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DESIGNING AND USING AN INFORMATION INFRASTRUCTURE IN RADIOLOGY

Prepare – Share - Compare IT

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*“To my family- without your help...
this would have been a mission impossible”*

ABSTRACT

Radiology informatics is changing the way that work practice and planning of work are conducted in the radiology department and between radiology departments. Today, the need for sharing of information between organizations is increasing in parallel with the growth in both patient mobility and healthcare specialization. This sets demands on the information infrastructure in use regarding interoperability issues as well as distribution problems with the focus on metadata quality in the information shared. The new shared approach marks the beginning of a change from a local to an enterprise workflow. The challenges are to develop useful and secure services for different groups related to the radiological information infrastructure. It involves continuous negotiation with people concerning how they should collaborate within the enterprise. Therefore qualitative action research methods and quantitative methods were used in this thesis. The objective of this research was to understand how to use distributed information in a change process where radiology departments needed to invest in and use new technology that had not been used before in their local workflow, using simulation as a tool for changes in work practice. A further objective was to understand what types of metadata were needed for a radiology enterprise workflow across organizational boundaries. The quality of metadata used in the information infrastructure is critical to the use and benefits this enterprise workflow will gain throughout the patient healthcare process. It is concluded that only a few items of shared metadata are needed to support an effective enterprise workflow. This means that the technical fully working cross-organizational solution is hindered to function as an information infrastructure for collaboration between all departments and hospitals in the region if the quality of metadata elements is poor. It would thus be warranted that as many elements of metadata that has a national semantic definition taken by agencies become mandatory across the society. All semantic standardization initiatives, e.g. Snomed CT are enablers for cross-organizational workflow. It is of importance for interoperability that the agreed semantic models are implemented both in vendor systems and in local workflow so they can support new cross-organizational services around the patient's health as shown in VGR.

In conclusion, this thesis shows that the transformation of digital data in local systems into virtual information in an information infrastructure creates greater potential for using the digital information to improve planning and logistics within the information infrastructure in use, regardless of the local systems involved. Quality control and management of the data make it possible to derive information from it. Quality work should be done based on an information model grounded in useable standards and legal sources for metadata elements. The key success factor seems to be creating and holding an information infrastructure with quality of the metadata elements. Implementing an information infrastructure takes time and therefore needs special attention from a strategic viewpoint.

LIST OF PUBLICATIONS

The four papers included in this study are listed below:

- I. Lindsköld L, Wintell M, Aspelin P, Lundberg N. (2012). Simulation of Radiology Workflow and Throughput. Radiology Management. 2012 July-August: 47-55
- II. Lindsköld L, Gustavsson S, Edgren L, Wintell M, Lundberg N. (2012). The process of defining a radiology enterprise workflow across organizational boundaries - *Which metadata are required?* Submitted Journal of Data Quality
- III. Lindsköld L, Edgren L, Wintell M, Lundberg N. (2012). Cross-organizational Workflow in Radiology -*An empirical study of the quality of shared metadata elements in VGR, Sweden. Accepted with revision, Acta Radiologica*
- IV. Lundberg N, Wintell M, Lindsköld L. (2010). The future progress of teleradiology -*an empirical study in Sweden*. Eur J Radiol. 2010 Jan;73(1):10-9

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LIST OF ABBREVIATIONS

ACR	American College of Radiology
AH	Alingsås Hospital
CT	Computed Tomography
DICOM	Digital Imaging in COmmunication in Medicine
EA	Enterprise Architecture
EIA	Enterprise Information Archive
GE	General Electric
GUI	Graphical User Interface
HIS	Hospital Information System
HL7	Health Level 7
HSA	National-directory over healthcare employees in Sweden
HTTP	HyperText Transfer Protocol
HTTPS	Hypertext transfer protocol over secure socket
ICT	Information and Communication Technology
ICU	Intensive Care Unit
IHE	Integrating the Healthcare Enterprise
IOS	International Organization for Standardization
IS	Information Systems
MB	MegaByte
MRI	Magnetic Resonance Imaging
NEMA	National Electrical Manufacturers Association
OSI	Open Systems Interconnection
PACS	Picture Archive and Communication Systems
PET/CT	Positron Emission Tomography / Computed Tomography
RIS	Radiology Information System
SNOMED	Systematized Nomenclature of Medicine -- Clinical Terms
US	Ultrasound
WADO	Web Access to DICOM Persistent Objects
VGR	Region Västra Götaland
VNA	Vendor Neutral Archive
XDS	Cross Enterprise Document Sharing
XDS-I	Cross Enterprise Document Sharing for Imaging
XML	Extensible Markup Language

1 INTRODUCTION

“The soft-minded man always fears change. He feels security in the status quo, and he has an almost morbid fear of the new. For him, the greatest pain is the pain of a new idea”.
- Martin Luther King Jr.

This thesis addresses how digital data from radiology in VGR can be used in an information infrastructure to create added value for medical professionals and institutions in their cross-organizational workflow or change management, and ultimately for patients, if the data quality is sufficient.

With a history of more than 100 years, the discipline of radiology reflects continuous development, intertwined with technological development. In recent decades, the radiology profession has undergone dramatic changes – first with the transition from analogue to digital technology, followed by the progression to distributed systems and to being part of a larger information infrastructure [1, 2]. These changes are profound, because they amplify or even extend our essential social skills, and our characteristic social failings as well.

By the mid-1990s, most of the imaging modalities in radiology had been digitized, enabling use of the new concept from the 1980s called Picture Archiving and Communication System (PACS). PACS was the door opener for distributed radiology [3-8], intertwined with the Radiology Information Systems (RIS) that hold the textual information concerning the patient’s visits and history.

One conclusion that could be drawn from the findings of Lundberg [2] and Fridell [9, 10] is that digitalization relates more to technology, and distribution relates more to collaboration in a social context. In this scenario, we can start to understand what happens when captured digital data are transformed into information, and can thereby be shared via distribution to anyone or to a specific individual. It is a little bit like walking into the distance beyond imagination, where everything is shareable if everyone understands what is shared [11]. Those insights create new work steps in completely new ways, and even sometimes the possibility to simulate the outcome of a change before it is implemented. Think about if you were the only person who had a computer connected to Internet – would that be any joy? Today, creating substantial knowledge collaboration without limits is one of the key features in developing enterprise workflows in radiology. However, this requires semantic interoperability in order to share, gather, interpret, and organize the implicit meanings of the digital content in the radiology enterprise workflow [11, 12].

Previously radiology work was supported by a complex manual information distribution process, it was supported by shelves, tables, boards, transporters, tape- recorders,

secretaries, telephones etc.[2] . Yesterday's radiology work was in general supported by local RIS and PACS systems in VGR, printers, faxes, CD-burners, administrative support etc. were used for sending and receiving between departments and organizations. Today in VGR the information infrastructure bridge the local to the enterprise workflow. The radiology virtual workflow has no longer any physical boundaries in VGR. It opens up for new services for all healthcare actors. The patient can now be involved in new ways in the healthcare work. The road towards establishing the virtual stage is the focus of this thesis. Figure 1 illustrates that change.

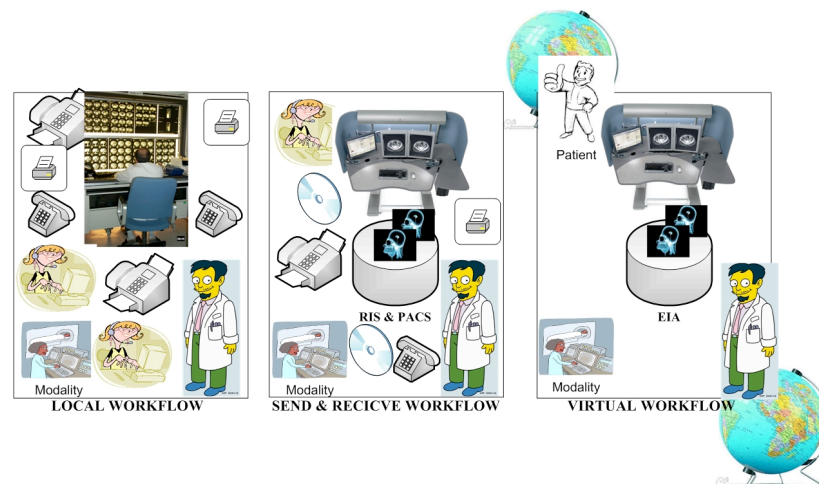


Figure 1. Inspired by Lundberg (7) Describing the road map to virtual workflow in healthcare.

The transformation of healthcare depends on interoperability and interaction, enabling distribution from where services are produced to where they are needed [13]. The reengineering of healthcare to reduce waste caused by unnecessary costs, errors, delays, and futile repetition demands a dynamic use of information about the patient [14]. At a technical level, the deployment of the necessary solutions is on a “plug and play” basis. In the social context, the need for agreement on technical standards that allow sharing as well as semantic and syntax standards for collaboration is a prerequisite [15-17].

The standard that will have an impact will be Digital Images and COmmunication in Medicine (DICOM) [18], which has been around for a long time. This standard ensures that digital images can be shared between different PACS, and can also be distributed via web technologies using part 18 of the DICOM standard Web Access to DICOM Persistent Objects (WADO) for sharing outside the PACS systems. Transmission of textual information will almost certainly be based on Health level 7 (HL7) [19], which is a common messaging standard for the exchange of information between healthcare systems.

The context of the information will probably be dependent on the Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT) [20] for radiology. One could regard HL7 as providing the grammar as a standardized structure for healthcare communication, rather like Swedish or English grammar. SNOMED CT provides semantic operability in the exchange of clinical information among applications and

organizations at a level of granularity and coding that is sufficient for the receiving system to use the information for clinical decisions, research, quality assessment, and patient safety. In this case, DICOM provides the syntactically correct topic as a basis for collaboration. To intertwine these standards for meaningful use on an enterprise level, a framework has been agreed on for Integrating the Healthcare Enterprise (IHE) [21].

IHE is a global association of Healthcare vendors, user organizations, associations of clinical professionals and an advocacy group that promote interoperability through the coordinated use of established standards as mentioned above. IHE establishes integration profiles, which are specifications that identify standards to be used and precisely define how they will meet interoperability challenges.

Simulation is defined in this thesis as the technique of building a model of a real or proposed system so that the behavior of the system under specific conditions may be studied.

Data quality is defined in this thesis on the basis of two aspects: first, the dependence of perceived quality on the user's needs; second, the "fitness for use", which is the ability to satisfy the requirements of intended use in a specific situation [22-26].

Technical enterprise architecture as used in this thesis is a rigorous description of the structure of an enterprise (blueprint). This description is comprehensive, including software applications and computer systems.

The definition of enterprise used in this study refers to cross-organizational actors using the same information model and technical frameworks across places, time and activities.

Enterprise workflow is the action required to span a healthcare visit over organizational borders.

In this thesis, information infrastructure is used as defined by Hanseth [27], with the addition of the aspect that over time the information infrastructure changes; it is designed to support a range of activities; it is a technology built as a layer on another technology, integrated with other infrastructures into networks with no limits. Furthermore, it is shared by and is open to a larger community, including heterogeneous entities such as humans, technological components, organizations, and institutions.

2 AIM OF THE STUDY

*“Judge of a man by his questions,
rather than by his answers”.*
-Voltaire

The overall research question in this study is: How can we design and use a radiology information infrastructure by focusing on interoperability via data quality and technical standards that support cross-organizational workflow as well as the use of other new services in VGR?

Technology development in radiology has been the driving factor for change, supporting clinicians in the diagnosis and treatment of patients. The formalized procedures become more complex as more of the steps are computerized.

This thesis emphasizes three different views – work practice changes, understanding the meaning of data quality when sharing information, and introducing new services in work practice when the focus changes from local to enterprise workflow.

The overall research question is addressed by considering the following issues:

1. How have simulation services been used in radiology, in particular, to predict the outcome of work practice changes?
2. How useful can simulation be to predict the future outcome of radiology examination throughput changes in the radiology department of Alingsås Hospital, Sweden, after both the investment in a new magnetic resonance imaging (MRI) suite and the closing down of two suites?
3. What metadata elements are needed to support the radiology enterprise workflow across organizational boundaries?
4. What elements of metadata are missing or semantically incorrect in the radiology information infrastructure?
5. How can an innovative approach to teleradiology inside the radiology information infrastructure be deployed?

3 BACKGROUND

*“The real voyage of discovery lies not in seeking
new landscapes but in seeing with new eyes”.*

-Marcel Proust

This section provides a brief description of simulation and data quality from a radiological perspective, as well as the information systems (IS), medical informatics and medical management perspective, when using an information infrastructure as a base for collaborative work and development of shared services.

It is important to understand how a radiology department becomes more intertwined with other departments in radiology when we use a information infrastructure to share information between local systems with today's information and communication technologies (ICT).

3.1 RADIOLOGY; A VISION THROUGH HUMANITY

Since the discovery of X-rays in 1895 [1], continuous development has occurred in this field. New imaging technologies have entered the market [1], Common to the new technologies is that they are based on bits and bytes (digital) [1], enabling the information to be shared freely with anyone who can access the flat digital world, where we can capture, identify and share information at the speed of light. For humanity, the challenge to collaborate in an effective way around the patient will open up new ways of delivering healthcare in the years to come.

The radiology department acts as a service provider for hospitals and healthcare units, carrying out diagnostic and treatment interventions as well as providing remote services to other departments such as reading of examinations, second opinions, or expert advice.

The size of the departments may vary from just a few employees to more than 500 employees. Today more actors are entering the arena in VGR, giving the patients more choices to consider.

3.2 MODALITIES IN RADIOLOGY

The technical equipment that creates the images used in radiology depends on the respective modalities. The imaging technology most commonly used today is conventional radiography with photographic plates as a replacement for the analogue technique, in which a photographic film was exposed to radiation and later developed chemically to create the image. The photographic plate collects and counts the radiation which passes through the patient and the result is processed by computers to create the digital image. The number of images used in a conventional radiography examination varies from 1-15 depending on the reason for the examination. For skeletal

examinations, a front and a side image is normally required for the examined object. The size in megabytes for conventional radiographic images is around 12 MB.

Computed tomography, invented in 1973, is a technology that creates cross-sectional images placed together in a volume, where the user can select the view required. The number of images used in one examination may vary from 30 to 20 000 images, depending on the volume that is acquired. The same applies to magnetic resonance imaging, invented in 1940 but first used in healthcare at the beginning of 1985, where the patient lies in a powerful magnetic field. MRI provides good contrast between the different soft tissues of the body, which makes it especially useful in imaging the brain, muscles, the heart, and tumors. Unlike some other medical imaging modalities, MRI does not use ionizing radiation. Different protocols can be used to make it easier to see differences in contrast; these also increase the number of images created per examination. The number of images may vary from 100 to 60 000 per examination. The size is normally around 0.5 to 1 megabyte (MB) for both CT and MRI.

The use of ultrasound (US) in obstetrics started in the mid-1960s. Later, ultrasound was used in radiology as an imaging technology that allows various organs in the body to be examined. The machine transmits high-frequency sound waves, which are reflected from body structures. A computer receives these reflected waves and uses them to create an image. There is no ionizing radiation exposure. The numbers of images per examination vary widely, because one of the benefits of ultrasound is that it can handle multiframe images (video). A study may have a volume of 1 GB to 1 TB, depending on the time interval during which the images are acquired. For single static images, the size is normally 0.3 MB.

In VGR, the number of images that a radiologist has to review in average has increased from 2006, when the average number of images per examination was 56, to 2011, when the average number of images per examination was 85.

3.3 IT SYSTEMS IN RADIOLOGY

The two major types of IT systems developed to take care of the digital workflow in a radiology department are Radiology Information Systems and Picture Archive and Communication Systems [3-6, 8, 28-39].

The RIS system was developed to help the departments with administrative tasks, such as scheduling, billing and logistics. Today, the RIS also handles request and report information as well as communication with PACS and other electronic patient record systems in use in healthcare.

PACS has existed for about 25 years and was developed in Europe. However, the first system was not installed in Europe, but in the USA at the beginning of 1980 at the University of Pennsylvania, UCLA, and Kansas City University. A few more or less successful installations also took place in the Netherlands, Belgium, Austria, the UK,

France, Italy, Scandinavia and Germany. Most of these systems were installed with a focus on a system to be connected to a radiology department.

The first system to also integrate other users (clinicians) was implemented in the beginning of 1990 at the Hammersmith Hospital, London and in Vienna (SMZO). There are a number of references describing the development of PACS [3-6, 32, 33, 39-41]. PACS is closely related to RIS. The radiology modalities combined with PACS and RIS have together created the digital radiology department. The benefit of digital images is that they can be seen by anyone, wherever they are, as long as the image and related information is in a standard format.

3.4 STANDARDS USED

For radiology images, the DICOM standard has been crucial for the success of distribution of images between actors in healthcare [18]. The first step toward a standard for radiology images was taken in the mid-1980s by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA). They created a much needed relationship between the clinicians and radiologists who needed to share digital images and the vendors who could develop a system to provide this. Today all modality and PACS manufacturers – for example, General Electric (GE), Philips, Siemens, Fuji and SECTRA – support the standard, and it is easy to connect an imaging modality to a PACS system.

It seems to be more challenging to handle the textual information in the RIS systems. Worldwide, standardized message flow uses Health Level 7 (HL7). "Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the application level. HL7 provides standards for interoperability between IS systems in use [19]. In Sweden, the adaptation of using HL7 in RIS communication with other systems has been slow.

3.5 SIMULATION – SEE THE WORLD BEFORE THE WORLD IS THERE

Simulation techniques could be one tool to provide help for imitation of the real-world process or system over time [42]. Simulation can take advantage of data already gathered in our systems to generate a model of the workflow to answer “what if” questions. It must be recognized that in a complex organization such as a hospital, the success or failure of any change proposal is judged by many different individuals using different criteria, e.g., staff, patients, or managers.

Simulation in radiology alone does not provide the whole answer. For a more complete answer, the entire hospital needs to be included in the simulation model, as well as other facilities that have daily interactions with the hospital. In order to obtain a more precise result, all human and personnel factors need to be included in the model, and any data used must be reliable.

Research fields illustrate a simulation evolution. First, the IS field focused on technical issues. Second, the medical management field focused on the upcoming complexity in work and how simulation could predict consequences of change. Third, the medical informatics field focused on overall workflow issues, taking more entities and relations into consideration in the simulation technology.

3.6 DELUGE OF DATA - RIDE THE WAVE OR DROWN?

The amount of data that is produced from the modalities and PACS/RIS systems and transformed into information could be valuable for use in simulation, e.g. using the experience of others to improve planning for the future. This can be investigated by looking at questions such as: How are we planning for changes today? Are we only adjusting the technology to suit our present workflow? Can we find new ways of doing today's work with the help of technology, and thereby increasing the efficiency and effectiveness of the utilization of radiologic resources?

The explosive growth in the amount of data created in hospitals continues to accelerate. Both the production and the distribution of those data volumes impose demands on the information infrastructure involved. One key factor is that if the data quality is low from an enterprise perspective, the value of the information it represents is less meaningful for the recipient. An example is issuing the numeric data from the laboratory analysis but not the meaning of the analysis. This is like receiving a telephone directory with no names associated with the telephone numbers. Who should you call?

This thesis focuses on the data quality of workflow metadata in radiology, e.g. missing data elements and semantically incorrect data elements. Medical decisions are made in the context of a particular task, hence understanding contextual evaluation of data quality such as findings of patient's medical history is particularly important when the data is being used [43]. Recent research suggests that data quality, when assessed by the decision makers who use it, is not necessarily perceived as intrinsic, but as subjective and context-dependent [43-45].

3.7 RELATED RESEARCH

In this section, I provide a brief description of the related research used for understanding my findings. The section also includes a description of how this thesis work is positioned in relation to the related research.

Related research in healthcare has been conducted in several fields. Of these, I have been exploring medical management, medical informatics and information systems (IS). I will briefly point out some areas from the research fields that link to the findings in this thesis.

Medical management research supports a science- based management practice in healthcare where competence, knowledge, material and other assets can best be used and developed to improve human health.

As Bohmer states on page 9 [46]: *“The mission of health care delivery organizations is gradually shifting from the provision of service to the generation of outcomes”*.

Norrman & Arvidsson, state on page 21, [47]: *“Technological evolution has always implied the opportunity to break out of constraints. It has become possible to produce more with fewer resources, to eliminate restrictions due to distance and time, to accumulate and preserve knowledge and build into new systems. But technological innovation must be accompanied by social and institutional innovation if prosperity is to be realized”*.

In Europe, many research and development projects are ongoing to achieve an infrastructure for national health information [48]; examples include Sweden [49], the UK [50], Denmark [51] and Finland [52].

The goal for those initiatives includes 1) involving patients in their own health, 2) preparing the information for seamless sharing, 3) implementation of standards, nomenclatures, codes and semantic interoperability, and finally 4) development of data security infrastructure and policies supported by national laws and regulations.

It is obvious that dramatic changes are taking place in healthcare today. The medical management research field strives to empower and engage the patient as well as to change the current organization of healthcare delivery. Studies in this field show that data collection and mining is an excellent investment in understanding complex systems. So it seems meaningful that we have access to large amounts of information, enabling better decision support.

Studies within the medical management field have shown that simulation models can increase understanding of complex systems in transformation [53-65]. In addition, studies show that data collection and mining represent an excellent investment in understanding complex systems and that simulation models can be applied for change management.

In order to assess the effect of various proposals for new operating models, communication models, use of spaces, and patient flow simulation models as a planning tool, simulation can be applied to give the user as realistic a model of the real-world system as possible [66-72]. The intention of the simulation system has been to provide support for making the best decisions prior to change and to obtain users' acceptance of change prior to and during the implementation of a change process.

Medical informatics is a discipline at the intersection of medical management and information systems. It deals with the use of IT systems, devices, and methods required for optimizing the acquisition, storage, retrieval, and application of information in health and biomedicine. Medical informatics tools include not only computers but also guidelines for the use of standards, formal medical terminologies, structured codes and organization in information models. The use of information models is a prerequisite for obtaining data quality in practice. Information models are applied to all areas in medicine, such as nursing, clinical care, dentistry, pharmacy, public health, occupational

therapy, radiology, pathology, clinical chemistry and (bio)medical research. The framework for medical informatics lies in the use of standards, creating the necessary tools for interoperability when combined with information models that harmonize the semantic use. “The European Union's Member States are committed to sharing their best practices and experiences to create a European eHealth Area, thereby improving access to and quality of health care at the same time as stimulating growth in a promising new industrial sector. The European eHealth Action Plan plays a fundamental role in the European Union's strategy”. The recently released report “Redesigning health in Europe for 2020”, [73] highlights the need for reorganization of today's healthcare to better use information infrastructures for healthcare. Work on this initiative involves a collaborative approach among several parts of the Commission's services [74].

Various studies [75] conducted from the early 1970s until today [66-68, 71, 76-91] have obvious relevance for the design and use of simulation models within radiology transformation from analogue to digital technologies with the focus on computer systems and network utilization. These studies illustrate how simulation models can be used to predict the performance of a given computer system configuration using a given workflow. In particular, models have been used for evaluating different PACS solutions [66-72, 80, 82, 92-94]. Studies show that simulation can provide a decision support system regarding network topology, storage requirements, and number and types of radiology equipment [ibid].

It therefore seems meaningful that we have a good structure in the data we are gathering, and that they are useful for sharing with those with whom we would like to share them, e.g. patients, health authorities, and other healthcare organizations and providers.

Information systems are the study of complementary networks of hardware and software that people and organizations use to collect, filter, and process, create, and distribute data or information. Studies contributing important knowledge of design and implementation of information and communication systems (ICT) in general within healthcare [69, 70, 72, 92, 93, 95-115] are relevant to the design and implementation of simulation models within healthcare. These studies suggest that information technology has the potential not only to introduce new logic and rationale, but also to create new interrelations between healthcare personnel and departments. In addition, studies within this field have shown how animated simulation models can be fed with data collected from the real world [67, 70, 96, 98, 100, 102, 106]. This data can be used to simulate suggestions for improvements, such as the scheduling of existing resources and the addition of resources. These studies also suggest that simulation results do not take into account all the complexity of the real world [75].

Silver [116] defined information systems as “implemented within an organization for the purpose of improving the effectiveness and efficiency of that organization. Capabilities of the information system and characteristics of the organization, its work systems, its people, and its development and implementation methodologies together determine the extent to which that purpose is achieved”. Specifically, the role of

implementing healthcare standards such as HL7 and DICOM has been discussed in this thesis, as well as the use of simulation software to predict outcome of changes.

One can see the research fields of medical management, medical informatics and information systems as three perspectives used to provide a better understanding of how healthcare should become safer, more efficient and effective when change is made. Patients, clinicians, managers and researchers will be able to share relevant information at the right time and in the right place. This guarantees both confidential and authorized use of information. In Figure 2, the relationship between those perspectives is shown.

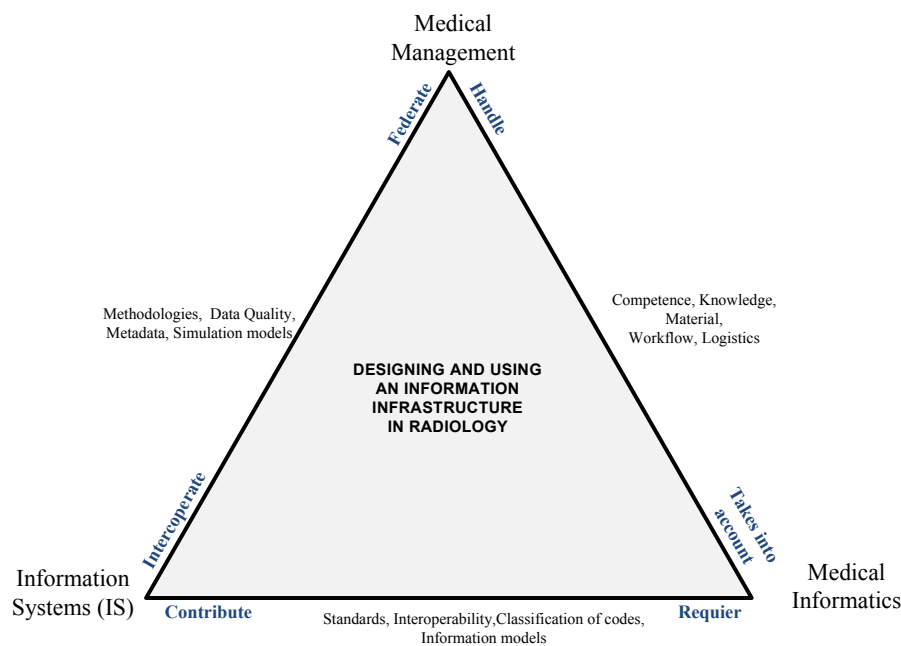


Figure 2. Describing this thesis positioning in relation to the Medical Management, the Medical Informatics and the Information Systems research field in healthcare.

As shown in Figure 2, this thesis is based on systems theory, where the parts from the different research fields are put together as a whole by focusing on the information infrastructure. In systems theory, we explore the way things affect one another within a given whole. It is also a way of relating to issues by seeing them as part of larger context – the system – instead of considering them in isolation [117].

This increases the likelihood that the entire information infrastructure can be established without sub-optimization. When sub-optimization occurs, a change perceived as good for one part of the system creates problems for the other parts and the entire system [118]. The different perspectives used in Figure 2 can be used to avoid sub-optimization when creating an information infrastructure for use in an enterprise workflow.

4 THEORETICAL FRAMEWORK

*“Facts do not cease to exist because they are ignored”.-
Aldous Huxley*

4.1 INFORMATION INFRASTRUCTURE

Hanseth’s [27, 119-121] principles of information infrastructures have been applied in this thesis. These principles are described from a VGR perspective as follows: 1) the information infrastructure is a *shared resource* among the radiology healthcare professionals in VGR; 2) the data from different local RIS and PACS systems in VGR are integrated through *standardized* DICOM objects; 3) the VGR infrastructure is *open* because it could include any kind of data – radiology has simply served as a starting point for the development of this infrastructure, 4) it is *heterogeneous*, as the information infrastructure in VGR consists of social and technical components. This thesis also adds to Hanseth’s [27, 119-121] theory of information infrastructures by contributing a fifth, sixth and seventh, these are the: *security*, *service* and *time* principles. Whereas the 5) *security* principle focuses on legal and ethical issues from the following perspectives: 1) intrusion and access control, 2) data integrity, 3) data continuity and legal requirements [15]. Human integrity and ethical issues are always important, especially in healthcare.

In VGR, these concerns have been addressed by developing the “virtual box” in the information infrastructure [15]. The box provides secured central virtual storage of local data in compliance with security guidelines and legislation. It is possible to distribute information to a new virtual secured “box” shared by limitless collaborating units. The VGR infrastructure is built up by different 6) *services*. These services cannot be identified on beforehand as their existence and properties are given to them in a step by step process through the development and use of the information infrastructure. It could be either more supportive services that are “invisible” e.g. holding no end user interface or new and innovative end user services.

The information infrastructure supports the innovation and development of new services through its aggregated principles that it is built up of. It is finally 7) *time* dependent because when data are shared from different sources and put together virtually as a whole across organizational boundaries this is done at a specific time [122]. When time pass different data will be shared using the same service i.e. the content of the information infrastructure is updated and changed over time. The outcome of the information infrastructure will therefore hold different meanings over time. Time has a contextual meaning for the information infrastructure.

The service principle relates to the fact that the radiological information infrastructure is a “social technology” without properties [123]. Properties are given to the regional information infrastructure through the development and use of services on it. In this thesis, a number of collaborative services will be illustrated. These are just a few

illustrations of what services could be developed when data are securely shared. An infinite number of services can be developed.

The challenge is to identify the relevant services, e.g. which services fulfil healthcare needs. An information infrastructure without services is simply a costly technology of no use. The usefulness of the information infrastructure is completely dependent on the services that it provides. New services are identified and developed by individuals. Services in information infrastructures are thus social elements.

According to this definition many actors are included in the information infrastructure. In VGR examples of these are the: PACS and RIS systems, secretaries, transporters, application of terminology and semantics, information models, networks, computers, people using the services provided by the information infrastructure, etc. included in the infrastructure. It links humans and technologies together over distances that span a number of activities; it requires the uniformization of many existing practices and systems [2, 124].

It is important to stress that the view of technology as something that could mediate our activity towards other humans or towards objects is, and has been, an essential contribution to our view of infrastructure in use [2]. However, as local technology emerged as an infrastructure and network supporting interactive communication regionally in VGR, new perspectives considering interconnections and links in widely connected networks were developed. Hence, the infrastructure perspectives were developed.

This perspective differs from the local tool perspective. Applying this perspective, it is possible to understand artefacts linked together into networks and infrastructures crossing the boundaries between communities [2].

This implies that technologies could be understood both internally, that is, in terms of their interconnections and roles they play within a community, and externally, in terms of the way they mediate relations among communities regional, national and international.

4.2 IDENTIFICATION OF METADATA

The identification of metadata in a radiological process requires focusing on the parts that constitute “wholes” rather than on isolated parts. This perspective is a feature of systems theory, where concepts about the structure of systems as “entities with boundaries within which physical and mental energy are exchanged internally more than they are across the boundary” according to Payne [125].

Payne refers to the set of conceptual steps identified in systems theory by Greif and Lynch [126], to describe how data is applied in different conceptual steps in a workflow process. These conceptual steps are applied in this project to identify metadata in a workflow process. They consist of:

- **Input** - “energy” fed into the system from another system, e.g. the request from the referring physician arrives for the attention of the radiology department.
- **Throughput** – How the energy is used within the system, e.g. what information is meaningful to use in the local workflow
- **Output** – Effects on the environment of the energy passed out beyond the boundary of a system, e.g. useful information from radiology for the referring clinician
- **Feedback** – Information and energy passed to the system caused by its outputs affecting the environment, which informs it about the results of its output, e.g. what metadata elements are needed for the semantic interoperability necessary to engage in a secure discussion regarding a specific patient and examination.

The application of a systems theory focus on concepts, in this case to metadata, in workflow processes is fundamental to the design of a workflow process for sharing medical information in a healthcare enterprise. This is because it facilitates data quality assurance with respect to process-based information. When a shared standard of data quality is achieved, the access and use of information is simplified in the healthcare enterprise. The metadata elements identified are represented by nodes of strategic collaboration around the patient’s health. In these nodes of collaboration, a small amount of information yields highly practical effects, as the quality of the data is reliable. Meaning that the perceived information for the intended user is meaningful and trustworthy, e.g. correct Patient ID, Patient Name and so on.

The information infrastructure and metadata theories applied in this thesis align well with one another. Both the information infrastructures theory and the metadata theory support processes within and across organizational borders. The information infrastructure theory has supported my understanding of the transition from local to enterprise. In this thesis the information infrastructure theory can be seen as the umbrella theory that the metadata theory actually is an inferior part of. The purpose of the metadata theory is to support the more detailed identification of elements of metadata that supports the contextual meaning and thereby sharing of information over organizational borders.

The theoretical framework has supported my thesis work with the understanding on how important metadata are for sharing in an information infrastructure, in particular when information is shared in a patient care process that spans over more than one healthcare organisation. The metadata element needed for sharing in radiology are less than one might expect, the metadata theory helped to identify the sources of the metadata used for secure sharing timely around the patients care process. Building the platform for introduction of new services, with focus on patient care any time- any place –any way.

5 MATERIAL

*“If I would asked my customers what they wanted,
they would have said a faster horse”.*
-Henry Ford

The material used for this study originates from VGR, geographically located on the west coast of Sweden. VGR was formed in 1999 by merging Skaraborg, Älvsborg and Bohus county councils and parts of the City of Göteborg. At the time of the merger, there were 17 active hospitals providing care for the inhabitants in the region. The Sahlgrenska University Hospital, in Gothenburg and Bohus county, is a cluster of hospitals associated with the Sahlgrenska Academy at the University of Gothenburg in Sweden. The current Sahlgrenska University Hospital was formed in 1997 by integrating the three hospitals Sahlgrenska University Hospital, Östra Hospital and Mölndals Hospital. The Sahlgrenska University Hospital has been operated by VGR since the health region was established in 1999. In terms of population, the region is the second largest of Sweden's counties and it is subdivided into 49 municipalities. Its population of 1,590,000 amounted to 17% of Sweden's population in 2011. The material is based on the period from 2006 until 2011, with a focus on the radiology departments managed by VGR. However, more actors and other radiology services were established in the healthcare arena during this time; for example, in 2011, the number of teleradiology examinations exceeded 30,000. The region is undergoing continuous transformation to better meet the needs of its inhabitants and following the guidelines from the government to meet tomorrow's need for eHealth, i.e. deployment of the national patient overview [49] as an example. In 2002, a decision was made to digitize all radiology departments in the region to better meet future needs for cooperation and sharing information concerning patients. This led to an agreement to create an Enterprise Information Archive (EIA) for radiology information, where both textual information and images could be shared (stored and distributed), from every hospital's local RIS and PACS systems, from the same virtual repository.

The design and use of the Information Infrastructure for sharing meant that a stronger focus was needed on healthcare standards and data quality issues in order to assure patient safety and patient rights. Another benefit from sharing information, beyond the quality of care for the patient, was the opportunity to learn from others and make it possible to faster introduce new services for the inhabitants.

Because the thesis is based on different kinds of materials, different methods have been used. In addition, there have been several organizational changes within VGR over the period from 2006 until 2012.

5.1 INTRODUCTORY STUDIES

A systematic literature review was undertaken to identify case, pilot, and preliminary studies conducted, using simulation as a planning tool prior to changes or alterations to

work practice and processes [75]. Two databases were used in June/July 2006, with a supplementary search conducted in March/April 2007: PubMed to overall cover the medical field and the Association for Computing Machinery digital library to cover the information system (IS) field at large. The studies included were published between 1970 and May 2007 and were intended to present the state of simulation during this period.

My research on cross-organizational sharing of radiology information based on qualitative data started in August 2003. Qualitative action research studies and quantitative studies were used as the approach in four introductory studies. This introductory research gave me an overview of problems facing cross-organizational sharing within radiology in VGR, Sweden and provided leads for future interesting studies. It also helped me to identify structural problems and to realize that the same problems are shared everywhere. In addition, it gave me an important network of people working in the same area of healthcare, as well as the contacts I already had as a radiology manager and radiographer. From the start, it was clear that the overall research ideas would relate to digitalization of radiology as well as to problems and possibilities related to digital cross-organizational sharing.

In the introductory phase the following papers contributed to my overall understanding of simulation, challenges and strategies related to cross-organizational work and should therefore also be mentioned:

- Wintell M., Lindsköld L., Gustafsson S., da Silva N., (2006). **Building an IT healthcare enterprise by taking the standards to the limits "and sometimes beyond that"**. *Medical imaging: PACS and imaging informatics*. Proc SPIE. 2006. p. 6145- 50
- Lindsköld, L., Wintell M., Lundberg N., (2008). **Prepare to share: it is all about e-care**. *Hospital Information & Technology Europe Summer Vol 1 No 2 2008*
- Lindsköld L., Aspelin P., Jacobsson B., Lundberg N., (2008). **The use of simulation in radiology**. *Radiology Management*. 2008 May-Jun;30(3):55-62
- Lindsköld, L., Wintell, M., Lundberg, N., (2010). **Interoperability in Healthcare – Major Challenges in the Creation of the Enterprise Environment** Vol. 7628: *Medical Imaging 2009: Advanced PACS-based Imaging Informatics and Therapeutic Applications*, Brent J. Liu; William W. Boonn, Editors, 762811
- Lindsköld, L., Wintell, M., Lundberg, N., (2010). **Pitfalls in Radiology Informatics when deploying an Enterprise Solution**. Vol. 7628: *Medical Imaging 2010: Advanced PACS-based Imaging Informatics and Therapeutic Applications*, Brent J. Liu; William W. Boonn, Editors, 76280Q
- Carlsson G., Wintell M., Lindsköld, L., (2010). **Displaying Dicom-SR reports on non-SR aware radiology workstations** Stockholm, Sweden Vol. 7628: *Medical Imaging 2010: Advanced PACS-based Imaging Informatics and Therapeutic Applications*, Brent J. Liu; William W. Boonn, Editors, 762811
- Wintell, M., Lundberg, N., Lindsköld, L., (2011) **XDS in Healthcare, Could it lead to a duplication problem? Simulated field study from VGR Sweden** *Medical Imaging 2011: Advanced PACS-based Imaging Informatics and Therapeutic Applications*, SPIE

5.2 FIRST STUDY (QUANTITATIVE STUDY)

- Simulation of Radiology Workflow and Throughput

The work is based on information from the radiology department at Alingsås Hospital (AH) in Sweden, which is part of the information infrastructure in VGR. The AH radiology department is one of 24 radiology departments in the 17 hospitals in VGR; see Figure 3. AH has a small radiology department with a throughput of some 34,000 examinations per year. The simulation data was collected from the information infrastructure and the local requirements. The enterprise architecture in 2006 held 24 radiology departments. The reference data set concerning, MRI examinations, which were not initially offered at AH, was based on 8 MRI installed laboratories in the enterprise, containing data from 2004, 2005 and 2006. All other reference data were based on AH data in their technical enterprise architecture, containing data from 2005 and 2006.

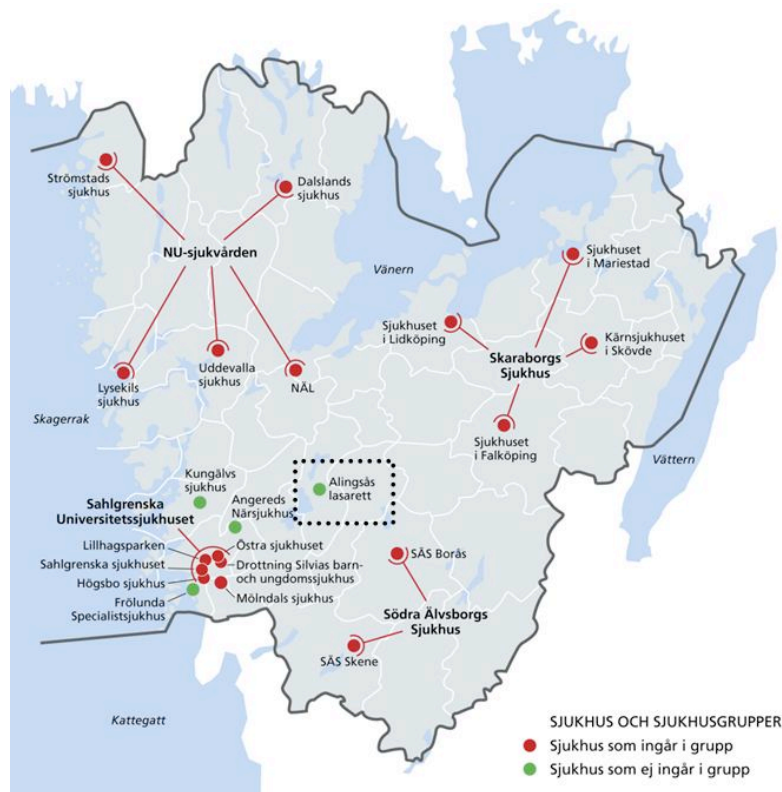


Figure 3. VGR geographical locations of the hospital groups and Alingsås Hospital.

The radiology departments offer a number of services to patients and care providers, and can be seen as a production line. The challenge for the radiology department is to find the most efficient way to fulfil the service requested from the users. There are a number of medical professions working at the radiology department. The classification of medical professions in this study is presented in Table 1.

Table 1. Number of employees in each profession in this study in 2006.

Medical profession	Number of employees in 2006
Radiologists	6
Radiographers	12
Assisting nurses	6
Secretaries	4
Total:	28

The type of services and the number of laboratories in this group, with their utilization in the radiology department at AH before the introduction of MRI services, are presented in Table 2. Note that second opinions are provided by the radiologist in the reading area and not by a specific laboratory.

Table 2. Number of laboratory rooms and the yearly production in 2006.

Type of Laboratory room	Number of Rooms year 2006	Examinations / year 2006
Second Opinion	1	888
Conventional	4	24960
Fluoroscopy	2	1212
Ultrasound	1	2448
Computed Tomography	1	4740
Total:	9	34 248

Patients can arrive in the radiology department from two different routes. One entry point is from the trauma centre, while the other is used for both in-house and ambulatory patients. The different possibilities for patients to enter the radiology department and the physical layout at AH are shown in Figure 4.



Figure 4. Entrances for patients and the physical layout of the radiology department at AH.

The simulation case required the use of data sets from EIA, i.e. containing data from similar modalities in other radiology departments and local data. In practice, it involved simulation of the medical staff's work and timing of patient examinations and diagnosis. It also showed the effects of changes in the use of physical space and resources.

Multimedia discrete event simulation, the technique used in this study, is one way of building up models to observe the time-based (or dynamic) behavior of a work process. There are formal methods for building simulation models and ensuring that they are credible. During the experimental phase in this study, the models were executed (run over time) in order to generate results, i.e. illustrating the outcome of another work process. In the simulation model, 600 examinations are described and divided into four sections, used in the simulation. 1) Examination identification (what was examined). 2) Time spent by each profession for the examination and time between two examinations. 3) Time spent by each profession for completion of the examination result. 4) Consumables and laboratory cost.

In Table 3, * indicates that the data are from the EIA, the sign ^ indicates local conditions and measurements.

Table 3. The data attributes used for the simulation divided into four sections.

STUDY IDENTIFICATION:	ID. Code*	Comment*	Priority^	Examination time*
	The code to identify the examination request	The plain text following the code	Priority - first choice of laboratory	Total time of examination
EXAMINATION TIME SPLIT:	Assisting nurse ^	Radiographer^	Intermediate time^	Radiologist's time in laboratory^
	Number and time for Assisting Nurse	Number and time of radiographers	Time between two examinations	Time that radiologist spent in laboratory
EXAMINATION FOLLOW UP:	Radiologist's reading time^	Radiologist's conference time^	Secretary's time^	
	For both primary reading and secondary reading.	The time the radiologist takes for the examination in a conference	The time for a secretary to write the report and release it	
CONSUMABLES & LABORATORY COST	Number of Images *	Contrast *	Consumables^	Laboratory in use ^
	Average number of images used	Contrast agent used in ml, if used.	Cost of other consumables	Rent, service cost, etc.

5.3 SECOND STUDY (ACTION RESEARCH)

- The process of defining a radiology enterprise workflow across organizational boundaries

Action research is a method that encourages researchers to experiment through action and to reflect on the effects of their intervention and the application of their theories [127-129]. Action research is conducted without attempting to distance or separate oneself from the activity or area that is the subject of research. The goal is to contribute to the solution of people's practical problems in a real situation [130, 131]. Knowledge is gained through action and for action [132]. Action research has recently been applied in the medical field [128, 129]. The focus of the study has been on getting the shared workflows to function successfully in the day-to-day environment, e.g. obtaining regional patient history and first/second opinion for use in teleradiology.

Collaboration with users, mainly radiologist and radiographers formed in different working groups has been central in the analysis of the shared workflow data elements. The task of the working groups work was to identify relevant metadata supporting regional patient history, first and second opinion as well as sending images only for the enterprise workflow. The data collection has been conducted by the help of these three working groups, each group meeting lasted for approximately two hours. The group leader took notes of the meetings to document what metadata the group considered to be important for their perspective on shared workflow. The notes were distributed to the members of the working group and were reviewed at the next meeting.

Thereafter the notes were analyzed and categorized by three of the four researchers, first one by one and then together to reach consensus on what metadata were needed for cross-organizational work. See Figure 5 for an overview of the different groups and their responsibilities.

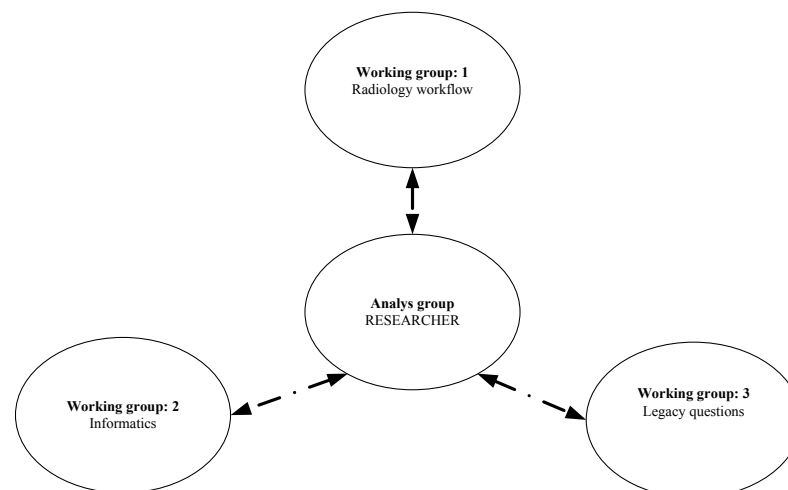


Figure 5. Illustration of working groups involved in the identification of metadata to be used in the enterprise workflow in VGR, and their relation to the researcher.

For the distribution of participants by profession in the working groups see Table 4. The individuals involved were selected by purposeful sampling [133]. The members of the working groups are drawn from the radiologists, radiographers, IT specialists, secretaries, radiology managers, and legal experts in the organizations associated with the project. Participants collaborated in the development of the information infrastructure through face-to-face discussion groups, in all 37 individuals participated in the process of identifying metadata.

Table 4. Material overview: consisting of number of actors and groups included in study

Profession	WG1	WG2	WG3
Radiologists	8	1	0
Radiographers	8	3	0
Radiology engineers	0	0	0
IT specialists	1	1	0
Secretaries	4	4	0
Radiology managers	0	0	6
Healthcare managers	0	0	0
Legal expert	0	0	1
Total:	21	9	7

More specifically the working groups focused on questions related to metadata elements needed for cross organizational sharing of information. However they did this from their perspective, i.e. from radiology workflow perspective, informatics perspective and legacy questions perspective.

Table 5. Number of meetings within each working group.

	WG1	WG2	WG3
Number of meetings	3	10	2

The number of group meetings is described in Table 5. Most meetings in the groups were done in the informatics groups. That group also created the information model.

5.4 THIRD STUDY (QUANTITATIVE)

- Cross-organizational Workflow in Radiology

This work is based on an information infrastructure supporting the radiology workflows in VGR, in use since 2006. The enterprise workflow includes different RIS and PACS systems. The technically enterprise architecture includes four different RIS systems and five different PACS systems. All radiology departments have translated and merged their imaging information from local RIS formats and PACS formats into the alignment of shared information models, technical standards/frameworks, worldwide healthcare standards and interoperability/interaction technology. In 2012, more than 430 terabytes of

information (equivalent to more than 800 million images) had been stored and distributed across enterprise architecture in the shared information infrastructure in VGR.

Included in this study were the 24 publicly owned radiology departments in the VGR shared enterprise workflow. The departments that were included used 160 different modalities, connected to three different PACS with eight databases in use and two different RIS with eight databases in use. See Table 6.

Table 6: Hospital groups and hospitals included in the study, showing departments, number of modalities in use and RIS / PACS databases 2011.

Hospital Groups, Hospitals included in this study	Number of Departments	Number of Modalities	Number of RIS DB	Number of PACS DB	RIS Vendor	PACS Vendor
Hospital Group 1. University,	8	53	2	2	SECTRA /	SECTRA/G
Hospital Group 2. NU	4	31	1	1	SECTRA	AGFA
Hospital Group 3. SÄS	4	24	1	1	SECTRA	SECTRA
Hospital Group 4. SkaS	4	28	1	1	SECTRA	SECTRA
Hospital 1. Alingsås	1	9	1	1	SECTRA	SECTRA
Hospital 2. Kungälv	2	11	1	1	SECTRA	SECTRA
Hospital 3. ESS	1	4	1	1	ADAPT	GE
Total:	24	160	8	8		

A quantitative method was chosen to identify whether metadata was missing or if it held syntax or semantic errors. The metadata analyzed included 1) patient name, 2) patient-ID, 3) institutional department name where the study was performed, 4) name of the referring physician, and 5) study description in plain text.

The metadata analyzed came from four hospital groups with their own RIS and PACS, and three stand-alone hospitals with their own RIS and PACS, as described in Table 6.

Only the missing data was identified over the longitudinal period of six years (first Wednesday in March for each of the years 2006 to 2011).

When exploring semantic and syntax errors, the study included findings from the first Wednesday in March year 2011.

The VGR information model [134] for metadata is based on the syntax and semantics defined by Swedish legal sources and technical standards. The metadata, their semantic, syntax and legal sources are described in Table 7.

Table 7. Description of metadata used for achieving cross-organizational data sharing in VGR, Sweden.

Metadata	Syntax	Semantic	Legal sources
(1) Patient name	Surname^ First name	Needs to contain something, letter or number. Surname^First name ^^, should always be present.	Swedish tax agency register: a name registered at birth or of entry into Sweden, as determined by the Swedish Population Registration Act, (1991:481)
(2) Patient –ID	YYYYMMDDXXXX	Swedish national personal identification number comprising the date of birth, a 3-digit number and a checksum digit.	The Swedish tax agency creates a record at the time of birth or of entry into Sweden, as determined by the Swedish Population Registration Act, Folkbokföringslag (1991:481)
(3) Institutional department name	Department of Radiology	Used name information from HSA- National Directory, which contains the official name of the Institutional department name	The name used in the HSA – National Directory- a national address directory of healthcare service providers, linking all regional-level eDirectories.
(4) Referring physician	Surname^ First name	Used name information from HSA- National Directory. Surname^ First name ^^.	The name used in the HSA directory
(5) Study description	Plain text description Example: CT Brain	Text used to describe the study to the radiologist/ consumer/clinician.	The Swedish codes to define radiology services are applied. This set of codes is called the “Classification of radiology studies – 1991” (KRÅ-91).

(1: <http://www.opengov.se/govtrack/sfs/1991:481/> accessed 2011-08-04)

(2:

[http://www.skatteverket.se/download/18.5cbdbba811c9a768f0c80002830/717b04.pdf?posid=47&sv.search.query.allword=s=personal id number](http://www.skatteverket.se/download/18.5cbdbba811c9a768f0c80002830/717b04.pdf?posid=47&sv.search.query.allword=s=personal+id+number) accessed 2011-08-04)

(3: <http://www.epractice.eu/en/news/325554> accessed 2011-08-04)

(4: <http://www.epractice.eu/en/news/325554> accessed 2011-08-04)

(5 <http://www.socialstyrelsen.se/klassificeringochkoder/atgardskoder/> accessed 2011-08-04)

5.5 FOURTH (ACTION RESEARCH)

- The Future Progress of Teleradiology

In essence, the material is divided into individuals and radiology units with their producing systems. Individuals collaborated in the development of the information infrastructure through face-to-face discussion groups and blogs: 37 individuals in physical discussion groups and 34 individuals active in the blog.

See Table 8 for the distribution by profession. They have all been interested in the development and change that distributed radiology can achieve in their daily workflow.

Table 8. Number of actors and activities in this study

Profession	Group discussion	Blog
Radiologist	1	3
Radiographers	4	8
X-ray engineers	6	6
IT specialists	5	0
Physicist	1	1
Secretaries	5	9
X-ray managers	8	0
Vendor representatives	4	4
Total:	37	34

The individuals involved in the group discussion were selected by their superior manager; access to the blog was granted by the director of the department. Out of the radiology managers three were radiologist by profession, two radiographers, one physicist and two nurses, the vendor representative were from General Electric and SPECTRA.

The work is based on the 24 departments in the public healthcare sector clustered into one university group, three hospital groups and two small hospitals. Four PACS vendors and three RIS vendors are producers in the information infrastructure. Table 9 shows details of the hospital groups with the number of departments and the Vendors involved.

Table 9: Presentation of type of hospitals, number of departments and vendors involved in this study

Hospital groups and Hospital	No. of departments	PACS/RIS vendors
Sahlgrenska University	10	GE Centricity PACS/ Adant
Hospital Group 1: SKaS	3	Siemens PACS and RIS
Hospital Group 2: NU	6	Agfa PACS/ Sectra RIS
Hospital Group 3: SÄS	3	Sectra PACS/RIS
Alingsås Hospital	1	Sectra PACS/RIS
Kungälv Hospital	1	Sectra PACS/RIS
Total:	24	

6 METHOD

*“Everything is hard before it is easy”
-Johann Wolfgang von Goethe*

In this section, a description of the methods used for this thesis is presented, where the study design combines quantitative and qualitative methods, an approach known as triangulation. Triangulation refers to the use of more than one approach to the investigation of a research question in order to enhance confidence in the ensuing findings [135, 136]. In the next section, triangulation in general and why it was chosen for this study will be described.

6.1 TRIANGULATION

Medical informatics is a research field where several different methods are widely applied. This is because the field deals both with social behavioral issues, such as work practice and health care management, and with technical issues, such as data quality and software design. Medical informatics studies are usually founded on one of these approaches - either social or technical research. However, for this study, we chose to combine these research methods to cover both work practice issues from a social perspective and data quality issues from a technical perspective. According to Dootson [137], the rationale of using triangulation is that the results obtained from two or more methods can be combined to enhance confidence in the findings.

The word “triangulation” derives from surveying, where it refers to the use of a series of triangles to map out an area from several perspectives [135]. According to Jick [136], uncertainty about the research result is greatly reduced when a finding has been confirmed by two or more independent method processes.

This study applies a methodologically inspired triangulation, also referred to as a mixed-method research design [135]. I have combined quantitative and qualitative research methods to provide a more complete set of findings than could be arrived at through the administration of one of the methods alone. However, in this study the same data have not been correlated by collecting them with different methods. Instead, different data have been collected using different methods. I have cross-complemented my research by using different methods. This is referred to as between-method triangulation [138]. The design of the cross-organizational workflow employed both focus groups and data collection from different sources as well as simulation. The different sets of findings mutually supported how the design of the cross-organizational work was to be developed. Data had to be combined and looked upon as a whole in order to understand both technical and social issues related to cross-organizational workflow. Such workflow is new and innovative within healthcare. It includes many different organizations, professional groups, activities and data sources and is thus highly complex by nature. In order to

achieve data richness, triangulation could provide a way to enhance the credibility of complex research work.

Applying focus groups in the investigation of general issues related to workflow and practice could be a way of understanding the complexity. Through quantitative studies of data sources, it was possible to identify the acts of individuals in various medical contexts. The general discussions were more focused on how things should be and how participants wished things were, while quantitative studies shed light on the current situation and reality related to work. Through the qualitative studies, important topics were identified and could thereafter be discussed in the focus groups.

With the use of different methods and sources to collect data, there is always a risk of inconsistency of data quality. However, in this study the large data sets derived from 24 radiology departments using the same agreed information model based on Swedish legal sources provide assurance of the quantitative data quality. The action research data were collected from a consortium representing 24 radiology departments. The high number of actors involved is another factor that increases the probability of receiving high-quality data. When more than one theory is used, the likelihood of identifying new questions at hand increases. These new questions may hinder the researcher's ability to explore the subject at issue in enough depth. In addition, using several different research methods is very time consuming. It takes time for the researcher to adjust and use different methods. Also, it requires more time to combine findings from different methods compared to using just one.

6.2 FIRST STUDY (QUANTITATIVE STUDY)

- Simulation of Radiology Workflow and Throughput

In this study, quantitative data analysis has been used to design and implement the simulation of the utilization of work spaces and examination throughput performance. To build the platform and its relations within the simulation model, a quantitative approach was applied using measurable data from different sources. The reference data for the simulation were collected by means of Structured Query Language (SQL) queries to the EIA, and by local measurements e.g. physical layout of spaces.

A simulation service consists of four parts: 1) *the reference data*, including real-life output figures from seven other radiology departments in enterprise architecture in this case, i.e. *base information*; 2) *information on local requirements*, e.g. number of employees, opening hours, and physical layout of spaces; 3) the *process module*, which contains and visualizes all activities and their relations in a workflow; 4) *results*, which visualize the impact and results of the altered workflow based on reference material and the local requirements. Part 1 and 2 are input modules to the simulation, part 3 is the running process module, and part 4 is the output model visualizing the results: organizational change. Commercially available software was used to develop the model. The model was written and run in Arena™ simulation software. For basic setup of data used in the model and the input of data and output of information, Microsoft Excel was

used. The model could thus be accessed from any computer with the Microsoft operating system installed and the following programs: Microsoft Excel TM and a runtime version of Arena TM simulation software from Rockwell Automation, USA. The simulation service consists of four parts in three modules, see Figure 6.

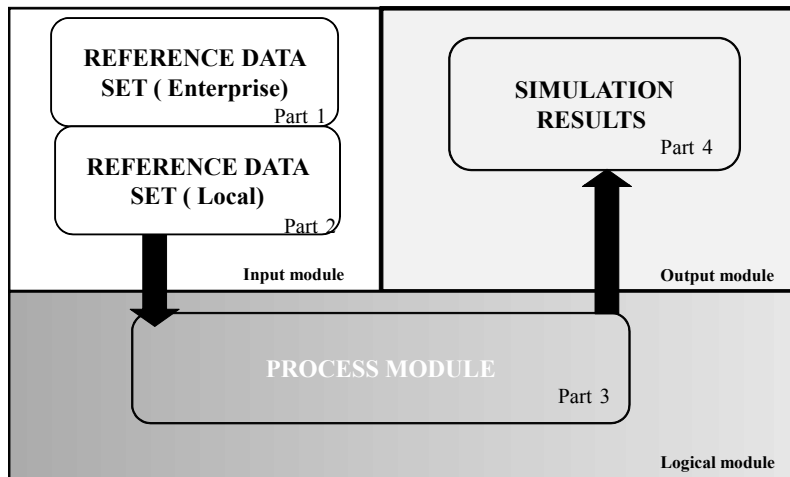


Figure 6. The three modules building up the simulation model.

The simulation model could be described as a decision support tool using discrete event simulation. Software was used for discrete event simulation to build up the model to observe the time-based (or dynamic) behaviour of the services provided at the AH radiology department. In practice, this is achieved by applying flow charts that would be used in the model. With the help of a computer, the simulation service creates a model in which different processes and flows in an organization are described.

The model visualizes the relationship between different activities and generates data to demonstrate the impact of altering an input parameter or an activity. Queues and bottlenecks can be shown as well as how resources are used and how the demands on time and quality are met.

During a simulation, the software controls the object randomly according to certain predetermined patterns (stochastic distributions), which are built into the model through the logic. In a stochastic process there is some indeterminacy in its future evolution described by probability distributions. This means that even if the initial condition (or starting point) is known, there are many possibilities the process might go to, but some paths may be more probable and others less so.

The simulation software keeps track of resources and where they are in the workflow process description. The simulation software supports visualization dynamically

generated on the basis of staged activities in the workflow process with the logic applied for the scenario. The discrete event-driven simulation model describes the movement of patients through a series of events, which are assumed to happen at discrete points in time. The structure of the model reflects the pattern and timing of the service provided at the radiology department.

The logic process module located in **ARENA** TM behind the discrete event-driven (dynamic) simulation service applied is as follows: We were using ARENA TM software for discrete event simulation to build up the model to observe the time-based (or dynamic) behaviour of the radiology service provided at the AH radiology department. In practice, this is achieved by applying flow charts that will be used in the model. See Figure 7 for an example.

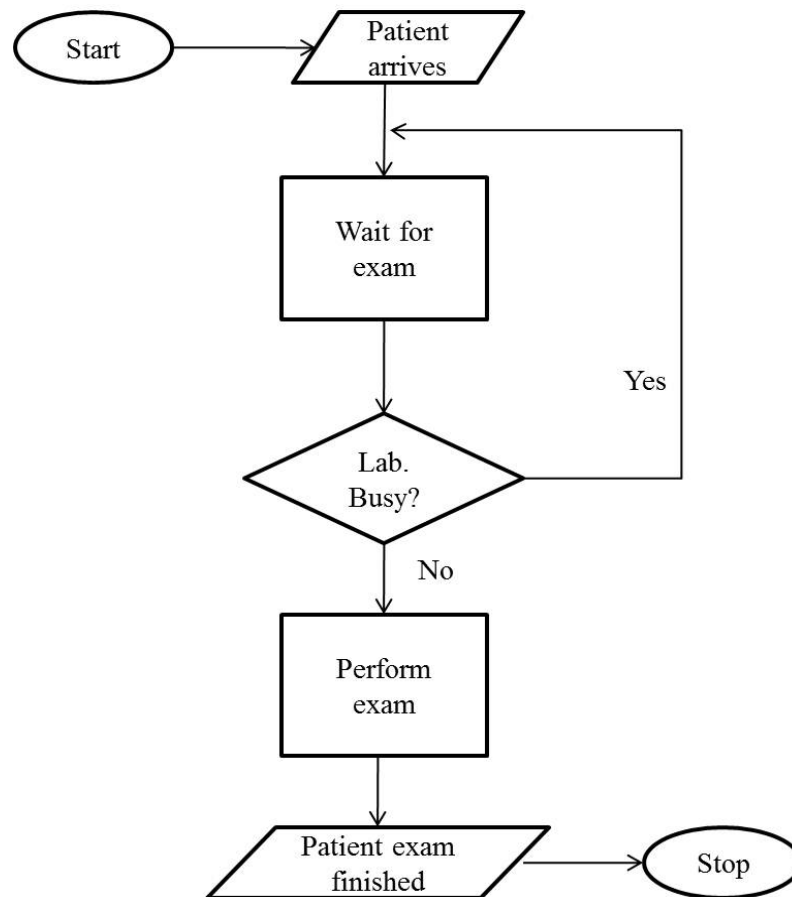


Figure 7. Example of a flow chart diagram used in the model.

With the help of a computer, the simulation services create a model in which different processes and flows in an organization are described. The model visualizes the

relationship between different activities and generates data to demonstrate the impact of altering an input parameter or an activity. Queues and bottlenecks can be shown as well as how resources are used and how the demands on time and quality are met.

The simulation software keeps track of resources and where they are in the workflow process description. The simulation software supports visualization dynamically generated on the basis of staged activities in the workflow process with the logic applied for the scenario.

The discrete event-driven simulation model describes the movement of patients through a series of events, which are assumed to happen at discrete points in time. The structure of the model reflects the pattern and timing of the service provided at the radiology department.

The Output module visualizes the outcome and results from the simulation. We were using the same Excel TM application that was used for the two different input parts of the model to display the output and results from the discrete event simulation performed.

The scenario that was simulated is described as follows:

- a) The throughput volume was stable, i.e. using the data figures from the year before
- b) One new MRI laboratory was opened
- c) Two laboratories were closed down to make room for the MRI

The following information was returned from the simulation to the Microsoft Excel TM application for review:

- a) The usage in % of the utilization for each laboratory
- b) The number of examinations performed per day and laboratory
- c) Staff requirements per day and profession

6.3 SECOND STUDY (ACTION RESEARCH)

- The process of defining a radiology enterprise workflow across organizational boundaries

Action research is a method that encourages researchers to experiment through action and to reflect on the effects of their intervention and the application of their theories [5-7]. Action research has recently been applied in the medical field [128, 129]. As this paper reports on the process of identifying the metadata elements needed to share radiology information, the need for collaboration between researchers and practitioners may be obvious. The focus of the study has been on getting the shared workflows to function successfully in the daily routines. There has been an iterative cycle of planning-action-reflection throughout the project, with an emphasis on development, change, and collaboration with the medical staff. In practice, solving problems associated with the sharing of information to support collaboration over time and geographical space has been part of the action. During this process, it has been possible to reflect on any suggestions relating to the data elements needed to support regional collaboration around radiology studies.

The scalability and flexibility of data elements has been necessary for an increasingly shared workflow. In the collaboration between users and the research team, the research team had the role of communicating information between users and the vendors of the PACS/RIS systems used. Collaboration with users has been central in the analysis of the shared workflow data elements. In the work of describing and analyzing metadata which are required for enterprise workflow firstly a number of work steps were identified as central, according to the users involved in working groups. These central work steps were: 1) getting to know the patients demographics, 2) getting to know the content in patient electronic request, 3) knowing where request was sent from and 4) knowing that the report is written on the request. Those work steps were identified in the radiology information systems database tables.

It was important for the working groups that the steps included an input-, throughput- and output phase as well as offered feedback loops. Each step included a number of information objects. To qualify as a metadata object a data element needed to be included in all phases. The scope of this study includes the staff in radiology related to the shared virtual workflow in the VGR region, but excludes any focus on the clinicians' use of the virtual workflow, although they are included in it in practice.

6.4 THIRD STUDY (QUANTITATIVE)

- Cross-organizational Workflow in Radiology

A quantitative method was chosen to identify whether metadata were missing or whether they contained syntax errors or semantic errors. Data were collected by means of Structured Query Language (SQL) queries to the EIA. SQL is a standardized query

language for relational databases. A relational database is built up with tables that have relations between them.

The SQL requests provided data from a total of six days, spread over six years: the first Wednesday in March for each of the years 2006 to 2011. Only the missing data were identified over the longitudinal period of six years. The missing metadata of entries for patient name, patient ID, name of the institution and department where the study was performed, name of the referring clinician, and study description in plain text were analyzed through the identification of missing data.

The findings related to missing data led us to investigate syntax and semantic errors as well. For semantic and syntax errors, the study included findings from the year 2011. The VGR information model for metadata is based on the syntax and semantics defined by Swedish legal sources. The metadata as well as their semantic structure, syntax and legal sources are described previously in Table 7.

The study focused on the empirical pitfalls that may arise when metadata are used from different local workflows in an information infrastructure for enterprise workflows. In practice, this has been done by comparing the syntax and semantic conformance with the information model used.

The data collected were first retrieved via SQL from the shared EIA. Second, they were used in the statistical analysis application Statistica 10.0™. Third, missing data as well as semantic and syntax errors were identified through quantitative data analyses.

6.5 FOURTH STUDY (ACTION RESEARCH)

- The Future Progress of Teleradiology

As the purpose of this project was to implement a distributed radiology service, the need for collaboration between researchers and users was obvious. The focus has been on practical issues. There has been an iterative cycle of plan-act-reflect throughout the project with an emphasis on development, change and collaboration with users. In practice, solving current and real-life problems in specific radiological work activities has been part of the action. During this process, it was possible to reflect on any suggestions for development immediately.

The solutions to problems were implemented promptly in accordance with existing radiological work processes. In the collaboration between users and the research team, the research team had the role of communicating information between users and vendors of the systems involved. Collaboration with the users has been central in the workflow analysis and information infrastructure structure.

7 RESULT

*“Nature is an infinite sphere of which the centre is everywhere and the circumference is nowhere.”
-Blaise Pascal*

Several introductory action research studies exploring the radiology infrastructure, interoperability and standards were carried out between August 2006 and May 2011 [15-17, 139, 140]. Also an introductory literature review was completed 2008 [75].

The introductory literature review within the medical management field has shown that simulation models can increase understanding of complex systems in transformation [53-65]. In addition, studies show that data collection and mining represent an excellent investment in understanding complex systems and that simulation models can be applied for change management. In order to assess the effect of various proposals for new operating models, communication models, use of spaces, and patient flow simulation models as a planning tool, simulation can be applied to give the user as realistic a model of the real-world system as possible [66-72]. The intention of the simulation system has been to provide support for making the best decisions prior to change and to obtain users' acceptance of change prior to and during the implementation of a change process.

These introductory studies provided insights into how to continue my research with more precise issues on the challenges involved in designing and adopting cross-organizational sharing based on qualitative data. The studies were subsequently followed up with quantitative studies. The aim of the quantitative studies was to improve understanding and provide strategies for cross-organizational radiology work in VGR and in general. Below, I summarize and relate the five papers that address the research issues of the thesis.

7.1 FIRST STUDY (QUANTITATIVE)

- Simulation of Radiology Workflow and Throughput

In this paper, we investigate and explore, through the use of simulation, whether a MRI could be funded and implemented in AH without hiring any more medical professionals and whether the simulated results were consistent with the real-life results over time. When simulation data were collected, they were converted into Excel™ format. The simulation program retrieved and loaded data from the Excel files and automatically converted the data into the format used by the simulation program. The simulations were carried out based on two scenarios, one without the implementation of a new MRI and one with the implementation of a new MRI. In the later scenario, the simulation also included closing down two older X-ray laboratories at AH.

In Table 10, the results from the simulation scenarios in 2006 are compared with the real-life throughput year 2008 and 2009.

Table 10. Simulation results, from year 2006 for year 2008, of number of examinations throughput, per 28 days divided upon radiology modality services compared to real life examination throughput from 2008 and 2009. These results are taken after the department had invested in and implemented one new MRI laboratory and closed down two laboratories, at AH.

Laboratory	Simulation from 2006 of the expected examination throughput results 2008	Facit- examinations throughput 2008	Actual examinations throughput 2009
MRI	176	172	206
CT	412	440	481
US	220	256	259
Conv.	705	629	622
Conv. 2	0	0	0
Trauma	1 235	1288	1449 ¹
Fluoro.	80	73	61
Fluoro. 2	0	0	0
Second Opinion	68	52	43
Total 28 days	2896	2910	3121
Total per year	34 752	34 915	37 452

In Table 11, the top row states the number of professionals who are scheduled to work on any given normal weekday. The number of professionals multiplied by an 8-hour workday indicates the total production time (hours/day) for each group of professionals during a normal workday. The average time for each group of professionals is listed for both scenarios used, with and without MRI and laboratories closed down.

Table 11. Human resources utilization, by means of hours, expected hours for simulated work year 2008, for two scenarios: 1) Without a new MRI laboratory and no changes in the number of laboratories, 2) With one new MRI laboratory implemented and two laboratories closed down. The simulation was conducted in year 2006 regarding the expected simulated hours of work 2008.

Medical profession	Radiologist	Radiographers	Assisting nurse	Secretaries
Number of professionals at work, normal weekday	5	7	3.75	2.75
Total working hours -per weekday e.g. profession times 8 hours working day X Number of persons at work.	40	56	30	22
1) No. of expected hours utilized in laboratory production, without any changes in laboratory recourses regarding year 2008	22	24	24	12
2) No. of expected hours utilized in laboratory production, with one new MRI laboratory and two closed laboratories regarding year 2008	24	40	27	12

¹ The number of examinations for conventional radiography increased in 2009 because the hospital was forced to perform more orthopedic operations.

7.2 SECOND STUDY (ACTION RESEARCH)

- The process of defining a radiology enterprise workflow across organizational boundaries

In the work of describing and analyzing metadata which are required for enterprise workflow firstly a number of work steps were identified as central, according to the users involved in this study.

These central work steps were: 1) getting to know the patients demographics, 2) getting to know the content in patient electronic request, 3) knowing where request was sent from and 4) knowing that the report is written on the request.

Those work steps were identified in the radiology information systems database tables. It was important for the working groups that the steps included an input-, throughput- and output phase as well as offered feedback loops. Each step included a number of information objects.

To qualify as a metadata object a data element needed to be included in all phases. The qualified metadata are shown in Table 12. For all checked data element and workflow steps, see appendix 1 in the original article.

Table 12. Identified and suggested metadata by Working Group 1: radiology workflow questions, 2: informatics; 3: legacy questions.

Workflow Steps	Input	Throughput	Output	Feedback
Metadata Element: Patient Demographics				
Patient ID	X	X	X	X
Patient name	X	X	X	X
Metadata Element: Patient Electronic Request				
Patient-ID	X	X	X	X
Institutional department name	X	X	X	X
Referring Physician according to Swedish healthcare address	X	X	X	X
Metadata Element: Patient arrival department				
Institutional department name	X	X	X	X
Metadata Element: Patient report				
Examination description in plain text	X	X	X	X

The data elements that were qualified as metadata elements needed for cross-organizational sharing were by the researcher also analyzed if there were any national sources available for those metadata, the identified sources are shown in table 13.

The table also includes the working group's discussion for the identification of the need for that data element in a shared enterprise workflow, as well as their national sources and semantics, in the Swedish context.

Table 13. Metadata sources needed for regional patient history and first/second opinion and image send only in VGR.

Discussion	Metadata	Metadata sources	Data element Semantics ⁷
When treating a patient, the clinician needs to know the name of the patient.	(1) Patient name	Swedish tax agency (Skatteverket – SKV) at the time of birth or of move to Sweden, as determined by the Swedish Population Registration Act, Folkbokföringslag (1991:481)	Surname^ First name
The Patient ID in Sweden is unique for each person, and is a prerequisite to ensure that the patient demographics are secured.	(2) Patient-ID	(Skatteverket – SKV) at the time of birth or of move to Sweden, as determined by the Swedish Population Registration Act, Folkbokföringslag (1991:481)	YYYYMMDDXXXX
Within an enterprise workflow, it is necessary to understand who the producer of the examination is.	(3) Institution department name	The name used in the HSA – National Directory- a national address directory of healthcare service providers, linking all regional-level eDirectories.	Department of Radiology XX
The identification of the referring clinician is essential if additional information is needed about the patient.	(4) Referring physician	The name used in the HSA directory	Surname^ First name
Plain text details used in the region to indicate to the consumer what the clinical examination concerned	(5) Study description	The Swedish codes to define radiology services are applied. This set of codes is called the “Classification of radiology studies – 1991” (KRÅ-91).examinations – 1991” (Krå91).	Plain text description Example: CT Brain

(1: <http://www.opengov.se/govtrack/sfs/1991:481/> accessed 2011-08-04)

(2: [http://www.skatteverket.se/download/18.5cddbba811c9a768f0c80002830/717b04.pdf?posid=47&sv.search.query.allwords=personal id number](http://www.skatteverket.se/download/18.5cddbba811c9a768f0c80002830/717b04.pdf?posid=47&sv.search.query.allwords=personal+id+number) accessed 2011-08-04)

(3: <http://www.epractice.eu/en/news/325554> accessed 2011-08-04)

(4: <http://www.epractice.eu/en/news/325554> accessed 2011-08-04)

(5 <http://www.socialstyrelsen.se/klassificeringochkoder/atgardskoder/> accessed 2011-08-04)

7.3 THIRD STUDY (QUANTITATIVE)

- Cross-organizational Workflow in Radiology

In this section firstly the summary of missing data relating to the five data elements is presented in Table 14, thereafter the summary of semantic errors related to data elements of metadata are presented.

Table 14. Percentage of missing metadata elements collected from the first Wednesday in March from 2006 to 2011.

Missing data Red =missing data in percentage							
	Data elements	2006	2007	2008	2009	2010	2011
Hospital group 1. University	No missing data	0 %	0 %	0 %	0 %	0 %	0 %
	Total data element included:	926	932	1135	1226	1116	1303
Hospital group 2. NU	Institutional department name	7 %	12 %	7 %	0,5 %	0,5 %	0 %
	Total data element included:	624	568	528	619	644	760
	Institutional department name	37 %	42 %	44 %	39 %	19 %	13 %
Hospital group 3. SÄS	Referring physicians name	0 %	0 %	0 %	10 %	8 %	0,4 %
	Study description	0 %	0 %	0 %	10 %	8 %	0 %
	Total data element included:	409	409	393	487	533	481
Hospital group 4. SkaS	Institutional department name	27 %	67 %	71 %	61 %	1 %	13 %
	Referring physicians name	0 %	0 %	0 %	0 %	1 %	0 %
	Total data element included:	15	18	31	504	515	560
Hospital 1. Alingsås	Institutional department name	47 %	57 %	0 %	33 %	2 %	46 %
	Total data element included:	156	150	134	144	158	128
	Institutional department name	87 %	86 %	58 %	52 %	27 %	25 %
Hospital 2. Kungälv	Referring physicians name	0 %	0 %	0 %	11 %	11 %	0 %
	Study description	0 %	0 %	0 %	11 %	11 %	0 %
	Total data element included:	171	174	154	221	205	220
Hospital 3. FSS	No missing data	0 %	0 %	0 %	0 %	0 %	0 %
	Total data element included:	70	70	81	80	77	85

As shown in Table 14 the data quality improves over time, e.g. less metadata elements are missing in the enterprise radiology service. It also shows that it is only Hospital Group 1, University Hospital SU and Hospital 3, FSS using the regionally developed RIS system that has no missing data elements of metadata.

In the following section the semantic errors of data elements is presented in percentage. The semantics of the stored data elements in VGR are compared against the semantic guidelines from the Swedish legal sources to identify the errors.

Table 15. Percentage of incorrect semantic content of the data elements relating to Patient names in terms of the information model used in VGR.

Patient name Red =Incorrect semantic use			
According to Swedish tax agency	Incorrect semantic use in %	Correct semantic use in %	Total data elements included
Hospital group 1. University SU	99,8 %	0,2 %	1303
Hospital group 2. NU	100 %	0 %	760
Hospital group 3. SÄS	100 %	0 %	481
Hospital group 3. SkaS	100 %	0 %	560
Hospital 1. Alingsås	100 %	0 %	128
Hospital 2. Kungälv	100 %	0 %	220
Hospital 3. FSS	100 %	0 %	85

Patient name was in majority incorrect semantically applied in compliance to both the regional information model in VGR, the DICOM data model and to the Swedish tax agency register (national) guidelines. The variation in semantics for patient name varied from the one in the information model “Doe^Joe” to five other ways of semantically presenting the name. These five other ways are shown more in detail in Table 16.

Table 16. Patient name variations for all hospitals in relation to the specifications in the information model used in VGR.

Patient name variation Red =Incorrect semantic use			
Semantically correct	Incorrect semantic	In %	Total data elements included
Doe^John		0,07 %	3
	DOE^JOHN	54,66 %	1933
	Doe, John	37,26 %	1318
	John Doe	7,46 %	264
	Doe^JOHN	0,52 %	18
	DOE, JOHN	0,03 %	1
	Total:	100 %	3537

The ^ sign is the delimiter used in the DICOM standard to indicate the space between the surname and first name. The ^sign never occurs in a viewing application that natively supports DICOM objects.

Table 17. Patient-ID variations for all hospitals in relation to the specifications in the information model used in VGR.

Patient-ID Red =Incorrect semantic use			
According to HSA-National Directory	Incorrect semantic use in %	Correct semantic use in %	Total data elements included
Hospital group 1. University SU	0 %	100 %	1303
Hospital group 2. NU	0 %	100 %	760
Hospital group 3. SÄS	0 %	100 %	481
Hospital group 3. SkaS	0 %	100 %	560
Hospital 1. Alingsås	0 %	100 %	128
Hospital 2. Kungälv	0 %	100 %	220
Hospital 3. FSS	0 %	100 %	85

All of the studies included a patient-ID in the correct metadata field, with the correct syntax and semantics. Sweden has a long tradition of using the national identification number as a patient-ID. The national identification number is a key metadata field in Sweden, and it is used routinely in many different aspects of daily life: it is difficult to receive one's salary or to buy a car without this number.

Table 18. Institutional department name variations for all hospitals in relation to the specifications in the information model used in VGR.

Institutional department name Red =Incorrect semantic use				
According to HSA-National Directory	Incorrect semantic use in %	Correct semantic use in %	Missing	Total data element included
Hospital Group 1. University, SU	0 %	100 %	0 %	1303
Hospital Group 2, NU	99,5 %	0 %	0,5 %	760
Hospital Group 3, SÄS	84 %	4 %	12 %	481
Hospital Group 4, SkaS	87 %	0 %	13 %	560
Hospital 1, Alingsås	13 %	41 %	46 %	128
Hospital 2, Kungälv	40 %	23 %	37 %	220
Hospital3, FSS	0 %	100 %	0 %	85

The name of the institutional department name where the study was performed is the metadata field that had the highest percentage of missing entries as seen in Table 18. In the local systems, the Institutional department name was represented by all sorts of different abbreviations. These abbreviations had a local meaning for the different

accounting and other administrative systems. And did not follow the HSA-National Directory [141] naming.

Table 19. Referring physician's name variations for all hospitals in relation to the specifications in the information model used in VGR. One patient was missing from Hospital group 3, SÅS.

Referring physicians's name Red =Incorrect semantic use			
According to HSA-National Directory	Incorrect semantic use in %	Correct semantic use in %	Total data elements included
Hospital group 1. University	100 %	0 %	1303
Hospital group 2. NU	100 %	0 %	760
Hospital group 3. SÅS	100 %	0 %	(1 missing)480
Hospital group 3. SkaS	100 %	0 %	560
Hospital 1. Alingsås	100 %	0 %	128
Hospital 2. Kungälv	100 %	0 %	220
Hospital 3. FSS	100 %	0 %	85

The coding for the “referring physician's name”, giving the name of the doctor responsible for the request, were 100 % semantically incorrect in relation to the VGR information model, as seen in Table 19. At Hospital group 1. University SU and Hospital 3. FSS several instances of incorrect syntax were used: instead of the personal name, numerals and letters combined were used to indicate where the invoice should be sent instead of identifying responsible doctor.

Semantic variation was also visible in the different layouts used for displaying the name of the referring physician, which were not consistent with the national HSA ID used in the regional information model.

Table 20. Plain text variation for study descriptions presenting the five most commonly used study codes in the VGR region.

Number of different study descriptions per each selected KRÄ-91 code		
Krä-91 [code]	KRÄ-91 Study description in plain text	Number of different plain text descriptions
[32000]	Heart and lungs (with or without heart volume judgment)	4
[63900]	Hip joint with half axial lateral image	8
[63800]	Hand or part thereof (intermediary fingers)	15
[64800]	Calcaneus, metatarsal, toes	13
[81000]	CT brain	9

The five most frequently used KRÅ-91 codes represented almost 30% of all entered “study descriptions”. In total, there were 285 unique study codes listed in terms of the Swedish national classification index, KRÅ-91. Therefore one would expect that there would be a maximum of 285 unique plain texts of “Study descriptions” entered. Instead, there were 417 different plain text descriptions. Table 20 shows the number of instances in which the plain text descriptions of the top five study codes are not described correctly in terms of KRÅ-91.

The semantic variation in the study descriptions was found to be considerable. When different plain text interpretations exist for the same code in the region, this is liable to cause misunderstandings. It is especially confusing when study descriptions from different departments are shared in the same view from the regional service as seen in Table 21.

Table 21. Plain text for study descriptions divided by hospital groups and individual hospitals for the five most commonly conducted studies in VGR.

Study description Red =Incorrect semantic use							
KRÅ-91 Study description in plain text	Hospital group 1, University SU	Hospital group 2, NU	Hospital group 3, SÅS	Hospital group 4, SkaS	Hospital 1, Alingsås	Hospital 2, Kungälv	Hospital 3, FSS
Heart and lungs (with or without heart volume judgment)	Heart and lungs	LUNGS	LUNGS	X-ray Lungs	LUNGS HEART AND LUNGS	LUNGS	Heart and lungs
Hip joint with half axial lateral image	Pelvis/ Hip Joints	HIP	HIP DX	HIP JOINT	HIP	HIP right	Pelvis/ Hip Joints
		HIP SIN	HIP	Hip joint		HIP left	Hip joint
Hand or part thereof (intermediary fingers)	HAND	HAND OR PART THEREOF	Wrist-Schapoideum	Hand/ Finger	Hand/ Fingers	Hand/ Fingers	Hand or part thereof fingers
	HAND DX						
	HAND SIN		Hand		Hand and fingers left	hand and fingers left	
	HAND left						
	HAND right		Hand or part thereof, fingers			hand and fingers right	
Calcaneus, metatarsal, toes	HEEL, BONE, METATARSAL-TOES	FOOT	Foot	Foot, calcaneus, toes	Calcaneus, metatarsal, toes	Foot/Calcaneus /Toes	HEEL, BONE, METATARSAL-TOES
	Foot		foot/calcaneus /toes left	FOOT DX		FOOT right	
			foot/calcaneus /toes right	FOT SIN		FOOT left	
CT brain	DT Brain	DT BRAIN	Computed tomography brain without and with contrast	DT Brain	CT BRAIN WITHOUT CONTRAST	CT BRAIN WITHOUT CONTRAST	DT Brain
	Computed tomography brain without contrast					CT BRAIN WITHOUT AND WITH CONTRAST FAIN	
	DT Brain with/ without contrast						
	DT Brain without / with contrast						
	Brain DT Angio						

The semantic variation in the study descriptions was found to be considerable both between and within each hospital. For example in Study description five column two it is illustrated that there are five different ways of naming the study CT brain at hospital group 1.

The problem with this semantic variation is that when a radiologist search for CT brain at the hospital the search misses to identify all the studies of CT brains that are called something else. This means that the radiologist may overlook some investigations or comments in an individual's case history.

The problem is liable to cause misunderstandings that have the potential to be harmful from a patient safety perspective.

In Figure 8, the regional patient overview shows that the Patient name, Referring Physician and Study description in plain text are not consistent with the information model used.

Patient name	Patient ID ^Δ	Date of birth	Study date	Referring Phys.	Description	Accession no.
Doe, John	191010101010	1910-10-10	2011-03-03	5698	Datortomografi hjärna utan och me...	HSA2
Doe, John	191010101010	1910-10-10	2011-06-02	Lena Olofsson...	DT HJÄRNA	HSA4
Doe John	191010101010	1910-10-10	2011-03-02	Svensson^S...	DT Hjärna	HSA3
Doe, JOHN	191010101010	1910-10-10	2011-04-10	*Information ...	CT HJÄRNA	HSA4
DOE, JOHN	191010101010	1910-10-10	2011-06-27	*Information ...	CT HJÄRNA UTAN OCH MED KO...	HSA5

Figure 8. Example screen shot “regional patient overview” from the enterprise workflow in VGR.

The search is done on patient name (Doe, John). The search list shown misses all the examinations that Doe John has conducted and that are registered as John Doe in any semantic way, see Table 17.

7.4 FOURTH STUDY (ACTION RESEARCH)

- The Future Progress of Teleradiology

A number of services have been developed and implemented in the radiological information infrastructure in VGR. These services are: 1) First (initial) diagnosis, second opinion, and send (transmission of) images only, 2) Regional patient overview, e.g. viewing DICOM structured reports (DSR), 3) Agreements on computed based and automatic collaboration between independent sites, e.g. “around the clock services”, 4) Examination pool and 5) Free text search in diagnostic reports combined with other search criteria, i.e. type of examination, date of examination, patient name, gender, patient age.

Description of Initial Diagnosis, Second Opinion and Send Images Only Services

Initial diagnosis and second opinions are the traditional teleradiology services. In addition, there is a service for sending images only. In this project, all these services are implemented in the information infrastructure.

In Figure 9 the workflow for sending a request for a second opinion is shown in four screenshots.

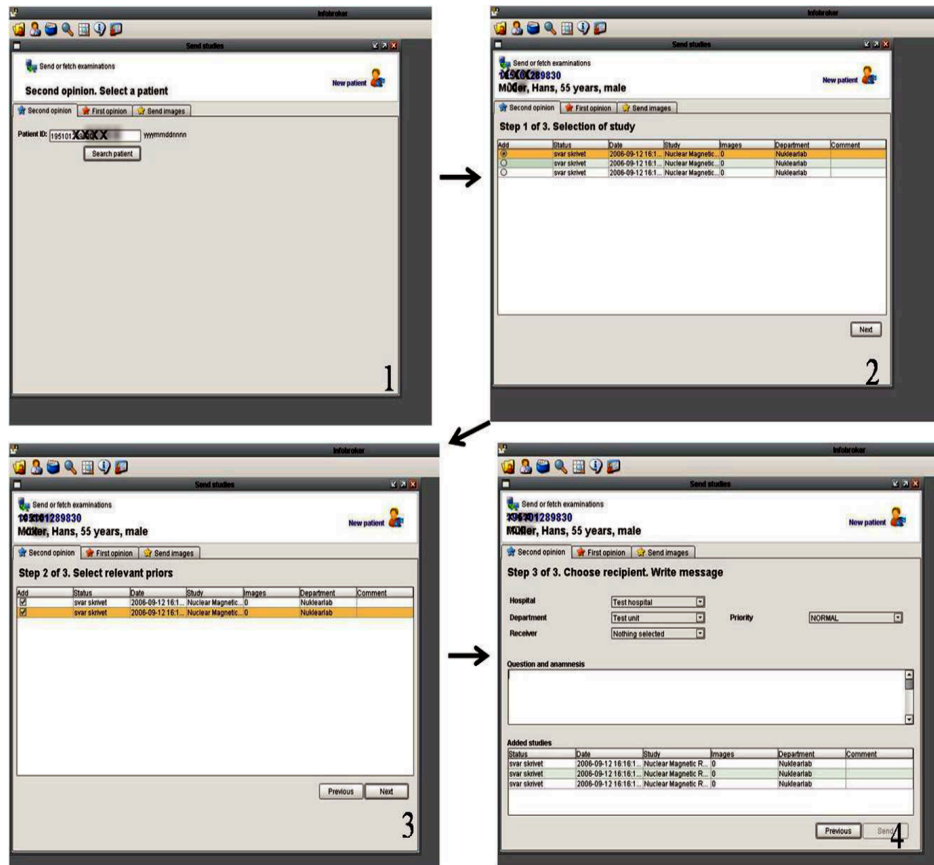


Figure 9. The different steps when sending an examination for second opinion.

Description of Strategic Decisions related to the First Diagnosis, Second Opinion and Send Images Only Service

It was found that to initiate an action in a regional workflow there was a need for a signal to start the workflow. A signal system was therefore implemented in the solution.

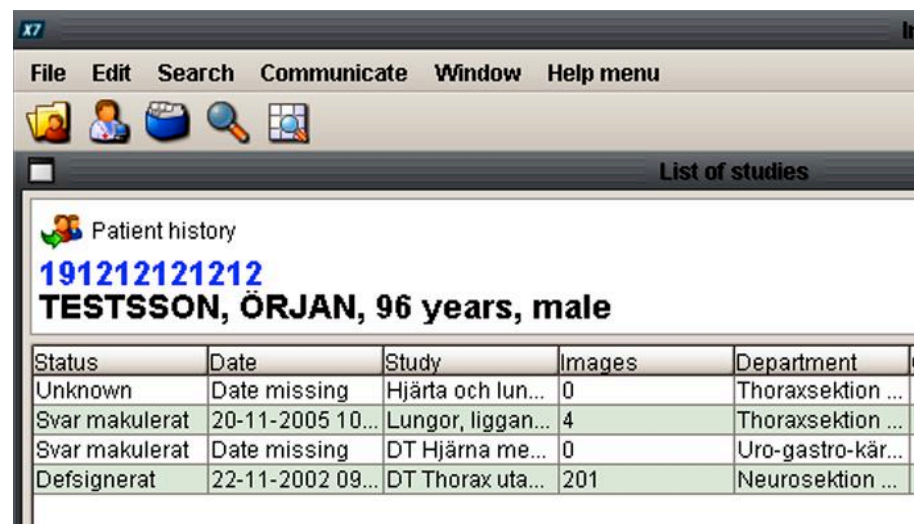
The sharing itself does not mean that any action in the workflow will be taken. The degree to which the sender of the regional request would be able to decide to whom it should be addressed was also discussed. As a result, it was decided that from the start, only transmission of examination requests to department level would be allowed.

Another strategic decision was that it must be possible to reject a request to provide an initial diagnosis or second opinion. It was considered important that the radiological professionals involved could manage the volumes of examinations related to the

enterprise workflow, subject to their local workflow, where the number of patients who will require an examination is hard to predict and the request is impossible to reject.

Description of the Regional Patient Overview Service

The regional patient overview is the historical and holistic information about the patient's radiology visits within the region. The concept of sharing data from all regional departments provides the framework for viewing the X-ray history of patients from the region in one GUI; see Figure 10. This feature was well received by all the healthcare professionals.



Status	Date	Study	Images	Department
Unknown	Date missing	Hjärta och lun...	0	Thoraxsektion ...
Svar makulerat	20-11-2005 10...	Lungor, liggan...	4	Thoraxsektion ...
Svar makulerat	Date missing	DT Hjärna me...	0	Uro-gastro-kär...
Defsignerat	22-11-2002 09...	DT Thorax uta...	201	Neurosektion ...

Figure 10. Regional patient overview.

The overview in Figure 10 includes the following information: examination status, examination date, type of examination, number of images produced and radiology department.

In the radiological information infrastructure, the request and report as well as images are combined in one graphical view. In practice, this combined view is a DICOM structured report object. In Figure 11, the combined DSR object is illustrated through a DICOM web viewer.



Figure 11. Combined view of a DSR object through a DICOM viewer.

Description of the strategic functionality decisions related to the service patient overview

Implementing this service caused conflicts within the region between the departments that were willing and those that were not willing to share their images promptly after they had been produced. A strategic decision was made: the original images were to be stored in the EIA and not in the local PACS. The images stored locally were copies of the originals in the central archive. This resolved the issue of sharing images promptly.

Another strategic decision concerned the need to implement consistent terminology within the region. Various terms were being used for the same concept – for example, four different ways of spelling CT Brain.

Semantic differences are not understood by technical actors as information models or standards; they are understood by people, and people must agree on regional semantic models if they want to collaborate in a shared and distributed information infrastructure.

A regional information model was agreed on to sort out the regional semantic problems. When the data from the different vendors' systems were inserted into the radiological information infrastructure, their semantic interoperability was checked against the regional information model.

In this way all regional information could be shared between all actors using the information infrastructure services.

Descriptions of the Agreements between Hospitals, e.g. “Around the Clock Service”

Agreements specify the negotiated terms for virtual collaboration between different physical radiological units. After the establishment of an agreement between units, automatic collaborative activities are initiated between departments according to the terms of the agreement.

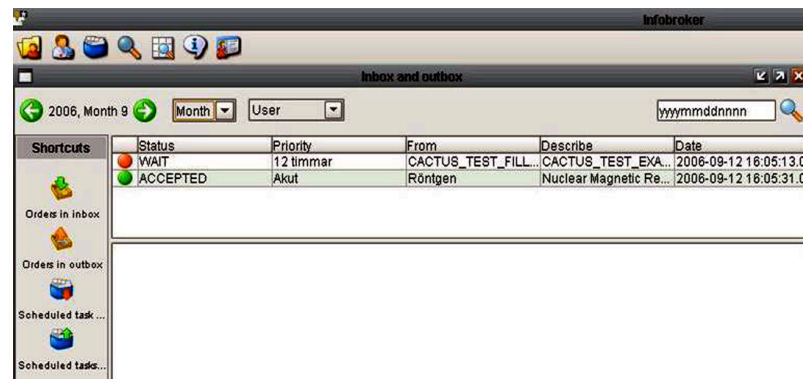
For instance, an agreement might state that all types of MRI knee examinations at hospital A should be diagnosed at hospital B. Another collaboration agreement might be that after 17:00 all examinations produced at hospital A should be read at hospital C.

Description of the strategic functionality decisions related to the agreements between hospitals

A strategic decision was made to place external examinations in the local work lists of hospital C automatically. This meant that radiologists at hospital C used the same work activities and workflow regardless of whether examinations had been produced internally or externally.

Description of the Examination Pool

The examination pool functioned as a marketplace where radiology examinations could be “auctioned”, i.e. they could be taken over and diagnosed by another unit within the region. This service was implemented to balance local peaks and excess capacity of work load jointly within the region. Priority examinations had been sent outside the region for first and second teleradiology opinions. See Figure 12.



Status	Priority	From	Describe	Date
WAIT	12 timmar	CACTUS_TEST_FILL...	CACTUS_TEST_EXA...	2006-09-12 16:05:13.0
ACCEPTED	Akut	Röntgen	Nuclear Magnetic Re...	2006-09-12 16:05:31.0

Figure 12. Overview of examination pool.

Description of the strategic functionality decisions related to the diagnostic pool

In the past examinations were sent outside the region for initial (first) and second teleradiology opinions. It was strategically decided that peaks of workload would now instead be solved internally within the region.

Description of the Free Text Search in Diagnostic Reports Combined with other Criteria

Another benefit of sharing reports and requests in the same information infrastructure was the possibility to search the regional archive, which contained a vast amount of medical information. In addition, advanced search engines could be applied to sift through the structured stored data in the information infrastructure. In practice, any healthcare professional with access to the regional network could perform free text searches combined with other search criteria. See Figure 13.

The 'Advanced search' window contains the following search criteria:

- Sex of the patient: Male
- Study date: must from 12-May-2009 to 12-May-2009
- Age of patient: from 50 years 0 Months to 70 years 0 Months
- Study description: must contain Colon
- Report: must contain Polyper

On the right side, there are checkboxes for 'Affiliated patients' and 'Maiden names', and radio buttons for 'Locally' and 'Regionally' (which is selected). A 'Search' button is located at the bottom right.

Figure 13. Search criteria's used in the radiology information infrastructure.

The search resulted in 461 matching objects that fulfilled the search criteria specified in Figure 13. If we click in the list retrieved from the EIA, we can confirm the reference to polyps in the report; see Figure 14.

The 'Infobroker' window displays the following information:

- Patient:** 30-07-2008, SAs-RBOR, SAs 195, Anders Ingemar, 57 years, male
- Images:** 62 Series
- Referral with reports and images:** Referral, Report at study level, Colon Med Dubbelkontrast
- Regional identity missing for sending RIS**
- Referral:** SE, Priority: Rutin, 30-07-2008, SAs-Lb Kir Avd 2 Övre Mag-Tarm/Kärl, SAs
- Question:** Malignitet? Divertiklar? Polyper? (marked with a red checkmark)
- Clinical History:** Tid väs frisk pat. Nu vårdad för akut divertikulit. Haft en episod med divertikulit för 15 år sedan. Då utredningen varit ua. Tacksam uppföljande colonrtg om 4-6v.
- Study:** SE, 01-10-2008, SAs-RBOR, SAs, Colon Med Dubbelkontrast, Series 62 Images
- Report at study level — Designat:** 30-09-2008
- Report:** 2008-09-30 Colon med dubbelkontrast
- Text:** I sigmoideum men framför allt också i cecapolen ses rikligt med divertiklar. Det ses inga tumorsuspekta förändringar eller strukturerande områden. P g a de rikliga divertiklarna i cecapolen samt tätställd haustra kan mindre slemhinneförändringar inte diagnostiseras.

Figure 14. Report from the search results confirming that the term polyps appears in the free text.

Description of the strategic service decisions related to free text search in diagnostic reports combined with other criteria

There is an upcoming strategic decision related to terminology and semantics to be used in reporting diagnostic findings. If two different departments use different terminology and semantics to describe the same finding, no free text search can identify the relationship. Everyone sees the potential for building teaching applications around the information infrastructure. This however, calls for harmonized terminology and semantics in reporting according to the regional information model. According to Hanseth [27], standards are built by users from both a technical and a user standpoint, and from that relationship solutions are created. Our conclusion on the transition from a local to a regional workflow is that some solutions can only be created and acted on when the problems are experienced in reality.

8 DISCUSSION

“By three methods we may learn wisdom; first by reflection which is noblest; second by imitation, which is easiest; and third by experience, which is the bitterest.”
-Confucius

8.1 METHOD DISCUSSION

The combination of action research and quantitative analyses enabled this thesis to provide richer and more valid results because the sharing domain was considered from different angles and approaches. These different perspectives were ways to find interesting new themes for further data collection and analyses. An introductory literature review [75] provided insight into the complexity that faces healthcare in connection with the use of digital information for collaboration and sharing. Action research identifies and addresses both theoretical and practical problems together with practitioners through action [126, 131, 142]. The quantitative findings clearly demonstrated the lack of data quality as well as how this can jeopardize sharing in real life. The combination of different methods made it possible to focus on detailed parts and their impact on the whole in collaborative contexts.

The use of different methods made it possible in this thesis to better describe how important it is that data quality is in place before new services are deployed in the road map for healthcare, “Prepare to share, it’s all about care”.

8.2 THE TRANSITION FROM LOCAL TO ENTERPRISE WORKFLOW

In 2002, VGR in Sweden, a health region with 1.5 million inhabitants, made a strategic decision to digitize all radiology departments within its jurisdiction. In 2012, this includes a total of 34 departments both private and publicly owned. The health authority invested in an enterprise service of information sharing using local RIS and PACS systems to access cross-border radiology information. In the enterprise service all the local RIS and PACS systems were a part of the regional service and its Information Infrastructure using the same EIA. For teleradiology purposes, the cross-organizational borders extend as far as to Barcelona, in Spain and Sydney in Australia.

During the deployment of the digital radiology department the local workflow changed [28, 29, 143, 144] at the same time, the rest of the healthcare environment were gradually becoming more and more digital. Demands of access to information were rising but hard to fulfill because most of the data collected were stored and used in proprietary format. The use of standards in healthcare as DICOM and HL7 has been a prerequisite to sharing of information between healthcare organizations [144].

The change from being an image/report producer to a process driven consultant within the electronic management of radiology information increases complexity for the radiology organization in many ways. Radiology has progressed from producing analogue images combined with typewritten reports to produced digital images and reports, on a path to eliminating paper and film entirely [2, 29]. This enables a stronger focus on the patient's needs and expectations regardless of where images and clinical information are produced, diagnosed, and used [15]. Meaning that the barriers for sharing of information dynamically are reduced and open up for a enterprise workflow approach.

The enterprise service makes use of global healthcare standards as HL7 and DICOM, [18, 19], for communication of the shared information.

The regional service captures and manages different types of metadata elements from various sources processed in different ways and store them in an EIA, this storage is a Vendor Neutral Archive (VNA) , by means of using the same negotiated information model [134] based on healthcare standards.

We focus on shared metadata because medical professionals are dependent on updated medical information in the delivery of care. Patients are becoming increasingly mobile and the information needs to follow that path, regardless if the information comes from several external local sources of information. Using a semantic framework based on an agreed information model enables cross-organizational sharing of information. Unlike previous studies that have focused on quality metadata alone, a key contribution of this study is that it explores the effects of metadata in the radiology enterprise service that supports cross-organizational sharing of dynamic information about the patients' visits, in VGR.

Metadata is abstracted data about data [145]. It is a categorization of data on a higher level. Within each metadata category there are data elements [11, 145]. These data elements are originally captured from different standalone systems, processing methods to capture them vary from standalone system to standalone system, using different local storage units, and having different end-usage targets from the start.

For example the virtual enterprise workflows include shared access to the regional patient history and first/second opinions through digital teleradiology and sending images only over organizational borders. The scope of this thesis includes medical staff from radiology related to the enterprise workflow in VGR, but excludes any focus on the clinicians' use of the virtual workflow, although they are included in it in practice.

Shared metadata represents the semantic interoperability that must be in place to support enterprise workflow across radiology organizational boundaries. The use of metadata between actors marks the beginning of a progress change from a local workflow (i.e. in one radiology department) to an enterprise workflow (i.e. when the patient's process spans over several radiology departments). In the enterprise workflow collaboration

could be established both between actors in the region and with actors outside the region debouching into a common workflow for the patient's best "Good Care".

8.3 HARNESSING THE POWER OF AN INFORMATION INFRASTRUCTURE

This thesis includes examples of the information infrastructure from the perspective of radiological use. However, tomorrow's key users of the information infrastructure will be clinicians and patients. The information infrastructure is not limited to a particular medical specialty such as radiology, nor is it geographically limited. It could be used by any specialty and any individual as long as they have appropriate access rights and useful services for them. The carrier of these changes is today the distribution of meaningful information without limits, using the digital networks that connect the world at the speed of light.

Clinicians will outnumber radiology users by far in future when they obtain access to the infrastructure. It is commonly known that clinicians use radiological images as a central tool. Patients, on the other hand, will be asking for more control of their medical history and will use second opinions more frequently in their search for healthcare. For both clinicians and patients, lack of access to the information they need may cause delays in progress.

Technology has caused extensive changes in radiology, resulting in socio-technical challenges for both the individual and the technology. The outcome of the change is dependent upon the individual's willingness to change as well as how this willingness to change fits in with the new technology [146-152]. During recent decades, the installation of PACS together with RIS has increased rapidly. An important aspect of this has been the standardization of work regarding DICOM, HL7, as well as technological developments in the computer and software industry worldwide [153]. These systems and standards create the basic layer to enable the information infrastructure for radiology in the years to come, enabling a streamlined process-driven functionality for radiology information in delivering patient care [1, 40, 151, 152, 154-156]. An information infrastructure is designed to support a range of activities: it is a technology built as a layer on another technology, integrated with other infrastructures into networks with no limits. Further, it is shared by and open to a larger community, including heterogeneous entities such as humans, technological components, organizations, and institutions [157].

In this study, the term information model act as a formal representation of entity types that includes their properties, their relationships and the base functions that can be performed on them, e.g. sending requests and reports, or scheduling a patient. The entity types in the information models are real-world objects, such as patient demographics, findings, results, classification code systems in use, connection to legal sources and semantic interoperability, etc.[158]. The information model provides formalism to the description of a problem domain without constraining how that description is mapped to

an actual implementation, i.e. not guiding how data flows are technically sent but specifying what content data should have when they are sent. The DICOM data model, HL7 data model and XML schemas have been used to make information available and shared within the information infrastructure. This is made possible through the overlying VGR information model layer, which is more specific about how each of the technical standard's semantic interoperability should be used within the information infrastructure.

The metadata used in the negotiated information model in VGR have national sources. These elements of metadata were identified as needed for the virtual collaboration around the patient's health. In these virtual collaboration activities, a small amount of metadata yields highly practical effects, providing that the perceived information from the information infrastructure is meaningful and trustworthy for its users. In this way, elements of metadata can be shared in various contexts and practices in a flexible way.

The technical enterprise architectures in this thesis describe the composition of subsystems, relationships internally and with the external environment, guiding principles for the information technology and its design, and the evolution of an enterprise [159, 160]. We refer to the technical enterprise architecture as a blueprint with systems, services and other parts and functionalities described. The technical enterprise architectures compose an underlying layer of the information infrastructure in use.

One information infrastructure can combine more than one technical enterprise architecture layer and thereby create more users of the same service, e.g. using Skype, where the user can be inside a technical enterprise architecture and seamlessly be connected to an user inside another technical enterprise architecture. Neither is the information infrastructure limited to radiological information per se; it could hold any kind of information. Researchers and students are also potential users of the information infrastructure.

The infrastructure could easily become an important source of information for continuous medical training. However, it can only be applied by these groups if the information infrastructure has secure services and trustworthy metadata that provide relevant access to information. Those services are hosted in the technical enterprise architecture used by the organization.

The challenge is to identify the relevant services, e.g. which services fulfil healthcare needs. An information infrastructure without services is simply a costly technology of no use. The usefulness of the information infrastructure is completely dependent on the services that it provides. New services are identified and developed by individuals. Services in information infrastructures are thus social elements.

In the Region of Västra Götaland: 1) the information infrastructure is a *shared resource* among the radiology healthcare professionals in VGR; 2) the data from different local RIS and PACS systems in VGR are integrated through *standardized* DICOM objects; 3) the VGR infrastructure is *open* because it could include any kind of data – radiology has simply served as a starting point for the development of this infrastructure; 4) it is *heterogeneous*, as the information infrastructure in VGR consists of social and technical components; 5) it's *secure* by focusing on legal and ethical issues; 6) supporting collaborative *services*; and 7) is *time* dependent as shared data from different sources that are put together virtually as a whole across organizational boundaries change over time. See figure 15. The virtual workplace only exists for a certain time; when it is needed and used, the virtual workplace can aggregate information from several technical enterprise architectures at the same time. It can bridge to other information infrastructure when needed.

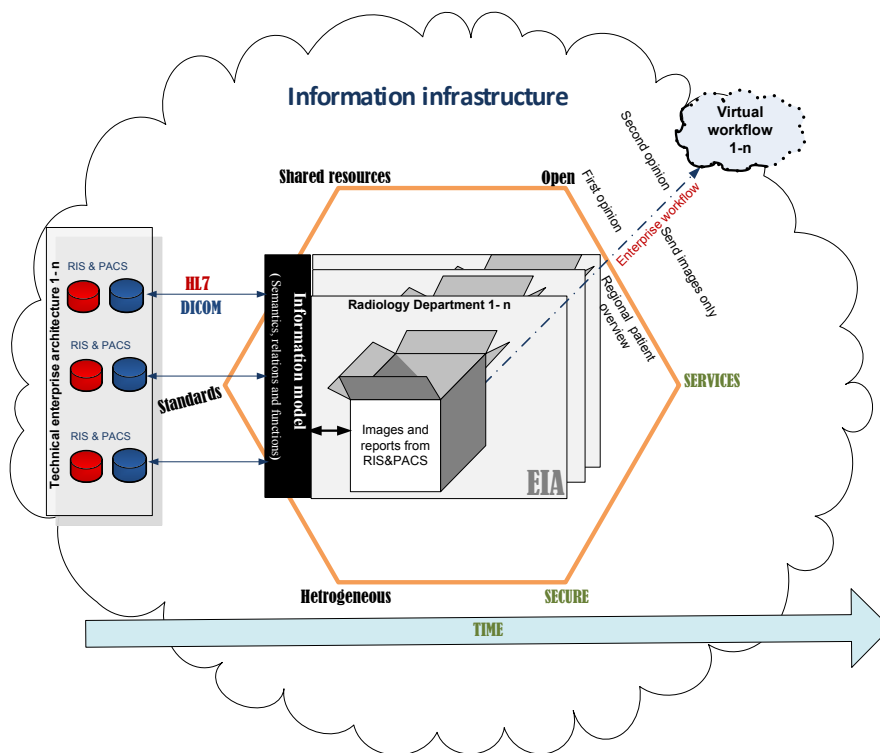


Figure 15. The information infrastructure and its principles and parts.

A virtual workplace, i.e. a service inside the information infrastructure, enables healthcare work to be conducted on a holistic view of the information gathered around the patient's needs in a virtual workflow. This information may come from different technical enterprise architectures, all shared in the information infrastructure. By means of the information infrastructure, information is available regardless of where and when it is produced as long as the system holding the information is linked to the information

infrastructure. This means that medical professionals can digitally communicate in real time with subspecialists who have relevant expertise, across organizational borders, for instance through Skype. The patient could eventually also easily fit into the information infrastructure with his/hers own produced data in the future. *An information infrastructure fits the needs of a future collaboration driven healthcare organization “Any time – Any place- Any way”*.

Contextual aspects of the technology work practice are important and need to be considered. The implementation of information systems into the radiological practice is a process of repeated negotiations. In the trajectory of negotiations that follow, the social and material aspects of work, including the technology itself, may all be transformed [151]. The development and adoption of new technologies, including social, material, technological, and political elements, cannot be fully understood by looking at one activity in isolation [161]. One interesting area to discuss is the meaningfulness of the digital data produced and stored: how the data can be transformed into meaningful information and shared to create knowledge. Is there a quality issue that needs to be solved before the full potential of an information infrastructure can be achieved?

8.4 IDENTIFYING THE POSSIBILITIES WITH INFORMATION INFRASTRUCTURES

Are there ways to predict unwanted changes when the physical environments of healthcare grow more complex and are more widely distributed? If there are no studies, these transformations may be ad hoc surprises, causing various problems and frustrations in practice.

In spite of the comprehensive changes made within healthcare and radiology, the use of simulation to facilitate change has not been fully explored. This is surprising, as the results from previous studies were promising [66, 67, 69-71]. This indicates that there is a reason to implement simulation methods to a larger extent to predict the outcome of planned changes in radiology work, e.g., patient flow, workflow, resources needed, prediction of throughput, and planning of equipment and spaces needed. Simulation has been successfully used on limited and less comprehensive issues [66, 67, 69-71]. The overall lack of simulation projects is surprising, especially when one considers the successful results of simulation work during the 1980s as well as the drastic and costly changes in healthcare during the last decade. Simulation can be a reliable source when the organization is aiming for fundamental change in work practice and not just superficial adjustments to routines. If work changes require a change among the staff and the way they think about their work, simulation could be a technique to help individuals understand the process of change [75].

What is really needed to develop an information infrastructure can presumably only be identified through its development in practice, by the practitioners involved in action. If this assumption is correct, action research is a relevant method for this development. This thesis emphasizes that information infrastructures are completely dependent on

social elements. Without continuous negotiations between healthcare professionals, vendors and researchers, the infrastructure is not usable for collaborative services [16, 17, 27, 28, 150, 161]. Information without services that make it possible to use the information is like a history book without years and dates or a telephone directory that is not in alphabetical order.

In summary, although the starting point for development of the VGR information infrastructure was radiology, there are no limitations on what medical information could be included and no limits on which healthcare professionals could use the services, regardless of their geographical location. The challenge for healthcare practitioners is to develop useful secure services for different groups related to the radiological information infrastructure as well as the harmonization of metadata for sharing purposes. Today we can realize what we dreamed of doing yesterday. Services can easily be used and adopted inside the information infrastructure. As an example, the transformation of teleradiology services in VGR during the last decade, from a specific work task to an embedded service inside the information infrastructure is completed.

8.5 TELERADIOLOGY

Teleradiology has been around for a long time in healthcare. The concept comes from telemedicine, which was defined as the “delivery of healthcare and sharing of medical knowledge over a distance using telecommunication systems” [162-166]. The first attempts at using telemedicine were early in the 1960s, mostly based on interactive television [167]. These early experiments suffered from inadequate technology. Little progress took place during the 1970s and 1980s. Teleradiology was the forerunner for moving images from one location to another via a communication link [165]. The beginning of the 1990s saw advancements in teleradiology. Technologies were in place for direct digital acquisition of images with smart image compression for image transmission over communication channels such as the Internet [164-166, 168]. Today, in the 2010s, teleradiology is no longer limited to moving images electronically from one place to another; it also involves the capability of managing an information infrastructure, extending from the department in the hospital towards cross-organizational sharing over large geographical areas [144, 166, 169-171]. The need for “delivery of healthcare and sharing of medical knowledge over a distance” is not new. One example from radiology in VGR in the 1980s was the need to transport patients from one hospital to another hospital because the first hospital did not have CT facilities installed. Another example from the region was the lack MRI in one hospital that made it necessary to move patients to a hospital where such examinations could be performed. When technology was deployed (for example, CT and MRI were installed in almost all institutional departments), other questions arose, such as: “Should this patient be moved to the university hospital for operation of his head injury or can nothing be done?” As a result, images were sent by taxi from the local hospitals to the university hospital for a second opinion. The main reason was that the organization was still trapped in the traditional film-based system with the associated bottlenecks, as shown in Figure 16.

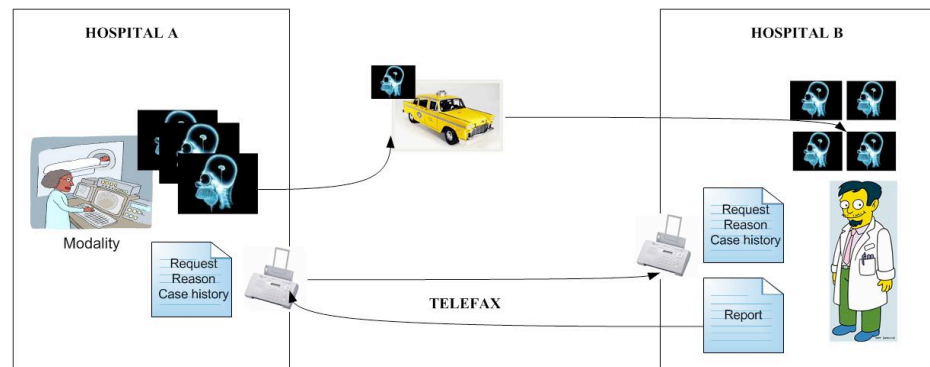


Figure 16. The use of TAXI for distribution of images for second opinion from radiology in the 1990's VGR.

When a patient arrived at the hospital for examination of traumatic injuries, the question might arise whether the patient should be transported to the university hospital for further treatment. Often, the neurosurgeon wanted to see the images in consultation with a neuroradiologist before the patient was admitted to the university hospital. The fastest way to distribute the images might then be to send them by taxi from the local hospital to the university hospital. The doctor at the local hospital communicated with the university hospital by telephone and sent faxes about findings from examination of the trauma patient.

These processes were time consuming and could have an impact on the outcome for the patient's health. When more modalities started to be digital, it became possible to send images via a standardized network to shared resources in the network, such as digital laser cameras for printing of radiology images.

Some of the local hospitals in VGR gained experience in digital transmission of images over a network to a laser camera placed in the university hospital, so that the images could be printed automatically (figure 17).

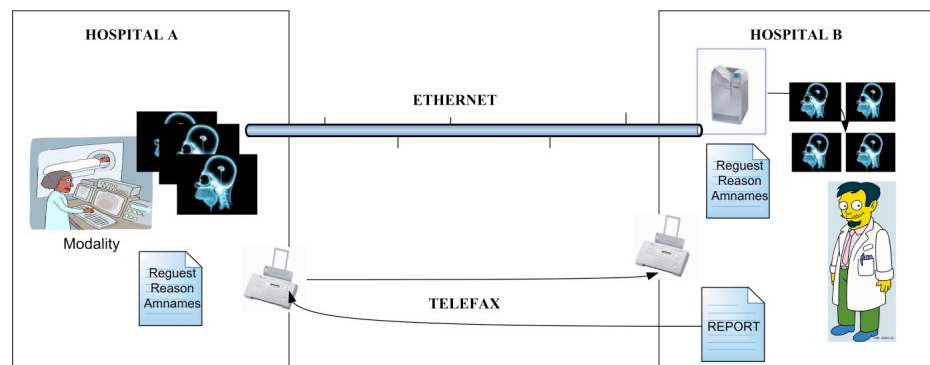


Figure 17. Remote printing between a local hospital and the University hospital in VGR.

By the end of the 1990s, it became possible to use shared resources across organizational boundaries in VGR. The reasons were that use of the DICOM standard was now widespread and the laser camera technologies that were able to communicate with the network protocol via the DICOM standard were available. The hospitals also shared networks within the geographical region.. With minimal changes in the local workflow, health practitioners could print images in a location different from the one they normally used. At first, these changes were useful; images for trauma patients could easily be printed out at the university hospital and the images could be discussed between the actors in connection with the patient's treatment. Administration of the local workflow changes was easy. Both from a cost perspective and from a network perspective, the limitation was the setup of the remote printing, which was based on a point-to-point connection. The system functioned as a local printer and the number of connections that a laser imager could handle was limited.

However, paper documentation continued to be important for the receiving actor and for patients' safety. It was necessary to fax the request to the receiving party, to fax the report on the findings in reply, and to enter the data from the paper report into the local RIS or scan the paper document with the findings into the local RIS. This functioned best if the sending and receiving side were in contact with each other during the transmission of the images, indicating the number of images and the purpose of the images that were printed out at a remote location. Otherwise, the output just became a stack of images that nobody took responsibility for. In the late-1990s Picture Archiving and Communication Systems [1, 3-5, 8, 172] were starting to enter the radiology departments in VGR, meaning that the same images could be handled within more than one place at the same time

The reason that they could be sent from one PACS workstation to another was the use of the standard for Digital Imaging and COmmunications in Medicine [18]. DICOM is a worldwide standard for medical images. In 1985, a joint committee was formed with representatives from the American College of Radiology (ACR) and the American National Electrical Manufacturers Association (NEMA) with one purpose: to develop a universal imaging standard for digital modalities and imaging devices. In 1993, the standard was named DICOM and it included images from domains other than radiology. One of the successes in the work with DICOM was that it involved all actors – healthcare personnel as well as vendors and manufacturers of equipment and systems. The work is organized in committees with varying scope, which meet periodically within working groups in which anyone can take part. Those working groups update (through correction proposals) and add new functionalities (through supplements) to series of technical documents that are used by the manufacturers as guidelines for specific types of data transfers between imaging devices, display workstations, printers and archive media [1-5, 8, 18, 39, 172, 173]. Offline media files are covered in Part 10 of the DICOM standard [18]. Part 10 describes how to store medical imaging information on removable media (e.g. CDs and DVDs). It also mandates the presence of a media directory, the DICOMDIR file, which provides index and summary information for all the DICOM files on the media. The local PACS could now burn a CD/DVD with

the patients' images included on the CD/DVD. The images could be sent via postal services or in urgent cases by taxi; see figure 18.

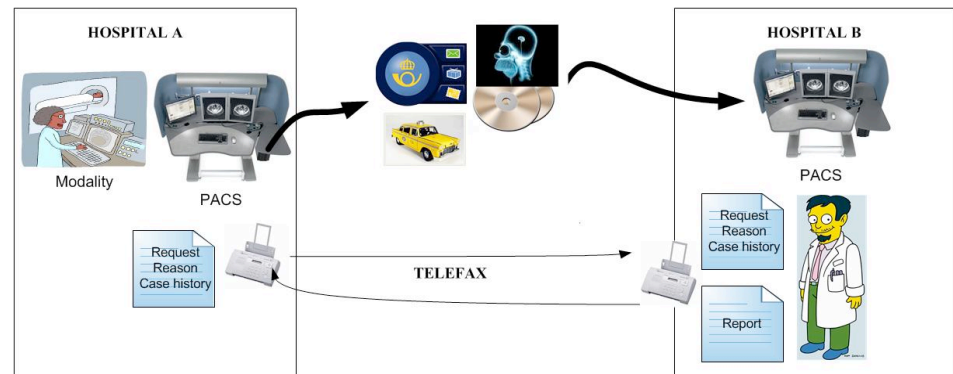


Figure 18. Transportation of CD/DVD between PACS systems in VGR.

Handling the transfer of CDs and DVDs between hospitals was easier because of the smaller format, but the logistics involved greater risks. Correct labelling of the CD/DVD was important because the recipient of the CD/DVD was not always the radiology department; it could be the orthopaedic clinician or the orthopaedic department, who did not know anything about the patients' images that were stored on the CD/DVD. The paperwork was not always sent at the same time as the CD/DVD, creating a great deal of extra administration work for both the sending and the receiving actor involved. The smaller format also made it easier to misplace or lose the CD.

In VGR, a DICOM server was installed at the beginning of 2003. The local hospitals could send their images directly to the server, and from the server the images could be imported to the PACS used in the university hospital. All the transactions took place over the VGR Network. See figure 19.

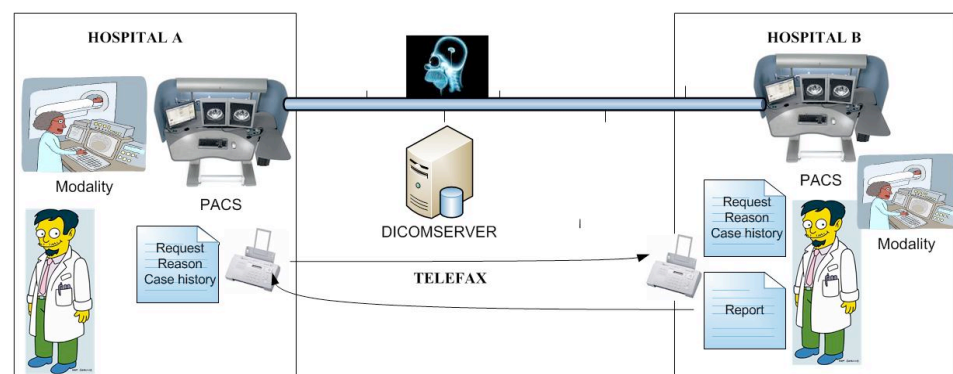


Figure 19. The usage of the Dicomserver in VGR.

It was now easier to send images over the network to the DICOM server destination. The radiology request information still needed to be faxed or sent by postal mail to the recipient. The report that was completed remotely was faxed back to the requesting radiology department, where the report was scanned in as a document image in the RIS system. A transcription of the report was entered in the RIS so that it could be distributed through the normal channels to the clinicians who had submitted the request.

The new feature was that images could be sent in two directions, if both hospitals had their own PACS. Images from examinations that were performed at the university hospital could be sent to the local hospital and imported into the local PACS if the patient was scheduled for a follow-up examination at the local hospital. This was more convenient than sending CDs between the hospitals.

In 2005, a decision was made in VGR that a radiology EIA service should be used for all DICOM objects, including textual information (request& report) and images, se figure 20.

This was the first attempt to use a Vendor Neutral Archive (VNA) [174] for radiology in VGR, even before the concept of VNA was known. A VNA normalizes PACS images and make image exchange possible, even when multiple divergent PACS or radiology departments are involved. When using a VNA, radiologists can continue to operate with their system/vendor of choice, further strengthening productivity, satisfaction, and organizational loyalty.

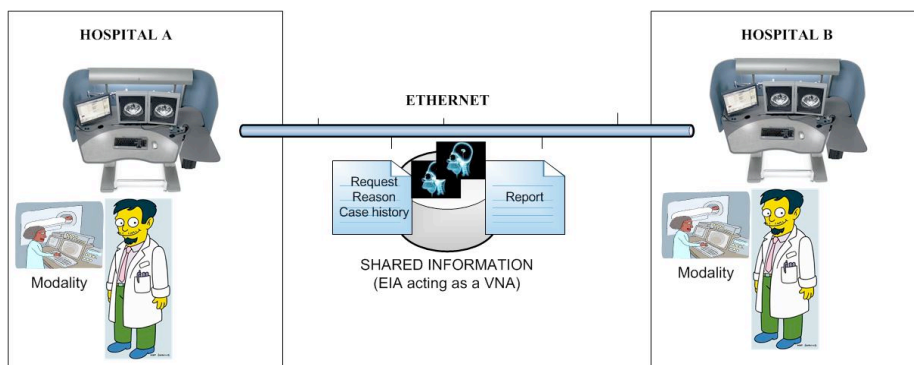


Figure 20. Use of the EIA as a VNA.

A VNA only concerns DICOM objects and does not support any RIS logistics, such as status of examinations, viewing of planned examinations, etc. However, the RIS information concerning request and the final report is stored in the information infrastructure as DICOM Structured Reports (DSR). The images and the reports are thereby stored in the same repository and can be retrieved through common DICOM Query Retrieve. The radiology enterprise service in VGR today that supports cross-organizational sharing of dynamic information about patients' visits is an important information infrastructure, where services such as teleradiology can be used as a part of

the enterprise workflow and not treated as a separate service in the region. In figure 21, we illustrate how different technical enterprise architectures can be combined into one information infrastructure. This approach makes it easy to connect or disconnect any technical enterprise architecture and thereby increase the flexibility of the organizations that belong to the same information infrastructure, i.e. interaction instead of point-to-point integration.

A number of enterprise services have been developed and deployed in the radiological information infrastructure in VGR. These services are: 1) First (initial) diagnosis, second opinion, and send (transmission of) images only, 2) Regional patient overview, e.g. viewing DICOM structured reports (DSR), 3) Agreements on computed-based and automatic collaboration between independent sites, e.g. “around the clock services”, 4) Examination pool and 5) Free text search in diagnostic reports combined with other search criteria, e.g. type of examination, date of examination, patient name, gender, patient age. Please see article 4 in this thesis for further details.

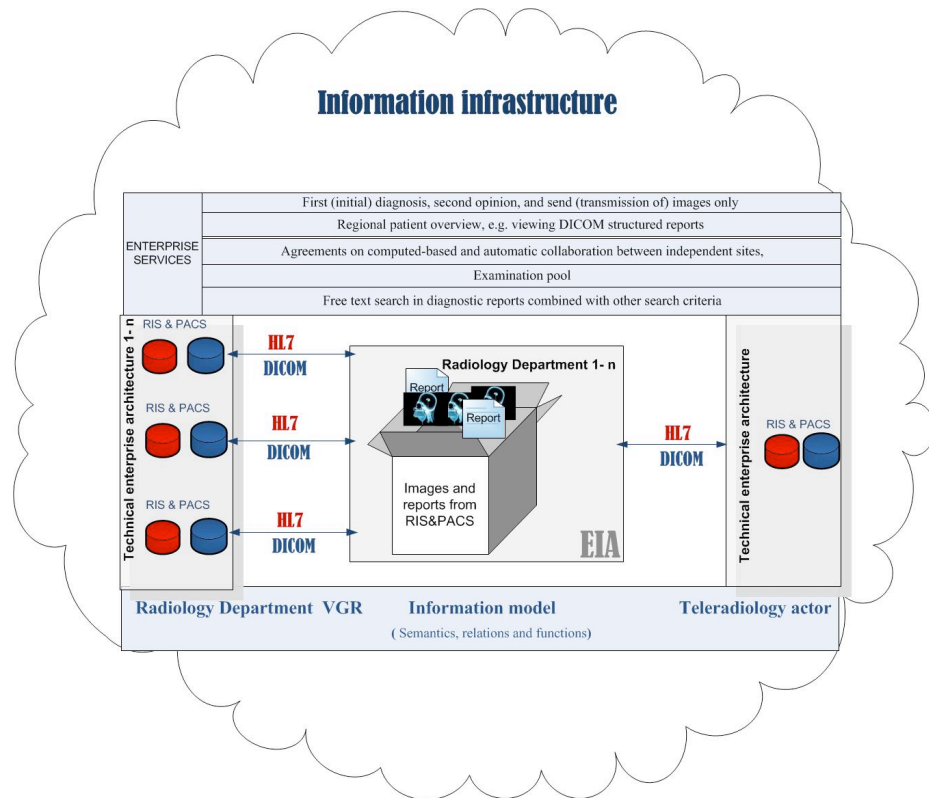


Figure 21. Overview of the existing Information Infrastructure in VGR that supports teleradiology as an integrated part in the enterprise workflow.

The user of the teleradiology service inside the information infrastructure in VGR can easily share examinations with any actor inside the information infrastructure. The sharing is based on widely used standards, meaning that the dynamics of the

information infrastructure can be virtually shared depending on the needs of the health practitioner [131].

The radiological information infrastructure developed and used in VGR is quite different from the traditional use, perception and definition of teleradiology. Below is the definition of teleradiology from the European Union in their document COM (2008), page 5:

“Teleradiology is a telemedicine service which involves the electronic transmission of radiographic images from one geographical location to another for the purposes of interpretation and consultation. Teleradiology has developed alongside the gradual shift in medical imaging from film-based to digital-based technologies.”

VGR has no need of specific teleradiology solutions as specified above, and no need to send and receive information as information instead is shared across organizational borders in a centralized storage, available from all local PACS systems. Their intention is instead to find new collaborative ways to work as they already share all image information. Here is focus on the establishment on the virtual regional radiology workflow processes instead of sending and receiving image diagnostic information.

The central difference between the traditional European Union definition of teleradiology and the definition used in this paper is the understanding of teleradiology as providing securely shared information for limitless collaboration and not the electronic transmission of radiographic images supporting specific work tasks.

Teleradiology is one important service in healthcare that could be exploited in larger volumes to make healthcare more efficient. However, other services could also make healthcare more efficient. An example that has been proven fruitful by research studies is simulation [67, 70, 71, 175, 176]. It has been shown that simulation is a useful tool to identify the effects of planned changes.

8.6 THE USE OF SIMULATION IN RADIOLOGY

Looking through the literature, only a few articles discussing simulation as a tool for changing work practice appeared in the literature every year [2, 75]. It is surprising that none of the studies in this literature review relate to the importance of having a standardized information model related to the simulation system. The information model is a description of the input data, defining every name of dataset in a uniform way that will be used in the simulation system. Standardized input data is a prerequisite to design a generic simulation model. However, a few studies emphasized the importance of having structured data [69, 94, 177, 178].

The number of interactions between actors (e.g., humans, information systems, etc.) is continuously growing [147, 151, 157, 179]. New technologies and their adaptation in healthcare work practice and workflow represent an undisputed challenge for the

profession [67]. Changes in the healthcare information infrastructure globally are placing new demands on the actors [10]. The speed of making medical decisions and the confidence in such decisions changes the terms of work practice and thereby the practice of medicine. What yesterday was considered best practice no longer applies today. Therefore, the profession needs to find strategies for adapting quickly to changes, including new technologies, to incorporate them into existing standards and to use them in the daily work processes. One way might be data mining the vast amount of digital data that is produced and stored in today's application databases [11] .

This thesis has illustrated through a real-life simulation study that it is possible to predict the effects of future changes in radiology. It showed a difference of only a 0.5% between the real-life throughput and the simulated future throughput one year after the simulation was performed. These findings indicate that there is reason to implement simulation methods more widely to predict the outcome of planned changes in radiology work, e.g. patient flow, resources needed, prediction of throughput, planning of equipment, and spaces needed for enterprise workflow. The challenge of simulation is to obtain access to relevant and high-quality reference data. This requires an alignment of all healthcare actors to follow the agreed information model in the same way. Standardized high-quality data sets as reference input are a requirement to design a generic simulation model of high probability.

Nevertheless, there are challenges. First, all healthcare actors must understand, follow, and use the enterprise information model and the technical framework in the same way. Second, the semantics of data must be consistent in the information infrastructure according to the information model. A potential disadvantage of the enterprise information model is the strict requirements of harmonization of data. Where the challenge is to use the same semantics and mean the same thing regarding one object/service within the entire enterprise. An example could be the description of examination time. Was it when the examination was ordered, booked, started, ended or was it the time for reporting? Third, the concept of sharing an information model within an enterprise is new and realization of its potential is scarce among organizations. No doubt, a holistic way of sharing data enables staff to inform each other and work together around the patient across boundaries in new meaningful ways.

Still, a few studies have emphasized the importance of having structured data [69, 94, 177, 178]. Standardized high quality data sets as reference input is a requirement to design a generic simulation model of high probability [75]. When having access to an enterprise information archive with quality data, the implementation of a service such as simulation is quite straight forward.

Healthcare facilities and networks that understand the significance of an enterprise information model can plan for the future with entirely new perspectives, maximizing the possibilities of a managed change of work. Using an information infrastructure could visualize the actual work conducted and offer the possibility to react quickly when obstacles occur. Sharing information within an enterprise could increase the quality of healthcare outcomes. When information is shared, there is nothing to hide

within the enterprise; thus the integrity of units must be considered as well as patient integrity. A certain level of surveillance can be tolerated, but there are personal limits that must be considered and openly discussed.

8.7 DATA QUALITY

This thesis has shown the problems of following a relatively simple information model in practice. It is a challenge for healthcare actors to use the same semantics and mean the same thing regarding one element of metadata within an enterprise workflow. An example is the description of examination types. Are the same examination codes represented by the same plain texts in the local RIS and PACS systems, in paper 3 in this thesis it's illustrated that the examination codes are not, although the information model was implemented in the region more than six years ago. The cumbersome process to reach alignment is due to many things. One is the concept of sharing an information model within an information infrastructure, to accept sharing regionally i.e. to let go of your local information and to start collaborating on a larger basis regionally. This means that efficiency can increase within the enterprise with the same or increased quality. It is possible to utilize the resources on an enterprise level much more actively and effectively than they are utilized today. There is no need to start searching for new support in Australia when colleagues in the enterprise could be accessible for support. If it proves difficult to identify support within the region, support may be sought outside the existing enterprise architectures of the information infrastructure. If so, the new enterprise architecture, initially regarded as outside the information infrastructure, will be included in the information infrastructure. In this way, new enterprise architectures may be linked to the existing information infrastructure as time passes. This is a way to ensure that the information infrastructure allows optimal efficiency and quality over time.

In healthcare, knowledge has traditionally meant power; in the future, collaboration will be power. A holistic way of sharing information enables health practitioners to inform each other and work together around the patient cross-organizationally in meaningful new ways, where the focus will be on the patient, where the patient will reclaim to be in the centre and not his or her diagnosis.

These new virtual ways of working require access to shared information across organizational boundaries. This calls for the identification and standard setting of relevant quality of metadata to support enterprise workflows as well as to address patient safety issues.

Systems theory were used in this thesis, and in particular Greif and Lynch's theory as described in chapter 7 in Payne: [125] conceptual steps to identify metadata in order to identify the content of the shared information model. By following conceptual steps, we could identify the metadata needed for sharing and virtual workflow in an information infrastructure. The metadata elements used for sharing in an information infrastructure were few compared to the number of metadata elements needed to carry out the local workflow.

Despite the poor overall quality of the metadata elements, one realizes the benefit in Sweden of the unique personal identification number [180, 181] combined with the birth date that follows Swedish citizens throughout their lives. With respect to metadata quality, the data in the study showed that all data elements with personal identification were 100% correct. This has a high impact on patient safety in Swedish healthcare. The Swedish initiative on creating a unique identification for each actor/ institution/ department/ individual working in healthcare, i.e. the HSA-ID, and a unique identification for each individual working in healthcare [182] will most likely also have a major impact on patient safety and trust towards information shared. This is because such identification can provide a secure audit trail indicating where something is done, by whom it is done and who requested it to be done.

A typical example is identifying who is requesting what today in healthcare. Results from this study show that the referring physician's name often does not follow the information model. The result is that when an existing teleradiology service is used, the recipient of the requested service may not be able to find the telephone number for the referring physician to call if rapid feedback is required. In those cases, the teleradiology radiologist needs to contact the department that has sent the teleradiology request, inform them of the findings and ask them to contact the referring physician or to obtain the telephone number and call. In both cases, valuable time could be saved with correct use of the HSA-ID for the requesting physician.

In the example above, using semantically secured interoperable data would strengthen the information infrastructure, as there would be more high quality and instantly understandable information in the information infrastructure producing usefulness.

This thesis also illustrates that today's use of the Swedish framework for codes of radiology examinations is not sufficiently useful for cross-organizational work. The variations in plain text examination codes might have an impact on patient safety if the codes are shared in a cross-organizational workflow, without awareness of the way in which codes are used locally. It is likely that the harmonization of the plain text descriptions of the medical examination codes will increase when the Snomed CT [20] standard is implemented in Sweden. In 2009, the decision was taken to implement Snomed CT in Swedish healthcare. However, no deadline has been specified for implementation of this standard in radiology.

However, our findings indicate that the quality of metadata is poor for launching extended services and the reason is the lack of semantic interoperability. This means that parallel systems need to exchange information via sending and receiving services manually instead of sharing the information from a digital source. Some individuals may identify a particular data element as being central and important, while the same data element may be peripheral and irrelevant for others.

8.8 INFORMATION INFRASTRUCTURES LINKING PATIENTS

The information infrastructure opens up for the patient to become a more engaged and active part in the healthcare process, “Any time”.

The focus to invite the patients within the information infrastructure could stimulate to the increased patient management and coordination of the health care services and thereby the creation of more effective use of the healthcare organizations resources, “Any Place”.

This also means that the patient could produce and consume health information in a more effective way than today. Examples of this could be measurement of blood pressure, request for visits and information of patient status regarding pain, nutrition and sleep, “Any-way”.

8.9 LESSONS LEARNED

- The Ten Commandments for sharing information

#1 Have control and own your own data

#2 Use standards instead of local deviations

#3 Start to collaborate in the information infrastructure instead of waiting for the "one system"

#4 Create an information model and follow it rigorously

#5 Identify the needed metadata for sharing – find their source

#6 Let the practitioners decide the usage of the information

#7 Use resources already in place

#8 Persistence – Persistence – Persistence

#9 Give in to sharing

#10 Sharing is Caring

9 CONCLUSION

“Everything should be as simple as possible, but no simpler”.
-Albert Einstein

Globally, healthcare is making huge investments in eHealth. Implementing eHealth is not a straightforward process. Local workflows must be catered for in parallel with the need to design eHealth information infrastructures. In conclusion, this thesis is an example of how these two can coexist, e.g. how you can support the local whilst supporting the design of an information infrastructure in healthcare. The overall research question in this study was: How can we design, implement and use a radiology information infrastructure by focusing on the VGR information model, its data quality, its semantic interoperability and the relationships for cross-organizational workflow as a whole?

The conclusion from this study (paper 1) was that in order to simulate you need to access high-quality reference data. The study involved a real-life simulation example based on reference data from the VGR information infrastructure. As this data, i.e. examination time and number of images per examination, was of high quality, it was possible to estimate the effects of the change with a new MRI laboratory and the closure of two laboratories. The simulation in 2006 differed with a margin of only 0.5 % from real-life throughput in 2008. These results confirmed that simulation could support departments, hospitals, and regions in understanding changes in the healthcare process prior to changes being made by illustrating different future scenarios and their predicted outcomes. It also showed that access to quality reference data from an information infrastructure is a key feature in the simulation of the outcome of planned changes in work. It was shown that simulation opens up new ways of planning and carrying out changes in the healthcare organization. The study indicates that the use of simulation to facilitate change has not been fully explored. This is surprising, as the results from simulation are promising. This indicates that there is a reason to implement simulation methods to a larger extent to predict the outcome of planned changes in radiology work, e.g. patient flow, workflow, resources needed, prediction of throughput, and planning of equipment and spaces needed. In summary, simulation presents opportunities for cutting costs and increasing business value.

It was also (paper 2) illustrated that new virtual ways of working require access to shared information across organizational boundaries. This calls for the identification and standard setting of metadata elements to support enterprise workflow as well as patient safety and integrity issues. Action research and working group methodology allowed individuals to reach agreement about the value of data elements over time. System theory supported the working groups' focus on the cross-organizational level of sharing as well as on the local level of sharing. The metadata used for enterprise workflow were few compared to the metadata needed for the local workflow. Those metadata were 1) The information must belong to a specific patient ID; 2) The patient must have a name connected to the ID; 3) The department responsible for undertaking

the radiological examination must be identified; 4) There must be an identified referring consultant responsible for the investigation request; and 5) A plain text summary must accompany the information dispatched from the responsible department. Standardized and harmonized data elements are a requirement for sharing information in an information infrastructure across different healthcare organizations. It was concluded that deliberations about semantic operability are at least as important as deliberations about technical interoperability. Addressing the identification of the appropriate elements of metadata for workflow across radiology boundaries is a major requirement for successful collaboration in a virtual workflow.

It takes (paper 3) much longer than one expects to create a semantically harmonized enterprise service that enables efficient and dynamic cross-organizational sharing of radiology information. This study illustrates that the level of missing metadata elements is improved over time, but the semantics of metadata elements are still poor. This means that the technical fully working cross-organizational infrastructure is hindered from functioning as an efficient information infrastructure supporting collaboration between all departments and hospitals in the region. It is important for interoperability that vendor systems and local workflow are adapted to the agreed semantic models, otherwise it is difficult to reuse this information in new cross-organizational services as the patient history service in VGR. The aim of the information infrastructure is to support secure virtual workflows that contribute to more efficient eHealth as a whole (paper 4). Using action research to develop and implement the radiology information infrastructure in a healthcare region with an unlimited number of actors is a social act. It involves continuous negotiation with people concerning how and why they should collaborate with new actors within the region to achieve new ways of working together. It was concluded that the need for teleradiology as a service provided “by somebody” has disappeared in VGR, as the strategic decision of making an information infrastructure was carried out in real life since 2006; today it is a shared service embedded in the innovative radiology information infrastructure. The information infrastructure in VGR is just a starting point for a novel and limitless telemedicine service including limitless healthcare actors and activities.

In summary, acceptance of sharing information in healthcare involves a long and winding journey, but the persevering infrastructure-oriented organization will find new ways of collaboration around and with the patient. This will nurture a more open-minded, hopeful and life-affirming approach, in which the whole is more important than the parts; a place where newcomers are welcomed just as the experienced professionals are appreciated. The more we know about each other and their work, the higher the probability that we can support each other as well as the patients. Technology used for distribution and communication is the most efficient tool for sharing; it offers collaboration without borders. Use technology as the platform for creative thinking, as it has no limits. Will you continue to do as you have always done, or should you do something you have never done before in order to achieve greater usefulness? That is the challenge.

10 FUTURE RESEARCH

*“The strangest thing about the future is that they will be
referring to our time as “the good old days”.”
- John Steinbeck*

The importance of shared metadata for designing a virtual workflow in healthcare is a prerequisite for creating new innovative virtual workplaces. Anecdotal information shows that the shared metadata are represented by elements holding national semantics. In practice, the national semantics are not mandatory in healthcare systems delivered today. All RIS systems include these data elements, but with varying semantic quality [16, 17]. This however needs to be studied in greater detail in future work.

The power of simulation is also not fully understood in healthcare [75], the increasing volumes of data that is collected in healthcare could be used for other purpose than as per today just on a patient individual level. Further research in “Big Data” is a prerequisite for collaboration without limits. The more we know about you as a group the more we can learn from you as an individual.

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