Introducing Information and Communication Technology to Radiologists

Impact on Process and Outcome

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Preface

In the dawn of health informatics, I was among those who argued strongly that Information and Communication Technology (ICT) would improve health care (1-5). After having changed my career path to radiology, I was given the opportunity to investigate whether this improvement had actually come true. This dissertation is the result of my investigation. Even though the starting point was my own curiosity, I hope that at least some of our observations might be useful for others attempting to use ICT to improve Diagnostic Imaging.

Acknowledgements

This dissertation is the result of a long process and the support and encouragement of many people.

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I am grateful to Fredrik Dahl for providing the necessary methodology for the statistical challenges and for helping me to implement them, and to all those who provided the necessary data sets, images and reports for my study. I would also like to thank all my friends and colleagues at the Health Services Research Centre and at the Diagnostic Imaging Centre for interesting discussions.

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Summary

Background
Akershus University Hospital introduced Information and Communication Technology (ICT) to its radiology department in 2005. Both images and reports were stored and communicated electronically instead of as printed film and paper. The images and reports were also made available to clinicians directly from the Electronic Patient Record (EPR).

Objective
The objective of this study was to retrospectively assess whether the introduction of ICT improved diagnostic imaging and health care. The objective was addressed by investigating whether the introduction of ICT made radiology reports available sooner to clinicians, whether they read them sooner, whether this had an impact on the length of patient hospital stay, and whether any improvement in reporting was achieved without reducing the diagnostic accuracy.

Material and methods
The basic design of this study was a before-after study using two cross-sectional data collections. The establishment of hypotheses was in part assisted by a data splitting method.

Most analyses were based on data retrieved retrospectively from the hospital information systems; the Radiology Information System (RIS), The Picture Archiving and Communication System (PACS) and the EPR. These data were partly recorded by health care professionals as part of their daily work, and partly created by automatic logging of their activities. Person-identifiable attributes were removed for both patients and health care professionals before the statistical analysis. Supplementary data was collected manually from work lists and routine descriptions. Diagnostic accuracy was addressed by comparing a retrospective classification of lesions reported in the original reports with lesions identified in an independent re-analysis of the images.

The data were analysed using the two-sided non-parametric Mann-Whitney U-test for ordinal and the T-test for nominal data.

Results
The median report turnaround time (RTAT) – the time from the images were acquired until they were reported - was initially reduced by 84% for the preliminary version and by 44% for the final version of the reports. Over the observation period, the median RTAT increased slightly for preliminary reports, and was reversed almost back to the pre-ICT level for final reports. However, the percentage of preliminary reports available for the clinical afternoon round increased over the observation period. Radiologists used the flexibility of the system to give priority to preliminary ultrasound (US) and all Computed Tomography (CT) reports.
Both preliminary and final reports were immediately sent to the EPR. The median time until the final reports were opened by a clinician was 2.8 to 3.9 hours. The use of final reports did not vary much over the observation period. In total, 88% of the final reports had been opened 4 weeks after they became available in the EPR. For preliminary reports, the median time until they were opened was 40 to 50 minutes. Only 42% of them were read. Preliminary CT and US reports were opened sooner than CR reports.

There was no general reduction in length of patient hospital stay (LOS) after the ICT introduction. There was, however, a reduction in LOS for patients with one or more CT scans, from 5.3 to 3.9 days. This reduction was significant both in itself and relative to the non-CT group.

It has been feared that more lesions would be missed than when images were printed on film. Our study did not identify any such deterioration. On the contrary, when both certain and uncertain findings were included, the detection sensitivity was actually improved.

**Conclusion**

The introduction of ICT led to reports being available for and read by clinicians earlier than before, however not all effects proved sustainable. We also found that radiologists used the flexibility offered by the system to give priority to certain report categories. The study indicated that length of stay was reduced for patients that had CT scans during their stay. Diagnostic sensitivity of chest radiographs did not deteriorate. Our findings indicate that when ICT is introduced in the radiology department of a large hospital, a few improvements may follow. However, our findings also indicate that an ICT introduction may have an untapped potential, and that not all effects are necessarily sustained. We did not observe important adverse consequences of the ICT introduction.
List of papers


In the text, these papers are referred to by their Roman numerals.

Errata

Unfortunately, the black and white signs in the legend of Figure 1 in Paper I were exchanged. White columns represent final reports, black columns preliminary reports.

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CR</td>
<td>Computed Radiography</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record (used in the US)</td>
</tr>
<tr>
<td>EPR</td>
<td>Electronic Patient Record (used in Europe)</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>LOS</td>
<td>Length Of hospital Stay</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>PACS</td>
<td>Picture Archiving and Communication System</td>
</tr>
<tr>
<td>RIS</td>
<td>Radiology Information System</td>
</tr>
<tr>
<td>RTAT</td>
<td>Radiology report TurnAround Time</td>
</tr>
<tr>
<td>US</td>
<td>Ultrasound</td>
</tr>
</tbody>
</table>

An extensive list of collected data is presented in Table 1
1. Introduction

The purpose of this dissertation was to study the impact of introducing information and communication technology (ICT) to radiologists at Akershus University Hospital (AHUS) in 2005.

The idea of storing and communicating images in electronic format is more than 30 years old (23), and there are several commercially available systems. Different aspects of this technology’s impact on diagnostic imaging have been studied, with various results. Most studies are of economic aspects. Becker & Aronsen, e.g., reported that almost all studies focus on direct costs and ignore indirect costs and benefits (7). Some studies of the introduction of ICT in diagnostic imaging have indicated a return on investment (7-15); others have not been able to demonstrate profitable results (7;15-19). In a study covering 15 vendors and 275 sites, Ondo concluded that the most common benefit of PACS was the cost savings from film and storage (12). Only a few studies have focused on the impact of ICT on the quality of diagnostic imaging and health care (see section 1.4).

ICT is not a generic entity. Even though the basic functionality is similar in different systems, there are significant differences between them. They also evolve over time. Different systems and different versions of these systems may consequently have different impacts on the various aspects of diagnostic imaging. In addition, the impact not only depends on the systems that are introduced, but also on how the introduction is performed. Studies have suggested that organisational measures are as important as the technical system properties (20-22).

The introduction of ICT to radiologists at Akershus University Hospital in 2005 was based on the accumulated knowledge of how to realize benefits from ICT, and the systems were ‘state-of-the-art’ at that time. For this dissertation we chose to focus primarily on quality aspects, to study whether the ICT introduction had had an impact on the quality and efficiency of diagnostic imaging and patient care.

1.1 ICT in diagnostic imaging

We have used the term “ICT” as a collective term for all computer-based systems in Diagnostic Imaging. The following section briefly refers to some of its major components. This is not intended as a comprehensive presentation of the components, just as a guide to readers who may not be too familiar with the area.

Modalities and image acquisition

‘Modalities’ is a collective term for all equipment used to make diagnostic images. Most modalities rely heavily on advanced ICT, and all images referred in this study were in a digital format. The most frequently used modalities were:
CR – Computed Radiography, using Image Plates instead of film. In this study, the term also includes Digital Radiography (DR), using digital X-ray sensors.

CT - Computed Tomography, employing tomography (imaging by sections or sectioning) created by computer processing of signals from digital X-ray sensors.

US - Ultrasound or diagnostic sonography, an ultrasound based imaging technique.

MRI - Magnetic Resonance Imaging – an imaging technique based on nuclear magnetic resonance.

There are other categories of modalities, including radioscopy, mammography and nuclear medicine. These were not addressed specifically in this study.

Diagnostic images are often also referred to as radiographs.

**PACS**

A Picture Archiving and Communication System (PACS) is a combination of hardware and software intended to store, communicate and present medical images in digital format. The medical images originate from dedicated equipment (the modalities), are stored on disc or tape, communicated through a network, and presented on computer monitors (also referred to as soft-copy images).

The term PACS is at least 30 years old (23), and over the years has been used to describe various systems with various degree of complexity and sophistication, from simple systems storing and presenting images from one modality to complex inter-hospital systems. A standard for image representation and communication – DICOM (24), established by the American College of Radiology (ACR) and the American National Electrical Manufacturers Association (NEMA) during the 1980s – greatly facilitated the development and dissemination of the PACS systems.

Even though PACS is a generic term used to cover various systems with different properties such as storage capacity, communication speed, screen resolution and user interaction models, the scientific literature has a tendency to assess the impact of the different systems as though they were the same. Often, the system’s brand and version is not even mentioned. Of course, the literature attempts to address the more generic aspects of these systems. However, in some situations, it would be appropriate to question whether a specific observation was caused by a particularly brilliant or inadequate system, rather than by the more generic aspects of using technology to communicate medical images.

The PACS system in this study was the Siemens® Sienet v. 40 software package with MagicWiew® 1000W work stations, MagicStore® server, and MagicWeb® web application for clinicians. There was no major upgrade or change of the systems during the study period.
RIS
The term Radiology Information Systems (RIS) covers systems supporting administrative tasks such as scheduling, lab administration, reporting and accounting. In some cases, the RIS is an autonomous system. In others, it is a component in a more comprehensive Hospital Information System or Record System. Some of the RIS functionality may also be provided by the PACS systems, so that PACS could be installed as a stand-alone system.

The RIS systems are usually integrated with PACS. The integration level and method may vary. Typically, however, images can be opened in PACS simultaneously with patient data and a description of the examination in RIS. PACS may also duplicate information from RIS, for efficiency purposes. Usually, the terms RIS and PACS are used together without specifying how the different tasks are divided between them.

In this study, a dedicated RIS was used: Siemens® MagicSAS v. 42. No major upgrade or change was made to the RIS system during the study period.

EPR
An Electronic Patient Record (EPR), in American literature often referred to as an Electronic Medical Record (EMR), is a system that acts as an electronic repository of medical and administrative information related to patients. The actual content of an EPR may vary greatly, from a limited patient summary to a comprehensive medical record. For the purpose of this study, the EPR is a system that a clinician can use to retrieve and read radiology reports. In our case, the EPR could also be used to initiate the opening of images in MagicWeb®. Our EPR was DIPS EPJ®, a Norwegian solution.

Communication
Communication is used as a term to cover all hardware and software involved in transferring information between systems. This includes, of course, the network – a Gigabit network (10^9 bits per second) was used in this implementation. It does, however, also include specific software to transfer messages represented in a standard format. In this implementation, a message broker was used, and the messages were expressed according to the KITH XML standards (25). Images were communicated over the network between modalities and the PACS system using the DICOM standard (24), while communication between RIS and PACS used a proprietary protocol.

1.2 Diagnostic Imaging work flow
The introduction of ICT modified the radiologists’ work flow. To facilitate the reading of this dissertation, the basic elements of the diagnostic imaging work flow is outlined. The most important aspects are illustrated in Figure 1. The order of some of the major tasks may vary; the task sequence in Figure 1 represents a typical case. This description covers the work flow at Akershus University Hospital. It is, however, similar to the work flow in most hospitals.
Elements of the basic diagnostic imaging workflow of particular relevance for this study. The round corner boxes represent the most important tasks in the diagnostic imaging workflow, and a typical sequence. The thin arrows to the left and right represent communication of images and reports between tasks and systems in the pre- and post-ICT period. The squares to the left represent temporary and permanent archives for film and reports pre-ICT, while the cylinders to the right represent the corresponding archives post-ICT. Availability and use of information for the various tasks are not illustrated.

Patients, clinicians and referrals

The diagnostic imaging workflow is, in most cases, initiated by a contact between a patient and a clinician. In the following, the term ‘clinician’ is used for any medical doctor that has direct contact with and responsibility for a patient and that may refer a patient to diagnostic imaging. The patient is anyone who receives health care.

The contact can be an outpatient visit or a contact during a hospital stay (inpatient). The start of a hospital stay is referred to as the ‘admission;’ the end is referred to as ‘discharge.’ A hospital stay in Norway has to be at least 5 hours, a contact shorter than 5 hours would be classified as an outpatient visit. The length of a hospital stay (LOS) is the period between admission and discharge.

The underlying assumption of diagnostic imaging is that the result of an examination in some way may help the clinician to make a diagnosis or monitor the progress of a treatment, and that the result outweighs the strain to the patient. The clinician fills in a referral form that is communicated to the Department for diagnostic imaging. For rou-
tine cases during the observation period, the referral was either mailed or carried to the radiology department. In emergency cases, the appointment was often done by phone, and the referral accompanied the patient.

**Pre-examination tasks**

Prior to the examination, the referral is assessed, and if acceptable, an appointment is scheduled. The patient is escorted to a laboratory in accordance with the appointment.

In the pre-ICT period, the referral document was carried to the relevant laboratory prior to image acquisition. In the post-ICT period, the referrals were scanned and made available as scanned images from the RIS.

**Image acquisition**

Image acquisition, often referred to as the ‘examination,’ takes place at a laboratory where dedicated modalities are used to produce the diagnostic images.

All images in the observation period were acquired by some form of digital technology. Before the PACS introduction, these images were printed on film by dedicated film printers. After PACS, they were transferred to the PACS database. Just prior to the PACS introduction, images were transferred and stored in the PACS database while still being printed and read on film. This was a prerequisite for the assessment of diagnostic accuracy in Paper IV.

Once the image acquisition part is finalised, the images are made available to radiologists for diagnostic purposes. In the post-ICT period, as soon as the images were acquired (within five minutes), they were also available hospital-wide to clinicians with legal access to the EPR. The images were not physically stored in the EPR database, but were accessed from the patient’s record and displayed in a separate window (figure 1). Conceptually, the system behaved as if the images were a part of the record.

**Preliminary reading and reporting**

In radiology, studying an image is often referred to as “reading.”

In the pre-ICT period, the images and the paper referrals were carried to light boxes in the Radiology department. Images and reports from previous examinations were fetched from the film archive, and the old images were hung next to the new images on the light boxes. Radiologists read the referrals and images, reviewed previous examinations, and recorded their reports on tape. Secretaries assembled and transcribed the recordings, printed the reports, and placed them next to the light boxes. These reports were regarded as preliminary reports. Clinicians wanting to look at images or read preliminary reports had to walk to the department.

In the post-ICT period, work lists in RIS notified the radiologist about new images available for reading. The radiologist used RIS to retrieve scanned referral documents, images from the current and previous examinations in PACS and the reports from previous examinations in RIS. Images were displayed on two high-resolution comput-
er screens, and the referral, work list and previous reports on a third standard computer screen. During the study period, radiologists still recorded their reports on tape. The preliminary reports were available to clinicians in the EPR within five minutes after the secretaries had finished transcribing them in RIS. The preliminary reports were communicated between RIS and EPR as electronic messages.

In both periods, urgent findings were usually also communicated directly to the referring clinician by telephone. A clinician would thus not have to wait for the radiologist’s report if the radiologist believed that immediate clinical action would be required. Also, clinicians frequently called the radiologist on duty to get a preliminary opinion in important cases.

**Final reading and reporting**

In the pre-ICT period, a specialist in radiology would review the preliminary paper report and look at the images. If he was satisfied with the report content and typing, he would sign the report. If he was not satisfied, he would write corrections on the paper or dictate a new report, so that the secretary could make a new version for the final signature.

This routine fulfilled several purposes. One purpose was to check for any typing errors, another to improve diagnostic accuracy. Several studies have indicated that diagnostic accuracy is improved if images are read on two separate occasions, preferably by two different radiologists (26-28). It was also required that all reports were signed by specialists in radiology. Frequently, the preliminary reports were made by junior radiologists. When a paper report was signed, it would be mailed to the referring physician, while a copy would be stored in the imaging archive in an envelope together with the film.

In the post-ICT period, special work lists were made in RIS for examinations that needed be signed. A specialist in radiology would review the report and the corresponding images. The radiologist would type any corrections directly into the report and sign it electronically. Once a report was signed, an electronic copy would be transmitted to the EPR as a message (within five minutes), and replace the preliminary report. The version handling functionality of the EPR would also keep the preliminary report so that it could be made available if requested.

**Report Turnaround Time**

In this study, we have defined Report Turnaround Time (RTAT) as the time from the finalisation of the image acquisition until the finalisation of report typing. There would consequently be two report turnaround times for one examination, one for the preliminary and one for the final report.

**Clinical demonstration**

A ‘clinical demonstration’ or ‘radiology round’ is a meeting between radiologists and clinicians. During the meeting, the radiologists present images and interpretations.
This presentation may lead to a discussion about the case, the need for supplementary examinations, etc. Typically, the demonstrations take place in the morning.

In the pre-ICT period, the clinical demonstration was organised around the light boxes. Most demonstrations presented for a clinical unit all examinations that had been performed since the previous demonstration. Typically, a specialist in radiology would combine tasks related to clinical demonstration and final reporting, so that the preliminary reports were corrected in preparation for the demonstration, and were retyped and signed after the demonstration. For examinations performed during the night, the preliminary reporting would be done as part of the preparation, and the review and signature would be done just before the images were moved from the light boxes to the archive.

The concept of clinical demonstration was continued after the ICT introduction. However, only selected cases were presented, and the selection was made both by the clinicians and the radiologists. Both recent and older cases could be presented. Preliminary reports could be corrected and signed in relation to the clinical demonstration. As the demonstrations did not comprise all the examinations, separate work processes were made for the signature tasks.

**Clinical decision**

The result of imaging diagnostics, the images and the radiologist’s report, is not the only ground for clinical decision-making. However, the result may be an important part of this ground, and the availability of images and reports may influence both the quality of the decision-making and when the decision is made.

In major emergency cases, the clinician frequently calls the radiologist on duty or walks to the radiology department to receive the result, discuss the case or view the images. This was done both before and after the ICT introduction of the current study. The ICT did not include systems for direct communication between radiologists and clinicians, such as video conferencing or other forms of cooperation technology.

Most cases do not have this degree of urgency, and the clinician will look for the results of diagnostic imaging as part of the clinical routine. In the pre-ICT period, clinicians frequently visited the radiology department prior to their afternoon rounds to look at images and available preliminary paper reports. They also got the results as part of the clinical demonstration in the morning, before the morning round. In the post-ICT period, they could open the images and reports from the EPR. Selected cases were also presented during clinical demonstrations.

The EPR supplied a clinical work list function to make clinicians aware of new reports. Only signed radiology reports were listed. A report was included in one, and only one, work-list. The list was selected according to referring clinician, patient affiliation and other clinical criteria. A report was not removed automatically from the list if it was viewed by a clinician; it had to be explicitly checked out of the list.
1.3 Assessing quality in diagnostic imaging

Webster’s dictionary defines “quality” as “degree of excellence; superiority in kind” (29). This generic definition applies to quality in diagnostic imaging, of course, but a more specific definition would be preferable when assessing the impact of ICT on quality. Unfortunately, such a definition is difficult to find. The Scandinavian textbook of radiology discusses quality assurance and quality control, focusing on technical quality and radiation issues, but does not define the term (30). Other textbooks do not address the topic at all (31;32). The editorial introducing the “Quality initiative” of the RadioGraphics journal did not define quality (33), and even the paper titled “Defining Quality in Radiology” did not actually define the term (34).

However, even without a definition, diagnostic imaging has always focused on quality and safety. Traditionally, the focus has been on radiation doses and equipment control (35;36), and the quality of the radiographers’ work has been measured by reject rate (37-39). More recently, the literature has included errors performed by radiologists among the quality issues (40-42), also addressing inter-observer variations (43). Johnson et al described “four main areas of quality that need to be addressed for a complete quality and safety program in radiology; safety, process improvement, professional outcome assessment, and satisfaction” (44).

The publication of the American Institute of Medicine’s 1999 report To err is Human: Building a safer Health System (45) has increased the interest for quality and quality assessment in medicine, and the development of quality metrics for diagnostic imaging (34;46-49).

Swensen & Johnsen (50) used a care delivery map, based on the patients’ path from the physician to the radiology department, as a framework for assessing quality. Safety was regarded as the foundation for the care processes, outcome assessment as a measure of radiologist accuracy, and service as patient satisfaction. Even though published in an American journal, most of this framework is applicable also in Scandinavian health care.

The preparation of quality metrics rely to a large extent on ICT, so manual registration would not be feasible. However, the direct and indirect impact of ICT on these metrics may vary. For the purpose of this introduction, we have found it useful to distinguish between the following areas, all related to the quality of diagnostic imaging. This is not intended as an exhaustive list, but rather a framework for addressing the ICT related impact:

a) Test selection and preparation.

Are the most appropriate examinations selected? Appropriateness includes considering the clinical information and questions, the strain to the patient and the cost to society. Are the tests done in time?
b) **Image acquisition.**
Are the acquired images acceptable? Acceptability includes depiction of relevant abnormalities as well as limitations of stress to the patient. Consequently, it includes traditional safety measures.

c) **Reading and reporting**
Do the radiologists identify all relevant abnormalities? Are the radiologists’ interpretations and reports appropriate, based on existing medical knowledge and experience, and do they contain appropriate suggestions for follow-up examinations?

d) **Communication.**
Are the results of the examination available in time for the relevant clinical decisions, and communicated in a way the clinicians understand? Are the clinical questions answered?

e) **Service.**
Are the referring physician, the patient and the radiology staff satisfied with the service?

f) **Outcome.**
Did the results have a positive effect on the patients’ health or on the health care cost?

g) **Organisational and other aspects.**
Other aspects not covered by the above.

The impact ICT may have on these areas is in part a direct effect of the ICT, when manual routines are replaced or eliminated and communication occurs literally at the speed of light, rather than at walking speed. Other effects are caused by ICT’s power to enable the organization to work in a different way. ICT should not be regarded as a magic bullet that automatically generates all the desired effects (51). The positive outcome also relies on how the ICT is introduced, adopted and developed in the organization (52;53). Such issues are only addressed to a limited extent in this study.

### 1.4 The impact of ICT on quality aspects of diagnostic imaging
Several authors have, at different points in time, studied the impact of ICT on various aspects of diagnostic imaging. The following is a summary of some of the most significant studies, organised according to the framework described in the previous paragraph.

a) **Test selection and preparation**
ICT could, and perhaps should, be used to facilitate test selection, referral and conformance to appropriateness criteria (54-56). Studies have reported positive effects of order entry and decision support systems (57-59).

When information about previous and planned examinations is readily available, one might expect a reduction in duplication of examinations. However, in a Canadian ten-
hospital survey, You et al did not find a reduction in duplicate imaging examinations after the introduction of PACS (60).

One study concluded that the transition to filmless operation was associated with increases in inpatient and outpatient utilization of radiologic services (61). However, there was a 19% decrease in the number of imaging examinations per visit.

b) Image acquisition

Traditionally, the quality of image acquisition is measured by rejection rate – the rate of examinations that need to be repeated because their quality is regarded as too low for diagnostic purposes. After PACS, Siegel et al showed an 84% reduction in retakes, from 5% to 0.3% (9). Weatherburn et al did not find a significant reduction (62).

Radiation dose is another important and traditional metric. In a comprehensive and well-documented study, Weatherburn et al reported that the use of PACS was not significant in creating any differences in the dose for single images, as compared with film image capture (63). The introduction of PACS was, however, significant in the reduction of the examinations’ total dosage. The authors did not present an explanation for this observation.

Several studies have focused on radiographers’ efficiency. Reiner et al showed a 31% reduction in the time used to make a chest radiograph, and a 37% reduction for imaging the spine (64;65). However, in another study they reported an overall initial 10.8% drop in radiographers’ productivity, followed by a 27.8% increase in productivity beyond year one (66). Redferne et al found that a filmless system decreased the amount of time necessary to produce radiographs (67).

c) Reading and reporting

Time, accuracy and completeness are important quality aspects of the radiologists reading.

Time

Several authors have performed before/after studies of the time needed to perform radiology reading, with ambiguous results. Reiner et al indicated a 16.2% reduction in the overall time required for soft-copy interpretation of CT compared with that of film (68). Lindhardt also found faster reporting (20), while other authors reported that the overall viewing time was longer for images displayed on a monitor (69;70). Fleisher et al reported that PACS had no effect on the time taken to read a series of exams (71), while an American survey of 40 sites reported an overall retarded productivity, at least initially (72).

In some sites, speech recognition is used for the radiologists’ reporting. Speech recognition enables immediate access to the reports after the radiologists have completed their work (73). Some studies report that this technology reduced the radiologists’ productivity (70;74;75), others report enhanced productivity (72;76-78).
Diagnostic accuracy

Several prospective studies have compared diagnostic accuracy when reading images on film (hard copy) and on screen (soft copy).

Lindhardt concluded in a prospective study that, regarding quality of images for diagnostic purposes, CR imaging was never inferior to film systems, and was actually superior for several clinical entities. He stated that images can be read in 2K (a resolution of 2,000 horizontal pixels) without any loss of clinically important information (79). Eng et al observed in a prospective study a higher accuracy when reading images on film than on digital monitors (80). However, they concluded that a difference of equal or greater magnitude was associated with the training level and physician specialty of each observer. Other prospective studies have focused on cervical spine examinations (81), detection of chest lesions (82), neonatal examinations (83), paediatric emergency pictures (84) and emergency department radiographs (85), without identifying any difference between hard-copy and soft-copy interpretation of radiographs.

A prospective study of the accuracy of interpretation of CT scans showed that soft-copy interpretation using computer workstations produced statistically significant improvement in combined measurement of sensitivity, specificity, and overall accuracy for chest, brain, and chest-abdominal CT scans compared with film interpretation (86). Another prospective study of abdominal masses came to the same conclusion (87).

Hertzberg et al found no difference for sonography (88). It should be added that this study was based on a tradition where dedicated sonographers (radiographers with additional training) perform the studies, while radiologists read the images. In Europe, most sonography examinations are performed by radiologists.

One study showed a major increase in incidental findings, mostly due to an increased field of scope (89). In the authors’ opinion, the follow-up costs of these findings exceeded the benefits.

Unread images

Siegel et al concluded that one of the major benefits of the PACS introduction was the almost complete elimination of 'unread' imaging studies. The 8% unread imaging study rate pre-PACS dropped to approximately 0.3% (9). Hayt et al also reported a reduction in the percentage of unread images (70), while Evers et al reported a higher rate of unread studies the year after PACS was implemented (90).

d) Communication

A radiology report has less significance if it is not available to the clinicians in time for the relevant clinical decisions, such as treatment choice and monitoring.

The term Report Turnaround Time (RTAT) is often used to cover the time from either referral or image acquisition until the report is available. Reiner et al showed a decrease in overall report turnaround time from 26 hours to approximately 2 hours (61),
and Twair et al a reduction from 25h 19m to 3h 40m (91). Other studies have similar results (92-96).

Holman et al studied the medical impact of making preliminary reports available (97). He concluded that immediate electronic transfer of a preliminary radiology report results in a small but important number of adverse outcomes; however, if a final edited report follows within 24 hours and referring physicians are called whenever the preliminary report contains erroneous information, the benefits of rapid information transmission may outweigh the additional risks.

Reiner et al showed an 82% reduction in in-person consultation rate for general radiography, and a 44% reduction for cross-sectional imaging despite an increase in the volume of studies (98).

In a survey, 29% of the respondents answered that they did not need the traditional clinic-radiological conference after the introduction of PACS, while 52% wanted it to continue (99).

**e) Service**

In an English study, the radiology staff said that they preferred PACS to the previous, conventional radiology service (100). An American study, however, reported a low overall satisfaction rate with the soft-copy environment on the part of the radiology staff. Of the respondents in their survey, 98% indicated that an "ideal" soft-copy environment would have a positive effect on their efficiency (101).

Lindhardt concluded that CR and PACS in the radiological department have many advantages, but the benefits of the digital image distribution being linked to the other digital patient data was by far the most important aspect of digital imaging (79).

In an English study, Pilling et al reported that the majority of the hospital staff judged PACS to be a major advance for the hospital (102). Another English study came to the opposite conclusion; the proportion of respondents who were unsatisfied with the written reporting services for inpatients was statistically higher after the introduction of PACS (6). Bryan et al did not identify an improvement in the quality of radiology reporting service (103;104).

An Australian study reported that the introduction of the RIS/PACS was well received by senior clinicians, and was helpful in clinical decision-making. Patient management was improved and the time taken to arrive at clinical decisions was reduced, particularly in neurosurgery (105).

There was a strong (92%) preference for PACS vs. film (3 %, with 5% undecided) among the clinicians in the Baltimore VA Medical Center (9). According to their surveys, the average clinician estimated that he or she saves approximately 50-70 minutes per day. In Baltimore, the use of PACS was favoured over film by a majority of surgeons and their staff (106).
f) Outcome
Nitrosi et al reported a decreased Length of Stay (LOS) after PACS, with a 12% improvement for neurology patients (92). Watkins observed a 25% reduction in LOS for patients with a total knee replacement procedure, but no reduction for patients with a total hip replacement (107). He concluded that it was unlikely to be a true PACS effect. An Australian study did not find any reduction in LOS (105).

Redfern et al observed that a PACS workstation significantly decreased the delays in obtaining image information that often occurred alongside high unit occupancy and high aggregate severity of illness, and suggested that it may improve unit efficiency under conditions of high physician workload (108). Mattern et al reported that a filmless electronic imaging practice within their urgency care centre greatly improved radiology image and report delivery times, as well as improved clinical efficiency (109). However, Watkins reported that, although PACS significantly improved the speed of delivery of routine images to the ICU, the instigation of image-based clinical actions was determined by other organisational factors. There was no discernible difference between the film and PACS periods in terms of the time interval from the examination to the image-based clinical action (21).

ICT enables clinicians to read the pictures themselves. Weatherburn et al reported that when PACS was introduced to clinicians in an accident and emergency department, the number of false negatives was reduced, but the rate of serious misdiagnosis did not change (110).

g) Organisational and other aspects
Siegel et al concluded, in a paper summarizing eight years of experience, that the greatest benefit of the transition to a digital system had been the ability to use it as a tool to reengineer overall work flow, both in the image department and throughout the health care enterprise (9;111). The number of work steps was reduced from 59 to 10. Lindhardt also emphasised the organisational changes that PACS made possible (20).

Fridell et al reported, in a longitudinal study with a qualitative perspective, that the average radiologist’s professional role moved from that of offering individual professional expertise to becoming more of an actor in a network (22). The diagnostic practice changed, as reading x-ray films was seen as an art form before PACS, requiring years of training. Once everyone could view digital images, including 3-dimensional technology, it was easier for other clinicians to see and interpret the images and the skills become accessible to everyone. The change in technology use as a result of the shift to digital images led to increased radiologist specialization.

Some of the divergent observations reported in the introduction to this dissertation could perhaps be explained by differences in technology, others by the different approaches to the introduction, adoption and development in the organization (52;53).

Pare and Trudel demonstrated the importance of treating a PACS deployment not simply as a rollout of new technology but also as a project that would transform the
organization (112). They stressed the importance of anticipating and addressing organizational and behavioural challenges from the very first phase of the process, in order to ensure that all participants would be committed to the project. They concluded that in order to maximize the likelihood of PACS success, it appeared crucial to adopt a proactive implementation strategy, one that took into consideration all the technical, economic, organizational, and human factors, and did so from the first phase of the process.

Law and Zhou (113) reported that most training put the emphasis on the use of display workstations. They concluded that with the great potentials for further development, a more comprehensive education program on PACS is called for.

It should be added that ICT may be important to produce the metrics used to assess quality. Assuming that the production and study of these metrics have a positive impact on quality, or at least function as a safeguard against quality reduction, ICT may also have an indirect impact on the quality of diagnostic imaging (34;46;47;50). Similarly, ICT may facilitate peer review, another area that might have an impact on diagnostic accuracy (114;115).

1.5 Unanswered questions

The results reported in the literature are divergent, and in some cases contradictory. In many areas, it is not possible to draw an unambiguous conclusion regarding the impact of ICT. It should, however, be remembered that the impact may depend on a multitude of factors, including the type of ICT introduced, the way this introduction is performed, the skill of all persons involved, training, etc. It should also be remembered that organisations evolve over time, and that the status observed at one point in time is not necessarily identical to the status before or after. In addition, most of the studies are of organisations that would be classified as innovators and early adaptors, not the late majority (116).

The purpose of this study was partly to document a case of introducing ICT, partly to address questions not yet covered in the literature, such as:

- Will the impact be different in an organisation belonging to the late majority than in the organisations typically covered by the literature? (Paper I)
- Is the impact stable over time, or does it evolve in a positive or negative direction? (Paper I)
- Does improved availability of radiology reports lead to improved clinical use of these reports? (Paper II)
- When do actually clinicians read radiology reports, do they read them all, and what influences their reading? (Paper II)
- Do the patients benefit from any improvements in the reporting routine, and is this reflected in the patients’ length of stay? (Paper III)
- Even though the technology has the potential to maintain diagnostic accuracy, is it really maintained in a real life situation? (Paper IV)
2. Objective

The objective of this study was to retrospectively assess whether the introduction of ICT in support of diagnostic imaging at Akershus University Hospital in 2005 improved the quality of diagnostic imaging and health care.

The study focused on the radiologists’ reading and reporting, clinical use of the radiology reports and the impact of this use. *Paper I* assessed whether over time the ICT introduction reduced the time from when images were acquired until the images and the radiologists’ reports were available to clinicians. *Paper II* assessed whether the clinicians over time read the reports sooner. *Paper III* focused on whether improvements in report availability had an impact on the patients’ length of stay. Finally, *Paper IV* addressed whether any improvement was achieved without reducing the diagnostic accuracy.

3. Material and methods

Approval for the conduct of this study was obtained from the Norwegian Social Science Data Service (NSD) and the Regional Ethics Committee, and it was exempted from review by the Duke University Medical Centre Institutional Review Board. The latter was necessary due to the involvement of co-supervisor Truls Østbye in the study.

3.1 Setting

This study was made from the radiologists’ perspective – ICT enabled changes in the radiologists’ diagnostic work and the clinical use of their reports. Consequently, the core event was the introduction of RIS and PACS to radiologists in May/June 2005, and the integration of these systems with the EPR to make the result of diagnostic imaging available to clinicians.

The Radiology department actually introduced its first RIS in 1999, in form of a radiology module in the Hospital Information System (InfoMedix ®). This was replaced by a dedicated RIS in May 2004 (Siemens MagicSAS ®). The RIS systems were used for appointment scheduling, lab organisation, report typing and printing, etc. They did, however, not influence the radiologists’ work flow until PACS was introduced one year later.

The EPR system (DIPS ® EPJ) was also introduced in 2004. However, the system did not contain all medical information at that stage. Parts, including the radiology reports, were stored in paper folders. After the PACS introduction, radiology reports were sent to the EPR.
<table>
<thead>
<tr>
<th>Data Item</th>
<th>Description</th>
<th>Retrieved from</th>
<th>Used in paper</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>RIS</td>
<td>PACS</td>
</tr>
<tr>
<td>Person ID</td>
<td>National Unique Patient ID (used to merge data sets, then erased)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Admission time</td>
<td>Time stamp identifying admission</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Clinical unit</td>
<td>The ward / department / clinic responsible for the patient</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Discharge time</td>
<td>Time stamp identifying discharge</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Discharge diagnosis</td>
<td>Primary ICD-X diagnosis associated with the hospital stay</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Referral ID</td>
<td>Unique ID identifying the referral (used to merge data sets)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Image acquisition time</td>
<td>Time stamp from the completion of image acquisition</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Modality</td>
<td>Equipment used to acquire the images</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Accession number</td>
<td>Unique ID identifying image acquisition (used to merge data sets)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Examination title</td>
<td>Pre-defined text describing the examination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preliminary report log</td>
<td>Log time of when the preliminary report was finalised</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Preliminary report author</td>
<td>Radiologist making the preliminary report.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final report log</td>
<td>Log time of when the final report was finalised. Identical to signature time</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Final report text</td>
<td>Wording of the final report</td>
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<td></td>
</tr>
<tr>
<td>EPR entry</td>
<td>Log time when a report was entered into the EPR</td>
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<td>x</td>
</tr>
<tr>
<td>EPR access</td>
<td>Log time for when a report was first accessed</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>EPR work list log</td>
<td>Log time when a report was checked out of the work list</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Image</td>
<td>Image in digital format</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RTAT</td>
<td>Report Turnaround time, for preliminary and final reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOS</td>
<td>Length of stay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathological finding</td>
<td>A visible lesion in an image, a described lesion in a report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual demonstration</td>
<td>Time of traditional clinical demonstration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paper report availability</td>
<td>Time the paper report was available at the ward</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1.
Data elements used in this study, including definition, source and where they are referred.
Normalt

Patologi (spesifiseres under)

<table>
<thead>
<tr>
<th>Patologi i:</th>
<th>Uspes/ generelt</th>
<th>Høyre lungeregion</th>
<th>Venstre lungeregion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor / nodulus</td>
<td></td>
<td>Øvre Midtre/ Hilus</td>
<td>Nedre</td>
</tr>
<tr>
<td>Infiltrat / konsol-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dering / fortetning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atelektase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumothorax</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stuvning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KOLS/emfysem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Væske</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoraxvegg patologi</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(pleuvra, costae, etc)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annen patologi</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2
Form used to classify images and reports in Paper IV (in Norwegian).

3.2 Design and data sets
The basic design of this study was a before-after study using cross-sectional data collections. The study was performed retrospectively, partly to avoid the Hawthorne effect (117), partly because we wanted to assess the real impact of the ICT in this setting, based on previous reports of its potential. The establishment of hypotheses was in part assisted by a data-splitting method.

The study was mostly based on examination and patient-related data retrospectively extracted from the various data systems, but some were collected manually through observation or classification, and some were estimated based on the daily routine. Information about radiologists working at the department was manually collected from paper work plans.

The data items used are listed in Table 1.

A separate classification form, illustrated in Table 2, was used to classify images and reports in Paper IV. The data was punched into Excel twice, to reduce data errors attributable to punching.

3.3 Selection of study periods
In Paper I and II, our focus was not only the impact of the intervention itself, but how the impact evolved over time. Consequently, we collected data from several periods, starting four months before the intervention, and then every four months during the
next two years. A major system upgrade prevented us from monitoring the change over a longer time period.

Paper III focused on the possible effects of the reduced radiology report turnaround time (RTAT) on the length of the patients’ hospital stay (LOS). We consequently selected time periods where the RTAT was actually reduced, based on the results in Paper I.

In Paper IV, the pre-ICT period was established by the preliminary database storage of images, prior to the ICT introduction. In this period, images were printed and read on film, but also stored digitally in the database. This enabled us to make a double blind assessment of diagnostic accuracy. We chose the corresponding period two years later for the post-ICT period, the latest possible option before the system upgrade.

3.4 Data splitting

The concept of statistical significance is important for applied science (118). The statement “X is correlated with Y at significance level alpha” signifies “If no true correlation between X and Y exists, the probability of obtaining the observed correlation is less than alpha.” Standard practice has been to set alpha at 0.05, which literally allows for a 5% chance of erroneously reporting a significant finding (Type I error).

In this dissertation, several hypotheses were established and tested against the collected data. In some of the cases, our hypotheses were established prior to data collections. In others, we had no definite opinion about what the impact of the ICT introduction might be.

It might be tempting to address a data set with a large number of hypotheses, in search for anything of interest buried in it, and selectively report only those identified as “significant” by the statistical software package. However, when multiple hypotheses are tested, the general rule of thumb is to divide alpha by the number of hypotheses, referred to as a Bonferroni correction. The conduct described above would be labelled hypothesis fishing or data dredging, and would render the P-values almost completely meaningless.

In this study, we used a data-splitting procedure to counteract this effect, as proposed by Dal et al (118). The data set is randomly split in two parts. This allows the investigator to identify the hypotheses in the first part, while remaining blind to the second part until the hypotheses are specified. True hypothesis testing is then performed using only the second part of the data set. Once a hypothesis is supported, the entire data set can be used for estimating the effect size. The purpose of this approach is to ensure the proper use of the term statistical significance. Once a significant finding is established, it is regarded as preferable to obtain the most accurate parameter estimates possible.
4. Summary of the results

4.1 Impact on radiologists’ reporting – Paper I
For preliminary reports, the median report turnaround time (RTAT) was initially reduced by 84%, from 12.3 h to 1.9 h. Over the observation period, the median RTAT increased to 3.2 h. There was an initial 44% reduction in median RTAT for final reports, from 22.8 h to 12.8 h. However, over the observation period, the median RTAT increased to 21.7 h, nearly the same as before the intervention. All these changes were statistically significant. The result was analysed per modality, and emergency cases were analysed separately. This analysis showed that radiologists gave priority to all CT reports and preliminary US reports. The percentage of preliminary reports available for the clinical afternoon round increased over the observation period.

4.2 Impact on clinical use of the reports – Paper II
In total, only 42% of the preliminary reports were opened four weeks after they were entered in the EPR. The number increased over the observation period. The median time from when a preliminary report was available until it was opened was 40 to 50 minutes. In total, 88% of the final reports had been opened 4 weeks after they became available in the EPR. Reports from routine inpatient cases had the highest score (92%), followed by inpatient emergency cases (89%) and outpatient cases (86%). The difference between these groups was significant. The use of final reports did not vary much over the observation period. The median time until they were opened was 2.8 to 3.9 hours. Emergency case reports were not opened earlier than routine in-patient cases. Preliminary CT and US reports were opened sooner than CR reports. There was no difference for final reports. Orthopaedic surgeons read the final reports significantly later than other medical specialists. Compared to an estimate of when reports were available to clinicians in the pre-ICT period, there was no major reduction in time from image acquisition until the time that the content of the reports was available to clinicians.

4.3 Impact on Length of Stay – Paper III
We did not find a general significant reduction in LOS after the ICT introduction. We did, however, find a significant reduction in LOS for patients with CT scans. The median in-patient stay for this group was reduced from 5.3 days to 3.9 days, and was significant both in itself and relative to the non-CT group. The CT patient group was heterogeneous. 1,275 different discharge diagnoses were used for the 8,892 included cases. To reduce the impact of heterogeneity and possible routine change, the analysis was also performed on a reduced data set, including only patients with diagnoses used in both the CT and non-CT group before and after the ICT introduction. The LOS reduction was also significant in this subset.
4.4 Impact on diagnostic accuracy – *Paper IV*

This study did not indicate a reduction in diagnostic accuracy. On the contrary, the sensitivity was increased. When both certain and uncertain findings were included, the sensitivity increased from 0.51 to 0.74 (p=0.046). The increase when only certain findings were included and when uncertain findings were excluded from the gold standard was not significant. A review of the false negative cases did not reveal any bias from specific diagnostic groups.
5. General discussion

This study identified some areas where the quality of Diagnostic Imaging was improved after the introduction of ICT – although not all effects proved sustainable – and we found no important adverse consequences. Each observation is described and discussed in the corresponding paper, and not repeated here. In this chapter, I choose to focus only on some points related to methodology and study design, and some general observations arising from the combination of the papers.

5.1 Methodology and study design

In her textbook “Research Methods in Health,” Ann Bowling writes that (119):

“The evaluation of health services is usually based on the collection of data about the structure, inputs, process, outputs and outcomes of the service ... Structure refers to the organisational framework for the activities, process refers to the activities themselves, and outcome refers to the impact (effectiveness) of the activities of interest (e.g. health services and interventions) in relation to individuals (e.g. patients) and communities. Health outcome relates to the impact of the service on the patient.”

The structural change in this study was the introduction of ICT to support diagnostic imaging and the communication of results, and the organisational change that was enabled by and made as part of this introduction. However, the objective of this study was to assess the impact on process and outcome induced by this change, with a special focus on quality aspects. We chose radiology reporting as a model, as this provided an opportunity to address both the impact on the radiologists’ imaging interpretation, the clinical use of the results of diagnostic imaging, and patient outcome.

Structural change

We did not analyse the relative contribution of different components of the structural change on the reported results. Most papers made on this subject simply refer to them as the impact of PACS (21;22;70;98;103;120). While the quality and properties of the PACS and the other ICT components obviously are important for the result, other authors have stressed the importance of other aspects, such as user involvement, workflow redesign, organisational change as well as sufficient training (98;112;113; 121-123). The ICT in this project was regarded as ‘state-of-the-art’ at the time of introduction, and the project management was well aware of, and tried to draw upon, the accumulated knowledge. This included an extensive evaluation period before the selection of ICT, active involvement of key personnel from an early stage, a wide organisational consensus process on the workflow re-design, extensive training, etc. The measures were consequently based on the current recommendations, and the study focus was the impact of the sum of all these measures.

Even though the sum of the structural changes, rather than each component, was the focus of this study, the papers briefly referred to some individual aspects. In paper I, the discontinuation of the involvement of key personnel was one of the factors that
were referred to as possible explanations for the deterioration of some of the positive
effects of ICT’s introduction. In paper II, an insufficiency in the automatic work list
function in the EPR was responsible for some of the missed reports. In paper IV, the
presence of tools for imaging manipulation was described as contributing to the diag-
nostic accuracy.

**Alternative and supplementary approaches**

Alternative approaches could be chosen for studying the impact of the ICT introd-
uction on the process and outcome of diagnostic imaging.

Observational studies could provide a supplementary perspective on how the radiolo-
gists used the technology to improve their work, and on the flexibility to give some
reports priority over others. Fridell et al reported, in a longitudinal qualitative study
that the radiologists’ professional role moved from that of offering individual profes-
sional expertise to becoming actors in a network (22). It is, however, recommended
that the investigator should observe unfamiliar social settings and interactions, as he
or she is then less likely to ignore or take activities for granted (119). The author of
this dissertation was highly familiar with the setting, and was directly involved in the
introduction of ICT as one of the ‘key personnel.’

Clinicians’ use of radiology reports could be addressed in observational studies. This
could provide important supplementary information as to when and how they acquired
the results of diagnostic imaging, and perhaps demonstrate other reasons for missing a
report besides mere technological insufficiencies. It could perhaps also throw light on
reasons why the new technology did not seem to cause a reorganisation of their rou-
tines. This might be a topic for further studies.

Surveys could indicate both radiologists’ and clinicians’ levels of satisfaction. We did
not choose this approach, mostly because several authors have performed similar stud-
ies (6;11;99;101;102;112;124-129).

Clinical outcome could be measured in many ways. We chose the length of hospital
stay, as this is a fairly easy parameter to retrieve and compare, and could be used to
include all relevant patient groups and all types of diagnostic imaging. The use of this
parameter as an indicator of clinical outcome has been discussed by previous authors
(103;105;107). We performed sub-group analyses based on discharge diagnosis and
modality. We did, however, not identify specific diagnostic or treatment categories
where improved availability of radiology reports would have any clinical importance
greater than usual. Quantitative methods could perhaps suggest such areas, and be
used in a mixed-method approach to study this in more detail. This is perhaps also a
subject for future studies.

In paper IV we studied diagnostic accuracy in chest radiograph interpretation. Several
authors have previously studied accuracy in controlled environments (79;81;85;130).
The advantages of these studies are several. The same images can be studied both on
screen and on film, thus eliminating any bias from the differences in lesions. It is pos-

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sible to make a selection of cases, e.g. to identify problem areas. Pneumothorax has been suggested as a problem area for digital monitors. It is also possible to involve the same persons, to reduce the impact of inter-observer variation (122;131;132). Such studies, however, only indicate the potential of the technology. The participating radiologists know that their work is monitored, and they typically work uninterrupted in ideal environments with sufficient time and sufficient tools, very different from the daily clinical reality. We know that individual factors, such as the availability and condition of the reading room, is important (129).

The approach we chose in paper IV intended to document the impact of ICT in a real life clinical setting. To achieve this, different radiologists were involved, different cases were used, and we limited the study to address the identification of lesions. The latter choice was made partly to be able to provide a manageable classification system to the participating radiologist (Table 2), and partly because we had no indication that the introduction of ICT would influence the radiologists’ classification of lesions, only their identification. The number of images selected was a result of a power calculation, limited by the period where images were stored digitally while still being interpreted on film prints as part of the daily routine. Unfortunately, the data washing showed that some of the cases had to be excluded. The remaining data was, however, sufficient to perform the desired calculation and conclude with reasonable certainty.

As a consequence of the ICT introduction, the CT protocols were modified fairly soon. This prevented us from performing a similar study on CT examinations – the examinations were visibly different, so we would not be able to make a blinded study.

Reducing bias in data collection

Most data were retrieved retrospectively from the various ICT systems. This approach was advantageous in several aspects. Neither the radiologists nor the clinicians recording and using the data as part of their daily routine were aware of this study. We would thus avoid the Hawthorne effect (117), the phenomena that awareness of being observed influences how a person works. Most data were extractions of data used in patient care, and the logging of such use. The data thus represented ‘real life’ cases, and we were able to extract samples from different points in time after the structural change. We used large samples in the three first studies. This reduced the chance of a type I error, and allowed for sub-group analyses in some cases. It should be added that we retrieved data from comparable periods of the year, to avoid any bias introduced by differences in patient population, environmental factors, etc.

There are special challenges related to retrieving data from information systems that are not developed for or adapted to research purposes, but only focus on the support of health-care related activities. A typical data system has a set of ‘screens’ and ‘dialog boxes’ to be used to enter or retrieve data in a clinical setting. Of course, these systems are thoroughly tested to ensure that complete and correct data sets are entered and retrieved in the correct settings. This is usually documented in various user and system manuals. Unfortunately, the process behind the screen is not always equally
clear, in particular after several updates, upgrades and local adaptation. When data for research purposes is extracted directly from the database, what the data actually represents is not always well-documented. E.g., in the current systems, a database column intended to store information about articles of consumption during an examination was instead used to mark whether an examination should be included in a clinical demonstration.

We have used multiple strategies to ensure that the data used in this study actually represent what they are intended to represent. We read all available documentation, including the database table names. We drew upon the knowledge of people working full time with running and maintaining the systems, both at the hospital and at the software vendor. We have, however, also made random samples of data retrieved from the databases and compared them with the output of the same samples in the running system. We selected, e.g., all examinations for a particular day from the retrieved data set and compared each recording with information displayed by the running system. After extensive testing, we feel confident that the data we have retrieved actually represents what we claim they represent.

It should be added that there was no significant change in the systems during the study period, so any bias in data storage, retrieval or interpretation would apply equally for all extracted data. There was a major RIS upgrade after two years. In order to avoid any bias introduced by this upgrade, we decided not to include periods after the upgrade in the study.

**Control group**

The basic design of this study was a before-after study using cross-sectional data collections. Even though the introduction of ICT to support diagnostic imaging was the most important event that year, it was probably not the only structural change, and not the only event that could influence clinical medicine. We have used work lists and production data to assess the manpower in diagnostic imaging, and informal interviews with a selection of clinicians to identify major changes in clinical medicine, but this does not exclude important factors such as diagnostic improvements or changes in manpower that we were not aware of. Ideally, we should have had a control group, e.g. introduce ICT to only some of the radiologists in certain parts of the organisations, in support of only some of the clinical departments. Due to the magnitude and complexity of the introduction itself, and the cross-modality work routines of the radiologists, this was not possible. There was also no similar hospital we could use as a control for this purpose, in part because we were among the last hospitals to introduce ICT, and in part because we would not have the opportunity to influence factors such as manpower, routine changes or clinical improvements in either of the hospitals.

**5.2 Our findings**

Paper I suggested that radiologist prioritized CT reports, and in particular emergency CT reports. Paper II indicated that clinicians opened more final CT reports and opened them sooner than CR reports. A supplementary analyses of the data set not included in
the study showed that significantly more of the preliminary CT reports were opened than CR reports (55% vs. 36%, p<0.01). In paper III, we observed a significant reduction in length of hospital stay for CT patients. When taken together, these data indicate that both radiologists and clinicians gave priority to CT reports, and this seemed to have an effect on patient outcome. We do not have information available to help us analyse whether this was intentional or unintentional, and can only speculate as to what the cause might be. From a radiologist’s perspective, the interpretation of CT examinations may be more interesting than the interpretation of CR; the examination is more complex and more detailed, and can answer more complex clinical questions. Also, a radiologist might believe that a clinician will be more likely to interpret a CR than a CT examination by himself, making the radiologist’s CT examination more important. This complies with the observation that the radiologist becomes more of an actor in a network after the introduction of ICT (22). From a clinical point of view, a CT examination provides more information, thus perhaps making it more important to reaching a clinical decision. Also, it is only used in cases with a sufficient degree of severity to justify both the resources involved and the radiation to the patient. Possibly, clinicians give priority to the more severe cases. As indicated above, both observational studies and questionnaires could perhaps be used to provide information answering these questions.

Intentionally or unintentionally, the priority given to CT reports seems to have had a positive impact on the length of hospital stay. The studied post-ICT period was selected intentionally because it represented a point in time where the RTAT for both preliminary and final reports were reduced. We have not analysed possible underlying mechanisms to explain this observation. It is possible that the earlier availability of CT reports led to earlier and better clinical decisions and treatment, so that the patient could return home sooner. However, it is also possible that some patients awaited the result of a CT examination before being discharged. As suggested previously, supplementary studies could provide more information on this topic. We chose not to extend the study with a data set representing two years after the ICT introduction. This choice was made as part of the study design because paper I indicated that much of the effect on RTAT for final reports deteriorated over time, but was maintained in general for preliminary reports, and that some reports were given higher priority than others. It would be much more difficult to interpret the two year results. Also, our primary objective was to see whether a general reduction in RTAT was accompanied by a reduction in LOS. There was almost no general reduction in RTAT for final reports two years after the ICT introduction.

Our study indicated an untapped reserve of potential for ICT. The clinicians did not read a higher percentage of final reports over time, even if the work list function improved. The time from when a report was available until it was opened did not change. This is similar to the results reported by Watkins, stating that even though the images were available sooner with PACS, the time interval from the examination to the clinical action did not change (21). We also observed a deteriorating reduction in
RTAT for radiology reports. We have not analysed possible reasons for these observations in detail. Our data do not, however, support the idea that the introduction of ICT is a ‘magic bullet,’ where the technology in itself is both necessary and sufficient to produce all the positive effects (51). Our data do also not support a view, often stated by ICT consultants, that the positive effects will evolve over time, given that the organisation introduces ICT as a “strategic decision.” If anything, our data suggests that benefits are achieved by a combination of technological and organisational measures.

Commercially available monitors display images with lower resolution and lower contrast than film. It has consequently been feared that more lesions would be missed than when images were printed on film. On the other hand, most ICT systems offer tools to facilitate reading, such as zoom and pan, contrast manipulation and edge enhancement. Also, ICT facilitates access to previous studies to be used for comparison. Previous prospective studies have indicated that, under ideal conditions, the two methods are equivalent. Our study (Paper IV) indicated that this can also be the case in ordinary situations. We did not explore whether this was a consequence of the tools available, or whether the lesions were of such a character that the difference in resolution and contrast was unimportant.

6. General conclusions

The introduction of ICT led to reports being available for and read by clinicians earlier than before the introduction. However, not all effects were sustained over time. Radiologists used the flexibility offered by the new RIS/PACS systems to prioritize certain report categories, and these reports were also read earlier by the clinicians than they were before the ICT introduction. The study indicated that length of stay was reduced for patients who had a CT scan during their stay, but not for other patient categories. Diagnostic sensitivity of chest radiographs did not deteriorate, and it is possible that it was actually improved.

Our studies indicate that when ICT is introduced to the radiology department of a large hospital, a few improvements may follow. The studies did, however, also suggest that the introduction in itself does not ensure that the ICT is used to its full potential. We did not observe important adverse consequences of the ICT introduction.
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Does improved access to diagnostic imaging results reduce hospital length of stay?
A retrospective study.

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Does improved access to diagnostic imaging results reduce hospital length of stay?  
A retrospective study

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Abstract

Background: One year after the introduction of Information and Communication Technology (ICT) to support diagnostic imaging at our hospital, clinicians had faster and better access to radiology reports and images; direct access to Computed Tomography (CT) reports in the Electronic Medical Record (EMR) was particularly popular. The objective of this study was to determine whether improvements in radiology reporting and clinical access to diagnostic imaging information one year after the ICT introduction were associated with a reduction in the length of patients’ hospital stays (LOS).

Methods: Data describing hospital stays and diagnostic imaging were collected retrospectively from the EMR during periods of equal duration before and one year after the introduction of ICT. The post-ICT period was chosen because of the documented improvement in clinical access to radiology results during that period. The data set was randomly split into an exploratory part used to establish the hypotheses, and a confirmatory part. The data was used to compare the pre-ICT and post-ICT status, but also to compare differences between groups.

Results: There was no general reduction in LOS one year after ICT introduction. However, there was a 25% reduction for one group - patients with CT scans. This group was heterogeneous, covering 445 different primary discharge diagnoses. Analyses of subgroups were performed to reduce the impact of this divergence.

Conclusion: Our results did not indicate that improved access to radiology results reduced the patients’ LOS. There was, however, a significant reduction in LOS for patients undergoing CT scans. Given the clinicians’ interest in CT reports and the results of the subgroup analyses, it is likely that improved access to CT reports contributed to this reduction.

Background
The implementation of a Radiology Information System (RIS) and a Picture Archiving and Communication System (PACS), and the integration of these systems with the Electronic Medical Record (EMR), may improve the use of diagnostic imaging in clinical practice. This Information and Communication Technology (ICT) can reduce the radiologists’ reporting time, and make the reports and images instantly available to clinicians hospital-wide [1-10].

In May 2005, RIS and PACS (Siemens MagicSAS® and MagicView®, Erlangen, Germany) were introduced to radiologists at a Norwegian five-hundred bed university-affiliated hospital. Both systems were integrated with the EMR (DIPS EPJ®, Bodo, Norway). This complete technology shift will be referred to below as ‘the ICT introduction’. Before the ICT introduction, radiologists read images on film. Clinicians had to walk to the Radiology Department to look at these images. Reports were printed and distributed on paper. For emergency ultrasound (US) cases, handwritten summaries accompanied the patients returning to the wards.

After the ICT introduction, images were immediately (within five minutes) available hospital-wide to clinicians with legal access to the patient’s record. All radiology reports were entered directly into the EMR as soon as they were finished (also within five minutes). The reports were issued in two versions: a preliminary
version after one radiologist’s examination of the images, and a final version once a specialist in radiology had verified the conclusion.

In a previous study of the impact of this ICT introduction, we observed that the radiology turnaround time (RTAT), i.e. the time from the examinations until the reports were completed, was reduced after one year [11]. For preliminary reports, the median RTAT was reduced from 13.4 to 2.7 hours. For final reports, median RTAT was reduced from 22.6 to 15.1 hours. Two years after the ICT introduction, the RTAT for final reports was back to the pre-ICT level, and has, for various reasons, continued to increase. The RTAT for preliminary reports also increased somewhat, except for preliminary CT reports.

In a study of clinicians’ use of the reports in the EMR, we observed that clinicians read reports soon after they were available [12]. The median time from a preliminary report becoming available in the EMR until it was opened were available [12]. The median time from a preliminary report being available in the EMR until it was opened was 0.8 hours for Computed Tomography (CT) reports, and 1.1 hours for Computed Radiography (CR) reports. Significantly more of the CT reports than CR reports were read (55% vs. 36%, p < 0.01). For final reports, the median time was 3.3 hours for CT and 3.5 hours for CR. Significantly more final CT reports were read than CR reports (91% vs. 87%, p < 0.01). Before the ICT introduction, the median time until the result was presented during a radiology round - a meeting between clinicians and radiologists - was 18 hours. However, important results were often communicated orally.

The Magnetic Resonance Imaging (MRI) service was limited and varied somewhat during the observation periods. MRI reporting was consequently not studied separately. The Department did not offer MRI examinations of emergency cases.

The capacity for performing the diagnostic imaging examinations did not change between the two periods.

The objective of the current study was to assess whether the improvements in radiology reporting and clinical access to diagnostic imaging information one year after the ICT introduction were associated with a corresponding reduction in the length of patients’ hospital stay (LOS).

Methods

Approval for this study was obtained from the Norwegian Social Science Data Service (NSD) and the Regional Ethics Committee, and the Duke University Medical Centre Institutional Review Board exempted this study from review.

Data relating to all hospital stays for all patients discharged between February 1st and 28th 2005 and between February 1st and 28th 2006 were retrieved from the hospital EMR. These periods were chosen because of the documented improvement in availability and access to the results of diagnostic imaging.

Patients from psychiatric and geriatric wards were excluded. All other patients were included, even if they had been admitted and discharged the same day. The data set included the date and time of admission and discharge, discharge diagnoses, number and categories of imaging examinations, and the clinical department responsible for the patient. LOS was calculated from the admission and discharge time stamps.

We did not have a strong a priori hypothesis as to how the different aspects of the ICT introduction would influence clinical practice, and thereby length of stay, or if there would be differences between different modalities, patient groups or clinical departments. Rather than creating hypotheses through deduction or by performing a feasibility study, our hypothesis generation was assisted by a data splitting approach. This approach guards against (unintended) hypothesis fishing, and ensures the integrity of the computed p-values [13]. The data set was randomly split into two parts. The first part, the exploratory data set (33%), was used to assist in generating the hypotheses. The remaining data, the confirmatory data set (67%), was used to test the hypotheses. The reported p-values for changes in LOS for each modality and for the whole patient group are based on the confirmatory data set. Once a hypothesis had been verified, the complete data set was used for quantification, and is presented in the figure and tables. The purpose of splitting data in this way was to ensure that our statistical tests were performed on data that were not used to generate the hypotheses.

Changes in LOS within each subgroup (e.g., Tables 1 and 2) were analyzed using the two-sided non-parametric Mann-Whitney U-test. To compare changes in LOS between subgroups (Table 2), an independent sample t-test was used. The change in the number of examinations was analysed using the chi-square test. The significance levels (predetermined at α < 0.05) are reported. SPSS (v. 15.0, © SPSS Inc.) was used for data management and analysis.

Results

The study included 8,892 hospital stays. A total of 1,275 different primary discharge diagnoses were used

Table 1 LOS before and after the ICT introduction for all patients with one or more imaging diagnostic examinations

<table>
<thead>
<tr>
<th></th>
<th>Stays</th>
<th>Mean</th>
<th>Median</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-ICT</td>
<td>4,244</td>
<td>3.50 days</td>
<td>1.72 days</td>
<td>0.08 days</td>
</tr>
<tr>
<td>Post-ICT</td>
<td>4,648</td>
<td>3.34 days</td>
<td>1.50 days</td>
<td>0.08 days</td>
</tr>
</tbody>
</table>

p = 0.43
Most patients, 57.6%, were discharged without receiving any diagnostic imaging examinations. CR was the most frequent diagnostic imaging examination: during their hospital stay, 35.2% of patients had one or more CR examination, whereas 11.8% of the patients had one or more CT scans. The Neurology department was the most frequent user of CT - 36.1% of their patients had one or more scans, while 18.7% of general surgery patients and 14.7% of orthopaedic surgery patients had CT scans. US examinations were performed for 7.4% of the patients, while only 2.5% received MRI scans.

Table 1: LOS before and after ICT for patients with discharge diagnoses recorded in both periods in both groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Stays</th>
<th>Mean (d)</th>
<th>Median (d)</th>
<th>SE</th>
<th>Stays</th>
<th>Mean (d)</th>
<th>Median (d)</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-ICT</td>
<td>1,509</td>
<td>1.96 d</td>
<td>0.56 d</td>
<td>0.10</td>
<td>194</td>
<td>8.42 d</td>
<td>5.46 d</td>
<td>0.68</td>
</tr>
<tr>
<td>Post-ICT</td>
<td>1,579</td>
<td>1.84 d</td>
<td>0.56 d</td>
<td>0.09</td>
<td>255</td>
<td>6.06 d</td>
<td>3.00 d</td>
<td>0.54</td>
</tr>
</tbody>
</table>

All durations are in days. The reduction in LOS for the CT group was significant alone (p < 0.03) and when compared to the non-CT group (p < 0.01).

The mean and median LOS before and after the ICT introduction are presented in Table 1. There was no significant reduction in LOS (p = 0.43 in the confirmatory data set). However, the exploratory analysis indicated a significant reduction in LOS for one subgroup of patients - patients who had one or more CT scans during their hospital stay. This was verified by the confirmatory data set.

Figure 1 shows the median LOS for the main modality groups. The median in-patient stay for patients with CT scans was significantly shorter (p < 0.04) after the ICT introduction (3.9 days) than before (5.3 days), a 26% reduction. The reduction in LOS for the CT patient group was also significant compared to patients who received no CT scans during their hospital stays (p < 0.05). There was a reduction in LOS for MRI and CR patients, and an increase in LOS for US patients. These changes were, however, not statistically significant.

The clinical departments and support units were asked to identify major improvements in procedures or routines between the two observation periods. None were reported that should have had a significant impact on LOS. The data set was also investigated by referring unit, but there were no significant changes for any individual clinical department. There was no statistically significant increase in the number of patients with CT scans from the pre-ICT to the post-ICT period.

The CT patient group was heterogeneous, as 445 different primary discharge diagnoses were used for these 1,049 patients. To reduce the impact of this heterogeneity and to reduce the impact of any diagnostic routine changes not reported by the clinicians, a subset of patients were selected based on discharge diagnosis. We only included diagnostic patient groups where some - but not all - had CT scans in the pre-ICT period, and some - but not all - had CT scans in the post-ICT period. This would exclude diagnostic patient groups that was examined by CT only in one of the periods, and the effect of any diagnostic improvement would apply to both CT and non-CT patients alike. This subgroup consisted of 3,537 patients with 59 different discharged diagnoses (presented in Table 2). The changes in LOS was first analysed separately for CT patients in this subgroup, and then compared to the non-CT patients. There was a significant reduction (p < 0.03) in LOS for CT patients in this subgroup. The reduction was also significant (p < 0.01) when comparing the CT to the non-CT patients.

Discussion

In previous studies of the ICT introduction [11,12] we found a RTAT reduction from 13.4 to 2.7 hours for
preliminary, and from 22.6 to 15.1 hours for final reports. We also observed faster and more comprehensive clinical access to the results of diagnostic imaging after the introduction of RIS and PACS, and the integration of these with the EMR system. The current study did not reveal a corresponding significant reduction in LOS (Table 1). This finding is similar to those reported by others [2,14,15].

However, we found a significant reduction in LOS for one group of patients - patients who had undergone CT scans (Fig. 1). Our previous studies indicated a particular clinical interest in the radiologists’ CT scan reports. CT scans have become an important part of modern medicine, and provide detailed information that cannot be acquired more efficiently in other ways. It is therefore possible that some clinical decisions are delayed until the results of these scans are available, and that earlier availability of results can lead to earlier clinical actions which, in turn, lead to improved patient care and earlier discharge. CT is often also used to exclude serious conditions, and patients frequently wait for a negative CT examination report before being discharged. In this study we observed a significant reduction in LOS for CT patients both between the pre-ICT and post-ICT periods, and relative to patients who did not undergo CT examinations. It is likely that the ICT-enabled improved access to CT reports is responsible for at least part of this reduction.

The reduction in LOS for the MRI patients was not statistically significant. Only 2.5% of the patients had an MRI scan, and it is possible that this sample size was too small to demonstrate an actual reduction. However, it is also possible that the ICT introduction did not reduce LOS for this patient group. As MRI capacity was limited, MRI was primarily used for complex cases where the result of various clinical examinations would be compared before any diagnostic conclusion was made. Also, in non-emergency cases, patients would frequently be discharged before the results of the various examinations were available, with a scheduled follow-up in the outpatient department to make the final diagnostic conclusion. In such cases, improved access to reports would not influence LOS.

CR was the most frequent type of diagnostic imaging in this study. In our experience, CR is mostly used to supplement clinical examinations and laboratory tests, and decisions will rarely be postponed by a delayed radiology report. For example, a patient with clinical signs of pneumonia may get antibiotics before the results of the radiographs are available. Orthopaedic surgeons often prefer to interpret the images directly, rather than wait for the radiologist’s opinion. In addition, many CR results are negative. We would therefore not expect a major reduction in LOS for patients examined with this modality even with improved access to the radiologist’s diagnostic reports. The observed small reduction was not statistically significant.

For US patients, the observed increase in LOS was not significant. In the pre-ICT period, handwritten reports with the main conclusions from the examination accompanied emergency patients to the ward or clinical examination room. The clinicians would consequently have the radiologists’ opinion available at least as early as with the post-ICT routines, and they could read the results without having to log on to the EMR. This may outweigh any effect the ICT introduction may have had on routine cases.

Nitroci et al. [8] reported a reduction in LOS after PACS implementation. The reduction was largest for neurology patients. In our study, the neurology department was the most frequent user of CT scans. However, whether we included all neurology patients or only the subset of neurology patients that had undergone any form of imaging diagnostics, the reduction in LOS we observed was not significant. The neurology patients constituted, however, only 7.5% of the total patient group.

Watkins et al. [14] studied the influence of PACS on the LOS for two specific surgical procedures (total hip replacement and total knee replacement). They observed a 25% reduction for one of the procedures and no reduction for the other. They concluded that it was likely not a true PACS effect.

There were no other major changes in the hospital organisation or diagnostic approach between the two observation periods, neither according to clinicians’ reports nor from our experience. However, new procedures, new routines and new approaches are continuously introduced, and clinicians may have forgotten about changes that could have influenced the LOS. In our study we have tried to compensate for the ever-changing environment in two ways. First, we included all somatic patients. For CT patients, 445 different diagnoses were used as discharge diagnoses, and even though new routines may have been introduced for some of these diagnoses despite the reports from the clinicians, most clinical procedures were probably unchanged after one year. Second, we selected a subset of patients with discharge diagnoses used for patients in all four categories; for patients before and after the ICT introduction, both with and without CT scans (Table 2). This should reduce the impact of changes in routines relating to specific diagnoses, as they would apply to both the CT and non-CT groups. This would also reduce the effect of the diagnostic heterogeneity. As indicated, the reduction in LOS was significant also for CT patients in this reduced patient group. Because of the large variety in diagnoses, we have not analysed
specific diagnostic groups or adjusted for diagnostic variations.

It should be noted that we compared heterogeneous groups. The mean LOS for patients without CT scans was less than three days, and six to seven days for CT patients. For the reduced set of diagnoses, the mean for patients without CT scans was less than two days, and six to eight days for CT patients.

There is a strong financial pressure to increase productivity and reduce LOS - the average LOS for all hospitals in Norway was reduced from 5.1 days in 2005 to 5.0 in 2006 [16]. It is likely that such pressure has a greater impact on patients with longer hospital stays. Most of the patients who received CT scans were in this group.

Conclusion

Our study showed that even with an ICT-enabled improved clinical access to the results of diagnostic imaging, we could not identify a corresponding reduction in the length of hospital stay when all patients were considered together. However, one subgroup of patients, namely those with CT scans, had 25% shorter hospital stays after the introduction of RIS and PACS, and the integration of these systems with the EMR. Given the clinicians’ particular interest in CT reports it is likely that this reduction in length of hospital stay in part was caused by the improved clinical access to these reports. New clinical routines and a general drive towards efficiency may also have contributed to the result.

List of abbreviations


Competing interests

The authors declare that they have no competing interests.

Authors’ contributions

PH originated the idea for this study and prepared the manuscript. PH and PG performed the statistical analysis. All authors participated in the design of the study and interpreted the data, and all have read and approved the final manuscript.

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