Adverse events due to unnecessary radiation exposure in medical imaging reported in Finland

T. Tarkiainen[a, *]

tarja.tarkiainen@ppshp.fi

M. Haapea[b]

marianne.haapea@ppshp.fi

E. Liukkonen[c]

esa.liukkonen@ppshp.fi

O. Tervonen[d]

osmo.tervonen@ppshp.fi

M. Turpeinen[e]

miia.turpeinen@ppshp.fi

J. Niinimäki[d]

jaakko.niimaki@ppshp.fi(jaakko.niinimaki@ppshp.fi)

[a]Department of Diagnostic Radiology, Research Unit of Medical Imaging, Physics and Technology, Oulu University Hospital, POB 50, 90029 OYS, Oulu, Finland

[b]Department of Diagnostic Radiology, Medical Research Center, Oulu University Hospital and University of Oulu, Finland

[c]Department of Diagnostic Radiology, Oulu University Hospital, Finland

[d]Department of Diagnostic Radiology, Research Unit of Medical Imaging, Physics and Technology, Oulu University Hospital and University of Oulu, Finland

[e]Administrative Centre, Research Unit of Biomedicine, Oulu University Hospital and University of Oulu, Finland

*Corresponding author.

Abstract

Introduction

Adverse events in radiology are quite rare, but they do occur. Radiation safety regulations and the law obligate organizations to report certain adverse events, harm and near misses, especially events related to patients' health and safety. The aim of this study was to describe and analyse incidents related to radiation safety issues reported in Finland.

Methods

The data were collected from incident reports documented by radiology personnel concerning notifications of abnormal events in medical imaging made to the Radiation and Nuclear Safety Authority between 2010 and 2017. During these eight years, 312 reports were submitted. Only events reported from radiology departments were included; nuclear medicine, radiotherapy and animal radiology cases were excluded. The final number of reports was 293 (94%).

Results

The majority of the 293 approved reports were related to computed tomography (CT, 68.3%) and to X-ray examinations (27.6%). Altogether 82.9% of those irradiated were adults, most of whom were exposed to unnecessary radiation through CT (86.5%), 5.5% were children, and 4.4% pregnant women. The most common effective dose of unnecessary radiation was 1 mSv or less (89.7% of all examinations). The highest effective doses were reported in CT (from under 1 mSv–20 mSv and above). The reasons for the adverse events were incorrect identification (32%), incorrect procedure, site or side (30%); and human errors or errors of knowledge

(20%).

Conclusion

Adverse events occurred especially in CT examinations. It is important to collect and analyse incident data, assess the harmful events, learn from them and aim to reduce adverse events.

Implications for practice

This study emphasizes the need for radiological personnel to obtain evidence-based information on adverse events and focus on training to improve patient safety.

Keywords: Adverse events; Incident reporting; Imaging errors; Patient safety

Abbreviations: STUK, Radiation and Nuclear Safety Authority of Finland; ST, Guides Radiation Safety Guides; IOM, Institute of Medicine; CTDI, Computer Tomography Dose Index; IAEA, International Atomic Energy Agency

Introduction

In healthcare, the main purpose of reporting adverse events and near-misses is to improve patient safety by learning from such experiences.[1] Systematic analyses of these reports is a good way to develop a safety culture in healthcare.[2] Although a single report does not necessarily lead to a change in healthcare systems, pooling and analysing reports can highlight gaps and faults in the environment. It is necessary to investigate what occurred and, why it occurred, and to determine the deficiencies in the system that allowed the incident to take place.

An accident is usually preceded by a wide variety of contributing factors and a chain of events. To understand the circumstances, a root case analysis of the collected data can prove beneficial.[3,4] Radiation safety in medical imaging is carefully regulated in many countries and reporting of adverse events is mandatory. Finland regulates the fundamental principles of radiation protection in healthcare. First, radiation of a patient must be justified, i.e. the benefits derived from the procedure must exceed any possible detriment. Secondly, the use of radiation must be optimized, i.e. the procedure must be arranged so that radiation doses to patients and personnel do not exceed the level required for the purpose, and the dose must be kept As Low As Reasonably Achievable (ALARA) (ICRP103). Thirdly, the principle of application of dose limits to individuals must be observed in planned exposure situations[5–7]

Modern medical imaging requires complicated equipment and harm or injury is always possible.[8] Technology, equipment and medical devices are vital for modern healthcare, but they do not come without risks arising from, for example, inappropriate use, insufficient user training, device failure, and inadequate inspection and maintenance.[9,10] According to root cause analysis, these errors can be classified as latent and caused by, for example, hardware, installation, materials, or protocols; or as culture-based, active, knowledge-based or skill-based.[5]

The ‘To Err Is Human’ report (1999) by the Institute of Medicine (IOM) brought attention to medical errors. The IOM recommends a strategy to reduce adverse events by providing leadership, promoting effective team functioning, creating a learning environment and implementing nonpunitive systems for reporting and analyses.[11] To date, Zygmont et al. (2017) have developed these guidelines to focus on educational curricula, effective data infrastructures, designed reporting systems, and validated performance measures.[12]

In Finland, when an incident concerns radiation safety, it is reported to the Radiation and Nuclear Safety Authority (STUK). According to Finland's Radiation Act (859/2018) any abnormal event pertaining to the use of radiation that is substantially detrimental to the radiation safety of workers, patients or the environment must be reported.[7,13] Instances that must be reported include cases of accidental exposure to the patient, patient's assistant or personnel; significant over- or underdose, for example, excessive radiation during radiological interventions; and significant unplanned exposure of the lower abdomen or a pregnant patient. Conventional events leading to minor additional exposure (e.g. projection error, movement of patient) do not need to be reported.[14]

This study aimed to analyse Finland's radiation safety reports and the causes and consequences behind them. We also aimed to describe the types of most frequently reported adverse events and to narrate and clarify the incidents that occur in medical imaging.

Methods

Study design

STUK granted permission for this research in March 2018. De-identified radiation safety incident reports were sent to the researcher digitally. The protection of anonymity involved the de-identification of patients and staff, equipment manufacturers and the hospitals in which the adverse events had occurred.

Data selection

This study examined all the incident reports on x-rays, computed tomography (CT), fluoroscopy, mammography, angiography, and intervention examinations from Finland's radiology departments. Reports on nuclear medicine, radiotherapy, cardiology, operation rooms, and dental or animal radiology were excluded. CT-guided interventional procedures were combined with CT, and one intervention with angiography. Imaging personnel report information on incidents to STUK using a form that collects data regarding the responsible holder of the safety license, the name of the radiation safety officer, when and where the incident occurred, a description of the type of incident and examination, persons exposed to radiation, estimated radiation dose, immediate corrective action, and the root cause.

Data analysis

The data were analysed using IBM SPSS Statistics for Windows version 25 (IBM Inc.2017). They included information on the type of incident and examination, a description of how the event affected the individuals (e.g. unnecessary radiation dose) and the cause of the incident as presumed by the informer. The data were used to investigate the numbers of examinations and notifications, what kind of adverse events had occurred, who received the unnecessary dose, and the radiation doses. The underlying causes of the adverse events and near misses were also categorised. Five categories were identified: the wrong (incorrect) patient (identification and referral errors), a pregnant patient or staff member, equipment malfunction, human errors or errors of knowledge, and incorrect procedures, sites or side errors.

The estimated absorbed effective whole-body radiation doses that the patients received were also reported in millisieverts (mSv). If the dose was reported as a Computer Tomography Dose Index (CTDI), the equivalent dose was calculated. All reported doses were estimations rather than exact doses. The International Atomic Energy Agency (IAEA) classification of major radiological examinations in the category of radiation doses was applied in this study. IAEA's dose categories are: 1) low dose of ≤1 mSv, 2) intermediate dose of 1–5 mSv and 3) high doses of 5–20 mSv.[15] A category of 4) high (very high) doses of ≥20 mSv was added.

Results

Radiology safety reports from 2010 to 2017

In total, 483 safety incident reports from Finland's radiology departments were sent to STUK during 2010–2017. Of these reports, 312 concerned radiological imaging and 171 nuclear medicine. Dental, cardiological, operating room, radiotherapy and animal imaging examinations (total of 19 reports) were excluded, because these reports were submitted from outside radiology departments, as well as those of nuclear imaging. The number of reports included in the analysis was N = 293.

During 2010–2011, only 16 reports were registered. From 2012, the average number of reports was 46 per year (Fig. 1). The majority of examinations were CT scans (n = 200, 68.3%), followed by X-ray examinations (n = 81, 27.6%). The combined number of fluoroscopy, mammography, angiography and interventional procedures was small (n = 12.4.1%) (n=12, 4.1%).

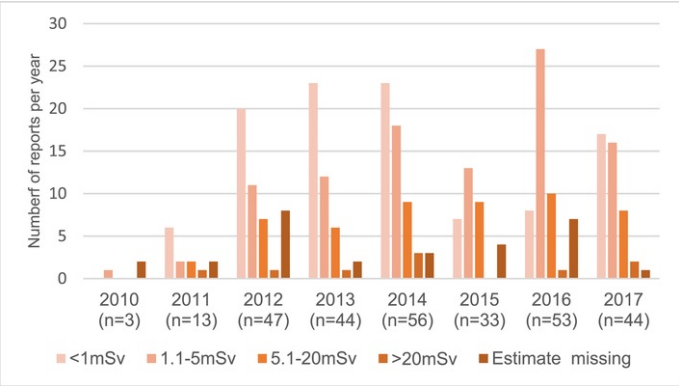

Figure 1 Number of reports and effective doses per year during 2010–2017 in Finland.

alt-text: Figure 1

Unnecessary radiation doses

Most of the individuals exposed to unnecessary radiation were adults (n = 243, 82.9%) and the majority, 173 (86.5%), were exposed to unnecessary or excessive radiation during CT. Only one near miss situation related to equipment malfunction was reported. The number of unnecessary radiation exposures of children (0–16 years) was 16 (5.5%) and pregnant women 13 (4.4%). Seven reports (2.4%) concerned the simultaneous exposure of patients and

staff and 14 (4.8%) reports of unnecessary radiation concerned hospital personnel (e.g. anaesthetic nurse). Radiation exposure of hospital personnel was most common (64.3%) during CT examinations (Table 1).

Table 1 Groups of individuals being exposed to unnecessary radiation by different radiological modalities during years 2010–2017 in Finland.

alt-text: Table 1

Modality	Adult patient		Child[a]		Pregnant and foetus		Hospital personnel		Patient and staff[b]		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Radiography	62	76.5	8	9.9	5	6.2	4	4.9	2	2.5	81	27.6
Computed Tomography	173	86.5	8	4	6	3	9	4.5	4	2	200	68.3
Fluoroscopy	5	62.5	0	0	2	25	0	0	1	12.5	8	2.7
Mammography	2	100	0	0	0	0	0	0	0	0	2	0.7
Angiography	1	50	0	0	0	0	1	50	0	0	2	0.7
Total	243	82.9	16	5.5	13	4.4	14	4.8	7	2.4	293	100

a 0-16 years.

b more than one person exposed to radiation.

As Fig. 1 shows, the amount of extra doses varied from 2010 to 2017. In 2015 and 2016, the highest amount of unnecessary radiation was between 1 and 5 mSv. In the other years, the largest category was under 1 mSv. The highest class doses (>20 mSv) were not reported often, typically one to three times per year. Most of the low doses had occurred in radiography: 68 (75.3%) of all examinations were under 1 mSv. In CT, unnecessary radiation doses covered a broad range, from under 1 mSv to over 20 mSv. In mammography and angiography, the doses were under 1 mSv. In fluoroscopy, three reports of unnecessary radiation were under 1 mSv, two were under 5 mSv, and one was over 5 mSv (Fig. 2).

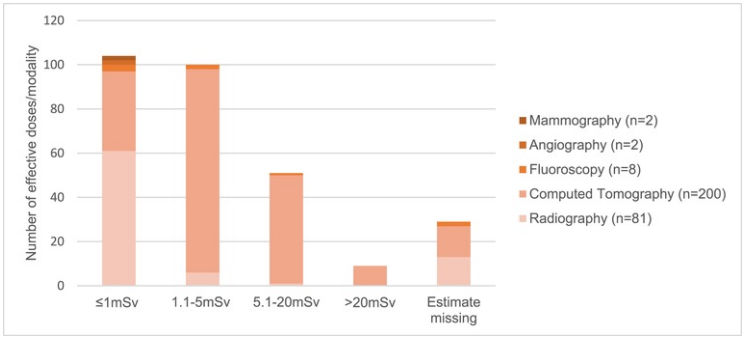

Figure 2 Estimated effective dose amounts of patient's unnecessary radiation in radiology modalities during years 2010–2017 in Finland.

alt-text: Figure 2

The radiation dose was over 20 mSv in nine reports. One child and one pregnant woman exposed to radiation were in this category. The reason for the child's unnecessary radiation was incorrect protocol: the abdomen of a four-year-old boy had been examined using head CT protocol instead of the paediatric abdomen procedure. The highest reported doses were from 32 mSv to 40 mSv. Three patients were exposed to unnecessary radiation (two patients 32 mSv and one patient 33 mSv) due to administration of the incorrect dose of intravenous contrast agent, and the examination had to be repeated. The largest effective dose to a single patient was 40 mSv. This was caused by the analysis technique being changed during a CT examination, resulting in unwanted ECG-gating throughout the examination.

Reports of low doses (<1 mSv) of unnecessary radiation were most common among children, pregnant women and hospital staff. However, both children and pregnant women also received intermediate and very high doses. The largest estimated dose to a foetus was 34 mSv, during multiple examinations. In three other reports, the effective doses to a foetus during abdominal CT were estimated as 2.5 mSv, 8 mSv and 9.8 mSv.

Several reports mentioned that more than one person had experienced unnecessary radiation at the same time. Two or three people had been exposed to radiation simultaneously (had been in the same room) according to 30 notifications. Equipment errors in radiography and CT devices had caused several unnecessary radiation exposures to a number of patients. In some cases, tens or hundreds of patients, and in one case thousands of patients, were exposed. In the largest case, approximately 14 000 patients were exposed to excessive radiation in chest radiography. The root cause of the event was the incorrect connection of a measuring chamber during device installation. While the faulty connection was active between 2008 and 2015, approximately 2000 patients per year had received an additional 0.015 mSv dose in postero-anterior chest radiograph.

Reported causes of adverse events

Table 2 shows the root causes of the adverse events. Incorrect patients were examined in 93 (32%) cases. The largest number of reports of improperly identified patients was in CT (62%). The main reasons for misidentified patients were unverified identifications and errors in referrals. Pregnant patients or staff members were exposed to extra radiation in 16 cases. In these cases, the patients' pregnancies had not been identified properly and pregnant staff members were accidentally exposed to extra radiation.

Table 2 The reasons of adverse events expressed in reports to STUK[a] during years 2010–2017 in Finland.

alt-text: Table 2

Modality	Incorrect patient		Pregnant patient or staff		Equipment malfunction		Human errors and errors of knowledge		Wrong procedure, site or side		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Radiography	34	37	5	31	16	44	14	24	12	13	81	28
Computed Tomography	58	62	9	56	17	47	42	71	74	83	200	68
Fluoroscopy	1	1	2	13	1	3	2	3	2	2	8	2
Mammography	0	0	0	0	2	6	0	0	0	0	2	1
Angiography	0	0	0	0	0	0	1	2	1	1	2	1
Total	93	32	16	6	36	12	59	20	89	30	293	100

[a] Radiation and Nuclear Safety Authority of Finland.

Most of the equipment malfunctions had occurred in CT (47%) and radiography (44%). Fluoroscopy, angiography and mammography examinations together contributed to less than 10% of incidents caused by equipment malfunctions. Examples of events following equipment faults were interrupted examinations, missing images, and service or installation faults. Poor image quality was mentioned twice.

Human errors and errors of knowledge had occurred 59 times (20%) 42 cases of which (71%) had occurred in CT. The most common root causes for the errors were improper use of the contrast agent injector, wrongly selected protocols, or incorrectly positioned slices. In radiography, the most often reported human error was imaging the wrong site or side. The majority of incorrect procedures (83%) had occurred in CT.

Discussion

Annual reports and radiation doses

This study indicates the necessity of collecting and analysing radiological adverse event reports. In Finland, approximately 3.7 million radiographic examinations are performed annually. The annual number of CT scans has increased in Europe and many other countries.[8,16–18] We also found that the largest number of incident reporting involves CT examinations. In Finland, STUK's active role since 2012 in giving instructions to hospitals and radiology departments has boosted incident reporting and increased the number of annually received reports to almost 50.

The average annual radiation dose a Finn receives from radiographic examinations is approximately 0.45 mSv, whereas the average effective dose of abdomen CT is 7 mSv.[18,19] In the current study, the most common excessive dose category of CT was between 1 and 5 mSv (46%) and the second most common between 5 and 20 mSv (24.5%). In nine highest dose reports, the radiation dose was between 32 and 40 mSv. Previous studies have also reported highest unnecessary doses in CT examinations[20,21,].[22] A child or human foetus is more sensitive to the effects of radiation, so in these groups, avoiding unnecessary radiation is of utmost importance.[17,19,23] In the current study,

pregnancy was not verified in two reports and in two cases, the patient denied pregnancy. A pregnant staff member had been exposed to unnecessary radiation in two cases in radiography and in a CT room when the radiation was accidentally switched on. In one of the incidents, pregnancy had not been adequately ruled out for a female trauma patient because of her young age. The patient underwent multiple CT examinations and an interventional angiography, resulting in an estimated dose of 34 mSv to the foetus. The imaging and procedures were performed to save the patient's life, but had the pregnancy been known, some of them could have been replaced by sonography or magnetic resonance imaging.

Root cases of adverse events

According to our results, the type of adverse event was reported, but a detailed description of why and how the incident had occurred was not always given. Ten reports (3.4%) contained no description of the incident. Moreover, the records of the incident in some reports were so sparse that neither the adverse event nor the reason could be identified, for instance ‘repeated CT scans’ and ‘wrong patient’. The same underlying cause could be identified in several reports. For example, in cases of erroneous contrast medium injections in CT, the examination had to be repeated because no contrast agent was injected into the patient or the scan was started at the incorrect time point. Previous studies have reported similar findings.[23,24]

The root causes of the incidents included incorrect patient identification, equipment problems, human errors, and errors of knowledge. A referral written incorrectly or for the wrong patient was also found to be the root case of unnecessary radiation. In three cases, the patients’ suddenly feeling sick had caused unwanted radiation exposure to a radiographer, who had to hasten to the CT room while the radiation was still on. In seven cases, both an adult patient and a staff member had been exposed to excessive radiation because a radiographer or student had pressed the radiation button too soon or by mistake. It is possible that all such incidents are not reported, because the amount of radiation is minor. However, reporting these minor radiation incidents is important because if it occurs regularly, it may be caused by a device design error. In eleven cases, the reason for unnecessary radiation exposure to children was a lack of knowledge regarding proper examination procedures, incorrect identification or improper administration of the contrast medium.

STUK has instructed radiology departments to perform annual self-assessments. All tests are to be performed appropriately and documented properly.[25,26] In one case, thousands of patients were exposed to extra radiation by chest radiography examinations over a seven-year period. This case shows the importance of comprehensive approval tests once the equipment is installed and the necessity of continual, regular quality control tests. The installation setup and tests of radiological equipment are crucial, because in the event of an error, the effects can be serious and far reaching.

Mansouri et al. discovered that safety incidents occur most frequently during CT. This includes diagnostic test orders when the wrong patient is tested, medical and technical errors, and incorrect test errors.[23] Similarly, in our study, the most often mentioned mistakes: incorrect procedures, wrong patients, human errors, errors of knowledge, and equipment malfunctions, all occurred during CT scans. It is impossible to estimate from the incident reports how many of the mistakes were a result of knowledge or skill gaps. However, it is likely that the number of these faults could be decreased by means of education and training.

Despite the fact that harmful events are rare, it is highly probable that not every incident is reported. Several researchers have estimated that at least 60% of adverse events remain unreported.[4,12,22,27] The reason for this could be the lack of knowledge regarding why and how to make a report, or a cumbersome reporting system. It may also be that some frequently occurring incidents are considered ‘normal’ events. The reason that only one near miss case was reported is probably STUK's instructions (since 2015) to compile and report information on minor abnormal events once a year. It is highly probable that these instructions have also mediated the number of reports of unnecessary intermediate dose radiation during 2015–2016 (Fig. 1), because since 2015 only 1 mSv or greater exposure was reported separately. Near misses may be considered harmless and therefore unnecessary to report, or reporting may be regarded as too time-consuming. This is unfortunate, since learning from these near misses may reduce patients' radiation doses in the future. Public authority supervision is also important, because it guides operational efficiency and reporting methods.

Limitations

The main limitation of this study is its reporting-based study material, which is incomplete and inconsistent. The data revealed the root cases and numbers of radiology adverse events, but were not comprehensive. It is very likely that all unnecessary or overexposure radiation examinations were not reported. In some of the reports, the adverse events focused on multiple patients over a long period, and we were unable to obtain the exact numbers of exposed individuals. For this reason, the results are presented by number of reports rather than by number of patients exposed to radiation. In addition, the incident descriptions in some reports were so short that it was impossible to know what the preceding reasons for the incident were.

Conclusion

Regardless of the fact that medical imaging is quite safe, we, as radiological professionals, must be fully aware of adverse events. As radiology examination volumes grow every year, we can conclude that the number of adverse events will also increase. Patient safety should be at the centre of everything we do,[28] and to improve quality, correct procedure should be the goal in every case.[29] These are good principles for us all. As ionising radiation can be

harmful to patients or staff members, it is our responsibility to do our work as well and as safely as possible. To improve safety, it is important to report adverse events and near misses and seek to learn from them. In this way, we improve our safety culture for the benefit of the patient.

Conflict of interest statement

None.

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