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a study of models needed for interoperability in the Danish health system

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Transversal Interoperability for Interdisciplinarity in e-Health:

*- A Study of models needed for interoperability
in the Danish Health System*

By
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Aalborg University
2011

Transversal interoperability for interdisciplinarity in e-Health
- *A Study of models needed for interoperability in the Danish Health System*

By Louise B. Pape-Haugaard, M.Sc.BMEI

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Preface

The dissertation is submitted in fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Health, Science and Technology, April 2011. This doctoral dissertation presents the results of research carried out during my doctoral studies at the Medical Informatics Group, Department of Health Science and Technology, Aalborg University, Denmark. The research was supervised Associate Professor Stig Kjær Andersen, and funding was partially provided by Connected Digital Health in Denmark.

Abstract

In this dissertation the demands for models used for sharing and (re-)use of patient-centered information in a national it-architecture are covered. This is done through an explorative case-study of a Danish national eHealth project: ‘the vision of Shared Medication Record (SMR)’. The foci are on three stated objectives; interoperability of heterogeneous health data, transactional challenges, and interoperability assessment model. The dissertation uses demands for interoperability through a service-oriented architecture. Findings of this study have been described in four previously published papers, and it is these four papers which form the core of this dissertation.

To share and (re-)use information electronically is a basic property of interoperability. Sharing and (re-)using patient information is a basic tool for healthcare professionals in their work. By having the best level of information, they can optimize patient-treatment and quality of care. SMR provides medicine-centered information across sectors and organizations in the health system. The medicine-centered information is stored centrally and contains comprehensive information on interoperable concurrent medication.

However, e-Health is organized as a plethora of heterogeneous stand-alone systems addressing various clinical needs, and with a lack of interoperability. One way to create interoperability between heterogeneous and autonomous systems is by describing models for interoperability which can support, guide and be a blueprint for future implementation processes of interoperable solutions. Hence, one means of obtaining the benefits of interoperability within the SMR model is to utilize an SOA.

In the process of creating a generic model the technological limitations and experiences with SMR SOA-designed Web Services have been analyzed. The technological limitations are investigated throughout the four papers that comprise the core of the dissertation:

I: *Pitfalls when integrating terminology systems and EHRs*. Through a literature review and workshops this paper covers the clash between theory and practice, and the depth of the existing challenges when seeking interoperability without a generic model.

II: *Integration of Health Records by Using Relaxed ACID properties between Hospitals, Physicians and Mobile Units like Ambulances and Doctors*. The current constraints in the database theory are explored followed by an analysis of how these constraints can be met in order to relax the hard ACID properties. It is concluded that the vision of ubiquitous information is easier to fulfill when variation in time and space is included.

III: *How to ensure sustainability in heterogeneous distributed systems through architectural approach*. In this paper the theory from paper II is compared to the SMR

model. We are primarily comparing from the application layer to the backend layer to proof that the specified design criteria in fact does fit the SMR model.

IV: Interoperability through an architectural paradigm shift using Shared Medication Record as case. This paper is based in analyzes of existing architectures and compare this to the architectural paradigm shift which is induced by the SMR model. It is shown that shifting from the existing message-based architecture to the SMR model's SOA is reasonable due to the increased interoperability in eHealth when applying this SMR model.

Several different methods are applied in these papers in order to cover the different research objectives necessary to explorative enhance whether a generic model as SOA-designed WS can be used for interoperability in eHealth. In paper I review and workshops with primary keys in Danish eHealth are applied, in paper II design and development of database's theoretical opportunities are applied, in paper III and IV comparative studies are applied. In order to support these studies, nine qualitative interviews have been conducted, seven of which were with national SMR stakeholders and two to explore undocumented national and international interoperability possibilities.

In this dissertation's analysis it is concluded that:

- An EHR reference model which is based upon either existing EHRs' information models or on terminology models will contain several ambiguity problems and thereby be difficult to implement in realistic settings.
- Relaxed ACID properties can be necessary to include in the database design in order for SOA-designed WS to be an applicable and realistic generic model based upon the requirements to information access in the SMR vision.
- That a taxonomy to assess the interoperability level can be used, and that through the SOA-designed WS an increased level of interoperability compared to the current model for exchange of information in eHealth will occur.

Overall it is concluded that SOA-designed WS to ensure transversal interoperability for interdisciplinarity can be deployed in e-Health. The challenge of heterogeneity in health data can be minimized through applying SOA-designed WS. The challenge of transactions in SOA can be managed by relaxing the ACID properties. The relaxed ACID properties can be implemented in realistic settings. The SOA-designed WS increases the level of interoperability compared to current architecture and can be assessed along three evaluative parameters. In addition to the challenges identified, the findings offer new insight into the challenge of creating an interoperable service-oriented architecture for the organizations involved in deploying an architectural paradigm shift. The organizations face the challenge of re-organizing responsibility and making more efficient use of interdisciplinary resources.

Danish summary/Dansk resumé

I denne afhandling afdækkes de krav, der kan stilles til en generisk model for deling og genbrug af patient-centreret informationer i en national it-arkitektur. Dette er gjort igennem et eksplorativt casestudie af det danske nationale eSundheds projekt: »Fælles MedicinKort (FMK)«. Fokusområdet i afhandlingen omhandler tre dele for at opnå interoperabilitet i eSundhed; heterogene sundhedsdata, backend transaktionsudfordringer, og evaluering af interoperabilitet. Der tages udgangspunkt i de krav, en service-orienteret arkitektur (SOA) stiller til interoperabilitet. Resultaterne af disse undersøgelser er beskrevet igennem fire artikler, og det er disse fire artikler, som udgør kernen i denne afhandling.

At dele og (gen-) bruge oplysninger elektronisk er en grundlæggende interoperabilitets egenskab. Deling og (gen-) brug af patientinformation er et redskab for sundhedspersonale i deres arbejde, idet et velfunderet informationsniveau er et væsentligt element i optimering og effektivisering af sundhedspersonalets arbejde med patientplejen. Visionen for FMK er, at medicin-centreret information skal være indeholdt og på sigt anvendes på tværs af sektorer og organisationer. Det er intentionen, at FMK skal anvendes af læger, sygeplejersker, socialrådgivere og andre faggrupper. Den medicin-centreret information skal lagres centralt og indeholder delbare (interoperable) udtømmende information om patienternes aktuelle medicineringsstatus.

I dag er eSundhed organiseret som en overflod af heterogene stand-alone-systemer, der alle adresserer forskellige kliniske behov og som informationsmæssigt ikke hænger tilstrækkeligt sammen. En vej til at skabe interoperabilitet mellem heterogene og autonome systemer i eSundhed er at beskrive en generisk model for interoperabilitet, som kan fungere som støtte og vejledning samt som er et blueprint af fremtidige implementeringsprocesser af interoperable systemer.

I processen med at skabe den generiske model, tages der udgangspunkt i analysen af de teknologiske begrænsninger og erfaringer, som er indeholdt i FMK-modellen, som er undersøgt i fire artikler:

I: *Pitfalls when integrating terminology systems and EHRs*. Denne artikel afdækker, igennem et litteraturstudie og workshop, det sammenstød der er mellem teori og praksis, samt dybden af de eksisterende udfordringer, der faktisk foreligger, når der forsøges at skabe interoperabilitet uden en generisk model.

II: *Integration of Health Records by Using Relaxed ACID properties between Hospitals, Physicians and Mobile Units like Ambulances and Doctors*. Her undersøges først de nuværende begrænsninger i databaseteorien, hvorefter det undersøges hvordan disse begrænsninger kan imødekommes og dermed bløde op for kravene til de

underliggende database-karakteristika (relaxed ACID properties). Det konkluderes at, vision om allestedsnærværende information lettere kan opfyldes, når der tages hensyn spredning i tid og rum.

III: *How to ensure sustainability in heterogeneous distributed systems through architectural approach.* I denne artikel sammenstilles teorien fra Paper II med FMK modellen. Vi sammenligner fra applikationslaget til backend-laget for at eftervise hvorvidt de specificerede designkriterier kan passe ind i FMK modellen.

IV: *Higher level of interoperability through an architectural paradigm shift.* Denne artikel baserer sig på analyser af den eksisterende arkitektur og sammenligner den med det arkitekturskifte, FMK-modellen medfører. Det påvises, at skiftet fra den eksisterende meddelesbaseret arkitektur til FMK-modellens SOA kan give en øget interoperabilitet i eSundhed.

I artiklerne anvendes flere forskellige metoder for at imødekomme de forskellige forskningsspørgsmål, der alle er nødvendig for eksplorativt at belyse hvorvidt en generisk model som SOA-designede webservices (WS) kan anvendes til at skabe interoperabilitet i eSundhed. I Paper I benyttes litteraturstudier og workshops afholdt med nøglepersoner i det danske eSundheds kreds, i Paper II er der tale om at designe og udvikle database teoretiske muligheder som tilgodeser de væsentlige forudsætninger som karakteriserer eSundhed, i III og IV er der tale om komparativt studier. For at understøtte disse studier, er der derudover udført ni kvalitative interviews. Syv af disse har været med nationale FMK interessenter og to er udført for at udforske udokumenterede nationale og internationale interoperabilitetsmuligheder.

I afhandlingens analyse delkonkluderes det, at:

- En generisk model, som baserer sig på enten de eksisterende EPJ-systemers informationsmodel eller på en terminologisk informationsmodel vil indeholde mange tvetydigheder, og vil være svært realiserbart i praksis,
- Relaxed ACID properties er nødvendige at inkludere i database-designet og implementeringen for, at SOA-designede WS kan være en anvendelig model grundet de krav der er til adgangen af information i visionen af FMK-modellen.
- At der kan anvendes en taksonomi til at måle interoperabilitetsgraden, og at der igennem den SOA-designede WS-model vil der kunne opnås højere interoperabilitet end ved at anvende den nuværende model for udveksling af information i eSundhed.

Samlet konkluderes det, at SOA-designede WS kan sikre at tværgående interoperabilitet kan implementeres i e-sundhed. Heterogeniteten kan minimeres ved at anvende SOA-designede WS. Udfordringen af transaktioner i SOA kan styres ved at relax ACID egenskaberne. SOA-designede WS øger interoperabiliteten i forhold til nuværende arkitektur, og kan evalueres på tre parametre.

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Through three years of intensive work, a number of people have contributed with their knowledge and support to my research and to my academic career. Digital Health in Denmark has assisted me by funding part of my research.

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Finally, I would like to thank my parents for taking good care of my two children during busy times. Most importantly, thanks to my husband, Torben, for his faith, encouragement, support and patience.

Louise Bilenberg Pape-Haugaard
Aalborg, April 1st 2011

Abbreviations

ACID	Atomicity, Consistency, Isolation, Durability
e-Health	e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.
HCP	Healthcare professionals
HDN	Health Data Network
Interdisciplinary	Characterized by participation of two or more disciplines to support patient treatment
Medicine-centered information	Information regarding the patient's medicine including historical, active, passive, concurrent prescriptions
Patient-centered information	Information regarding the patient's entire medical record.
SMR	Shared Medication Record
SMR model	SOA-designed web services
SMR vision	The project that needs to be carried out in order to achieve the vision of SMR
SOA	Service oriented architecture
SOAP	Simple object access protocol
SOA-tolerant WS	The WS is designed to be tolerant towards SOA as in 'it can co-exist with a pure, full-blown SOA'
Transversal interoperability	Cross-organizational interoperability
VANS	Value Added Network Service
VPN	Virtual Private Network

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WS	Web Services
WSDL	Web service definition language
XML	eXtensible Markup Language which is a rule set for encoding documents electronically

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PART 1:

PROBLEM ANALYSIS

In this part, the background to research on interoperability is discussed. The central focus is with respect to SMR, and includes conceptual and methodological issues to bridge the four papers (I-IV).

There is nothing like looking, if you want to find something. You certainly usually find something, if you look, but it is not always the something you were after.

J.R.R. Tolkien

1. Introduction

This chapter contains a short introduction to the dissertation in respect to objectives, publications and dissertation structure.

This dissertation presents models necessary to obtain interdisciplinary and transversal interoperability in e-Health. It focuses on the Shared Medicine Record (SMR), which involves healthcare professionals in obtaining and using information, infrastructure, privacy and security, and web services technologies, Service-oriented architecture and interoperability in e-Health.

1.1. Objectives

The main goal of this dissertation is to analyze what as a minimum is needed in e-Health for creating interoperability. Further, it seeks to identify the fragile elements in generic models as SOA-designed web services.

1.2. Publications

The dissertation is structured as a collection of four papers. The four papers are referred to in the text using Roman numerals I-IV. A summary of the papers is presented below:

No.	Title	Publication	Co-authors
I	Pitfalls when integrating terminology systems and EHRs	<i>Conf. of Scandinavian Health Informatics</i>	AR Rasmussen KH Rosenbeck SK Andersen
II	Integration of Health Records by Using Relaxed ACID properties between Hospitals, Physicians and Mobile Units like Ambulances and Doctors	<i>International Journal of Handheld Computing Research (IJHCR)</i>	L Frank
III	How to ensure sustainability in heterogeneous distributed systems through architectural approach	<i>Conf. of Special Topic in EFMI</i>	L Frank
IV	Higher level of interoperability through an architectural paradigm shift	<i>Conf. of Biomedical Engineering and Information</i>	

My contributions to these papers were as follows:

- I. Collecting data through both review and workshop. Literature review and interpretation of EHR reference models. Organization and facilitation of workshop and interpretation of results. Main writer of the manuscript except for the ‘Method’ section, and final editing of the manuscript.
- II. Exploring e-Health stakeholders’ requirements for ubiquitous information and realizing e-Health visions such as SMR, it is necessary to develop new database theory. Collecting and analyzing data from literature and interviews with international stakeholders. Wrote sections of the manuscript (introduction, related research, discussion and conclusion), and edited the final manuscript.
- III. Developing the method for exploring how relaxed ACID properties comply too SMR. Collecting and analyzing data through seven qualitative interviews. Wrote the manuscript.

1.3. Dissertation structure

The dissertation is organized into three main sections. The ‘Problem Analysis’ discusses the background to research on interoperability with respect to SMR, including conceptual and methodological issues to bridge the four papers (I-IV). The middle section, ‘Studies’, is excluded from this publication. The final section, ‘Discussion and Conclusion’, summarizes the findings and presents key research implications.

2. E-Health – the operational context of the Shared Medication Record

This chapter introduces the settings and comprehension of e-Health in a Danish perspective with respect to SMR.

There has been a general anticipation concerning improved quality of care, optimizing resources, and security in healthcare followed by implementation of clinical IT systems. However, it should be noted that the claims of long-term potential benefits have not been supported by research. A recent review concludes that there is an enormous gap between the postulated and empirically proven benefits of e-Health.[1] On the other hand, in [2] it is argued that the positive impact is dependent upon access to information anytime, anywhere. In other words, we need to consider interoperability as a prime driver before we can draw any conclusions as to the anticipated benefits of e-Health.

As used here, the term ‘interoperability’ refers to the ability to utilize ‘something’ from System A in System B. In our case, the ‘something’ is information. Hence, interoperability between heterogeneous and autonomic systems is the ability to share and (re-)use information. This might seem trivial or simple, but when trying to obtain interoperability, different demands arise.

E-Health represents the promise of information and communication technologies being used to improve health and healthcare systems. However, as shown in the review [3] there exist an overwhelming number of definitions of e-Health. That definition of e-Health which seems most comprehensive was proposed by Eysenbach [4].

e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.

The organizational framework of healthcare influences the premise of *transversal interoperability for interdisciplinarity* in e-Health. In Denmark, patients are covered by the national public health service. Healthcare services are governed by three authorities [5]:

- 1) National state institutions are responsible for the legal framework, and *coordination* of delivered health services in regions and municipalities.
- 2) The five Regions are directly *responsible* for delivering primary and secondary health services (e.g. paying general practitioners, operating the hospitals). In addition, the regions are responsible for the health data generated, documented, and the media used for documentation. The Regions

employ a wide spectrum of healthcare professionals (hospital staff, caregiving nurses, highly specialized doctors, etc.).

- 3) Denmark's 98 Municipalities are directly *responsible* for health promotion, prevention, rehabilitation, and elder care. In addition, the municipalities are responsible for the health data documented, and the media used for documentation. The municipalities employ a range of healthcare professionals (district nurses, general practitioners).

The organizational framework for healthcare emphasizes the administrative separation of the autonomous regions and municipalities. The fragmentation of healthcare services has led to e-Health being organized as a plethora of heterogeneous stand-alone systems addressing various clinical needs.

The heterogeneous systems are a result of independent actors having selected various e-Health applications for their respective sectors, which to some extent is due to the diversity of reimbursement schemes for different providers and services. [6] A by-product of the heterogeneous stand-alone systems is the generating of heterogeneous health data. The problems derived from heterogeneity in health data originate in either proprietary systems or deployment of different health standards and terminologies with embedded information models, i.e. HL7, CEN/ISO EN13606 EHR standard, openEHR or ICD9, ICD10 or SNOMED CT. [7-9] [10,11]

When converting this organizational framework into the premise of transversal interoperability for interdisciplinarity in e-Health, it can be concluded that transversal interoperability is necessary due to the heterogeneous organizations and sectors, whereas interdisciplinarity is necessary because of the heterogeneous professional profiles within the organizational frame.

In this dissertation, the concept of e-Health is to be understood in terms of Eysenbach's definition above. The emphasis is on the health services and information shared through internet-related technologies for improvement of healthcare in a national setting where medical informatics intersects with public health. When considering e-Health from the SMR perspective, SMR should be considered as part of e-Health, insofar as it concerns health services and information delivered through the Internet.

2.1. The Vision of interoperability through Shared Medication Record

The heterogeneity in healthcare services is reflected in the healthcare systems, because these systems have to address various clinical needs. This is clearly seen in the clinical decision process as the healthcare professionals (HCP) rely on different factors in the interaction with patients, especially documentation from earlier encounters. This is illustrated in Figure 1 (Inspired by [27])

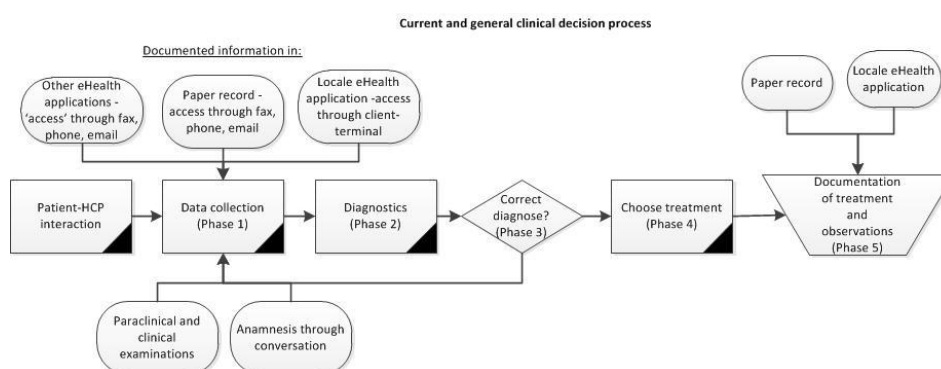


Figure 1 is an illustration of the clinical decision process. Inspired by [27]

In Figure 1 the ideal world of the clinical decision process is illustrated through the different phases in this process. Phase one refers to the data collection which is based on a) the patient's prior encounters with healthcare through the documented information, b) new paraclinical and clinical examinations, and c) conversation with the patient, when possible. Following the data collection is the synthesizing of collected information. In phase two, the synthesized information is used together with the nosographic knowledge. In phase three, there is assessment and evaluation of the diagnostic data. If the diagnosis is assessed as being incorrect, a new round of data collection is initiated. If it is assessed as correct, the necessary treatment will be initiated. Finally, in phase five, the documentation occurs. This documentation is entered in the patient's record, either in an electronic health record or a paper health record.

As seen in the simplified illustration of the clinical decision process, there is great emphasis on data collection, and there is a clear indication of needing information during the HCP-patient interaction. Sharing and (re-)using patient-centered information is therefore an essential tool for HCPs in their work. Only by having the best level of information can they optimize patient treatment and achieve the anticipated quality of care.

Due to the organization and fragmentation of healthcare, the data collection for HCPs is both complex and time-consuming. Through the current application of the MedCom

EDIFACTs in Denmark, there is access to standardized gross-grained data structures. Information through standardized syntax and semantics are exchanged through electronic messages from legacy systems. These EDIFACTs are electronic messages which are pushed to a central mailbox, and pulled by a system, which has to manually integrate the messages. However, in cases without available discharge summaries or medicine records, the individual HCP has to rely on the patients to provide information. In an ideal world data collection and data documentation occur timely, but in the real world data collection can be based on paraclinic and clinic examinations of the patient and through conversation, which does not necessarily occur in chronicle orders or timely. Organizational resources do not allow for time-consuming data collections. Ideally documentation should occur immediately in the interaction with the patient, but in the real world this documentation can be postponed till later by being dictated, memorized or written on a post-it.

The vision of SMR is that the interoperation of data in the clinical context of SMR can reduce *data collection* complexity. This is illustrated in Figure 2.

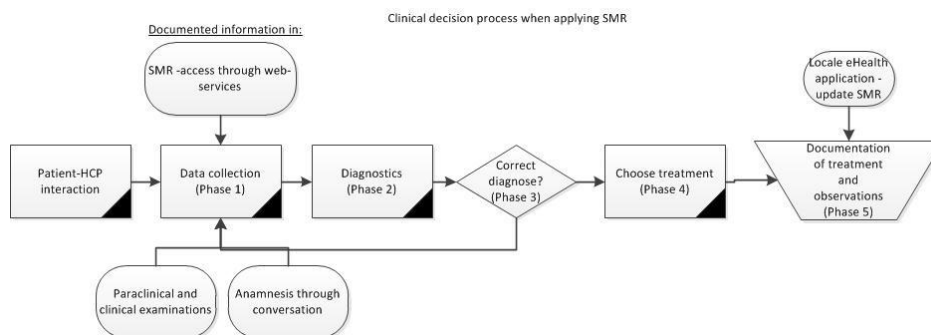


Figure 2 illustrates the clinical decision process in SMR.

The overall phases 1-5 in Figure 2 are identical to the clinical decision process in Figure 1, but the different access points for data collection in phase one have been condensed into a single access point (SMR). However, to be able to benefit from one access point, the medicine-centered information must be reconciled on SMR as illustrated in the fifth phase. Otherwise, the SMR will not contain the concurrent medicine-centered information. Thus, phase five can be considered as a weak link in the SMR clinical process. Further, another weak link can be identified in the first phase. Even though it is cumbersome to access the necessary medicine-centered information in several different places, it actually has the hidden effect of quality insurance. Quality insurance occurs because the medicine-centered information originates from different sources, and the requiring HCP will synthesize the gathered information. If medical discrepancies in the medicine-centered information exist the HCP is likely to identify that medicine error. Contrarily, in SMR where information is only accessed through one location the error will be persistent, because there is not any

visible discrepancy in the prescribed medication list. In short, research indicates that some medication errors will be reduced –even eliminated – when digitalization of medicine-centered information occurs. On the other hand, new medication errors will occur. The gravity of these errors is still to be explored.

The main objective of the SMR vision is that it can contain medicine-related information that will be used across sectors and organizations, i.e., in a transversal interdisciplinary manner. The medicine-centered information is to be stored centrally and is to contain comprehensive information on interoperable concurrent medication. The technological challenge of the project is to demonstrate how to enable web services (WS) to function as the communicating media in e-Health.

3. Shared Medication Record

This chapter introduces the settings and comprehension of e-Health in a Danish perspective with respect to SMR. Furthermore, an analysis of relevant issues in service-oriented architecture, web services and privacy in SMR is presented. The presentation of the SMR is based on the analysis of seven qualitative interviews (cf. additional data on the web), presentations from Digital Health and MedCom (cf. [12-25] and the SMR project team site [17]).

SMR is a vision rooted in the Danish National Strategy for Digitalization of the Danish Healthcare Service. [21] The SMR vision was initiated as a national project in early 2007 and is still ongoing. The long-term objective of the national project is that SMR can interface with the regional heterogeneous Computerized Physician Order Entry System (CPOE). [18,26] The overall of the SMR is to give Danish patients correct and secure medical treatment. [16]

3.1. Potential benefits and drawbacks of Shared Medication Record

The potential benefits are described in the business case for SMR which contains estimated qualitative benefits. The qualitative benefits are based on assumptions as:

- Increased patient security in medicine when patients are transferred from one sector to another
 - Reduction in medication errors
 - Reduction in transfers of data
 - Reduction in maintenance of data in many places
- SMR is a foundation for new services underpinning secure and errorless medication
- SMR project will be a pioneering pilot ensuring all the necessary experiences needed to develop online system integration in eHealth

Furthermore there are assumptions in the business case regarding labour-saving technologies and more efficient working processes as:

- SMR keeps the medication information in one site meaning that GPs will use less time supporting nursing homes / district nurses
- SMR enhances the it-support for medication reconciliation
- Reduction of admissions and readmissions as a consequence of medication errors.

These qualitative benefits are unfortunately not agreed upon in the scientific literature. On the contraire, there seems to be drawbacks when digitalizing health data medication. Well performed studies have been conducted to understand what happen when we digitalize medication records. Neither of these studies contains an indication of a significant reduction in medication errors just by digitalization of the information nor will we have a significant reduction in errors just by having the information available. Actually there is a risk for an incline in new medication errors.

3.2. The design of SMR

In the design of SMR there has been attached importance to use open-source and open-standards both nationally and internationally. These standards are illustrated in Figure 3.

In the following emphasis will be upon analyzing two central elements derived from the illustrated standards (cf. the blue circles). The elements are web services in service-oriented architecture (SOA) and 'privacy and security'.

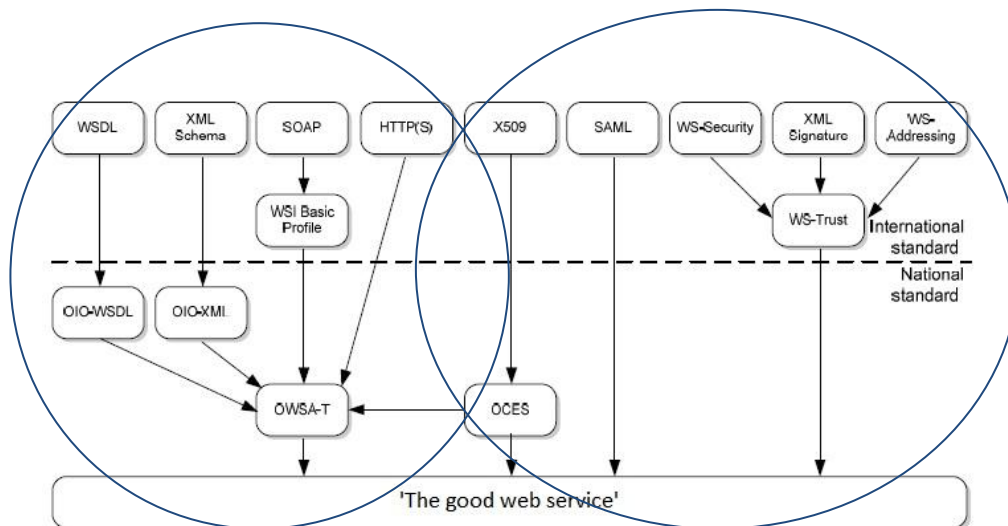


Figure 3 illustrates the standards used in the design of SMR [18]

3.2.1 SOA-designed web services in SMR

The SOA-designed WS in SMR addresses concurrent medicine-centered information. SOA can be defined as an approach that addresses demands from loosely coupled, heterogeneous and distributed computing. This definition ought to serve the interoperability challenges in e-Health well, considering that SOA can serve as a blueprint for organizing systems, establishing communication, and coordinating mechanisms among included components. [28-34] Hence, the benefits of interoperability within the SMR model can be realized via a generic SOA approach, where SOA provides the frames for basic interoperability.

In short a SOA-designed web service is the frontend which communicates to the application layer, which contains the application of protocols and standards used for exchanging health data between heterogeneous actors on the internet or internet-related technologies. [19,25,32,34-40] The backend of the SMR model's SOA-designed WS is a relational database (MySQL with the database engine InnoDB) and not a NON SQL-based database. This choice of backend database ensures application of the traditional Atomicity, Consistency, Isolation and Durability properties as defined by [41]. For a web service to create a suitable sharing environment (interoperability) between systems, it typically requires a consolidation of standardized protocols. The consolidation would therefore involve the following protocols:

- Message protocol: XML for structuring the messages
- Transport protocol: simple object access protocol (SOAP) for transferring the message
- Description protocol: Web Service Description Language (WSDL) defines and describes the available services

Sharing information is possible through the architecture that supports SMR because it is organized in a service-oriented context meaning by which the user accesses information through a single running instance (defined in the WSDL). Relevant information in the web service can be interoperated in to the requesting system. [19,20]

Applying these standards in web services can increase interoperability. This would in turn allow dynamically publishing, and aggregating of web services. There are two competing main web services architectures (.NET and J2EE), even though the web services are independent of platform. [19,25,35] For the SMR case, J2EE architecture has been applied.

In the current version of SMR, 23 services are available. The clinical content in the web service is based upon an overall model though which the real world can be understood. Furthermore, in [12], the interface descriptions are given to technical stakeholders. This comprehensive document is needed when implementing SMR.

Implementation is carried out through a listing of the 23 web services and through the published WSDL that needs to be implemented in at client site.

3.2.2 Privacy and security in SMR

When attempting to share health data across organizations and sectors, there arise issues such as privacy, security and confidentiality. Legal requirements protect the patient's data from being distributed to others than relevant HCPs. These legal requirements have their roots in the patient privilege to have confidential encounters with the HCP. [19,43-49]

Access to SMR is obtained through the secure national infrastructure, health data network (HDN). The infrastructure is deemed to be secure, and thereby protects the transmitted data to maintain privacy because of the patient health data. To handle security issues such as confidentiality and integrity, VPN with cryptographic tunneling protocol has been deployed in Danish e-Health. This solution is illustrated in Figure 4. As shown, all communication is carried out through this central hub.

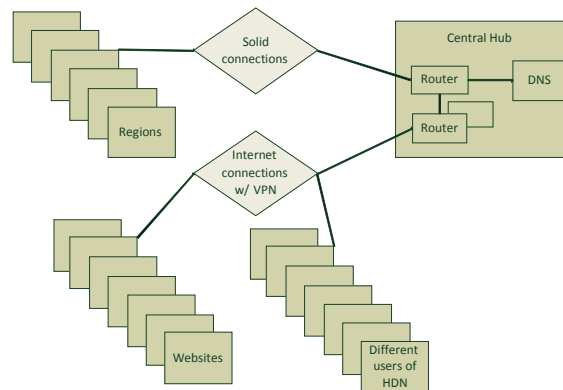


Figure 4 illustrates the secure health data network as is in Denmark. Inspired by [23]

The application of VPN infrastructure constrains registration of access-points to be manual, which can be considered as an authentication, but because these access-points merely are ip-addresses there is high trust to the decentralized security procedures. Even though this administration is somewhat inconvenient, it shields unwanted users from accessing the infrastructure, thus shielding patient-centered information in the transversal scenario. [21]

In the SMR, patient-centered information is moved out of the hospital and into centralized databases. This means that a different and more fine-grained manner to handle authentication, authorization and non-repudiation is needed. Authentication, authorization and non-repudiation respectively means establishing the identity of a

user, determining if the requester is allowed to receive a service, and ensuring that an interchange of data has occurred.

The WS-security issues need to be handled because of the ownership of SMR. It is the Danish Agency of Medicine who is the system owner and thereby also responsible for the data and information. [12] This is needed while SMR (and thereby the Danish Agency of Medicine) cannot base access on trust –trusting that the consumers are who they pretend to be. Nor can they rely on organizational user registration, as was the case for access to the VPN. [19][42] The security property has great importance, because of the change in data ownership. The Danish Agency of Medicine is the owner and provider of SMR and thereby also responsible for data and information. This situation places high demands on the identity based WS which is the security capacity of consumers requesting and updating information from SMR, because of the underlying construct of trust.

Handling these security issues through application of web services in Danish e-Health adds value to the security compared to the ‘as-is’ communication through EDIFACTS. Even though, authentication, authorization, and non-repudiation are added as a security capacity through the web service profile the technological complexity rises.

3.3. Visual representation of SMR

There are two *major* goals with SMR; medication error reduction and ubiquitous access to concurrent medication. These goals roughly indicate that there are three levels of stakeholders; 1) *the patient herself –it is her medication, her life and her body directly involved with medication*, 2) *healthcare professionals –it is the healthcare professional prescribing, dispensing, administrating, delivering and treating based upon medication information*, 3) *the secondary or tertiary group consuming medication information –it is the researchers who can use the organized medication information in future research and it is the politicians who indirectly can use medication information in their politics*. The healthcare professionals are explicitly parted into GPs, specialists (such as otologists), Emergency centers incl. staff, nursing homes & institutions incl. staff, pharmacies, district nursing, hospitals incl. staff. These three groups are illustrated in Figure 5. This diversity between stakeholders puts high demands on how the medication information in SMR is presented, shared, and updated.

All healthcare professionals, regardless of affiliation, have to subscribe to one interface in order to achieve the benefits of having concurrent medicine-centered information available. [43] This also means that the user will not access information at the site where information is recorded, but on the centralized platform. In this manner the user will only need to ‘know’ one place to find information regarding medication. This is illustrated in Figure 5.

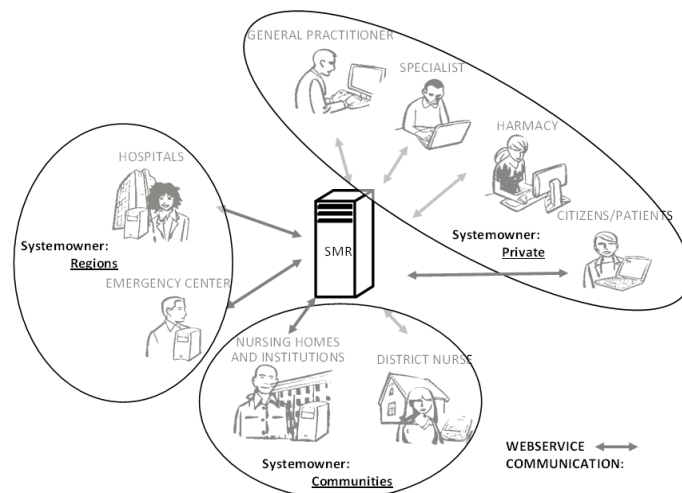


Figure 5 illustrates the vision of how the communication will be distributed in a heterogeneous e-Health environment. Inspired by [15].

SMR can be described as a central repository, providing the patient's present concurrent medication together with a history of former prescription medication. SMR also includes generic names, dosages, schedules and prescribers. Investigating the clinical content in SMR has been done through iterative workshops by clinical project gatekeepers with clinicians (primary chief physicians and general practitioners). From the workshops, use cases were derived, validated and recompiled. [13,22] The use cases were presented to technical project gatekeepers who then generated the technical proposed solution. The pilot project was documented in this report: [22].

As stated above, SMR is a vision, and is thus an ongoing project. The technical solution still needs to be implemented. However, pilots to demonstrate whether the SMR vision can be realized have been conducted. These pilots have included some of the stakeholders (53 general practitioners, 38 specialized doctors from the hospitals, and a few stakeholders at the GPs' offices). Some of the main conclusions from the pilots were [22]

- Clinicians involved in the pilots believe that SMR has potentials. However, it is decisive that the decentralized part of SMR is suitable implemented.
- The centralized part of SMR has sufficient functionalities to interface to client systems in GP-systems and EHRs which will support utilization of SMR in clinical working procedures.
- Due to the fact that SMR is a national solution with many different components from stakeholders, efficient support is a precondition for trouble-free operation.

In other words, the pilot has established that a) clinicians adoption of SMR is important for the success, b) the SMR WS is ready for implementation, and c) many stakeholders are involved and includes many components, which is equivalent to the complexity of operation and maintenance for SMR centrally. In the decentralized context i.e. consumers of SMR, there are different risk factors. One of the greater challenges is what happens in the decentralized systems when the centralized repository is updated. When shifting versions central how can that be maintained at the decentralized consumers?

To assess the adoption rate of SMR it is needed that SMR is implemented in the Danish Health System, because of the transversal focus. Hence, it is currently not relevant to explore the clinicians' adoption of SMR. Contrary to this, it is highly relevant to explore whether these SMR WS with the influence of many stakeholders and components can be generalized to a model for interoperability in e-Health.

When considering the SMR model through an SOA perception, it is important to pinpoint the different factors influencing the model. These are illustrated in Figure 6. In fact all these factors are part of SMR, and each plays a role in determining, whether this model can be generalized and can be transformed into a generic model.

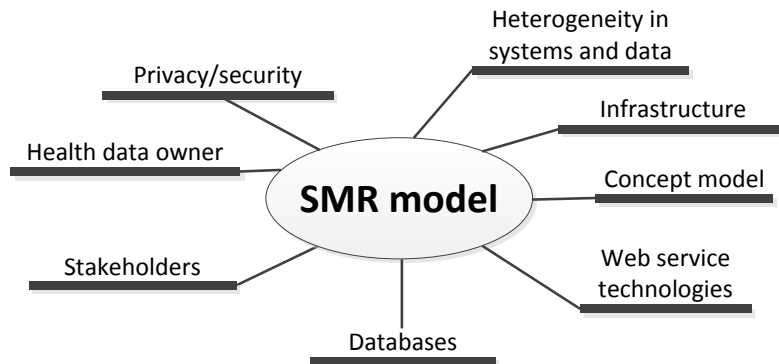


Figure 6 illustrates the different factors involved in the SMR model

4. SMR WS as a generic SOA-designed WS model

This chapter analysis related research to the findings in SMR to further explore a generic model

Research on interoperability in e-Health has been carried out for nearly two decades. [44-55] Recently, we have also seen research on creating interoperability through SOA.

[28,29,31,32,56-61] Findings of these studies conclude that implementing SOA paradigm, as is the case for SMR, poses several challenges: 1) how to manage heterogeneous elements in an interoperable environment, 2) how to manage the direct transactional issues, 3) how to assess the level of interoperability, and 4) how the implementation of SOA-designed WS can diffuse throughout the healthcare organization, so as to ensure developer participation and manage quality assessment of services.

The factors influencing the SMR model, as illustrated in Figure 6, can be traced to these challenges.

The first challenge 1) how to manage heterogeneous elements in an interoperable environment is directly traceable to **the heterogeneity in data, the infrastructure** and development of **concept models (including some WS technologies)**.

Infrastructure is a precondition for interoperability; without an infrastructure, interoperability cannot occur. This applies to the clinical systems as well – without clinical systems or registries, there will be nothing to interoperate. Nevertheless, it can be argued that interoperability is challenged at three levels; syntactical, schematic/structure and semantic. [62]

When considering *syntactical interoperability*, the focus is on ensuring the heterogenic health data's structure and formats as they are generated in structured databases, text repositories, both semi-structured and structured, and data in generic and domain specific formats. When considering *structural heterogeneity*, it is seen that the cause is based on the organization of database schemes with different meta-properties and structures. These inconsistencies in structure and schemes are based on the use of different data models, which is a result of the application of different healthcare standards.

Whereas both syntactical and schematic/structural levels of interoperability were unilateral, the semantic level is bilateral. However, generally *semantic heterogeneous* health data are caused by different perspectives on a concept or metadata. The bilateral semantic level can be divided into an ontological and a terminological understanding. The ontological understanding deals with different ideas of how the real world is described. The terminological understanding concerns the use of different wording of identical concepts. [62] These issues of heterogeneity are needed to be managed in all means used to achieve interoperability.

The second challenge 2) how to manage the direct transactional issues involves the **databases**. It deals with the direct transactional issues, because these are directly reflected in the ACID properties and how to implement these in the database design and thereby also **the web services technologies**, because WS are not per default abiding to the ACID properties, which gives a distortion of using WS in SOA.

Given the main objective of the SMR model, which is to have ubiquitous medicine-centered information available at all times, it is of utmost importance that the model can handle direct transactions. Handling direct transactional issues in SOA imposes strict requirements on the database structure and architecture. Given the current and valid properties of transactions (ACID properties [41]), it is nearly impossible to implement SOA in database surroundings. This is somewhat paradoxical, since SOA was invented to handle loosely coupled heterogeneous, autonomous and distributed systems, i.e. distributed databases. Related research shows that there exist different solution models for this problem, either by relaxing the ACID properties or by generalizing the ACID properties. [63] [64] These issues are seen in the backend of SMR, and this issue needs further investigation.

The third challenge 3) how to assess the level of interoperability is directly related to the **heterogeneity in systems, privacy/security and health data owners**. It involves the lack of assessment models for interoperability

In e-Health, the following taxonomy [65] has been applied to seek consensus on interoperability. This taxonomy, illustrated in Table 1, describes the interoperability levels in an e-Health setting.

Table 1 illustrates the interoperability taxonomy. [65] The requirements are derived from analysis of the document [65].

Level	Semantic description	Requirements
Level 0	No interoperability at all	Basic paper records or IT silos without the possibility to extract any electronic information regarding a patient at the point of care.
Level 1	Technical and syntactical interoperability (no semantic interoperability)	Receive electronic documents. Human intervention needed to understand the transmitted information.
Level 2	Two orthogonal levels of partial semantic interoperability <ul style="list-style-type: none"> • <i>Level 2a</i>: unidirectional semantic interoperability • <i>Level 2b</i>: bidirectional semantic interoperability 	Secure internet access to extracts of an EHR. Standardized encoding of extracts. 2a : Manual: Standardized gross-grained data structures – manual mappings between received data set. 2b : Automatic: Standardized fine-grained data structures – mappings have to be performed per data set of a standard message.
Level 3	Full semantic interoperability, sharable context, seamless co-operability	Seamlessly integrate patient-centered information from providing system to requesting system. Standardized EHR reference model. Standardized library containing clinical data structures. Standardized terminology/ontology.

The challenge in creating interoperability between heterogeneous systems lies in the bilateral semantic level, because of the relatively simple means of creating interoperability in the other two levels. In level one, syntactical interoperability is managed in SMR through the XML message protocol and the SOAP transport protocol. In level two, schematic/structural interoperability is managed in SMR by allowing only specific meta-properties and structures in the interoperated database scheme. Issues related to privacy/security (as seen in level two) are heavily dependent on ownership of health data.

The fourth challenge 4) how the implementation of SOA-designed WS can diffuse throughout the healthcare organization, so as to ensure developer participation and manage quality assessment of services, involves the **stakeholders**. All stakeholders are organizational elements who will be influenced by the implementation of SOA-designed WS.

When SOA-designed web services are implemented in an e-Health setting such as the Danish, it is inevitable that this implementation will penetrate deep into the organization.

The shift of responsibility is seen early in the progress, because so far, the organization has been consolidated into three domains (regions, which contain hospitals and funding GPs and municipalities), each with responsibility for collecting and documenting the patients' health data within their respective domains.

Traditionally, there is a wide diversity across the organizations and sectors in the process of *how and which* health data are documented. The GPs typically have the function of being a 'gate-keeper' in healthcare. The GP is the primary contact for the patient, and it is the GP who refers the patients to other authorities. In the municipalities, the primary users of health data are the district nurses and health visitors. Their main need is to see discharge summaries and prescribed/altered medication. The hospitals, on the other hand, have large autonomous complex IT systems such as EHRs, laboratory systems, PACS and administrative systems. Moreover, both hospitals and municipalities strive to organize workflows across various occupational and professional tasks and work groups, i.e., implemented in the transversal systems. It is especially in the complex clinical IT systems that the hospitals are seeking this benefit. Hence, from a regional point of view, most efforts are put into creating these heavy complex clinical IT systems.

In this sense, the incentive (and the reimbursement) for a random region to be responsible for providing the service to the other regions, as with the SMR model, seems vague. This need for a reimbursement incentive has also been seen in the collective bargaining between the GPs and public health services. [66]

Therefore, when dealing with SOA-designed WS at a centralized level, it is necessary that the national level take responsibility for the services and carry out analysis, design and implementation for the front-end of the published services.

5. Research objectives

In this chapter the research objectives in this dissertation is presented. The research objectives are derived from the former chapter.

To share and (re-)use information electronically is a basic property of interoperability. Sharing and (re-)using patient-centered information is also one of the basic tools for healthcare professionals in their work, because only by having the best level of information can they optimize patient-treatment and thereby quality of care. However, e-Health is organized as a plethora of heterogeneous, stand-alone systems addressing various clinical needs. Hence, a generic model for interoperability between heterogeneous and autonomic systems in e-Health is needed.

The main objective of this research is to evaluate the SMR model as a model for transversal interoperability for interdisciplinarity in e-Health. To achieve this objective, four challenges were identified reformulated into the following three sub-objectives:

- A. Exploring interoperability in given paradigms
 - Research question:
How to manage heterogeneous elements in an interoperable environment? (Paper I)
- B. Exploring transactional issues
 - Research questions:
How to manage the direct transactional issues in SOA? (Paper II)
How to realize direct transactional issues in SOA? (Paper III)
- C. Assessing interoperability to a taxonomy
 - Research questions:
How to assess and evaluate the level of interoperability? (Paper IV)

Even though the uncertainties of how SOA propagates throughout the healthcare organization are highly interesting and relevant, these have only been explored indirectly because the SMR vision has yet to become fully operational.

6. Methods

In this chapter the qualitative research is presented. The empirical data are used to analyze SMR and is therefore a cornerstone in the dissertation.

This research concentrates on investigating, exploring and assessing whether a SOA-designed web service model can be used as a generic model for creating interoperability in e-Health. The research was carried out as a literature review,

workshop, observations and qualitative interviews. The empirical data has been used to analyze SMR and as background material for papers II-IV. In paper I review and workshops with primary keys in Danish e-Health are applied, in paper II design and development of database's theoretical opportunities are applied, in paper III and IV comparative methods are applied. The methods applied in the individual sub-objectives are documented in four separately published papers.

6.1. Qualitative research

In order to understand how SMR operates, we need to understand the experiences, expectations and social positions of three different groups; representatives from the clinical gatekeepers, technical central gatekeepers, and technical client gatekeepers. These respondents have been chosen by their involvement in the SMR vision. Hence, the qualitative research interview proved to be the most appropriate method of gathering knowledge about how these groups approach SMR.

There is an obvious risk of bias in the responses when I asked members of the pilot project team and the decision-makers as to their views about SMR. On the basis of these interviews, I expect to obtain broader knowledge about the potential interoperability of these services within Danish e-Health and especially the pitfalls, benefits, processes and technical insights derived from working with SMR. This empirical knowledge will reflect the actual implementation challenge posed by SMR, the national position on its use and user expectations towards SMR, thereby providing a base for further considerations and analytic approach towards requirements to an architecture supplying the everyday needs of these groups.

When using qualitative research interviews for data analysis, it is important to be aware of the fact that respondents present themselves as professional people; therefore, the given answers will be based on what the respondents *believe they do or on their solicited* and not necessarily *what they actually do or believe in a specific situation*. Exploring what they actually do or their situationally-determined opinion cannot be sufficiently documented through qualitative interviews.

The qualitative research interview

Steinar Kvale [67] defines a research interview as: 'an interview with the purpose to secure description of the respondents' life world in preparation for construing the meaning of described phenomena'. The qualitative research interview has an object, a structure and is thematized. The characteristic is its structure, which is an asymmetrically controlled dialogue with foci on predefined themes.

The perspective I choose to have in my interviews is based partly upon the ontology covering the world as relatively stable for the respondents. This is because the world is subject to fundamental and relatively unalterable codes of conduct, and partly on the

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By Louise B. Pape-Haugaard, M.Sc.BMEI

vague ontology in a phenomenological / hermeneutic view. This approach is appropriate because some of the respondents (decision-makers and clinicians) have the ability to change the world due to their insight.

7. Overview of the Studies

In this chapter an overview of the four individual papers is provided.

The focus of this doctoral dissertation is an exploratory study of models to ensure interoperability, exemplified through SMR. It is especially the technological possibilities that have been investigated. From the previous chapter, it is evident that such technological possibilities can form a model of SOA-designed WS, including application of relevant database theory. The objective of the findings presented in this dissertation is therefore to explore how interdisciplinary and transversal interoperability can be implemented in e-Health, in order to explain some of the challenges involved in deploying this generic model.

7.1. Studies employed in the dissertation

Paper I addresses the first objective (sub-objective A) of investigating the current paradigm for creating interoperability and identifying problems in this paradigm. This is carried out through a comprehensive literature review on ISO/CEN EN13606 information models and terminology models such as SNOMED CT in order to explore the issues raised when seeking to interoperate these autonomous research paradigms. The findings reveal that ambiguity at different levels is contained within the two models, and that the ambiguity increases when these are interoperated. In order to comprehend the impact of these findings a workshop was arranged with both researchers and practitioners. The variation in key issues, depending on whether they are theoretical or empirical, is quite intriguing, because from a practical perspective, it is believed by informants that these issues can be handled through decision-making, and from a theoretical perspective, the focus is on ambiguity.

Paper II addresses the second objective (sub-objective B) of exploring whether the relaxation of ACID properties can benefit the stakeholders' visions and requirements for ubiquitous care in e-Health. This is carried out through the re-organization of well-known atomicity, consistency, isolation and duration properties. These properties are applied in database theory in order to keep 'dirt', inconsistent and unreliable data away from the databases. However, a relaxation of the consistency property provides clearance in the database transaction to relax the ordinary requirements. This means that flexibility can be built into the database, and when this is done, it also allows to accede the SOA-based challenge of direct transactions. Moreover, the paper provides a detailed description of how to design the architecture of a flexible database.

Paper III addresses the second objective (sub-objective B) as well. In this paper the aim is to verify that the relaxed ACID properties can in fact be deployed in a practical setting such as the SMR model. This is done by considering the database design of

SMR and the access functionality of the SMR interface compared to the design criteria given in paper II. In the comparison of the practical setting and the theory emphasis was primarily on server site, meaning that the heterogeneity was minimal. Moreover, because flexibility in databases has been used widely in practical settings for decades, it can be difficult to conclude that it is the relaxed properties which are applied and not a generalization of properties. Nevertheless, there are clear indications of applied read-only services. Furthermore, the paper still raises the question of whether the SMR model is clinically applicable.

Paper IV addresses the third objective (sub-objective C) of assessing the SMR model's influence on the interoperability level as described by semanticHEALTH, and compares it to the existing communication media (EDIFACTS). Three variables were used to compare the two technologies. The paper demonstrates that it is technologically meaningful to generate an architectural paradigm shift to SOA-designed web services. However, I find it important to emphasize that the existing communication media is needed together with the web service technology, because of the type of information exchanged in current media. This means that both asynchronous and synchronous communication is needed to complement different kinds of interoperations. It is also important to notice that the paper indicates the re-organization of stakeholders' tasks when shifting to SOA.

In short, the findings in the paper provide new insight into the challenge of creating an interoperable service-oriented architecture given to the organizations involved in deploying an architectural paradigm shift. The organizations are challenged by re-organization of responsibility, interdisciplinary resources, selecting appropriate web services for future information sharing, and orchestrating database construction and maintenance. The findings also raise questions regarding whether service-oriented architecture can support an even higher degree of interoperability by applying centralized terminologies, which is a precondition for semantic and pragmatic interoperability.

PART 2:

STUDIES

Exclude from the publication of this dissertation, however, they can be found through the following references:

1. Pitfalls when integrating terminology systems and EHRs. / Pape-Haugaard, Louise B. ; Rasmussen, Anne Randorff ; Rosenbeck, Kirstine Hjære ; Andersen, Stig Kjær.
In: SHI2010 Proceedings : 8th Scandinavian Conference on Health Informatics, 23-24 August 2010, Copenhagen, Denmark. ed. / Ann Bygholm ; Pia Elberg ; Ole Hejlesen. Trondheim : TAPIR Akademisk Forlag, 2010. p. 34-38.
Research - peer review › Conference article
2. Integration of Health Records by Using Relaxed ACID Properties Between Hospitals, Physicians and Mobile Units Like Ambulances and Doctors. / Frank, Lars; Pape-Haugaard, Louise B.
In: International Journal of handheld Computing Research. Vol. 2, issue 4, 2011, p. 29-41
Research - peer review › Journal article
3. How to ensure sustainable interoperability in heterogeneous distributed systems through architectural approach. / Pape-Haugaard, Louise B. ; Frank, Lars.
In: Studies in Health Technology and Informatics, Vol. 165, 2011, p. 94-98.
Research - peer review › Conference article
4. Higher level of interoperability through an architectural paradigm shift / Pape-Haugaard, Louise B.
In: Biomedical Engineering and Informatics (BMEI), 2011 4th International Conference on, Vol. 4, 2011, p. 2122-2127
Research – peer review › Conference article

PART 3:

DISCUSSION & CONCLUSION

In this part the most important discussions on the studies are presented. Each sub-research objective is discussed in relation to the main research objective: searching interoperability in e-Health. The section is finalized with future work based on the findings presented in this thesis.

8. Discussion and conclusion

In this chapter the discussion and conclusion are presented. Each research objective is discussed in relation to the applied method and an overall conclusion is given together with future research.

This research has evaluated whether the SMR model can be generalized as a model for interdisciplinary and transversal interoperability. To achieve this objective the following sub-objectives were discussed, as illustrated in Figure 7 below:

- A. Exploring interoperability in given paradigms
 - *How to manage heterogeneous elements in an interoperable environment? (Paper I)*
- B. Exploring transactional issues
 - *How to manage the direct transactional issues in SOA?(Paper II)*
 - *How to realize direct transactional issues in SOA? (Paper III)*
- C. Assessing interoperability to a taxonomy
 - *How to assess and evaluate the level of interoperability? (Paper IV)*

In connection with these sub-objectives, this research also sought to demonstrate how an implementation of SOA-designed WS may influence the responsibilities in healthcare. This is illustrated in Figure 7 in the blue background circle. Exploring how the implementation of SOA can propagate throughout the healthcare organization and

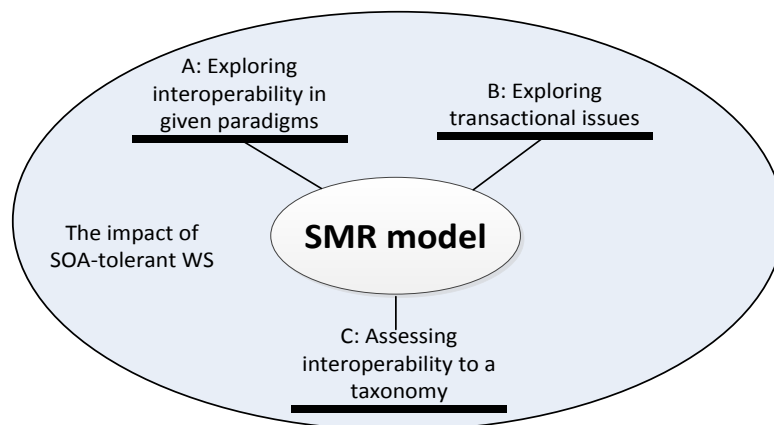


Figure 7 is an illustration of the sub-objectives explored to evaluate the SMR-model

the ensuing uncertainties is rather difficult given the state of the SMR vision. However, what is seen and observed in correlation with the SMR vision is the shift in ownership of health data. When health data are centralized, the institute collecting the data must also provide data to the centralized server, and other HCPs can subscribe to these health data. Ensuring developers' participation requires a system of incentives. It is closely connected to the shift in responsibility and ownership of data. Managing the quality assessment of the services is difficult due to a lack of an assessment model. [69]

8.1. Discussion of interoperability in the given paradigm (Paper I)

To explore the sub-objective of interoperability in the given paradigm for interoperability and through that, the heterogeneous health data, it was established that the current paradigms for interoperability are modeled through reference models or through terminology systems. Therefore, a review of the scientific literature was conducted, as was a workshop involving practitioners.

The method used for this study is illustrated in Figure 8.

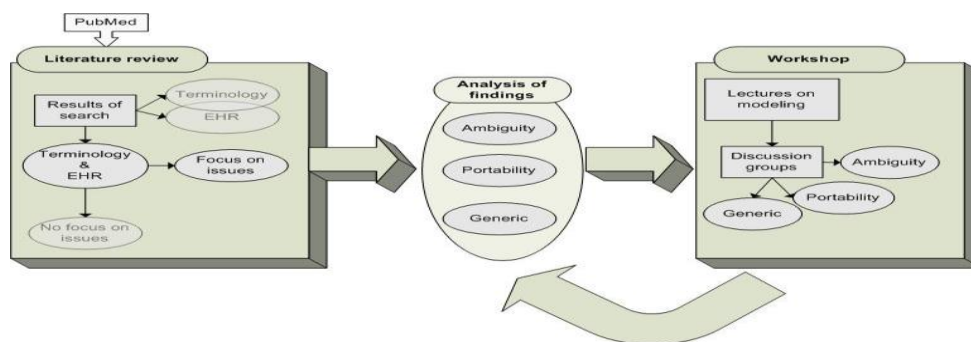


Figure 8 illustrates the method applied in paper I

What needs to be emphasized from the applied method is the interaction between science and practice. However, this method can be criticized for lacking an adequate model for handling the key issue of ambiguity pointed out in the paper. On the other hand, what we discovered in the workshop with practitioners was the faith in governance being able to manage this ambiguity issue. This is a clash between research and practical needs over a very central issue of interoperating heterogeneous health data. One consequence of this 'struggle' can be that the research is not capable enough to apply it in the practical settings. Another consequence is that research in this domain is seeking to explore non-existent problems.

Furthermore, it is documented that the current paradigms for interoperability conflict with each other. Even more interesting is that neither paradigm (reference models or terminology systems) is sufficient in itself. Nevertheless, this paper highlights the diversity in key challenges in heterogeneous health data when seeking interoperability.

It also raises the question of whether another approach for interoperability can be applied because of the complexity in applying reference models as a means of achieving interoperability.

The SMR model is an alternative to be dependent on a single EHR reference model, but alternatively the SMR model is a reference model for interoperability in e-Health. The reference model serves to interoperate clear defined health data. SMR is based on open source and open standards. The choice of open source and open standards means that SMR can be dissociated from monopolistic or monolithic and proprietary systems. Even though that maintenance, control and transactions are centralized. Syntactical and schematic/structural levels of interoperability are embraced in a stable and secure manner. The bilateral semantic level of interoperability is assumed to be managed partly in the concept model and partly in the XML-schemes.

Through this study, the research objective of *exploring interoperability in given paradigms* has been analyzed. Thereby, it is concluded that the challenge of heterogeneity in health data can be minimized by applying SOA-designed WS.

8.2. Discussion of transactional issues in SOA-designed WS (Paper II & III)

To explore the sub-objective of transactional issues in SOA-designed WS, it was first investigated how these relaxed ACID properties could be implemented. Focus was then placed on how the relaxed ACID properties could be understood in relation to SMR in order to ensure that theory could be deployed in a practical setting. In short these relaxed ACID properties are a technical approach to support and solve issues of responsibilities of health data between HCPs.

Managing the transaction issues can be accomplished by applying the countermeasure transaction model, as documented in papers II and III. The countermeasure transactions model is used to minimize problems caused by missing or insufficient ACID properties. It involves client transactions (root transactions) and single site server transactions (sub-transactions). All communication with the user is managed from the root transaction, and all data are accessed through sub-transactions. The basics in ACID properties are: *Atomicity* is typically a 'black and white' world meaning either all transactions are executed or neither is executed, also called the 'all or nothing' rule. *Consistency* is that transactions always operate on a consistent view of the database and that when the transaction has ended the database is left in a consistent state. *Isolation* is to pretend that each transaction is executed exclusively i.e. it seems that only one transaction is done at a time. *Durability* guaranties that once a transaction is committed its effects are persistent. As the ACID properties are created to ensure concurrent transactions a consistent view of data, they can also influence performance and availability.

Therefore, when applying an SOA it is needed to reflect upon how the ACID properties are implemented because of the potential concurrent demands for services. Using the countermeasure transaction model involves that the atomicity property is implemented by using compensatable, pivot and retrievable sub-transactions. Thereby it is allowed to commit/execute a part of the transaction and the transaction can still be considered atomic. The Consistency property is undefined in databases using relaxed ACID properties because per default such databases are inconsistent. The Isolation property can be implemented by locking records used by a transaction. A locked record cannot be used by other transactions before the locks are released which is when the transaction is committed. The durability property of databases with relaxed ACID properties is implemented by using the local Durability property of the local databases involved.

In these papers, we recommend a combination of architectures in order to realize this model, i.e., both centralized and decentralized solutions. However, in paper III, when considering architecture for SMR, including the countermeasure transaction model, it is reasonable to select the centralized solution. Applying either solution has a price. Relaxing or generalizing the properties will, according to [41], affect the reliability, consistency and atomicity of the database. However, one can argue that due to the infrequent update of health data, it might be possible to implement these solutions. Moreover, when applying these solutions, one has to understand the need to re-organize the ownership of health data.

Whether the transactional issues can in fact be resolved in healthcare in a secure and stable manner on a greater scale is still an issue for discussion. Research indicates that in other non-clinical domains, these relaxed implementations of ACID properties are possible and able to maintain consistency in the databases. In e-Health the relaxed/generalized ACID properties are not as widely accepted. This may be due to several factors: lack of sufficient research, in security in SOA or inadequately developed service-oriented paradigms. However, in both papers II and III, we have demonstrated how to implement these properties and investigate whether it is possible.

Through this study, the research objective of *exploring transactional issues* has been analyzed. It is concluded that the challenge of transactions in SOA can be managed by relaxing the ACID properties and furthermore the relaxed ACID properties can be implemented in realistic settings.

8.3. Discussion of assessing interoperability to a taxonomy (Paper IV)

To explore the sub-objective of assessing interoperability to a taxonomy and comparing two communicating media, Paper IV analyzed whether the SMR model would increase the level of interoperability compared to the existing communication media. This was carried out by applying the method illustrated in Figure 9. In Paper IV, it was shown that when comparing the SMR model to the existing communication media

(EDIFACTS), an increased level of interoperability could be identified. This finding is significant because it supports the possibility and the need to shift from the existing architectural paradigm to an SOA paradigm. The methods applied in Paper IV are shown in Figure 9 below.

A recent review [1] reveals that the anticipated benefits of e-Health have not been documented in the literature. In [2], a major conclusion is that to truly benefit from the

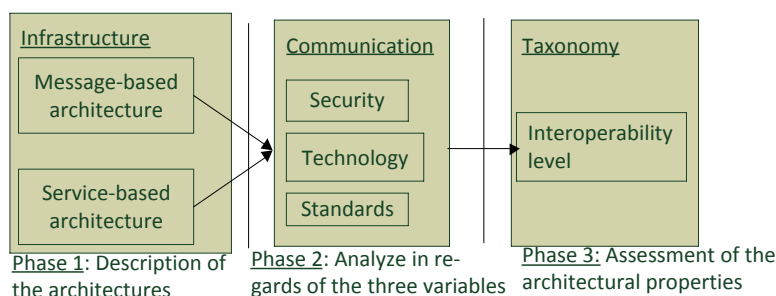


Figure 9 illustrates the method applied in Paper IV

digitalization of healthcare, *interoperability* is required. Interoperability is also required so that patients can experience a seamless continuity of care in the point of care situation. Considering the stated taxonomy [65] (cf. table 1, p.- 19 -), it is imperative that seamless care involve ‘seamless co-operability and sharable context’, i.e., a level three interoperability. A comparison of the traditional computer science perception of interoperability to the taxonomy is shown in table 2.

Table 2 schematic overview of semanticHEALTH taxonomy and the perception in computer scientific of interoperability

Level	semanticHealth taxonomy	Computer science perception
Level 0	No interoperability at all	
Level 1	Technical and syntactical interoperability (no semantic interoperability)	Syntactical interoperability
Level 2	Two orthogonal levels of partial semantic interoperability <ul style="list-style-type: none"> • Level 2a: unidirectional semantic interoperability • Level 2b: bidirectional semantic interoperability 	Structural interoperability
Level 3	Full semantic interoperability, sharable context, seamless co-operability	Bilateral semantic interoperability <ul style="list-style-type: none"> • Terminological • Ontological

At level three, semanticHEALTH requires a common reference model and digital terminology library. This is not the case in the conventional computer science view. Rather, there is a full acknowledgement of the fact that there is a call for heterogeneous, autonomous and distributed systems. Thus, it can be discussed whether

level 3 in the taxonomy provides a sufficient definition of 'Full semantic interoperability'.

In SMR, creating a level three in interoperability is done during the development process through workshops where wording and perception of the real world was discussed equally to functionalities. In addition, the granularity of presented information in the clinical system may differ between systems. Moreover, this also means that creating consensus on wording and perception of the real world is a manual process in the way the SMR model has been designed. Nevertheless, the SMR model seeks to interoperate legacy systems through web services in SOA, but without dependency on an EHR reference model. The technologies used in the SMR model for creating interoperability have a sufficient level of maturity, which might be a decisive factor.

Through this study, the research objective of *assessing the interoperability level* has been analyzed. It is concluded that the SOA-designed WS increases the level of interoperability compared to current architecture and can be assessed through evaluation of three parameters.

8.4. Conclusions regarding the applicability of the SMR-model for transversal interoperability for interdisciplinarity in e-Health

One strategy in e-Health is to avoid gigantic, monopolistic and monolithic systems, but if the condition to achieve this level is to use an EHR reference model, it seems unrealistic for national e-Health stakeholders to achieve this level due to economic constraints, political agendas and multi-vendor strategies. Using SOA ought to serve as an alternative for using a single EHR reference model because of the potentials of preserving existing infrastructure, systems, and reuse of information. It is a paradox that a pronounced goal is full semantic interoperability across borders, and at the same time, forms a condition which constrains vendors to a common reference model, even though [65] also concludes that 'Semantic operability will be achieved only gradually, beginning with applications with high benefit and modest cost.' Of course, there is a difference between everyday social media and personal health records. However, perhaps the time has come for a shift in e-Health, for an acceptance of the heterogeneous, autonomous and distributed systems. This will also necessitate solutions for interoperability.

The challenge of heterogeneity in health data can be minimized by applying SOA-designed WS. The challenge of transactions in SOA can be managed by relaxing the ACID properties. The relaxed ACID properties can be implemented in realistic settings. The SOA-designed WS increases the level of interoperability compared to current architecture and can be assessed through evaluation of three parameters.

Overall, it is concluded that SOA-designed WS can be deployed in e-Health in order to help ensuring transversal interoperability in eHealth.

In addition, to the identified challenges, the findings offer new insight into the challenge of creating an interoperable service-oriented architecture given to the organizations involved in deploying an architectural paradigm shift. The organizations are challenged by re-organization of responsibility and interdisciplinary resources.

The findings also raise questions regarding whether service-oriented architecture can support even higher degrees of interoperability by applying centralized terminologies, which is a precondition for semantic and pragmatic interoperability.

8.5. Future research

What needs to be emphasized is that this research has created the base and understanding of SOA-designed WS as a direct factor influencing the organization of healthcare. In addition, it is demonstrated that applying SOA-designed WS involves user-driven innovation as regards stakeholders representing both a technical developer group *and* a clinical content group. To fully comprehend the propagation of SOA throughout the healthcare organization would require either a fully implemented SMR model or several different SOA-designed WS pilots. Therefore, future research in service-oriented architecture in e-Health is recommended in order to fully understand the *consequences* of SOA propagation throughout healthcare.

This research has documented that applying SOA-designed WS in the national IT organization of healthcare will increase the level of interoperability. However, this is not generic. It is valid only for the participants in the development phase. Moreover, the applied terminology is useful only in this circumscribed setting. Thus, more research in this area is needed. What could be very interesting is to investigate and explore *whether and how* a terminology such as SNOMED CT can be applied as a web service. Moreover, it would also be valuable to study whether this will add clinical relevance and higher semantic interoperability to the generic model of SOA-designed WS. In addition, future research on relevant patient-centered information should be conducted so as to ensure that significant information in other clinical domains can be interoperated.

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