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MASTER OF SCIENCE BY RESEARCH

Does altering the exposure parameters (kV and mAs) affect the entrance skin dose and image quality of paediatric patients undergoing extremity imaging using DR equipment?

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Does altering the exposure parameters (kV and mAs) affect the entrance skin dose and image quality of paediatric patients undergoing extremity imaging using DR equipment?

By

Ami Boyle

Your Award MScR

May 2017



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Does altering the exposure parameters (kV and mAs) affect the entrance skin dose and image quality of paediatric patients undergoing extremity imaging using DR equipment?

By

Ami Boyle

May 2017

A thesis submitted in partial fulfilment of the University's requirements for the Degree of Master of Science by Research



Certificate of Ethical Approval

Applicant:

Ami Boyle

Project Title:

Exploring How Altering Exposure Factors Effects the Entrance Skin Dose for Paediatric Extremity Imaging Using Direct Radiography

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Medium Risk

Date of approval:

08 February 2017

Project Reference Number:

P46841

CANDIDATES DECLARATION

CANDIDATES DECLARATION

CANDIDATES DECLARATION

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Abstract

Background

The field of radiography has seen tremendous advancement in the technologies used to capture and store images. The radiation dose received by patients is kept As Low As Reasonably Achievable (ALARA), whilst producing a diagnostic X-ray. The introduction of Direct Radiography (DR) has been reported to reduce the image quality, and manufacturers are promoting a change in practice from historical imaging techniques. Limited literature is available to support changing practice, causing unrest within the radiographic workforce.

<u>Aim</u>

Identify how radiology departments can achieve optimum image quality at the lowest radiation dose to the paediatric patient. The study aimed to firstly evaluate current practice by measuring the effect that manipulating exposure parameters (kV and mAs) has on Entrance Skin Dose (ESD) and image quality (IQ) for paediatric patients undergoing DR imaging of their extremities; and secondly to compare the performance (as defined by ESD and image quality across a range of kV and mAs settings) of two different pieces of DR equipment currently in service within the researchers NHS Trust.

Method

A local evaluation of current practice was undertaken on two different DR systems (DR1 and DR2). Quantitative experiments across a range of exposure parameters (40-63kV and 0.63-3.1mAs) assessed the effects on ESD and image quality. A patient phantom enabled simulation of a paediatric extremity skin surface. IQ was assessed by three consultant radiologists. Both ESD and IQ results were statistically analysed using a combination of parametric and non-parametric tests.

Results

All images assessed were of diagnostic image quality. DR1 produced lower ESD and improved image quality compared to DR2. ESD was lowest at 63kV / 0.63mAs on both DR1 and DR2. Optimum contrast was achieved at 42kV / 3.1mAs on DR1 and 40kV / 2.5mAs on DR2. Resolution was highest at 63kV / 0.63mAs for DR1, and did not vary for DR2.

Conclusion

Image contrast was improved with little increase to the ESD on both DR1 and DR2 when using a low kV, high mAs combination. This study has highlighted differences in both radiation output and image quality between the two DR systems currently in service. Further clinical evaluation is warranted to investigate the reasons for this.

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List of Abbreviations

ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
AP	Anteroposterior
AXR	Abdomen X-ray
CNR	Contrast-to-noise ratio
CR	Computed Radiography
СТ	Computed Tomography
CXR	Chest X-ray
DAP	Dose-Area Product
DI	Deviation Index
DQE	Detective Quantum Efficiency
DR	Direct Radiography
DRL	Diagnostic Reference Level
ED	Effective Dose
EI	Exposure Index
ESAK	Entrance Surface Air Kerma
ESD	Entrance Surface Dose
ICRP	International Committee on Radiological Protection
IQ	Image Quality
IR	Interventional Radiology
kV	kiloVoltage
mA	milliAmpere
MAD	Mean absorbed dose
mAs	milliAmpere per second
NCRP	National Committee on Radiation Protection
PA	Posteroanterior
QA	Quality Assurance
S	second
SID	Subject-Image-Receptor Distance
TLD	Thermoluminescent Dosimeter

Chapter 1 - Introduction

This thesis will share a research project conducted to evaluate the potential for increasing image quality on two different Direct Radiography (DR) systems and identify the radiation dose implications for paediatric patients. The following sections within this chapter will outline the aims and objectives of the research project and provide background information whilst also supporting the rationale for why this project was undertaken.

This research project was conceptualised through clinical experience, where an observed decrease in the diagnostic image quality of x-rays was reported to the author and the departments management team by Radiologists working within the department. This was especially noted for paediatric extremities where the intricate details of bone (such as trabecular pattern) were not visible, and concerns that pathology may be missed as a result. Evidence of this became apparent shortly after the installation of a brand-new piece of DR equipment within the department. This aimed to increase efficiency and the diagnostic quality of X-rays within the Emergency Department. The department already had an older piece of DR equipment which was also evaluated in this research project as the image quality had been questioned by the radiologists working within the department on occasion.

Radiation safety is paramount in radiography practice. Due to this Radiographers are unable to alter the amount of radiation they admit to patients outside of the departments' protocol without thorough investigation by a local radiation physics team. Lack of professional guidance and workforce education means that department managers do not have the knowledge to amend protocols and therefore may potentially not provide images of a high diagnostic quality at the lowest radiation dose to the patient.

1.1. Justification for Study

Radiographers work within the As Low As Reasonably Achievable (ALARA) principle which means that they need to maintain low patient radiation doses and optimum image quality when performing diagnostic imaging examinations using ionizing radiation. This sets out the main theme for this research project which broadly explored the development of technology in relation to the ALARA principle in a specific area of imaging practice. This was achieved by means of evaluating the existing conflict between current practice protocols and recommendations for best practice when using DR systems for paediatric imaging. Evaluating the effect that exposure parameters (kilovolts (kV) and milli-Ampere per second (mAs)) had on the radiation dose output, measured as Entrance Skin Dose (ESD), and image quality (contrast and resolution) allowed the researcher to identify at which combination of exposure parameters the best image quality could be achieved at the lowest

ESD to the patient. Evaluation of the two different DR systems (DR1 and DR2) used within the Trust allowed for direct comparison of the results, and led to the researcher ascertaining whether the same combination of exposure parameters is deemed best on both or whether optimal exposure parameters are equipment specific.

The results of the literature review, detailed in Chapter 2, highlighted that reported image quality (contrast) will improve at a lower kV but there is little clarity or empirical evidence surrounding the impact on ESD and the effect on the resolution of the image. Hence the rationale for this local evaluation. This research project required a quantitative methodology to investigate the radiation output of the two pieces of equipment and the consequential effect on image quality. As ionizing radiation causes potentially harmful effects, the researcher identified that it would be unethical to perform this research project on patients, therefore a patient phantom was used to mimic the depth of a paediatric extremity.

1.1.1 Research Question

Does altering the exposure parameters (kV and mAs) affect the entrance skin dose and image quality of paediatric patients undergoing extremity imaging using DR equipment?

1.1.2 Research Aim

The key aim of this research project was to identify how radiology departments can achieve optimum image quality at the lowest radiation dose to the paediatric patient. Accordingly, the study aimed to firstly evaluate current practice by measuring the effect that manipulating exposure parameters (kV and mAs) has on ESD and image quality for paediatric patients undergoing DR imaging of their extremities; and secondly to compare the performance (as defined by ESD and image quality across a range of kV and mAs settings) of two different pieces of DR equipment currently used within a large specialist children's hospital within the UK.

1.1.3 Research Objectives

The objectives of this research project were to:

- 1. Conduct the research project in an ethical manner by using a patient phantom instead of exposing patients to excessive amounts of ionizing radiation
- Comparison of ESD measured on two pieces of DR equipment using the same settings
- Compare current exposure protocols to others recommended by manufacturers and published literature

4. Monitor image quality to confirm claims within literature and quality control selected exposure parameters

1.1.4 Hypotheses

The rationale for each of the following hypotheses is outlined within the literature review (Chapter 2):

1) As the kV is decreased the ESD will increase on both DR1 and DR2.

2) When set with identical exposure parameters DR1 and DR2 will deliver equivalent ESD.

3) When set with identical exposure parameters DR1 and DR2 will deliver equivalent image quality.

4) Based on current practice higher kV will deliver superior image quality.

The research aim and objectives helped direct both the initial scoping literature search and the main literature review, the results of which helped to refine the overall research question, hypotheses and experimental design.

1.2. Background

1.2.1 Development of Technology

The evolution of digital technologies within the radiographic field has been present since the 1970's (IAEA 2015). The term digital radiography or digital imaging encompasses two key modalities seen within most X-ray departments around the UK today; Computed Radiography (CR) and Direct Radiography (DR). Table 1 shows the development timeline of these digital technologies.

Prior to CR and DR technological advances film-screen (analogue) imaging was used to produce diagnostic X-ray images. This required manual processing of the X-ray films with the use of potentially harmful chemicals and a dark-room (IAEA 2015). The move to digital imaging was promoted as a more efficient system and expelled the use of the harsh and unreliable chemical processing by converting digital signals into digital images viewed on a computer screen. The advent of the wireless DR flat-panel detector in 2009 makes the viewing of these digital images almost instantaneous. (Körner et al. 2007).

Table 1: Timetable of developments in digital technologies (reproduced and adapted fromKörner et al, 2007 and Lanca and Silva, 2012)

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1.2.2 The Physics

To understand how the development from film-screen to digital radiography has effected clinical practice it is necessary to understand how X-rays are produced. Briefly, X-rays are produced by causing a sharp change in direction of charged electrons travelling at speed towards a target. A detailed explanation of this process can be found in Appendix 1.

The amount of x-ray radiation that the patient receives is determined by the radiographer. They are responsible for setting appropriate exposure parameters (kilovoltage (kV), milliampere (mA) and seconds (s)). Appropriate in this context means the correct amounts of each parameter to produce an image of diagnostic quality for the clinical question being asked within safe radiation dose limits for the patient. The radiographer will make this decision based on the anatomy of interest and the size of patient to be imaged, whilst working within the ALARA principle (Barba & Culp 2015).

Table 2 describes the role of the exposure parameters and the affects they have on the resultant image. It is commonplace that the milliAmpere (mA) and seconds (s) are combined to form milliAmpere per second (mAs).

Table 2: Roles of exposure parameters when taking an X-ray. The effect of exposure

 parameters on image quality

PARAMETER	ROLE	AFFECT ON IMAGE
Kilovoltage (kV)	Affects quality and intensity of beam:	Contrast / greyscale - too
	• Quality: the higher the kV, the more	little kV results in a
	penetrative the beam	decrease in the
	 Intensity: the higher the kV, the 	differentiation between soft
	more energy the beam has making it	tissues and bone
	more efficient	
Milliampere (mA)	Affects the intensity of the beam:	Blackening of image – too
	Intensity: the rate of flow of the	much mA results in too
	electric charge carriers, concerned	many photons reaching
	with the amount of X-ray photons	image receptor causing a
	produced	dark image, too few results
		in a light image
Seconds (s)	The length of time the patient is	Image sharpness
	exposed to the X-ray beam.	(movement artefact)

The paediatric population is knowingly more radiosensitive to the possible effects of radiation than adults, due to their rapid cell division and longer life expectancy. Compared with the adult patient population, paediatric patients present at varying stages of skeletal and organ development owing to different levels of inherent contrast on X-ray images. This is especially apparent in the paediatric extremity where the hyaline cartilage is converted into bone, a process which continues until early adulthood (18-25years) (Jones et al. 2015). Patient movement is a possible cause of reduced image sharpness (resolution), however immobilisation protocols should be followed in an aim to reduce this (Jones et al. 2015). The paediatric population benefits from a short exposure time, which aids in overcoming the lack of co-operation often witnessed and reduces these negative effects that can be seen on the images (European Commission, 1996), highlighting the need for justification and optimization of radiation dose and image quality (Jones et al. 2015). Current European guidelines do not define recommended exposure time for paediatric extremities, however it is recommended that <10ms is used for imaging of the pelvis and <20ms for a lateral skull to avoid motion unsharpness being evident on the image.

Despite the factors detailed above X-ray is recommended as the first line of investigation for paediatric focal bone pain, due to its efficient nature and availability (Royal College of Radiologists (Great Britain) 2012).

The ALARA principle, also known as, As Low As Reasonably Practicable (ALARP), used in practice today first came into discussion in 1954. Table 3 depicts the timeline of the ALARA principle that radiographers now work to, formulated by the National Committee on Radiation Protection (NCRP) and the International Committee on Radiological Protection (ICRP) (Miller & Schauer 2015).

YEAR	PUBLICATION	DEFINITION
1954	NCRP - Report 17	"Radiation exposure should be kept at the
		lowest practicable level"
1954	ICRP – Recommendations of the	"The radiation exposure of the patient
	ICRP	should be reduced as much as is
		compatible with successful diagnostic
		investigation or therapeutic treatment"
1959	ICRP – Publication 1	"All doses be kept as low as practicable,
		and that any unnecessary exposure be
		avoided"
1965	ICRP – Publication 9	"All doses be kept as low as readily
		achievable, economic and social
		considerations being taken into account"
1973	ICRP – Publication 22	"As low as reasonably achievable,
		economic and social considerations being
		taken into account"
1977	ICRP – Publication 26	"As low as reasonably achievable,
		economic and social factors being taken
		into account"
ABBREVIATIONS:		
NCRP - National Committee on Radiation Protection		
ICRP - International Committee on Radiological Protection		

Table 3: Development of the ALARA principle. (Adapted from Miller & Schauer, 2015)

Today the ALARA principle underpins all protocols adhered to by Radiographers ensuring optimal diagnostic quality is achieved on all images at the lowest possible patient dose (Willis & Slovis 2004).

Currently the European Guidelines are considered the most comprehensive for the imaging of paediatrics, however, these were written is 1996 for film-screen imaging and recommend the use of a high kV technique and added filtration (current Trust protocol) to ensure a quick exposure time and low ESD (Knight, 2014).

1.2.3 Radiation Dose

There are several definitions that can be used to explain the effects that radiation exposure has had on the patient, this created difficulty when comparing literature. The two most common definitions of radiation dose that are used within literature are the Effective Dose (ED) and the Entrance Skin Dose (ESD). ED is related to the radiation dose received by the tissues and organs within the body and cannot be directly measured, but rather calculated using specialist software. The ESD is what this research project will focus on. This is the measure of the radiation dose that interacts with the skins surface at the point where the X-ray beam enters the patient. This can be directly measured using a special piece of equipment called a dosemeter (Parry et al 1999).

1.2.4 Changes to Practice

Film-Screen

When using the now mostly redundant film-screen imaging, exposure parameters (kV and mAs) were selected to ensure enough x-rays were produced to penetrate the area of anatomy being imaged and be received by the imaging plate. The film-screen imaging systems were less sensitive to receiving x-rays than the new digital imaging systems causing changes in the contrast and resolution of the images if not enough, or too much radiation was received. Incorrect exposure parameters would be easily identifiable on the processed image, with an image that was either too light (under-exposure) as not enough x-rays were received or too dark (over-exposure) where too many x-rays penetrated the patient (Hess & Neitzel 2012).

Using the high kV, low mAs technique described in the European Commission Guidelines (European Commission, 1996) produced a higher quality X-ray beam and the additional filtration prevented the lower quality beam and unnecessary radiation dose reaching the patient. Although it is discussed that diagnostic image quality can suffer slightly with the addition of the filtration, it was deemed acceptable to allow this reduction in image quality to lower the overall radiation dose received by the patient. The added filtration used is generally made from copper or aluminium, or sometimes a combination of the two. This

technique has been used for many years within the radiography profession and underpinned the teaching of a large group of radiographers (Hardwick & Gyll 2004).

Digital

In comparison the introduction of digital imaging technologies means that the dose received by the detector is no longer a boundary to the exposure parameters chosen, but the decision made only on the thickness of the anatomy to be imaged (Barba & Culp 2015). This is due to the wider latitude and increased sensitivity offered by digital image receptors coupled with the ability to alter the contrast and brightness of an image during post-processing (Hess & Neitzel 2012). There is potential within these digital systems to actually increase patient dose due to the inability to easily detect over or under-exposed images as film-blackening does not exist at the higher exposures (Uffmann & Schaefer-Prokop 2009). Without updated national guidelines to assist policy writing within radiology departments there is room for misjudgement of the exposure parameters needed by radiographers (Hayre 2016).

Literature states that this increase in sensitivity eliminates the need for the high kV technique and due to this added filtration can also be omitted, which has a negative effect on image quality (Hess & Neitzel 2012). In doing this it is considered that image contrast can be improved and patient dose lowered (Jones et al. 2015). It is however important to note that when the kV is decreased the mAs must be increased (Hess & Neitzel 2012), and according to current knowledge, increasing the entrance skin dose the patient will receive as mAs is directly related to patient dose (PiDRL 2015).

With a lack of national Dose Reference Levels (DRLs) for paediatric plain film imaging set in the UK, difficulty in defining acceptable patient doses exists (Public Health England 2016). DRLs provide a guideline for the radiation dose a patient should receive when undergoing diagnostic examinations. The aim is for a collaboration of professional societies and authorities to use current national dose data to create a limit which should not be repeatedly exceeded for each examination using ionising radiation, improving the optimization of patient protection. An investigation carried out by PiDRL (2015) showed that no national DRLs exist for paediatric plain film imaging examinations, as focus has been on the high dose imaging modalities such as Computed Tomography (CT) and Interventional Radiology (IR), this is supported by the report by Public Health England (2016).

Although literature provides some evidence that a change in technique is justified, this knowledge has not reached the radiographers currently using the equipment. Moore et al (2012) does state that there is a need to re-educate the workforce to minimise excessive radiation exposure to patients, although this is not evident in practice. An ethnographic study

conducted by Hayre (2016) emphasizes the need for this education by exploring radiographers' techniques when using DR equipment. The results show that radiographers are still using the high kV technique and are unaware of the optimization potential of DR systems.

1.3 <u>Summary</u>

This chapter has introduced the problem and following on set out the research question, aim and objectives and reviewed literature found from a scoping study of the topic area. The flow chart illustrated in Figure 1, details the main processes that were undertaken throughout this research project. They were a review of the current available literature, a pilot study which preceded the main research project to ascertain whether the order of radiation exposure impacted on the radiation output reading, collection of both radiation dose and image quality data for the main research project and statistical analysis of this data. The following chapters of this thesis describe these processes in detail and provide justifications for the decisions made.

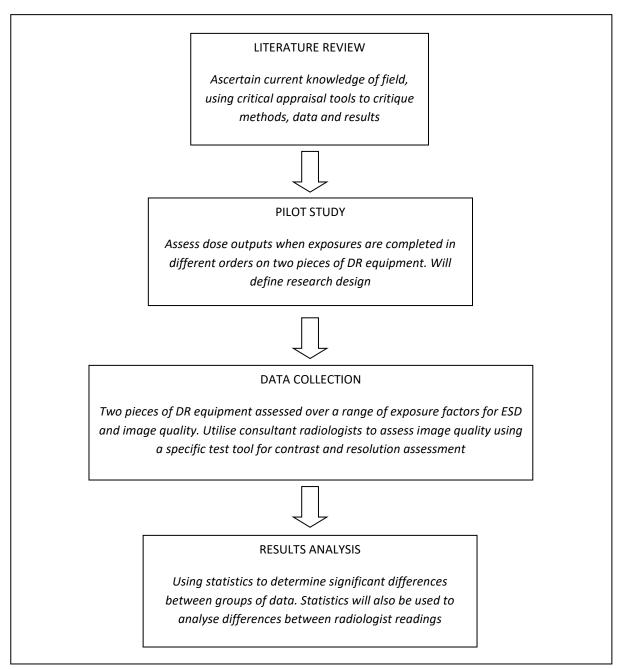


Figure 1 Flowchart of research project processes undertaken

Chapter 2 - Literature Review

The previous introductory chapter set out the aims and detailed the current knowledge within the field of digital radiography. The transition between analogue and digital imaging has been described, and the factors which influence x-ray production and patient dose. An indepth literature review was required and subsequently conducted to extract further data surrounding this topic. Here the process will be described and critically debated.

2.1 Search Strategy

A scoping literature review was conducted to enable analysis and synthesis of previously undertaken research within this topic area. With the growing awareness of evidence-based practice within healthcare there is more emphasis on the importance of literature reviews within studies or even as a standalone methodology, such as systematic reviews (Aveyard, et al, 2016). This review aimed to support the empirical background to the research project. To guarantee a comprehensive literature review was completed a search strategy was devised to enable a systematic search of all available literature within the field. Developing a search strategy is a process that requires continual assessment and refinement, also known as an iterative process (Aromataris and Riitano, 2014).

2.2 Purpose Statement

The aim of this literature review was to source and appraise literature that exists around the management of paediatric patients' entrance skin dose and image quality when using DR imaging equipment. To do this effectively the scope of the research question needed to be defined. Using the PICO framework as set out below, it was possible to focus the definition with more clarity so that relevant literature could be searched (Howard, 2017). This framework is used readily in evidence-based medicine to formulate patient-specific clinical questions (Huang et al. 2006).

Population/problem – Paediatric patients

Intervention – Low kV technique on a DR system

Comparison/Control – High kV technique on a DR system

Outcome – Entrance skin dose and image quality

An initial scoping search (Appendix 2) revealed that defining the area of the body to be xrayed resulted in few relevant results, so it was decided that the population would incorporate the axial and appendicular skeleton. Following discussion of the PICO framework, it became apparent that it was necessary to expand the population to include studies carried out on adult patients to broaden the amount of literature to be reviewed, however this would need to be taken into consideration during the critiquing process.

Following the scoping search, a general search was completed using online databases relevant to the radiographic field. Following this other sources were searched to ensure other literature was not missed; other literature included conference proceedings, white papers and grey literature. The search strategies adopted by the researcher included a combination of keyword and subject headings in a systematic order to avoid confusion and duplication of searches which would impact on time constraints.

The primary outcome of this literature review was to establish what evidence currently exists to inform changes to imaging protocols with regards to maintaining low patient dose and improving image quality when using DR imaging systems.

Secondary outcomes:

- To identify other useful data sources concerning the characteristics of DR technology in terms of manufacturer differences, image quality implications and user experience
- Identify gaps within the field of knowledge and recommendations for further study if defined

2.3 Search Terms

Keywords were firstly defined using the literature review aim and outcomes concluded from compiling the PICO framework as outlined in Section 2.2. There were five main terms that were identified as suitable for searching the literature with regards to the desired outcomes of the literature search. Table 4 shows how each term was expanded to allow thorough searching of literature. The usefulness of these keywords and phrases would be determined by the relevance and quality of the search results (Aromataris and Riitano, 2014).

In addition to keywords and phrases the subject index terms (MeSH or CINAHL Headings) feature available on some databases was used and, alongside this the explode function to widen the search criteria and allow identification of literature not defined by the keywords. The researcher sought assistance from a dedicated librarian to oversee the search strategy and assist in the formulation of search terms for more effective searching to be carried out.

EXPLODED TERM	ALTERNATIVE KEYWORDS	SUBJECT INDEX TERMS
Paediatric	pediatric	
	child* (to include child/children)	
kV	kVp	
	kilovoltage	
	"tube potential"	
	"exposure factors"	
	"exposure parameters"	
	"high kV technique"	
"Entrance skin	dose	(MM "Radiation Dosage")
dose"	"entrance skin exposure"	
	"patient dose"	
	"radiation dose"	
	dosage	
	"radiation exposure"	
	"surface entrance dose"	
	"effective dose"	
	"dose optimization"	
	exposure	
X-ray	X ray	(MM "Radiography")
	radiograph	(MM "Radiographic Image
	"diagnostic radiograph"	Enhancement")
	"diagnostic imag*" (to include	(MM "Digitizers")
	image/imaging)	
	"general imaging"	
	"plain-film imaging"	
DR	DDR	(MM "Radiologic
	"digital imaging"	Technologists")
	"direct digital imaging"	(MM "Computed
	"direct radiography"	Radiography")
	"direct digital radiography"	
	"digital radiography"	

Table 4: Keywords and search terms utilized within literature search

Boolean operators enabled more efficient searching to be carried out. The use of AND allowed keywords to be searched simultaneously for literature containing all words included in the search, for example TI radiation AND TI (dose OR dosage* OR exposure*). The OR operator allowed alternative keywords within the same group to be searched for.

2.4 Sources of Literature

2.4.1 Electronic Databases

Advice was sought from a University librarian on the most appropriate electronic databases for searches within this field. Recommendations were made due to the availability of literature from allied health professionals, and therefore likely to return positive searches within radiography. Initially only four electronic databases were recommended (CINAHL, MEDLINE, Cochrane library and Scopus), however due to limited results the researcher expanded this search to include two more (PubMed and Joanna Briggs Institute), although this impacted on the time constraints of this study. The databases searched are detailed in Table 5, the corresponding appendices illustrates the searches that were conducted.

Table	5: Databases searched for relevant literature

DATABASE	SEARCH STRATEGY
CINAHL	Appendix 3a & Appendix 3b
MEDLINE	Appendix 3c
Cochrane Library	Appendix 3d
Scopus	Appendix 3e
PubMed	Appendix 3f
Joanna Briggs Institute (JBI)	Appendix 3g

For all searches detailed in Table 5 the search terms were restricted to title, abstract and keyword apart from the JBI search which only used the subject index terms as previous keyword searches had yielded no results. The researcher conducted fewer searches on some databases as it was apparent that duplicate results were appearing with no new relevant literature.

Following the limited results from these sources a check of systematic review databases, as recommended from the CASP website, was conducted yielding no results. (Appendix 3h)

As it was not feasible within the time constraints to re-run searches, search alerts were set up on both CINAHL and MEDLINE as these produced the highest number of relevant results.

2.4.2 Hand searching

Following the main search of the databases the researcher also carried out reference searching of the articles that were considered relevant for the literature review. This shed light on several guidelines that have been written by organizations in addition to those written by diagnostic radiographer governing bodies. The researcher also has a monthly subscription to the Society and College of Radiographers (ScoR) who release three journals: *Synergy Imaging and Therapy Magazine, Synergy News* and *Radiography*; these were hand checked monthly and one article (Hayre, 2016) was deemed relevant from this search.

2.4.3 Internet searching

In addition to using the online databases the researcher deemed another good source would be Google and Google Scholar. This returned several results that did not appear on the database search including manufacturer brochures and access to professional societies and their reports and guidelines, for example the American College of Radiologists.

Google Scholar also returned several of the articles already found from the online databases so it was deemed appropriate to set-up search alerts for search strategies on this site.

Google Scholar offers a function which shows where the papers have been previously cited. This was utilized to find additional literature, however it only produced irrelevant or duplicate results.

2.4.4 Grey literature

Grey literature has been defined as 'That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers' (Barratt & Kirwan 2009).

One source of grey literature was a website specifically for members of the radiography profession to share their knowledge on several areas within the field. A section of this website allows members to "blog" their findings and experiences. Four pieces of relevant literature were found dating from 2000, and included articles as well as presentation slides.

Conference proceedings were also found from the search engine, which were deemed topical as the conference was regarding ALARA with digital imaging technologies and was

held by a large paediatric radiography campaign in America, *Image Gently,* whose mission is to ensure the safe imaging of paediatric patients.

2.5 Inclusion and Exclusion Criteria

To ensure the articles retrieved were of relevance to the research project inclusion and exclusion criteria were identified. Table 6 describes the criteria chosen.

Table 6: inclusion/exclusion criteria applied to refine literature search

Inclusion	
0	Title demonstrates high relevance to proposed study
0	Abstract demonstrates high relevance to proposed study
0	Investigation into lowering patient dose on DR systems is specified
0	Investigation into improving image quality on DR systems is specified
0	Experimental design contains key features of the proposed study and can support
	the proposed study
Exclusion	
0	Non-English language papers
0	Papers investigating the dose and image quality characteristics of either film-screen
	or CR imaging systems

- Papers investigating DR systems which are not used for general X-ray imaging
- Papers discussing image processing technologies to improve image quality

Development of digital technologies has progressed steadily since the 1990's (IAEA 2015) so there was no date range specified and it was then down to the researcher to define which technology was being investigated from the title or by reading the abstract.

Literature written in English language only were included for practical reasons, and as the researcher concluded that any key papers written surrounding this topic would have been translated and made readily available, and obtaining translation would have impacted on time constraints of the project.

The inclusion of study populations has already been briefly discussed. The population was widened as an initial search for paediatric studies regarding dose management was limited in terms of its results. Although adult studies were also included the results could not fully translate to the topic area as paediatrics are more radiosensitive and are at differing stages of skeletal development, they did however provide insight into suitable methodologies and

considerations to be made. Studies that did not focus on human populations (e.g. animals) were excluded as too many variables would arise.

Following the systematic searching of online databases and other sources, duplicates were removed and literature abstracts were screened for evidence. Literature was excluded if it did not meet the inclusion and exclusion criteria. All search results were documents and the process is demonstrated in the PRISMA diagram below (Figure 2).

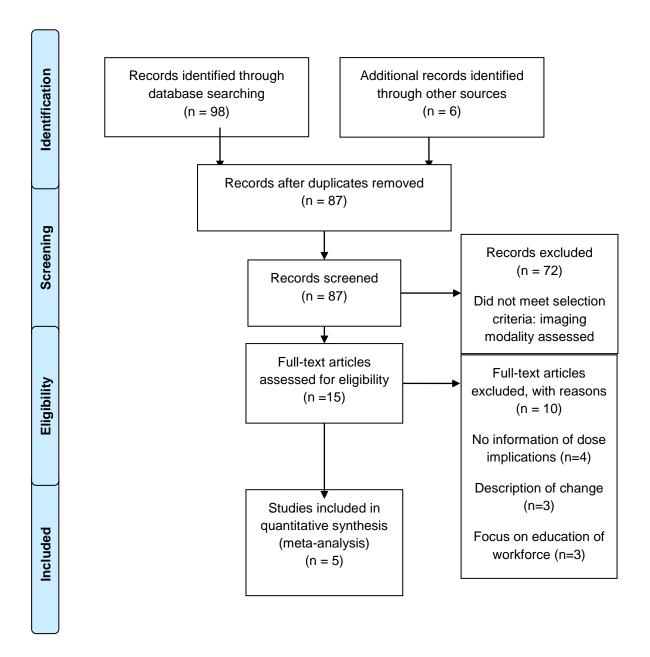


Figure 2 PRISMA 2009 diagram showing process of inclusion from literature review

Of those papers that were included from the screening process, the full text was then read for eligibility and was excluded if imaging modalities other than DR were being explored or the discussion surrounded imaging with use of an anti-scatter grid, used for imaging thicker areas of anatomy to improve image quality. One paper (Moore et al, 2012) was excluded on the grounds of eligibility as it became apparent the discussion surrounded the use of the Exposure Index (EI) and Deviation Index (DI) to determine image quality, not patient dose. After screening the grey literature (n=6) using the inclusion and exclusion criteria detailed in Table 6, it was concluded that none of them fit the criteria for this research project. This was due to most them discussing the imaging processing software and discussing the background of implementing DR.

The eligible papers were then collated, resulting in a combination of journal articles (n=5). Studies were stored electronically and duplicates managed using the Mendeley referencing software.

2.6 <u>Summary table</u>

Table 7 shows the data extraction process completed for the journal articles. This process involved reading the articles fully and extracting the important data relating to the topic area. This allowed synthesis of the data and highlights gaps in the knowledge base and the need for further evaluation of current practice.

1. Jones et al (2014). British Journal of Radiology. London

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

2. Aldrich et al (2006). Journal of Digital Imaging. Vancouver

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

3. Knight (2014). Journal of Medical Radiation Sciences. Brisbane

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

4. Lehnert et al (2011). American Journal of Radiology. Frankfurt

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

5.	Hess and Neitzel	(2011)). Fortschr Röntgenstr.	Hamburg

White Paper

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

2.7 <u>Critical Appraisal of Literature Results</u>

The field of literature retrieved was limited from these searches. Although many of the online database searches yielded a number of results, most were relevant to other imaging modalities such as Computed Tomography (CT). With CT removed from the search the number of results decreased from over 1000 to 271, however many these were still irrelevant to this research project, investigating alternative topics and imaging modalities within the field. One journal article found from the search (Barba & Culp 2015), although excluded due to the set criteria, investigating the dose implications of CR against film-screen, could be utilised as the experimental methodology was similar to the planned research project and highlights key aspects for the researcher to consider, including placement of the dose meter and appropriate alteration of exposure parameters.

With many journal articles and grey literature not being deemed relevant and not meeting the criteria a total of five articles were finally critically reviewed (Figure 2).

The use of a tool for critical appraisal allows for a systematic, in-depth look at literature and allows structure to identify whether the study is valid, the results are clinically important and whether it applies directly to the proposed field of radiography (CASP, 2013).

The appraisal tool used by the researcher was devised through a combination of two existing tools see appendix 4, the Joanna Briggs Institute *"Checklist for Quasi-Experimental Studies"*, designed to test the methodological quality of the studies and to detect any level of bias that may be present in the design, conduct or analysis (JBI 2016), and the *"Clinical Appraisal Skills Programme (CASP) Randomised Control Trials Checklist"* (CASP 2013). In using a combination of the two checklists it was possible to thoroughly appraise the literature in terms of quality, but also extract relevant data to the proposed study.

Following the appraisal process one further article (Körner et al. 2007), was excluded as it merely explained the differences between how the different technologies work, with no focus on dose optimization to add to the knowledge base which influenced this research project.

2.8 Data Extraction

During the appraisal process, relevant data from each of the appraised articles was extracted, as demonstrated in Table 7. Data extracted included:

- Author, year of publication and country of origin
- The study question/aim
- The variables used

- Method used and the sample chosen
- Control mechanism or comparison
- What equipment was used
- How the analysis of both dose and image quality were performed
- The results
- Any strengths or weaknesses within the study

Using the data collected for each section it was possible to identify the available information and knowledge gaps within this field. This in turn served to reflect the need for this study and supported both the primary and secondary aims of the literature review.

2.9 <u>Results</u>

The extracted data were divided into themes relating to this research project. The themes derived from both the critical appraisal tool and the methodology included; sample, equipment, radiation dose analysis and image quality analysis.

2.9.1 Sample

Of the retrieved articles the study samples varied making it difficult to synthesize the results (utilizing adult, patient phantoms and literature sample groups). However, Aldrich et al (2006) describes how they used adult patients of an "average" size, which was then specified as a patient with a body mass of $70 \text{kg} \pm 10 \text{kg}$. The paediatric population varies greatly in their size and weights so it was not possible to directly relate the results from this article, however the results could relate to some teenage patients as they can be the size of an average adult. This study concerns itself with chest, abdomen and pelvis imaging rather than extremity imaging. Conversely, Lehnert et al (2011) imaged a 58-year-old male cadaver. Although this study stated several extremity body parts were imaged this piece of literature focusses on the results gained from ankle imaging. Although the sample of these pieces of literature could not directly relate to this research project, the anticipated research design was similar. Lehnert et al (2011) used four radiologists to score the images based on a 9 point scale devised by the researcher. This research project also utilised radiologists to score images based upon the selected image quality test tool. Therefore, relevance was established through experimental set-up as well as considerations for further research in this area in the future, to include the axial skeleton and larger patients.

The remaining articles (n=3) focused on the need of the varied paediatric population undergoing imaging using DR. For example, Knight (2014) aimed to produce a protocol for imaging paediatric patients within their radiology department in Brisbane. They used a

literature review to inform their scientific experiments, although the methods of which are not detailed in their published article. Direct contact was made with the author to obtain this information. There were two main phases to the scientific aspect of this study; the first being establishment of a baseline noise (grainy appearance on the image) acceptability using a fixed kV and varying mAs with radiologist image quality evaluation, followed by experiments using varying kV and mAs on different projections of each body part. Using a patient phantom Knight (2014) used the Dose-Area Product (DAP) which he stated was directly proportional to the ESD to monitor patient dose, no additional literature could be found to support this statement (Section 3.4).

The study produced by Hess & Neitzel (2011) explored the paediatric extremity and conducted experiments using a patient phantom made up of 1cm slab of Polymethyl Methacrylate (PMMA) to represent the soft tissue with a 1mm sheet of aluminium placed on top to represent bone. These experiments were carried out in a laboratory setting and it is stated within the article that the results were extreme, meaning they may not reflect the amount of dose reduction or image quality improvements that will be seen in clinical practice. It was not conversed what was meant by this statement but the researcher believes this would be due to variations in practice, such as patient development and size and individual department protocols. The use of a patient phantom was mirrored by Jones et al (2014) who sought to explore the results gained by Hess & Neitzel (2011). Interestingly, Jones et al (2014) used an anthropomorphic phantom said to simulate a paediatric foot aged 0-1year for the initial experiments and within the same article conducted a follow up clinical audit on post-mortem patients aged 1-15 months to verify their experimental results. Although this is more ethical than imaging live patients there was no description of how long the postmortem patients had been deceased or whether they were frozen. No literature was found comparing tissue densities in relation to radiation dose readings, so it is unclear whether this should be considered when reviewing the data. The methods undertaken by Jones et al (2014) relate to the approach of the researcher undertaking this research project. An initial assessment utilizing a phantom was used to establish the safety of altering exposure factors in terms of patient dose, and future research to include an audit of clinical images was then undertaken.

The results published in the articles focussing on the paediatric population are certainly more relevant to this research project, however difficulty in directly comparing the results stems from the varying samples.

2.9.2 DR Systems

Four different DR systems were identified within the review. Two were assumed to have used an under-couch detector and the remaining three utilizing a wireless detector. The current research project will utilize two DR systems, the Philips Digital Diagnost with wireless detector and the Siemens Luminos with under-couch detector. The systems identified and the articles in which they are investigated are listed in the Table 8.

 Table 8: Equipment used in literature

EQUIPMENT	ARTICLE
Siemens Axiom Aristos MX	Jones et al (2014)
Philips Digital Diagnost	Aldrich et al (2006)
	Hess & Neitzel (2011)
	Knight (2014)
Siemens Ysio	Knight (2014)
Kodak Direct View DR7500	Lehnert et al (2011)

The Philips Digital Diagnost was investigated most (n=3: Aldrich et al (2006), Hess & Neitzel (2011) and Knight (2014)). One study, Aldrich et al (2006) was published before the implementation of wireless flat panel detectors in 2009, therefore it is assumed that a fixed wall mounted digital detector was used to capture the digital image. Although still utilized in practice, it is not the first choice when imaging paediatric extremities, due to the distance and additional material between the patient and the image receptor (Bruce 2005). As previously stated, this study was concerned with the axial skeleton (Chest, abdomen and pelvis) making the choice of this equipment justified. In combination, this limits the applicability of these data to the current investigation.

The manufacturers' specifications for the version of this system investigated in the other two articles (Hess & Neitzel (2011) and Knight (2014)) and utilized in this research project details an image matrix of 2330x2846 pixels, a pixel pitch of 148µm (micro-millimetres) and an image resolution of up to 3.38 lp/mm (line pairs per millimetre) with a detector material of caesium iodide. All other systems, discussed below, only appeared in one study demonstrating the scope of research that needs to be conducted in this area due to the number of DR systems that are on the current market.

Two Siemens systems were identified from the retrieved articles; neither were included in this research project. Jones et al (2014) utilizes a Siemens Axiom Aristos MX over-couch

digital X-ray system, and was the only study to state investigation of the under-couch caesium iodide detector set-up. A search was conducted to ascertain further equipment specifications; these were unavailable from the manufacturers' website. The DICOM (Digital Imaging and Communications in Medicine) system which is used to view the images was found under *"Radiography Legacy Systems"*, meaning this technology is not up to date and availability is limited. This poses an issue for the external validity and relevance of this study as the technology is no longer up to date in the current market. The second Siemens system utilized by Knight (2014) was the Siemens Ysio which comprises of a flat panel detector not specified in the article. The manufacturers' specifications for this system depict four different detectors that are available on the current market, the image matrix and resolution of these are not detailed and can therefore not be compared to the systems being used in this research project.

Lehnert et al (2011) investigated the Kodak DirectView DR7500 system. Although not specified within the article, investigation into the manufacturer specifications highlights that this system utilizes a caesium iodide under-couch detector and due to the ergonomics of this study it is assumed this was the method used to image the cadaver. This system provides an image matrix of 3000 x 3000 pixels, a pixel pitch of 143µm but no resolution was specified in either the article or the manufacturer brochure. The pixel pitch described here indicates that the pixels on this DR system are smaller than that of the Philips Digital Diagnost, producing a slightly sharper image. However, this is not necessarily noticeable in clinical practice (Maher, 2015).

2.9.3 Radiation Dose

As previously discussed radiation dose is defined in several ways to demonstrate the effect on the patient, with different values and measuring methods. Two main dose data collection methods emerged from the appraisal process. The DAP (Dose Area Product) is a measurement of radiation received by the patient which is calculated and presented by the imaging equipment, the DAP meter is usually positioned on the X-ray tube to measure the amount of radiation being emitted. This is commonly used in practice to ensure excessive or insufficient amounts of radiation are not given, it offers a quick reference tool for radiographers. Two articles use the DAP reading for data collection. One was Knight (2014) who used the DAP to ensure there is no excessive increase in the ESD received by the patient when manipulating exposure parameters. As previously stated Knight (2014) specified that DAP was directly proportional to the ESD, communication with a local physicist disputes this, however an estimation of ESD can be made from the DAP reading if the field size and focus to skin distance is known (Anon 2001). It was also communicated that the Philips Digital Diagnost system used here does not have a physical DAP meter installed, but rather uses a calculation based on the x-ray tube output and field size to give an estimated DAP reading and use of an independent dosemeter would be a more reliable method.

In comparison Aldrich et al (2006) uses the DAP reading to manually calculate the Effective Dose (ED) for their exposures using ED conversion coefficients. In addition, Jones et al (2014) was concerned with the ED but collects the data using a Unfors Xi Detector – multiparameter measurement QA dose meter beneath the limb and goes on to calculate the ED using PMXMC software. Placing the dose meter beneath the limb will measure the amount of radiation attenuation rather than how much is reaching the skins surface. This differs from the other studies who place the data collection tool above the patient. As in the study conducted by Lehnert et al (2011) who places a Mul-O-Meter 503L dosemeter at the level of the skins surface to measure the ESD received by the patient. The current research project placed the dosemeter above the patient to measure the amount of radiation reaching the skins surface, it is not stated nor understood what the benefit of placing the dosemeter under the patient would have in the study by Jones et al (2014), but this method would not comply with the aims of this research project, as the ESD would not be measured.

These methods were clearly defined in the above reviewed articles, however Hess & Neitzel (2011) did not define the equipment used to measure the dose. Of interest was that the article does state that the incident air kerma was measured, which according to a diagram included in this article, is best measured using a dosemeter. Air kerma is the measure of the kinetic energy released in matter (kerma) in the air above the patient, measured in μ Gy. The readings received were then converted into mean absorbed dose (MAD) using specialist software, Monte Carlo, again differing from the other articles.

Beam filtration was used in some of the retrieved studies with the aim to reduce ESD. Although most retrieved studies reported better image quality at a lower kV and removal of filtration, Lehnert (2011) reports a 7.3% ESD reduction with the addition of a 1mm aluminium filter and using 75% of the mAs, however the other retrieved studies do not support this.

2.9.4 Exposure Parameters

As discussed in section 1.2.2, exposure parameters are selected to ensure the correct amount of radiation is used to produce an image of acceptable diagnostic quality. Current practice follows protocols formed by the radiology department, however the basis of the techniques used are widespread throughout the radiography community. From the literature reviewed, it was possible to identify a range of exposure factors that had been evaluated. Aldrich et al (2006) identify a kV range of 70-125 used when imaging their study sample, this was an acceptable range within their study as it examined image quality of the axial skeleton in an adult population. This range was eliminated from this research project, as it is too high for paediatric extremities.

Focus was then directed to those pieces of literature that investigated the paediatric population to identify relevant exposure parameters. Hess & Neitzel (2012) used five kV settings (40, 44, 50, 57 and 66), they used a simulation programme to calculate the appropriate mAs to use to maintain a constant patient dose, this was not documented. Similarly, Jones et al (2014) used a kV range of 40-64.5 with a corresponding mAs range of 0.5-3.6, however the exact exposure combinations were not identified in the article.

The most explicit explanation of exposure parameters found to be clinically justified were detailed in the study by Knight (2014). Only the new, low kV exposure parameters were detailed in the within the article, however this was particularly informative in terms of kV and mAs combinations that have resulted in positive outcomes for paediatric extremities. The kV range used by Knight (2014) spanned 40-66 with the higher end being applicable for adult sized patients, and the mAs range spanned 1.6-4, which agrees with low kV imaging techniques recommended by manufacturers.

2.9.5 Image Quality

Image quality can be subjective, and in some radiology departments imaging protocols are derived from the viewing preferences of radiologists. This impacts on external validity of all research projects conducted in the clinical environment as the same preferences may not apply elsewhere. The study by Hayre (2016), described how radiographers are worried about criticism for poor image quality and are therefore increasing the exposure factors (especially the kV) used to create a sharper image. Interestingly, image quality were assessed by radiologists and reporting radiographers in all but one study (Hess & Neitzel 2012), as this was a laboratory based study which used the contrast-to-noise (CNR) ratio which was determined from the mean standard deviation of the pixel values within the digital image. It was within this study that a 42% increase in CNR was reported *"without dose penalty"*, indicating image quality can be improved without an increase in patient dose.

The use of data collection during clinical practice was undertaken in two of the studies. Aldrich et al (2006) used an unspecified number of radiologists to evaluate the images. This is likely due to data collection taking place during clinical practice and so patient pathways were not disrupted. This study concluded that noise within the images was reduced by increasing the patient dose when imaging the axial skeleton on DR systems. Aldrich et al (2006) states that *"all images were of diagnostic quality"*, however no statistical evidence is apparent for the evaluation of image quality, suggesting objective data are presented indicative of image quality.

Direct communication with Knight (2014) clarified that radiologist feedback was obtained to assess image quality within the scientific experiments undertaken. They looked specifically at the signal-to-noise ratio (SNR), but admitted that evaluating the CNR would have been more beneficial to clinical practice. It was communicated that the image contrast was monitored throughout, and when this was deemed undiagnostic the exposure parameters were not altered past this point. Knight (2014) reports an increase in image quality when using a lower kV, which concurs with Hess & Neitzel (2011).

When using several radiologists to score a selection of images there is the possibility that the results are not consistent. To overcome this Lehnert et al (2011) uses an intraclass correlation (ICC) (type is not defined within literature) to determine whether there is statistically significant agreement between the results. As the current research project used three consultant radiologists to assess the image quality the reliability between the raters must be assessed. ICC was used within this research project to assess the reliability between x-ray exposures, however, the use of non-parametric statistical tests (Section3.6.2) was deemed more relevant. Lehnert et al (2011) allowed the radiologists to window the images to gain optimal viewing conditions. This research project sets guidelines for the radiologists to ensure equality in image viewing conditions as only a single test tool image was viewed and not clinical images (Section3.3.4).

Arguably, all studies in the review found image quality, mainly image contrast, could be improved when using a lower kV and removing the additional beam filtration. However, these results are seldom coupled with the dose implications and although both are discussed the trade-off between dose and image quality is not identified. Absence of certain factors also impact of the external validity of these articles. Hess & Neitzel (2011) identified that the kV levels that were used for evaluation but do not state the mAs setting that were selected. Additionally, Knight (2014) provided a comprehensive list of the exposure parameters now used within their department following the experiments being carried out. The exposure parameters selected for this research project will reflect what has been gathered (Table 10) from the data in these studies as well as current Trust protocols (Section 3.3.3).

2.10 <u>Summary</u>

Following the literature review, search and critique it became apparent that although some literature exists to determine the effects of altering exposure parameters on image quality, there were a lot of factors which have contributed to the lack of change in clinical practice. The need for specific dose implications relating to the paediatric patient population would better inform practice and allow for informed protocol amendments. While the patient population of two studies (Aldrich et al, 2006, Lehnert, 2011) do not match that under consideration in this research project, the experimental methods and data collection tools can be applied and manipulated to fit with a paediatric population. The need to compare the two styles of DR systems has also been highlighted, as there is currently no evidence of this within literature.

Chapter 3 - Methodology

The previous chapter detailed the literature review, search and critique conducted around the research topic. This chapter outlines how that study was conducted to meet the research aim and objectives detailed in Chapter 1.

3.1 <u>Underpinning Methodology</u>

It was important to first identify the paradigm in which this research project sat, forming a foundation for the processes that were undertaken. A paradigm is made up of a researchers' beliefs which can be divided into the categories detailed below:

- Ontology what constitutes reality? Is there only a single truth or are there several truths created by individuals?
- Epistemology how is knowledge created and found? Can it be measured or does it need to be interpreted?
- Methodology how will this be found out?
- Methods what techniques are used to collect and analyse the data?

Creating clarification on the researchers' ontology and epistemology allowed for the methodological strategies of this research project to be devised (Scotland 2012). The components detailed below are indicative that this research project lies within the positivism paradigm (Patel 2015):

Ontology

The laws of physics have not changed (Knight 2014). The researcher believed that there is only one reality that relates to the objectives of this research project, meaning there can only be one conclusive truth from the data. The data cannot be changed by individual creation.

Epistemology

Through accumulation of the researcher's experience and evidence review, the best way to create the knowledge detailed by the research objectives in Section 1.1.3, was to measure the radiation output and image quality of both pieces of equipment. The numerical data would not require interpretation, but rather statistical analysis.

Methodology

The researcher planned to undertake experimental research to investigate the research hypotheses for both radiation dose and image quality.

Methods

As the researcher planned to measure the radiation dose output and the image quality using a numerical scoring system a quantitative design was appropriate which led to the need for statistical analysis of the results.

Following identification of the positivism paradigm and the need to collect numerical, experimental data regarding radiation dose to enhance current literature supports the need for this research project to be of a quantitative design. A previous study undertaken within the constructivist paradigm used an ethnographic methodology gained views and opinions of radiographers regarding manipulating exposure factors in line with the development of technology (Hayre, 2015). Studies of a similar nature that have been carried out in this field make use of the positivism paradigm, undertaking quantitative, experimental designs to draw conclusion on radiation dose and image quality (e.g. Knight 2014; Hess & Neitzel 2012).

When equipment is installed into radiology departments there is a certain amount of personalisation such as, image processing software and system applications. Furthermore, some departments require paediatric specific software. This makes it very difficult to generalise the results between departments or manufacturers causing limitations in terms of dissemination, however the methods used in this research project will inform further investigation. Due to this an experimental design evaluating local practice was conducted to evaluate the current protocols in place within the researchers Trust, using the equipment available. Whilst arguably small this was important as dissemination of the experimental techniques will allow other departments to be informed about the processes that resulted in the conclusions met by this project, which will inform further evaluations to improve patient imaging pathways on a local level.

3.2 Ethics

Ethical approval was granted from Coventry University via the CU Ethics online system, (Appendix 5). This system allows for a controlled process of review and authorisation of research projects, taking into account the risk factors perceived (Coventry University 2009). As no patient participation was required and an evaluation of current practice was undertaken, full ethical approval from the Health Research Authority (HRA) was not required. Three consultant Radiologists were recruited within the study as assessors of image quality. This was ethically assessed by CU Ethics and the Trust Research & Development (R&D) approval department where the research project was carried out. Approval was gained from the R&D department within the Trust in which the experiments were carried out. A protocol was devised detailing the nature of the research project, (Appendix 6), and reviewed by the R&D department before approval was given, (Appendix 7). A letter of access was also obtained by the Radiology Department Manager approving access to the department and use of the equipment for the purpose of completing this research project. Within this letter stated the researchers' competencies and training records were up to date with regards to using the equipment, see Appendix 8.

3.2.1 Recruitment

To ensure image quality was optimised for better patient outcome three consultant radiologists were recruited into the study to score a set of quality assurance images. The researcher considered the following criteria for participation:

- Consultant radiologist currently in post at the investigators Trust
- One years' experience as a consultant radiologist at the time of image assessment
- Current role requires reporting on paediatric plain film images

As the researcher works within the Trust the experiments were carried out in and already has professional relationships with the radiologists, they were approached via another radiographer who was working within the department. The radiographer was briefed on the research project and asked to distribute the radiologist participation leaflet (Appendix 9), which detailed what would be required of them during the image evaluation process of this research project. Names of the radiologists willing to undertake the image quality assessment were then passed onto the researcher. It was emphasised that participation was not mandatory and their professional capacity would in no way be affected by their response. Unwillingness to participate would not be disclosed to the researcher. Following identification radiologists willing to take part informed consent was gained by the researcher via email confirmation (Appendix 10).

3.3 Equipment Specification

3.3.1 Phantom

A 1cm Perspex patient phantom was used to raise the dosemeter to a height that would mimic the level of a paediatric extremity skin surface giving a reading of the amount of radiation reaching the patients skin surface, as used by Hess & Neitzel (2011). However, the aluminium insert to represent bone is not required as this will not be used to assess image quality.

3.3.2 Imaging Equipment

Two pieces of Direct Radiography (DR) x-ray equipment were used for this evaluation (Table 9). The equipment chosen was supplied by different manufacturers. The source to image-receptor distance (SID) differs between the pieces of equipment due to the placement of the image detector, however the patient remains the same distance from the X-ray source, (Figure 8).

		(DR1 and DR2) specifications		
Equipment	DR1	DR2		
	Philips Digital Diagnost	Siemens Luminos dRf Max		
Detector	SkyPlate – wireless flat panel	Under-couch detector		
	detector			
Detector Material	Caesium Iodide (CsI)	Ceasium Iodide (CsI)		
Detector Size	35cm x 43cm	43cm x 43cm		
Image Matrix	2330 x 2846 pixels	Unavailable from		
		manufacturer		
Pixel Pitch (µm (micro-	148	Unavailable from		
millimetres))		manufacturer		
Image Resolution (Ip/mm	3.38	3.4		
(line pairs per millimetre))				
Installation Year	2016	2010		

 Table 9 Imaging equipment (DR1 and DR2) specifications

Both pieces of equipment have the option to add levels of filtration to the x-ray beam. The materials these filters are made of differ between the two pieces of equipment. DR1 uses a combination of copper and aluminium, whereas DR2 uses copper. Current protocol utilizes these filters, however through communication with the local radiological physics team it was concluded that for this research project no added beam filtration will be used as it is not common place in all radiology departments, especially those not specialised in paediatrics, such as District General Hospitals, so to enhance external validity filtration was removed. Removing the filtration also allowed for the same exposure conditions across both pieces of equipment and allowed for comparison of the results.

Although these differences exist both pieces of equipment are used to gain diagnostic images of paediatric patients using the same techniques in current clinical practice, with DR2 being used for most of the non-accidental imaging (NAI) surveys conducted, requiring a high image quality specification. Equipment selection was made to allow for comparisons to be explored in terms of radiation dose output and image quality.

3.3.3 Exposure Factors

The exposure parameters were selected using a combination of published literature and current clinical practice. The kV settings were chosen to demonstrate a scale between 40kV and 63kV, and using professional knowledge mAs was selected in a corresponding scale to produce images of diagnostic quality. Some kV settings (40kV and 60kV) were repeated with different mAs settings due to differences within published literature and Trust protocol. Table 10 shows the exposure parameters chosen for evaluation and where the figures were sourced.

kV	mAs	SOURCE
40	2.5	Exposure parameters giving highest image quality score, stated by
		Jones et al. (2014)
40	3.1	Exposure parameters selected for hand imaging age 0-3 years by
		Knight (2014)
42	3.1	kV selected for lateral hand imaging age 0-3 years by Knight (2014), 4
		mAs recommended but lower exposure tested.
46	2.5	kV selected for hand imaging age 3-18 years by Knight (2014)
48	2	Exposure parameters selected for wrist imaging age 3-7 years by
		Knight (2014)
50	2	Exposure parameters selected for lateral hand imaging age 3-12
		years and wrist imaging age 8-17 years by Knight (2014)
52	1.4	kV selected for elbow and foot imaging age 3-7 years by Knight
		(2014)
55	1.6	Exposure parameters selected for knee imaging age 0-6 months by
		Knight (2014)
57	1.2	Exposure parameters selected for knee imaging age 6 months – 3
		years by Knight (2014)
60	1	Exposure parameters selected for ankle imaging age 0-2 years, knee
		and lower leg imaging age 0-1 year and wrist imaging age 1-4 years
		as per current Trust protocol
60	0.8	Exposure parameters selected for foot, hand and wrist imaging age 0-
		1 year as per current Trust protocol
63	0.63	Exposure parameters selected for finger imaging age 1-3 years, and
		kV selected for knee imaging age 5-15 years as per current Trust
		protocol

 Table 10: Justification of exposure parameters used

3.3.4 Data Collection

Two strands of data were collected in this study. Firstly, the ESD data was collected using a dosemeter, QUART DidoEASY R. The department currently uses this equipment to carry out the monthly quality assurance program and it is regularly calibrated as per manufacturer guidelines. The ESD output of each set of exposure parameters was measured in micro-Gray (μ Gy) across all exposure parameters, eliminating the need for manual conversions into the same units.

Secondly, the image quality data was collected using the TOR18 Leeds Test Tool (Figure 3), which is used to monitor brightness and contrast level adjustment, resolution and low contrast large detail detectability (Leeds Test Objects 2017). Again, used by the department to carry out the monthly quality assurance program. This tool was placed directly onto the patient phantom in place of the dosemeter and an x-ray image taken at each of the parameters specified in Table 11. It requires the assessor to count the number of circles (contrast) and line pairs (resolution) seen, making it a subjective tool as it is dependent on the eyesight of the assessor, justifying the need to use more than one consultant radiologist who are qualified and experienced to observe subtle changes in image quality in their daily duties. Figure 3 shows how this tool appears as an X-ray image on the Picture Archiving and Communications System (PACS) viewing monitors. Unacceptable image quality would be considered should the score drop more than 20% below the baseline set for that piece of equipment which is defined within the local quality assurance protocol.

Contrast Reso Figure 3 TO

Contrast circles: 18 in total

Resolution line pairs: 21 in total

Figure 3 TOR18 Leeds Test Tool used to assess contrast and resolution

Each of the three radiologists recruited for this study assessed each image on the same PACS monitor, in the same environment. It was not possible to vary the order of the images at the time of data collection due to restrictions on the PACS system, but would be considered in future studies. During image quality data collection the radiologists were allowed to zoom in and out to the same level of the image to better view the line pairs, however adjusting the window level (contrast and brightness) was prohibited as this could not be easily controlled to maintain viewing conditions.

3.4 Pilot Study

Prior to the main research project a pilot study was conducted to eliminate the presence of confounding variables that may have affected the outcome of the main experiment. To inform the design of this research project, order bias was investigated to explore any potential order effect of exposure parameter settings on the output readings. It was hypothesised that no order bias exists, however, no evidence could be found within current literature to support this.

A range of five exposure parameter sets were made over three phases to cover the exposure parameters used in the main experiment. Table 11 shows both the systematic and randomized orders that were undertaken to ensure the radiation dose received by the dosemeter did not differ depending on whether a high kV was used at the start, middle or end of the phase. Each phase was separated by a five-minute cool down period in which the equipment was not used, deemed appropriate by the researcher as it allowed x-ray production to cease and potential contamination of the next phase to be eliminated. The exposure factors were selected using a combination of published literature and current Trust protocol as depicted in Section 3.3.3.

Phase	kV	mAs
1	40	2.5
LOW KV	46	2
TO HIGH	50	1.2
KV	57	1.6
	63	1
2	50	1.2
RANDOM	46	2
ORDER	63	1
	40	2.5
	57	1.6
3	63	1
HIGH KV	57	1.6
TO LOW	50	1.2
KV	46	2
	40	2.5

Table 11 Pilot phases and exposure parameters used to collect ESD output data

3.4.1 Pilot Study Method

The specifications used are detailed in Section 3.3.2. These were set up as they are used in clinical practice, imaged in Figure 4 and Figure 5.

DR1

The Philips Digital Diagnost DR system (DR1) with wireless flat panel detector; *"Pilot study"* was input under the patient registration system, the "Hand – Child" program was selected to ensure an appropriate processing algorithm was used. The algorithm is created by the manufacturers and is specific to this equipment and age of patient. The large SkyPlate was utilized with a 110cm SID as per Trust protocol. All filtration was removed. Figure 4 shows the set-up of the equipment, with the patient phantom and dosemeter placed in the centre of the X-ray field, with the beam collimated to 23cm x 17cm.

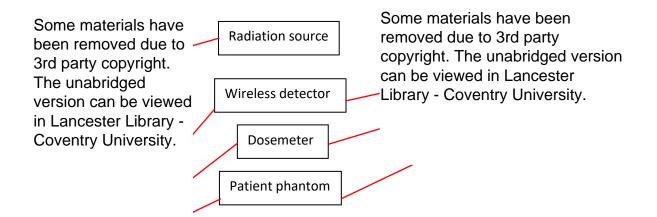


Figure 4 Set-up of DR1 for pilot study phases 1-3

DR2

The Siemens Luminos DR system (DR2) with under-couch detector; *"Pilot study"* was input under the patient registration system, the "Hand – 1-5 years" program was selected to ensure an appropriate processing algorithm was used, again created by the manufacturer. The researcher deemed the "child" program on DR1 to be equivalent of the "1-5years" program on DR2. A 115cm SID was used as per Trust protocol, this is a fixed distance which cannot be reduced due to the design of the equipment. All filtration was removed. Figure 5 shows the set-up of the equipment, with the patient phantom and dosemeter placed in the centre of the X-ray field, with the beam collimated to 23cm x 17cm.

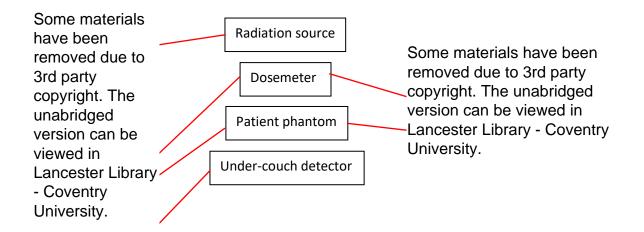


Figure 5 Set-up of DR2 for pilot study phases 1-3

Following set-up, pilot phases 1-3 were carried out on DR1, (Table 11). Three exposures were made for each combination of exposure parameters. The five-minute rest period followed each phase. Phases one to three were then repeated on DR2 incorporating the rest period between each phase.

Both the ESD and Dose-Area Product (DAP) were recorded, and managed in Microsoft Excel. The DAP was recorded as this was identified in literature to be equivalent to ESD when investigating paediatric extremities (Knight 2014). The DAP represents the total amount of radiation the patient receives for that exposure; it provides a general reference and guideline for the radiation risk to the patient but does not define the radiation dose received by the patient to a specific area (Philips 2004) (Section 2.9.1).

3.4.2 Pilot Study Data Analysis

Each exposure combination was completed three times consecutively and intraclass correlation coefficient (ICC) tests were conducted to assess the reliability of ESD readings across the range of exposure parameters (kV and mAs combinations; Table 11). This was initially conducted using the data from DR1 and DR2 combined. Koo and Li (2015) devised a flow diagram to aid selection of appropriate ICC models. Using this flow diagram, (Appendix 11), the two-way mixed ICC model was chosen for this analysis as it is recommended for the test/retest reliability study. SPSS software (version 24) was used to conduct the analysis.

Two further ICC analyses were then carried out to separately examine variability within each piece of DR equipment.

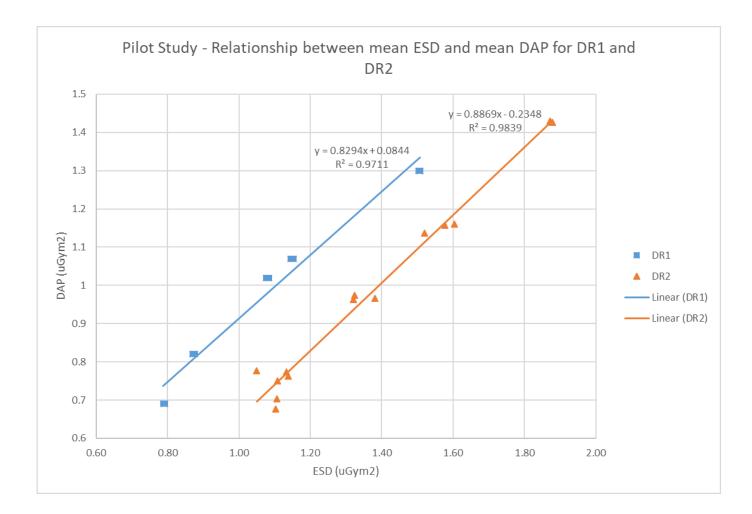
3.4.3 Pilot Study Results

Correlation between the three consecutive exposures was identified (ICC = 0.984, p = 0.0001). Highlighting there is little variability between the ESD outputs of both DR machines over three repeat measures. ICC was then carried out on DR1 (0.999, p=0.0001) and DR2 (0.975, p=0.0001), concluding no order effect exists between the three phases. Justifying the calculation of the mean ESD from triplicate measures for each set of exposure parameters for both DR1 and DR2 (Figure 6).

Table 12 shows the mean ESD and mean DAP data from the pilot study. The mean ESD was calculated from the three consecutive exposures for each set of exposure parameters, and the mean DAP was recorded to enable identification of any relationship between DAP and ESD in clinical practice. A Pearson's correlation coefficient was conducted (Figure 6), showing a positive correlation (p = 0.0001) between the mean ESD and mean DAP of DR1 and DR2 combined, with 77% of the variance in DAP accounted for by ESD ($R^2 = 0.774$). Conducted separately DR2 showed less variance ($R^2 = 0.984$) than DR1 ($R^2 = 0.971$). It is believed that the remaining 23% of unexplained variance is due to two main factors:

- a) DR1 estimates the amount of radiation reaching the patient, using calculations based on the exposure parameters set and the field of view. This method fails to take into account the low energy part of the X-ray beam which does not reach the patient or scatters and is not received by the patient.
- b) DR2 measures the amount of radiation leaving the X-ray tube, but does not take into account the low energy part of the x-ray beam which scatters and does not reach the patient

Figure 6 Pilot Study - Pearson's correlation showing relationship between mean ESD and mean DAP for DR1 and DR2



		P1 (MEAN)			P2 (MEAN)			P3 (MEAN)					
		ESD	DAP	ESD	DAP	ESD	DAP	ESD	DAP	ESD	DAP	ESD	DAP
KV	MAS	DR1	DR1	DR2	DR2	DR1	DR1	DR2	DR2	DR1	DR1	DR2	DR2
		(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)	(µGym²)
40	2.5	0.87	0.82	1.10	0.68	0.79	0.69	1.14	0.76	1.15	1.07	1.52	1.14
46	2.0	1.08	1.02	1.32	0.97	1.08	1.02	1.32	0.96	1.50	1.3	1.87	1.43
50	1.2	0.79	0.69	1.13	0.77	1.15	1.07	1.60	1.16	0.79	0.69	1.05	0.78
57	1.6	1.51	1.3	1.88	1.43	0.87	0.82	1.11	0.75	1.08	1.02	1.38	0.97
63	1.0	1.15	1.07	1.58	1.16	1.51	1.3	1.87	1.43	0.88	0.82	1.11	0.70

Table 12: Pilot Results showing the mean ESD and mean DAP data of both DR1 and DR2

Figure 7 demonstrates the effect that kV has on the ESD over the three phases for both DR1 and DR2. It was observed that similar patterns emerged from both pieces of equipment, although it is noted that the ESD from DR2 is greater than that of DR1, by 30% on average across all exposure combinations. This increase in radiation output for DR2 means that each patient imaged is receiving an average of 30% more radiation to their skin surface per X-ray taken, than if they were to have the same examination conducted on DR1. As the Trust uses very low doses in comparison to other imaging centres this increase is not detrimental to the patients' health, however, it may cause concern should these results become available in the public domain.

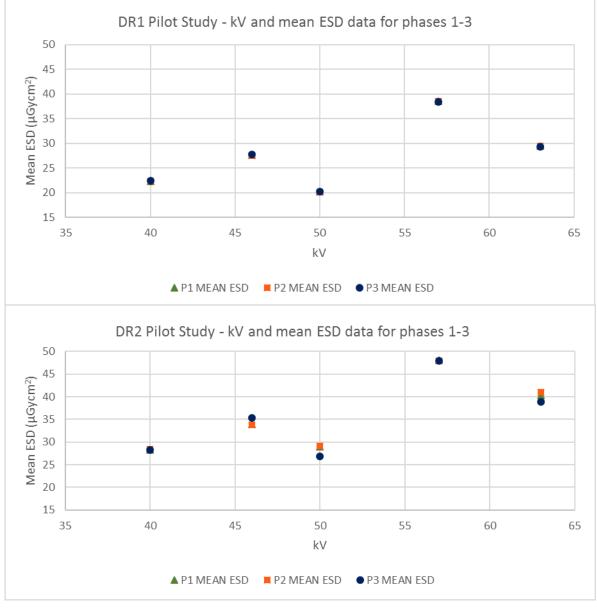


Figure 7 Mean ESD over kV range for DR1 and DR2

3.4.4 Pilot Study Conclusion

From the data collected and the analysis undertaken it was concluded that no order effect exists over the range of exposure parameters applied. This informed the main research project as the exposures could be carried out in an order preferable to the researcher.

The 30% difference in ESD from both pieces of equipment was noted and would be investigated further in the main research project over a wider range of exposure parameters.

The relationship between the mean ESD and mean DAP provides a good guideline for the approximate radiation dose received by the patient in clinical practice, however it was not deemed accurate enough to be used as a tool to collect dose data by the researcher for this research project as only 77% of change in DAP is accounted for by change in ESD.

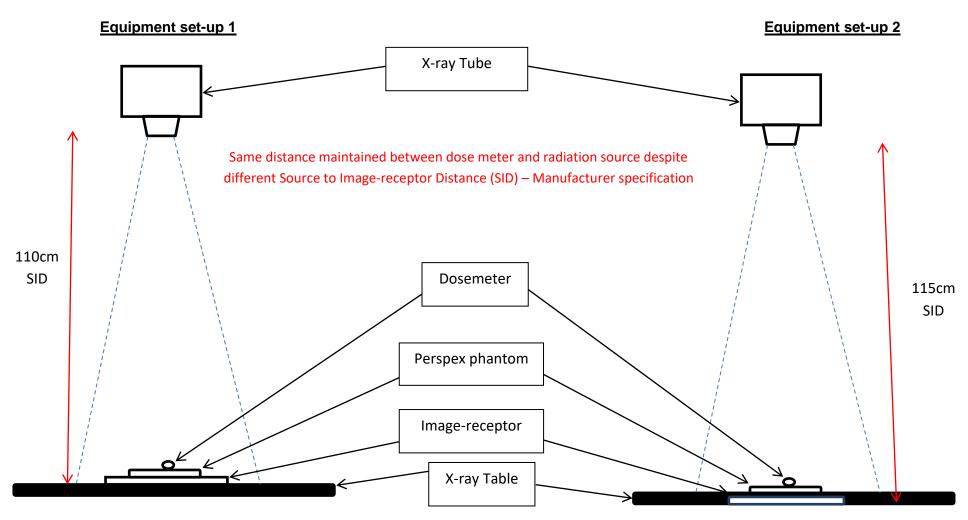
3.5 Research Project Design

The research question and hypotheses of this proposal are a good fit to a quantitative design, (see Section 3.1). The need to collect numerical, experimental data regarding radiation dose to enhance current literature excludes a qualitative design. A quantitative design also fits well to the image quality analysis aspect to this research project, allowing for a numerical scoring system to be used.

The two pieces of equipment detailed in Section 3.3.2 were set-up as similarly as possible, (Figure 8). The diagram demonstrates the positioning of the equipment as well as the differences mentioned in Section 3.3.2, such as the position of the imaging detector and the consequent SID. This set-up was identical to that used in the pilot study explained in Section 3.4.

Twelve (n=12) exposure parameters were selected using evidence from published literature and current Trust protocol, further explanation of this can be found in Section 3.3.3. Each combination of exposure parameters (kV and mAs) were repeated three times and the mean calculated as per the pilot study (see Section 3.4).

The dosemeter was then replaced by the TOR18 image quality testing tool and an image was taken at each exposure parameter combination, bringing the total number of exposures per equipment to 48. These images were numbered with no correlation to the exposure parameters, as a reference to the researcher before being sent to PACS for assessing.



For image quality test: replace dosemeter with TOR18 Image quality test tool

Figure 8 Main research project equipment set-up diagram

3.6 Data Analysis

SPSS (Version 24) statistical software was utilised for the statistical analysis of the results from the project, these are outlined below in Sections 3.6.1 and 3.6.2.

The researcher used visual analysis of the data before embarking on statistical analysis. This allowed the presence of patterns within the data to be identified by plotting the means of the data onto scatter graphs created in Microsoft Excel. Plotting the means of the data ensured clarity of the graphs, if the raw data were plotted there would be too many data points which would cause confusion. This made it possible to place the data from the two pieces of equipment on the same graph and identify any differences or similarities that existed.

3.6.1 Entrance Skin Dose

The experiment design required three exposures to be taken consecutively at each exposure parameter set to ensure reliability of ESD output measurements. The pilot study detailed in Section 3.6 used intraclass correlation coefficients (ICC) tests to confirm that there was little variability in these output measurements. This allowed for the mean ESD to be calculated for each exposure parameter set which was used for the data analysis.

A paired *t*-test was conducted to compare the mean ESD results of DR1 against DR2 and establish whether there was a statistically significant difference between the pieces of equipment. The 2-tailed *t*-test was chosen as the hypothesis for this research project did not state whether one piece of equipment would produce a higher ESD than the other.

3.6.2 Image Quality

Standard deviation between the three radiologists scores was calculated to determine the variation between scores. The lower the standard deviation, the less variation existed between the radiologist scores. Inter-rater reliability was tested initially using the Friedman Test to identify whether difference between raters existed. A Wilcoxon test was then performed to find between which raters the difference occurred.

Non-parametric statistical testing was required for the image quality analysis as interval data was collected and so the equivalent of the paired *t*-test was utilized; the Wilcoxon Test. The raw data was analysed using this method to compare the scores from DR1 and DR2, again the *p*-value would suggest whether statistical significance exists.

Analysing both ESD and image quality in the ways described above allow for comparisons to be made between the pieces of equipment with statistical significance to support the

researcher's conclusions. Chapter 4 will illustrate the results achieved from the experiments detailed in this Chapter.

Chapter 4 – Results

The previous chapter detailed the methods used for this investigation. This chapter will communicate the results. It is important to note that all image quality results were within safe limits as per the Trust quality assurance protocol.

4.1 Data Overview

Table 13 demonstrates the mean ESD, as justified in the pilot study, contrast and resolution data collected for both DR1 and DR2.

The mean ESD was calculated and deemed appropriate to use within the data analysis as the results from the pilot study showed agreement (Section 3.4).

With reference to Table 13, DR1 produced a lower mean ESD in comparison to DR2, alongside higher contrast and resolution scores.

ĸv	MAS	MEAN ESD (μGycm²)		MEAN CO	NTRAST	MEAN RESOLUTION		
		DR1	DR2	DR1	DR2	DR1	DR2	
40	2.5	22.35 ^{±0.18}	28.19 ^{±0.16}	16 ±0	15 ±1	18 ±1	16 ±0	
40	3.1	27.85 ^{±0.15}	35.88 ^{±0.15}	16 ±0	15 ±0	17 ±0	16 ±0	
42	3.1	32.81 ^{±0.39}	41.58 ^{±0.33}	16 ±1	15 ±0	17 ±1	16 ±1	
46	2.5	34.73 ^{±0.40}	42.13 ^{±0.17}	16 ±0	15 ±0	16 ±1	16 ±1	
48	2	30.95 ^{±0.32}	38.32 ^{±0.52}	16 ±0	15 ±0	18 ±2	16 ±0	
50	2	34.81 ^{±0.37}	42.41 ^{±0.30}	16 ±0	15 ±0	18 ±1	16 ±1	
52	1.6	31.44 ^{±0.10}	39.04 ^{±1.64}	16 ±0	15 ±1	16 ±1	16 ±0	
55	1.4	32.10 ^{±0.06}	38.38 ^{±0.23}	16 ±0	15 ±0	18 ±1	16 ±1	
57	1.2	28.33 ^{±0.29}	37.59 ^{±0.07}	16 ±0	15 ±0	18 ±1	16 ±1	
60	1	26.26 ^{±0.03}	34.08 ^{±0.17}	16 ±0	15 ±0	18 ±1	16 ±0	
60	0.8	20.65 ^{±0.30}	28.27 ^{±1.72}	16 ±1	15 ±1	18 ±1	16 ±1	
63	0.63	16.20 ^{±0.03}	24.64 ^{±0.37}	16 ±0	15 ±1	19 ±1	16 ^{±1}	

Table 13 Mean ±SD ESD and image quality (contrast and resolution), for DR1 and DR2

4.2 Entrance Skin Dose (ESD)

As with the pilot study analysis (Section 3.4.2) a scatter plot was produced to enable visual assessment of the effect that the kV had on the ESD (Figure 9), and whether the resultant pattern was as predicted in the hypotheses detailed in Section 1.1.3. Both the mean ESD data from DR1 and DR2 were plotted for direct comparison.

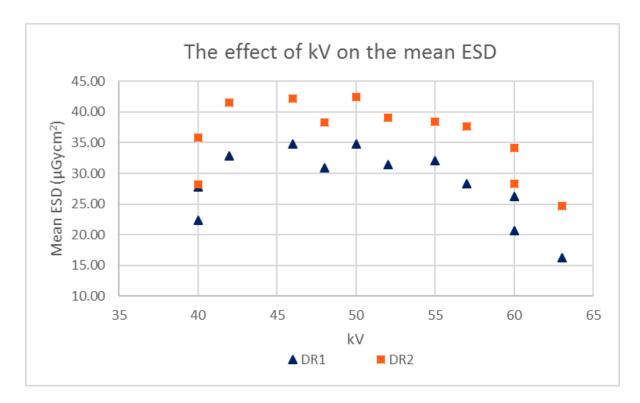


Figure 9 Scatter graph showing how the kV effected the mean ESD for DR1 and DR2

Figure 9 shows that both DR1 and DR2 follow the same pattern of ESD over the range of kV parameters selected. From the lowest point on the graph (63kV) the ESD increased steadily as the kV was reduced until 55kV where the ESD levelled, before dropping down again at 40kV.

Figure 10 shows the pattern created by the mAs data. In comparison to the kV data (Figure 9) there is a gradual positive gradient until 1.5mAs where the points level out. It is assumed that the low point illustrated at 2.5mAs, for both DR1 and DR2, is the result from the 40kV and 2.5mAs combination of exposure parameters which is aligned to Figure 9 also with the lowest point plotted at 40kV.

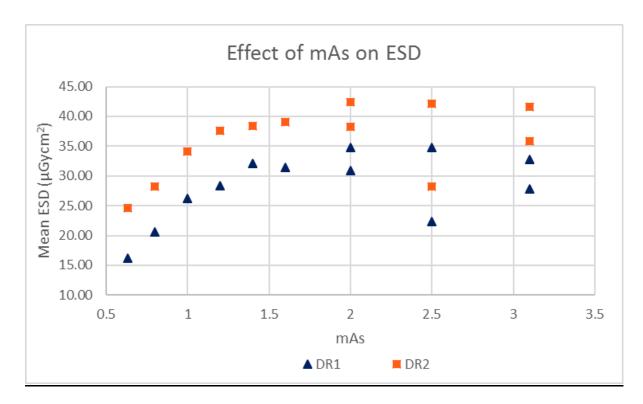


Figure 10 Scatter graph showing how the mAs effected the mean ESD on DR1 and DR2

Following visual analysis of Figure 9 and Figure 10, the lowest mean ESD (63kV and 0.63 mAs) and the highest ESD (50 kV and 2 mAs) on both DR1 and DR2 were identified.

DR2 produced a higher (by an average of 29%) ESD at each kV value compared with DR1 (p=0.0001), concurring with the pilot study which was calculated at 30%. Table 14 shows the output differences between DR1 and DR2 for the exposure parameters used, it is observed that the largest difference (52%) between radiation outputs occurs at 60kV and 0.63mAs.

KV	MAS	%
		DIFFERENCE
40	2.50	26%
40	3.10	29%
42	3.10	27%
46	2.50	21%
48	2.00	24%
50	2.00	22%
52	1.60	24%
55	1.40	20%
57	1.20	33%
60	1.00	30%
60	0.80	37%
63	0.63	52%

Table 14 Percentage ESD output difference between DR1 and DR2

4.3 Image Quality

All images were scored as being clinically acceptable for both contrast and resolution by each of the three clinical assessors. Mean \pm SD values are reported in Table 13.

4.3.1 Contrast

Friedman analysis indicated that contrast scores did not vary between observers for DR1 (p = 1.000), whereas contrast did vary (p=0.039) between observers for DR2. Subsequent Wilcoxon tests revealed that this difference for DR2 existed between observers 1 and 3 (p=0.046). However, this was the result of only four out of twelve contrast scores being different between these two observers, with observer 3 scoring the image one point higher for contrast on each occasion.

DR1 consistently scored higher for each contrast assessment than DR2 (p=0.0001). It was noticed that not all points on the graphs (Figure 11(a) and 11(b)) were visible, this is due to overlap of the points at the same kV and mAs being given the same score. On both pieces of equipment, the lowest contrast scores were given at 60kV and at 0.8mAs.

Figure 11(a) illustrates that the effect of kV on the image contrast, with a range of two contrast score points including the highest (DR1 = 42kV, DR2 = 40kV) and lowest (DR1 = 60kV, DR2 = 52kV, 60kV and 63kV) image contrast scores. Figure 11(b) shows the effect that the mAs has on the contrast score points including the highest (DR1 = 3.1mAs, DR2 = 2.5mAs) and the lowest (DR1 = 0.63mAs, DR2 = 0.63mAs, 0.8mAs and 1.6mAs) contrast scores.

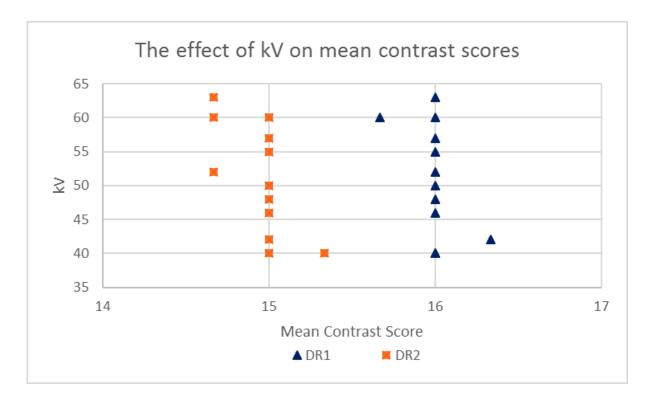


Figure 11(a) Scatter graph showing the effect of kV on the mean contrast scores for DR1 and DR2

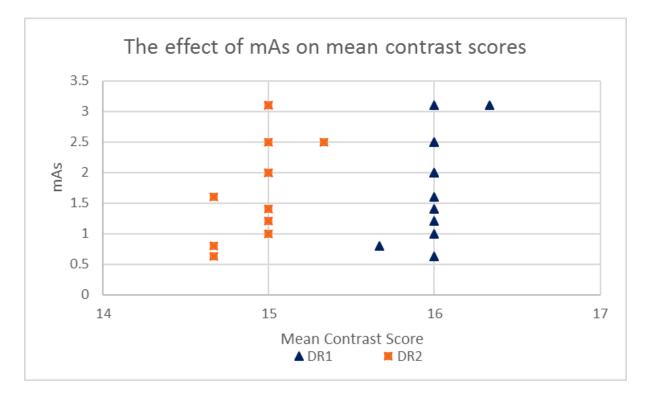


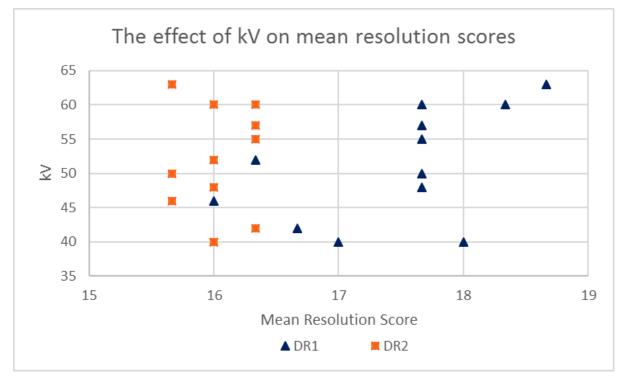
Figure 11(b) Scatter graph showing the effect of mAs on the mean contrast scores for DR1 and DR2

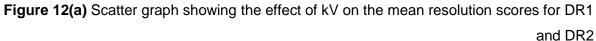
4.3.2 Resolution

Friedman analysis indicated that the resolution scores varied between observers for DR1 (p = 0.021), and DR2 (p=0.066). A Wilcoxon test revealed that the difference identified for DR1 was between observers 2 and 3 (p=0.013), this result is due to only two of the twelve scores being the same, with observer 3 scoring lower than observer 2 in most cases. For DR2 the Wilcoxon test identified a difference of borderline significance between observers 1 and 3 (p=0.059). On inspection of these results, differences exist in seven of the twelve cases with observer 3 scoring lower than observer 1 on six of these occasions.

For DR1 the exposure parameters 46kV and 2.5mAs were clearly identified as producing the lowest resolution scores. There was no clear exposure parameter set in the case of DR2, with 63kV / 0.63mAs, 50kV / 2mAs and 46kV / 2.5mAs producing the lowest scores. It was identified that DR1 scored consistently higher for resolution than DR2 (p = 0.0001).

Similarly, the results plotted in Figure 12 show the consistent higher scoring of DR1 over DR2 but this time looks at the effect of kV and mAs respectively on the resolution scores. The range of scores for a given kV is greater for DR1 than DR2 thus indicating that altering kV has a greater effect on the resolution produced by DR1 (Figure 12a). Likewise, Figure 12(b), demonstrates that altering the mAs also has a greater effect on the scores given for resolution on DR1.





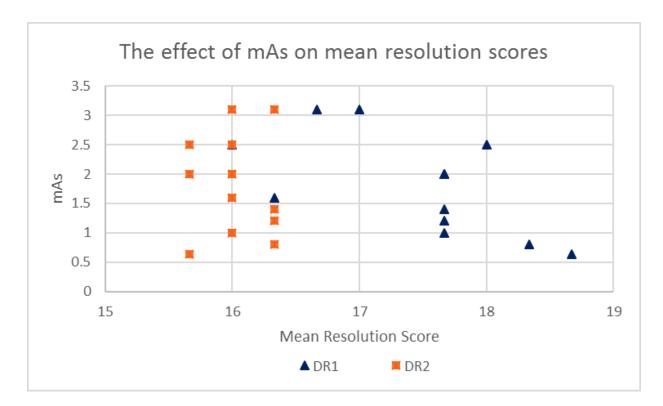


Figure 12(b) Scatter graph showing the effect of mAs on the mean resolution scores for DR1 and DR2

4.4 Summary of Results

Table 15 details at which exposure parameters the highest and lowest contrast scores occurred for both DR1 and DR2.

 Table 15 Summary of exposure parameters producing highest and lowest contrast scores

 for DR1 and DR2

Equipment	Highest Contrast Score	Lowest Contrast Score
DR1	42kV / 3.1mAs	60kV / 0.8mAs
DR2	40kV / 2.5mAs	52kV / 1.6mAs
		60kV / 0.8mAs
		63kV / 0.63mAs

Table 16 shows the exposure parameters at which the highest and lowest resolution scores occurred for both DR1 and DR2.

 Table 16 Summary of exposure parameters producing highest and lowest resolution scores

 for DR1 and DR2

Equipment	Highest Resolution Score	Lowest Resolution Score
DR1	63kV / 0.63mAs	60kV / 0.8mAs
DR2	42kV / 3.1mAs	46kV / 2.5mAs
	55kV / 1.4mAs	50kV / 2mAs
	57kV / 1.2mAs	63kV / 0.63mAs
	60kV / 0.8mAs	

The results illustrate that for DR1 the lowest ESD can be achieved at 63kV / 0.63mAs (Table 13). This combination of exposure parameters produced the highest resolution score (mean = 19), however contrast was reported to be better at 42kV / 3.1mAs (Mean = 17). The highest ESD was reported at 50kV / 2mAs, with the lowest contrast score occurring at 60kV / 0.8mAs (Mean = 16) and lowest resolution score at 60kV / 0.8mAs (Mean = 18).

DR2 concurs that the lowest ESD can be achieved at 63kV / 0.63mAs (Table 13), however this combination of exposure parameters scored within the lowest range for contrast and resolution. The highest contrast was reported at 40kV / 2.5mAs (Mean = 15) and the highest resolution was identified across a range of exposure parameters. Again, the highest ESD was seen at 50kV / 2mAs, which was included within the range of lowest scores for resolution.

For both DR1 and DR2 it is worth noting that the image quality results given by the radiologists were not distinctly different between the exposure parameters tested. The image quality differences recorded may be a product of image noise, an irregular granular pattern on the image which degrades the quality. Noise occurs when too few x-ray photons reach the image detector. Increasing the mAs is said to decrease the level of noise visible on an X-ray image, however mAs is directly linked to patient dose, and so increasing the mAs would increase the patient dose. It is necessary to establish the correct balance between image quality and patient dose to ensure an effective diagnostic imaging service (Reddy et al, no date).

In summary, the data from DR1 and DR2 has shown that a lower kV range combined with a high mAs range produced optimum image contrast. The data from the resolution scores lacks the same clarity and results differ between DR1 and DR2, and both DR1 and DR2 provide ESD outputs of the same pattern, with a high kV and low mAs producing lowest ESD.

Chapter 5 - Discussion

Exposure to excessive amounts of radiation can have detrimental effect on a persons' health. The extent of this effect is dependent upon the amount of radiation received and the sensitivity of the organs exposed to the X-rays (WHO 2016). Paediatric patients have an increased sensitivity to the harmful effects of radiation due to their rapid cell division and longer life expectancy (Jones et al. 2015). Radiographers adhere to the ALARA principle as described in Section 1.1 of this thesis, which aim to minimise the amount of radiation a patient is exposed to when undergoing diagnostic imaging procedures.

This research project was an evaluation of current practice. Aim 1) was to identify which exposure parameters (kV and mAs) produce the lowest ESD whilst maintaining image quality. Additionally, aim 2) was to compare the performance for two DR systems currently in service in the researchers' Trust. This was achieved by performing experiments to collect data that mimicked the ESD a paediatric patient would be exposed to and assessing the image quality over a range of exposure factors on two different machines currently used in clinical practice.

It should be noted that this research project was a local evaluation utilizing local imaging protocols designed by the department alongside kV and mAs combinations investigated in the literature, and results may vary within other radiology departments. This could be due to different equipment manufacturers, image detector material, additional filtration used, image processing algorithms or the clinical/diagnostic requirements of the image.

The following Sections will discuss the results illustrated in Chapter 4 and examine the findings with reference to the literature appraised in Chapter 2.

5.1 Entrance Skin Dose

As described in Section 1.2.4, there are currently no nationally recognised Dose Reference Levels (DRL's) for paediatric X-ray imaging, resulting in no guidelines on acceptable dose limits of paediatric examinations (Public Health England 2016). Due to this, defining what is an acceptable increase is commonly the role of the individual department and local physics team.

Figure 9 demonstrates that the lowest ESD could be achieved when using a higher kV (63), supporting current protocol used within the researchers Trust (Table 11). Hypotheses 1 (Section 1.1.4) proposed that as the kV was decreased, the ESD would increase. Although the lowest ESD was seen at the highest kV the results did not show the linear increase in ESD predicted, and the highest ESD was seen in the mid-range of kV's used (50kV). Knight

(2014), concluded that the patient dose could be lowered or maintained when using a low kV and high mAs combination of exposure parameters, here the dose was compared between Computed Radiography (CR) and DR, which this research project did not investigate. Knight (2014) did not demonstrate reduction in patient ESD seen between the high kV, low mAs and the low kV, high mAs combinations. The results of this clinical evaluation showed a slight increase in ESD when using a low kV and high mAs but one that could be clinically justified should a higher level of diagnostic image quality be required for diagnosis, which is discussed further in Section 5.2.

Within the study by Knight (2014), it was stated that DAP is directly proportional to ESD in the case of paediatric extremity imaging. This was investigated as part of the initial pilot study to understand whether a relationship exists, (Section 3.4), as no literature could be found to support this claim. Using Pearson's correlation, it was observed that 77% change in DAP was accounted for by a change in ESD when imaging paediatric extremities (Section 3.4.3). DAP is a useful reference within clinical practice, although it must be considered that a DAP meter measures the amount of radiation dispelled from the X-ray tube, not the exact amount of radiation received by the patient (Anon 2001). Therefore, it is reasonable for DAP to be used as a guideline of ESD received by paediatric patients undergoing extremity imaging during clinical practice. A more accurate tool for measuring patient dose is required to validate claims of dose reduction, as seen in the studies by Jones et al (2015) and Aldrich et al (2006).

Drawing on the evidence and experience of the researcher it is felt that this study is the only one conducted to directly compare two styles of DR equipment directly. Whilst small this is therefore an important contribution to the field. Studies identified within the literature referred to CR and film-screen imaging as references for their claims of dose reduction and improved image quality. For example, Aldrich et al (2006) directly compared film-screen imaging, CR and DR in terms of effective dose received by the patient when undergoing imaging of their chest, abdomen and pelvis. Effective doses refer to the amount of dose received by the patient, this requires specific software for it to be calculated. CR is an older technology in which the image receptor requires a certain radiation dose to produce an image, DR does not as it is more sensitive (Section 1.2.4).

The results of this research project indicate a radiation dose output increase of 20-52% (mean difference of 29%) when using DR2 compared to DR1 (Table 14), which was also demonstrated during the pilot study where a 30% mean difference in radiation output when using DR2 over the same exposure parameters. Current imaging protocols within the Trust evaluated within this research project utilize a high kV, low mAs technique to achieve

diagnostic images on paediatric patients. It was at this combination of exposure parameters that the highest difference (52%) was observed between DR1 and DR2 (Table 14). Therefore, patients being imaged on DR2 using the current image protocols are receiving a 52% higher ESD than those patients being imaged on DR1. This has been communicated to the department who are due to carry out an investigation. A difference in radiation output was not identified during the literature review as comparisons between DR equipment design had not been made, illustrating the benefit of completing this project. Creating awareness for radiology departments and allowing formulation of appropriate imaging protocols using the methods demonstrated in this research project.

5.2 Image Quality

Statements were made within several pieces of the literature that image quality could be greatly increased when using a low kV and high mAs combination of exposure parameters on DR systems to produce images (Hess & Neitzel 2012; Jones et al. 2015; Knight 2014). The results of this research project have not demonstrated this dramatic increase in the image quality, this may be due to the results not being compared to CR or film-screen imaging. The results of the current study show little difference between the scores given by the assessors, this could be due to several factors including the image quality measuring tool chosen for this research project, or the image processing software installed on the equipment compensating for the differences in the exposures. Further investigation could see evaluation of contrast-to-noise ratio (CNR) which is far less subjective than the TOR18 test tool and eliminates the need for assessors. CNR was used as the image quality assessment tool by Hess & Neitzel (2012) and Jones et al (2015), which is an objective measure for assessing the amount of contrast observed between structures of an image to determine it clinical usefulness (Seibert n.d.). Excessive amounts of noise on an image degrade the visibility of structures, this is especially apparent on low dose images as not enough x-ray photons reach the image detector. Optimal image quality is achieved when the correct levels of both contrast and noise are achieved (Huda & Abrahams. 2015), which can be measured using CNR, this was not investigated within this small study. One drawback of using the CNR as an assessment tool is that its calculation depends upon the dynamic range of the detector and the processing of the raw data by the manufacturer, producing a relative quantity which is only significant when comparing with values from the same equipment (Oberhofer et al. 2009). This made it unsuitable for this research project as no direct comparison between DR1 and DR2 would be possible, due to the different manufacturers and design. Knight (2014) did not use a tool to assess image quality as the primary focus of the study was the impact on patient dose. Images of a phantom were taken and radiologists were asked to rate which images they deemed acceptable, the methods

were not detailed within the literature, however it was concluded that image quality for some extremity images could be improved when a low kV, high mAs combination of exposure parameters was used. The current study saw an increase in image contrast when using this combination of exposure parameters which is in agreement with Knight's (2014) study.

Lehnert et al (2011) considered the possibility of memory effect of the assessors during their image quality analysis. This was something conveyed to the researcher at the time of data collection which may have impacted on the sensitivity of the contrast and resolution scores. As all the images were of the same object in the same position, it was possible to imagine where another circle may appear and count this as part of the score. Using breaks between sets of images or extreme exposures would aid in reducing this, however due to the time constraints of this project it was not possible to repeat image quality evaluation.

Hypothesis 3 (Section 1.14) stated that *"When set with identical exposure parameters DR1 and DR2 will deliver equivalent IQ"*. From the results illustrated in Section 4.3, DR1 scored consistently higher than DR2 on all images over all exposure parameters for both contrast and resolution, refuting hypothesis 3. The differences could potentially be attributed to the age of the equipment, DR2 was installed in 2010, whereas DR1 was installed in 2016 and therefore boasts the more up to date image processing software. Another factor could be the placement of the imaging detector, in DR2 this is situated beneath the table, which means the X-ray photons must pass through the patient and the table before reaching the detector; Compared with DR1 where the detector is situated directly underneath the patient with no extra material for the X-ray photons to pass through. Two of the three radiologists assessing image quality preferred the visual appearance of the images from DR1, stating they were more *"pleasing to the eye"*, whereas the one radiologist preferred the visual appearance of the DR2 images, however this was not reflected in their scores.

Although statistical analysis showed significant differences between the scores of the three radiologists, the real-world significance is not detrimental to the overall image quality produced by either DR1 or DR2. The largest standard deviation occurred in the contrast scores (SD= \pm 2), which in clinical evaluation is equal to two of the eighteen circles on the TOR18 test tool. Resolution saw a standard deviation of (SD= \pm 1) which is equivalent to one set of line pairs out of twenty-one.

5.2.1 Contrast

Due to the developing skeleton of the paediatric patient the amount of inherent contrast is reduced compared to adults. This can cause difficulty in reporting diagnostic images where clinically significant details may be lost if the incorrect exposure parameters are used (Jones

et al, 2015). The contrast of an image is the ability to differentiate between two different anatomical structures, for example bone against muscle. The better the contrast of an image, the easier this differentiation is, as shown in Figure 3 where the small circles around the perimeter show the difference in contrast.

For both DR1 and DR2, the contrast scores were consistent for each piece of equipment when plotted against both the kV and mAs (Figure 11(a) and 11(b)), with DR1 most commonly scoring 16 out of 18 and DR2 scoring 15 out of 18. The reason for this consistency may be due to the memory effect as discussed previously. The range of exposure parameters used in this research project was similar to that used by Hess & Neitzel (2011), where it was concluded that image quality (measured as CNR) can be improved for paediatric extremity imaging when using 40kV – the mAs used was not specified. As stated in Section 4.3 the contrast was scored better at a low kV and high mAs combination (42/3.1) on DR1 by one contrast circle from one of the three observers, compared with the 40kV/2.5mAs combination on DR2, which again was one contrast circle from one of the three observers. This result concurs with the Hess & Neitzel (2011) stating that a low kV improves image contrast on a DR system of the same manufacturer as DR1, although the strength of this conclusion would require further investigation.

5.2.2 Resolution

The paediatric population is generally smaller than the adult population, meaning their internal structures are also smaller. Resolution, also referred to as spatial resolution, on X-ray images is the ability to see small structures side by side, shown in Figure 3, identification of the individual lines within a group is required (Anon 2010). Resolution is directly linked to the speed at which an X-ray is taken, and this is especially applicable in paediatrics where a fast exposure time reduces the appearance of movement artefact on an image (Hardwick & Gyll 2004).

Resolution did not appear to be an assessment factor in any of the studies reviewed within this research project. Jones et al (2014) discusses how image sharpness (resolution) should be a consideration when assessing image quality. It is stated that if local patient immobilization techniques are followed correctly, movement artefact should be minimised on images of paediatrics. As current European guidelines (European Commission 1996), do not define a recommended exposure time for the paediatric extremity, clinical audit would be beneficial in identifying the effect using a longer exposure time in order to increase image quality (low kV, high mAs combination) (Section 1.2.2). Despite this, CNR was assessed to look at the changes in the x-ray beam quality as low contrast was the reason given for loss of diagnostic quality. This alludes to it being the contrast that effects the ability to

diagnostically assess an image rather than the resolution. This could be assessed with the use of clinical images in a future audit.

In comparison to the contrast scores obtained from the radiologists, the resolution scores (Figure 12(a) and 11(b)) were demonstrated across a larger range of scores (DR1 = 16-19 out of 21, DR2 = 15-17 out of 21). This is likely attributed to the assessors' ability to observe small changes on an image, as the spaces line pairs decrease in size reducing the ability to define separate lines, making this test more subjective than the contrast test. The optimum combination of exposure parameters for resolution on DR1 was a high kV and low mAs (63/0.63), which supports current protocols used within the department. However, for DR2 there were four exposures that scored higher than the others for resolution (42/3.1, 55/1.4, 57/1.2 and 60/0.8) not defining whether use of a high or low kV would be beneficial.

5.3 <u>Workforce Education</u>

This research project was devised through clinical practice where workforce education had not occurred alongside technological advancements, and therefore preventing changes in imaging protocols. Hayre (2016) reports the attitudes of radiographers using DR equipment, and found that it was commonplace for radiographers to increase the amount of radiation they expose their patients to achieve acceptable image quality. This was also observed by the researcher in their own Trust prior to commencing the current research project.

Although the benefits of DR imaging have been widely promoted it is likely that these benefits are not being seen in practice as protocols are derived from a combination of the European guidance (European Commission 1996), and radiographer experience for using CR and film-screen. The existing European guidance is based on film-screen imaging utilizing additional filtration and exposure parameters which do not fall below 60kV (Section 1.2.4). This was considered by Jones et al (2014), when investigating how manufacturer algorithms installed on equipment may not be suitable for paediatric imaging and recommending protocols be devised with a multi-disciplinary approach to achieve high quality digital radiographs whilst maintaining ALARA.

In identifying the exposure parameters at which optimum image quality can be achieved at the lowest ESD to the patient, it is predicted that this will lower the number of repeated exposures that will occur due to insufficient image quality, which will in turn reduce patient dose (Jones et al. 2015). It should be emphasized that the use of traditional dose optimization techniques, such as beam collimation and lead protection, should still be utilized to further reduce the radiation dose received by the patient (Knight 2014). Development of

paediatric DRL's would provide limits for safe exposure of paediatrics, and enable concise guidelines to be created for this varied patient group.

5.4 <u>Summary</u>

This research project has compared two different DR systems in terms of ESD and image quality when altering exposure parameters, whereas other literature available in this field have compared DR systems to older technologies (CR and film-screen) to conclude that image quality can be improved at a lower dose to the patient when using a low kV technique. It has been observed that image quality was deemed better on DR1 which utilized a wireless detector placed directly under the patients' extremity, compared with DR2 where the imaging detector is beneath the table. The ESD results show a higher output on DR2 by an average of 30% which will require further investigation on a local level. Although this research project would benefit from further investigation to strengthen the claims, it provides methods of how evaluation can be completed on a local level.

As resolution was not considered as an assessment criteria within other literature, it is believed that it is the contrast scores which apply more relevance to the overall perceived image quality. However, clinical assessment would be required to monitor the impact of image unsharpness should protocols be changed. It has been demonstrated that no large ESD penalty exists when using the low kV, high mAs technique and this also contributes to an improved image contrast on both DR1 and DR2.

This chapter has placed the findings of this research project within the context of the field of literature that currently exists. Protocols should be formed with a multi-disciplinary approach to ensure image quality and patient dose are optimized. Providing adequate education for radiographers on the abilities of DR technology compared to CR and film-screen would inform better exposure parameter selections with no dose penalty to the patient.

Chapter 6 - Conclusion

This research project supports and enhances the body of literature, with findings from an experimental study where the ESD and image quality (contrast and resolution) implications have been investigated for two DR systems within the field of paediatric extremity imaging.

This research project, along with published literature indicates that changing imaging techniques to keep up with technology must occur to provide an optimized imaging service to benefit the paediatric population.

The results identify that the lowest ESD can be achieved when using a high kV, low mAs combination of exposure factors. However, hypothesis 1 (Section 1.1.4) is refuted as the highest ESD was not seen at the lowest kV, highest mAs combination but rather within the mid-range of exposure factors selected. These results were seen on both DR1 and DR2. Through communication with the local physics team the safety of patients is not under threat when altering the exposure parameters from a high kV to a low kV, allowing for safe clinical evaluation to proceed from here.

It was hypothesized (hypothesis 2 - Section 1.1.4) that when the same exposure parameters were selected DR1 and DR2 would deliver equivalent ESD. This is refuted as the results of this study demonstrate that ESD from DR1 was on average 30% lower than that of DR2. Further local investigation is required in conjunction with the local radiation physics team to identify reasons for this. Current considerations include the age of DR2 compared with DR1, configuration of DR2, however, no conclusive reasoning has been discovered at this stage. Hypothesis 3 predicted that the image quality would be equivalent for DR1 and DR2 over the same exposure parameters, this was also refuted with DR2 scoring consistently lower than DR1 for both contrast and resolution, indicating a poorer image quality. As stated previously, all images were deemed within diagnostic limits as per the quality assurance protocol within the Trust.

Hypothesis 4 sought to test whether high kV, low mAs technique would result in a higher image quality score. The highest contrast scores were seen at a low kV, high mAs technique for both DR1 and DR2, resolution however, was scored highest when using a high kV, low mAs technique for DR1. DR2 resulted in no definitive exposure combinations to achieve optimum image resolution. Clinical investigation is required to identify the roles that contrast and resolution play in the overall diagnostic quality of X-rays for paediatric extremities.

The methods used in this research project are easily replicated within other radiology departments, promoting clinical experiments to better understand the equipment.

Dissemination of these methods will inform the workforce and build the confidence of radiographers to be involved with the formulation of protocols.

6.2 Limitations

This research project was a small-scale evaluation of local clinical practice within the researcher's Trust, focussing only on a single area of paediatric anatomy using a patient phantom. The results may not be generalized to other radiology departments; however, the methods can be replicated for local conclusions to be drawn.

The image quality testing tool is one used in quality assurance testing at the researcher's Trust. This tool can be subjective depending on the assessor, and it is also possible for scoring errors to occur when several images of the same tool are viewed, as discussed in Section 5.2, time constraints meant repeating data collection was not possible. The results of this study would benefit from assessment of clinical images to confirm findings.

6.3 <u>Recommendations for Further Research</u>

Further investigation would involve clinical audit to compare image quality and patient dose over the same range of exposure parameters. This has already begun within the Trust that this research has been undertaken. Clinical images that utilized the high kV, low mAs technique have been collected from PACS, along with the exposure information (kV, mAs and DAP) detailed on the radiology information system. The Trust have now changed their imaging protocols so that the low kV, high mAs technique is being used. Clinical images are currently being collected along with the exposure information. It is proposed that once enough data is collected several radiologists will be asked to score the images with no knowledge of which protocol is used. This would produce a more reliable image quality test; however, it was necessary to complete this research project first to understand the radiation dose implications to the patient.

It would also be useful to investigate other areas of anatomy using the audit method detailed above, especially the axial skeleton which is greater in depth and differs in inherent contrast from extremities. This would provide knowledge of the optimum exposure parameters for all areas of anatomy to obtain diagnostic image quality and complete imaging protocols to be devised.

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Appendices