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Data Sharing and Shared Workflow in Medical Imaging

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Hereby I declare that this doctoral thesis, my original investigation and achievement, submitted for the doctoral degree at Tallinn University of Technology has not been submitted for any academic degree

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TTÜ KIRJASTUS

LIST OF ABBREVIATIONS

ACM – Automatic Capacity Management
ATNA – Audit Node and Node Authentication
BPPC – Basic Patient Privacy Consents
DICOM – Digital Imaging and Communication in Medicine
CDI – Center for Diagnostic Imaging
ebXML – Electronic Business using eXtensible Markup Language
EHR – Electronic Health Record
EHR System – Electronic Health Record System
EPR – Electronic Patient Record
ETCH – East Tallinn Central Hospital
HIE – Health Information Exchange
HL7 – Health Level Seven
HL7 CDA – HL7 Clinical Document Architecture
HUS – Hospital district of Helsinki and Uusimaa
ICT – Information and Communication Technology
IHE – Integrating the Healthcare Enterprise
ISO – International Organization for Standardization
JPEG – Joint Photographic Experts Group
LOINC – Logical Observation Identifiers Names and Codes
OASIS – Organization for the Advancement of Structured Information Standards
PACS – Picture Archiving and Communication System
PDF – Portable Document Format
PHR – Personal Health Record
RIS – Radiology Information System
SNOMED-CT – Systematised Nomenclature of Medicine – Clinical Terminology
SSL – Secure Sockets Layer
TIFF – Tagged Image File Format
TLS – Transport Layer Security
URL – Uniform Resource Locator
VNA – Vendor Neutral Archive
VPN – Virtual Private Network
XCA – Cross-Community Access
XCA-I – Cross-Community Access for Imaging
XCPD – Cross-Community Patient Discovery
XDS – Cross Enterprise Document Sharing
XDS-I – Cross-enterprise Document Sharing for Imaging
XDW – Cross-Enterprise Document Workflow

PREFACE

The sharing of medical images and clinical data, as well as the exploitation of shared workflows, are used to achieve higher quality, safer and more efficient diagnostic processes and image reporting results. Implementation of data sharing and shared workflow requires the recognition of the different actors involved and the processes that influences the successful deployment of the reporting service. Also the benefits and barriers of data sharing and shared workflows need to be taken into account. Data sharing and shared workflows can be implemented in different levels: inside one healthcare organisation, between organisations in one region, across country borders, or also between a patient and a healthcare organisation. The factors that influence how successfully digital data sharing and shared workflows are implemented in cross-organisational teleradiology include: technical interoperability, organisational structure (including trust), reporting service quality, semantic accuracy (including working in more than one language), security and privacy, legal, and reimbursement. In this thesis, the results of two teleradiology projects (Baltic eHealth and R-Bay) implemented among numerous European countries during 2004-2009 are presented. The thesis also explores the theoretical arguments about the actors and processes that influence the successful implementation of data sharing and shared workflow. This thesis set out a new, comprehensive approach that takes into the account different factors which would lead to the successful implementation of cross-organisational teleradiology services and describe recent technologies and new models to support data sharing and shared workflow in medical imaging.

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LIST OF ORIGINAL PUBLICATIONS

Paper I Pohjonen H, **Ross P**, Kamman R, Blickman J. Pervasive access to images and data – the use of computing grids and mobile/wireless devices across healthcare enterprises. IEEE Transactions on Information Technology in Biomedicine. 2007 Jan; 11 (1):81-6 17249406

Paper II Pohjonen H, **Ross P**, Blickman J. Extending the radiological workplace across the borders. Medical Imaging and Informatics. Lecture Notes in Computer Science, 2008, Volume 4987/2008, 12-17, DOI: 10.1007/978-3-540-79490-5_3.

Paper III **Ross P**, Sepper R, Pohjonen H. Cross-border teleradiology-experience from two international teleradiology projects. European Journal of Radiology 73 (2010) 20–25

Paper IV **Ross P**, Pohjonen H. Images crossing borders: image and workflow sharing on multiple levels. Insights into Imaging, 2010, Vol 2, No 2, 141-148

Authors´ contribution

The author of this thesis was responsible for: setting up the organisational and technical framework of the Baltic eHealth and the R-Bay project, developing a multilingual structured reporting tool, specifying of service models for shared workflow implementation (including e-marketplace), and investigating the feasibility and the benefits of implementing a cross-organisational teleradiology service (Paper III and IV). The author also was the main contributor in defining multiple organisational levels in data sharing and shared workflow, as well as analysing the barriers and benefits in cross-organisational teleradiology (Paper IV). In Paper I the clinical use of streaming technology for image viewing, and analysing the implications of this for clinical workflow was the responsibility of the author with other authors. In Paper II, the author, plus others, was responsible for discovering and discussing the organisational change and feedback issues. However, the intellectual input of every author of the above papers should not be underestimated.

1. INTRODUCTION

Utilisation of digital data in healthcare and development of information technology are changing the health data management process and allowing re-engineering of clinical workflows (Siegel *et al.* 2002). In this paper, cross-organisational data sharing and shared workflow in medical imaging are discussed and focussed on.

Data sharing in medical imaging enables entitled healthcare professionals, administrators and citizens to simultaneously and asynchronously access medical images and image related data, with this sharing not being dependent on the place or time.

Shared workflow is a healthcare process management model which allows a multi-site approach to the defined clinical or healthcare administrative process. Shared workflows utilise shared medical databases, standardised data and data exchange profiles, and related legal, security, financial and organisational rules.

In medical imaging, the shared workflow is a virtual reporting process, where the referral letter, relevant prior imaging and other clinical data, the examination and the report/second opinion can originate from separate locations but form a seamless process.

1.1 Data sharing

Today, in many settings clinical data and images are available from any location in the world right after the acquisition for the patient and healthcare professionals upon them being given the relevant entitlement. This is enabled by the digitalisation of medical images and related data, common standards, secured data exchange platforms, and RIS, PACS and EPR integration (Ng *et al.* 2006).

Evolution of digitalisation and DICOM standard

Evolution of data sharing in radiology started from digitalisation of radiological exams in 1970ies (Wiley 2005). The main incentive to digitalise medical images was to replace labour-intensive and inefficient analogue film reading environment in radiology department with computerized images to optimize the increasing workload. Evolution of information technology also opened new horizons for diagnostic image processing after their acquisition. The first digital images were produced by nuclear medicine, angiography and computed tomography (CT) equipment (Thrall 2005). New imaging modalities increased considerably the number of diagnostic exams and consequently required establishing a proper storage environment. At the early stage of digitalisation, radiology images were stored in a proprietary format close to the individual imaging modality. The lack of common standards in digital imaging hindered establishment of universal image archives (4). It also appeared that stand alone computer workstations did not facilitate the overall efficiency in image reporting because different modalities demanded specific workstations. This evolution motivated academic radiologists to work out universal standard for digital images in medicine which could allow archiving and retrieval of different exams and communication of image data, where the universal standard for images was not dependent on the equipment vendor. The initial version of standardised terminology was created in the mid of 1980ies and the DICOM (Digital Imaging and Communication in Medicine) standard was published on 1993 (DICOM 2011). This initiative allowed vendors to elaborate and manufacture multi-modality archiving and communication systems – picture archiving and communication system (PACS). Today, DICOM is the main technical and interoperability standard for data sharing in medical imaging. It defines the rules for digital imaging and communication of diagnostic and therapeutic information in disciplines that use digital images and associated data.

In spite of common standards the implementation of digital modalities and PACS has been time lengthy and labour-intensive all over the world. This was caused mainly by the fact that implementation of the DICOM standard in digital imaging and PACS leaded also to the changes of clinical workflows (Siegel *et al.* 2002).

An example of a large scale project of digitalisation of medical images during the first decade of this century was the National Program for IT in the UK where local service providers were appointed to implement central PACSes throughout the country (RCR 2009).

In addition to the digitalisation of medical images, the digitalisation of patients´ administrative and clinical data demanded healthcare providers to address interoperability issues where data was stored in different non-communicable information systems inside the same healthcare organisation (Thrall 2007b). The lack of clinical and administrative communication required interfacing of digital imaging technology with other information systems which took into account clinical workflows and pathways (Faggioni *et al.* 2010; Thrall 2005).

Evolution of cross-organisational data sharing

Along with the development of interoperability standards in medical imaging the integration of databases evolved in consecutive stages. Data sharing between healthcare providers started with point-to-point integrations followed by simultaneously accessible central databases, and most recently, by many-to-many connections (Størkson *et al.* 2009, RxEye 2011).

Point-to-point connection allows healthcare professionals located in one institution access to medical data collected and stored in another institution. In this example, two organisations would agree about the technical standards for data sharing, organisational and security rules, *etc*. There can be more organisations that are connected to the same database and use the data simultaneously. However, technical interoperability and contractual relations remain bilateral between two healthcare providers. Every new connection demands new agreements between collaborating parties.

An example of extensive point-to-point integration is the medical data exchange in Denmark. During the last two decades the exchange of data was established between hospitals, general practitioners, visiting nurses and pharmacies using a secure network linking the entire healthcare service (Edwards 2006). Communication of messages was based on internationally accepted standards (Sundhed 2011).

In the medical imaging field, one of the first, large scale shared PACS installations in the world is HUS-PACS in Finland (Pohjonen *et al.* 2004). The PACS of the hospital district of Helsinki and Uusimaa (HUS) has a common image database for 21 hospitals which serve 1.5 million inhabitants in 32 communities. It also serves 53 primary healthcare centres and 9 primary healthcare hospitals (Iakovidis *et al.* 2004). The annual amount of data handled and stored in the HUS-PACS is more than 20 Tb.

However, neither point-to-point connections nor shared databases are effective if the user needs to share more than one database. To support simultaneous access to different databases, a more effective many-to-many approach is used (R-Bay 2009). This setting uses a central integration platform which communicates with different databases. Each healthcare organisation has only one integration to the central platform. There is no need for multiple agreements between different healthcare providers and databases. All data exchange issues are covered using technical integration and by a contract between the healthcare provider and the integration platform.

Many-to-many database integration is achieved by using the Integrating the Healthcare Enterprise (IHE) standard profiles, particularly cross-organisation data sharing profiles like the Cross Enterprise Document Sharing (XDS). XDS is not a standard itself but a set of technical and organisational agreements which describe how to use international standards like DICOM and Health Level Seven (HL7) most effectively in the shared healthcare environment.

Canada is deploying a nation-wide interoperable health information exchange (HIE) platform called Canada Health Infoway (Mendelson *et al.* 2008; Canada

Health Infoway 2011). It integrates different health databases throughout the country using XDS and other IHE standard profiles. Each citizen is provided with a secure and private longitudinal health record of his or her key health information within the health system. Images are communicated through a network of 12 diagnostic imaging repositories which consolidate imaging results.

Regional or nation-wide HIE platforms which have potential for creation of virtual electronic health record systems (EHR System) are implemented in many countries. HIE platforms store and communicate not only imaging but many other types of clinical and administrative information. In Estonia the nation-wide HIE platform is available since September 2008. The Estonian platform is a single nationwide global HIE platform as it comprises the whole country, registers virtually all residents' medical history from birth to death, and is based on the comprehensive State-developed basic IT infrastructure. There are various information systems that are connected to the central HIE platform messaging services to exchange patient summaries, radiology reports, time critical data, *etc.* (Sepper *et al.* 2011).

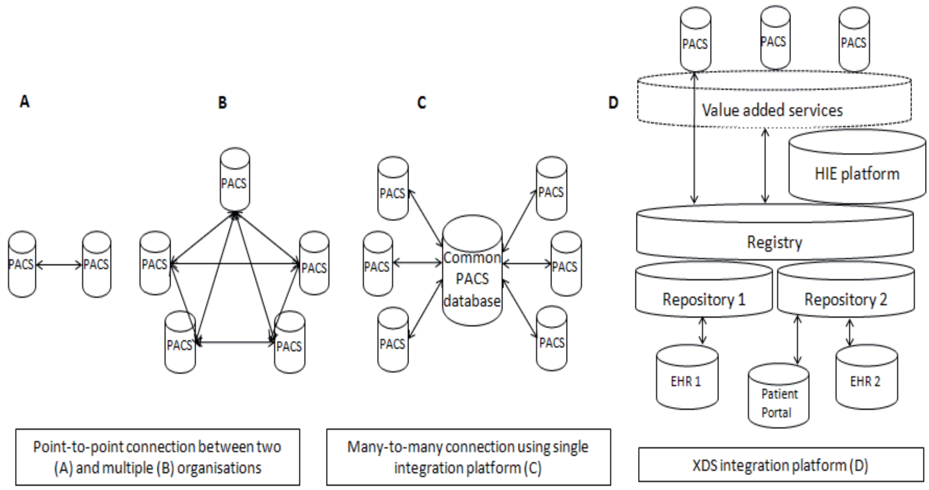

Fig. 1. Evolution of database integrations. Database integration started from point-to-point connections followed by many-to-many connections. XDS integration profile allows sharing of different health related data all over the healthcare community.

Different levels of data sharing

Images and related data can be shared inside the organisation, between the organisations in one region or across country borders, and also with the patient who could have instant secure access to the medical data and images. All those levels exist simultaneously today but are in use in different extension depending on the business process of a particular imaging service. Extending the workplace across different borders requires that technical and standardization issues be addressed, but also that organisational, semantic, quality and feedback related, and legal and financial issues (paper **III**) be taken into consideration. Proper handling of the above-mentioned subjects paves the way for the trustful relations between the healthcare professionals and between the healthcare professionals and patients (Barneveld Binkhuysen *et al.* 2011).

Data sharing has evolved from the linear data flow from one healthcare professional to another, to real digital data sharing across the enterprise and across organisations (Pohjonen *et al.* 2004).

Classic data flow in a healthcare organisation is linear (Saluse *et al.* 2010). It means that the clinical information and images are stored on the paper, film or isolated digital data storage media and almost all data is moving with the individual patient or physician. Simultaneous and asynchronous access to the patient health data is complicated and limited to the copies taken from the original papers or films. Also the use of digital images burned on to CDs or DVDs falls into the linear data flow category (Mendelson *et al.* 2008). In radiology, the linear data flow is based on the separate referral, films or CD/DVD, and report (Flanders 2009). Every step is dependent on the previous activity. The main limitation of linear data flow is a fragmentation of clinical process – every subsequent diagnostic or care process can usually start only after the previous activity is completed or is not at all connected to the previous episode (Hacklander *et al.* 2005).

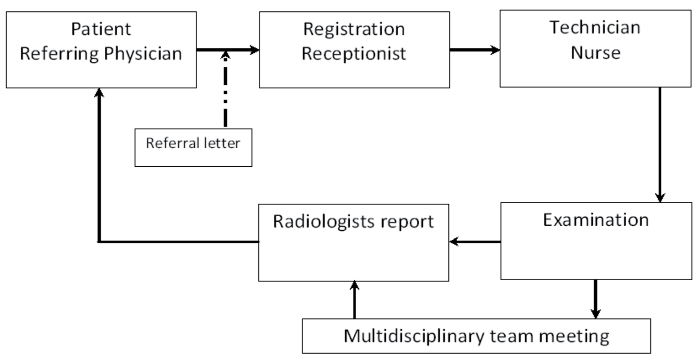

Fig. 2. Linear data flow. Patient data moves with patient. The information is shared with only a few healthcare professionals along the diagnostic and treatment process.

Development of digital imaging and the PACS allowed new types of data sharing between the different healthcare actors. Digitalisation of images and related medical data allowed for the opportunity to perform different tasks in the patient’s diagnostic and care pathway simultaneously and distribute work across clinical specialties. Simultaneous access enabled time to be saved, avoided unnecessary exams and reduced repeated radiation exposure (Kenny *et al.* 2008). Possibility to share data also changes the work process in radiology. Clinical information is available instantly for different users inside the healthcare institution or for users outside the healthcare facility who would access it remotely. The individual patient or physician is no longer the only information carrier.

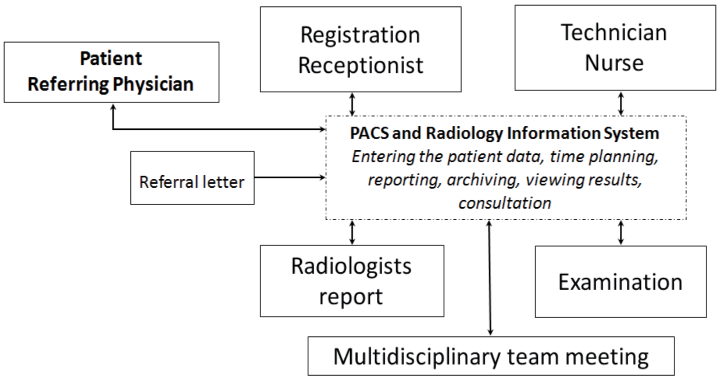

Fig. 3. Simultaneous data sharing. Patient data is accessed any time and from any place allowing implementation of new services. The exchange of the information is among all relevant parties.

Image sharing in radiology started inside the imaging unit. During the first phase integrations were implemented between radiology information systems (RIS), imaging modalities and PACS'. The further development of this set up was an information exchange with administrative software for financial and statistical reporting (Benjamin *et al.* 2009). Departmental or specialty oriented imaging integration was used widely by radiology departments to achieve filmless imaging process inside the department. For clinicians, the images were delivered from the PACS through image viewing workstations at their workplaces. The process was conducted by the radiology unit.

The next level of image sharing was initiated by the clinicians who also demanded access to the imaging related databases. The data exchange was established between the RIS-modality-PACS installation and other clinical information systems, e.g. laboratory information system, pathology information system, EPR, *etc*, in the individual healthcare institution. The objective was to integrate the imaging results of the individual patient with other clinical data. Extending the workspace outside the radiology domain brings new standards for clinical data exchange and management (paper **I**). This is caused by the fact that usually textual and numeric information in the EPR or other hospital information systems is organised according to the HL7 standard.

The consecutive level of image sharing is the exchange of images and related data between the different healthcare institutions. Also the sharing of images with the patient follows the rules of this level. Extending image sharing outside the healthcare institution brings along the need to increase data exchange security. Both DICOM and HL7 standards are supporting data exchange through secure virtual private networks (VPN) or secure socket layers (SSL) (DICOM 2011; HL7 2011). Inter-organizational data exchange does not bring along any additional needs for digital medical data standardisation. However, at this level, additional agreements on clinical classificators and terminology of exchanged information should be achieved to guarantee unambiguous meaning of clinical content. Semantic and linguistic interoperability is even more important in teleradiology, where cooperation can extend beyond one's own country borders (ESR 2011). The number of standard terminologies, classificators or vocabularies that could be used for multilingual purposes is limited. Most of the available terminologies are complex and do not support shared workflows or processes.

Standards for medical data and image communication are supporting the exchange of information between different actors in the healthcare domain. However, standards are mainly enablers for data exchange and do not in and of themselves facilitate the re-engineering of processes or the development of new services in healthcare (Indrajit *et al.* 2007). To utilise standards for workflow re-engineering and implementation of new services, there is a demand for standard profiles which facilitate communication across healthcare organisations.

1.2 Shared workflow

Despite of the availability of shared databases, there are still two types of workflow settings in healthcare organisations – linear workflow and shared workflow. Workflow sharing is implemented either internally in the healthcare enterprise or across organisations. The focus of this paper is to explore and discuss cross-organisational workflow sharing.

1.2.1 Linear workflow

In linear workflow, the imaging and reporting is performed according to agreed and fixed actions along the reporting process. A reporting worklist is pre-defined and images are assigned to the given radiologists or departments. The reporting process is built in consecutive steps and if the worklist is fixed, the changing of it demands manual interference. Linear workflow does not allow dynamically changing the worklist and assigning new exams or removing unreported exams from the worklist. Accordingly, it makes it almost impossible to follow and adjust different service levels for different customers; for example, adjusting radiologists´ workloads, taking into account the complexity of exams in the worklist and avoiding the reporting of only the simple cases, *etc*.

In the Baltic eHealth project, point-to-point connections were established among hospitals in Denmark, Estonia and Lithuania. The workflow was established among the hospitals in a way that Danish patients' images were reported on by radiologists located in Estonia or Lithuania (Baltic eHealth 2007). Another linear cross-border teleradiology workflow example is Telemedicine Clinic which provides sub-specialty radiology service to different clinics in United Kingdom (UK), Scandinavia, Spain, *etc*. It has central hubs in Barcelona, Spain and Sidney, Australia which are connected to several reporting service customers and providers (Telemedicine Clinic 2011, Eklöf *et al.* 2007).

1.2.2 Cross-organisational shared workflow

In cross-organisational shared workflow settings, referral letters, images or reports originate from different organisations. They are organised according to agreed process rules and combined to create a virtual worklist. Depending on the purpose, the worklist is created either to fulfil the reporting service agreement, or to follow the availability of radiologists or even workload, *etc*. Compared to linear workflow it allows automatic capacity management (ACM) and forms a seamless and very effective reporting process.

Medical imaging shared workflow is set-up using many-to-many teleradiology settings and/or using global worklists. Global worklist can be implemented on a many-to-many e-marketplace type of platform and supported by dynamic routing of images or relevant documents.

The global worklist approach enables sharing of the workflow by implementing standardised software and platforms for sharing. It allows creation of global worklists which are extending the limits of a single healthcare enterprise. With a global worklist in radiology, it is possible to avoid manual management of who reads what and where. Point-to-point connections which support mainly linear workflow can be replaced by matrix type of many-to-many connections. Radiologists serving healthcare facilities can accomplish remote reading and reporting across different hospitals or large geographical areas. This is an excellent way to increase reporting quality or balance workload locally or regionally between sites with different RIS or PACS (Pohjonen 2010). Manual workflow management can be replaced with ACM.

Integration of administrative and financial software with the global worklist creates a new type of brokering services, the so-called e-marketplaces. The e-marketplace regulates, in addition to the clinical radiology workflow, also the reimbursement. It is also a controlled way to practise radiology with transparent quality assurance, centralised certification databases and uniform data privacy and security policies. In this brokering service set-up, end-customers and teleradiology providers from different organisations can interact through a central connection platform. The concept follows the many-to-many connection principle.

There are examples of the implementation of inter-organisational shared workflows and global worklists in different places in the World. In the Western Norway Health Care Region (Helsevest), the XDS-based communication platform was used to integrate 4 different RIS and 5 PACS solutions within 15 hospitals and several private radiology units (Størkson *et al.* 2009). In North America, similar shared workflow implementations are in commercial use. Companies like Telerays or Virtual Radiologic in the United States (USA) and Real Time Radiology in Canada integrate hospitals, imaging centres and radiologists to work together (Telerays 2011; Virtualrad 2011; Real Time Radiology 2011). Also e-marketplace types of brokering services are evolving. The partially EU-funded market validation project, R-Bay, concerning cross-border teleradiology, was one of the first dealing with implementation and evaluation of an eMarketplace (R-Bay 2009).

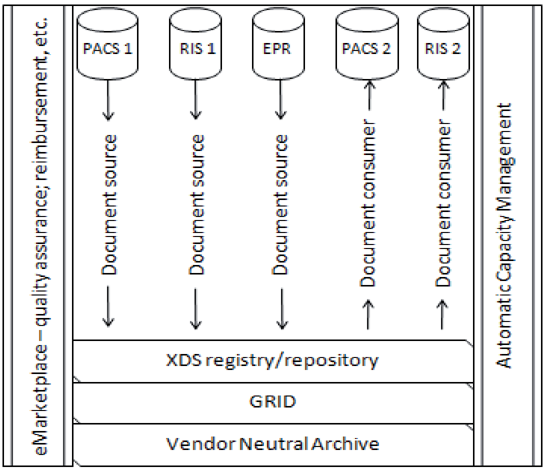

Fig. 4. Shared workflow based on XDS profile and shared databases.

1.3 Aims of the study

The main aim of this research is to investigate the feasibility and benefits of cross-organisational data sharing and shared workflow implementation in medical imaging. The research is based on practical teleradiology projects conducted between European countries during 2004–2009: Baltic eHealth and R-Bay. Technical and semantic interoperability, organisational, security, privacy, and legal issues are addressed simultaneously.

In Baltic eHealth, a cross-border teleradiology service was established using point-to-point integration and linear workflow model. Baltic eHealth was followed by R-Bay where many-to-many integration was used and shared workflow scenarios were described.

The sub-tasks of this study are:

1. Determining the benefits and barriers to overcome in implementing novel services based on shared data and workflow.
2. Investigation of usability of multilingual structured reporting.
3. Specification of importance of service models for shared workflow implementation, incl. e-marketplace.
4. Description of merits of shared digital data processing and delivering technologies used in radiology – data streaming and grid computing.

2. SUBJECTS AND METHODS

The research upon which this thesis work is based arose from the implementation of two cross-border teleradiology projects (Baltic eHealth and R-Bay) that took place during the period 2004 to 2009. These projects lead to four articles (paper **I-IV**) where different aspects of cross-border teleradiology, and cross-organisational data sharing and shared workflow, were discussed.

During the projects Baltic eHealth and R-Bay, 649 cross-border teleradiology cases were studied. These projects involved 4 different clinical set ups. There was one second opinion service (The Netherlands – Czech Republic) and three primary reporting services (Denmark – Estonia; Denmark – Lithuania; Finland – Estonia). The sizes of the hospitals, participated in the projects, varied from 230 (Czech Republic) to 1100 (Lithuania) beds affiliating from 585 (Czech Republic) to 9500 (the Netherlands) employees.

In both cases, the creation of a cross-border teleradiology service began with the building of a professional and trusting relationship between the clinical partners. It included on-site visits and familiarisation with clinical radiology workflows in each hospital. Each partner appointed a certain radiologist to act as the responsible person for communication between project partners. In the clinical workshops, different incentives, potential barriers and the required technology, to exploit cross-border teleradiology, were discussed. Clinical workshops highlighted the predicted benefits of data sharing and shared workflow.

In the R-Bay project, 171 different radiology cases from Finland were reported in Estonia, and 45 radiology cases from Denmark were reported in Estonia. However, only knee X-ray images were reported. For second opinions, 283 Czech radiology cases were randomly selected, patient identification data was removed, and the cases were then interpreted by the Dutch hospital. A consultation portal (a sort of radiology "eMarketplace") was used to facilitate many-to-many connections between the teleradiology customers and providers.

To transfer images, streaming technology was used in both projects. Properties and benefits of recent technologies and models to support data sharing and shared workflow (incl. VNA, grid computing, eMarketplace-type of platforms and automatic capacity management (ACM)) were discussed in workshops and described based on the review of recent literature.

To overcome the language barrier in cross border reporting, a structured multi-lingual reporting tool (SRT) was created by radiologists participating in the Baltic eHealth project. There were no institutions in the projects speaking the same language. For reporting, three types of linguistic solutions were used. In primary reporting either the SRT or the native language of the customer was used. All second opinions were written in English. The SRT was built to carry out a semantic translation of findings rather than a word for word translation.

The radiologist carrying out a cross border reading used a structured reporting template with his or her own language. The report was created using previously created templates and drop down menus with multiple choices. For report findings that were not covered by the templates, there was an option for the radiologist to write free text which was translated by an interpreter. The SRT was used for translation of 195 knee X-ray reports from the Estonian or Lithuanian language into the Danish language. The rest of 454 reports were written in the customers' native language or in English (second opinions). Referral letters were translated by interpreters into English or the radiologists' native language.

In the Baltic eHealth project, a total of 39 knee X-rays were reported on by three consultant radiologists from each country. The goal was to discover inter-observer variability. To evaluate the discrepancy among the various radiologists' reports, a four grade feedback solution was used (grade 1 and grade 2 – clinically insignificant discrepancy; grade 3 and grade 4 – clinically significant discrepancy). In the R-Bay project, the quality and content of all reports was discussed between the radiologists of the customer and radiology service providing hospitals, and the necessary adjustments were agreed. Organisational, semantic (incl. language) and legal barriers that were recognised in both projects were described in several workshops.

To construct a comprehensive framework for investigating the benefits, barriers and feasibility of cross-organisation data sharing and shared workflow, practical experience and theoretical arguments (e.g. recent scientific literature) must both be considered. The reason for this is that during the years that these projects were carried out, both technology and organisational aspects progressed remarkably. Here we include a description of new models for shared workflow that have been implemented during recent years but which were not available at the time the teleradiology projects were being implemented. We also discuss new advances in standard profiles and technologies for data sharing and shared workflows (like the recently developed IHE profiles, VNA and ACM). When a health care facility wants to implement new e-health services, all the actors and transactions in a cross organisational data sharing and shared workflow process need to be identified and taken into account. When carrying out this process, there are many lessons to be learnt from the Baltic eHealth and R-Bay projects, together with recent advances in the medical data exchange standard profiles and emerging models for shared workflow.

3. RESULTS AND DISCUSSION

3.1 Benefits of data sharing and shared workflow

Any new method or model implemented in healthcare must provide clear evidence of benefits for a patient and/or public health (Geenhalgh *et al.* 2008; Winblad *et al.* 2011). It also has to be accepted by healthcare professionals (Pilling 2003). The main expectations are that the new proposed service increases safety, quality, accessibility and efficiency of the healthcare service and that the cost of the delivered service remains in the budgetary limits (Fontaine *et al.* 2010; Institute of Medicine 2003; Hoffmarcher *et al.* 2007). In addition to the healthcare provider, the citizens and society must benefit from the innovation in healthcare, though the benefits frequently appear through different mechanisms (Saluse *et al.* 2010; Lundgren *et al.* 2003).

3.1.1 Benefits for the radiology community

Pervasive and simultaneous access to the images, clinical data and processing functions increases the quality and effectiveness of reporting (Thrall 2005).

For the radiologist, medical data and image sharing across organisations opens simultaneous access to the relevant clinical data, referrals, prior images and reports, and current exam. The reporting radiologist can also view, in addition to the data available in local RIS, other relevant clinical information. Sharing EPR case summaries could be a valuable asset in the case of complicated clinical situations. This is especially valid when the patient has a history of visiting multiple healthcare institutions (paper **IV**). Data sharing makes radiologist more informed about the patient´s actual clinical situation. There is no longer a need to make repeated exams because images can be retrieved from other storages. The above-mentioned features support radiologists to make comprehensive interpretations of imaging findings. Sharing images and related data also increases the importance of the radiologist as a clinical consultant to help make the best diagnosis and choose the best treatment for the patient (Thrall 2007b).

Today, in many hospitals, the radiologist, as the specialist having the most advanced skills and tools to get access to the different clinical databases, has become the central actor in conducting multidisciplinary meetings, clinical consiliums and clinical-radiological consultations, which in turn allows radiologists to improve the diagnostic and therapeutic impact of imaging (Dalla Palma 2000).

Sharing of image information with other partners provides the opportunity for the radiologist to receive relevant feedback to the report or image quality and also share the best imaging practices with colleagues (Thrall 2007a). Access for all users to the same system features and functionalities, that is not dependent on the application, equipment or location, makes the use of EPR, RIS and PACS easier, more comfortable, trustworthy and efficient (paper **I**). Sharing common reporting software also brings along new tools for image processing and interpretation. It decreases training times by providing service-oriented applications that are focussed on the particular needs of various clinical users (papers **I** and **II**). Shared databases avoid unnecessary downloading of big data sets to the local database. This increases security and data consistency.

Sharing of databases of different healthcare providers allows building of a global shared worklist across different PACS and RIS. It enables creation of new models of imaging and reporting workflows, e.g. from remote reporting of trauma and emergency cases during off-hours and across multiple hospitals, to specialised reporting of oncology cases and assessing the treatment effect, to using global teaching and reference databases while reading difficult cases, *etc*. (Mendelson *et al.* 2008; Adler *et al.* 2009). Shared workflow opens a wide range of workflows across organisations and gives options to choose the most appropriate working environment (Thrall 2007b).

Workflow sharing increases competition in the labour market among radiologists and has the potential to increase radiologists´ income. Radiologists can benefit from ACM which helps to share workload more equally; in the sense of both the number of reports as well as in exam complexity. Sharing of imaging and reporting services makes it possible to build new competitive advantages like sub-specialty readings, opportunities to ask and to give second opinions, to even out workload peaks, and to get back-up in case of illness, vacation, *etc*. Another advantage for radiologists or healthcare providers is the possibility to compete in the image reporting market, with shorter reporting times, better quality, lower price, *etc*. (papers **III** and **IV**).

Use of dedicated tools over the Internet increases not only the diagnostic quality of radiologists' work, but these tools also help develop imaging interpretation skills and knowledge of clinicians, including improved communication with patient (Fridell *et al.* 2011). Image interpretation becomes a more integral part of daily clinical work along the patient care pathway. Pervasive access to patient data also supports patient-centric and highly nomadic clinical workflow (paper **II**).

For biomedical research and clinical studies, the use of shared imaging repositories and/or software and computational resources, enables valuable multi-institutional collaboration (Sharma *et al.* 2009, Mendelson *et al.* 2008). Shared image related databases can be linked together with the other sources of patient data, which makes it possible to implement decision support algorithms based on the evidence-based medical databases. Imaging data can also be analysed in relation to genomics or other research purposes (paper **I**).

3.1.2 Benefits for the healthcare provider

For the healthcare institution, the sharing of databases and workflows opens the whole market of reporting service providers (paper **IV**). It enables coordinated sharing of imaging and reporting resources that would allow for evening out of workload peaks, avoiding picking of lucrative cases by radiologists, problem-solving in diagnostic and treatment processes, and follow-up in a virtual, dynamic, multi-institutional setting with health professionals.

By using radiologists with different subspecialties the healthcare institution has opportunity to increase overall reporting quality and competitiveness (paper **III**). It is possible to distribute and integrate current data with other relevant data throughout the patient care pathway.

The benefits for healthcare institutions also includes improving reporting capacity, shortening reporting times, using the opportunity for second opinions, and highlighting shared services as a reference for the hospital to attract patients. The opportunity to increase radiologists' income with additional shared service work is also beneficial for the service provider. Data sharing and shared workflow allow establishing universal quality assurance schemes and demonstrating transparency of results (papers **III** and **IV**). Sharing workflows allows diagnostic imaging readings to become more standardized (paper **II**) and open for benchmarking. Consequently, this makes implementation of clinical guidelines more feasible.

The possibility to separate imaging from reporting leads to the consolidation of operations, especially regarding ambulatory imaging services and imaging in geographically remote areas. Both RIS and PACS services can be performed virtually allowing for new workflows based on sub-specialty, the availability of resources, urgency, or other clinical features. Searches of large, complex and distributed repositories of data can be completed locally and time efficiently.

From the economical point of view, shared databases and workflows lower exploitation costs through universal and centrally upgraded applications (paper **II**). Also, scalability in a universal application guarantees high reliability. With shared databases and workflow, it allows the administration of healthcare providers to gain an overview of imaging methods and patient groups through the RIS, PACS and EPR and use this information to estimate the profile and cost of imaging for specific radiology units or healthcare organisations.

3.1.3 Benefits for the society

Usually digitalisation of the healthcare processes generates intangible benefits for the patient and community. However, it is difficult to show positive social impact from innovative action. Though digitalisation of data and re-engineering of workflow are particularly heterogeneous processes by nature and difficult to evaluate, there is evidence that it is society that receives the biggest benefit from the data sharing and shared workflow (Saluse *et al.* 2010; Lundgren *et al.* 2003; American Diabetes Association 2008). Members of society benefit through quicker and more thorough analysis of imaging services. Based on the reports from the shared databases of a particular region's healthcare system, a forecast of healthcare costs for imaging management will have stronger evidence. The quality of data emerging from RIS, PACS and EPR will enable further scientific research to be carried out about the medical imaging processes as well as diagnostic and care pathways. An overall improvement in imaging management leads to a more informed and optimised use of imaging methods, thus decreasing overall healthcare costs. The benefits for the society also include benchmarking of healthcare providers leading to the increase of effectiveness and quality, improved planning of resources and optimisation of investments at the regional or national level. Benefits derived from the quicker access to imaging and treatment are: increased productivity, fewer disability and sick leave payments, more years of healthy life, quicker return to labour market, *etc*. The list is not exhaustive but introduces areas where the use of shared databases and workflow sharing has an impact on society (Saluse *et al.* 2010).

3.1.4 Benefits for the patient

For the patient, the most important change in using the shared database is the opportunity to become more involved in the imaging process (Castro 2009). A patient has access to their own medical data and images, collected and stored in different health care institutions during multiple visits to various physical locations (paper **IV**). This improves patient´s knowledge about their own health condition, previously performed exams and potentially avoids unnecessary radiation exposure of the patient caused by not needing to duplicate the taking of radiological images (Castro 2009; Kenny *et al.*2008). It also helps in planning of time and other resources in case an imaging procedure is needed.

Better informed and treated patients can return to their normal lives much faster. Consequently, in addition to improving the quality of patients' lives, this also has a positive economic effect on the state through increasing tax revenue while decreasing sick leave costs (Saluse *et al.* 2010).

A referring physician is able to forward relevant referral letters and previous imaging results directly through the shared database, eliminating the need to see the patient in person. Healthcare professionals are able to make more efficient and informed selections of patients, when booking appointments and compiling waiting lists for procedures, if they have access to imaging data from the RIS, EPR or PACS. The time needed to visit doctors will decrease as the number of required visits decreases due to the availability of shared information. It also has been shown that more transparent information flow leads to better communication between the patient and the physician (Fridell *et al.* 2011).

3.2 Prerequisites for data sharing and shared workflow

3.2.1 Digitalisation of medical images and related data

For data sharing and implementation of shared workflow, analogue film and text must be replaced by digital images, text and numeric data. This prerequisite is valid for every step of the clinical pathway. Lack of digitalisation of all related images and clinical data leads to inefficiencies in the seamless flow of imaging data and hinders sharing of information (Thrall 2005, Thrall 2007b).

Digitalisation of medical images is achieved by converting analogue signals produced by different imaging modalities into computer processable digital values (Huang 2010). A digital image is composed of a set of picture elements, or pixels, which has a number or digit assigned to it, which is based on the amount of exposure the sensor received (Gormez *et al.* 2009). Pixels are aligned in a number of columns and rows, which would then form digital images. If the digital image is three dimensional, then the picture element is called a voxel.

The most frequently used imaging modality is an X-ray, which represents 60–70% of all radiological exams. It is followed by ultrasound, computed tomography, magnetic resonance and nuclear medicine imaging. Today, digital X-ray images are produced indirectly by computed radiography (CR) or directly using digital radiography (DR) modalities. Other radiological images are already in a digital format when they are generated (Huang 2010).

PACS is used to acquire, store, query, retrieve, display and process medical images and associated data originating from different imaging modalities. PACS integrates these sub-systems by digital networks and software applications (Huang 2010). It allows effective communication, for patient care, of DICOM and non-DICOM images. As a separate medical imaging technology, it is a prerequisite for image sharing and shared workflow. PACS provides a platform for a single point of access for images and related data and also integrates images from other healthcare information systems.

To achieve digitalisation of the whole imaging pathway, digital images should be accompanied by patients′ digital data, including administrative data. For medical documentation, the most widely used interoperability standard is HL7. It provides a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical activity and the management, delivery and evaluation of health services (HL7 2011). HL7 covers a wide range of healthcare processes while DICOM concentrates mainly on medical imaging and the related exchange of data.

Today the integration of different healthcare information systems has evolved to the enterprise and cross-organisational level. For effective image communication, PACS installations now serve multiple hospitals and large geographical areas.

3.2.2. Standards and standard profiles

Standards in medical imaging specify values, rules and guidelines to achieve optimal, continuous and repeatable image processing results. Standards are approved by a recognised international or national standardisation body and made available to the public (Directive 98/34/EC). In medical data sharing, the most commonly used standards are DICOM and HL7. These standards are used for image and health related data communication.

The two goals of standard profiles are to describe rules on: 1) how to use standards in a coordinated way for data sharing between different clinical databases; and 2) implementation of the most optimal clinical workflows (IHE 2011c). The IHE has become one of the main standard profiles used by healthcare professionals and the healthcare industry. It is the standard profile that uses DICOM, HL7, Organization for the Advancement of Structured Information Standards (OASIS), security standards, *etc*. Standards and standard profiles enable healthcare professionals from different healthcare domains or geographical regions to simultaneously use different databases and to share workflows to achieve the best clinical and administrative result.

3.2.3 Integrating the Healthcare Enterprise (IHE)

The IHE profiles were established to improve health related digital data sharing. IHE profiles were formed in 1997 by the common initiative of healthcare professionals and the healthcare industry. The IHE promotes the coordinated use of established standards to achieve specific clinical goals (IHE 2011c). The aim is not to develop new integration standards but define integration rules that describe how to use and follow standards already in use (Fernandez-Bayó *et al.* 2010). The IHE does this via a description of technical frameworks for the implementation of established messaging standards. It is also a forum for coordinating and testing integrations of computer systems in healthcare.

The IHE standard profiles are organised according to topics like clinical, IT-related and other domains to address specific clinical needs for supporting optimal patient care (IHE 2011c). In addition to radiology, other clinical domains are cardiology, laboratory related issues, radiation oncology, patient care coordination and eye care. IT-related issues are focussed on IT infrastructure (ITI) domain (Lugnegard 2010). Other domains are patient care devices and anatomic pathology. Profiles regulating cross-organisational data sharing and shared workflows fall into the so-called “cross-profile” family. Today, the most central of them is the XDS profile.

One example of IHE profile implementation is the correction of accidentally entered incorrect patient data – the correction must extend backwards into all databases. This correction is described by the IHE Radiology's Patient Information Reconciliation (PIR) integration profile. This profile allows changing patient data through different databases that are involved in the particular process (assumes healthcare professional is entitled to make the changes). Though development of the IHE profiles aims to cover data exchange between equipment of different vendors, not all platforms are communicating seamlessly. For instance, corrections between PACS and VNA are not yet standardised and need further development.

The IHE identifies a subset of the functional components of healthcare enterprises, called actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions (IHE 2011c). However, it leaves a number of significant aspects of any solution up to the particular implementation to define. This means that large parts of a national solution would need to be specified and built, including: security solutions, repository document semantics, affinity domain and information governance policies, and version and configuration management. A number of gaps in a national solution would be covered by profiles that have only recently been proposed by the IHE. This includes image transfer standards suitable for large implementations and notification mechanisms. These profiles are described below. The IHE is continuously carrying out standard profile development initiatives and the testing of every new implementation is of the utmost importance. There are new profiles undergoing testing and it could take a number of years until they are mature enough for a national or cross-country solution (IHE 2011c).

In radiology, the IHE supports data exchange between different modalities and information systems according to defined clinical needs, workflows or planned services (Siegel *et al.* 2001). However, in addition to radiology, the IHE extends to many other clinical and operational fields and intends to support communication among different modalities, clinical subspecialties and healthcare user groups.

3.2.4 IHE standard profiles for data sharing and shared workflow

As described above, to standardise the communication of images and related data across healthcare organisations, there is a need for system architecture and guidelines that specify conditions for data sharing.

The Cross Enterprise Document Sharing (XDS) profile has been developed as an IHE information technology infrastructure profile that manages the exchange of documents that healthcare organisations have decided to share. From a single point of entry, XDS profile makes it possible to use patient medical data stored in different archives and managed by diverse applications.

The XDS profile defines a set of actors and transactions which allow documents to be registered in a single central registry, for them to be queried and also retrieved. It registers and shares documents between healthcare enterprises. The XDS allows the healthcare provider to share medical data without replacing the existing local or regional legacy information system or infrastructure (paper **IV**). The sharing of documents is limited to a defined group of organisations. This group of healthcare organisations is named the XDS Affinity Domain and is defined as a group of healthcare enterprises that have agreed to work together using a common set of policies and common infrastructure. This group does not follow any geographical or regional definition. However, there can be only one document registry for each XDS Affinity Domain (IHE 2011c). A document registry contains an entry for every registered document including defined sets of metadata elements. It holds a Uniform Resource Locator (URL) for a repository where each document is actually archived. There are usually different document archives communicating with document registry. Thus, even though the Affinity Domain is not geographically defined, it identifies the location of the single document registry. The logs of different transactions in the domain are stored in the audit repository. The XDS re-uses open source ebXML registry methodology to provide a centralised method of indexing documents (IHE 2011c).

The XDS profile uses a document registry to capture the metadata about a document, including a pointer to the location of the document in a repository. It separates metadata and the actual content. This allows XDS to support a wide range of documents. Logical separation simplifies document exchange and enables existing information systems to use a wide variety of document formats (PDF, HL7 CDA, simple text documents) (Fernandez-Bayó *et al.* 2010).

A healthcare IT system can act either as a document source or as a document consumer. In case of acting as document source, the provider archives a document in a repository in a transparent, secure, reliable and persistent manner, and registers it in the central document registry to allow for retrieval request. In case the healthcare organisation is a document consumer, the healthcare organisations IT system queries the data about a particular patient from the document registry, and according to the profiles describing the document properties, finds, selects and retrieves it from the repository where the document is archived (Fernandez-Bayó *et al.* 2010).

To deal with patient privacy and consent issues, there is a Patient Care Coordination profile called Basic Patient Privacy Consents (BPPC) that enables XDS Affinity Domains to be more flexible in the privacy policies that it can support. BPPC provides mechanisms to record patient privacy consents, enforce these consents, and create Affinity Domain defined consent vocabularies that identify information sharing policies (ACC 2009).

The XDS also demands the use of the IHE ATNA (Audit Node and Node Authentication) profile. The ATNA profile ensures that all transactions between involved servers are carried out securely and only with other trusted nodes in the network. It makes use of the Transport Layer Security (TLS) protocol to encrypt data being exchanged over an insecure network. The ATNA profile is responsible for the receipt and persistent storage of audit log events within the affinity domain. Audit events are required whenever an application imports, exports or queries protected health information (Lugnegard 2010).

The Cross-enterprise Data Sharing for Imaging (XDS-I) extends the XDS to share images, diagnostic reports and related information across healthcare organisations. It is a profile that brings additional advantages to teleradiology networks. For example, a reporting radiologist has access to relevant imaging data stored in other healthcare institutions in the region (Fernandez-Bayó *et al.* 2010). The XDS-I profile specifies actors and transactions that allow users to share imaging information across enterprises. Images need to be indexed and published in a central document registry. The XDS-I defines the information to be shared, such as sets of DICOM instances (including images, evidence documents, and presentation states) and diagnostic imaging reports.

The XDS-I allows images to be located and retrieved remotely. The overall result is a three stage process for retrieval. The process starts with locating documents and reports for a patient in the registry. The next step is the retrieving of documents from the repository. Finally, a reference from the document or report to the image source is followed and the image is retrieved.

The XDS and the XDS-I reference a number of logical actors that are able to send and receive specified transactions.

The Cross-Community Access (XCA) profile is an IHE profile also defined under IT infrastructure. The XCA profile is developed to allow two or more registers to communicate with each other. It supports the means to query and retrieve patient-relevant medical data held by other communities. Such communities may have XDS Affinity Domains which define document sharing using the XDS profile, or it may be with respect to other communities, no matter what is their internal sharing structure (IHE 2011c). The data query and retrieval from other communities is performed through the XCA initiating or responding gateway. Normally, there is only one gateway for a particular affinity domain. This one gateway will send requests to all external communities. Organisations may host any type of healthcare application such as EPR, patient health record (PHR), PACS, *etc*. A community is identifiable by a globally unique id (homeCommunity Id). Membership of an organisation in one community does not preclude it from being a member in another community. Such communities can share their domain documents using the XDS profile but they can also share documents with other communities with different internal sharing structure that implement the XCA profile.

The Cross-Community Patient Discovery (XCPD) profile complements the XCA profile by helping locate communities which hold a patient's relevant health data and by translating of patient identifiers across communities holding the same patient's data (IHE 2008). This profile is not relevant for domestic data exchange if the nation has one personal identification number. However, to communicate with healthcare information systems located in other countries, a regional or national information system with unique personal identifier should be compliant with the XCPD profile.

While the XDS-I profile supports the exchange of images and radiology workflows across healthcare organisations, it does not support the interchange of medical images between the communities. The XDS-I does not provide the framework and guidelines outside the XCA Affinity Domain. For example, to also share DICOM images, there is an extension of the XCA (like the XDS-I is for the XDS). The XCA-I allows query and retrieval of medical images and related data from other communities because the current DICOM mechanisms are not sufficient to handle cross community access.

There is European eHealth Project, called epSOS (European Patient Smart Open Services), to inter-connect national health data exchange platforms in order to view patients' summaries and e-Prescription/e-Dispensing data across national boundaries (epSOS 2011). The epSOS project aims to demonstrate that it is feasible to inter-connect National health data exchange platforms by using the XCA profile for any EU Member State that has eHealth services. This would allow residents of those countries to be offered these services when they travel abroad (paper **IV**).

Also, profiles describing cross-organisational workflow sharing are emerging. The Cross-Enterprise Document Workflow (XDW) profile enables participants in a multi-organizational environment to manage the status of documents involved in a clinical workflow (IHE 2011b). The prerequisite for XDW implementation is that cross-organisational document sharing infrastructure (XDS, XCA) already exist. The XDW uses a workflow document to track the different tasks related to the clinical event. The workflow document does not include any clinical information but contains information about the status of the particular clinical document in the workflow and maintains historical records of tasks. It uses the XDS document registry and repository to create and update the workflow document. The XDW allows one to see if the document is either registered, the ordered service is booked, scheduled or completed, *etc*. (Pariso *et al.* 2010). This helps healthcare providers from different organisations to follow the status of diagnostic or the treatment process throughout the clinical event with relationship to one or more documents and can see who has made changes associated to the workflow. The XDW is not intended to support any specific workflow. On the contrary, it is workflow-independent interoperability infrastructure that facilitates the integration of multi-organisational workflows. It is also scalable up to regional and nation-wide settings.

3.2.5 Common semantics: terminologies, classifications and vocabularies

Today, information about the health of an individual patient, public health or information used for the research purposes is processed and presented, in most cases, using computers. In addition to the standardisation of health data and data exchange protocols, semantic interoperability is an important issue in data exchange. Semantic interoperability does not differ between digital and analogue set-ups. To understand unambiguously the full meaning of a patients´ medical data requires utilisation of internationally or locally accepted clinical terminologies, vocabularies and classificators, and even more widely, the definitions of links and relations between them. For clinical data representation there is a need for shared models that are linked to standard terminologies and classifications. Standard representation of the full meaning of a patient's medical data requires integrating terminologies and classifications with models of context and other relationships (Healthcare Terminologies 2006). Terminologies and classifications form the foundations of information content in healthcare information systems (Healthcare Terminologies 2006).

In shared environments, semantic issues tend to be more visible because the data is more easily accessed and compared. Semantic interoperability is especially important in data sharing across organisations (papers **III** and **IV**).

Terminologies and classifications have different uses. Terminologies are used to primarily capture clinical information while classificators are utilised for secondary data use. Terminologies are highly detailed and have substantial granularity allowing standardization of the recording of the patient's findings, events and circumstances (Healthcare Terminologies 2006). They are mainly used to collect and present clinical information. In healthcare different healthcare systems and health related professionals have developed terminologies for their own purposes. The essential characteristic of terminology is a definition and an accurate specification of meaning. Terminologies must allow unambiguous communication of meaning across different healthcare areas and among health professionals and consumers. However, for practical clinical work, terminologies lack reporting rules and guidelines. The reason is that the intended meaning of terms can be different according to their context and in the context of use. The main limitation in sharing medical terminologies is the lack of conceptual integration of terms. Conceptualization of terminology using ontology helps utilisation of terminologies in different healthcare areas (Gangemi *et al.*).

Systematised Nomenclature of Medicine – Clinical Terminology (SNOMED-CT) is one of the most widely used systematically organised computer processable collections of medical terminology (IHTSDO 2011). However, to use SNOMED-CT for radiology reporting requires additional work to aggregate large numbers of terms from different SNOMED-CT hierarchies into the form that is usable and to which radiologists, referring physicians and patients are accustomed. Using SNOMED-CT terms only makes the report too granular and structured while physicians and patients are still used to getting reports in a more colloquial form.

For practical use, terminologies are aggregated to form context specific, semantically accurate medical vocabularies and libraries. Also mapping of terminology and classification databases and codes is performed to improve the usability of digital health data.

In the Baltic eHealth and R-Bay projects, a structured radiology reporting tool was used to translate radiology reports (paper **III**). The reporting tool was based on anatomical and clinical terminologies which were aggregated to form semantically equivalent and computer processable sentences in different languages. The tool translated radiological findings from one language to another. The reporting radiologist chose a sentence describing normal or specific pathological findings. Sentences that characterised pathologies were embedded into drop down menus describing the severity of the finding in more detail, specifying anatomic location, or including classification of pathology. Sentences were created in English and translated into Danish, Estonian and Lithuanian languages by radiologists who spoke the respective language. The translation followed the semantic meaning of the English language original sentence and also followed the structure of a particular description rather than using word for word translation. Although the concept received positive feedback from clinical users, it was limited to only one anatomic region and had very limited clinical use (paper **III**).

The IHE standard also uses multiple terminologies. They are integrated into software layers that provide access to and mapping among diverse terminologies stored in a database. Commonly used terminologies are useful in practical application of the XDS and XCA standard profiles. These include SNOMED-CT, Logical Observation Identifiers Names and Codes (LOINC), several HL7 vocabularies, some ISO standards and language codes (IHE 2011c).

Classificators are intended for quality of care measurement, reimbursement, statistical and public health reporting, operational and strategic planning, and other administrative functions. A classification system groups similar diseases or procedures and organises related information for easy retrieval or other data processing purposes. They are hierarchical and provide guidelines and reporting rules for effective use. ISO 17115 defines a classification as 'an exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose' (ISO 17115:2007). Classification involves the categorisation of relevant concepts for the purposes of systematic recording or analysis. The categorisation is based on one or more logical rules. Coding rules must be incorporated in the classification. Coding indicates the source terminology for a particular code. However, the compliance to use classificators in different clinical conditions is not always at an acceptable level. Today there are more than 20 comprehensive terminology and classification systems in healthcare facilities around the world. Additionally, there are a number of terminologies and classifications developed for a particular specialty or application.

To integrate different terminologies and classifications for shared information processing and shared workflows, different systems are mapped for simultaneous use of systematised lists. Mapping creates linkages between controlled content from one terminology or classification scheme to another. It enables data stored in different archives to be reused. Mapping reduces errors, increase consistency and reduces costs. It allows the retrieval of information from EPR, factual databanks, bibliographic databases, full-text sources and expert systems. However, these links are built according to a specific contextual basis and are unlikely to be 100% accurate.

3.3 Recent technologies and models to support data sharing and shared workflow

Exchange of large data sets over long distances and among different databases demands tools for secure, reliable and quick image transmission (paper **I**). Recent technologies that use shared computing power and streaming of pre-processed data using Internet protocols allow data sharing and implementation of shared workflow. This is done in a manner that follows security and privacy rules, is carried out in a timely manner and is convenient for healthcare professionals.

Use of the current array of PACS products and image processing tools replaces dedicated, stand-alone PACS workstations with web-based PACS and RIS. These Web-based PACS and RIS communicate with other information systems throughout the healthcare domain (Wang *et al.* 2011). Radiologists, radiographers and clinicians can use the same, single platform which provides them with diagnostic tools, advanced image processing methods as well as with remote meeting platforms on the web.

3.3.1 Streaming technology

Streaming technology allows secure transmission of standardized, large data sets through low network bandwidths (paper **II**). Streaming allows sending of portions of data from a source to a client for processing or viewing, rather than sending all the data first before any processing or viewing (papers **I** and **II**). Medical imaging streaming is a valuable method to retrieve large volumes of image information over limited bandwidth or large geographical areas. It provides access to images and reports from different PACS archives and on a variety of client devices. Streaming creates vendor neutral applications: images are retrieved from PACS and can be viewed on any DICOM-viewer that is installed on client‘s standard computer or mobile device. Images are never stored outside the PACS but streamed only for viewing. In addition to PACS, VNA storage applications can be used as a source for image streaming.

Streaming methods can be categorized as raw streaming, intelligent downloading, or adaptive streaming of functionality. In healthcare settings, predominantly adaptive streaming and intelligent downloading are used (paper **I**).

In adaptive streaming, only frame-buffer views of the data or results of the data analyses are streamed. Using the power of the server, DICOM images are modified and processed. While the image is modified, this method does not send frame images from the server to the client each time the image properties are changed. Only final screen images are compressed and then transmitted to client devices in accordance with requirements regarding bandwidth usage, image quality, and interaction rates. This streaming method adapts to changing conditions in order to meet these requirements (Medical Insight 2009). The emphasis of the technology for adaptive streaming of functionality is to provide remote access to full system functionality, using the best combinations of local and remote processing of medical data.

Intelligent downloading is a form of streaming whereby only relevant portions of data set required for immediate viewing or processing are downloaded to a client. In general, processing of the data occurs locally at the client’s. Additional downloading may occur in the background in anticipation of other viewing or processing requests (papers **I** and **II**).

3.3.2 Vendor neutral archiving (VNA)

Vendor neutral archiving is a term that is used to describe archiving applications that are free from vendor imposed limits on how, when, where and what a healthcare enterprise does with its digital documents and images (DeJarnette 2009). VNA can be used not only to archive medical images but also to be a repository for other digital medical data.

VNA aims to allow healthcare enterprise to break the physical connection between the application and its content. It enables healthcare enterprises to own medical digital data and effectively share it across different organisations and clinical specialities. This is achieved by using vendor neutral middleware based on IHE standard profiles technical framework for context management.

Initially the trend in digital medical data archiving was towards disparate specialty or departmental repositories that were managed by vendor specific applications. This resulted in the creation of multiple data silos inside the enterprise. Communication between the silos required expensive and resource demanding integration (Benjamin *et al.* 2009). Furthermore, the lifespan of archiving media, including PACS archives and software applications, is much shorter than the expectations of patients and clinicians regarding archiving media, or the demands made by clinical data retention policies. When digital data or image management applications become depreciated or are upgraded, the data is migrated from previous applications to new ones. Usually, this is a costly activity that also requires a temporary outage during normal working periods. Vendor specific, fragmented archives in healthcare enterprises have the potential to compromise archived data by not providing access to the most accurate and relevant data at the point of care (Benjamin *et al.* 2009).

Vendor neutrality requires the usage of widely accepted standards at all component interfaces (DeJarnette 2009). The features that characterise VNA are tag mapping and morphing, clinically-based information lifecycle management and universal viewer support, IHE compliancy, *etc*. (Werb *et al.* 2011). VNA allows archiving any type of digital clinical content that can be associated with a patient or a study, including non-DICOM content such as PDF files, video files, sound files, JPEG, and TIFF images. The solution interfaces with other clinical information systems for communication of reports, results, workflow, *etc*., by way of HL7. VNA enables use of different PACS applications from multiple vendors, integrates archived data sets into the virtual archive and avoids costly migration and re-indexing of data. The data ownership shifts from the archive vendor to the healthcare enterprise because the archived data can be managed using any standardised application independent of a particular vendor. Consequently, healthcare organisations can implement and provide unique services to facilitate sharing of data, while maintaining different clinical assets under common patient records (Tera Medica 2011).

3.3.3 GRID computing

Implementation of new e-services in healthcare requires coordinated use of heterogeneous information systems. Grid technologies aim to provide the framework to enable dynamic, flexible sharing of computational and storage resources through interoperable middleware based on open standards (HL7 2011). A computational grid consists of both hardware and software infrastructure that provides dependable, consistent, wide spread, and inexpensive access to high-end computational capability and storage resources (Foster *et al.* 2004).

A storage grid is storage architecture that employs multiple interconnected storage nodes so that any node can communicate with any other node. Distributed storage provides a high level of redundancy with almost no downtime, evens out performance under conditions of fluctuating load and is highly scalable. It enables different healthcare organisations to integrate and share data across organisations (Erberich *et al*. 2007). A storage grid can interconnect different PACS archives and other storage media like vendor neutral archives. This concept allows special middleware containing meta-data indices with the full contents of each separate archive to be placed above the storages located in different enterprises (paper **I**).

Grid computing utilises combined computer resources, connected via the internet, from multiple administrative locations. This allows additional computing resources to be achieved. It provides access to resources that are not subject to centralized control, uses standard, open, general purpose protocols and interfaces, and can deliver various levels of service. Grids consist of networks of computers, storage, and other devices that can pool and share resources (Berman *et al.* 2003). To perform desired tasks, grid-enabled software is built on open, standard frameworks and protocols (Sharma *et al.* 2009). Though grid architecture was initially not intended to be used in the healthcare sector, it has now been well adapted to the public health information systems. It promotes an open, transparent, collaborative network that leverages open source software and infrastructures, enables continuing existence of legacy applications, supports a strong security model, uses standards and service-oriented architecture, allows distributed and federated database and web services access, and enables push and pull multi-directional data exchanges (Faggioni *et al.* 2010; Foster *et al.* 2001). Grid technology can be deployed at the department level but the main value of it emerges when using grid in enterprise-wide or multiple enterprise settings.

Grid computing and streaming of medical data and images gives powerful tools for data transmission and sharing in the healthcare environment. Grid-computing for electronic medical records is being enabled by the use of interoperability standards and standard profiles for integrating disparate systems and sources of data (paper **I**).

Health grids are evolving all over the world to solve increasing demand for data computing and analysis for healthcare and research purposes. One example is MammoGrid which has effectively demonstrated the viability of the grid by using its power to enable radiologists from geographically dispersed hospitals to share standardised mammograms, compare diagnoses and perform sophisticated epidemiological studies across national boundaries (The Healthgrid White Paper 2008).

In radiology, the grid computing infrastructure is used to virtualize PACS services (Faggioni *et al.* 2010). In accordance with the XDS-I profile, the registry containing the meta-data index to the full contents of each separate PACS or other archive, is placed above the various archives deployed in different locations. All meta-data are kept updated and synchronized across instances via various database features for maintaining data concurrency (paper

I). Virtualization of PACS services allows designing workflows based on different clinical purposes or client needs (Benjamin *et al.* 2009). It also supports multi-site installations and integration of disparate PACS archives. Grid computing architecture can be extended to also virtualize other healthcare services.

In the Baltic eHealth and R-Bay projects, grid-type architecture and streaming technology was used to manage radiological workflow in cross-border teleradiology services (paper III). Initially, healthcare organisations were connected securely through dedicated Internet-based networks. Images were acquired and stored in separate archives of different hospitals. Cross-border image communication was managed by using a secure, manageable and flexible vendor-neutral clinical data archive and a teleradiology communication platform. Streaming technology was used to retrieve images from remote locations for viewing and reporting in the central node.

3.3.4 Emerging models for shared workflow

Radiology services are evolving towards cross-enterprise and cross-speciality models. Images and imaging data are shared across different clinical specialties and several organisations (Benjamin *et al.* 2009; Lundberg *et al.* 2010). This allows streamlining of image-related workflow. Radiologists are increasingly working simultaneously in different workflow settings, in more integrated environments with other clinical specialists. Consequently, new models of data and workflow sharing are used.

3.3.4.1 eMarketplace-type platforms

Radiology service portals using many-to-many connection principle is a type of brokering service (papers **III** and **IV**). This service allows customers of the radiology service and teleradiology providers from different organisations to interact through a central connection platform. With such an integrated platform, the whole market opens up with only one integration. The radiology groups or healthcare enterprises who are considering implementing cross-organisational teleradiology can compare prices of reporting, availabilities, response times, quality assurance schemes, procurement rules, sub-specialities, *etc*. (paper **IV**). The service portal can be used to balance the workload between sites with different RIS and PACS, share one global worklist, use dynamic sharing rules, and generate business reports.

Many-to-many radiology service portals enable teleradiology to be practised in a controlled environment allowing uniform data privacy and security policy.

For the customer, it provides more choice with only one central integration, allows 24/7 coverage through contracting multiple reporting providers, makes it possible to compare prices, availabilities and response times for the reports and to select sub-specialists from different teleradiology providers (paper **IV**).

For teleradiology service providers, the eMarketplace makes it possible to build competitive advantages like sub-expertise, availability, correctness of the reports, more affordable prices, different service level agreements, *etc*. It shows proven quality via the established quality assurance scheme (transparency of the results), makes it easier to integrate the customer and provider systems, and guarantees back-up in the case of a temporary shortage of personnel. The service provider can solve, in addition to the problem of the shortage of image readers, other clinical tasks like participating in the planning of procedures to find the best diagnostic approach, discussing reports in multi-disciplinary meetings, and facilitating clinical communication. Therefore, the teleradiology service has to be implemented in close co-operation with the customers (papers **III** and **IV**).

Table. 1. Potential advantages of shared many-to-many type of eMarketplace approach for the teleradiology customers and teleradiology service providers

Added value for the customer	**Added value for the provider**	**Added value for both sides**
Opens up the whole market of teleradiology reporting providers with one integration	Opens up the whole customer market with one integration	Makes it easier to integrate the teleradiology customer and provider's systems
Makes it possible to compare availabilities and response times for reports	Makes it possible to build other competitive advantages like sub-expertise, availability, correctness of the reports, *etc*.	Security and privacy issues are addressed using transparent and controlled schemes
Makes it possible to select sub-specialists from a wider pool	Makes it possible to compete with lower prices	Contracts and payments are handled through the single platform
eMarketplace is taking care of the certifications	Using established quality assurance scheme as a reference for proven quality	Access to the procurement documents from the single platform
Makes it possible to compare reporting prices and take the best available price	Back-up in case of illness, vacation, temporary increased workload or complexity	Transparent quality requirements and schemes for the quality control
24/7/365 cover through multiple providers		Makes it possible to make contracts applying different service level agreements
Allows different models of payment		

An example of a company offering an eMarketplace-type of central portal is the Swedish company RxEye. It provides public and private healthcare organisations with the service for buying and selling quality assured image reading services.

RxEye uses one central platform to provide both radiology service sellers and buyers with radiology reporting quality assurance, create procurement documents, send offers for reporting services and apply for image reporting. The central platform avoids complex technical projects for each assignment and provides customers with simplified and standardized contracts and other administrative documents (RxEye 2011). Another example is the project in Northern Finland, where a collaboration platform is used to carry out reporting between multiple hospitals. In North-America, similar shared workflow implementations are in commercial use. For instance, companies providing radiology reporting integrate hospitals, imaging centres and radiologists. A single integrated worklist, viewer and reporting system is provided (Telerays 2011; Virtualrad 2011).

3.3.4.2 Automatic capacity management (ACM)

While many-to-many connection provides the infrastructure for the shared services it does not automate workflows nor provide users with quality assurance tools directly. To achieve managed service levels and enable anonymous feedback for quality assurance shared workflow platforms, including automatic workflow capacity management platforms, are created.

The idea of ACM is not just assigning exams from different PACSes to the radiologists´ worklist but creating dynamically balanced workflows. In order to meet different service level agreements, exams are assigned to radiologists´ worklists dynamically based on the current need (Benjamin *et al.* 2009). In case there is a worklist of more than one hundred exams, it is not possible to follow the "urgency factor" in every case and to guarantee that urgent images are reported in a timely manner. ACM allows exams to be distributed among radiologists for online reporting based on urgency, complexity, modality, *etc*., depending on the current situation. This makes reporting times extraordinarily rapid. It also shares exams fairly for all reporting radiologists avoiding picking of the simplest or best reimbursed cases only – no radiologist gets better revenue reports or simpler cases only.

An example of a company using the ACM platform is the Canadian teleradiology service company Real Time Radiology. It uses the platform for active service level management and for quality assurance and monitoring. The platform enables active management of response times and service levels, automated case management and status reporting, and dynamic routing of workload and capacity management. From the quality perspective, it gives qualification and license oversight, continuous quality assurance and monitoring, and enables multi-read workflow management. Also the setting and oversight of applicable standards and requirements for the services can be provided. The expansion of the platform allows for the possibility to conduct a remote review of radiologists´ reports (Canadian Healthcare Technology 2010). The key element for the implementation of the dynamic engine of ACM platform is that it is in accordance with both HL7 and DICOM standards, and XDS and XDS-I standard profiles. Using standard profiles paves the way for rapid deployment and integration of systems and allows it to work across different PACS platforms.

3.4 Barriers for data sharing and shared workflow

The challenges that arise when implementing cross-organisational data sharing and shared workflows depend on the level of data sharing (paper **IV**). These challenges include trust between healthcare professionals, trust between healthcare professionals and patients and issues related to service quality, cross-organisational interoperability, legal clarity and reimbursement. Depending on the level of sharing, the interoperability issues are technical, organisational (including the seamless medical data exchange between different information systems), or semantic (including language). Barriers without crossing state borders tend to be mainly technical, organisational and financial. At the cross-border level, legal and language issues dominate (paper **IV**).

Despite data sharing or a shared workflow setup, the fundamental condition in establishing and maintaining teleradiology services is achieving trust between the parties involved (paper **III**). For instance, in the Baltic eHealth project comparison of X-ray reports was performed between Danish, Estonian and Lithuanian radiologists to achieve mutually accepted clinical quality. This comparison of 39 cases resulted in 31 cases with the same findings and conclusions (80%), 4 cases had insignificant differences in findings and conclusions (10%) and in 4 cases there were two different opinions (10%). The common understanding of the report structure and the description of pathologic findings was found. In R-Bay there was found that it is necessary to have continuous mutual discussions concerning reported cases.

Part of this “achieving of trust” also includes clinical acceptance by referring physicians. Teleradiology customers wants to evaluate: accreditation and sub-specialization of radiologists, the overall reporting capacity of the service provider, the structure and the language quality of the report, the quality of image viewing and reporting equipment (availability of PACS and RIS or a teleradiology reporting platform, resolution of monitors, *etc*.), availability of fast internet networks, and to ascertain that the necessary security measures are in place (paper **III**, Jarvis *et al.* 2005; Barneveld Binkhuysen *et al.* 2011). The provider of the teleradiology reporting service must become acquainted with the customers’ current clinical radiology workflow (transfer of clinical data, multidisciplinary meetings, average report turnaround times, *etc*.), to examine the quality of images, to agree on the minimum number of projections, series or sequences of uploaded images for reporting, to ensure the availability of relevant priors and clinical history, and to estimate the potential volume of outsourced exams (paper **III**). Those principles are valid for both in-house and cross-enterprise settings.

Barriers for data sharing and shared workflow depend on the sharing models. The sharing model can be implemented within one organisation, between organisations in one region or across country borders, or between a healthcare enterprise and citizen (paper **IV**).

3.4.1 Inside the healthcare organisation

Although this paper focuses on cross-organisational data sharing and shared workflows, it is important to note that most of the barriers to teleradiology have their origin from initial teleradiology setups inside one and the same organisation. In-house data sharing and in-house shared workflow still represent a majority of cases where images and workflows are shared. Although substantial research is done to define standards and profiles for cross-organisational implementation, most data sharing implementations are used for one organisation's internal workload balancing. Implementation of image sharing and shared workflow decreases remarkably the time between image acquisition and the availability of the image's report in the healthcare environment. Quick image sharing places higher demands for image quality and the image management process but does not require any additional legal measures as long as the images do not cross organisational borders (paper **IV**). However, administration of user rights and management of log files are new tasks for the organisation and need complementary resources. Today, sharing of images across the organisation is almost a must in every organisation where PACS is installed. Consequently, re-engineering of imaging-related processes require additional human resources. Underestimation of the importance of the re-engineering process at the earlier stage of PACS implementation was the main obstacle to achieving positive results with new communication model (Siegel *et al.*2002; Bandon D *et al.* 2005).

Still today, incomplete integration of imaging modalities, PACS, RIS and EPR, as well as partial digitalisation of images and related data (Fernandez-Bayó *et al.* 2010) is the main barrier for image and workflow sharing at the organisational level. Information sharing is not achieved in an effective manner where imaging standards and communication profiles are not fully applied. Absence of full digitalisation of all images, lack of interfaces between RIS and imaging modality or PACS and EPR, *etc*., hinders the potential advantages of image and workflow sharing (Pechet *et al.* 2010).

3.4.2 Between healthcare organisations

Sharing images and workflow between healthcare organisations creates new challenges regarding quality control, trust, legal issues, reimbursement, workflow management, and interoperability of EPR, RIS and PACS.

The most important challenge is to ensure that reporting of images outside the organisation does not in any way reduce the quality of radiology services provided to the citizen (McCall 2010; COM/2008/0689 final; 90). To achieve this goal, relevant healthcare organisations must work towards creating a professional, trustful relationship between clinical partners. Trust can be developed by on-site visits and familiarisation with clinical radiology workflows at hospitals. Also, the appointment of one particular radiologist to act as the responsible person for inter-organisational teleradiology communication is needed (paper **III**).

Integration of EPR, RIS and PACS using IHE XDS standard profiles is still an exception rather than a rule. Using proprietary solutions for inter-enterprise health information system integration is a complex task and can be deployed mainly on a point-to-point integration basis. Consequently, this makes implementation of the real shared workflow a hard to achieve task. Implementation of XDS-I standard profile for sending and receiving images, which would allow image sharing between organisations, demands additional resources for upgrading software applications so that they are compatible with IHE standard profiles.

Transfer of image-related data outside the imaging facility requires additional identification, safety and security measures (Pechet *et al.* 2010). European Union (EU) Directives on the Processing of Personal Data and the Protection of Privacy in the Electronic Communication Sector (Directive 95/46/EC; Directive 2002/58/EC) specify a number of specific requirements relating to confidentiality and security that telemedicine and all other interactive on-line services have to meet in order to safeguard individuals' rights. These legal acts also set-out requirements for providers of electronic communication services over public communication networks to ensure confidentiality of communications and security of their networks (Health Information Technology 2010; COM/2008/0689 final). In Europe, in most cases, this is usually solved by bilateral contracts between the organisations addressing licensing, liability, accreditation and the registration of imaging services and professionals.

From the EU legislation point of view, telemedicine is both a health service and a social information service. Telemedicine falls under secondary EU legislation, in particular the EU Directive on Electronic Commerce (paper **IV**; COM/2008/0689 final; Directive 2000/31/EC).

The reimbursement of teleradiology services in inter-organisational workflow sharing is an issue that often causes difficulties and is seldom solved automatically with clinical set-ups (Lundberg *et al.* 2010). Usually the financial software of the healthcare institution is not integrated with the clinical software, thus making the financial management of inter-organisation teleradiology difficult.

3.4.3 Across country borders

The basic issues that need to be addressed in an interorganisational setting (quality and trust, interoperability, identification, security, legal issues) also apply to cross-border settings. However, the legal issues are more complex because of the differences in healthcare, and in particular, how EU member states regulate telemedicine (Barneveld Binkhuysen *et al.* 2011). EU legislation regulating teleradiology services consists of multiple directives and legal documents, which makes the interpretation of the legal system in the EU extremely complex. Besides the EU directives, there are additional legislative documents which have to be considered in implementing teleradiology services (paper **IV**).

Additional issues to be addressed are semantic interoperability and language. In the Baltic eHealth and R-Bay projects, one of the main limiting factors for full deployment of cross-border teleradiology services was the lack of commercially available radiology report translation software (paper **III**). There is no professional and commercially available radiology report translation software (Pohjonen *et al*. 2006).

The EU recognition of radiologists by member states is regulated by the Directive on the Mutual Recognition of Qualifications (Directive 2005/36/EC). To receive permission to practice radiology in another EU country usually requires additional administrative work by each radiologist intending to report on images in an EU member state different than his or her EU member state. The recognition of professional qualifications by the host member state allows radiologists to practice radiology, including teleradiology, in that host member state under the same conditions as its nationals.

Regarding the harmonisation of technical interoperability, the EU Directive on Technical Standards and Regulations establishes a procedure that imposes an obligation on EU member states to notify the Commission and each other of all draft technical regulations concerning products and information society services, including telemedicine, before they are passed as national laws (paper **IV**, Directive 98/34/EC).

The legal relations between the patient and healthcare provider are governed by national and EU legislation. The responsibilities of both parties are usually fixed in the teleradiology service contract. This applies for teleradiology practiced both within one country and cross-border. If the teleradiology service provider resides outside the EU, the above-mentioned principles do not apply unless contractually fixed (paper **IV**).

3.4.4 Image sharing with citizens

Sharing digital images via the web with patients is a new feature in medical imaging management (Winblad *et al.* 2011). The main barrier to sharing digital images with patients is user identification security and secured access to electronic health record (EHR) and PACS. Usually, user identification and access rights to images in PACS are designed for healthcare professional. The identification of a particular citizen is usually done by using credentials for EHR or PHR. In this setting, images are opened using a URL link between the EHR and PACS. Another limiting factor is a lack of citizen friendly viewers which can provide thin, client applications and use low bandwidth networks. PACS' user interfaces are too complicated for the use of ordinary citizens (paper **IV**).

Some countries in the EU demand the patient's written consent when patient data crosses organisational borders (paper **IV**). The Cross-Border Healthcare Directive states that patients should be fully informed about the various options regarding diagnosis and treatment in order to make a conscious choice between the various options (Directive 2011/24/EU).

Medical image viewing platforms for the patient are already in use in some countries. For instance, in Estonia the patient portal iPatient is used to give patients' access to medical images via the Internet. The access is secured by using a national ID-card. Patients can access their own images by using simple viewing platform which uses streaming technology. A similar concept is used by the Center for Diagnostic Imaging, USA. A patient is provided with a password protected account. Via the account, the patient obtains access to the booking service, receives preparation and appointment instructions, and can view his or her diagnostic reports and images (paper **IV**).

3.5 Discussion

Predicted outcomes of cross-organisational teleradiology

Implementation of interoperable ICT applications and shared services in healthcare has been considered one of the main instruments to increase healthcare quality, safety and availability and decrease the rate of continuous increases in healthcare expenditures (Potts *et al.* 2011, Winblad *et al.* 2011). The planning of a new application or service demands precisely identifying the actors involved and predicted outcomes, characterisation of parties who will benefit from the change, and outlining of potential barriers. It is evident that data sharing and shared workflows in medical imaging allow limitless collaboration between different actors and implementation of new services in the healthcare domain (Lundberg *et al.* 2010). To achieve the anticipated benefits of a new application, all the collected health related information needs to be stored in a standardised, shared, consistent and non-redundant form (Winblad *et al.* 2011). In designing a new healthcare service, if one under emphasises the importance of the integrity and availability of the medical information, while simultaneously trying to take into account technical and semantic interoperability, changes in the workflow, security and privacy issues, and legal environment, the result is an increase of unorganized data in the health sector (Hanseth 2007). Accordingly, this decreases the usability of digital health data and reduces the trust of users towards to the data sharing and shared workflows.

One of the aims of Baltic eHealth was to increase the availability of healthcare services in remote areas, thus providing equal access to the healthcare for all citizens. In the R-Bay project, new data sharing and shared workflow models were found to result in higher quality and more effective radiology service. In addition to technical issues, the changes in daily routines that ICT brings about include organisational, semantic, legal and financial issues which make the implementation of IT applications complex (papers **III** and **IV**). Consequently, successful implementation of a new cross-organisational IT application or service needs careful planning and recognition of multiple and sometimes disparate issues (paper **II**).

Benefits of cross-organisational data sharing and shared workflow for radiologists and the radiology community

Teleradiology has traditionally been used for either decreasing the costs of imaging services or providing second opinions (The Healthgrid White Paper 2008; Daucourt *et al.* 2005; Roine *et al.* 2001). These initiatives are usually not initiated by radiology departments but come from hospital administrations or governments (paper **III**). None of these initiatives have clear incentives for local radiologists to support implementation of cross-organisational teleradiology services. Still, using the most recent advances in technology and organisation of digital data sharing and shared workflows, there are potential benefits that cross-organisational teleradiology can offer the radiological community (Bradley 2008).

If the healthcare organisation has a policy to outsource the reporting of routine exams (conventional X-ray, head CT, MRI of spine or knee, *etc*.), the local radiologists will have time to report more "interesting" cases, sub specialize or have time for meetings with clinicians (Reponen 2008; Eklöf *et al.* 2007; 13 Levy *et al.* 2006). The use of ACM gives the opportunity not to interfere with local worklists, but to send exams, that are assigned for the reporting by a teleradiology provider, to the corresponding worklist. Similarly, access to relevant priors and other clinical data can be achieved simultaneously using the XDS profiles and many-to-many integration, which in turn has the potential to increase the quality of reporting. Finally, the report from the teleradiology provider is sent back to the local RIS without using local resources workforce or changing daily routines. ACM also provides radiologists with a means of quality control and assurance supporting the achievement of commonly accepted quality criteria, which then in turn builds trust between clinicians, local radiologists and teleradiology providers.

Cross-organisational or cross-border teleradiology can give access to highly specialised expertise (Bradley 2008). This feature could be used as an additional benefit in case of rare pathologies or specific findings. Data sharing with other radiologists increases the confidence of local radiologist and allows more specific imaging technologies to be used. This however, raises the question of data structuring and automated translation of referral letters and radiology reports. Baltic eHealth and R-Bay showed that radiologists would accept the use of a multilingual structured reporting tool if it will reliably cover a major part of the findings of a particular imaging modality (paper **III**).

Specialization within cross-border teleradiology leads to the next positive result. A radiologists' income is often related to the volume of reported exams or depends on the complexity of the exams he or she performs. Thoroughly planned outsourcing of images or services gives, to a certain extent, the opportunity to increase either the volume of specific exams or their complexity. ACM in turn provides radiologists with automatic tools to follow agreed service levels. It also makes sure that radiologists would not pick easy or highly lucrative cases only. The threat of unfair selection of images in teleradiology is one of the main concerns of local radiologists. This now can be avoided with transparent workflow sharing. Customers of teleradiology can avoid recruiting their own radiologists during the night time or during the holidays by connecting through many-to-many type of integrations (paper **III**).

Sharing workflows, using common shared databases and using reporting policies throughout the organisations allows radiologists to join teleradiology groups part time. The European Telemedicine Clinic is an example of profiting from cross-border networking (Telemedicine Clinic 2011). They use more than 70 accredited sub-specialist radiologists who focus on specific diagnostic areas including neuro, body, musculoskeletal, PET-CT, mammography screening and nuclear medicine. A majority of those radiologists are also working in hospitals. In the Baltic eHealth and R-Bay projects, a similar trend was found. In both cases, radiologists were interested to join cross-border teleradiology service providers only part time.

Finally, sharing of standardised data has the potential to provide radiologists with tools that help them to compare dynamic changes in image findings and to present them in an easily understandable and reproducible manner. In addition to the advantage of viewing relevant clinical data from different databases, reporting and presentation tools enable radiologists to perform highly comprehensive and valuable reports.

Trust as the fundamental condition in establishing and maintaining teleradiology services

Trust is the most fundamental condition in establishing and maintaining teleradiology services (paper **III**). This is true in all cases: where healthcare professionals become accustomed to their new IT applications or services, between the customer and the service provider in cross-organisational service set ups, and where a citizen's consent is needed to share their health information over the Internet. Also the IHE standard profiles for cross-organisational data sharing and shared workflows lay down the basic principle that all involved parties must follow agreed upon rules.

Although teleradiology has been used almost three decades and there is the expectation that cross-organisational teleradiology will be used to a wide extent in the future, the reality is that the number of European institutions using teleradiology across organisations is limited (paper **IV**). One of the main reasons for this seems to be the complexity of organisational issues, including achievement of trust between the reporting service provider and the customer. Radiology professionals believe that at the initial phase, the establishment of cross-organisational reporting services will be an additional burden to their daily routine. New integrations with other databases and applications are seen as factors that increase the complexity of workflow. This in turn increases the risks to lower reporting efficiency and decrease overall reporting capacity (Hanseth 2007).

To achieve the acceptance of teleradiology by radiology professionals, careful planning of the service is needed. In the Baltic eHealth and R-Bay projects, the building of trust started from the creation of a professional relationship between the clinical partners (paper **III**). This included on-site visits and familiarisation with the clinical radiology workflow in each hospital. Each partner appointed a certain radiologist to act as the responsible person for cross-border teleradiology communication. In the workshops, different incentives to use cross-border teleradiology and prerequisites to achieve clinical acceptance were discussed.

Both cross-border teleradiology projects showed that at the initial phases, the radiologists and administrative officials of each country had only limited knowledge about the education requirements, experience, sub specialisation, language skills and the professional quality of the reports, of the other country's radiologists providing cross-border teleradiology services. The general assumption was that it would take a lot of time for teleradiology providers to understand the requirements of the clinical partners and to adapt with the local radiology department's workflow. Also, establishing a shared worklist was organisationally a challenge. It required substantial effort to explain to the radiologists the reasons why it was beneficial to share images and workflows with radiologists from another organisation. Similar examples can be drawn from the other international teleradiology projects. At the beginning of this century, the UK government's policy was to increase imaging service capacity by outsourcing radiology reporting. This policy did not achieve the desired results because the quality of reports and set out service level were not fully accepted by local radiologists and referring physicians (Jarvis *et al.* 2005).

If the benefits and barriers are discussed and agreed among the involved parties, the new service could be used to improve workflows and reporting capacities inside the organisation. Inter-organisational sharing of databases and workflows tend to accelerate the development of a particular organisation (Hanseth 2007). Cross-organisational teleradiology demands very clear agreements about the technical set up of the data sharing, specific characterization of workflows, agreement about the semantic interoperability, *etc*. This in turn brings up the need to review the current organisational processes and in many cases leads to the re-engineering of local workflows technical applications according to internationally accepted technologies, and standards and standard profiles. Sharing of common workspace with other organisations will sometimes bring changes not only in local workflow but will give new ideas how to improve the design and functionality of reporting software applications locally (Lundberg *et al.* 2010). Cross-organisational workflow sharing results in an understanding that data presentation tools must enable mobile data access to support clinicians´ patient-centred and highly nomadic workflow (paper **I**).

Another important feature concerning trust extends outside healthcare organisations. Sharing digital images via the web with patients is a new feature in a medical imaging management. It raises the question of the security of imaging data transfer outside the imaging institution and the readiness of the citizen to view highly specific imaging reports and images. Healthcare organisations need to manage personal information in a manner that takes into consideration individual sensitivities. The citizen has to consent to image distribution and be informed that he or she has instant access to images and reports. In this setting, the secure user identification offered by Health Information Exchange platforms is the key element. Based on the experience of East Tallinn Central Hospital (ETCH), Estonia, and Center for Diagnostic Imaging (CDI), USA, the acceptance by citizens to view their own medical images via the Internet is surprisingly high (paper **IV**, Steve Fisher, Center For Diagnostic Imaging, St. Louis Park, Minn., USA, personal communication). Authentication of the person accessing the web application is based either on an ID card or the ability to set up a password-protected account. Through that account, he or she can pre-register on-line to receive appointment preparation and appointment instructions, to book the time for imaging procedures, to submit personal medical data and to also view their diagnostic reports and images.

However, to maintain acceptable levels of security and data integrity for citizens who wish to access their own medical images and relevant health data, it is recommended to use dedicated image viewers and VNA solutions. Also, the implementation of the IHE BPPC profile is mandatory because it provides a mechanism to record patient privacy consents and deal with patient privacy issues.

Baltic eHealth and R-Bay projects have proved that organisational planning is needed before the implementation of cross-organisational workflow sharing (papers **III** and **IV**). The factors that will enhance or hinder the development or implementation of the service should be considered. This includes finding out the groups which will support and the groups which will block the development of teleradiology services. To gain support or buy-in for the teleradiology service inside the organisation, a strategy to communicate the information about the new service with radiologists and/or other clinical specialists should be in place. Also the delineation of problems or pitfalls that one can anticipate affects the success of the service (paper **II**). Only when the organisation is ready and prepared for integrating remote reporting as part of the radiological service of a hospital, is there a chance in succeeding to build trust in cross-organisational teleradiology. The remote reporting service provider should be closely involved in the organisational change management of the customer. The customer should become familiar with the specialists and the organisation of the service provider in order to build trust. Documents should be exchanged which describe the backgrounds of the professionals involved in the project and the core project team, their skills and abilities to execute the business case strategy. The personnel needs, the roles of the key project team members, and the role of an outside supervisory board, if any, should be identified (Rozenblum *et al.* 2011).

Maintaining clinical quality

In cross-border teleradiology, special attention must be paid to clinical quality (paper **III**). Based on the experience of the Baltic eHealth and R-Bay projects, this goal is achievable. When buying a remote reporting service the customer wants proof of quality, known and accepted processes and protocols, transparency, possibilities for peer review and double blind readings from time to time (Barneveld Binkhuysen *et al.* 2011). On the other hand, the service provider expects access to the relevant data, feedback on discrepancies and learning from other specialists.

Where the service provider is not in the same building or even in the same country, feedback from radiologists and also clinicians is essential in building and maintaining trust in a remote reporting situation. Ensuring transparency in performance and use of quality indicators is a prerequisite for a sustainable, cross-organisational teleradiology service (Barneveld Binkhuysen *et al.* 2011). The customers for remote reporting should be able to give digital feedback easily and in a user-friendly way. At the same time, learning is enabled by systematic automation of feedback on different levels between participants in the healthcare process. Constructive feedback creates a safe environment for individual self-improvement. The feedback software should be easy to use and preferably desktop-integrated with the local RIS and PACS (paper **II**).

The quality of radiology reports also depends on the availability of relevant medical and administrative data distributed among different databases across healthcare organisations. In addition to the description of image findings and conclusions, the content of the report includes financial and statistical statements (Benjamin *et al.* 2009). Information about the patient's health condition is acquired from different sources: narrative text from the patient, relative or previous medical files; objective findings of different measurements and examinations presented in a textual, numeric or graphic form or as images. For cross-organisational workflow sharing, the unambiguous understanding of the meaning of presented health data is an ineluctable condition. Healthcare terminology, classificators and nomenclatures have been synthesized from textual and numeric information and conclusions. They are used to systematise, standardise and structure health information. Despite the attempts to implement common terminology, classificators and nomenclatures on the national or international level, only a small part of health related information is presented in a structured way. The main part of the subjective information concerning a patients´ health is still stored in textual low-structured form. The use of semantics, ontology and linguistics in the same field in cross-organisational settings is an exception rather than the rule. The presentation of patient data should follow data integrity, availability and confidentiality requirements. Medical data has to conform to clinical needs and must be presented in accordance with legal regulations. Convenient design of presentation applications for images, previous studies and medical data, is also of utmost importance to seamlessly fit into daily routine workflows.

Aggregation of clinical data and single sign access to clinical database

Access to large amounts of various health data delivered by disparate sources demands tools that present only the data which is relevant to a particular imaging case. Effective access to image data and analysis tools can benefit radiologists by increasing reporting capacity and quality. It enables radiologists to make more comprehensive reports that are based on wider knowledge of a patient's current health condition (paper **I**).

Health information collected from the different sources about a patient or healthy citizen has to be presented to healthcare professionals or the citizen for evaluation, analysis and decision making in a systematic manner. The goal is to streamline the use of medical data according to the user profile. These profiles should be developed according to agreed semantic and technical interoperability standards; they should follow organisational set-ups, and take into account security and privacy regulations, and the relevant legal environment. Profiled information opens the way to create new, data enriching radiology services in complex healthcare networks.

In cross-organisational workflow setting, the comparison of current and previous image findings is an unsolved issue. Even if the previous report is available, the comparison of the size, shape, number and location of the finding is a tedious task (Thrall 2007b). With few exceptions, the report only provides narrative text or in the case of templates, they differ from one organisation to another (ESR 2011). The situation is even more complex if the service is provided across national borders (paper **III**). For clinical acceptance, the report must clearly and in easily interpretable form, present the character and dynamics of the finding (ESR 2011). Unfortunately there are no widely used internationally agreed structured reporting standards. For instance, the DICOM structured report and SNOMED-CT can be used to cover most of the imaging findings, but the outcome of the report is too structured and not acceptable to referring physicians and patients (paper **III**).

For teleradiology practised across country borders, semantic interoperability is an additional barrier. Transferring clinical data and reports across boundaries or regions raises the question of the language of the request and the language of the report. Cross-border teleradiology service providers are currently using almost exclusively radiologists who can report in their customer's native language. The linguistic quality of the report is as important as the trust between clinical partners and the quality of the radiology service. To date, the language and semantic content of reports is an integral part of the whole teleradiology service and risks interfering with patients' diagnostic and treatment decisions (Jarvis *et al.* 2005). Unfortunately, there are no commercially available multilingual translation programs for cross-border teleradiology (Pohjonen et al. 2006). Lack of automatic translation tools is the main obstacle for development of cross-border teleradiology in countries other than the UK or the US, or for neighbouring countries with related languages.

In the Baltic eHealth project, a structured, multilingual translation tool (SRT) was created to deliver the report in a foreign language (paper **III**). The SRT covered knee x-ray findings only and therefore had limited use. Despite its narrow scope, it received positive feedback from users. The SRT used semantic translation of findings rather than word for word translation. Selecting sentence in one language automatically generated sentences in the other language. The SRT contained more than 500 different sentences or phrases for one anatomic region. For findings not covered by the text set out in the SRT, there was an option to write free text which could be translated by an interpreter. The Baltic eHealth and R-Bay projects proved that one of the main barriers to cross-border teleradiology development is the language issue.

Structuring reports into a computer processable mode has great impact on future research involving computer assisted and automated image interpretation. Combining images with the imaging report and surgical and pathological findings will open completely new IT applications and services.

Wide spread access to images and medical data is what is required by highly non-stationary workflows of many healthcare professionals. Traditionally, physicians have made notes on paper in every place where the clinical information is collected – wards, offices, examination rooms, *etc*. This workflow is only converted into a digital environment in very few places in the world. Today, the use of the IHE profiles, implementation of secure identification schemes and modern digital data transmission technologies have the potential to support fully digitalized shared workflows throughout the care pathway.

In Estonia, to secure access to the national data exchange platform (called Electronic Health Record System), X-Road is used (RIA 2011). It is based on the principle of using one integrated set of user interfaces for organising communication with databases. The system ensures sufficient security for handling inquiries made to the databases and responses received. The technical solution of the project does not lie in the transition of all databases to some larger data management system, but in the creation of unified user interfaces for different databases (Cell Network 2005). Citizens and institutions can join and use the X-Road free of charge. Identification of the person is based on the compulsory ID-card issued by the state. ID-card is used both for identification of the user and for digital signing of documents, e.g. discharge letters, radiology reports *etc*. (Tiik *et al.* 2010). Citizen can use ID-card to securely access their own medical files (including medical images) stored in different clinical databases (Sepper *et al.* 2011).

Interoperability standards and standard profiles

Image and related data sharing across organisations is enabled by the use of interoperability standards. The DICOM standard for images and image related data sharing is a mature and widely used standard. For medical documentation exchange, the HL7 standard is most commonly used. Even though both standards are supporting data sharing and, to a certain extent also workflow sharing, they are not enough to allow implementation of cross-organisational workflow sharing. In radiology, image sharing and shared workflows across organisations is achieved by using IHE IT and radiology infrastructure standard profiles. These profiles are providing organisations, which are aiming to share databases and workflows, with a set of integration rules. These integration rules describe how to use standards like DICOM and HL7 to create cross-organisational common workflows. Those profiles also cover measures that should be taken to identify the patient or healthcare provider within different databases, handle patient consents, describe authentication processes, and ensure data transaction security and their audits.

In cross-organisational teleradiology, the IHE profiles enable healthcare enterprises to maintain their own applications, often legacy RIS and EPR applications, and concentrate on data sharing using standard profiles. With few exceptions, there is no need for the information to flow back to the initial data sources. The documents and images can be stored in different repositories and the metadata of the document can be stored in the document registry. To ensure the integrity of the imaging data, the integration between the RIS and PACS of the teleradiology customer and teleradiology service provider should insure that the imaging report will be transferred to the RIS of the referring institution. As discussed earlier, the option to correct patient data in case of name changes, incorrect image data, *etc*., must be made available.

In today's healthcare IT sector, implementation of data exchange standard profiles (XDS-family) in cross-organisational data and workflow sharing is one of the most critical issues. On the one hand, healthcare institutions and organisations responsible for healthcare IT development acquire large information systems and also imaging equipment that is HL7 and DICOM compatible. The rationale behind this is that the fulfilment of standard criteria for data exchange is enough to justify proceeding with modern IT solutions. This is true if the goal of implementing a new IT application is data sharing and exchanging information inside one healthcare organisation, or establishing point-to-point connections between different organisations. Using data exchange standards only also gives more freedom for the organisation to make its own IT and equipment decisions and makes planning of IT system implementation more robust. In this case there is no need to take into consideration care pathways and workflows practised in other institutions.

On the other hand, relying only on DICOM, HL7 and other data exchange standards limits the organisation to share workflows with other organisations. One can send and retrieve images or other health related data to and from databases located in different healthcare domains but the sharing of workflows among different domains is limited. To share workflow, organisations must agree, in addition to data sharing standards, the methods, policies, infrastructure and architecture of the use of common databases and workflows.

The IHE cross-organisational standard profiles are developed to enable data sharing and shared workflows. It aims to define integration rules using standards already in use. However, the implementation of XDS profiles is still a challenge all over the world. There are two main obstacles to implement standard profiles.

First, implementation of standard profiles demands agreement on a single, common central document registry inside the group of healthcare organisations that share the same health information policy. The group using the common registry belongs to the same affinity domain. There is no practical reason to establish the XDS registry only for one or a couple of healthcare organisations. The effect of workflow sharing is evolving to a larger extent where the majority of organisations responsible for imaging in the same logical healthcare domain are using the same registry. The benefit is that this solution covers longitudinally most of the diagnostic and care episodes of the citizen's health history. Establishment of a common registry needs agreement between the organisations and usually the approval of health policy makers. The need for agreement is an organisational challenge because it demands that decision makers at the regional and healthcare organisation levels accept a change in the information sharing paradigm (paper **IV**, Adler *et al.* 2009).

Secondly, the compliance of information systems and medical devices with XDS and XDS-I is still an unachieved task in many organisations. Although XDS profiles allow healthcare organisations to continue using existing local or regional legacy information systems or infrastructure, the support of the XDS family profiles demands substantial investment.

In the Baltic eHealth and R-Bay projects, the IHE profiles were not used. Therefore cross-border teleradiology reporting was not integrated into the local workflow. DICOM conformance was not enough to include cross-border teleradiology reporting into the daily radiology routine. Reporting abroad as well as uploading images to the teleradiology platform interfered with the internal workflow and decreased reporting and imaging efficiency. The benefits of using teleradiology service did not outweigh the negative impact of interfering with daily workflow.

Implementing new standard profiles results in adding new regulations and mutual agreements in the system. This in turn increases the complexity and risk of failure (Hanseth 2007). However, IHE standard profiles do not create any new standards but have the goal of making processes across different healthcare domains more transparent and regulated. Before publishing the IHE profiles, they are tested against different information systems in an open interoperability testing event for vendors and users called Connectathon (IHE 2011a). Successful testing interoperability performance makes the IHE compliant information systems reliable in everyday data and workflow sharing environments.

Fortunately, the implementation of IHE profiles is increasing worldwide. The affinity domains are integrating healthcare organisations of different sizes, starting from a single community and extending to cover the entire region, state or even the whole country. The frontrunners are North-America and Europe. In the US, the policy called "health information meaningful use" is endorsing health information exchange (HIE) platforms to connect healthcare institutions in the same geographical area or organisational dimension (Walker *et al.* 2005; Flanders 2009). IHE profiles give HIE organisations a tool to share high-value patient information with relatively low-cost and add incrementally new information sources (Health Information Technology 2010). In Canada, the Canada Health Infoway is designed to consolidate disparate and disperse imaging data to centralized storage facilities and to server infrastructure that supports integration of existing RIS and PACS by means of XDS-I (Mendelson *et al.* 2008; Canada Health Infoway 2011). In Europe, there is a large scale project to implement XCA profile called epSOS. It is composed of 47 partners from 26 countries. The aim of epSOS is to build and evaluate service infrastructure demonstrating cross-border interoperability between HIE platforms or EPR systems in Europe. The information and services that are exchanged between countries include access to patient summaries, cross-border use of electronic prescriptions including information about medication dispensing, integration of emergency services and European Health Insurance Cards, and patient access to health data. The cornerstone of the project is relying on IHE cross-organisational data exchange profiles.

Extending teleradiology across different regions and larger geographical areas brings along the need to use the XCA and XCA-I profiles for cross-community image sharing and shared workflows. As IHE profiles mature quickly, this could bring new challenges before the full implementation of teleradiology. Interfacing diverse databases from different domains raises the issue of data size and response time. In the XDS data is returned in one synchronous response while in the XCA queries spanning multiple domains will result in larger amount of data. Accordingly, query and retrieval of documents can take relatively long time leading to the need to define the timeframe of expected length of the query result or use of asynchronous mode of transactions. The excessive data size and response time issues are not yet completely solved in this profile. The feature to communicate health data between multiple communities demands definition of the response time in case not all communities are accessible or there is another source of impaired data access.

EU strategy and legal documents to support wider use of e-health services

Cross-organisational sharing of imaging data and workflows are implemented on different levels – cross-organisational sharing inside one region and across country borders somewhere else, and data sharing between healthcare organisations and citizen. While technical interoperability standards and organisational issues do not differ significantly between the different partnerships, the legal and financial issues should be addressed differently.

Legal issues concerning teleradiology in the EU are regulated by EU directives and member states legal acts. Besides EU directives there are additional EU legislative rules and also documents issued by the European Society of Radiology (ESR), which, however, are not legally binding. The fact that teleradiology is regulated by multiple directives and legal acts makes the interpretation of the legal system in the EU extremely complex (paper **IV**).

The regulation of the provision of healthcare services in the EU follows the subsidiarity principle which means that decisions about the organisation and financing of healthcare remains with the EU Member States.

Besides the directives and legal acts directly regulating teleradiology, there are several other legal issues that apply to cross-organisational data sharing. Firstly, regulations concerning relations between the patient and teleradiology provider located in an EU Member State or outside the EU. Secondly, should cross-border teleradiology service providers be licensed or should they only be licensed if the service provider is located outside the EU. The third issue is patients´ rights to view and share their own medical data through the Internet. This topic also involves ethical issues about the viewing of specific medical documents.

The definitive view of the ESR is that teleradiology service should be always defined as a medical act (UEMS 2009). Otherwise the requirements for teleradiology providers are not obvious and teleradiogy could be practised by non-radiologists or even by non-physicians (Pattynama 2010). In some EU countries, teleradiology is not considered a medical act. In Germany, teleradiology faces legal restrictions. In case of primary reading using teleradiology in Germany, special governmental permission is needed, which is valid for a maximum of 3 years. In general, this permission should be restricted to night-time and weekends; only in special cases of insufficient local resources could teleradiology also be allowed in the daytime (paper **IV**).

From the EU legislative view point, teleradiology follows telemedicine's regulations. According to the EC Treaty and EU secondary legislation, telemedicine is both a health service and an information society service. This means that even though healthcare is regulated by the legislative acts of the particular EU Members States, teleradiology must also follow the rules for the provision of commercial electronic services (COM/2008/0689 final). For teleradiology services, the service offered by a professional must comply with the rules of the EU Member State of origin. This applies to teleradiology services between the healthcare providers, radiology groups and/or private radiologists, and follows the country of origin principle (paper **IV**). Also the American College of Radiologists recommends that radiologists who reports from outside the US should be board-certified in the US and carry licences and malpractice coverage in the state where the exam is performed (Wachter 2006).

One of the basic concepts in the provision of teleradiology services is that a new service should not in any way harm the patient. A comparison of the quality of radiology service is an achievable task if teleradiology is provided in the same manner and circumstances as in-house radiology. For example, a comparison of results of a mammography screening, or the reporting of elective radiology exams, *etc*., is easy to perform.

However, cross-border teleradiology is very often used when it is the only way to provide patients with timely radiology service. It is not possible to compare situation, where radiologists work part time for both a cross-border teleradiology company and a local hospital (i.e. local service is still retained), with situation, where cross-border teleradiology services are restricted and radiologists leave their own country and go work in another country, with the result that the local service is closed down. It is not a proper comparison to ask which of these alternatives is better for the patient and society. Also, one cannot compare reporting quality issues with the opportunity to get reporting carried out several weeks earlier if teleradiology is used, plus the related opportunity to begin timely care earlier. The same difficulties in making comparisons exist if one tries to compare using teleradiology during off-hour reporting at remote locations, or using teleradiology to ensure back-up in case radiologists are ill or radiologist positions cannot be filled, *etc*.

Additionally, implementing new cross-organisational workflows will enable healthcare providers to implement completely different value-adding services. Sharing workflows across different organisations and even countries will allow value-adding services like wider sub specialization (increasing reporting quality), make reporting financially more effective, decrease reporting times, enable use of different service level agreements, *etc*.

According to the Directive on the Mutual Recognition of Qualifications, the recognition of radiologist who have completed radiology residency in one EU Member States by another EU country is almost a formality (Directive 2005/36/EC). At the same time, there is no established mutual exchange of the status of licenses nor potential criminal findings of particular radiologists covering all EU. This demands establishing adequate monitoring and accreditation mechanisms across the EU so that a radiologist who has sanctions against him or her practising in one Member State could not use cross-border teleradiology to report in another EU country. The ESR shares the views expressed in the 2007 Portugal Agreement. This Agreement supports the exchange of registers of medical professionals of EU Member States as well as sharing on-line information about disciplinary and criminal findings against health professionals (Healthcare Professionals Crossing Borders 2007).

If a radiologist does not have a license to practise in any EU country, then that person has no right to provide teleradiology reporting services to any facility in an EU country. This means that radiologists who have completed radiology residency outside the EU need to apply for accreditation in an EU country.

The legal relationship between the patient and healthcare provider are governed by national and EU legislation. With respect to diagnostic services or treatment, the patient almost always has insurance with respect to the services he or she receives from a local healthcare provider in an EU Member State. Consequently, issues of medical errors or other conflicts are elaborated according to the EU Member State's jurisdiction. This does not change when teleradiology is practised within the EU. In the case of a conflict, the patient can sue the local healthcare provider, and if the local provider sees that the medical error was caused by a teleradiology provider, it can sue the teleradiology provider (Pattynama 2010). The responsibilities of both parties are usually fixed in the teleradiology service contract. If the teleradiology provider resides outside the EU, the above-mentioned principles do not apply unless contractually agreed.

For the wider use of eHealth, including teleradiology, important strategic documents have been recently issued at the European level: the Commission Recommendation on Cross-Border Interoperability of Electronic Health Record System (2008/594/EC), the Commission Communication on Telemedicine for the Benefit of Patients, Healthcare System and Society (COM/2008/0689 final), the Cross-Border Healthcare Directive, which includes relevant articles about teleradiology (Directive 2011/24/EU), and the Ministerial Conference Final Declaration about European Co-operation on eHealth (Europe´s Information Society 2011).

Those documents include strong recommendations for the implementation of telemedicine and eHealth. EU authorities underline the importance of the political and strategic commitment of Member States to using eHealth, building confidence and the acceptance of eHealth services, bringing legal and ethical clarity and ensuring protection of personal health data, and solving interoperability issues (COM/2008/0689 final). Implementation of teleradiology services will greatly benefit from the EU Commission supporting collaboration between health professionals and patients for wider use of telemedicine. This is achieved by the EU Commission making specific recommendations on how to improve confidence in and acceptance of telemedicine (paper **IV**). It is also in line with this paper's finding that implementation of IHE interoperability profiles needs strong commitment from health policy decision makers (Adler *et al.* 2009).

The topic of a patient's informed consent is not uniformly regulated in the EU. In the Baltic eHealth project, informed consent was not required from the patients in Denmark despite of the fact that the radiology reports were performed in Estonia or Lithuania. The rationale behind that decision was that the responsibility for the diagnosis and treatment remained with the Danish hospital and in case the patient would sue, the hospital that was sued could in turn sue the teleradiology provider. In the R-Bay project, the practise was the opposite because in Finland, which was one of the participating countries, the law requires that if a patients data crosses organisational borders, the patient's informed consent is needed. In addition, in cases of cross-border teleradiology, the image should not have any personal identification data attached to it.

A recently adopted EU directive on the application of patients′ rights in cross-border healthcare requires EU Member States to take measures to ensure the interoperability of means for the provision of eHealth services, including teleradiology (Directive 2011/24/EU). It is stated that when healthcare is provided in an EU Member State other than that where the patient is an insured person, such healthcare is provided in accordance with the legislation of the Member State where treatment takes place. The above-mentioned healthcare is provided in accordance with standards and guidelines on quality defined by the Member State where treatment takes place. The ESR shares the same view that responsibility for the report obtained via teleradiology should remain with healthcare facility in the Member State where the imaging procedure is performed (UEMS 2009).

New legal issues arise with respect to data sharing with the patient over the Internet. The EPR and EHR hold no general view and there is no agreement what data, if any, can the patient view. In Estonia where the *opt out* of health data archiving principle is used, legislation defines the set of medical documents that should be available from the central HIE platform and are therefore also accessible online for the patient. On the contrary, in some EU countries, the archiving of health data centrally is based on the *opt in* principle, which means that the patient should approve the storing of any documents in the central repository prior to it being sent. The experience of patients' viewing medical data and images from the central repository in Estonia is surprisingly positive. The trend is that patients would like to view even more data that can be seen today. Three years of experience shows that patients use the opportunity to securely access medical data and images through the web portal. The feared negative outcome, like unexpected behaviour caused by the patient not understanding medical information, has not transpired. However, new types of data sharing bring up legal and reimbursement issues where: A) the patient would like to share the care pathway with different healthcare organisations; and

B) the patient's right to ask for a second opinion is based on only the digital data accessed via the Web.

Decreasing the barriers to implementation of cross-organisational shared workflow

Even though there have been a lot of work done to implement data exchanges between healthcare organisations, seamless data exchange and implementation of truly shared workflows are emerging only slowly. Establishing cross-organisational data exchanges is a task with a multiple actors and transactions (Lundberg *et al.* 2010). Therefore it demands clear implementation strategies and setting out and agreeing on predicted outcomes from all healthcare stakeholders.

In the Baltic eHealth and R-Bay projects, the provision of the ability to obtain relevant clinical data and previous images was only partly successful. Clinical data and relevant priors were available only for a particular study and therefore some of the relevant clinical information might not have been available. This was mainly caused by the fact that in many cases, despite available data exchange standards and standard profiles, we used very limited integration of EPR, RIS and PACS; there was only one integration between the teleradiology reporting platform and the intermediate teleradiology archive (paper **III**). Surprisingly we also discovered that other cross-border teleradiology implementations have similar, low-level integrations. Widely used cross-border teleradiology solutions rely upon service providers' RISes-PACSes. Images are uploaded from customers' PACSes to an intermediate teleradiology archive. This central hub is easily accessed by reporting radiologists via the web. However, requests are scanned and uploaded to the archive as an additional image or they are copied from the customer's RIS to the service provider's one. This results in no opportunity to acquire additional clinical information in most current teleradiology settings. Similarly, only images of a particular exam are uploaded (paper **III**). The above-described workflow did not fit into the departmental workflow of any of partners involved in those projects and therefore the cross-border teleradiology service did not evolve into a new business service. This problem will remain unsolved until the older, legacy systems that do not have compliance with standards and standard profile support are replaced or upgraded to support the XDS and other IHE profiles (papers **III** and **IV**).

Sharing of data and workflows across organisations changes the data ownership paradigm. The healthcare organisation is no longer the owner of the patient's health data but the ownership shifts to the patient. Understanding this shift and changing the healthcare service strategy into transparent, standardised and patient centric workflows and care pathways is one of the main successes that has resulted from implementing cross-organisational data sharing and shared workflows.

The implementation of new cross-organisational business models that benefit from the IHE standard communication profiles and data transfer technologies has not occurred at the expected pace. The eMarketplace type of many-to-many connections in teleradiology has been used in only a few cases. This is due to different factors. Firstly, inability to implement IT-systems that are IHE compliant and offer sufficient integration. Positive examples of many-to-many integrations and central service portals, like those used by the Swedish company RxEye and the Canadian company Real Time Radiology, is achieved by the use of standards and standard profiles. This was not the case with the R-Bay project and explains why the use of R-Bay portal was stopped after EU funding ended. The other reason of discontinuing the R-Bay service was the inability to find trustworthy, multilingual computer supported translation software for cross-border radiology. The drawback of wider interfacing is the complexity of integrations, which leads to the need for additional organisational and financial resources plus it would all require more time. To achieve seamless RIS and PACS integration with EPR across different organisations demands analysis of the currently used data standards and, more often than not, the need to add additional standards, standard profiles or interfaces.

Secondly, organisational and reimbursement issues, particularly the reluctance of decision makers to accept the change in the information ownership paradigm, is limiting the use of shared services. To get wider acceptance of eMarketplace-type of solutions, it is reasonable to start the implementation inside one region or country, and only then extend the service across country borders. Implementing more eMarketplaces locally allows using the same reimbursement schemes for all involved parties. This in turn makes the use of the common portal more transparent.

Legal complexity is the third limiting factor in cross-organisational and cross-border (even more so than for cross-organisational) teleradiology services. Fortunately, the EU is taking steps to harmonise national legislation in the area of eHealth, including teleradiology. The EU also supports implementation of teleradiology services nationally and across country borders. Interoperable teleradiology and eHealth settings have to follow internationally approved standards and profiles. The standard profiles to solve technical interoperability issues are XDS and XDS-I. Also, certification procedures are being agreed to for medical IT systems.

Future visions to provide teleradiology services on a cross-organisational level

Data sharing and shared workflows across organisations, different regions and even country borders open new ways of working for radiologists and other healthcare professionals. Recent developments in data sharing and in implementation of shared workflows allow pervasive access to images and related clinical and administrative data, and remove differences between internal and cross-organisational workflow management.

Storage grids and VNA are enablers for dedicated applications to carry out specific, planned activities in the care pathway. Those applications can be developed based on open standards and software (Ratib 2009). This in turn supports the use of a new generation of handheld and mobile devices like tablets, iPads, *etc* (Reponen *et al.* 2005). The data can be used at anytime and anywhere depending on when and where the decision process, imaging or reporting takes place. For clinical staff involved in the delivery of care, successful integration of different healthcare databases make the information technology systems just as important and mission-critical as the imaging modalities (paper **I**).

ACM and managed service levels provide radiologists with powerful tools to fulfil the expectations of the patient and referring physician. Quality assurance and monitoring can be carried out for the whole set of reports throughout different organisations. This factor, together with the list of transparent qualifications, licensing requirements and feedback from the referring healthcare facility, results in, increasing the transparency of the service and builds trust in favour of the teleradiology provider. Also, notification of the status of reporting is achieved by using shared workflow profiles. This removes borders from in-house and cross-organisational workflow. Reporting can be performed in the most reasonable way taking into account agreed service levels, complexity, subspecialties, *etc*. Radiologists can report images that are acquired in different locations and stored in a shared environment.

4. CONCLUSIONS

This investigation showed that new models of data sharing and shared workflows that are based on recent medical data transfer technologies and internationally approved interoperability standard profiles (IHE XDS, XDS-I, *etc.*) are the instruments that facilitate cross-organisational and cross-border implementation of teleradiology. However, organisational issues including the relatively low support of the radiology community, semantic interoperability especially the lack of computer supported translation softwares, differing legal requirements within the EU, and reimbursement issues all remain barriers that should be solved separately in every particular setting.

Defining the scope of planned teleradiology services should include a list of the predicted benefits and potential barriers. This will avoid excessive complexity during integrations. Wider implementation of cross-border teleradiology services also depends on governmental and administration decisions and most importantly, these decisions should include clear and understandable incentives approved by the international radiology community.

The tool to overcome language barriers in cross-border teleradiology is computer supported structured reporting translation software. Without the automatisation of the report translation, the teleradiology service does not support seamless sharing of cross-border reporting workflow.

Achieving trust between the parties is achieved by adopting transparent quality assurance schemes, mutual recognition of qualifications within the EU as well as outside the EU, uniform criteria for accreditation of teleradiology providers, secure data communication protocols and agreements, and the support of evolving laws within the EU.

Data sharing and shared workflows can only be successfully implemented if all data used along the whole diagnostic and/or care pathway is digitalised and transactions among the different actors in the workflow are performed in an electronic environment.

To date, streaming technology and storage grids are the data transmission and storage technologies that facilitate cross-organisational data sharing and shared workflows. Storage grids provide scalability, data redundancy, allow implementation of VNA and utilise many-to-many type of communication.

Data sharing and shared workflows provide the opportunity for radiologists and other healthcare community professionals to implement new services. Among those services are ACM, e-marketplace-type of integrations for cross-organisational workflow sharing, uniform quality assurance schemes and finally, sharing images and image-related-data with patients.

Cross-organisational and cross-border teleradiology has considerable potential to become a mature healthcare service. However, seamless implementation of data (including image) sharing and shared workflows requires:

a) more research in the areas of structured reporting and automatic report translation;

b) improved organisational implementation of new services; and

c) legal and semantic interoperability.

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ABSTRACT

In this work implementation of cross-organisational data sharing and shared workflows in medical imaging are discussed and different actors that influence the successful implementation of cross-border teleradiology are investigated. Also the benefits and barriers of data sharing and shared workflows are described. The research is based on two practical teleradiology projects conducted between European countries during 2004-2009: Baltic eHealth and R-Bay.

Cross-border teleradiology has been used to a certain extent for already more than two decades. Despite high expectations, it has not gained wide use. Reasons for its relatively infrequent use start from technical interoperability issues in the early stage of the service, to organisational, semantic and legal issues that arise at later stages.

The rapid development of imaging and related data transfer technology and the interoperability standards and standard profiles during the last decade have enabled the creation of fundamentally new models of data sharing and shared workflows. These technologies and standards are implemented mainly in departmental and enterprise settings. However, new concepts have potential to also facilitate cross-organisational health data communication, including cross-border teleradiology services. Also citizens have the opportunity to share their own health related information with healthcare organisations.

The challenges in the implementation of digital data sharing and shared workflows in cross-border teleradiology include technical interoperability, organisational (including trust), quality, semantic (including language), security and privacy, legal, and reimbursement issues. Barriers without crossing state borders tend to be mainly technical, organisational, quality related and financial. At the cross-country level the legal and language problems dominate.

Technical interoperability has recently benefited from the digital data sharing and shared workflow standard profiles developed by the Integrating the Healthcare Enterprise (IHE) initiative. If IHE profiles are followed by all parties involved in the teleradiology service, technical interoperability in cross-border teleradiology is achieved. Vendor neutral archiving (VNA), grid storage and streaming technology are other technical applications that support cross-border data sharing and developing of new cross-organisational shared workflows.

In teleradiology services crossing state borders, language issues remain unsolved. Also, the legal and reimbursement issues differ by EU Member States. However, the EU has recently taken concrete steps to support implementation of teleradiology across country borders.

Achieving trust between the healthcare providers and successful implementation of the IHE profiles, data streaming and grid technology, security and privacy measures, and resolving semantic and legal issues, opens radiologists and healthcare providers with new models of data sharing and shared workflows. Many-to-many connections enable the use of eMarketplace-type of portals, automatic capacity management (ACM) and other cross-organisational services.

Cross-border teleradiology has the potential to become a mature healthcare service if recent interoperability standards and technological advancements are used. The implementation of it depends on the recognition of the benefits and potential barriers. The blueprint of a new cross-border teleradiology service should also include a clear definition of the expected outcome and understandable incentives approved by the radiology community.

KOKKUVÕTE

Käesolevas töös vaadeldakse, kuidas meditsiinilises radioloogias toimib organisatsioonide vahel ühiste andmebaaside ja töövoogude jagamine ning uuritakse erinevaid tegureid, mis mõjutavad organisatsioonide- ja riikidevahelise teleradioloogia edukust. Samuti kirjeldatakse jagatud andmebaaside ja töövoogude kasusid ja nende rakendamisel ette tulevaid takistusi. Antud uurimus põhineb kahel praktilisel teleradioloogia projektil (Baltic eHealth ja R-Bay), mis viidi läbi 2004-2009. aastal mitme Euroopa riigi osavõtul.

Teleradioloogiat on riikide vahel kasutatud teatud ulatuses juba rohkem kui kaks aastakümmet, kuid vaatamata suurtele lootustele ei ole see meditsiiniteenus leidnud laialdast poolehoidu. Suhteliselt vähese rakendamise põhjuseid on mitmeid, alates vähesest tehnoloogilisest infovahetusvõimest teleradioloogia algusaastatel kuni lõpetades hiljem väljendunud organisatsiooniliste, semantiliste ja õiguslike probleemidega.

Radioloogiliste piltide ja nendega seotud andmete edastamise tehnoloogia ning infovahetuse standardite ja standard profiilide kiire areng viimase aastakümne jooksul on võimaldanud fundamentaalselt uute andmejagamise ja jagatud töövoogude mudelite loomist. Need tehnoloogiad ja standardid on rakendatud peamiselt osakonna või asutuse tasemel. Samas omavad uued lahendused potentsiaali aidata kaasa nii organisatsioonide kui ka riikide vahelisele terviseandmete kommunikatsioonile. Lisaks tekib kodanikul võimalus jagada oma terviseandmeid tervishoiuteenuse osutajatega.

Väljakutsed organisatsioonide- ja riikidevahelises teleradioloogias, mis tulenevad jagatud andmebaaside ja töövoogude rakendamisest, võivad tuleneda tehnoloogilise infovahetusvõime puudustest, organisatsioonilistest ja usaldust puudutavatest aspektidest, teenuse kvaliteedist, semantilistest ja keelelistest probleemidest, turvalisuse ja privaatsusega ning teenuse kulude hüvitamisega seonduvatest asjaoludest. Kui teleradioloogiat praktiseeritakse ühe riigi piires, siis on võimalikud takistused seotud peamiselt tehnoloogia, organisatsiooni, kvaliteedi või teenuse rahastusega. Riikidevahelise teleradioloogia puhul domineerivad õiguslikud ja keelega seotud probleemid.

Viimastel aastatel on tehniline infovahetusvõime kiiresti edasi arenenud tänu digitaalsete meditsiiniandmete andmevahetust ja jagatud töövooge toetavate standardprofiilide arendamisele. Andmevahetuse ja töövoogude standardprofiile arendab rahvusvaheline organisatsioon IHE (ingl. k. – *Integrating the Healthcare Enterprise*), millest tulenevalt kutsutakse neid IHE-profiilideks. Kui standardprofiile kasutatakse kõigi teleradioloogia teenusega seotud osapoolte poolt, siis on võimalik saavutada organisatsioonide vahel kõrge infovahetusvõime. Organisatsioonide vahelist terviseandmebaaside ja töövoogude jagamist ning uute organisatsioonidevaheliste jagatud töövoogude arendamist toetavad lisaks IHE standardprofiilidele ka tarnijasõltumatu arhiveerimise lahendus (ingl. k. – *Vendor neutral archiving (VNA)*), grid arhiveerimise ja andmete voogeadastuse (ingl. k. – *streaming*) tehnoloogia.

Riikidevahelise teleradioloogia teenuse puhul ei ole leitud lahendust tõlkeküsimusele. Samuti erinevad õiguslikud ja kulude hüvitamisega seotud küsimused Euroopa Liidu (EL) siseselt. Viimastel aastatel on EL siiski astunud konkreetseid samme piire ületava teleradioloogia rakendamise toetuseks.

Selleks, et radioloogias ja tervishoiu valdkonnas laiemalt saaks kasutusele võtta uusi andmejagamise ja jagatud töövoogude mudeleid, tuleb saavutada usalduslik suhe tervishoiuteenuse osutajate vahel ning edukalt rakendada IHE profiile, andmete voogedastuse ja grid tehnoloogiad ning lahendada turvalisuse ja privaatsusega seotud küsimused ning semantilised ja legaalsed aspektid. Sellised andmevahetusmudelid, mis ühendavad omavahel mitmeid andmebaase (ingl. k. – *many-to-many connection*) võimaldavad kasutusele võtta avatud radioloogia teenuseportaale nagu *eMarketplace* ning rakendada automaatset töömahu haldamist (ingl. k. – *automatic capacity management (ACM)*) ja teisi organisatsioonidevahelisi teenuseid.

Organisatsioonide- ja riikidevaheline teleradioloogia omab potentsiaali areneda laialt kasutatavaks tervishoiuteenuseks. Selleks tuleb võtta kasutusele viimasel ajal välja arendatud andmevahetusstandardid ning meditsiiniliste piltide edastamise ja arhiveerimise tehnoloogilised lahendused. Teleradioloogia rakendamine sõltub sellest, kui hästi osatakse ära tunda ja kirjeldada uue teenuse kasud ja võimalikud takistused. Uue piire ületava teleradioloogia teenuse planeerimisel tuleb selgelt välja tuua ka oodatav tulemus ja radioloogia valdkonna spetsialistide poolt aktsepteeritavad põhjendused.

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3. Education

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Tallinn University of Technology	2011	Faculty of Science; Faculty of Mechanical and Instrumental Engineering / PhD
Tartu University	1996	Department of Radiology and Oncology, Residency of Radiology / Radiologist
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4. Language competence/skills (fluent; average, basic skills)

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Estonian	Mother tongue
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Name of the course	Time of the study	Educational organisation
European Health Leadership Program	1/2005	INSEAD, France
Course of Radiologic Pathology	2/1996-4/1996	Armed Forces Institute of Pathology, Washington DC, USA
Residency course	10/1995-12/1995	Department of Radiology, Oulu University, Finland

6. Professional Employment

Period	Organisation	Position
From 2010	Estonian E-Health Foundation, Estonia	eHealth expert
From 2010	Tallinn University of Technology, Estonia	Lecturer
From 2006	Technomedicum, Tallinn University of Technology, Estonia	Member of the Supervisory Board
From 1996	Tallinn Central Hospital / East Tallinn Central Hospital, Estonia	Radiologist
2004-2010	East Tallinn Central Hospital, Estonia	Member of the Board, Director of Research and Development
2005-2010	Estonian E-Health Foundation	Member of the Supervisory Board
2002-2008	Estonian Health Insurance Fund	Member of the Supervisory Board
2002-2004	East Tallinn Central Hospital, Estonia	Head of Diagnostic Clinic
1994-1996	Department of Radiology and Oncology, Tartu University, Estonia	Resident
1992-1994	Tallinn Seamen's Hospital, Estonia	Internship
1991	Department of Internal Medicine, Helsinki University, Finland	Internship

7. Scientific work

The effect of the use of e-health services on diagnostic and treatment processes in healthcare.

8. Main areas of scientific work/Current research topics

a. Investigation of the actors and processes influencing the implementation of shared workflow
b. The use of digital medical databases in development of early diagnostic algorithms.
c. Research of a medical text as a sublanguage of medicine.

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Keel	Tase
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European Health Leadership Program	1/2005	INSEAD, Prantsusmaa
Course of Radiologic	2/1996-4/1996	Armed Forces Institute of

Pathology		Pathology, Washington DC, USA
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6. Teenistuskäik

Töötamise aeg	Tööandja	Ametikoht
Alates 2010	Eesti E-Tervise Sihtasutus	E-tervise ekspert
Alates 2010	Tallinna Tehnikaülikool	Lektor
Alates 2006	Tehnomeedikum, Tallinna Tehnikaülikool	Nõukogu liige
Alates 1996	Tallinna Keskhaigla / Ida-Tallinna Keskhaigla	Radioloog
2004-2010	Ida-Tallinna Keskhaigla	Juhatuse liige – arendusjuht
2005-2010	Eesti E-Tervise Sihtasutus	Nõukogu liige
2002-2008	Eesti Haigekassa	Nõukogu liige
2002-2004	Ida-Tallinna Keskhaigla	Diagnostikakliiniku juhataja
1994-1996	Radioloogia ja onkoloogia osakond, Tartu Ülikool	Resident
1992-1994	Meremeeste haigla	Intern
1991	Helsingi Ülikooli sisehaiguste osakond	Intern

7. Teadustegevus

Elektroonsete tervishoiuteenuste kasutusele võtmise mõju tervishoius toimivatele diagnostika- ja raviprotsessidele

8. Teadustöö põhisuunad

   a. Jagatud töövoo rakendamist mõjutavate tegurite ja protsesside uurimine.
   b. Digitaalsete kliiniliste andmebaaside kasutamine haiguste varajase diagnoosimise algoritmide välja töötamiseks.
   c. Meditsiinitekstide kui meditsiini allkeele uurimine.

PAPER I

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Pervasive Access to Images and Data – The Use of Computing Grids and Mobile/Wireless Devices across Healthcare Enterprises

Hanna Pohjonen, Peeter Ross, Richard Kamman and Johan Blickman

Abstract—**Emerging technologies are transforming the workflows in healthcare enterprises. Computing grids and handheld mobile/wireless devices are providing clinicians with enterprise-wide access to all patient data and analysis tools on a pervasive basis. In this paper, emerging technologies are presented that provide computing grids and streaming-based access to image and data management functions, and system architectures that enable pervasive computing on a cost-effective basis. Finally, the implications of such technologies are investigated regarding the positive impacts on clinical workflows.**

Index Terms—**Clinical Workflows, Computing Grids in Healthcare, Enterprise-Wide PACS, Handheld Devices, Mobile Computing, Pervasive Computing, Streaming.**

I. Introduction

THE advancement of medical imaging technology has transformed the way clinicians perform diagnoses and treat patients, to the point that such technologies are today an indispensable part of medicine. Virtually all hospitals rely on numerous imaging modalities such as ultrasound, CT, MRI, DR, CR, SPECT, PET and others. Similarly, information technology systems are rapidly becoming just as important and mission-critical in the delivery of care. Certain of these emerging IT technologies are providing clinicians with enterprise-wide access to all patient data and analysis functions on mobile and wireless handheld devices. Such *anytime, anywhere* pervasive coverage matches the highly nomadic workflows of many healthcare practitioners, and has the potential to significantly impact clinical workflows.

The underlying techniques that enable pervasive computing in the healthcare sector are specialized grid computing systems, and advanced streaming methods that allow mobile and light clients to function as full-featured clinical workstations. This paper presents such emerging technologies in detail.

Finally, pervasive image and data management systems have the ability to transform clinical workflows, mostly in the areas of improved communication (clinician-to-clinician, clinician-to-patient) and improved dissemination of information. Such impacts are also investigated in this work.

II. Grid Computing and the Streaming of Images and Analysis Functions

A. What Is Streaming?

Streaming is a broad term that refers to sending portions of data from a source to a client for processing or viewing, rather than sending all the data first before processing or viewing. A television signal is a form of streaming – the source data are located at a central location and a signal is created to present the time-varying data on local devices (televisions); in this example, the opposite of streaming would be to download a video sequence from a website for viewing on a local PC.

For information technology, client-server systems are used together with streaming technologies to overcome various limitations such as limited bandwidth connections, clients that are not powerful enough for the computation tasks required, and the handling of large data sets.

B. Media Streaming

Streaming is generally associated with the concept of transmitting over time large media files from servers to clients over networks for viewing or listening. Because the data being streamed are sequential in time, the challenge is to ensure receipt of enough of the data on the client side at any point in time in order to enable real-time viewing or listening of the signal. Techniques have been developed to make media streaming methods robust over connections with variable and possibly minimal bandwidths, and these include the use of caches and buffers on the clients, and multiple streams of data that are either redundant or vary regarding bandwidth requirements (varying compression rates). However, media streaming over the internet still presents formidable barriers to widespread adoption [1].

Although traditional streaming can be used with medical image data such as cine ultrasound sequences (which are looped video signals), the effective streaming of medical image data in general presents a fundamental technical challenge. This is because the data to be streamed are not usually sequential in time, but rather are determined in response to user actions to interact with the data and invoke analysis functions that reside on a server. Thus, buffering operations and other techniques cannot be relied upon to provide smooth and acceptable frame-rates over connections with variable Qualities of Service (QoS).

QoS is achieved by a set of methods and policies, and is measured in terms of consistent and reliable bandwidth capacity, latency and other factors in network connections. For the external Internet, and many internal networks, QoS often varies widely over the period of a connection.

C. Types of Streaming for Medical Images and Data

There are several types of streaming technologies that are recognized and being used to handle medical image data.

1) Raw Streaming: This is used to provide application services through thin clients. The complete contents of frame-buffers on the server side are directly transmitted to clients. This technology is not widely adopted for medical solutions for a number of reasons, including high bandwidth requirements, and the poor scalability of servers.

2) Intelligent Downloading: A form of streaming whereby only the data required for immediate viewing or processing are downloaded to a client. In general, processing of the data occurs locally on the client. Additional downloading may occur in the background in anticipation of other viewing or processing requests.

3) Adaptive Streaming of Functionality: In some cases, adaptive streaming of functionality is similar to raw streaming in that data are not downloaded to clients, only frame-buffer views of the data or results of data analyses are streamed. The power of the server is used to render final screen images which are then compressed and transmitted to client devices in accordance with requirements regarding bandwidth usage, image quality, and interaction rates. The streaming method adapts to changing conditions in order to meet these requirements.

In other cases, streaming of functionality transmits data to clients in accordance with various parameters and preferences regarding performance goals, bandwidth consumption, and available client resources. The data are then processed locally on the client.

The emphasis of the technology for adaptive streaming of functionality is to provide remote access to full system functionality, using the best combinations of local and remote processing of medical data, in order to optimize multiple goals involving users and/or the computing infrastructure.

D. Grid Computing

As defined in [2], a computing grid "is a standards-based application/resource sharing architecture that makes it possible for heterogeneous systems and applications to share compute and storage resources transparently." Numerous service-oriented architectures (SOA) have been built into grid systems for industries such as finance and manufacturing, and it can be argued that effective electronic medical record systems will come to resemble computing grids.

For the healthcare enterprise, the advantages of grid computing are that various heterogeneous systems can interoperate, and computing resources can be distributed throughout an enterprise, rather than being confined to a particular workstation or system.

As the amount of patient data grows, and analyses become more complex, grid-computing can provide a scalable and efficient technique for meeting the increasing computational needs. For example, in a single electronic medical record, one server could be analyzing patient test results against a database and displaying the results, while two other servers could be processing image data and displaying the results in the same electronic record. SOA provides the structures and standards that allow disparate computing resources and services, and data sources, to be integrated into a computing grid.

Grid-computing for electronic medical records is being enabled by the adoption of standards for interoperability, and by the use of meta-data techniques for integrating disparate systems and sources of data.

E. Broadband Wireless - The Next IT Revolution?

The use of streaming and grid computing in the healthcare sector is expected to become widely adopted by healthcare enterprises for a variety of reasons.

In the general IT area, broadband wireless technologies that are reliable, affordable and extensively available are expected to revolutionize the future use of the internet and to be disruptive to a large number of industries [3], [4]. The convergence of mobile telephony and fast connections to the internet will spawn a new generation of services and systems through which users will have ubiquitous access to information and tools, allowing pervasive computing to fulfill its goal of having computers disappear into the background [5].

It is expected that healthcare enterprises will adopt broadband wireless technologies together with specialized services to form ubiquitous medical IT systems that focus on patient data and care delivery and not on computer software and hardware. Already today there is a significant trend towards the adoption of handheld devices for various types of applications in radiology [6].

F. Advantages of Streaming and Grid Computing

There are a number of distinct advantages to healthcare enterprises in combining grid computing and mobile/wireless streaming in an image and data management system.

1) Access to full clinical functionality: by offering access to exactly the same system features and interfaces on all access devices and at all locations, users become more comfortable, efficient and standardized regarding daily workflows.

2) Lower installation and deployment costs: streaming client applications can be very thin and thus require minimal configuration and setup activities on the client side. This is important for large or ASP-based configurations in which many users must be quickly and easily hooked up to the system, often employing heterogeneous client devices.

3) Predictable scalability: streaming systems and grid platforms scale linearly with the number of users, the number of sites, and the amount of data handled.

4) Increased reliability: because grid-based streaming servers typically provide redundant services, a failure of a client workstation or a server node can be easily and quickly overcome.

5) Effective use of bandwidth: streaming technologies and computing grids can use bandwidth in a manner that can be well estimated, and in many cases such bandwidth usage is more efficient than with traditional web-based solutions (involving data downloading).

6) Increased security and data consistency: because data can be prevented from being downloaded to local clients, and only streamed for interactive viewing, an additional level of data security can be provided. Streams can also be required to be encrypted. Additionally, streaming requires only a single copy of data to be stored, which is accessed as needed, rather than maintaining multiple copies in order to meet distribution demands.

7) Decreased training times: by providing service-oriented applications that are focused on the particular needs of various clinical users, overall training times can be significantly reduced.

III. System Architectures - Streaming

In this section various architectures are presented that can provide optimal and pervasive access to medical images, patient data and analysis functions.

A. Adaptive Streaming

As described in the previous section, streaming methods can be categorized as *raw streaming*, *intelligent downloading,* or *adaptive streaming of functionality*.

Raw streaming is a relatively simple technique and is not used extensively in healthcare applications so the method is not further considered here.

Intelligent downloading is a streaming technique that focuses on getting the most relevant data to the user in the shortest amount of time. The iSyntax streaming technology from Philips Incorporated was the first intelligent downloading technology used in a PACS system, employing multi-resolution data representations and wavelet compression to transmit 2D image data “Just-In-Time” to client stations [7]. iSyntax is not able to handle streaming of 3D reconstructions currently.

The core technology behind the image/data distribution technology from IDX Systems Corporation is the patented “Pixels-on-Demand” concept, which is basically an intelligent, adaptive and region-of-interest-based technique for progressively updating relevant regions to present full-fidelity data where and when required, as determined by the perceptual relevance of the regions (“streaming by quality”) [8].

The Adaptive Streaming Module (ASM) from Medical Insight A/S uses the power of the server device to render final screen images which are then streamed to client devices in accordance with requirements regarding bandwidth, image quality, and interaction rates [9]. Like iSyntax and Pixels-on-Demand, the ASM also produces full-fidelity and full-resolution images when required, regardless of the device type or the connection type. However, unlike iSyntax and Pixels-on-Demand at the moment, the ASM can also stream *functionality* to client devices because of the use of server-side computing. That is, if a 3D reconstruction analysis is required of a large volume data set, the ASM can easily perform the reconstructions on the central server and stream the full-resolution results to thin or mobile/wireless clients [10]. The ASM can also download data to a client device if this is deemed acceptable and improves overall system performance. This streaming technology from Medical Insight has recently received FDA clearance to market the first full-featured clinical workstation that is a wireless or mobile PDA or mobile telephone. Finally, the ASM is able to change compression and other parameters to adapt to changing QoS conditions for a connection, thus maintaining interactivity in user sessions.

Aquariusnet from TeraRecon Incorporated is a client-server based system in which specialized hardware on the server streams functionality to thin clients [11], much like the ASM.

Finally, the Vitrea system from Vital Images Incorporated is being enabled with streaming capabilities in the ViTALConnect product, allowing streaming of functionality to client devices for the 3D visualization of volume data [12].

B. Advances to Adaptive Streaming and Downloading

One of the areas in which streaming technology can be improved is by combining the methods of adaptive streaming of functionality with intelligent downloading. By doing this, the advantages of both methods can be retained, thereby eliminating the disadvantages or either method alone.

For example, intelligent downloading is important in certain situations for diagnostic reporting – radiologists demand the best performance in terms of system responsiveness, which can only be obtained if the data are being processed locally and not on a server that streams the results of the processing. Similarly, there is no advantage to the streaming of functionality that is essentially textual, such as the interaction with a reporting tool – bandwidth can be saved by running the reporting locally (if the client device can support the operation).

In Fig. 1, a general architectural concept is presented for the combination of adaptive streaming of functionality with that of intelligent downloading. Although not available commercially today, there are research and development tasks underway to introduce an image and data management product based upon such technology.

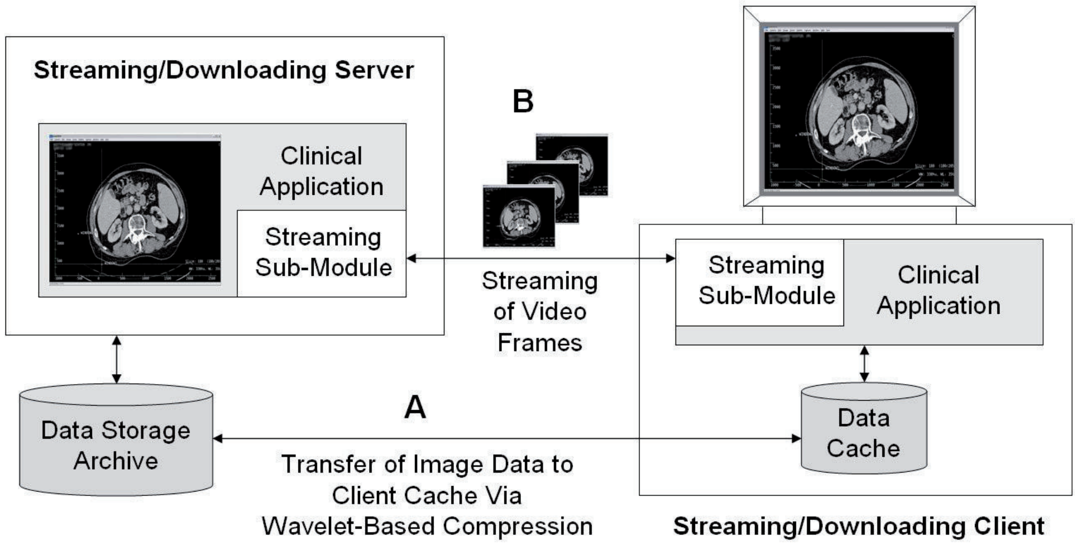

Fig. 1. Architecture of an advanced streaming method that combines intelligent downloading with adaptive streaming of functionality. Based on a number of parameters and factors, the client can decide to download data for local processing (A) or to use the resources of the server for data processing (B). The client is a user station such as a PC, laptop or handheld device.

C. Display Technology Considerations

Streaming technology can provide access to images and analysis functions throughout a healthcare enterprise and on a variety of client devices. But how is such access controlled – to ensure that interpretations are not made on devices that may not be able to display images properly?

Firstly, in the United States, applications must be cleared by the FDA to be used for primary diagnosis, or to be used for clinical referral. This process involves a consideration of hardware display options and the type of data being viewed and analyzed. To-date, the FDA has not cleared any applications for use in primary diagnostics on handheld wireless or mobile devices (research being done in this area, however), although certain applications have been cleared for clinical referral and review on such devices. Applications must also be labeled according to this intended use.

Secondly, with certain streaming technologies, it is possible to view images at full-fidelity and full-resolution on devices with small displays. This is because the complete data set being examined is located on the server, and when a zoomed view is presented on the client, that partial image is the same as it would appear on a large display. The only disadvantage is that the full-resolution view is only partial, which may require panning and scrolling to see the entire image, whereas on a high-resolution display the entire image is visible at once.

IV. System Architectures – Grid Computing

In this section, grid computing architectures are discussed as part of the infrastructure that can support pervasive access to images, patient data and analysis functions across healthcare enterprises.

A. Why Grid Computing?

There are a number of factors that are driving healthcare organizations to require the sharing of data and resources across a heterogeneous mix of hardware platforms and software systems. Such interoperability is needed to support electronic patient records, which in many European nations are now being designed or implemented at a national level. In the United States, many health care organizations are consolidating operations, especially regarding ambulatory services, which also requires the sharing of data and resources across enterprises.

Furthermore, as the healthcare sector begins adopting new practices and technologies, such as evidence-based medicine and genomics, the need will further grow for linking together and analyzing all the different sources of patient data.

Finally, if pervasive access to patient data and analysis tools is to be provided via mobile and wired devices, the hardware resources supporting these functions must be distributed across enterprises in order to ensure the overall robustness of the technology, and to avoid bottlenecks introduced by the centralization of resources.

B. Virtualized PACS Grids across Enterprises

A good example of an emerging grid computing infrastructure is the virtualization of PACS services. In this concept, a software module is placed above various PACS systems or archives that may be located in an enterprise. Such a module will then contain a meta-data index to the full contents of each separate archive. Hierarchies keep track of which meta-data indices are available at which module instance. All the meta-data are kept updated and synchronized across instances via various database features for maintaining data concurrency.

If the meta-data are predominantly DICOM-specific and pertain to patient image data, then such a module is providing a form of virtualized PACS services (VPACS) that support multi-site installations involving disparate PACS archives. Such a module needs to support full DICOM services on its own, as is evidenced by the existence of DICOM Conformance Statements for such a product.

One major advantage of virtualized PACS services is that searches of large, complex and distributed repositories of data can be completed locally and extremely rapidly. Furthermore, if the VPACS module is part of a server that can support clients, the subsequent access to the required data and analysis functions can be done via intelligent downloading to the local server or via adaptive streaming from a remote server.

Fig. 2 illustrates the general architecture of such a grid computing system.

C. Electronic Medical Records

If a grid computing architecture also supports virtualized services involving patient data in addition to radiological images (for example, laboratory reports, journals, and multi-media data), then such a system is considered to be a form of an electronic patient record. The IHE Cross-Enterprise Document Sharing (XDS) Profile describes such an architecture and the necessary transaction protocols to handle such data in a standardized manner [13]. In such a case, using XDS terminology, a virtualized services module is referred to as a Document Registry, and data archives are referred to as Document Repositories.

XDS is being adopted by a number of vendors to ensure interoperability among healthcare IT systems. Certain PACS archives have also been extended to support efficient management of non-DICOM data objects [14].

Streaming technologies can also be an effective part of electronic medical record (EMR) systems. That is, with an application programming interface (API) that is standards-based, access can be made from within an EMR system to the computing capabilities of servers for processing image data and streaming the results.

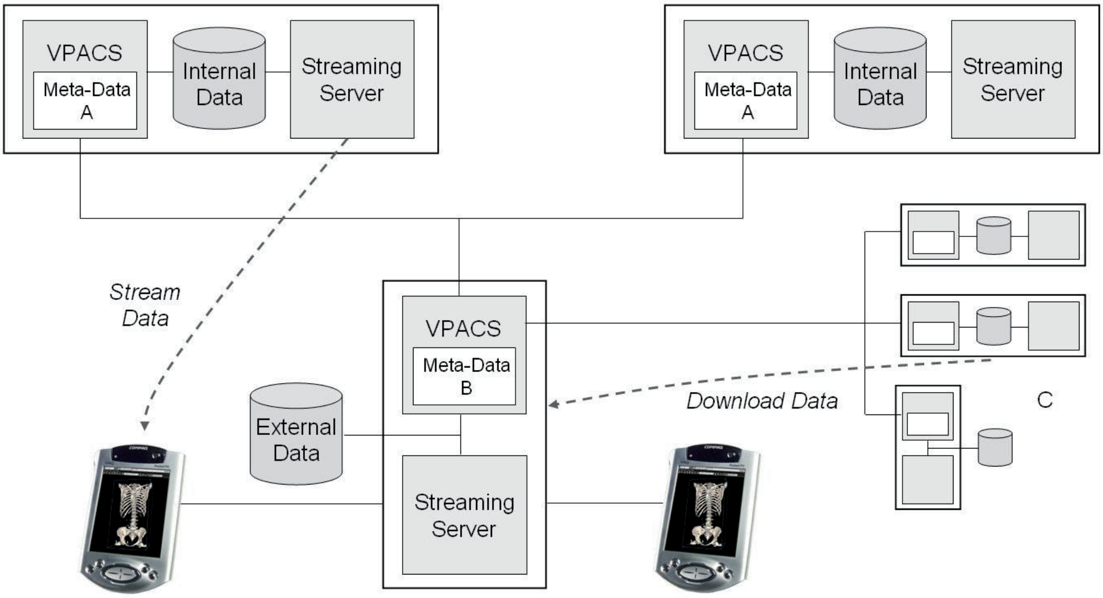

Fig. 2. Architecture of a grid computing system for handling PACS image data. Each site has a VPACS instance and a data archive that is either internal to the grid computing system, or is an external archive. Each VPACS instance holds a meta-data index of the contents of the internal and external data repositories. Some meta-data indices are the same (A) while others may contain additional information (B). Such hierarchies of meta-data indices ensure efficient handling of large, complex and distributed repositories of data. For example, there is no need for each of the three larger instances of the system to have full knowledge of the three smaller instances (C) if the queries and requests for data from the smaller instances are infrequent. Only the VPACS instance with meta-data B needs to maintain concurrency with the smaller instances, and can make this information available as need to the instances with meta-data A.

When remote data are needed for processing at a particular site, the grid computing system can elect to stream the data from the remote streaming server (left), or the data can be downloaded to the site for local processing.

V. Impacts on Clinical Workflows

As pervasive access to images, patient data and analysis functions becomes available across healthcare enterprises via mobile and wireless devices, there are a number of impacts to clinical workflows that may be expected.

A. *The Nomadic Healthcare Worker*

The workflow of clinicians is patient-centric and also highly nomadic – rarely are they able to accomplish all necessary tasks by remaining at a single location for an extended period of time (an office, for example). However, clinicians have difficulty in moving outside their own environments because of the need to have access to those IT systems that support their work.

Similarly, contacts with patients at the bedside can be challenging because disparate sources of patient data need to be assembled for effective communication.

However, pervasive and mobile access to patient data and analysis tools can open up new avenues of communication for clinicians, both amongst themselves and with patients, as well as new avenues of mobility to support nomadic workflows.

B. *The Radiologist and the Data Explosion Crisis*

It is widely perceived that radiologists are inundated by the increase in the amount of imaging studies being ordered, as well as by the increasing size of the studies themselves. By providing rapid and pervasive access to image data and analysis functions, especially 3D tools, radiologists can be more effective in their workflows. Additionally, pervasive access to image data and analysis tools, especially at remote locations, such as at home while on-call, can eliminate many late-night trips into the radiology department to diagnose studies involving trauma and emergency cases (whole-body scans).

An example of emerging IT technologies being applied to help manage radiological workloads is the Baltic eHealth network which is currently using the streaming and grid-computing technologies from Medical Insight in trans-national remote-reporting between Denmark, Estonia and Lithuania [15]. Structured multilingual reporting templates are also utilized. Both streaming and structured reporting are powerful tools for remote reporting across borders, enabling the utilization of radiologist resources from different countries, and in the respective native languages.

C. *Mission Critical Systems and the Medical IT Specialist*

At many healthcare organizations, the IT department has grown to size and importance that approaches many clinical departments. Medical IT specialists are given the difficult tasks of maintaining and supporting mission-critical systems that are accessed by a large and disparate group of clinical users. By introducing systems that minimize support and maintenance requirements because of interoperability and the use of simple (light, thin) clients, the overall burden on IT departments can be reduced. Also, pervasive systems need to be distributed in terms of computing resources, and this makes the overall infrastructure more robust.

VI. Conclusion

In this paper, emerging technologies have been presented that can provide pervasive access to medical images and patient data using mobile and wireless devices. The emphasis has been on describing new technologies that are currently being deployed, and to provide a sense for what the delivery of care may involve in the not-too-distant future. Important changes appear to be on the horizon for healthcare organizations regarding IT technologies and clinical workflows.

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PAPER II

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Extending the radiological workplace across the borders

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Abstract: Emerging technologies are transforming the workflows in healthcare enterprises. Today, several vendors offer holistic web-based solutions for radiologists, radiographers and clinicians - a single platform for all users. Besides traditional web, streaming technology is also emerging to the radiological practice in order for improving security and enabling the use of low network bandwidths.

The technology does not set limitations any more: today, the digital workplace knows no boundaries; remote reporting, off-hour coverage, virtual radiologists are all ways to offer imaging services in a non-traditional way. The challenge, however, is to provide trust over distance – across organizational or even national boundaries. In the following three different aspects important in building trust in remote reporting are discussed: 1) organizational change issues, 2) continuous feedback and 3) legal implications.

Keywords: web, streaming, remote reporting, cross-border

1. Introduction

Thus far dedicated stand-alone PACS workstations have dominated the way how radiologists work and web-based tools have been used for delivering images to clinicians mainly. The main reasons for not using web for diagnostic work have been the lack of diagnostic and sophisticated analysis tools - like 3D reconstruction - in web solutions.

This is changing: today several vendors offer holistic web-based solutions for radiologists, radiographers and clinicians - a single platform for all users. These solutions provide the radiologists with diagnostic tools, advanced image processing methods as well as meeting folders all in web.

The technology does not set limitations any more: today, the digital workplace knows no boundaries; remote reporting, off-hour coverage, virtual radiologists are all ways to offer imaging services in a non-traditional way. The challenge, however, is to provide trust over distance – across organizational or even national boundaries.

2. Material and methods

Traditional web

The web-based solution provides healthcare professionals with enterprise-wide access to all patient data and analysis functions. Such anytime, anywhere pervasive coverage matches the highly nomadic workflows of many healthcare practitioners, and has the potential to significantly impact clinical workflows.

Consultations between clinicians and radiologists become easier and more efficient when the same platform is used and the professionals can log in using any end-terminal regardless of their profile. Consultations can occur via a web conference as well – the same screen can be shared by the clinician and the consulting radiologist – or by a resident and a senior radiologist.

Web-based diagnostics integrated with web RIS enables a virtual radiological environment to be built, where radiologists can remotely use viewing tools and RIS via VPN across organizational or national borders. Pervasive access to image data and analysis tools at home while on-call can eliminate many late-night trips into the radiology department to diagnose studies involving trauma and emergency cases.

The new generation web-architecture enables built-in redundancy and easy software/hardware updates. The platform is adjustable for different end-terminals and network bandwidths and overall training times can be significantly reduced. By introducing systems that minimize support and maintenance the overall burden on IT departments can be greatly reduced.

Web client applications can be thin and thus require minimal configuration and setup activities on the client side. This is important for today's large or ASP-based configurations in which many users must be quickly and easily hooked up to the system.

Streaming technology

Besides traditional web, streaming technology is also emerging to the radiological practice. Streaming is a broad term that refers to sending portions of data from a source to a client for processing or viewing, rather than sending all the data first before processing or viewing. In the imaging field streaming technology is used to overcome various limitations such as limited bandwidth connections, clients that are not powerful enough for the computation tasks required, and the handling of large data sets.

There are two types of streaming relevant in the imaging field. Intelligent downloading is a form of streaming whereby only the data required for immediate viewing or processing are downloaded to a client. In general, processing of the data occurs locally on the client. Additional downloading may occur in the background in anticipation of other viewing or processing requests.

In adaptive streaming of functionality data are not downloaded to clients, only frame-buffer views of the data or results of data analyses are streamed. The power of the server is used to render final screen images which are then compressed and transmitted to client devices.

In other cases, streaming of functionality transmits data to clients in accordance with various parameters and preferences regarding performance goals, bandwidth consumption, and available client resources. The data are then processed locally on the client.

In other words, the goal of the technology for adaptive streaming of functionality is to provide remote access to full system functionality, using the best combinations of local and remote processing of medical data.

3. Results

The main advantages of streaming technology include

1) Effective use of bandwidth: streaming technology can use bandwidth in a manner that can be well estimated, and in many cases such bandwidth usage is more efficient than with traditional web-based solutions (involving data downloading).

2) Increased security and data consistency: because data can be prevented from being downloaded to local clients, and only streamed for interactive viewing, an additional level of data security can be provided. Streams can also be required to be encrypted. Additionally, streaming requires only a single copy of data to be stored, which is accessed as needed, rather than maintaining multiple copies in order to meet distribution demands.

3) Access to full clinical functionality: by offering access to exactly the same system features and interfaces on all access devices and at all locations, users become more comfortable, efficient and standardized regarding daily workflows. Handheld mobile/wireless devices can provide clinicians with enterprise-wide access to all patient data and analysis tools on a pervasive basis.

4) Predictable scalability: streaming systems scale linearly with the number of users, the number of sites, and the amount of data handled.

4. Discussion

The workflow of clinicians is patient-centric and also highly nomadic – rarely are they able to accomplish all necessary tasks by remaining at a single location for an extended period of time (an office, for example). However, clinicians have difficulty in moving outside their own environments because of the need to have access to those IT systems that support their work. Similarly, contacts with patients at the bedside can be challenging because disparate sources of patient data need to be assembled for effective communication. There is also a clear need to extend the workplace outside the organizational or even national borders – for both clinicians and radiologists.

Therefore pervasive and mobile access to patient data and analysis tools can open up new avenues of communication, both amongst professionals and with patients, as well as new avenues of mobility to support nomadic workflows.

When extending the workplace across organizational and national borders, the technology is not the limiting factor. With traditional web and especially combined with streaming technology we can build a secure and trusted workplace which knows no boundaries. The issue, however, is to build trust over distance – between the service providers and the customers for the reporting service. In the following three aspects important in building trust are discussed: organizational change issues, feedback and legal issues.

Organizational change issues

When outsourcing reporting service the factors in the current organizational environment that will enhance or hinder the development or implementation of the service should be considered:

- What groups will support the development of the remote reporting service? Why?
- What groups will block the development of the remote reporting service? Why?
- How will you convey the message to gain support or buy-in for the development of the remote reporting service in your organization?
- What problems or pitfalls can you anticipate that will affect the success of the remote reporting service?

Only when the organization is ready and prepared for integrating remote reporting as part of the radiological operation of a hospital, there is a chance in succeeding to build trust in the service.

The remote reporting service provider should be tightly involved side in the organizational change management of the customer. The customer should get familiar with the ‘face’ of the service provider in order to build trust. The backgrounds of the project champion and the core project team, their skills and abilities to execute the business case strategy should be described. The personnel needs, the roles of the key project team members, and the role of an outside council if any should be identified. Staffing requirements and organizational structure in terms of responsibilities and reporting relationships should be clarified. At least the following questions should be answered:

- What are the roles and responsibilities of the project champion and the project team?
- Who are the key leaders, what is their experience with similar projects?
- Does the project team have training or learning needs to support the success of the proposed project?
- Describe the function of outside supporting professional services, if any.
- What are the reporting relationships between the key project team members?

Continuous feedback

When buying a remote reporting service the customer wants proof of quality, known and accepted processes and protocols, transparency, possibilities for peer review and double blind readings from time to time. On the other hand, the service provider expects access to the relevant data, feedback on discrepancies and learning from other specialists.

Feedback – both from radiologists but also from clinicians - is essential in building and maintaining trust in a remote reporting situation where the service provider is not in the same building or not even in the same country; ensuring transparency in performance and quality indicators is a prerequisite for a self-sustainable remote radiology business case. The users (i.e. the customers for the remote reporting) should be able to give digital feedback easily and in a user-friendly way.

At the same time learning is enabled by systematic automation of feedback on different levels between participants in the healthcare process. Constructive feedback creates a safe environment for individual self-improvement. The feedback software should be easy to use and preferably desktop-integrated with the local RIS/PACS.

Legal implications

In building remote reporting business case you should consider the main issues that may arise from the need to manage personal information in a manner that takes into consideration both individual sensitivities and the need to provide healthcare practitioners (and, potentially, patients, administrators and others) with access to health records. In particular, you need to demonstrate that you have understood the trust and security implications arising from the legal and clinical environment in which the remote reporting service is to operate.

The following issues should be discussed and agreed on between the service provider and the customer:

- How will patient information be stored, transmitted and used so that it is kept confidential and only shared with those individuals who have a legitimate need to see it? Will encryption and electronic signatures be needed? How will patient consent be recorded and, if necessary, used to govern access to information?
- How all actions performed will be associated with the identifiable individual who performed those actions? What manual and automated facilities will be required to maintain and subsequently process any audit trail / security log etc.?
- What processes will be used to address disaster recovery and business continuity?
- Who will provide the service and who, ultimately, will be responsible for the care of the patient – will clinical responsibility be shared, in fact, between several clinicians?
- How much will the patient be told about how their information is used and how will their informed, voluntary consent be obtained? Who, under what circumstances, may act on behalf of the patient to grant or withhold consent?
- What legislation governs the capture, storage, dissemination and destruction of information? Are there different legal considerations in different relevant countries? What are the legal implications if the information management process fails to achieve the required or expected Quality of Service as might be described in terms of confidentiality, integrity (e.g. completeness and correctness), and availability (e.g. timeliness) of information?
- Will the service be offered locally, nationally or internationally? If so will the radiologists involved need to be qualified and insured to practice in another country? Will it be necessary for them to revalidate their qualifications or take new ones?
- If the service is to be provided online, how will contracts be created and entered into and how will payments be collected?

In conclusion, building trust in remote reporting is a complex and challenging task that should be carefully considered from several points of view in order to assure a self-sustainable remote reporting service.

PAPER III

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Cross-border teleradiology—Experience from two international teleradiology projects

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ABSTRACT

Teleradiology aims to even radiologists' workload, ensure on-call services, reduce waiting lists, consult other specialists and cut costs. Cross-border teleradiology widens this scope beyond the country borders. However, the new service should not reduce the quality of radiology. Quality and trust are key factors in establishment of teleradiology. Additionally there are organizational, technical, legal, security and linguistic issues influencing the service. Herein, we have used experiences from two partially European Union funded telemedicine projects to evaluate factors affecting cross-border teleradiology.

Clinical partners from Czech Republic, Denmark, Estonia, Finland, Lithuania and the Netherlands went through 649 radiology test cases in two different teleradiology projects to build trust and agree about the report structure. Technical set-up was established using secure Internet data transfer, streaming technology, integration of workflows and creating structured reporting tool to overcome language barriers.

The biggest barrier to overcome in cross-border teleradiology was the language issue. Establishment of the service was technically and semantically successful but limited to knee and hip X-ray examinations only because the structured reporting tool did not cover any other anatomical regions yet.

Special attention has to be paid to clinical quality and trust between partners in cross-border teleradiology. Our experience shows that it is achievable. Legal, security and financial aspects are not covered in this paper because today they differ country by country. There is however an European Union level harmonization process started to enable cross-border eHealth in general.

1. Introduction

Well-established standards in diagnostic imaging and high bandwidth connections inside and between the radiology departments have changed the way how the radiology service functions. Progress in information and communication technology has created tools for re-engineering traditional radiology workflow. Picture archiving and communication system (PACS), radiology information system (RIS) and electronic patient record (EPR) have enabled radiologists to use matrix workflow management, where patient data and images can be accessed at any time and any location if the radiologist is entitled to do so. Those achievements have potential to allow quick development of teleradiology services.

Teleradiology is the transmission of images and associated data between locations for the purpose of primary interpretation or consultation and/or clinical review [1]. Currently teleradiology is widely used as a complementary option in the present clinical radiology workflow. Remote reporting of images is well accepted in most of countries. Teleradiology is used in local or regional health care to rationalise on-call services, to improve the reporting capacity of health care organizations, to balance the workload across radiologists or domestic health care institutions, and to link remote imaging facilities with a central hospital. For image transmission secure point-to-point connections are used. Despite the benefits listed above and the fact that teleradiology has been practised in European Union (EU) in certain extent for more than two decades the real boost of cross-border service has not been achieved. Currently there are only few commercial companies in EU providing cross-border teleradiology service. The number of reported exams

Abbreviations: PACS, picture archiving and communication system; RIS, radiology information system; EPR, electronic patient record; VPN, virtual private network; SRT, structured multilingual reporting tool; DICOM, digital imaging and communications in medicine; SNOMED, systematized nomenclature of medicine; CT, computed tomography; MRI, magnetic resonance imaging; PET-CT, positron emission tomography-computed tomography.

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is around 100 000–200 000 per year compared to approximately 500 million exams performed annually in EU.

Historically teleradiology was used in 1980s as a second opinion service to give interpretation of images from remote locations [2]. In the last decade the primary reporting has replaced the second opinion. This has turned the focus from technical integration and service organization to clinical quality, legal and reimbursement issues. The same requirements apply to cross-border teleradiology. It is of utmost importance that use of cross-border teleradiology does not in any way reduce the quality of radiology services provided to the citizen. This means common agreement about licensing, accreditation and registration of telemedicine services and professionals, as well as agreement about liability, reimbursement and jurisdiction.

The main incentive of the health care provider to use cross-border reporting is to solve the shortage of reporting resources in the daily production. This trend is amplified by the expectation to get reporting with lower costs. Those incentives are not necessarily shared by radiologists. There is an uneven distribution of skilled radiologists in EU and in other countries. The number of radiologists currently working in the European countries is between 60 and 250 per one million inhabitants. In Japan the corresponding number is 36 [3]. In EU the relative surplus of radiologists is mainly in the new member states. The fact that radiologists' income in those countries is in certain extent lower makes outsourcing pressure even more inevitable.

The cross-border teleradiology service can be established between two institutions (point-to-point connection) or using a wider radiology network (many-to-many connection or a radiology eMarketplace). The former one is a classical connection where two health care institutions are securely connected to each other. There is no access to a third party. Many-to-many connection is achieved by using a central node or platform through which several health care providers can securely get connected.

The purpose of this study was to find out the possible challenges in building a cross-border teleradiology service like semantic interoperability, acceptance and quality assurance, and also to work out the good opening that could be gained from an eMarketplace approach.

We have used our experience on two partially EU funded telemedicine projects – Baltic eHealth and R-Bay – to evaluate factors affecting cross-border teleradiology. Legal, security and financial aspects are not covered because today they differ country by country. There is however an EU level harmonization process started to enable cross-border eHealth in general.

2. Materials and methods

2.1. Cross-border projects and the technical set-up

We studied 649 cross-border teleradiology cases in two different teleradiology projects—Baltic eHealth and R-Bay. This resulted in 4 different clinical set-ups. There was one second opinion service (The Netherlands–Czech Republic) and three primary reporting services (Denmark–Estonia; Denmark–Lithuania; Finland–Estonia). The size of the hospitals participated in the projects varied from 230 (Czech Republic) to 1100 (Lithuania) beds affiliating from 585 (Czech Republic) to 9500 (the Netherlands) employees.

The Baltic eHealth project was conducted from 2004 to 2007 under Interreg IIIB program [4]. During the project more than 200 hospitals from Denmark, Sweden, Norway, Estonia and Lithuania were connected into one dedicated secure IP-based network. Three hospitals from Denmark, Estonia and Lithuania used the network to establish the cross-border teleradiology service. X-ray images taken in Denmark were reported in Estonia and Lithuania. There were altogether 150 exams reported.

In Baltic eHealth we established the cross-border teleradiology service between Denmark and Estonia as well as between Denmark and Lithuania by using a point-to-point connection between the institutions. This is a classical connection where two health care institutions are securely connected to each other. A web based viewing and reporting platform was used. The selected examinations were sent from the local PACS to the intermediate teleradiology archive. Streaming technology was used for image viewing [5]. The request was copied from the local RIS to the teleradiology reporting platform and the final report was also transferred manually back to the local RIS. There was no technical integration between the local systems and teleradiology platform. No access to a third party was created.

The R-Bay project was a European eTEN market validation project [6]. The project had eleven partners from eight European countries. The clinical partners came from Czech Republic, Denmark, Estonia, Finland, Lithuania and the Netherlands. R-Bay is an online eMarketplace, a consultation portal, for buying and selling of imaging related telemedicine services.

In the R-Bay project 171 different radiology cases from Finland were reported in Estonia. Between Denmark and Estonia the corresponding number was 45 in this project. However, only knee X-ray images were reported. For second opinion 283 Czech radiology cases were randomly selected, anonymized and interpreted by the Dutch hospital.

In R-Bay we used a consultation portal (a radiology eMarketplace) to facilitate many-to-many connections between the teleradiology customers and providers. Many-to-many connections were achieved by using a central node through which several health care providers can securely get connected although with one integration only. The examinations were transferred from the local PACS to the intermediate teleradiology archive and reported using the viewing tool of the consultation portal. Streaming technology was used also in this project. Transfer of requests and final reports was similar to Baltic eHealth. The technical connection between the parties was established using secure VPN tunnels. Access to the patient data was permitted only for health care personnel who had been entitled by the health care institution.

2.2. Semantic interoperability

There were no institutions participating in the projects speaking the same language. For reporting three types of linguistic solutions were used. In primary reporting either the structured multilingual reporting tool (SRT) or the native language of the customer was used. All second opinions were written in English.

Structured multilingual reporting tool (SRT) created by radiologists participating in the Baltic eHealth project was used to deliver the report with a foreign language. The idea of SRT is to translate radiology exam findings automatically from one language to another. Today this tool supports four languages (Danish, English, Estonian and Lithuanian) and two anatomical regions (knee and hip). The radiologist uses a structured reporting template with his or her own language. In this template the possible findings are described. The radiologist creates the report using available templates and pulls down menus of multiple choices (Fig. 1). SRT uses semantic translation of findings rather than word for word translation. Selecting the sentence in one language generates automatically sentences in the three other. SRT contains more than 500 different sentences or phrases for one anatomic region. For uncovered findings there was an option to write free text which can be translated by an interpreter. SRT was used for translation of 195 knee X-ray reports from Estonian or Lithuanian language into Danish language. The rest of 454 reports were written in the cus-

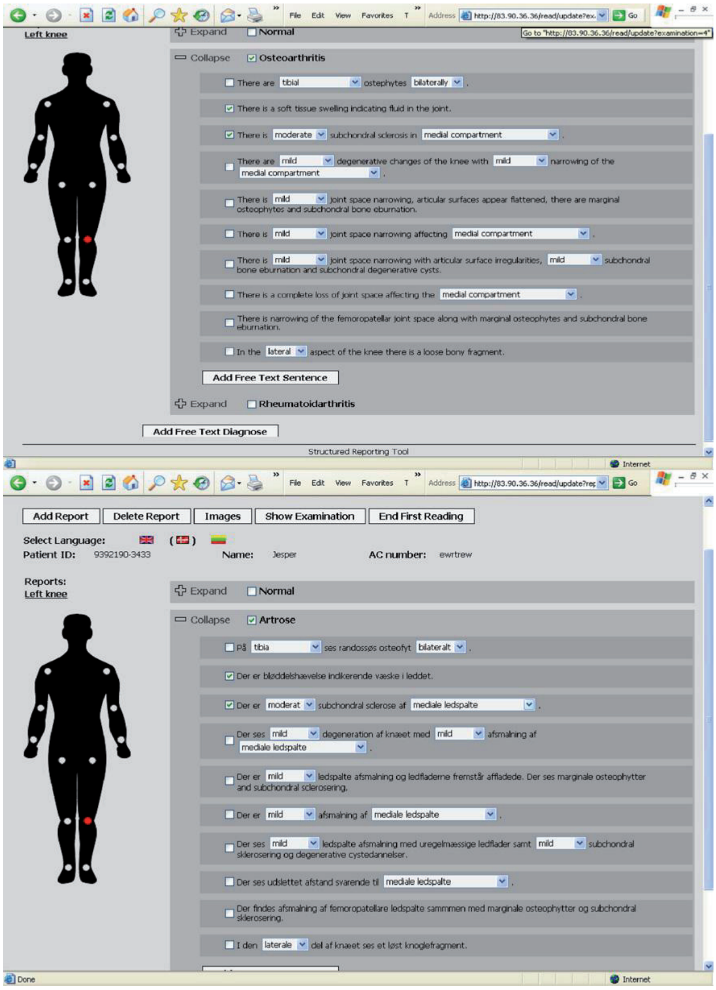

Fig. 1. Example of the structured multilingual reporting tool (SRT) of the knee X-ray in English (A) and Danish (B). The radiologist starts reporting by choosing the side of the imaged knee (marked red on the anatomic figure). The report consists of templates of commonly used findings which are semantically similar in both languages. Pull down menus are integrated into the templates to specify severity or the location of the finding. After marking the correct template(s) the program creates the final report. The report is available automatically in both languages.

tomers' native language or in English (second opinions). Referral letters were translated into English or radiologists' native language by interpreters.

2.3. Acceptance and quality assurance

Establishment of the cross-border teleradiology service started in both projects from the creation of a professional trustful relationship between the clinical partners. It included on-site visits and familiarization with the clinical radiology workflow in each hospital. Each partner appointed a certain radiologist to act as the responsible person for cross-border teleradiology communication.

In the clinical workshops different incentives to use cross-border teleradiology were discussed.

In the Baltic eHealth project knee X-ray images taken in Denmark were reported in Estonia or Lithuania. For quality assurance images were also read by a Danish radiologist. To establish a mutually acceptable structure for the report and to compare report quality a number of test cases were reviewed. In Baltic eHealth total of 39 knee X-ray exams were reported by three consultant radiologists from each country to find interobserver variability. For evaluation four grade feedback solution (grade 1 and grade 2—clinically insignificant discrepancy; grade 3 and grade 4—clinically significant discrepancy) was used.

In R-Bay the quality and content of all reports were discussed between the radiologists of the customer and provider hospitals and necessary adjustments were agreed when needed.

3. Results

3.1. Cross-border integration and the technical set-up

The number of cross-border teleradiology service reported cases was too low to evaluate the satisfaction of the clinical personnel. Also, the cross-border teleradiology service did not develop into a routine practice in any of the participating hospitals. Nevertheless, the overall feedback pointed that the use of cross-border teleradiology service should not change the daily clinical routines. The lack of the integration between the teleradiology platform and the local RIS and PACS resulted in manual transfer of requests and reports. This and anonymization of images resulted in higher personnel costs in customer hospitals. Integrations between the teleradiology reporting platform and local RIS or PACS were not done because of high integration prices.

The consultation portal was not used as a true eMarketplace in this study, but the potential advantages of many-to-many connections were discussed with the customer hospitals and several teleradiology providers.

We found the following potential advantages in the R-Bay approach over the traditional point-to-point connections of Baltic eHealth:

The added value for the customer side:

- opens up the whole market with more choices with one integration only,
- makes it possible to compare availabilities and response times for the reports,
- makes it possible to select sub-specialists from a wider pool,
- the eMarketplace is taking care of the certifications,
- makes it possible to compare prices and take the best price available,
- 24/7 cover through multiple providers,
- pay as you go—service particularly good for smaller volume end-users.

The added value for the provider side:

- opens up the whole customer market with one integration only,
- makes it possible to build other competitive advantages like sub-expertise, availability, correctness of the reports, etc.,
- makes it possible to compete with lower prices,
- one can show proven quality via the established quality assurance scheme (transparency of the results),
- back-up in case of illness, vacation, etc.

The added value for both sides:

- makes it easier to integrate the customer and provider systems,
- the eMarketplace is taking care of the security and privacy issues,
- the eMarketplace is taking care of the contracts, payments, etc.

3.2. Semantic interoperability and SRT

The biggest barrier to overcome in cross-border teleradiology was the language issue. Establishment of the service was technically and semantically successful but limited to knee and hip X-ray examinations in primary reporting (Baltic eHealth) because the SRT did not cover any other anatomical regions yet. It was found to be difficult and time consuming to cover a new anatomical region in SRT. However, in most EU countries it is demanded that the report to be included in the EPR must be in the native language. Also approximately 20% of the reports made by SRT were translated by the interpreter because of the lack of a particular descriptive sentence.

3.3. Acceptance and quality assurance

The incentive to accept cross-border teleradiology was different depending on the role of the hospital. The incentives were to improve reporting capacity, even workload peaks, to improve reporting times, to outsource routine exams, to use an opportunity for a second opinion, to exploit cross-border service as a hospital reference in attracting patients, and to increase radiologists' income.

Special attention has been paid to clinical quality and trust between partners in cross-border teleradiology. To date, our experience shows that it is achievable. In the Baltic eHealth project comparison of X-ray reports resulted in 31 cases with the same findings and conclusions (80%), 4 cases had insignificant differences in findings and conclusions (10%) and in 4 cases there were two different opinions (10%). The common understanding of the report structure and the description of pathologic findings was found. In R-Bay we found that it is necessary to have continuous mutual discussions concerning reported cases.

4. Discussion

One fundamental condition in the establishment and maintaining of the teleradiology service is achievement of trust between the customer and provider. Clinical acceptance is a prerequisite for cross-border teleradiology as well which has been shown in both evaluated projects. By our experience the customer wants to evaluate accreditation and sub-specialization of radiologists, the overall reporting capacity of the service provider, the structure and the language quality of the report, the quality of image viewing and reporting equipment (availability of PACS and RIS or a teleradiology reporting platform, resolution of monitors, etc.), availability of fast network, and to ascertain that the necessary security measures are in place. The provider of the reporting service has to get acquainted with the customers' current clinical radiology workflow (transfer of clinical data, multidisciplinary meetings, average report turnaround times, etc.), to examine the quality of images, to agree on the minimum number of projections, series or sequences and necessary uploaded images for diagnosis, to ensure the availability of relevant priors, and to estimate the potential volume of outsourced exams.

In both, Baltic eHealth and R-Bay we used very limited integration of EPR, RIS and PACS: in both projects there was only one integration between the teleradiology reporting platform and the intermediate teleradiology archive. Surprisingly we found that also other cross-border teleradiology implementations have similar low-level integrations. Widely exploited cross-border teleradiology solutions rely upon service providers' RIS-PACS. Images are uploaded from customers' PACS to the intermediate teleradiology archive. This central hub is easily accessed by reporting radiologists via web. However, requests are scanned and uploaded to the archive as an additional image or they are copied from the customers' RIS to the providers' one. This ends with no opportunity to acquire additional clinical information in most current teleradiology settings. Similarly only images of a particular exam are uploaded. Retrieving of relevant priors is not possible or it is time consuming. In Baltic eHealth and R-Bay we used streaming technology in two clinical settings (Denmark–Estonia; Denmark–Lithuania). This allowed retrieving of additional images directly from customers' PACS to the teleradiology platform. In streaming images are retrieved from customers' PACS to the teleradiology platform but not downloaded there. This gives quick access to any relevant image while maintaining security.

Implementing the eMarketplace concept opens the teleradiology market with one technical integration only. A eMarketplace offers a secure platform to buy and sell broad variety of goods and services in many areas outside health care. The R-Bay concept could be compared to the eBay platform. However, R-Bay should not be only the secure platform for consumption and provision of imaging services but it must serve customers and providers with the quality assurance, e-contract and e-billing solutions. On the customer side the new approach opens the market of teleradiology providers. Through the eMarketplace the customer can compare availabilities and response times for reports, select sub-specialists from a wider pool, and compare prices. A eMarketplace takes care of the certifications and adjusts the integration costs because of the single integration. On the other hand, providers can benefit from the access to the entire customers' market where novel competition possibilities led them to compete for better quality, service prices, and lower integration costs. This is achieved by using transparent quality assurance scheme or competitive advantages like sub-expertise, availability, correctness of the reports, etc. eMarketplace also takes care of security, privacy and financial (contracts, payments, etc.) issues which is beneficial for both sides. It is under continuous discussion today whether eMarketplaces will take over the traditional teleradiology and offer a controlled centralized way to practise teleradiology.

One specific issue in cross-border teleradiology is semantic interoperability. Transferring clinical data and reports across boundaries or regions rises up the question of the request and report language. By our knowledge cross-border teleradiology service providers are currently using almost exclusively radiologists who can report in the customers' native language.

The linguistic quality of the report is as important as the trust between clinical partners and quality of the radiology service. To date, the language and semantic content of reports are the integral parts of the whole radiology service and has hazard to interfere patients' diagnostic and treatment decisions [2]. We did not find any commercially available multilingual translation programs for cross-border radiology [7]. Lack of automatic translation tools is the main obstacle for development of cross-border teleradiology in other countries than United Kingdom or United States (US), or neighbouring countries with relative languages.

In both teleradiology projects the option to use DICOM Structured Reporting or SNOMED instead of SRT was studied. We did not find any other solution than SRT that could be used for translation of X-ray findings at clinically acceptable level. Our studies in the Baltic eHealth and R-Bay projects showed that SRT has been well accepted by radiologists as a reporting and translation tool. As the templates covered substantial part of the knee X-ray findings it was not too complicated to create sentences from the pull down menus. However, SRT was not meant to be used as a commercial product. To become a program accepted by radiologists for daily use there must be more than knee and hip X-ray templates, integration to RIS-PACS and more user friendly design. SRT-type of a multilingual translation program has potential to overcome linguistic barriers in cross-border teleradiology. However, further efforts must be put to improve language quality, software design and integration with the teleradiology workflow for SRT.

The initiative to outsource radiology reporting is usually not coming from the radiology department but from the hospital administration or government. This is carried by the understanding that prolonged imaging waiting lists are the main reasons why patients can not get in time access both to planned care and emergency care [1]. Besides of the intent to reduce waiting lists this trend is amplified by the expectation to get reporting with lower costs. However, radiology is a highly specific profession. To demonstrate competence radiologist has to complete medical school with residency and to be licensed by a competent professional authority. As a result the number of radiologists is relatively low world-wide [8]. The institution where radiology is practised has to be accredited as well. Accordingly radiologists are not usually willing to share their already settled daily routines. The incentives to outsource reporting should be understandable and achievable for the local radiologist and the radiology community. This particularly emphasises the importance of engagement of the radiology community in planning the cross-border teleradiology service.

Cross-border teleradiology can offer potential benefits for both radiologists and the radiology community.

Firstly, outsourcing of image reporting in a certain extent improves reporting capacity. By our experience the outsourcing of routine images like conventional X-ray or certain CT (head, abdomen, etc.) and MRI (spine, knee, etc.) exams is the most widely used practise in the middle sized and high volume departments. This gives local radiologists time to report more "interesting" cases or time for meetings with clinicians. Outsourcing emergency radiology done outside the working hours is another alternative to decrease radiologists' workload. This releases local radiologists from night shifts and they can concentrate on reporting in normal working hours. Similarly can be solved vacancies during the staff member annual leaves, study leaves or sickness. Outsourcing could also be a strategic decision like in Singapore where the government explained off shoring X-rays (i.e. 'simpler work') as a strategy to free public sector radiologists to transition more quickly to more advanced modes of investigation including CT and MRI [8]. The similar effect could be observed in some Eastern European countries, e.g. Estonia and Hungary where radiologists providing teleradiology service have access to high number of specific examinations (MRI of the knee or spine) while the number of exams done in their own department is not rising on the same levels because of the lower number of expensive diagnostic equipment. This helps developing more quickly highly specialized radiologists in the countries of relatively less developed economies.

Secondly, cross-border teleradiology could give an access to highly specialized reporting. This feature could be used as an additional benefit for the patient in case of rare pathology or specific finding.

Specialization in cross-border teleradiology leads to the third outcome. Radiologists' income is often related to the volume of reported exams or depends on the complexity of the study. Thoroughly planned outsourcing of certain images or services gives opportunity to increase either the volume of specific exams or complexity of them. Nighthawk service in the US is a good example: US board certified radiologists residing in different time zones offering night time emergency radiology reading [8]. The Nighthawk company can use normal working hour fees and the customer hospital avoids recruiting their own radiologists at the night time. The European Telemedicine Clinic is another example profiting from cross-border networking [9]. They use more than 70 accredited sub-specialist radiologists who focus on specific diagnostic areas including neuro, body, musculoskeletal, PET-CT, mammography screening and nuclear medicine. Majority of those radiologists are also working in the hospitals. We found the similar trend in the Baltic eHealth and R-Bay projects. In both cases radiologists were interested in reporting cross-border teleradiology only part time.

5. Conclusions

Cross-border teleradiology is a new type of service in the emerging international health care environment which can be used to make radiology more universally available, improve radiology service and consolidate international radiologists' community. We used experiences from two cross-border teleradiology projects conducted 2004–2009 to evaluate factors affecting cross-border teleradiology. We have found that cross-border teleradiology is currently a narrow service limited by the linguistic barriers, trust and legal issues. Regarding organizational issues and technical integration it is an extension of a teleradiology service practised inside the borders of the country. The supporting factor for higher acceptance of cross-border teleradiology is wider implementation of teleradiology inside the country.

The most important challenge is to ensure that teleradiology does not in any way reduce the quality of radiology services provided to the citizen. Cross-border teleradiology has considerable potential to become mature health care service. However, realization of this potential requires more research in areas of structured reporting, language and semantic interoperability. Also compatibility of different PACS, RIS and EPR systems should be improved.

Cross-border teleradiology is rather a service than technology and has to be taken as such. Implementation of it depends not only on the administration or governmental decision but should also include clear and understandable incentives approved by the international radiology community.

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PAPER IV

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REVIEW

Images crossing borders: image and workflow sharing on multiple levels

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Abstract Digitalisation of medical data makes it possible to share images and workflows between related parties. In addition to linear data flow where healthcare professionals or patients are the information carriers, a new type of matrix of many-to-many connections is emerging. Implementation of shared workflow brings challenges of interoperability and legal clarity. Sharing images or workflows can be implemented on different levels with different challenges: inside the organisation, between organisations, across country borders, or between healthcare institutions and citizens. Interoperability issues vary according to the level of sharing and are either technical or semantic, including language. Legal uncertainty increases when crossing national borders. Teleradiology is regulated by multiple European Union (EU) directives and legal documents, which makes interpretation of the legal system complex. To achieve wider use of eHealth and teleradiology several strategic documents were published recently by the EU. Despite EU activities, responsibility for organising, providing and funding healthcare systems remains with the Member States. Therefore, the implementation of new solutions requires strong co-operation between radiologists, societies of radiology, healthcare administrators, politicians and relevant EU authorities. The aim of this article is to describe different dimensions of image and workflow sharing and to analyse legal acts concerning teleradiology in the EU.

Keywords Teleradiology · Radiology information systems (RIS) · Workflow · Legislation as topic · Information dissemination

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Introduction

The sharing of medical images, relevant clinical data and reports between healthcare organisations or between healthcare organisations and the citizen is changing dramatically: in addition to linear point-to-point connections, the matrix type of many-to-many connections is emerging. The latter allows patient information to be shared across workspaces and communities, as well as medical experts to be accessed across state borders. This new type of communication, endorsed by eHealth tools, has been noticed by the European Union (EU) and national authorities to be an instrument to be used to shorten waiting lists, to optimise the use of resources and to enable productivity gains [1–3].

National electronic patient data exchange platforms are being built all over Europe to support data sharing across organisations in a trusted and secure way. There is also the European eHealth Project, called epSOS, to connect national platforms to each other in order to view patients' summaries and e-Prescription/e-Dispensing data across national boundaries. The epSOS project aims to demonstrate that it is feasible for any EU Member State providing eHealth services for its residents to also offer these services when they travel abroad [4].

Teleradiology has been used for remote consultations for approximately three decades [5, 6]. Despite the long

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tradition and the fact that it is currently the most advanced telemedicine service, the number of healthcare institutions using teleradiology has been limited in Europe. Only in recent years have the development of information technology (IT) and well-established standards in diagnostic imaging enabled the use of teleradiology to a larger extent. Image sharing leads to the next service level, which is imaging-related workflow sharing. However, there is still a considerable amount of hesitancy in implementing teleradiology in daily practice throughout the radiology and healthcare community. The main barriers to the implementation of teleradiology service crossing organisational or state borders are technical and semantic interoperability and legal issues.

Although the implementation of the new type of workflow is strongly supported by the EU authorities, the responsibility for making eHealth a success remains mainly with the Member States. To achieve the full potential of telemedicine the Member State has to be involved actively in integrating it into health services [1].

In November 2008 the European Commission published a communication on telemedicine for the benefit of patients, healthcare systems and society. The main aims of this communication were to establish legal clarity in eHealth and telemedicine, to solve interoperability and technical issues, to facilitate market development, and to build acceptance of telemedicine services [1].

The purpose of this article is to describe the different dimensions of image and workflow sharing that have been allowed by the recent development of an electronic healthcare environment. There is also a review of the legal acts concerning teleradiology in the EU.

Dimensions and evolution in image and workflow sharing

In linear workflow, the image information is carried either by the healthcare professional or the patient. The information is available only in one place at one time. This illustrates the situation in diagnostic imaging before the introduction of digital images—the image was taken in the radiology department and after that shared with only a few people during a long time span.

Today, medical images are available from any location in the world straight after acquisition for the patient and for healthcare professionals, if they have the relevant entitlement. This is enabled by secure communication provided by picture archiving and communication systems (PACS), digital archives and secure data exchange platforms. This allows image sharing inside the organisation, between the organisations in one region or across country borders, and also gives the patient the possibility to have instant access to the images. Consequently, image sharing leads to shared workflows between the different parties.

There are new emerging standards and profiles to support sharing of medical information. Integrating the Healthcare Enterprise (IHE) standards for document and image sharing are growing fast. The Cross-Enterprise Document Sharing (XDS) registers and shares electronic health-record documents between healthcare enterprises. Cross-Enterprise Document Sharing for Imaging (XDS-I) extends XDS to sharing images, diagnostic reports and related information across a group of care sites [7].

In the following, the different levels of image and workflow sharing are described.

Sharing images inside the healthcare organisation

Although the production of images remains mainly the responsibility of the radiology department, as in previous times, the digital images are available to the referring physicians all over the healthcare institution right after acquisition. This is decreasing the management time of stationary and ambulatory care patients. Quick image sharing places higher demands for image quality and the image management process but does not require any additional legal measures as long as images do not cross the organisational borders. However, administration of user rights and management of log files are new tasks for the organisation and need complementary resources. Sharing of images across the organisation is almost a must everywhere that PACS are installed. The radiology departments or groups use shared workflow inside the institution to re-engineer the imaging and reporting processes according to the imaging technique, anatomical or clinical subspecialty, emergency, or other agreed workflow feature.

Sharing images between healthcare organisations

Sharing images between the healthcare organisations creates new challenges regarding quality control, trust, workflow management, legal issues, reimbursement and interoperability of electronic patient records (EPR), radiology information systems (RIS) and PACS. The most important challenge is to ensure that reporting of images outside the organisation does not in any way reduce the quality of radiology services provided to the citizen [6]. The benefits of inter-organisational image sharing are: the availability of sub-specialist opinions and specialist case transfer in case there is a lack of particular local knowledge, provision of on-call emergency reporting and radiological services to remote rural communities, improvement of the reporting capacity of healthcare organisations, and balancing the workload across radiology departments [6, 8]. The technical issues in sending and receiving the images seem to be almost solved: well established digital imaging and communication standards and standard profiles like XDS-I allow image sharing between organisations [7].

Modern IT systems allow the building of a global shared worklist across different PACS and RIS, not only for the viewing and sharing of data but also for truely shared workflow. This opens new options for radiology providers. Sharing of the workflow can be achieved without replacing the existing local or regional investments but implementing standardised software and platforms for sharing. With the global worklist it is possible to avoid the manual management of who reads what and where [3, 9]. The study is locked from the global worklist when being read but unlocked and updated after reading is complete. Radiologists serving multiple healthcare facilities can accomplish remote reading and reporting across large geographical areas. This is an excellent way to balance workload locally or regionally between sites with different RIS or PACS [3].

Cross-enterprise document sharing can also provide reporting radiologists with access to other relevant clinical data than available in RIS. Sharing EPR case summaries could be a valuable asset in the case of complicated clinical situations. This is especially valid when the patient has a history of visiting multiple healthcare institutions.

A good example of countrywide usage of shared workflow is Ireland, where they are deploying a nation-wide system to enable any examination to be viewed and reported anywhere in the country regardless of the original place of imaging. Another good example is the project in northern Finland, where a collaboration platform can be used to carry out reporting between multiple hospitals [10]. Through the reporting platform there is a possibility to carry out reporting and consultations over the Internet using a virtual private network channel, to provide a forum for specialists in the region to view and report images, irrespective of their location. In the Western Health Region of Norway, an integration platform is used to integrate four RIS and five PACS within 15 hospitals and several private enterprises. The solution is based on sending and receiving request and report messages in HL7 or CEN/XML format. Through desktop integration with the local RIS and PACS, the integration platform offers secure, simple and fast inter-organisational access to images and relevant clinical information. The solution provides safe Web access to radiological requests, reports and images, combined with an option of retrieving this information into local systems when needed [11].

The reimbursement of teleradiology services in inter-organisational workflow sharing is an issue that often makes difficulties and is seldom solved automatically with the clinical set-up. Usually the financial software of the healthcare institution is not integrated with the clinical software, thus making the financial management of the imaging between the organisations difficult. Until recently, reimbursement has been agreed by bilateral contracts between two healthcare organisations. However, new models of brokering reimbursement schemes are evolving. There are examples of inter-organisational brokering services, so-called eMarketplaces, under development in the EU and North America. The partially EU-funded market validation project, R-Bay, concerning cross-border teleradiology was one of the first dealing with implementation of an eMarketplace [12].

The eMarketplace has a brokering function and gets paid according to transactions through the eMarketplace. It is a controlled way to practise teleradiology with transparent quality assurance, centralised certification databases and uniform data privacy and security policies. In this brokering service set-up, end-customers and teleradiology providers from different organisations can interact through a central connection platform. The concept follows the many-to-many connection principle. With such an integrated platform, the whole market opens up with one integration only and the stakeholders can compare prices, availabilities, response times, quality, sub-specialities, etc. Today the same concept is deployed in Denmark and England, where one of the eMarketplace research projects is now turning more commercial.

In North America, similar shared workflow implementations are in commercial use. Companies like Telerays or Virtual Radiologic in the United States (USA) and Real Time Radiology in Canada integrate hospitals, imaging centres and radiologists to work together [13–15]. A single integrated worklist, viewer and reporting system are provided. Telerays built their concept on an online auction and a reading room in which radiologists can download radiology cases and upload final interpretation reports for placement in the patient's medical record. Only radiologists pre-approved by the hospitals and imaging centres are allowed to bid on the contracts. Each radiologist must answer questions about their educational background and practice history as well as standard disclosure questions including previous licensure issues, sanctions, etc.

Transfer of image-related data outside the imaging facility requires additional identification, safety and security measures. Still, in most cases, at least in Europe, this is usually solved by bilateral contracts between the organisations addressing licensing, liability, and accreditation and registration of imaging services and professionals. Unfortunately the complex legal environment, the need for multiple contracts in the case of point-to-point connections and resource demanding integration of EPR, RIS and PACS has made an inter-organisational shared workflow a demanding task—even despite the availability of internationally agreed IHE standards like XDS or XDS-I. There is a clear need for new models of management of cross-site imaging workflow, including the eMarketplace.

Sharing images across country borders

The basic components that need to be addressed in an inter-organisational setting (quality and trust, interoperability, identification, security, legal issues) apply also to the cross-border settings. However, the legal issues are more complex because of the differences in healthcare and particularly telemedicine regulations among the Member States. Additional issues to be addressed are semantic interoperability and language.

The incentives of the healthcare provider to use a cross-border imaging service are to gain access to sub-specialists, to solve the shortage of radiologists or to lower the reporting costs. In addition to the need for the new models of management of imaging workflow described in the inter-organisational setting the international cross-border setting needs a reliable solution for translating reports, which is currently not commercially available in teleradiology [6].

In North America, shared workflow implementations across national borders are in commercial use. Nighthawk Radiology Services uses image reading centres in Australia and Switzerland to decrease night time reporting in emergency radiology, utilising the time difference [16]. Final reports are dictated by the local group the next morning, when previously obtained imaging studies and additional medical histories are available [17].

Sharing images with citizens

Digital medical images have been distributed to the patients in the linear way of sharing—images have been either printed on film or burned onto CD or DVD. This makes the citizen an information carrier and does not allow sharing of images using the matrix set-up. Only recently the advances in user identification, data privacy and security, and streaming technology have allowed the citizen to access personal image files in PACS. In this model the citizen is no longer the carrier of image information but can open images irrespective of the location or time. Sharing digital images via the Web with patients is a new feature in medical imaging management. Secure user identification by PACS, RIS or EPR is the key element. Access to the images opens up new options for the patient: sharing images with other clinical specialists and improving his or her knowledge of the treatment process.

In Estonia, there is a nationwide solution for the archiving and sharing of medical data called the Estonian Health Information System (EHIS). Radiology reports and image links are also stored in the EHIS. Authentication of the person accessing the EHIS is based on the ID card, which is a compulsory document for the purposes of personal identification, including electronic identification, in Estonia. Although the images are not yet accessed through the EHIS, some of the hospitals allow patients to access their images in PACS using ID card identification. Besides secure identification, a user-friendly viewing application is provided to the patient so that he or she can view the images from their own computer without requiring a wide bandwidth or advanced personal computer properties. The viewing solution for the patient uses adaptive streaming technology. Acceptance of this feature by citizens has been surprisingly high. In 2009 the average number of patient queries was 800 per month for the radiology department, making approximately 170,000 images annually.

A similar concept has been implemented in the Center for Diagnostic Imaging (CDI), USA. The patient provides the CDI with their email address, which triggers the ability to set up a password-protected account. Through that account, he or she can pre-register on-line to receive preparation and appointment instructions, to book the time for imaging procedures, to submit personal medical data and also view their diagnostic reports and images. CDI consists of more than 50 centres in ten States nationwide (Steve Fisher, Center For Diagnostic Imaging, St. Louis Park, Minn., USA, personal communication).

Legal aspects of telemedicine at the EU level

EU legislation regulating teleradiology and eHealth services consists of multiple directives and legal documents, which makes the interpretation of the legal system in the EU extremely complex. Besides EU directives, there are additional legislative documents like the *EU Communication on Telemedicine* [1] and the *White Paper in Teleradiology* issued by the European Society of Radiology (ESR) [18]; however, these have no legal power.

The definitive view of ESR regarding teleradiology is that a radiological act must always be defined as a medical act, even if it is performed remotely using information and communication technology tools [19]. Otherwise teleradiology could be practised by non-radiologists or even by non-physicians [20]. In some EU countries, teleradiology is not considered a medical act. In Germany, teleradiology faces legal restrictions. In the case of primary reading, special governmental permission is needed, which is valid for a maximum of 3 years. In general, permission should be restricted to night-time and weekends; only in special cases of insufficient local resources could teleradiology also be allowed in the daytime. At the location of the imaging a specially educated physician has to be present to approve the indication and to control the procedure. The teleradiologist must be a radiologist or in the case of X-ray examinations a specially trained and licensed physician (Prof. Dr. Thomas Hackländer, Solingen, Germany, personal communication) [21].

From the EU legislation point of view, telemedicine is both a health service and a social information service. Telemedicine falls under secondary EU legislation, in particular the *EU Directive on Electronic Commerce* [1, 22].

The European Court of Justice has stated that health services are considered to follow the fundamental principle of freedom of movement. This applies despite the subsidiarity principle of healthcare provision or the way in which it is organised or financed [1, 23]. This includes the freedom for citizens to seek and receive medical treatment from another Member State, regardless of how the service is delivered, i.e. also by telemedicine.

Regarding the harmonisation of technical interoperability the *EU Directive on Technical Standards and Regulations* establishes a procedure that imposes an obligation on Member States to notify the Commission and each other of all draft technical regulations concerning products and information society services, including telemedicine, before they are adopted by national laws [1, 24].

The directive on electronic commerce defines rules for the provision of telemedicine services both within and between Member States. For teleradiology services, the service offered by a professional must comply with the rules of the Member State of origin. This applies to teleradiology services between the healthcare providers, radiology groups and/or private radiologists and follows the country of origin principle.

Telemedicine is also recognised in the proposal for a *Directive on the Application of Patients' Rights in Cross-Border Healthcare* [1, 21, 25]. This directive is currently under review. The proposal addresses patients' cross-border mobility including their ability to access services across borders. If adopted, the directive would require the Commission and Member States accordingly to take measures to ensure the interoperability of means for the provision of eHealth services, including teleradiology. It is stated that when healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare is provided in accordance with the legislation of the Member State where treatment takes place. The above-mentioned healthcare is provided in accordance with standards and guidelines on quality defined by the Member State where treatment takes place [25]. Also, ESR demands that teleradiology should be the responsibility of the Member State where the patient undergoes the imaging procedure or telemedical referral [19].

EU Directives on the Processing of Personal Data and the Protection of Privacy in the Electronic Communication Sector [26, 27] specify a number of specific requirements relating to confidentiality and security that telemedicine and all other interactive on-line services have to meet in order to safeguard individuals' rights. These acts also provide requirements for providers of electronic communication services over public communication networks to ensure confidentiality of communications and security of their networks [1].

Cross-border teleradiology raises the question of the recognition of professionals between the Member States. ESR underlines that even if the recognition of professionals is legally regulated by the *Directive on the Mutual Recognition of Qualifications* it is important to establish standardised European training curricula and structures for all radiologists [19, 28]. The recognition of professional qualifications by the host Member State allows radiologists to practice radiology, including teleradiology, in that Member State under the same conditions as its nationals [1]. The directive establishes the criteria for a set of regulated professions according to which qualifications obtained in one Member State are recognised by another but does not indicate adequate monitoring and accreditation mechanisms. ESR supports the 2007 Portugal Agreement which deals with exchanging registers of medical professionals of Member States and sharing on-line information about disciplinary and criminal findings against health professionals [29].

The legal relations between the patient and healthcare provider are governed by national and EU legislation. Considering diagnostic services or treatment, the patient has almost always an insurance relationship with a local healthcare provider in the Member States. Consequently, issues of medical errors or other conflicts are elaborated according to the Member State's jurisdiction. This does not change when teleradiology is practised within the EU. In the case of a conflict the patient can sue the local healthcare provider, and if the local provider sees that the medical error is caused by a teleradiology provider, it can sue the teleradiology provider [20]. The responsibilities of both parties are usually fixed in the teleradiology service contract. If the teleradiology provider resides outside the EU, the above-mentioned principles do not apply unless contractually fixed.

Regarding the patient's informed consent for teleradiology, it is not regulated by the EU legislation. Some countries, like Finland, demand the patient's informed consent when patient data cross the organisational borders. The *Proposal of Cross-Border Healthcare Directive* states that patients should be fully informed about the various options regarding diagnosis and treatment in order to make a conscious choice between the various options [20].

More legal clarity is needed in the next few years in the area of teleradiology and eHealth. This will be obligatory to achieve the anticipated benefits of new data-sharing models in healthcare.

Discussion

The benefit of digitalisation in healthcare is the possibility to share medical data, including medical images, and workflows between healthcare providers or healthcare providers and patients irrespective of the place or time. Sharing of images or workflows can be done on different levels—inside the organisation, between organisations inside the country or across the country borders, and with citizens.

The EU is driving the change in the organisation and management of healthcare. Implementation of eHealth and telemedicine to enable change is gradually gaining support at the national, regional and local levels. The drivers for implementation of new services are:

– Increasing healthcare quality
– Increasing availability (easier and faster access to care)
– Decreasing the costs of healthcare services

The role of teleradiology in current radiology settings has been discussed thoroughly at international meetings and in scientific papers in recent years. The extent of how much teleradiology and remote reporting will be used in the future may vary by region or country but it is widely accepted that teleradiology will remain an option in the provision of radiology services [8, 17, 30].

The challenges that arise when images cross borders depend on the level of data sharing. Mostly they deal with interoperability, legal clarity, quality and trust. Depending on the level of sharing the interoperability issues are technical, organisational (including the seamless medical data exchange between different information systems), or semantic (including language). In inter-organisational teleradiology the workflow management and interoperability of EPR, RIS and PACS is an issue. Barriers without crossing state borders tend to be mainly technical. At the cross-country level the legal and language issues dominate.

However, to re-engineer the workflow in a manner that patients' medical data and also the care workflow are shared between the different organisations to achieve the best care for a patient is still a challenge. For instance, the eMarketplace type of many-to-many connections in teleradiology is emerging slowly. One of the reasons for this is the inability of IT systems to offer sufficient integration in many cases. Previous projects to implement eMarketplace-type applications have not been very successful with regard to technical interoperability [6]. The problem will be adequately solved only if all parties are using XDS and XDS-I standards. Unfortunately the problem remains unsolved until the older systems without XDS-I support are replaced. The situation is somehow similar to the time before the introduction of the DICOM standard. The other reason for the slow emergence of eMarketplaces seems to be the reluctance of decision makers at the regional or healthcare institution level to accept the change in the information sharing paradigm. The mind-set is changing more slowly than changes in technology.

The future solution to implementing teleradiology services at the inter-organisational and international levels could be the eMarketplace, however. It enables teleradiology to be practised in a controlled way, allowing transparent quality assurance and uniform data privacy and security policy. Through centralised quality assurance, for example, every tenth examination can be automatically double-read and any discrepancies discussed. The eMarketplace can be used to balance the workload between sites with different RIS/PACS, share one global worklist, use dynamic sharing rules (groups of sites, type of data), and generate business reports (who has reported and what). For the *customer*, it opens up the whole market, providing more choices (but with integrating into only one), allows 24/7 cover through multiple providers, makes it possible to compare prices, availabilities and response times for the reports and to select sub-specialists from a wider pool. For the *teleradiology provider*, it opens up the whole customer market. In addition, the eMarketplace makes it possible not only to compete by offering lower prices but also to build other competitive advantages like sub-expertise, availability, correctness of the reports, etc. It shows proven quality via the established quality assurance scheme (transparency of the results), makes it easier to integrate the customer and provider systems, and guarantees back-up in the case of a temporary shortage of personnel. The success in implementing many-to-many teleradiology applications also depends on the ability of the service provider not only to solve image reading but also to participate in the planning of procedures to find the best diagnostic approach, to discuss the reports in multidisciplinary meetings and to facilitate clinical communication. Therefore, the teleradiology service has to be implemented in co-operation with the customers.

Fortunately, the EU has taken concrete steps to support the implementation of eHealth and telemedicine, including teleradiology, nationally and across country borders. Interoperable teleradiology and eHealth settings have to follow internationally approved standards and profiles. The standard profiles to solve technical interoperability are XDS and XDS-I. Also, certain certification procedures are being agreed for medical IT systems.

For the wider use of eHealth, important strategic documents have been recently issued at the European level: the Commission Recommendation on Cross-Border Interoperability of Electronic Health Record System [31], the Commission Communication on Telemedicine for the Benefit of Patients, Healthcare System and Society [1], and the Ministerial Conference Final Declaration about European Co-operation on eHealth [32]. There is also the proposal of the Cross-Border Healthcare Directive, which includes relevant articles about teleradiology.

Those documents include strong recommendations for the implementation of telemedicine and eHealth. For instance, the Member States should have assessed and adapted national regulations to allow telemedicine to be used by the end of 2011. EU authorities underline the importance of the political and strategic commitment of Member States to using eHealth, building confidence and the acceptance of eHealth services, bringing legal and ethical clarity and ensuring protection of personal health data, and solving interoperability issues. It is beneficial for the implementation of new shared teleradiology services when the Commission continues to contribute to European collaboration between health professionals and patients for greater application of telemedicine and makes specific recommendations on how to improve confidence in and acceptance of telemedicine [1].

It is noted that legislation concerning eHealth and teleradiology services in the EU is very complex. The EU takes steps to harmonise national legislation in the area of eHealth. As stated in the treaties of the EU, healthcare follows the principle of subsidiarity [33]. It is the Member State's responsibility to decide on the organisation and delivery of their health services and medical care. Definition of medical acts is a matter for the Member States as well. As a general principle, the classification of specific telemedicine services as medical acts should ensure that these meet the same level of requirements as equivalent non-telemedicine services (e.g. teleradiology vs radiology). This principle ensures that adequately regulated health services are not replaced by less well-regulated telemedicine services and it avoids discrimination between providers of the same service, which would be incompatible with the *Directive on Electronic Commerce* [1, 20].

Concerning the legal regulations of teleradiology and eHealth, the national legislations differ between the Member States. There are various legal approaches regarding teleradiology and eHealth in general: remote archiving of medical data, patients' informed consent, patient claims, etc. Below, there are some examples of differences in legal regulations. Centralised remote archiving is illegal in the Czech Republic, but is an aim in the deployment of the national image archiving solution in France. There are various practicalities in the patients' informed consent to sharing medical data. In some Member States, the physical presence of the patient and the health professional is required, which is a clear obstacle to using teleradiology. In some countries, for example in Austria and Germany, this requirement restricts to practise teleradiology. Moreover, limitations in law or administrative practices often make reimbursement of telemedicine services difficult [1].

Regarding patients' rights, one can usually make a claim against the hospital or another local healthcare provider; in the Netherlands a claim can also be made against the teleradiology provider [20]. The situation is more complex if the teleradiology provider resides outside the EU. In this case the EU legislation does not apply and potential conflicts should be foreseen while making the contract. If the radiologist is reporting outside the EU but works for a company registered in the EU, EU legislation should apply. Yet, clarifications are needed and the market seems to be evolving more rapidly than the directives and laws.

The pace of the delivery of necessary standards and legal certainty must follow a relatively quick time scale because otherwise the rapid development of the eHealth service market would amplify the uncertainty with regard to legal issues and inefficacious interoperability.

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