Diplomarbeit

European Guidelines for AP chest X-rays in intensive care: routinely satisfiable in a paediatric radiology division? – A retrospective data analysis.

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Eidesstattliche Erklärung

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Graz, am 15.11.2018 *Maximilian Meister eh*

Preface

I've been following the development of Medical Expert Systems since the final years of my studies, and in particular those related to Radiology. Medicine is changing, new evidence is emerging every day, and both at a pace only hardly perceivable by a single human mind. While soft artificial intelligences and other tools supporting the work of radiologists are still in their cradles of development, I was delighted to be able to work with a tool that has the potential to become part of this future and ever changing high tech medicine.

Acknowledgement

Firstly, I would like to express my sincerest gratitude to Prof. Erich Sorantin for giving me the opportunity to conduct this study for my thesis. His patience and guidance significantly contributed in all the time of writing this thesis. Additionally he gave me plenty liberties and time to develop the study according my ideas, which I’m evermore thankful for. I could not have imagined having a better advisor for my study.

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Abstract

Introduction: In 2014 a precursor study was conducted to analyse whether the requirements of the European Commission guidelines for AP/PA radiographs in children were satisfied in day-to-day operations. A semi-automatic tool for time efficient quality audits, as well as possible amendments to the guidelines were proposed. This study was adapted to further analyse the adequacy of the aforementioned tool, and the feasibility of the EC guidelines for children in paediatric intensive care.

Methods: Seven hundred twenty-three unprocessed chest X-rays (47.7% female, 52.3% male, aged 0 to 18 years) were acquired from the local PACS, and examined qualitatively and quantitatively using the aforementioned tool. Qualitative requirements and field sizes were evaluated according to the standards proposed by the EC guidelines.

Results: Mean overexposure of 43±17%, and mean tissue overexposure of 38±16% were found, thus being generally well within tolerance. Satisfaction for the qualitative parameters was less satisfactory with 9.1% (66/723) of all examinations fulfilling all qualitative criteria. Merely 8.2% (59/723) of the total images met all qualitative criteria, and did not show minimal field size truncations or overexposure beyond tolerance.

Discussion: The purpose was to audit the quality of chest X-rays of paediatric intensive care (PIC) patients taken with a mobile unit. Using the tool, inadequate field sizes and inspiration depths were found. Further support for the use and the development of the tool were strengthened. Debateable issues with the guidelines mentioned by the precursor study gained further credibility.

Zusammenfassung

Einleitung: 2014 wurde eine Vorläuferstudie durchgeführt um zu evaluieren, ob die europäischen Richtlinien für AP/PA Thorax-Röntgen im Routinebetriebe umsetzbar sind. Ein halbautomatisches Computerprogramm wurde vorgestellt, welches in Zukunft zeiteffiziente Qualitätsüberprüfungen ermöglichen soll. Darüberhinaus wurden möglich Anpassungen der Richtlinien vorgeschlagen. Diese Studie wurde der Besagten nachempfunden um die Eignung des Programms und die Umsetzbarkeit der Guidelines im pädiatrisch-intensivmedizinischen Umfeld zu evaluieren

Methoden: 723 rohe und unbearbeitet AP Thorax-Röntgenbilder (47.7% weiblich, 52.3% männlich, im Alter von 0 bis 18 Jahren) wurden aus den Archiven erhoben und bezüglich qualitativer und quantitativer Kriterien, gemäß der europäischen Richtlinien untersucht.

Ergebnisse: Bei 43±17% mittlerer, und 38±16% mittlerer Gewebe Überbelichtung, lag diese dementsprechend im Toleranzniveau. Die Qualitativen Standards konnten nur in 9,1% (66/723) erfüllt werden. Lediglich 8,2% (59/723) aller Bilder erfüllten die qualitativen Merkmalen zur Gänze, und wiesen weder Beschneidungen der Mindestfeldgrößen noch Überbelichtungen außerhalb der Toleranz auf.

Diskussion: Der Grund zur Durchführung dieser Studie war die Qualitätsprüfung der AP Thorax-Röntgenbilder die mit dem mobilen Röntgengerät auf der pädiatrischen Intensivstation akquiriert wurden. Durch die Verwendung des Programms wurden inadäquate Feldgrößen und Inspirationstiefen aufgedeckt. Zusätzlich wurde die Eignung des Programms zur Durchführung solcher Überprüfungen weiter bestätigt. Probleme mit Ausführungen in den Richtlinien, welche bereits in der Vorgängerstudie dargeboten wurden, gewannen zusätzliche Glaubwürdigkeit.

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List of abbreviations

AAPM. *The American Association of Physicists in Medicine*

ACR. *American College of Radiology*

AEA. *Actual Exposed Area*

ALARA. *As Low As Reasonable Achieveable*

ANOVA. *Analysis of variances*

ARRS. *American Roentgen Ray Society*

ASRT. *American Society of Radiologic Technologists*

DGPR. *Dutch Group of Paediatric Radiologists*

EC. *European Commission*, *European Commission*

ESPR. *European Society of Paediatric Radiology*

EURATOM. *European Atomic Energy Community*

GPR. *Gesellschaft für Pädiatrische Radiologie*

IAEA. *International Atomic Energy Agency*, *International Atomic Energy Agency*

ICRP. *International Commission on Radiological Protection*

IGA. *Image Gently Alliance*

MaxFS. *Maximum Field Size*

MinFS. *Minimun Field Size*

NICHD. *National Institute of Child Health and Human Development*

NVvR. *Nederlandse Veriniging voor Radiologie*

PIC. *Paediatric Intensive Care*

PICU. *Paediatric Intensive Care Unit*

ROI. *Region of Interest*

SFIPP. *Société Francophone d'imagerie pédiatrique et prénatale*

SPR. *Society of Paediatric Radiology*

STR. *Society of Thoracic Radiology*, *Society of Thoracic Radiology*

UNSCEAR. *United Nations Scientific Committee on the Effects of Atomic Radiation*

WHO. *World Health Organization*

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1 Introduction

Chest X-ray studies rank among the most frequently performed radiographic procedures in children (1-5). To illustrate the specific needs of this radiation sensitive sub-population the reader will be given a short overview on paediatric radiology and related fields. The first pages of the following introductory chapters represent a short glimpse into the history of paediatric radiology, its societies, and leading proponents across Europe and the United States. Furthermore radiation safety programs, and various guidelines will be introduced to the reader. The concluding chapters of the introduction will cover present-day observations concerning implementations in the paediatric intensive care (PIC) patient sub-population and the reasoning that lead to carrying out this study.

1.1 A brief history of paediatric radiology in Europe and the United States of America

Paediatric radiology has a history of more than 120 years. Presenting a detailed summary of its European and American history would go beyond the scope of this thesis. Nevertheless the following chapter aims at introducing the reader to its colourful history.

1.1.1 Vanguard

Paediatric radiology dates back to 1896. In Europe Dutch scientists took the first image of a child's hand at an exposure time of 75 minutes (6). During the same year a 14-year-old's broken wrist was radiographed with a 20-minute exposure at Dartmouth College marking the advent of paediatric radiology in America (7).
Two years after Wilhelm Conrad Roentgen's discovery, Theodor Escherich set up the first paediatric X-ray facility at the Anna-Kinderspital *(Anna children's hospital)* in 1897. He was the first Professor in Paediatrics at the medical faculty of the University of Graz (6, 8). In the subsequent thirty years many other institutions followed throughout Austria, Germany, Switzerland and the Netherlands. Including well-known clinics such as the university hospitals of Heidelberg and Tübingen, the Charité in Berlin, the Children's Hospital of Zurich, or the Sophia Kinderziekenhuis Rotterdam *(Sophia children's hospital),* among others (6).

The aforementioned facilities usually consisted of an X-ray chamber and a dark room, and were often administrated by associated institutes of physics.

1.1.2 Early years: 1900s – 1950s

Right around the time of the discovery of X-rays, Dr John Caffey was born in Utah (9). Caffey spearheaded the American research with many notable publications such as his early publications and the first edition of "Caffey's Pediatric X-Ray Diagnosis". Ironically he had been initially training to become a paediatrician, but was assigned to become the first radiologist in his house. Luckily he enjoyed is added duty. His fundamental contributions in the field of paediatric roentgenology fuelled the enthusiasm of new followers throughout the United States, Canada and France, and consequently led to the first meeting and founding of the (American) Society for Paediatric Radiology (SPR) in 1958 (7, 9, 10). Notable founding members include Dr Frederic Silverman, disciple of Caffey's and first elected president of the SPR, as well as Dr Edward Neuhauser, founder of the world's first paediatric radiology fellowship in 1949. Jacque Lefèvbre, who later became essentially involved in the foundation of the European Society of Paediatric Radiology (ESPR), as well as a precursor of the French "Société Francophone d'imagerie pédiatrique et prénatale" – *(Francophone Society for paediatric and prenatal Imaging)* (SFIPP) was the only European present (7, 9-12).

Advancements in the field continued on both continents. In Europe similar minded paediatricians claimed the domain of paediatric radiography and produced fundamental books. Notable examples include P. Reyher's "Das Röntgenverfahren in der Kinderheilkunde" *(The X-ray method in Paediatrics)* in: H. Bauer "Bibliothek der physikalisch-medizinischen Techniken" *(Library of physical-medical engineering),* J. Duken's "Die Besonderheiten der röntgenologischen Thoraxdiagnostik im Kindesalter" *(Particularities of radiographic thorax diagnostics in childhood),* and S. Engel and L. Schall's "Handbuch der Röntgendiagnostik und –Therapie im Kindesalter" *(The handbook of radiographic diagnostics and therapy in infancy)* (6).

Learning to carry out X-ray studies became an essential skill when training to become a paediatrician in Germany from the 1920s through 1950s. Paediatric Radiology turned into a domain of paediatricians. Many notable examples on the list such as M.A. Lassrich (University Hospital of Hamburg), A. Giedion (University Hospital of Zurich), I. Nitz (Charité Berlin) or M. Fink (University Hospital of

Innsbruck) were trained paediatricians. To the contrary their American counterparts had been radiologists prior to their progressive endeavour of shaping paediatric radiology (6, 7, 9, 10).

1.1.3 Formative years: 1950s – 2000

Since the late 1950s paediatric radiology had already been evolving from its archaic cradles. Image amplifiers, stronger X-ray tubes, automatic film processing and more careful collimation of the X-ray beam started to become routine in the early 1960s. Early forms of technical assistants were hired to support radiologist by performing imaging and developing films. Paediatric radiology started to spread its wings and special studies such as myelography, angiocardiography in children, and the interpretation of neuroradiological studies were either possible for the first time or started to become more frequent (7).

The need for societies of paediatric radiologists had become increasingly clear. Caffey was the first to be approached by North American paediatricians as well as radiologists to take on the task. To their dismay he declined the offer, but referred them to Silverman. Simultaneously, yet separately Neuhauser also tried to set up meetings. He had already held an executive position at the American Roentgen Ray Society (ARRS) and ultimately succeeded at the task. The first meeting of the SPR took place one day prior to the meeting of the American Roentgen Ray Society (ARRS) in 1958. Being a trained radiologist wasn't a requirement since many of the invited were paediatricians and physicians rather than their hosts. Their annual meetings immediately became a success through the wise choice of date, the interest in the field, and their rather informal, yet stimulating course. Neuhauser became the first president by acclamation, followed by Silvermann who followed him as president-elect. Nevertheless even the early meetings in the sixties included topics which set the importance of paediatric radiology in stone. A notable example would be the radiographic distinction between epiglottitis from croup (7, 9, 10).

In the sixties, around the same time as in the United States, the first generation of paediatric radiologists emerged in Europe. They mostly originated from a group of clinically trained paediatricians who had undergone additional training in radiology. Soon enough European counterparts to the SPR emerged. The ESPR as well as the "Arbeitsgemeinschaft für Pädiatrische Radiologie" were founded in 1963 in Paris, and Cologne respectively. The latter became the "Gesellschaft für

Pädiatrische Radiologie" (GPR; *Society for paediatric radiology)* for all German, Austrian, and Swiss paediatric radiologist. Strikingly M. A. Lassrich was a founding member of both societies (8).

In France the works of the "Paris group" under the directive of Lefèbvre formed a precursor of the SFIPP, which was officially founded in 1989. Lefèbvre and his French peers were very well connected with leading figures like Caffey, Neuhauser, Silvermann and Lassrich. Their early international collaborations and involvement essentially let the to founding of the ESPR in 1964, as mentioned above (11, 12).

A little further north, in 1973 the "work group of paediatric radiologists" first met in Rotterdam. In 1977, also Rotterdam, the founding meeting of the Dutch Group of Paediatric Radiologists (DGPR) was held. Notable members include Botenga, Bröker, Jonkers, Kramer, Meradji and Staalman (6).

Unbeknownst to these pioneers European paediatric radiologists would continue struggling with a prolonged identity crisis. It wasn't until years later that the field was recognised as a subspecialty in Germany (1987) and Switzerland (1990). In Austria paediatric radiology is a mandatory field when training to become a radiologist nowadays, but it still isn't acknowledged as an independent subspecialty. However there's an influential work group within the "Österreichische Röntgengesellschaft" (OERG; *Austrian Roentgen Society*), founded by Richard Fotter in 1989. The Dutch share a similar fate with the Austrians. Their work group was recognised by the „Nederlandse Veriniging voor Radiologie" (NVvR, *Dutch Society for Radiology*) in 1983, and later became a section of the NVvR in 1999. The Dutch also require mandatory training in paediatric radiology when training to become a radiologist (6, 8, 12).

The nineteen-nineties led to further international collaboration between the different societies. Paediatric radiology had already become a point of interest in the western medical world. Through academic co-operations across Europe and the US various publications on the good practice in the acquisition of paediatric studies emerged. The American College of Radiology (ACR) routinely published and revised Clinical Practice Guidelines with support of similar societies, including the SPR since 1993 (12). Particularly relevant guidelines in the context of this thesis include the ACR – SPR Practice Parameter for the Performance of Chest Radiography, the ACR – SPR Practice Parameter for the Performance of portable

(Mobile Unit) Chest Radiography (13, 14), and primarily The EC European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics (EUR16261) in 1996 (15).

1.1.4 International Collaboration: 2000 to date

Over the past decades the European and American societies, and authorities have worked on decisively important projects and publications. To further paediatric radiology various clinical practice guidelines, and recommendations have been published. A more in-depth look at these will be covered in the following chapters. The Image Gently Alliance, an international Alliance for Radiation Safety in Paediatric Imaging, was formed in 2007 driven by the idea behind the ALARA principle – "As Low As Reasonably Achievable". Every five years the ESPR and SPR hold co-joint meetings at the IPR Congress, to foster international relations (16-18).

While international co-operation, and research continue to thrive observations on the current state of paediatric radiology lead to numbing conclusions. The recognition of the subspecialty is not as prevalent as one might think, and patients regularly won't be able to be examined by trained paediatric radiologists, but rather general radiologists. An Inquiry at the "Statistisches Bundesamt, Wiesbaden" *(Federal Bureau for Statistics of Germany)* was made. As of a report from 16.5.2018 there have been 178 trained and practising paediatric radiologists in Germany, compared to 10.654 General Radiologists. Alarmingly merely 1,67% of all German radiologists are trained in a sub-specialty relevant to 16,21% of the entire German population (8, 19, 20). Meaning, paediatric radiologists are still underrepresented in relative and absolute terms. On a side-note, another inquiry was made at the GPR in early September 2018. According to their database 115 members were registered at the society as paediatric radiologist. This vanishingly small number across Germany, Switzerland, and Austria, suggests the hidden figures could be even lower across German speaking countries put together.

1.2 Radiation protection in Paediatrics

Radiation protection is one of the biggest hallmarks in the acquisition of high quality radiographic examinations. Children are a specially radiation sensitive population and need strict and suitable radiation protection (21). Caffey was one of the first physicians to advocate against unnecessary radiographic procedures in children (22). It has taken decades until radiation safety programs and recommendations we've come to know were developed. The following chapter will give the reader an alphabetical overview on some prominent institutions and their recommendations concerning optimal practice in paediatric radiology.

1.2.1 Institutions

Various institutions have worked to promote, and guide radiation protection in the general, and paediatric population. The spectrum of these institutions reaches from small, donation funded non-governmental organisations to super governmental institutions. The content of these recommendations predominately cover radiation protection and acquisition technique, and a select few comprise additional diagnostic requirements for medical healthcare professionals and radiologists. This chapter will cover a selection of brief summaries covering the histories and modes of operation of some of the most well established institutions.

1.2.1.1 The European Commission (EC)

The European Commission was formed in 1967 through a merger of the European communities, and was initially called the Commission of the European communities until the treaty of Lisbon. As a super governmental body the commission has released numerous publications on a vast spectrum of issues over the past decades. Directives on radiation protection by antecedent institutions such as the European Atomic Energy Community (EURATOM; EAEC), and Guidelines for adult radiology had already intensified the need for quality criteria in paediatric radiology (23). In 1996 the former EC Directorate-General XII: Science, Research and Development published the *“European Guidelines on quality criteria for diagnostic radiographic images in paediatrics”* which will be introduced in chapter 1.2.2.3.(15).

1.2.1.2 The Image Gently® Alliance (IGA)

The Image Gently ® campaign originates from a committee within the SPR that took up work in 2006, and later became a joint initiative of the ACR, SPR, ASRT, and AAPM (24). Since its formation the IGA has released a set of publications and campaigns, and built a global network to promote excellence in paediatric imaging through free educational campaigns, and collaborations with other organisations (17, 25-29). Chapter 1.2.1.2 will introduce the reader to some prominent IGA campaigns and recommendations most relevant to this thesis. A summary of its history, and a list of its worldwide supporting and partner societies can be found on the official website of the IGA.

1.2.1.3 The International Atomic Energy Agency (IAEA)

The IAEA – founded in 1957 – is the most well established international organization in the field of nuclear energy. Their primary goal is to advocate for the nonviolent use of nuclear energy. It serves as a global forum for international research, collaborations and the peaceful use of nuclear technology. The Organization promotes a plethora of programs in science, nuclear safety, and security standards. Among these programs they've published an array of recommendations related to medicine, and radiology in particular (4, 5, 30-33). A quick summary of these recommendations concerning paediatric radiology will be presented in chapter 1.2.2.1.

1.2.1.4 International Commission on Radiological Protection (ICRP)

The ICRP is an independent, international charity that was founded at the International Congress of Radiology in Sweden in 1928. Its initial mission was to provide information and recommendations on radiation protection in medicine and physics. Since its inception the organizations has increased its scope of operation and become a major proponent of radiation protection (34). The ICRP has developed the International System of Radiological Protection, and has helped at setting industry, topical and regional standards many of which were also implemented in national regulations (35). Additionally, the ICRP recently announced the plan to provide free access to all former publications and educational materials.

1.2.1.5 United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

The United Nations Scientific Committee on Effect of Atomic Radiation was established after a resolution of the United Nations General Assembly in 1955. The UNSCEAR is a supernational institution with a current membership count of 27 nations. The incentive to form the organisation was to precisely define exposures of the world's population to ionizing radiation. The organisations' mode of operation doesn't include legislative power to set radiation protection standards, but rather the obligation to regularly provide the General Assembly with reports on the *Sources and Effect of Ionizing Radiation* (36-38). These highly regarded reports are widely referred to in publications made by other prominent Radiation Safety Organisations like the IAEA, and ICRP (39).

1.2.1.6 The World Health Organisation (WHO)

The WHO was founded in 1948, and has since become one of the most well-established and revered institutions through their work in international public health. Their leading role in the eradication of smallpox is just one of many achievements and on-going programs of the organisation. Relevant to this thesis the WHO has published and array of recommendations related to radiation protection (40-43). Most of these are the outcome of collaborative efforts of the WHO with other organizations like the IAEA and the UNSCEAR. A select few of those will be briefly introduced in chapter 1.2.2.3.

1.2.2 Programs and recommendations

The following chapter will summarise programs and recommendations developed by the aforementioned institutions. Clinical practice guidelines will be presented more thoroughly, whereas other recommendations will be summarized in a more trivial fashion to avoid redundancies or going beyond the scope of thesis.

1.2.2.1 ACR-SPR – Practice Parameters

The American College of Radiology (ACR) has released a collaborative series of interlinked clinical practice guidelines called the „ACR Practice Parameters and Technical Standards“. Relevant to this thesis the ACR, SPR and STR have published co-joint recommendations for the performance of chest radiography through stationary and mobile units (13, 14, 44). The *“ACR-SPR-STR Practice Parameters for the performance of chest radiography”,* and *“[…] for the performance of (mobile unit) chest radiography”* feature well structured information on a wide array of technicalities regarding the performance of chest radiography. General goals, particular indications, individual specifications of examination, documentation, equipment specifications, radiation safety, and quality control are discussed. Both publications feature information specific to adults and children, and regularly cross-reference other ACR publications e.g. concerning special indications for patients in intensive care or general good practice (44, 45). For this study all images were acquired using a mobile unit. The author chose to exclusively summarize recommendations for the relevant information on paediatric patients, supplemented by the therein cross-referenced *“ACR Appropriateness Criteria ®”* for patients in intensive care (14, 45).

The introductory chapters cover general recommendations goals, indications and contraindications for the performance of chest radiography using a mobile unit. Offered examples include the clinically or radiologically indicated examination of the cardiopulmonary system. Further superficially summarised indications include patients with life supporting devices, who are critically ill, cannot be transported to the stationary unit or require immediate assessment following interventional procedures (14, 44, 46-55).

The ACR advocate for qualified and specialised personnel, specifically emphasising radiologists require two years of prior documented training in paediatric radiology. Recommendations for radiologic technologists and medical physicists are made in accordance with the *"ACR-SPR Practice Parameters for General Radiography".* They demand written electronic request for the procedure listing signs, symptoms and patient history to ensure appropriate outcomes. Diagnostic requirements include peak inspiration, reproduction of the lung apices, costophrenic sulci, upper airway, and upper abdomen. The lower thoracic spine and retrocardiac mediastinum should also be visible in optimally shot studies (14, 56). Quality audits are promoted as well as the development of repeat-rate control programs to minimise unnecessary repetitions. Further recommendations on radiation safety are given referencing publications by the IGA and the ACR – Appropriateness Criteria ® (14, 45, 57).

1.2.2.2 **ALARA – *"As Low As Reasonably Achievable"***

The ALARA principle in its original form dates back to UK legislature (58).
In recent decades the term has been used rather exclusively in association in publications on radiation protection. It has also been adopted by the SPR, and later by the IGA to promote radiation safety in paediatric radiology. Since 2001 the SPR has held a series of ALARA conferences to discuss and promote dose management in paediatric radiology. ALARA has since become a synonym for radiation protection in paediatrics (18, 59-62).

1.2.2.3 European Commission (EC) Guidelines

In 1996 the EC published the *"EC European Guidelines on quality criteria for diagnostic radiographic images in paediatrics"* addressed by this thesis. The guidelines were developed through the efforts of paediatric radiologists of the Lake Starnberg Group, and international collaboration of healthcare professionals, researchers and institutions. The publication is divided into four principal chapters covering the quality criteria, a summary of the underlying research, guidelines on the implementation of audits, and a listing of all institutions involved in the development of the guidelines. The first chapter lists quality criteria including comprehensive recommendations for chest, skull, pelvis, full spine, segmental spine, abdomen, and urinary tract examinations (15).
General recommendations include the strict justification of procedure, and the disapproval to reject low quality images that maintain relevant diagnostic information. Audits of rejected images are encouraged to achieve optimisation, with a primary goal being to reduce unnecessary repetition.

In a more detailed fashion image criteria are defined as anatomical structures that need to be reproduced on a radiograph to offer the best possible conditions for diagnosis. Acknowledging the absence of a unified international nomenclature they propose custom key characteristics like “visualisation”, “reproduction”, and “visually sharp reproduction”. Reference values of 200 μGy for the entrance surface dose (ESD) to the patient are provided for the standard five-year-old. Due to a lack of representative dose values for all age groups no detailed recommendations were provided at the time. Additionally, examples of good technique are presented proposing optimal acquisition settings and patients positioning. Diagnostic requirements for chest X-Rays recommended by the EC guidelines can be found below (*see table 1).* Anti-scatter grids are recommended for special indications and adolescent patients. Auto exposure control is not advised for infants and younger children.

Point	***Newborn (< 29 days)***	***Children (> 29 days)***
1.1	*Performed at peak of inspiration*	*Performed at peak inspiration, expect for suspected foreigen body aspiration*
1.2	*Reproduction of the thorax without rotation and tilting*	
1.3	*Reproduction of the chest must extend from the cervical trachea to T12/L1 (part of the abdomen may be included for special purposes)*	
Tolerance	*Up to 1 cm beyond all MinFS edges*	*Up to 2 cm beyond all MinFS edges*
1.4	*Reproduction of the vascular pattern in central half of the lungs*	*Reproduction of the vascular pattern in central 2/3 of the lungs*
1.5	*Visually sharp reproduction of the trachea and the proximal bronchi*	
1.6	*Visually sharp reproduction of the diaphragm and costo-phrenic angles*	
1.7	*Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum*	

Table 1 Diagnostic requirements according to the EC European Guidelines on quality criteria for diagnostic radiographic images in paediatrics: PA/AP chest radiographs (15)

1.2.2.4 IGA – Image Gently Alliance “Back to Basics”

Image gently was called to life in 2006, as mentioned before. The initial incentive to form the committee came from the SPR who were alerted by „skyrocketing“ frequencies in CT scans performed in children (24). The Alliance became committed to promote „assurance“, „collaboration“, „education“, and „openness“ to everyone occupied with paediatric radiographic imagery (17, 24). Over the past decade the IGA has launched several campaigns, of which one was the most relevant to this study. In 2012 the Image Gently Back to Basics campaign for digital radiography was brought in to being (27, 63). The campaign promotes ten steps to manage patient dose in paediatric digital radiography, and therefore radiation protection in children.

The first step encompasses the goal to educate health care professionals by making them revisit the fundamental principles of digital radiography. They advise being knowledgeable about the difference between direct digital, computed, and film-screen radiography. They advocate for direct digital radiography due to higher detective quantum efficiency (DQE), thus needing less radiation exposure compared to computed radiography (64-66).

Step two is aimed at raising awareness about the limitations of digital radiography. Direct visual feedback on exposure has become a thing of the past through digital radiography. Modern machines are capable to produce adequate greyscale images of over- and underexposed studies. Increased exposure leads to decreased digital noise. The campaign advocates to be informed about proper acquisition techniques, and the tortuous path of using brightness or noise as a direct qualitative feedback. Exposure creep awareness needs to be raised, and monitored by indicators and routine image quality analysis (17, 62).

Step three summarizes the need to be informed about the International Electrotechnical Commissions (IEC) standard on exposure terminology. They advise to target deviation index (DI) values ranging from -1 to 1 (64).

Step four advocates a team approach to develop “technique charts” specific to the patients’ metrics, the study performed and equipment available. Furthermore limitations of automatic exposure control (AEC) sensors regarding paediatric patients are discussed. Choosing body part thickness over age or weight as determining factors for acquisitions techniques is additionally encouraged in step five. The subsequent sixth step promotes the adequate use of anti-scatter grids concluding that they should be strictly used for solid body parts thicker than 12 centimetres.

Step seven is directed at radiologic technologists and radiologists. The authors emphasise the benefits of proper collimation before exposure. Digital cropping might fleet the inattentive radiologists eyes and lead to unnecessary overexposures and increase the dose area product (DAP).

Step eight advocates to display technique factors on all workstations including DAP, tube voltage, mAS, target exposure index (EI), and deviation index (DI). The following ninth step promotes to be informed about EI and DI to avoid exposure creep. The last tenth step summarizes the importance of all the previous steps by promoting the development of quality assurance tools and programs.

1.2.2.5 International Atomic Energy Agency (IAEA)

The IAEA has published an array of recommendations for adults and children alike (4, 5, 30-33). These recommendations predominantly address the work field of medical physicists regarding optimization in dosimetry, calibration and maintenance of X-ray equipment. To a lesser degree they propose information on proper acquisition techniques. Fully summarizing the IAEA's recommendations would undoubtedly go beyond the scope of this thesis. The author has chosen to summarize elements of these recommendations most relevant to the study. A brief summary of the recommendations on correct X-ray image acquisition techniques for chest studies in paediatrics will be presented accordingly. For the interested reader the author recommends a look at the "IAEA Human Health Series Vol.24 – Dosimetry in Diagnostic Radiology for Paediatric Patients" (5) and "IAEA Safety Reports Series No. 71 – Radiation Protection in Paediatric Radiology" (4).

The IAEA recommends specific attention to the special requirements of paediatric patients prior to the purchase, configuration, and during commissioning phases of radiographic equipment followed by additional performance tests. Furthermore they advocate interdisciplinary cooperation, as well as routinely performed dose audits to achieve optimal result. Broadly speaking they recommend expert workforces, dedicated paediatric equipment, and custom procedures to assure optimal conditions and outcomes (60, 67-73).

This is coherent with prior evidence porposing that best diagnostic performance at a satisfactory dose can only be achieved by well-trained staff using well-configured equipment (73).

Accordingly, they support positioning devices for infants and toddlers to improve image quality, and to keep the patient dose per image reasonably low by reducing the number of unnecessary images. They propose that collimation of the radiation beam should be tight, and no larger than the actual area of diagnostic interest. Tight collimation will improve image quality, and lead to less irradiated tissue through reduced scatter radiation. The primary approach to reduce unnecessary irradiation is justified examination, and the consideration alternatives – namely non-ionizing procedures (4, 5).

Due to the highly specialised nature of these publications the author has chosen not to consider them as the primary reference point of this study. In the author's opinion the EC Guidelines offer more accessible information on proper image acquisition techniques.

1.2.2.6 International Commission on Radiological Protection (ICRP)

The ICRP frequently releases publications and educational materials. Recommendations for the paediatric sub-population are a central theme of the *"ICRP Publication 121 Radiological Protection in Paediatric Diagnostic and Interventional Radiology",* as well as several free educational materials. These offer a broad set of strategies how to acquire qualitative images, while keeping exposure at appropriate levels. They convey a more practical approach for healthcare professionals than other publications on radiation protection, but leave out additional diagnostic requirements.

Throughout these recommendations several instructions on how to reduce exposure, while attaining high quality images are proposed. Foremost they demand rigorous justification of radiological procedures, followed by proper information of the child and its parents. They advocate immobilization, and thorough verification of the patients' identities. Field sizes need to be appropriate in terms of size, centring point, film focus-distance, and must not be set automatically. Shielding should be applied within a centimetre of the field edges. Appropriate exposure settings comprised of as-short-as-possible exposure times, kVp above 60, and added filtration are encouraged. Furthermore they advocate against the unnecessary use of anti-scatter grids. Audits are to be held for rejected films. Optimisations should be achieved through collection and analysis of these rejects. A further emphasise is put on the request that procedures are to be performed by specifically trained personnel (74, 75).

1.2.2.7 WHO – World Health Organization

The organisation has launched several initiatives in their global effort to improve diagnostic imaging. Starting with the "Global Steering Group for Education and Training in Diagnostic Imaging (1999)" the WHO set out to "Train the trainers".

Partnerships were struck with specialised societies like the ESR and ACR, among many others. Through their collaborative efforts a variety of publications were released since 2001. These recommendations labelled the "technical series" (41, 59), as well as specialised publications for radiologists (40, 42, 43) provide detailed information on radiation protection and image acquisition. Most recently the WHO released the "Bonn Call-for-Action" in conjunction with the IAEA to promote further global initiatives on radiation protection (76).

The technical series provide a plethora of information for radiologic technologists and medical physicists on the proper acquisition of images and calibration of equipment regarding X-rays. Very limited information about diagnostic requirements is given. Most relevant to this thesis they propose the following: for all patients unable to stand diagnostic requirements include peak inspiration, the visibility of the lung apices, diaphragm and costophrenic angles, as well as the reproduction of the retrocardiac lung and spine. (41, 42)

1.3 Scope of thesis: chest x-rays in paediatric intensive care

A precursor study was conducted at the same radiologic division in 2014 (77). The goal was to analyse whether image quality during day-to-day operations was satisfactory. Furthermore a study performed in Germany revealed discrepancies at Paediatric Intensive Care Units (PICU) in Germany. The author analysed the quality of chest studies relating to the various healthcare professions involved. Among other things the author observed recurrent shortcomings due to a lack of properly trained personnel during night shifts, the acquisition of studies by radiologists rather than radiographic technologists, and indications made by unqualified personnel (78).

In addition, as well as to the best knowledge of the author no comprehensive set of recommendations on quality criteria for chest X-rays for paediatric intensive care patients exist. A thorough search of the relevant literature yielded limited results.

To base the study on the recommendations by the Image Gently Back to Basics initiative would not deliver representable results, since they advocate the development of custom, tailor-made "technique charts". Recommendations by various radiation protection agencies and other organizations were mostly directed at individual professions within the work chain but didn't include quantifiable requirements. The "*ACR – SPR Practice Parameters*" and "*ACR – Appropriateness Criteria ®*" were the first contender to European guidelines, due to their practical and broad content, covering multiple fields in an in-depth and well-structured way. Ultimately the "*EC European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics*" were chosen because they offer more detailed and well structured diagnostic requirements, therefore making them the most accessible and feasible option for evaluation.

2 Materials and Methods

The study was designed and remodelled after a pre-cursor study from 2014 evaluating a non-PIC patient population at a single paediatric radiology division (77). After completion of the study design, and following general proceedings raw DICOM images were collected from the local PACS to be analysed retrospectively. Images were processed semi-automatically using an open source software image processing application. The compiled data was consequently analysed using IBM SPSS statistical software.

2.1 General Proceedings

An approval by the local ethics committee (29-558 ex 16/17) was acquired prior to the collection of the raw DICOM images from the archives. Furthermore the study was approved, and sponsored by the Medical University of Graz.

2.2 Image acquisition

Images were gathered from a single paediatric radiology division. Raw DICOM studies of PIC patients over a time period of five years, from 2013 thru 2017 were acquired. A total of 723 images, all of which were acquired with the mobile unit DX-S (Agfa-Gevaert N.V., Mortsel, Belgium) are included in the sample.

2.3 Image analysis

A semi-automatic analysis was performed using a custom Fiji ImageJ Macro proposed by a preceding study examining a non-PIC patient population. DICOM headers and radiographic markers appeared to diverge in a vanishingly small number of cases. Therefore, the author of this thesis chose to append the Macro enabling him to additionally pick positioning and beam path manually as described per image markers.

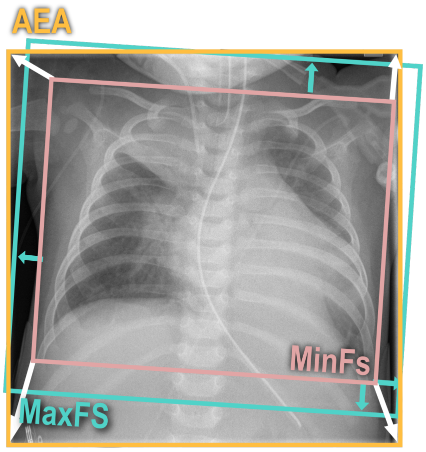


Fig. 1.: Image field sizes: MinFS (red), MaxFS(teal), and AEA(orange)

2.3.1 Image processing software (Fiji ImageJ)

Fiji is an ImageJ based open source java application used to process and analyse images. A macro was acquired from the second observer to analyse the collected set of images.

2.3.2 Work Flow

The author processed all images on a personal computer at the division running Fiji ImageJ, an open source distributed image-processing software.

2.3.2.1 Overview: Semi-automatic image evaluation

The images were loaded into ImageJ and processed with the custom macro tool. Several manual steps needed to be carried out to enable the macro to compute the desired information.

i. ***Image Analysis***

   The author examined all images manually to ensure they were not cropped digitally. Images showing a “silver lining” or peripheral exposure through scatter radiation outside the collimated area were included.

ii. ***Image rotation***

   The centre of the first and twelfth thoracic vertebrae, as well as both costophrenic recesses were marked thereby enabling the macro to straighten the image, and to calculate rotation. (*Fig. 2a&b)*

iii. ***Field sizes***

   Four-sided polygons were traced to measure the actual exposed area (AEA *Fig. 2c*). Subsequently the macro proposed a square representing the minimal field size (MinFS; *Fig. 2d*) according to the EUR16261 guidelines. The square could be adjusted manually when needed. The maximum tolerated field size (MaxFS; *Fig. 2e)* was computed automatically by the macro. (*Fig. 1*)

iv. ***Qualitative Parameters according to EUR16261***

   The image quality needed to be examined regarding its qualitative features. In case of a truncated MinFS the examiner was asked to verify whether the cropped images were still diagnostic.

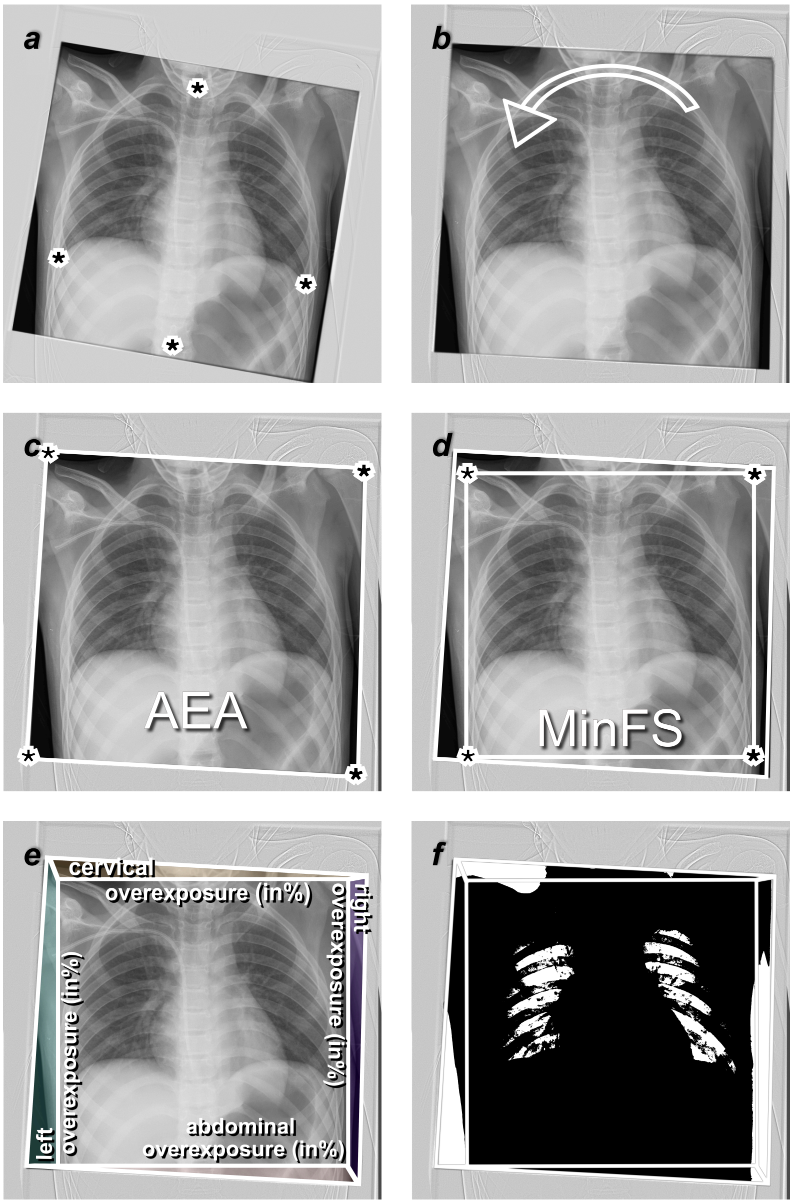
v. *Patient positioning and beam direction*

Patient positioning and beam path were selected manually. Additionally the macro extracted the relevant redundant metadata as mentioned above.

vi. *Computation and output*

Finally the image was automatically transformed by the macro. The greyscale image was converted to black and white to enable the macro to approximate differences between tissue and air *(Fig. 2f)*. Consequently an array of computed data was printed out to a spreadsheet, which in turn was transferred to a software for statistical analysis.

Fig 2 Work Process Steps: The sample shows an eleven-year-old boy whose chest X-ray was taken at the PICU. The visibility outside the collimated field was enhanced to make scatter radiation more presentable in this figure. The stars depict the manual inputs made by the observer.



2.3.2.2 In depth: Fiji Macro script and computations

This subchapter is meant to give the reader a deeper look at the execution of the aforementioned custom Fiji ImageJ macro. The java code of the macro was written by S. Tschauner, MD (Division for Paediatric Radiology, Department of Radiology, Medical University of Graz, Austria). The author of this study acquired the code and made negligible amendments. The interested reader is encouraged to make an inquiry at the division to acquire a copy of the code.

i. General Data

In the first few steps the script acquires and computes a number of general data. It will acquire image height and width, and subsequently calculate the image size. Sexes, and the dates of birth and examination will be selected enabling it to automatically compute the patients' ages and categorise them in different groups according to the NICHD paediatric terminology (79).

ii. ROI Selections

The user is prompted with a dialog to select regions of interest (ROIs) needed to align the image vertically and calculate rotation *(Fig 2 a).* ROIs are defined as x & y coordinates. The code was written to ensure they could be placed in any possible order. Afterwards the rotation is computed using trigonometric functions, automatically evaluating the relative position of each point *(Fig. 2b)*. Furthermore the canvas expanded automatically if parts of the image were outside the initial area after rotation, thus ensuring no artificial truncations.

iii. Area selection & computation

Next a dialog will give the observer a cue to draw a four-sided polygon at the outer edges of collimation, enabling it to compute the AEA *(Fig. 2c).* Again, the code was written to ensure points could be placed in any order possible, using x and y coordinates. Following the previous selection the area outside the AEA will be cleared. Using the initial ROI coordinates from the first step the program will now propose a preliminary rectangle representing the MinFS, and prompt the observer to adjust it if need be *(Fig. 2d).* The script will subsequently start to compute a multitude of parameters including the areas of the MinFS and AEA, as well as the tolerated MaxFS. Additionally overexposures (cervical, abdominal, and lateral), as well as respective distances relative to MinFS and MaxFS, and the distances from the costophrenic angles to the AEA are calculated during this step *(Fig. 2e)*.

iv. Qualitative Parameters & Computations

Prior to the manual input of the next step the program will automatically create polygons and compute whether the costophrenic angles (ROI selection) are within the MinFS, MaxFS or AEA, thus enabling it to estimate qualitative features including truncation and tilting. Further estimations of qualitative parameters are computed using the “getStatistics” function, returning the area, average pixel value, minimum pixel value, maximum pixel value, and standard deviation of the pixel values and histogram of the active image selection. Thereby the program receives further parameters to estimate “Point 1.7 - Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum“.

After the first batch of manual inputs and calculations the observer will be prompted by a dialogue to evaluate the qualitative features of the images.

All qualitative parameters can be estimated before manual input, except for “Point 1.4 – reproduction of the vascular pattern” and „Point 1.5 – reproduction of the trachea and proximal bronchi”, because the calculations needed are to intricate for the script. Afterwards the observer is shown another dialogue, to manually fill out whether qualitative features were met. An additional checkbox, asking whether the image is diagnostic is revealed in case the program had previously computed a truncation of the MinFS.

v. Tissue Overexposure

Finally, the program will select the AEA, run “get(Statistics)” , and convert tissue in to black and air into white, according to predetermined thresholds. Consequently it will draw a series of polygons and calculate absolute and relative tissue overexposures *(Fig. 2e & f).*

vi. Output

All measured, computed and input values are printed into a spreadsheet in Fiji, and can be exported into .txt or .xslx format. Furthermore the potential observer is given the option to choose which parameters are printed out by editing the macro. A full glossary of all measured and computed parameters can be found in the appendix.

2.4 Statistical analysis

The sample size was calculated a priori using G*Power 3.1. recommending the analysis of at least 303 images (α error probability = 0.05, effect size f = 0.25, Power of 95%) (80, 81). The data was analysed with SPSS Statistics Version 24 software (IBM Corp 2016., Armonk, NY) using descriptive statistics, t-tests, ANOVA, and regression analyses. The author performed all analyses, and p-Values less than 0.05 were considered significant. Inter- and intra-observer agreement were examined through a random sample of 37 images (5.12% of the total sample) using Cohen's Kappa and Inter Class Correlations. The second observer (staff member) had developed the macro, and thus didn't require any training or information.

3 Results

A total of 723 studies (47.7% female 52.3% male) were collected and analysed using the aforementioned software. 99.3% of all images were shot in supine anterior-posterior chest view, with the remainder in semi erect position. The mean age of all patients was 5.2 years. Beam collimation had been applied in all 723 cases, and no digital cropping was observed. 8.2% (59/723) of the total number of images met all qualitative diagnostic requirements, and didn't show MinFS truncations or exposure beyond tolerance, as proposed by the EC guidelines. The achieved power was calculated at 99,996% (n=723, f = 0.25, α err – 0.05); computed post hoc using G*Power 3.1. DICOM header Information on patient positioning was coherent in 99.4% (719/723) of all images, and beam path in all.

3.1 Qualitative Parameters

The data acquired for the qualitative parameters was scaled nominally. Descriptive statistics, chi-square, and t-tests were used during the analyses. 49.7% of all images presented MinFS truncations, but were still diagnostic in 99.7% of these cases.

3.1.1 Descriptive Statistics

Descriptive statistics were used to compute frequencies occurring between NICHD paediatric terminology based age groups, and qualitative parameters according to the EC guidelines. 49.7% (359/723) of all images showed MinFS truncations. Out of all 723 images, 9.1% (66/723) fulfilled all qualitative parameters of the diagnostic requirements proposed by the EC guidelines. Good inspiration was found 56.3% (407/723) of cases. 43.2% (312/723) didn't show signs of tilting and/or rotation. The vascular pattern in the central halves of the lungs was visible in 94.1% (680/723) of cases. The upper airways were less apparent with 73.3% (530/723). Visually sharp diaphragms and costophrenic angles could be observed in 46.9% (339//723) of all images. 92.5% (660/723) showed a good representation of the spine and paraspinal structures, as well as the retro cardiac mediastinum. See table 2 for all related findings.

	in total	*newborn*	*infant*	*toddler*	*early childhood*	*middle childhood*	*early adolescence*
	(0-18 years) *n= 723*	(0-29 days) *n = 120*	(1-12 months) *n = 120*	(13-24 months) *n = 108*	(2-5 years) *n = 125*	(6-11 years) *n = 121*	(12-18 years) *n = 129*
Cropped Images	359 (49.7%)	83 (69.2%)	51 (42.5%)	51 (47.2%)	63 (50.4%)	53 (43.8%)	58 (45.0%)
Images correct based on EUR16261	66 (9.1%)	3 (2.5%)	24 (20.0%)	20 (18.5%)	15 (12.0%)	2 (1.7%)	2 (1.6%)
Good Inspiration? (EUR16261 POINT 1.1)	407 (56.3%)	65 (54.2%)	78 (65.0%)	65 (60.2%)	79 (63.2%)	58 (47.9%)	62 (48.1%)
No tilting? (EUR16261 POINT 1.2)	312 (43.2%)	32 (26.7%)	30 (25.0%)	55 (50.9%)	68 (54.4%)	59 (48.8%)	68 (52.7%)
Vascular pattern? (EUR16261 POINT 1.4)	680 (94.1%)	110 (91.7%)	112 (93.3%)	104 (96.3%)	115 (92.0%)	117 (96.7%)	122 (94.6%)
Bronchi apparent? (EUR16261 POINT 1.5)	530 (73.3%)	63 (52.5%)	86 (71.7%)	92 (85.2%)	107 (85.6%)	100 (82.6%)	82 (63.6%
Recessus apparent? (EUR16261 POINT 1.6)	339 (46.9%)	48 (40.0%)	41 (34.2%)	52 (48.1%)	63 (50.4%)	69 (57.0%)	66 (51.2%)
Paraspinal apparent? (EUR16261 POINT 1.7)	669 (92.5%)	115 (95.8%)	113 (94.2%)	101 (93.5%)	120 (96.0%)	110 (90.9%)	110 (85.3%)

Table 2 Descriptive Statistics: Qualitative variables in total, and divided into age groups (%)

3.1.2 Chi Square tests

Chi square tests were performed to examine the relations between age groups and the qualitative parameters of the EUR16261 guidelines. First the qualitative parameters were compared to age groups collectively.

A significant difference between the age groups and overall qualitative correctness was examined ($\chi^2(5) = 53.26, p = .00, \varphi = 0.27$). The infant subgroup showed most correct images at a percentage of 20.0% (24/120). To the contrary only 1.6% (2/129) of all patients in early adolescence met all diagnostic requirements according to the EC guidelines. *(see table 2)*

Further tests were performed to evaluate relations between age groups and remaining individual qualitative parameters. The results showed a significant association between age groups and the quality parameter “Point 1.1 – good inspiration” $(\chi^2(5) = 14.1, p = .02, \varphi = 0.14)$. At a correctness of 47.9% (58/121) inspiration was the poorest in middle childhood, and the best in infants with 65.0% (78/120).

Tilting and rotation were examined subsequently. Results showed a significant association between the age groups and the quality parameter “Point 1.2 – reproduction of the thorax without rotation or tilting” $(\chi^2(5) = 44.88, p = .00, \varphi = 0.25)$. Based on the EC guidelines “Rotation and tilting” were the poorest in infants at 25% (30/120) and the best in patients in early childhood at a percentage of 54.4% (68/125).

“Point 1.3 – Reproduction of the chest must extend from just above the apices of the lungs to T12/L1“ was not evaluated directly, since it was already analysed in reverse through the number of cropped images. A significant relation between age groups and image truncation was found $(\chi^2(5) = 23.81, p = .00, \varphi = 0.18)$. At 69.2% (83/120) the subgroup for newborns showed the highest percentage of cropped images compared to the infant subgroup showing a relative percentage of 42.5% (51/120).

No significant relation between age groups and “Point 1.4 – reproduction of the vascular pattern” $(\chi^2(5) = 4.82, p = .44, \mathrm{ns})$ could be found.

However a significant relation for “Point 1.5 – reproduction of the trachea and proximal bronchi” was found $(\chi^2(5) = 55.80, p = .00, \varphi = .23)$. Worst fulfilment was found in newborns with 52.5% (63/120), and best in patients in their early childhood with 85.6% (107/125).

Next the relation between the various groups and “point 1.6 – visually sharp reproduction of the diaphragm and costophrenic angles” was inspected. A significant result was observed $(\chi^2(5) = 44.88, p = .00, \varphi = 0.25)$. The lowest percentage of 34.2% (41/120) was seen in infants, whereas patients in their middle childhood showed the highest percentage of visually sharp diaphragms with 57.0% (69/121).

A final chi-square tests was performed to examine the relation between age groups and “Point 1.7 - Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum“ ($\chi^2(5) = 14.99, p = .01, \varphi = 0.14$). At 96.0% (120/125) the best results were observed in children in their early childhood. The worst results at 85.3% (110/129) were found in early adolescents.

3.1.3 t-Tests

The qualitative parameteres were additonally examined using t-tests. Every point of the EC guidelines was evaluated relative to the age of the patients.

3.1.3.1 Good Inspiration – EUR16261 Point 1.1

„1.1. Performed at peak of inspiration“

The relation between adequate inspiration and age was evaluated using t-tests. A statistically significant difference between images with adequate inspiration and images without adequate inspiration regarding the age of the patients was discovered. Images with adequate inspiration showed a significantly lower mean age ($\bar{x} = 4.59, s = 5.60$) compared to images with inadequate inspiration ($\bar{x} = 5.87, s = 5.89$). Images with adequate inspiration showed the mean patient age was 1.28 years lower ($95\% - CI[0.43, 2.13]$) compared to the mean age for inadequate inspiration ($t(721) = 2.99, p = .00$).

3.1.3.2 Image rotation and tilting – EUR16261 Point 1.2

„1.2. Reproduction of the thorax without rotation and tilting“

Another significant difference concerning image rotation was found *(see Fig. 3.)* The patients with rotated images were significantly younger ($\bar{x} = 4.37, s = 5.43$) than patients whose images were rotated ($\bar{x} = 6.17, s = 6.02$).

The mean age of patients with rotated images was 1.8 years ($95\%\ CI[2.64, -0.96]$) lower than in patients with rotated images ($t(721) = -4.21, p = .00$).

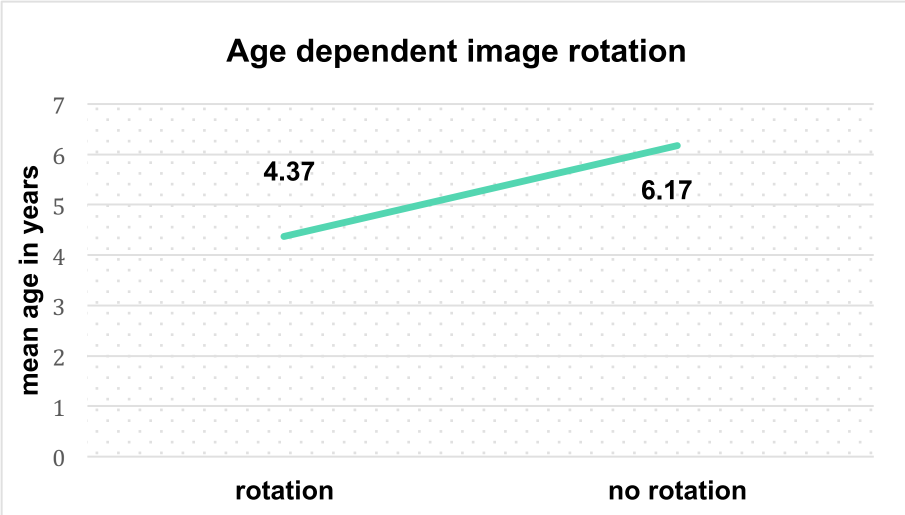


Fig 3 Differences in mean patient age regarding image rotation.

3.1.3.3 MinFS Truncation

„1.3. Reproduction of the chest must extend from the cervical trachea to T12/L1(part of the abdomen may be included for special purposes)"

A statistically significant difference between cropped images and uncropped images regarding the age of the patients was found. Cropped images were found predominantly in younger patients ($\bar{x} = 4.60, s = 5.55$) compared to patients with uncropped images ($x = 5.68, s = 5.92$). Accordingly the mean patient age for cropped images was 1.08 years lower ($95\% CI[0.24, 1.92]$) than the mean age of patients without cropped images ($t(721) = 2.52, p = .01$).

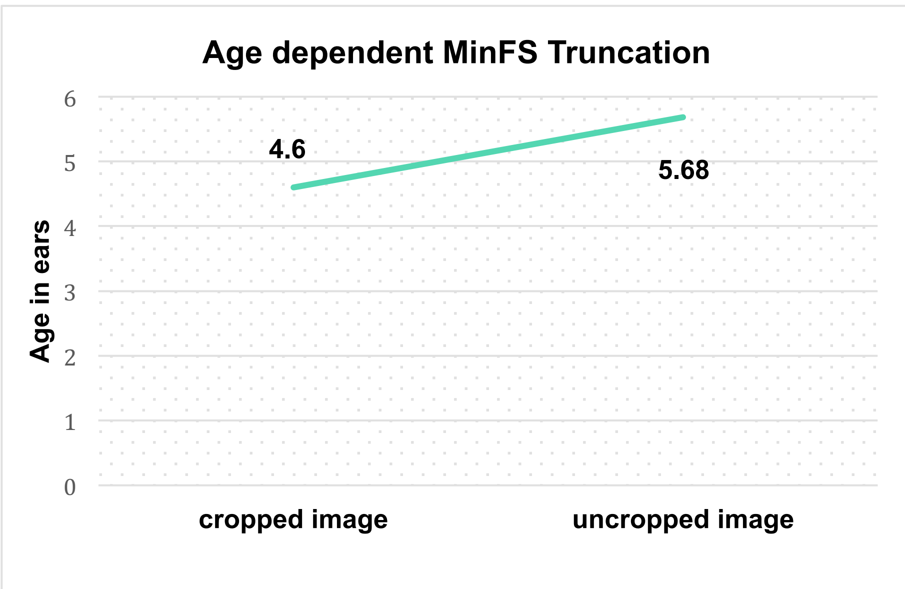


Fig 4 Differences in minFS truncation regarding mean patient age.

3.1.3.4 Vascular pattern – EUR16261 Point 1.4

„1.4. Reproduction of the vascular pattern in central half of the lungs"

No statistically significant difference between images with, and without visual reproduction of the vascular pattern relating to the age of the patients ($t(721) = -.98, p = .33, ns$) could be found.

3.1.3.5 Trachea & Bronchi – EUR16261 Point 1.5

1.5. Visually sharp reproduction of the trachea and the proximal bronchi

Similarly, a statistically significant difference between images regarding the visual reproduction of the trachea in relation to the age of the patients ($t(721) = -.42, p = .67, ns.$) was not observable.

3.1.3.1 Sharp Diaphragm – EUR16261 Point 1.6

1.6. Visually sharp reproduction of the diaphragm and costo-phrenic angles

A significant difference between images with sharp reproduction of the diaphragm and costo-phrenic angles, relating to the age of the patients was observed.

The mean patient age in visually sharp images was significantly higher ($\bar{x} = 5.76, s = 5.93$) than in patients with images without a visually sharp reproduction of the diaphragm ($x = 4.60, s = 5.56$). A mean age difference of 1.16 years ($95\% - CI[-2.00, -0.32]$) was observed ($t(721) = -2.72, p = .00$).

3.1.3.2 Paraspinal – EUR16261 Point 1.7

„Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum"

A significant difference between images regarding the reproduction of the spine in relation to the age was discovered. Patients shown in images where the structures were reproduced were found to be younger ($\bar{x} = 4.95, s = 5.69$) than their counterparts without reproduction of the spine, paraspinal structures and mediastinum ($\bar{x} = 7.59, s = 6.10$). A difference in mean patient age of 2.64 years ($95\% - CI[1.05, 4.23]$) less for images with a visually good reproduction was found ($t(721) = 3.26, p = .00$).

3.2 Quantitative Parameters

The analysis with the aforementioned semi-automatic tool allowed for the measurements and calculations of various quantitative parameters. A full list of all collected quantitative parameters can be found in the appendix.

Mean image rotation was balanced at 0.07±5°, at maximum values ranging from 22.0° to left, and 24.3° degrees to the right. Interference statistics were used to evaluate relations between observed exposure values and age. Corresponding results are found in chapter 3.2.2

3.2.1 Descriptive statistics

Descriptive statistics were used to describe frequencies in general overexposure, and tissue overexposure regarding different age groups. Additionally frequencies of examinations showing diagnostic field sizes and overexposure within tolerance were determined. As mentioned before 49.7% (359/723) of all images showed field size truncations, therefore disabling the tool to calculate overexposures for those studies. The remaining 51.3% (364/723) images showed a mean overexposure in relation to MinFS of 43±17%. Mean tissue overexposure in relation to MinFS was observed to be at 38±16%. 29.7% (108/364) of all uncropped images, and therefore 14.9% (108/723) of all images showed field sizes and overexposure within tolerance *(table 3).* Furthermore, overexposure and tissue overexposure were examined in their relation to MinFS and respective sub areas (left, right, cervical, abdominal; *see table 4*). At 13.9±7.0% the highest percentage of overexposure in relation to MinFS was observed in the cervical area. Followed by 12.6±10.4% for the abdominal, and 8.2±4.4% for the lateral sub areas. Corresponding findings for mean tissue overexposure and related findings can be found in table 4.

sample mean $\overline{x}$ Standard deviation ±s	**_in total_** (0-18 years) *n= 364*	**_newborn_** (0-29 days) *n = 37*	**_infant_** (1-12 months) *n = 69*	**_toddler_** (13-24 months) *n = 57*	**_early childhood_** (2-5 years) *n = 62*	**_middle childhood_** (6-11 years) *n = 68*	**_early adolescence_** (12-18 years) *n = 71*
Mean overexposure in relation MinFS (in%)	43±17	51±21	50±19	.40±17	36±15	44±17	41±15
Mean tissue overexposure in relation to the MinFS (in%)	38±16	44±19	44±17	34±14	31±13	38±16	37±13
Studies with diagnostic field sizes and overexposure within tolerance	108 (29.7%)	7 (18.9%)	29 (42.0%)	25 (43.9%)	28 (45.2%)	11 (16.2%)	8 (11.3%)

Table 3 Overexposure and tissue overexposure in relation to minFS (in %), and diagnostic studies within tolerance

sample mean $\overline{x}$ *SD (s)*		**_Total_** *(n =364)*	**_Left area_**	**_Right area_**	**_Cervical area_**	**_Abdominal area_**
Overexposure in relation to the MinFS (in %)	$\overline{x}$ (%)	42.97	8.38	8.03	13.90	12.63
	s (%)	17.49	4.64	4.23	7.04	10.38
	Min (%)	8	0	0	0	0
	Max (%)	111	29	25	38	70
Tissue overexposure in relation to the MinFS (in %)	$\overline{x}$ (%)	37.56	6.53	5.98	12.68	12.37
	s (%)	15.83	3.69	3.34	6.75	10.11
	Min (%)	8	0	0	0	0
	Max (%)	102	21	21	38	67

Table 4 Overexposure and tissue overexposure in relation to minFS and sub areas

Subsequently, various distances were measured and put into relation to the various possible field sizes. *(see fig 5, table 4)*

Observed mean distances from respective MinFS edges to their AEA borders were 20±12mm for cervical, 10±8mm for lateral and 9±22mm for abdominal respectively. Notably the mean abdominal distance in relation to MinFS turned out to be negative with -1.2±8.6mm in the newborns sub group. The corresponding mean distances from the MaxFS borders to their respective AEA edges were -9±21mm (abdominal), 1±12mm (cranial), and -8±8mm (lateral). Sinuses were cropped in 4.14% of all images, in coherence with a mean distance from the abdominal MinFS border to the lower costophrenic angle of 36±23mm. Furthermore sinuses were increasingly cropped with age, ranging from 0% in newborns, and 2.5% in infants up to 9.3% for patients in their early adolescence.

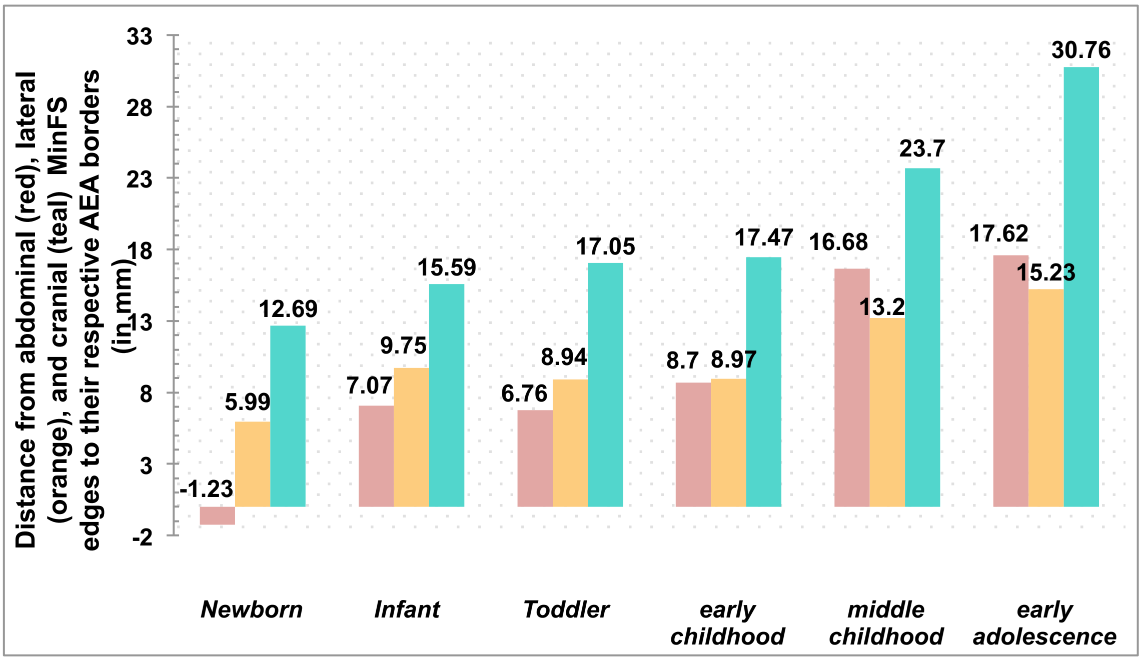


Fig 5 Bar graph visualising the distances from sub area edges to their respective AEA borders (in mm). Newborns are showing a negative mean abdominal distance. See table 4.

sample mean $\overline{x}$ standard deviation(s)	i*n total* (0-18 years) *n= 723*	*newborn* (0-29 days) *n = 120*	*infant* (1-12 months) *n = 120*	*toddler* (13-24 months) *n = 108*	*early childhood* (2-5 years) *n = 125*	*middle childhood* (6-11 years) *n = 121*	*early adolescence* (12-18 years) *n = 129*
$\overline{x}$ *distance from the abdominal MinFS edge to the caudal collimation border (mm)*	9.42 (21.81)	-1.23 (8.56)	7.07 (13.08)	6.76 (14.28)	8.70 (16.99)	16.68 (28.44)	17.62 (31.76)
$\overline{x}$ *vertical distance from the abdominal MinFS edge to the lower costophrenic angle (mm)*	35.54 (22.63)	19.47 (7.38)	23.81 (11.15)	30.78 (12.93)	36.87 (15.22)	47.02 (23.30)	53.33 (31.81)
$\overline{x}$ *vertical distance from the abdominal AEA edge to the lower costophrenic angle (mm)*	44.96 (26.79)	18.23 (9.13)	30.88 (13.4)	37.54 (14.38)	45.56 (16.36)	63.70 (27.75)	70.96 (27.08)
$\overline{x}$ *distance from the cervical MinFS edge to the cranial collimation border (mm)*	19.72 (12.19)	12.69 (6.03)	15.59 (6.95)	17.05 (8.62)	17.47 (9.21)	23.70 (12.79)	30.76 (15.83)
$\overline{x}$ *distances from the lateral MinFS edges to the respective collimation borders (mm)*	10.43 (8.44)	5.99 (5.22)	9.75 (6.40)	8.94 (6.86)	8.97 (6.69)	13.2 (9.65)	15.23 (10.69)
$\overline{x}$ *distance from the abdominal MAXFS Edge to the respective AEA Border (mm)*	-8.92 (21.31)	-11.23 (8.56)	-12.93 (13.0)	-13.24 (14.28	-11.30 16.98)	-3.32 (28.44)	-2.38 (31.76)
$\overline{x}$ *distance from the cranial MAXFS Edge to the respective AEA border (mm)*	1.38 (11.79)	2.69 (6.03)	-4.41 (6.95)	-2.95 (8.62)	-2.53 (9.21)	3.70 (12.79)	10.76 (15.83)
$\overline{x}$ *distance from lateral MAX FS edges to the respective AEA borders (mm)*	-7.91 (8.39)	-4.01 (5.22)	-10.25 (6.40)	-11.06 (6.86)	-11.03 (6.69)	-6.80 (9.65)	-4.77 (10.69)

Table 5 Borders in relation to minFS, maxFS and AEA (in mm)

3.2.2 Interference statistics

One-way analyses of variance (ANOVA) and regression analyses were performed to examine metric data. Various metric parameters regarding overexposure were examined regarding their relations to the various age groups (ANOVA), as well as age in years (regression analysis). Furthermore requirements for univariate ANOVA were verified because of discrepancies in the distribution of various subgroups. No significant outcomes were discovered in regression analyses and ANOVA of areas not mentioned in the following chapters.

3.2.2.1 Requirements to conduct an ANOVA for Overexposure in relation to MinFS & age groups

i. Normal distribution

The dependent variables were not normally distributed in all age groups. Overexposure (in %) in relation to MinFS was normally distributed in newborns (0-29 days; $p > .05$), but not in infants (1-12 months; $p < .05$), toddlers (13-24 months; $p < .05$), early childhood (2-5 years; $p < .05$), middle childhood (6-11 years; $p < .05$), and early adolescence (12-18 years; $p < .05$), as assessed by the Shapiro-Wilk test ($\alpha = .05$). It has been pointed out that ANOVA is stable against the violation of this requirement. Furthermore, it is suggested to refrain from using an inferior statistical procedure (82).

ii. Statistical outliers

Eleven statistical outliers were found which can be described as mild. All of them deviated lower than 3 times the interquartile range. Outliers were kept in the data set because no plausible reasons to exclude them were found.

iii. Homogeneity of variances

Homogeneity of variances was asserted using Levene's test affirming that equal variances could be assumed ($p = .21$)

3.2.2.2 Requirements to conduct an ANOVA for tissue overexposure in relation to MinFS & age groups

i. Normal distribution

Overexposed tissue % in relation to MiniFS was only normally distributed in newborns (0-29 days; $p > .05$) and children in early adolescence (12-18 years; $p > .05$). The subgroups for infants (1-12 months; $p < .05$), toddlers (13-24 months; $p < .05$), early childhood (2-5 years; $p < .05$), and middle childhood (6-11 years; $p < .05$), didn't show normal distributions as assessed by the Shapiro-Wilk test ($\alpha = .05$).

ii. Statistical outliers

Twelve statistical outliers were found, which again can be described as mild. All of these twelve outliers lay within less than three times the interquartile range. Hence they were not excluded from the sample. There was one extreme outlier, which deviating more than three times the interquartile range. Because only one such extreme outlier was found, and no plausible reason could be found as to why, the data was not excluded.

iii. Homogeneity of variances

Homogeneity of variances for overexposed tissue % in relation to MiniFS was asserted using Levene's test that asserted equal variances could be assumed ($p = .25$).

3.2.2.3 Results – ANOVA to analyse overexposure (in relation to MinFS) and age groups

Significant differences between the age groups and overexposures in relation to MinFS was observed as seen in figure 6 ($F(5) = 6.82, p < .00, \eta^2 = .09$). A Bonferroni post-hoc analysis revealed significant ($p < .01$) differences in overexposures between newborns and patients in early childhood ($.14, 95\% - Cl[.04, .25]$), infants and toddlers ($.10, 95\% - Cl[.01, .19]$), infants and patients in early childhood ($.15, 95\% - Cl[.06, .23]$), as well as patients in their infancy and early adolescence ($.10, 95\% - Cl[.01, .18]$). Meaning newborns ($\bar{x} = .51, s = .21, n = 37$) showed a significantly higher percentage of overexposure in relation to MinFS compared to patients in early childhood ($\bar{x} = .36, s = .15, n = 69$). Additionally, infants ($\bar{x} = .50,\ s = .19, n = 69$) showed significantly higher overexposures than toddlers ($\bar{x} = .41,\ s = .17, n = 57$), as well as patients in their early childhood ($\bar{x} = .36, s = .15, n = 62$), and early adolescence ($\bar{x} = .41, s = .15, n = 71$). *(see table 4)*

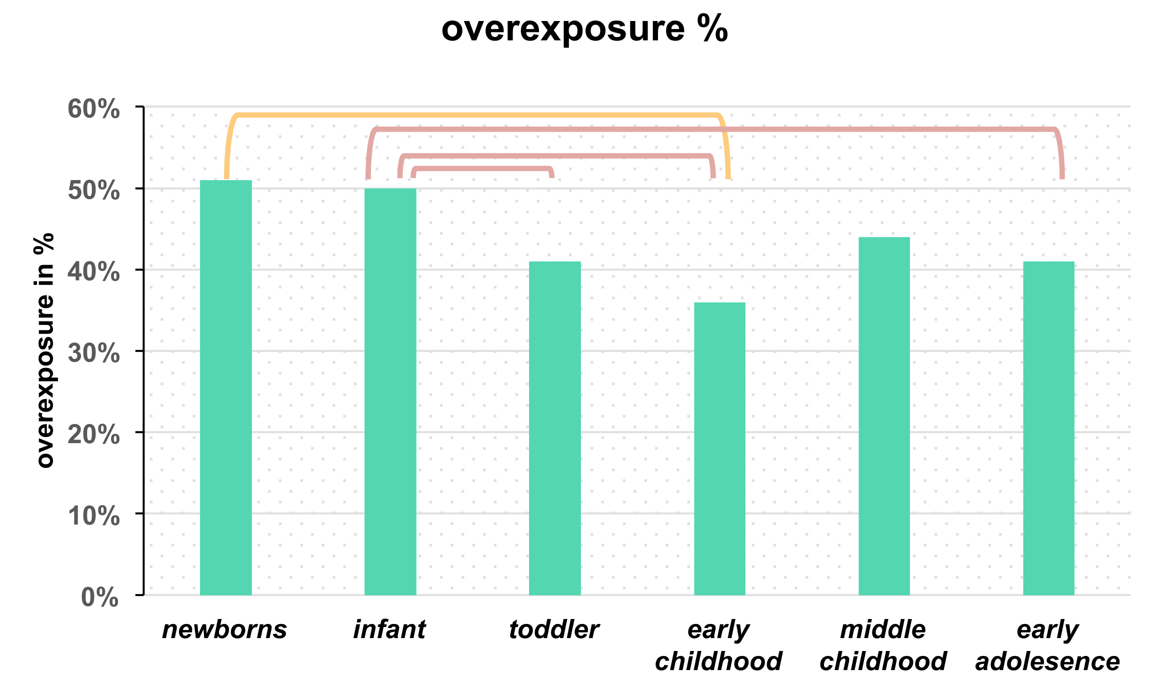


Fig 6 ANOVA: General overexposure (in %) compared to age groups.

3.2.2.4 Results – ANOVA to analyse tissue overexposure (in relation to minFS) and age groups

A second univariate ANOVA was conducted to analyse differences between age groups and overexposed tissue in relation to MinFS. Again, a statistically significant difference was observed ($F(5) = 7.14, p < .00, \eta^2 = .09$). Bonferroni Post-Hoc analysis revealed significant ($p < .02$) differences between the overexposed tissue between newborns and toddlers ($.10, 95\% - Cl[.01, .21]$), as well as patients in early childhood ($.13, 95\% - Cl[.04, .23]$). Furthemore differences between infants and toddlers ($.10, 95\% - Cl[.02, .18]$), and patients in early childhood ($.13, 95\% - Cl[.06, .21]$) were observable. Newborns showed more tissue overexposure ($\bar{x} = .44, s = .19, n = 37$) than toddlers ($\bar{x} = .34, s = .14, n = 57$), and patients in early childhood ($\bar{x} = .31, s = .13, n = 62$). Infants ($\bar{x} = .44, s = .17, n = 69$) showed more overexposed tissue % in relation to

MiniFS as toddler ($\bar{x} = .34, s = .14, n = 57$), and patients in their early childhood ($\bar{x} = .31, s = .13, n = 62$). *(see table 4, Fig. 7)*

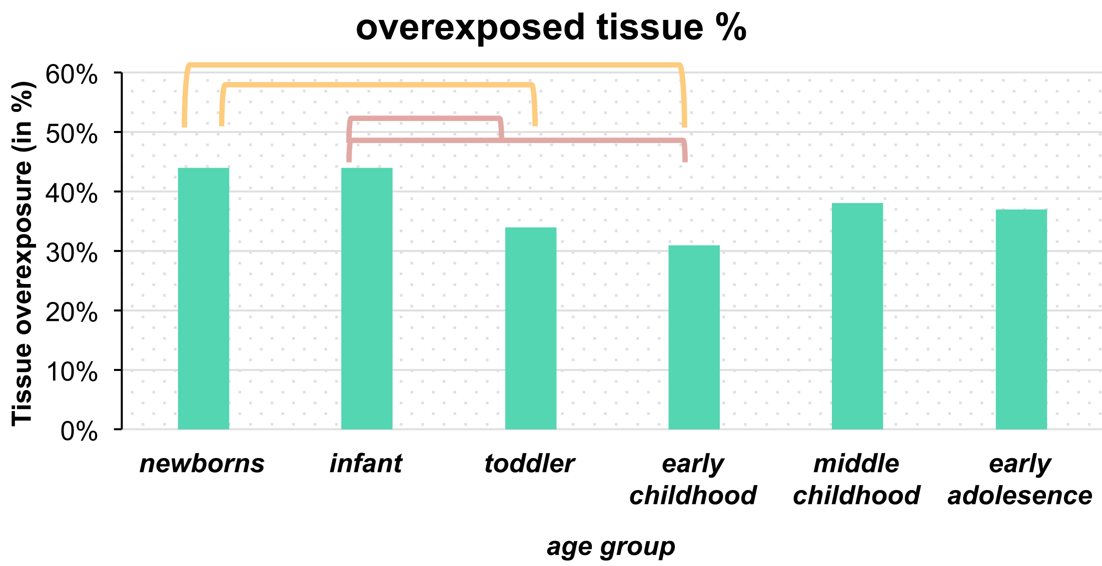


Fig 7 ANOVA: Overexposed tissue (in %) compared to age groups.

3.2.2.5 Results – Regression analysis: overexposure in relation to MinFS (in%) compared to age in years

An impact by the patient age in years on the overexposure % in relation to MinFS ($F(1, 362) = 3.906$, $p = .049$) was observed. Each cumulative year resulted in a reduction of 0.3 % in overexposure in relation to MinFS. Accordingly the variance in overexposure can be explained by the age of the patients in 1.1% of all cases. This can be seen as a small effect ($f = .11$) according to Cohen (83).

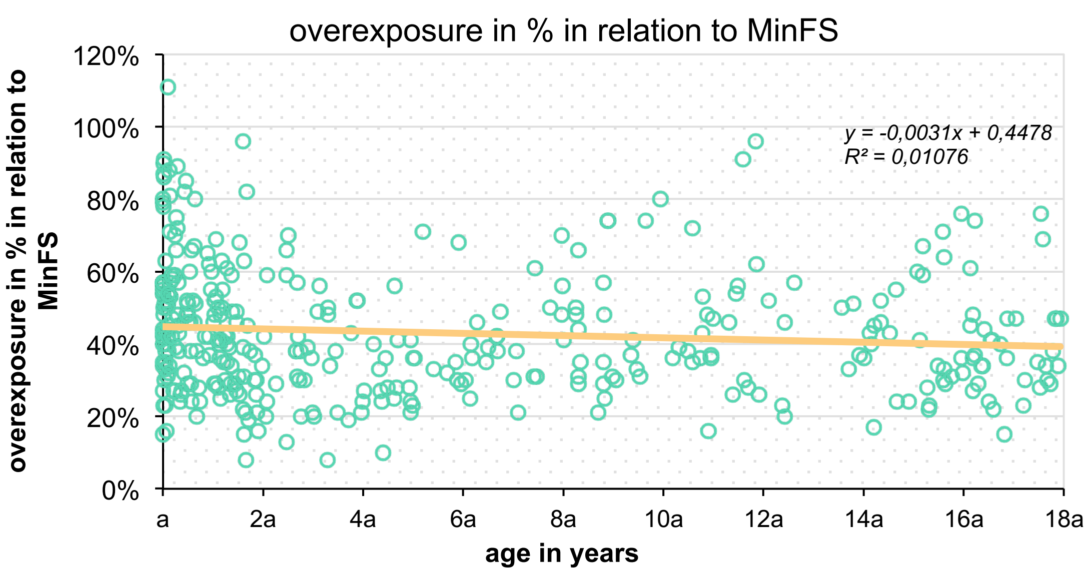


Fig 8 Regression Analysis: Overexposure in relation to minFs (in %) compared to age in years.

3.2.2.6 Results – Regression analysis: Percentage of cervical tissue overexposure (in %) compared to age in years

A regression analysis was conducted to examine the impact of patient age on cervical tissue overexposure 0-100 % (F(1, 362) = 24.300, p = .00). Each year in age resulted in a reduction of cervical tissue overexposure by 0.5%. 6.3% of the variance of cervical tissue overexposure can be explained by the patient age, a medium effect (f = .26).

3.2.2.7 Results – Regression analysis: cervical tissue overexposure in relation to MinFS (in%) compared to age in years

Accordingly, a medium effect (f = .25) was observed regarding the impact of patients age on the cervical tissue overexposure in % in relation to MinFS (F(1, 362) = 23.312, p = .000). Each added year resulted in a reduction of the cervical tissue overexposure in % in relation to MinFS by 0.3%. 6.1% of the variance in cervical tissue overexposure can be explained by the patient age.

3.2.2.8 Results – Regression analysis: Combined lateral tissue overexposure relation to MinFS (in%) compared to age in years

An additional regression analysis was performed to evaluate the impact of patient age on the relative lateral tissue overexposure % (F(1, 362) = 59.935, p = .00). Relative overexposures from the left and right sub-areas were added to compute combined lateral values. Each cumulative year in age resulted in an increase of the relative lateral tissue overexposure by 1%. 14% in variance is explainable through the age of the patients in years, representing a strong effect (f = .41).

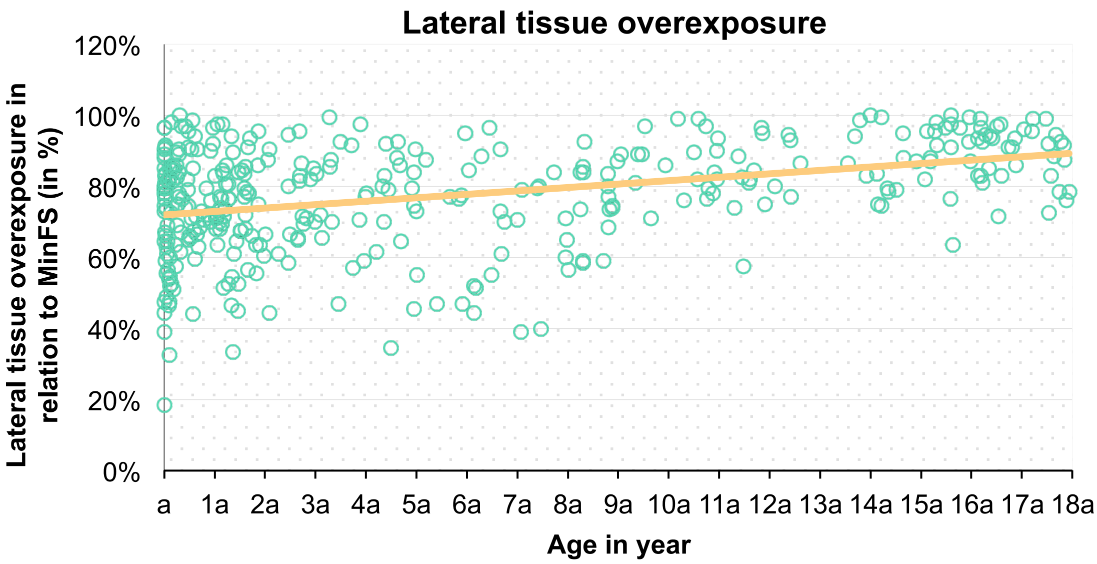


Fig 9 Regression Analysis: Overexposure in relation to minFs (in %) compared to age in years

3.2.2.9 Results – Regression analysis: Tolerated overexposure compared to age in years

Logically, an impact by the patients age on the tolerated overexposure % (F(1, 362) = 20.705, p = .00) was observed (Fig. 9). Each cumulative year in age resulted in an increase of the tolerated overexposure by 0.7%. 60% of the variance was explainable by the patient age. According to Cohen this is almost a medium effect (f = .24). An abrupt spike in tolerance was noticed, with a peak at an age of roughly 1.5 months. The x-axis in figure 11 was scaled logarithmically to

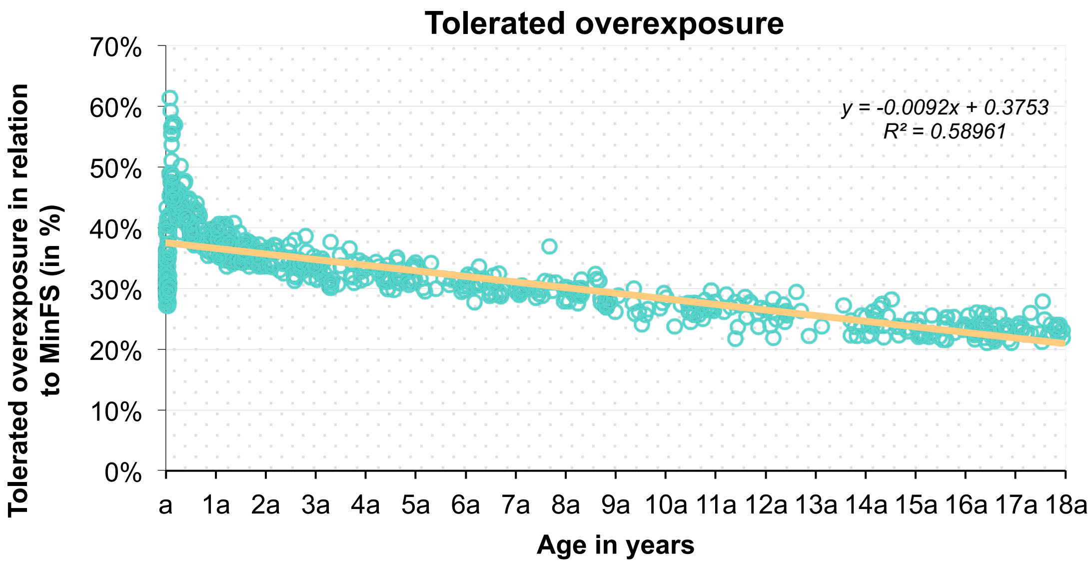


Fig 10 Regression Analysis: Tolerated age-dependant overexposure.

demonstrate this observation.

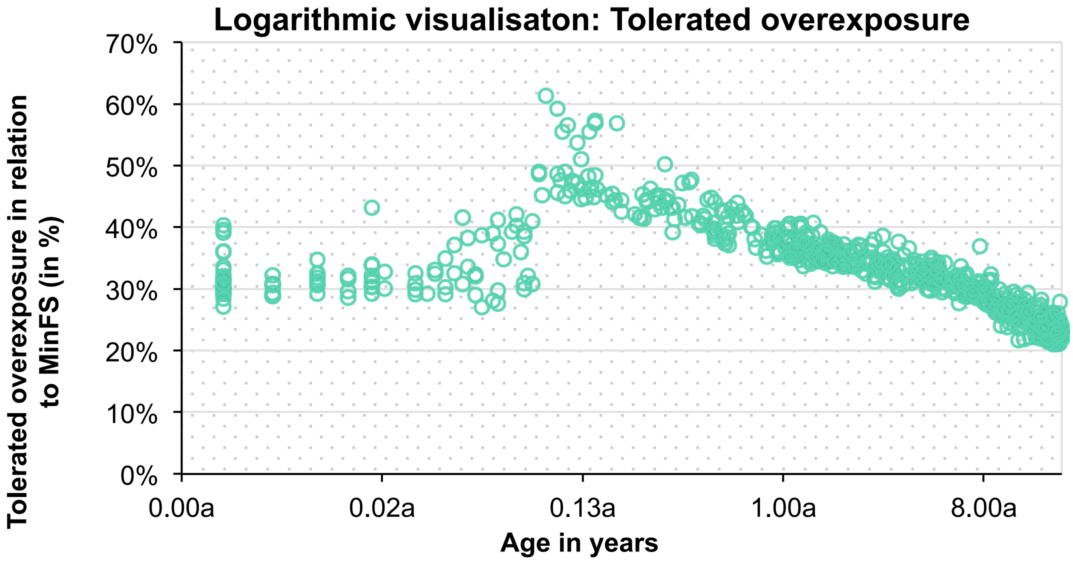


Fig 11 Regression Analysis: Tolerated age-dependant overexposure (Logarithmic visualisation)

3.3 Reliability testing

All qualitative points were evaluated regarding their inter- and intra observer reliability. An overall inter-rater reliability of k = 0.72 was observed, as compared to k = 0.85 for intra-observer agreement. Poor inter-rater agreement was found for points 1.1 “inspiration” (k = 0.41), 1.2 “rotation and tilting” (k = 0.38) and 1.6 “diaphragm” (k = 0.40). Furthermore absolute agreement was found for the diagnostic value of cropped images. A two-way mixed single measure inter class correlation was conducted to evaluate inter-rater and intra-observer reliabilities regarding the qualitative parameters. Overall ICC between observers was .99 at a 95% confidence interval from 0.99 to 0.99 $(F(719,719) = 1.158, p < 0.0001)$. ICC for the intra-observer rating was also .99 at a 95% confidence interval from 0.99 to 0.99 $(F(704,704) = 1.159, p < 0.0001)$.

4 Discussion

The observed results lead to the conclusion that the diagnostic requirements defined by the EC guidelines for AP/PA chest radiography in paediatrics were only marginally met. Using the tool, inadequate partial overexposures and inspiration depths were found. 8.16% (59/723) of the total number of images met all qualitative diagnostic requirements, and didn't show MinFS truncations or exposure beyond tolerance, as proposed by the EC guidelines. Double the percentage reported for non-PIC patients in the pre-cursor study (77), yet still unsatisfactory. Further support for the use and the development of the tool were strengthened. Debateable issues with the guidelines mentioned by the precursor study gained further credibility. This leaves the question whether the guidelines are feasible for day-to-day operations in their current state.

4.1 Relevant observations

Mean fulfilment of qualitative requirements was relatively unsatisfactory, but acceptable at large. Quality criteria on “inspiration”, “rotation and tilting”, as well as “sharp diaphragm and costophrenic angles” revealed the lowest rates of satisfaction. Newborns, and children over six years showed the lowest percentages of overall satisfaction. Subjective interpretation regarding qualitative criteria was revealed. While the EC guidelines state that no diagnostic image should be rejected due to unsatisfactory image quality, the ambiguous wording leaves excessive room for interpretation (15). No directions are given on how the presence of clinical support devices and installations, or extensive pathologies affecting image quality should be interpreted (e.g.: poor visualisation of the spine due to numerous spinal screws; poor visualisation of the diaphragm due to pleural effusion). An epidemiologic study has found the highest PICU admission rates in newborns and infants, substantially decreasing with age. Children older than one year routinely presented pre-diagnosed chronic illness. Respiratory problems were discovered to be a primary factor across all age groups until taken over by trauma related admissions of children aged four years and older (84). Possibly these observations could be reflected in the relatively low satisfaction of the qualitative parameters in children younger than one, and older than six years in this study. *(see chapter 3.1. table 1)*

Low inter-rater agreement was found for the qualitative parameter “performed at peak inspiration”. It has been previously suggested that to amend this point by clarifying the meaning of “peak inspiration”. Optimal inspiration depths according to three age groups were introduced. Visibility of at least 10 posterior ribs above the diaphragm for patients older than six, 9 in children aged two to five, and 8 in children aged zero to two years was recommended (77, 85-88). This suggestion gains stronger validity as similar results were re-produced for PICU patients in this study. Similar observations were made regarding “rotation and tilting”. The EC guidelines fail to clearly define rotation and tilting. The results suggest high subjectivity, further verifying earlier suggestions to amend the definition.

Further subjectivity was found regarding the visualisation of the diaphragm. In several studies the author observed visually sharp reproduction of either the costophrenic angles or the diaphragm, but worse reproduction of the respective counterpart. Adhering to the wording of the EC guidelines these pictures didn’t meet the qualitative requirements. Poor inter-rater agreement could be observed in this regard. Again, the author suggests refining the definition.

High rates of fulfilment were reproduced for all other quality requirements. Redundancies had previously been reported for points 1.4 “vascular pattern” and 1.7 “spine” and were reproducible in this study strengthening the proposition to merge them (77).

Homogenous, international terminology for studies in paediatrics is needed, and in the narrower sense this includes radiographic terminology (15, 89-91). To a certain extent the EC guidelines fail to offer definitions for quality criteria that are not susceptible to subjective interpretation. Homogenised, consensus based nomenclature might be helpful to diminish ambiguities. Furthermore international collaborations on clinical practices guidelines could be facilitated through homogenous nomenclature (90, 91).

Observations of the precursor study concerning issues with the recommended abdominal MinFS margin at T12/L1 could only be partially reproduced for PIC patients. The mean abdominal MinFS margins were generally set too low in newborns, and became increasingly high with advancing age, yet in overall mean distances remained within tolerance. Accordingly abdominal exposures were generally found to be within tolerance, indicating adequate collimation in this sub area. Very high percentages of cropped sinuses in early adolescence suggest

margins set too high for this age group. Furthermore vertical distances from the AEA and MinFS borders to the costophrenic angles suggest room for adjustments across all age groups. *(Fig 5, table 5)* A strict abdominal margin at TH12/L1 represents an arbitrary, static choice, and should be re-evaluated. Setting the abdominal margin based on individual patient metrics, only requiring the inclusion of the costophrenic sulci and upper abdomen, as supported by the ACR, SPR and IGA, as well as the previous study could be beneficial as previously discussed in literature (13, 14, 27, 77).
Diametrical the mean distances from cervical MinFS edges to the AEA borders were substantially higher. Mean distances from the cranial MaxFS edge to the AEA border revealed adequate height in children aged one month to five years. To the contrary newborns, and children older than six years showed means in distance exceeding the recommendations. Coherently cranial overexposure was found to be exceeding tolerated values in newborns, toddlers, and children older than six years. The author was not able to present any valid explanations for this observation, suggesting room for improvement at the division.

The ICRP describe patient positioning and immobilisation as hallmarks of radiographic technique (74, 75). Unfortunately no observations regarding differences in quality due to patient positioning could be made since almost all pictures were shot in supine position. While younger non-PIC patients tend to be non-compliant toward immobilisation, it was assumed that PIC patients tend to be severely incapacitated, and therefore shouldn't pose the same problems (92, 93). Interestingly impacts by the patient age on the image overexposure could be observed. Supportive of the earlier assumption no findings could reveal an impact by the age on abdominal overexposure. Medium effects were observed regarding the impact on cranial overexposure, suggesting a reduction of overexposure with increasing patient age.
Conflictingly the EC guidelines don't clearly define lateral borders. In this study the outer borders of the thoracic ribs were used as MinFS reference points. Unexpectedly, age appeared to have a strong impact on lateral overexposure. While lateral overexposure was generally within tolerance the findings suggest increasing overexposure with increasing patient age. (Fig 9)

These observations leave room for interpretation, and the underlying cause might very well be multifactorial. The presence of trauma related instalments such a thoracic catheters, or subcutaneous tissue increasing with age could be possible explanations for the findings. Varying indications need to be considered, thus a strict anatomical border might not be feasible. Further research might be needed to help defining adequate lateral borders.

In this study 96% of all images were found to include all necessary anatomical structures required. Low unavoidable retake rates are assumed, as MinFS truncations barely affected the diagnostic value of these images mirroring findings reported in previous studies (77, 94, 95). Additionally 100% (359/359) of the cropped image didn’t lose their diagnostic value.

Tolerance was found to be above average in infants, peaking at an age of 1.5 months. This was caused by an increase in tolerance from 1 to 2 cm for children older than one month. It has been suggested to move the modulator from one to three months (77). Tolerance needs to be adjusted. The results indicate that a reduced tolerance of 1 cm might very well be possible up to an age of five years without increasing rates of MaxFS exceedances. Children are a highly susceptible to radiation. With newborns and infants accounting for the highest rates in PICU admissions of children an increase in tolerance from one to two cm after 29 days seems arbitrary (84). The author recommends a re-evaluation of the proposed age-dependent tolerances.

Possible amendments to the pre-existing requirements could include the following:

1. The minimal field size should extend from the lung apices to the abdominal margin including the costophrenic angles and upper abdomen. The thoracic ribs should be used as lateral landmarks (13, 14, 77).
2. Age dependant inspiration depth: at least eight posterior ribs in children aged 0 to 2 years, nine in early childhood, and 10 in all older patients (77).
3. Patient Rotation: spinous processes horizontally centred, and clavicle heads at a vertebral level between T2 and T4 (77).
4. Visually sharp reproduction of the diaphragm ranging from the top to the costophrenic angles.
5. Visually sharp and high contrast reproduction of the retrocardiac vasculature, vascular pattern, spine, and paraspinal structures (13, 14, 77).

Adding a supplementary option to identify quality criteria that cannot be evaluated due to the extent of pathologies and/or medical interventions could help to warrant coherent, high value data for quality audits. A possible suggestion would be to label requirements as fulfilled if diagnostic information could be obtained regardless of the specific requirement, thus leaving less room for potential inconsistencies.

4.2 Limitations

A similar study analysing the feasibility of the EC guidelines in a paediatric non-PICU population was conducted in 2014 (77). The results had been discussed internally, which left the question whether the previous study had an impact. Simple analyses were conducted. Data from images taken before 2014 were compared with newer ones. No statistically significant differences could be found.

While quantitative inter-observer agreement was excellent, inter-observer reliability for qualitative parameters was less persuasive, albeit being substantial according to Cohen. Multifactorial causality for this circumstance is assumed. The author of this thesis who was a medical student at time of this writing made all observations. The second observer is a trained paediatric radiologist and designer of the tool used for this study. Ambiguous wording of the qualitative requirements, and divergent experience might have contributed to the divergence. Due to these facts the data quality of this study might only be excellent for quantitative findings, and good in general.

The retrospective design of the study didn’t allow for linking of the examinations with the responsible operator of the mobile unit, as no such information was stored in the DICOM headers. Exposure parameters from the DICOM headers were not analysed, but were reported to be routinely below recommended levels in national audits (77, 96).

4.3 Conclusion

The study strengthens the proposition to use the provided semi-automatic tool for quality audits, offering excellent validity for quantitative parameters and good informative value for qualitative parameters derived from the diagnostic requirements for chest radiographs according to the EC guidelines.

Through this study partial overexposures were discovered at the division for paediatric radiology sponsoring this study. Additionally the author came to the conclusions that the realisation of objective quality audits could possibly be hindered by quality criteria defined too vaguely, and by the lack of homogenous terminology. The observed outcomes, and suggestions made by the pre-cursor study and discussed literature further strengthen the proposition to amend diagnostic requirements for chest radiographs in the "*European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics*". Finally, the author strongly supports continued development of the tool according to new emerging evidence.

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Annex – Project plan

Europäische Richtlinie zur Erstellung von Thoraxröntgenbildern: Sind die Vorgaben im täglichen intensivmedizinischen Routinebetrieb einer pädiatrischen Klinik einzuhalten – eine retrospektive Datenanalyse?

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5 Wissenschaftlicher Hintergrund

Eine möglichst genaue Einblendung einer mit Röntgenstrahlung zu untersuchenden Körperregion gilt als wichtiger Faktor in der Reduktion pädiatrischer Strahlenexposition. Die Europäische Kommission veröffentlichte 1996 Richtlinien (1), welche das empfohlene Belichtungsareal bei Thoraxaufnahmen kranial direkt oberhalb der Lungenspitzen und kaudal auf Höhe T12/L1 empfiehlt. Obwohl Thoraxröntgenbilder zu den häufigsten radiologischen Untersuchungen zählen (2), waren bei Kindern – im Gegensatz zu Erwachsenen (3) – nur semi-quantitative (4) oder qualitative (5) Studien zu diesem Thema verfügbar. Eine Vorgängerstudie der MUG (6) zeigte inadequate Feldgrößen, Überbelichtungsflächen, Entfernungen und Patientenpositionierungen auf. Weiters wurden fragwürdige Inhalte der EC Guidlines hingewiesen und ein neues Werkzeug zu Prüfung der Qualität von Thoraxröntgenbildern vorgeschlagen.

6 Ziel

Die Ergebnisse der Studie sollen als Evaluierung der Istsituation bei der Erstellung von pädiatrischen Thoraxröntgenbildern von InstensivpatientInnen dienen. Die bereits entwickelten(6) Messmethoden sollen als Qualitätssicherungstool weiter geprüpft werden. Im weiteren Verlauf soll die Praxis der Thoraxbildgebung weiter optimiert werden.

7 Patient/innen

≥97 IntensivpatientInnen, die an der Abteilung für Kinderradiologie Graz ab Juli ein Thoraxröntgen erhalten haben. Wir erwarten ca. 80 PatientInnen pro Monat und

werden die Daten erheben bis alle nach Alter festgelegten Subgruppen gefüllt sind.
Eingeschlossen werden alle Patient/innen von 0-18 Jahren.

1 Zielgrößen (Endpunkte)

1.1 Hauptzielgrößen

- Altersabhängige relative Überbelichtungsfläche im Verhältnis zur empfohlenen minimalen Feldgröße (MFS) nach EC Richtlinien.

1.2 Nebenzielparameter

- Erlaubte Überbelichtungsfläche nach EC Richtlinien
- Überbelichtungsflächen an allen 4 Thoraxseiten
- Getroffenes Gewebe (absolut und relativ) an allen 4 Thoraxseiten und gesamt
- Bildrotation
- Qualitative Merkmale nach EC Richtlinien
- Alter, Geschlecht
- DICOM Daten zur Dosis
- Körpergröße und Gewicht
- Bildbeschnitt, Konformität nach EC Richtlinien
- Gonadenschutz

2 Methodik

Retrospektive Analyse unter Verwendung archivierter, unprozessierter Thoraxröntgenbilder der Abteilung für Kinderradiologie. Die Bilder sollen mittels der OpenSource-Software ImageJ unter Verwendung eines Macro-Script halbautomatisch analysiert werden.

3 Statistik

3.1 Geplante Auswertung

Die Hauptzielgröße und alle übrigen Daten werden je nach Skalenniveau mittels deskriptiver Statistik, t-Test/ANOVA und Regression analysiert.
Verteilungsabhängig sollen Mittelwerte und Standardabweichungen bzw. Mediane und Quartile berechnet werden.
Kategorische Daten werden als absolute und relative Häufigkeiten dargestellt.
Eine Analyse der Intra/inter-Observer-Variabilität der qualitativen Parameter soll mittels Cohen's Kappa erfolgen.

3.2 Fallzahlplanung:

Die Mindestfallzahl von 97 PatientInnen ergibt sich aus einer einfaktoriellen Varianzanalyse
(1-Way ANOVA Pairwise, 2-Sided equality, http://powerandsamplesize.com/Calculators)
Wir erwarten ca. 20 Datensätze pro Woche und hoffen ab spätestens Oktober mit der retrospektiven Datenanalyse beginne zu können.
Alle Patienten werden mit einer fortlaufenden Nummer codiert (pseudonymisiert). Die auszuwertenden Daten werden nur mit diesem Code versehen in einer in einem SPSS-Datenblatt auf einem PC mit Zugriffsbeschränkung an der Abteilung für Kinderradiologie gespeichert und anschließend ausgewertet.
Nur autorisierte Personen haben Zugriff auf die Originaldaten.

4 Nutzen-Risiko Evaluierung

Die eingeschlossenen Patienten haben keinen direkten Nutzen von der Studie.
Da es sich allerdings um die rein retrospektive Auswertung ihrer Daten handelt ist auch kein Risiko zu erwarten.
Das einzig mögliche Risiko, das Bekanntwerden der sensiblen Patientendaten wird durch die Pseudonymisierung und Zugriffsbeschränkung minimiert.
Die Ergebnisse dieser Studie können als Grundlage zur Hypothesengenerierung für weitere Studien dienen.

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Annex – Fiji Glossary – Codebook excerpt

```
"ID" id;                                  // ID
"FILENAME" filename;                      // FILENAME
"Name" name;                              // PATIENT NAME
"DOB" dob;                                // DATE OF BIRTH
"DOE" doe;                                // DATE OF EXAMINATION
"AGE_YEARS" ageyears;                     // AGE YEARS
"AGE_DAYS" agedays;                       // AGE DAYS
"AGE_GROUP" agegroup;                     // AGE GROUP
"SEX" sex;                                // GENDER


"ROTATION_DEGREES" a;                     // IMAGE ROTATION IN DEGREES
"CENTERED" centered;                      // IMAGE CENTRED YES 1, NO 0
"VALID" valid;                            // IMAGE DIAGNOSTIC + NOT CROPPED YES 1, NO 0
"CORRECT" corr;                           // IMAGE CORRECT BASED ON EUR16261 YES 1, NO
"DIAGNOSTIC" diag;                        // IMAGE DIAGNOSTIC YES 1, NO 0

"GOOD_INSPIRATION" inspiration;           // EUR16261 POINT 1.1 YES 1, NO 0
"NO_TILTING" tilting;                     // EUR16261 POINT 1.2 YES 1, NO
"VASC_PATTERN" vascular;                  // EUR16261 POINT 1.4 YES 1, NO 0
"BRONCHI" bronchi;                        // EUR16261 POINT 1.5 YES 1, NO 0
"RECESSUS" recessus;                      // EUR16261 POINT 1.6 YES 1, NO 0
"PARASPINAL" paraspinal;                  // EUR16261 POINT 1.7 YES 1, NO 0


"MINFS_SINUS_CROPPED" minfs_reces_crop;   // COSTO-PHRENIC ANGLE OUTSIDE MINIMAL FIELD SIZE [MinFS] YES 1, NO 0
"MAXFS_SINUS_CROPPED" maxfs_reces_crop;   // COSTO-PHRENIC ANGLE OUTSIDE MAXIMAL FIELD SIZE [MaxFS] YES 1, NO 0
"AEA_SINUS_CROPPED" aea_reces_crop;       // COSTO-PHRENIC ANGLE OUTSIDE ACTUAL EXPOSED AREA [AEA] YES 1, NO 0

"OVEREXP_PERCENT" overexpose;             // OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_TISSUE" oexptiss;                // OVEREXPOSED TISSUE % IN RELATION TO MinFS
"OVEREXP_ALLOWED_PERC" oexp_allowed;      // OVEREXPOSURE TOLERATED AGE-DEPENDENTLY 1 or 2 cm BY EUR16261 %
"OVEREXP_PERCMINUSALLOW" oexpminus;       // OVEREXPOSURE - TOLERATED OVEREXPOSURE % IN RELATION TO MinFS
```

"OVEREXP_PERC_L" overexpose_l; // LEFT OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_PERC_D" overexpose_d; // ABDOMINAL OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_PERC_R" overexpose_r; // RIGHT OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_PERC_U" overexpose_u; // CERVICAL OVEREXPOSURE % IN RELATION TO MinFS

"OVEREXP_TISS_PER_L" oexptiss_l; // LEFT TISSUE OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_TISS_PER_D" oexptiss_d; // ABDOMINAL TISSUE OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_TISS_PER_R" oexptiss_r; // RIGHT TISSUE OVEREXPOSURE % IN RELATION TO MinFS
"OVEREXP_TISS_PER_U" oexptiss_u; // CERVICAL TISSUE OVEREXPOSURE % IN RELATION TO MinFS

"OVEREXP_TISS_RELATIVE_L" oexptiss_rel_l; // RELATIVE LEFT TISSUE OVEREXPOSURE 0 - 100 % IN RELATION TO MinFS
"OVEREXP_TISS_RELATIVE_D" oexptiss_rel_d; // RELATIVE ABDOMINAL TISSUE OVEREXPOSURE 0 - 100 % IN RELATION TO MinFS
"OVEREXP_TISS_RELATIVE_R" oexptiss_rel_r; // RELATIVE RIGHT TISSUE OVEREXPOSURE 0 - 100 % IN RELATION TO MinFS
"OVEREXP_TISS_RELATIVE_U" oexptiss_rel_u; // RELATIVE CERVICAL TISSUE OVEREXPOSURE 0 - 100 % IN RELATION TO MinFS

"TOLERANCE" tolvar; // AGE-DEPENDENT TOLERANCE MM

"MINFS_CENTER_WIDTH" minfs_centerwidth; // WIDTH OF MinFS mm
"MINFS_CENTER_HEIGHT" minfs_centerheight; // HEIGHT OF MinFS mm
"MINFS_ASPECTRATIO_H_W" minfs_aspectratioheightwidth; // MinFS ASPECT RATIO

"MINFS_DISTANCE_LEFT" minfs_distanceleft; // DISTANCE LEFT MinFS TO RESPECTIVE AEA BORDER mm
"MINFS_DISTANCE_DOWN" minfs_distancedown; // DISTANCE ABDOMINAL MinFS TO RESPECTIVE AEA BORDER mm
"MINFS_DISTANCE_RIGHT" minfs_distanceright; // DISTANCE RIGHT MinFS TO RESPECTIVE AEA BORDER mm
"MINFS_DISTANCE_UP" minfs_distanceup; // DISTANCE CERVICAL MinFS TO RESPECTIVE AEA BORDER mm
"MINFS_DISTANCE_SINUS" minfs_distancerec; // VERTICAL DISTANCE MinFS TO COSTO-PHRENIC ANGLES mm

"MAXFS_DISTANCE_LEFT" maxfs_distanceleft; // DISTANCE LEFT MaxFS TO RESPECTIVE AEA BORDER mm
"MAXFS_DISTANCE_DOWN" maxfs_distancedown; // DISTANCE ABDOMINAL MaxFS TO RESPECTIVE AEA BORDER mm
"MAXFS_DISTANCE_RIGHT" maxfs_distanceright; // DISTANCE RIGHT MaxFS TO RESPECTIVE AEA BORDER mm
"MAXFS_DISTANCE_UP" maxfs_distanceup; // DISTANCE CERVICAL MaxFS TO RESPECTIVE AEA BORDER mm
"MAXFS_DISTANCE_SINUS" maxfs_distancerec; // VERTICAL DISTANCE MaxFS TO COSTO-PHRENIC ANGLES mm

"AEA_DISTANCE_SINUS" aea_distancerec; // VERTICAL DISTANCE AEA TO COSTO-PHRENIC ANGLES mm

"EXPOSURE" expos; // EXPOSURE
"EXPOSTIME" expost; // EXPOSURETIME

"KVP" kvp; // KVP
"AREADOSE" areados; // AREADOSE
"TUBECURR" tubecur; // TUBECURRENT
"SOURCEDIST" sdist; // SOURCEDISTANCE
"STUDYCODE" studcod; // STUDYCODE
"MAN" man; // MANUFACTURER
"MOD" mod; // MODALITY
"DICOM_POSITION" position; // DICOM POSITION METADATA

"AP_PROJECTION" AP; // AP
"PA_PROJECTION" PA; // PA
"POS_STANDING" standing; // Standing
"POS_LYING" lying; // Lying
"POS_SITTING" sitting; // Sitting
"POS_PRONE" prone; // Prone