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CLINICAL AUDIT AND QUALITY ASSURANCE IN THE IMAGING PROCESS

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ACADEMIC DISSERTATION

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications referred to in the text by their Roman numerals.

I **Hirvonen-Kari M**, Salo S, Dean K, Kivisaari L. Effect of clinical audits of radiation use in one hospital district in Finland. *Acta Radiologica 2009; 50: 389–395*.

II **Hirvonen-Kari M**, Järvinen H, Kivisaari L. Clinical audits and regulatory inspections - double efforts and expenses for radiation protection? *Acta Radiologica 2010; 51: 619–624*

III Lönnroth N, **Hirvonen-Kari M,** Timonen M, Savolainen S, Kortesniemi M. Transition in occupational radiation exposure monitoring methods in diagnostic and interventional radiology. *Radiation Protection Dosimetry 2012; 151: 58–66.*

IV **Hirvonen-Kari M**, Sormaala M. J, Luoma K, Kivisaari L, Lohman Martina. Quality of Chest Radiograph Reports. *Submitted*.

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ABBREVIATIONS

AAPM	The American Association of Physicists in Medicine
ACR	American College of Radiology
ALARA	As Low As Reasonably Achievable
ANOVA	Analysis of variance
APDs	Active personal dosimeters
BSS	Basic Safety Standards, Directive 96/29/Euratom
CT	Computed tomography
CAR	The Canadian Association of Radiologists
DRLs	Diagnostic reference levels
EC	European Commission
ESR	European Society of Radiology
EU	European Union
FMA	Finnish Medical Association
GPs	General practitioners
HIS	Hospital information system
Hp(d)	Personal dose equivalent
HUCH	Helsinki University Central Hospital
HUS	Hospital District of Helsinki and Uusimaa
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IPEM	Institute of Physics and Engineering in Medicine
IR	Interventional radiology
K	Cohen's kappa
MED	MED-directive - EC Council directive 97/43/EURATOM

MRI	Magnetic resonance imaging
MSAH	Ministry of Social Affairs and Health
mSv	Millisievert
µSv	Microsievert
PACS	Picture and communication archiving system
PDCA	Plan, do, check, act
PET	Positron emission tomography
QA	Quality Assurance
QAIP	Quality Assurance and Improvement Program
QAP	Quality Assurance Program
QC	Quality Control
RCR	The Royal College of Radiologists
RIS	Radiology information system
SPSS	Statistical Package for the Social Sciences
ST Guides	Regulatory Guides on radiation safety
STUK	Radiation and Nuclear Safety Authority
THL	National Institute for Health and Welfare
TLDs	Thermoluminescent dosimeters
TUH	Turku University Hospital

ABSTRACT

Recent decades have witnessed a large and rapid expansion of medical imaging technologies with the development of digital imaging, computed tomography (CT), intervention radiology (IR), magnetic resonance imaging (MRI) and positron emission tomography (PET). The average effective dose per capita in Finland, received from X-ray examinations and interventional radiology has risen within reasonable levels, but the proportional CT scan dose sustained by the population out of the total population dose has increased and is currently over 50% from the total population dose in medicine. These technical developments and an increase in diagnostic examinations have raised concerns regarding the quality and safety of imaging practices. Organizations using medical imaging modalities should have a documented quality assurance (QA) program, as well as methods to justify the use of new radiological procedures ensuring the safe operation and adequate quality of clinical images and the imaging process.

According to decree 423/2000 departments using ionizing radiation should be audited in all essential aspects at intervals not exceeding five years. Clinical audits should be arranged to expediently complement the self-assessment of activities. Reports of the two clinical audit periods were evaluated at 14 diagnostic radiation departments in the Hospital District of Southwest Finland (I). Recommendations given during the first clinical audit period were largely implemented by the second run. Auditing appeared to positively affect radiological imaging quality in our study.

The use of ionizing radiation always requires a safety license and on-site inspections. The Radiation and Nuclear Safety Authority (STUK) is Finland's regulatory body controlling safety aspects of radiation utilization, and ensuring that safety guidelines defined by the Radiation Act are followed. The contents of the clinical audits and regulatory inspections of radiological procedures were examined and overlaps were searched for in 20 radiological imaging departments in the Hospital District of Helsinki and Uusimaa (HUS) (II). Radiation safety organizations, examination and personal dosimeter usage guidelines, patient doses, the quality control of equipments and self-assessments were evaluated by both the clinical auditors and the inspectors. Clinical audits and regulatory inspections have partly addressed similar topics.

The personal equivalent doses of 267 radiation employees were monitored using personal dosimeters at the HUS Helsinki Medical Imaging Center (III). A personal dosimeter was worn by a total of 116 radiologists and 151 radiographers. Exposure monitoring results exceeding the registration threshold were observed in the personal dosimeters of 59 radiologists and 14 radiographers during a five-year period. Only 10 angiography radiologists recorded doses above 10 mSv during the five-year period. Individual exposure monitoring is justified for radiologists working in interventional procedures.

Report quality was examined at the HUS Helsinki Medical Imaging Center. An experienced chest radiologist re-reported 293 chest radiograph examinations in accordance with the original request and without identifying patients (IV). Two experienced radiologists compared the content of the initial and re-reported reports. Three referring physicians evaluated the usefulness of the reports. Radiologists mostly addressed the questions posed by referring physicians, but separate conclusions were seldom included. Significantly shorter reports were initially prepared by general radiologists (29 words on average) than by the chest radiologist (93 words on average) in her re-reported reports. Inter-observer agreement between the two radiologists revealed that identical opinions of the findings was low (0.31), due to unstructured reports containing differing quantities of information. Referring physicians considered the reports clear and intelligible.

1. INTRODUCTION

Radiology has experienced significant technological development during recent decades, and the use of radiation in medical applications continues to increase worldwide. New imaging techniques have concurrently improved and enhanced patient care. These technical developments and the associated increasing range of applications have also raised concerns regarding the quality and safety of imaging practices, as the use of radiation in medical diagnostic examinations causes over 99% of man-made radiation exposure (Faulkner et al. 2010, Sources and effects of ionizing radiation 2010, Le Heron et al. 2010, Shortt et al. 2008). Departments using ionizing radiation should have a documented quality assurance program (QAP) to ensure the quality of patient care and examinations, and adequate clinical image quality. This includes written imaging protocols, assessment of patient and staff absorbed doses and a documented education and training program (Chera et al. 2012, Kruskal et al. 2011 and 2009, Sandborg et al. 2010, Brenner and Hricak 2010). Internal and external auditing are also important tools for improving patient care and outcomes in health care and radiology. Auditing must be an integral part of the overall quality improvement process in clinical practice, and should be considered essential in quality management. Auditing involves examining a practice and assessing it against standards and criteria of high-quality practices, while quality control relates to equipment process monitoring. All clinical staff is required to actively participate in the audits, and a Quality Culture must be created in every organization whose objective is delivering the highest possible level of health care (Tamm et al. 2012, Faulkner et al. 2010, Iqbal and Pidikiti 2010, Sandborg et al. 2010, Reiner 2010a, Kruskal et al. 2009, Guide ST 1.1/2005).

All essential aspects of radiology departments should be audited at intervals not exceeding five years. The concept of clinical audit is introduced in the European Commission (EC) Council directive 97/43/EURATOM (also known as the MED-directive), and European Union (EU) member states should carry out clinical audit in accordance to national procedures (Council directive 1997). Clinical auditing is a systematic and independent review of medical radiological procedures, carried out to ensure the quality of radiology. Finland is a pioneer country in implementing a clinical audit into practice. Nearly all departments utilizing diagnostic radiation underwent their first audit period before the end of 2005. The second clinical audit period began in 2006. Auditing is a

laborious, time-consuming, and expensive process for radiology departments. Auditing effects on radiological processes should therefore be evaluated to determine whether a positive outcome has been gained.

Before the commencement of clinical auditing, international principles specified that a country's legal infrastructure should ensure the establishment of a legislative and statutory framework for regulating the safety of facilities and activities, including the medical use of radiation. This framework also includes a regulatory body responsible for authorization, regulatory reviewing and assessment, inspection, and enforcement (IAEA 2000). The Radiation and Nuclear Safety Authority (STUK) is the regulatory body controlling radiation utilization safety in Finland, and implementing regular inspections of all radiation practices. Regulatory control procedures include a safety license, approval and registration procedures, on-site inspections, and monitoring of employee exposure levels. Regulatory controls are carried out every one to five years, depending on the radiological practices. Costs of the first inspection and regulatory control, including an annual fee for each license, are defined in the Radiation Act (1991), the Act on Criteria for Charges Payable to the State (Act 150/1992), and in the decision by the the Ministry of Social Affairs and Health (MSAH) regarding charges and grounds for payment (Decision 580/1993). The combination of regulatory inspections and clinical audits increases expenses and unnecessary overlaps waste resources.

Radiology department staffs are one important factor in ensuring patient safety and radiology process quality. Staff competence is also a target of clinical audit and regulatory controls performed by STUK. Radiology personnel are required to have duty-appropriate current knowledge concerning ionizing radiation and its effects, radiation protection, radiation legislation, and other regulatory instructions. Supplementary staff training, provided in five-year periods, must include at least the minimum amounts of radiation protection training. The appropriate quantity and content of supplementary training is presented in the Regulatory Guides on radiation safety (Guide ST 1.7/2012 and 1.8/2012). Personnel under risk of radiation exposure are divided into categories A and B. Individual monitoring is mandatory for category A personnel, but discretionary for category B personnel (Guides ST 1.6/2010, 7.1/2007 and 7.4/2008). High-quality radiation equipment, staff competence and training, and correct working procedures have led to very low current measured effective doses of workers, except in interventional

radiology. Occupational radiation exposure monitoring is therefore always adapted to local working conditions and the type or level of radiation exposure involved.

Radiologists help the caring physician form a diagnosis that aids in effective and concise patient management. This is achievable only if the referring physician provides all diagnostic information which justifies the requested radiological examinations, as well as providing information of previous exposures (Akinola et al. 2010, ACR 2010, Radiation Protection 118/2007, Cohen et al. 2006, Department of Health 2000, Council Directive 1997*)*. The most important communication tool used by radiologists in transmitting their observations to referring physicians is the radiology report. Having received the report, the physician can make correct care decisions for patient treatment. The report should include a description of findings, an answer to the clinical question, a separate conclusion, and it should be easily understandable. Report quality and clarity are always important, but especially so in situations when the clinician and radiologist cannot meet. (Grieve et al. 2010, Kahn et al. 2009, RCR 2006, Robert et al. 2006, Ridley 2002).

2. LITERATURE REVIEW

2.1. Quality assurance and the improvement process in radiology

Medical imaging and interventional radiology are undergoing rapid change due to technological advances, new imaging techniques, and faster imaging data processing. Radiographic systems have undergone the Digital revolution (Nitrosi et al. 2009). Digital techniques can potentially improve radiological practices, but they also increase the risk of radiation overuse. The main advantages of digital imaging are clear, i.e. a wide dynamic range, post-processing, multiple viewing options, and electronic transfer and archiving options, but overexposures can occur without adverse impacts on image quality (ICRP 2004). Awareness of and interest in the quality of care and patient safety in medical imaging and interventional radiology are concurrently increasing (Korir el al. 2012, Rubin 2011, Lau 2007). To ensure high-quality image processing, every imaging organization must formulate a quality assurance and improvement program (QAIP). Quality assurance (QA) examples include the justification of imaging procedures, written protocols for all standard imaging procedures, the selection and acceptance testing of new imaging equipment, periodic equipment quality control, adequate staff training, assessment of patient and staff absorbed doses, and methods for properly managing high-risk patients e.g. fetuses, children, and patients undergoing high-dose procedures (Lau et al. 2011, Sandborg et al. 2010). QAIP structure and components vary depending on department and hospital size, the nature of the practice and services offered, and the institutional culture of quality and safety (Chera et al. 2012, Kruskal et al. 2011 and 2009). Quality assurance and performance improvements should be directed at the whole imaging process, and throughout every stage of the patient's journey, beginning with the receival of a request and ending with the imaging report reaching the referrer.

Figure 1 presents one structural option of the imaging process. The process begins with the caring physician and patient making a joint decision of requesting an imaging examination, and comes to an end when the physician receives the imaging report. Several phases occur between the request and the report, and these phases must be implemented at a level ensuring adequate examination results from the perspective of both patient and physician. The entire imaging process should be evaluated, as each of its phases influences the others and process quality must remain high. Internal audit or

self-assessment should be the first priority when no earlier experience with auditing exists. Internal audits or self-assessments are designed to familiarize staff with general auditing technology, and help employees identify their strengths as well as weaknesses most in need of urgent improvement. Regular internal audits or self-assessments can build up and maintain an open attitude for external audits, and provide experience and background information used to derive maximal benefit from external audits. Audits are valuable because they ensure that internal experts recognize the weaknesses and improvement possibilities in their longstanding and routine practices (Centonze 2011, ESR 2010, Radiation protection 159/2009, National Institute of Clinical Excellence 2002).

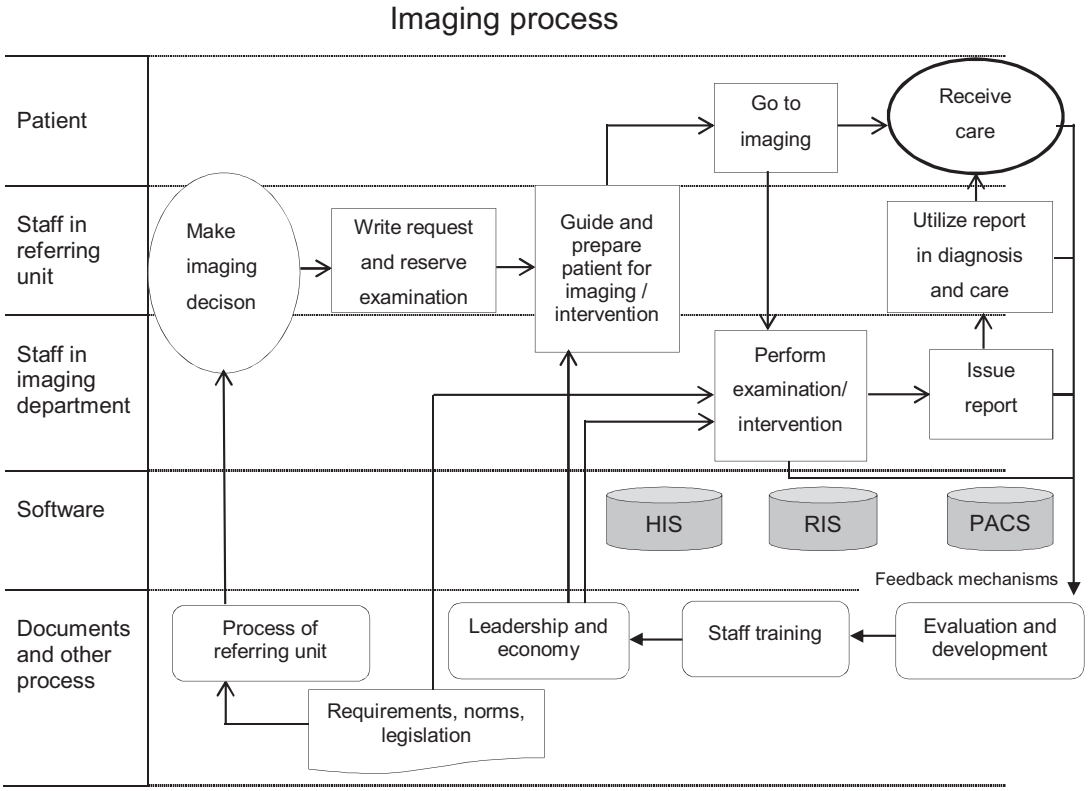

Figure 1. The imaging process.

QA is a proactive process, carried out by analyzing, developing, and implementing improvement measures for each examination stage, to ensure better exposure, positioning, and diagnostics of the final images while minimizing exposure (Rubin 2011,

Lau 2007). Quality control procedures were therefore implemented to standardize and define the minimum requirements of high-quality radiology service. These requirements have been reviewed worldwide by health institutions, e.g. the International Commission on Radiological Protection (ICRP 2004 and 2007b), the American Association of Physicists in Medicine (AAPM 2002), the Institute of Physics and Engineering in Medicine (IPEM 2005), the European Commission (EC 1996a and 1996b), all of which monitor the practice and quality control of radiology. The implementation of QA procedures can be derived from existing national standards (Charnock et al. 2011, Lessa et al. 2008, Schreiner-Karoussou 2006, The Kings Centre 2005, AAPM 2006). The Radiation Act (1991) and Decree 423/2000 are national standards in Finland. Stipulating guidelines have been given in the ST Guides, issued by STUK, to act as instructions for radiology quality control.

A Quality Assurance Program (QAP) presents the principal tasks involved in supervising operating conditions, e.g. the principles for preventing radiation dosage errors. QAPs include quality control techniques used to test components of the radiological system, and verify satisfactory equipment operation. Further administrative procedures or management actions are designed to verify that:

- quality control techniques are performed properly and according to a planned timetable
- results of these techniques are evaluated promptly and accurately
- necessary corrective measures are executed in response to these results.

International and national QA requirements are mainly concerned with the quality of equipment functioning, but all elements of the imaging process should be included in the evaluation process (Figure 2). Professional staff competence is a key factor affecting the quality of imaging and clinical practices and employee radiation exposure levels. The work quality of radiology professionals is becoming increasingly regulated. Self-assessment is the first phase of QA in the imaging process, and clinical auditing is a necessary form of evaluation.

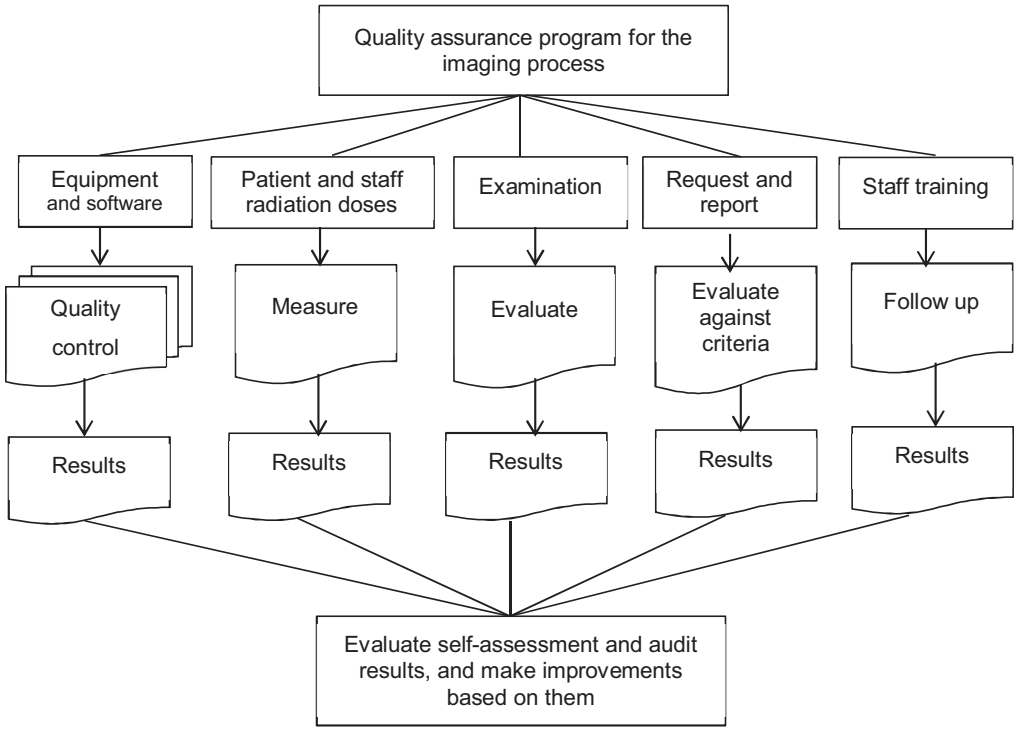

Figure 2. A quality assurance program as part of an improvement process.

2.2. Self-assessment

2.2.1. Patient radiation exposure

Cumulative ionizing radiation exposure has simultaneously significantly increased in the population along with the growing diagnostic power of radiological imaging techniques. This is due to an increase in diagnostic examinations, as well as higher radiation doses associated with these examinations, especially with computed tomography (CT) scans (Berlin 2011, Brenner and Hricak 2010, Le Heron et al. 2010, Amis et al. 2007, Moores 2006). CT scans are the single largest source of medical radiation delivered to the general population. Optimizing patient doses received from radiographic examinations is

therefore crucial, especially with CT scans and when examining children (Callaham 2011, Yu et al. 2011, Young et al. 2011, Maree et al. 2007, Nickoloff and Alderson 2007, Vassileva 2002).

One fundamental aspect in patient dose optimization is the collection of patient dose information, which can be compared with appropriate diagnostic reference levels (DRLs). International and national health care facilities have established DRLs for the most common radio-diagnostic procedures (Decision 2011, Hart et al. 2009, Department of Health 2007, Decision 2007, Decision 2005a and 2005b, IPEM 2004, ICRP 2001). DRLs have proven a useful assurance tool when optimizing patient doses in diagnostic radiology (ICRP 2007b, Tonkopi et al. 2012, McCollough 2010, Edmonds 2009). DRLs are country-specific, and should be periodically updated. Local reviews of DRLs and patient doses should be performed every one to three years, or following any change in clinical practice (Wood et al. 2012, Decision 2011, Treier et al. 2010, IPEM 2004).

Optimizing radiographic examination patient doses requires researched knowledge and cooperation between the radiologist, radiographer, and physicist. Researched knowledge of patient doses received from various examinations is nowadays available. Patient radiation exposure levels have been measured during low-dose examinations, such as chest X-rays, but especially during high-dose CT examinations. Specific diagnostic reference levels have been proposed based on these measurements (Grewal et al. 2012, Coakley et al. 2011, Pantos et al. 2011, Callaham 2011, Martin 2011a, Vano 2009, Muhogora et al. 2009, Bauhs et al. 2008, Kanal et al. 2007, ICPR 2007a, Boone et al. 2001). Patient dose audits can be performed using data from hospital radiology information systems (RIS), if appropriate information fields have been included in examination records (Charnock et al. 2011, Wilde et al. 2011, Moores et al. 2010, Fazakerley et al. 2010).

2.2.2. Radiation protection of medical staff

The use of radiation in medical applications continues to increase, and 4 billion X-ray examinations are performed yearly worldwide (Le Heron et al. 2010). Yearly 4 million of these are performed in Finland, 8.3% of which are CT examinations and 1.6% are angiography and interventions (Rantanen 2011). The increasing number of examinations

does not always mean that medical staff are exposed to higher radiation doses. Working habits and the working environment must be arranged so that staff and patient radiation exposure is kept as low as possible.

The occupational exposure level associated with X-ray imaging procedures is highly variable. Radiography, mammography, and general CT are situations where personnel do not need to be physically close to the patient. Occupational radiation doses from fluoroscopy-guided interventional procedures are the highest registered among medical staff. Interventional radiology (IR) was originally developed for radiologists, but is now also used by other medical specialists e.g. cardiologists, urologists, gastroenterologists, neurosurgeons, and traumatologists. Specialists performing interventional X-ray procedures, e.g. radiologists and cardiologists, are often exposed to significantly higher radiation doses than physicians and nurses working in other fields of radiology. Staff doses received per procedures vary greatly, depending on screening times and individual proximity to the X-ray tube. Reported doses ranged from a few microsieverts (μSv) up to several millisieverts (mSv) per procedure, with higher values mainly recorded from the hands. Radiation exposure levels measured from the hands of an assisting person were significantly lower compared with the hands of an operating person (Martin 2011b, Le Heron et al. 2010, Kuipers et al. 2010, Häusler et al. 2009, Petrucci 2008).

Optimizing procedure protocols and the proper use of protective devices and shields might ensure that occupational doses received by medical staff in X-ray imaging are as low as reasonably achievable (ALARA) (Kim et al. 2012, Korir et al. 2012, Sánchez et al. 2012 and 2010, Dimitriou and Kamenopoulou 2011). Optimization and improved radiation protection measures can be achieved through continued education and training in radiation physics and radiation protection. Adequate additional tools are needed to keep personal doses in accordance with the ALARA principle e.g. lead aprons, protective eyewear, and gloves. Further individual radiation monitoring is needed to ensure that dose limits are not exceeded. It is important that personal dosimeters are worn correctly, and monitoring of the fingers and hands may be indicated in some cases (Korir et al. 2012, Sánchez et al. 2012 and 2010, Dimitriou and Kamenopoulou 2011, Le Heron et al. 2010).

Doses received by interventional operators can potentially be high, and it is therefore important that the doses received by several parts of body (e.g. hands, thyroid gland, torso) be effectively monitored. Occupational radiation exposure monitoring is traditionally performed using passive dosimeters such as thermoluminescent dosimeters (TLDs). Passive TLDs do not allow online exposure monitoring, which is important for efficient optimization of the occupational radiation protection level. Active personal dosimeters (APDs) provide real time dose assessment in during exposure as well as selectable alarm levels, which are very useful when optimizing procedures and warning interventionists whenever scatter dose rates rise too high or radiation protection tools are not being properly used, providing an opportunity to improve personal protection accordingly. (Korir et al. 2012, Martin 2011b, Clairand et al. 2011 and 2008, Le Heron et al. 2010, Sánchez et al. 2010).

2.2.3. Radiological reports

Examination requests and imaging reports are usually the only form of communication between radiologists and other physicians (Iyer et al. 2010, Hall 2009, Kahn et al. 2009, Depasquale 2005). A high-quality referral is a requisite for assessing examination justification, minimizing patient exposure, and preventing unnecessary radiological examinations or X-rays. This is achieved only if the referring physician offers essential diagnostic information justifying the requested radiological examination, along with information concerning previous exposures (ACR 2010, Akinola et al. 2010, Radiation protection 118/2008, Triantopoulou et al. 2005, Department of Health 2000, Council Directive 1997). The EC and the Canadian Association of Radiologists (CAR) have e.g. written referral guidelines for imaging (Radiation protection 118, CAR 2012). On the other hand, the appropriate construction, clarity, and clinical focus of a radiological report are essential to improving patient care safety. A written radiological report is part of a patient's permanent health record and interprets the clinical content of an investigation. Generally accepted reporting guidelines have previously not existed, and earlier guidelines were based on personal judgement and individual opinion (Wallis and McCoubrie 2011). Now several organizations (e.g. the American College of Radiology (ACR), CAR, the European Society of Radiology (ESR), and the Royal College of Radiologists (RCR)) have written guidelines for the optimal communication of diagnostic imaging findings. The key components of a radiological report include an examination

title, history/indication, a description of technique, a comparison of findings, and a conclusion (Wallis and McCoubrie 2011, ESR 2011a, ACR 2010, CAR 2010, RCR 2006). Diagnostic imaging reports must include demographic information, such as the patient's name, name(s) of the referring physician(s) or other health care provider(s), and name or type of examination, date, clinical indications, and the following:

- history
    - identified and recorded clinical question
    - the need for technical details
    - technical quality should be mentioned, particularly when suboptimal
    - date and type of any comparative study
- findings
    - clear, descriptive terminology, avoiding impressions until the conclusion
    - findings in a logical manner, with most important ones mentioned first
    - verify important findings when possible
    - mention pertinent negatives only, and avoid lists of incidental findings
- a comparison with previous examinations, if appropriate
- a correlation with complementary examinations
- any correlation with clinical symptoms and findings, if present
- conclusions
    - brief reports may not require a conclusion
    - answer the clinical question
    - list differential diagnoses and further investigations
- name of reporter and facility, date.

A high-quality radiological report is timely provided, promptly available, accurate, easily understandable, thorough, clear, and attempts to answer the specific question warranting the radiological study (Wallis and McCoubrie 2011, ESR 2011a, Iyer et al. 2010, CAR 2010, IAEA 2010, Spottswood et al. 2009, Kahn et al. 2009, RCR 2006, Ridley 2002). The imaging report is an integral part of radiology, and all examinations should be reported by qualified and trained radiological medical practitioners/physicians.

As radiological reports, constituting important legal documents, become a permanent part of patient medical records, radiologists are obligated to convey their imaging interpretations to the referring physicians in the most useful manner possible. Hospital-

based clinicians can visit radiology departments to discuss the reports and attend meetings, whereas those based at a primary health care practice do generally not have this benefit. If the endusers of radiological reports are unsatisfied with report quality, the radiology department services will be redirected (Wallis and McCoubrie 2011, Iyer et al. 2010). Imaging report quality must therefore be regularly evaluated. Studies on clinicians' views of radiological reports may help to improve both professional communication and patient care.

2.3. Guidelines and criteria of clinical audit in Europe and Finland

2.3.1. The European Commission directive and its implementation

General principles for radiation protection of individuals and the concept of medical radiological practice assessment were introduced in the EC MED-directive (Council directive 1997). This directive defines guidelines for all aspects of radiological practice, i.e. equipment, quality control (QC), patient dose evaluation, diagnostic reference level assessment related to procedure complexity, personnel training, and clinical audit. An external clinical audit examines the structures and processes of a clinical department, with the objectives of 1) improving patient care quality, 2) promoting the effective use of resources, 3) enhancing the promotion and organization of clinical services, and 4) furthering professional education and training (Faulkner et al. 2010, Radiation protection 159/2009). The purpose of clinical audits is to improve the quality and outcome of patient care by reviewing radiological practices, procedures, and results against agreed standards for good medical radiological procedures.

Clinical audits should address the critical issues of patient radiation protection, the overall quality system, as well as all aspects of radiological services covering structure, process, and outcome (Table 1). It should be a systematic and continuing activity with multidisciplinary involvement (ESR 2011b, Patel 2010a and 2010b, Järvinen 2009, Donabedian 2005).

Table 1. Priorities of the clinical audit of diagnostic radiology practices.

Structure	Authority policies and radiation safety responsibilities Training levels, competence, and continuous professional staff development Adequacy and quality of facilities and equipment
Process	Justification and referral practices, including referral criteria Availability and quality of examination and treatment guidelines Optimization procedures Patient doses and comparison with nationally accepted reference levels Quality assurance and quality control program Emergency procedures for medical radiation incidents Reliability of information transfer systems
Outcome	Follow-up method of examinations and treatment outcomes

EU member states are required to implement the content of the MED-directive and clinical audit in accordance to national procedures. Finnish radiation legislation was revised in 1998 (Radiation Act 1998), and MED-directive content was supplemented with the Decree on the medical uses of radiation issued by MSAH in 2000 (Decree 423, 2000). Other EU member states have supplemented the MED-directive with laws, decrees, or other regulations. These are usually issued by the national health ministries or special radiation protection authorities. Most countries also regulate the practical implementation of clinical audit, which usually concerns both external and internal audits and self-assessments. Clinical audit frequency varies from one to five years, and is regulated by approximately one third of all European countries. By 2008 clinical audits were carried out regularly in Finland, France, Germany, Lithuania, Poland, Slovakia, Slovenia, the United Kingdom and Switzerland (Draft Appendix 1/2008).

Most European countries performed clinical auditing only occasionally, and mainly internally, instead of issuing external and independent audits. Several problems were also identified, including incomplete national legislation, poor understanding of clinical audit purposes, lack of a formal auditing framework, lack of criteria for high-quality practice

standards, difficulty in employing sufficient numbers of auditors, and insufficient time and lack of specific training available for auditors (Faulkner et al. 2010, Järvinen 2009, Draft Appendix 1/2008, Draft appendix 2/2008). EU member states hope to harmonize clinical auditing. The EC and the International Atomic Energy Agency (IAEA) have issued clinical auditing guidelines in response to these problems (Radiation protection 159/ 2009, IAEA 2009). The ESR has additionally summarized the long EC guidelines into a short summary document (ESR 2011a).

High-quality clinical auditing can provide objective evidence of patient care and outcome quality improvements. This is possible only by completing auditing cycles leading to improvements in clinical practice and service provisioning (Iqbal and Pidikiti 2010, Merle et al. 2009). It must be realized that clinical audit on its own is of little value. All audit reviews must be timely incorporated into a feedback system, which assesses audit outcomes and introduces improvements to the audited process (Faulkner et al. 2010, IAEA 2010).

2.3.2. Clinical audit in Finland

Clinical audit described in §39c of the Radiation Act (1991) should complement self-assessment in an expedient manner. All essential aspects of radiation utilization must be audited at intervals not exceeding five years. The content requirements of clinical audits are specified in Decree (423/2000).

The MED-directive and Finnish legislation do not propose any specific guidelines for organizing audits. The Finnish Medical Association (FMA) along with various other societies, the Association of Finnish Local and Regional Authorities and STUK have created evaluation criteria for clinical audit in Finland. These organizations formed a working group to prepare the audit program, recruit auditors, form an auditing organization, and organize training (Soimakallio 2009). This working group issued practical guidelines for clinical audits. General audit principles require auditors to be qualified and experienced experts working independently of the service or process to be audited. Auditors should therefore not have worked at the department in question for five years prior to its auditing. The audit team usually consists of a radiologist and a

radiographer, but a physicist is also present in interventional radiology and CT departments, and a cardiologist in cardiology departments.

The MSAH set up an advisory committee for the coordination and follow-up of clinical audits before the first audit period ended in 2004. This advisory committee has evaluated the suitability and coverage of the criteria used in clinical audits, and issued eight recommendations dealing with practical issues. Some of these recommendations changed the clinical audit process before the second audit period began, and helped the organization in question prepare for audit (Soimakallio 2009, Finnish advisory committee for clinical audit 2012).

Recommendations issued by the advisory committee:

- Number 1 (updated 1.6.2011). The education, competence, and independence of auditors in clinical audit.
- Number 2 (1.7.2006). The development of clinical audit in medical radiation: recommendations for the second audit period.
- Number 3 (15.12.2006). Consideration for clinical audit accreditation of health care nuclear medicine departments.
- Number 4 (1.5.2008). Decree 423/2000 defines ten important points of clinical audits and their considerations.
- Number 5 (1.12.2009). The clinical audit report and its retention period.
- Number 6 (1.12.2009). EU recommendation concerning clinical audit and its considerations in Finland.
- Number 7 (1.2.2011). Self-assessment in health care radiation.
- Number 8 (1.3.2013). Good policy criteria and criteria development.

Nearly every department using diagnostic radiation in Finland was audited during the first audit period before the end of 2005. The second clinical audit period began in 2007, evaluating the effects of the first audit. The audit process is laborious, time-consuming and expensive for the radiological departments, and Finland is a forerunner in implementing clinical audit. Audit effects on the radiological process should therefore be carefully evaluated, to determine any positive outcomes.

2.4. Legal requirements of radiation utilization in Finland

Ionizing radiation utilization is a current requirement in European and Finnish health care. A comprehensive quality and safety culture in the medical use of ionizing radiation has been progressively developed throughout the EU. The EC has issued legal requirements for patient radiation and safety requirements for medical devices. The most important directives adopted on the basis of the Euratom Treaty are Directive 96/29/Euratom, the Basic Safety Standards (BSS) Directive (Council directive 1996) covering the protection of personnel and the general public, the MED-directive 97/43/Euratom covering medical radiation utilization, and Council Directive 93/42/EEC concerning medical devices. The BSS- and MED-directives have been transposed to Finnish legislation with amendments to the Radiation Act (1142/1998), the Radiation Decree (1143/1998), and Decree 423/2000. Detailed instructions are also given in STUK's ST Guides.

The IAEA has produced standards and requirements for the inspection and enforcement of radiation practices. The safety standards assume that a single regulatory body is responsible for all aspects of radiation protection and safety. This regulatory body is required to have adequate authority and jurisdiction to carry out inspections in an effective, informed, and unhindered manner (IAEA 2000). The IAEA-TECDOC-1526 report (2007) contains guidelines for preparing both the methods and contents of inspection. STUK is Finland's regulatory body controlling safety aspects of radiation utilization, and ensuring that safety guidelines defined by the Radiation Act are followed, and regular inspections of all radiation practices are carried out.

Radiation utilization requires a safety license and regulatory control, which involves approval and registration procedures, on-site inspections, and monitoring doses received by employees (Requirements 2012). When starting a radiation practice, radiation utilization and equipment are checked during the first or implementation inspection. Further inspections are carried out every one to five years depending on the radiological practice. The inspections ensure, e.g. that (Inspection 2012):

- radiation devices, sources, and actions fulfill all requirements
- radiation shielding, quality control and safety arrangements are adequate
- maximum or operational values are not exceeded
- radiation exposure is monitored

- radioactive materials and waste are handled appropriately
- staff have adequate training and competence
- instructions for using radiation devices and sources exist
- a QAP is in use.

Expenses of the first inspection and regulatory control are paid for by the health care departments, including an annual fee for each license and separate charges for each regulatory inspection (in diagnostic radiology). The charges are based on Article 69 of the Radiation Act and the MSAH decision regarding expenses and grounds for payment (Decision 580/1993).

Regulatory inspections and clinical audits are very comprehensive, and incur extra costs to radiology departments. It is important that these two independent activities focus on sufficiently different areas of operation, to supplement each other without resulting in unnecessary overlaps and resource wasting.

3. AIMS OF THE STUDY

The purpose of the present investigation was:

1. To evaluate the benefits of the audit process by comparing the results of two consecutive audits of the same departments (I).

2. To examine the contents of clinical audits and regulatory inspections of radiological procedures and search for overlaps (II).

3. To study occupational exposure data of radiology department staff and to evaluate how doses relate to each radiation exposure category (III).

4. To analyze the content of chest radiograph reports and the usefulness of chest radiograph reports for the referring physicians (IV).

4. MATERIALS AND METHODS

4.1. Consecutive clinical audits (Study I)

Our retrospective study data consisted of reports of the two clinical audit periods at the diagnostic radiation departments in the Hospital District of Southwest Finland, including the Turku University Hospital (TUH). The Medical Imaging Centre of Southwest Finland includes 14 radiology departments. During the first audit period 11 departments were audited in December 2003, one in January 2004, and two in January 2005. During the second period all 14 departments were audited in November 2007.

The criteria set used in the first period differed in some respects from criteria in the second period. Only criteria identical in both periods were included in our study.

Statistical analyses were performed using the Statistical Package for the Social Sciences; SPSS Incorporated, Chicago, Illinois, USA (SPSS 15.0 software). The results were analyzed using frequencies, crossover tables, and the Pearson Chi-Square, and the audit report recommendations underwent content analysis. A deductive content analysis is based on an earlier theory or model, and therefore moves from general to specific (Gerbic and Stacey 2005, Hsieh and Shannon 2005). Deductive content analysis was used because the classification of our study data was based on existing reference frames found in Decree 432/2000.

4.2. Clinical audits and regulatory inspections (Study II)

Our study involved 20 radiological imaging departments belonging to the Hospital District of Helsinki and Uusimaa (HUS). Our study data consisted of clinical audit reports compiled from audits of all the departments between October 2004 and May 2005, and of regulatory inspections of current procedures performed from October 2004 to May 2008. These inspections were not performed at two of the study hospitals, one of which also included three health center departments. We analyzed 23 audit reports and 18 inspection reports in total.

Results were analyzed using content analysis and frequencies. SPSS 17.0 was used for statistical analysis. Deductive content analysis was used to classify reports content according to a pre-existing 10-point list of relevant issues taken from Decree 423/2000.

4.3. Effective dose of radiation employees (Study III)

The personal equivalent doses of 267 radiation employees were monitored using personal dosimeters between 2006 and 2010 in the HUS Helsinki Medical Imaging Center. Other radiation employees (approximately 360 persons) are not entitled to individual occupational monitoring. Personal dosimeters were worn by 229 university hospital employees, 37 regional hospital employees, and one health center radiographer. Personal dosimeters were worn by 116 radiologists and 151 radiographers in total. Category A included 49 radiologists, and category B included 67. All radiographers (151) were classified into category B.

Statistical analyses were carried out using SPSS 17.0. Results were analyzed using frequencies and analysis of variance (ANOVA). *P*-values less than or equal to 0.05 were considered statistically significant.

4.4. Chest radiograph reports (Study IV)

Our retrospective study was carried out at the HUS Helsinki Medical Imaging Center with approval from the Ethics Committee of the University of Helsinki. Successive chest radiograph pictures and reports 293 in total were collected from the Picture and communication archiving system (PACS). These initial reports were prepared by experienced general radiologists at the regional hospital. An experienced chest radiologist working at the Helsinki University Central Hospital (HUCH) re-reported the initial examinations in accordance with the original request using the same initial X-ray pictures and without identifying patients. The initial reports were not seen by chest radiologist.

Two experienced radiologists independently compared the content of the initial and re-reported reports to specific criteria. The usefulness of both the initial and re-reported

reports of 50 chest X-ray examinations, originally ordered by three referring physicians, were evaluated by these same physicians. The criteria used to evaluate the reports were their medical facts, clarity, and intelligibility.

Statistical analyses were performed using SPSS 17.0 statistical software. Results were analyzed using crossover tables, the Pearson Chi-Square test, and ANOVA to provide the means of several groups. We calculated the agreement of two radiologists over the initial and re-reported report content using the overall proportion of agreement and the Cohen's kappa (*K*). The *K*-index has been developed as a measure of agreement that is corrected for chance (Kundel and Polansky 2003, Landis and Koch 1977).

5. RESULTS

5.1. The benefits of clinical audits

Auditing a radiology department required approximately one day during each period. The audits were generally performed by a radiologist and a radiographer. A physicist was present in the audit of three departments during the first run and in the audit of seven units (50%) during the second run.

Auditors assessed 42 questions in each audited department. During the first clinical audit period ten of the audited questions were in good condition in each department and 35 questions during the second period. The questions that have produced positive development in the departments after the first audit are shown in Table 2.

Table 2. Questions which have produced positive development by the second audit.

	First run		Second run	
	Yes	No	Yes	No
Recommendations for clinicians concerning referral content	9	5	14	
Follow-up of individual training	7	7	14	
Recording of staff refusal to perform a requested examination	7	6	14	
Comparison of self-assessment results	3	11	9	5
Utilization of self-assessment results	3	11	8	6
Recording of patient doses	8	6	14	
Recording patient pregnancy (female)	9	5	14	

The audit reports contained 80 improvement recommendations concerning the first audit period, and 53 recommendations concerning the second audit run. Recommendations were classified into the existing reference frames using content analysis (Decree 432/2000). The X-ray departments received approximately six recommendations per department (range 4–12) during the first period and four per department (range 2–6) during the second period. The largest number of recommendations (22 out of 80) given during the first audit concerned the 'examination instructions'-category, while only nine out of 53 recommendations concerned that category during the second audit. Fourteen radiation dosage recommendations were given during the first period and 11 during the second period. However, QC recommendations doubled from five to ten. Staff training recommendations lowered from 11 to seven, and self-assessment recommendations from eight to six.

5.2. Similarities between clinical audits and regulatory inspections

An average audits and inspection was carried out in one day. Audits were mainly performed by a radiologist and a radiographer and inspections were performed by one inspector. A physicist joined the audit team in CT and angiography departments.

Similar issues were examined by both the audits and inspections, and the common viewpoints are shown Table 3.

Table 3. Issues and main viewpoints most often assessed in clinical audits and inspections.

Assessed issue	present in audits %	present in inspections %	Main viewpoint of	
			audits	inspections
Radiation safety organization	100	100		
Written examination guidelines	100	100	Conformance to guidelines for high-quality practice	Existence of guidelines
Results of patient doses	100	100		
Guidelines for using dosimeters	100	100		
Quality control of equipment: guidelines, results	100	100		
Self-assessment practices	100	100	Applied criteria	
Use of radiation protection shields	100	94	Shield usage	Shield adequacy
Guidelines for monitoring patient pregnancy	100	89		Written instructions for patients
Staff training	100	78		

Auditors issued recommendations and inspectors issued either recommendations or requirements. The following issues were appointed by both clinical audits and inspections:

- building a QAP
- forming staff training programs (follow-up, initiation) and ensuring sufficient training
- creating self-assessment practices and performing self-assessment
- measuring patient doses and comparing them to diagnostic reference levels
- evaluating clinical image quality as a part of self-assessment.

5.3. Effective dose of radiation employees

During the five-year period from 2006 to 2010, accumulated exposure monitoring results exceeding the registration threshold (0.1 mSv) were observed in the personal dosimeters of 73 employees (27%, N=267), 59 of which were radiologists and 14 were radiographers. The mean measured personal dose equivalent (Hp(d)) of radiologists was 2.7 mSv, with a maximum of 45.1 mSv reached by one radiologist. The mean measured Hp(d) of radiographers was 0.0 mSv, with a maximum of 1.3 mSv, and all were category B employees.

The personal dosimeters of 38 category A radiologists (N=59) recorded measurable doses exceeding the registration threshold, ranging from 0.1 mSv to 45.1 mSv. The Hp(d) of 21 category B radiologists ranged from 0.1 mSv to 31.0 mSv. The Hp(d) of 10 category A radiologists and three category B radiologists was over 10 mSv. All worked in angiography.

Angiography is centralized into three radiology departments at HUCH. During the five-year period the measured Hp(d) of category A angiography radiologists (N=14) ranged from 3.0 mSv to 45.1 mSv, with only one radiologist recording 45.1 mSv and six radiologists were recorded between 10–20 mSv. Measured Hp(d) ranged from 0.0 mSv to 31.0 mSv with category B radiologists (n=13), with two radiologists recording approximately 30 mSV and 11 radiologists recording doses under 8 mSv. A total of 48 radiographers worked in angiography, with four radiographers recording measurable doses of 0.1 mSv (two radiographers), 0.3 mSv, and 0.9 mSv, accumulated over the five-year period.

5.4. Chest radiology report quality

Initial and specialist-evaluated chest radiograph report content

The relevant study problem or question was forthcoming in 189 of the 293 requests. The question posed by the referring clinician was addressed nearly always by both general radiologists and the chest radiologist. Further CT imaging, radiographic follow-up using

chest radiographs, and a comparison of new and older radiographs were recommended much more frequently by the chest radiologist than the general radiologists.

General radiologists included separate conclusions more frequently than the chest radiologist. The mean length of the original reports and the chest radiologist's re-statement were 29 and 91 words, respectively.

Agreement in the finding evaluation of the reports

The initial and re-reported reports were independently read by two experienced radiologists unable to identify the radiologists who wrote the reports. They estimated the heart, lung and pleura findings as 1 = an identical finding or no clinically significant difference and 2 = a differing finding. The content of the initial and re-reported reports was assessed as identical in 193 cases (N=293). Calculating inter-observer agreement between the two radiologists revealed identical opinions of the findings. The overall agreement proportion was 0.66, which indicates a 66% agreement percentage between interpretations. The corresponding kappa value was 0.31.

The referring physicians' evaluations of the initial and specialist-evaluated reports

The referring physicians regarded 68% of the short initial reports as clear, 54% of the medical facts sufficient, and the information of 44% lacking. The specialist-evaluated longer reports were clear in 94%, the amount of medical facts were sufficient in 80% and excessive in 20% of the cases.

6. DISCUSSION

6.1. Clinical audit and regulatory inspection efforts (I, II)

Comparisons of clinical audit and regulatory inspection reports indicate that these external procedures partly address similar topics, and unnecessary overlaps were observed. The emphasis of these two procedures is different. Clinical audits comprehensively assess clinical procedures and compare them with accepted clinical

practices, while regulatory inspections mainly examine conformity to basic regulatory requirements and equipment quality. Auditors' recommendations and the requirements and recommendations of inspectors partly covered the same topics, e.g. forming a QAP and staff training programs, performing self-assessment, and measuring patient doses. EC clinical audit guidelines (Radiation protection 2009) state that clinical audits should be developed in a way which minimizes unnecessary overlaps with regulatory inspections, and avoids the duplication of efforts. Further development of clinical audits should be performed in cooperation with regulatory authorities to ensure better supplementation of regulatory inspections and other quality assessment activities of organizations.

Audit reports are written based on the specified criteria and questionnaire. The audited departments fulfilled the audit criteria satisfactorily during both periods, but performed better during the second period. Issues pointed out during the first audit were resolved by the departments. The clinical audits showed especially positive effects on daily radiation work as a whole. Although the criteria were satisfactorily fulfilled, the audit reports of the second period still contained 53 improvement recommendations. The number of recommendations issued during the first period was 80.

Patient doses

The population's cumulative ionizing radiation exposure has simultaneously increased significantly. Medical exposures account for 98% of the dose contribution from all artificial sources and they are now the second largest contributor to the worldwide population dose, representing about 20% of the total (Vano 2011). This is because the number of diagnostic examinations performed early has increased and the radiation doses associated with these examinations has risen, especially with CT scans (Berlin 2011, Brenner and Hricak 2010, Le Heron et al. 2010, Amis et al. 2007, Moores 2006). Nowadays patient radiation doses have been measured, especially in CT, and specific diagnostic reference levels have been proposed (Tonkopi et al. 2012, Coakley et al. 2011, Pantos et al. 2011, Callaham 2011, Vano et al. 2009, Bauhs et al. 2008, Kanal et al. 2007, Boone et al. 2001, Radiation protection 109/1999). It is therefore very important to optimize patient doses received from each radiographic examination, especially with CT scans and when examining children (Callaham 2011, Yu et al. 2011, Young et al. 2011, Maree et al. 2007, Nickoloff and Alderson 2007, Vassileva 2002). Referring

physicians must be aware of the patient dose levels received from X-ray examinations, particularly those received from interventional and CT procedures (Vano 2011).

The highest number of recommendations (11) issued during the second audit were given to the measurement and recording of patient doses and to the comparison of delivered doses with reference levels. These categories received nearly the same number of recommendations (12) during the first period. One reason for this might be that a physicist was included in the audit team in all other department. Fortunately, optimizing patient doses received from radiographic examinations is currently a well-researched topic. Cooperation between different authorities (radiologists, radiographers, physicists, and referring physicians) is necessary for reducing the effects that ionizing radiation has on the human body. It is topic requiring further attention in both self-assessments and the third clinical audit period. Patient dose measurement results should also be evaluated during regulatory inspections.

QAP and QC

All radiological departments must have QAPS, including written definitions of quality assurance functions (Radiation protection 159/2009, Guide ST 1.1/2005). The purpose of QA is to confirm that organizations meet issued quality requirements in all respects. A QAP includes justifications for the imaging procedures, written protocols for all standard imaging procedures, selection and acceptance testing of new imaging equipment, periodic equipment quality control, adequate staff training, assessment of patient and staff absorbed doses, and methods to properly manage high-risk patients (Salazar and Abujudeh 2012, Lau et al. 2011, Sandborg et al. 2010). Organizations use quality control to ensure that radiation sources, and associated equipments and instruments are in good condition.

QC recommendations were issued more often during the second audit (10 times) than during the first audit (5 times), possibly because a medical physicist was present more often for the second period audits (50%) than for in the first period audits (21%). Controlling the quality of monitors was especially recommended, leading to the construction of a special program for this purpose. Regulatory inspections also require QAPs.

Staff training

Radiology presents multiple opportunities for improving patient care safety. Radiology department personnel must understand the basic requirements of equipment and procedural safety and how to promote and improve safety in the future (Johnson et al. 2012). The minimum qualifications and continuing education of all staff working in radiological services are consistent with clinical requirements, and meet appropriate national regulatory requirements. All staff should have adequate task training, and individual personnel records should be maintained and available for auditors and inspections. (Radiation protection 159/2009, RCR 2003). Radiation organization directors should ensure that their staff receives supplementary training to keep their radiation protection knowledge and skills up to date. Each radiation employee in Finland needs a minimum of 40 hours of radiation protection training during each five-year period (Guide ST 1.7/2012).

Staff training recommendations were issued to seven units during the second run, which is fewer than during the first run (eleven). Staff training was also checked by the inspectors.

Self-assessment

The whole imaging process should be evaluated during self-assessment, beginning with the request and ending with the imaging report. Assessing quality control measurements only is not sufficient (Chera et al. 2012, Kruskal et al. 2011, Cohen 2009, Reiner 2009, Staven et al. 2004). A radiology request and an imaging report are the primary communication methods between a radiologist and a referring physician, and they are also important medico-legal documents (Wallis and MCCoubrie 2011, Reiner 2010b). Referring physicians must be aware of imaging referral guidelines for preventing unnecessary X-ray examinations. Request and report quality should therefore be regularly evaluated. The creation of a written audit document and a structured data collection format simplify the assessment process (Uberoi 2009, Swinson 2008, Jarrit et al. 2004). Some radiology organizations (*e.g. ACR, CAR, ESR, RCR)* and the EC have created guidelines for the optimal communication of diagnostic imaging findings, and

these guidelines present self-assessment quality parameters. The RCR has also created guidelines for the use of double reporting (RCR 2010).

Auditors issued eight recommendations for self-assessment and the utilization of its results during the first period and six during the second one. The effects of radiation examination were not also assessed in clinical audits. Present results indicate that self-assessments were not adequately performed during the first clinical audits. Results of this study and earlier studies also stress the importance of using well-documented guidelines and standards for high-quality clinical practices as a basis for auditing (Reiner 2010a, ESR 2010, Plumb et al. 2009, Øvretveit 2007, Zissiadis et al. 2006, Jarritt et al. 2004).

6.1.1. Current and future clinical audits in Europe

A clinical audit has been implemented into Finnish national procedures, and all radiology departments have been audited twice by the end of 2010. The implementation status of a clinical audit varies widely among EU countries. The RCR has actively promoted medical auditing for over 15 years (Ryall 2008). Some countries have also realized that clinical audit is a useful part of QA, where colleagues evaluate work in regards to high-quality clinical practice (ESR 2011c, Shortt et al. 2008). But in many countries clinical audits are only occasional or have never been implemented in practice (Faulkner et al. 2010, Järvinen 2009). Several problems have been identified, e.g. incomplete national legislation, poor understanding of the purpose of clinical auditing, lack of a formal auditing framework, lack of criteria for high-quality practice standards, and difficulty with providing specific training for auditors (Draft appendix 2/2008). IAEA organized an international conference in 2008, where participants emphasized the need for a comprehensive and harmonized approach to QA covering both technical and management issues, to ensure patient safety. Advice is also needed on relevant measurements for the constancy checks of modern departments (Shortt et al. 2010, Sandborg et al. 2010, Patel 2010a and 2010b). EU member states hope to harmonize the clinical audit process. The EC issued new clinical audit guidelines in 2009 (Radiation protection159/2009), the IAEA has also issued guidelines (IAEA 2010), and the ESR has summarized EC guidelines in a short summary document (ESR 2011b).

Clinical audits should:

- be a multi-disciplinary, multi-professional process
- follow accepted rules and standards based on international, national or local legal regulations, or guidelines developed by international, national or local medical and clinical professional societies
- be a systematic and continuing process, whereby recommendations issued in the audit reports are implemented
- be performed by auditors with extensive knowledge and experience of the radiological practices being audited
- combine both internal and external assessments to achieve optimal outcomes. Rather than an actual audit, the internal auditing of small departments can take the form of a self-assessment.

Clinical and internal auditing is a tool designed to improve patient care quality, the experiences and outcomes of care against defined standards, and the implementation of change based on audit results. Further clinical audits should address critical issues in patient radiation protection and the overall quality system, as well as the three essential main elements of health care practices, i.e. structure, process, and outcome (ESR 2011b and 2010, Patel 2010a and 2010b, Järvinen 2009, Donabedian 2005, Shaw 2003).

Procedures and performance should be examined in audits against agreed standards for high-quality medical radiological procedures. High-quality practice criteria should be the basis for assessments in all types of audits – external, internal or self-assessment. Currently high-quality practice criteria are available through local, European or international legislation, recommendations and publications by international and national professional societies, and peer-reviewed research (Soimakallio et al. 2011, ESR 2010). How familiar auditors are with these criteria is a problem and preliminary consensus is also required for treatment-specific criteria. On the other hand, clinical audits can be useful as benchmarking tools for improving criteria, but this requires background data from previous research and a common acceptance of criteria, against which clinical audit operations can be evaluated.

A clinical audit requires careful planning and scheduling, strong stakeholder commitment and involvement, openness, and transparency. A clinical audit project also requires a

significant investment of time, skill, and monetary resources. A clinical audit requires auditors with extensive knowledge and experience of the radiological practices under audit. High-quality clinical audits can provide objective evidence of quality improvements in patient care outcomes. This is possible only by the completion of the auditing cycles, which intend to improve clinical practices and the provision of services (Centonze 2011, Iqbal and Podikiti 2010, Merle et al. 2009). It must be realized that clinical and internal audits on their own are of little value. All audit reviews must be efficiently incorporated into a feedback system, which assesses audit outcomes, implements necessary changes, and improves the audited process. A re-audit is carried out to ensure process improvement.

6.2. Occupational radiation protection (III)

The use of radiation in medical applications and fluoroscopically-guided interventional procedures continues to increase, while occupational exposure levels associated with X-ray imaging procedures vary considerably, ranging from potentially negligible in chest X-rays to significant in complex interventional procedures. Interventional radiologists, cardiologists, and other interventional physicians are exposed to higher radiation levels than other personnel working with medical X-ray techniques. Fluoroscopic time varies considerably per procedure, from a few minutes to several hours. Employee dose per procedure ranged from a few µSv up to a few mSv. An interventional physician taking all appropriate radiation protection precautions is unlikely to be exposed to an effective dose exceeding 10 mSv/year, and the dose is most likely in the range of 1–4 mSv/year (Duran et al. 2012, Korir et al. 2012, Martin 2011b, Le Heron et al. 2010, Kuipers et al. 2010 and 2008, Häusler et al. 2009). Current occupational dose limits recommended by the ICRP (2007b), and mandated in the International Basic Safety Standards (IAEA 2011), are given in Table 4. The accumulated personal equivalent doses of 10 radiologists in our study exceeded 10 mSv during a five-year period. Each of these radiologists worked in angiography.

Table 4. Occupational Exposure Dose Limits.

Dose quantity	Occupational dose limit
Effective dose	20 mSv per year averaged over five consecutive years (100 mSv in 5 years)
Equivalent dose in:	
Lens of the eye	20 mSv per year, averaged over a predefined period of five years, with no single year exceeding 50 mSv
Skin[a]	500 mSv in a year
Extremities (hands and feet)	500 mSv in a year

[a]Averaged over 1 cm^2 of the most highly irradiated area of skin.

Simple methods for reducing or minimizing occupational radiation doses include minimizing fluoroscopy time and the number of acquired images, utilizing available patient dose reduction technologies, using protective shielding, using imaging equipment with performance controlled through a QAP, and wearing personal dosimeters to monitor exposure levels. The effective utilization of these methods requires both the appropriate education and training in radiation protection for all interventional personnel and the availability of appropriate protective tools and equipment. Regular reviews and investigation of personnel monitoring results, accompanied when appropriate by changes in procedural performance and utilizable equipment, will ensure the continual improvement of radiation protection practices in interventional radiography and angiography (Durán et al. 2012, Kesavachandranet et al. 2012, Le Heron et al. 2010).

International organizations have published recommendations for the quantities and units to be used in occupational dosimetry. National regulations provide specific requirements for personal dosimeters in interventional and clinical practices (Miller et al. 2010, ICRP 2007b, Radiation protection 116/2000). Category A employees include personnel liable to receiving effective doses higher than 6 mSv per year (Council directive 1996, Guide ST 1.6/2010). Occupational radiation exposure monitoring can currently be performed using TLDs and APDs. The strengths of APDs include real-time dose monitoring, dose rate information, accurate measurement at low doses, access to personal dose information, and direct recording of dose measurements into the database (Clairand et al. 2011 and 2008, Ginjaume 2011, Ginjaume et al. 2007, Borowski et al. 2010, Ankerhold et al. 2009).

The yearly accumulated average dose of most workers in our study was below 0.5 mSv, equivalent to the effective dose an average person receives from medical exposures per

year, while the annual accumulated natural background exposure level in Finland is 3.14 mSv (effective dose). We conclude that accumulated personal equivalent doses are generally very small, and only a few angiography radiologists are exposed to higher doses. A revised categorization of radiation works must be based on the working profile. Radiologists and other interventional physicians should belong to category A and use TLDs or APDs when working in radiative environments, such as angiography or interventional radiology. Other radiologists and all radiographers would be classified into category B, and their occupational monitoring can be implemented with group dosimeters using either APDs or TLDs.

6.3. Chest radiology report quality (IV)

Medical team radiologists help make diagnoses that aid in effective and concise patient management. Referring doctors are responsible for collecting diagnostic information that justifies the requested radiological examinations as well as information of previous exposures (ACR 2010, Akinola et al. 2010, Triantopolou et al. 2005). A radiology report should ideally address the needs of the referring clinician. Currently some organizations have issued guidelines for radiology reports. A typical radiology report follows the logical and inductive structure of a findings description, including relevant clinical information, a working diagnosis, and/or pertinent clinical signs and symptoms, and additionally the relevant question to be answered (Wallis and McCoubrie 2011, Akinola et al. 2010, ACR 2010, CAR 2010, Oswald et al. 2009, Berlin 2008, RCR 2006, ACR 2000). According to earlier studies a relevant question was posed in under half of the requests, and a probable clinical diagnosis was proposed in 18–63% of the requests (Akinola et al. 2010, Depasquale and Crockford 2005). 66% of the requests examined in our study included a relevant question, and radiologists nearly always addressed the question posed by referring physicians. This result is in line with previous studies.

A conclusion is the most important part of an imaging report and it should contain a differential diagnosis, or a definitive diagnosis when possible, and suggestions for further treatment or examination. The conclusion may be called a summary or an impression (Wallis and McCoubrie 2011, Cohen 2009, Sistrom et al. 2009, Lee et al. 2006, Cohen et al. 2006, Sistrom and Honeyman-Buck 2005, Ridley 2002, Hall 2000). According to Cohen (2009), a report conclusion is too frequently merely a restatement of the findings.

Cohen suggests that referring clinicians should not have to draw their own diagnostic conclusions from the radiologist's description of findings, as this should be done by the radiologist. On the other hand, it is acceptable that conclusions are not required in brief reports. A report of more than four lines should contain a conclusion (Wallis and McCoubrie 2011, Pool 2010). A study by Bosmans et al. (2009) found that between 14% and 100% of the CT reports in eight hospitals included a conclusion; the reports consisted of seven to 366 words. A study by Robert et al. (2006) found the mean word count in reports with separate conclusions to be 88 (range 26–190 words), while the mean word count in reports without separate conclusions was 86 words (range 34–133 words). No relationship was found between total report length and the presence of a conclusion. In our study 7% to 34% of the reports included a separate conclusion, depending on the radiologist, which is similar to those of earlier studies. The longest report consisted of 221 words, written by a chest radiologist, and the shortest report consisted of 10 words, and was written by a general radiologist. As in previous studies, our study found no correlation between report length and the existence of a separate conclusion.

The style of radiology reports varied greatly, but over time an ideal format has generally been accepted. However, report style is still influenced by the personal preferences and experiences of the radiologist (Bosmans et al. 2011 and 2009, Wallis and McCoubrie 2011). Brevity and clarity are important elements of imaging reports. The clarity of the written report depends on the ability of radiologists to convey their image interpretations and analyses and on how easily the reader can extract this information (Bosmans et al. 2011, Pool 2010, Sistrom et al. 2009). Report quality must be independent of the radiologist in question, and this can be evaluated using inter-observer agreement. The overall inter-observer agreement mean in a study by Xarier-Souza et al. (2012) was 79% and corresponding kappa values were good (0.72) for the presence of pneumonia. This study assessed the inter-observer agreement in the interpretation of several radiographic features in chest radiographs. The inter-observer agreement mean was 65% (change from 59% to 62%) and 91% (78%–97%) in Johnson and Kline (2010) and Stavem et al. (2004) respectively, but the corresponding kappa values were 0.48 (0.37–0.55) and 0.19 (0.03–0.28), respectively. Both studies had three pairs of observers. Inter-observer agreement between the initial and re-reported reports assessed by two radiologists was 66% in our study and the corresponding kappa value was fair (0.31). The reports were non-structured and contained varying amounts of information, which complicated result comparisons. Referring physicians face the same difficulties as radiologists when

comparing report contents. Further study on why inter-observer agreement was fair even when the initial reports were prepared by experienced radiologists and the same radiographs were re-reported by the chest radiologist is needed.

Unlike hospital clinicians, general practitioners (GPs) seldom meet radiologists to exchange views, and usually rely solely on the written radiology report. GPs use radiology reports for clinical decisions and informing patients and professional colleagues. GPs in Espeland and Berheim's study (2007) stated that high-quality referrals lead to better radiology reports. According to previous studies clinicians expect clear, accurate, and detailed reports including radiologists' comments, a conclusion of findings even for examinations with no specific findings, and recommendations for further imaging (Doğan et al. 2010, Grieve et al. 2010, Reiner 2010a, 2010b and 2009, Plumb et al. 2009, Espeland and Berheim 2007, Kundel and Polansky 2003). Using structured reports with common vocabulary and standardized language may facilitate the referring physicians' understanding of report content (Schwartz et al. 2011, Reiner 2010c, Pool 2010, Johnson et al. 2010a, Hall 2009, Kahn et al. 2009, Boland et al. 2008, Dunnick and Langlotz 2008, Weiss and Langlotz 2008). Voice recognition systems also offer the opportunity to create standardized, higher quality reports (Seto and Friedman 2012, Iyer et al. 2010).

Although phenomenal technologic advances have occurred in the generation and transmission of the written word through digital dictation and the Internet, the content and format of radiology reporting has changed very little since the first medical radiograph was produced (Flanders and Lakhani 2012). As face-to-face contact between referring physicians and radiologists has waned with the dissemination of enterprise imaging distribution systems, the quality of the written report has taken on even greater importance and the obligation to improve the product is more relevant today than it was in the past (Scharzt et al. 2011). All reports have three cardinal features: (1) content, (2) structure, and (3) style. Compromises in any of these features can produce substantial changes to report quality and have detrimental effects on communication with the clinician and on customer satisfaction (Flanders and Lakhani 2012). The prototypical radiology report is divided into six main sections: (1) title of examination, (2) relevant clinical history and indication, (3) technique, (4) comparison, (5) findings, and (6) conclusion / summary / impression (Wallis and McCoubrie 2011, ACR 2010). Comparing reports more frequently in university hospitals is important for educational value, to improve future report quality and radiological understanding (Sharpe et al. 2012).

6.4. Future prospects

Health care quality is important to patients and the government, which funds health services. Service audits are necessary to ensure coherent service provision and appropriate care which comply with accepted national and international standards, and to ensure staff adherence to professional standards (Salazar and Abujudeh 2012, Patel 2010a and 2010b). The new Health Care Act (1326/2010) of Finland requires public health care services to be based on evidence and high-quality practices. Public health care providers must formulate plans for QA and the execution of patient safety. The MSAH has issued a decree on QA and the execution of patient safety (Decree 341/2011*)*. QA plans define the responsibilities, procedures, and structures of QA and the execution of patient safety. Realization of the plan requires regular follow-up and the implementation of necessary improvements. All employees have the right and responsibility to maintain and develop their knowledge and skills, and to take part in additional training. The Association of Finnish Local and Regional Authorities has published the 'Quality Guide of Public Health Services' (2011) and the National Institute for Health and Welfare (THL) has published the 'Patient Safety Guide' (2011) to help execute these actions. These new recommendations and decrees concern the whole health care service sector, including radiology. This is a good start, although evaluation follow-up has not been determined.

A QAP and QC are required by regulatory authorities. QAP content must be evaluated systematically, keeping in mind: problems identification, the application of corrective measures, and the improvement of clinical guidelines. Audits and assessments must target the whole imaging process. They should be initiated as a joint decision by both directors and personnel, and executed as a continuous process rather than once every five years. Self-assessments or internal audits should be a continuous process in radiological departments, performed between external clinical audits. Self-assessments are designed to help individuals identify their skills as well as areas requiring further development. Assessment tools focusing on performance should be seen as a diagnostic test of overall competence. An assessment tool should aim to be as sensitive and specific as possible. Such tools are likely to be introduced into radiology training, and both trainee and consultant radiologists and the whole staff should familiarize themselves with

the concepts behind what is likely to become part of their working practice (ACHE 2011, Augustine et al. 2010).

QAPs should provide appropriate training for all personnel responsible for QA, and especially for those directly involved with QC testing and audit performance. A continuous education program is necessary for keeping personnel up-to-date, and to ensure that audits and assessments become a routine part of accepted clinical practices (ESR 2011c). Internal and external auditors should be competent, well-trained, and knowledgeable about the audited modalities and their appropriate criteria. It will be possible, in the future, to perform clinical audit as cross audits at least in university hospitals, making use of clinical audit in this way.

Audits should not be a simple administrative task, but a living and progressing pathway helping us develop more quality-focused daily work. The interval-based auditing process includes five stages: preparing for audit, criteria selection, data collection, implementation of changes, and re-auditing (Patel 2010a and 2010b, Faulkner et al. 2010, Vargha 2009). Future self-assessments should also address examination outcomes, including cost/benefit aspects, which are not easily verified during external audits or regulatory inspections (Nitrosi et al. 2009 and 2007, Blaivas and Lyon 2007, Clevert et al. 2007, Brem et al. 2006, Gazelle et al. 2005, Hollingworth 2005). Audits are required for evaluating current practices, but implementing necessary changes based on audit and assessment results is equally important (Apekey et al. 2011, Glickman et al. 2007).

Controlling the quality of equipment and audits is a routine element of radiology, but implementing the recommendations and re-auditing after implementation should also become a normal part of the process. Internal and external audits are time-consuming, require substantial effort and money, and should be cautiously undertaken to ensure the selection of appropriate standards and criteria for the audit. Audit and quality control results must be applied, and corrective and preventive actions (SFS-EN ISO 9001/2008) implemented to ensure patient and employee safety and high-quality patient care. Quality improvement must focus on structural change, processes and outcomes, but this is insufficient. Leadership, culture, and education are essential elements of quality.

Evaluation results help us identify improvement areas and begin process development. Improvement opportunities can be identified by heeding customer opinions. Customers of the imaging process include both the patients and clinicians ordering the imaging studies. The first step in an imaging process improvement project is identifying and prioritizing improvement opportunities to be found in the work process. The next step is forming an effective project team, including representatives of all process participants. An achievable aim must then be formulated, appropriate measures selected, and baseline data collected to determine how best to achieve the given aim. Plans are established and implemented using regular measurements and reviews, followed by necessary adjustments. These so-called PDCA (planning, doing, checking, and acting) cycles are repeated until the aim is achieved or modified and the project closed (Tamm et al. 2012, Johnson et al. 2010b). A new achievable aim must then be formulated, and a new process improvement project begun. The quality improvement auditing cycle is illustrated in Figure 3 (Faulkner et al. 2010, ESR 2010, IAEA 2010, Adam 2009).

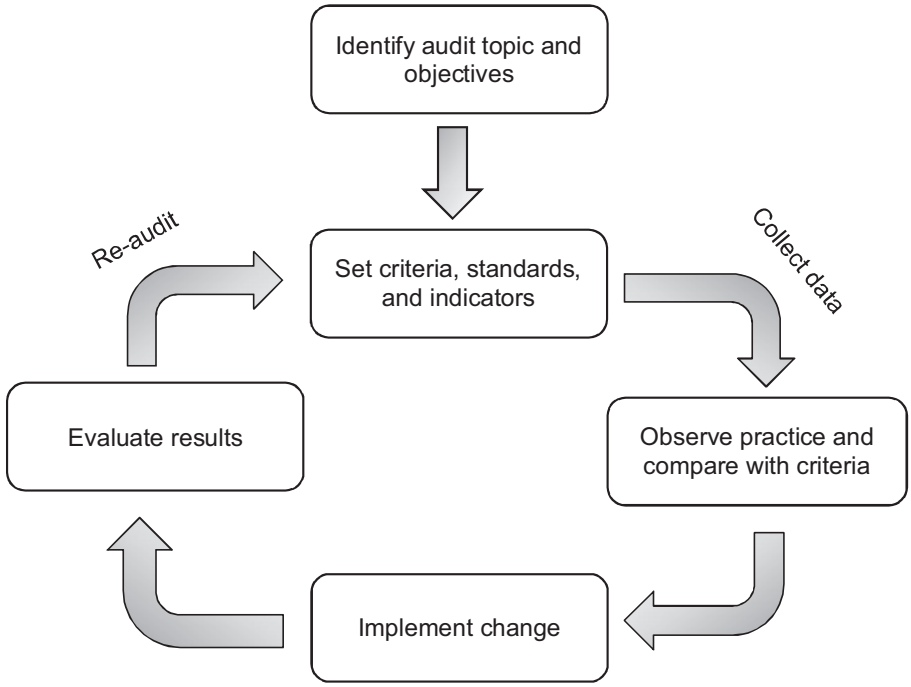

Figure 3. The audit cycle.

7. CONCLUSIONS

The effects and contents of clinical audits compared with regulatory inspections

Radiology departments have changed their working procedures according to observations and recommendations made during clinical audit. The development of the imaging process appears to have benefitted from clinical audits. Radiation utilization was in accordance with the requirements and standards of high-quality medical procedures at every audited unit during both evaluations. Audit criteria were satisfactorily fulfilled at the audited units during both runs, but were clearly improved during the second run. Recommendations made during the first run had largely been implemented by the second run. Clinical audits and regulatory inspections have partly addressed similar topics, and unnecessary overlaps were observed for some interest points. However, the emphasis of these two activities has been different: a broader and deeper view of clinical procedures was taken in comparison to high-quality clinical practice in clinical audits, while regulatory inspections mainly examined conformity to basic regulatory requirements.

Effective doses of radiation personnel

Accumulated personal equivalent doses were generally very small, with only a few angiography radiologists reporting higher doses. The highest effective dose per year was low compared to the mean dose received from natural background radiation. A revised categorization of radiation personnel in justified, to be based on the working profile of the radiologist and on observed accumulated doses. Occupational radiation exposure monitoring can be performed using either active APDs or passive TLDs. However, an active real-time dosimetry system is warranted for supporting radiation protection strategies where optimization aspects, including the improvement of working methods, are essential.

Chest radiology report quality

Radiological reports are the most important means of communication between radiologists and referring medical doctors. Radiologists mostly addressed the relevant question posed by the referring physician, but a separate conclusion was seldom included. Reports by the chest radiologist were longer and they issued more recommendations for further imaging compared to reports by general radiologists. Inter-observer agreement on chest radiographs was low because unstructured reports contained differing quantities of information. Variations in the structure and length of radiological reports implicate a need not only for guidelines and training, but also for local QAPs.

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REFERENCES

AAPM Report No. 74. Quality control in diagnostic radiology. Report of Task Group 12. American Association of Physicist in Medicine. 2002. [Accessed April 14th 2012]. Available from: http://www.cdphe.state.co.us/hm/rad/xray/aapmrpt74.pdf

AAPM Report 93. Acceptance testing and quality control of photostimulable storage phosphor imaging systems. Report of AAPM Task Group 10. American Association of Physicists in Medicine. 2006. [Accessed April 14th 2012]. Available from: http://www.cdphe.state.co.us/hm/rad/xray/aapmrpt93.pdf

ACHE Healthcare Executive. Competencies Assessment Tool 2012. A supplement to Healthcare Executive magazine 2011. [Accessed April 14th 2012]. Available from: http://www.ache.org/pdf/nonsecure/careers/competencies_booklet.pdf

ACR. The American College of Radiology. Practice guidelines for communication of diagnostic imaging findings. Communication Diagnostic Radiology:1–6. Revised 2010 (Resolution 11). [Accessed April 14th 2012]. Available from: http://www.acr.org/secondarymainmenucategories/quality_safety/guidelines/dx/comm_diag_rad.aspx

ACR, American Collage of Radiologists The ionising radiation (medical exposure) regulations 2000, with supplementary guidance on good practice. Statutory Instrument No.1059, 2000. [Accessed April 14th 2012]. Available from: http://www.legislation.gov.uk/uksi/2000/1059/pdfs/uksi_20001059_en.pdf

Act on Criteria for Charges Payable to the State. 150/1992.

Adam J. Guide to carrying out an audit project. What is clinical audit, and who should do it? Imaging Management 9:16–18, 2009.

Akinola R, Wright K, Orogbemi O. Radiology request forms: are they adequately filled by clinicians? Int J Radiol 12:1–15, 2010.

Amis ES, Butler PF, Applegate KE, Birnbaum SB, Brateman LF, Hevezi JM, Mettler FA, Morin RL, Pentecost MJ, Smith GG, Strauss KJ, Zeman RK. American College of Radiology White Paper on radiation dose in medicine. J AM Coll Radiol 4:272–284, 2007.

Ankerhold U, Hupe O, Ambrosi P. Deficiencies of active electronic radiation protection dosemeters in pulsed fields. Radiat Prot Dosim 135:149–153, 2009.

Apekey T, McSorley G, Tilling M, Siriwardena AN. Room for improvement? Leadership, innovation culture and uptake of quality improvement methods in general practice. J Eval Clin Pract 17:311–318, 2011.

Augustine K, McCoubrie P, Wikinson JR, McKnight L. Workplace-based assessment in radiology -where to now? Clinical Radiology 65:325–332, 2010.

Bauhs J, Vrieze T, Primark A, Bruesewitz M, McCollough G. CT Dosimetry: Comparison of measurement techniques and devices. RadioGraphics 28:245–253, 2008.

Berlin L. Communicating the harmful effects of radiation exposure from medical imaging: malpractice considerations. Health Phys 101:583–588, 2011.

Berlin L. Standards for radiology interpretation and reporting in the emergency setting. Pediatr Radiol 38:S639–644, 2008.

Blaivas M, Lyon M. Frequency of radiology self-referral in abdominal computed tomographic scans and the implied cost. Am J Emerg Med 25:396–399, 2007.

Boland G, Guomataes A, Mueller P. Radiology report turnaround: expectations and solutions. Eur Radiol 18:1326–1328, 2008.

Boone J, Nelson T, Lindfors K, Seibert J. Dedicated breast CT: Radiation dose and image quality evaluation. Radiology 221:657–667, 2001.

Borowski M, Poppe B, Looe HK, von Boetticher H. Is it really not possible to use electronic personal dosemeters in clinical exposure situations? Fortschr Röntgenstr 182:773–779, 2010.

Bosmans J, Weyler J, De Schepper A, Parizel P. The radiology report as seen by radiologists and referring clinicians: Results of the cover and rover surveys. Radiology 259:184–195, 2011.

Bosmans J, Weyler J, Parizel P. Structure and content of radiology reports, a quantitative and qualitative study in eight medical centers. Eur J Radiol 72:354–358, 2009.

Brem MH, Böhner C, Brenning A, Gelse K, Radkow T, Blanke M, Schlechtweg PM, Neumann G, Wu IY, Bautz W, Hennig FF, Richter H. Evaluation of low-cost computer monitors for the detection of cervical spine injuries in the emergency room: an observer confidence-based study. Emerg Med J 23:850–853, 2006.

Brenner DJ, Hricak H. Radiation exposure from medical imaging. Time to regulate? Jama 304:208–209, 2010.

Callahan MJ. CT dose reduction in practice. Pediatr Radiol 41:S488–S492, 2011.

CAR, Canadian association of Radiologists. Standard for communication of diagnostic Imaging Findings. 2010. [Accessed April 14th 2012]. Available from: http://www.car.ca/uploads/standards%20guidelines/20101125_en_standard_communication_di_findings.pdf

CAR, Canadian association of Radiologists. Diagnostic Imaging Referral Guideline. 2012 [Accessed March 4th 2013]. Available from: http://www.car.ca/en/standards-guidelines/guidelines.aspx

Centonze M. Clinical audits: the European Society of radiology perspective. J Am Coll Radiol 8:438–442, 2011.

Charnock P, Jones R, Fazakerley J, Wilde R, Dunn AF. A preliminary study into performing routine tube output and automatic exposure control quality assurance using radiology information system data. Radiat Prot Dosim 147:215–219, 2011.

Chera BS, Jackson M, Mazur L M, Adams R, Chang S, Deschesne K, Cullip T, Marks LB. Improving quality of patient care by improving daily practice in radiation oncology. Samin Radiat Oncol 22:77–85, 2012.

Clairand I, Bordy J-M, Daures J, Debroas J, Denozière M, Donadille L, Ginjaume M, Itié C, Koukorava C, Krim S, Lebacq A-L, Martin P, Struelens L, Sans-Mercé M, Tosic M, Vanhavere F. Active personal dosemeters in interventional radiology: Tests in laboratory conditions and in hospitals. Radiat Prot Dosim 144:453–458, 2011.

Clairand I, Struelens L, Bordy J-M, Daures J, Debroas J, Denozière M, Donadille L, Gouriou J, Itié C, Vaz P, d'Errico F. Intercomparison of active personal dosemeters in interventional radiology. Radiat Prot Dosim 129:340–345, 2008.

Clevert D-A, Stikel M, Jung EM, Reiser M, Rupp N. Cost analysis in interventional radiology – A tool to optimize management costs. Eur J Radiol 61:144–149, 2007.

Coakley FV, Gould R, Yeh BM, Arenson RL. CT radiation dose: What can you do right now in your practice? AM J Roentgenol 196:219–225, 2011.

Cohen M. Content of a radiology report. Pediatr Radiol 39:1254–1254, 2009.

Cohen MD, Curtin S, Lee R. Evaluation of quality of radiology requisition for intensive care unit patients. Acad Radiol 13:236–240, 2006.

Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. European Commission. OJ L 180:22–27, 1997.

Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. European Commission. OJ L 159:1-114,1996.

Decision 11/3020/2011. Reference levels for the patient's radiation exposure for conventional X-ray examinations of adults. STUK. 8 November 2011. [Accessed April 14th 2012]. Available from: http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/en_GB/stohjeet/_files/87026717054403972/default/Decision-11-3020-2011.pdf

Decision 19/310/06. Reference levels for the patient's radiation exposure for computer tomography examinations of adults. STUK 27 March 2007. [Accessed April 14th 2012].]. Available from: http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/fi_FI/stohjeet/_files/85769141820197242/default/Paatos-vertailutasot_TT_27032007.pdf (in Finnish)

Decision 27/310/05. Reference levels for the patient's radiation exposure for cardiology radiology. STUK 28 December 2005a. [Accessed April 13th 2012]. Available from: http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/fi_FI/stohjeet/_files/85769141816396151/default/Paatos-pdf-Potilaan_sateilyaltistuksen_vertailutasot_kardiologisessa_radiologiassa_paatos_ja_ohje.pdf (in Finnish)

Decision 26/310/05. Reference levels for the patient's radiation exposure for X-ray examinations of children. STUK 28 December 2005b. [Accessed April 14th 2012]. Available from:

http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/fi_FI/stohjeet/_files/85769141815216502/default/Paatos-pdf-Potilaan_sateilyaltistuksen_vertailutasot_lasten_rontgentutkimuksissa_paatos_ja_ohje.pdf (in Finnish)

Decision by the Ministry of Social Affairs and Health regarding charges and grounds for payment. 580/1993. (In Finnish)

Decree 423/2000. Decree of the Ministry of Social Affairs and Health on the medical use of radiation 10.5.2000.

Decree by the Ministry of Social Affairs and Health regarding for quality assurance and execution of patient safety program. 341/2011. (In Finnish)

Department of Health. Guidance on the establishment and use of diagnostic reference levels (DRLs). 2007. [Accessed August 15th 2012]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074067

Department of Health. The ionising radiation (medical exposure) regulations, with supplementary guidance on good practice, Statutory Instrument No. 1059. 2000. [Accessed April 14th 2012]. Available from: http://www.legislation.gov.uk/uksi/2000/1059/pdfs/uksi_20001059_en.pdf

Depasquale R, Crockford M. Are radiology request forms adequately filled In? An Audit Assessing Local Practice. Malta Medical Journal 17:36–38, 2005.

Dimitriou P, Kamenopoulou V. Education and training issues in individual monitoring of ionizing radiation. Radiat Prot Dosim 144:588–591, 2011.

Doğan N, Varlibas N, Erpolat Ö. Radiological report: expectations of clinicians. Diagn Interv Radiol 16:179–185, 2010.

Donabedian A. Evaluating the quality of medical care. The Milbank Quarterly 83:691–729, 2005.

Draft Appendix 1: Summary of regulatory frameworks in the EU Member States. International Workshop on Clinical Audi. Book of abstracts and general information. Tampere 7–10.9.2008. Available from: www.clinicalaudit.net.

Draft Appendix 2: Summary of problems in the implementation of clinical audits. International Workshop on Clinical Audit. Book of abstracts and general information. Tampere 7–10.9.2008. Available from: www.clinicalaudit.net.

Dunnick N, Langlotz C. The radiology report of the future: A summary of the 2007 Intersociety conference. J Am Coll Radiol 5:626–629, 2008.

Durán A, Hian SK, Miller DL, Le Heron J, Padovani R, Vano E. A Summary of recommendations for occupational radiation protection in interventional cardiology. Cathetr Cardiovasc Interv 81:562–567, 2013.

EC, European Commission. European guidelines on quality criteria for diagnostic radiographic images. EUR 16260. Luxembourg: European Commission, 1996a.

EC, European Commission. European guidelines on quality criteria for diagnostic radiographic images in paediatrics. EUR 16261. Luxembourg: European Commission, 1996b.

Edmonds KD. Diagnostic reference levels as a quality assurance tool. The Radiographer 56:32–37, 2009.

Espeland A, Baerheim A. General practitioners' views on radiology reports of plain radiography for back pain. Scand J Prim Health Care 25:15–19, 2007.

ESR, European Society of Radiology. Good practice for radiological reporting. Guidelines from the European Society of Radiology. Insights Imaging 2:93–96, 2011a.

ESR, European Society of Radiology. European commission guidelines for clinical audit: statement by the European society of radiology. Insight imaging 2:97–98, 2011b.

ESR, European Society of Radiology. Is the radiological community within Europe ready for audit? Insight Imaging 2:375–377, 2011c.

ESR, European Society of Radiology. Clinical audit – ESR perspective. Insight Imaging 1: 21–26, 2010.

Faulkner K, Järvinen H, Butler P, McLean I. D, Pentecost M, Rickard M, Abdullad B. A clinical audit programme for diagnostic radiology: The approach adopted by the international atomic energy agency. Radiat Prot Dosim 139:418–421, 2010.

Fazakerley J, Charnock P, Wilde R, Jones R, Ward M. Application of a statistical software package for analysis of large patient dose data sets obtained from RIS. Radiat Prot Dosim 139:455–458, 2010.

Finnish advisory committee for clinical audit. [Accessed April 15th 2012].]. Available from: http://www.clinicalaudit.net/index_eng.html

Flanders AE, Lakhani P. Radiology reporting and communications: a look forward. Neuroimaging Clin N Am 22:477–496, 2012.

Gazelle G, McMahon P, Siebert U, Beinfeld M. Cost-effectiveness analysis in the assessment of diagnostic imaging technologies. Radiology 235:361–370, 2005.

Gerbic P, Stacey E. A purposive approach to content analysis: designing analytical frameworks. Internet and Higher Education 8: 45–59, 2005.

Ginjaume M. Performance and approval procedures for active personal dosemeters. Radiat Prot Dosim 144:144–149, 2011.

Ginjaume M, Bolognese-Milsztajn T, Luszik-Bhadra M, Vanhavere F, Wahl W, Weeks A. Overview of active personal dosimeters for individual monitoring in the European union. Radiat Prot Dosim 125:261–266, 2007.

Glickman SW, Baggett KA, Krubert CG, Peterson ED, Schulman KA. Promoting quality: the health-care organization from a management perspective. Int J Qual Health C 19:341–348, 2007.

Grewal RK, Young N, Collins L, Karunaratne N, Sabharwal R. Digital chest radiography image quality assessment with dose reduction. Australas Phys Eng Sci Med 35:71–80, 2012.

Grieve F, Plumb A, Khan S. Radiology reporting: a general practitioner's perspective. Br J Radiol 83:17–22, 2010.

Guide ST 1.1 / 23 May 2005. Safety fundamentals in radiation practices. Helsinki 2005.

Guide ST 1.6 / 10 December 2009. Operational radiation safety. Radiation and nuclear safety authority. Helsinki 2010.

Guide ST 1.7 / 10 December 2012. Radiation protection training in health care. Radiation and nuclear safety authority. Helsinki 2012.

Guide ST 1.8 / 17 February 2012. Qualifications of persons working in radiation user's organization and radiation protection training. Radiation and nuclear safety authority. Helsinki 2012.

Guide 7.1 / 2 August 2007. Monitoring of radiation exposure. Radiation and nuclear safety authority. Helsinki 2007.

Guide St 7.4 / 9 September 2008. The dose register and data reporting. Radiation and nuclear safety authority. Helsinki 2008.

Hall F. The radiology report of the future. Radiology 251:313–316, 2009.

Hall F. Language of the radiology report: primer for residents and wayward radiologists. AM J Roentgenol 175:1239–1242, 2000.

Hart D, Hillier M. C, Wall B. F. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. Br J Radiol 82:1–12; 2009.

Health Care Act. 1326/2010. Issued in Helsinki on 30 December 2010.

Hollingworth W. Radiology cost and outcomes studies: Standard practice and emerging methods. Am J Roentgenol 185:833–839, 2005.

Hsieh H-F, Shannon S. Three approaches to qualitative content analysis. Qualitative Health Research 15:1277–1288, 2005.

Häusler U, Czarwinski R, Brix G. Radiation exposure of medical staff from interventional procedures: a multicenter study. Eur Radiol 19:2000–2008, 2009.

IAEA. Radiation protection and safety of radiation sources: International Basic Safety Standards. No. GSR Part 3. International Aatomic Energy Agency. Vienna, 1–303, 2011. [Accessed April 8th 2012]. Available from: http://www-pub.iaea.org/MTCD/Publications/PDF/p1531interim_web.pdf

IAEA Human Health Series No. 4. Comprehensive clinical audits of diagnostic radiology practices: a tool for quality improvement quality assurance audit for diagnostic radiology improvement and learning (QUAADRIL). International Atomic Energy Agency Vienna, 1–209, 2010. [Accessed April 8th 2012]. Available from: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1425_web.pdf

IAEA, International Atomic Energy Agency. Legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety. Safety Standards Series No. GS-R-1. IAEA, Vienna 1–36, 2000. [Accessed April 8th 2012]. Available from: http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1093_scr.pdf

IAEA, International Atomic Energy Agency. Guidelines for clinical audits of diagnostic radiology practices: A tool for quality improvement. IAEA, Vienna 2009.

IAEA-TECDOC-1526. Inspection of radiation sources and regulatory enforcement. (Supplement to IAEA Safety Standards Series No. GS-G-1.5) IAEA, Vienna 2007. [Accessed April 8th 2012]. Available from:

http://www-pub.iaea.org/MTCD/publications/PDF/te_1526_web.pdf

ICRP. International Commission on Radiological Protection. Managing patient dose in Multi-Detector Computed Tomography (MDCT). Publication 102. Ann ICRP 37:1-80, 2007a.

ICRP. International Commission on Radiation Protection. Radiation protection in medicine. Publication 105. Ann ICRP 37:1–63, 2007b.

ICRP. International Commission on Radiation Protection. Managing patient dose in digital radiology. Publication 93. Ann ICRP 34:1–73, 2004.

ICRP. Reference levels in medical imaging: review and additional advice. Supporting Guidance 2. Ann ICRP 31:33–52, 2001.

Inspections of use of radiation. [Accessed April 8th 2012]. Available from: http://www.stuk.fi/sateilyn_kaytto/valvonta/en_GB/tarkastukset/ (In Finnish)

IPEM. Recommended standards for the routine performance testing of diagnostic X-ray imaging systems. Report No. 91. The Institute of Physics and Engineering in Medicine. 1–112, 2005.

IPEM. Guidance on the establishment and use of diagnostic reference levels for medical X-ray examinations. Report No. 88. The Institute of Physics and Engineering in Medicine. 1–44, 2004.

Iqbal H.J, Pidikiti P. Audit of orthopaedic audits in an English teaching hospital: Are we closing the loop? Open Orthopaedics J 4:188–192, 2010.

Iyer VR, Hahn PF, Blaszkowsky LS, Thayer SP, Halpern EF, Harisinghani MG. Added value of selected images embedded into radiology reports to referring clinicians. J Am Coll Radiol 7:205–210, 2010.

Jarritt P, Perkins A, Woods S. Audit of nuclear medicine scientific and technical standards. Nuc Med Commun 25:771–775, 2004.

Johnson CD, Miranda R, Osborn HH, Miller JM, Prescott SL, Aakre KT, KreckeKN, Broderick DF. Designing a safer radiology department. Am J Roentgenol 298:398–404, 2012.

Johnson A, Chen M, Zapadka M, Lyders E, Littenberg B. Radiology Report Clarity: A cohort study of structured reporting compared with conventional dictation. J Am Coll Radiol 7:501–506, 2010a.

Johnson CD, Miranda R, Aakre KT, Roberts CC, Patel MD, Krecke KN. Process improvement: What is it, Why is it important, and How is it done? Health Care Policy and Quality. Clinical Perspective. Am J Roentgenol 194:461–468, 2010b.

Johnson J, Kline JA. Intraobserver and interobserver agreement of the interpretation of pediatric chest radiographs. Emerg Radiol 17:285–290, 2010.

Järvinen H. Clinical audit in the European Union. Bridging the cap between guidelines and implementation. Imaging Management 9:14–6, 2009.

Kahn C, Langlotz C, Burnside E, Carriro J, Channin D, Hovsepian D, Rubin D. Toward best practices in radiology reporting. Radiology 252:852–856, 2009.

Kanal K, Stewart B, Kolokythas O, Shuman W. Impact of operator-selected image noise index and reconstruction slice thickness on patient radiation dose in 64-MDCT. AM J Roentgenol 189:219–225, 2007.

Kesavachandran CN, Haamann F, Nienhaus A. Radiation exposure of eyes, thyroid gland and hands in orthopaedic staff: a systematic review. Eur J Med Res. 2012 Oct 30;17:28. doi: 10.1186/2047-783X-17-28.[PubMed - in process]

Kim KP, Miller DL, de Gonzalez AB, Balter S, Kleinerman RA, Ostroumova E, Simon SL, Linet MS. Occupational radiation doses to operators performing fluoroscopically-guided procedures**.** Health Phys 103:80–99, 2012.

Korir GK, Ochieng BO, Wambani JS, Korir IK, Jowi CY. Radiation exposure in interventional procedures. Radiat Prot Dosim 152:339–344, 2012.

Kruskal JB, Eisenberg R, Sosna J, Sham Yam C, Kruskal JD, Boiselle PM. Quality initiatives.quality improvement in radiology: Basic principles and tools required to achieve success. RadioGraphics 31:1499–1509, 2011.

Kruskal J, Anderson S, Yam C, Sosna J. Qaulity Initiatives. Strategies for establishing a comprehensive quality and performance improvement program in a radiology department. RadioGraphics 29:315–329, 2009.

Kuipers G, Velders XL, Piek JJ. Exposure of cardiologists from interventional procedures. Radiat Prot Dosim 140:259–265, 2010.

Kuipers G, Velders XL, de Winter RJ, Reekers JA, Piek JJ. Evaluation of the occupational doses of interventional radiologists. Cardiovasc Intervent Radiol 31:483–489, 2008.

Kundel H, Polansky M. Measurement of observer agreement. Radiology 228:303–308, 2003.

Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 33:159–174, 1977.

Lau LS, Pérez MR, Applegate KE, Rehani MM, Ringertz HG, George R. Global Quality Imaging: Improvement Actions. J Am Coll Radiol 8:330–334, 2011.

Lau LS. Leadership and management in quality radiology. Biomedical Imaging and Interventional Journal 3:e21: 1-7, 2007. [Accessed April 8th 2012]. Available from: http://www.biij.org/2007/3/e21/e21.pdf

Lee R, Cohen MD, Jennings GS. A new method of evaluating the quality of radiology reports. Acad Radiol 13:241–248, 2006.

Le Heron J, Padovani R, Smith I, Czarwinski R. Radiation protection of medical staff. Eur J Radiol 76: 20–23, 2010.

Lessa PS, Caous CA, Arantes PR, Amaro E Jr, Campello de Souza F. Decision theory applied to image quality control in radiology. BMC Med Inform Decis 8:51, 2008.

Maree G, Irving B, Hering E. Paediatric dose measurement in a full-body digital radiography unit. Pediatr Radiol 37:990–997, 2007.

Martin CJ. Management patient dose in radiology in the UK. Radiat Prot Dosim 147:355–372, 2011a.

Martin CJ. Personal dosimetry for interventional operator: when and how should monitoring be done. Br J Radiol 84:639–648, 2011b.

McCollough CH. Diagnosticreference levels.Copuright © 2010 American College of Radiology. www.imagewisely.org. November 2010.

Merle V, Moret L, Pidhorz L, Dujardin F, Gouin F, Josset V, Graveleau S, Petit J, Riou F, Lombrail P, Zernichow P. Does comparison of performance lead to better care? A pilot observational study in patients admitted for hip fracture in three French public hospitals. Int J Qual Health Care 21:321–329, 2009.

Miller DL, Vañó E, Bartal G, Balter S, Dixon R, Padovani R, Schueler B, Cardella JF, de Baère T. Occupational radiation protection in interventional radiology: A joint guideline of the Cardiovascular and Interventional Radiology society of Europe and the Society of Interventional Radiology. Cardiovasc Intervent Radiol 33: 230–239, 2010.

Moores B M, Charnock P, Ward M. Web-based tools for quality assurance and radiation protection in diagnostic radiology. Radiat Prot Dosim 139:422–429, 2010.

Moores B. Radiation safety management in health care – The application of quality function deployment. Radiography 12:291–304, 2006.

Muhogora WE, Ahmed NA, Beganovic A, Benider A, Ciraj-Bjelac O, Gershan V, Gershkevitsh E, Grupetta E, Kharita MH, Manatrakul N, Milakovic M, Ohno K, Omrane LB, Ptacek J, Schandorf C, Shabaan MS, Stoyanow D, Toutaoui N, Wanbani JS, Rehani MM. Patient doses in CT examinations in 18 countries: initial results from International Atomic Energy Agency projects. Radiat Prot Dosim 136:118–126, 2009.

National Institute of Clinical Excellence. Principles of best practice in clinical audit. National Institute for Clinical Excellence, 2002. [Accessed November 2nd 2012]. Available from: http://www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf

Nickoloff E, Alderson P. A comparative study of thoracic radiation doses from 64-slice cardiac CT. Br J Radiol 80:537–544, 2007.

Nitrosi A, Bertolini M, Borasi G, Botti A, Barani A, Rivetti S, Pierotti L. Application of QC-DR software for acceptance testing and routine quality control of direct digital radiography systems: Initial experiences using the Italian Association of Physicist in medicine quality control protocol. J Digit Imaging 6:656–666, 2009.

Nitrosi A, Borasi G, Nicoli F, Modigliani G, Botti A, Bertolini M. A filmless radiology department in a full digital regional hospital: Quantitative evaluation of the increased quality and efficiency. J Digit Imaging 20:140–148, 2007.

Oswal D, Sapherson D, Rehman A. A study of adequacy of completion of radiology request forms. Radiology 15:209–213, 2009.

Pantos I, Thalassinou S, Argentos S, Kelekis NL, Panayiotakis G, Efstathopoulos EP. Adult patient radiation doses from non-cardiac CT examinations: a review of published results. Br J Radiol 84:293–303, 2011.

Patient safety guide. National Institute for Health and Welfare. ISBN 978-952-245-481-2. Helsinki 2011.

Patel S. Identifying best practice principles of audit in health care. Nursing Standard 24:40–48, 2010a.

Patel S. Achieving quality assurance through clinical audit. Nursing Management 17:28–34, 2010b.

Petrucci C. Assessment of the effective dose to personnel in interventional radiology: a review of methods. Radioprotection 43:35–52, 2008.

Plumb AA, Grieve FM, Khan SH. Survey of hospital clinicians' preferences regarding the format of radiology reports. Clin Radiol 64:386–394, 2009.

Pool F. Quality of the written radiology report: a review of the literature. J Am Coll Radiol 7:634–643, 2010.

Public health act 1326/30.12.2010. (In Finnish)

Quality guide of public health service. Kuntaliitto. 1. painos Helsinki 2011. (In Finnish)

Radiation Act 27.3.1991/592 and change 23.12.1998/1142.

Radiation Decree 20.12.1991/1512 and change 23.12.1998/1143

Radiation protection 109. Guidance on diagnostic reference levels (DRLs) for medical exposure. European Commission. 1999. [Accessed May 31st 2012]. Available from: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/109_en.pdf

Radiation protection 116. Guidelines on education and training in radiation protection for medical exposures. Luxembourg: European Commission. Directorate-General for the Environment, 2000. [Accessed May 31st 2012]. Available from: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/116.pdf

Radiation protection 118. Update Mars 2008. Referral guidelines for imaging. Directorate-General for Energy and Transport. Directorate H — Nuclear Energy. Unit H.4 — Radiation Protection. 2007. [Accessed May 31st 2012]. Available from: http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_update_en.pdf

Radiation protection 159. European commission guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy). European Commission. 2009. [Accessed May 31st, 2012]. Available from: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/159.pdf

Rantanen E (toim.). Säteilyn käyttö ja muu säteilylle altistava toiminta. STUK-B 131. Vuosiraportti 2010. Helsinki 2011. [Accessed April 14th 2012]. Available from: http://www.stuk.fi/julkaisut_maaraykset/tiivistelmat/b_sarja/fi_FI/stuk-b131/_files/85650577522820247/default/stuk-b131-nettiin.pdf (In Finnish)

RCR, Royal College of Radiologists. Peer review: guidance on the use of double reporting. London: The Royal College of Radiologists 2010. [Accessed November 29th 2012]. Available from: http://www.rcr.ac.uk/docs/radiology/pdf/BFCR%2810%291_peer_review.pdf

RCR, Royal College of Radiologists. Standards for the reporting and interpretation of imaging investigations. The Royal College of Radiologists 2006. [Accessed May 31st 2012]. Available from: http://www.rcr.ac.uk/docs/radiology/pdf/StandardsforReportingandInetrpwebvers.pdf

RCR, Royal College of Radiologists. Individual Responsibilities – A Guide to Good Medical Practice for Radiologists. The Royal College of Radiologists 2003. [Accessed November 29th 2012]. Available from: http://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=193

Reiner BI. Quantifying radiation safety and quality in medical imaging, part 4: The medical imaging agent scorecard. J Am Coll Radiol 7:120–124, 2010a.

Reiner B. Uncovering and improving upon the inherent deficiencies of radiology reporting through data mining. J Digit Imaging 23:109–118, 2010b.

Reiner BI. Customization of Medical Report Data. J Digit Imaging 4:363–373, 2010c.

Reiner BI. The Challenges, opportunities, and imperative of structured reporting in medical imaging. J Digit Imaging 22:562–568, 2009.

Requirements during the use of radiation devices. [Accessed April 18th 2012]. Available from: http://www.stuk.fi/sateilyn_kaytto/kayttovaatimukset/en_GB/kaytonaikaisetvaatimukset/ (In Finnish)

Ridley L. J. Guide to the radiology report. Aust Radiol 46:366–369, 2002.

Robert L, Cohen M, Jennings G. A new method of evaluation the quality of radiology reports. Acad Radiol 13:241–248, 2006.

Rubin DL. Informatics in radiology. Measuring and improving quality in radiology: Meeting the challenge with informatics. RadioGraphics 31:1511–1527, 2011.

Ryall CJ, Barter S, Duncan KA, Lumb P. AuditLive–A national radiology audit template library–the UK experience. International Workshop on Clinical Audit, Tampere 7–10.9.2008.

Salazar GM, Abujudeh H. Quality assurance in interventional radiology. AM J Roentgenol 199:W441–W443, 2012.

Sánchez RM, Vano E, Fernández JM, Rosales F, Sotil J, Carrera F, García MA, Soler MM, Hernández-Armas J, Martínez LC, Verdú JF. Staff doses in interventional radiology: a national survey. J Vasc Interv Radiol 23:1496–1501, 2012.

Sanchez R M, Vano E, Fernández JM, Gallego JJ. Staff radiation doses in a real-time display inside the angiography room. Cardiovasc Intervent Radiol 33, 1210–1214, 2010.

Sandborg M, Nilsson J, Gustafsson A. Efficient quality assurance programs in radiology and nuclear medicine in Östergötland, Sweden. Radiat Prot Dosim 139:410–417, 2010.

Schreiner-Karoussou A. Review of image quality standards to control digital x-ray systems. Radiat Prot Dosim 117:23–25, 2005.

Schwartz LH, Panicek DM, Berk AR, Li Y, Hricak H. Improving communication of diagnostic radiology findings through structured reporting. Radiology 260:174–181, 2011.

Seto B, Friedman C. Moving toward multimedia electronic health records: how do we get there? J Am Med Inform Assoc 19:503–505, 2012.

SFS-EN ISO 9001. Quality management systems. Reguirements. Finnish Standards Association SFS. 2008.

Sharpe RE, Surrey D, Gorniak RJT, Nazarian L, Rao VM, Flandes AE. Radiology report comparator: a novel method to augment resident education. J Digit Imaging 25:330–336, 2012.

Shaw C. Experiences on clinical audit in the UK. International symposium on practical implementation of clinical audit for exposure to radiation in medical practices. Tampere, Finland 82–85, 2003.

Shortt K, Davidsson L, Hendry J, Dondi M, Andreo P. International perspectives on quality assurance and new techniques in radiation medicine: outcomes of an IAEA conference. Int J Radiation Oncology Biol Phys 71:S80–84, 2008.

Sistrom CL, Dreyer KJ, Dang PP, Weilburg JB, Boland GW, Rosenthal DI, Thrall JH. Recommendations for additional imaging in radiology reports. Multifactorial analysi of 5.9 million examinations. Radiology 253:453–461, 2009.

Sistrom CL, Honeyman-Buck J. Free text versus structured format: information transfer efficiency of radiology reports. AM J Roentgenol 185:804–812, 2005.

Soimakallio S, Alanen A, Järvinen H, Ahonen A, Ceder K, Lyyra-Laitinen T, Paunio M, Sinervo T, Wigren T. Clinical audit: development of the criteria of good practices. Radiat Prot Dosim 147:30–33, 2011.

Soimakallio S. Implementing external clinical audits in radiological practices. The experience in Finland. Imaging Management 9:19–20, 2009.

Sources and effects of ionizing radiation. United Nations Scientific Committee on the Effects of Atomic Radiation. Unscear 2008. Report to the general Assembly with Scientific Annexes. Volume 1. United Nations, New York, 7–9, 2010. [Accessed May 31st 2012]. Available from: www.unscear.org/docs/reports/2008/09-86753_Report_2008_GA_Report_corr2.pdf

Spottswood S, Liaw K, Hermanz-Schulman M A, Milmes M, Moore PE, Patterson B, Chen H, Kan JH. The clinical impact of the radiology report in wheezingans nonwheezing febrile children: a survey of clinicians. Pediatr Radiol 39:348–353, 2009.

Stavem K, Foss T, Botnmark O, Andersen O, Erikssen J. Inter-observer agreement in audit of quality of radiology requests and reports. Clin Radiol 59:1018–1024, 2004.

Swinson S, Tapp M, Brindley R, Chapman S, Offiah A, Johson K. An audit of skeletal surveys for suspected non-accidental injury following publication of the British Society of Paediatric Radiology guidelines. Clin Radiol 63:651–656, 2008.

Tamm EP, Szklaruk J, Puthooran L, Stevens BL, Modaro C. Quality Initiatives. Planning, setting up, and carrying out radiology process improvement projects.

RadioGraphics 32:1529–1542, 2012.

Tonkopi E, Daniels C, Gale MJ, Schofield S.C, Sorhaindo VA, Vanlarkin JL. Local diagnostic reference levels for typical radiographic procedures. Can Assoc Radiol J 63:237–241, 2012.

Treier R, Aroua A, Verdun FR, Samara E, Stuessi A, Trueb PhR. Patient doses in CT eximinations in Switzerland: implemententation of national diagnostic reference levels. Radiat Prot Dosim 142:244–252, 2010.

Triantopoulou C, Tsalafoutas I, Maniatis P, Papavdis D, Raios G, Siafas I, Velonakis S, Koulentuanos E. Analysis of radiological examination request forms in conjunction with justification of X-ray exposures. Eur J Radiol 53:306–311, 2005.

Uberoi R, Milburn S, Moss J, Gaines P. British Society of Interventional Radiology Iliac Artery Angioplasty-Stent Registry III. Cardiovasc Intervent Radiol 32:887–895, 2009.

Vano E. Global view on radiation protection in medicine. Radiat Prot Dosim 147:3–7, 2011.

Vano E, Sanches R, Fernandez JM, Gallego JJ, Verdu JF, Gonzalez de Garay M, Azpiazu A, Segarra A, Hernandez MT, Canis M, Diaz F, Moreno F, Palmero J. Patient dose reference levels for interventional radiology: A national approach. Cardiovasc Intervent Radiol 32:19–24, 2009.

Vargha A. Harmonising clinical audit in European diagnostic radiology. What needs to be done to improve uptake? Imaging Management 9:22, 2009.

Vassileva J. A phantom for dose-image quality optimization in chest radiography. Br J Radiol 75:837–842, 2002.

Wallis A, McCoubrie P. The radiology report: Are we getting the message across? Clin Radiol 66:1015–1022, 2011.

Weiss D, Langlotz C. Structured reporting: Patient care enhancement or productivity nightmare? Radiology 249:739–747, 2008.

Wilde R, Charnock P, McDonald S, Moores B. M. Qualifying the use of RIS data for patient dose by comparison with dicom header data. Radiat Prot Dosim 147:329–332, 2011.

Wood TJ, Davis AW, Moore CS, Beavis AW, Saunderson JR. Validation of a large-scale audit technique for ct dose optimisation. Radiat Prot Dosim 150:427–433, 2012.

Xavier-Souza G, Vilas-Boas AL, Fontoura MS, Araújo-Neto CA, Andrade SC, Cardoso M-R, Nascimento-Carvalho CM; the PNEUMOPAC-Efficacy Study Group. The inter-observer variation of chest radiograph reading in acute lower respiratory tract infection among children. Pediatr Pulmonol Aug 8 2012. doi: 10.1002/ppul.22644. [Epub ahead of print]

Young C, Taylor AM, Owens CM. Paediatric cardiac computed tomography: a review of imaging techniques and radiation dose consideration. Eur Radiol 21:518–529, 2011.

Yu L, Bruesewitz MR, Thomas KB, Fletcher JG, Kofler JM, McCollough CH. Optimal tube potential for radiation dose reduction in pediatric CT: Principles, clinical implementations, and pitfalls. RadioGraphics 31:835–848, 2011

Zissiadis Y, Harper E, Harper C. Development of a clinical chart audit programme. Australas Radiol 50:349–354, 2006.

Øvretveit J, Scott T, Rundall T, Shortell S, Brommels M. Improving quality through effective implementation of information technology in healthcare. Int J Qual Health Care 19:259–266, 2007.

ORIGINAL PUBLICATIONS

I

ORIGINAL ARTICLE

ACTA RADIOLOGICA

Effect of Clinical Audits of Radiation Use in One Hospital District in Finland

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Hirvonen-Kari M, Salo S, Dean K, Kivisaari L. Effect of clinical audits of radiation use in one hospital district in Finland. Acta Radiol 2009;50:389–395.

Background: A clinical audit is a systematic, independent, and documented process to improve the quality of radiological processes and radiation safety for patients.
Purpose: To evaluate the effect of an audit process by comparing the results of two consecutive audits at the same units.
Material and Methods: Audits were carried out twice at each imaging unit in the southwest hospital district of Finland: first, at the end of 2003, and again in November 2007. Both evaluations were carried out in a similar way: by interviewing personnel and examining documents, independent experts from other hospital districts ensured that diagnostic medical imaging processes at each unit were carried out according to generally accepted standards for good medical radiological procedures. The results of the consecutive audits were compared in order to analyze the effects of the clinical audits.
Results: The use of radiation was in accordance with the requirements and standards of good medical procedures at every audited unit during both evaluations. The list of audit criteria was fulfilled satisfactorily on both occasions at all of the audited units, and clearly better during the second run. In the first audit, the auditors made 80 recommendations for improving diagnostic procedures and, in the second audit, 53 recommendations. During the first audit, most of the recommendations (22/80) concerned instructions in the fundamental practice of examining a patient. During the second audit, most recommendations were in the category of radiation doses.
Conclusion: The clinical audit had a positive impact on the practice of work procedures in radiological departments. Most of the recommendations made after the first audit had been taken into consideration by the time of the second audit.

Key words: Audit criteria; compare; evaluate; impact; radiological department

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In 1997, the European Union Council Directive 97/43/EURATOM (MED Directive) introduced the concept of clinical audits for the assessment of medical radiological practices (1). The objective of MED Directive was to achieve the optimum diagnostic efficacy at reasonable patient radiation doses and to reduce the number of unnecessary patient exposures.

The European Union member states are required to implement the content of MED Directive and clinical audits in accordance with national procedures. Finland reformed its radiation law in 1998 (2) and implemented the content of the MED Directive with a decree from the Ministry of Social Affairs and Health in 2000 (3). The decree defines the main criteria of a clinical audit. These audits should be arranged so that they complement the self-assessment of activities in an expedient manner.

All units using radiation should be audited in all essential respects at intervals not exceeding 5 years. Almost all units that use diagnostic radiation had been audited (the first run) before the end of the year 2005 in Finland. The audit process is a laborious, time-consuming, and expensive task for the radiological units. The effect of the audit on the radiological process should therefore be carefully

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evaluated to determine whether it has had a positive outcome.

In 2007, the so-called second run of clinical audits began in Finland, making it possible to evaluate the effect of the initial clinical audits.

Material and Methods

The study material consisted of reports of the two runs of the clinical audit at units using diagnostic radiation in the Southwest Finland Hospital District, which includes the University Hospital of Turku. The Medical Imaging Centre of Southwest Finland includes 14 radiology units. Different units are located in university hospitals (A-, U-, and T-Hospitals, Angiology, Dentistry), in regional hospitals (Surgical Hospital, Loimaa, Paimio, Raisio, Salo, Turunmaa, Uusikaupunki), and in health centers (Käsityöläiskatu, Parainen). In addition to traditional radiographs, magnetic resonance (MR) and ultrasound examinations are conducted at the units. Computed tomography (CT) and vascular examinations are also part of the selection of examinations available.

There are around 250 employees at the Medical Imaging Centre of Southwest Finland, and approximately 300,000 diagnostic examinations are conducted annually. The personnel includes approximately 50 radiologists, 130 radiographers, and 60 other members of staff. The modalities and the numbers of personnel and examinations performed at different departments in 2007 are shown in Table 1.

The first-run clinical audits in the hospital district units were carried out for 11 units in December 2003, one unit in January 2004, and two units in January 2005. Not all units evaluated belonged to the Medical Imaging Centre of Southwest Finland during the first run, but all units were audited according to the same criteria and are included in the comparison. The second run was carried out in November 2007. Two to six radiographers and one to three radiologists were interviewed in each audit by means of a questionnaire prepared by experts (Appendix 1). In the radiology units of the university hospitals, one physicist was also interviewed at each unit. The auditors used the question list (Appendix 1) when they interviewed personnel. The responders freely answered the questions according to the situation at their unit.

In addition, hospital documents and working procedures were examined by auditors in each unit. Before the audit, the auditors were acquainted with material such as quality manuals, safety licenses, guidelines for examinations, imaging and quality-control procedures, and so on. Auditors made their conclusions based on the responses of personnel and the above-mentioned documents, and included these in each unit's audit report.

The clinical audit was based on a set of criteria used in all the audits, and was carried out by a radiologist and a radiographer. In interventional radiology and CT units, the group was augmented by a physicist. All auditors were from a district other than the audited district. All auditors have to be experts in radiation work and have at least 2 days of instruction on the principles of audit processes in order to be competent as auditors. The chief auditor has to have 1 week of audit instruction at an approved educational institution in order to be qualified for the work.

Table 1. Medical Imaging Centre of Southwest Finland: modalities, examinations, and employees at radiology units

	Radiology units at hospitals	Modalities	No. of examinations/ year	Employees
University hospitals	A-Hospital	Radiography, CT, ultrasound, MR	69,727	70
	U-Hospital	Radiography, bone density (DEXA), CT, fluoroscopy, mammography	30,867	38
	Angiology	Vascular (Doppler) ultrasound	4563	18
	Dentistry	Radiography, CT	4414	3
	T-Hospital	Radiography,CT, ultrasound	19,188	14
Area hospitals	Surgical Hospital	Radiography, fluoroscope, CT, ultrasound	42,867	34
	Loimaa	Radiography, CT, ultrasound	18,931	10
	Paimio	Radiography, ultrasound	13,004	9
	Raisio	Radiography, fluoroscope, ultrasound	11,024	8
	Salo	Radiography, fluoroscope, CT	29,845	18
	Turunmaa	Radiography, DEXA, fluoroscope, ultrasound	8892	5
	Uusikaupunki	Radiography, mammography, ultrasound	17,631	9
Health centers	Käsityöläiskatu	Radiography, DEXA, ultrasound	19,373	6
	Parainen	Radiography, ultrasound	4941	2

The criteria used in the first run differed in some respects from the criteria in the second run. Only those criteria that were exactly the same were included in this study. The results of the audits were compared to determine their effects.

Statistical analyses were done with SPSS software (version 15.0; SPSS Inc., Chicago, Ill., USA). The results were analyzed with frequencies, crossover tables, and the Pearson chi-square test, and recommendations were treated to content analysis. In the analysis of references, deductive analysis of content was used, while classification of the study material was based on existing frames of reference (Decree 432/2000).

Results

Time necessary for audit

The process of auditing a radiation unit took approximately 1 day in each run. In the first run, two small units were audited in half a day, but during the second run four small units were audited in half a day. The difference in duration between the runs was not statistically significant. Generally, the audits were performed by a radiologist and a radiographer. A physicist joined the group in the audit of three units (21%) in the first run and in the audit of seven units (50%) in the second run. This difference was significant ($P \leq 0.05$; Pearson chi-square test).

General improvement on audited questions

During the first clinical run, responses to 10 audit questions were considered good in all units; during the second run, 35 responses to questions ($n = 42$) were considered good in all units. The answers to the questions that showed the most improvement are shown in Table 2.

Before the second run, all units had been given recommendations for clinicians concerning the content of referrals; during the first run, five units had not been given these recommendations. All units followed up personnel education in the second run, but seven units did not follow up this recommendation in the first run. The differences for both these questions were significant ($P \leq 0.05$; Pearson chi-square test).

All units conducted some kind of assessment. In the second audit, five units did not compare the results of self-assessment against anything (question 10.2), and in the first audit 11 units did not compare the results of self-assessment. Three units had utilized the results of self-assessment (question 10.3) in the first run, but in the second audit, eight units had utilized the results of self-assessment. The differences in response to questions 10.2 and 10.3 were significant ($P \leq 0.05$; Pearson chi-square test).

The following processes also showed a positive development after the first run, but the differences between the two runs were not statistically significant: recording patient doses; recording data when the radiographer or the radiologist refuses to perform an examination; guidelines for using alternative examination methods; guidelines for using X-ray radiation protection shields; and determining and recording whether a patient is pregnant.

Recommendations

Even though the criteria were fulfilled satisfactorily, the audit reports contained 80 recommendations for

Table 2. Summary of findings in response to questions that produced a positive development

	First-run answers		Second-run answers	
	Yes	No	Yes	No
Has the department given recommendations to clinicians for writing referrals?	9	5	14	
Do you have instructions on how to record data when either the radiographer or the radiologist refuses to perform the requested examination?	7	6	14	
Do you have guidelines for using alternative examination methods?	8	4	14	
Do you have instructions in the use of radiation protection shields?	10	4	14	
Do you have instructions on how to determine whether a patient is pregnant?	9	5	14	
Do you have a set method for recording patient doses?	8	6	14	
Do you have instructions on how to organize and follow up: -basic training updates -the continuing education system -additional education?	7	7	14	
Do you have guidelines for making an assessment in the department?	10	4	14	
Do you have guidelines on the comparison of results?	3	11	9	5
Do you have guidelines on how the results should be utilized?	3	11	8	6

further improvement in the first audit run and 53 recommendations in the second audit run. Recommendations were classified with content analysis based on the existing frames of reference (Decree 432/2000). The resulting recommendations are shown by category in Fig. 1. The X-ray units received approximately six recommendations per unit (range 4–12) in the first run and four per unit (range 2–6) in the second run.

Instructions for examinations. The set of instructions and practices pertaining to a basic patient examination accounted for most of the recommendations (22 out of 80) during the first audit, but only nine of 53 recommendations during the second audit. Most of the recommendations in this category consisted of verifying whether a patient is pregnant (six times), improving or updating instructions for the preparation and performance of an examination (seven times), and the use of an X-ray radiation protection shield (four times) in the first run. During the second run, most of the recommendations for this category consisted of improving instructions for the preparation and performance of examinations (four times), recording answers on patient documents to the question of whether a patient is pregnant (twice), and paying attention to the X-ray beam collimation in radiographic examinations (twice).

Radiation doses. Fourteen recommendations were given in the category of radiation doses in the first run and 11 recommendations in the second run. Auditors recommended recording all the information necessary for calculating the patient dose at a later date (six times in the first run and once in the second run). Measurement of patient dose and comparison of reference levels as a sample was recommended (six times in the first run and 10 times in the second run).

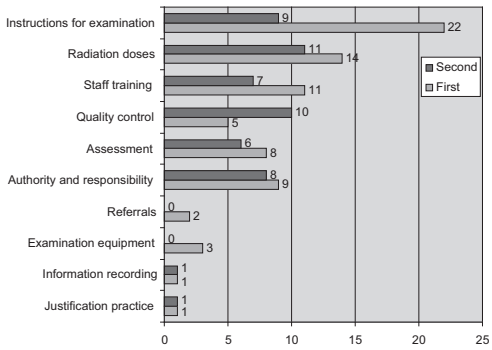

Fig. 1. Number and type of recommendations given after the first and second clinical audits, classified by Decree 423/2000.

Quality control. Recommendations for quality control were given more in the second audit (10 times) than in the first (five times). In both runs, recommendations consisted of instruction to carry out quality control of modalities. Conducting a quality control of monitors was recommended in the second run, while constructing a quality program was recommended in the first run.

Staff training. Recommendations for educating staff (an induction program and follow-up basic training with updates and additional education) were given to 11 units in the first run and, in the second run, to seven units. In the first run, auditors provided recommendations for maintaining a register of radiation protection training for staff (eight times) and one recommendation to organize radiation protection training, draw up an initiation program, and provide a plan for radiation protection training. In the second run, auditors recommended documenting the radiation protection training in a register (six times) and making sure that staff receive the necessary radiation protection training (once).

Assessment. Auditors recommended self-assessment to eight units in the first audit and six units in the second audit. In the first run, auditors recommended annual self-assessment (five times) and developing and expanding the self-assessment procedure (three times). In the second run, auditors recommended drawing up a plan for self-assessment (three times) and developing and expanding the self-assessment procedure (three times), e.g., as an evaluation of imaging quality.

Authority and responsibility. Recommendations for the category of "Determining authority and responsibility" were given almost as many times (eight) in the second run as in the first (nine times). The second time, the recommendations consisted of using the expertise of a medical physicist. The first time, the expertise of a medical physicist was recommended (three times), as was updating the organization of radiation use (three times) and documenting guidelines for first aid (twice) as well as for a quality-control handbook (once).

Discussion

The audit reports are based on specified criteria and on a questionnaire. The criteria of the first and second runs differed a little, because the Finnish Advisory Committee for the Clinical Audit, established by the Ministry of Social Affairs and Health, had given some new recommendations for emphasizing the clinical audit. Only criteria that were exactly the same were included in this study. The audited units satisfactorily fulfilled the list of audit criteria during both runs, but performed better during the second run. Even though the audited units were not under the administration of the same center in the first run, all units were audited using the same criteria. The clinical audit showed positive effects, especially on daily radiation work as a whole, even though the results contained the radiation units of only one hospital district.

Although the criteria were fulfilled satisfactorily, the audit reports contained 53 recommendations during the second run, while the number of recommendations was 80 during the first run. Recommendations from the second run differed from those of the first run. The reasons for this could be a result of the new recommendations by the authorities and that a physicist was more often included in the auditing group.

Most of the recommendations ($n = 11$) in the second audit, almost as many as in the first run ($n = 14$), were concerned with how to measure and record patient dose and how to compare the given dose to a reference level, although these criteria were required by state authority. One reason for this might be that a physicist was included in the auditing group in every other unit.

During the second audit run, recommendations were given on how to use the expertise of a medical physicist. Co-operation with different authorities—radiologists, radiographers, and physicists—is necessary in order to reduce the effect of ionizing radiation on the human body. With the growing diagnostic power of radiological imaging techniques, collective effective doses to the population have continued to rise (4). Both in digital radiography and in CT, overexposure will reduce image noise. This can happen without the radiographer being aware of it, and radiologists seldom complain about image noise being too low. Therefore, it is very important to optimize patient dose in each radiographic examination, especially in those for children (5–7). Radiation doses have been measured particularly in CT (8–11). Optimizing patient dose in radiographic examinations is a much-researched area today and requires co-operation among radiologists, radiographers, and physicists. It is also an area that requires further attention, both in terms of self-assessment and in the next (third) clinical audit run.

The responsible party has a duty to ensure that radiation sources and associated equipment and instruments are in good condition, and that the instructions and procedures concerning their use are appropriate. The purpose of quality assurance is to confirm that the organization meets quality requirements in all respects. A radiological unit must have a quality assurance program that includes written definitions of the functions used for assuring quality (12). Recommendations for quality control were given more (10 times) in the second audit than in the first audit (five times), perhaps because of the attendance of a medical physicist more often during the second run (50%) than in the first (21%). The quality control of monitors was especially recommended, and this led to the construction of a special program for this purpose.

The responsible parties should ensure that the staff in their service receives supplementary training in order to keep their radiation protection knowledge and skills up to date. It is necessary to maintain records of the supplementary training. Each employee using radiation needs a minimum amount (40 hours) of radiation protection training every 5 years (13). Recommendations for training staff were given to seven units in the second run, fewer than in the first run ($n = 11$).

The category of self-assessment still requires attention. Recommendations for assessment and using its results were given eight times in the first run and six in the second. The audit process is easy if a written audit document has been created to facilitate the audit procedure (14). The entire radiation process must be evaluated step by step in different self-assessments. To assess the quality of the imaging procedure, requests and radiologists' reports also need an auditing tool consisting of quality parameters (15).

In conclusion, the list of audit criteria was satisfactorily fulfilled in both runs at the audited units, but was better fulfilled during the second run. The use of radiation was at safe levels in both runs and better in the second audit. The audit seems to have had positive effects on the quality of radiological imaging. The causes for the recommendations made during the first run of the audit had been largely corrected by the time of the second run.

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References

1. European Union. On health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom. Council Directive 97/43/Euratom of 30 June 1997. Official J Eur Commun 1997;L180:22–7.
2. Radiation Act 27.3.1991/592 and amendment 23.12. 1998/1142.
3. Decree of the Ministry of Social Affairs and Health on the medical use of radiation 10.5.2000/423.
4. Moores B. Radiation safety management in health care – the application of quality function deployment. Radiography 2006;12:291–304.
5. European Commission. European guidelines on quality criteria for diagnostic radiographic images, EUR 16260. Luxembourg: European Commission; 1996.
6. Maree G, Irving B, Hering E. Paediatric dose measurement in a full-body digital radiography unit. Pediatr Radiol 2007;37:990–7.
7. Nickoloff E, Alderson P. A comparative study of thoracic radiation doses from 64-slice cardiac CT. Br J Radiol 2007;80:537–44.
8. Kanal K, Stewart B, Kolokythas O, Shuman W. Impact of operator-selected image noise index and reconstruction slice thickness on patient radiation dose in 64-MDCT. Am J Roentgenol 2007;189:219–25.
9. Vassileva J. A phantom for dose-image quality optimization in chest radiography. Br J Radiol 2002;75:837–42.
10. Bauhs J, Vrieze T, Primark A, Bruesewitz M, McCollough G. CT dosimetry: comparison of measurement techniques and devices. Radiographics 2008;28: 245–53.
11. Boone J, Nelson T, Lindfors K, Seibert J. Dedicated breast CT: radiation dose and image quality evaluation. Radiology 2001;221:657–67.
12. Safety fundamentals in radiation practices. Guide St 1.1. Radiation and Nuclear Safety Authority, 23 May 2005.
13. Radiation protection training in health care. Guide St 1.7. Radiation and Nuclear Safety Authority, 17 February 2003.
14. Jarritt P, Perkins A, Woods S. Audit of nuclear medicine scientific and technical standards. Nuc Med Commun 2004;25:771–5.
15. Stavem K, Foss T, Botnmark O, Andersen O, Erikssen J. Inter-observer agreement in audit of quality of radiology requests and reports. Clin Radiol 2004;59: 1018–24.

Appendix 1. Audit criteria (in accordance with Finnish Decree 423/2000)

1 Determining authority and responsibility

1.1 Has the department determined the responsibilities of the organization in the use of medical radiation according to the National Radiation Safety Guidelines?

1.2 Have the responsibilities of medical physicists been determined and has their expertise been used?

1.3 Has the quality system currently used in the department been documented?

2 Referrals and recommendations for writing referrals

2.1 Has the department given recommendations to clinicians for writing referrals and basic instructions?

2.2 Are the contents and model of the referrals according to law?

3 Justification practice and communication

3.1 Do you have a system to check on the justification for an examination?

3.2 Do you have instructions on how to record data when either the radiographer or the radiologist refuses to perform the requested examination?

3.3 Do you have guidelines for using alternative examination methods?

4 Instructions for common practice for examining patients using ionizing radiation

4.1 Do you have instructions on how to prepare a patient for the examination and care afterwards? Is the performance of the examination documented with date and approval?

4.2 Do you have instructions in the use of radiation protection shields?-for personnel?-for patients?

4.3 Do you have instructions for examinations performed by other healthcare personnel?

4.4 Do you have instructions for identifying the patient examined?

4.5 Do you have instructions on how to determine whether a patient is pregnant?

4.6 Do you have instructions on how and by whom a patient is to be held during an examination using radiation?

4.7 Do you have a written documentation system for how to record a patient's refusal to be examined?

4.8 Do you have instructions on how a portable examination should be performed and what kind of criteria portable examinations must fulfill? (ICU, ER, CCU, OR, recovery)

4.9 Do you have instructions regarding the use of dosimeters by personnel?

4.10 Do you have guidelines for purchasing of equipment?

Appendix 1 (*Continued*)

1 Determining authority and responsibility	
4.11 Do you have instructions on how to place an order for radio-labeled medicines (isotopes)?	
5 Examination and treatment equipment	
5.1 Do you have a current and valid equipment registry?	5.2 Do you have instructions for training personnel to use new equipment?
5.3 Do you have guidelines on maintenance of the equipment?	5.4 Do you have instructions on how to respond in the event of breakdown of equipment?
5.5 Do you have instructions on how to handle old equipment and devices when they are removed from use?	5.6 Do you have written instructions on how to use the X-ray equipment located outside the X-ray department?
6 Radiation doses caused by various examinations and achieved results	
6.1 Do you have instructions on how to follow up patient doses?	6.2 Do you have a set method for recording patient doses?
6.3 Do you evaluate the results achieved by the examinations and treatments?	6.4 Examination/intervention statistics—do you have/use them?
6.5 Do you have a record of all the radiological examinations written/stated in the patient file?	6.6 Do you have instructions on how to use the feedback system?
7 Quality of information received from examinations, recording information, and communication	
7.1 Do you have instructions on how to record examination information?	7.2 Do you have instructions on film trafficking and how to archive foreign films?
7.3 Do you have guidelines on how to follow up film usage?	
8 Staff training	
8.1 Do you have an induction program for various employee groups?	8.2 Do you have instructions on how to organize and how to follow up:-Basic training updates? – The continuing education system?-Additional education?
8.3 Do you have professional literature available?	
9 Determining quality control and its use	
9.1 Do the individual modalities have their own quality-control instructions?	9.2 Do you have instructions for use of a reserve back-up system?
10 Assessment, results, and the use of results	
10.1 Have you made an assessment in the department, and, if so, when?	10.2 Against what have the results been compared?
10.3 How have the results been utilized?	

II

ORIGINAL ARTICLE

ACTA RADIOLOGICA

Clinical audits and regulatory inspections – double efforts and expenses for radiation protection?

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Background: Clinical audit as a systematic examination of medical procedures improves the quality and outcome of patient care. The purpose of a regulatory inspection is to check and verify that the operation and facilities are in full conformance with all legal requirements.
Purpose: To examine the content of the clinical audits and regulatory inspections of radiological procedures and whether these overlap, and to evaluate the costs to radiological units.
Material and Methods: Clinical audits were carried out at each imaging unit of Helsinki University Hospital (HUS) Medical Imaging Center in Finland in 2004 and 2005. The regulatory inspections were carried out after the clinical audits from 2005 to late 2007. The contents of the clinical audit and inspection reports were analyzed statistically and by content analysis. The results of the audits and the inspections were compared to analyze the overlaps, differences, and costs.
Results: The validity and conditions of the safety license, lines of authority, and responsibilities for the use of radiation and patient doses caused by different examinations were evaluated in both audits and inspections. The coverage and frequency of quality control procedures were monitored in every audit and inspection, but inspectors, in addition, checked radiation output. The costs of clinical audit and inspection were under 20 cents per radiological procedure. The auditors gave 98 recommendations, while inspectors gave 62 recommendations and 25 requirements. In clinical audits most of the recommendations concerned guidelines for examining a patient. In the inspections most recommendations were in the category of quality assurance activities.
Conclusion: The clinical audits and regulatory inspections were cheap and had few overlapping topics, but several differences were apparent: in clinical audits, a broader and deeper view of the clinical procedures was taken by comparison with good practices, while regulatory inspections have mainly verified conformance to basic regulatory requirements.

Key words: Audit criteria; quality; cost; radiation practices

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Council Directive 97/43/EURATOM (the MED-directive) (1) introduced the concept of clinical auditing. A clinical audit is a systematic, independent, and documented process to improve the quality of the radiological processes and the radiation safety of patients. Recent surveys have indicated that the status of implementation of the clinical audits varies widely among countries (2). In some countries there has been almost no implementation of clinical audits thus far, and few countries have a long tradition of audit implementation. In Finland, almost all units for diagnostic radiology were audited for the first time by late 2005.

International principles specify that the legal infrastructure in a country should ensure that a legislative and statutory framework is established to regulate the safety of facilities and activities, including the medical use of radiation. This also includes a regulatory body having the responsibility for authorization, regulatory review and assessment, inspection, and enforcement (3). The MED-directive (1) states that Member States should ensure that a system of inspection enforces the provisions introduced in compliance with the Directive. In Finland the Radiation and Nuclear Safety Authority (STUK) is the regulatory body and carries out regular inspections of all radiation practices.

The systems of regulatory inspections and clinical audits are very comprehensive and introduce extra costs to radiology units. As a result, the primary aim of this study was to analyze whether these two external activities focus on sufficiently different areas of operation

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to supplement each other without resulting in unnecessary overlap and waste of resources. A second aim was to review the typical costs of clinical audits and regulatory inspections to radiological units.

Material and Methods

This study involved 20 radiological imaging units at the Helsinki University Hospital (HUS), which performed approximately 800 000 radiological examinations and interventions in 2007, including plain radiography, mammography screening, ultrasound, computed tomography (CT) with interventions, angiography with interventions, and magnetic resonance imaging (MRI). The study material consisted of reports from (a) clinical audits carried out at all units between October 2004 and May 2005 and (b) regulatory inspections of current procedures performed from the time of the clinical audits to May 2008. These inspections were not carried out in two hospitals, one of which also included three health center units. In these two hospitals about 120 000 examinations (15% of all examinations) were carried out in 2007.

The results from the reports were analyzed with content analysis and frequencies. Statistical analyses were done with the SPSS (Statistical Package for the Social Sciences; SPSS Incorporated, Chicago, Ill., USA) version 17.0 statistical PC program. Deductive content analysis was used to classify the contents of the reports based on a pre-existing 10-point list of relevant issues from Decree 423/2000 (see below). Such analysis is applied when the structure of analysis is classified on the basis of previous knowledge. The account of clinical audit and inspection consisted of all the costs (labor, travel, accommodation) of auditing and inspection. The total costs of clinical audit and inspection were divided by the number of examinations in 1 year.

Clinical audits

Finland has implemented the contents of the MED-directive (1) mainly with Decree 423/2000 issued by the Ministry of Social Affairs and Health (4). The Decree specifies 10 points of interest that should at least be covered in clinical audits. Clinical audits are performed by qualified and experienced experts who are independent of the responsible party. Clinical audit should be repeated every 5 years.

The clinical audits were based on a set of criteria in accordance with Decree 423/2000 (4). The 10 points of interest covered are as follows:

- specification of authority and responsibilities,
- referrals and recommendations guiding the issuing thereof,
- the practice and information flow observed in assessing justifications,
- guidelines and practices for procedures involving exposure to radiation,
- equipment for examinations and treatment,
- radiation doses arising from procedures and the examination and treatment results achieved,
- quality, recording, and flow of information on procedures,
- staff training,
- definition and application of quality assurance activities, and
- self-assessments of activities, assessment results, and the use of results.

The clinical audits were carried out by a radiologist and a radiographer, but the group was augmented by a physicist when interventional radiology or CT was used. All auditors had to be from a healthcare district other than the one audited. The report of clinical audit consisted of results of all 10 points and each point consisted of several questions.

Regulatory inspections

In Finland the use of ionizing radiation in healthcare requires a safety license in accordance with the Radiation Act (5) (except for conventional dental practices). The safety license is granted by STUK, which is a regulatory body that controls all use of radiation in conformance with legislation and regulations for radiation safety. Regulatory control procedures also include on-site inspections, which are carried out every 1–5 years, depending on the nature of the radiological practices. The most demanding use of ionizing radiation in diagnostic radiology (CT, angiography) is inspected every 3 years, conventional radiography (including mammography) every 5 years, and screening mammography every 2 years ($\pm$1 year). The costs of regulatory control are charged by the healthcare units, including an annual fee for each license and separate charges for each regulatory inspection (in diagnostic radiology). The charges are based on Article 69 of the Radiation Act and the decision by the Ministry of Social Affairs and Health regarding charges and grounds for payment (6).

The purpose of the inspection is to monitor and verify that the operation and facilities are in full conformance with all legal requirements. The inspectors include trained physicists, engineers or radiographers. To be qualified as inspectors, they must receive further training and practical experience at STUK. The report of inspection consists of a summary of inspection procedures and a list of the requirements or recommendations given, based on the observations.

Table 1. Number of audits and inspections per duration

	Duration (days)						
Parameter	0.5	1	1.5	2	3	4	8
Audit	7	9	1	4	1	1	…
Inspection	…	9		2	5	1	1*

*Inspection covered four separate units at two hospitals.

Table 2. Number of audits and inspections per size of the audit and inspection team

	Size of team (no. of persons)		
Parameter	1	2	3
Audit	…	20	3
Inspection	11	5	2*

*One of these was a large unit, consisting of four separate units in two hospitals.

Results

Number of reports, duration of procedure, and size of the team

A total of 23 audit reports and 18 inspection reports were analyzed in this study. The difference in number was the result of one of the radiological departments, which comprised four separate units, each of which received an audit report, while all four received only one joint inspection report. The inspections were not carried out in two hospitals.

The duration of audits varied between half a day and 4 days (mean 1 day). The duration of the inspections varied between 1 day and 8 days (mean 1 day); however, the longest inspection of 8 days covered four separate units at two hospitals (Table 1).

The audits were performed mainly by a radiologist and a radiographer (20 times), accompanied by a physicist in three cases (13%). The inspections were performed by 1 inspector in 11 units, by 2 inspectors in 5 units, and by 3 inspectors in 2 units (Table 2).

Common checking points in audits and inspections

Auditors checked 58 points within 10 points of interest in their auditing. Both auditors and inspectors partly checked the same issues in their inspections. The common checking points in the audits and inspections, based on the data recorded in the reports, are shown in Table 3.

Table 3. Items of common checking points in clinical audits and regulatory inspections as recorded in the corresponding reports: main viewpoint of procedures is given if different in the audits and inspections

	Recorded in audits		Recorded in inspections		Main viewpoint in	
Item assessed	*n*	%	*n*	%	Audits	Inspections
Safety license and radiation safety organization	23	100	18	100		
Providing of medical physicist's expertise	22	96	13	72		
Radiation protection training of staff	23	100	14	78		
Written guidelines for examinations	23	100	18	100	Conformance to guidelines for good practice	Existence of guidelines
Use of radiation protection shields.	23	100	17	94	How to use the shields	Adequacy of shields
Follow-up of patient doses: guidelines, results	23	100	18	100		
Guidelines for monitoring the patient's pregnancy	23	100	16	89	Practice in monitoring	Existence of written instructions for patients
Guidelines for using personnel dosimeters	23	100	18	100		
Guidelines for personnel health examination (for work with radiation)	23*	100	9	50		
Evaluate the results achieved by the examinations (Outcome)	21	91	6	33		
Quality control of equipment: guidelines, results	23	100	18	100		(Included monitoring of radiation output)
Guidelines for maintenance of the equipment	23*	100	5	28		
Self-assessment practices	23	100	18	100	Quality of self-assessments, applied criteria	Existence of self-assessment practice

*≤0.01, Pearson chi-square test – the difference rate was highly significant between clinical audit and inspection.

Recommendations and requirements

A total of 98 recommendations were given in the clinical audits of the 23 radiological units and 62 recommendations and 25 requirements in the regulatory inspections. The number of recommendations (audits) and requirements and recommendations (inspections), classified in accordance with the 10 topics of interest specified in Decree 423/2000, are shown graphically in Fig. 1. Inspectors did not give any recommendations or requirements that could be classified to category referrals or justification and these categories are missing in Fig. 1. Inspectors gave recommendations or requirements, which could not be classified in any 10 points category and these were assigned to the category "Other".

Typical examples of the topics that were addressed in the recommendations given in *clinical audits* were as follows, "(both)" indicates that they were given in both clinical audit and inspection:

- recording of average patient dose,
- instructions for using radiation protection shields,
- recording of patient's pregnancy,
- recording of information needed for calculation of the patient dose (both),
- building up the quality assurance program or initiating a quality control program for specific equipment (mammography) (both),
- training programs (list, follow-up, initiation) (both),
- creating self-assessment practice and performing self-assessment (both), and
- organizing customer feedback questionnaires.

Typical examples of the topics that were addressed in the requirements (*) or recommendations given in *regulatory inspections* were as follows:

- radiation protection between examination room and control room*,
- classification of radiation workers and frequent monitoring of the classification (classes A and B)*,
- measuring the patient dose and comparing it with diagnostic reference levels (both),

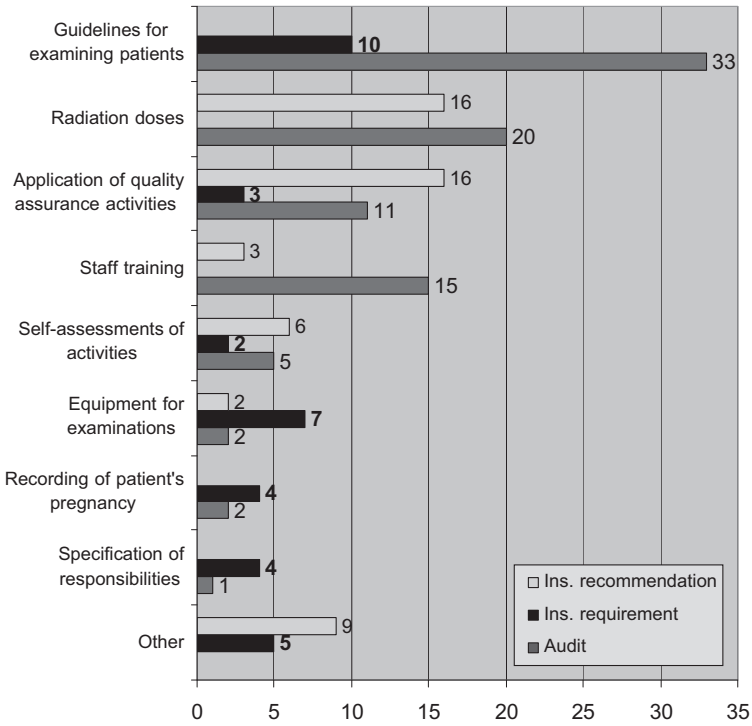

Fig. 1. Number of recommendations received in the clinical audits and requirements and recommendations in the inspections, classified by Decree 423/2000.

- decreasing radiation doses of given examinations,
- building up of quality assurance program* (both),
- ensuring sufficient training of the staff (both),
- evaluation of clinical image quality as a part of self-assessment (both),
- marking the total filtration on the X-ray equipment*,
- repairing a warning light*, and
- access control to the imaging room during use.

Costs

The costs of both clinical audits and regulatory inspections to radiological departments are dependent on the number of performers (auditors or inspectors) and working days needed. The total costs consist of labor, travel, and accommodation costs, with labor clearly predominant.

The total cost for a single audit day with two auditors averaged €2666, which also included the work of auditors before the auditing visit. The costs of a complete audit varied from small units to large units in the range from €1333 to €10 646. The total cost of a single inspection day with one to three inspectors averaged €896 and varied from €840 to €10 469.

The costs of the first clinical audit at the HUS Medical Imaging Center were about €80 000. The costs of the inspections were €43 500, but not every unit was inspected. Clinical audits must be performed once every 5 years and inspections every 2–5 years. The number of examinations at the HUS Medical Imaging Center is about 800 000 yearly, about four million in 5 years. The costs of clinical auditing per examination are about 10 cents (once in 5 years) and the costs of inspection per examination are about 7 cents (once per 2–5 years). The cost of clinical auditing per 5 years examination (about four million) is about 2 cents. The costs of inspection depend on the frequency of inspection.

Discussion

The status of implementation of the clinical audits varies widely among countries. The Royal College of Radiologists has actively promoted medical auditing for over 15 years (7). Some countries have also noted that clinical audit is a useful part of quality assurance, wherein colleagues evaluate completed work from the perspective of good clinical practice (8). Financing of clinical audits also varies in different countries, from fees to government support and mutual agreements (9).

Our findings support the feedback from regulatory inspections that to some extent there has been unnecessary overlapping of procedures between the first clinical audits and regulatory inspections. Most of the items in Table 3 were monitored in all audits and inspections. In some cases there was a clear difference in the coverage or main viewpoints of the assessments, while in others this remained unclear and unnecessary overlap in the procedures may have occurred. Organizational safety arrangements and implementation of technical quality control programs were the points of interest that have been checked in inspections and audits. Both auditors and inspectors performed checks regarding organizational arrangements and technical quality control programs.

Carrying out the practice in accordance with regulations was typically monitored in regulatory inspections, while the specific details were assessed in clinical audits. Auditors examined the radiation work of the staff as a whole in comparison to the available information on and experience in good medical practices regarding the use of radiation. As can be seen from Fig. 1, guidelines for examinations have been greatly emphasized in clinical audits. Auditors checked guidelines for practical work and patient safety and safe working habits of the staff.

Self-assessments should be a continual process in the radiological units between external clinical audits and should also address the outcome of the examinations, including cost/benefit aspects (10–15), which cannot be easily verified in external audits or regulatory inspections. The present results indicate that self-assessments were not adequately covered in the first clinical audits. The results of this study also stress the importance of having relatively well-documented guidelines for good clinical practice, as a basis for the audits (16–18).

Labor costs are the main costs in both clinical audits and regulatory inspections and, therefore, total costs are directly proportional to the number of persons (auditors or inspectors) involved and the length of the audit (Tables 1 and 2). When counted per number of examinations, the costs of both clinical auditing and regulatory inspection become very small.

Comparison of the contents of clinical audits with that of regulatory inspections has some limitations as for the conclusions. First, the contents of an inspection were sometimes difficult to classify in accordance with the points of interest given for clinical audits in Decree 423/2000. Second, the study was conducted at a single large medical imaging center, and although the center consisted of several radiological units at a university hospital, district hospitals, and health centers, the results may not apply to all radiology units in Finland.

In conclusion, comparison of the reports of clinical audits and regulatory inspections at a single large medical imaging center has indicated that each of these external procedures has partly addressed the same topics. For some points of interest, unnecessary overlap was observed. In most cases, however, the emphasis in

these two activities has been different: in clinical audits, a broader and deeper view of the clinical procedures was taken by comparison with good clinical practice, while regulatory inspections have mainly examined conformance to basic regulatory requirements. Review of the costs of clinical audits suggests that these are a rather reasonable investment for improving the quality of the practices. Further development of clinical audits should be done in cooperation with regulatory authorities so that clinical audits will better supplement regulatory control, as well as other quality assessment activities.

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References

1. European Union. On health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom. Council Directive 97/43/Euratom of 30 June 1997. Official J Eur Commun 1997; No L 180:22–7.
2. International symposium on practical implementation of clinical audit for exposure to radiation in medical practices. Tampere, May 24–27, 2003.
3. International Atomic Energy Agency. Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Standards Series No. GS-R-1. Vienna: IAEA; 2000.
4. Decree of the Ministry of Social Affairs and Health on the medical use of radiation 10.5.2000/423.
5. Radiation Act 27.3.1991/592 and change 23.12.1998/1142.
6. The decision by the Ministry of Social Affairs and Health regarding charges and grounds for payment. 580/1993.
7. Ryall CJ, Barter S, Duncan KA, Lumb P. AuditLive – A national radiology audit template library – the UK experience. Book of abstracts and general information. International Workshop on Clinical Audit, Tampere, September 7–10, 2008.
8. Shortt K, Davidsson L, Hendry J, Dondi M, Andreo P. International perspectives on quality assurance and new techniques in radiation medicine: outcomes of an IAEA conference. Int J Radiat Oncol Biol Phys 2008;71:S80–S84.
9. Draft Appendix 1: Summary of regulatory frameworks in the EU Member States. Book of abstracts and general information. International Workshop on Clinical Audit, Tampere, September 7–10, 2008 (www.clinicalaudit.net).
10. Blaivas M, Lyon M. Frequency of radiology self-referral in abdominal computed tomographic scans and the implied cost. Am J Emerg Med 2007;25:396–9.
11. Gazelle G, McMahon P, Siebert U, Beinfeld M. Cost-effectiveness analysis in the assessment of diagnostic imaging technologies. Radiology 2005;235:361–70.
12. Clevert D-A, Stikel M, Jung EM, Reiser M, Rupp N. Cost analysis in interventional radiology – a tool to optimize management costs. Eur J Radiol 2007;61:144–9.
13. Brem MH, Böhner C, Brenning A, Gelse K, Radkow T, Blanke M, et al. Evaluation of low-cost computer monitors for the detection of cervical spine injuries in the emergency room: an observer confidence-based study. Emerg Med J 2006;23:850–3.
14. Hollingworth W. Radiology cost and outcomes studies: standard practice and emerging methods. Am J Roentgenol 2005;185:833–9.
15. Nitrosi A, Borasi G, Nicoli F, Modigliani G, Botti A, Bertolini M. A filmless radiology department in a full digital regional hospital: quantitative evaluation of the increased quality and efficiency. J Digit Imaging 2007;20:140–8.
16. Jarritt P, Perkins A, Woods S. Audit of nuclear medicine scientific and technical standards. Nucl Med Commun 2004;25:771–5.
17. Øvretveit J, Scott T, Rundall T, Shortell S, Brommels M. Improving quality through effective implementation of information technology in healthcare. Int J Qual Health Care 2007;19:259–66.
18. Zissiadis Y, Harper E, Harper C. Development of a clinical chart audit programme. Australas Radiol 2006;50:349–54.

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TRANSITION IN OCCUPATIONAL RADIATION EXPOSURE MONITORING METHODS IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

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Radiation exposure monitoring is a traditional keystone of occupational radiation safety measures in medical imaging. The aim of this study was to review the data on occupational exposures in a large central university hospital radiology organisation and propose changes in the radiation worker categories and methods of exposure monitoring. An additional objective was to evaluate the development of electronic personal dosimeters and their potential in the digitised radiology environment. The personal equivalent dose of 267 radiation workers (116 radiologists and 151 radiographers) was monitored using personal dosimeters during the years 2006–2010. Accumulated exposure monitoring results exceeding the registration threshold were observed in the personal dosimeters of 73 workers (59 radiologists' doses ranged from 0.1 to 45.1 mSv; 14 radiographers' doses ranged from 0.1 to 1.3 mSv). The accumulated personal equivalent doses are generally very small, only a few angiography radiologists have doses >10 mSv per 5 y. The typical effective doses are <10 μSv y^{-1} and the highest value was 0.3 mSv (single interventional radiologist). A revised categorisation of radiation workers based on the working profile of the radiologist and observed accumulated doses is justified. Occupational monitoring can be implemented mostly with group dosimeters. An active real-time dosimetry system is warranted to support radiation protection strategy where optimisation aspects, including improving working methods, are essential.

INTRODUCTION

Occupational radiation exposure monitoring is traditionally performed with thermoluminescent dosimeters (TLD), also used in Finland. The Finnish monitoring regulations, which follow the European norms (Council Directive 96/29/ Euratom[(1)]) and the national Radiation and Nuclear Safety Authority (STUK), a subordinate of the Ministry of Social Affairs and Health, provide regulatory guides to align practical implementation of radiation safety. STUK also acts as a regulatory body as part of the EURATOM treaty. All users of ionising radiation need a safety license that is granted by STUK, and the regulations are to be followed by all radiation users.

Workers who may be exposed to radiation are divided into categories A and B. Category A are those whose effective dose exceeds or may exceed 6 mSv y^{-1}, including potential work-related exposure. Category B are those who are not included in category A. Individual monitoring is required for category A workers but discretionary for the category B workers. Group dosimeters can be applied for persons who do not work in the direct vicinity to the X-ray beam during the exposure (e.g. imaging from the control room) for monitoring the working conditions. Working places in radiation work are defined as controlled area and supervised area, where the effective dose per year may exceed 6 and 1 mSv, respectively. The exposure monitoring period for category A and B workers is 1 and 3 months, respectively. There is one accredited dosimeter service in Finland where the dosimeters have to be shipped in the end of each period. The dose measured is the personal dose equivalent $H_p(d)$ and the registration thresholds are 0.1 mSv for $H_p(10)$ and 2 mSv $H_p(0.07)$ for 1 month monitoring period.

HUS Helsinki Medical Imaging Center is a municipal enterprise within the Hospital District of Helsinki and Uusimaa. It has 32 radiology departments and represents the largest radiological organisation in Finland. Departments are located in university and regional hospitals and in heath centres across the capital area of Helsinki and its neighbouring towns. All major digital radiology modalities are included in the technical infrastructure (digital radiography, computed tomography, angiography, mammography, dexa, magnetic resonance imaging and ultrasound). In 2010, the total number of examinations and interventions was ~900 000 and the total number of personnel was about 820, including about 180 radiologists, 490 radiographers, 10 physicists and 140 other personnel. The number of radiation workers was about 630.

Recently, the necessity of individual radiation exposure monitoring of radiation therapists was discussed[2]. The occupational exposure settings are considerably different in radiology, where lower photon energies are applied with relatively low dose levels but where the staff can be located in direct vicinity to the primary beam. The aim of this study was to review the data on the occupational exposures in a large central university hospital radiology organisation; how the doses are related to work tasks and to the radiation work categories, and to revise the radiation worker categories and the method of occupational exposure monitoring for the different profession groups. Additionally, the development of electronic personal dosimeters is evaluated and their potential use in the digital radiography department is assessed.

ACTIVE PERSONAL DOSIMETERS

There has been growing interest in using active personal dosimeters (APDs) as personal dosimeters instead of passive dosimeters such as TLDs or film dosimeters. The basic problem with the passive TLD methodology is that it does not allow on-line exposure monitoring which is the key factor for efficient optimisation in the level of occupational radiation protection. APDs have several advantages compared with passive dosimeters and the mechanical tolerance and environmental immunity of APDs have become better in recent versions. Still questions arise on how they function in electromagnetic and magnetic fields, low and high temperatures and high humidity. In general, these are more of a problem for APDs than passive dosimeters. The main advantage of APDs is the possibility for on-line reading providing the workers with means to follow their radiation dose more accurately to improve their working practices.

Progress in getting APDs to be an official dosimetry system in Europe has been going on since 2007. The regulations on dosimetry services in the European countries vary, resulting in very varied customs, even though often the type of dosimeter for the legal dose recording is not specified. In certain countries APDs have to be used on the side in high dose workplaces while the legal dose still comes from the passive dosimeter. Czarwinski *et al.*[3] describes the German framework for official dosimetry and procedures that are needed to get APDs as official dosimeters instead of the passive system. Tests needed are software solutions, testing of APD dosimetry systems in different facilities and quality assurance with calibration possibilities.

A thorough overview of available APDs shows that the technical characteristics for both beta and photon APDs have reached the reliability level of regulations and are even better than passive dosimeters in most radiological applications[4]. The UK and Switzerland were the only countries in 2007 that had legal dosimeter services based on APDs[4]. In the UK there has been running an approved dosimetric service based on the Siemens EPD1 for 10 y at nuclear power plants[5, 6].

The international standard describing the performance requirements of APDs is IEC 61526[7]. The major limitation of IEC 61526 is that its scope does not cover pulsed fields. Most electronic dosimeters are not designed to measure pulsed radiation fields but constant level background fields or suddenly increasing fields. The majority of clinical radiation usage is pulsed fields. The pulse lengths may vary considerably, depending on radiation source and the operational parameters of the instruments. They are characterised by high dose rates of up to 55 Sv h^{-1} and of short pulse durations (20 ms) and with typical pulse frequencies from 1 to 20 s^{-1}. In recent years several works on APDs in pulsed fields has been published[8–11]. The first studies indicated that APDs do not measure pulsed fields correctly[8]. According to Borowski *et al.*[9] the dose can be severely underestimated in certain direct radiation fields, while otherwise the EPD Mk2.3 dosimeter fulfils the requirements for a legal personal dosimeter.

Clairand *et al.*[10] tested selected APD devices for use in interventional radiography and angiography and came to the conclusion that there is still a need for improvement in APD technology. There are certain devices that can detect low-energy X-rays and function as required by standards in continuous fields but in pulsed fields their response is satisfactory at low energies and low dose rates but >10 Sv h^{-1} only one model, the DIS-1, gave good results. When the pulse frequency is changed from 1 to 20 s^{-1} the variation in the measured dose is 30%. In hospital environments, the APDs generally gave a lower dose than the reference passive dosimeter. This could be taken into account by correction factors after testing. Ginjaume *et al.*[11] has described methods to overcome the deficiencies of APDs as they do fulfil the international standards for photon radiation[4], the accuracy, repeatability and reproducibility are better than those of passive dosimeters. There are several countries that have approved dosimeter services with APDs in use, these include UK, Switzerland and Sweden, where the first is using Siemens EPD Mk2 and the latter two DIS-1 dosimeters.

A recent test with various radiation fields including X-ray, gamma, beta radiation and pulsed fields describes well the deficiencies of APDs[12]. Only 3 out of 13 dosimeters were able to measure $H_p(10)$ and $H_p(0.07)$ for both X and gamma radiation, respectively. These were MGPi DMC 2000XB, Thermo Mk2 and Atomtex AT3509B. For pulsed fields, the tested pulse width was 1.6 s and the dose

rate was 1.5 Sv h^{-1}. Only MGPi DMC 2000XB, MGPi DCM 2000X and Thermo Mk2 performed well in all the tested qualities.

Philips has come out with a new electronic system, Dose Aware, for monitoring doses in interventional angiography. It has recently been tested in a hospital environment[13] and is suggested to be used as a tool to reduce personal dose by guiding the correct use of protection devices.

The Rados DIS-1 is aimed for as legal personal dosimeter (approved by authority) within medical applications and Doseco, the Finnish accredited dosimeter service, is planning a pilot project at different locations in the near future[14]. Generally, the majority of APDs are not aimed for legal personal dosimeters, or for replacement of passive dosimeter, but rather to increase the awareness of workers about the radiation environment they are working within. When APD doses are compared with TLD doses care should be taken[15]. Disagreements between active and passive dosimeters can arise, even though both would have acceptable accuracy, they can be differently normalised and their biases can be in opposite directions.

EFFECTIVE DOSE AND THE DOSE DETERMINED BY DOSIMETERS

The effective dose is the suitable variable to indicate a uniform dose value in case of different exposures of various body parts in order to evaluate the risk of late radiation injuries. The effective dose E is the sum of the average absorbed organ doses H_T in the individual organs and in the tissues of the body due to external or internal radiation exposure multiplied by the tissue weighting factors w_T:

$$E = \Sigma_T w_T H_T \quad (1)$$

The dose of radiation workers is recorded as personal dose equivalents $H_p(10)$ and $H_p(0.07)$ for deep and shallow doses, respectively. The personal deep dose $H_p(10)$ in the case of whole-body exposure to penetrating radiation is a roughly estimated value for the effective dose and the organ doses of deep organs, and the skin dose $H_p(0.07)$ is an estimated value for the skin dose. The true relationship between the personal dose equivalent recorded by personal dosimeters and the effective dose is not straightforward. The dose measured above the protective lead apron may vary significantly with changing irradiation conditions and placement of the TLD. For an accurate estimation of the effective dose, the irradiation conditions have to be known. There are several studies[16–20] where the dose has been measured with multiple dosimeters, phantoms, various angles and different protective clothing to reach an estimate of the workers' effective dose. Faulkner and Marshall[16] concluded in their studies that the reading from a dosimeter worn on top of a 0.35-mm lead apron should be divided by a factor between 2 and 60 to get the effective dose. Niklason *et al.*[17] published a similar result; the dosimeter above apron overestimates the effective dose by a factor of 25. The thyroid neck shield reduces greatly the effective dose. Kicken *et al.*[18] determined that the dosimeter reading should be divided by 24–45 if a thyroid shield is used and by 12–15 when it is not used. In their study a 0.5-mm lead apron was used and the dosimeter was worn on neck. In Petrucci's[19] review, it is concluded that for the best estimate of the effective dose two dosimeters are needed one above apron and one under apron, and for more precise estimate the tube voltage has to be taken into account. Siiskonen *et al.*[20] have used Monte Carlo simulations for estimating effective doses in interventional radiology. The reported overall uncertainty of the conversion coefficient from $H_p(10)$ to effective dose was 60% for specified projections and X-ray tube voltage settings, including 30% uncertainty from mathematical modelling (basic physical interactions, patient model, apron model, etc.) and around 50% uncertainty from positions of the worker, patient and the simulated dosimeter. Siiskonen *et al.* concluded that the often-used conversion coefficient of 1/30 for an external dosimeter reading to effective dose with apron overestimates the effective dose. A more accurate estimate for the ratio of measured personal equivalent dose to effective dose is 1/60 when the dose is measured above apron and 1/120 when the person is also wearing the thyroid shield. However, in certain exposure conditions this may give an underestimation for effective dose.

The ranges of the above factors arise from the complex and highly variable exposure settings. The largest variation arises from the projection used; is the patient exposed from vertical (overcoach/undercoach), horizontal or oblique angle where the resulting scattered and transmitted radiation fields are very different. Also the tube voltage has an effect on the effective dose. Simulations published by Siiskonen *et al.*[20] indicates that increasing the tube voltage from 60 to 100 keV would change the conversion factor from 150 to 52 in the vertical undercoach exposure. Radiologists, when working, use a wide range of projections; their distance from the patient varies, the tube voltage varies and the angle of their TLD shifts, and all this is measured as a single number by the TLD. In the later calculations here, a conservative factor of 1/30 was used to convert $H_p(10)$ to effective dose, where the effective dose is not underestimated in any radiation condition[20, 21]. The range of the factor is 44–258 when a thyroid shield is used, as is the case in the hospitals

here. The use of the thyroid shield decreases the effective dose by a factor of 2[21].

MATERIALS AND METHODS

Occupational monitoring in HUS Helsinki Medical Imaging Center is performed according to generally established guidelines. The TLDs are worn on top of the lead apron at chest height. The dosimeters of category A workers are sent every month to the accredited laboratory for reading and for category B every 3 months. The general guideline is that a person who has the potential risk to get a 6 mSv or higher dose per year should be in category A.

In this study, the personal equivalent doses of 267 radiation workers were monitored using personal dosimeters during the years 2006–2010. Other radiation workers (about 360 persons) are not within individual occupational monitoring. Instead, there are 34 group dosimeters in use. The use of group dosimeters was gradually increased from 2008 along with follow-up of the dosimeter readings and staff feedback. Discussions with radiology personnel were carried out in the radiology departments by the radiation protection officers. The transition from personal exposure monitoring to group dosimeters was approved in each department. The use of group dosimeters was related to tasks where workers can avoid direct vicinity from the primary X-ray beam and the patient. Personal dosimeters were worn by 229 workers in university hospitals, 37 workers in regional hospitals and by 1 radiographer in a health centre. In total 116 radiologists and 151 radiographers wore a personal dosimeter. Forty-nine radiologists were classified into category A and they all worked at two different departments in university hospital; 218 workers (67 radiologists and 151 radiographers) were classified into category B and they worked in five different university hospital departments, in two regional hospitals and in one health centre.

Statistical analyses were carried out with the SPSS (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL, USA) version 17.0 statistical software. The results were analysed with frequencies and analysis of variance. P-value ≤ 0.05 were considered statistically significant.

RESULTS

Accumulated exposure monitoring results exceeding the registration threshold were observed in the personal dosimeters of 73 workers (27 %, $n=267$) in the period 2006–2010, which were divided into 59 radiologists and 14 radiographers. Results of the measured personal dose equivalent ($H_p(10)$) of the staff are shown in Figure 1. The personal dose equivalent of 57 radiologists was under the registration threshold of 0.1 mSv, 23 radiologists <1.0 mSv and 36 radiologists had ≥ 1.0 mSv. All radiologists who have a dose of >10 mSv are working with angiography. Furthermore, 138 radiographers had no

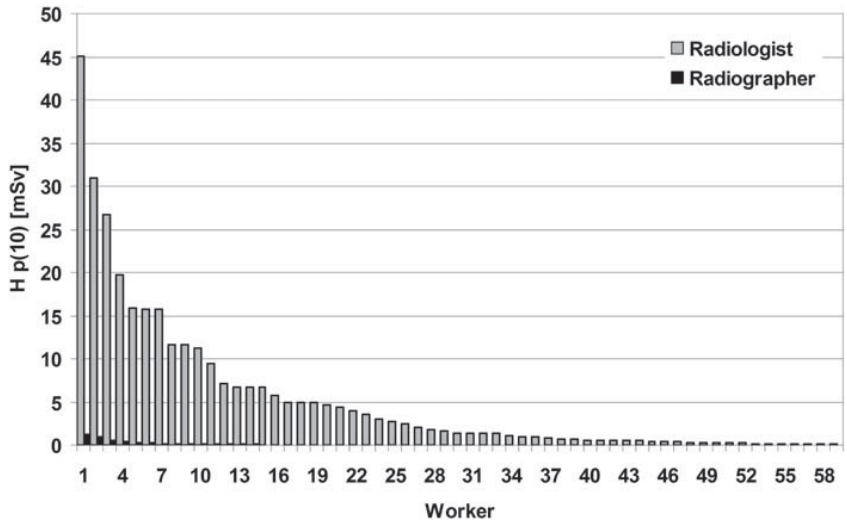

Figure 1. The total accumulated personal dose equivalent of the 73 workers (59 radiologists and 14 radiographers) in the period 2006–2010. The rest of the radiation workers with a personal dosimeter (194 workers) had no dose exceeding the registration threshold.

measured dose, 13 radiographers had <1.0 mSv and only 1 radiographer had a dose >1.0 mSv (1.3 mSv).

The measured personal dose equivalent of radiologists had a mean of 2.7 mSv with a maximum at 45.1 mSv reached by one radiologist. Measured personal dose equivalent of radiologists and radiographers are shown in Table 1. The difference between the measured personal dose equivalent of the radiologists and the radiographers is statistically significant (P=0.000, analysis of variance). Measured dose exceeding the registration threshold was recorded in 38 of the category A radiologists (n=49) personal dosimeters and the doses ranged from 0.1 to 45.1 mSv. Measured dose exceeding the registration threshold was recorded in 35 of the category B classified workers (n=218) personal dosimeters. The personal dose equivalent of 21 category B radiologists ranged from 0.1 to 31.0 mSv and the personal dose equivalent of 14 radiographers ranged from 0.1 to 1.3 mSv. Result of all measured personal dose equivalents of category A and B workers exceeding the registration threshold are shown in Figure 2.

Angiography is centralised to three radiology departments of the university hospital. Measured personal dose equivalent of category A radiologists (n=14) working with angiography was from 3.0 to 45.1 mSv and for category B radiologists (n=13) from 0.0 to 31.0 mSv (Figure 3). In total, 48 radiographers were working with angiography, all of them classified under category B. Four radiographers had a measured dose, which was 0.1 mSv (two radiographers), 0.3 and 0.9 mSv accumulated during the 5-y period.

In the period 2009–2010, the measured personal dose equivalent of 32 group dosimeters was under registration threshold and two group dosimeters had personal dose equivalents of 0.6 mSv $H_p(10)$ and 0.8 mSv $H_p(10)$, respectively, within monitoring periods of 3 months.

Table 1. Measured personal dose equivalent of radiologists and radiographers using personal dosimeter for the period 2006–2010.

	Measured personal equivalent dose (mSv) of staff			
	Median	Mean	Maximum	Minimum
Radiologist	0.1	2.7	45.1	0.0
Radiographer	0.0	0.0	1.3	0.0

DISCUSSION

There are approximately 630 radiation workers at the radiological organisation, of which 267 are monitored by personal dosimeters, and the rest by group dosimeters. In 2008 a major change was made in the organisation as 236 from a total of 505 workers were changed from personal dosimeter monitoring to group dosimeter monitoring, as their dose had been zero for years. Since the application of group dosimeters in the beginning of 2009, the follow-up of the dosimeter results have shown no considerable readings. In only two instances have group dosimeters had readings above the registration threshold in the

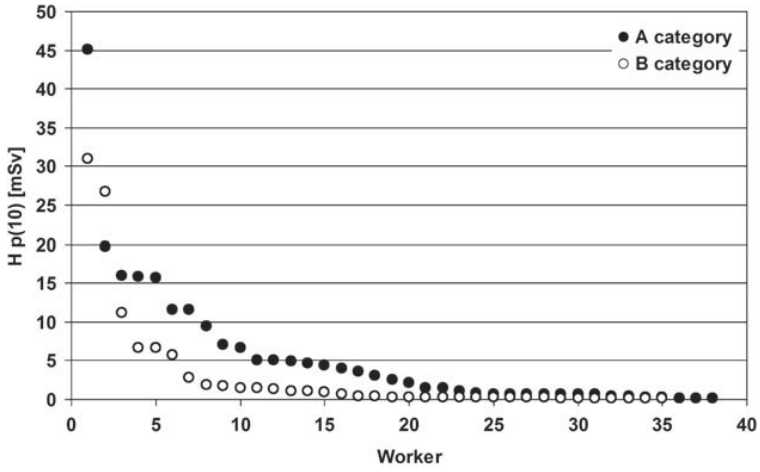

Figure 2. The accumulated personal dose equivalent (exceeding the registration threshold) of A and B category workers in the 5 y period.

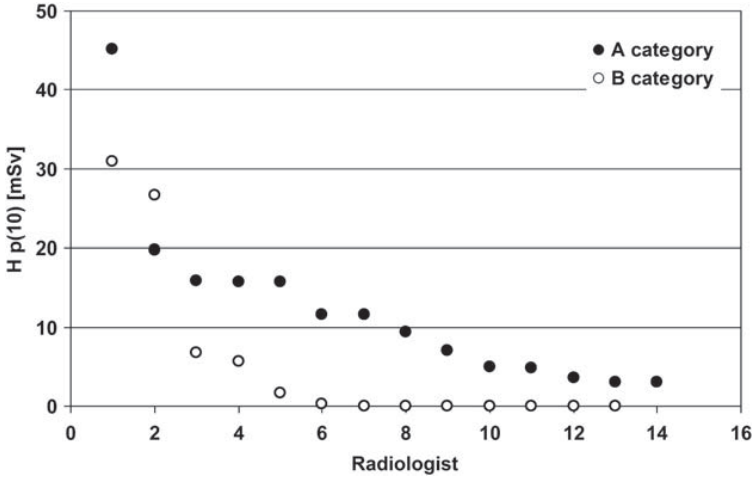

Figure 3. The personal dose equivalent accumulated during the 5 y period of A and B category radiologists working with angiography.

3 month monitoring period. Currently, the electronic interface at the dosimetry service provider is considered to be changed to enable monitoring of the results also below the official registration threshold. Thus, the dose levels between 0.1 and 0.3 mSv could be reviewed for the 3-month monitoring period (category B and group dosimeters).

Out of those 267 radiation workers who are monitored by a personal dosimeter, only 73 had a measurable dose over this 5 y study period. The same trend has been observed in other studies as well. There are only a few radiologists who work with the most complicated procedures and accumulate relatively high doses[22, 23] but the doses of others are at the level of background radiation. Yearly accumulated average dose of 47 out of 73 workers was <0.5 mSv, which is the same value that an average person receives as an effective dose from medical exposures per year while the annual accumulated natural background exposure (as effective dose) level in Finland is 3.14 mSv[24]. The Finnish Radiation Authority STUK keeps records of all people in Finland that might be exposed to radiation in their work. In the period 2006–2010, persons working in occupational health had an average dose of 0.29 mSv y^{-1}[25]. In this study, the average dose per person when all monitored workers are included is 0.24 mSv, a value somewhat below the average in Finland.

Considering the 5 y period of data and taking into account that it is collected over the lead apron, the annual effective dose for each worker can be estimated. Applying the conservative coefficient of 1/30 for person equivalent dose conversion to effective dose[20] results in only seven workers accumulating an effective dose >0.1 mSv y^{-1} (Figure 4). The work done during the past years in radiation protection to improve working methods, shielding and applying modern technology with better optimisation tools ensures that even the mostly exposed interventional radiologists can feel relatively safe.

According to Finnish legislation, radiation safety authorities must be notified of any abnormal event involving the use of radiation that is substantially detrimental to safety[25]. Furthermore, the Finnish authority STUK reports all abnormal events in the annual reports. For example, there were 31 cases in 2010 in which abnormal incidents or situations occurred or were suspected, of which 22 were related to industry, research and education and 9 were related to medical uses of radiation[25]. All of the nine incidents were related to patients getting an unplanned radiation exposure or a larger than planned dose, none were related to occupational exposure to radiation. During the years 2006–2010 there has been annually about 1500 X-ray tubes in use in Finland and more than 4500 radiation workers under surveillance but not a single incident has been reported with occupational exposure hazard in the use of medical X rays. With such control coverage, notable statistical occurrence of abnormal events with elevated occupational exposure levels would have been observed. Thus, there should not be relevant exposure factors beyond the scope of applied radiation protection regime.

Observed results provide ground for revising the radiation work categorisation and measuring practices at the radiological organisation. If the accumulated personal equivalent doses are small then the precision of the dosimeters have higher significance. The results of exposure monitoring may not deviate

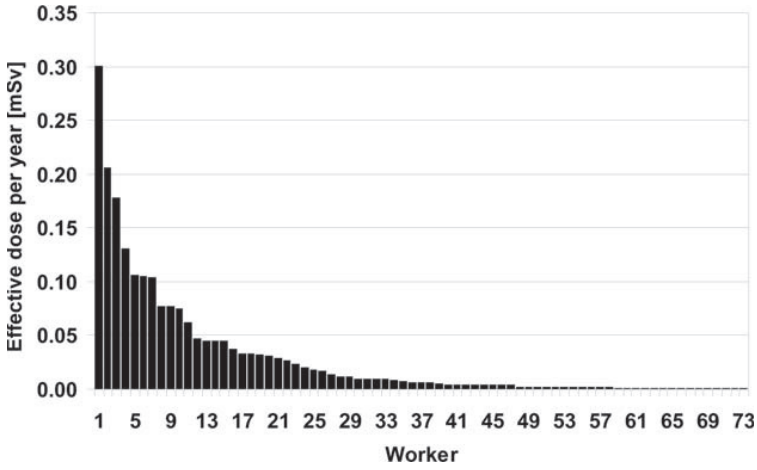

Figure 4. The annual radiation exposure in millisievert of 73 workers calculated by using the conservative conversion coefficient of 1/30 from personal equivalent dose to effective dose[20].

from the true value with 95 % confidence more than 33 % below or 50 % above, when measuring photon radiation and when the measured dose approaches the annual dose limit. When a worker in category A is on the limit of receiving 0.1 mSv month^{-1}, but stays just below, no dose is registered. Shifting this worker to category B with registration period to 3 months is justified. This would leave only a few radiologists who have high doses to category A and shifting the rest to category B. There were 10 radiologists who had received a personal equivalent dose $>$10 mSv during 5 y (see Figure 1) and all of them were working with angiography. This would suggest that only radiologists who are active at angiography should be in category A (Figure 5). The dose registration threshold at STUK for category B is 0.3 mSv for the 3 month period, but the dosimeter accuracy enables reading of 0.1 mSv considering the background dose variation which has to be taken into account in the level of uncertainty when applying TLDs with longer dose accumulation periods. Correct placement of the background dosimeter minimises this uncertainty. However, APDs would give improved tools for efficient occupational monitoring in real time.

The accumulated dose over the 5 y period for 14 out of the 151 radiographers ranged from 0.1 to 1.3 mSv, and only one had a value $>$1.0 mSv. An annual maximum accumulated personal equivalent dose of 0.26 mSv corresponds to an effective dose of 9 μSv y^{-1} which is negligible compared with the natural background radiation exposure of 3.14 mSv. As a change in the monitoring practice, all radiographers should be excluded from individual monitoring and targeted to monitoring of the work conditions by group dosimeters to detect the small exposures as efficiently as possible.

Application of group dosimeters means a practice where several persons use a single dosimeter. Records on personal working hours can be utilised for rough estimation of average exposure levels per worker (assuming constant exposure conditions) but the results cannot be used for determining the actual personal doses. In each examination event, the group dosimeter is used by a group member with the greatest assumed exposure, outside the range of workers with individual monitoring. The group dosimeter is placed outside the lead apron—as in the case of the individual monitoring. The group dosimeter results are included in normal follow-up, which also helps to detect a possible need for individual monitoring.

By maintaining good working methods, the radiographer doses are kept low and by monitoring the environment with on-line active dosimeters any abnormal incident or accident can be detected. The orientation of the new workers would also be performed in a more informative way by using active dosimeters to learn optimised working methods during the examinations or procedures as they occur. With APDs workers are able to see immediately the accumulated dose and to set alarms to detect when the dose rate exceeds set value.

Accumulated personal equivalent dose of 25 radiologists is 1 mSv or less during the 5 y period and of 57 radiologists the dose is under the registration threshold of 0.1 mSv. The annual maximum effective dose is 7 μSv within this group. These are radiologists who occasionally work at interventions or angiography, while mainly they are working as hospital

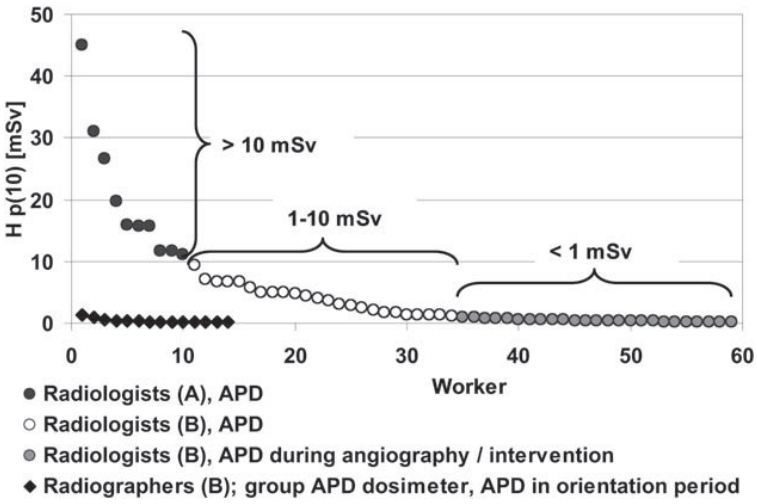

Figure 5. Suggestion for future categories, where the limit between A and B radiologist is defined by active participation in angiography, aligning the accumulated dose during 5 y >10 mSv. The vast tail of radiologists, who have an accumulated dose of 1 mSv or less over 5 y, would only use APDs when they are working in the radiative environment such as in angiography or interventions. All radiographers would be in category B and within monitoring of working conditions by group dosimeters.

doctors with tasks excluding high exposures. If radiologists are only occasionally working in radiative environments it would be much more efficient for them to have an APD with an immediate response of the possibly elevated exposure level during a procedure. APDs can be assigned flexibly on-demand to enable variable amount of APDs per angiography or interventional room. Thus, the performing radiologist can use one of them as personal dosimeter and radiographers as a group dosimeter or as a learning tool.

The above given categories by work task are congruent with the data from the whole country. In STUK annual report 2010[25], the average doses in occupational health in Finland in 2010 divided into categories by work title are given. Also here, the radiologists working in angiography receive the highest average doses: 3.4 mSv for all workers subject to individual monitoring and 6.2 mSv for workers whose dose exceeds the recording level, whereas in this study this latter was 4.1 mSv. On the national scale, other radiologists receive an average of 2.4 mSv and in this study the average was 0.35 mSv. Radiographers received an average of 0.4 mSv and in this study 0.07 mSv, determined only for dose readings exceeding the threshold.

With a new categorisation as depicted in Figure 5, the amount of dosimeters needed at an organisational level would decrease from 267 to ~50, even when A and B radiologists would all use an APD.

The capability to measure pulsed fields should be further assessed to apply APDs in general exposure monitoring. According to the performed survey, the DIS-1 dosimeter is a good candidate for this assessment. When the amount of dosimeters is reasonably low then the costs of changing the system from passive to active dosimeters is acceptable. By retaining the passive dosimeters, the monthly posting of TLDs to the accredited laboratory consumes time and money. Furthermore, the basic problem remains—the passive TLD methodology does not allow on-line exposure monitoring which is the key factor for efficient optimisation in the level of occupational radiation protection. The strengths of APDs are on-line dose reading, dose-rate information, accurate measurement at low doses and access for each worker to their dose information and direct reading of dose measurements to the database. Real-time data are required to facilitate systematic improvements in working methods under various exposure conditions within different clinical radiology facilities with diverse examination profiles and modalities. Electronic dosimetry system is the only feasible choice for such purpose.

CONCLUSIONS

In this study, the dose accumulation of radiation workers at a large central university hospital radiology organisation has been reviewed. It is concluded that the accumulated personal equivalent

doses are generally very small, only a few angiography radiologists have higher doses. The highest effective dose is 0.3 mSv y^{-1}, a small value compared with the mean dose from natural background radiation. A revised categorisation of radiation workers based on the working profile of the radiologist and observed accumulated doses is justified. Considering the observed exposure levels, the occupational monitoring can be implemented mostly with group dosimeters, using either APDs or passive TLDs. However, active real-time dosimetry system is warranted to support radiation protection strategy where the optimisation aspects, including improving working methods, are essential.

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REFERENCES

1. European Commission. *Council Directive 96/29 EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation*. Off. J. Eur. Commun. L159, 39 (1996).
2. Dube, S., King, R. P. and Orton, C. G. *Point/counterpoint. Radiation therapists should not have to wear personnel dosimetry badges*. Med. Phys. **37**(6), 2401–2403 (2010).
3. Czarwinski, R., Kaulard, J. and Pfeffer, W. *Official dosimetry with personal electronic dosimeters—the framework in Germany*. Radiat. Prot. Dosim. **125**(1–4), 267–270 (2007).
4. Ginjaume, M., Bolognese-Milsztajn, T., Luszik-Bhadra, M., Vanhavere, F., Wahl, W. and Weeks, A. *Overview of active personal dosimeters for individual monitoring in the European union*. Radiat. Prot. Dosim. **125**(1–4), 261–266 (2007).
5. Weeks, A. R., Pottinger, M. P. and Clarke, P. W. *The BNFL legal electronic dosimetry service*. In: Proceedings of the Third EC/IOSE Workshop on Occupational Exposure Management at NPPs, Portoroz, Slovenia, 17–19 April (2002).
6. Clarke, P. W. and Weeks, A. R. *Implementation of an electronic personal dosimetry system (EPD) at Oldbury-on-Severn power station*. J. Radiol. Prot. **21**(45), 45–55 (2001).
7. International Electrotechnical commission, *Radiation protection instrumentation. Measurement of personal dose equivalent Hp(10) and Hp(0.07) for X, gamma, neutron and beta radiation—Direct reading personal dose equivalent meters.*, and IEC 61526, v3. IEC (2010).
8. Ankerhold, U., Hupe, O. and Ambrosi, P. *Deficiencies of active electronic radiation protection dosimeters in pulsed fields*. Radiat. Prot. Dosim. **135**(3), 149–153 (2009).
9. Borowski, M., Poppe, B., Looe, H. K. and von Boetticher, H. *Is it really not possible to use electronic personal dosimeters in clinical exposure situations?* Fortschr. Röntgenstr. **182**, 773–779 (2010).
10. Clairand, I. *et al*. *Active personal dosimeters in interventional radiology: tests in laboratory conditions and in hospitals*. Radiat. Prot. Dosim. **144**(1–4), 453–458 (2011).
11. Ginjaume, M. *Performance and approval procedures for active personal dosimeters*. Radiat. Prot. Dosim. **144**(1–4), 144–149 (2011).
12. Clairand, I. *et al*. *Intercomparison of active personal dosimeters in interventional radiology*. Radiat. Prot. Dosim. **129**(1–3), 340–345 (2008).
13. Sanchez, R., Vano, E., Fernandez, J. M. and Gallego, J. J. *Staff radiation doses in a real-time display inside the angiography room*. Cardiovasc. Intervent. Radiol. **33**, 1210–1214 (2010).
14. Prof. Sauli Savolainen, University of Helsinki, Finland and Managing Director Hannu Hyvönen, Doseco Ltd, Finland, Personal communications.
15. Gilvin, P. and McWhan, A. *Different versions of the right answer: the importance of measurement uncertainty in radiation dosimetry*. Radiat. Prot. Dosim. **144**(1–4), 62–66 (2011).
16. Faulkner, K. and Marshall, N. W. *The relationship of effective dose to personnel and monitor reading for simulated fluoroscopic irradiation conditions*. Health Phys. **65**, 502–508 (1993).
17. Niklason, L. T., Marx, M. V. and Chan, H. P. *Interventional radiologists: occupational radiation doses and risks*. Radiology **187**, 729–733 (1993).
18. Kicken, P. J. H., Kemerink, G. J., Schultz, F. W., Zoetelief, J., Broerse, J. J. and van Engelshoven, J. M. A. *Dosimetry of occupationally exposed persons in diagnostic and interventional arteriography. Part II: Assessment of effective dose*. Radiat. Prot. Dosim. **82**, 105–114 (1999).
19. Petrucci, C. *Assessment of the effective dose to personnel in interventional radiology: a review of methods*. Radioprotection **43**(1), 35–52 (2008).
20. Siiskonen, T., Tapiovaara, M., Kosunen, A., Lehtinen, E. and Vartiainen, E. *Monte Carlo simulations of occupational radiation doses in interventional radiology*. Br. J. Radiol. **80**, 460–468 (2007).
21. Salomaa, S. and Suhonen, N., Eds. STUK-A248, Research activities of STUK 2005–2010. Radiation and Nuclear Safety Authority of Finland (2011).
22. Häusler, U., Czarwinski, R. and Brix, G. *Radiation exposure of medical staff from interventional procedures: a multicenter study*. Eur. Radiol. **19**, 2000–2008 (2009).
23. Heron Le, J., Padovani, R., Smith, I. and Czarwinski, R. *Radiation protection of medical staff*. Eur. J. Radiol. **76**, 20–23 (2010).
24. Mustonen, R., Ed. *Surveillance of environmental radiation in Finland*. Annual report 2008. STUK-B 103. Radiation and Nuclear Safety Authority of Finland (2009).
25. Erkki, Rantanen, Ed. *Radiation practices*. Annual report 2010. STUK-B 137. Radiation and Nuclear Safety Authority of Finland (2011).

Quality of Chest Radiograph Reports

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Abstract

Background: Request for examination and imaging report are most important communication instruments between clinicians and radiologists. An accurate and clear report helps referring clinicians to make care decisions for their patients.

Purpose: To evaluate the contents of initial and re-reported chest reports, to assess the inter-observer agreement, and to evaluate how clear the contents of the reports are for the referring physicians.

Material and Methods: The content and the agreement of the reports were analyzed by comparing the initial reports with those of a chest radiologist, the specialist re-reported 293 studies. Referring physicians evaluated the contents of 50 reports regarding medical facts, clarity, and intelligibility of the reports. The results were analyzed using cross-over tables, Pearson Chi-Square, analysis of variance and kappa statistics.

Results: Radiologists mostly addressed the question posed by the referring physician. A separate conclusion in the report was included more often (22%) by the general radiologists while the re-reports by a chest radiologist contained a conclusion in 7% of cases. The chest radiologist reported almost 50% more findings in her reports than the general radiologists. Inter-observer agreement between the initial and the specialist evaluated reports was 66%, but the kappa value was 0.31. The referring physicians considered the reports clear / intelligible in 94% of chest radiologist re-reported studies and in 68% of initial reports.

Conclusion: The quality of radiology reports was rather good even if the contents of the reports varied depending on the radiologists. Low inter-observer agreement on chest radiographs was a consequence of the fact that the non-structured reports contained different quantities of information, complicating the comparison. Referring physicians considered both short and long radiology reports to be clear.

Keywords: Request, Radiology report; Referring physician; Inter-observer agreement

Introduction

Most communication between radiologists and clinicians is based upon requests for an examination and radiological report (1-5). The request for imaging should include a specific question to be answered, in addition to relevant clinical information, a working diagnosis, and/or pertinent clinical signs and symptoms (6-9). Many organizations (*e.g. The European Society of Radiology, the Royal College of Radiologists, the American College of Radiology and the Canadian Association of Radiologists)* have created guidelines for optimal communication of diagnostic imaging findings (10-13). In addition to the description of findings and the posing of specific questions, it is recommended that the report should also contain a separate conclusion. A good radiological report should also be promptly available, accurate, easily understood, correct, and clear (4, 14-16).

A clear request is needed by the radiology unit, while the referring clinician requires an accurate report. The quality of imaging reports must be the same regardless of the radiologist or the time for the report. The aim of this study was to analyze the contents of initial and re-reported chest reports, and to compare the findings reported by general radiologists to those of a chest radiologist and to assess the inter-observer agreement. The other aim was to analyze whether our chest radiograph reports were clear and easily understood by the referring physicians.

Material and Methods

Content of chest radiograph reports

This retrospective study was performed at Helsinki University Central Hospital. The study was approved by the Ethics Committee of the University of Helsinki. The study materials consisted of 293 successive chest radiograph examination reports from the end of December backwards until enough reports were included to the sample. We selected chest radiograph, because it is most frequently performed study in our practice. The materials were collected from a Picture Archiving and Communication System (PACS). The collected materials consisted in 157 pa and lateral chest radiographs, 104 bedside chest radiographs from the radiology department and eleven from the outside radiology department, and 21 frontal chest radiographs. Previous chest radiographs were used in 205 cases. 21 examinations were control examination. In 125 of requests the clinical question was concerned with lung condition, in 90 of requests the clinical question was connected to heart symptoms (e.g. decompensation), and in 57 of re-

quests the clinical question was pneumonia. Experienced general radiologists reported the initial reports in regional hospital. A radiologist working at the Department of Chest Radiology at our University Hospital re-reported the same 293 examinations one year later in accordance with the original request, without patient identifying information and the initial reports, but using the same initial chest radiographs. The general radiologists were unaware of the study design, but the Ethics Committee had approved this. The researcher evaluated the length (word count) of the initial and specialist re-reported reports, and evaluated whether the question posed had been adequately answered, possible recommendations for further imaging had been made and whether a specific conclusion was included in the report.

Agreement of findings

Two experienced radiologists (evaluator 1 and evaluator 2) compared the initial and specialist re-reported reports with regard to specific findings in them:

b) heart size: 1 = normal; 2 = abnormal

c) lung: 1 = normal; 2 = acute infection; 3 = neoplasm; 4 = non-acute chronic disease; 5 = lung based on heart condition; 6 = atelectasis

d) pleura: 1 = normal; 2 = pleural fluid; 3 = pleural thickening /or calcification.

The two evaluators estimated the findings in the two reports as 1 = identical finding; 2 = different finding; 3 = different finding, but with no clinically significant difference.

Uncertain findings in the report were excluded from the analysis.

Referring physicians' evaluation of initial and specialist evaluated reports

Three referring physicians independently evaluated the medical facts, clarity, and intelligibility of both the initial and specialist re-reported reports of 50 chest x-ray studies that had been ordered by them. These three physicians had referred most of patients to chest examinations in regional hospital, while the other referring physicians had sent only a couple of patients for chest examinations at the study point. One year later the three referring physicians evaluated only the reports of their own patients and without X-ray pictures and case histories. The quantity of medical facts in the reports was evaluated on a three-point scale: excessive, sufficient, or lacking. The clarity and content of reports was evaluated using the following scale: 1) clear, 2) intelligible, 3) unclear, and 4) essential information missing.

Statistical analysis

Statistical analyses were carried out with SPSS (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL, US) version 17.0 statistical software. The results were analyzed with cross-over tables, the Pearson Chi-Square test, and analysis of variance (ANOVA) to provide the means of groups. *P*-values ≤ 0.05 were considered significant. Agreement was expressed as percentage of identical reading of both the evaluators and by Cohen kappa (*k*). The *k* –index has been developed as a measure of agreement that is corrected for change. To interpret the kappa values, the classification according to Landis and Koch (17) was used indicating the strength of agreement as: poor (≤0.20), fair (0.21-0.40), moderate (0.41-0.60), good (0.61-0.80) and very good (0.81-1.00).

Results

Content of initial and specialist evaluated chest radiograph reports

The mean length of initial reports was 29 words and the length of re-reported reports was 91 words (Table 1). The difference in mean length of the reports was significant for the chest radiologist as compared to the general radiologists (p = 0.000, Anova – analysis of variance).

The relevant problem/question was included in 189/ 293 requests. The question posed by the referring clinician was nearly always addressed in the initial reports (187/189), and in 184/189 specialist evaluated reports. The chest radiologist recommended further imaging; CT in 65 cases (22%), radiographic follow-up using chest radiographs 55 times (19%) and comparison of new radiographs with older radiographs 49 times (17%). The general radiologists recommended CT twice (1%) for further imaging and follow-up chest radiographs 16 times (6%). A separate conclusion in the report was included by the general radiologists in 22% of cases (65/293 reports); and the re-reports by a chest radiologist contained a separate conclusion in 7% of cases (21/293 reports). The differences in the conclusion included to reports between the general radiologists and chest radiologist was significant (p = 0.000, df 1, Pearson Chi-Square test).

Chest radiographs were reported as normal in 73 initial reports. Re-reported chest radiographs were reported as normal in 9 cases, but in 25 cases possible findings could not excluded.

Agreement in evaluation of findings in reports

Two evaluators (radiologists) compared the initial and specialist re-reported chest radiograph reports (n=293) independently and blinded to any reference to proper names in the text. The opinion of the first evaluator was that in the initial reports and the re-reported reports there were the identical findings (or no clinically significant difference) in 42% (123) of evaluated report pairs. The opinion of the second evaluator was that the evaluated report pairs consisted the identical findings (or no clinically significant difference) in 47% (138) of the cases (Fig. 1).The difference in the coherence of findings between two evaluators was significant (p = 0.001, df 2, Pearson Chi-Square test). How two radiologists evaluated the agreement of findings in 293 initial and specialist re-reported is shown in Table 2 as a 2 x 2 format. The bolded number describes situations, when both evaluators had exactly the same opinions in their findings for the initial and specialist re-reported reports. Calculating the overall proportion of agreement (p_0) we

get 0.66, which indicates that the two radiologists agree in 66% of their interpretations. The corresponding kappa value (k) was 0.31. The k is calculated by means of expected to agree by chance (p_e) and overall agreement p_0. An example of a request and initial and re-reported reports is shown in Table 3.

$$p_0 = \frac{81+112}{293} = 0.66 \qquad p_e = \left(\frac{124}{293}\cdot\frac{138}{293}\right)+\left(\frac{169}{293}\cdot\frac{155}{293}\right) = 0.51$$

$$k = \frac{0.66-0.51}{1-0.51} = 0.31$$

Agreement of heart findings between the initial and specialist re-reported reports was 77% and 79% according to the two evaluators. The chest radiologist reported abnormalities of the heart more often than the other radiologists (85 vs. 43 cases).

Agreement between lung findings of the initial and specialist re-reported reports was 45-47% depending on evaluators. The chest radiologist reported lung findings in 284/286 chest radiographs and the general radiologists reported findings in 123/136 chest radiographs depending on evaluators.

Agreement between pleural findings of the initial and specialist re-reported reports ranged between evaluators 42% and 46%. The chest radiologist reported some pleural findings in 170/150 of 293 chest radiographs and in the initial reports pleural findings in 82/73 of 293 chest radiographs depending on the opinion of evaluators 1 and 2.

Referring physicians' evaluation of the initial and specialist re-reported reports

The three referring physicians deemed the medical facts to be sufficient in 54% (n=27), lacking in 44% (n=22), excessive in 2% (n=1) of the initial reports, sufficient in 80% (n=40) and excessive in 20% (n=10) of the specialist re-reported reports. The difference between the initial and the specialist evaluated reports was significant (p=0.000; df =2; Pearson Chi-Square test).

Initial reports were classified as either clear or intelligible in 68% (n=34), unclear in 14%, and lacking information in 18% of cases. Specialist evaluated reports were clear or intelligible 94% (n=47), and unclear in 6%.

Discussion

The purpose of a radiology report is to provide an answer to the clinical question, a description of the relevant and/or unexpected findings and a conclusion or interpretation of the findings in a clinical context (2, 11, 18-19). In early studies specific questions were posed in 25-41% of requests and a probable clinical diagnosis was given in 18-63% of requests (3-4). In our study the relevant problem/question was included in 66% of the requests and all radiologists addressed almost always the question posed by the referring physician. This result is in line with previous studies.

An imaging report should have a definitive conclusion, with diagnosis or differential diagnosis, referring physicians should not be made to draw their own diagnostic conclusion from the radiologist's description of the findings. This should have been done by the radiologist (20-21). There has been very little study of the lengths of reports, and the lengths of reports of CT examinations have usually been studied. In the study of Bosmans et al. (22) the number of reports without a conclusion varied between 0% - 86%, and the longest report consisted of 366 words, the shortest report was only 7 words. Reports in academic centers were apparently longer than those in peripheral hospitals. In the study of Robert et al. (15) the mean word count in reports with a separate impression was 88 (range 26-190 words), in reports without a separate impression it was 86 words (range 34-133 words). No relation was found between the total length of the report and the presence of a conclusion. The necessity of a separate conclusion has also been questioned for brief reports (23). In our study a separate conclusion was included in 7% to 22% of reports depending on the radiologist. The longest report, by a chest radiologist, consisted of 221 words, and shortest report, by a general radiologist, consisted of 10 words. The chest radiologist reported more possible findings and used more such expression as "it cannot exclude". As in previous studies, no correlation between the length of the report and a separate conclusion was found in our study.

Radiologists may recommend further imaging to confirm their findings. According to a prior study recommendations have more than doubled from 1995 to 2008. Experienced radiologists give fewer recommendations for additional imaging. Examinations with specific findings are more likely to evoke recommendations for further imaging (24). In our study the chest radiologist, working at the university hospital, recommended CT as further imaging in 22% of 293 cases while the experienced general radiologists recommended CT only twice, although they had CT available. Our hypothesis is that at the

university hospital the normal work up of a patient with problems regularly includes further examinations with CT may be the explanation for our findings.

The chest radiologist reported almost 50% more heart, lung and pleural findings than experienced general radiologists. This can be due to differences in the local practice regarding the expected length of the report and the need to describe normal findings or findings of minor clinical significance. Some of the chest radiographs were follow-up studies after previous or ongoing heart or lung illness, which the local radiologists were probably familiar with, resulting in short reports concerning only the ongoing problem.

Inter-observer agreement on chest radiographs has been evaluated in only a few studies. Agreement has been generally high, 91% (change from 78% to 97%) in the study of Stavema et al. (25), and 65% (change from 59% to 62%) in the study of Johnson and Kline (26), however the corresponding kappa (*k*) values were 0.19 and 0.48, respectively. In the study of Stavema et al. and Johnson and Kline there were three pairs of observer. In the study of Xarier-Souza et al. (27) the overall inter-observer agreement mean was 79% and the *k* value was 0.72 for the presence of pneumonia. This study assessed the inter-observer agreement in the interpretation of several radiographic features in the chest radiographs and two radiologists read patient's clinical data independently. In our study, an inter-observer agreement between initial and specialist re-reported reports was 66% as assessed by two evaluators. The corresponding kappa value was 0.31, which is fair in the classification according to Landis and Koch (17). The reports were non-structured and contained different amounts of information, which complicated result comparison. A referring physician faces the same difficulties as a radiologist when comparing report contents.

What are clinicians' preferences regarding radiology reports? According to the previous studies, clinicians expected clear, accurate, detailed reports with radiologists' comments, a conclusion of findings even for examinations without specific findings, and recommendations for further imaging (28-30). The clarity of the written report depends on how well the radiologists convey their interpretation of results and how easily the reader can extract this information (2, 23). In our study referring clinicians considered the specialist long reports as clear or intelligible in 94% and containing sufficient medical fact in 80% of cases, and the initial short reports as clear in 68% and containing medical fact in 54% of cases.

The language used to describe the imaging findings is important to ensure appropriate communication with the referring physician and there must be a reliable mechanism in place whereby the clinician can discuss the findings in complex cases (13, 29, 31-

32). The use of structured reports with a commonly used vocabulary and a standardized language may facilitate the referring physicians' understanding of the content of reports (3-4, 23, 33).

A limitation of this study is that we did not assess the usefulness of all mentioned findings in reports to patient care. Second, the study was conducted at a single large medical imaging center, and although the center consisted of several radiological units at a university hospital, regional hospitals and health centers, the results may not apply to all radiology units.

In conclusion, this study has shown the radiology reports provided answers to the questions posed clinicians, they were clear and contained enough medical facts but the content of the non-structured reports were difficult to compare. Radiologists need more formal training regarding the structure and content of radiology report. The quality of reports should be evaluated regularly by using double reading, as a part of a quality assurance program.

Conflicts of interest: None

REFERENCES

1 Flanders AE, Lakhani P. Radiology reporting and communications: a look forward. *Neuroimaging Clin N Am* 2012;**22**:477-96

2 Bosmans J, Weyler J, De Schepper A, *et al*. The radiology Report as Seen by Radiologists and Referring Clinicians: Results of the Cover and Rover Surveys. *Radiology* 2011;**259**:184-95

3 Hall F. The Radiology report of the Future. *Radiology* 2009;**251**:313-6

4 Kahn C, Langlotz C, Burnside E, *et al*. Toward Best Practices in Radiology Reporting. *Radiology* 2009;**252**:852-6

5 Depasquale R, Crockford M. Are radiology Request Forms Adequately Filled In? An Audit Assessing Local Practice. *Malta Medical Journal* 2005;**17**:36-8

6 Bozkurt S, Kahn CE. An Open-Standards Grammar for Outline-Style Radiology Repot Templates. *J Digit Imaging* 2012;**25**:359-64

7 Wallis A, McCoubrie P. The radiology report: Are we getting the message across? *Clin Radiol* 2011;**66**:1015-22

8 Akinola RA, Akinkunmi M, Wright KO, *et al.* Radiology request forms: are they adequately filled by clinicians? *The Internet Journal of Radiology* 2010;**12**:doi:10.5580/e4a

9 Radiation protection 118. Update Mars 2008. Referral guidelines for imaging. Directorate-General for Energy and Transport. Directorate H — Nuclear Energy. Unit H.4 *Radiation Protection.* 2007.

10 European Society of Radiology. Good practice for radiological reporting. Guidelines from the European Society of Radiology. *Insights Imaging* 2011;**2**:93-6

11 American Collage of Radiologists. ACR practice guideline for communication of diagnostic imaging findings. Revised 2010;1-6

12 Canadian association of Radiologists. CAR Standard for Communication of Diagnostic Imaging Findings. 2010

13 Royal College of Radiologists. Standards for the reporting and interpretation of imaging investigations. Review 2009

14 Grieve FM, Plumb AA, Khan SH. Radiology reporting: a general practitioner's perspective. *Br J Radiol* 2010;**83**:17-22

15 Robert L, Cohen MD, Jennings GS. A New method of Evaluation the Quality of Radiology Reports. *Acad Radiol* 2006;**13:**241-8

16 Ridley LJ. Guide to the radiology report. *Aust Radiol* 2002;**46**:366-9

17 Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;**33**:159-74

18 Department of Health. The Ionising Radiation (Medical Exposure) Regulations 2000, with supplementary guidance on good practice, Statutory Instrument 2000 No.1059

19 Oswal D, Sapherson D, Rehman A. A study of adequacy of completion of radiology request forms. *Radiology* 2009;**15**:209-13

20 Cohen M. Content of a radiology report. *Pediatr Radiol* 2009;**39**:1254

21 Cohen MD, Curtin S, Lee R. Evaluation of quality of radiology requisition for intensive care unit patients. *Acad Radiol* 2006;**13**:236-40

22 Bosmans J, Weyler J, Parizel P. Structure and content of radiology reports, a quantitative and qualitative study in eight medical centers. *Eur J Radiol* 2009;**72**:354-8

23 Pool F. Quality of the Written Radiology Report: A Review of the Literature. *J Am Coll Radiol* 2010;**7**:634-43

24 Sistrom C, Dreyer K, Dang P, *et al*. Recommendations for Additional Imaging in Radiology Reports. Multifactorial Analysi of 5.9 Million Examinations. *Radiology* 2009;**253**:453-61

25 Stavema K, Fossa T, Botnmarka O, *et al*. Inter-observer agreement in audit of quality of radiology requests and reports. *Clin Radiol* 2004;**59**:1018-24

26 Xavier-Souza G, Vilas-Boas AL, Fontoura MS*, et al.* The inter-observer variation of chest radiograph reading in acute lower respiratory tract infection among children. *Pediatr Pulmonol* Aug 8 2012. doi: 10.1002/ppul.22644. [Epub ahead of print]

27 Johnson J, Kline JA. Intraobserver and interobserver agreement of the interpretation of pediatric chest radiographs. *Emerg Radiol* 2010;**17:**285-90

28 Reiner B. Uncovering and improving upon the inherent deficiencies of radiology reporting through data mining. *J Digit Imaging* 2010;**23**:109-18

29 Plumb AA, Grieve FM, Khan SH. Survey of hospital clinicians' preferences regarding the format of radiology reports. *Clin Radiol* 2009;**64**:386-94

30 Espeland A, Baerheim A. General practitioners' views on radiology reports pf plain radiography for back pain. *Scand J Prim Health Care* 2007;**25**:15-9

31 Johnson A, Chen M, Zapadka M, *et al.* Radiology Report Clarity: A Cohort Study of Structured Reporting Compared With Conventional Dictation. *J Am Coll Radiol* 2010;**7**:501-6

32 Spottswood S, Liaw K, Hermanz-Schulman M A*, et al.* The clinical impact of the radiology report in wheezingans nonwheezing febrile children: a survey of clinicians. *Pediatr Radiol* 2009;**39**:348-53

33 Dunnick N, Langlotz C. The Radiology Report of the Future: A Summary of the 2007 Intersociety Conference. *J Am Coll Radiol* 2008;**5**:626-9

Table 1. The length of initial and re-reported reports.

The length of reports							
Initial				Re-reported			
Median	Mean	Maximum	Minimum	Median	Mean	Maximum	Minimum
28 words	29 words	84 words	10 words	89 words	91 words	221 words	26 words

Table 2. The inter-observer agreement in the evaluation of agreement of finding in initial and specialist re-reported reports.

Evaluator 1	Evaluator 2		
	Same finding	Different finding	Total
Same finding	**81**	43	124
Different finding	57	**112**	169
Total	138	155	**293**

Table 3. One example from a request, initial and re-reported report.

Request	Initial report	Re-reported report
Supine chest radiograph: 55-year old woman suffering from high blood pressure, Diabetes mellitus type 2, bipolar disorder, asthma and chronic obstructive pulmonary disease. Reason for admittance was decreased general health, fever (39.9C/103.8F), pulmonary crackles on auskultation. Clinical question: pneumonia?	Comparison to prior upright chest radiograph 12th of Nov. No findings explaining the fewer and the decreased general health is seen. The lung parenchyma appears normal. The heart is compensated. No obvious pleural fluid is detected in the supine view.	Comparison to prior PA Chest 12th of Nov. The inspirium is now less good. Possibly due to patient's habitus the diaphragms are elevated. The size of the heart is unchanged, and within normal limits, no decompensation. Similar to the prior study there are some linear atelectasis mediobasally on the right side. Lateral to the left hilus and in the lingula mild opacification can be visualised, however, this finding can be explained by nonoptimal insirium and summation. Follow-up images of the chest, PA and side view is recommended. No obvious pneumonic parencymal infiltrates are seen and no other new findings.

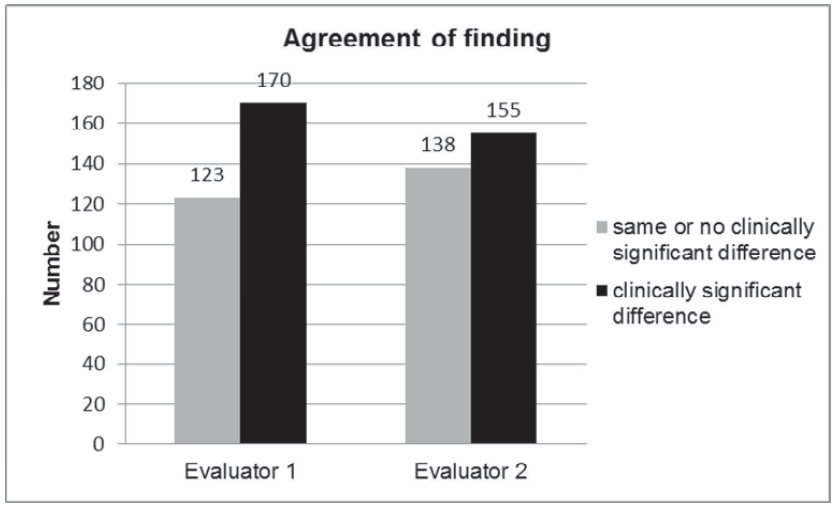

Fig. 1 Agreement of findings as assessed by two evaluators between initial and specialist re-reported reports