently the users wanted to experience each role. Answers to this type of question were reported using a 6-point Likert scale ranging from Very frequently (1) to Not at all (6).

3. It is important to me that the EMR system does [role-related experience] Or It is important to me that the EMR system does not [role-related experience]

The purpose of this type of question was to understand the importance of each situated role. These statements were formulated based on the roles nature. For favorable roles, we asked about the importance of their presence. For unfavorable roles, we asked about the importance of their absence. Answers to these statements were reported using a 4-point Likert scale ranging from Strongly agree (1) to Disagree (4).

4.2.2 Survey Analysis

The purpose of the survey was threefold: (i) validating the situated roles through the experiences of the users, (ii) understanding how often the users want to experience each situated role, and (iii) understanding how important each situated role is to the users. In the following subsection, we describe how we analyzed the survey data to reach our conclusions regarding the three previous points.

Validation of the Situated Roles

Based on the survey responses, we consider that a role-related experience is validated if at least one respondent reports experiencing it occasionally.

We also categorize the role-related experiences into three categories reflecting the extent to which they are currently experienced by the users:

1. Frequently: more than 50% of the respondents experienced it at least frequently.
2. Occasionally: more than 50% of the respondents experienced it at least occasionally.

3. Rarely: more than 50% of the respondents experienced it rarely at most.

Desired Frequency of the Situated Roles

We categorize the role-related experiences into three categories reflecting the extent to which they are wanted to be experienced by the users:

1. Frequently: more than 50% of the respondents wanted to experience it at least frequently.
2. Occasionally: more than 50% of the respondents wanted to experience it at least occasionally.
3. Rarely: more than 50% of the respondents wanted to experience it rarely at most.

Importance of the Situated Roles

We assign an importance score for each situated role-related experience by aggregating the answers of all the respondents in each user group.

4.3 Results

In total, we asked about 14 EMR role-related experiences. We received five survey responses from obstetricians, ten from midwives [86], and 413 from pregnant Japanese women [87]. Therefore, when reporting the survey results, we consider three users groups: OB, MW, and PW referring to Obstetricians, Midwives, and Pregnant Women, respectively.

4.3.1 Validation of the Situated Roles

To validate the situated roles, we analyzed the responses regarding the users current experience. We looked at the midwives, obstetricians, and pregnant women's answers separately.

Certain EMR role-related experiences could only be experienced by the obstetricians and the midwives and cannot be currently experienced by the pregnant women. Regarding these role-related experiences, we did not get feedback from the pregnant women.

The extent to which the respondents experience the situated roles is shown in Table 4.1.

Table 4.1: The extent to which the respondents experience the situated roles

Role	EMR role-related experience	OB	MW	PW
Messenger	EMR system is used to exchange information between the providers	Frequently	Frequently	Occasionally
Alien	EMR system is easy to use	Occasionally	Rarely	NA
Summarizer	EMR system can provide a quick summary of the pregnancy	Frequently	Frequently	NA
Alien	EMR system is easy to learn	Occasionally	Rarely	NA
Alien	EMR system is well integrated with the medical devices in the clinic	Occasionally	Occasionally	NA
Gossip	Sensitive psycho-social information is documented in detail in the EMR	Occasionally	Rarely	Rarely
Third Wheel	EMR system does not interrupt the communication	Occasionally	Frequently	Frequently
Assistant	EMR system is used to prepare for the check-ups	Frequently	Frequently	NA
Assistant	EMR system is used to manage the antenatal care appointments	Frequently	Frequently	NA
Bureaucrat	EMR system does not interrupt the clinical process	Frequently	Occasionally	NA
Wingman	EMR system supports the explanation	Occasionally	Rarely	Occasionally
Accomplice	EMR system is used to pause the communication when needed	Rarely	Occasionally	NA
Bouncer	EMR screen can be seen by the pregnant women during check-ups	Frequently	Occasionally	Occasionally

Table 4.2: The extent to which the respondents want to experience the situated roles

Role	EMR role-related experience	OB	MW	PW
Messenger	EMR system is used to exchange information between the providers	Frequently	Frequently	Frequently
Alien	EMR system is easy to use	Frequently	Frequently	NA
Summarizer	EMR system can provide a quick summary of the pregnancy	Frequently	Frequently	NA
Alien	EMR system is easy to learn	Frequently	Frequently	NA
Alien	EMR system is well integrated with the medical devices in the clinic	Frequently	Frequently	NA
Gossip	Sensitive psycho-social information is documented in detail in the EMR	Occasionally	Rarely	Occasionally
Third Wheel	EMR system does not interrupt the communication	Frequently	Frequently	Frequently
Assistant	EMR system is used to prepare for the check-ups	Frequently	Frequently	NA
Assistant	EMR system is used to manage the antenatal care appointments	Frequently	Frequently	NA
Bureaucrat	EMR system does not interrupt the clinical process	Frequently	Frequently	NA
Wingman	EMR system supports the explanation	Frequently	Occasionally	Occasionally
Accomplice	EMR system is used to pause the communication when needed	Rarely	Occasionally	NA
Bouncer	EMR screen can be seen by the pregnant women during check-ups	Frequently	Frequently	Frequently

4.3.2 Desired Frequency of the Situated Roles

To understand the desired frequency of each situated role, we analyzed the users responses for how frequently they would like to experience the roles. We looked at the midwives, obstetricians, and pregnant women’s answers separately.

The extent to which the respondents want to experience the situated roles is shown in Table 4.2.

4.3.3 Importance of the Situated Roles

As for the users’ priorities, we assign an importance score for each situated role by aggregating the answers of all the respondents in each user group. The importance of the different situated roles is shown in Table 4.3.

Table 4.3: The importance of the different role-related experiences

Role	EMR role-related experience	OB	MW	PW
Messenger	EMR system is used to exchange information between the providers	3.8	4.0	3.46
Alien	EMR system is easy to use	4.0	4.0	NA
Summarizer	EMR system can provide a quick summary of the pregnancy	3.8	4.0	2.76
Alien	EMR system is easy to learn	3.8	3.9	NA
Alien	EMR system is well integrated with the medical devices in the clinic	3.8	3.6	NA
Gossip	Sensitive psycho-social information is documented in detail in the EMR	3.4	3.6	2.75
Third Wheel	EMR system does not interrupt the communication	3.2	3.8	2.73
Assistant	EMR system is used to prepare for the check-ups	3.4	3.5	NA
Assistant	EMR system is used to manage the antenatal care appointments	3.4	3.8	2.37
bureaucrat	EMR system does not interrupt the clinical process	3.2	3.6	NA
Wingman	EMR system supports the explanation	2.8	2.9	2.40
Accomplice	EMR system is used to pause the communication when needed	2.4	2.4	NA
Bouncer	EMR screen can be seen by the pregnant women during check-ups	1.6	2.3	2.61

4.4 Discussion

The Experiences, Wants, and Needs of the Antenatal Care Providers

Our results show that the users' experiences with the EMR system and their aspirations regarding it are dependent on the nature and purpose of their job. Even though the experiences and aspirations of the midwives and the obstetricians overlapped for certain situated roles (the messenger, the summarizer, the assistant, and the alien), they differed for the others. Therefore, the redesign efforts should not only take into consideration the antenatal care context, but also the different types of users in this context. One direction to explore is the possibility of having a different EMR system for the midwives and for the obstetricians instead of having a general antenatal care EMR system.

The results also show that, for the antenatal care providers, the EMR system is viewed first and foremost as a tool for supporting the workflow. The messenger, summarizer, assistant, and alien were very important situated roles for both groups. Facilitating the communication with the pregnant women was viewed as secondary in certain cases, as with the bouncer and accomplice roles. These results shed light on safe redesign targets, ones that improve the EMR systems capabilities as a practice management tool.

The results also highlight the need to better understand the reasons behind the ambivalence of the accomplice and gossip roles. This is especially true now, as the move towards a more patient-centered and biopsychosocial model of care is widely advocated for in medical informatics research communities.

Through the gossip role, the case study showed that in certain cases psychosocial infor-

mation goes undocumented. The importance of documenting sensitive psychosocial information is particularly clear in cases of concern over Domestic Violence (DV). In Japan, approximately one in every 20 women may experience DV during pregnancy [88] and addressing it is particularly difficult because Japanese people value endurance and keeping family secrets [89]. Further investigations should be conducted to understand if the gossip role is imposed by the EMR system's design as it might be creating a feeling of distrust for the medical staff, or if it is a result of the medical staff's uncertainty regarding the laws governing healthcare data.

As for the accomplice role, it is created by the staff to pause the conversation with the pregnant women. It was found to be ambivalent and somewhat important for both the midwives and obstetricians. In this case, the reasons behind this role should be further understood since it presents a possible conflict between the needs of healthcare providers and patients, thus raising the question: Whose needs should we consider when we are designing EMR systems?

The Experiences, Wants, and Needs of the Pregnant Women

Our survey results showed that Japanese women want to easily see the EMR screen during antenatal care checkups and want the providers to occasionally use it as an explanation support tool. They want to manage their appointments electronically, have their psychosocial information documented in detail, and have access to their pregnancy summary. They think it is very important that their providers to exchange their medical records electronically. And finally, they do not want the EMR system to interfere with the communication during the checkups. Our survey further showed that for Japanese women, the most important EMR-related experience is the exchange of information between their different healthcare providers.

Design Implications

To improve the usability and usefulness of the EMR systems, designers can amplify the favorable roles (the roles wanted to be experienced frequently) and minimize the unfavorable roles (the roles wanted to be experienced rarely). To align their design activities with the priorities of the users, designers can focus on the roles reported as important by the users. To increase the impact of their redesigns, the designers can focus on minimizing unfavorable roles that are frequently experienced, e.g., the alien, or amplifying favorable roles that are less frequently experienced, e.g., the wingman.

To respect the priorities of the antenatal care providers and the pregnant Japanese women, we need to address the EMR systems interoperability issues that technically hinder the exchange of EMRs, and the EMR systems security issues that legally and socially hinder this exchange.

Furthermore, we need to adopt a holistic view of health when designing EMR systems. Pregnant women understand the importance of their psychosocial state for the well-being of their pregnancy. We need to align our viewpoints with theirs and shift from designing biomedical EMR systems to designing biopsychosocial EMR systems. In addition to creating data models and spaces for psychosocial information in the EMR systems, we need to address the security and ethical challenges that relate to it.

In other respects, pregnant Japanese women want EMR-supported explanations and summaries to better understand their pregnancies. This implies that they view the EMR as a tool that provides them with information and awareness regarding their pregnancy. Adopting their viewpoints would require us to shift our view of EMR systems from tools that support note-taking and healthcare bureaucracy to tools that promote communication, woman-centeredness and autonomy.

Finally, EMR systems are usually customized according to the needs and preferences of the healthcare providers that will use them. However, women with different demographics or at different stages of pregnancy were shown to have different experiences, aspirations, and priorities regarding the use of EMR systems [87]. Future EMR system designs could accommodate these differences by automatically adapting their functionality according to the particular needs and preferences of the healthcare receiver. By doing so, we would obtain person-centered EMR systems that fit the vision of person-centered healthcare systems [90].

Alignment of Priorities

Our results showed that the priorities of the three user groups were mostly aligned. We found that the groups agreed on the most important and the least important roles. The most important roles were the ability to exchange EMR information, and being able to have a summary of the pregnancy. The least important role was providing online access for the pregnant women to see the contents of their EMRs. Even though the priorities of the user groups were mostly aligned, we found some interesting misalignment.

The first misalignment involved the obstetricians and the midwives. The obstetricians

reported that it is more important to use the EMR system to prepare for the check-ups than preventing the EMR system from interrupting the communication during the check-ups. The midwives reported otherwise.

The second misalignment involved the antenatal care staff and the pregnant women. For both the obstetricians and the midwives, it is more important to use the EMR system as an explanation support tool and to manage the antenatal care appointments, than to allow the pregnant women to see the EMR screen during the check-ups. However, the pregnant Japanese women reported that it is more important for them to be able to see the EMR screen during the check-ups.

4.5 Conclusion

In this chapter, we introduced a method that allows the designers to validate the situated roles of the EMR systems and to understand wants, and priorities of the users.

In cases where the resources are limited, designers have to prioritize which features to (re)design. Using the feedback of the users, the designers can construct a user-centered design strategy by aligning their design goals with the wants and priorities of their users.

However, after applying the method to our case study, we found that the users may have different and sometimes conflicting priorities. Moreover, we realized that the features of the EMR system are highly interdependent; if we modify one feature, we will indirectly affect the other features of the system. This lead us to the following question: ‘When we have different stakeholders with different priorities and features that are highly interdependent, how can we prioritize the EMR features to (re)design?’

To answer the previous question, in Chapter 5, we propose a user-centered effect-based method to prioritize the features to (re)design.

Chapter 5

Prioritizing EMR Features to Redesign

When adopting a user-centered redesign approach, designers have to consider which EMR features are the most important to their users. In the previous chapter we proposed a method that allow the designers to identify the wants and priorities of the users. However, prioritizing EMR features could be complicated because: (i) EMR systems have multiple users with differing, and sometimes conflicting, priorities and (ii) modifying one feature of the EMR system would affect the other features of the EMR system.

In this chapter, we propose a method for prioritizing the features to target when redesigning an EMR system [91]. The method takes into consideration the different priorities of the users and the interdependency of the different features. We illustrate the method using our case study and using the results of Chapter 4. Our results highlight the importance of considering the different user groups and the interdependency of the different EMR features. Designers could use the proposed method to support their decision-making during EMR (re)design projects [91].

5.1 Introduction

Previous studies exposed multiple (re)design opportunities to improve the usefulness and usability EMR systems such as: integrating them better into existing workflow and practices [5–7], making them easier to navigate, making it easier to find information inside of them [8, 10]11, extending their functions to support all the tasks performed by their

users [4, 11, 12], increasing their levels of interoperability [92], and improving their learnability and usability [85], among many others.

Multiple (re)design opportunities exist to improve the design of an EMR system. Usually, due to limited available resources, the designers cannot act upon all of them. Therefore, they have to choose which EMR features to target in their (re)design. To make this choice, designers have to know which EMR features are the most important to work on, in other terms, they have to prioritize the EMR features to (re)design.

If the designers are adopting a user-centered design approach, they would prioritize the EMR features following the priorities of their users [93]. However, EMR systems have multiple types of users with differing, and sometimes conflicting, priorities. For example: patients may consider having access to their EMRs as very important, while their healthcare providers may view it as not important at all. Therefore, taking into consideration the priorities of all the user groups is needed to provide optimal designs.

Moreover, modifying one feature of the EMR system could affect other features of the EMR system. For example: extending the functionalities of the EMR system might decrease its level of usability – having more functions makes the system harder to use. On the other hand, making the EMR system easier to learn may render it easier to use. Accordingly, we consider that the overall effect of modifying an EMR feature consists of a direct effect i.e., the effect it has on the modified feature and a cascade effect i.e., the effect it indirectly has on the other EMR features.

In this chapter, we propose a method that allows designers to prioritize EMR features to (re)design. The method takes into consideration (i) the priorities of the different user groups and (ii) the interdependency between the different EMR features. The method provides designer with a way to rank different the EMR features based on their respective importance to the users and the overall effect of modifying them. To illustrate the method, we apply it on our case study where we prioritize the EMR features to redesign in an EMR system used in Japanese antenatal care settings.

5.2 Methods

Our method consists of four steps, as shown in Fig. 5.1

- In Step 1, we identify the importance of the different EMR features to the different user groups.

- In Step 2, we analyze the interdependency between the different EMR features.
- In Step 3, we compute the overall effect (direct effect + cascade effect) of modifying each EMR feature.
- In Step 4, we calculate the priority score for redesigning the different EMR features. The priority scores can then be used to identify the most strategic EMR features to (re)design.

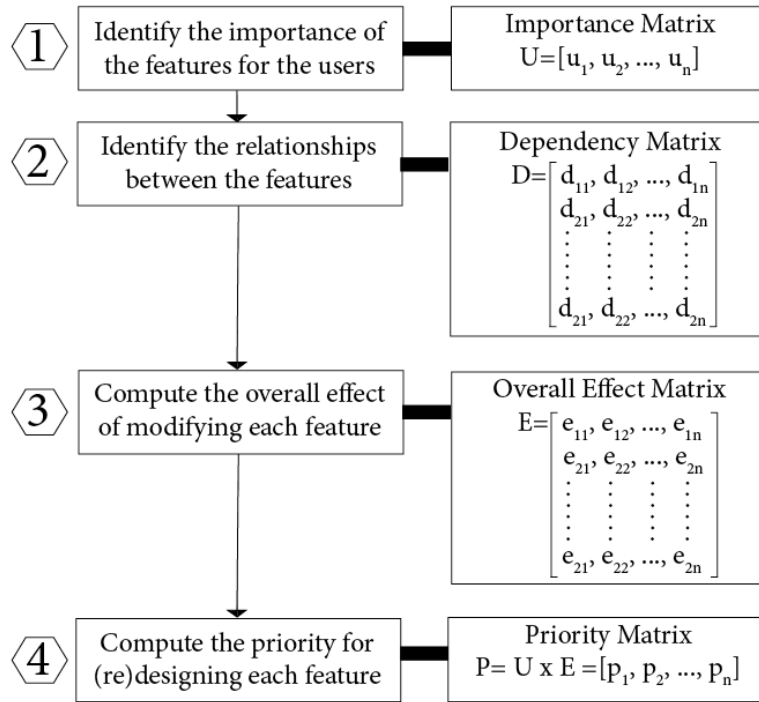


Fig. 5.1: Four steps to prioritize the EMR feature to (re)design.

5.2.1 Identifying the Importance of Different EMR Features to the users

In the previous chapter, we surveyed five obstetricians, ten midwives, and 413 pregnant women in Japan. We asked them about the importance of each EMR feature. They reported the importance of the EMR features on a 4-point Likert scale of Very Important (4), Important (3), Slightly Important (2), Not important at all (1). Based on the results of the survey, we created the importance matrix of the features as follows:

Suppose we have n features $F = \{f1, f2, \dots, fn\}$ and l respondents $R = \{r1, r2, \dots, rl\}$. The respondents indicated the importance of each EMR feature on a 4-point Likert scale. We obtain the features importance matrix, $U = [u_i]_n$, by aggregating the answers of the l

respondents using:

$$u_i = (1/l) \sum_{k=1}^l u_i^k, i = 1, 2, \dots, n$$

where u_i^k is the answer of respondent r_k regarding the importance of feature f_i and u_i is the importance score of feature f_i to one user group.

We created three feature importance matrices for three different user groups: Obstetricians (U_o), Midwives (U_m), and Pregnant women (U_p).

Certain EMR features could not be experienced by the pregnant women and could only be experienced by the obstetricians and midwives, for example: the data being automatically collected from the medical devices used in the clinic. Regarding these features, we did not get feedback from the pregnant women. We assigned their importance scores as the average score given by the pregnant women for the other EMR features. We discuss the rationale behind this decision and its consequences in the Discussion section.

By giving the three user groups an equal weight, the feature importance matrix $U = [u_i]_n$ is calculated as:

$$U = 1/3(U_o + U_m + U_p)$$

where u_i is the importance score of feature f_i .

5.2.2 Identifying the Relationship between the EMR Features

As mentioned earlier, designers can have multiple EMR features to (re)design. One possible way to prioritize the EMR features to (re)design can be based on the users priorities identified in Step 1. However, the different EMR features are highly interdependent i.e.; modifying one EMR feature may affect other features of the EMR system. Therefore, designers need to take into consideration the interdependency of the features to strategically prioritize them when they (re)design.

We conducted an analysis to identify the relationships between the EMR features. We assumed that feature f_i negatively influences feature f_j when improving f_i leads to a

deterioration of f_j . Similarly, we assumed that feature f_i positively influences feature f_j when improving f_i leads to an improvement of f_j .

In our analysis, we rated the level influence between the different EMR features. We rated the direct influence of feature f_i on feature f_j using a scale of Very strong negative influence (-0.9), Moderate negative influence (-0.6), Weak negative influence (-0.3), Weak positive influence (+0.3), Moderate positive influence (+0.6), Strong positive influence (+0.9).

Once we agreed over the influence levels, we formed the feature dependence matrix as $D = [d_{ij}] (n \times n)$ where all the principal diagonal elements are zeros and d_{ij} represents the degree to which feature f_i influences feature f_j .

5.2.3 Computing the Overall Effect of Modifying each Feature

In this step, we calculated the overall effect of redesigning every single EMR feature. The overall effect of modifying feature f_i encompasses the direct effect on f_i and the indirect effect on the other EMR features.

Let $A = [a_{ij}] (n \times n)$ be the direct effect matrix where a_{ij} represents the direct effect of modifying feature f_i on feature f_j . All the principal diagonal elements of matrix A are equal to 1 whereas $a_{ij} = 0$ where $i \neq j$.

The overall effect matrix E is calculated by adding the direct effects to the indirect effects of modifying each EMR feature. E is computed as follows:

$$E = A + A \times D + A \times D^2 + \dots + A \times D^h, h \rightarrow \infty$$

$E = [e_{ij}] (n \times n)$ where e_{ij} is the overall effect that modifying feature f_i has on feature f_j .

5.2.4 Computing the Priority for Targeting each EMR Feature

To identify the features that are more important to (re)design, we take into consideration the following two factors: (i) the importance of the EMR features to the users; this information is based on the users feedback, and (ii) the overall effect of (re)designing the different EMR features; the direct and the indirect effect that (re)designing each feature has.

Therefore, we compute the priority matrix by multiplying the importance matrix by the

overall effect matrix : $P = U \times E$. The calculation would result in $P = [p_i]_n$ where p_i represents the priority score for (re)designing feature f_i .

5.2.5 Example to Illustrate the Method

Step 1

Let's suppose we are conducting an EMR redesign project. In our project we could redesign two EMR features f_1 and f_2 . We ask our users for feedback regarding the importance of the two features. Using their feedback we create the importance matrix for f_1 and f_2 . Supposing that:

$$U = \begin{bmatrix} 2 & 3 \end{bmatrix}$$

is the importance matrix for features f_1 and f_2 . This importance matrix implies that f_1 is less important than f_2 . Therefore, if we are following a user-centered design approach, we can assume so far that redesigning f_2 is more important than redesigning f_1 .

Step 2

At this step, we conduct an analysis of the features' interdependencies. Let's suppose that through our analysis, we conclude that (i) f_1 has a moderate positive influence on f_2 and (ii) f_2 has no influence on f_1 . In this case, based on our analysis, the dependency matrix of f_1 and f_2 is:

$$D = \begin{bmatrix} 0 & 0.6 \\ 0 & 0 \end{bmatrix}$$

Step 3

In this step, we compute the overall effect matrix that reflects the direct and indirect effects of redesigning f_1 and f_2 . The direct effect matrix is:

$$A = \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix}$$

The overall effect matrix is computed as:

$$E = A + A \times D + A \times D^2 + \dots + A \times D^h, h \rightarrow \infty$$

$$E = \begin{bmatrix} 1 & 0.6 \\ 0 & 1 \end{bmatrix}$$

This shows that redesigning f_1 has a moderate indirect influence on f_2 , while redesigning f_2 has no influence on f_1 .

Step 4

In this step, we calculate the final priority matrix as:

$$P = U \times E = \begin{bmatrix} 3.8 & 3 \end{bmatrix}$$

The resulting priority scores show that redesigning f_1 is more important than redesigning f_2 . The change in priorities between Step 1 and Step 4 is due to the indirect effect that redesigning f_1 has on f_2 . These results illustrate the need to consider the interdependency of the features when redesigning EMR systems.

5.3 Results

5.3.1 Importance of the Different EMR Features to the Users

Table 5.1 shows the EMR features and their respective importance to the users. (IR) indicates the initial ranking of the features as indicated by the users from highest to lowest. Each feature was assigned a code name to be used in the next steps due to space limitations.

U_o , U_m , and U_p represent the importance scores provided by the obstetricians, midwives, and pregnant women, respectively. U is the aggregation of the three scores and reflects the importance of the features for the three user groups together.

The three groups agreed on importance of twelve features. However, the pregnant women indicated that viewing their EMRs during and after the check-ups was important to them.

Table 5.1: The Importance of Different EMR Features to the Users

Code	EMR feature	IR	Uo	Um	Up	U
EXCHANGE	EMR system is used to exchange information between the providers	1	3.8	4.0	3.46	3.75
EASY USE	EMR system is easy to use	2	4.0	4.0	2.67*	3.56
SUMMARY	EMR system can provide a quick summary of the pregnancy	3	3.8	4.0	2.76	3.52
EASY LEARN	EMR system is easy to learn	4	3.8	3.9	2.67*	3.46
INTEGRT	EMR system is well integrated with the medical devices in the clinic	5	3.8	3.6	2.67*	3.36
PSYCHO-SOCIAL	Sensitive psycho-social information is documented in detail in the EMR	6	3.4	3.6	2.75	3.25
NOT INT COMM	EMR system does not interrupt the communication	7	3.2	3.8	2.73	3.24
PREP	EMR system is used to prepare for the check-ups	8	3.4	3.5	2.67*	3.19
SCHEDULE	EMR system is used to manage the antenatal care appointments	9	3.4	3.8	2.37	3.19
NOT INT PROCESS	EMR system does not interrupt the clinical process	10	3.2	3.6	2.67*	3.16
EXPLN	EMR system supports the explanation	11	2.8	2.9	2.40	2.7
PAUSE SCREEN	EMR system is used to pause the communication when needed	12	2.4	2.4	2.67*	2.49
SCREEN ACCESS	EMR screen can be seen by the pregnant women during check-ups	13	1.6	2.3	2.61	2.17
WEB ACCESS	EMR can be accessed online by the pregnant women	14	1.0	2.3	2.30	1.87

* Importance scores were calculated by averaging the other importance scores reported by the pregnant women

Conversely, the antenatal care providers did not view that feature as important.

The overall top priorities for the three user groups were: (1) the use of the EMR system to exchange information between the antenatal care providers, (2) the EMR system being easy to use, and (3) the EMR system providing them with a quick summary of the pregnancy course.

The overall lowest priorities for the three user groups were (12) EMR system being used to pause the communication when needed, (13) the pregnant women viewing the EMR screen during the check-ups and (14) the pregnant women viewing their EMRs online.

5.3.2 Relationships between the EMR features

Through an analysis that we conducted, we identified the interdependencies between the EMR features.

Fig. 5.2 shows the map of interdependencies.

In the map, the nodes represent the different EMR features. The EMR features are named using their code names shown in Fig. 5.1. The weighted arrows, connecting the nodes, represent our rating of the degree to which feature f_i influences feature f_j .

The dependency matrix $D = [d_{ij}](n \times n)$ was formed according to the map.

Table 5.2: Final Ranking of EMR Features to Redesign

Feature code	P	Initial Ranking	Final Ranking	Change
EXCHANGE	4.19	1	5	-4
EASY USE	6	2	4	-2
SUMMARY	9.19	3	1	+2
EASY LEARN	7.06	4	3	+1
INTEGRT	8.55	5	2	+3
PREP	1.72	6	12	-6
NOT INT PROCESS	2.5	7	10	-3
PSYCHO-SOCIAL	3.19	8	6	+2
NOT INT COMM	3.19	9	7	+2
SCHEDULE	3.16	10	8	+2
EXPLN	2.7	11	9	+2
PAUSE COMM	2.49	12	11	+1
SCREEN ACCESS	0.91	13	13	0
WEB ACCESS	0.84	14	14	0

5.3.3 Priority for Targeting each EMR Feature

After conducting the calculations in Step 3 and Step 4, we got the final priority matrix. The final priority scores converged at $h=10$. In Table 5.2, (P) represents the final priority scores for the different EMR features after taking into consideration the features' relationships. (Initial Ranking) indicates the initial ranking of the features based on the importance scores reported by the users. (Final Ranking) indicates the final ranking of the features based on the final priority scores. (Change) indicates the change in the ranking of the feature after taking into consideration the features' relationships.

We see that the ranking of the EMR features changed after taking into consideration the interdependency of the features. Previously, the most important feature to redesign was regarding the ability to exchange information using the EMR system. After taking into consideration the interdependency of the features, we see that this feature was ranked fifth.

After calculating the overall effect of redesigning the features, the most important EMR feature to redesign was found to be (1) the implementation of automatic summary generation in EMR systems. In second, third, and fourth place were (2) the integration of EMR systems with the used medical devices, (3) the improvement of the learnability of the EMR systems and (4) the improvement of the usability of EMR systems.

The least important EMR features to redesign were (12) EMR system being used to pause the communication when needed, (13) granting the pregnant viewing access to the EMR

screen during the check-ups and (14) granting the pregnant women online viewing access to their EMR.

5.4 Discussion

In this chapter, we proposed a method that helps designers prioritize the EMR features to (re)design. By taking into consideration the priorities of the different user groups, our proposed method aligns with the user-centered design paradigm where design activities must respect the needs, preferences and priorities of the users. Furthermore, our proposed method regards EMR systems as complex dynamic systems. In addition to the users priorities, the method takes into consideration the interdependency of the different EMR features.

We applied the method to our case study of redesigning antenatal care EMR systems in a Japanese clinical setting. For our case study, we considered three different user groups: obstetricians, midwives, and pregnant women. The results of the survey showed that the three user groups mainly have aligned priorities. However, the ability of the pregnant women to access their EMRs was viewed differently by the healthcare providers and the pregnant women. This shows the importance of considering the opinions of the different users when redesigning EMR systems.

The survey responses initially showed that the three users groups regarded the exchange of information between the different antenatal care providers as the highest priority. However, after considering the interdependency of the features, the most important EMR feature to redesign was found to be the automatic generation of summaries from the EMR notes. This change in rankings highlights the importance of considering the interdependencies between the features when (re)designing EMR systems.

The method's results show that two most important features to redesign are the automatic generation of summaries from the EMR notes and the integration of the medical devices with the EMR system. Indeed, the automatic generation of EMR summaries majorly reduces the need for manual data lookup and analysis. By doing so, it reduces the interference with the clinical workflow and communication. Moreover, it enables the exchange of EMR summaries, the preparation of the check-ups, and the explanation of the pregnancy course. Similarly, the integration of the medical devices with the EMR system majorly reduces the need for manual data input. By doing so, it makes the EMR system easier to use and reduces the interference with the clinical workflow and communication. These

results imply that the most important EMR design goals are the efficient and effective storing and viewing of health data. This is not surprising since it reflects the fundamental functions of an EMR system – (i) viewing previously stored health data and (ii) storing health data for future viewing.

In the following subsections, we discuss the various design choices that we made throughout our case study and how these choices may have affected our end results.

5.4.1 Giving Weights to the Opinions of the Different User Groups

In our application of the method on the case study, we assigned equal weights to the opinions of the three user groups. If we were to adopt a patient-centered, some may argue that we should assign more weight to the opinions of the pregnant women. One way to do that would be by considering that the obstetricians and the midwives form one group of users: the antenatal care providers. Consequently, we would have two user groups with equal weights: the antenatal care providers and the pregnant women. However, in this case, another important question would arise: how should the weights be distributed within the antenatal care providers group? Since there is no definitive answer to these questions, we believe that the EMR designers could decide the distribution of the weights depending on what they see fit in their particular situation.

5.4.2 Dealing with the Missing Data

As mentioned earlier in the methods, certain EMR features cannot be currently experienced by the pregnant women. Therefore, we did not ask for feedback from the pregnant women regarding these features. The importance score of the features was assigned as the average of the other importance scores for the other EMR features. To address the issue of the missing scores, other approaches could have been employed. One way would be to give those features the lowest possible score; another way would be to only consider the opinions of the obstetricians and the midwives for these EMR features. However, in our application of the method, we considered these features to be neutral for the pregnant women, and therefore we assigned to them the average importance score that the women gave the other features. We made this decision to avoid biasing the final priority scores because, in our data, the antenatal care providers gave higher importance scores on average.

5.4.3 Analyzing the Relationships between the EMR Features

The analysis of the relationships between the features was conducted by three researchers until they reached an agreement. Based on the result of their analysis, the final priorities were computed. Surely, different designers may have found different relationships between the features, resulting in different final priorities. The subjectivity of the designers is a clear limitation of this method. However, any design process is tainted with the subjectivity of the designers. Therefore, even though we cannot completely avoid the designers' subjectivity in the process, we could reduce by defining strict criteria on how to analyze and rate the level of influence between the different features. Future work could aim to develop guidelines for designers to support their analysis of the features' interdependencies.

In other respects, when answering the survey, the users may have considered some of the features dependencies. For example, some users may have considered the overall effect of integrating the medical devices with the EMR system when rating its importance. Therefore, some influences may be accounted for twice. Further research is needed to find ways to counter this effect when applying the method.

On another note, other important criteria may affect the decision of which features to redesign. These criteria include the cost of the redesign activity, its difficulty, and its alignment with other preset strategies. This method only provides the designers with information about which redesign could have the biggest user-desired effect on the EMR system. Since other criteria are also important to consider, further work is needed to incorporate this method into a method with a larger scope; one that allows the designers to consider other important criteria when (re)designing EMR systems.

Using our case study, we highlighted the importance of considering the different user groups and the interdependency of the features. To assess the practical value of this method, it is important to evaluate it as a decision-aid tool for designers in redesign projects.

Finally, it is important to note that even though we proposed this method to prioritize EMR features to (re)design, the method can be used by designers of other complex systems where multiple user groups are involved and the system's features are interdependent.

5.5 Conclusion

In this chapter we presented a method to prioritize EMR features to (re)design. The method takes into consideration the priorities of the different users and the relationships between the different EMR features. The method allows the designers to rank features based on the direct and indirect effects of targeting them.

We applied the method in Japanese antenatal care settings. The top priority features to redesign were (i) the implementation of automatic summary generators in EMR systems and (ii) the integration of EMR systems with the used medical devices.

The results showed the importance of taking into consideration the priorities of the different users and the interdependency of the EMR features. The proposed method could be used as a tool to support designers in making strategic decisions during the initial system redesign phase.

Part II

Methods for Implementing Interoperable, Adaptable, and Performant EMR Databases

Chapter 6

Modeling Clinical Concepts Using openEHR Archetypes

This chapter addresses the first task that EMR database designers have to undertake: clinical data modeling i.e., creating the data models representing the health concepts that the EMR database has to store and manipulate.

The approach that designers adopt for clinical data modeling could affect the database's cost of implementation, cost of adaptation and levels of interoperability. We propose following a two-level modeling approach and reusing existing Detailed Clinical Models (DCM) to lower the cost of system adaptation and increase the system's level of interoperability.

We investigate the feasibility of the approach through a case study of modelling the health concepts involved in an antenatal care EMR system. We show that it is worthwhile for EMR system designers to reuse existing DCMs to improve the interoperability and adaptability of their systems' databases.

6.1 Introduction

The promised benefits of the widespread adoption of EMR systems are numerous. However, the lack of interoperability between the EMR systems is a major barrier to achieve these promises. Interoperability is defined by the Institute of Electrical and Electronics Engineers as the ability of two or more components to exchange information and to use the information that has been exchanged [94]. The lack of interoperability hinders the access

to, and the sharing of data between the different EMR systems. Furthermore, it hinders the activities that require the EMR data to be processed by computers.

To tackle the EMR interoperability issue, multiple standards were developed during the last three decades. These standards could be split into two major categories: (i) messaging standards such as HL7 v2.5 ¹ and (ii) architecture standards such as openEHR [95] and CEN EN 13606 [96]. Messaging standards aim to standardize the messages exchanged between EMR systems. On the other hand, architecture standards aim to standardize how EMR systems are implemented.

Since this work deals with the design and implementation of EMR systems, we will mainly focus on EMR architecture standards. These standards structure the data that the EMR system stores and process through the use of Detailed Clinical Models (DCM). DCMs are formal representations of clinical concept in terms of elements and the relationships between them. DCMs are usually created through the input of clinicians or clinical researchers and are meant to be reused in EMRs or other Healthcare Information Technology (HIT) system implementations [97]. By reusing existing DCMs, the interoperability of EMR systems can be increased.

In addition to publishing DCMs, the most used EMR architecture standards adopt a two-level modeling approach that separates the domain knowledge i.e., the health concepts from the schema of the database. This is done through the introduction of an information reference model that specifies a set of classes covering all possible types of information meant to be stored in EMR systems. The health concepts represented by DCMs are then coded in terms of constraints over the reference model classes. By adopting this two-level modeling approach, we can increase the adaptability of the EMR system by not having to change the database schema when the clinical requirements change.

Even though designers have access to these EMR standards and DCMs, understanding and following EMR standards is a difficult task and it remains unclear how feasible it is to reuse DCMs for EMR design projects. For EMR designers, following EMR standards and reusing DCMs is worthwhile only if it provides with a fast and easy way to implement interoperable EMR systems.

To answer these question, we conduct an experiment where we go through the data modeling process of an antenatal care EMR system by reusing existing DCMs. We reuse openEHR archetypes i.e., DCMs created by the openEHR foundation. Through our experiment, we

¹HL7 Organization. [<http://www.hl7.org>]

evaluate if existing archetypes are easily reusable and if they cover most of the health concepts that we needed to model.

6.2 Background

6.2.1 Traditional EMR Database Design

Traditionally, the vendors of EMR systems developed the systems based on internal and proprietary standards. Since each vendor adopted a different standard, sharing the information between the EMR systems was a complicated task. Currently, it is widely recognized that using non-proprietary standards for building EMR systems is a requirement to address the interoperability problem and facilitate the exchange of information between EMR systems.

Previously, the developers hard coded the health concepts into the database schema when they implemented the EMR systems' databases. This approach, referred to as 'single-level' modeling approach resulted in complex database schemas that are difficult to modify. The complexity and non-adaptability of the database resulted in EMR systems that are expensive to develop and adapt. The adaptability of the EMR database is particularly important because as clinical requirements frequently change, developers have to change the EMR database schema accordingly.

Due to the high development costs and high adaptation costs, healthcare organizations avoided replacing their outdated EMR systems or adapting them to their continuously changing needs. Often, this would result in healthcare organizations being stuck with EMR systems that do not fit their clinical requirements.

6.2.2 EMR Interoperability Standards

Creating interoperable EMRs is one of the enduring challenges in healthcare. In the last decades, multiple standards and specifications were developed with the aim to solve the interoperability problem. The most commonly known standards are HL7, openEHR, and ISO/CEN EN13606 [96]. Since this work deals with the design and implementation of EMR systems, we will focus on one of the earliest promoters of the two-level modeling approach and a commonly used EMR architecture standard: openEHR.

6.2.3 openEHR

openEHR is a set of open-source specifications for a complete EMR architecture. The purpose of openEHR is to support the constructions of distributed, patient-centered, life-long, shared care health records [?]. The specification is said to be based on 15 years of research and real-world implementation experiences and lessons [96]. The healthcare community was demanding interoperable and adaptable EMR systems to answer the need for health data exchange and for systems that adapt to fit the continuously changing clinical requirements. To address these needs, openEHR presented the two-level modeling approach as a way for developing interoperable yet adaptable EMRs. The openEHR specification contains guidelines on how to create, store, maintain, and query EMRs.

To enable syntactic interoperability i.e. data-types interoperability, openEHR provides a stable reference information model (RM). The RM is reduced to a relatively small set of classes to support the medico-legal requirements and record management functions. To enable semantic interoperability, clinical knowledge concepts are captured in a structured way, in what is called Archetypes and Templates. Archetypes and Templates are expressed in Archetype Definition Language (ADL). An Archetype is a DCM that contains a maximum data set about a particular clinical concept and represents that concept by constraining instances of the openEHR RM. Grouping multiple Archetypes to model a specific healthcare scenario results in a Template. Consequently, the information stored in the EMR conforms to the Archetypes definitions as instances of the RM [92].

6.3 Methods

We investigate the feasibility of the approach through a case study of modelling the health concepts involved in an antenatal care EMR system.

We assume that an antenatal care EMR system should allow the exchange of information between the healthcare providers and pregnant women. Thus, the EMR system has to allow the healthcare providers to record the health data gathered during the routine clinical check-ups and allow the pregnant woman to record pregnancy related health information. The information recorded by the pregnant women may include pregnancy related symptoms, easily measured biological parameters and information regarding their psychosocial condition.

Accordingly, the antenatal care EMR system comprises of two modules:

1. A clinical check-up module: the healthcare providers use this module during the routine clinical check-ups.
2. A home monitoring module: the pregnant woman uses this module from her home.

6.3.1 Identifying Health concepts

To create data models, we have to identify the involved health concepts. We do that by analyzing the antenatal care process. The purpose of the analysis is to build an understanding of the involved users, the information that they process, and the data flow in their processes.

Usually, the analysis requires the involvement of the end-users of the EMR system, resulting in high time and human resources costs particularly when clinical experts are involved. To avoid the high cost of involving the users in the early analysis stage, we undertake a review of existing domain guidelines since they offer a rapid way of gathering a large corpus of information regarding the process.

However, clinicians and pregnant women will be the eventual users of an antenatal care EMR system. If the system does not satisfy the clinical requirements, the clinicians will not adopt it. To ensure the alignment with clinical requirements, the identified health concepts need to be clinically validated by domain experts.

Guidelines review

To rapidly gather a large corpus of knowledge and gain an initial understanding of the antenatal care process, we review the existing literature concerning the antenatal care provision process and guidelines for obstetrical practices in Japan [82]. In the review, we search for the involved health concepts in the antenatal care process. The search results in an extensive list of relevant health concepts.

Domain-Expert Input through a Questionnaire

To ensure the antenatal care EMR system aligns with the needs and requirements of the clinical staff, the identified health concepts and processes must be clinically validated through the input of domain experts. We conduct the first validation via a questionnaire to an practicing obstetrician.

To subsequently construct the Templates, the use-cases of the EMR system in terms of data input also need to be identified. Therefore, the obstetrician is asked to review our understanding of the whole process and validate the occurrence of the health concepts in the different stages of the antenatal care process.

Furthermore, the pregnant women will use the antenatal care EMR system to report pregnancy related health information. Since, patient-generated data in the healthcare industry is new and not well documented, the information judged as reliable and worthy of collection from the pregnant women is also identified through the obstetrician's input.

Domain-Expert Input through a Semi-Structured Interview

In addition to obstetricians, the antenatal care process involves midwives and nurses. Accordingly, The EMR system must also align with their needs. Moreover, the pregnant women commonly share their psychological, social and pregnancy concerns with their midwives. In our proposed EMR system, the information communicated by the pregnant women to their midwives would be assigned to the home monitoring module.

To further validate the data requirements and identify pregnancy information communicated by the pregnant women, we conducted a semi-structured interview with a midwife. The purpose of the interview is to identify the information that the pregnant women communicate to the antenatal care providers and the stages in which that communication takes place.

Through the interview, we aim to identify additional health concepts relating to the social and psychological aspects of health, since this kind of information is usually communicated with the midwife rather than the obstetrician.

6.3.2 Preparing Archetypes and Templates

In our data modelling task, we use clinically validated openEHR Archetypes. Following the openEHR methodology, health concept models should first be represented by Archetypes and then grouped into Templates.

Preparing Archetypes

More than 600 published openEHR Archetypes exist in a public Archetypes web repository or Clinical Knowledge Manager (CKM) ². The CKM allows the governance over the published Archetypes through strict administration and review activities. Each published Archetype contains a maximal data set needed to represent a specific health concept, making it possible to use the Archetype in any possible clinical scenario. For example, the blood pressure Archetype can be used to represent a blood pressure measurement taken in a clinic and a blood pressure measurement taken using a home monitoring device. By reusing the existing Archetypes found on the CKM, we reduce the need for creating the data models from scratch.

We analyze the Archetypes found on the CKM with regard to their purpose, use and misuse descriptions. The Archetype that is judged fit for representing a specific clinical concept is further analyzed with regard to its available data points and its ability to fulfill our data requirements.

Some generic Archetypes, usually representing laboratory tests and symptoms, have to be specialized to fit the specific data requirements. On the other hand, certain concepts may not have already published Archetypes that can represent them. In those cases, new Archetypes have to be created from scratch.

An Archetype editor is used for the creation of new Archetypes and the specialization of already existing Archetypes. The tools used for the Archetypes preparation are depicted in Fig. 6.1. In our work, we use the open-source Archetype Editor ³ provided by the openEHR foundation and Ocean informatics Inc.

Preparing Templates

After we finish preparing the Archetypes, we create Templates by grouping a number of relevant Archetypes together. The Templates represent models of use-cases where multiple health concepts are involved. The same Archetype can be used in multiple Templates, for example the same blood pressure Archetype is used in all the Templates that contain blood pressure measurements.

The Templates are then created using the Template Designer (TD), an open-source tool

²<https://www.openehr.org/ckm/>

³<https://www.openehr.org/downloads/archetypeeditor/home>

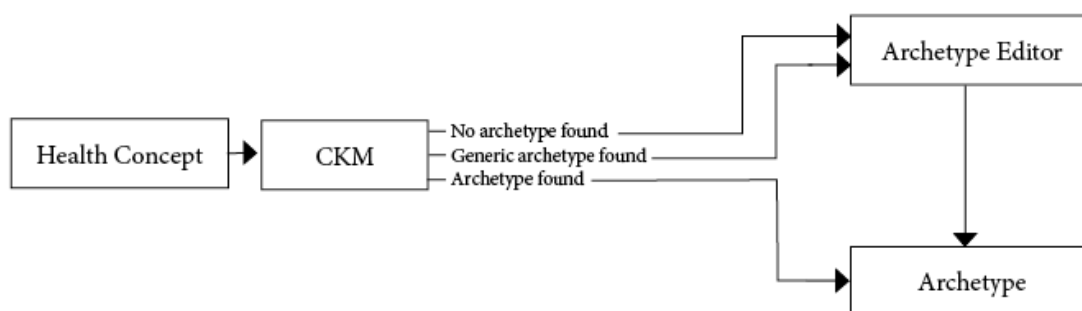


Fig. 6.1: The archetype modelling process and the tools used

provided by Ocean Informatics Inc.⁴ The TD allows the creation of openEHR Templates from Archetypes. It enables the user to constrain Archetype elements, and to exclude optional Archetype nodes that are not relevant to the current use-case, as well as bounding terms and subsets in Archetypes to external terminologies such as SNOMED-CT [98] and LOINC [99].

6.3.3 Evaluation

The feasibility of reusing openEHR Archetypes is evaluated according to the following criteria:

The External Reuse Level

The External Reuse Level corresponds to the rate at which the need for data models creation is reduced. It is calculated as follows: $(D + S)/T$

D corresponds to number of concepts mapped to directly usable Archetypes, S corresponds to the number of concepts mapped to Archetypes requiring specialization and T corresponds to the total number of required concepts.

The Versions of the Employed Archetypes

version 1 Archetypes are the stable Archetypes that went through review processes and are less likely to change in the future. version 0 Archetypes are likely to radically change in future review processes.

⁴<https://oceanhealthsystems.com/products/template-designer>

6.4 Results

6.4.1 Domain Analysis Results

A detailed description of the antenatal care process in terms of data communication and recording is shown in Fig. 6.2. ‘W’ refers to the pregnant woman, ‘O’ refers to the obstetricians and ‘M’ refers to the midwife.

After gathering and validating the information regarding the antenatal care process and the involved health concepts, we classified the health concepts into two categories corresponding to: (i) the clinical check-up module and (ii) the home monitoring modules:

- Providers generated data: data generated by the healthcare providers during the routine check-ups. These health concepts correspond to the clinical check-up module and are shown in Table 6.1.
- Women generated data: data generated by the pregnant women, be it from their homes, their encounters with their healthcare providers or through their pregnancy notes. These health concepts correspond to the home-monitoring module and are shown in Table 6.2.

Table 6.1: The health concepts that are included in the clinical check-up module

Health concepts	
Initial History and Physical	Chorionic Villus sampling
Family Medical History	Cell Free Fetal DNA
Lifestyle	Nuchal translucency Ultrasound
Pregnancy Test	Amniocentesis
Estimated date of birth	Hepatitis B and C
Height	Syphilis
Weight	Rubella
Edema Check	PT PTT Fib
Blood Pressure	Tuberculosis
Urine tests	HIV
Pelvic Exam	Complete Blood Count
Ultrasound Scan	Blood Sugar
Fetal Heartbeat Check	HGPO -1
Length of Fundus Uteri	Group B Streptococci
Non-stress Test	Pap Smear Test
Blood Type and Rhesus Factor	
Gonorrhea and Chlamydia cultures	
Maternal Serum Screen	

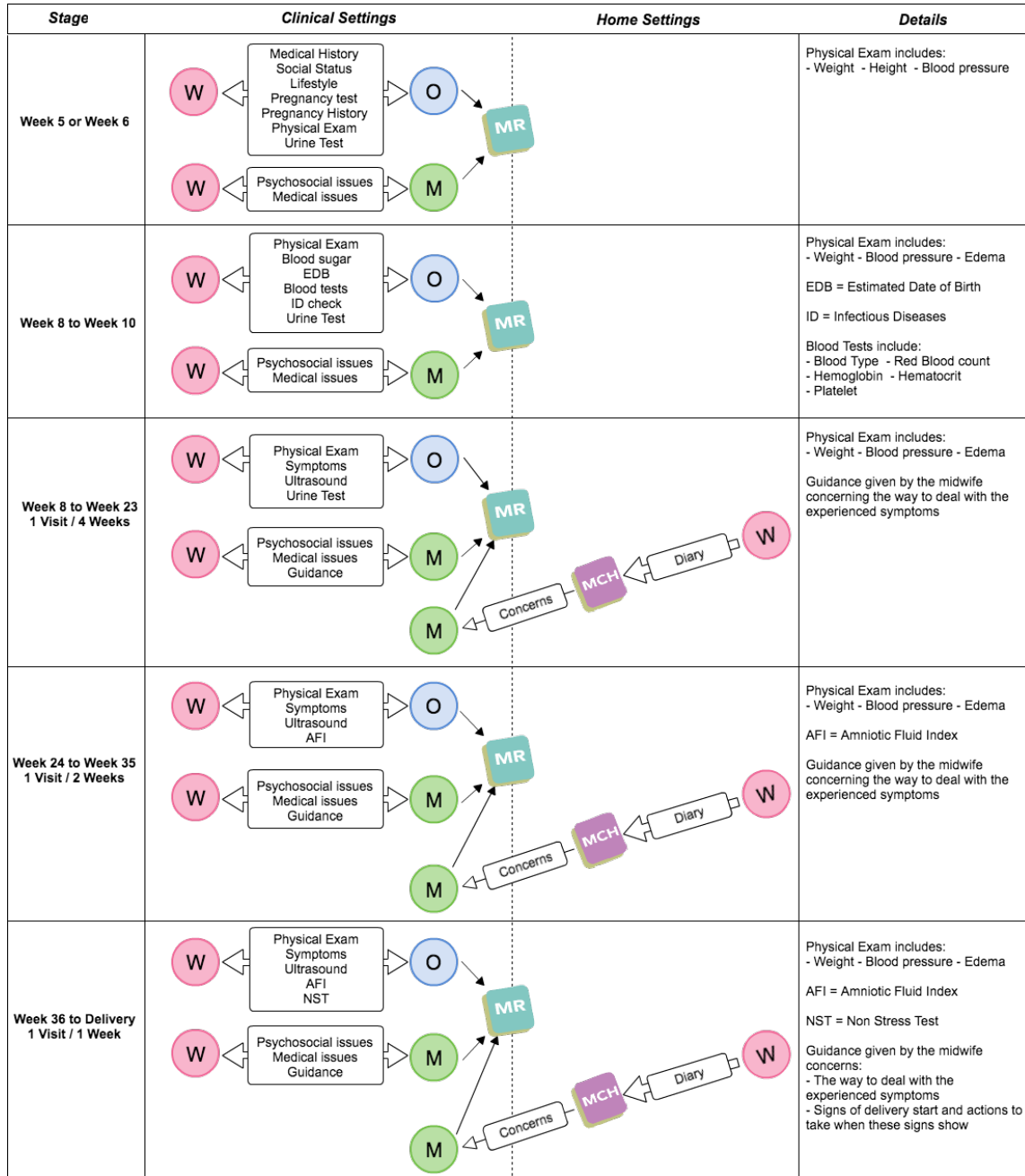


Fig. 6.2: The antenatal care process as described by the midwife

Table 6.2: The health concepts that are included in the home monitoring module

Health concepts
Weight
Blood Pressure
Blood Sugar
Genital Bleeding
Pelvic Pain
Heartburn
Hemorrhoids
Backache
Abdominal Pain Constipation
Anxiety
Nausea
Vomiting
Carpal tunnel syndrome Varicose veins
Vaginal Discharge
Frequent Uterus contractions Baby movement
Screening for Depression PTSD Screening

6.4.2 Evaluation of the Data Modeling Process

In total, we identified 52 health concepts that are involved in the antenatal care process. The mapping of the health concepts to their respective Archetypes is shown in Table 6.3.

25 Archetypes found on the CKM could be directly reused i.e., they required no modification, to represent 26 health concepts, which account to 50% of the identified concepts. The same Archetype *openEHR-EMR-OBSERVATION.lab_test_blood_glucose.v1* was used to represent a blood sugar measurement and a glucose challenge test. Six generic Archetypes found on the CKM required specialization to represent 25 concepts, which account to 48% of the identified concepts. These concepts represented specific laboratory tests and pregnancy symptoms. And, only one Archetype was created from scratch to represent Post Traumatic Stress Disorder (PTSD) screening.

In total, 32 Archetypes were required to represent the 52 concepts for the data modeling of the antenatal care EMR system. Regarding our evaluation criteria, the results of the experiment were:

1. The External Reuse Level allowed by openEHR Archetypes was 98%.
2. Out of the 31 useful Archetypes found on the CKM at the time of our experiment, 29 Archetypes were version 1 and two Archetypes were version 0.

Table 6.3: The mapping of the health concepts to openEHR archetypes

Concept	Archetype	Aspect	Use category
Initial History and Physical	openEHR-EHR-COMPOSITION.problem_list.v1	Clinical	Direct Use
Family Medical History	openEHR-EHR-COMPOSITION.family_history.v1	Clinical	Direct Use
Social Status	openEHR-EHR-EVALUATION.social_summary.v1	Social	Direct Use
Lifestyle	openEHR-EHR-COMPOSITION.lifestyle_factors.v1	Social	Direct Use
Screening for Depression	openEHR-EHR-OBSERVATION.edinburgh_pnd_scale.v1	Psychological	Direct Use
Pregnancy Test	openEHR-EHR-OBSERVATION.pregnancy_test.v1	Clinical	Direct Use
Estimated date of birth	openEHR-EHR-EVALUATION.pregnancy.v1	Clinical	Direct Use
Height	openEHR-EHR-OBSERVATION.height.v1	Clinical	Direct Use
Weight	openEHR-EHR-OBSERVATION.body_weight.v1	Clinical	Direct Use
Edema Check	openEHR-EHR-CLUSTER.oedema.v0	Clinical	Direct Use
Blood Pressure	openEHR-EHR-OBSERVATION.blood_pressure.v1	Clinical	Direct Use
Urine tests	openEHR-EHR-OBSERVATION.urinalysis.v1	Clinical	Direct Use
Pelvic Exam	openEHR-EHR-CLUSTER.palpation_of_cervix.v1	Clinical	Direct Use
Ultrasound Scan	openEHR-EHR-ACTION.imaging_exam.v1	Clinical	Direct Use
Fetal Heartbeat Check	openEHR-EHR-OBSERVATION.fetal_heart.v1	Clinical	Direct Use
Fetal growth	openEHR-EHR-CLUSTER.palpation_of_fetus.v1	Clinical	Direct Use
Length of Fundus Uteri	openEHR-EHR-CLUSTER.palpation_of_uterus.v1	Clinical	Direct Use
Non-stress Test	openEHR-EHR-OBSERVATION.fetal_heart-monitoring.v1	Clinical	Direct Use
Blood Type and Rhesus Factor	openEHR-EHR-OBSERVATION.lab_test-blood_match.v1	Clinical	Direct Use
Tuberculosis	openEHR-EHR-OBSERVATION.mantoux.v1	Clinical	Direct Use
HIV	openEHR-EHR-OBSERVATION.lab_test-immunology.v1	Clinical	Direct Use
Complete Blood Count	openEHR-EHR-OBSERVATION.lab_test-full_blood_count.v1	Clinical	Direct Use
Blood Sugar	openEHR-EHR-OBSERVATION.lab_test-blood_glucose.v1	Clinical	Direct Use
HGPO -1	openEHR-EHR-OBSERVATION.lab_test-blood_glucose.v1	Clinical	Direct Use
Group B Streptococci	openEHR-EHR-OBSERVATION.lab_test-microbiology.v1	Clinical	Specialization
Pap Smear Test	openEHR-EHR-OBSERVATION.laboratory_test-histopathology.v0	Clinical	Specialization
Gonorrhea and Chlamydia cultures	openEHR-EHR-OBSERVATION.lab_test-microbiology.v1	Clinical	Specialization
Maternal Serum Screen	openEHR-EHR-OBSERVATION.lab_test.v1	Clinical	Specialization
Chorionic Villus sampling	openEHR-EHR-OBSERVATION.laboratory_test-histopathology.v0	Clinical	Specialization
Cell Free Fetal DNA	openEHR-EHR-OBSERVATION.lab_test.v1	Clinical	Specialization
Nuchal translucency Ultrasound	openEHR-EHR-ACTION.imaging_exam.v1	Clinical	Specialization
Amniocentesis	openEHR-EHR-OBSERVATION.lab_test.v1	Clinical	Specialization
Hepatitis B and C	openEHR-EHR-OBSERVATION.pathology_test.v1	Clinical	Specialization
Syphilis	openEHR-EHR-OBSERVATION.pathology_test.v1	Clinical	Specialization
Rubella	openEHR-EHR-OBSERVATION.pathology_test.v1	Clinical	Specialization
PT PTT Fib	openEHR-EHR-OBSERVATION.lab_test.v1	Clinical	Specialization
Genital Bleeding	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Pelvic Pain	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Heartburn	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Hemorrhoids	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Backache	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Abdominal Pain	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Constipation	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Anxiety	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Nausea	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Vomiting	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Carpal tunnel syndrome	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Varicose veins	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Vaginal Discharge	openEHR-EHR-CLUSTER.symptom_sign.v1	Clinical	Specialization
Frequent Uterus contractions	openEHR-EHR-OBSERVATION.uterine_contractions.v1	Clinical	Direct Use
Baby movement	openEHR-EHR-OBSERVATION.fetal_movement.v1	Clinical	Direct Use
PTSD Screening	openEHR-EHR-OBSERVATION.pc-ptsd.v0	Psychological	Creation

6.5 Discussion

The ready to use Archetypes provided by openEHR proved to reduce the need for data models creation. Therefore, we can conclude that reusing existing DCMs is feasible and provides EMR designers with an easy way to improve their systems' levels of adaptability and interoperability.

However, it is important to note that almost half of the concepts were mapped to generic Archetypes that require specialization. In this study, the effort required to specialize Archetypes was not evaluated. The benefits of the openEHR Archetypes, in terms of data modeling effort reduction, could be precisely validated only after an evaluation of the effort required for Archetypes specialization. Moreover, only two out of the employed Archetypes were already translated to Japanese. For the development of a localized antenatal EMR system in Japan, the remaining Archetypes require translation. These translation efforts add to the data modeling efforts and were not considered in this study.

Moreover, while ready-to-use Archetypes proved beneficial, the learning of the openEHR methodology was not a straightforward or trivial task. The learning could be facilitated by publishing more tutorials for beginners that describe in details the modeling process as a whole. In fact, we found that some Master thesis dissertations that we found online helped us better understand the process since they contain comprehensive descriptions of the methods.

Finally, the movements in healthcare indicate that psychosocial aspects will soon be part of our health profiles. In this research, the social concepts and one psychological concept could be mapped to existing openEHR Archetypes. However, the only Archetype requiring creation from scratch corresponded to a psychological concept. These outcomes suggest that in continuity to previous efforts done by the openEHR community targeting psychosocial aspects, further development of psychosocial Archetypes might be needed.

6.6 Conclusion

In this Chapter, we showed that it was feasible and worthwhile for EMR designers to reuse existing DCMs to model the health concepts involved in an EMR system. By doing so, EMR designers can improve their systems' adaptability and interoperability while reducing their data modeling tasks.

Chapter 7

Implementing EMR Databases using openEHR Specifications and Graph Databases

In the previous chapter, we showed that it was feasible and worthwhile to reuse existing DCMs to model the health concepts involved in an EMR system. These DCMs are usually published by major EMR standardizing bodies and are publicly accessible. Once the data modeling task is finished, the designers have their set of DCMs ready. The next step is to implement the database that processes these DCMs. Following an EMR interoperability standard does not require the designers to follow any specific database implementation approach. The designers are free to choose the database technology and implementation approach. Their choice, in this case, directly affects the system's level of usability and maintenance costs.

In this chapter, we build on the previous chapter and propose a database implementation approach for openEHR databases that results in faster queries and less storage space requirements.

7.1 Introduction

The low level of interoperability is considered a major technical barrier since it hinders the sharing of data between EMRs as well as its consequent processing by computers [100].

To address the interoperability issue, multiple EMR interoperability standards were developed in the last two decades. The most commonly used standards such as HL7, CEN ISO 13606, and openEHR adopted a two-level modeling approach, i.e. an archetype-based modeling approach where the physical representation of the data is completely separated from the data models of the clinical concepts [96,101]. Therefore, when building EMR systems following the two-level modeling approach, the database stores the health concepts as instances of an Information Reference Model [92].

In this previous chapter, we studied the feasibility of modeling health concepts using openEHR archetypes. openEHR is a technology-independent specification for implementing EMR databases. It defines an information Reference Model (RM) but does not commit the developers to using any particular database technology. Consequently, EMR system developers have to decide which persistence technology and approach to use when building the EMR databases following the openEHR specifications. These decisions could affect the system's usability and eventually its maintainability cost. This is important because in addition to a lack of interoperability, the users of EMR systems often suffer from their low levels of usability, and their high maintainability costs [102–104].

In this chapter, we first start by giving some background about openEHR, openEHR database implementations, and graph databases. We then describe how a persistence approach could affect the EMR system's usability and maintainability costs. Then we propose an openEHR implementation approach that results in fast clinical querying and efficient storage. Our proposed approach employs a labeled property graph database by directly mapping the openEHR RM structure to the graph structure. We evaluate our proposed approach by comparing it to the most commonly adopted approach; the Object Relational Mapping (ORM) approach [105]. For the evaluation, we artificially simulate different size antenatal care EMR databases, where we run likely querying scenarios. We compare the performance of our approach with the ORM approach using two main criteria: the query response time and the required storage space.

7.2 Background

7.2.1 How the Database Implementation Can Affect EMR Systems

EMR users often suffer from the low usability and efficiency of EMR systems [106]. Multiple factors could contribute to the low usability and efficiency of EMR systems. One factor

that is particularly relevant to our work, and could be affected by design, is the system's response time. In fact, the EMR system's response time i.e., the time a transaction needs to be executed when using the system is a common EMR effectiveness metric and usability factor [107, 108].

Multiple system elements could affect the system's response time. These elements include the CPU, the network, and the database [108]. In the case of EMR systems, most of the tasks require browsing the databases. Thus, we can assume that the database query response time would significantly affect the EMR system's overall performance and therefore its usability [109].

When healthcare providers use EMR systems in clinical settings, they usually generate, retrieve, and update data from individual patients' health records. To do so, they execute Create, Read, Update, and Destroy (CRUD) operations on the database. To improve the performance of EMR systems in clinical settings, EMR designers could aim to minimizing the execution time of these CRUD operations.

In addition to the usability concerns voiced by EMR users, the organizations that consider implementing EMR systems are usually concerned about the cost of maintaining these systems. If EMR systems are adopted and used, the organizations expect a rapid growth in data quantity. The growth in data size would necessitate greater storage capacities. This problem is usually addressed by scaling up i.e., buying larger storage, or scaling out i.e., distributing the data over multiple servers [110, 111]. Both approach are costly for the organizations. Therefore, reducing the required storage space for EMR data is of interest since it may reduce the maintainability costs of EMR systems.

Considering that the query execution time and storage efficiency are crucial to the overall performance and future maintainability costs of EMR system, the aim of this chapter is to provide an EMR database implementation approach that results in faster query execution times and reduces the storage requirements.

7.2.2 openEHR Database Implementations

When building EMR systems following the openEHR archetype-based modeling approach, the data repository has to store instances of the openEHR information Reference Model (RM). The RM contains multiple classes in a deep tree hierarchy as shown in Fig. 7.1.

Since the openEHR RM has a tree structure, an openEHR EMR would have the structure

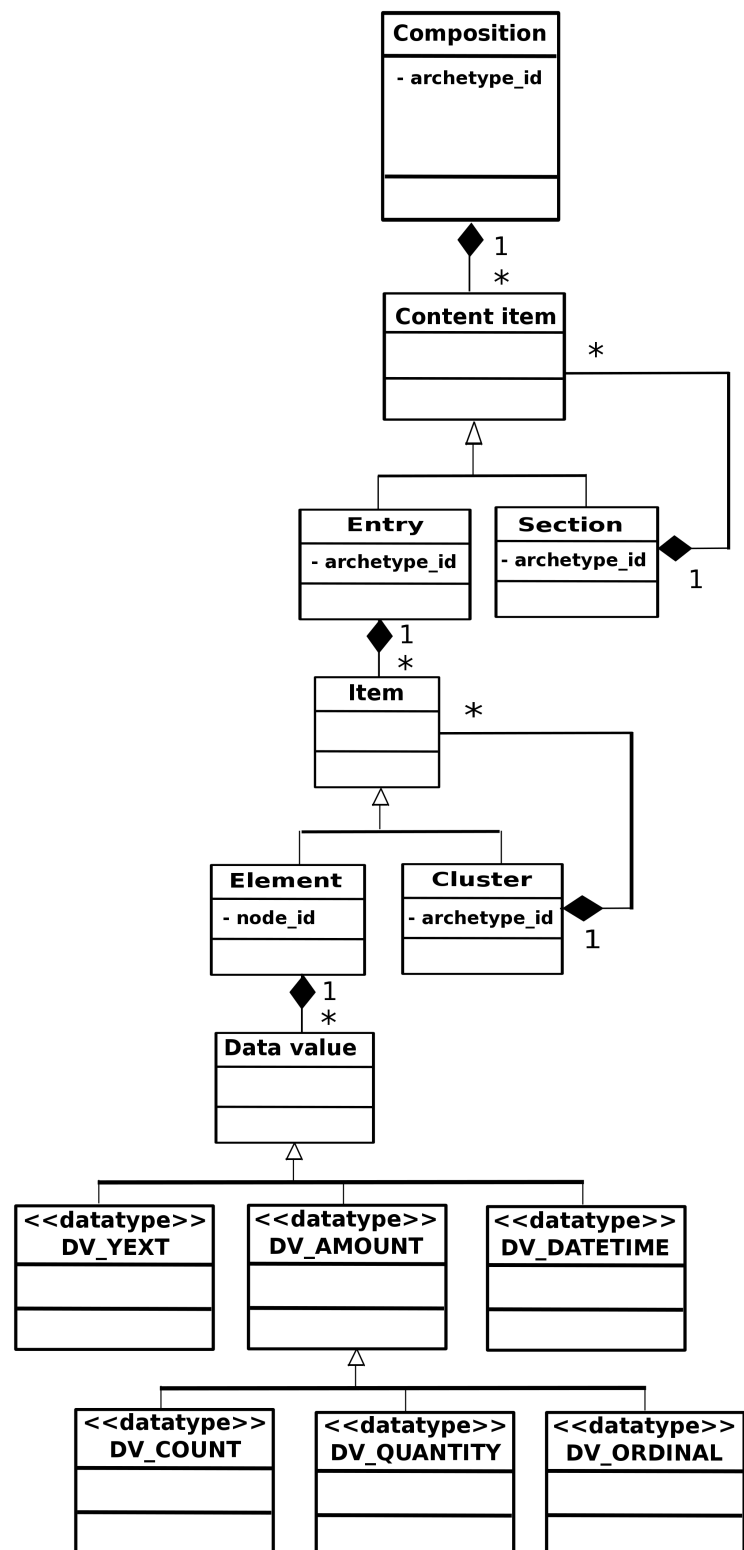


Fig. 7.1: The openEHR Reference Model

of a directed rooted tree, a graph-like data structure. When clinical queries regarding a specific patient are executed, the tree structure is queried starting from the top node containing the unique EMR ID.

Multiple openEHR implementation approaches have been previously explored and implemented most often using Relational and XML databases [105]. However, previous research and discussions suggest that these approaches are less than optimal for storing and querying archetype-based datasets [112, 113]. Proposing and evaluating new implementation approaches could be of value for EMR designers adoption the openEHR approach.

Using a relational database implies that multiple JOIN operations need to be executed when querying the tree structure, leading the system's performance to deteriorate with the increase of data. Moreover, due to the complex structure of the RM and the impedance mismatch between the RM and the relational model, the schema can be hard to model. As for XML databases, they do not perform as well as relational databases [114] and they were found to require larger memory and storage space to process and store the information [115].

Recently, graph databases have been developed as a possible replacement for relational databases when dealing with graph-like data structures [116]. Graph databases are optimized for storing and querying graph-like structures. Since the RM has a graph-like structure, mapping it to a graph model and consequently storing it in a graph database is straightforward. Moreover, instead of joining multiple tables to query the tree, a graph database starts by locating the initial node and consequently executing traversals. Since the cost of traversals is not affected by the number of records in the database [117], graph databases must theoretically scale better than their relational counterparts in the case of openEHR repositories.

7.2.3 Graph Databases

Graph databases were invented to counteract some limitations of the relational databases regarding highly interconnected data and continuously evolving data models. In a graph data model, information is represented using nodes and edges [118]. Nodes represent the entities, and the relationships between those entities are manifested by the edges that connect them.

Graph databases can be split into two categories:

1. Native graph storage and processing

2. Non-native graph storage and processing

In a native graph storage technology, the underlying structure of the database is optimized to store graph-like data, ensuring that nodes and relationships are written close to each other. Non-native graph databases store the graph data, i.e. node data, and relationship data in other database technologies, e.g. relational tables, which can lead to slow querying as these models are not optimized for graph-like data.

In a native graph processing technology, the database does not rely on global indexes to gather the data. Rather, index-free adjacency is used. Index-free adjacency means that each node references its adjacent nodes, so instead of using global indexes, the nodes act as indexes for their nearby nodes. Theoretically, the complexity of executing graph traversals is $O(1)$ in a graph database using index-free adjacency [117], in comparison to an average of $O(\log(n))$ for a binary search to locate an index entry in a relational database.

One commonly used and well-documented graph database is Neo4j¹. Neo4j uses native graph storage and processing and employs the labeled property graph model. In the labeled property graph model, nodes and edges can have properties associated with them and nodes can be tagged with labels representing their different roles [117]. An example is shown in Fig. 7.2, where A, B, and C are nodes. A, B, and C are labelled ‘EHR,’ ‘Composition,’ and

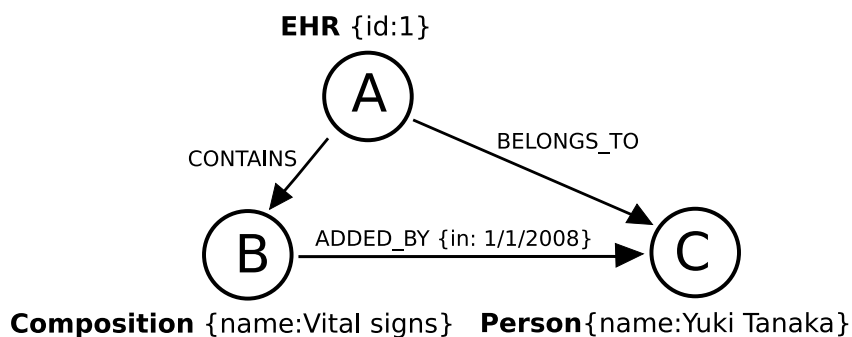


Fig. 7.2: The graph model

‘Person’ respectively. A has ‘id’ as a node attribute, while B and C have a name’ attribute. A is connected to B via a relationship of type ‘CONTAINS’ and to C via a relationship of type ‘BELONGS TO.’ B is connected to C via a relationship of type ‘ADDED BY’ with ‘in’ as a relationship property.

¹<https://neo4j.com/product/>

7.3 Methods

To implement the EMR database following the openEHR approach, we first created a graph model representing the openEHR RM. Afterwards, we used Neo4j, a labeled property graph database technology, to store openEHR archetyped data as instances of the openEHR RM.

To evaluate the proposed implementation approach, we conducted a performance evaluation where we compared our approach to an ORM approach in terms of query response times and required storage space. To conduct the performance evaluation, we artificially generated datasets simulating a pregnancy home-monitoring data repository. To compare the query response times, a set of application-specific queries differing in complexity were identified and executed over both database implementations.

7.3.1 Graph Model of the openEHR RM

Following the openEHR specification, clinical information is represented using openEHR archetypes, which are modeled as constraints over the openEHR RM classes. To query the archetypes' structure, openEHR includes a path mechanism specifying the path to reach archetype nodes starting from the root node of the archetype structure in an XPath-compatible syntax. Each path identifies an archetype node using openEHR RM class attributes as attribute names and 'archetype_id' or 'archetype_node_id' as predicates.

To create the graph model of the openEHR RM, openEHR RM classes were mapped into graph nodes. The relationships were modeled following the openEHR RM class hierarchy and named in accordance with the class attributes employed in the openEHR path mechanism, as shown in Fig. 7.3.

Accordingly, a set of mapping rules was designed for storing archetype structures in a labeled property graph database:

- Each archetype is mapped to a subgraph.
- Each archetype node path is mapped to a branch in the subgraph.
- Each archetype node is mapped to a node in the subgraph.
- Each archetype node corresponds to a class in the RM. The RM class names are mapped to node labels in the subgraph.

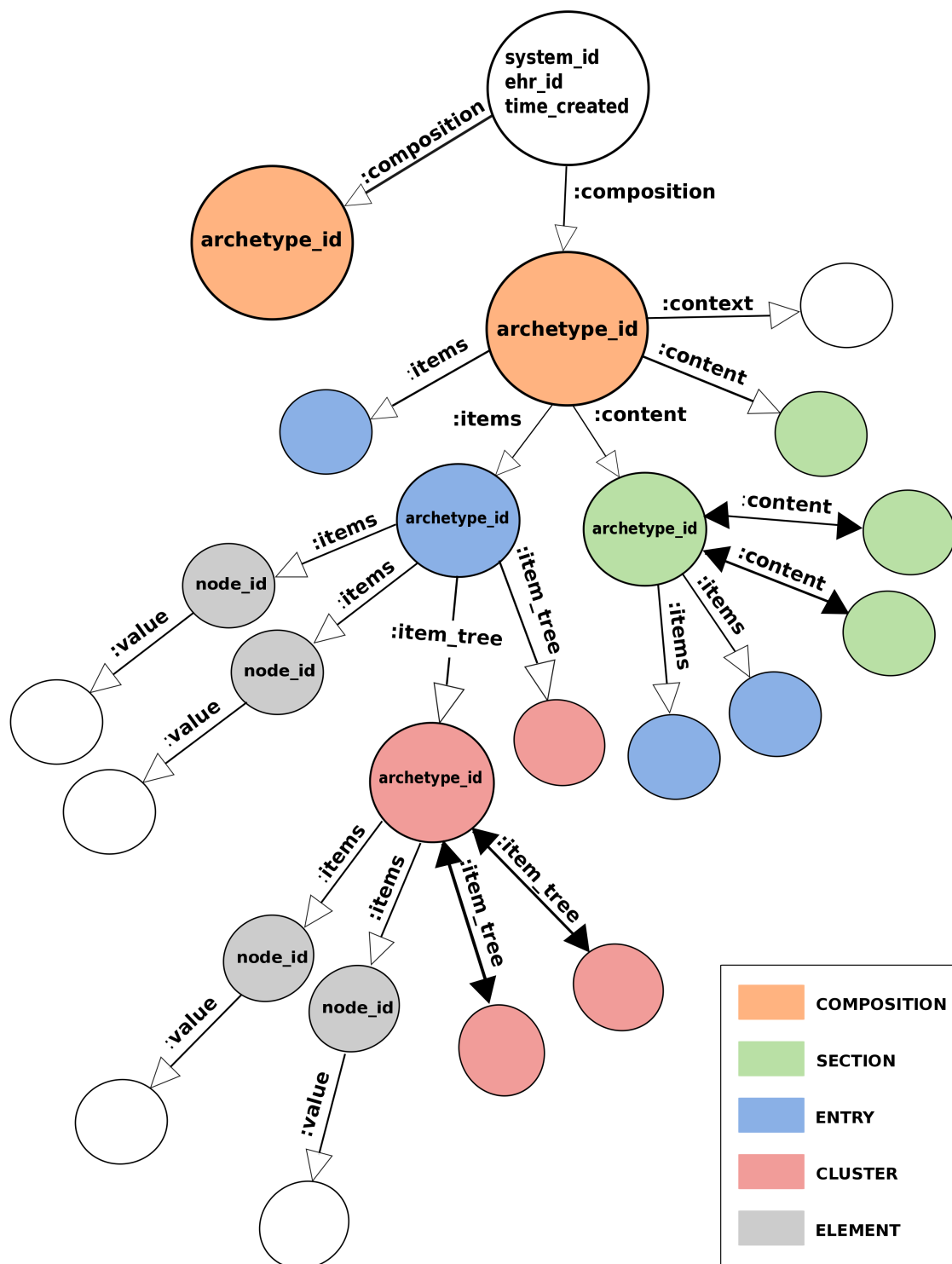


Fig. 7.3: The graph model of the openEHR reference model

Table 7.1: Example of an extracted leaf node path

Leaf node class	Element
Path	[openEHR-EHR-OBSERVATION.bodyweight.v1]/data[at0002]/events[at0003]/state[at0008]/items[at0009]

- ‘archetype_id’ and ‘archetype_node_id’ attributes are mapped to node properties in the subgraph.
- Class attributes are mapped to relationship types.

7.3.2 Storing Archetyped Data with Neo4j

In our proposed implementation approach, we use Cypher to write the queries that store and retrieve openEHR data. Cypher is a declarative graph query language for Neo4j graphs. To store archetyped data, leaf node paths were extracted from the archetypes’ definitions, as shown in Table 7.1.

After the mapping rules were applied, Cypher CREATE statements were formulated to store the corresponding graph branches. The code below shows the Cypher CREATE statement needed to store the extracted node path previously shown in Table 7.1.

```
CREATE
(OBSERVATION\{archetype_id: ‘openEHR-EHR-OBSERVATION.body_weight.v1’})
-[:data]->(HISTORY{archetype_node_id: ‘at0002’})-[:events]->
(POINT_EVENT{archetype_node_id: ‘at0003’})-[:state]->
(ITEM_TREE{archetype_node_id: ‘at0008’})-[:items]->
(ELEMENT{archetype_node_id: ‘at0009’})
```

To retrieve archetyped data, we write Cypher queries that traverse the graph structure. In the queries, we indicate the class attributes as relationship types and the node predicates, i.e., ‘archetype_id’ and ‘archetype_node_id’ as node attributes.

7.3.3 Test Datasets Generation

To evaluate the repository implementation approach, we needed datasets containing a large number of records that complied with the openEHR data models. However, structured EHR data are difficult to obtain and usually governed by strict privacy laws when available.

To ensure our ability to share the dataset used in this evaluation in the future and thus guarantee the reproducibility of this experiment, we decided to artificially generate the datasets. By doing so, we sacrificed some realism in favor of accessibility.

We artificially generated datasets simulating a pregnancy home-monitoring data repository. The simulated repository corresponds to an application that would allow pregnant women to view information relating to their pregnancy and to report pregnancy related symptoms. The contents of the datasets corresponded to clinical concepts and realistic data entries identified through discussions and interviews with antenatal care experts. The structure of the data was dictated by the openEHR RM and definitions of the archetypes. The dataset generation process is shown in Fig. 7.4.

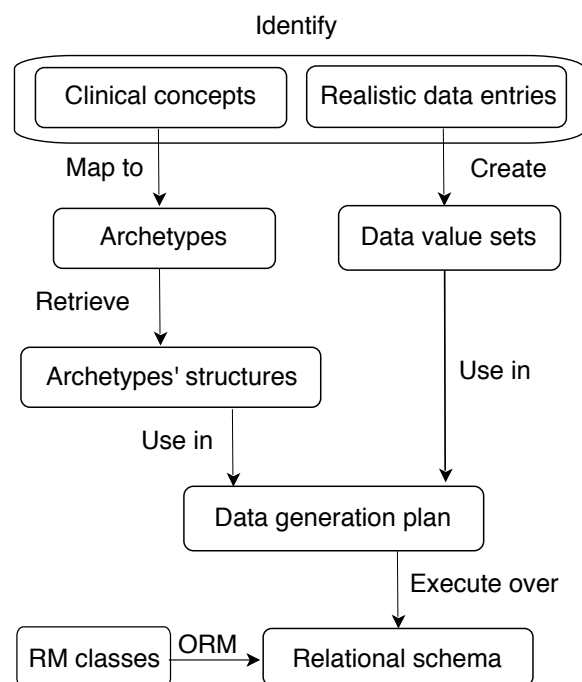


Fig. 7.4: The dataset generation process

We started by reviewing the Japanese Obstetrical guidelines to gain an initial understanding of the antenatal care concepts and processes [59]. Following the review, we conducted two semi-structured interviews with an obstetrician and a midwife. During the interviews, we took notes describing the information flow during the care process. We also identified the clinical information that they considered relevant to report when using a pregnancy home-monitoring application. During the interview with the obstetrician, we used a checklist to determine the possible symptoms that pregnant women may experience and the information the pregnant women need to provide when reporting such symptoms. The interviews allowed us to identify the clinical concepts that could be involved in a preg-

nancy home-monitoring application and a list of realistic data entries that we could use to populate the database.

Next, we mapped the clinical concepts to openEHR archetypes available in the openEHR Clinical Knowledge Manager (CKM) ² and created data value sets corresponding to the possible data entries. The high-level structure of the simulated records along with the employed archetypes is shown in Fig. 7.5.

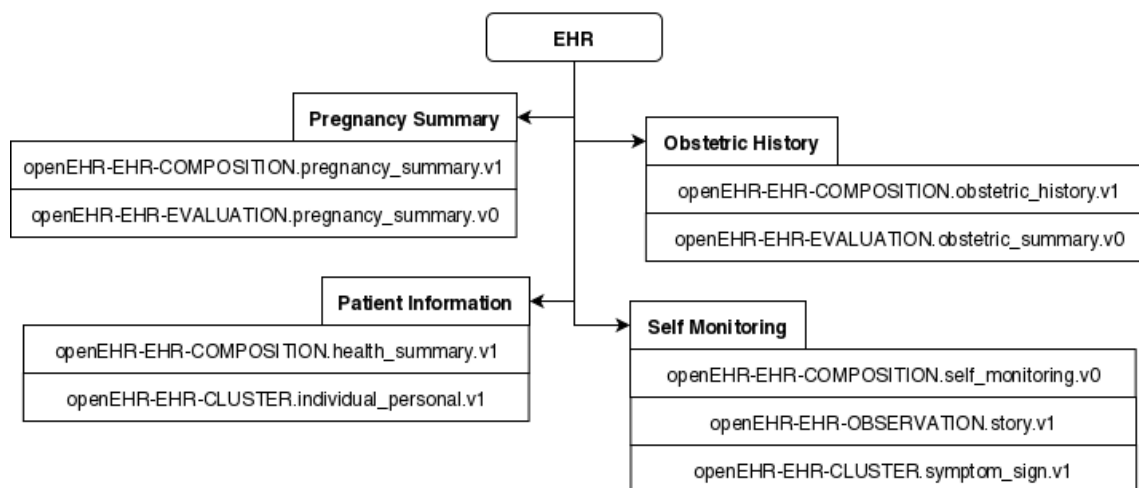


Fig. 7.5: The high-level structure of the simulated records

The simulated EHR records were modeled to contain the date of birth, the obstetric history, the current pregnancy summary, and reports of pregnancy-related symptoms. In total, 11 archetypes found on the CKM were used without modification and four templates representing the different types of compositions were created using the Ocean Informatics Template Designer ³. Each of the generated EHR records includes five compositions with a total of 42 nodes, out of which 19 nodes are leaf nodes containing the data entries.

We then applied an ORM approach to design a relational schema allowing the persistence of the required archetypes over classes from the openEHR RM. The relational schema over which the data generation plans were executed is shown in Fig. 7.6. The plans were executed using Microsoft Visual Studio 2010 to populate a Microsoft SQL Server database [119].

Each generated record contained one date of birth entry, one obstetric history entry, one pregnancy summary entry and two reports of pregnancy symptoms. To generate the

²<https://www.openehr.org/ckm/>

³<http://www.oceanhealthsystems.com/products/template-designer>

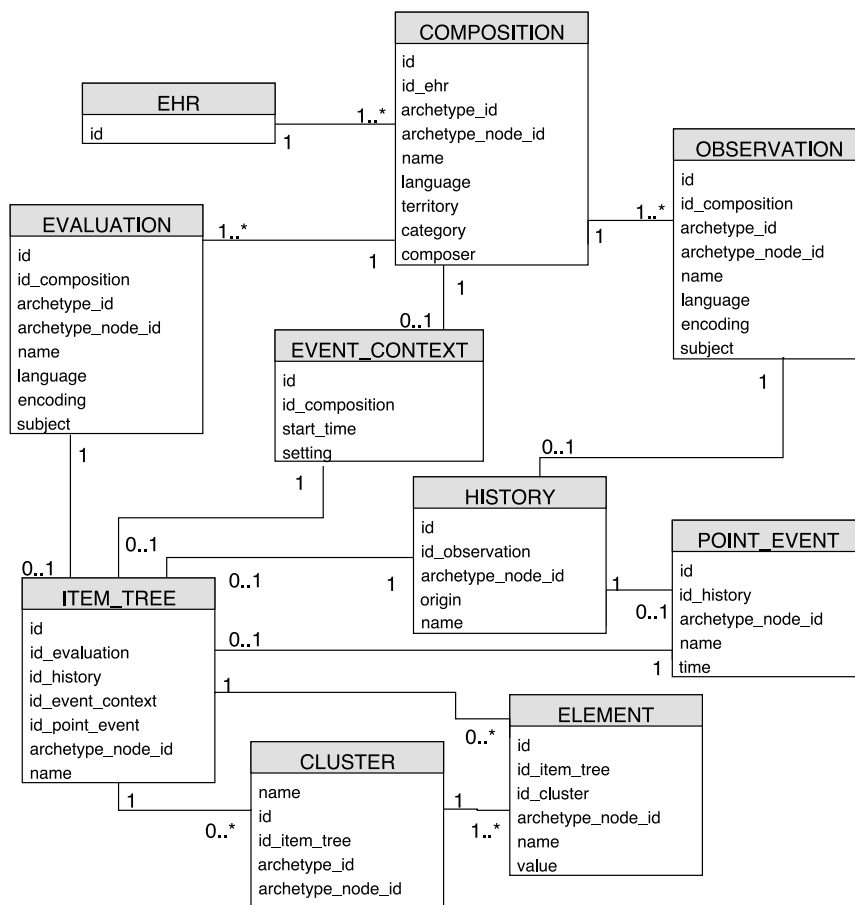


Fig. 7.6: The relational schema over which the data generation plans were executed

records, we created 24 data generation plans using Microsoft Visual Studio 2010. First, we generated the EHR compositions with unique IDs. Then each generation plan was applied to create different branches of the EHR record as shown in Fig. 7.7, 7.8, 7.9, and 7.10.

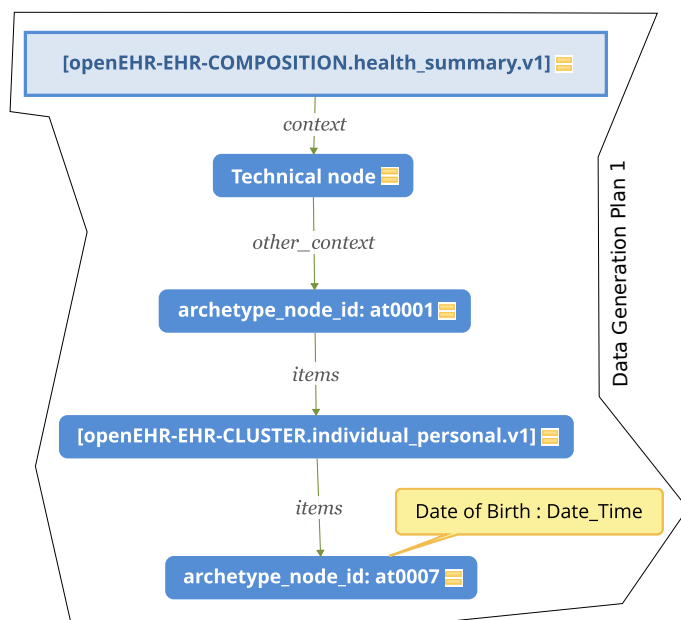


Fig. 7.7: The first set of data generation plans

The generation plans contained possible value lists that were randomly assigned in a uniform way across all the generated instances. In certain cases, we had to create rules to make sure the data made sense. For example, when generating the estimated dates of birth and the dates of conception, we made sure that the estimated date of birth would be nine months after the date of conception.

In total, five different size datasets were generated to evaluate the effect of dataset size on the performance of queries and required storage space. Sets named S1K, S5K, S10K, S50K, and S100K contained 1000, 5000, 10000, 50000, and 100000 records respectively.

In the prefecture where this research was conducted, approximately 20000 births take place every year. In the institution where the EHR application is being developed, it is estimated that 15 antenatal visits occur daily and up to 300 women receive antenatal care in a year. The institution is a major university hospital; therefore, we expect that other institutions would provide care for a smaller number of women per year. Taking into consideration the previous estimations, the size of the datasets aims to simulate the following situations:

- S1k, containing 1000 records, simulates a situation in which the application is used

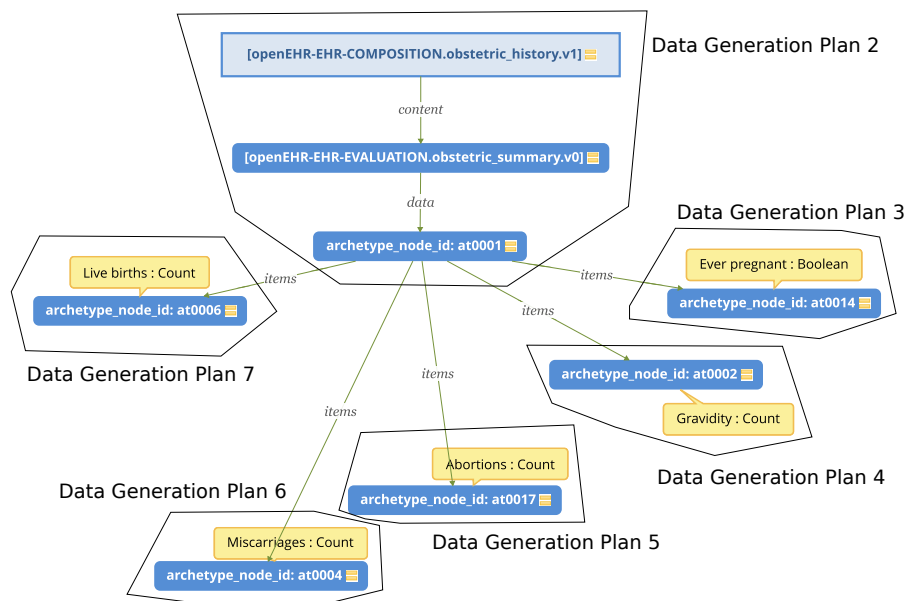


Fig. 7.8: The second set of data generation plans

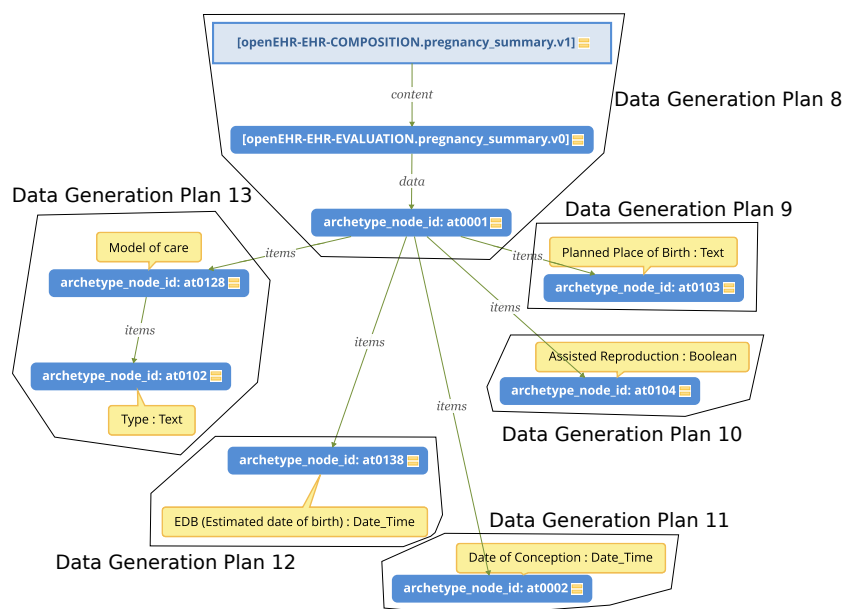


Fig. 7.9: The third set of data generation plans

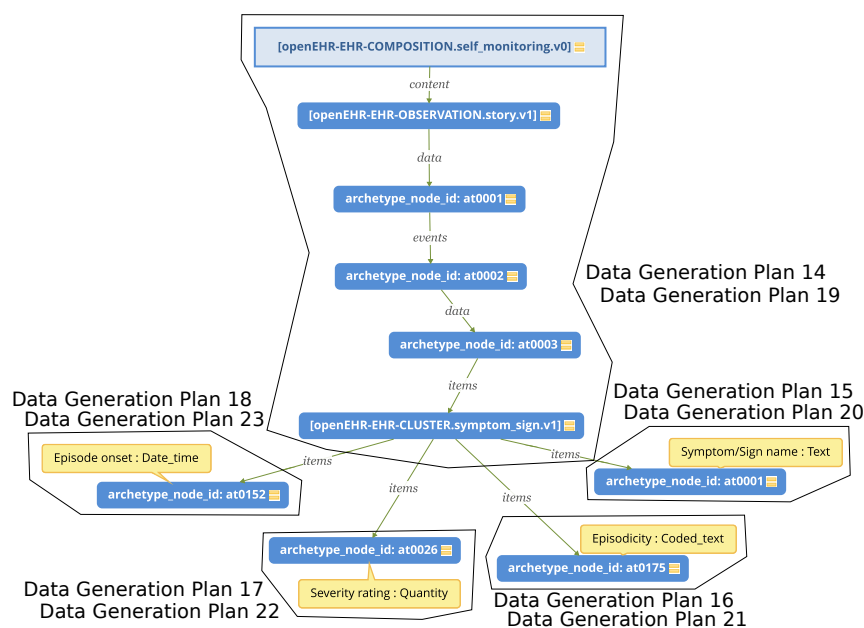


Fig. 7.10: The fourth set of data generation plans

in one institution (200 pregnancies/year) over five years.

- S5k, containing 5000 records, simulates a situation in which the application is used in three major institutions (1000 pregnancies/year) over five years.
- S10k, containing 10000 records, simulates a situation in which the application is used by 10% of the pregnant women (2000 births/year) over five years.
- S50k, containing 50000 records, simulates a situation in which the application is used by 50% of the pregnant women (10000 births/year) over five years.
- S100k, containing 100000 records, simulates a situation in which the application is used on a prefectural level (20000 births/year) over five years.

After the datasets were created in Visual Studio 2010, they were exported as comma-separated values (CSV) files. The CSV data was imported into Neo4j and merged into a graph structure aligning with the proposed graph model of the opened downloaded as Neo4j database via <http://openehr-test-dataset.herokuapp.com/dataset.html>.

7.3.4 Evaluation Setup

To create the query set used in the performance evaluation, we identified usage scenarios expected to occur in clinical and home monitoring settings when using the home-monitoring application. Each usage scenario was mapped to a query.

Accordingly, we identified a set of seven queries:

- Q1- Find the health information present in one health record
- Q2- Add a new symptom entry to one health record
- Q3- Update a symptom entry in one health record
- Q4- Find the symptoms list in one health record
- Q5- Create a health record
- Q6- Add the date of birth, pregnancy summary, and pregnancy history to one record
- Q7- Find the symptoms reported since period X in one health record

Equivalent SQL and Cypher queries were written to represent the seven identified queries. As mentioned earlier, in the institution where the EHR application is being developed, it is estimated that 15 antenatal visits occur daily and up to 300 women receive antenatal care in a year. According to these estimations, the query requests would have different frequencies and are estimated as follows:

- Frequency of Q1, Q2, Q3, Q4: 250 times/day
- Frequency of Q5, Q6, Q7: 30 times/day

Similar to [113], the evaluation criteria were the required storage space and query response time. However, in this study we considered clinical queries since they are the types of queries required in the application's usage scenarios. Clinical queries return requested data values existing in a specific EHR. The performance evaluation was conducted using:

1. Intel(R) Xeon(R) CPU E5-3620 v3 @ 2.40 GHz 2.40 GHz with 32GB of memory, over Windows 10 Enterprise version 1607 64-Bit operating system
2. Neo4j Community version 3.0.1
3. Microsoft SQL Server 2016

The queries were executed using Neo4j browser and Microsoft SQL Server Management Studio 2016. If not configured otherwise, Neo4j assumes that all of the RAM on the machine is available to run the Neo4j server. Similarly, Microsoft SQL Server dynamically changes its memory requirements based on the available system resources. To ensure a fair comparison, the maximum server memory for Microsoft SQL Server was set at 32GB. Each query was executed 15 times over the five different datasets in both database technologies.

7.3.5 Labeling and Indexing

Both Microsoft SQL Server and Neo4j have an indexing mechanism to accelerate query executions. In Microsoft SQL Server, the queries perform JOIN operations over the tables using the id' property. The archetype id' and archetype node id' attributes are used as conditions in the WHERE clauses of the SQL queries. To optimize the performance of Microsoft SQL Server, indexes are applied over the id,' archetype_id,' and archetype_node_id' columns in all tables. Indexes which could possibly improve the query response time and were indicated as missing by Microsoft SQL Server Management Studio were also applied.

In Neo4j, the query response time could be improved through the creation of node labels. In the labeled property graph model, nodes can have any number of labels assigned to them, indicating the role of the node in the domain. Labels can be used in queries to identify the starting nodes for a traversal, thus allowing for more efficient node lookups. If the nodes are labeled, schema indexes can be created for each label and property combination.

In Neo4j, schema indexes are helpful to locate the start node of each query. Once the start node is located, Neo4j executes traversals over the queried path. Two indexing strategies were applied in Neo4j. The first strategy is similar to the indexing strategy applied with SQL Server, where indexes were created for the following (Label, Property) combinations: (EHR, id), (COMPOSITION, archetype_id), (EVALUATION, archetype_id), (OBSERVATION, archetype_id), (ITEM_TREE, archetype_node_id), (HISTORY, archetype_node_id), (POINT_EVENT, archetype_node_id), (EVENT_CONTEXT, archetype_node_id), (CLUSTER, archetype_id), (ELEMENT, archetype_node_id). In the second strategy, we only indexed the (EHR, id) combination since all of the queries deal with individual EHR records, implying that the starting node is located by searching for a specific EHR id. When comparing the performance of both implementation approaches, the first Neo4j indexing strategy was used since it resulted in faster query response times.

7.4 Results

We compare our approach using Neo4j with an ORM approach using Microsoft SQL Server in terms of required storage space and query response time. We first show the required storage space in both approaches after the indexing was applied. Then, we show how query response times compared using both approaches.

7.4.1 Storage Space Requirement

Fig. 7.11 shows the required storage space for each of the databases after the indexing was performed. The Microsoft SQL Server database required less storage space for the S1K, S5K, and S10K datasets. Neo4j required less storage space for the S50K and S100K datasets.

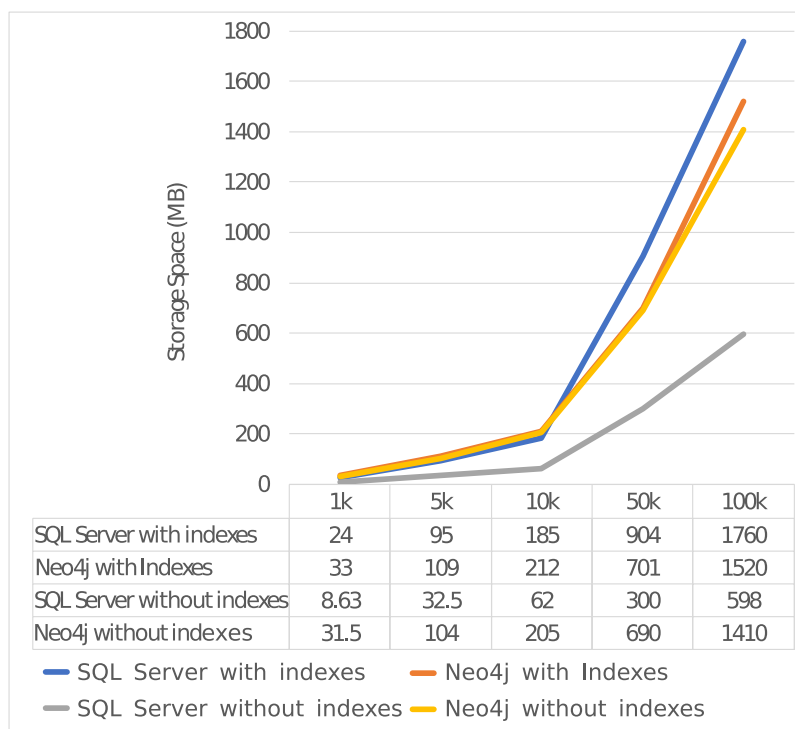


Fig. 7.11: The required storage space for each dataset

7.4.2 Query Reponse Times

The dataset size and the type of query are the two main factors affecting the query response times in both implementation approaches. At first, we show the effect of the dataset size

and then we show the effect of the query type.

Fig. 7.12 shows how both implementation approaches performed for the different size datasets. The queries are grouped together to simulate a complete usage scenario of the home-monitoring application. Neo4j performed better than Microsoft SQL Server for all of the dataset sizes. However, Neo4j had a large number of outliers, while Microsoft SQL Server maintained a more stable performance. The outliers were mainly the result of submitting a query to the server for the first time, meaning that these outliers would not occur in a system in which the server has been warmed up.

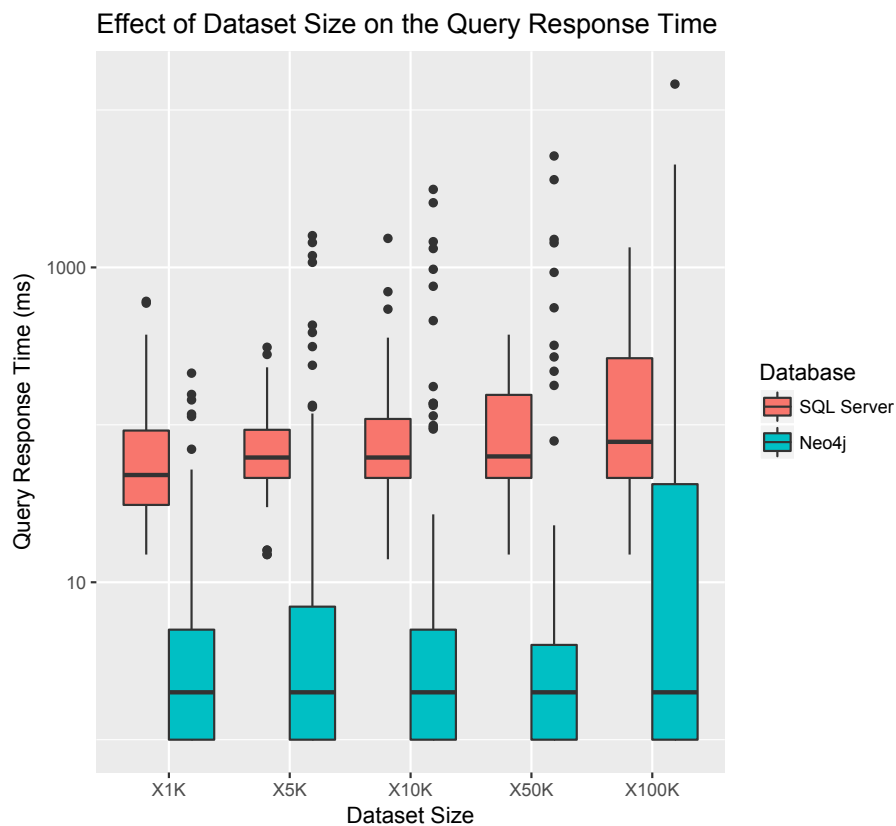


Fig. 7.12: Comparison of the query response times for the two implementation approaches with different size datasets

Fig. 7.13 shows how both implementation approaches performed for the different types of queries. The response times for each query over the different dataset sizes are grouped together. Neo4j performed better than Microsoft SQL Server for all the query types. The results also show that the type of query has almost the same effect over the performance of both implementation approaches where Q2, Q3, and Q7 have a longer response time with both implementation approaches.



Fig. 7.13: Comparison of the query response times for the two implementation approaches with different queries

7.5 Discussion

We proposed an implementation approach of openEHR databases using a labeled property graph database. We compared a Neo4j implementation of the proposed approach with a Microsoft SQL Server implementation of the commonly used ORM approach. The results confirm that the ORM approach is not optimal for storing and querying openEHR data and that the graph model could provide a better overall performance. On the other hand, we can see that Neo4j had a larger number of extreme outliers. These outliers were mainly the response times that corresponded to the first time a certain query was submitted to the server. We can conclude that Neo4j has a limited performance with ad-hoc queries. However, ad-hoc queries could be avoided in clinical settings. In the institution in which this research was conducted, about 90 percent of the queries are cached beforehand. Therefore, the limited performance of Neo4j for ad-hoc queries would not be a practical concern for the performance of clinical queries.

In terms of required storage space, the Microsoft SQL Server implementation required less space for the smaller datasets while the Neo4j implementation required less space for the larger datasets. One way to explain this is by looking at the effect of indexing on the required storage space in both database technologies, shown in Fig. 7.14.

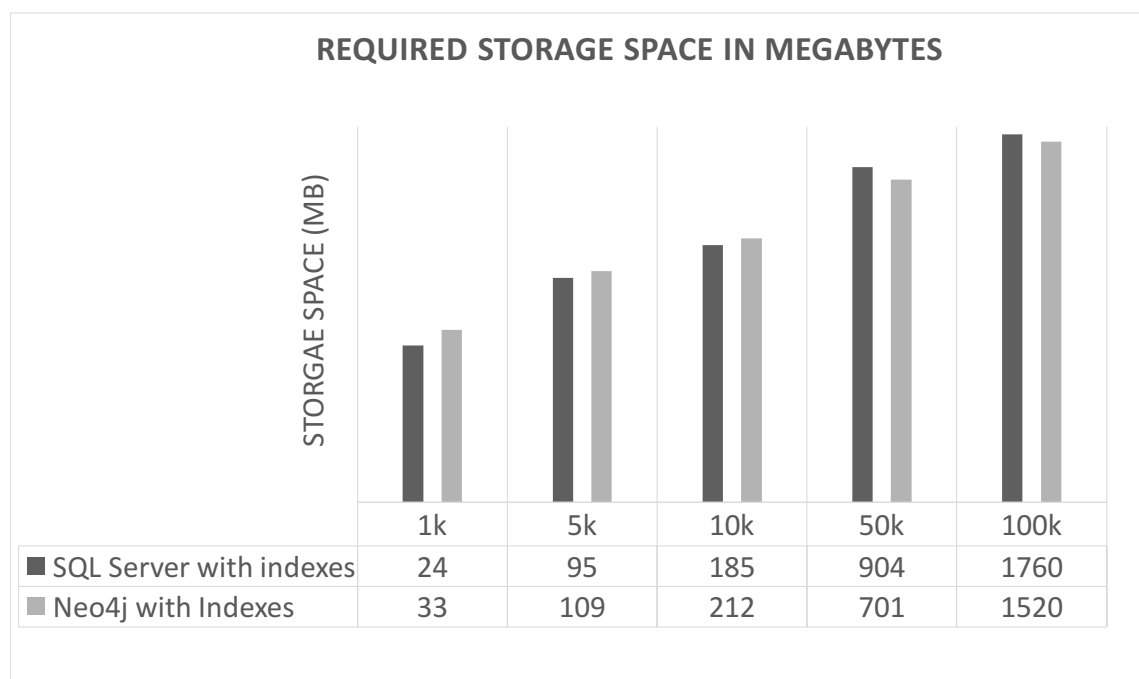


Fig. 7.14: Effect of indexing on storage space requirements

Without indexes, the Microsoft SQL Server implementation of the ORM approach requires the least storage space. However, we see a threefold increase in the required storage space after the indexes were added. For Neo4j, adding the indexes increased the required storage by a maximum of ten percent. Indexing cannot be practically avoided because it greatly reduces the query response times when JOIN operations over large tables are executed. Thus, these results suggest that for larger datasets, Neo4j would be more space efficient.

In addition to a promising overall performance, the proposed approach using Neo4j was more straightforward and easier to implement. For example, during this study, Cypher queries required less than half the number of Logical Lines of Code (LLOC) than those required for the SQL queries. The ease of implementation was due to the semantic alignment between the openEHR RM and the labeled property graph model, the schema-less nature of graph databases, and the declarative nature of Cypher. Furthermore, using Neo4j's browser, we were able to directly visualize the patient EHR as a semantic graph. A survey of openEHR learning approaches [120] proposed the use of interactive graphical representations to browse and manipulate EHR instance data to learn openEHR, a process usually described as difficult and time consuming. The ease of implementation and visualization allowed by Neo4j could be of value for beginners approaching openEHR.

Limitations of this study include the nature of the used datasets and the limited number

of explored clinical use-cases. The first limitation resulted from a lack of access to real datasets, a common issue faced by different groups testing the performance of clinical repository implementations. To conduct the performance evaluation, we used artificially generated datasets instead of real EHR data. The EHRs in the generated datasets contain five compositions each, a number likely to be surpassed in a real production scenario. However, since we could generate different size datasets, we consider it sufficient to highlight the difference in performance between the two implementations when the dataset size grows.

On the other hand, the simulated datasets used for the evaluation do not include image or video files. In reality, EHR data is heterogeneous and includes variable data types. To handle a variety of data types, a polyglot or hybrid persistence approach for storing and querying EHR data could be applied. Further research is required to determine which database technology and implementation approach fits for each type of openEHR data and how these technologies can be integrated smoothly in a polyglot-persistent systems schema.

Finally, we note that the number of use-cases explored in this study is limited and does not represent a full usage scenario, nor do they consider concurrent transactions, which is essential when evaluating the performance of clinical querying over an EHR repository.

7.6 Conclusion

In this chapter, we proposed an EMR database implementation approach following the openEHR specifications and using labeled property graph databases. We compared the proposed approach with an implementation of the commonly used ORM approach. Our results confirmed that the ORM approach is not optimal for storing and querying openEHR data and that the graph model could provide a better overall performance. The proposed approach could be used by EMR designers to implement performant EMR databases when following the two-level modeling approach described in EMR interoperability standards.

Chapter 8

Discussion

In this dissertation, we presented an evolutionary design process for EMR systems where designers continuously adapt the EMR system to the needs of their users. To support the designers in their evolutionary design of EMR systems, we presented a set of design and redesign methods and showcased them using a case study of an EMR system in Japanese antenatal care settings.

Within the evolutionary design process, as shown in Fig. 2.1, the presented methods support the designers in steps 1, 2, 3, and 4 with the initial database design, and in steps 5, 6, and 7 with defining and prioritizing redesign requirements. Methods that allow the designers to produce and implement interface (re)designs were not in the scope of this dissertation.

In Part I (Chapters 3, 4, and 5), we explored methods for defining and prioritizing context specific EMR system requirements. The proposed methods allow the designers to (i) understand a system in situ, (ii) understand the users attitudes in terms of preferences and priorities, and (iii) prioritize the features to redesign in an EMR system.

These methods could be used to define and prioritize the context specific requirements of other IT systems. However, it is important to keep in mind that the rationale behind the methods aimed to address the particular challenges that designers may encounter when designing evolutionary EMR systems. For other types of IT systems, other design methods may prove fitter.

In Part II (Chapters 6 and 7), we explored methods for implementing interoperable, adaptable, and performant EMR databases. The proposed methods allow the designers to im-

plement databases that (i) follow interoperability standards, (ii) can be easily adapted to changing clinical requirements, and (iii) maintain a good performance when the size of EMR data grows.

Even though we evaluated graph databases for EMR systems storing openEHR data, the implementation method could be applied for any IT system where the data needs frequently change frequently and where the data has a tree structure with deep hierarchy.

In addition to providing methods to support EMR system designers, Chapters 3, 4, and 5 contribute to the necessary widening of the design construct in EMR System Design Research by providing the designers with ways to (i) understand the unarticulated intentions and requirements of the EMR systems' users, and (ii) align their intentions with the intentions of the users.

In the next sections, we will discuss aspects relating to EMR system design that became evident to us through this work.

8.1 Defining the Requirements of EMR Systems

Through this research, it became clear to us that automated methods are needed to define the context specific requirements of EMR systems. The existing methods, including the one that we presented in this dissertation, require human agents to collect data and analyze it in order to define the users' requirements. This approach may have been feasible under the traditional EMR design approach where defining the users' requirements is usually done once at the beginning of the project. Following our proposed design approach, the designers are expected to continuously define the requirements of the users and adapt the systems accordingly. In this case, the need for a human to continuously collect and analyze data is costly and inefficient. Therefore, methods that automate the data collection and analysis phases are needed to lower the cost and labor required to define the systems' context specific requirements.

8.2 Person-Centered EMR Systems

In other respects, different users have different experiences, wants, and priorities regarding the use of EMR systems. Therefore, it would be difficult to satisfy all the users if we present them with one EMR system design. To address this problem, current EMR

systems are customized for the group of users that they are targeted at. However, in this research, we found that the users' attitudes may greatly differ within one group of users. Moreover, since the EMR system is used in the presence of multiple actors, the attitudes of an individual user regarding the use of the EMR system may differ depending on the other people that are involved. These considerations lead us to a complex situation where each combination of EMR users would require an EMR system that is customized to their particular dynamics. Future research could explore the extreme customization of EMR systems that accommodates these differences by automatically adapting the systems' functionality according to the particular needs and preferences of the involved actors. By doing so, we would obtain person-centered EMR systems that fit the vision of person-centered healthcare systems.

8.3 Controlling Data in EMR Systems

In addition to complex technical and functional requirements, EMR systems present us with complex social questions and requirements to address. Questions that are frequently discussed regard the inevitability of losing our privacy, our rights to own and control our health data, the price of our data and the real beneficiaries of big health data, etc.

Previously, EMR data used to be stored in the computers of the healthcare providers. Nowadays, providers of cloud-based EMR systems store the health data on their own servers. It is common for such companies to outsource the administration of their databases. Therefore, it is the companies' responsibility to maintain the security of the data and provide detailed information about the location of their servers, the people that have access to the servers, and the security measures that they employ.

Moreover, the healthcare providers that buy these systems have the responsibility to monitor the companies' practices and make sure that they treat their patients' data responsibly.

Finally, the patients, should be fully informed about the EMR systems that are in use and have the ability to refuse to have their data documented in them. Refusing to have their data documented in the EMR system of their healthcare provider is difficult because: (i) patients are not usually given the option, (ii) when visiting a healthcare providers, patients are usually ill and need the providers' care, and (iii) the doctor-patient power hierarchy inescapably affects the patients' agency [121]. Further research is needed to explore the real and perceived control patients have over their health data, and how we can increase this control through design.

8.4 EMR Systems as Agents of Change

In addition to these important and pressing questions, EMR system designers also have to reconsider the role of EMR systems in respect to the current structure and way of doing things. As we saw in Chapter 3, EMR systems could be used in ambivalent ways due to constraints imposed by the current reality. For example, as illustrated by the *Accomplice* role, EMR systems can be used by the healthcare providers to pause the communication with the care receivers. Another example is illustrated by the *Gossip* role, where healthcare providers intentionally write sensitive psycho-social information ambiguously inside the EMRs. In cases such as these, should EMR systems be agents of change or should they be tools that serve the current reality, and thus reinforce it. If the answer is that EMR systems should be agents of change, another questions arises: "As agents of change, which value system should EMR systems serve?"

Chapter 9

Conclusion

To conclude, we describe the contributions of this work and directions for future research.

9.1 Contributions

In this research, we proposed multiple design methods for improving the design of EMR systems. In chapter 2, we described and discussed traditional EMR design approaches. We then presented a structured EMR design process that treats the EMR system as an evolutionary prototype that requires continuous adaptation to fit the contextual needs of its users. Accordingly, chapters 3-7 contributed in design methods to support the evolutionary design process of EMR systems.

Extracting the situated roles of EMR systems

Chapter 3 investigated a method to identify the users' needs by looking at the ways they appropriate the system. The method focuses on identifying the situated roles of the EMR systems, i.e., the unintended ways the users engage with the system in its context of use. This kind of method is applied after the system is implemented and used and could be useful for gathering the needs that the users cannot articulate or are not aware of.

Understanding the experiences, wants, and priorities of EMR system users

In Chapter 4, we provided a method to validate the situated roles of the EMR system through the users' feedback. The method allows the designers to understand the current

experiences, wants, and priorities of the users and map them into design implications. This method could be used by designers who want to align their design activities with the wants and priorities of their users.

Prioritizing EMR features to redesign

In Chapter 5, we proposed a design decision-support method that allows designers to prioritize the EMR feature to (re)design. The method takes into consideration the priorities of the different user groups and the interdependency of the EMR system's features. The method's results expose the features whose redesign would generate the largest desired effect for its users. This method would be useful for designers faced with multiple features to (re)design but have limited resources and are unable to address all of them.

Modelling clinical concepts using openEHR archetypes

In chapter 6, we showed that it was feasible and worthwhile for designers to reuse existing clinical data models in the data modeling process of an EMR system. By doing so, designers can increase the interoperability of their systems and reduce their data modeling tasks.

Implementing EMR databases using openEHR and graph databases

In chapter 7, we proposed using a graph database for implementing performant EMR databases following the two-level modeling approach adopted by major interoperability standards. We compared our approach with the most commonly used approach and showed that our approach performs better in terms of query response times and storage requirements. The proposed implementation approach allows designers to design EMR databases that follow interoperability standards, have fast response times, and require less storage space. This would eventually result in more usable systems that cost less to maintain.

9.2 Future directions

Future research could build on this research in various ways to improve and optimize the design activities and outcomes of EMR system designers.

Monitoring the situated roles of the system

To evaluate the situated roles of the EMR system, future work could try to assess the roles by automatically collecting and analyzing usage logs from the EMR system. If the system's roles could be automatically and continuously monitored, the designers could evaluate their design outcomes by analyzing the changes in the roles between the pre-redesign and post-redesign phases.

Supporting designers in prioritizing the features to redesign

To prioritize the EMR features to redesign, future work could evaluate the proposed method as a decision-support method by looking at its usefulness for the designers. An objective evaluation could investigate how using the method practically affects the designers' priorities. A subjective evaluation could ask the designers about their perceived usefulness of the method. Furthermore, the prioritization method could be expanded in scope to include other important criteria for prioritizing the features to redesign such as: the difficulty of the task, its cost, and its alignment with pre-existing visions and strategies.

Another possible research direction would be to look at different mediums for communicating the information to the designers. Instead of providing the priority scores or the final rankings of the features, it could be valuable to visualize the interactions that take place between the features and the partial effects that modifying one feature has on each other feature. Finally, the creation of a web app to enable the widespread use of the method, improve its usability, and allow its evaluation could be undertaken in the future.

Evaluating the performance of EMR databases

In our work, we generated artificial datasets to evaluate the performance of the database implementation approach. Future work could aim to publicly provide real EMR data and use-case scenarios to allow researchers to benchmark their EMR database implementations.

In other respects, future EMR systems would be used by multiple users concurrently; therefore, it would be valuable and essential to evaluate the EMR systems' database performance with concurrent transactions.

Finally, EMR databases could also be used to conduct epidemiological research. The types of queries used in clinical research differ greatly from the ones used in epidemiological research. Therefore, a possible research direction could be to investigate the performance of different EMR repository implementations with queries used in epidemiological research.

Bibliography

- [1] I. O. M. D. O. H. C. Ser, *Computer-based Patient Record: An Essential Technology for Health Care*. National Academies Press, 1991.
- [2] D. F. Sittig, A. Wright, J. Ash, and H. Singh, “New unintended adverse consequences of electronic health records,” *Yearbook of medical informatics*, vol. 25, no. 01, pp. 7–12, 2016.
- [3] C. S. Kruse, K. Kothman, K. Anerobi, and L. Abanaka, “Adoption factors of the electronic health record: a systematic review,” *JMIR medical informatics*, vol. 4, no. 2, p. e19, 2016.
- [4] V. Blijleven, K. Koelemeijer, M. Wetzels, and M. Jaspers, “Workarounds emerging from electronic health record system usage: consequences for patient safety, effectiveness of care, and efficiency of care,” *JMIR human factors*, vol. 4, no. 4, p. e27, 2017.
- [5] K. M. Cresswell, A. Worth, and A. Sheikh, “Integration of a nationally procured electronic health record system into user work practices,” *BMC medical informatics and decision making*, vol. 12, no. 1, p. 15, 2012.
- [6] J. Aarts, J. Ash, and M. Berg, “Extending the understanding of computerized physician order entry: implications for professional collaboration, workflow and quality of care,” *International journal of medical informatics*, vol. 76, pp. S4–S13, 2007.
- [7] P. Carayon, B.-T. Karsh, R. Cartmill, P. Hoonakker, A. S. Hundt, D. Krueger, T. Thuemling, T. Wetterneck, P. F. Brennan, J. Walker, *et al.*, “Incorporating health it into workflow redesign: Request for information summary report,” *AHRQ publication*, no. 10-0074, 2010.

- [8] R. H. Miller and I. Sim, "Physicians use of electronic medical records: barriers and solutions," *Health affairs*, vol. 23, no. 2, pp. 116–126, 2004.
- [9] A. F. Rose, J. L. Schnipper, E. R. Park, E. G. Poon, Q. Li, and B. Middleton, "Using qualitative studies to improve the usability of an emr," *Journal of biomedical informatics*, vol. 38, no. 1, pp. 51–60, 2005.
- [10] J. S. Ash, P. N. Gorman, M. Lavelle, T. H. Payne, T. A. Massaro, G. L. Frantz, and J. A. Lyman, "A cross-site qualitative study of physician order entry," *Journal of the American Medical Informatics Association*, vol. 10, no. 2, pp. 188–200, 2003.
- [11] M. E. Flanagan, J. J. Saleem, L. G. Millitello, A. L. Russ, and B. N. Doebbeling, "and computer-based workarounds to electronic health record use at three benchmark institutions," *Journal of the American Medical Informatics Association*, vol. 20, no. e1, pp. e59–e66, 2013.
- [12] G. Marcu, A. K. Dey, and S. Kiesler, "Designing for collaborative reflection," in *Proceedings of the 8th International Conference on Pervasive Computing Technologies for Healthcare*, pp. 9–16, ICST (Institute for Computer Sciences, Social-Informatics and , 2014.
- [13] J. M. Walker and P. Carayon, "From tasks to processes: the case for changing health information technology to improve health care," *Health Affairs*, vol. 28, no. 2, pp. 467–477, 2009.
- [14] D. Scott and I. N. Purves, "Triadic relationship between doctor, computer and patient," *Interacting with Computers*, vol. 8, no. 4, pp. 347–363, 1996.
- [15] C. Pearce, M. Arnold, C. Phillips, S. Trumble, and K. Dwan, "The patient and the computer in the primary care consultation," *Journal of the American Medical Informatics Association*, vol. 18, no. 2, pp. 138–142, 2011.
- [16] C. Pearce, K. Dwan, M. Arnold, C. Phillips, and S. Trumble, "Doctor, patient and computera framework for the new consultation," *International journal of medical informatics*, vol. 78, no. 1, pp. 32–38, 2009.
- [17] R. Frankel, A. Altschuler, S. George, J. Kinsman, H. Jimison, N. R. Robertson, and J. Hsu, "Effects of exam-room computing on clinician-patient communication," *Journal of general internal medicine*, vol. 20, no. 8, pp. 677–682, 2005.

- [18] Z. Kazmi, "Effects of exam room ehr use on doctor-patient communication: a systematic literature review," *Journal of Innovation in Health Informatics*, vol. 21, no. 1, pp. 30–39, 2014.
- [19] N. Booth, P. Robinson, and J. Kohannejad, "Identification of high-quality consultation practice in primary care: the effects of computer use on doctor–patient rapport," *Journal of Innovation in Health Informatics*, vol. 12, no. 2, pp. 75–83, 2004.
- [20] C. Pearce, H. Walker, and C. O'Shea, "A visual study of computers on doctors' desks," *Journal of Innovation in Health Informatics*, vol. 16, no. 2, pp. 111–117, 2008.
- [21] W.-S. Chan, M. Stevenson, and K. McGlade, "Do general practitioners change how they use the computer during consultations with a significant psychological component?," *International journal of medical informatics*, vol. 77, no. 8, pp. 534–538, 2008.
- [22] A. B. Als, "The desk-top computer as a magic box: patterns of behaviour connected with the desk-top computer; gps' and patients' perceptions.," *Family practice*, vol. 14, no. 1, pp. 17–23, 1997.
- [23] D. Greatbatch, C. Heath, P. Champion, and P. Luff, "How do desk-top computers affect the doctor-patient interaction," *Family practice*, vol. 12, no. 1, pp. 32–36, 1995.
- [24] E. Montague and O. Asan, "Dynamic modeling of patient and physician eye gaze to understand the effects of electronic health records on doctor–patient communication and attention," *International journal of medical informatics*, vol. 83, no. 3, pp. 225–234, 2014.
- [25] J. Noordman, P. Verhaak, I. van Beljouw, and S. van Dulmen, "Consulting room computers and their effect on general practitioner–patient communication," *Family practice*, vol. 27, no. 6, pp. 644–651, 2010.
- [26] M. A. Alkureishi, W. W. Lee, M. Lyons, V. G. Press, S. Imam, A. Nkansah-Amankra, D. Werner, and V. M. Arora, "Impact of electronic medical record use on the patient–doctor relationship and communication: A systematic review," *Journal of general internal medicine*, vol. 31, no. 5, pp. 548–560, 2016.

- [27] C. Safran, P. C. Jones, D. Rind, B. Bush, K. N. Cytryn, and V. L. Patel, "Electronic communication and collaboration in a health care practice," *Artificial intelligence in medicine*, vol. 12, no. 2, pp. 137–151, 1998.
- [28] S. M. Strayer, M. W. Semler, M. L. Kington, and K. O. Tanabe, "Patient attitudes toward physician use of tablet computers in the exam room," *Family medicine*, vol. 42, no. 9, p. 643, 2010.
- [29] S. E. Ross, J. Todd, L. A. Moore, B. L. Beaty, L. Wittevrongel, and C.-T. Lin, "Expectations of patients and physicians regarding patient-accessible medical records," *Journal of medical Internet research*, vol. 7, no. 2, p. e13, 2005.
- [30] A. Hassol, J. M. Walker, D. Kidder, K. Rokita, D. Young, S. Pierdon, D. Deitz, S. Kuck, and E. Ortiz, "Patient experiences and attitudes about access to a patient electronic health care record and linked web messaging," *Journal of the American Medical Informatics Association*, vol. 11, no. 6, pp. 505–513, 2004.
- [31] J. Walker, S. G. Leveille, L. Ngo, E. Vodicka, J. D. Darer, S. Dhanireddy, J. G. Elmore, H. J. Feldman, M. J. Lichtenfeld, N. Oster, *et al.*, "Inviting patients to read their doctors' notes: patients and doctors look ahead: patient and physician surveys," *Annals of internal medicine*, vol. 155, no. 12, pp. 811–819, 2011.
- [32] S. S. Woods, E. Schwartz, A. Tuepker, N. A. Press, K. M. Nazi, C. L. Turvey, and W. P. Nichol, "Patient experiences with full electronic access to health records and clinical notes through the my healthvet personal health record pilot: qualitative study," *Journal of medical Internet research*, vol. 15, no. 3, p. e65, 2013.
- [33] M. Baldry, C. Cheal, B. Fisher, M. Gillett, and V. Huet, "Giving patients their own records in general practice: experience of patients and staff.," *Br Med J (Clin Res Ed)*, vol. 292, no. 6520, pp. 596–598, 1986.
- [34] B. Fisher and N. Britten, "Patient access to records: expectations of hospital doctors and experiences of cancer patients.," *Br J Gen Pract*, vol. 43, no. 367, pp. 52–56, 1993.
- [35] G. Hawley, J. Hepworth, S. A. Wilkinson, and C. Jackson, "From maternity paper hand-held records to electronic health records: what do women tell us about their use?," *Australian Journal of Primary Health*, vol. 22, no. 4, pp. 339–348, 2016.

- [36] J. D. Halamka, K. D. Mandl, and P. C. Tang, "Early experiences with personal health records," *Journal of the American Medical Informatics Association*, vol. 15, no. 1, pp. 1–7, 2008.
- [37] D. M. Zulman, K. M. Nazi, C. L. Turvey, T. H. Wagner, S. S. Woods, and L. C. An, "Patient interest in sharing personal health record information: a web-based survey," *Annals of internal medicine*, vol. 155, no. 12, pp. 805–810, 2011.
- [38] K. Caine and R. Hanania, "Patients want granular privacy control over health information in electronic medical records," *Journal of the American Medical Informatics Association*, vol. 20, no. 1, pp. 7–15, 2012.
- [39] P. H. Schwartz, K. Caine, S. A. Alpert, E. M. Meslin, A. E. Carroll, and W. M. Tierney, "Patient preferences in controlling access to their electronic health records: a prospective cohort study in primary care," *Journal of general internal medicine*, vol. 30, no. 1, pp. 25–30, 2015.
- [40] K. Morris, G. Yamamoto, S. Hiragi, S. Ohtera, M. Sakai, O. Sugiyama, K. Okamoto, M. Nambu, and T. Kuroda, "Designing an authorization system based on patient privacy preferences in japan.," *Studies in health technology and informatics*, vol. 247, pp. 71–75, 2018.
- [41] T. Delbanco, D. M. Berwick, J. I. Boufford, G. Ollenschläger, D. Plamping, and R. G. Rockefeller, "Healthcare in a land called peoplepower: nothing about me without me," *Health Expectations*, vol. 4, no. 3, pp. 144–150, 2001.
- [42] W. Richardson, D. Berwick, J. Bisgard, L. Bristow, C. Buck, and C. Cassel, "Institute of medicine. crossing the quality chasm: A new health system for the 21st century," 2001.
- [43] R. Jayadevappa and S. Chhatre, "Patient centered care-a conceptual model and review of the state of the art," *The Open Health Services and Policy Journal*, vol. 4, no. 1, 2011.
- [44] R. M. Epstein and R. L. Street, "The values and value of patient-centered care," 2011.
- [45] G. Demiris, L. B. Afrin, S. Speedie, K. L. Courtney, M. Sondhi, V. Vimarlund, C. Lovis, W. Goossen, and C. Lynch, "Patient-centered applications: use of information technology to promote disease management and wellness. a white paper by the amia

- knowledge in motion working group,” *Journal of the American Medical Informatics Association*, vol. 15, no. 1, pp. 8–13, 2008.
- [46] J. J. Saleem, M. E. Flanagan, A. L. Russ, C. K. McMullen, L. Elli, S. A. Russell, K. J. Bennett, M. S. Matthias, S. U. Rehman, M. D. Schwartz, *et al.*, “You and me and the computer makes three: variations in exam room use of the electronic health record,” *Journal of the American Medical Informatics Association*, vol. 21, no. e1, pp. e147–e151, 2013.
- [47] H. A. Simon, *The sciences of the artificial*. MIT press, 1996.
- [48] K. Peffers, T. Tuunanen, M. A. Rothenberger, and S. Chatterjee, “A design science research methodology for information systems research,” *Journal of management information systems*, vol. 24, no. 3, pp. 45–77, 2007.
- [49] J. McKay, P. Marshall, and R. Hirschheim, “The design construct in information systems design science,” *Journal of Information Technology*, vol. 27, no. 2, pp. 125–139, 2012.
- [50] R. H. Von Alan, S. T. March, J. Park, and S. Ram, “Design science in information systems research,” *MIS quarterly*, vol. 28, no. 1, pp. 75–105, 2004.
- [51] W. Kuechler and V. Vaishnavi, “The emergence of design research in information systems in north america,” *Journal of Design Research*, vol. 7, no. 1, pp. 1–16, 2008.
- [52] T. Jokela, N. Iivari, J. Matero, and M. Karukka, “The standard of user-centered design and the standard definition of usability: analyzing iso 13407 against iso 9241-11,” in *Proceedings of the Latin American conference on Human-computer interaction*, pp. 53–60, ACM, 2003.
- [53] R. M. Schumacher and S. Z. Lowry, “Nist guide to the processes approach for improving the usability of electronic health records,” *National Institute of Standards and Technology*, 2010.
- [54] A. M. Davis, “Operational prototyping: A new development approach,” *IEEE software*, vol. 9, no. 5, pp. 70–78, 1992.
- [55] A. Oakley, “The origins and development of antenatal care,” in *Effectiveness and satisfaction in antenatal care*, pp. 1–21, Spastics International Medical Publications/William Heinemann Medical Books, 1982.

- [56] I. Hildingsson, H. Haines, M. Cross, J. F. Pallant, and C. Rubertsson, "Women's satisfaction with antenatal care: Comparing women in sweden and australia," *Women and birth*, vol. 26, no. 1, pp. e9–e14, 2013.
- [57] J. Searle, "Fearing the worst-why do pregnant women feel at risk?," *Australian and New Zealand Journal of Obstetrics and Gynaecology*, vol. 36, no. 3, pp. 279–286, 1996.
- [58] S. Bureau and S. Center, "Statistical handbook of japan 2017," *Tokyo: Ministry of Public Management*, 2017.
- [59] H. Minakami, T. Maeda, T. Fujii, H. Hamada, Y. Iitsuka, A. Itakura, H. Itoh, M. Iwashita, T. Kanagawa, M. Kanai, *et al.*, "Guidelines for obstetrical practice in japan: Japan society of obstetrics and gynecology (jsog) and japan association of obstetricians and gynecologists (jaog) 2014 edition," *Journal of Obstetrics and Gynaecology Research*, vol. 40, no. 6, pp. 1469–1499, 2014.
- [60] H. Nishida, "Perinatal health care in japan.," *Journal of perinatology: official journal of the California Perinatal Association*, vol. 17, no. 1, pp. 70–74, 1997.
- [61] N. T. Miyaji and M. Lock, "Monitoring motherhood: sociocultural and historical aspects of maternal and child health in japan," *Daedalus*, vol. 123, no. 4, pp. 87–112, 1994.
- [62] Y. Nakamura, "Maternal and child health handbook in japan," *JMAJ*, vol. 53, no. 4, pp. 259–265, 2010.
- [63] M. Iida, S. Horiuchi, and K. Nagamori, "A comparison of midwife-led care versus obstetrician-led care for low-risk women in japan," *Women and Birth*, vol. 27, no. 3, pp. 202–207, 2014.
- [64] H. Yasunaga, T. Imamura, S. Yamaki, and H. Endo, "Computerizing medical records in japan," *International journal of medical informatics*, vol. 77, no. 10, pp. 708–713, 2008.
- [65] O. Santiago, Q. Li, N. Gagliano, D. Judge, C. Hamann, and B. Middleton, "Improving emr usability: A method for both discovering and prioritizing improvements in emr workflows based on human factors engineering," in *AMIA Annual Symposium Proceedings*, vol. 2006, p. 1086, American Medical Informatics Association, 2006.

- [66] I. M. Zadvinskis, J. G. Smith, and P.-Y. Yen, "Nurses experience with health information technology: Longitudinal qualitative study," *JMIR medical informatics*, vol. 6, no. 2, p. e38, 2018.
- [67] M. A. Clarke, J. L. Belden, and M. S. Kim, "How does learnability of primary care resident physicians increase after seven months of using an electronic health record? a longitudinal study," *JMIR human factors*, vol. 3, no. 1, p. e9, 2016.
- [68] C. Rathert, T. H. Porter, J. N. Mittler, and M. Fleig-Palmer, "Seven years after meaningful use: Physicians and nurses experiences with electronic health records," *Health care management review*, vol. 44, no. 1, pp. 30–40, 2019.
- [69] C. S. Kruse, M. Mileski, A. G. Vijaykumar, S. V. Viswanathan, U. Suskandla, and Y. Chidambaram, "Impact of electronic health records on long-term care facilities: Systematic review," *JMIR medical informatics*, vol. 5, no. 3, p. e35, 2017.
- [70] P. P. Morita and J. A. Cafazzo, "Challenges and paradoxes of human factors in health technology design," *JMIR human factors*, vol. 3, no. 1, p. e11, 2016.
- [71] J. Carroll, "Completing design in use: closing the appropriation cycle," *ECIS 2004 Proceedings*, p. 44, 2004.
- [72] E. M. Fleming, "Artifact study: A proposed model," *Winterthur Portfolio*, vol. 9, pp. 153–173, 1974.
- [73] G. DeSanctis and M. S. Poole, "Capturing the complexity in advanced technology use: Adaptive structuration theory," *Organization science*, vol. 5, no. 2, pp. 121–147, 1994.
- [74] W. J. Orlikowski, "Using technology and constituting structures: A practice lens for studying technology in organizations," *Organization science*, vol. 11, no. 4, pp. 404–428, 2000.
- [75] P. Dourish, "The appropriation of interactive technologies: Some lessons from placeless documents," *Computer Supported Cooperative Work (CSCW)*, vol. 12, no. 4, pp. 465–490, 2003.
- [76] G. Fischer, "Exploring richer ecologies between designers and users," in *Conversations Around Semiotic Engineering*, pp. 21–29, Springer, 2017.

- [77] A. Krischkowsky, B. Maurer, and M. Tscheligi, "Captology and technology appropriation: unintended use as a source for designing persuasive technologies," in *International Conference on Persuasive Technology*, pp. 78–83, Springer, 2016.
- [78] W. Van Der Vegte, Y. Kitamura, Y. Koji, and R. Mizoguchi, "Coping with unintended behavior of users and products: ontological modelling of product functionality and use," in *ASME 2004 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference*, pp. 683–692, American Society of Mechanical Engineers, 2004.
- [79] L. A. Suchman, *Plans and situated actions: The problem of human-machine communication*. Cambridge university press, 1987.
- [80] L. Suchman, "Response to vera and simon's situated action: A symbolic interpretation.," 1993.
- [81] M. Vaismoradi, H. Turunen, and T. Bondas, "Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study," *Nursing & health sciences*, vol. 15, no. 3, pp. 398–405, 2013.
- [82] H. Minakami, Y. Hiramatsu, M. Koresawa, T. Fujii, H. Hamada, Y. Iitsuka, T. Ikeda, H. Ishikawa, H. Ishimoto, H. Itoh, *et al.*, "Guidelines for obstetrical practice in japan: Japan society of obstetrics and gynecology (jsog) and japan association of obstetricians and gynecologists (jaog) 2011 edition," *Journal of Obstetrics and Gynaecology Research*, vol. 37, no. 9, pp. 1174–1197, 2011.
- [83] V. Braun and V. Clarke, "Using thematic analysis in psychology," *Qualitative research in psychology*, vol. 3, no. 2, pp. 77–101, 2006.
- [84] S. de Lusignan, C. Pearce, P. Kumarapeli, C. Stavropoulou, A. Kushniruk, A. Sheikh, A. Shachak, and K. Mendis, "Reporting observational studies of the use of information technology in the clinical consultation," *Yearbook of Medical Informatics*, vol. 20, no. 01, pp. 39–47, 2011.
- [85] S. Helou, G. Yamamoto, E. Kondoh, H. Tamura, S. Hiragi, O. Sugiyama, K. Okamoto, M. Nambu, and T. Kuroda, "Understanding the roles of emr systems in japanese antenatal care settings.," *Studies in health technology and informatics*, vol. 251, pp. 257–260, 2018.

- [86] S. Helou, V. Abou-Khalil, G. Yamamoto, E. Kondoh, H. Tamura, S. Hiragi, O. Sugiyama, K. Okamoto, M. Nambu, and T. Kuroda, "Understanding the situated roles of electronic medical record systems to enable redesign: Mixed methods study," *JMIR human factors*, vol. 6, no. 3, p. e13812, 2019.
- [87] S. Helou, V. Abou-Khalil, G. Yamamoto, E. Kondoh, H. Tamura, S. Hiragi, O. Sugiyama, K. Okamoto, M. Nambu, and T. Kuroda, "Understanding the emr-related experiences of pregnant japanese women to redesign antenatal care emr systems," in *Informatics*, vol. 6, p. 15, Multidisciplinary Digital Publishing Institute, 2019.
- [88] S. Suzuki and M. Eto, "Domestic violence against women during pregnancy in japan," *Journal of maternal-fetal and neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians*, vol. 30, no. 4, pp. 497–498, 2016.
- [89] M. Nagae and B. L. Dancy, "Japanese womens perceptions of intimate partner violence (ipv)," *Journal of interpersonal violence*, vol. 25, no. 4, pp. 753–766, 2010.
- [90] S. Steglich, *I-centric user interaction*. PhD thesis, Berlin Institute of Technology, 2003.
- [91] S. Helou, V. Abou-Khalil, G. Yamamoto, E. Kondoh, H. Tamura, S. Hiragi, O. Sugiyama, K. Okamoto, M. Nambu, and T. Kuroda, "Prioritizing features to redesign in an emr system," *Studies in health technology and informatics*, vol. 264, p. 1213, 2019.
- [92] S. Garde, P. Knaup, E. J. Hovenga, and S. Heard, "Towards semantic interoperability for electronic health records," *Methods of information in medicine*, vol. 46, no. 03, pp. 332–343, 2007.
- [93] C. M. Johnson, T. R. Johnson, and J. Zhang, "A user-centered framework for re-designing health care interfaces," *Journal of biomedical informatics*, vol. 38, no. 1, pp. 75–87, 2005.
- [94] A. Geraci, F. Katki, L. McMonegal, B. Meyer, J. Lane, P. Wilson, J. Radatz, M. Yee, H. Porteous, and F. Springsteel, *IEEE standard computer dictionary: Compilation of IEEE standard computer glossaries*. IEEE Press, 1991.

- [95] D. Kalra, T. Beale, and S. Heard, "The openehr foundation," *Studies in health technology and informatics*, vol. 115, pp. 153–173, 2005.
- [96] P. Schloeffel, T. Beale, G. Hayworth, S. Heard, H. Leslie, *et al.*, "The relationship between cen 13606, hl7, and openehr," *HIC 2006 and HINZ 2006: Proceedings*, p. 24, 2006.
- [97] W. Goossen, A. Goossen-Baremans, and M. Van Der Zel, "Detailed clinical models: a review," *Healthcare informatics research*, vol. 16, no. 4, pp. 201–214, 2010.
- [98] K. Donnelly, "Snomed-ct: The advanced terminology and coding system for ehealth," *Studies in health technology and informatics*, vol. 121, p. 279, 2006.
- [99] C. J. McDonald, S. M. Huff, J. G. Suico, G. Hill, D. Leavelle, R. Aller, A. Forrey, K. Mercer, G. DeMoor, J. Hook, *et al.*, "Loinc, a universal standard for identifying laboratory observations: a 5-year update," *Clinical chemistry*, vol. 49, no. 4, pp. 624–633, 2003.
- [100] D. Kalra and B. Blobel, "Semantic interoperability of ehr systems," *Studies in health technology and informatics*, vol. 127, p. 231, 2007.
- [101] A. Begoyan, "An overview of interoperability standards for electronic health records," *USA: society for design and process science*, 2007.
- [102] F. Hamid, "Providers' acceptance factors and their perceived barriers to electronic health record adoption," in *141st APHA Annual Meeting (November 2-November 6, 2013)*, APHA, 2013.
- [103] A. Vishwanath and S. D. Scamurra, "Barriers to the adoption of electronic health records: using concept mapping to develop a comprehensive empirical model," *Health Informatics Journal*, vol. 13, no. 2, pp. 119–134, 2007.
- [104] J. S. Ash and D. W. Bates, "Factors and forces affecting ehr system adoption: report of a 2004 acmi discussion," *Journal of the American Medical Informatics Association*, vol. 12, no. 1, pp. 8–12, 2005.
- [105] S. Frade, S. M. Freire, E. Sundvall, J. H. Patriarca-Almeida, and R. Cruz-Correia, "Survey of openehr storage implementations," in *Proceedings of the 26th IEEE International Symposium on Computer-Based Medical Systems*, pp. 303–307, IEEE, 2013.

- [106] J. L. Belden, R. Grayson, and J. Barnes, “Defining and testing emr usability: Principles and proposed methods of emr usability evaluation and rating,” tech. rep., Healthcare Information and Management Systems Society (HIMSS), 2009.
- [107] J. Nielsen, *Usability engineering*. Elsevier, 1994.
- [108] W.-S. Li, W.-P. Hsiung, O. Po, K. S. Candan, and D. Agrawal, “Evaluations of architectural designs and implementation for database-driven web sites,” *Data & Knowledge Engineering*, vol. 43, no. 2, pp. 151–177, 2002.
- [109] S. Balsamo, M. Marzolla, A. Di Marco, and P. Inverardi, “Experimenting different software architectures performance techniques: a case study,” in *ACM SIGSOFT Software Engineering Notes*, vol. 29, pp. 115–119, ACM, 2004.
- [110] S. Frost, “Drowning in big data? reducing information technology complexities and costs for healthcare organizations,” 2015.
- [111] M. Cottle, W. Hoover, S. Kanwal, M. Kohn, T. Strome, and N. Treister, “Transforming health care through big data strategies for leveraging big data in the health care industry,” *Institute for Health Technology Transformation*, <http://ihealthtran.com/big-data-in-healthcare>, 2013.
- [112] S. M. Freire, E. Sundvall, D. Karlsson, and P. Lambrix, “Performance of xml databases for epidemiological queries in archetype-based ehds,” in *Scandinavian Conference on Health Informatics 2012; October 2-3; Linköping; Sverige*, no. 070, pp. 51–57, Linköping University Electronic Press, 2012.
- [113] S. M. Freire, D. Teodoro, F. Wei-Kleiner, E. Sundvall, D. Karlsson, and P. Lambrix, “Comparing the performance of nosql approaches for managing archetype-based electronic health record data,” *PloS one*, vol. 11, no. 3, p. e0150069, 2016.
- [114] J. Green, “Comparison of the relative performance of xml and sql databases in the context of the grid-safe project,” *University of Edinburgh*, 2008.
- [115] D. Megginson, *Imperfect XML: Rants, Raves, Tips, and Tricks... from an Insider*. Addison-Wesley Professional, 2004.
- [116] R. Angles, “A comparison of current graph database models,” in *2012 IEEE 28th International Conference on Data Engineering Workshops*, pp. 171–177, IEEE, 2012.

- [117] I. Robinson, J. Webber, and E. Eifrem, *Graph databases: new opportunities for connected data.* ” O’Reilly Media, Inc.”, 2015.
- [118] M. Hunger, R. Boyd, and W. Lyon, “The definitive guide to graph databases for the rdbms developer,” *Neo Technology*, 2016.
- [119] S. El Helou, T. Karvonen, G. Yamamoto, N. Kume, S. Kobayashi, E. Kondo, S. Hiragi, K. Okamoto, H. Tamura, and T. Kuroda, “Generation of openehr test datasets for benchmarking.,” *Studies in health technology and informatics*, vol. 245, p. 1266, 2017.
- [120] E. Sundvall, D. Siivonen, and H. Öрман, “Approaches to learning openehr: a qualitative survey, observations, and suggestions,” in *Proceedings from The 14th Scandinavian Conference on Health Informatics 2016, Gothenburg, Sweden, April 6-7 2016*, no. 122, pp. 29–36, Linköping University Electronic Press, 2016.
- [121] F. Goodyear-Smith and S. Buetow, “Power issues in the doctor-patient relationship,” *Health Care Analysis*, vol. 9, pp. 449–462, Dec 2001.

List of Publications

Peer-Reviewed Journals

[J1] [Samar Helou](#), Victoria Abou-Khalil, Goshiro Yamamoto, Eiji Kondoh, Hiroshi Tamura, Shusuke Hiragi, Osamu Sugiyama, Kazuya Okamoto, Masayuki Nambu, and Tomohiro Kuroda. *Understanding the EMR-Related Experiences of Pregnant Japanese Women to Redesign Antenatal Care EMR systems*, Informatics. vol. 6, no. 2, p. 15. Multidisciplinary Digital Publishing Institute, 2019.

[J2] [Samar Helou](#), Victoria Abou-Khalil, Goshiro Yamamoto, Eiji Kondoh, Hiroshi Tamura, Shusuke Hiragi, Osamu Sugiyama, Kazuya Okamoto, Masayuki Nambu, and Tomohiro Kuroda. *Understanding the Situated Roles of Electronic Medical Record Systems to Enable Redesign: Mixed Methods Study*, JMIR Hum Factors 2019;6(3):e13812 DOI: 10.2196/13812

[J3] [Samar Helou](#), Shinji Kobayashi, Goshiro Yamamoto, Naoto Kume, Eiji Kondoh, Hiroshi Tamura, Shusuke Hiragi, Kazuya Okamoto, and Tomohiro Kuroda. *Graph Databases for openEHR Clinical Repositories*, International Journal of Computational Science and Engineering, 2017 (Forthcoming).

Peer-Reviewed Conferences

[C1] [Samar Helou](#), Victoria Abou-Khalil, Goshiro Yamamoto, Eiji Kondoh, Hiroshi Tamura, Shusuke Hiragi, Osamu Sugiyama, Kazuya Okamoto, Masayuki Nambu, and Tomohiro Kuroda. *Prioritizing Features to Redesign in an EMR System*, Studies in health technology and informatics, 264, pp.1213-1217.

[C2] [Samar Helou](#), Goshiro Yamamoto, Eiji Kondoh, Hiroshi Tamura, Shusuke Hiragi, Osamu Sugiyama, Kazuya Okamoto, Masayuki Nambu, and Tomohiro Kuroda. *Understanding the Roles of EMR Systems in Japanese Antenatal Care Settings*, Studies in health technology and informatics, 251, pp.257-260.

[C3] Samar Helou, Tuukka Karvonen, Goshiro Yamamoto, Naoto Kume, Shinji Kobayashi, Eiji Kondoh, Shusuke Hiragi, Kazuya Okamoto, Hiroshi Tamura, and Tomohiro Kuroda. *Generation of openEHR Test Datasets for Benchmarking*, Studies in health technology and informatics, 245, pp.1266-1266.

[C4] Shinji Kobayashi, Koray Atalag, Eric Sundvall, Christian Chevalley, Samar El Helou, Sebastian Garde, Ian McNicoll *The openEHR Developers' Workshop*, Health - Exploring Complexity: An Interdisciplinary Systems Approach (HEC2016), Munich, Germany, August, 2016. URL: openehr.atlassian.net/wiki/spaces/resources/pages/38436884

[C5] Samar El Helou, Naoto Kume, Shinji Kobayashi, Eiji Kondoh, Yuki Uranishi, Kazuya Okamoto, Hiroshi Tamura, and Tomohiro Kuroda. *Graph databases for openEHR repositories*, Proceedings of Health - Exploring Complexity: An Interdisciplinary Systems Approach (HEC2016), Munich, Germany, August, 2016.

[C6] Samar El Helou, Naoto Kume, Shinji Kobayashi, Eiji Kondoh, Yuki Uranishi, Kazuya Okamoto, Hiroshi Tamura, and Tomohiro Kuroda. *Design of Archetype-based Clinical Concept Models: Towards Interoperable Antenatal Care EHR Systems*, Proceedings of the 35th Japan Conference of Medical Informatics, 35, pp.250-253.

Non Peer-Reviewed Conferences

[C7] Samar El Helou, Naoto Kume, Shinji Kobayashi, Eiji Kondoh, Yuki Uranishi, Kazuya Okamoto, Hiroshi Tamura, and Tomohiro Kuroda. *Exploring Graph Databases with openEHR in Antenatal Care Settings*, Proceedings of the First International Symposium on Big-data Analytics in Science and Engineering (BASE 2015), Aizu, Japan, December, 2015.

[C8] Samar Helou, Goshiro Yamamoto, and Tomohiro Kuroda. *A Socio-Technical Approach to Understanding EMR Systems in their Context of Use*, Proceedings of Ubiquitous Healthcare (Uhealth2018), Kyoto, Japan, December, 2018, pp.63.