Graciano do Nascimento Nobre Paulo

OPTIMISATION AND ESTABLISHMENT OF DIAGNOSTIC REFERENCE LEVELS IN PAEDIATRIC PLAIN RADIOGRAPHY

Tese de Doutoramento em Ciências da Saúde - Ramo das Tecnologias da Saúde, orientada pelo Senhor Professor Doutor Eliseo Vaño e pelo Senhor Professor Doutor Adriano Rodrigues e apresentada à Faculdade de Medicina da Universidade de Coimbra.

Setembro de 2015

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Universidade de Coimbra

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Tese de Doutoramento em Ciências da Saúde-Ramo das Tecnologias da Saúde apresentada à Faculdade de Medicina da Universidade de Coimbra

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September de 2015

UNIVERSIDADE DE COIMBRA

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Acknowledgements

The development of this thesis would not have been possible without the help of several friends that followed me from the first minute. To all of them my sincere thank you, for sharing outstanding moments and helping me to remove the stones from a long and winding road.

To Professor Eliseo Vaño, Cathedratic Professor of Medical Physics of the Complutense University of Madrid, a world-renowned expert in the field of Radiation Protection a special thanks, for having accepted to supervise this thesis and for all that I have learned from him in the past years. I have no words to express my gratitude for his permanent support and outstanding advices. His vision and knowledge has been the main contributor for building bridges between health professionals towards a continuous improvement in the quality and safety of healthcare services all around the world.

To Professor Adriano Rodrigues, a distinguished Doctor of Internal Medicine of Coimbra Hospital and University Centre, Professor of the Medical Faculty of the University of Coimbra, that has dedicated his life to the development of the Nuclear Sciences Applied to Health in Portugal, a special thanks for trusting in me and for having accepted to supervise this thesis. Thank you for encouraging me to move forward and for making me believe that it was possible.

To Professor Joana Santos, Director of the Medical Imaging and Radiotherapy Department of ESTESC-Coimbra Health School, my recognition and gratitude. Without her the achievement of this objective would not have been possible. Her support, energy and engagement were the main pillars for the development of this thesis.

To Professor Filipe Caseiro Alves, a distinguished Medical Radiologist, Cathedratic Professor of the Medical Faculty of the University of Coimbra and Director of the Radiology Department of the Coimbra Hospital and University Centre, a special thank you for his permanent support and for opening doors for what has been a fruitful cooperation for applied research in the field of medical imaging.

To Dr. Amélia Estevão, a distinguished Medical Radiologist of the Radiology Department of the Coimbra Hospital and University Centre, a special thanks for her outstanding contribution for obtaining the approval to develop this thesis.

To all Radiologists and Radiographers from the three Portuguese Paediatric Hospitals, especially the Senior Radiographers, Filomena Oliveira, Fernanda André, Alda Pinto, Cristina Almeida and Dalila Ferreira, a special thanks for the assistance provided during the data collection.

To all the Radiologists from the Paediatric Hospital of Coimbra a special thanks for their contribution to this study.

To Dr. Pinto Machado, a senior Medical Radiologist a special thanks for his help, advice and cooperation and for all that he has taught me through out my professional life.

To my Professor, João José Pedroso de Lima, one of the most prominent Portuguese professor of medical physics, my inspiration and reference, both as a person and as an academic, my special thanks.

To all Professors from the Medical Imaging and Radiotherapy Department of ESTESC-Coimbra Health School a special thanks for their support.

To all Professors from ESTESC-Coimbra Health School a special thanks for their support and understanding.

To my colleagues from the Board of Management of ESTESC-Coimbra Health School, Professor Jorge Conde and Professor Ana Ferreira a special thanks for their support and patience.

To all my Radiography and Medical Imaging & Radiotherapy students with whom I have the privilege to learn everyday, a special thanks for being the real ambassadors of ESTESC-Coimbra Health School.

To all the staff of ESTESC-Coimbra Health School with whom I have the privilege to work with a special thanks.

I would like to dedicate this thesis to my family starting by my parents Carlos and Alice for being my heroes and for teaching me the fundamental values of life.

To my younger sister Carla for always being there for me when I needed.

To my two sons, César and Inês, the essential part of my life, to whom I apologise for allowing my work to take the time that I should have dedicated to them.

To Laila, my wife, an outstanding woman. I can't find enough words in the dictionary to describe what you represent in my life. Nothing would have been possible without you. This thesis is yours. I will never be able to compensate the time out of home and when at home closed in my office. Thank you for sharing your life with me.

Music is my passion and it was my companion during days and nights while writing this thesis. I would like to quote one of the most popular and influential musicians of the history of Rock & Roll:

No, you can't always get what you want
But if you try sometime, you just might find
You get what you need

Sir Michael Philip "Mick" Jagger

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Abstract

Purpose: This study aimed to propose Diagnostic Reference Levels (DRLs) in paediatric plain radiography and to optimise the most frequent paediatric plain radiography examinations in Portugal following an analysis and evaluation of current practice.

Methods and materials: Anthropometric data (weight, patient height and thickness of the irradiated anatomy) was collected from 9,935 patients referred for a radiography procedure to one of the three dedicated paediatric hospitals in Portugal. National DRLs were calculated for the three most frequent X-ray procedures at the three hospitals: chest AP/PA projection; abdomen AP projection; pelvis AP projection. Exposure factors and patient dose were collected prospectively at the clinical sites. In order to analyse the relationship between exposure factors, the use of technical features and dose, experimental tests were made using two anthropomorphic phantoms: a) CIRS™ ATOM model 705®; height: 110cm, weight: 19kg and b) Kyoto kagaku™ model PBU-60®; height: 165cm, weight: 50kg. After phantom data collection, an objective image analysis was performed by analysing the variation of the mean value of the standard deviation, measured with OsiriX® software (Pixmeo, Switzerland). After proposing new exposure criteria, a Visual Grading Characteristic image quality evaluation was performed blindly by four paediatric radiologists, each with a minimum of 10 years of professional experience, using anatomical criteria scoring.

Results: A high heterogeneity of practice was found and the established Portuguese DRL values (Kerma Air Product percentile 75, KAP_{P75} and Entrance Surface Air kerma percentile 75, $ESAK_{P75}$) were higher than the most recent published data. The national DRLs established for Portugal are: CHEST: KAP_{P75}, 13mGy.cm^2, 19mGy.cm^2, 60mGy.cm^2, 134mGy.cm^2, 94mGy.cm^2, respectively for age groups <1, 1-<5, 5-<10, 10-<16, 16-≤18. ABDOMEN: KAP_{P75}, 25mGy.cm^2, 84mGy.cm^2, 140mGy.cm^2, 442mGy.cm^2, 1401 mGy.cm^2, respectively for age groups <1, 1-<5, 5-<10, 10-<16, 16-≤18. PELVIS: KAP_{P75}, 29mGy.cm^2, 75mGy.cm^2, 143mGy.cm^2, 585mGy.cm^2, 839mGy.cm^2, respectively for age groups <1, 1-<5, 5-<10, 10-<16, 16-≤18.

DRLs by patient weight groups have been established for the first time. The post optimisation DRLs by patient weight groups are: CHEST: KAP_{P75}, 9mGy.cm^2, 10mGy.cm^2, 15mGy.cm^2, 32mGy.cm^2, 57mGy.cm^2, respectively for weight groups <5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg. ABDOMEN: KAP_{P75}, 10mGy.cm^2, 20mGy.cm^2, 61mGy.cm^2, 203mGy.cm^2, 225mGy.cm^2, respectively for weight groups <5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg. PELVIS: KAP_{P75}, 15mGy.cm^2, 18mGy.cm^2, 45mGy.cm^2, 75mGy.cm^2, 79mGy.cm^2, respectively for weight groups <5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg.

$ESAK_{P75}$ DRLs for both patient age and weight groups were also obtained and are described in the thesis.

Significant dose reduction was achieved through the implementation of an optimisation programme: an average reduction of 41% and 18% on KAP_{P75} and $ESAK_{P75}$, respectively for chest plain radiography; an average reduction of 58% and 53% on KAP_{P75} and $ESAK_{P75}$, respectively for abdomen plain radiography; and an average reduction of 47% and 48% on KAP_{P75} and $ESAK_{P75}$, respectively for pelvis plain radiography.

Conclusion: Portuguese DRLs for plain radiography were obtained for paediatric plain radiography (chest AP/PA, abdomen and pelvis). Experimental phantom tests identified adequate plain radiography exposure criteria, validated by objective and subjective image quality analysis. The new exposure criteria were put into practice in one of the paediatric hospitals, by introducing an optimisation programme. The implementation of the optimisation programme allowed a significant dose reduction to paediatric patients, without compromising image quality.

Keywords: diagnostic reference levels; paediatric radiology; radiation protection; optimisation.

Resumo

Objetivo: Este estudo teve como objetivo propor Níveis de Referência de Diagnóstico (NRD) para a radiologia convencional pediátrica e otimizar os procedimentos radiológicos mais frequentes em Portugal, partindo de uma análise e avaliação das práticas atuais.

Materiais e Métodos: Foram recolhidos dados antropométricos (peso, altura e espessura anatómica da estrutura radiografada) de 9.935 doentes, referenciados para um exame radiológico, para um dos três hospitais pediátricos existentes em Portugal. Os NRDs nacionais foram calculados para os três procedimentos radiológicos mais frequentes: radiografia do tórax AP/PA; radiografia do abdómen AP; radiografia da bacia AP. Os factores de exposição associados aos procedimentos bem como os valores de dose no doente foram recolhidos de forma prospectiva em cada um dos hospitais.

Por forma a analisar a relação entre os parâmetros de exposição e a respectiva dose, foi efetuado um estudo experimental usando dois fantomas antropomórficos: a) modelo CIRS™ ATOM 705®; altura: 110 centímetros, peso: 19 kg e b) modelo Kyoto kagaku™ PBU-60®; altura: 165 centímetros, peso: 50 kg. Na sequência do estudo experimental nos fantomas, foi efetuada uma avaliação objectiva das imagens, através da análise da variação do valor médio do desvio-padrão, medidos com o software OsiriX® (Pixmeo, Suíça). Com base nos resultados obtidos foram propostos novos parâmetros de exposição, para cada um dos procedimentos em estudo. Para validar os novos parâmetros de exposição em procedimentos clínicos foi efetuada uma avaliação subjetiva da qualidade das imagens radiológicas, através do método Visual Grading Charateristics (VGC), realizada de forma independente por quatro especialistas em radiologia pediátrica, cada um com um mínimo de 10 anos de experiência profissional utilizando, para tal, critérios de avaliação anatômica.

Resultados: Foi identificada uma grande heterogeneidade na forma de efetuar os procedimentos radiológicos em estudo, tendo sido calculados os NRD para Portugal, definidos como percentil 75 do Produto Dose-Área, (KAP_{P75}) e percentil 75 da dose á entrada da pele ($ESAK_{P75}$) que se revelaram mais elevados quando comparados com os dados mais recentes publicados na literatura. Os NRDs estabelecidos para Portugal são: TÓRAX AP/PA: KAP_{P75}, 13mGy.cm^2, 19mGy.cm^2, 60mGy.cm^2, 134mGy.cm^2, 94mGy.cm^2, respectivamente para os grupos etários <1, 1-<5, 5-<10, 10-<16, 16-≤18. ABDOMEN: KAP_{P75}, 25mGy.cm^2, 84mGy.cm^2, 140mGy.cm^2, 442mGy.cm^2, 1401 mGy.cm^2, respectivamente para os grupos etários <1, 1-<5, 5-<10, 10-<16, 16≤18. BACIA: KAP_{P75}, 29mGy.cm^2, 75mGy.cm^2, 143mGy.cm^2,

585mGy.cm^2, 839mGy.cm^2, respectivamente para os grupos etários <1, 1- <5, 5- <10, 10- <16, 16-≤18.

Foram também estabelecidos pela primeira vez os NRDs por grupos de peso dos doentes. Os NRDs obtidos após o processo de otimização por grupos de peso dos doentes são: TORAX AP/PA: KAP_{P75}, 9mGy.cm^2, 10mGy.cm^2, 15mGy.cm^2, 32mGy.cm^2, 57mGy.cm^2, respectivamente para os grupos de peso <5kg; 5-<15kg; 15-<30kg; 30- <50kg; ≥50kg. ABDÓMEN: KAP_{P75}, 10mGy.cm^2, 20mGy.cm^2, 61mGy.cm^2, 203mGy.cm^2, 225mGy.cm^2, respectivamente para os grupos de peso, <5kg; 5-<15kg; 15- <30kg; 30-<50kg; ≥50kg. BACIA: KAP_{P75}, 15mGy.cm^2, 18mGy.cm^2, 45mGy.cm^2, 75mGy.cm^2, 79mGy.cm^2, respectivamente para os grupos de peso <5 kg; 5-<15kg; 15-<30kg; 30- <50kg; ≥50kg.

Os NRDs relativos à $ESAK_{P75}$ para ambos os grupos de idade e de peso dos doentes também foram obtidas e estão descritos na tese.

Foi conseguida uma redução significativa na dose nos doentes após a implementação do programa de otimização: uma redução média de 41% e 18% respectivamente nos valores de KAP_{P75} e de $ESAK_{P75}$ para a radiografia do tórax AP/PA; uma redução média de 58% e 53% respectivamente nos valores de KAP_{P75} e de $ESAK_{P75}$, para a radiografia do abdómen; uma redução média de 47% e 48% respectivamente nos valores de KAP_{P75} e de $ESAK_{P75}$, para a radiografia da bacia.

Conclusão: Foram definidos os NRDs nacionais para as radiografias do Tórax AP/PA, Abdómen e Bacia. O estudo experimental efetuado permitiu definir critérios de exposição mais adequados e devidamente validados através da avaliação objectiva e subjetiva das imagens radiológicas. A implementação do programa de otimização permitiu uma significativa redução da dose nos doentes pediátricos sem comprometer a qualidade da imagem.

Palavras chave: níveis de referência de diagnóstico; radiologia pediátrica; proteção radiológica; otimização.

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Abbreviation Index

AAPM	American Association of Physicists In Medicine
AEC	Automatic Exposure Control
ALARA	As Low As Reasonably Achievable
AP	Antero-Posterior
APDH	Associação Portuguesa Para o Desenvolvimento Hospitalar
APIC	Associação Portuguesa de Intervenção Em Cardiologia
ARS	Administração Regional de Saúde
ASRT	American Society of Radiologic Technologists
AUC	Area Under the Curve
BaFX:Eu2+	Barium Fluorohalide activated With Europium
BEIR	Biological Effects of Ionizing Radiation
BMI	Body Mass Index
BSF	Backscatter Factor
CaWO4	Calcium Tungstate
CHLC	Centro Hospitalar de Lisboa Central
CHP	Centro Hospitalar do Porto
CHUC	Centro Hospitalar e Universitário de Coimbra
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
CPD	Continuous Professional Development
CR	Computed Radiography
CsI	Cesium Iodide
CT	Computed Tomography
DAP	Dose Area Product
DDM2	DoseDataMed 2
DI	Deviation Index
DICOM	Digital Imaging and Communications in Medicine
DQE	Detective Quantum Efficiency

DR	Digital Radiography
DRLs	Diagnostic Reference Levels
E	Effective Dose
EC	European Commission
ECSC	European Coal and Steel Community
EEC	European Economic Community
EFOMP	European Federation of Organisations for Medical Physics
EFRS	European Federation of Radiographer Societies
EI	Exposure Index
EI_t	Target Exposure Index
EMDD	European Medical Device Directive
ESAK	Entrance Surface Air Kerma
ESPR	European Society of Paediatric Radiology
ESR	European Society of Radiology
EU	European Union
ExT	Exposure Time
FPD	Flat-Panel Detectors
FS-S	Floor Stand Standard
FSD	Focus-Skin Distance
Gd2O2S:Tb	Terbium-Doped Gadolinium Oxysulfide
GDP	Growth Domestic Product
Gy	Gray
HR	Human Resources
HVL	Half Value Layer
IAEA	International Atomic Energy Agency
IAK	Incident Air Kerma
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units
ID	Identification
IEC	International Electrotechnical Commission

IP	Image Plate
IR	Interventional Radiology
KAP	Kerma Area Product
KSC	Knowledge, Skills and Competences
kV	Tube Voltage
LaOBr:Tm	Thulium–Doped Lanthanum Oxybromide
LNT	Linear No-Threshold
mA	Tube Current
mAs	Tube Current Time Product
MED	Medical Exposure Directive
MITA	Medical Imaging and Technology Alliance
MRI	Magnetic Resonance Imaging
MTF	Modulation Transfer Function
NHS	National Health Service
NPS	Noise Power Spectrum
OD	Optical Density
OECD	Organisation for Economic Co-Operation and Development
P75	75th Percentile
PA	Postero-Anterior
PACS	Picture Archiving and Communication System
PHE	Public Health England
PiDRL	European Diagnostic Reference Levels for Paediatric Imaging
PSL	Photostimulated Luminescence
QA	Quality Assurance
RHA	Regional Health Authority
ROC	Receiver Operating Characteristic
ROI	Regions of Interest
S/F	Screen/Film
SD	Standard Deviation
SI	International System of Units

SID	Source Image-Receptor Distance
SNK	Student-Newman-Keuls
SNR	Signal-To-Noise Ratio
SSD	Source Skin Distance
STUK	Finnish Radiation and Nuclear Safety Authority
Sv	Sievert
TFT	Thin-Film Transistors
TLD	Thermoluminescent Dosimeters
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
VGC	Visual Grading Characteristic
VS	Vertical Stand
WHO	World Health Organization
W_R	Radiation-Weighting Factor
W_T	Tissue-Weighting Factor

Introduction and objectives

According to 97/43/EURATOM (Medical Exposure Directive - MED) Directive the promotion and establishment of Diagnostic Reference Levels (DRLs) is mandatory for EU member states. In Portugal the Directive was transposed into national law by decree-law 180/2002, 8 August. Evidence shows significant differences in daily radiological practice at European, national and hospital levels, with obvious impact on the collective effective dose received by the population.

Data from European countries shows a wide variation in common DRLs, which may be due to differences in socio-economic conditions, regulatory regimes, level of activity of professional bodies and in the structure of health care systems (private/public mix). International radiation protection bodies such as the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP) recommend that each country should carry out its own national DRL survey (Edmonds, 2009).

Researchers question whether there is any justification to explain the use of an exposure that is 10, 20 or even 126 times higher than that used by another institution to obtain similar diagnostic images (Gray et al., 2005). Published studies (Carroll & Brennan, 2003; Johnston & Brennan, 2000) reported wide variations in patient doses for the same radiographic examinations among hospitals in the United Kingdom. These variations are attributable to a wide range of factors such as type of image receptor, exposure factors, number of images, type of anti-scatter grid and level of quality control.

The Portuguese health and/or radiation protection authorities have never taken any kind of formal action to define DRLs, neither by adopting the existing ones from the European guidance documents, nor by defining DRLs through surveys at national level.

In fact the DRL concept, the need for optimisation and radiation protection in Portugal has only started to be known and to be discussed in the last five years, through research activities driven by higher education institutions in radiography and research centres in combination with radiology departments.

There are published Portuguese National DRLs for paediatric head and chest CT (Santos, Foley, Paulo, McEntee, & Rainford, 2014), however there is a need for the official regulatory authorities to adopt and implement them.

The first known study developed in Portugal in the field of paediatric radiology optimisation resulted in a 70% reduction on Entrance Surface Air Kerma (ESAK) and exposure time for paediatric chest X-ray, after a transition from screen/film (S/F) to Computed Radiography (CR) systems (Paulo, Santos, Moreira, & Figueiredo, 2011).

The findings of this study were the motivation for the development of this thesis, as they raised several research questions:

- What type of practice is being used for paediatric plain radiography?
- How do the exposure parameters influence patient dose exposure and image quality in paediatric imaging?
- What is the impact of an optimisation programme in paediatric patients' exposure?

These research questions will be addressed within the framework of this thesis.

To achieve this, a major and several specific objectives have been defined:

Major objective:

Obtain DRLs for paediatric plain radiography.

Specific objectives:

- Measure and evaluate KAP and ESAK in the most frequent paediatric plain radiography procedures and derive numeric values of DRLs;
- Compare the obtained results with the "European guidelines on quality criteria for diagnostic radiographic images in paediatrics" and other published results;
- Optimise exam procedures in order to improve radiographers' best practice;
- Re-evaluate DRLs after optimisation actions and analyse the impact on patient dose;
- Develop a methodology to decrease radiation exposure in children, when feasible.

Figure 1 shows the design structure of the study developed in this thesis in order to accomplish the defined objectives.

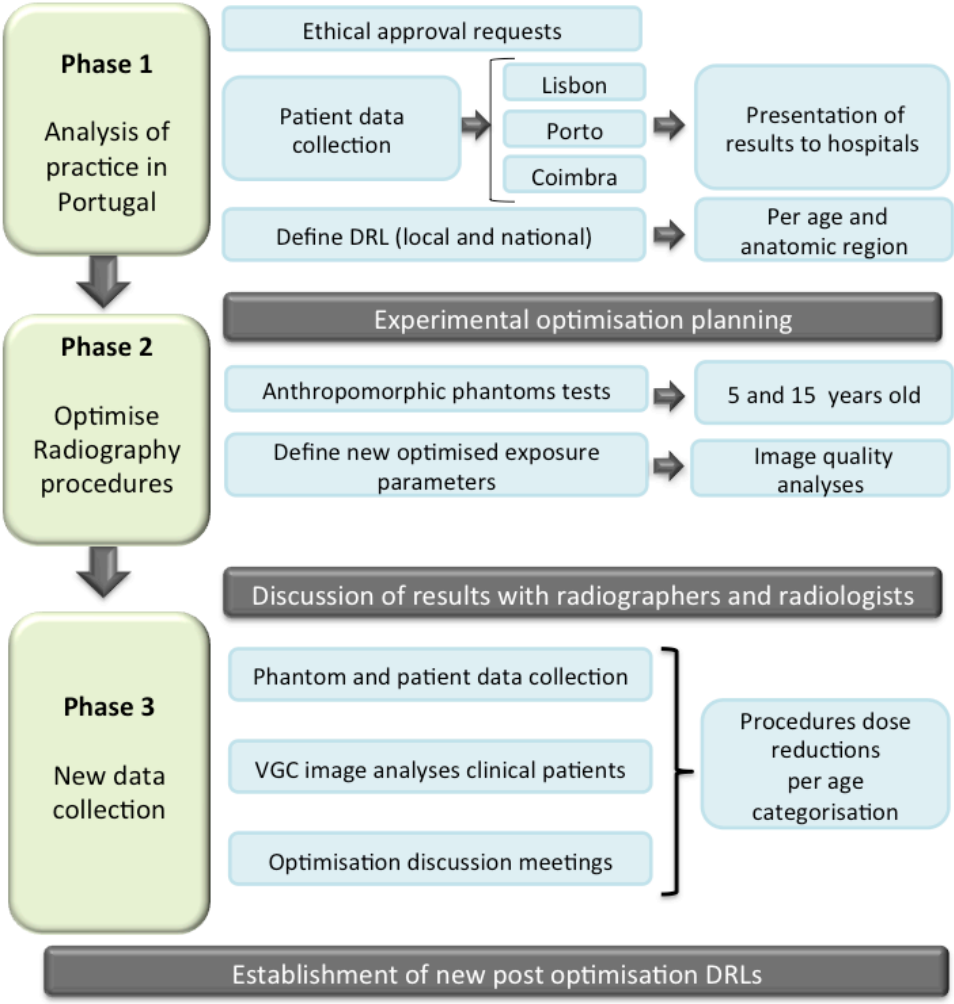

Figure 1: Schematic map of research activity and phases of the overall thesis

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1 Background

Technological evolution and new scientific developments have driven the health care sector towards an unprecedented increase of its organisational complexity. One of the major contributors to that increase was, without doubt, the development of medical imaging technology.

After Roentgen presented his manuscript, "*On a new kind of Ray*, *A preliminary Communication",* to the Wurzburg Physical Medical Society in 1895, radiology has transformed itself from a scientific curiosity to one of the main pillars of modern health care, becoming one of the scientific areas that contributed significantly to the understanding and dealing with the disease (Gagliardi, 1996). Since that special moment, the radiology body of knowledge has been constantly developing, driven by a permanent technological (r)evolution and is now integrated in a large spectrum of medical imaging procedures (Lança & Silva, 2013).

It is interesting to observe that 120 years after the revolution triggered by Roentgen's discovery of medical imaging, there are still persisting problems, similar to those described in 1910 by Eddy German, one of the pioneers of the Radiographer profession in the United States: *"It was difficult to find two operators who were anywhere near in accord regarding technical procedure. Some would advise certain procedures and others entirely different programs"* (Terrass, 1995).

Despite the scientific knowledge and the technological development in the past 120 years, the reality described by Eddy German in 1910 still applies to today's practice of medical imaging. The reasons are manifold: (a) the lack of harmonisation of professional practice at all levels; (b) a communication gap between science and professional practice; (c) a delay in integrating the new technology concepts of medical imaging into curricular programmes of health professions; (d) a barrier between manufactures/equipment developers and clinical practice.

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1.1 Portuguese Healthcare Context

According to the Portuguese National Institute of Statistics (www.ine.pt), Portugal has 10,427,301 inhabitants, of which 19.8% are less than 19 years old (data from 2013).

The Portuguese population has access to a healthcare system that is characterised by three coexisting, overlapping systems: the national health service (NHS), a universal, tax-financed system; public and private insurance schemes for certain professions (which are called health subsystems); and private voluntary health insurance. Thus, the Portuguese healthcare system has a mix of public and private funding. The NHS, which provides universal coverage, is predominantly funded through general taxation. The health subsystems, which provide healthcare coverage to between 20 and 25 per cent of the population, are funded mainly through employee and employer contributions (including contributions from the state as the employer of public servants). Close to 20% of the population is covered by voluntary private health insurance. About 30% of total expenditure on healthcare is private, mainly in the form of out-of-pocket payments (both co-payments and direct payments by the patient), and to a lesser extent, in the form of premiums to private insurance schemes and mutual institutions (Barros & Simões, 2007).

Portugal has a health expenditure of 10.2% of its Growth Domestic Product (GDP), above the average value (9.3%) of the Organisation for Economic Co-operation and Development (OECD) countries (OECD, 2013). However this indicator represents the effort that the population makes to have access to the healthcare system.

New medical technologies, such as digital radiography (DR), computed tomography (CT) and magnetic resonance imaging (MRI) are improving diagnosis and treatment, but are also increasing health expenditure (OECD, 2013).

Considering the decrease of the Portuguese GDP in the last 5 years, the health expenditure per inhabitant has obviously decreased. Nevertheless Portugal presents better health indicators than the majority of the OECD countries. It is of interest that Portugal has one of the lowest infant mortality rates: 3.4 deaths/1000 births (OECD, 2015).

According to article 64 of the Portuguese Constitution (Assembleia da República, 2005), the NHS is public and provides universal coverage.

The NHS, although centrally financed by the Ministry of Health, has a strong Regional Health Authority (RHA) structure since 1993, comprising five health administrations (Administração Regional de Saúde – ARS): ARS Norte, ARS Centro, ARS Lisboa e Vale do Tejo, ARS Alentejo and the ARS Algarve.

In each RHA a health administration board, accountable to the Minister of Health, manages the NHS. The management responsibilities of these boards are a mix of strategic management of population health, supervision and control of hospitals, and centralised direct management responsibilities for primary care/NHS health centres. The RHAs are responsible for the regional implementation of national health policy objectives and for the coordination of all levels of healthcare (Barros & Simões, 2007). This organisation structure does not include Madeira and Azores, since they have a special autonomous statute, however with the obligation to follow and respect the Portuguese Constitution.

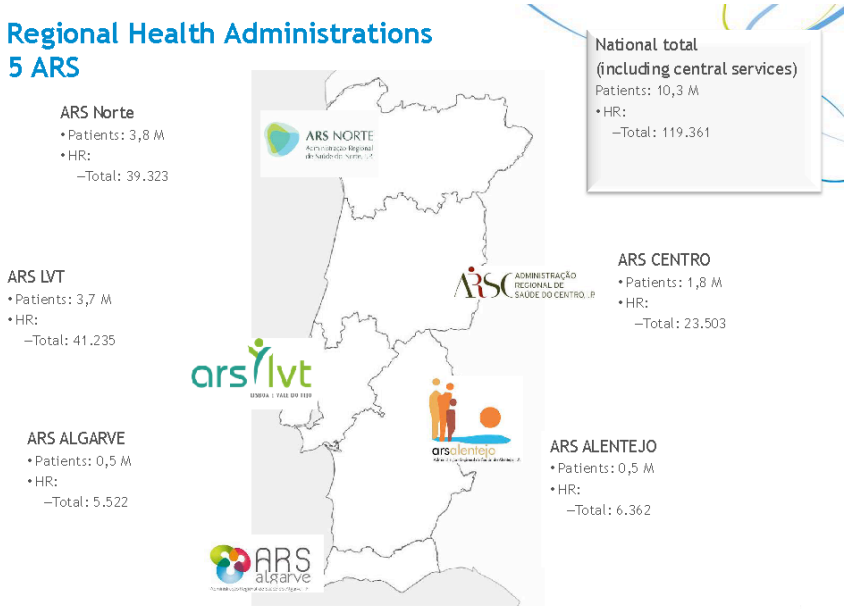

Figure 2: Portuguese map indicating the Regional Health Authorities (RHA). Number of patients and human resources (HR) in each RHA (ACSS, 2015).

In Portugal a patient is classified as paediatric until 18 years of age (Alto Comissariado da Saúde, 2009). Healthcare services to the paediatric population can be provided in any healthcare centre throughout the country. However, there are three dedicated paediatric hospitals in Portugal: Hospital Maria Pia do Porto (ARS Norte); Hospital Pediátrico de Coimbra (ARS Centro); Hospital de D. Estefânia de Lisboa (ARS Lisboa e Vale do Tejo). These dedicated paediatric hospitals have recently been integrated into major hospital centres, respectively: Centro Hospitalar do Porto (CHP), Centro Hospitalar e Universitário de Coimbra (CHUC) and Centro Hospitalar de Lisboa Central (CHLC).

These three major centres serve as reference hospitals for paediatric patients in Portugal, who need access to differentiated healthcare in all medical fields. The three centres have practitioners exclusively dedicated to paediatrics and are in general equipped with up-to-date technology.

1.2 European and Portuguese legal frameworks on ionising radiation

In 1957, six founding States (Belgium, France, Germany, Italy, Luxembourg and the Netherlands) joined together to form the European Atomic Energy Community (Euratom) and signed the Euratom Treaty in Rome. The main objective of the Euratom Treaty is to contribute to the formation and development of Europe's nuclear industry and to ensure security of supply.

Before the European Community was founded, there had been the Founding Treaties: European Coal and Steel Community (ECSC), European Economic Community (EEC) and Euratom. In 1967 they were all merged to become later the European Union. While the first two ended, Euratom is left unchanged and was added as a protocol only to the new EU Lisbon Treaty (European Union, 2007).

The current version of the Euratom Treaty (European Commission, 2012) comprises 177 articles, from which the articles quoted below are of relevance to medical imaging:

- Article 2: *"… the Community shall … establish uniform standards to protect the health of workers and of the general public and ensure that they are applied"*;
- Article 30: *"Basic standards shall be laid down within the Community for the protection of the health of workers and the general public against dangers arising from ionising radiations";*
- Article 31: *"The basic standards shall be worked out by the Commission after it has obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts, and in particular public health experts, in the Member States".*

Based on the Euratom Treaty the European Commission has published several Directives (binding legislation to be implemented by EU Member States): Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

All these directives were repealed by the Council Directive 2013/59/Euratom (European Commission, 2013a), with the main objectives to consolidate the existing European radiation protection legislation into one document and to revise the requirements of the Euratom Basic Safety Standards.

According to article 106 of Directive 2013/59/EURATOM, the Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive by 6 February 2018. Therefore European Member States have three years to adapt their national legislation to the new European requirements.

This thesis is mainly focused on the establishment of DRLs, a concept introduced by the ICRP (International Commission on Radiological Protection, 1996) and adopted for the first time by the European Commission through the 97/43/EURATOM Directive (European Commission, 1997) as: *"dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment"*.

With Directive 2013/59/EURATOM (European Commission, 2013a), the European Commission made a clear progress and strengthened the requirements in regard to DRLs by changing the relevant text from: *"Member States shall promote the establishment and the use of diagnostic reference levels for radiodiagnostic examinations"*; to: *"Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations"*. The reference to DRLs in the new Directive is related to optimisation and included in article 56 (European Commission, 2013a).

Another important concept included in the EURATOM Directives from the beginning is Clinical Audit, described as: *"a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary;"* (European Commission, 1997, 2013a).

The European Commission realised the lack of understanding of how to implement such an important concept in daily practice and published the Guidelines on Clinical Audit for Medical Radiological Practices (European Commission, 2009) as a tool to facilitate the achievement of its general objectives: a) improve the quality of patient care; b) promote the effective use of resources; c) enhance the provision and organisation of clinical services; d) further professional education and training.

Article 18 of Directive 2013/59/EURATOM is related to education, information and training in the field of medical exposure. According to this article, *"Member States shall ensure that practitioners and the individuals involved in the practical aspects of medical radiological procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection"*.

To give guidance to Member States the European Commission published the Guidelines on radiation protection education and training of medical professionals in the European Union (European Commission, 2014a). These guidelines were developed under the MEDRAPET project following the European Knowledge, Skills and Competences (KSC) model (European Commission, 2008a) and represent an

important tool for education institutions, health authorities and regulatory authorities to implement and audit education and training programmes in radiation protection.

Portugal is a member of the European Atomic Energy Community (Euratom) (European Commission, 2012), the IAEA and the OECD Nuclear Energy Agency.

As member of the Euratom Community, Portugal has to comply with the EU Directives laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

There is no single framework act governing the nuclear sector in Portugal. Instead, more than 100 laws, regulations and decrees set out provisions governing nuclear activities, frequently derogating each other implicitly, to the point where it becomes a matter of doctrinal debate to identify which provisions are applicable (OECD, 2011).

The main legal instruments governing the use of ionising radiation in healthcare in Portugal are:

- Regulatory-Decree Nº. 9/90, of 19 April, amended by Regulatory-Decree Nº. 3/92, of 6 March, regulating the rules and directives concerning protection from ionising radiation;
- Decree-Law Nº. 492/99, of 17 November, revised by Decree-Law No. 240/2000, of 26 September, approving the legal framework for the licensing and control of activities carried out in private health units using ionising radiation, ultra-sound or magnetic fields for diagnostic, therapeutic or preventive;
- Decree-Law Nº. 165/2002, of 17 July, amended by Decree-Law No. 215/2008, of 10 November, setting out the competencies of the bodies intervening in the field of protection against ionising radiation, as well as general principles of such protection;
- Decree-Law Nº. 167/2002, of 18 July, amended by Decree-Law No. 215/2008, of 10 November, setting out the legal framework for the licensing and functioning of entities active in the field of radiological protection;
- Decree-Law Nº. 180/2002, of 8 August, amended by Decree-Law No. 215/2008, of 10 November, setting out the legal framework for the protection of people's health against the dangers arising from ionising radiation in medical radiological exposures;
- Decree-Law Nº. 222/2008, of 17 November, setting out basic safety rules concerning the sanitary protection of the population and of workers against dangers arising from ionising radiation.

Some of these legal instruments were implemented after the European Commission decided to send a reasoned opinion to Portugal for failure to fulfil its obligations

related to basic safety standards for the protection of the health of workers and the general public from ionising radiation.

Portugal has notified transposition measures, which are dispersed in various legislative texts, instead of a coherent and consolidated legal framework. The European Commission considers Portuguese legislation on radiation protection too complex, creating uncertainty for the citizens regarding the relevant transposition provisions in force (European Commission, 2007a).

At present, Portugal fulfils all legal requirements regarding the transposition of the Euratom Directives. However, although the majority and most important aspects of the basic safety standards for protection against the dangers arising from exposure to ionising radiation are legally published, the requirements are not observed in daily practice. It is not even possible to clearly identify, in the complex and entangled Portuguese legislation, who acts as the national radiation protection authority responsible for ensuring the implementation of the radiation protection standards.

The topic of this thesis is particularly focused on article 61, nº 1, paragraph (a) of the Directive 2013/59/EURATOM (European Commission, 2013a): *"Special practices: Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure: of children".*

1.3 The shift of paradigm in medical imaging

The advent, consequent development and integration of computer technology into health industry were the trigger for the conception of digital imaging systems in radiology, significantly improving imaging performance. Through an exponential increase in the number of procedures, medical imaging departments contributed to an unprecedented change in patient workflow as well as to enhanced diagnostic capabilities. Throughout the world, and in particular in developed countries, conventional fluoroscopic and S/F radiography have been replaced by digital systems, CR or DR (Busch & Faulkner, 2006).

Digital radiography brought several advantages to medical imaging procedures, due to its wide dynamic range, the possibility to store and transfer images digitally and most of all, due to the image post processing capabilities that the systems offer. However, despite all these technological features, with clear benefits for the workflow of medical imaging departments, patient overexposure to ionising radiation might occur without visible impact on image quality. Radiographers were used to S/F systems that were by themselves a "self-control" system, since low or high exposures would deliver a "non diagnostic image" to the radiologists responsible for image interpretation. An overexposed image was too black, and an underexposed image was too white.

The image processing algorithms of digital systems are standardised for each imaging procedure. Therefore adequate gray-scale images are displayed correctly despite underexposure or overexposure (Don et al., 2013). In digital systems, good images are obtained for a large range of doses (International Commission on Radiological Protection, 2004). Due to the fact that in digital systems there is a separation between acquisition, processing and image display, a radiograph can have an acceptable diagnostic quality, but could be under or overexposed (Herrmann et al., 2012).

Another reason related to the increase of patient dose, together with the wide dynamic range of digital imaging systems, is the lack of training and/or the short adaptation period to the novel technology installed. Very often digital systems are used in the same way as S/F technology, including the use of the same exposure factors, submitting patients to higher doses without being perceived (International Atomic Energy Agency, 2011). It might happen that non-optimised exposure factors produce suboptimum image processing, hiding relevant diagnostic information (C. Schaefer-Prokop, Neitzel, Venema, Uffmann, & Prokop, 2008).

All these aspects combined with the lack of well-established methods to audit patient doses in digital systems can increase the problem of patient radiation exposure (Eliseo Vaño et al., 2007).

Therefore a special attention must be given to continuous professional development (CPD) of radiographers, radiologists and medical physicists, in order to ensure that adequate knowledge, skills and competences are acquired when making the transition from S/F radiography to digital systems (Nyathi, Chirwa, & Van Der Merwe, 2010).

There is no doubt that the shift of paradigm in medical imaging has significantly contributed to a better and faster healthcare delivery. However, there are evident challenges for radiographers, radiologists, medical physicists, and other health professionals directly involved in the use of ionising radiation, related to adapting to this new digital environment. Education and training are definitely among the major challenges (European Commission, 2014a). This education and training process is even more important in paediatric radiology, where maintaining diagnostic imaging quality with an achievable quality dose is even more critical (Moore et al., 2012).

Although recognising the potential of digital systems to improve the practice of medical imaging, the ICRP became aware of the risk of overuse of radiation. To manage the identified risks, the ICRP published several specific recommendations, including appropriate training, particularly as regards patient dose management, revision of the DRLs, and frequent patient dose audits (International Commission on Radiological Protection, 2004).

As far as the situation in Portugal is concerned, there is no official data regarding the number and type of radiography equipment installed. However according to the authors' knowledge and information, the majority (if not all) Portuguese public and private medical imaging departments have shifted towards CR and/or DR systems.

1.4 Plain Radiography Detector Systems

A traditional X-ray image is formed by different shades of gray (grayscale), each one representing the tissue and organs X-ray attenuation properties. For a given X-ray energy, the attenuation coefficient rises with the increase of the atomic number of the radiographed anatomical structure.

There are several events that occur when photons and electrons interact with matter, such as attenuation, absorption and scattering, transforming the energy of the original primary X-ray beam. An X-ray image is therefore made from the capture of the energy output after the interaction of X-ray with the matter. The energy capture process can be done by using (1) a screen-film or (2) a digital system.

1.4.1 Screen-film Systems

For decades S/F systems in combination with various intensifying screens have been the standard for medical imaging because of their functional utility and perceived high-image quality, and have been used to capture, display, store and communicate medical imaging.

A S/F system (figure 3) is composed of:

1. Cassette: a flat, light-tight container in which X-ray films are placed for exposure to ionising radiation and usually backed by lead to eliminate the effects of back scatter radiation;
2. Intensifying screens: a plastic sheet coated with fluorescent material (phosphors), which converts photon energy to light.
3. Film: consists of an emulsion-gelatin containing radiation sensitive silver halide crystals, such as silver bromide or silver chloride, and a flexible, transparent, blue-tinted base

The two main phosphors used in the intensifying screens are: a) calcium tungstate ($CaWO_4$), also known as slow screens due to their lower efficiency, emitting light in the deep blue; b) rare earth phosphors, such as the terbium-doped gadolinium oxysulfide (Gd_2O_2S:Tb), emitting green light, or thulium–doped lanthanum oxybromide (LaOBr:Tm) emitting green light (International Atomic Energy Agency, 2014). Rare earth phosphors are more efficient at converting X-rays to visible light and thus further reduce the radiation to the patient.

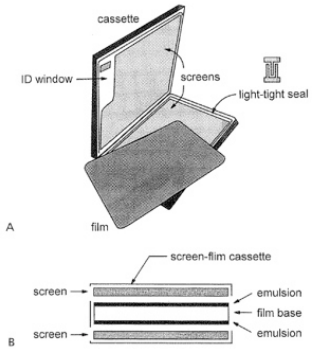

Figure 3: Screen-film receptor

(A) Opened cassette showing placement of film and position of screens, and (B) cross-sectional view through a dual screen system used in general purpose radiography with the film sandwiched between two screens.

The use of intensifying screens decreases the absorbed dose received by the patient compared to X-rays directly exposing the film. Films are typically exposed by 95% to 99% light and to 1% to 5% of X-ray photons when intensifying screens are used (Bushong, 2012).

The emulsion of an exposed sheet of X-ray film contains the latent image. Although it looks the same as that of the unexposed, the exposed emulsion is altered by the exposure to light. The latent image is recorded as altered chemical bonds in the emulsion, which are not visible. The latent image is rendered visible during film processing by chemical reduction of the silver halide into metallic silver grains, by chemical processing in a film processor (Lima, 2009).

Although the use of the screen-film as a detector system is becoming obsolete all around the world and even not existing any more in most European countries (Portugal has no public or private medical imaging department using screen-film systems, although official information is lacking), it is important to analyse some of the main features of this system, especially the denominated film characteristic curve, also known as the Hurter and Driffield (H&D) curve, a plot of a film's optical density (OD) as a function of the log exposure.

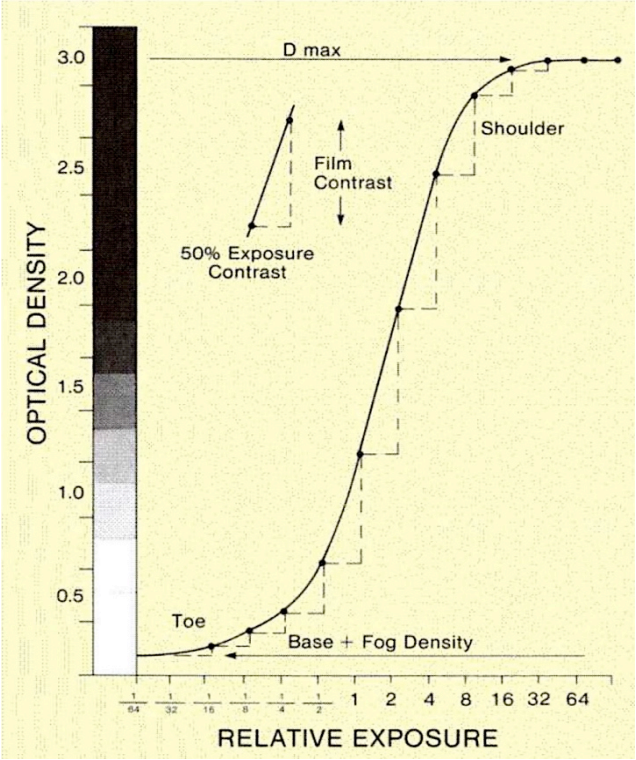

Figure 4: A Hurther and Driffield curve

The regions of the H&D curve include the toe, the linear region and the shoulder. The base + fog density corresponds to the OD of the unexposed film; adapted from (Sprawls, 2015)

When a film is exposed to the light from an intensifying screen, its response, as a function of X-ray exposure, is nonlinear and the curve has a sigmoid (S) shape. The toe is the low-exposure region of the curve (meaning that less radiation and consequently light reached that area of the film e.g.: bone, mediastinum, etc.). Between the toe and the shoulder of the curve is where ideally most of the radiographic image should be exposed. Beyond the shoulder are the areas of over-exposure (Lima, 2009). It is easy to understand that with a screen-film model the response of the system is limited to the slope between the toe and the shoulder of the curve, and therefore has a limited dynamic range, which leaves the radiographer with a very low margin of error when making radiographic exposure with diagnostic image quality (Haus, 1996).

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1.4.2 Digital Systems

The development of computer technology in the third quarter of the XXth century led to a dramatic change in the organisational structures of our society, especially in the developed countries. Although the impact was transversal in all sectors of the society, the advancement of computer technology created a major (r)evolution in the healthcare sector, particularly in medical imaging.

According to literature there are various different taxonomy approaches to define plain radiography digital systems (Lança & Silva, 2013), mainly due to the fact that several technologies were introduced in the market in a very short time period, which did not allow a consolidation of concepts and definitions.

Looking back in time and considering the technological features of plain radiography digital systems, the authors opted to use the taxonomy that splits digital systems in CR and DR (Korner et al., 2007; C. M. Schaefer-Prokop, De Boo, Uffmann, & Prokop, 2009).

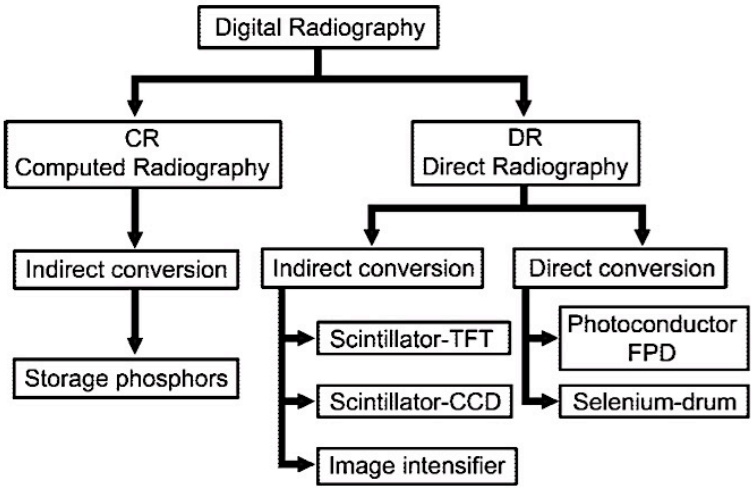

Figure 5: Taxonomy for plain radiography digital systems

(Korner et al., 2007)

The introduction of CR systems in medical imaging departments in 1983 triggered the transition from screen-film to digital environments (Cowen, Davies, & Kengyelics, 2007) and heralded the end of the traditional X-ray film.

For the first time a radiograph could be displayed and viewed at several places by different persons at the same time, owing to the development and implementation of the Picture Archiving and Communication System (PACS) in daily routine.

CR technology is still the most widely used digital acquisition method, mainly due to the fact that it allows the transition from S/F to digital systems without replacing the installed radiography equipment.

A CR system is composed of an image plate (IP), a CR reader and a viewing station. The IP is made of a thin layer of phosphor crystals implanted in a binder and fixed on a plastic substrate. The most frequently used phosphor material is barium fluorohalide activated with europium ($BaFX:Eu^{2+}$: where X represents one of the halogens used, bromine (Br), iodine (I) or chlorine (Cl) atoms) (Cowen et al., 2007). Although appearing quite similar to a regular intensifying screen, an IP functions quite differently.

Both intensifying screens and imaging plates rely on the principle of electron excitation. Intensifying screens use a rare earth phosphor, which is a fluorescent material that emits light photons after being stimulated by X-rays. These photons are converted to a latent image on the film using silver halide crystal centres as a storage medium. The IP uses a phosphorescence material ($BaFX:Eu^{2+}$) that, when exposed to X-rays, forms a latent image directly on the imaging plate itself, because the electrons of the screen are excited to a higher energy level and are trapped in halide vacancies. Holes created by the missing valence electrons cause Eu^{2+} to become Eu^{3+}.

This trapped energy can be released if stimulated by additional light energy of the proper wavelength by the process of photostimulated luminescence (PSL) (American Association of Physicists in Medicine, 2006). This latter process takes place in the CR reader.

Once the plate is inside the reader, the phosphor is scanned with a red laser beam, releasing the trapped electrons (at a high energy level), that emit light when going back to their normal level of energy (Lança & Silva, 2013). The emitted light is collected by a photodiode and converted into an electric signal to produce the digital image (figure 6).

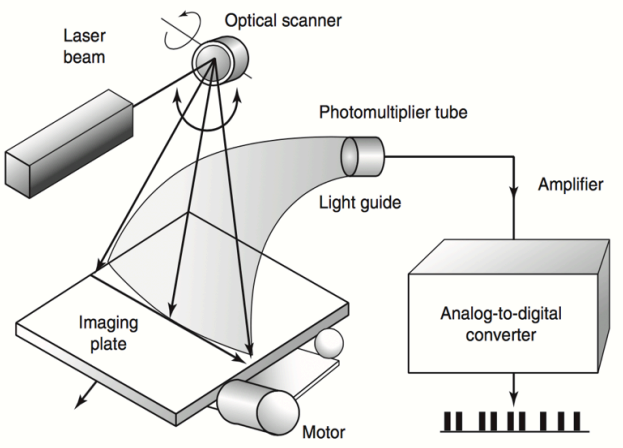

Figure 6: Schematic representation of a CR reader system
A laser beam scans the CR IP and releases the stored energy as visible light. A photomultiplier tube converts the light to an electric signal. A converter creates the digital image, which is then sent to the computer system. Adapted from (International Atomic Energy Agency, 2014)

After the plate is scanned inside the reader, it is exposed to an intense white light to erase it. This ensures that any residual image on the IPs is erased. IP's can be reused at least 10,000 times before they need to be replaced.

Although the implementation of CR systems has allowed the changeover from plain radiography to the new digital environment, the examination workflow has not changed much. Radiographers still have to:

- choose the size of the IP according to requested procedure;
- carry the IP to the X-ray equipment and put it in the right position on the potter-bucky;
- remove the IP after exposure and transport it to the CR reader.

DR systems were introduced in the market in the late 1980's early 1990's and immediately created high expectations, since the introduction of the new flat-panel detectors (FPD) promised to significantly improve patient workflow by dramatically decreasing the radiographic procedure time and the radiographer workload. It has been shown that by integrating the FPD systems into daily practice, productivity has been further enhanced, since the IP manipulation step has been eliminated (Dackiewicz, Bergsneider, & Piraino, 2000).

One of the key differences between FPD and CR is the fact that FPD have a direct readout matrix made of amorphous silicon (aSi) thin-film transistors (TFT) (aSi-TFT elements). This TFT layer is directly attached to an X-ray absorption medium (C. M. Schaefer-Prokop et al., 2009) and therefore the digital image is directly sent to a monitor display immediately after the exposure.

As shown in figure 7 there are two types of DR systems: a) those that use a scintillator (normally Cesium Iodide – CsI, doped with Thallium-Tl or Gadolinium Oxysulfide - Gd_2O_2S) as the absorption medium, which transforms X-ray into visible light, that is then captured by a photodiode or by a Couple Charge Device (CCD) or a Complementary Metal Oxide Semiconductor (CMOS)**:** ***indirect conversion***; or b) those that use a condensator material (normally amorphous selenium – aSe) attached directly to the TFT array: ***direct conversion***, where the absorbed X-ray energy is directly converted into charge, obviating the need to have an intermediate step transforming X-ray into light (Korner et al., 2007).

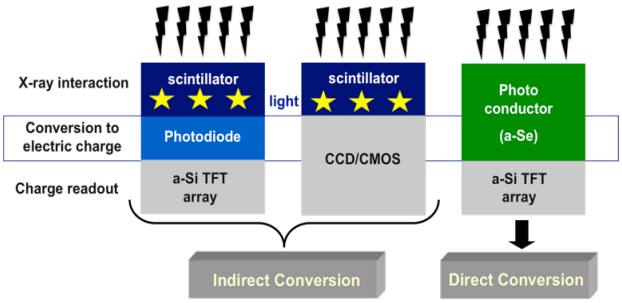

Figure 7: Schematic representation of DR systems

Adapted from (Chotas, Dobbins, & Ravin, 1999)

All the systems described are available in the market, with the Food and Drug Administration (FDA, United States of America) 510(k) clearance approval and with the CE mark, according to the European Medical Device Directive (EMDD) (European Commission, 2007b). It is important to note that both FDA (US Government, 2007) and EMDD do not require clinical trials for the pre market authorization of medical imaging equipment. The requirements taken into account are mainly related to quality and safety specifications.

Taking that into consideration, vendors are free to offer any type of DR system approved for the market. Therefore it is important to understand the different characteristics of each system that, depending on the material used, will lead to different physical performance of the detector.

Detective Quantum Efficiency (DQE) is currently established as the gold standard to measure the detector performance (Lança & Silva, 2013). When assessing the physical efficiency of a radiological digital detector, the measurement of image quality (using Signal-to-Noise Ratio - SNR) must be referred to the radiation dose used to create the image. In general terms, effective radiographic imaging demands the maximisation of recorded SNR, while minimising the radiation dose delivered to the detector (Cowen et al., 2007).

A good imaging detector in terms of its noise performance is one that produces an output signal with the same SNR as its incoming signal, i.e. does not alter the SNR. It is difficult, if not impossible, to improve SNR without degrading some other aspect of system performance (C. M. Schaefer-Prokop et al., 2009).

By definition, if a detector receives data with an SNR of SNR_{in}, from which it produces data with a SNR of SNR_{out}, then the DQE of the detector is:

$$DQE_{detector} = \left(\frac{\mathrm{SNR_{out}}}{\mathrm{SNR_{in}}}\right)^2$$

Equation 1: Detective Quantum Efficiency

An ideal (but unrealistic) detector preserves the SNR, recording every incident X-ray quantum, and which therefore has a DQE of 1. $DQE_{detector}$ always lies in the range $0>DQE_{detector}<1$. However, all detectors available on the market have a DQE always lower than 1 (Chotas et al., 1999).

No image detector can absorb all the incident X-ray photons with 100% efficiency (Cowen et al., 2007). Inevitably some X-ray photons pass through the detector, while some that are absorbed may be re-emitted and exit the detector. This loss in information carriers is compounded by secondary losses due to the presence of extraneous noise sources in the image detector itself.

For radiography applications with a high dose delivered to the detector, both direct and indirect conversion flat-panel detectors have a higher DQE than S/F systems or CR systems (Kotter & Langer, 2002).

The International Electrotechnical Commission (IEC) published a standard method for measurement of the DQE (International Electrotechnical Commission, 2015) that also included specifications for the measurement of two associated metrics that are important to characterise a detector: the Modulation Transfer Function (MTF) and the Noise Power Spectrum (NPS) (McMullan, Chen, Henderson, & Faruqi, 2009).

The MTF is a measure of the ability of an imaging detector to reproduce image contrast from subject contrast at various spatial frequencies. At a given spatial frequency, the value of the MTF will lie between zero and one. An MTF of zero means that no signal modulation is being reproduced, and an MTF of one indicates a perfect transfer of the signal. Typically, a system's ability to represent a signal decreases as the spatial frequency of the signal increases (James, Davies, Cowen, & O'Connor, 2001).

The NPS, also known as Wiener Spectra (after Norbert Wiener who pioneered its use), describes the noise properties of an imaging system (Park, Cho, Jung, Lee, & Kim, 2009) and is a metric of image quality, providing a more detailed description of the overall noise in an image (Lança & Silva, 2013).

Knowledge of the DQE, NPS, and MTF for DR, allows objective comparisons that can assist in the determination of appropriate and reasonable performance for a particular imaging application (American Association of Physicists in Medicine, 2006).

DR techniques have the potential to improve image quality and, given the higher sensitivity of their image receptors compared with S/F, also offer the potential for dose reduction. However, in practice, since image receptors also have a broader dynamic range than film, higher doses may also occur (International Atomic Energy Agency, 2007).

As shown in Figure 4 (pag. 41), the dynamic range gradation curve of S/F systems is "S" shaped, within a narrow exposure range for optimal film blackening. Radiographers were aware that S/F systems had a low tolerance for an exposure, resulting in failed exposures or insufficient image quality.

With the shift to the digital technology environment, radiographers started to use detectors with a wider and linear dynamic range, which in clinical practice virtually eliminates the risk of a failed exposure. Although the positive aspects of digital systems clearly prevail, radiographers need to understand, that special care has to be taken not to overexpose the patient by applying more radiation than is needed for obtaining a diagnostic quality image, because the detector function improves as radiation exposure increases.

This phenomenon, described in literature as *"exposure creep",* is defined as an unintended gradual increase in X-ray exposures over time that results in increased radiation dose to the patient when shifting from S/F to DR systems (Gibson & Davidson, 2012). In DR, image processing can compensate by up to 100% for under exposure and up to 500% for over exposure, and still produce a clinically acceptable image (Butler, Rainford, Last, & Brennan, 2010).

The described phenomenon can be easily seen in figure 8, (from Lança & Silva, 2013) in which, due to the linear signal response of digital systems, it is possible to have comparable quality images with an exponential difference in patient dose exposure.

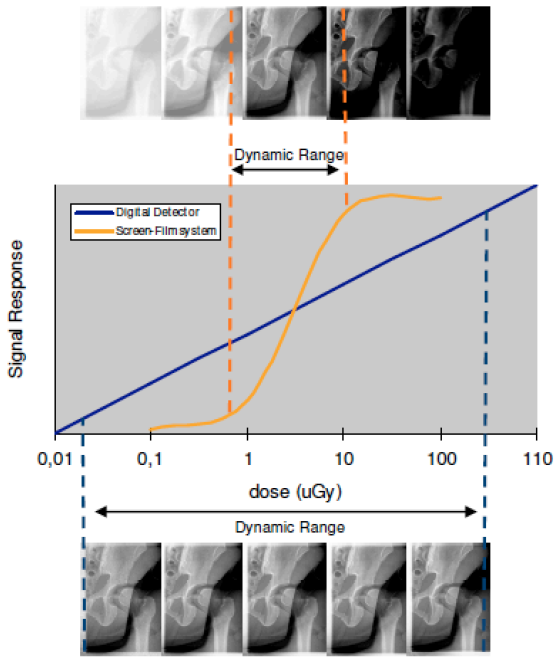

Figure 8: Dynamic range in digital and S/F systems (Lança, 2013)

To better understand this phenomenon and to maximise the potential of the technological features of the imaging equipment, there is a need for a permanent multidisciplinary approach, involving medical physicists, radiographers and medical doctors, to develop harmonised standards of practice towards the best diagnostic image quality at the lowest dose possible.

DR systems have an enormous potential for high image quality at lower doses. However, overexposed images can easily go unnoticed, resulting in unnecessary overexposure and potential harm to the patient (Seibert & Morin, 2011). Therefore optimisation should be used as a permanent process to reduce patient dose (Neofotistou, Tsapaki, Kottou, Schreiner-Karoussou, & Vano, 2005).

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1.5 Dose descriptors in radiography

Patient dosimetry in diagnostic imaging is complex and involves several uncertainties due to the large variation of technology and techniques.

The objective of dosimetry in radiological imaging is the quantification of radiation exposure within an approach to optimise the image quality to the absorbed dose ratio. The image quality should be understood as the relevant information appropriate to the clinical situation (International Commission on Radiation Units & Measurements, 2005).

There are several terms to describe radiation dose and confusion can arise through the inappropriate use of it from clinical procedures to patients (Nickoloff, Lu, Dutta, & So, 2008).

The key dosimetric quantities for use in general radiography and recommended (International Atomic Energy Agency, 2013) for paediatric patient dose are:

- incident air kerma $K_{a.i}$ (IAK);
- entrance surface air kerma, $K_{a.e}$ (ESAK);
- air kerma (or dose) area product, P_{ka} (KAP or DAP).

These are the recommended application-specific dosimetric quantities for the implementation of DRLs (International Commission on Radiation Units & Measurements, 2005), which have thus been used for this thesis.

IAK is measured for phantoms and is determined using recorded exposure parameters for patients. For patients, ESAK is typically determined from the IAK by applying the appropriate backscatter factor (BSF), but may also be measured directly with thermoluminescent dosimeters (TLD) or derived from the P_{ka} measured using a KAP meter (International Atomic Energy Agency, 2013). The BSF for radiography range from 1.25 to 1.60 for typical X-ray spectra and field sizes used for adults (Petoussi-Henss, Zankl, Drexler, Panzer, & Regulla, 1998). The backscatter factor depends on the X-ray spectrum, the X-ray field size, SID and the patient or phantom thickness.

According to International Commission on Radiation Units (ICRU) report 74 (International Commission on Radiation Units & Measurements, 2005):

- The IAK ($K_{a.i}$) is the kerma to air from an incident X-ray beam measured on the central beam axis at the position of the patient or phantom surface (Figure 9). Only the radiation incident on the patient or phantom and not the backscattered radiation is included. It is expressed in J/kg and the unit is Gray (Gy);
- The ESAK ($K_{a.e}$) is the kerma to air measured on the central beam axis at the

position of the patient or phantom surface (Figure 8). The radiation incident on the patient or phantom and the backscattered radiation are included. It is expressed in J/kg and the unit is Gray (Gy).

- The KAP or KAP (P_{KA}) is the integral of the air kerma over the area of the X-ray beam in a plane perpendicular to the beam axis (Figure 9). It is expressed in $J.kg^{-1}.m^2$ and the unit is $Gy.m^2$.

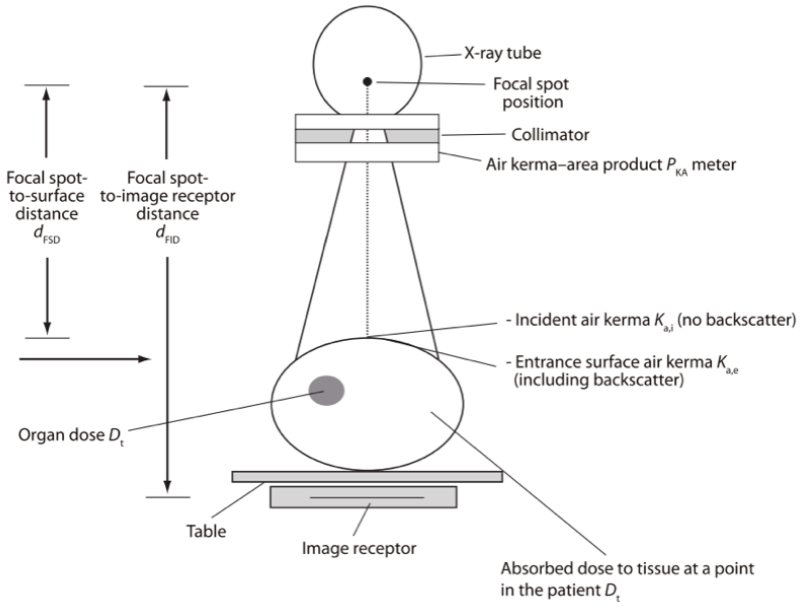

Figure 9: Schematic representation of a radiograph with some dosimetric and geometric quantities for determination of patient dose.
(ICRU report 74)

There are also ionising radiation risk-related dose quantities (International Commission on Radiation Units & Measurements, 2005) that have been recommended by ICRP, such as:

- ***Exposure:*** a measure of radiation based on its ability to produce ionisation in air under standard temperature and pressure. The International System of Units (SI) unit for exposure is Coulombs/kg in air.
- ***Absorbed dose:*** the amount of energy absorbed per mass is known as radiation dose (D_T). Radiation dose is the energy (Joules) absorbed per unit mass of tissue and has the (SI) units of Gray (1 Gy = 1 J/ kg).
- ***Equivalent dose:*** the term 'equivalent dose' is used to compare the biological effectiveness of different types of radiation to tissues. The (SI) dose equivalent (H_T) in Sievert (Sv) is the product of the absorbed dose (D_T) in the tissue multiplied by a radiation-weighting factor (W_R), often called the quality factor (International Commission on Radiological Protection, 2012). Equivalent dose is expressed as a summation to include the effects of

irradiation of tissue by more than one type of radiation.

$$H_T = \sum W_R \, . \, D_T$$

Equation 2: Equivalent Dose

- **Effective dose:** Effective Dose (E) is used to estimate the risk of radiation in humans. It is the sum of the products of equivalent doses to each organ/tissue (H_T) and the tissue-weighting factor (W_T) (International Commission on Radiological Protection, 2012). The unit of effective dose is the Sievert (Sv).

$$E = \sum W_T \, . \, H_T$$

Equation 3: Effective Dose

- **Collective dose:** Collective dose is defined as the dose received per person in Sv multiplied by the number of persons exposed per year i.e. man-Sievert per year. This unit is generally used for protection purposes and in population response calculations.

As one can see there are several dose quantities representing different concepts but yet using the same units. This can represent a problem amongst health professionals, especially between radiographers, radiologists and medical physicists, creating confusion in their daily practice. Therefore it could be beneficial to develop a new system where each unit immediately brings to mind the corresponding quantity to which it refers (Rehani, 2015).

Although the exposure index (EI) it is not considered by ICRU and ICRP as a dose descriptor, it could be understood as an exposure concept related to the patient due to its influence on image quality and the fact that it is related to the delivered dose required for any radiological image (Lança & Silva, 2013).

For some time DR systems have associated the EI to the concept of S/F “speed class”. This has created some conceptual misunderstanding and scientific confusion amongst users (Huda, 2005).

It is important to note that patient radiation dose and EI are not the same. The dose to the patient is determined by the radiograph exposure technique factors (kV, mAs, grid, source to image-receptor distance (SID), filtration, beam collimation), the X-ray beam penetrability and quality, as well as by the size and area of the body irradiated. The EI on the detector is determined by the remnant radiation (primary

radiation transmitted through the patient and scattered radiation transmitted from the patient) that is absorbed, converted to electronic signals, and transformed into a digital radiographic image (Seibert & Morin, 2011).

Currently each manufacturer has its own definition and reference values for EI (table 1). These EIs are entirely manufacturer-specific and vary greatly in terminology, mathematical formulas and calibration conditions. Moreover, in some systems, increasing EI values indicate increasing dose whereas for others the opposite is the case. This inconsistency between vendors has been a restriction to an effective use of EI and confusion is patent amongst professionals that use more than one system in daily practice (Mothiram, Brennan, Lewis, Moran, & Robinson, 2014).

Table 1: Manufacturer exposure index name and indicator of digital systems

Manufacturer	Name	Symbol	Exposure Indicator
Agfa	Log of median of histogram	lgM	Logarithmic value (lGm): the median value of the ROI histogram defines the lGm for the image. lGm is a deviation index as it compares the resultant lGm value to a reference lGm value.
Canon	Reached Exposure Value	REX	REX is a function of the brightness and contrast as selected by the operator
Philips	Exposure Index	EI	EI is inversely proportional to the air kerma incident on the image receptor. It is derived from a characteristic pixel value of the image.
Carestream	Exposure Index	EI	EI is a numerical value computed from the average code value of those areas of the image data that are used by the image-processing algorithm to compute the original tone scale. It has a logarithmic relationship with the air kerma incident on the detector.
Fujifilm	S value	S	S is related to the amount of amplification required by the photomultiplier tube to adjust the digital image. S is inversely proportional to exposure.
General Electric	Detector Exposure Index	DEI	DEI compares the detector exposure to the expected exposure value
Siemens	Exposure Index	EXI	The exposed field is divided into 3X3 Matrix, where the central segment is the ROI. EXI is calculated as the average out the original pixel values in the central segment. EXI value is directly proportional to dose. Doubling of EXI value represents a doubling of absorbed dose at image receptor.

The IEC and the American Association of Physicists in Medicine (AAPM) have been working separately on exposure value standardisation. Both efforts involve collaboration among physicists, manufacturers, and the Medical Imaging and Technology Alliance (MITA). IEC standard 62494-1 (International Electrotechnical Commission, 2008) was published in 2008, and the report of AAPM Task Group 116 (AAPM Task Group 116, 2009) was published in 2009.Even though the implementation of these standards is not a legal requirement, some manufacturers have already adopted them and others will likely follow (Don, Whiting, Rutz, & Apgar, 2012).

In digital X-ray imaging, an EI is used to describe radiation dose to the detector. The EI is a valuable tool in the optimisation process, since in digital imaging it is possible that the patient gets an inappropriately high radiation dose while the image quality is still acceptable.

According to the IEC standard 62494-1 (International Electrotechnical Commission, 2008) there are three new concepts that will be introduced in radiology departments:

1. *Exposure Index (EI):* the EI is the measure of the detector response to radiation in the relevant image region (typically the region for which the exposure parameters should be optimised) and is defined as:

$$EI = K_{cal}.100\mu Gy^{-1}$$

Equation 4: IEC Exposure Index

where K_{CAL} is the detector air kerma in µGy under beam quality RQA-5 calibration conditions (International Electrotechnical Commission, 2005b). The physical characteristics of a RQA-5 beam quality are:

- added filtration of 23.5mmAl;
- tube voltage of 70kV;
- Half Value Layer (HVL) of 7.1mmAl

EI is not a patient dose indicator representing only a relative exposure measure according to the type of the examination (Don et al., 2012).

2. *Target Exposure Index (EI_T):* the EI_t is an expected value of the EI when exposing the image receptor properly and obtaining an optimal radiographic image.
3. *Deviation Index (DI):* the DI quantifies how much the EI varies from the EI_t and is defined as:

$$DI = 10log\frac{EI}{EI_t}$$

Equation 5: IEC Deviation Index

Ideally, EI and EI_T should be the same and therefore DI would be 0. However, an acceptable DI value is expected to be between a -0.5 to 0.5 range. DI values of 1.0 to 3.0 correspond to 26% and 100% of overexposure, respectively, while DI values of -1.0 to -3.0 correspond to 20% and 50% of underexposure, respectively. One of the major advantages of the DI value is that it gives an immediate feedback to the radiographer about the appropriateness of the exposure (Don et al., 2012).

The IEC standard is a helpful tool to eliminate the various different terms and concepts implemented by the vendors and consequently end the existing confusion amongst radiographers, radiologists and medical physicists.

Since this is a new EI concept, there is a need to define proper EI_t for the most common examinations, taking into consideration the diagnostic image quality.

It is expected that in the near future all vendors implement this new IEC index standard in their equipment. It will be a major challenge for radiologists, radiographers and medical physicists (as individuals or through their scientific bodies representatives) to develop together with international organizations (such as ICRP and IAEA) EI_t reference values for the most common procedures, taking into account the patient characteristics and the clinical indication of the referral for the radiographic exposure.

1.6 Risks in paediatric imaging

The risk of exposure to radiation is a permanent topic on the agenda of global organisations like the ICRP (www.icrp.org), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, www.unscear.org), the IAEA (www.iaea.org) and the World Health Organization (WHO, www.who.int). The role of these global organisations is crucial, as they continuously evaluate and analyse the scientific literature about the effects of ionising radiation and also publish recommendations and guidelines on how to use ionising radiation in a safe way.

The 1990 recommendations of the ICRP defined two different types of potential effects on tissues and organs exposed to ionising radiation. These recommendations were formally replaced in 2007 (International Commission on Radiological Protection, 2007) by the following:

1. Deterministic or tissue reaction effects are characterised by a threshold dose below which they do not occur. Deterministic effects have a clear relationship between the exposure and the effect and the level of the effect is directly proportional to the amount of the dose received. These effects are often evident within hours or days. Examples of deterministic effects include erythema (skin reddening), skin and tissue burns, cataract formation, sterility, radiation sickness and death.
2. Stochastic effects are those that occur by chance and consist primarily of cancer and genetic effects. Stochastic effects often occur years after exposure. As the dose to an individual increases, the probability of developing cancer or a genetic effect also increases. For stochastic effects, there is no threshold dose below which it is relatively certain that an adverse effect will not occur.

Stochastic risks are of special concern in paediatric imaging, since children are more vulnerable than adults and have a longer life-span to develop long-term radiation-induced health effects like cancer.

It is well known that the natural background is by far the highest source of ionising radiation exposure for both children and adults and that there is significant geographical variation in the doses received. However, there are no differences between the doses received by children and adults in the same location. The average annual effective dose to an individual resulting from natural background radiation is approximately 2.4 mSv (UNSCEAR, 2013).

There is an on-going controversy among the scientific community about the acceptance of the Linear No-Threshold (LNT) model. The LNT model hypothesis assumes that the long term, biological damage caused by ionising radiation (essentially the cancer risk) is directly proportional to the dose, and that any

increment of exposure above natural background levels will produce a linear increment of risk. The LNT model hypothesis has other competing theories: a) the Threshold Model: very small exposures are harmless; b) the Radiation Hormesis Model: radiation at very small doses can be beneficial (Wall et al., 2006).

The French Academies consider that the LNT model for assessing carcinogenic risks induced by low doses, such as those delivered by diagnostic radiology, is not based on valid scientific data and might create anxiety amongst patients, although they acknowledge that the model can be practical for the organisation of radiation protection (Tubiana, 2005).

A different opinion is supported by the ICRP and by the National Academy of Sciences (Biological Effects of Ionizing Radiation - BEIR VII report) that recommends the use of the LNT model (Tubiana, Feinendegen, Yang, & Kaminski, 2009).

The BEIR VII committee concludes that current scientific evidence is consistent with the hypothesis that there is a linear dose-response relationship between exposure to ionising radiation and the development of radiation-induced solid cancers in humans (Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, 2006).

As stated above, radiation is one of the most extensively researched carcinogens, but the effects of low doses are still somewhat unclear. The weight of evidence from experimental and epidemiological data does not suggest a threshold dose below which radiation exposure does not cause cancer. If there is no such threshold, then diagnostic X-rays are likely to induce some cancers (González & Darby, 2004).

An increased risk of acute lymphocytic leukaemia from plain radiography and of fatal breast cancer from scoliosis series in children has been demonstrated and reported by some authors (Willis & Slovis, 2005). The younger the patient at the time of exposure, the greater the risk of developing a fatal cancer.

Despite all the controversies found in the literature, the LNT model hypothesis remains a wise basis for radiation protection at low doses and low dose rates (International Commission on Radiological Protection, 2005) and represents, until today, the best means for radiation-protection standards (Breckow, 2006).

The biological effects of ionising radiation in children are based on a very important trilogy: 1) radiosensitivity; 2) life expectancy; 3) radiation exposure. Considering this it is expected that for the same effective dose, the biological effects and lifetime risks are higher in children than in adults (International Atomic Energy Agency, 2012).

An UNSCEAR report from 2013 reviewed 23 different cancer types. Broadly, for about 25 per cent of these cancer types, including leukaemia and thyroid, skin,

breast and brain cancer, children were found to be clearly more radiosensitive. For some of these cancers, depending on the circumstances, the risks were found to be considerably higher for children than for adults. In diagnostic medical exposure, children may receive significantly higher doses than adults for the same examination, if the technical parameters for delivering the dose are not specifically adapted. Cancers potentially induced by exposure to ionising radiation at young age may occur within a few years, but also decades later. Estimates of lifetime cancer risk for persons exposed as children were described as uncertain and might be a factor of two to three times higher than estimates for a population exposed at all ages (UNSCEAR, 2013).

The size and weight of paediatric patients has a big impact on the radiation dose received. Smaller and lighter patients have lower attenuation of the primary X-ray beam and are therefore exposed to a higher radiation dose. In smaller and thinner paediatric patients the organs are closer and therefore more easily exposed to scattered radiation (Linet, Kim, & Rajaraman, 2009).

A basic knowledge of radiation risk is useful in counselling patients who express concern about this issue. In most cases, the benefits of indicated medical imaging will outweigh the relatively small excess of cancer risk, and patient management should not be altered on the basis of radiation risk. However, for certain subsets of patients, radiation risk should be of greater concern to the clinician (Lin, 2010).

Even knowing that there are several controversies regarding the quantification of risks and also a lack of agreement on how to present it, the best attitude for health professionals using ionising radiation in clinical practice is to perform a medical imaging procedure according to the ALARA principle, according to which radiation doses should be kept *As Low As Reasonably Achievable*, taking into account social and economic factors (International Commission on Radiological Protection, 1977, 2007).

Sometimes the abbreviation ‘ALARA’ is used as equivalent to the term ‘optimisation of protection’ or in replacement thereof. However, it should be kept in mind that the expression ‘as low as reasonably achievable’ is only part of the concept of optimisation. The entire concept implies, more precisely, keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic). In diagnostic imaging and x-ray-guided interventions, it means that the number and quality of images are sufficient to obtain the information needed for diagnosis or intervention (International Commission on Radiological Protection, 2013).

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1.7 The international context of Diagnostic Reference Levels

DRLs were introduced by ICRP as a practical tool for optimisation in diagnostic radiology and nuclear medicine (International Commission on Radiological Protection, 1996). Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task, is the overriding clinical objective. DRLs are used to help manage the radiation dose delivered to patients so that the dose is commensurate with the clinical purpose.

DRLs should be used as a form of investigation level to identify unusually high levels. If DRLs are consistently exceeded, a local review usually takes place. DRLs are not intended for regulatory or commercial purposes, nor do they represent a dose constraint, nor are they linked to limits or constraints (International Commission on Radiological Protection, 2001).

The radiation protection scheme used across Europe (and worldwide) is based on the recommendations of the ICRP, which are founded on the dose descriptors defined by the ICRU. The publication ICRP 60 (ICRP 1991) recommends a radiation protection system based on the system of dose limitation, which has also been an essential element in earlier ICRP documents such as ICRP 26 (ICRP 1977). ICRP 60 (ICRP, 1991) was substantially revised and updated in 2007 with the publication of ICRP 103 (ICRP 2007).

The ICRP system of radiation protection is based on three fundamental principles: justification, optimisation and dose limitation.

The principle of justification requires that any decision that alters the radiation exposure situation should do more good than harm; in other words, the introduction of a radiation source should result in sufficient individual or societal benefit to offset the detriment it causes.

The principle of optimisation requires that the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual exposure should all be kept as low as reasonably achievable, taking into account economic and societal factors. In addition, as part of the optimisation procedure, the ICRP recommends that there should be restriction on the doses to individuals from a particular source, which has led to the concept of dose constraints.

The principle of dose limitation requires that the dose to individuals from planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the ICRP.

Also the European Commission (EC) has strengthened the importance of DRLs in the recently published Council Directive 2013/59/EURATOM (European Commission, 2013a), laying down basic safety standards for protection against the dangers

arising from exposure to ionising radiation. The EC recognises that the technological and scientific developments in the medical field have led to a notable increase in the exposure of patients. Therefore the Directive should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of DRLs and the availability of dose-indicating devices.

Article 56 of the Directive 2013/59/EURATOM defines that Member States shall ensure the establishment, regular review and use of DRLs for radiodiagnostic examinations, having regard to the recommended European DRLs where available.

The use of DRLs generates complementary information and thus supports professional judgment. The use of DRLs is important to promote the review of practice in local sites. The establishment of DRLS at local level should be implemented with the involvement of radiologists, radiographers and medical physicists and should be regularly reviewed to improve best practice at lower doses (Santos, 2014).

Since ICRP introduced the DRL concept to the scientific and professional community in 1996, several initiatives were taken to try and make its use effective in daily practice. One of the most relevant steps was the inclusion of the DRL concept in the Euratom 97/43 Directive, which served as a trigger for several other actions, mainly national radiation protection authorities.

Aware of the importance of using the DRL concept as a tool to decrease dose exposure to the patients and the population, the EC published several guideline documents (European Commission, 1996a, 1996b) for both adult and paediatric plain radiography, with the main objective to achieve adequate image quality, comparable throughout Europe at reasonably low radiation dose per radiograph.

Another important guidance on DRLs for medical exposure was published by the EC in 1999 (European Commission, 1999), highlighting the importance of establishing DRLs for high-dose medical examinations, in particular CT and interventional radiology (IR) procedures and for patient groups that are more sensitive to radiation, especially children.

The RP 109 document recommends that DRLs for diagnostic radiology should be based on doses measured in various types of hospitals, clinics and practices and not only in well-equipped hospitals. The values should represent the 75th percentile of the ESAK (mGy) and/or the KAP (Gy.cm^2). According to the RP 109 guidance document, the KAP is a more practical dose descriptor, since the entire examination is recorded without interfering with the patient and the exam procedure.

Although extremely important, this guidance document (RP 109) only presents DRLs for plain S/F systems, and is only of limited value regarding paediatric patients, since the DRLs are based on a standard sized five-year old patient. In fact this limitation is major, since the 'paediatric population' includes the age range from birth until 18 years (European Commission, 2006), which implies a huge variation in patient weight, ranging from some grams to more than 100 kg. This enormous heterogeneity of patient characteristics, combined with the fact that pre-sets installed in radiological equipment are normally not adapted to them, makes defining DRLs and optimisation of procedures very challenging for this population.

There is also a lack of consensus in the literature regarding the best methodology to group paediatric patients in order to define a DRL. Some authors group patients according to: a) specific ages (0, 5, 10 and 15 years); b) division between new-borns and infants; c) age groups (<1, 1-<5, 5-<10, 10-<16, ≥16). Other authors (Kiljunen, Ja, & Savolainen, 2007) consider it a more practical method to present DRLs as a function of patient projection thickness. When paediatric DRLs are presented as a curve, hospitals can compare their patient doses directly against the graph, and the need for a large number of patients is significantly reduced. Some authors considered this method more adequate than the one established by the UK National Radiological Protection Board (NRPB-UK, now Public Health England) for setting paediatric DRLs (Hart, Wall, Shrimpton, Bungay, & Dance, 2000).

Attentive to the change of paradigm in medical imaging brought about by the shift to DR systems, the EC became conscious of the need to revise the existing guidelines and published an invitation to tender for a service contract, regarding European Guidelines on Diagnostic Reference Levels for Paediatric Imaging (European Commission, 2013b).

The 27-month project entitled European Diagnostic Reference Levels for Paediatric Imaging (PiDRL) was awarded to a consortium (ESR, EFRS, ESPR, EFOMP, & STUK, 2013) composed by the:

- European Society of Radiology (ESR);
- European Federation of Radiographer Societies (EFRS);
- European Society of Paediatric Radiology (ESPR);
- European Federation of Organisations for Medical Physics (EFOMP);
- Finnish Radiation and Nuclear Safety Authority (STUK).

The consortium is supported by an Expert Advisory Panel formed by representatives of the IAEA, the WHO, the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), the ICRP, the Public Health England (PHE, formerly HPA) as well as by an expert from the United States of America.

The aims of the PiDRL project Guidelines are:

- to recommend a methodology for establishing and using DRLs for paediatric radiodiagnostic imaging and IR practices;
- to update and extend the European DRLs for these examinations where sufficient experience and data are available for a consensus on DRL values;
- to promote the establishment and use of DRLs in paediatric radiodiagnostic imaging and IR practices so as to advance optimisation of radiation protection of paediatric patients.

DRLs are a good tool to comply with the ALARA principle as they can provide the stimulus to monitor and promote improvements in patient protection, by increasing dose awareness and focusing paediatric practice on achieving the required imaging quality that patients need.

Despite this scientific and legally binding framework and the recommendations from the international organisations, the use of paediatric DRLs in daily practice is far from being a reality in the EU.

A recent report from the DoseDataMed 2 (DDM2) project (European Commission, 2014b) shows that most EU countries have never established DRLs for paediatric imaging and that those few countries that have, just copied the recommended values from the EU guidance documents that, as already mentioned, entail several limitations. Only about one fifth of the countries defined their DRLs based on their own national patient dose surveys (figure 10).

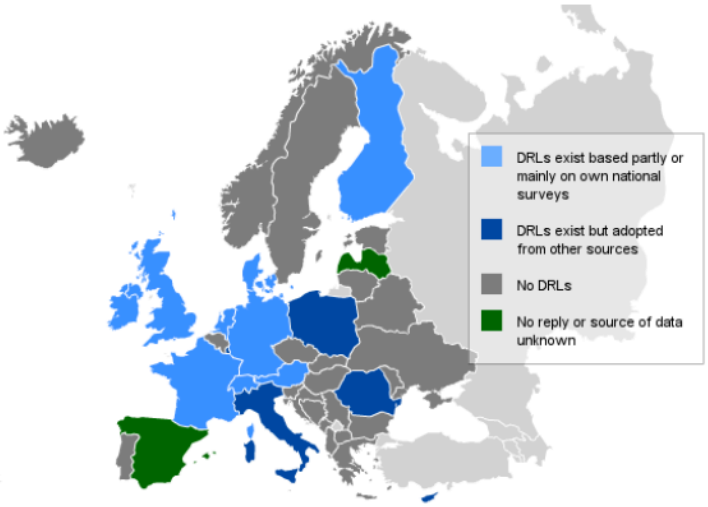

Figure 10: DRLs for paediatric plain radiography in European countries

From DDM2 (European Commission, 2014b)

The DDM2 report clearly shows that data collection and analysis is difficult at EU and even national levels, due to the lack of harmonisation of radiographic

procedures and patient categorisation. The review of current DRL systems has shown that there is an insufficient recording of the procedures used to establish DRLs and that the available information also reveals large differences in approaches. There is a lack of consistency regarding patient grouping (age, weight or other groups with a variety of options) and lack of clear recommendations on the dose quantities to be used. The discrepancies found amongst exam frequencies are also suggestive of the existence of limitations on the data infrastructure.

There is an urgent need to develop a European coding system for radiological procedures, both for adult and paediatric patients, to be used by all member states as a tool to easily fulfil the requirement of article 64 of Directive 2013/59/EURATOM, regarding the estimation of population dose: *"Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration where appropriate the distribution by age and gender of the exposed."*

This would be a fundamental tool for future population dose studies and would address one of the needs identified in the DDM2 report: *"in order to compare X-ray examination frequency data between countries, and to assign typical effective dose values to examinations, it is crucial that an "X-ray examination" is defined and counted in a consistent way"*.

A European coding system for radiological procedures would also contribute to the harmonisation of the *"language"* for medical imaging and therapy across Europe, giving healthcare providers a powerful tool for the future planning of health systems at local, regional, national and European levels. Such a project should also include the acquisition of data on the long-term consequences of radiation exposure.

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1.8 The Portuguese context of Diagnostic Reference Levels

The Portuguese health authorities have never promoted the establishment of clinical audit, education and training in radiation protection, the estimation of population dose, and Diagnostic Reference Levels, as defined in the 97/43 Euratom Directive (European Commission, 1997).

For the European DOSE DATAMED II project (European Commission, 2014b; Teles et al., 2013) a group of Portuguese researchers, scientific and professional societies, with the support of some regional health authorities, under the coordination of the Nuclear Technological Institute (ITN), joined efforts in order to estimate the Portuguese population dose using an international methodology (European Commission, 2008b).

It is important to point out that until today, Portuguese health authorities have never defined DRLs, neither for paediatric nor for adult imaging.

Nevertheless some researchers have conducted a national study to establish national computed tomography DRLs for adults and the paediatric population (Santos et al., 2014). The study (Santos et al., 2014) calculated and proposed Portuguese DRLs for adults and the paediatric population (Table 2 and 3). Large variations in volume computed tomography dose index ($CTDI_{vol}$) and dose-length product (DLP) values were found between clinical sites.

Table 2: Proposed Portuguese CT DRLs for adult MSCT examinations described as $CTDI_{vol}$ and DLP values.

Dose descriptor $CTDI_{vol}$ (mGy) and DLP (mGy cm)		
Body region	Mean (± SD)	75th percentile
Head	69.95 (14.66)	75
	802.21 (387.76)	1010
Neck	19.75 (17.96)	20
	384.72 (225.83)	465
Chest	12.39 (12.02)	14
	389.96 (228.30)	470
Abdomen	13.96 (8.03)	18
	562.72 (315.85)	800
Pelvis	17.23 (17.05)	18
	542.93 (314.32)	645
Cervical	36.33 (36.22)	39
	483.35 (279.34)	600
Dorsal	29.17 (22.13)	33
	654.89 (407.75)	780
Lumbar	34.62 (26.55)	38
	650.61 (371.58)	845
Joints	19.23 (16.08)	25
	320.03 (321.44)	405

Table 3: Proposed age-categorised national paediatric CT DRLs described as $CTDI_{vol}$ and DLP values.

Dose descriptor		$CTDI_{vol}$ (mGy) and DLP (mGy cm)	
Body region	Age	Mean (± SD)	75th Percentile
Head	0	39.42 (15.55)	48.31
		511.75 (228.26)	630.00
	5	44.60 (14.34)	49.95
		673.57 (239.78)	767.00
	10	52.32 (14.25)	69.95
		785.43 (269.86)	1096.37
	15	59.20 (12.53)	72.28
		929.81 (233.99)	1119.70
Chest	0	1.58 (0.87)	2.42
		26.31 (18.72)	42.75
	5	3.89 (2.17)	5.60
		98.33 (65.50)	138.50
	10	5.26 (4.03)	5.65
		175.77 (198.78)	186.00
	15	6.27 (4.30)	7.19
		212.18 (185.99)	194.50

The results from this study indicate that the most common adult Portuguese CT examinations are head, chest and abdomen, with DRLs of 75, 14 and 18 mGy $CTDI_{vol}$, respectively. These values are approximately 30% higher than European recommendations. Differences in protocols to image-specific anatomical regions are non-standardised, and a 20% dose variation was found across centres nationally. DRLs have also been established for six other CT examinations. The majority of proposed adult DRLs for CT examinations are higher than those of other European CT DRLs.

For paediatric head and chest CT examinations, the proposed DRLs described as $CTDI_{vol}$ are 48 and 43 mGy cm for new-borns, 50 and 6 mGy for 5-year old children, 70 and 6 mGy for 10-year olds and 72 and 7 mGy for 15-year old children, respectively.

For paediatric head and chest CT examinations, the proposed DRLs described as DLP are 630 and 43 mGy.cm for new-borns, 767 and 139 mGy.cm for 5-year old children, 1096 and 186 mGy.cm for 10-year olds and 1120 and 195 mGy.cm for 15-year old children, respectively.

The proposed DRLs for paediatric head CT examinations are higher than the European values, whereas the proposed chest CT examination DRLs are similar to European values across all age categories.

Some other studies were carried out in interventional cardiology (Graciano Paulo, Rocha, Lavandeira, Costa, & Marques, 2010; Graciano Paulo & Santos, 2012b) as a first attempt to analyse exposure to ionising radiation in adult patients and staff during interventional cardiac procedures. These studies have identified an urgent need to implement optimisation programmes in interventional cardiology. Due to the importance of the results obtained and the optimisation programme implemented at local level, the studies carried out since 2010 were awarded with the national prize (1st place, 2012) of the *Associação Portuguesa para o Desenvolvimento Hospitalar* (APDH) (Graciano Paulo & Santos, 2012a).

Considering the results of the referred studies and the lack of education and training in radiation protection, the *Associação Portuguesa de Intervenção em Cardiologia* (APIC), has implemented a continuous professional development programme in radiation protection and optimisation in interventional cardiology. The programme aims to raise awareness amongst health professionals working in cath-labs about the dangers arising from ionising radiation and the importance of optimising procedures according to the ALARA principle.

Unfortunately no study has been carried out in Portugal to determine national or even local DRLs for interventional cardiology procedures in paediatric patients, considered more complex than in adults and therefore result in high patient doses (Ubeda, Vano, Miranda, & Leyton, 2012). The publications from literature in this

field are very scarce. The most recently published study with the highest sample establishing local DRLs (Ubeda, Miranda, & Vano, 2015) found a reasonable linear correlation between KAP and body weight and proposed DRLs by patient weight groups (table 4). The results from this study are a good basis for future research in this area.

Table 4: KAP_{P75} values ($Gy.cm^2$) for diagnostic paediatric interventional cardiology procedures

Weight group (kg)	KAP_{P75} ($Gy.cm^2$)
<10	0.82
10 - <20	2.45
20 -<30	4.08
30 -<40	5.71
40 -<50	7.34
50 -<60	8.97
60 -<70	10.6
70 -<80	12.2

It is essential that Portuguese health authorities and health professionals understand the importance of defining DRLs, not only because of the legal requirement, but because it is important for the quality of care delivered to the patients as well as for the protection of staff.

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2 Establishment of DRLs in paediatric plain radiography

Considering the absence of guidelines, actions and recommendations by the Portuguese health authorities regarding the establishment of DRLs, the only official reference to use as a starting point for this study, was the EU guidance document RP 109 (European Commission, 1999) which recommends that DRLs for diagnostic radiology should be based on doses measured in various types of hospitals, clinics and practices and not only in well-equipped hospitals.

According to the RP 109 guidance document, the DRL in plain radiography should be higher than the median or mean value of the measured patient doses or doses in a phantom. Knowing that the curve giving the number of examinations and their doses is usually skewed with a long tail, it is recommended to use the 75th percentile (P75) value as a reference. The use of this percentile is a pragmatic first approach to identifying those situations in most urgent need of investigation (European Commission, 1999).

Following those recommendations, the 75th percentile of KAP and ESAK was calculated from the data collected prospectively in Hospitals A, B and C. As described in section 1.1, these three health care institutions are the only reference hospitals for paediatric patients in Portugal and are therefore representative of the paediatric population, with practitioners exclusively dedicated to paediatrics pathologies and equipped with up-to-date technology.

§

2.1 Materials and methods to determine national DRLs for chest, abdomen and pelvis plain radiography

During 2012 and 2013, anthropometric data (weight, height of patient and thickness of the irradiated anatomy) was collected from 9,935 patients, referred for a radiography procedure to one of the three dedicated hospitals for children in Portugal (Hospitals A, B and C). Exams made with mobile units were not included in this study. Institutional Review Board and ethical committee approval was obtained for this study.

National DRLs were calculated for the three most frequent X-ray procedures made at hospitals A, B and C: chest Antero-Posterior (AP)/Postero-Anterior (PA) projection; abdomen AP projection; pelvis AP projection. Exposure factors and patient dose were collected prospectively at the clinical sites. All exams were validated by both the radiographer and the radiologist and considered acceptable for the clinical task.

Data collection was carried out without interfering with the technical options for each imaging procedure used in each department.

Patient anthropometric characteristics (weight, height and Body Mass Index -BMI) were analysed in each age group as a process to define a standard patient for each of the groups and to allow future comparisons.

The exposure parameters (tube voltage (kV); tube current-time product (mAs) and exposure time (ExT-ms), Source Skin Distance (SSD-cm), as well as kerma-area product (KAP-mGy.cm^2) and entrance surface air kerma, including backscatter (ESAK-μGy) were also recorded (International Commission on Radiation Units & Measurements, 2005).

KAP and ESAK values were collected directly from the equipment console and manually registered in a table, together with patient data, including examination ID number, to allow future analysis, if necessary.

All devices measuring KAP (Diamentor M4-KDK, PTW®, Germany) had a valid manufacture calibration certificate, in accordance with IEC 60580 (International Electrotechnical Commission, 2000), with an accuracy of ±5% and were designed to measure KAP according to IEC 61267 (International Electrotechnical Commission, 2005a).

Although the radiography equipment had quality control maintenance provided by the manufacturer, equipment constancy using a calibrated RaySafe® XI dosimetry system (Sweden; www.raysafe.com) was also tested.

The measurements of weight, height and anatomical structure thickness of the patients were made using the same devices. A paediatric measurement rod was used to measure the anteroposterior thickness: from the dorsal region to the middle of the sternum (for chest); from the lumbar region to the umbilicus (for the abdomen); from the sacrum region to the symphysis pubis (for pelvis).

Hospital A uses a S/F system and is equipped with a *Diagnost* floor stand standard (FS-S) Bucky table plus a vertical stand (VS) and a RO 1750 X-ray tube assembled with a digital generator Optimus 50 kW (Philips Healthcare®, The Netherlands).

Hospital B uses a DR system *Essenta DR compact* with a flat-panel-detector based on amorphous silicon with a gadolinium oxysulfide scintillator and a RO 1750 X-ray tube assembled with a digital generator Optimus 50 kW (Philips Healthcare®, The Netherlands).

Hospital C uses a DR system Definium 6000 ceiling-suspended DR system with a flat-panel-detector based on amorphous silicon with a caesium-iodide scintillator and an overhead tube assembly, model 5139720, with a digital generator of 65 kW (General Electric®, USA).

Despite the fact that there are only three hospitals exclusively dedicated to paediatric patients at national level, there are no guidelines or standards of practice, with recommendations on what exposure parameters and technical features to use for plain radiography.

2.2 Results of national DRLs for chest, abdomen and pelvis plain radiography

The anthropometric characteristics of 9,935 paediatric patients referred to a radiography procedure to one of the three dedicated paediatric hospitals in Portugal were evaluated.

Patient age varied from newborn to 18 years. 50.4% (n=5005) of patients were male and 49.6% (n=4930) female (figure 11).

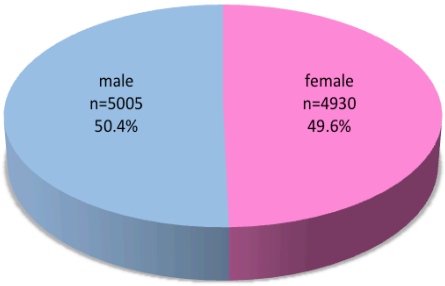

Figure 11: Patient distribution by gender

Table 5 summarises the anthropometric characteristics of the patients. Taking into consideration that data distribution is not symmetric, the median value was used as the preferred measure of central tendency to provide the necessary information to define a standard patient for each age group, as the median value is less affected by outliers and extreme values.

Table 5: Paediatric patients weight height and BMI (by age groups)

age groups (years)	*n*	Weight (kg)			Height (cm)			BMI (kg/m^2)		
		median	*P75*	(min-max)	median	*P75*	(min-max)	median	*P75*	(min-max)
<1	594	7	9	2-12	66	71	42-87	16	18	9-28
1-<5	1960	14	16	6-36	93	101	62-139	16	17	8-49
5-<10	2324	26	32	11-75	125	134	91-158	16	18	8-34
10-<16	4057	48	56	14-150	154	163	98-192	20	22	9-59
16-≤18	1000	58	66	31-117	166	172	117-192	21	23	14-40

The median values of patient weight, height and BMI in each age category are; (<1): 7kg, 66cm and 16kg/m^2; (1 to <5): 14kg, 93cm and 16kg/m^2; (5 to <10): 26kg, 125cm and 16kg/m^2; (10 to <16): 48kg, 154cm and 20kg/m^2; (16 to 18): 58kg, 166cm and 21kg/m^2, respectively.

Of particular note is the high diversity of weight, height and BMI values within each age group, especially in age group 10 to <16 years, with a high number of outliers and extreme values as shown in figures 12, 13 and 14.

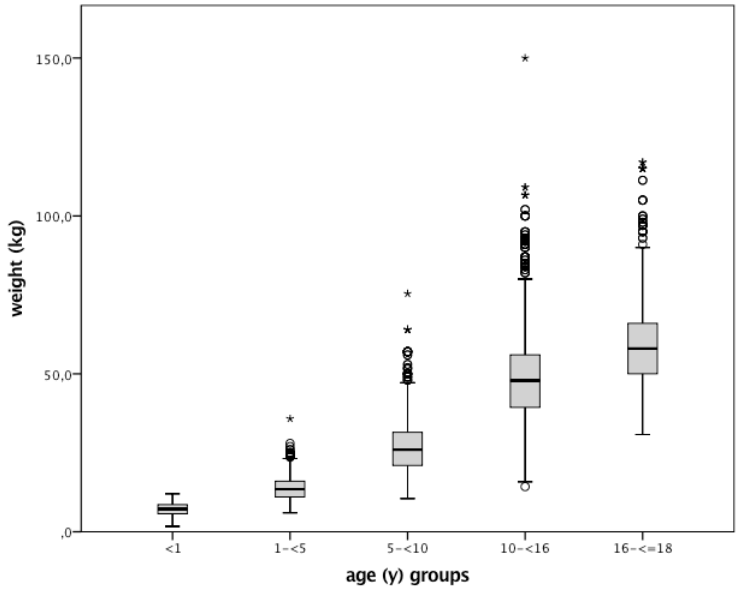

Figure 12: Weight per age group boxplot

25%-75%; - median; I - area without outliers; o – outliers; * - extreme outliers

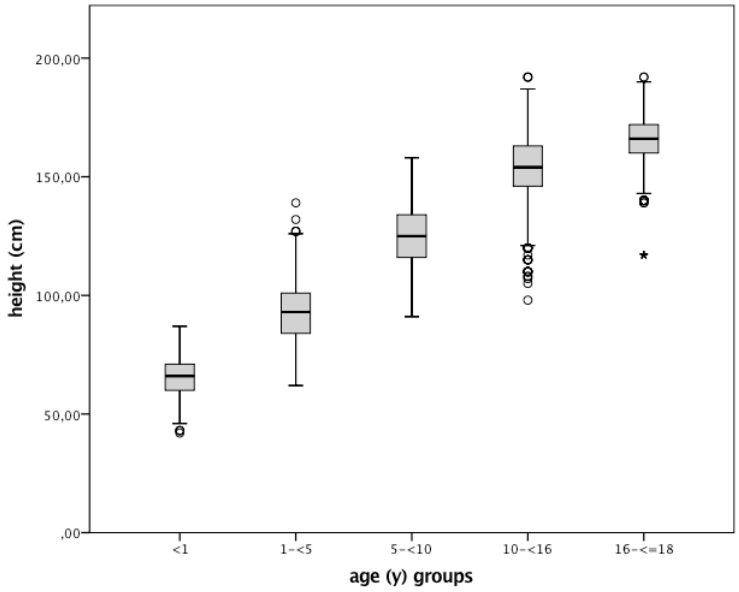

Figure 13: Height per age group boxplot

25%-75%; - median; I - area without outliers; o – outliers; * - extreme outliers

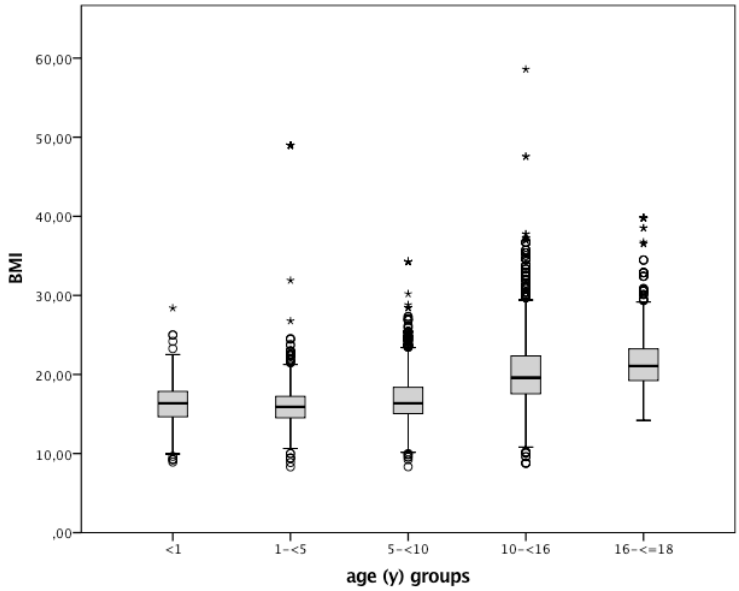

Figure 14: BMI (kg/m^2) per age group boxplot

25%-75%; - median; I - area without outliers; o – outliers; * - extreme outliers

This high data dispersion of patient anthropometric characteristics shown in figures 12 to 14, evidences the challenges radiographers have to face in daily clinical practice when trying to choose the most adequate exposure parameters in paediatric radiology in a harmonised and optimised way.

Table 6 summarises another important patient characteristic to take into consideration when performing a plain radiography: the thickness of the anatomical structure at the central point of exposure. A wide range of thickness values was found for each anatomical structure in each age group.

Table 6: Chest, abdomen and pelvis thickness per age group

age groups (years)	Chest (thickness, cm)				Abdomen (thickness, cm)				Pelvis (thickness, cm)			
	n	median	*P75*	(min-max)	n	median	*P75*	(min-max)	n	median	*P75*	(min-max)
<1	320	11	12	7-16	95	12	12	8-13	230	8	9	6-16
1-<5	673	13	14	10-24	120	14	15	10-18	259	10	12	7-17
5-<10	416	15	16	11-21	112	15	16	11-19	213	13	14	9-20
10-<16	326	18	19	13-33	105	17	19	12-25	214	16	18	10-27
16-≤18	254	20	21	15-24	98	20	27	15-27	194	19	20	15-28

The median values of patient chest, abdomen and pelvis thickness, measured in our sample, are similar to those published in literature (Hart et al., 2000; Wambani, Korir, Korir, & Kilaha, 2013).

Table 7, 8 and 9 shows the exposure parameters (kV, mAs, ExT), the use of Automatic Exposure Control (AEC) and anti-scatter grid, in each hospital practice, to perform an AP/PA chest, an abdomen A/P and a pelvis A/P plain radiography, respectively. The percentage shown in AEC and grid column is related to the frequency of the usage (0% never; 100% always).

Table 7: Exposure parameters of chest AP/PA projection

Age group	Hosp.	kV	mAs	ExT (ms)	SSD (cm)	AEC	Grid
		mean (min, max)	mean (min, max)	mean (min, max)	mean (min, max)		
<1	hosp. A	67 (63-73)	5.2 (4-6)	11.4 (8-17)	140 (137-145)	0%	100%
	hosp. B	76 (52-85)	1.7 (1-3)	2.7 (2-10)	158 (72-171)	0%	100%
	hosp. C	72 (58-80)	2.9 (1-19)	28.7 (4-222)	165 (128-194)	100%	0%
1-<5	hosp. A	68 (50-73)	5.8 (4-13)	11.9 (6-19)	136 (91-143)	0%	100%
	hosp. B	78 (66-96)	1.8 (1-8)	2.9 (1-12)	162 (81-187)	0%	100%
	hosp. C	74 (59-80)	2.4 (1-5)	25.0 (5-232)	160 (62-193)	100%	0%
5-<10	hosp. A	70 (57-77)	5.6 (4-6)	11.8 (6-17)	135 (103-146)	0%	100%
	hosp. B	79 (66-90)	2.7 (1-16)	4.3 (1-24)	160 (87-167)	11%	100%
	hosp. C	75 (55-110)	3.0 (0.5-8)	28.1 (2-100)	158 (76-188)	100%	0%
10-<16	hosp. A	73 (60-81)	5.8 (5-6)	11.5 (8-17)	132 (87-143)	0%	100%
	hosp. B	87 (70-125)	4.7 (1-108)	6.8 (2-41)	157 (79-179)	25%	100%
	hosp. C	90 (65-125)	3.0 (1-21)	33.5 (2-214)	156 (89-197)	100%	28%
16-≤18	hosp. A	75 (70-77)	6.0 (5-6)	11.1 (10-15)	134 (130-142)	0%	100%
	hosp. B	93 (73-125)	3.2 (1-21)	5.8 (2-32)	156 (127-188)	26%	100%
	hosp. C	101 (67-125)	2.1 (1-11)	22.1 (3-112)	156 (124-174)	100%	56%

With regard to table 7 it is important to note that the radiographers from Hospitals A and B always chose to use an anti-scatter grid and never used AEC, regardless of the patients' age. In Hospital A the mean values of kV used to perform a chest plain radiography are significantly lower and the mean values of mAs are significantly higher in all age groups ($p<0.05$, ANOVA statistical test with Post Hoc Test Student-Newman-Keuls - SNK). Hospital C shows significantly higher mean values of ExT in all age groups ($p<0.05$, ANOVA statistical test with Post Hoc Test - SNK). There is no significant difference between the SSD values used at the three hospitals.

Table 8: Exposure parameters of abdomen AP projection

Age group	Hosp.	kV	mAs	ExT (ms)	SSD (cm)	AEC	Grid
		mean (min, max)	mean (min, max)	mean (min, max)	mean (min, max)		
<1	hosp. A	n.a	n.a	n.a	n.a	n.a	n.a
		n.a	n.a	n.a	n.a		
	hosp. B	61	3.7	5.7	124	0%	91%
		(55-70)	(2-6.3)	(3-9.7)	(93-169)		
	hosp. C	62	4.5	8.6	122	100%	0%
		(67-68)	(1-10)	(2-23)	(103-141)		
1-<5	hosp. A	n.a	n.a	n.a	n.a	n.a	n.a
		n.a	n.a	n.a	n.a		
	hosp. B	67	4.6	8	110	11%	100%
		(48-81)	(1.8-10)	(2.8-49)	(80-165)		
	hosp. C	66	2.6	9.9	95	100%	33%
		(58-75)	(2-4)	(7-18)	(90-105)		
5-<10	hosp. A	57	36	79	84	0%	100%
		(56-58)	(32-40)	(62-97)	(83-85)		
	hosp. B	69	8.6	12.1	113	18%	98%
		(55-85)	(1.1-50)	(1.8-76)	(78-165)		
	hosp. C	69	3.5	18.2	93	100%	43%
		(67-80)	(1.5-7.5)	(6-33)	(74-130)		
10-<16	hosp. A	56	25	51	85	100%	100%
		(52-60)	(20-32)	(31-91)	(79-89)		
	hosp. B	72	14	21	112	29%	97%
		(60-85)	(2.8-64)	(4.3-99)	(80-160)		
	hosp. C	76	12	46	92	100%	18%
		(68-88)	(1.2-36)	(5-144)	(74-128)		
16-≤18	hosp. A	n.a	n.a	n.a	n.a	n.a	n.a
		n.a	n.a	n.a	n.a		
	hosp. B	77	40	75	117	35%	100%
		(70-90)	(2.8-249)	(5-497)	(87-146)		
	hosp. C	n.a	n.a	n.a	n.a	n.a	n.a
		n.a	n.a	n.a	n.a		

As shown in table 8, the radiographers from Hospitals A and B almost always used an anti-scatter grid when performing an abdomen procedure, independently of the patients' age. AEC is used without logic criteria in the three hospitals. In Hospital A the mean values of kV used to perform an abdomen plain radiography are significantly lower in all age groups and the mean values of mAs are significantly higher in age group 5-<10 ($p<0.05$, ANOVA statistical test with Post Hoc Test - SNK). Hospital B evidences significantly lower mean values of ExT in age groups 5-<10 and 10-<16 ($p<0.05$, ANOVA statistical test with Post Hoc Test - SNK).

Table 9: Exposure parameters of pelvis AP projection

Age group	Hosp.	kV	mAs	ExT (ms)	SSD (cm)	AEC	Grid
		mean (min, max)	mean (min, max)	mean (min, max)	mean (min, max)		
<1	hosp. A	51 (50-52)	13.5 (10-16)	29.3 (19-43)	92 (90-94)	100%	100%
	hosp. B	60 (46-70)	4.6 (2-7)	7.1 (3-11)	93 (84-102)	100%	72%
	hosp. C	67 (57-80)	3.0 (0.5-152)	7.8 (2-36)	91 (75-166)	100%	36%
1-<5	hosp. A	52 (52-57)	16 (13-20)	34 (25-34)	90 (85-95)	100%	100%
	hosp. B	62 (50-73)	5.7 (2-12)	9.2 (3-19)	92 (80-138)	100%	63%
	hosp. C	67 (60-76)	1.9 (0.4-6)	9.3 (2-32)	88 (70-103)	100%	34%
5-<10	hosp. A	55 (52-57)	21 (20-25)	35 (31-63)	88 (80-92)	100%	100%
	hosp. B	64 (55-73)	6.4 (3-11)	10 (5-17)	91 (76-123)	100%	88%
	hosp. C	69 (63-80)	3.0 (0.5-10)	14.1 (1-87)	86 (75-102)	100%	33%
10-<16	hosp. A	59 (55-70)	30.8 (16-44)	47.5 (25-68)	86 (79-90)	33%	100%
	hosp. B	72 (57-96)	16 (3-63)	30 (5-171)	88 (79-110)	11%	100%
	hosp. C	71 (66-85)	5.4 (1-16)	23.8 (5-75)	84 (73-99)	96%	42%
16-≤18	hosp. A	60 (60-60)	32 (32-36)	49 (49-53)	85 (84-86)	100%	100%
	hosp. B	69 (63-81)	16 (6-50)	25 (10-81)	83 (79-92)	100%	100%
	hosp. C	71 (66-80)	11 (3-35)	49 (14-173)	82 (75-90)	100%	67%

As shown in table 9, the radiographers from Hospital A always used an anti-scatter grid when performing a pelvis procedure, independently of the patients' age. AEC was used without logic criteria in the three hospitals. In Hospital A the mean values of kV used to perform a pelvis plain radiography are significantly lower and the mean values of mAs are significantly higher in all age groups ($p<0.05$, ANOVA statistical test with Post Hoc Test SNK). There is no significant difference between hospitals regarding the SSD.

As can be seen from the tables 7 to 9, the radiographers chose different exposure parameters, even within the same hospital and for the same age group of patients. This is clearly demonstrated by the high range of values of kV, mAs, ExT and SSD used for the same plain radiography procedure. Also additional technical features, such as AEC or the use of an anti-scatter grid are used differently.

2.2.1 National DRLs by age groups

DRLs will be proposed as the P75 value, considering paediatric patient categorisation by age groups (<1, 1-<5, 5-<10, 10-<16, 16-≤18) and by weight groups (<5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg) as suggested in the preliminary report of the PiDRL project (Damilakis, 2015).

According to the methodology described in section 2.1, the KAP_{P75} and $ESAK_{P75}$ values were calculated for chest, abdomen and pelvis and are shown in tables 10, 11 and 12 respectively.

Table 10: KAP & ESAK values for chest AP/PA (by age groups)

age groups (years)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**13**	2	140	8	**145**	7	380	49
1-<5	**19**	2	352	11	**181**	5	489	52
5-<10	**60**	2	378	20	**209**	5	706	98
10-<16	**134**	3	525	51	**234**	4	771	69
16-≤18	**94**	3	770	49	**88**	4	873	55

A wide dispersion of KAP and ESAK values for chest plain radiography (table 10) was observed in each age group. The high KAP_{P75} and $ESAK_{P75}$ values of age group 10-<16, when compared to the other age groups, are due to a high variation in values, most likely because in this age group the patients' anthropometric characteristics show a higher disparity. The opposite was found in age group 16-≤18.

Table 11: KAP & ESAK values for abdomen AP (by age groups)

age groups (years)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**25**	4	31	23	**70**	10	83	63
1-<5	**84**	10	301	35	**191**	19	438	69
5-<10	**140**	12	2031	75	**198**	24	2751	101
10-<16	**442**	27	3051	153	**583**	53	2688	228
16-≤18	**1401**	72	3481	246	**1258**	96	3041	428

A wide dispersion of KAP and ESAK values for abdomen plain radiography (table 11) was observed in each age group, with higher incidence in age groups 5-<10, 10-<16 and 16-≤18. Considerably higher values of KAP_{P75} and $ESAK_{P75}$ were observed in age group 16-≤18, most likely because of a non-adequate exposure protocol for this procedure.

Table 12: KAP & ESAK values for pelvis AP (by age groups)

age groups (years)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**29**	2	271	14	**125**	4	686	80
1-<5	**75**	3	626	31	**158**	11	1272	97
5-<10	**143**	5	1025	69	**232**	10	1443	155
10-<16	**585**	12	3965	224	**624**	25	5416	244
16-≤18	**839**	48	2758	254	**1204**	79	2507	303

A wide dispersion of KAP and ESAK values for pelvis plain radiography (table 12) was observed in each age group, with higher incidence in age groups 5-<10, 10-<16 and 16-≤18. Considerably higher values of KAP_{P75} and $ESAK_{P75}$ were observed in age group 16-≤18, most likely because of a non-adequate exposure protocol for this procedure.

For the purpose of this thesis, the KAP_{P75} and $ESAK_{P75}$ values presented in the tables will be considered as the "1st National DRLs per age group" in order to permit further analysis of the impact of the optimisation programme on patient doses.

2.2.2 National DRLs by weight groups

As already mentioned, the most frequent patient grouping found in literature is by patient age. However, some authors state that weight is generally more relevant as a parameter for patient grouping for DRLs in body examinations (Järvinen et al., 2015; Watson & Coakley, 2010). In our dataset, KAP was plotted against body weight. Both variables were found to have a statistically significant moderate positive correlation ($p<0.005$): $R^2=0.366$, $R=0.605$ for chest; $R^2=0.335$, $R=0.579$ for abdomen; $R^2=0.436$, $R=0.66$ for chest (G. Paulo, Vaño, & Rodrigues, 2015).

Since this was a prospective study, patients were weighed at the moment of the exam. Having collected each individual patient's weight, the weight groups were defined following the recommendations of the preliminary report of the PiDRL project (Damilakis, 2015): <5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg.

The KAP_{P75} and $ESAK_{P75}$ values were calculated for chest, abdomen and pelvis accordingly and are shown in tables 13, 14 and 15 respectively. As observed in the age groups, a wide dispersion of KAP and ESAK values was also found in all exams.

Table 13: KAP & ESAK values for chest AP/PA (by weight groups)

weight groups (kg)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**21**	2	138	9	**140**	10	380	68
5-<15	**16**	2	352	9	**155**	5	489	49
15-<30	**28**	2	447	15	**199**	5	573	57
30-<50	**131**	3	608	45	**228**	4	706	95
≥50	**145**	7	770	59	**189**	8	873	62

It is important to note the high KAP_{P75} values observed for chest plain radiography exams in weight groups 30-<50kg and ≥50kg when compared to the others (table 13), most likely due to an inappropriate exposure protocol for this procedure.

Table 14: KAP & ESAK values for abdomen AP (by weight groups)

weight groups (kg)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**30**	4	128	20	**70**	10	83	59
5-<15	**35**	10	249	25	**82**	19	345	63
15-<30	**138**	12	2031	71	**199**	24	2751	102
30-<50	**248**	24	3051	96	**285**	16	569	134
≥50	**1445**	62	3481	410	**1322**	79	3041	479

The high KAP_{P75} and $ESAK_{P75}$ values observed for abdomen plain radiography in weight groups 15-<30kg, 30-<50kg and ≥50kg (table 14) are most likely due to an inappropriate exposure protocol for this procedure.

Table 15: KAP & ESAK values for pelvis AP (by weight groups)

weight groups (kg)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**239**	5	241	9	**480**	28	480	71
5-<15	**37**	2	436	21	**125**	4	746	84
15-<30	**120**	3	944	68	**216**	10	1443	141
30-<50	**314**	12	1540	132	**327**	25	2181	190
≥50	**1164**	31	3965	356	**1217**	50	5416	379

Unexpectedly, an abnormally high KAP_{P75} and $ESAK_{P75}$ value was found in patients with less than 5kg. The authors consider that this is related to the inadequate usage of gonads protective shields, combined with inappropriate use of AEC. Also high KAP_{P75} and $ESAK_{P75}$ values were found in weight group ≥50, most likely due to an inappropriate exposure protocol for this procedure.

For the purpose of this thesis, the KAP_{P75} and $ESAK_{P75}$ values, presented in the tables will be considered as the "1st National DRLs per weight groups" in order to permit further analysis of the impact of the optimisation programme on patient doses.

2.2.3 National versus local DRLs

The data collected from the three paediatric hospitals of this study (phase 1) and presented in tables 10 to 12 gives a first indication of what could be considered as the "1st National DRLs" for chest, abdomen and pelvis plain radiography in Portugal. However, looking at the high discrepancy in exposure parameters and in the technical features used for each examination (table 7, 8 and 9) and given the fact that one of the hospitals used an S/F system, significant differences were found between KAP and ESAK values at each hospital, due to an obvious lack of a harmonisation of practice.

The discrepancy between KAP and ESAK values in each hospital is clearly evidenced in figures 15 to 20. In general, the highest KAP and ESAK values were observed in hospital A that used a S/F system. The high KAP and ESAK values from Hospital A had a negative impact on the "1st National DRLs" and were 3 to 4 times higher than the DRL values found in literature (Billinger, Nowotny, & Homolka, 2010; Roch & Aubert, 2013; Kristien Smans et al., 2008; Sonawane, Sunil Kumar, Singh, & Pradhan, 2011; Wambani et al., 2013).

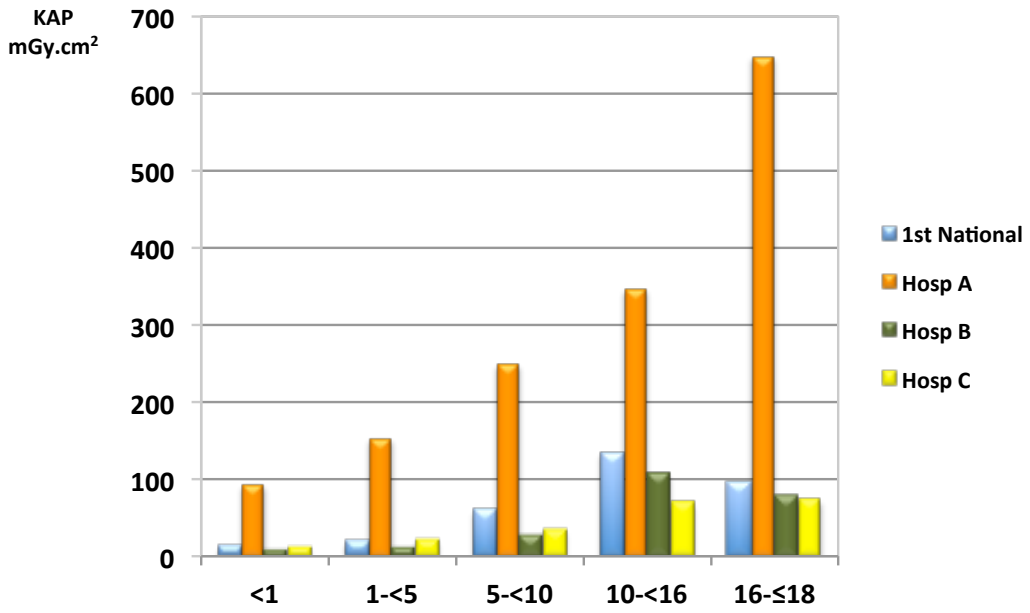

Figure 15: Comparison of the Hospitals' KAP_{P75} value with the "1st National DRL" for chest plain radiography

The KAP_{75} value from Hospital A for chest plain radiography is higher than the "1st National DRL" in all age groups.

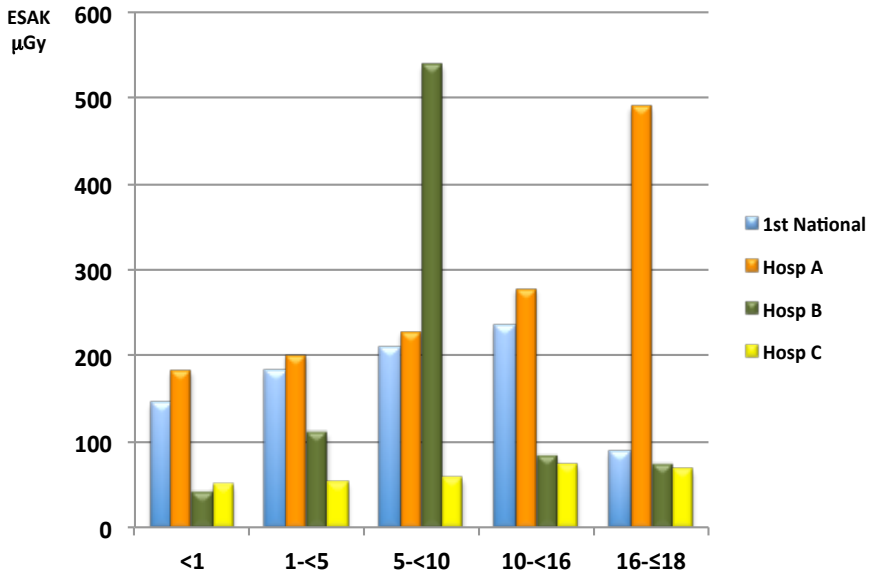

Figure 16: Comparison of the Hospitals' $ESAK_{P75}$ value with the "1st National DRL" for chest plain radiography

The $ESAK_{75}$ value from Hospital A for chest plain radiography is higher than the "1st National DRL" in all age groups. The same is verified in Hospital B in age group 5-<10.

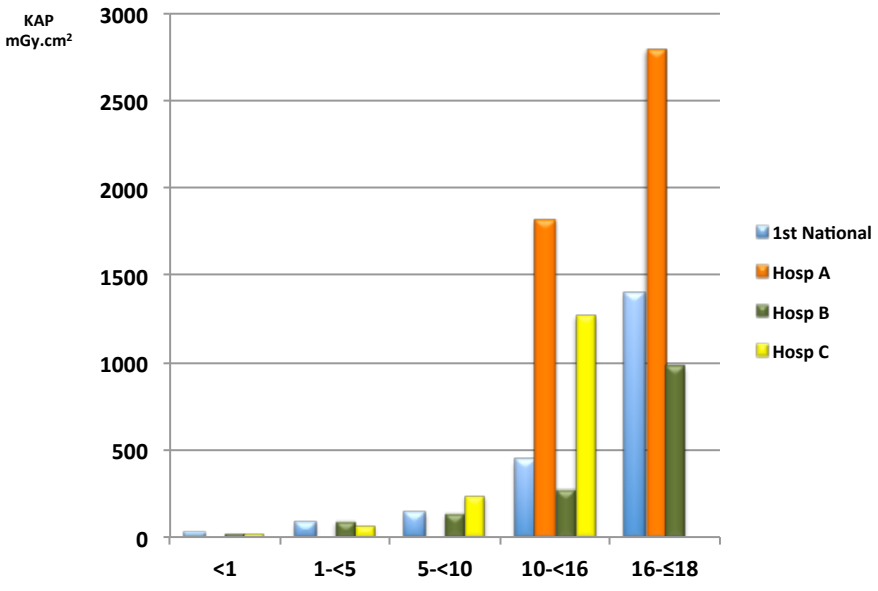

Figure 17: Comparison of the Hospitals' KAP_{P75} value with the "1st National DRL" for abdomen plain radiography

The KAP_{75} value from Hospital A for abdomen plain radiography is higher than the "1st National DRL" in all age groups (where data is available). The same is verified in Hospital C in age group 10-<16.

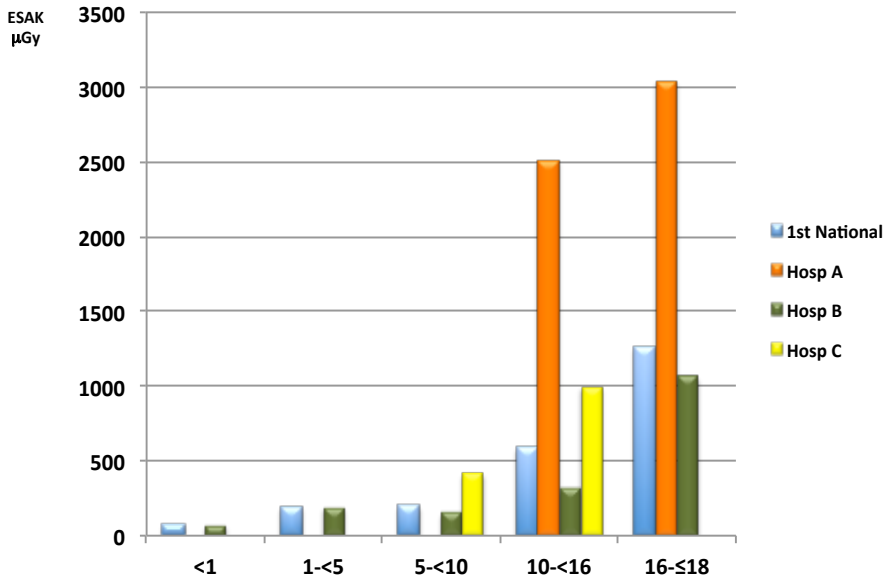

Figure 18: Comparison of the Hospitals' $ESAK_{P75}$ value with the "1st National DRL" for abdomen plain radiography

The $ESAK_{75}$ value from Hospital A for abdomen plain radiography is higher than the "1st National DRL" in all age groups (where data is available). The same is verified in Hospital C in age group 10-<16.

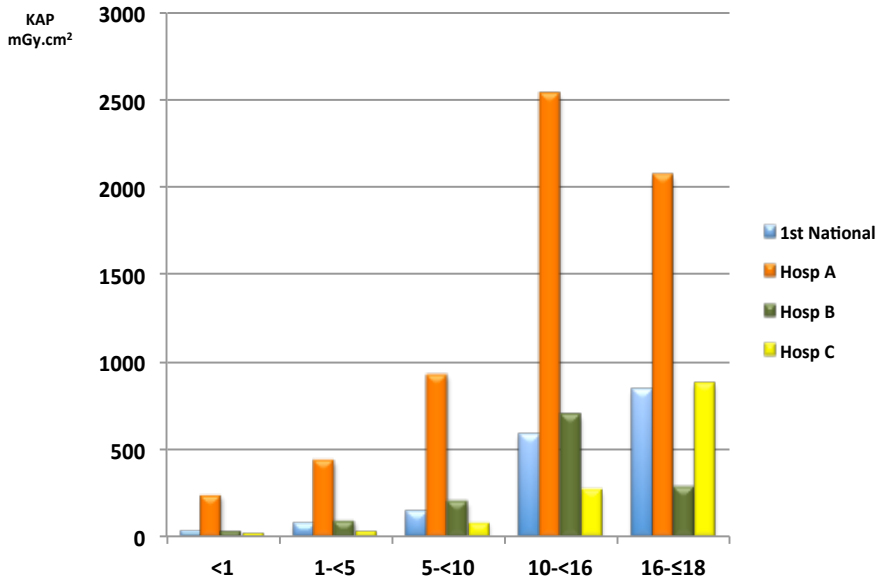

Figure 19: Comparison of the Hospitals' KAP_{P75} value with the "1st National DRL" for pelvis plain radiography

The KAP_{75} value from Hospital A for pelvis plain radiography is higher than the "1st National DRL" in all age groups. The same is verified in Hospital C in age group 16-≤18.

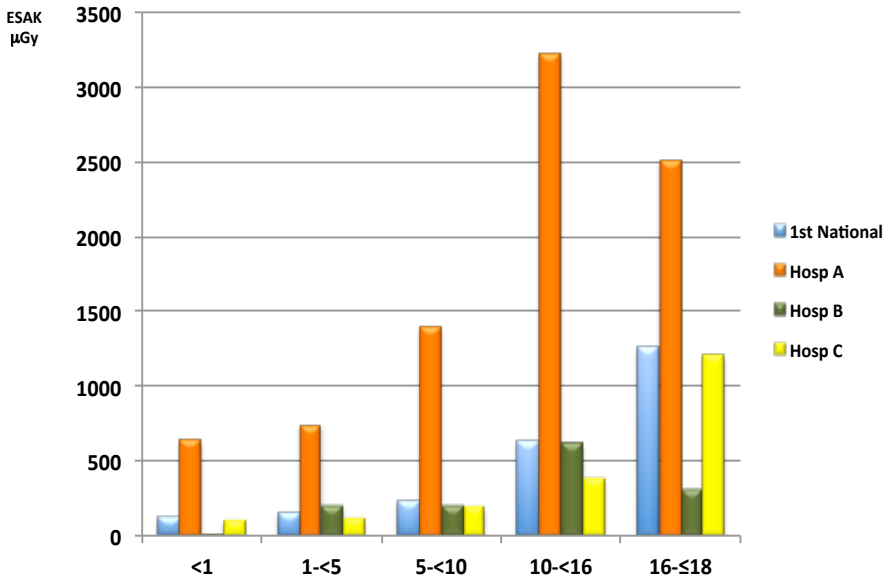

Figure 20: Comparison of the Hospital $ESAK_{P75}$ value with the "1st National DRL" for pelvis plain radiography

The $ESAK_{75}$ value from Hospital A for pelvis plain radiography is higher than the "1st National DRL" in all the age groups. The same is verified in Hospital B in age group 1-<5.

The heterogeneity of KAP_{P75} and $ESAK_{P75}$ values shown in figures 15 to 20 for chest, abdomen and pelvis plain radiography, clearly indicates the usage of a high variety of protocols for the same procedure by different radiographers (x-axis). To evidence that variety an example is shown in figure 21 about the choice of kV (y-axis) for chest plain radiography in each age group.

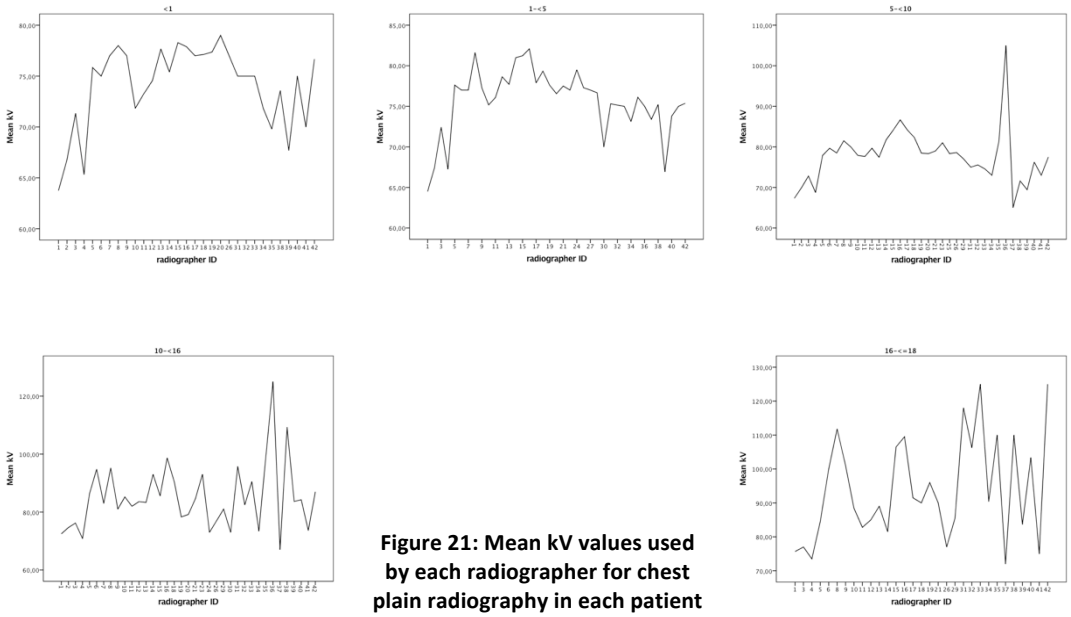

Figure 21: Mean kV values used by each radiographer for chest plain radiography in each patient age group

The results shown in section 2.2 were presented to the radiographers and radiologists at each hospital. None of the three hospitals has ever implemented any kind of optimisation process or has analysed the protocols and pre-sets configured in their equipment. All radiologists and radiographers were receptive to optimisation procedures with the objective to reduce exposure to patients.

§

2.3 Limitations of section 2

The paediatric DRLs were established from data collected at three dedicated regional public paediatric centres, each representing geographic regions of Portugal. However, it is important to take into consideration that a large proportion of paediatric plain radiography procedures is performed in general hospitals, potentially without tailored paediatric protocols. This dose data was not analysed during in this study.

By coincidence, the Portuguese Health Minister and the regional health authorities decided to close Hospital A when the results of this survey were presented. This hospital had the last radiology department in Portugal that still used an S/F system. Due to the closure, no additional optimisation measures were possible for plain radiography procedures for those systems that presented the highest dose values in this study.

Due to limited human and financial resources it was only possible to develop the optimisation process in one hospital. Considering the results from section 2.2, it was considered that Hospital C would benefit most from an optimisation programme.

§

3 Plain radiography optimisation phantom tests

The findings of the data collection in phase 1 of this research work indicated the need for further investigation with regard to optimisation of plain radiography protocols for paediatric examinations. A literature review of relevant optimisation tests in plain radiography examinations was undertaken and is presented in this chapter.

The next stage of this research work involved experimental testing to optimise the three most frequent procedures in plain radiography. This research activity included the use of quality assurance (QA) and anthropomorphic phantoms. The findings of this phase of the study are described and discussed in this chapter.

3.1 Optimisation in plain radiography

The European guidelines for paediatric imaging (European Commission, 1996a) provide a baseline for optimisation in terms of minimum tube potential and maximum ESAK. Changes in practice to meet these guidelines must be performed cautiously, as increased X-ray penetration may reduce image contrast and reduced dose can cause unacceptable signal-to-noise ratios (Martin et al., 2013).

Radiation doses to paediatric patients from plain radiography are relatively low, but because of the high frequency of these procedures, their optimisation is important for the radiology practice (UNSCEAR, 2013).

For an optimisation strategy to be effective, all health professionals involved in the use of X-ray equipment need to have knowledge and access to the results of performance tests and patient dose surveys. In addition there should be a continuing programme of assessment to track any changes in equipment performance. There should be close links between the radiographer, the medical physicist and the radiologist to provide a greater opportunity for optimisation (C. J. Martin, Le Heron, Borrás, Sookpeng, & Ramirez, 2013).

The main objective of optimisation of radiological procedures is to adjust imaging parameters and implement measures in such a way that the required image is obtained with the lowest possible radiation dose and maximised benefit (International Commission on Radiological Protection, 2013).

To achieve this goal, good practice in radiographic technique is needed and therefore special attention must given, simultaneously, to several aspects of the procedure, such as: a) patient positioning and immobilisation; b) accurate field size

and correct X-ray beam limitation; c) the use of protective shielding, when appropriate and d) optimisation of radiographic exposure factors.

Using a correct beam limitation is crucial to avoid unnecessary radiation dose outside the area of interest, and prejudice the image contrast and resolution by increasing the scattered radiation. Therefore proper collimation of the examined structure is necessary and preferred over the use of post-processing tools in CR or DR systems, such as imaging crop. This post-processing tool can potentially hide an increase in patient dose due to an unnecessarily overexposed area (International Commission on Radiological Protection, 2013; Moore et al., 2012).

Choosing the most adequate exposure factors and making the best effective use of the technological features available in the X-ray equipment, is crucial for obtaining the best diagnostic quality image with the lowest possible dose.

The kV, especially when using digital systems, should be used at the highest value, within the optimal range, considering the position and anatomical structure being examined, allowing the lowest quantity of mAs needed to provide an adequate exposure to the image receptor (Herrmann et al., 2012).

For chest, abdomen and pelvis exposure, the principle of using a high kV technique should be followed, since it would result in lower patient attenuation, and therefore lower dose for the same detector exposure. The kV should also be increased in each ascending age/size group due to the increases in tissue thickness, which requires more photon penetration (Knight, 2014).

It is important to take into consideration that whenever using higher kV values or imaging thicker structures, an increase of scatter radiation is expected and therefore an antiscatter grid should be used. The Image Gently programme (www.imagegently.org) and the American Society of Radiologic Technologists (ASRT) White Paper (Herrmann et al., 2012) recommend the use of anti-scatter grid above 10-12 cm thickness.

Another important technological feature to take into consideration is the use of additional filtration, which removes the lower energies from the X-ray spectrum and consequently raises the average beam energy for a constant kV. By removing the low energies from the spectrum, the ESAK to the patient is reduced (Brosi, Stuessi, Verdun, Vock, & Wolf, 2011).

The commonly used filters are made of copper (Cu) or aluminium (Al) or a combination of both. The European Guidelines recommend the use of 0.1 mm Cu + 1 mm Al or 0.2mm Cu + 1mm Al additional beam filtration for S/F systems, when considered appropriate (European Commission, 1996a). One potential consequence of using additional filtration is the reduction of image quality due to the decreased image contrast. However this disadvantage is of minor importance in digital systems

because image contrast may be selectively enhanced by using appropriate post processing tools (Brosi et al., 2011).

Once the medical examination using ionising radiation has been clinically justified and decided, the procedure must be optimised. Therefore the radiation dose which is delivered to the patient must be ALARA, but high enough for obtaining the required diagnostic information, taking into account economic and social factors. The written protocols (guidelines) for every type of standard practice should be optimised (European Commission, 2009).

An optimisation process should be understood as a dynamic process and as part of the clinical audit programme of the radiology department. The optimisation of clinical protocols for paediatric patients (Kostova-Lefterova, Taseva, Hristova-Popova, & Vassileva, 2015) should include the steps described in figure 22.

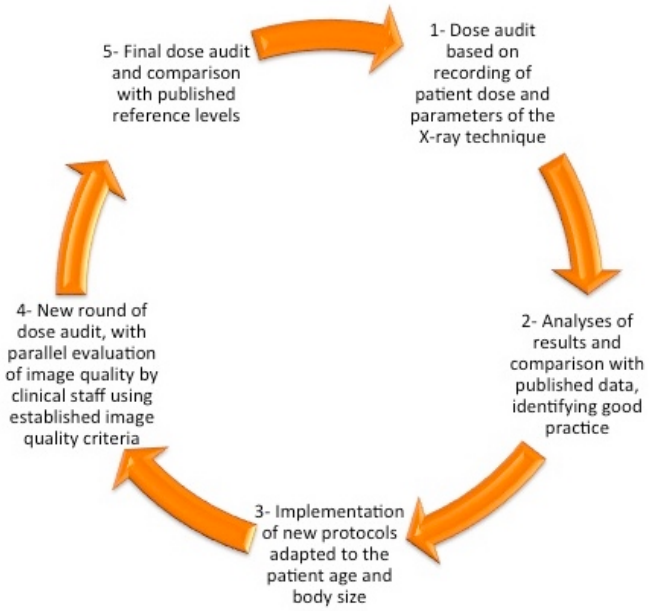

Figure 22: Optimisation of clinical protocols for paediatric imaging

By implementing this dynamic process, it is expected to reduce patient dose without interfering with diagnostic image quality. The secret for the success of this process is the continuous contribution of a multidisciplinary team involving radiographers, radiologists and medical physicists. This concept constitutes the pillars in the development and implementation of a patient safety culture in the medical imaging department.

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3.2 Experimental tests with anthropomorphic phantoms (objective image analysis)

To analyse the relationship between exposure factors, the use of technical features and dose, experimental tests were made using two anthropomorphic phantoms: A) CIRS™ ATOM model 705®; 110cm of height and 19Kg of weight and B) Kyoto kagaku™ model PBU-60®; 165cm of height and 50Kg of weight (figure 23).

A B

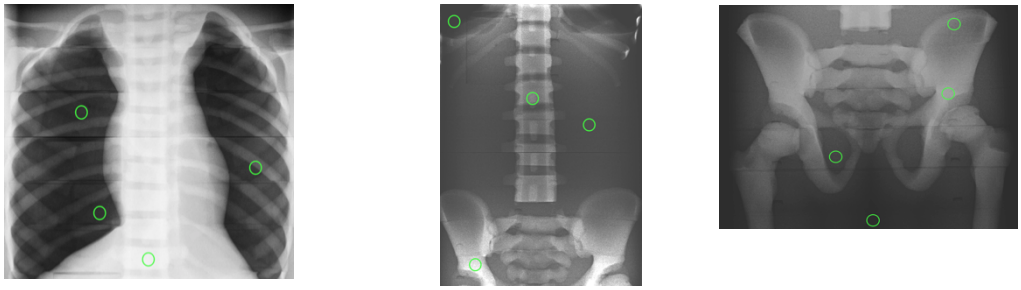
Figure 23: Anthropomorphic phantoms used in experimental tests
A - Phantom CIRS™ ATOM model 705; B- Phantom Kyoto kagaku™ model PBU-60

3.2.1 Methodology of experimental tests with anthropomorphic phantoms

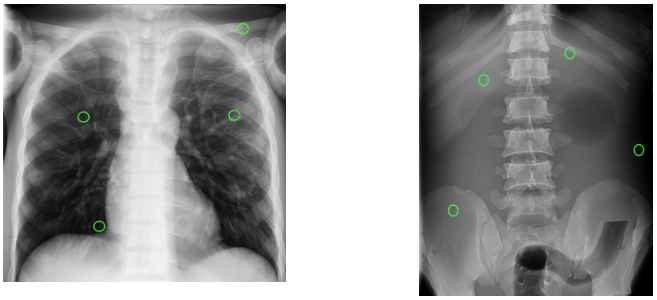
Phantom tests were performed at Hospital C, where the optimisation process of this study was carried out. Dose exposure data from the phantom tests was obtained using the same methodology as for the data collection of patient exposure data.

After data collection, an objective image analysis was performed by analysing the variation of the mean value of the standard deviation (SD), measured in four (green circles) Regions of Interest (ROI) in each image (figure 24). OsiriX® software (Pixmeo, Switzerland) was used to perform the ROI measurements.

The analysis of the SD values is well recognised as the standard method used to reflect the degree of noise when imaging parameters are changed (Sun et al., 2004; Sun, Lin, Tyan, & Ng, 2012). Higher SD values are related to an increase of image noise and to a decrease of dose values.



A - ATOM 705 chest | B - ATOM 705 abdomen | C - ATOM 705 pelvis



D - PBU-60 chest | E - PBU-60 chest abdomen

Figure 24: Example of ROI locations, for analyses with OsiriX® software (A to E)

Several acquisitions were made with different exposure factors, different combinations of AEC chamber settings, additional filtration and the use of an anti-scatter grid for chest, abdomen and pelvis examinations (tables 16 to 20). KAP and ESAK values were also registered for each exposure.

3.2.2 Results of phantoms experimental tests

Table 16 shows the results of the tests for the chest examination on CIRS™ ATOM model 705®. All exposures were made with a SID of 180 cm.

Table 16: Experimental tests for chest examination using CIRS™ ATOM model 705®

Test ID	Tube voltage (kV)	Tube current (mA)	Tube current time product (mAs)	Ext (ms)	ESAK (μGy)	KAP (mGy.cm²)	Grid	Additional Filtration	AEC chamber	SD Mean
1	90	339	2	7	18	5	no	0.3Cu	right	425
2	90	339	2	6	21	5	no	0.2Cu	right	442
3	90	323	2	5	29	7	no	0.1Cu	right	447
4	90	324	3	11	26	7	yes	0.3Cu	right	421
5	100	321	3	8	26	7	yes	0.3Cu	right	412
6	90	324	3	9	29	7	yes	0.2Cu	right	425
7	100	321	2	7	29	7	yes	0.2Cu	right	418
8	90	338	4	12	31	8	no	0.3Cu	central	412
9	100	323	2	6	35	9	yes	0.1Cu	right	420
10	90	324	2	7	35	9	yes	0.1Cu	right	424
11	90	323	4	11	35	9	no	0.2Cu	central	414
12	90	337	2	5	39	10	no	none	right	464
13	90	324	3	9	43	11	no	0.1Cu	central	427
14	90	326	2	6	53	14	yes	none	right	429
15	100	322	2	5	53	14	yes	none	right	425
16	90	319	7	23	55	14	yes	0.3Cu	central	388
17	90	334	6	18	61	16	yes	0.2Cu	central	390
18	90	326	3	8	65	17	no	none	central	443
19	90	320	5	17	78	20	yes	0.1Cu	central	398
20	90	324	5	15	121	31	yes	none	central	408

Exposure conditions mostly used in daily practice

New exposure conditions proposed

The test identification (ID) number 18 corresponds to the protocol most frequently used at Hospital C. Considering the recommendations of using additional filtration and anti-scatter grid for high kV procedures, it was decided together with radiologists and radiographers from the radiology department to start using the exposure conditions of test ID number 6: use additional filtration of 0.2mm of Copper and select the right AEC (corresponding to the right lung) chamber. The AEC chamber related to the right lung was chosen in order to avoid the AEC to include the density of the spine, mediastinum and sternum.

The exposure conditions as per test ID number 6 show a reduction of 55% and 56% on ESAK and KAP values, respectively, while not interfering on mAs and exposure time, when compared with the ones used at the department.

Despite the significant dose reduction (one sample T-test, $p<0.05$), no difference was found between the variations of the mean of SD values obtained from the four ROIs (one sample T-test, $p>0.05$).

Table 17 shows the results of the tests for abdomen examination on CIRS^{TM} ATOM model 705®. All exposures were made with a SID of 110 cm.

Table 17: Experimental tests for abdomen examination using CIRS^{TM} ATOM model 705®

Test ID	Tube voltage (kV)	Tube current (mA)	Tube current time product (mAs)	Ext (ms)	ESAK (µGy)	KAP (mGy.cm^2)	Grid	Additional Filtration	AEC chamber	SD Mean
1	75	253	2	9	66	16	yes	0.3Cu	central	307
2	70	255	4	16	70	17	no	0.3Cu	central	331
3	75	252	3	8	79	19	yes	0.2Cu	central	314
4	70	255	3	13	87	21	no	0.2Cu	central	323
5	75	253	2	7	106	25	yes	0.1Cu	central	322
6	70	255	3	11	115	28	no	0.1Cu	central	325
7	80	248	5	21	153	37	yes	0.3Cu	central	400
8	80	253	1	6	164	39	no	none	central	318
9	80	249	5	19	183	44	yes	0.2Cu	central	397
10	70	255	2	9	184	44	no	none	central	318
11	70	250	11	46	202	48	yes	0.3Cu	central	405
12	70	250	9	37	239	57	yes	0.2Cu	central	385
13	80	248	4	16	240	58	yes	0.1Cu	central	392
14	70	250	8	30	314	75	yes	0.1Cu	central	382
15	80	252	4	14	396	95	yes	none	central	383
16	70	251	6	24	516	124	yes	none	central	377

Exposure conditions mostly used in daily practice

New exposure conditions proposed

The test ID number 16 corresponds to the protocol most frequently used at Hospital C. Considering the recommendations of using additional filtration and anti-scatter grid for high kV procedures or to examine anatomical structures with high atomic number, it was decided together with radiologists and radiographers from the radiology department to start using the exposure conditions of test ID number 3: use additional filtration of 0.2mm of Copper and select the central AEC chamber.

The exposure conditions, as per test ID number 3, shows a reduction of 85% on ESAK and KAP values and a reduction of 67% of the ExT, when compared with the ones used at the department.

Despite the significant dose reduction (one sample T-test, $p<0.05$), no difference was found between the variations of the mean of SD values obtained from the four ROI's (one sample T-test, $p>0.05$).

Table 18 shows the results of the tests for pelvis examination on CIRS™ ATOM model 705®. All exposures were made with a SID of 110 cm.

Table 18: Experimental tests for pelvis examination using CIRS™ ATOM model 705®

Test ID	Tube voltage (kV)	Tube current (mA)	Tube current time product (mAs)	Ext (ms)	ESAK (µGy)	KAP (mGy.cm²)	Grid	Additional Filtration	AEC chamber	Gonads protection	SD Mean
1	75	200	4	21	129	24	yes	0.3Cu	central	no	386
2	75	200	5	23	138	25	yes	0.3Cu	central	yes	322
3	75	201	4	18	150	27	yes	0.2Cu	central	yes	299
4	75	205	4	18	150	27	yes	0.2Cu	central	no	376
5	75	204	3	14	182	33	yes	0.1Cu	central	yes	294
6	75	204	3	14	186	34	yes	0.1Cu	central	no	365
7	75	200	8	40	244	45	yes	0.3Cu	central	yes	262
8	75	204	2	12	283	52	yes	none	central	yes	282
9	75	200	7	34	285	52	yes	0.2Cu	central	yes	253
10	75	204	2	12	293	54	yes	none	central	no	355
11	75	200	5	27	342	62	yes	0.1Cu	central	yes	251
12	75	200	4	22	525	96	yes	none	central	yes	252

Exposure conditions most frequently used in daily practice

New exposure conditions proposed

The test ID number 12 corresponds to the protocol most frequently used at Hospital C. Considering the recommendations of using additional filtration and anti-scatter grid for high kV procedures or to examine anatomical structures with high atomic number, it was decided together with radiologists and radiographers from the radiology department to start using the exposure conditions of test ID number 4: use additional filtration of 0.2mm of Copper and select the central AEC chamber. It is important to note that the use of gonads protection increases ESAK and KAP values and therefore it was recommended not to use gonads protection, neither in females, due to the variety of the location of ovaries, neither in males, if the protection falls in the exposure area. The same recommendation was found in literature (Bardo, Black, Schenk, & Zaritzky, 2009; Fawcett & Barter, 2009)

The exposure conditions, as per test ID number 4, show a reduction of 71% on ESAK and KAP values, when compared with the ones used at the department.

Despite the significant dose reduction (one sample T-test, $p<0.05$), no difference was found between the variations of the mean of SD values obtained from the four ROIs (one sample T-test, $p>0.05$).

Table 19 shows the results of the tests for chest examination on Kyoto kagaku™ model PBU-60. All exposures were made with a SID of 180 cm.

Table 19: Experimental tests for chest examination using Kyoto kagaku™ model PBU-60

Test ID	Tube voltage (kV)	Tube current (mA)	Tube current time product (mAs)	Ext (ms)	ESAK (µGy)	KAP (mGy.cm²)	Grid	Additional Filtration	AEC chamber	SD Mean
1	100	320	3	9	32	24	yes	0.3Cu	right	529
2	110	317	2	7	33	24	yes	0.3Cu	right	526
3	100	320	3	8	35	26	yes	0.2Cu	right	533
4	110	317	2	6	37	27	yes	0.2Cu	right	528
5	100	321	4	12	41	30	yes	0.3Cu	left	529
6	100	322	1	4	42	31	no	none	right	542
7	100	321	2	7	43	32	yes	0.1Cu	right	533
8	100	319	4	13	44	32	yes	0.3Cu	all	528
9	110	317	2	6	45	33	yes	0.1Cu	right	530
10	100	339	3	10	46	34	yes	0.2Cu	left	526
11	100	320	4	11	48	36	yes	0.2Cu	all	527
12	100	338	3	9	56	41	yes	0.1Cu	left	532
13	100	322	3	9	59	44	yes	0.1Cu	all	528
14	100	321	2	6	66	49	yes	none	right	530
15	110	316	2	5	66	49	yes	none	right	532
16	100	334	3	8	86	63	yes	none	left	528
17	100	320	3	9	90	66	yes	none	all	531
18	100	317	9	29	99	73	yes	0.3Cu	central	518
19	100	315	8	25	109	80	yes	0.2Cu	central	522
20	100	316	7	22	136	100	yes	0.1Cu	central	524
21	100	315	6	21	211	156	yes	none	central	527

Exposure conditions most frequently used in daily practice

New exposure conditions proposed

The test ID number 21 corresponds to the protocol most frequently used at Hospital C. Considering the recommendations of using additional filtration and anti-scatter grid for high kV procedures, it was decided together with radiologists and radiographers from the radiology department to start using the exposure conditions of test ID number 3: use additional filtration of 0.2mm of Copper and select the right AEC chamber related to the right lung was chosen in order to avoid the AEC to include the density of the spine, mediastinum and sternum.

The exposure conditions, as per test ID number 3, show a reduction of 83% on ESAK and KAP values, when compared with the ones used at the department.

Despite the significant dose reduction (one sample T-test, $p<0.05$), no difference was found between the variations of the mean of SD values obtained from the four ROIs (one sample T-test, $p>0.05$).

Table 20 shows the results of the tests for abdomen examination on Kyoto kagaku™ model PBU-60. All exposures were made with a SID of 110 cm.

Table 20: Experimental tests for abdomen examination using Kyoto kagaku™ model PBU-60

Test ID	Tube voltage (kV)	Tube current (mA)	Tube current time product (mAs)	Ext (ms)	ESAK (µGy)	KAP (mGy.cm²)	Grid	Additional Filtration	AEC chamber	SD Mean
1	80	252	9	36	310	165	yes	0.3Cu	all	354
2	90	245	6	26	310	169	yes	0.3Cu	central	343
3	80	249	7	29	330	179	yes	0.2Cu	all	367
4	70	250	17	70	360	195	yes	0.3Cu	all	345
5	90	248	4	15	360	196	yes	0.1Cu	all	360
6	90	254	6	22	370	198	yes	0.2Cu	central	343
7	80	249	12	47	390	211	yes	0.3Cu	central	336
8	80	248	6	23	400	217	yes	0.1Cu	all	350
9	70	250	14	57	420	230	yes	0.2Cu	all	344
10	80	249	10	39	450	241	yes	0.2Cu	central	331
11	90	245	5	20	460	248	yes	0.1Cu	central	346
12	70	250	25	99	510	276	yes	0.3Cu	central	340
13	70	250	11	44	530	286	yes	0.1Cu	all	341
14	90	248	3	13	540	292	yes	none	all	359
15	80	248	8	32	540	294	yes	0.1Cu	central	343
16	70	250	20	81	600	327	yes	0.2Cu	central	340
17	80	248	5	19	630	339	yes	none	all	346
18	90	244	4	17	700	378	yes	none	central	342
19	70	251	16	64	780	419	yes	0.1Cu	central	340
20	80	248	7	27	860	465	yes	none	central	345
21	70	250	9	35	870	468	yes	none	all	346
22	70	250	13	52	1270	687	yes	none	central	338

Exposure conditions most frequently used in daily practice

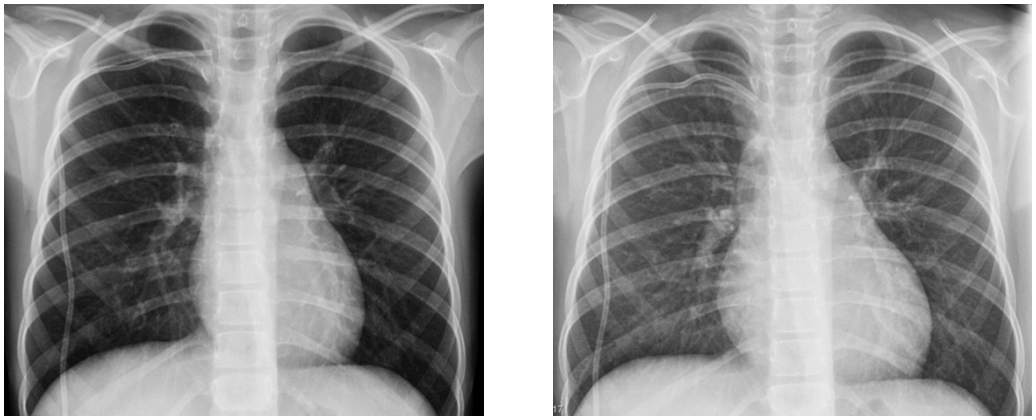
New exposure conditions proposed

The test ID number 21 corresponds to the protocol most frequently used at Hospital C. Considering the recommendations of using additional filtration and anti-scatter grid for high kV procedures or to examine anatomical structures with high atomic number, it was decided together with radiologists and radiographers from the radiology department to start using the exposure conditions of test ID number 3: use additional filtration of 0.2mm of Copper and select all the AEC chambers.

The exposure conditions, as per test ID number 3, show a reduction of 63% on ESAK and KAP values and a reduction of 44% of the ExT, when compared with the ones used at the department.

Despite the significant dose reduction (one sample T-test, $p<0.05$), no difference was found between the variations of the mean of SD values obtained from the four ROIs (one sample T-test, $p>0.05$).

An example of the influence of the AEC chamber in plain radiography is given in figure 25. Images A and B are from the same patient and were obtained at Hospital C (with an interval of 2 months). Chest plain radiography A was made with AEC and central chamber (exposure conditions used at the department). Chest plain radiography B was made with AEC and lateral right chamber. The exposure conditions were the same (90kV; 2mAs) for both exposures and the KAP and ESAK values were 3 and 4 times lower respectively in chest plain radiography B. When shown blindly to four radiologists, all of them defined chest plain radiography B as the one with the better diagnostic image.



A B

Figure 25: A: Chest plain radiography with AEC + central chamber; B: Chest plain radiography with AEC + lateral right chamber

3.3 Optimised exposure criteria for chest, abdomen and pelvis plain radiography

The results obtained from the anthropomorphic phantoms were discussed in a meeting with the radiologists and radiographers from Hospital C and a consensus was obtained to harmonise practice.

The new exposure criteria for abdomen plain radiography were defined taking into consideration the results of the anthropomorphic phantoms tests, the recommendations from literature and the outputs from the meetings with radiographers and radiologists from the radiology department.

The new exposure criteria for each age group were defined according to the results obtained from the anthropomorphic phantoms tests and by reviewing the exposure criteria published in the literature (Amaral, Matela, Pereira, & Palha, 2008; Cook et al., 2001; Don et al., 2013; Doyle, Gentle, & Martin, 2005; Knight, 2014; McCarty, Waugh, McCallum, Montgomery, & Aszkenasy, 2001; Moore et al., 2012; Graciano Paulo et al., 2011; Rizzi et al., 2014; K Smans, Struelens, Smet, Bosmans, & Vanhavere, 2010; Suliman & Elawed, 2013; Zhang, Liu, Niu, & Liu, 2013) and the outcome of several group meetings held with radiographers and radiologists working at the radiology department.

The new exposure criteria for plain radiography of chest, abdomen and pelvis per age group are defined in tables 21 to 23.

Table 21: New exposure criteria for chest plain radiography

Chest					
Age groups (years)	**Median weight (Kg)**	**Tube tension (kV)**	**Chamber**	**Grid**	**Additional filtration**
<1	7	70	central	no	0.1mm Cu
1-<5	14	80	central	no	0.1mm Cu
5-<10	26	90	Lateral right (right lung)	yes	0.2mm Cu
10-<16	46	100	Lateral right (right lung)	yes	0.2mm Cu
16-≤18	58	110	Lateral right (right lung)	yes	0.2mm Cu

For paediatric patients under 5 years, the most adequate option is to use the central ionisation chamber of the AEC system (considering that the patient chest does not cover lateral chambers), combined with an additional filtration of 0.1mm of copper, without the anti-scatter grid.

For patients above 5 years, the most adequate option is to use the lateral right ionisation chamber of the AEC (corresponding to the patient's right lung), to avoid the influence of the spine, the mediastinum structures (mainly the heart) and sternum, combined with an additional filtration of 0.2mm of copper, with anti-scatter grid.

The median of patient weight for each age group was provided as an indicator for radiographers to adapt the exposure conditions accordingly if necessary.

Table 22: New exposure criteria for abdomen plain radiography

Abdomen					
Age groups (years)	**Median weight (Kg)**	**Tube tension (kV)**	**Chamber**	**Grid**	**Additional filtration**
<1	7	65	central	no	0.1mm Cu
1-<5	14	70	central	no	0.1mm Cu
5-<10	26	75	central	yes	0.2mm Cu
10-<16	46	80	All	yes	0.2mm Cu
16-≤18	58	90	All	yes	0.2mm Cu

For paediatric patients under 5 years, the most adequate option is to use the central ionisation chamber of the AEC system (considering that the patient abdomen does not cover lateral chambers), combined with an additional filtration of 0.1mm of copper, without the anti-scatter grid.

For patients above 5 years, the most adequate option is to use all three chambers of the AEC, combined with an additional filtration of 0.2mm of copper, with anti-scatter grid.

The median of patient weight for each age group was provided as an indicator for radiographers to adapt the exposure conditions accordingly if necessary.

Table 23: New exposure criteria for pelvis plain radiography

Pelvis						
Age groups (years)	**Median weight (Kg)**	**Tube tension (kV)**	**Chamber**	**Grid**	**Additional filtration**	**gonads protection**
<1	7	65	central	no	0.1mm Cu	**only in males if protection is out of exposure field**
1-<5	14	70	central	no	0.1mm Cu	
5-<10	26	75	central	yes	0.2mm Cu	
10-<16	46	80	central	yes	0.2mm Cu	
16-≤18	58	90	central	yes	0.2mm Cu	

The new exposure criteria for pelvis plain radiography were defined taking into consideration the results of the anthropomorphic phantom tests, the recommendations from literature and the outcome of the meetings held with radiographers and radiologists working at the radiology department.

For paediatric patients under 5 years, the most adequate option is to use the central ionisation chamber of the AEC system (considering that the patient's pelvis does not cover lateral chambers), combined with an additional filtration of 0.1mm of copper, without the anti-scatter grid.

For patients above 5 years, the most adequate option is to use the central ionisation chamber of the AEC, combined with an additional filtration of 0.2mm of copper, with anti-scatter grid.

As indicated above, the use of gonads protection increases ESAK and KAP values. Therefore it was recommended not to use gonads, neither in females, due to the variety of the location of ovaries, nor in males, if the protection falls in the exposure area.

The median of patient weight for each age group was provided as an indicator for radiographers to adapt the exposure conditions accordingly if necessary.

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3.4 Subjective analysis of image quality (methodology and results)

Data for chest, abdomen and pelvis examinations (n=24 for each) pre/post the new exposure criteria were organised in Digital Imaging and Communications in Medicine (DICOM) format for the four age categories (<1; 1-<5; 5-<10; 10-<16) and presented for image quality review. In total 72 cases were prepared for image evaluation. Patient images were presented in Viewer for Digital Evaluation of X-ray images (ViewDEX 2.0) software (Hakansson et al., 2010).

Visual Grading Characteristic (VGC) image quality evaluation was performed blindly by four paediatric radiologists, each with a minimum of 10 years of professional experience, using anatomical criteria scoring. The anatomical criteria considered most important for each examination were chosen on a consensus basis between the four radiologists from the European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics (European Commission, 1996a), (table 24).

Table 24: Image analyses using anatomical criteria scoring and the five point scale

Body region	Criteria	Scale
Chest	1 - Reproduction of the vascular pattern in central 2/3 of the lungs	1 - Confident that the criterion is not fulfilled 2 - Somewhat confident that the criterion is not fulfilled 3 - Indecisive whether the criterion is fulfilled or not 4 - Somewhat confident that the criterion is fulfilled 5 - Confident that the criterion is fulfilled
	2 - Reproduction of the trachea and the proximal bronchi	
	3 - Visually sharp reproduction of the diaphragm and costo-phrenic angles	
	4 - Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum	
Abdomen	1 - Reproduction of the properitoneal fat lines consistent with age	
	2 - Visualisation of the kidney outlines consistent with age and depending on bowel content	
	3 - Visualisation of the psoas outline consistent with age and depending on bowel content	
	4 - Visually sharp reproduction of the bones	
Pelvis	1 - Reproduction of the necks of the femora which should not be distorted by foreshortening or external rotation	
	2 - Reproduction of spongiosa and cortex	
	3 - Visualisation of the peri-articular soft tissue planes	

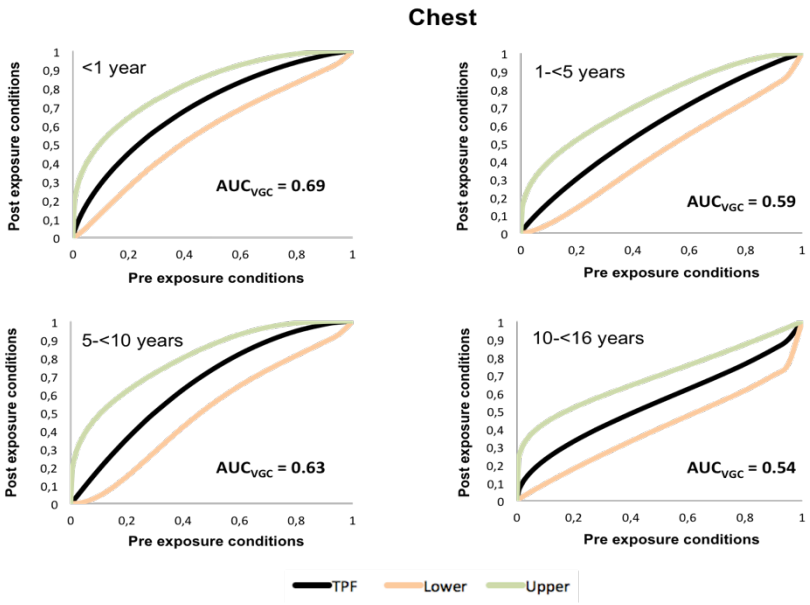
Images were analysed on a diagnostic workstation and the ambient luminance was measured with a Raysafe^{TM} Xi Light detector (Unfors RaySafe, Sweden) to ensure consistent ambient lighting conditions of less than 40 lux (Brennan et al., 2007).

Through VGC analysis, the observer uses multiple scale steps to state his opinion about the image quality (M Båth & Månsson, 2007). The observers of this study

gave their opinion by using a scale from 1 to 5 to classify the fulfilment of a specific criterion. Two data sets were therefore obtained before and after the new exposure criteria. The data from the two data sets were used to calculate the VGC data points. The referred points represent the VGC curve coordinates of a plot. The area under the curve (AUC_{VGC}) can be taken as a measure of the difference in the image quality between the pre and post settings. A curve equivalent to an AUC_{VGC} of around 0.5 indicates equality between both settings (Ludewig, Richter, & Frame, 2010). Values lower than 0.5 indicate better image quality of the "pre" settings. Values higher than 0.5 indicate better image quality of the "post" settings.

To perform VGC analyses, a web-based calculator for Receiver Operating Characteristic (ROC) Curves (John Eng., Maryland, USA) was used to analyse the AUC_{VGC} per criterion and radiologist (Eng, 2013). VGC analysis reviews the data as ordinal with no assumptions on the AUC_{VGC} distribution. A 0.5 AUC_{VGC} indicates no difference in the radiologists' rating before and after the new exposure criteria (the new exposure conditions were considered the true positive fraction for all the analysis) (M Båth & Månsson, 2007).

The Student's T-test (for Independent samples) was also used to compare image evaluation findings emanating from chest, abdomen and pelvis examinations pre and post the new exposure criteria and Cohen's Kappa testing to analyse the inter observer agreement ($p<0.05$) between radiologist evaluations, across data sets, in each of the four age categories. VGC analyses for each examination and across the age categories are summarised in figures 26 to 28.

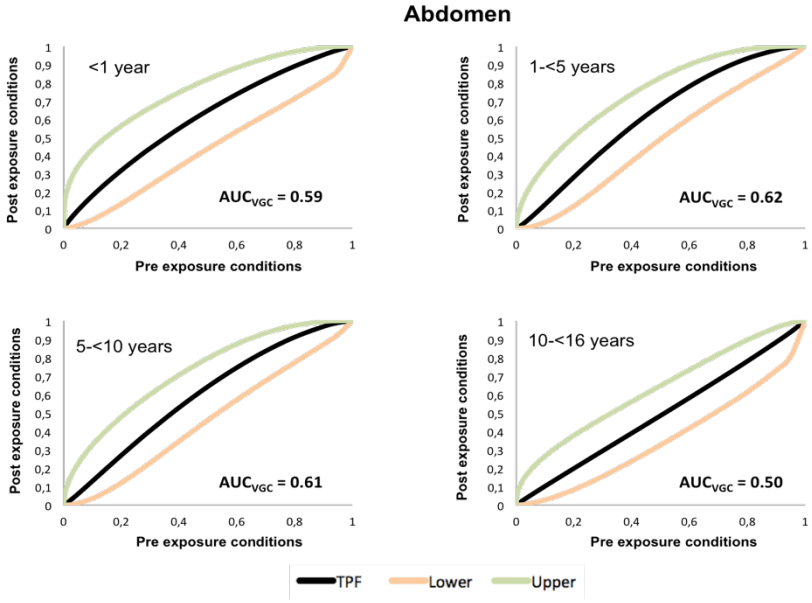


(TPF- true positive fraction; Lower - Lower VGC curve; Upper - Upper VGC curve)

Figure 26: Chest VGC analysis per age group
A - <1 year; B - 1<5 years old; C - 5<10 years old; D - 10>16 years old

As observed in Figure 26, the image quality of chest examination with the new

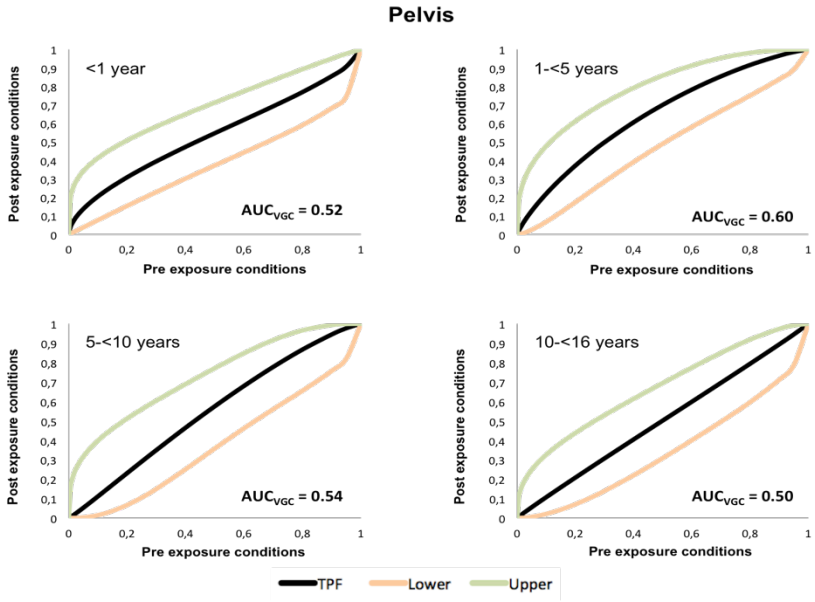
"post" exposure conditions obtained AUC_{VGC} values higher than 0.5 in all age groups. The age group with the highest AUC_{VGC} value (0.69) was <1 year.



(TPF- true positive fraction; Lower - Lower VGC curve; Upper - Upper VGC curve)

Figure 27: Abdomen VGC analysis per age group
A - <1 year; B - 1<5 years old; C - 5<10 years old; D - 10>16 years old

As observed in Figure 27, the image quality of abdomen examination with the new "post" exposure conditions obtained AUC_{VGC} values equal or higher than 0.5 in all age groups. The age group with the highest AUC_{VGC} value (0.62) was 1-<5 years.



(TPF- true positive fraction; Lower - Lower VGC curve; Upper - Upper VGC curve)

Figure 28: Pelvis VGC analysis per age group
A - <1 year; B - 1<5 years old; C - 5<10 years old; D - 10>16 years old

As observed in Figure 28, the image quality of pelvis examination with the new

"post" exposure conditions obtained AUC_{VGC} values equal or higher than 0.5 in all age groups. The age group with the highest AUC_{VGC} value (0.62) was 1-<5 years.

Looking at the VGC analysis (considering all anatomical image criteria), all the radiographic images acquired by using the new exposure parameters for chest, abdomen and pelvis examinations obtained an AUC_{VGC} value higher than 0.5 and therefore, the four radiologists considered the image quality at least equal to the examinations performed with the "pre" exposure parameters.

The same VGC analysis was performed for each of the anatomical criteria chosen by the radiologists according to the European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics (table 25) for chest, abdomen and pelvis examinations and for each age group.

Table 25: VGC analysis by anatomical criterion

Body region	Criteria	Age groups			
		<1	1-<5	5-<10	10-<16
Chest	1 - Reproduction of the vascular pattern in central 2/3 of the lungs	0.66	0.55	0.63	0.57
	2 - Reproduction of the trachea and the proximal bronchi	0.67	0.63	0.68	0.55
	3 - Visually sharp reproduction of the diaphragm and costo-phrenic angles	0.69	0.63	0.67	0.51
	4 - Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum	0.69	0.56	0.56	0.51
Abdomen	1 - Reproduction of the properitoneal fat lines consistent with age	0.57	0.67	0.58	0.51
	2 - Visualisation of the kidney outlines consistent with age and depending on bowel content	0.63	0.65	0.61	0.51
	3 - Visualisation of the psoas outline consistent with age and depending on bowel content	0.55	0.71	0.64	0.52
	4 - Visually sharp reproduction of the bones	0.66	0.51	0.56	0.51
Pelvis	1 - Reproduction of the necks of the femora which should not be distorted by foreshortening or external rotation	0.51	0.68	0.52	0.51
	2 - Reproduction of spongiosa and cortex	0.52	0.67	0.51	0.52
	3 - Visualisation of the peri-articular soft tissue planes	0.51	0.51	0.66	0.54

Image quality scores for chest examinations scored higher in all four image criteria and in all age groups. Age group <1 showed the highest scores for the criteria *"visually sharp reproduction of the diaphragm and costo-phrenic angles"* and *"reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum"* (AUC_{VGC} = 0.69).

Image quality scores for abdomen examinations scored higher in all four image criteria and in all age groups. Age group 1-<5 showed the highest scores for the criteria *"Visualisation of the psoas outline consistent with age and depending on bowel content"* (AUC_{VGC} = 0.71).

Image quality scores for pelvis examinations scored higher in all three image criteria

and in all age groups. Age group 1-<5 showed the highest scores for the criteria *"Reproduction of the necks of the femora which should not be distorted by foreshortening or external rotation"* (AUC_{VGC} = 0.67).

Based on the objective and subjective image analysis it can be concluded that the image quality obtained with the new exposure factors generally improved.

The results from both the objective and subjective image assessment validate the new exposure factors proposed to the radiology department of Hospital C.

The new exposure factors significantly reduced both ESAK and KAP values, without affecting image quality (in general image quality even improved).

§

3.5 Assessing the use of electronic cropping in plain imaging

As explained, proper collimation should be made before the exposure rather than using electronic cropping of the image after the exposure to avoid exposure of extraneous body parts (Moore et al., 2012). The ASRT White Paper (Herrmann et al., 2012) recommends that cropping should not be used as replacement for beam restriction that can be achieved through physical collimation of the X-ray field size.

It is considered bad radiography practice to digitally crop images instead of using proper collimation of the beam, as this leads to unnecessary radiation dose exposure to the patient. In addition, proper collimation of the examinations will also contribute to noise reduction on images (Nyathi et al., 2010).

To evaluate the use of the post-processing crop tool in daily practice, the irradiated and cropped areas, available in DICOM headers on the PACS system from 100 chest, 79 abdomen and 66 pelvis examinations were retrospectively analysed and compared (table 26).

Table 26: irradiated versus post processed image area

examination	age group (years)	mean irradiated area (cm^2)	mean post processed area (cm^2)	% cropped area
Chest	<1	260	210	19%
	1-<5	419	365	13%
	5-<10	650	575	12%
	10-<16	1038	921	11%
	16-<18	1296	1156	11%
Abdomen	<1	270	223	17%
	1-<5	592	500	15%
	5-<10	894	753	16%
	10-<16	1265	1067	16%
	16-<18	1385	1192	14%
Pelvis	<1	193	150	22%
	1-<5	314	237	24%
	5-<10	707	530	25%
	10-<16	1148	889	23%
	16-<18	1317	1030	22%

According to the data collected, the irradiated area is significantly higher ($p<0.05$, paired samples T-test) than the area needed to perform the analysed X-ray examinations.

The overexposed area was also verified in all patient age groups. This indicates that the cropping tool is being used on a regular basis and therefore contributes to the increase of patient dose and scattered radiation.

For chest examinations, the average percentage of cropped area ranged from 11 to 19%. The cropping was highest in patient age group <1 year.

For abdomen examinations, the average percentage of cropped area ranged from 14 to 17%. The cropping was highest in patient age group <1 year.

For pelvis examinations, the average percentage of cropped area ranged from 22 to 25%, with the highest cropping in patient age group 5-<10 years.

Results demonstrate that the use of post processing tools, such as electronic collimation, hides an unnecessary overexposure that could be substantially reduced if a bigger emphasis were given to an appropriate collimation before exposure.

These results were shown and discussed with the radiographers and radiologists of the radiology department of Hospital C. After the discussions with the department team, radiographers showed a strong commitment to use patient anatomical landmarks more effectively to ensure proper and adequate beam collimation.

3.6 Limitations of section 3

It is important to highlight that this study would benefit from using additional anthropomorphic paediatric phantoms (especially for new-born and 10 years). This would have given the possibility to provide more objective exposure criteria for all age groups. However, the model used, group discussion with radiologists and radiographers, combined with a thorough literature review, allowed to develop new exposure conditions that were considered adequate.

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4 Impact of the optimisation programme on patient doses

Following the model described in figure 22 and after optimisation of the exposure criteria for chest, abdomen and pelvis plain radiography, a final round of patient dose exposure collection was carried out with the objective to measure the impact of the optimisation programme on patient doses.

4.1 Material and methods to assess the impact of optimisation on patient doses

In November 2014, the radiology department of Hospital C started to use the new exposure criteria for chest, abdomen and pelvis plain radiography. To determine the post optimisation DRLSs, data has been collected using the same methodology as defined in phase 1 of this study as well as the same equipment. Exposure data and patient weight were collected from 30 patients for each age group and for each exam (chest, abdomen and pelvis).

It is important to note that all the data collected was from properly referred, clinically justified exams and none of them was repeated due to inadequate exposure conditions and therefore all considered clinically valid by the radiographer, the radiologist and the medical referrer.

Considering the use of the new exposure criteria that have been proposed to the radiology department for chest, abdomen and pelvis plain radiography, two major benefits were expected: a) a harmonisation of practice; b) a significant reduction of ExT, KAP and ESAK values between phase 1 and the post optimisation (post) results for chest, abdomen and pelvis.

As for the harmonisation of practice, all radiographers of Hospital C followed the new exposure criteria and considered a common guidance for the procedures very positive and beneficial.

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4.2 Results of the impact of optimisation on patient doses

Figure 29 shows the comparison between phase 1 and *post* optimisation ExT mean values for chest plain radiography.

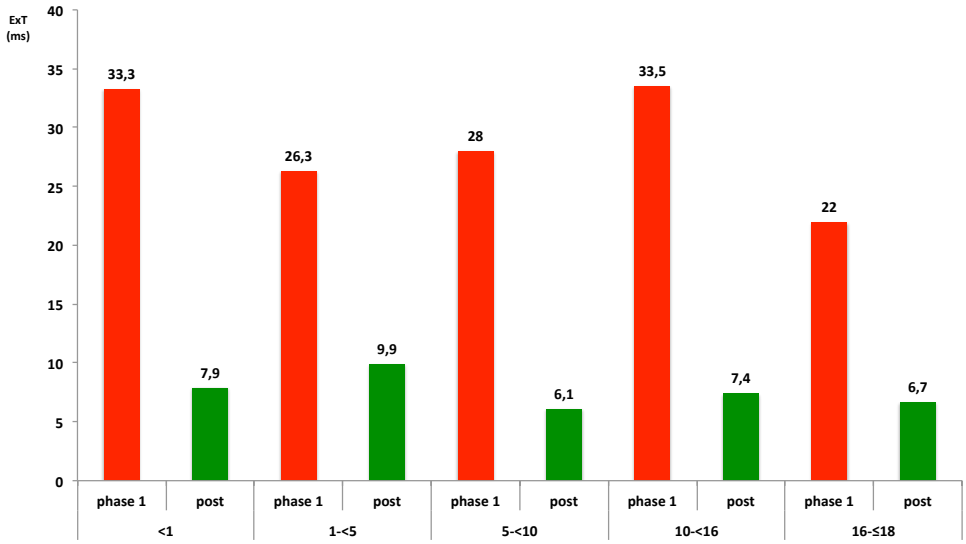

Figure 29: Exposure Time (ms) values for chest plain radiography: phase 1 *vs* post optimisation

Using the *post* optimisation exposure criteria led to a significant reduction ($p<0.05$, independent sample T-student test) of ExT in all age groups. The reduction was 76%, 62%, 78%, 78%, 70%, respectively for age groups <1, 1-<5, 5-<10, 10-<16, 16-≤18.

Figure 30 shows the comparison between phase 1 and *post* optimisation ExT mean values for abdomen plain radiography.

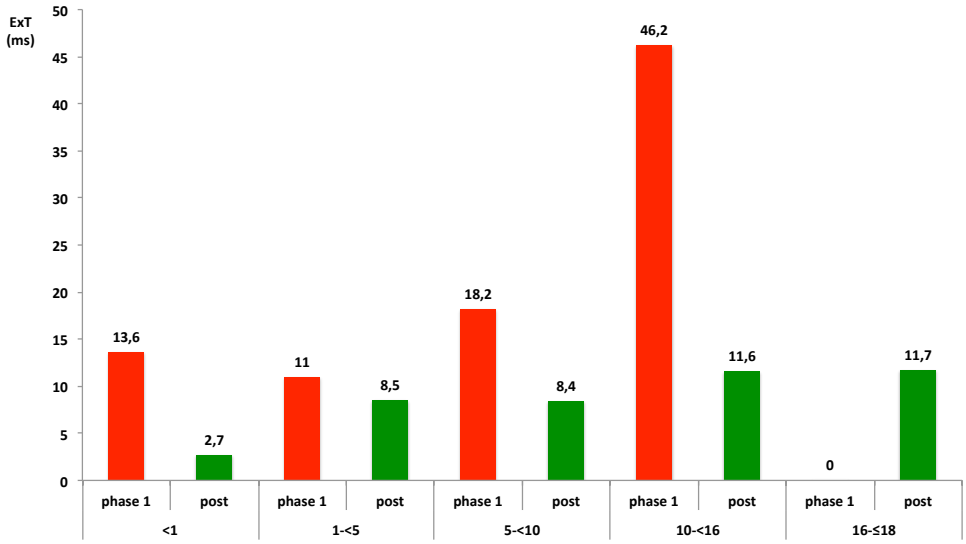

Figure 30: Exposure Time (ms) values for abdomen plain radiography: phase 1 *vs* post optimisation

Using the *post* optimisation exposure criteria, led to a significant reduction ($p<0.05$, independent sample T-student test) of ExT. The reduction was 80%, 23%, 54%, 75%, respectively for age groups <1, 1-<5, 5-<10, 10-<16.

Figure 31 shows the comparison between phase 1 and post optimisation ExT mean values for pelvis plain radiography.

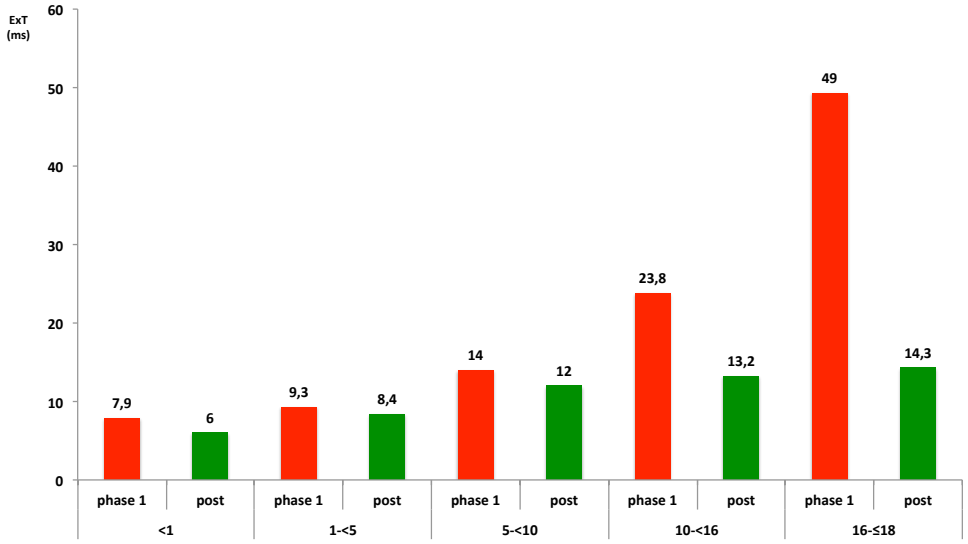

Figure 31: Exposure Time (ms) values for pelvis plain radiography: phase 1 *vs* post optimisation

Using the post optimisation exposure criteria led to a significant reduction ($p<0.05$, independent sample T-student test) of ExT. The reduction was 24%, 10%, 14%, 45%, 71%, respectively for age groups <1, 1-<5, 5-<10, 10-<16, 16-≤18.

The KAP and ESAK values measured with the new proposed exposure criteria followed, as expected, the same reduction tendency as observed with the ExT.

Tables 27 to 28 show the KAP_{P75}, $ESAK_{P75}$ and P75 variation of phase 1 compared with the post optimisation values for chest, abdomen and pelvis plain radiography in each age group.

The KAP_{P75} and $ESAK_{P75}$ values of the post optimisation phase are lower than in phase 1 for all three plain radiography procedures and in all age groups, indicating a lower patient dose exposure.

Table 27: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for chest plain radiography: phase 1 *vs* post optimisation (age groups)

age groups (years)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<1	phase 1	13	-29%	49	-31%
	post	9		34	
1-<5	phase 1	22	-55%	52	-23%
	post	10		40	
5-<10	phase 1	35	-60%	57	-9%
	post	14		52	
10-<16	phase 1	68	-40%	73	-18%
	post	41		60	
16-≤18	phase 1	73	*-22%*	67	*-7%*
	post	57		62	

Using the post optimisation exposure criteria for chest plain radiography reduced the KAP_{P75} values by 22 to 60%. The KAP_{P75} reduction was highest in age group 5-<10. The $ESAK_{P75}$ values were reduced by 7 to 31%, with the highest reduction in age group <1 (table 27).

Table 28: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for abdomen plain radiography: phase 1 *vs* post optimisation (age groups)

age groups (years)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<1	phase 1	34	*-41%*	77	*-17%*
	post	20		64	
1-<5	phase 1	72	*-35%*	110	*-30%*
	post	47		77	
5-<10	phase 1	250	*-70%*	415	*-76%*
	post	76		101	
10-<16	phase 1	1267	*-87%*	992	*-87%*
	post	170		126	
16-≤18	phase 1	*n.a.*	-	*n.a.*	-
	post	237		177	

Using the post optimisation exposure criteria for abdomen plain radiography reduced the KAP_{P75} values by 35 to 87%. The KAP_{P75} reduction was highest in age group 10-<16. The $ESAK_{P75}$ values were reduced by 17 to 87%, with the highest reduction in age group 10-<16 (table 28).

Table 29: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for pelvis plain radiography: phase 1 *vs* post optimisation (age groups)

age groups (years)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<1	phase 1	19	-26%	100	-24%
	post	14		76	
1-<5	phase 1	30	-7%	113	-12%
	post	28		99	
5-<10	phase 1	84	-39%	192	-43%
	post	51		110	
10-<16	phase 1	267	-79%	379	-68%
	post	55		120	
16-≤18	phase 1	876	*-89%*	1204	-86%
	post	93		164	

Using the post optimisation exposure criteria for pelvis plain radiography reduced the KAP_{P75} values by 7 to 89%. The KAP_{P75} reduction was highest in age group 16-≤18. The $ESAK_{P75}$ values were reduced by 12 to 86%, with the highest reduction in age group 16-≤18 (table 29).

Tables 30 to 32 show the KAP_{P75}, $ESAK_{P75}$ and P75 variation of phase 1 compared with the post optimisation values for chest, abdomen and pelvis plain radiography in each weight group.

The KAP_{P75} and $ESAK_{P75}$ values of the post optimisation phase are lower than in phase 1 for all the three plain radiography procedures and in all weight groups.

Table 30: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for chest plain radiography: phase 1 vs post optimisation (weight groups)

weight groups (kg)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<5	phase 1	21	-57%	140	-81%
	post	9		26	
5-<15	phase 1	16	-38%	155	-77%
	post	10		35	
15-<30	phase 1	28	-46%	199	-77%
	post	15		46	
30-<50	phase 1	131	-76%	228	-75%
	post	32		58	
≥50	phase 1	145	-61%	189	-65%
	post	57		67	

Using the post optimisation exposure criteria for chest plain radiography reduced the KAP_{P75} values by 38 to 76%. The KAP_{P75} reduction was highest in weight group 30-<50. The $ESAK_{P75}$ values were reduced by 65 to 81%, with the highest reduction in weight group <5 (table 30).

Table 31: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for abdomen plain radiography: phase 1 vs post optimisation (weight groups)

weight groups (kg)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<5	phase 1	30	-67%	70	-20%
	post	10		56	
5-<15	phase 1	35	-43%	82	-21%
	post	20		65	
15-<30	phase 1	138	-56%	199	-59%
	post	61		81	
30-<50	phase 1	248	-18%	285	-60%
	post	203		113	
≥50	phase 1	1445	-84%	1332	-88%
	post	225		160	

Using the post optimisation exposure criteria for abdomen plain radiography reduced the KAP_{P75} values by 18 to 84%. The KAP_{P75} reduction was highest in weight group ≥50. The $ESAK_{P75}$ values were reduced by 20 to 88%, with the highest reduction in weight group ≥50 (table 31).

Table 32: KAP_{P75}, $ESAK_{P75}$ and P75 variation values for pelvis plain radiography: phase 1 vs post optimisation (weight groups)

weight groups (kg)	exposure criteria	KAP (mGy.cm²)		ESAK (µGy)	
		P75	*P75 variation*	P75	*P75 variation*
<5	phase 1	239	-94%	480	-93%
	post	15		34	
5-<15	phase 1	37	-51%	125	-32%
	post	18		85	
15-<30	phase 1	120	-63%	216	-49%
	post	45		110	
30-<50	phase 1	314	-76%	327	-54%
	post	75		152	
≥50	phase 1	1164	-93%	1217	-87%
	post	79		156	

Using the post optimisation exposure criteria for pelvis plain radiography reduced the KAP_{P75} values by 51 to 94%. The KAP_{P75} reduction was highest in weight group <5. The $ESAK_{P75}$ values were reduced by 32 to 93%, with the highest reduction in weight group <5 (table 32).

Considering the post optimisation data analysis one can conclude that the two major benefits that were expected: a) a harmonisation of practice; b) a significant reduction of ExT, KAP and ESAK values between phase 1 and the post optimisation (post) results for chest, abdomen and pelvis were achieved. It is important to note that the quality of the images made with the new exposure criteria has been evaluated by paediatric radiologists and considered clinically acceptable.

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5 Post optimisation DRLs

After the optimisation process carried out at Hospital C, new DRL values by age and weight groups were defined. It is important to highlight that since November 2014 all radiographers of Hospital C have been using the new exposure criteria defined during the development of this thesis.

5.1 New DRLs by age group

Table 33 shows the new optimised KAP and ESAK DRLs for chest PA/AP plain radiography for each age group, considered as the P75 value.

Table 33: New KAP & ESAK values for chest AP/PA (by age groups)

age groups (years)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**9**	3	15	8	**34**	20	40	30
1-<5	**10**	5	18	9	**40**	25	50	35
5-<10	**14**	10	24	13	**52**	26	60	44
10-<16	**41**	20	56	35	**60**	27	68	51
16-≤18	**57**	29	59	49	**62**	32	85	57

Table 34 shows the new optimised KAP and ESAK DRLs for abdomen plain radiography for each age group, considered as the P75 value.

Table 34: New KAP & ESAK values for abdomen AP (by age groups)

age groups (years)	KAP (mGy.cm²)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**20**	8	21	10	**64**	15	66	60
1-<5	**47**	10	48	27	**77**	19	85	70
5-<10	**76**	50	85	68	**101**	70	103	85
10-<16	**170**	89	188	129	**126**	90	165	117
16-≤18	**237**	198	265	217	**177**	98	185	139

Table 35 shows the new optimised KAP and ESAK DRLs for pelvis plain radiography for each age group, considered as the P75 value.

Table 35: New KAP & ESAK values for pelvis AP (by age groups)

age groups (years)	KAP (mGy.cm^2)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<1	**14**	8	15	10	**76**	22	80	75
1-<5	**28**	12	35	22	**99**	75	107	97
5-<10	**51**	28	58	50	**110**	90	112	105
10-<16	**55**	32	65	54	**120**	95	130	112
16-≤18	**93**	60	101	83	**164**	145	169	156

These new DRLs were presented to the radiographers and radiologists and will be used by the radiology department of Hospital C as future reference for dose audit programmes.

5.2 New DRLs by weight group

Table 36 shows the new optimised KAP and ESAK DRLs for chest PA/AP plain radiography for each weight group, considered as the P75 value.

Table 36: New KAP & ESAK values for chest AP/PA (by weight groups)

weight groups (kg)	KAP (mGy.cm^2)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**9**	4	11	7	**26**	20	30	22
5-<15	**10**	3	15	8	**35**	24	40	32
15-<30	**15**	8	24	11	**46**	26	50	40
30-<50	**32**	10	56	21	**58**	27	60	48
≥50	**57**	30	59	48	**67**	32	85	55

Table 37 shows the new optimised KAP and ESAK DRLs for abdomen plain radiography for each weight group, considered as the P75 value.

Table 37: New KAP & ESAK values for abdomen AP (by weight groups)

weight groups (kg)	KAP (mGy.cm^2)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**10**	8	10	9	**56**	15	63	30
5-<15	**20**	8	21	18	**65**	19	85	60
15-<30	**61**	18	70	48	**81**	57	102	74
30-<50	**203**	60	265	92	**113**	82	185	102
≥50	**225**	125	245	193	**160**	98	182	132

Table 38 shows the new optimised KAP and ESAK DRLs for pelvis plain radiography for each weight group, considered as the P75 value.

Table 38: New KAP & ESAK values for pelvis AP (by weight groups)

weight groups (kg)	KAP (mGy.cm^2)				ESAK (µGy)			
	P75	min	max	median	P75	min	max	median
<5	**15**	8	15	12	**34**	22	35	28
5-<15	**18**	10	29	13	**85**	75	107	76
15-<30	**45**	18	50	28	**110**	81	110	99
30-<50	**75**	32	95	55	**152**	90	163	115
≥50	**79**	50	101	60	**156**	95	169	133

These new DRLs were presented to the radiographers and radiologists and will be used by the radiology department of Hospital C as future reference for dose audit programmes.

6 Discussion

Several research questions, major and specific objectives were formulated at the beginning of this thesis (page 26). A design structure for the study was developed in order to accomplish the desideratum conceived for this thesis (figure 22, page 95). This section discusses the main results achieved.

6.1 About patient characteristics

In the last two years, anthropometric and dose data from 9,935 paediatric patients was obtained in three dedicated paediatric hospitals of Portugal. To the best knowledge of the authors, this study has the largest sample of paediatric patients submitted to a plain radiography procedure that was prospectively analysed.

The patients were measured in terms of weight, height and anatomical thickness of the exposed structure, which allowed to propose values to define a "standard patient" in each age group, more frequently used in literature (table 6), as a tool to harmonise data collection for future studies and to decrease uncertainties due to the wide variation in patient characteristics, also identified by other authors (Gfirtner, Kaplanis, Moores, Schneider, & Vassileva, 2010): The lack of harmonisation makes the attempts of comparing findings a very difficult, if not impossible task.

Median values of patient chest, abdomen and pelvis thickness, measured in our sample (table 6, page 77), are similar to those published in literature (Hart et al., 2000; Wambani et al., 2013). The results from this thesis will contribute to future studies, such as the development of a DRL curve as a function of the patient anatomical projection thickness and or weight, as proposed by some authors (Kiljunen et al., 2007) or for the development of new radiographic pre-set parameters, based on patient's thickness, as proposed by other authors (Zhang et al., 2013).

6.2 About exposure parameters of phase 1

Results of this thesis have shown a large spread in the exposure parameters used for the same exam and age group, due to different choices made at the time of exposure (tables 7 to 9, pages 78-80). The same results were found in other studies (Kristien Smans et al., 2008; Sonawane et al., 2011), illustrating a clear need for standardisation in this domain.

The values of kV, mAs, ExT and SSD found in our results, combined with an inconsistent choice regarding the use of grid, AEC, protective shielding and X-ray beam limitation, are not according to International Guidelines (European Commission, 1996a; Herrmann et al., 2012; International Atomic Energy Agency, 2012; International Commission on Radiological Protection, 2013).

The authors corroborate the statement from Smans *et al*, that, if the exposure settings are not used according to the guidelines, there will be a large influence on patient dosimetry (Kristien Smans et al., 2008). This influence was identified in our results, showing an increase in patient doses due to inadequate use of exposure settings. Part of this problem is related to the fact that pre-sets in the radiographic equipment installed by the vendor are not adapted to paediatric patients as well as to a clear lack of education and training regarding the use of digital systems and how to maximise their use to the benefit of the patient.

Regarding the use of protective shielding, specifically the protection of gonads with lead, the recommendations given to the department took into consideration the recommendations from literature (Bardo et al., 2009; Fawcett & Barter, 2009; Herrmann et al., 2012).

6.3 About national DRLs

This is the first Portuguese study that prospectively analysed patient exposure data and anthropometric characteristics in a large scale and with data collected during each individual procedure.

As already mentioned, the heterogeneity of methodologies found in literature for data collection to establish DRLs makes the comparison of results a very challenging task. This challenge is even bigger when related to paediatric DRLs, due to the limited number of studies available associated with the huge variety of patient characteristics.

Another important challenge is the potential confusion caused by the units and subunits used in literature by different authors to report dose quantities. For example, to define ESAK values authors may use: mGy, mGy or Gy. To define KAP values, authors may present the values in $mGy.m^2$, $dGy.cm^2$ $Gy.m^2$ or $mGy.cm^2$. It is easy for the reader to compare ESAK values, however for KAP it can be difficult and create confusion, especially when the data collection is made through surveys.

To facilitate the work of radiographers and radiologists, a conversion table for KAP units and subunits as the one presented in table 39 should be available in the radiology departments.

Table 39: Conversion factors for KAP units

$1\ cGy.cm^2 = 1\ \mu Gy.m^2$
$1\ \mu Gy.m^2 = 10\ mGy.cm^2$
$1\ Gy.m^2 = 10000000\ mGy.cm^2$
$1\ dGy.cm^2 = 100\ mGy.cm^2$

It is important to note that the units displayed at the X-ray equipment monitor are not always the same as the ones sent to the PACS. For example, at Hospitals B and C, the equipment console displays KAP values in $dGy.cm^2$, however the value sent to the PACS through the DICOM header is in $mGy.cm^2$, which is 100 times smaller than the unit displayed on the monitor. This is obviously something to be corrected to avoid a confounding element for radiographers, radiologists and medical physicists.

For paediatric plain radiography the authors recommend the use of the following subunits with the aim to harmonise the presentation of results in future studies: μGy for ESAK and $mGy.cm^2$ for KAP. Using these subunits will avoid large decimal numbers of exposure quantities with several zeros (e.g. 0.0001) and will thus facilitate comparison of results.

The heterogeneity of patient grouping found in literature is also a considerable limitation when it comes to data comparison. Also, most studies do not allow the reader to identify and characterise the whole spectrum of exposure conditions as described in section 6.2.

In the following tables the results of the DRLs obtained in this study will be compared with different published reference values for chest, abdomen and pelvis projections.

Table 40: Comparison of values for chest AP/PA plain radiography $ESAK_{P75}$ (μGy) with other published data

age groups (years)	present study	Kostova et al (2015)	Billinger et al (2010)	EUR 16261 (1999)	Irish DRL (2004)	Hart et al (2000)	Wambani et al (2013)	Roch et al (2013)	Vaño et al (2008)
<1	145	30	52	80	57	50	50	80	51
1-<5	181	40	62		53	70	60	100	56
5-<10	209	70	82	100	66	120	70	200	91
10-<16	234	70	85		88		90		122
16-≤18	88								

The $ESAK_{P75}$ values for chest plain radiography obtained in our study are higher than the ones published in the literature and in the "European guidelines on quality criteria for diagnostic images in paediatrics" (Billinger et al., 2010; European Commission, 1996a; Hart et al., 2000; Kostova-Lefterova et al., 2015; Medical Council Ireland, 2004; Roch & Aubert, 2013; E Vaño et al., 2008; Wambani et al., 2013).

Table 41: Comparison of values for abdomen plain radiography $ESAK_{P75}$ (μGy) with other published data

age groups (years)	present study	Billinger et al (2010)	EUR 16261 (1999)	Irish DRL (2004)	Hart et al (2000)	Wambani et al (2013)	Vaño et al (2008)	Roch et al (2013)
<1	70	130	700	330	400	80	210	
1-<5	191	387		752	500	130	401	1000
5-<10	198		1000		800	170	947	1500
10-<16	583				1200	200	2288	
16-≤18	1258							

Regarding the $ESAK_{P75}$ values for abdomen plain radiography, our study shows the lowest values when compared with other published results besides the study from Wambani *et all* (2013).

Table 42: Comparison of values for pelvis plain radiography $ESAK_{P75}$ (μGy) with other published data

age groups (years)	present study	EUR 16261 (1999)	Irish DRL (2004)	Hart et al (2000)	Wambani et al (2013)	Vaño et al (2008)	Roch et al (2013)
<1	125	200	265	500	100	191	200
1-<5	158		475	600	120	673	900
5-<10	232	900	807	700	250	998	1500
10-<16	624		892	2000	360	2815	
16-≤18	1204						

As regards the $ESAK_{P75}$ values for pelvis plain radiography, our study shows the lowest values when compared with other published results besides the study from Wambani *et all* (2013).

Table 43: Comparison of values for chest plain radiography KAP_{P75} (mGy.cm^2) with other published data

age groups (years)	present study	Smans et al (2008)	Billinger et al (2010)	Kiljunen et al (2007)	Roch et al (2013)
<1	13	88	23	22	30
1-<5	19	189	26	26	50
5-<10	60	233	37	28	70
10-<16	134	395	73	47	
16-≤18	94				

The KAP_{P75} values for chest plain radiography of our study are the lowest in age group <1 and 1-<5. In age groups 5-<10 and 10-<16 the KAP_{P75} values are

approximately 2 to 3 times higher than the study presented by Kiljunen *et al* (Kiljunen et al., 2007).

Table 44: Comparison of values for abdomen plain radiography KAP_{P75} ($mGy.cm^2$) with other published data

age groups (years)	present study	Smans et al (2008)	Billinger et al (2010)	Roch et al (2013)
<1	25	21		
1-<5	84	49	110	350
5-<10	140	102		700
10-<16	442	237		
16-≤18	1401			

The KAP_{P75} values for abdomen plain radiography of our study are higher in all age groups when compared with the study showing the lowest values: Smans *et al* (Kristien Smans et al., 2008).

Table 45: Comparison of values for pelvis plain radiography KAP_{P75} ($mGy.cm^2$) with other published data

age groups (years)	present study	Smans et al (2008)	Roch et al (2013)
<1	29	19	40
1-<5	75	174	200
5-<10	143	174	400
10-<16	585	687	
16-≤18	839		

Looking at the KAP_{P75} values for pelvis plain radiography, our study shows the lowest values when compared with other published results, except age group <1.

Although DRL results are presented by patient weight group, it is not possible to compare the results, since there are no studies published with patient weight grouping, as recommended by the PiDRL project (Damilakis, 2015).

It is important to highlight that in terms of dosimetry, patient weight groups are more appropriate (Kristien Smans et al., 2008), but in practice, the age of the patient is more easily obtainable. To weigh paediatric patients at the time of the radiological procedure is not only time consuming for the procedure workflow, but requires the radiology department to have different types of scales available, as patient age ranges from new born to 18 years old. One option to surpass this bottleneck would be to recommend the integration of the weight data at the time of referral.

As outlined above, published results for paediatric examinations are scarce and vary widely as regards the methodology of collection and data presentation. This demonstrates an urgent need to harmonise practices and to implement optimisation programmes, especially now that the great majority of hospitals have digital systems and therefore the possibility to decrease patient dose exposure without interfering with image quality. Professional societies and regulatory authorities should raise awareness on a regular basis among radiology departments and health professionals about the importance of DRL data collection for a better implementation of dose optimisation.

6.4 About the optimisation tests

This study is, to the knowledge of the authors, the first to combine objective and subjective analysis of radiological images and was based partly on a conceptual framework presented by some authors (Magnus Båth, Håkansson, Hansson, & Månsson, 2005).

The objective analysis using anthropomorphic phantoms allowed comparing the impact on image quality of the exposure criteria used at the hospital site for chest, abdomen and pelvis procedures, by using several images produced with varying exposure criteria. With the phantom test results from section 3.2.2 (page 99) it has been demonstrated that the new proposed exposure criteria did not affect the objective image quality and allowed significant dose reduction in each exam.

To validate the new proposed exposure criteria, a subjective analysis of clinical images was made by four paediatric radiologists, using the European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics (European Commission, 1996a). Data was analysed using the VGC curves. Several authors consider this method as appropriate to measure image quality, because it offers high validity, as it is based on assessment of clinically relevant structures (International Atomic Energy Agency, 2014; Ludewig et al., 2010).

The results (section 3.4, page 109) demonstrated that the new recommended exposure conditions, produced even better image quality with a significant dose reduction for most age bands and diagnostic image quality was confirmed. Other authors have shown the same results (L. Martin et al., 2013).

In addition, all staff involved, including radiographers and radiologists, welcomed the opportunity to collaborate and were proactive in implementing the new optimised protocols. The authors consider that it is necessary and of utmost importance to include medical physicists in this process, not only to fulfil the legal

requirements, but because their knowledge and expertise improves the optimisation process.

During the optimisation phase of this study, the use of electronic cropping in plain imaging has been analysed and a significant overexposed area was found (from 11 to 25% - table 26, page 115) in all exams, resulting in unnecessary radiation exposure to the patient. Some authors identified the same problem (Soboleski, Theriault, Acker, Dagnone, & Manson, 2006; Tschauner et al., 2015), which can only be surpassed by raising awareness amongst radiographers and by identifying new anatomical landmarks for collimation.

6.5 About the impact of the optimisation programme on patient dose

Regarding the impact of the optimisation programme presented in section 4.2 (page 121), the results of this study show a clear reduction of patient dose without affecting the image quality for chest, abdomen and pelvis plain radiography procedures.

To the knowledge of the authors the studies on the optimisation process and their impact found in literature are only related to paediatric chest plain radiography. Some authors report the same reduction impact on patient dose for chest plain radiography after implementation of an optimisation programme (Carlander, Hansson, Söderberg, Steneryd, & Båth, 2010; Dabin, Struelens, & Vanhavere, 2014; Frayre et al., 2012; L. Martin et al., 2013; Rizzi et al., 2014; Sanchez Jacob et al., 2009), suggesting that such optimisation programmes should be carried out on a regular basis, especially when new X-ray equipment or post-processing tools are installed.

It is important to highlight that this study as well as those cited were developed in dedicated paediatric centres where it is expected that health professionals are more attentive to the needs of the paediatric population. As shown by some authors (Suliman & Elawed, 2013) it would be of major benefit if optimisation programmes for paediatric patients were also implemented in general hospitals.

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Conclusions

1. Portuguese DRLs for paediatric plain radiography (chest PA/AP, abdomen and pelvis) were established and compared with European guidelines and other studies published in the literature.
2. The DRLs (described as KAP_{P75} and $ESAK_{P75}$) were established by patient age and weight groups, following international recommendations and were obtained before and after an optimisation programme.
3. The optimisation programme showed a significant patient dose reduction impact in all age groups (<1, 1-<5, 5-<10, 10-<16, 16-≤18). Dose was reduced:
    a. by 22 to 60% and by 7 to 31%, respectively for KAP_{P75} and $ESAK_{P75}$ for chest plain radiography (table 27, page 123);
    b. by 35 to 87% and by 17 to 87%, respectively for KAP_{P75} and $ESAK_{P75}$ for abdomen plain radiography (table 28, page 124);
    c. by 7 to 89% and by 12 to 86%, respectively for KAP_{P75} and $ESAK_{P75}$ for pelvis plain radiography (table 29, page 124);
4. The optimisation programme showed a significant an expressive patient dose reduction impact in all weight groups (<5kg; 5-<15kg; 15-<30kg; 30-<50kg; ≥50kg). Dose was reduced:
    a. by 38 to 76% and by 65 to 81%, respectively for KAP_{P75} and $ESAK_{P75}$ for chest plain radiography (table 30, page 125);
    b. by 18 to 84% and by 20 to 88%, respectively for KAP_{P75} and $ESAK_{P75}$ for abdomen plain radiography (table 31, page 126);
    c. by 51 to 94% and by 32 to 93%, respectively for KAP_{P75} and $ESAK_{P75}$ for pelvis plain radiography (table 32, page 127);
5. Due to the sample size of this study (9,935) and the fact that all patients were weighed and measured, it was possible to recommend DRLs by weight groups.
6. This work allowed proposing new and harmonised exposure parameters (tables 21 to 23, pages 105-107) for chest, abdomen and pelvis plain radiography, facilitating dose reduction by up to 94% with image quality being maintained after a subjective image quality analysis using the Visual Grading Characteristics method.
7. Several corrections were made regarding the way the dose reduction technological features, available on the X-ray equipment, were used. Improvements were introduced especially about guidance regarding the use of automatic exposure control and the ionisation chambers, the antiscatter grid

and the use of additional filtration, leading to patient dose reduction without compromising image quality;

8. After the implementation of the optimisation programme, the following local DRLs were established for Hospital C:

    a. CHEST:

age groups (years)	KAP_{P75} ($mGy.cm^2$)	$ESAK_{P75}$ (µGy)
<1	9	34
1-<5	10	40
5-<10	14	52
10-<16	41	60
16-≤18	57	62

An average reduction of 41% and 18% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (age groups)

weight groups (kg)	KAP_{P75} ($mGy.cm^2$)	$ESAK_{P75}$ (µGy)
<5	9	26
5-<15	10	35
15-<30	15	46
30-<50	32	58
≥50	57	67

An average reduction of 55% and 75% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (weight groups)

    b. ABDOMEN:

age groups (years)	KAP_{P75} ($mGy.cm^2$)	$ESAK_{P75}$ (µGy)
<1	20	64
1-<5	47	77
5-<10	76	101
10-<16	170	126
16-≤18	237	177

An average reduction of 58% and 53% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (age groups).

weight groups (kg)	KAP_{P75} ($mGy.cm^2$)	$ESAK_{P75}$ (µGy)
<5	10	56
5-<15	20	65
15-<30	61	81
30-<50	203	113
≥50	225	160

An average reduction of 54% and 50% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (weight groups).

c. PELVIS:

age groups (years)	KAP_{P75} (mGy.cm²)	$ESAK_{P75}$ (µGy)
<1	14	76
1-<5	28	99
5-<10	51	110
10-<16	55	120
16-≤18	93	164

An average reduction of 48% and 47% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (age groups).

weight groups (kg)	KAP_{P75} (mGy.cm²)	$ESAK_{P75}$ (µGy)
<5	15	34
5-<15	18	85
15-<30	45	110
30-<50	75	152
≥50	79	156

An average reduction of 75% and 63% was achieved for KAP_{P75} and $ESAK_{P75}$ respectively (weight groups).

9. The optimisation programme presented in this thesis has led to an increased awareness of radiation protection amongst health professionals. Paediatric plain radiography doses have been reduced, however additional optimisation is necessary for other procedures, following the same methodology carried out by a multidisciplinary skilled and well-trained team, including a medical physics expert. Good practice is recommended by European guidelines and is a matter requiring further research.

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