PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS

By

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N Dip Radiography (Diagnostic)

B Tech Radiography (Diagnostic)

A dissertation submitted in fulfilment of the requirement for the degree

MASTER OF RADIOGRAPHY

(DIAGNOSTIC)

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30 JUNE 2022

DECLARATION

I, Olivia Lackay, declare that this thesis entitled **Paediatric chest diagnostic reference levels for three Northern Cape radiology departments**, which I hereby submit for the degree, Master in Radiography (Diagnostic), at the Central University of Technology, Free State, is my own work. I also declare that this thesis has not previously been submitted by me for a degree at this or any other tertiary institution. Where help was sought, it was acknowledged. All the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

… … 30 June 2022

Mrs Olivia Lilian Lackay **Date**

DEDICATION

I dedicate this dissertation to my husband, Julian, and two kids, Samson and Isabel.

I also dedicate this dissertation to God, our Heavenly Father, for being by my side every step of the way.

ACKNOWLEDGEMENTS

I wish to express my sincere thanks and appreciation to the following:

- My supervisors, Dr Je'nine Horn-Lodewyk, and Dr Henra Muller of the Department of Clinical Sciences, Faculty of Health and Environmental Sciences, Central University of Technology, Free State, for their incredible support, expert supervision and patience and for allowing me this wonderful opportunity and experience of learning and obtaining valuable knowledge.
- The Central University of Technology, Free State, for awarding a bursary to me for the purpose of doing this research.
- The researcher would like to thank the staff of the four participating hospitals for their assistance, support, kindness and patience shown throughout the research study.
- Dr Susan Acho, a medical physicist at the University of the Free State, for all her support and expert advice during the completion of this study.
- Mrs Ann Sweetlove, a medical physicist, for her earlier contributions and expert advice in the area of diagnostic reference levels.

ABSTRACT

Introduction: The risk of damaging radiation effects is higher in children because they have a longer life expectancy than adults. International radiation protection organisations emphasise the importance of dose optimisation. One tool that can be used to optimise the dose that a paediatric patient may receive from a radiological examination is called a diagnostic reference level.

Purpose: This study aimed to develop paediatric diagnostic reference levels (PiDRLs) for anteroposterior (AP) chest imaging for radiology departments in the Northern Cape Province (NCP).

Methods and materials: For this study, three radiology departments were investigated across four hospitals in the Northern Cape Province of South Africa. Paediatric patients frequently visit these research sites for radiological imaging. The purpose of this study was to create PiDRLs for three radiology departments in the Northern Cape province of South Africa. The researcher calculated the PiDRL for AP chest radiological examinations. PiDRLs were calculated by weight bands and age groups for all three NCP radiology departments. The researcher made use of a prospective and retrospective study design to reach the appropriate sample size for each weight band and age group. The sample size of 375 paediatric patients ranged from 0 to less than 12 years of age. DRLs are equipment specific, and therefore manufacturers of Siemens, Shimadzu and Dell were included in the research study. An image quality evaluation was conducted on the mobile units and X-ray equipment used by the departments to image paediatric patients. The researcher used a PBU-80 Newborn Whole Body, and the exposures as usually set by the radiographers. A comparison was also made to PiDRLs and variables in other studies, as reported in the literature.

Results:

The 75th percentile in weight groups and corresponding age groups are presented in the tables. The values are measured in units of milligray (mGy). The PiDRL for weight group 50kg to less than 80kg could not be calculated due to insufficient data for hospitals 1, 2a, and 2b. Further, the research could not calculate the PiDRL for the age group 10 years to less than 12 years in Hospital 2b for the Siemens x-ray equipment due to insufficient data.

	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell
Weight group	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**
<5kg	0.3	0.3	0.1	0.1	0.1
5kg to <15kg	0.2	0.1	0.2	0.1	0.1
15kg to <30kg	0.3	0.2	0.2	0.2	0.2
30kg to <50kg	0.3	0.1	0.3	0.2	0.1
50kg to <80kg					0.1

	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell
Age group	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**
<1 year	0.3	0.2	0.2	0.1	0.1
1 year to <5 years	0.2	0.2	0.2	0.1	0.1
5 years to <10 years	0.2	0.2	0.3	0.2	0.2
10 years to <12 years	0.3	0.2	0.3		0.1

The image quality results were evaluated on the image criteria, and the scoring of the images was based on the assessment image quality 7-point scoring card issued by the European Commission in 1996. The results revealed that all the AP CXR images were of high quality. The 75th percentile of this research study was somewhat higher compared to international studies, but the PiDRLs, on the other hand, were consistent with the European Diagnostic reference levels (EDRLs).

Conclusions: The PiDRLs were calculated for different age and weight groups for three radiology departments in four NCP hospitals. PiDRLs could not be calculated on the mobile units due to time constraints, but an image quality analysis was conducted. The PiDRLs calculated in this study were also consistent with international studies. However, this research study showed that the DRL could be revised and lowered in certain weight groups.

Keywords: diagnostic reference levels; paediatric diagnostic reference levels; conventional radiography; chest radiography; paediatric; dose optimisation; PiDRL.

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LIST OF ACRONYMS

AEC	**Automatic Exposure Control**
ADMS	**Automatic dose management software**
AHRQ	**Agency for Healthcare Research and Quality**
Al	**Aluminium**
ALARA	**As Low As Reasonably Achievable**
AP	**Anteroposterior**
BSF	**Backscatter factor**
CEC	**Commission of European Communities**
Cf	**Confer**
COVID-19	**Coronavirus disease of 2019**
CR	**Computed radiography**
CT	**Computed tomography**
$CTDI_{vol}$	**Mean volume-based CT dose index**
CXR	**Chest x-ray**
DAP	**Dose Area Product**
DLP	**Dose length product**
d_{FSD}	**Focus-to-skin distance**
DoH	**Department of Health**
DDR	**Direct digital radiography**
DR	**Digital radiography**
DRL	**Diagnostic reference level**
DRLs	**Diagnostic reference levels**
EC	**European Commission**
EDRLs	**European diagnostic reference levels**
ESAK	**Entrance skin air kerma**
ESD	**Entrance skin dose**
ESD_{air}	**Entrance surface dose to air with backscatter**
ESK	**Entrance skin kerma**
ESR	**European Society of Radiology**
EU	**European Union**
FAE	**Free air exposure**
FFD	**Focus-to-field distance**

Gy	**Gray**
hosp.	**hospital**
HVL	**Half-value layer**
IAEA	**International Atomic Energy Agency**
ICRP	**International Commission of Radiological Protection**
ICU	**Intensive care unit**
IR	**Interventional radiology**
ID	**Identification**
K	**Kerma**
$K_{a,e}$	**Entrance surface air kerma**
K_i	**Incident air kerma**
KAP	**Kerma-area-product**
kg	**Kilograms**
kVp	**Kilovoltage peak**
LDRLs	**Local diagnostic reference levels**
mA	**Milli ampere**
mAs	**Milli ampere per second**
mGy	**Milligray**
mm	**Millimetres**
mos.	**Months**
mR	**Milliroentgen**
MRI	**Magnetic resonance imaging**
n	**Sample size**
NC	**Northern Cape**
NCDoH	**Northern Cape Department of Health**
NCP	**Northern Cape Province**
NCRP	**National Council on Radiological Protection**
NDRLs	**National diagnostic reference levels**
NEXT	**Nationwide Exposure X-ray Trend**
NHRD	**National Health Research Database**
no.	**Number**
NRPB	**National Radiological Protection Board**
PA	**Postero-anterior**
PACS	**Picture Archiving and Communication System**

PiDRLs	**Paediatric diagnostic reference levels**
PII	**Personal identifiable information**
P_{It}	**The tube loading**
P_{KA}	**Air kerma-area product**
pt.	**Patient**
R	**Roentgen**
RSA	**Republic of South Africa**
RP	**Radiation protection**
SA	**South Africa**
SID	**Source-to-image distance**
SSD	**Source-to-skin distance**
TLDs	**Thermoluminescent dosimeters**
UFS HSREC	**University of the Free State Health Sciences Research Ethics Committee**
UK	**United Kingdom**
USA	**United States of America**
USEPA	**United States Environmental Protection Agency**
WHO	**World Health Organisation**
y	**Years**
Y(d)	**X-ray tube output measured at a specified distance**

DEFINITIONS AND TERMS

Air kerma-area product

Kerma area product, also known as the dose-area product (DAP), is the integral of air kerma (the energy extracted from an x-ray beam per unit mass of air in a small irradiated air volume; for diagnostic x-rays, the dose delivered to that volume of air) across the entire x-ray beam emitted from the x-ray tube. It is a surrogate measure of the amount of energy delivered to the patient (Kwon, Little & Miller 2011: online).

As Low As Reasonably Achievable (ALARA)

It is a fundamental rule in radiography to administer the minimum radiation dose to the patient without compromising the image quality, as stated by Škrk, Zdesar and Zontar (2006:1). This principle is known as the "ALARA" principle, which means "as low as reasonably achievable" (Seeram & Brennan 2006:2).

Automatic exposure control (AEC)

The automatic exposure control (AEC) is a device that measures the quantity of radiation that reaches the image receptors and, therefore, automatically terminates the exposure when the image receptor has received the required radiation intensity (Bushong 2016:91).

Chest x-ray (CXR)

Chest x-rays (CXR) produce images of the heart, lungs, blood vessels, airways, and the bones of the chest and spine. CXR can also reveal fluid in or around the lungs or air surrounding a lung (Mayo Clinic 2020: online).

Dose area product (DAP)

Dose monitoring may make use of ion chambers placed over the x-ray tube and collimator assembly; these systems have various acronyms such as kerma-area-product (KAP), roentgen-area-product, and dose-area-product meters. (Bushberg, Siebert, Leidholdt & Boone 2012:306).

Diagnostic reference level (DRL)

The International Commission on Radiological Protection (ICRP) defines DRL as a tool to assist in enhancing protection in medical exposures of patients for diagnostic and interventional procedures (Akpochafor, Omojola, Adeneye, Aweda & Ajay 2016: online). A DRL is a selected level of a radiation dose quantity for broadly defined types of equipment for typical examination groups of standardised patient sizes or, in specific circumstances, a phantom (ICRP 2016: online).

Digital radiography (DR)

Digital radiography replaces conventional radiographic techniques, the screen/film system by processing image data in digital (computer) rather than analogue form (Harisinghani, Chen, Weissleder & Wittenberg 2011: online).

Dose length product (DLP)

DLP reflects the total energy absorbed along the scan length (Vawda, Pitcher, Akudugu & Groenewald 2015:2).

Entrance skin dose (ESD)

Kerma to air from an incident x-ray beam measured on the central beam axis at the patient's position or phantom surface, including backscatter (Nyathi, Nethwadzi, Mabhengu, Pule & Van der Merwe 2009:2).

Entrance skin kerma (ESK) or IAK

The incident air kerma, Ki, is the kerma to air from an incident x-ray beam measured on the central beam axis at the position of the patient or phantom surface. This quantity does not include backscattered radiation. The unit for incident air kerma is the Gray (Nyathi 2012:36)

Entrance surface air kerma

Kerma (K) to air from an incident x-ray beam measured on the central beam axis at the position of the patient or phantom surface, which includes backscatter Nyathi *et al*. 2009:2).

European diagnostic reference levels (EDRL)

European DRLs were established using the median value of the distribution of the national DRLs for a specific radiologic task in standardised patient groups. European DRLs should be considered preliminary national DRLs in countries where national DRLs based on a specific nationwide survey are not available and used until appropriate national DRLs have been established (Granata, Soratin, Seuri & Owens 2019:2).

Focus-to-field distance (FFD)

The distance between the x-ray source and the detector (Bushberg *et al*. 2012:208).

Free air exposure (FAE)

The FAE at the point where the central x-ray beam strikes the body may be measured using an ion chamber (Olarinoye & Sharifat 2010:3).

Gray (Gy)

Gray (Gy) is the SI unit for absorbed dose, which measures the dose of ionising radiation that has been absorbed in any material (Bushberg *et al*. 2012:376).

Half-value layer (HVL)

The half-value layer (HVL) is defined as the thickness of material required to reduce the intensity (e.g., air kerma rate) of an x-ray or gamma-ray beam to one-half of its initial value (Bushberg *et al.* 2012:48).

Incident air kerma (K_i)

The incident air kerma (K_i) is defined as the kerma to air from an incident x-ray beam measured on the central beam axis at the position of the patient or phantom surface, which excludes backscatter (Nyathi *et al.* 2009:2).

Interventional radiology (IR)

Interventional radiology is a medical specialisation that involves performing a range of imaging procedures to obtain images of the inside of the body. The

interventional radiologist carefully interprets these images to diagnose injury and disease and perform various interventional medical procedures (Inside Radiology 2019: online). Most IR treatments are minimally invasive alternatives to open and laparoscopic (keyhole) surgery. As many IR procedures start with passing a needle through the skin to the target, it is sometimes called pinhole surgery (BSIR 2022: online).

Kerma (K)

The kinetic energy released in the matter (Bushong 2016:21).

Kilovoltage peak (kVp)

Kilovoltage peak is the peak potential applied to the x-ray tube, which accelerates electrons from the cathode to the anode in radiography (Radiopaedia 2022: online).

Local diagnostic reference levels (LDRL)

A local DRL (LDRL) is based on the third quartile (the 75th percentile) value of the distribution of patient doses obtained from radiology departments in a single large health centre or a group of health centres within a defined district for a defined clinical imaging task (European Society of Radiology (ESR) 2015).

Mean volume-based computed tomography dose index ($CTDI_{vol}$)

The weighted computed tomography dose index ($CTDI_w$), $CTDI_{vol}$, normalised by the helical pitch. $CTDI_w$ is an estimate of the average dose over a single slice in a CT dosimetry phantom (measured in mGy) (ICRP 2017: online).

Milliampere second (mAs)

A measure of radiation produced (milliamperage) over a set amount of time (seconds) via an x-ray tube. It directly influences the radiographic density when all other factors are constant (Radiopaedia 2022: online).

National diagnostic reference levels (NDRLs)

These DRLs should be set by an authoritative body for a specific radiologic task within standardised patient groups. They should be based on national patient

dose surveys involving a wide sample of institutions within the country. The national DRLs are based on the third quartile or the 75th percentile of the median values of the distribution of patient doses (Granata, Soratin, Seuri, & Owens 2019:2).

Paediatric diagnostic reference levels (PiDRLs)

The ICRP defines DRL as a tool to assist in enhancing protection in medical exposures of patients for diagnostic and interventional procedures (Akpochafor *et al*. 2016: online). The term 'child' is defined in the Children's Act of 1989, as a person under the age of 18 years (Hardy 2000:1). The Bill of Rights and the Children's Act define a 'child' as 'a person under the age of 18 years'. This means that all people under the age of 18 years are entitled to the protection guaranteed by section 28 of the Bill of Rights and the provisions of the Children's Act (Constitution of the Republic of South Africa Act 108 of 1996 & Section 28(3) Children's Act 38 of 2005 Section 1).

Source-to-image distance (SID)

The distance between the x-ray source and the detector (Bushberg *et al*. 2012:208).

Source-to-skin distance (SSD)

The distance from the x-ray tube's focal spot to the entrance skin layer (Bushberg *et al*. 2012:377).

Thermoluminescent dosimeters (TLDs)

Thermoluminescent dosimeters (TLDs) read the signal after exposure to ionising radiation (Bushberg *et al*. 2012:648). Radiation workers wear TLDs so that the radiation dose they receive can be monitored.

Tube output

Tube output is a measure of the intensity of the x-ray beam, typically normalised to mAs or to 100 mAs, at a specific distance from the source (focal spot) (Bushberg *et al.* 2012:248).

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1 CHAPTER 1: ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Paediatric radiological imaging is an extremely valuable diagnostic tool, but it is not without challenges compared to adult radiological imaging (Thukral 2015: online). One of these challenges is producing a good quality image the first time, thus preventing repeat exposures. As part of best practice, radiation dose should also be considered to avoid unnecessary radiation exposure to patients, especially paediatric patients. Importantly, paediatric patients are much more sensitive to radiation exposure than adult patients. Higher sensitivity to radiation exposure is caused by the rapidly growing tissue in paediatric patients. Moreover, the stochastic effects caused by radiation exposure in paediatric patients are significantly higher compared to adult patients. The reason is that children are expected to live long, and therefore, a higher rate of cell division occurs (Olgar & Sahmaran 2017:302).

In paediatric imaging, advanced technology allows these young patients to receive appropriate treatment for various illnesses. Chest imaging, especially with the commencement of the coronavirus disease of 2019 (COVID-19) pandemic, has formed the basis of the treatment process for patients infected with the SARS-CoV-2 virus. In March 2020, the World Health Organisation (WHO) declared COVID-19 a pandemic (Khan, Shah & Bhat 2020: online). Furthermore, the authors mentioned that radiological chest imaging plays a vital role in detecting and managing patients diagnosed with COVID-19. This contribution of diagnostic imaging to timeous diagnosis has encouraged physicians to refer paediatric patients for x-ray imaging examinations more easily. With this in mind, radiation optimisation and justification of radiographic exposures are definitely needed. Therefore, introducing diagnostic reference levels (DRLs) and implementing a quality control tool contributes to radiation optimisation in radiology departments examining paediatric patients.

As a concept, DRLs were first endorsed by the International Commission on Radiation Protection (ICRP) in 1991 and incorporated into European legislation with the Medical Exposure Directive 97/43/Euratom in 1997 (EC 2018: online). The diagnostic reference level (DRL) represents a defined level of radiation dose quantity in a test group for a standardised patient size or, in certain circumstances, a phantom (ICRP 2016: online). In other words, a DRL is a value calculated from a random threshold in a distribution of values obtained locally and can be obtained on a national or regional basis (Medical Council, Regulators of the Medical Profession in Ireland 2004: online). Further, DRLs are used to help avoid radiation dose to the patient that does not contribute to the medical imaging task (USEPA 2014: online).

There are benefits to implementing DRLs in paediatric radiology (Wulandari, Talumantak, Iffah, Ryangga, Ariwidiastutui & Triningsih 2018: online). These benefits include ensuring that the right dose is delivered in conformity with the As Low as Reasonably Achievable (ALARA) principle, thus contributing to patient safety (ESR 2015: online). Further, it is an effective instrument for optimising safety when it comes to the radiation exposure of patients to medical sources (ICRP 2017: online). Children have greater potential for radiation damage due to their longer lives (ICRP 2017: online). Publication number 135 of the ICRP (2017) notes that most children have a smaller body size than adults. Due to children's smaller bodies, there are more organs within or near the primary x-ray beam.

A study conducted by Wambani, Korir, Korir and Kilaha (2013:465) found that in Kenya, most paediatric radiography examinations are performed by technologists with little experience in paediatric imaging, using the same x-ray equipment as for adults. This research further suggests that x-rays should be fitted with air kerma product meters to enhance patient radiation dose protection, which is not always possible in low-income countries because of poor quality control measures. Another important point is that safety standards and paediatric radiology techniques should be developed for equipment. Some jurisdictions, for example, the European Union (EU), added a requirement stating that where an examination cannot be justified, it should be prohibited, and an alternative

technique that does not use ionising radiation should be considered (IAEA 2012: online). The reason for this is, as stated, an increase in potential stochastic risk in children due to the longer life expectancy (Wambani *et al*. 2012: online).

Consideration is needed to group patients for paediatric DRLs (PiDRLs) because of children's size (IAEA 2018: online). Notably, the dose levels for children should be calculated for different age groups. As a result, weight- or size-adjusted paediatric DRL values are critical as a tool for optimisation. It is not good practice to simply adjust adult imaging procedures to cater for paediatric diseases and patient sizes (ICRP 2017: online). Paediatric diseases and patient sizes cannot be accounted for by simple adaptation of adult imaging protocols (ICRP 2017: online). The ICRP Publication no. 135 also states that the European Commission (EC 2018: online) recommends utilising weight-based groups and indicating the age groups to which they correspond to determine optimal PiDRL (ICRP 2017: online). This is because an increase in size and weight in patients means an increase in radiation required in order to obtain good image quality compared to smaller patients. Therefore, it would be a relevant parameter for grouping patients for DRLs in weight bands and more accessible to obtain than with size parameters (EC 2018: online).

1.2 BACKGROUND TO THE RESEARCH PROBLEM

Billinger, Nowotny, and Homolka (2010:1572) emphasised that the concept of DRLs has not been well defined in paediatric radiology by the ICRP. Moreover, PiDRLs data collection can have challenges (Billinger *et al*. 2010:1572). On reflection, a chest radiograph is one of the most frequent radiographic requests in medical imaging and serves as a basis during a diagnostic investigation (Karami, Zabihzadeh, Danyaei & Shams 2016: online). Another factor contributing to frequent chest radiograph requests is the current world pandemic prompted by the spread of COVID-19. Radiology departments should therefore consider implementing PiDRL as a dosage optimisation technique.

Paediatric radiography is an area of clinical practice that involves qualified and student radiographers. Undergraduate radiography students receive formal training in paediatric radiography. Essentially, there are no guidelines for continuous development in this specialised radiography technique. Hardy (2000:27) also mentions that paediatric radiography is a sub-speciality in its own right but has not yet achieved the same recognition from the radiographic profession, primarily when a radiology department does not specialise in paediatric patients. In such instances, radiographers can lack an understanding of the relationship between exposure index (EI) and the visual appearances of image noise, thereby resulting in under- or overexposure to the paediatric patients (Moolman, Mulla & Mdletshe 2020:17). Therefore, there is a need for specifically-trained radiographers for paediatric imaging. Statutory and regulatory bodies must contribute to radiographers' awareness of patients' sensitivity to radiation.

In 1999 the EC published the Radiation Protection no. 109 (RP 109) 'guidance on DRLs for medical exposure' to radiation-sensitive patients, particularly children. The RP 109 specifies DRLs for different conventional radiographic examinations but only for five-year-old patients (EC 2018: online). Porto, Lunelli, Paschuk, Oliveira, Ferreira, Schelin, Miguel, Denyak, Kmiecik, Tilly and Khoury (2014:252) asserted that there are growing concerns about the amount of absorbed dose in patients undergoing radiographic examinations. An increase in computed tomography (CT) and interventional radiography and the change from conventional screen-film to digital radiography has raised particular concerns for implementing PiDRLs. Another major area of concern is the utilisation of adult radiological equipment for paediatric radiological examinations. Porto *et al*. (2014:252) stated that most x-ray equipment is not designed specifically for paediatric patients, and consequently, it is not optimised for the imaging of paediatric patients. Equipment used for paediatric radiology needs to be well-designed and suited for the purpose (IAEA 2012: online). African countries have difficulties providing adequate paediatric imaging because of a lack of resources. Private radiology departments are privileged to have state-of-the-art radiology equipment, but they serve only a small percentage of the population. Therefore,

most paediatric populations are deprived of access to proper paediatric imaging equipment (Andronikou, McHugh, Abdurahman, Khoury, Mngomezulu, Brant, Cowan, McCulloch & Ford 2011:814).

Digital radiography's image receptors are more sensitive than film, and it offers better image quality and potentially lower radiation dose (Williams, Krupinski, Strauss, Breeden, Rzeszotarski, Applegate, Wyatt, Bjork, Seibert 2007:372). Digital image receptors also have greater dynamic ranges than film, so higher doses are possible (IAEA 2007: online). Digital imaging systems have wide exposure latitude or dynamic range, resulting in exposure creep. When employing manual tube settings on digital x-ray equipment, the potential of a patient's dose is increased over time or without knowledge of the detrimental exposure. This is known as dose creep (Seeram 2019:214). Patients receive unnecessarily high radiation doses as a result of dose creep. Radiographic images with wide exposure latitude may also be characterised by high noise levels from low exposure or by higher radiation doses for patients due to increased exposure (Seeram 2019:214). The European Commission (EC) (2018: online) proposes that PiDRL research be used to produce new data for publishing, as current data is old and only represents a small portion of the paediatric radiology population (EC 2018:online).

According to Nyathi, Nethwadzi, Mabhengu, Pule and van der Merwe (2009: online), no published data on adult or paediatric DRLs in South Africa (SA) is currently available. Vawda, Pitcher, Akudugu and Groenewald (2015: online) suggested that since PiDRLs have not yet played a meaningful role in SA, no published local or national information on PiDRLs is available. Even though DRLs are acknowledged as being essential, fewer than half of EU countries have implemented them for paediatric examinations (EC 2018: online). The interest of this study lies in establishing PiDRLs for three Northern Cape radiology departments in SA.

1.2.1 Definition of DRL

The ICRP defines DRL as an instrument to guard against medical exposures of patients when procedures of interventional radiography or diagnostic radiography are required (Akpochafor, Omojola, Adeneye, Aweda & Ajayi 2016: online). The DRL value is calculated using a random criterion in a local distribution of data, and it can be gathered nationally or regionally (Medical Council Regulators of the Medical Profession in Ireland 2004: online). The concept was subsequently further developed, and practical guidance was provided in 2001 (ICRP 2017: online). DRLs help avoid radiation dose to the patient that does not contribute to the medical imaging task, as stated by the Federal Guidance report no. 14. PiDRLs will promote dose awareness and ensure that paediatric radiology departments actively manage recommended imaging quality (EC 2018: online).

1.2.2 Related DRL studies

Meyer, Groenewald and Pitcher (2016: online) pointed out that there is extensively documented research on DRLs published from high-income countries such as the United Kingdom (UK), the United States of America (USA), Canada, Japan, Australia and the Russian Federation. Very little published research is available on DRLs in low-income countries in regions such as Sub-Saharan Africa, East Asia and the South Pacific (WHO 2011: online). At the time of the study, there were no published data on PiDRLs for conventional paediatric chest imaging in SA.

In SA, PiDRLs for CT were established in an academic hospital in the Western Cape in 2015 (Vawda *et al*. 2015: online). The purpose of this study was to construct and define local diagnostic reference levels (LDRLs) for emergency paediatric head CT scans at a tertiary-level SA hospital, as well as to compare these to DRL data from Europe and Australia. The mean volume-based CT dose index ($CTDI_{vol}$) values were relatively constant across the age groups, ranging from 30 to 32 milligray (mGy). Further, the mean dose length product (DLP) values increased with patient age from 488 to 563 mGy.cm. The mean $CTDI_{vol}$

results were comparable to those reported for Australia, Switzerland, Germany, and the United Kingdom, indicating that the scans' technical specifications and clinical processes met international standards (Vawda *et al*. 2015: online).

A study conducted in Spain evaluated the automatic dose management software (ADMS) to calculate PiDRLs for children from birth up to five years old (Alejo, Corredoira, Sánchez-Muñoz, Huerga, Aza, Plaza-Núñez, Serrada, Bret-Zurita, Parrón, Prieto-Areyano, Garzón-Moll, Madero & Guibelalde 2018: online). The study utilises the entrance surface air kerma ($K_{a,e}$) method to determine DRL. The results were for chest imaging in newborn babies, and the local DRL surpassed the EC DRL by 113%. A reduction of 54% was obtained after the optimisation. The radiologist found no significant differences in the image quality during the blind test. Three paediatric radiologists had to evaluate the clinical image quality images of 40 studies before and after the optimisation had taken place. The image quality criteria were based on the EC's published image quality criteria of 1996.

Publication no.135, published in 2017, cited another study that extensively explored the ICRP guideline on DRLs in medical imaging (Nkubli, Nzotta, Nwobi & Zira 2020:38). Specifically, additional guides reviewed and updated concepts and methodological methods relevant to PiDRL in the new document, such as age-specific and weight-specific requirements, were indicated. Reasons to encourage the implementation of PiDRLs include patient dose variation, including unsuitable radiographic techniques or utilising adult exposure protocol for paediatric patients during their visit to radiology departments.

1.3 PROBLEM STATEMENT AND RESEARCH QUESTION

The problem that this study set out to address is the lack of PiDRLs in SA and the lack of calculated PiDRL in current or recent literature in SA. Searches on Pubmed, Google Scholar, Medline and Web of Science did not produce relevant dissertations or publications on PiDRL in the Northern Cape Province (NCP) in SA. However, a published article by Trauernicht and Pitcher (2021:291)

documented all published South African data on DRLs in preparation for establishing national DRLs. Data were collected systematically for fluoroscopy, CT and conventional paediatric imaging. Vawda *et al*. (2015: online) performed a retrospective analysis by calculating $CTDI_{vol}$ and DLP data from CT scans performed of the paediatric skull. The sample size included 30 patients that were divided into three age groups (0–2, >2–5 and >5–10 years). National DRLs found in Europe and Australia were compared with the LDRL values. Therefore, this study will commence by calculating PiDRLs for anteroposterior (AP) chest x-ray imaging for radiology departments in the NCP.

The following research question was formulated to address the problem:
What DRLs for AP chest imaging of paediatric patients at different hospitals in the NCP will ensure optimisation of protection in the radiation exposure of these patients?

1.4 PURPOSE, AIM AND OBJECTIVES OF THE RESEARCH STUDY

The purpose and aim, as well as the objectives, are discussed in the section below. The researcher will also briefly discuss how the research approach was used to achieve the study's aim.

1.4.1 Purpose

The purpose of the study was to improve dose optimisation by calculating PiDRL for three Northern Cape radiology departments in South Africa.

1.4.2 Aim

The aim of this study was to develop PiDRL for AP chest imaging for radiology departments in the NCP.

1.4.3 Objectives

Objectives are specific steps to be taken to achieve the aim and purpose of the study (Kothari 2004:19). Moreover, objectives accurately portray the characteristics of a particular individual, situation, or group. To achieve the aim of this research study, the following objectives were pursued:

i. To perform a literature survey relating to PiDRLs to aid the background of the research;
ii. To calculate PiDRL for various weight bands for AP chest imaging for the included radiology departments' x-ray equipment and mobile x-ray units for a range of weight based groups. The categories for the weight groups ranged from less than and up to 5 kilograms (kg), 5kg to less than 15kg, 15kg to less than 30kg, 30kg to less than 50kg and 50kg to less than 80kg, from each radiology department;
iii. To determine whether the 75th percentile value of the mean exposure settings for a specific weight-based group results in optimum image quality using a checklist after imaging a PBU-80 Newborn Whole Body Phantom (3.5kg)

1.5 DISTINCTION OF THE FIELD AND SCOPE OF THE RESEARCH STUDY

The research was directed toward conventional diagnostic radiography focussing on paediatric imaging. The scope of the research study entails the calculation of DRLs, more specifically, PiDRLs. PiDRLs are the calculation of DRL for specific medical imaging for children. In theory, calculating DRLs for diagnostic x-ray imaging tests for patients who are sensitive to radiation dosage, such as children, is advised. The term 'child' is defined in the Children's Act no. 38 of 2005 as a person who is under 18 years of age (SA Children's Act 2005:12). The findings of this study can be applied in the field of diagnostic radiology in calculating the PiDRL for three radiology departments in the NCP in SA.

1.6 SIGNIFICANCE AND VALUE OF THE RESEARCH STUDY

Radiographers should not adapt adult x-ray imaging protocols for paediatric patients (ICRP 2017: online). The ability to categorise PiDRL into weight or size groups is critical for reducing radiation exposure in these patients. The researcher determined that no DRLs for AP chest x-ray imaging for paediatric patients had been calculated for the NCP. Thus, this research will contribute to dose optimisation for paediatric patients in the NCP by establishing PiDRL for AP chest imaging.

1.7 RESEARCH DESIGN AND METHODS OF INVESTIGATION

A quote by Zora Neale Hurston states: “Research is formalised curiosity. It is poking and prying with a purpose” (Brainy Quote: online). The aim of this study was to develop PiDRL for AP chest imaging for radiology departments in the NCP. The researcher set objectives to achieve the research study’s aim. A brief discussion of the study design and methods follows.

1.7.1 Design of the study

The research method used in this study is descriptive, with quantitative data that was collected prospectively and retrospectively. The descriptive method can be explained by the information gathered about a certain local situation and compared to determine the norms or standards of other variables in the sample (Babbie 2015:525). Furthermore, it indicates that descriptive designs give rise to quantitative research to determine whether existing general theories are still valid (Brink, Van der Walt & Van Rensburg 2006:55). Quantitative data explains current theories by collecting numerical data analysed using mathematical methods, particularly statistics (Muijs 2010:1). The data are collected employing questionnaires, interviews and other evaluation instruments (Kothari 2004:1). This study entails analysis techniques conducted in quantitative research and includes descriptive and inferential statistics, which the researcher performed together with a statistician to analyse the quantitative data (Brink *et al*. 2006:55).

1.7.2 Methods of investigation

The researcher separated the process of the research study into three phases. Further, each phase was divided into subsections. Figure 1.1 depicts a schematic overview of the different phases of this research study. The first phase involved drafting the research protocol, which had to be presented to an evaluation committee. The committee included the Head of the Department of the Radiography Programme at the Central University of Technology, Free State. The evaluation panel was chaired by the Head of the Department of Clinical Sciences and it consisted of various experts in the field of radiography. A medical physicist was also on the evaluation panel.

The evaluation committee was part of phase one, and the researcher had to make a PowerPoint presentation, including the protocol for the research, to the evaluation committee. The evaluation committee approved and recommended amendments to the protocol. One of the suggestions was to include an image quality study on the mobile units at the research sites. During phase one, the University of the Free State Health Science Research Ethics Committee (UFS HSREC) as well as each radiology department included in the research study, granted ethical approval. Requests to conduct research at the various governmental and private radiology departments were sent out. During this phase, telephonic consent was obtained because the parent or guardian was not allowed in the hospitals because of COVID-19 restrictions implemented by the SA Government at the time.

Phase two involved the writing of an article for Chapter two. The article's title is "A practical guide for paediatric diagnostic reference levels (PiDRLs)." Also included in phase two was the data collection period. Data were collected prospectively and retrospectively. The image quality investigationon the mobile units was also conducted in phase two.

After the data collection, the researcher inserted all the collected information from the PiDRL checklist into an Excel spreadsheet to calculate the entrance skin dose

(ESD) with backscatter. Thereafter, various data could be obtained using the Shapiro-Wilk tests for analytical data. An image quality investigation was conducted, and the results of the chest images were evaluated according to the EC 1996 image quality criteria for newborns performed by the researcher. The image quality investigation was conducted on the x-ray units in the specified rooms and mobile units used for paediatric imaging. PiDRL were calculated for the x-ray units in the specified radiology rooms. The researcher evaluated the image quality results of the paediatric AP chest images acquired from the mobile units and x-ray units in the specified x-ray rooms at all three radiology departments in the NC.

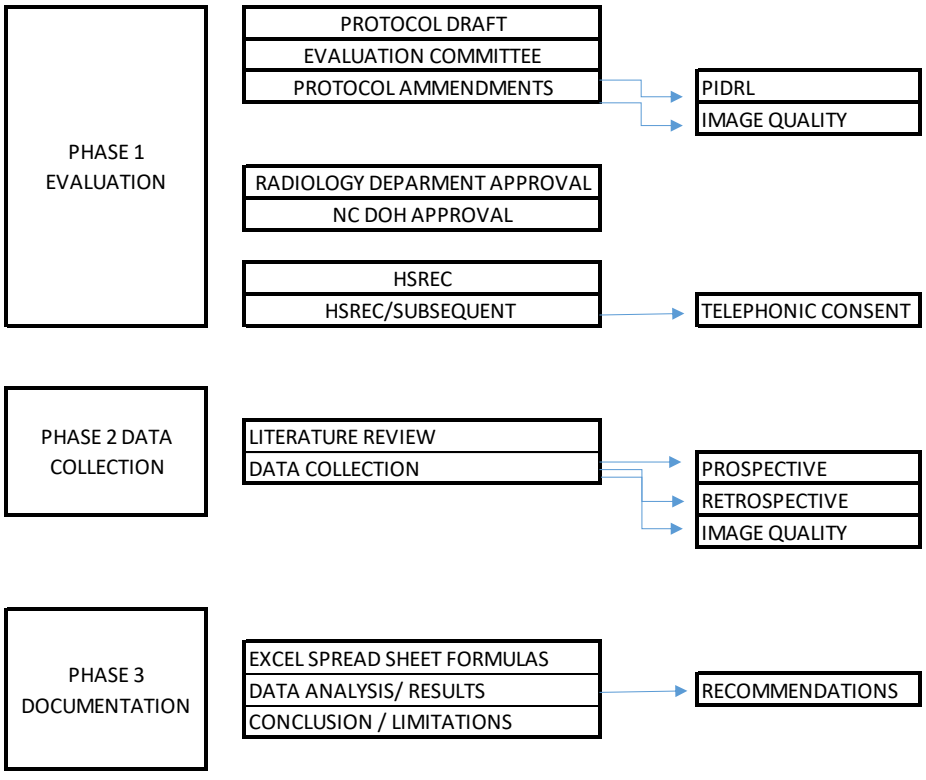

FIGURE 1.1 A diagrammatic description of the research

1.8 ETHICAL CONSIDERATIONS

The researcher issued a request letter to conduct the research to the respective radiology departments that have been identified as the research sites. The names

of the radiology departments were removed from this dissertation to ensure anonymity. After the researcher obtained the permission letters from the radiology departments, the researcher submitted this permission with other documentation to request ethical approval from the UFS HSREC [cf. Appendix 3]. Permission was granted in August 2020. The study was registered on the National Health Research Database (NHRD). The Northern Cape Department of Health (DoH) granted permission to conduct the study at the public radiology department. Data collection only commenced once the researcher obtained all the approvals from the HSREC, UFS and radiology departments.

For the data collection, the researcher gave each participant an information document containing a thorough and understandable explanation of why the study was being conducted. Importantly, a consent form had to be signed to participate in the research study. The aim and objectives were clearly stated in the information document. The information document was available in English, Afrikaans, and Tswana [cf. Appendix 5(a), (b) & (c)] to participants because of the diverse cultural differences in the NCP. The information document was made available in different languages to ensure effective communication about the study and prevent any misunderstanding of information. The document stated that all information collected would be kept confidential. No personal information was collected pertaining to the research participants. The researcher requested only information of a technical nature from the radiology departments for the calculation of the PiDRLs.

1.8.1 Project safety

The project is considered a low-risk project and excluded any interventional procedure for the patients. Furthermore, no additional medical examinations were required to negatively impact the workflow of the radiology departments in the NCP. Paediatric patients were not exposed to any additional radiation to calculate the PiDRL.

1.8.2 Information to participants

An information document [cf. Appendix 5(a), (b) & (c)] was compiled for the benefit of each participating patient's guardian or parent and summarised the nature of the research study. Further, the researcher specified the title of the study and its objectives in the information sheet. Further, the information document also specified that the patient was free to accept or reject the invitation to participate. This document also indicated that the researcher would not reimburse the participating patients.

1.8.3 Informed consent

The researcher provided each patient's guardian or parent with an information document and the written consent document. The participating patient's guardian or parent received a copy of the signed consent letter and information document. The original signed consent letter is kept in the researcher's archive for safekeeping. If the guardian or parent of the participating patient could not read or speak English, the researcher provided an interpreter or permission letters in either Afrikaans or Setswana were made available.

Children up to the age of 12 cannot consent to medical treatment of their own volition, nor can they assent (Medical Protection 2021: online). Therefore, the parent, guardian or caregiver would have to consent to the procedure and the inclusion in the study. The researcher conducted the research during the Level 2-3 lockdown period in SA. This resulted in patients being referred to the radiology department without an accompanying guardian. The general practitioner escorted the patient to the radiology department in certain situations. The researcher had to obtain telephonic consent from the guardian or parent, retrospectively in some cases. The researcher conducted the telephonic request for consent in the presence of a witness.

1.8.4 Right to privacy and confidentiality

The researcher did not collect any personally-identifiable information (PII) during the data collection period. The PII of the research participant was replaced with research identification codes (ID codes). Only questions of a technical nature were required from the radiology departments for the calculation of the PiDRL. The research data was securely stored in a locked cabinet. The researcher stored the electronic data on a password-protected computer.

1.9 APPLICATION OF THE FINDINGS

The outcomes of this study will be used to guide action. The research study's quantitative design method should be repeatable; therefore, other researchers should be able to calculate PiDRLs indicating valid results. When determining DRLs for radiology departments, it is best to consult a medical physicist (Gingold 2017:1135). A medical physicist will be able to study dose patterns by utilising dose analytical tools and comparing it with published DRLs to identify examinations. As a result, the researcher will share the findings with the radiology departments. Radiographers must have a fundamental comprehension of DRL.

A literature review article, was written for Chapter 2 of this dissertation. The title of the article, "A practical guide for paediatric diagnostic reference levels (PiDRLs)" was written as a guideline for radiographers to help in the calculation of PiDRL.

1.10 OUTLINE OF THE DISSERTATION

The researcher will report on the development of the research, the methods used to find an answer to the research question, and the outcome of the study. The following diagram, Figure 1.2, indicates the intended structure and arrangement of the research study.

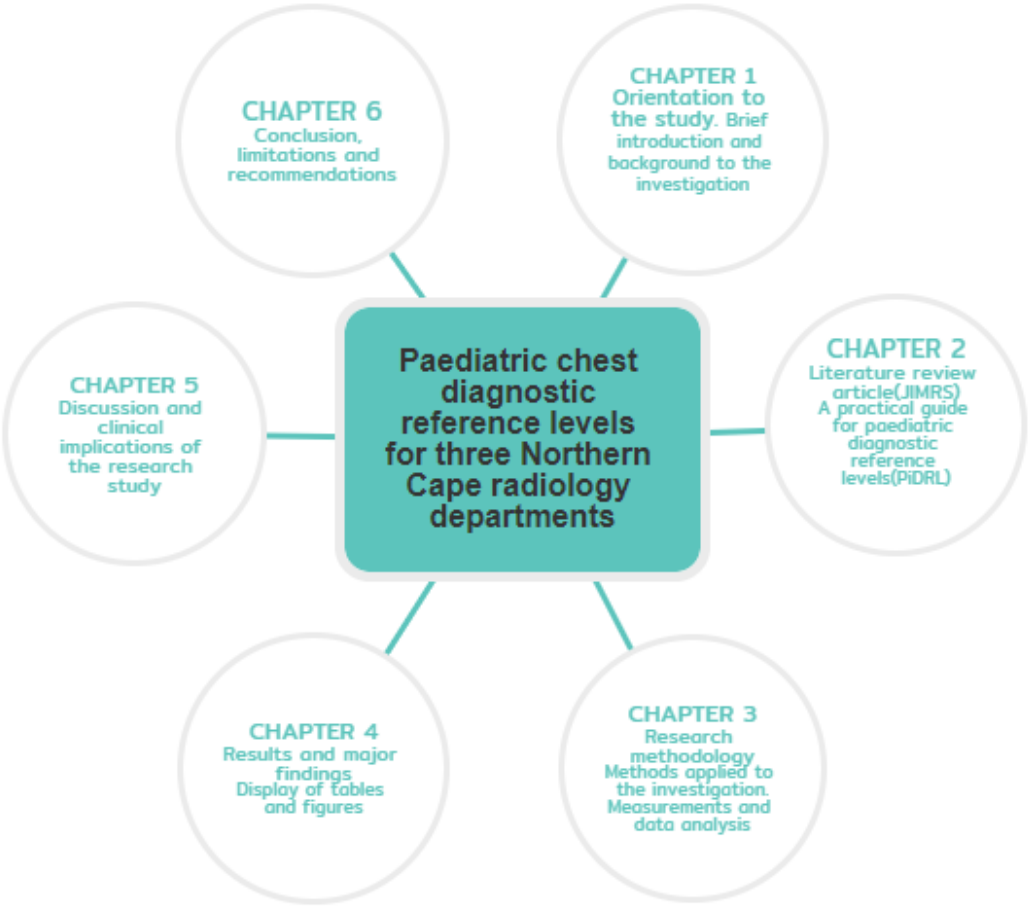

FIGURE 1.2 Diagram of the outline of the research study.

1.11 CONCLUSION

Chapter 1 provided the introduction and the background to the research study undertaken on the PiDRLs for three Northern Cape radiology departments. Chapter 2 is an article entitled “A practical guide for paediatric diagnostic reference levels (PiDRLs).” This article also includes a synthesis of the relevant literature. Consultation between the researcher and the supervisors was concluded, and agreed upon that to include the references after each chapter in this dissertation.

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2 CHAPTER 2: LITERATURE REVIEW (PUBLISHED PAPER)

A practical guide for paediatric diagnostic reference levels (PiDRLs)

This chapter is presented as the peer-reviewed article 'A practical guide for paediatric diagnostic reference levels (PiDRLs)' published in the *Journal of Medical Imaging and Radiation Sciences* on 21 January 2022. Available https://www.jmirs.org/article/S1939-8654(21)00306-4/fulltext

The front page of the article is shown in Appendix 1.

ABSTRACT

This guide was designed to provide a foundation for developing paediatric diagnostic reference levels (PiDRLs) for conventional radiography. In principle, the calculation of diagnostic reference levels (DRLs) is recommended for diagnostic x-ray imaging examinations for radiosensitive patients, such as paediatric patients. PiDRLs are fundamentally important when considering dose optimisation in diagnostic radiology, computed tomography and interventional radiology for paediatric patients. DRLs can assist to point to non-optimised practices and the improvement of paediatric dose optimisation. The purpose of this continuing medical education article is to give medical radiation professionals an overview of PiDRLs for conventional radiography, an understanding of the benefits, the data collection process and some of the calculation methods. The readers can use these steps to establish and implement PiDRLs for different examinations.

Learning objectives

After reading this article, the reader will be able to:

- explain the purpose and benefits of PiDRLs;

- state the contribution of PiDRLs to image quality;
- describe the considerations prior to data collection for PiDRLs;
- clarify the data collection steps for PiDRL calculation;
- identify the imaging parameters to calculate PiDRLs; and
- list the steps to calculate PiDRLs.

Keywords: diagnostic reference levels; paediatric diagnostic reference levels; conventional radiography; chest radiography; paediatric; dose optimisation; PiDRL

Introduction

In paediatric radiography, obtaining x-ray images with adequate image quality while using a low dose exposure is a priority to make a diagnosis. The paediatric patient has higher cell proliferation rates than adults and has an increased chance of developing delayed cancer due to a relatively longer life expectancy [1]. Children's radiation dose from diagnostic procedures can differ substantially because of their size and weight [2]. Therefore, special attention needs to be given to methods to reduce the dose of ionising radiation to children. Radiographers must limit technical errors by adapting imaging protocols for adults to children. Furthermore, radiographers should also consider both underlying clinical factors and different patient sizes to ensure radiation protection of the paediatric patient [2].

A diagnostic reference level (DRL) is a tool used to optimise patients' medical exposure protection in terms of radiation protection, dose optimisation and image quality [2,3]. A DRL is defined as the dose level for conventional radiographic diagnostic examinations for groups of standard-sized patients for a particular country or region's equipment [4]. DRLs are established in terms of easily measurable quantities or radiation metrics that determine the amount of ionising radiation used in radiological imaging procedures [5]. Furthermore, a DRL value is an estimated value of a DRL quantity that is set at the 75th percentile of the distribution of medians in a healthcare facility or across multiple healthcare facilities in a country [2,5].

DRLs are not exclusively applicable to an individual patient, but rather to several groups of patients from different institutions who undergo the same procedure at each institution. DRLs are derived from the 75th percentile of the median doses of patients from several institutions [5]. The size and age of patients in a specific sample should be controlled to compare exposure factors and, ultimately, the doses received during each procedure [2]. These factors are important to highlight because of the wide range of patient sizes in the paediatric population. Therefore, several different age, size and weight groups are required to generate

paediatric DRLs [6]. The DRLs calculated should be determined from a sufficient amount of patient dose data derived or collected from individual paediatric patients' data.

Should a local review indicate that the radiation doses fall outside the DRL value, immediate action is required. The reason why the DRL has been exceeded must be investigated [7]. Many international radiation protection committees have emphasised the importance of DRLs as one of the steps in optimisation. Medical radiation professionals should understand the basic concepts of DRLs and how to apply them correctly [2].

Paediatric patients' weight and size can be wide-ranging [8]. A premature infant's weight compared to an obese adolescent can differ by a factor greater than 100, and consequently, establishing paediatric diagnostic reference levels (PiDRLs) can be challenging [2]. Dose levels vary as a function of the patient's age, size or weight, and therefore, DRLs for specific age, size or weight groups need to be determined [6]. The European Commission (EC) recommended that research be performed on PiDRLs, as published data are outdated and only represent a small population of paediatric radiology patients [6]. Furthermore, there is a lack of standardisation of various sub-groups, resulting in little published literature on PiDRLs. This article will provide medical radiation professionals with a step-by-step guide to establish PiDRLs for conventional paediatric radiography.

Purpose and benefits of PiDRLs

The International Commission on Radiological Protection (ICRP) first recommended DRLs to radiology departments in 1991 [9], developing a benchmark from their derived radiation dose calculation [10]. The European legislation introduced DRLs in 1997 by the Medical Exposure Directive 97/43/EURATOM [11]. The ICRP defined DRLs as "a form of investigation level, applied to an easily measured quantity, usually the absorbed dose in air, or a tissue-equivalent material at the surface of a simple standard phantom or representative patient" [10]. The Commission of the European Communities

(CEC) defined DRLs as “dose levels in medical radiodiagnostic practices, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment, which are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied” [11]. The EC also further identified a need to establish DRLs for paediatric examinations [8].

The objective of DRLs is to limit radiation, especially the radiation dose that does not contribute to the clinical purpose of the image [12]. It is not a dose limit but rather a guidance value, and if DRL values exceed the calculated baseline values, investigations of the procedure and equipment must be undertaken, followed by corrective action [8,13]. Accordingly, DRLs must be calculated employing consistent methods, and reliable DRLs must be compared.

Modern radiology departments have imaging equipment such as computed radiography (CR) and direct digital radiography (DDR). The exposure index (EI) is built-in software to track EI values to ensure the correct use of the equipment and to optimise radiation dose [14]. When the EI dramatically increases or decreases in value, the radiographer should consider investigating radiation dose to patients. PiDRLs are used as a tool to ensure the protection of paediatric patients against unnecessary exposure to radiation during medical procedures.

The development of DRLs can be divided into two sub-categories: (i) the value and the role of DRLs in diagnostic radiography; and (ii) considerations before establishing PiDRLs.

PiDRLs contribution to image quality

The American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM) [15], as well as the National Council on Radiation Protection and Measurements (NCRP) [16] in the USA, noted that DRLs could be used to optimise image quality and dose [15,16]. In essence, DRLs are not directly related to image quality [17]. It does not imply that if the mean value of a DRL in a particular radiology department is above or below a specific baseline or

international value, the image is adequate or inadequate for that particular examination [18]. The primary objective in diagnostic radiography is to achieve an optimal quality image to obtain an appropriate diagnosis [19]. A high exposure does not necessarily mean that image quality is inadequate, whereas underexposed (inadequate) images are associated with low dose exposures [20]. By establishing DRLs, optimal radiation exposure will be ensured, and repeat examinations due to poor quality radiographs will be minimised, ensuring better image quality for the initial radiographic exposure [17]. On the contrary, if the dose value is significantly lower than the DRLs, there may be a cause of concern, indicating that adequate image quality may not have been achieved [16]. Therefore, health professionals involved in imaging children require a basic knowledge of children's physiology, medical imaging technology and requisite skills to perform patient dosimetry and analyse image quality [21].

Evidence has shown that DRLs should form part of a quality control (QC) programme [22]. DRLs should be recalculated quarterly and compared to the baseline values proposed by the AAPM Imaging Physics Committee Task Group [23]. It has been widely considered that establishing DRLs and reviewing these values will ensure that the applied exposure is neither too high nor too low to achieve the desired outcome and produce a quality radiographic image [24]. Maintaining image quality is essential for diagnosis, and despite a reduction in EI, the EC has developed criteria for assessing the image quality for adult and paediatric radiographs [25].

Considerations before establishing PiDRLs

The considerations before establishing PiDRLs can be divided into two categories: general and essential considerations, as shown in Figure 1. The general considerations include manual exposure control, automatic exposure control, calibration and quality control of equipment and ethical considerations.

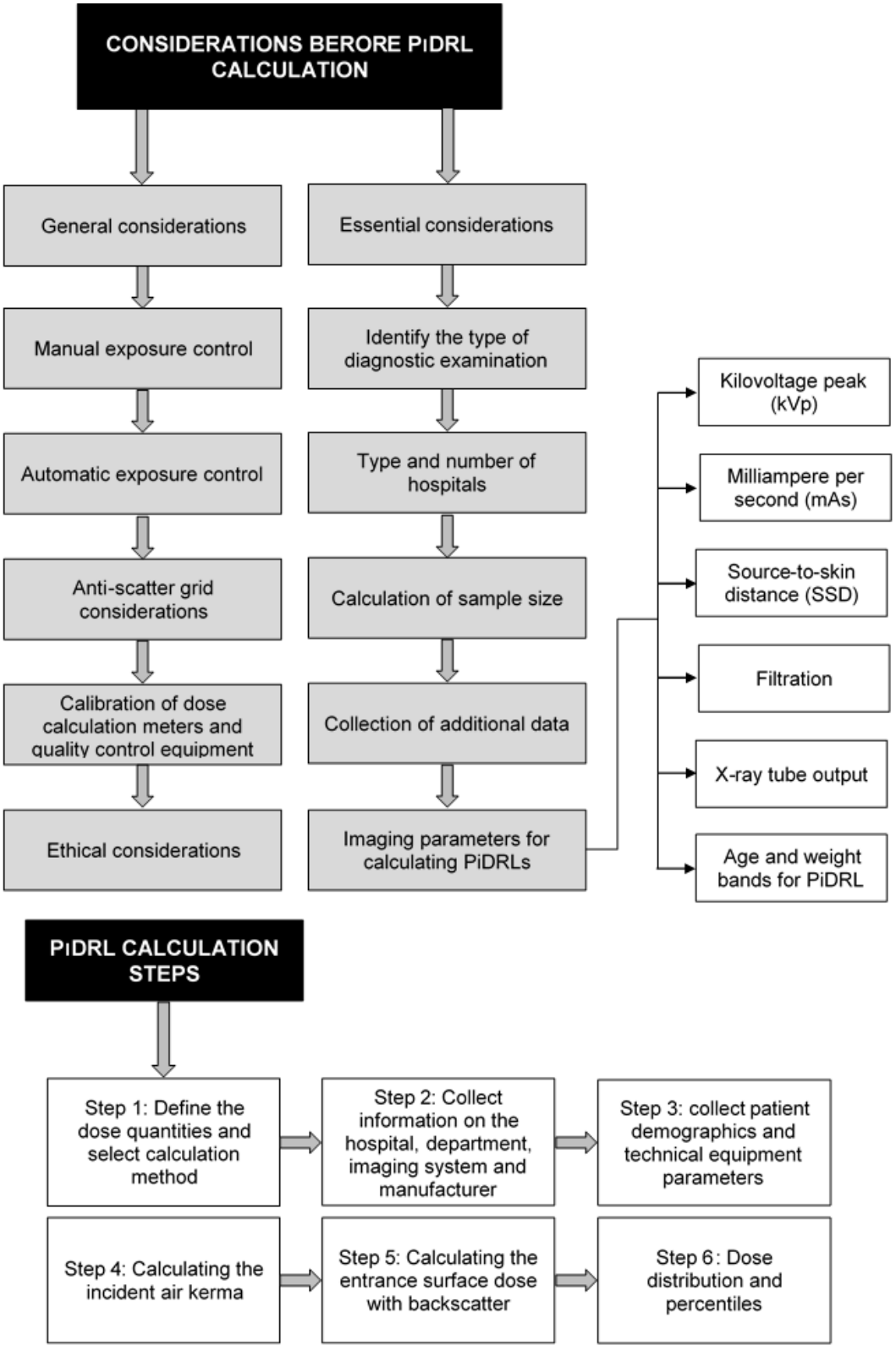

Figure 1. Diagrammatic overview of considerations to take into account when calculating PiDRLs.

Manual exposure control

Routinely, imaging can be performed using manual exposure charts or automatic exposure control (AEC), depending on the individual practice. When using manual exposure charts, the radiographer must consider technical factors when imaging an anatomical part and set a manual exposure on the control panel. The exposure chart should display information about the type of examination, source-to-image distance (SID), patient/part measurements (in cm), kilovoltage peak (kVp) setting, tube current measured in milliampere (mA), exposure time (s) setting, and which grid (Bucky) to select [26]. When the planned procedure differs from the information on the chart, such as larger or smaller measurements than those specified on the exposure chart, the operator must appropriately adapt the exposure settings [26]. Furthermore, the manual exposure setting can be used without a grid, depending on standard departmental practices [27].

Automatic exposure control

When AEC is used, the AEC chambers are energy-dependent, particularly in the lower voltage range. Still, the voltage required for screens and AEC chambers may not be the same, resulting in AEC devices lengthening the minimal exposure times [6]. Further, AEC systems were developed for adult radiographic imaging, limiting the use of AEC-controlled exposures for paediatric patients [2]. Children's much smaller bodies cannot adequately cover an individual AEC sensor's entire area [28]. Consequently, it can result in an under-or over-exposed image. The ICRP (Publication 185) recommends that radiographers set exposures manually for paediatric patients [6,28]. Therefore, substantial consideration should be taken when using the AEC device in paediatric radiography [6].

Anti-scatter grid considerations

Paediatric imaging seldom requires an anti-scatter grid as it results in an increased dose of approximately 100%. Grid use should always be justified by the need for an increase in image quality [29]. For instance, grid use is discouraged when the patient's body part thickness measures less than 10–12 cm. If possible, the radiographer should remove the anti-scatter grid for chest imaging of a paediatric patient [30].

Calibration of dose calculation meters and quality control equipment

Dosimeters used for patient dosimetry must be calibrated, and the date on which it was last calibrated must be noted [31]. Departments can acquire a medical physicist's assistance to confirm the accuracy of the DRL quantity data produced. Before commencing with the survey's data collection, the daily, monthly and annual x-ray imaging equipment performance must be within the tolerance values [2]. Subsequently, image quality should also be assessed.

Ethical considerations for PiDRL

Radiographers and other medical professionals have an ethical responsibility to optimise the risk-benefit relation of radiographic examinations for all patients. This risk-benefit relation is based on the principles of non-maleficence and beneficence. Given these principles, x-ray imaging must not solely be performed on paediatric patients for data collection for the calculation PiDRLs. Permission must be obtained from government departments and relevant ethics committees, as patient data will be accessed. These requirements may differ from country to country. Compulsory informed consent must also be obtained from the parent or legal guardian for the examination. Data can be collected retrospectively if a database with all the required data for PIDRL calculation is available. Furthermore, body weight, including physique, should be used in paediatric patient surveys, but adding weight data to x-ray imaging records is not a regular practice [28].

Five essential considerations applicable to the data collection process and calculating PiDRLs are discussed in this section. The essential considerations that should be noted before establishing PiDRLs are discussed in more detail.

Identify the type of diagnostic examination

Ideally, all radiographic examinations should have DRLs, but data collection can be time-consuming and will not be achieved instantaneously [32]. Decide to start with the most frequently performed examinations and those with the highest dose to the patient. This decision, which PiDRLs to be calculated first, can be made in

collaboration with managers of different medical centres who have insight into the most frequently performed examinations. Another reason to consider the calculation of DRLs is when sudden irregular high EI values for certain radiological examinations are suspicious.

Type and number of hospitals

DRLs can be established for individual countries (national), regions and institutions (local) [28]. This activity can be extensive depending on whether local or national DRLs are established. Establishing a local or facility-based DRL is indicated as a suitable starting point. The survey should include several diagnostic centres to adequately reflect the population in the identified area for which PiDRLs will be calculated [32]. Diverse diagnostic centres must be included, ranging from small clinics to large hospitals. The survey data must be representative of the existing practice from a comprehensive standpoint. This will be achieved by earmarking radiology practices that service paediatric patients frequently.

Calculation sample size

DRLs are not dose values for a person but rather the value of a radiation dose distribution of a representative group of patients or, in other words, a sample size of a particular x-ray examination for a specific radiology department in a typical x-ray room [33]. The sample size should be sufficient to ensure that the mean values represent usual practice in the radiographic facility [34]. The sample size used for each patient grouping and radiological procedure should be sufficient to ensure confidence in determining the typical dose. A representative sample of 10–20 patients per procedure type is needed for non-complex examinations, such as conventional radiography [6,35]. Many facilities find it challenging to conduct DRL studies for paediatric radiology [28]. The immediate challenge in a dedicated paediatric hospital is that there is no standard patient size, resulting in different diagnostic reference values for each examination [36]. Although DRL studies should include at least 20 patients, radiological investigations are only performed on a small number of paediatric patients within a specific weight group [28]. Furthermore, variables that could negatively influence sufficient data

collection are that fewer paediatric examinations are not frequently performed for particular patient sizes [2]. When using age bands to calculate PiDRLs, it is advised that a minimum of 30 patients' data be recorded per age band [32].

An automated data collection system can be introduced as a substitute for surveys where healthcare facilities provide dose data. A DRL curve, in which the dosimetric quantity is a function of the patient size parameter, has been suggested to overcome the lack of sufficient data due to a small number of paediatric examinations performed [37]. When comparing local patient data with the DRL curve, the data from at least ten consecutive patients, irrespective of age, size and weight, should be added as data points on the same graph. The DRL curve is skewed with a long tail; subsequently, if the individual patient dose points are above the DRL curve on the graph, the DRL has been surpassed [38].

Collection of additional data

Additional data that can be collected during the survey include the type of equipment, techniques used to acquire images, projection information, focal spot size, grid usage and the application of AEC. Also, specific patient information can be noted, such as gender, age, weight and body mass index (BMI).

Imaging parameters for calculating PiDRLs

Another challenge arises when deciding on the dose quantity for the reference level. For some modalities, the same dose metrics as for adults can be used [36]. Problems occur in general radiography where the chosen dose quantity (dose area product; DAP) cannot be employed for a number of examinations due to the insensitivity of the available parameters. A different approach is followed for all general radiography examinations, where DRLs are based on imaging parameters, standard protocols and quality assurance outcomes used to link these to more widely renowned dose indications [36]. Six key imaging parameters need to be considered when calculating DRLs for a specific department [20]. These parameters include (i) kilovoltage peak (kVp); (ii) milliampere-second (mAs); (iii) source-to-skin distance (SSD); (iv) filtration; (v) x-ray tube output; and (vi) patient age and weight bands [39].

Age and weight bands for PiDRL

The EC emphasised that the grouping of patients for PiDRLs should be considered because of children's different sizes [6]. Hence, the dose levels vary significantly not only by age but also at a given weight. Adults usually vary in size by a factor of 4 (40–160 kg body weight), whereas paediatric patients vary in size by a factor more than 100, from premature babies (e.g., 300–400 g) to obese adolescents (> 80 kg body weight) [2,6]. When DRLs for mass, size or age groups are defined, the groups should be defined unambiguously using intervals, e.g., body mass bands [35]. Therefore, paediatric patients should be grouped by weight because it is easily obtainable and recommended by the EC [6].

The ICRP recommended that when establishing PiDRL values for head examinations, age bands are used and not weight bands [2]. In circumstances where age is the only obtainable measure, age bands can be grouped around the corresponding age groups (i) less than 1 year; (ii) 1 to less than 5 years; (iii) 5 to less than 10 years; and (iv) 10 to 12 years or less than 15 years [2]. Outliers with nonsensical values for DRL qualities, such as very large patients, should be removed from the sample, as their data could significantly affect the mean distribution value [20]. Table 1 shows the IAEA's recommended weight groups (intervals) for body examinations and the suggested age groupings (intervals) for head examinations [40].

Table 1. Recommended weight groups for body examinations and age groupings for head examinations with a description [40].

Description	Weight groups (intervals) for body examinations	Age groups (intervals) for head examinations
Neonate	< 5 kg	< 1 month
Infant, toddler, early childhood	5 kg to < 15 kg	1 month to < 4 years
Middle childhood	15 kg to < 30 kg	4 years to < 10 years
Early adolescence	30 kg to < 50 kg	10 years to < 14 years
Late adolescence	50 kg to < 80 kg	14 years to < 18 years

PiDRL calculation steps

This section describes general steps for the PiDRL calculation for conventional radiography and the reason for applying each of the steps.

Step 1: Define the dose quantities and select the calculation method

Several practical dosimetric quantities have been established as suitable for medical x-ray imaging measurements [40,41]. The physical quantity (dose metric) used to establish DRLs should be appropriate to the imaging modality being evaluated [20]. The parameters are clearly defined and easy to measure and calculate, accessible and adapted to all equipment types to calculate PiDRLs [42]. Entrance surface dose (ESD) and dose-area product (DAP) can be used to measure the dose for conventional radiography [32]. The quantities that can be used to set PiDRLs are indicated in Table 2. In the literature, the terms "cumulative dose", "reference air kerma", "reference point air kerma" and "incidental air kerma at the patient entrance reference point" are used. These quantities are dose indicators that characterise radiation exposure for comparison of practice and not patient doses that may be used to estimate individual risk [43,44].

Table 2. Dose quantities for PiDRLs for different imaging modalities using conventional radiography [40,43].

Dose quantity	Symbol	Suggested unit	Other symbols derived from the literature	Similar quantity
Incident air kerma	$K_{a,i}$	Milligray (mGy) or Microgray (µGy)	IAK	–
Entrance-surface air kerma	$K_{a,e}$	mGy or µGy	ESAK	Entrance-surface dose (ESD)*
Air kerma-area product	P_{KA}	$mGy.cm^2$	KAP	–

*In the diagnostic radiology energy range, "air kerma" and "dose in air" are quantitatively equivalent.

The position of the point of measurement or calculation of the quantities in relation to the x-ray tube focal spot and the patient or phantom must be specified (Figure 2). Because diverging radiation beams are utilised in medical imaging, the kerma and dose will decrease with increasing distance from the x-ray tube focal spot, according to the inverse-square law [41]. Backscatter is radiation that is scattered backwards from the primary beam when penetrating the object. This backscatter would measure 15% to 30% higher than in free-air kerma [45]. Radiation backscattered from the patient or a phantom representing the patient will contribute significantly to the kerma or dose at the entrance surface; backscatter factors for general radiology range between 1.25 to 1.60 for conventional radiography [41,46].

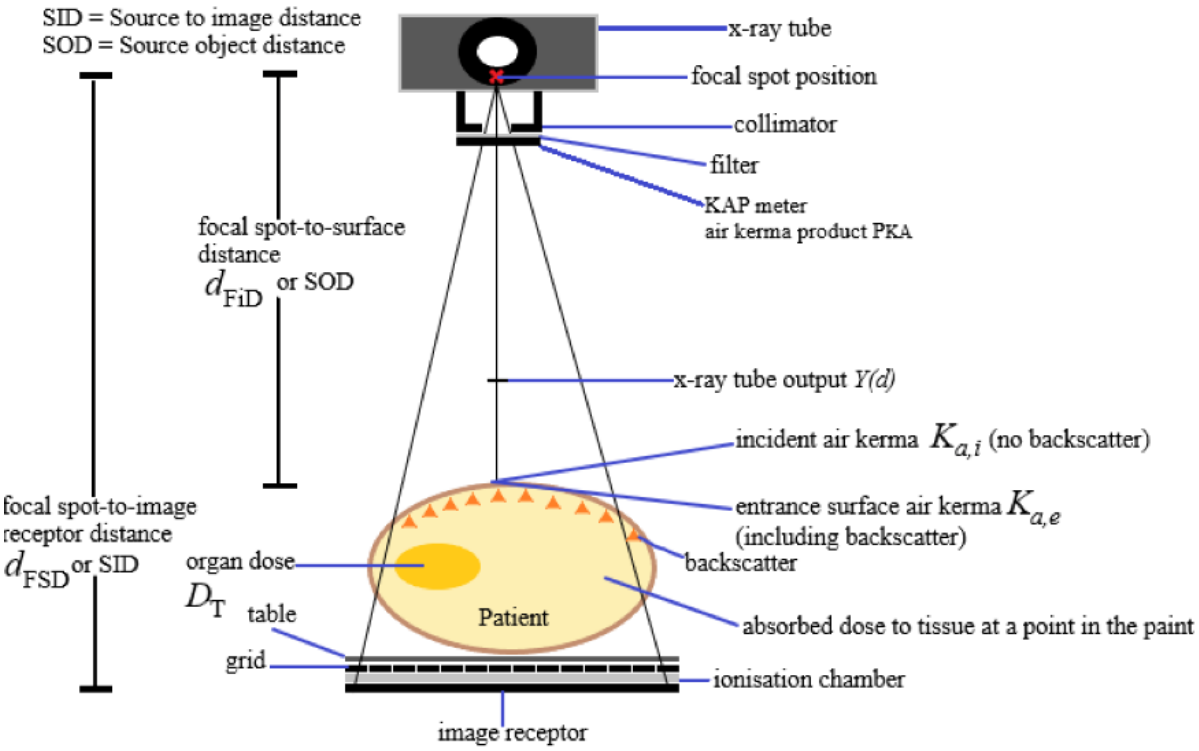

Figure 2. Dosimetric and geometric quantities for determining patient dose for conventional radiography [40,47].

Most of the dosimetric and geometric quantities recommended for determining patient dose are shown in a simple exposure arrangement for radiography, as illustrated in Figure 2.

Where available, DRLs should be used. Data on paediatric dosages frequently refer to dose levels (and thus DRLs) as entrance surface dose (ESD) [36]. Therefore, it is necessary to convert from kV/mAs to ESD to compare this data and contribute to the pool of available dose levels [41]. Incident air kerma ($K_{a,i}$) refers to the point where the central axis of the x-ray beam intercepts the plane corresponding to the surface of the patient or phantom (Figure 2). Hence, $K_{a,i}$ is calculated as 'free-in-air', i.e. in the absence of the patient or phantom. Practically all of the dose quantities will be measured using instruments calibrated in terms of air kerma.

Several qualifying terms are used to identify the measurement position and whether or not backscattered radiation from the patient is to be included. Subscripts are used to indicate incident (no backscatter) and entrance surface (containing backscatter) to specify whether backscatter is included or not in the air kerma [41]. For the dose quantities $K_{a,i}$ and $K_{a,e}$, subscripts are added to the symbol for the quantity (Figure 2). The first subscript indicates the material in which the quantity is expressed, such as 'a' for air. The second subscript indicates the measurement condition, which is the quantity of incidence or entrance surface, respectively denoted by 'i' or 'e' [41].

It is important to note that the $K_{a,i}$ must be calculated before the $K_{a,e}$ is calculated for each patient dose. Firstly, for the calculation process of PiDRL, there must be an understanding of what kerma is. Kerma (K) is an acronym for kinetic energy released in matter. K is defined as the kinetic energy transferred to charged particles by indirectly ionising radiation per unit mass [45]. Hence, $K_{a,i}$ is the kerma to air from an incident x-ray beam measured on the central beam axis at the patient's position or phantom surface, excluding backscatter [47]. The $K_{a,i}$ is also known as the entrance skin kerma (ESK) [45]. The measurement of absorbed dose to air, 'free-in-air', will have to be corrected to ESD by applying the inverse square law to obtain the dose at the focus-to-skin distance and multiplying it by an appropriate backscatter factor [25]. The ESD values are obtained from the recorded mAs and the x-ray tube output for each room [48].

When the ESD of each patient in the sample is calculated, the mean of the total sample can be calculated. The mean dose distribution is calculated by adding up all the individual ESD values and dividing them by the sample size [49].

The method using Tung's equation is described in other literature, as described in the calculation of ESD, is reliable, as it provides a quick estimate of air kerma that may be used to assess patient skin dose [50]. Exposure parameters such as kVp, mAs, tube output, SID and patient thickness can also be used to calculate the ESD. These factors also include the backscatter factor that depends on the half-value layer (HVL), kVp and field size and can be obtained according to IAEA guidelines [51,52].

Step 2: Collect information on the hospital, department, imaging system and manufacturer

Information on the hospital and department, and specifics on the imaging system and model, must be recorded in the Excel spreadsheet (Table 3). Whether a film/screen, CR or DR or a mobile unit were used should be included. Also, record the total filtration of the x-ray unit.

Step 3: Collect patient demographic information and technical equipment parameters

The patient data be recorded for each paediatric patient include age, height, weight and thickness (Table 3). Recorded technical parameters for each patient include kVp, mAs and whether a grid was used. The SID is an equation of the SSD, patient thickness (t_p) and the dead space between the detector's cover and the actual detector surface (air gap). The air gap between the patient and the detector is indicated as 2 cm [45]. The SSD can be estimated by knowing the SID, the thickness of the patient and the air gap. The equation to calculate the SSD is provided in Table 4.

Table 3. Example of information on a hospital imaging system for the PiDRL Excel spreadsheet for the calculation for different scenarios.

Hospital and department		Manufacturer and imaging system				Patient demographics				Technical equipment parameters					
Hospital	**Department**	**Manufacturer**	**Image system (CR/DR)**	**Mobile (yes/no)**	**Total filtration (e.g. mm Al eq)**	**Age (y/m)**	**Height (cm)**	**Weight (kg)**	**Thickness (t_p) (cm)**	**Bucky (yes/no)**	**kVp**	**mAs**	**SID (cm)**	**Gap* (cm)**	**SSD# (cm)**
A1	Radiology	SHIMADZU	DR	No	2.1	1 y	65	11.5	7.5	Yes	68	3.5	110	2	100.5
A1	Radiology	SHIMADZU	DR	No	2.1	8 m	65	7.6	13	Yes	65	3.5	110	2	98.0
A1	Radiology	SHIMADZU	DR	No	2.1	9 m	75	8.3	14	Yes	65	3.5	110	2	99.0
A2	Radiology	SIEMENS	DR	No	2.8	1 y	65	11.5	12	Yes	68	3.5	110	2	100.5
A2	Radiology	SIEMENS	DR	No	2.8	2 y	70	11.6	13	Yes	67	4.5	110	2	98.0
B	ICU	TOSHIBA	CR	Yes	2.5	4 y	101	16	12	No	75	2.5	180	2	168.0
B	ICU	TOSHIBA	CR	Yes	2.5	5 y	96	16.2	12	No	102	2.8	150	2	136.0

*Gap between patient and detector; #SSD: SID – (patient thickness gap between patient and detector)
PiDRL: paediatric diagnostic reference level; CR: computed radiography ; DR: digital radiography; Al eq: aluminium equivalent; y: years; m: months; kVp: kilovoltage peak; mAs: milliampere-second; SID: source-to-image distance; SSD: source-to-skin distance; ICU: intensive care unit.

Table 4. Equations that can be used in Excel spreadsheets to calculate technical parameters, dose quantity and DRLs

Technical parameter/ dose quantity/DRL equation	Excel spreadsheet equation	Equation as indicated in the literature
Average dose needed to calculate tube output	=(dose measurement 1+dose measurement 2)/2 [53]	Tube output (µGy/mAs)=a x (Tube Voltage (kVp)) + B x (Tube Voltage (kVp) +c Where a, b, c are fitting factors derived from tube output measurements derived from tube voltage [53]
Source-to-skin distance (SSD)	=SID–(patient thickness+air gap) OR =FFD–(patient thickness+air gap)	$d_{FSD} = d_{FTD} - t_p$ [54] OR $d_{FSD} = FFD - t_p$
Average dose (mGy) to calculate tube output	=(dose measurement 1+dose measurement 2)/2	$\mathrm{Y(d)} = \overline{M} N_{K,Q_0} k_Q k_{TP} / P_{It}$ [55]
Tube output (mGy)/mAs at 100 cm	=(Average dose/mAs)	Y(d,kV) = Ka(d,kV)/PIt [54]
Entrance surface dose (ESD) (mGy) at 100 cm	=(equation calculated)*mAs [55]	
ESD at corrected SSD	=(ESD at 100 cm*((100^2)/((SSD)^2))) [42]	$De = K_0$ x BSF x $(\mathrm{U}/100)^2$ x Q x $(1/DSS)^2$
ESD with backscatter factor (BSF) correction	=ESD*BSF [55]	Entrance air kerma $K_e = K_i B =$ ___mGy [56]
Diagnostic reference level (DRL)	=PERCENTILE.INC (ESD with BSF of all patients; 0,75) [57]	$ESD = \left(\frac{D}{It}\right)_0 x\ (It)\ x\ \left(\frac{FFD}{FSD}\right)^2 x\ BSF$
Incident air kerma calculation		$K_i = Y(d,kV) P_{It} \left(\frac{FFD}{FSD}\right)^2$ [Equation 3a for film/screen radiography] [58] OR $K_i = Y(d,kV) P_{It} \left(\frac{d}{d_{FSD}}\right)^2$ [Equation 3 for CR or DR radiography] [59]
ESD_{air}		ESD_{air}(mGy) = FAE (mR) x 0.008 77 x BSF [60]

SID: source-to-image distance; FFD: focus-to-film distance.

Calculating the focal-spot-to-surface distance

The incident air kerma is calculated from the x-ray tube output, *Y(d,kV)*, corrected for the focal spot-to-surface distance (d_{FSD}) using the inverse square law and combined with the exposure parameters recorded during patient examinations. The focal spot-to-surface distance is also known as the SSD. The tube focus to the patient surface distance (d_{FSD}) must be calculated (equation 1a or 1b) [59]. The d_{FSD} is calculated by subtracting the thickness of the patient (t_p) from the tube focus-to-patient support distance (d_{FTD}) for CR or DR equipment, as indicated in equation 1a.

$$d_{FSD} = d_{FTD} - t_p \qquad \text{[Equation 1a] [61]}$$

When film/screen systems are used, the tube focus-to-patient support is replaced by the focus-to-film distance (FFD), as indicated in equation 1b [54]:

$$d_{FSD} = FFD - t_p \qquad \text{[Equation 1b] [54]}$$

Calculation of the x-ray tube output measurements

The x-ray tube output ((*Y(d,kV)*) is the quotient of the air kerma ((*Ka(d,kV)*) measured at a specific distance (d) from the x-ray tube focal spot by the tube-current exposure-time product (P_{It}). Hence the following equation can be used:

$$Y(d,kV)=K_a(d,kV)/P_{It} \qquad \text{[Equation 2] [62]}$$

The tube output must be calculated with different kVp settings but with a fixed mAs at a specific distance (typically 100 cm). Since graphing (dose/mAs) is performed against kV, any mAs value for the tube output can be used. Because the dose (output) of an x-ray unit is linear to mAs, the dose (at 100 mAs)/100 mAs = dose (at 40 mAs)/40 mAs for each kV. Two dose measurements must be taken with a calibrated dosimeter, and then an average dose can be calculated (Table 5). The equation indicated in Table 4 to calculate tube output can be used. This calculation is performed for each of the kVps variables.

Table 5. Example information to calculate the tube output calculated at 100 cm for two different imaging units in a specific hospital.

Hospital A: Unit A1 – SHIMADZU						
Distance (d)	**kV**	**mAs P_{It}**	**Dose (mGy) measurement 1 at specific d**	**Dose (mGy) measurement 2 at specific d**	**Average dose (mGy)***	**Tube output (mGy)/mAs at 100 cm***
100	50	40	0.83	0.83	0.83	0.02
100	60	40	1.31	1.33	1.32	0.03
100	70	40	1.87	1.92	1.89	0.04
100	81	40	2.55	2.63	2.59	0.06
100	90	40	3.18	3.08	3.13	0.07
Hospital A: Unit A2 – SIEMENS						
Distance (d)	**kV**	**mAs P_{It}**	**Dose (mGy) measurement 1 at specific d**	**Dose (mGy) measurement 2 at specific d specific d**	**Average dose (mGy)***	**Tube output (mGy)/mAs at 100 cm***
100	50	40	0.64	0.64	0.64	0.01
100	60	40	1.03	1.03	1.03	0.02
100	70	40	1.48	1.48	1.48	0.03
100	81	40	2.04	2.04	2.04	0.05
100	90	40	2.54	2.53	2.53	0.06

*Equation indicated in Table 4.

The next step is to plot a graph (e.g., as shown in Figure 3) with the different kV and the tube output (mGy)/mAs data at 100 cm. The trend line reflects the relationship between dose/mAs and the kV at 100 cm for a specific unit. An equation describing the dose/mAs versus kV at 100 cm has been derived from the data collected from each unit, as shown in Table 4. An example of such an equation is:

$y = 0.0015x – 0.053$ for unit A1 or

$y = 0.0012x – 0.053$ for unit A2, as shown in Figure 3.

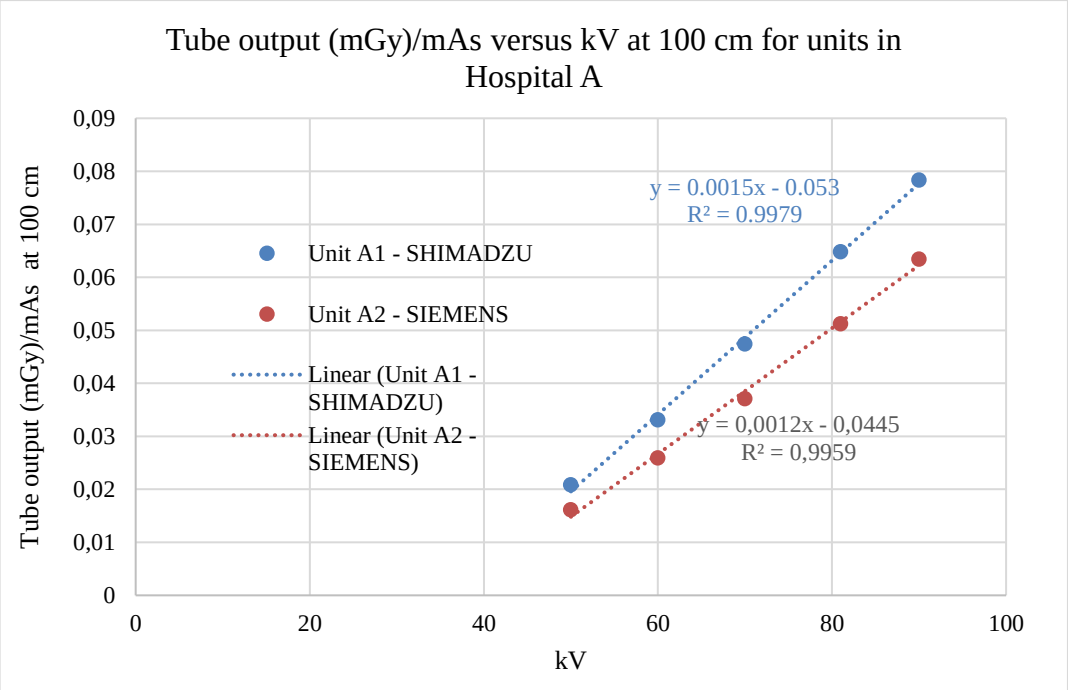

Figure 3. The tube output (mGy)/mAs versus kV at 100 cm for two different x-ray imaging units in a hospital.

The x in the equation represents the kV used for the patient. The equation can be used to calculate the ESD (mGy) at 100 cm. After the ESD has been calculated at 100 cm, another calculation must be performed to determine the ESD at the corrected SSD.

Table 6 indicates examples to calculate the ESD at 100 cm, and the ESD corrected at SSD, for example, for Unit A1.

Table 6. Example information to calculate the ESD at 100 cm and the ESD corrected at SSD.

kVp	mAs	SID	SSD corrected	Example of calculating the ESD (mGy) at 100 cm (equation A1)*mAs	Entrance skin dose (mGy) at 100 cm	Example of calculating ESD at corrected ESD (ESD at 100 cm)*(100)^2/(SSD)^2	ESD (mGy) at corrected SSD
50	1.8	100	89	((0.0015 x 50) – 0.053))*1.8	0.03	(0.03)*(100)^2/(89)^2	0.04
60	3.2	100	88	((0.0015 x 60) – 0.053))*3.2	0.11	(0.11)*(100)^2/(88)^2	0.15
55	2.5	100	90	((0.0015 x 55) – 0.053))*2.5	0.07	(0.07)*(100)^2/(89)^2	0.09
50	3.2	100	90	((0.0015 x 50) – 0.053))*3.2	0.07	(0.07)*(100)^2/(90)^2	0.08
65	3.5	110	103	((0.0015 x 65) – 0.053))*3.5	0.15	(0.15)*(100)^2/(103)^2	0.14

kVp: kilovolt peak; mAs: milliampere second; SID: source-to-image distance; SSD: source-to-skin distance; ESD: entrance skin dose; mGy: milligray

Calculating the backscatter factor (BSF)

The BSF accounts for the contribution from backscatter radiation. The BSF depends on kVp, field size, SID and body tissue [50]. Additionally, the BSF must be determined to calculate the ESD. BSFs for a wide range of clinical beam quality spectra in the domains of infant and paediatric radiology have been calculated and described in the literature [56]. Data for various phantom thicknesses are provided in the case of infant radiology. A medical physicist can be consulted if the calculated BSFs from the literature can be used in the calculation of the PiDRL. Table 7 shows an example calculation for ESD with BSF and PiDRL for a specific weight group. The equations for the calculations used are also indicated in Table 4.

There are different methods to determine PiDRLs. The primary data used to calculate the PiDRL are the measured dose, excluding the backscatter factor [32]. The primary data depends on the radiographic examination, and for conventional radiography, the primary data can either be ESD or DAP, as described in steps 4–6 of Figure 1 [58,63].

Step 4: Calculating the incident air kerma

The free air exposure (FAE) or $K_{a,i}$ is defined as 'free-in-air' without any backscatter. The American Association of Physicists in Medicine (AAPM) provided a measurement procedure for calculating FAE [64]. The FAE can be determined at the point where the central x-ray beam first strikes the body [50]. The SID must be set for clinical use. The ion chamber must be centred at a fixed distance from the focal spot [64]. A practical example of calculating the $K_{a,i}$ has been described in the literature [45].

Table 7. Example data to calculate ESD with BSF and PiDRL for Unit A1 for the paediatric patient weight group 0 to < 5 kg.

Patient no.	kVp	mAs	ESD without BSF (mGy)	BSF from literature [64]	ESD with BSF* (mGy)
1	50	1.8	0.49**	1.32	0.65
2	60	3.2	0.15	1.32	0.20
3	55	2.5	0.09	1.32	0.12
4	50	3.2	0.08	1.32	0.11
5	75	2.8	0.20	1.32	0.26
6	80	2.2	0.07	1.32	0.10
7	88	2.2	0.08	1.32	0.11
8	70	2.8	0.14	1.32	0.1
9	80	2.2	0.15	1.32	0.20
10	75	3.5	0.21	1.32	0.28
11	75	3.5	0.20	1.32	0.26
12	70	3.2	0.16	1.32	0.21
13	70	3.5	0.17	1.32	0.23
14	65	3.5	0.14	1.32	0.19
PiDRL*					0.25mGy or 250 µGy

*Use calculation in Table 4.
kVp: kilovolt peak; mAs: milliampere second; ESD: entrance skin dose; BSF: backscatter factor; mGy: milligray; PiDRL: paediatric diagnostic reference level
**Example of an extreme value or outlier

After calculating the d_{FSD}, the $K_{a,i}$ must be calculated by using equation 3. The $K_{a,i}$ is calculated as follows, where *Y(d,kV)* is the x-ray tube output (milliroentgen per mAs [mR/mAs]) measured at a specified distance *(d)* from the tube focus for the particular tube voltage and filtration used for the patient exposure. The P_{It} is the tube current-exposure time product, also known as the tube loading (mAs) for patient exposure.

$$K_{a,i} = Y(d, kV) P_{It} \left(\frac{FFD}{FSD}\right)^2$$ [Equation 3a for film/screen radiography] [58]

Or

$$K_{a,i} = Y(d, kV) P_{It} \left(\frac{d}{d_{FSD}}\right)^2$$ [Equation 3b for CR or DR radiography] [59]

Step 5: Calculating the entrance surface dose with backscatter

The entrance surface air kerma ($K_{a,e}$) or ESD_{air} (or ESAK) may be calculated from the $K_{a,i}$ by applying the appropriate BSF. The FAE is defined above as free-in-air with no backscatter [60]. Furthermore, the ion chamber must be positioned in the region of 23 cm above the tabletop to reduce backscatter radiation. The x-ray field must be slightly larger than the ion chamber. The measured free-in-air exposure is then used to calculate the FAE using the inverse square correction for the ion chamber to the entrance surface position. Standard methods for measuring the FAE for manual and automatic exposure control systems have also been described by the AAPM [64]. Alternatively, an FAE estimation can be made using the exposure data from Table B3 of the NCRP Report No. 102 [51].

A practical example of calculating FAE has been provided in the literature. The parameters are set at 80 kV, mAs and at a distance of 100 cm. Equation 4 can be used to calculate the FAE [61]:

FAE (mR) = tube output x ($kV^2/80^2$)(100^2/FSD) x mAs [Equation 4] [61]

Equation 5 [50] may be used to obtain the ESD_{air}, where 0.008 77 converts the exposure, in units milliroentgen (mR), into the absorbed dose to air, in units mGy. The following equation can be used to calculate the ESD to air with back scatter.

ESD_{air} (mGy) = FAE (mR) X 0.008 77 X BSF [Equation 5] [50,61]

Step 6: Dose distribution and percentiles

After calculating the ESD_{air} of each paediatric patient as described in step 2, the dose distribution of the sample size can be calculated. Step 3 will be the PiDRL value when the 75^{th} percentile of the dose distribution of the sample size is calculated (including the backscatter factor). The ICRP recommended that the DRL value be set at the 75^{th} percentile of the distribution of the median values for DRL quantities for specific examinations [2]. Hence, it would be reasonable to set the DRL value at the 75^{th} percentile of the distribution. The sample dose distribution can be used to calculate both the 50^{th} and 75^{th} percentiles.

Accordingly, DRLs are typical values of the 75th percentile of the distribution dose of a sample size for a specific x-ray room and standard-sized patients [42].

When one observes a dose distribution graph, the 75th percentile is the value above the median (50th percentile) in the dose distribution of a sample of participants/patients [20]. In diagnostic radiography, the statistical analytic curve on a graph is skewed with a long tail. Given the sample size of patient doses, the 75th percentile appears to be appropriate [65]. A clear balance between being very strict or very lenient is required, which explains why the 75th percentile (3rd quartile) is selected as a more reasonable value [66]. The reason for choosing the 75th percentile, rather than choosing the mean value, is that very few practice dose distributions would fall below the DRL, compromising a diagnosable outcome [12]. If the 95th percentile DRL value were chosen, more practice dose distributions would fall within the DRL. It would mean that there would be no need to investigate dose optimisation by reducing the radiation dose for the specific x-ray room, which may contribute to the unnecessary radiation dose that does not have an impact on the image quality [15].

The dose distribution must be arranged in ascending order, and then the following equation is used: 3(n + 1)/4, where n represents the size of the sample, to calculate the 75th percentiles. The number calculated should be the specific value of the distribution list [67]. The objective of the 75th percentile is to alert professionals of exceeding dosimetric values in their practice. The use of the 75th percentile (or 3rd quartile) of median patient doses will allow for the effective identification of "outliers," or institutions and practices with exceedingly high patient dosage levels relative to the majority of the other institutions [6].

This situation may be attributed to outdated x-ray systems or a lack of sufficient optimisation. More importantly, is that the final calculated DRL (75th percentile) will then represent the dose values below which 75% of all the institutions included in the process can achieve a clinically meaningful image. If another percentile were to be used, it would either be so high that most institutions would

already be below that specific dose value, or so low that it would be challenging to achieve a good clinical image at such a low dose value [2].

Careful considerations must be made when comparing calculated PiDRLs from different countries from the literature, as there are certain pitfalls [65]. Imaging practices are different and may not be relevant to your particular circumstances. Furthermore, other considerations that must be taken into account is the method of calculation, standard condition (e.g. phantom or patient), dose quantity and sample dose distribution (50^{th} and the 75^{th} percentile). This DRL value should be calculated for each anatomical region (for example, the chest) for a group of standard-sized patients examined with specific radiographic equipment in a radiology department [63]. A qualified medical physicist should be consulted in the process of calculating the DRL values [68].

Conclusion

In conclusion, PiDRLs can be implemented as a quality control tool and should be revised quarterly, then annually, to ensure dose optimisation. To implement PiDRLs in a radiology department, the medical radiation professional should have a basic perception of DRLs. Particular attention should be focused on the implementation of PiDRLs, because paediatric patients differ due to their size and weight at a specific age. Hence, grouping in weight bands is highly recommended. DRL is not a dose limit but rather a guidance value representing the 75^{th} percentile of the radiation dose distribution graph of the recommended sample size. PiDRL is not directly connected to image quality. Nevertheless, PiDRLs will ensure that dose optimisation minimises radiographic examination repeats and promotes best practice functionality.

Footnotes

Contributors: All authors contributed to the conception or design of the work the acquisition, analysis, or interpretation of the data. All authors were involved in drafting and commenting on the paper and have approved the final version.

Competing interests: The authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, nor other relationships or activities that could appear to have influenced the submitted work.

Acknowledgements:

The authors acknowledge Dr Daleen Struwig, medical writer/editor, for the technical and editorial preparation of the manuscript.

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Appendix - CME Article – Multiple-Choice Questions

1. Indicate if the following statement is true or false: diagnostic reference levels (DRLs) are directly related to image quality.

a) True

b) False

2. The imaging parameter/s when calculating DRLs is/are

a) kVp

b) mAs

c) Tube output

d) kVp, mAs and tube output

e) **kVp, mAs, SSD and tube output**

3. The purpose of paediatric diagnostic reference levels (PiDRLs) is to assist with

a) Dose optimisation

b) To reduce repeat radiographic examination

c) Patient care

d) Correct exposure parameters

e) Dose optimisation, to reduce repeat radiographic examinations and correct exposure parameters or e) a, b, d

4. Dose optimisation in radiology refers to

a) High exposure parameters

b) The maximum number of patients done in a day

c) Good quality images irrespective of the radiation dose

d) Good quality images considering low exposure settings

5. To establish PiDRLs for a radiology department, the following should be considered

a) AEC usage

b) Anti-scatter grid

c) Calibration of the quality control equipment

d) AEC usage, anti-scatter grid and calibration of the quality control equipment or All of the above

6. If DRLs in the department were exceeded, the following should be considered for corrective actions:

a) Investigation of the specific equipment and imaging procedure

b) Investigation of the specific exposure factors and the specific equipment

c) Change the radiographic image protocol

d) Procurement for new x-ray equipment

7. Indicate if the following statement is true or false: PiDRLs are calculated at the 75 percentile and the 25 percentiles.

a) True

b) **False**

8. Indicate if the following statement is true or false: PiDRLs can be performed once a year, and values may be compared to previous calculations.

a) **True**

b) False

9. Indicate if the following statement is true or false: The incident air kerma ($K_{a,i}$) should first be calculated before the entrance surface dose (ESD) can be calculated, depending on the method for calculating PiDRL.

a) **True**

b) False

10. Indicate if the following statement is true or false: The International Commission on Radiological Protection (ICRP) recommends a sample size of 30 patients for non-complex radiographic examinations as a guideline.

a) True

b) **False**

3 CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

3.1 INTRODUCTION

This chapter presents a discussion of the research design and methodology. The researcher employed a specific study design to find answers to the research question. The research methods used in this study comprised of checklists, namely the PiDRL checklist (cf. Appendix 7), the image quality assessment checklist (cf. Appendix 8) and the assessment image quality score card (cf. Appendix 10). The researcher will discuss the sampling method employed in this study. A discussion of the ethical considerations, data collection and statistical analysis will follow. This chapter will also include the validity and reliability of this research study in the discussion.

3.2 RESEARCH DESIGN

The researcher used a descriptive design. The researcher collected quantitative data prospectively and retrospectively. The descriptive method involves gathering information about a particular local situation and making comparisons to determine the norms or standards of other variables in the sample (Babbie 2015:525). The data were collected while the referred paediatric patients visited the radiology departments located in the NCP for chest x-ray examinations. As the sample size was not met due to various constraints, such as limited paediatric chest x-ray referrals, because of the COVID-19 pandemic (cf. Section 6.3 Chapter 6) during the data collection period, the researcher used a retrospective data collection method later in the data gathering process. The data collection period was from 24th August 2020 to 31st November 2021. The data analysis techniques used in the quantitative research included descriptive and inferential statistics. The researcher and a statistician performed the quantitative data analyses.

3.3 SITE SELECTION AND LOCATION

The sampling frame for selecting the research sites was the geographical location of the NCP in SA (cf. Figure 3.1). The NCP stretches over three hundred and seventy-two thousand square kilometres and is the most sparsely populated province in SA (South Africa info 2018: online). The NCP has five major government hospitals with three hundred kilometres between them and small clinics widely spread across the province. The number of private hospitals is minimal, with long distances between their locations (Municipalities of South Africa 2021: online). Paediatric patients receive health services in hospitals located in cities such as Kimberley, Kuruman, Upington, and De Aar. Figure 3.1 shows the geographical map of SA representing the NCP and the major cities within this province. Due to the vast distances between the major cities, the researcher purposely selected four hospitals with three radiology departments that routinely image paediatric patients within one day's drive from the researcher's primary residence. These radiology departments are located in Kathu, near Kuruman and Kimberley.

FIGURE 3.1 Map of South Africa indicating the different provinces and major cities, including the NCP (Britannica 2021: online)

3.4 EQUIPMENT SELECTION

Specific x-ray rooms are dedicated to performing conventional paediatric chest x-ray (CXR) imaging at the four hospitals selected as research sites. The four research sites in the NC included one government radiology department and two private radiology departments that perform paediatric AP chest imaging. The radiology department of Hospital 2 was housed between separate hospital buildings, Hospital 2a, Hospital 2b and Hospital 2c. Figure 3.2 depicts the number of rooms that are utilised for paediatric CXR imaging with computed radiography (CR) or digital radiography (DR) technology indicated for each radiology department.

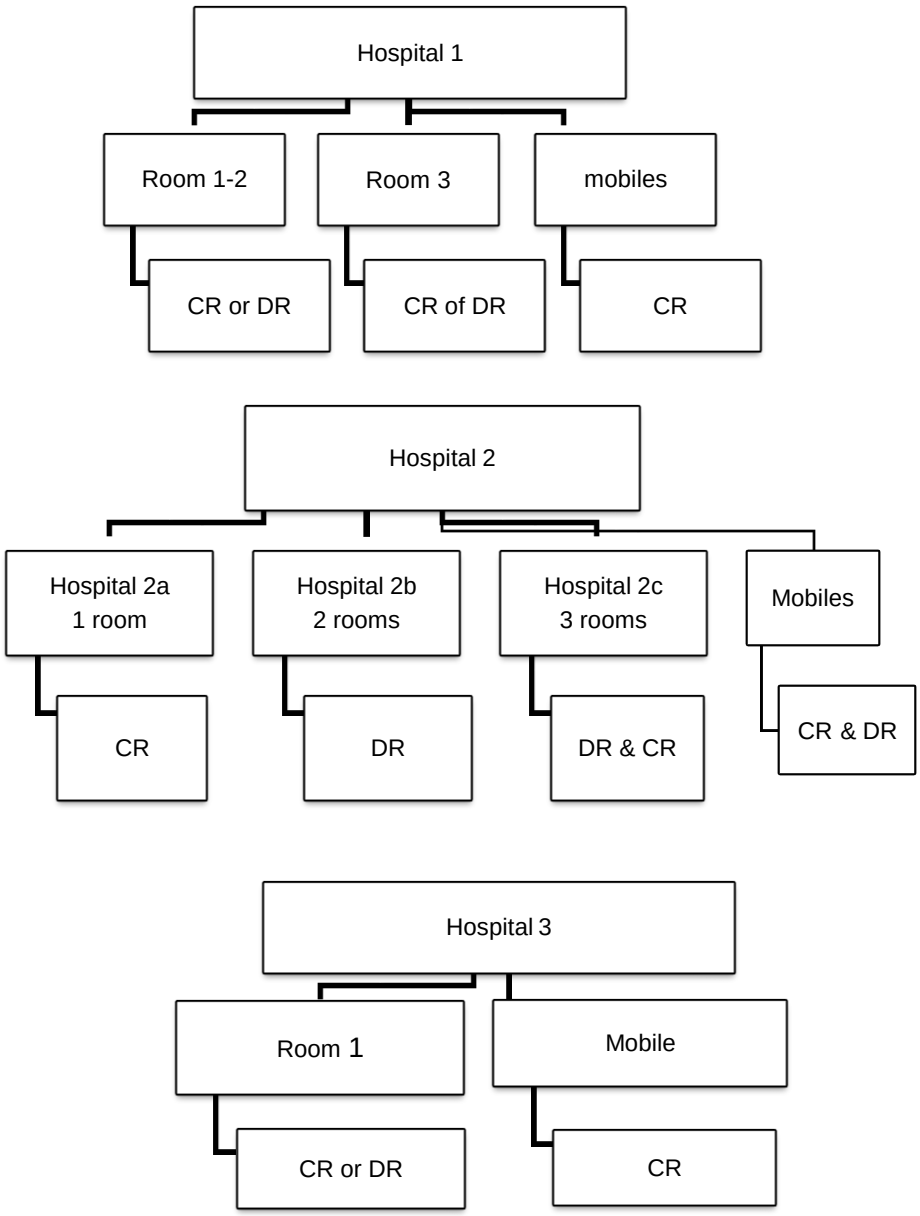


FIGURE 3.2 Illustration of the number of imaging rooms for paediatric CXR imaging as well as the mobile units indicating CR or DR mobile units

Figure 3.3 depicts an image of the x-ray room and control panel used for paediatric patient imaging at one of the radiology departments. The researcher recorded the information on the exposure parameters during data collection.

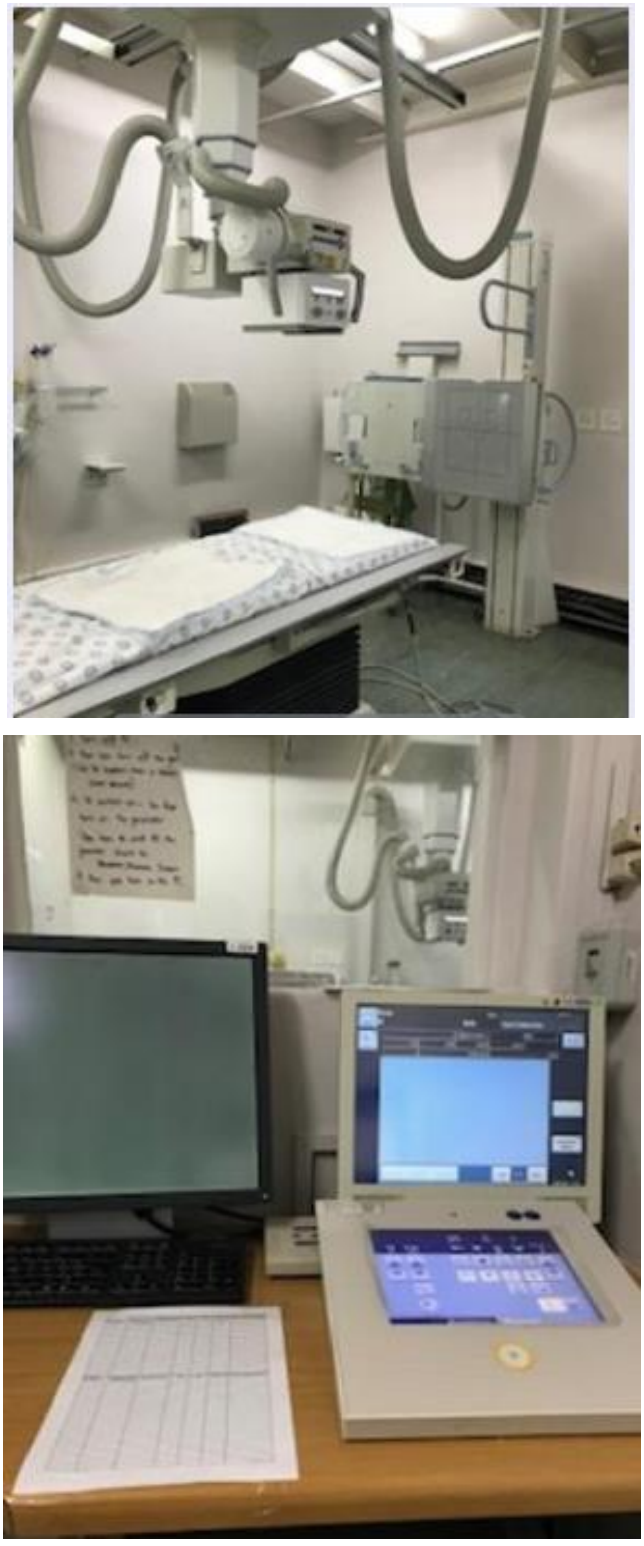


FIGURE 3.3 Images of an x-ray room and control panel used for paediatric CXR imaging [Permission from radiology department see Appendix 2(b)]

Table 3.1 summarises the different x-ray equipment information per room at the three radiology departments included in the study.

TABLE 3.1a Information on the x-ray equipment in each radiology department

	Hospital 1		**Hospital 2**		**Hospital 3**
Room number	Room 1	Room 2	Hospital 2a	Hospital 2b	Room 1
Manufacturer of the x-ray machine	Shimadzu	Siemens	Shimadzu	Siemens	Dell
Erect Bucky grid ratio	12.1	12.1	12.1	12.1	12.1
Inherent filtration of the x-ray tube (e.g., mm Al eq)	1.0	1.5	1.5	1.5	0.9
DR/CR For CR/DR digitiser system used	DR/CR Siemens /DR	DR/CR Siemens /DR	CR Agfa CR	DR/CR Canon DR	DR/CR Fudji DR
Annual QC tests date	Jan. 2021	Aug. 2021	Sept. 2021	Sep. 2021	Oct. 2021
Monthly QC tests date	done	done	done	done	done

Abbreviations: Al eq, aluminium equivalent; Aug., August; CR, computed radiography; DR, digital radiography; Jan., January; mm, millimetre; Sep., September; Oct., October; QC, quality control.

The researcher used a PBU-80 Newborn Whole Body Phantom during the image quality tests. Table 3.1b depicts the mobile units on which the researcher performed the image quality test using the image quality checklist.

TABLE 3.1b Information on the mobile units in the radiology departments

	Hospital 1			**Hospital 2**		**Hospital 3**
Mobile number	Mobile 1	Mobile 2	Mobile 3	Hospital 2a Mobile 1	Hospital 2b Mobile 2	Mobile 1
Manufacturer of the x-ray machine	Villa Visitor AR 30	Radiologia Mobilette	DR 100e Agfa	Siemens	Shimadzu	IMD BASIC 100-30
Inherent filtration of the x-ray tube (e.g. mm Al eq)	0.5	2.0	1.1	1.5	1.5	2.0
DR/CR CR/Digitiser DR/Detector	CR Agfa CR	CR Agfa CR	CR Agfa CR	CR Agfa CR	DR Canon DR	CR Fuji CR
Annual QC tests date	Nov. 2021	Nov 2021	Feb. 2021	Sep. 2021	Sep. 2021	Oct. 2021
Monthly QC tests date	Done	Done	Done	Done	Done	Done

Abbreviations: Al eq, aluminium equivalent; CR, computed radiography; DR, digital radiography; Feb., February; Sep., September.; Oct., October; QC, quality control; Nov., November.

The mobile units used in radiology departments for paediatric imaging are shown in Table 3.1b. Hospital 1 included three mobile units situated on strategic levels for efficient paediatric imaging. Hospital 2a utilised one mobile unit, also strategically situated near a paediatric ward. Hospital 2 utilises one mobile unit near the neonate unit. Further, Hospital 3 has one mobile unit near the paediatric wards. Hospital 2b had a direct DR mobile unit, while all the other hospitals have CR mobile units.

3.5 STUDY POPULATION

The study population is defined as individuals participating in a study, for example, a clinical trial where all the participants make up the study population (Farlex 2019: online). Further, Lues (2016:46) defines the population as all the members or units, of some clearly defined group of people, organisms, events or objects. The study population was paediatric patients referred to the NC research sites for CXR imaging between the 24th of August 2020 and the 30th of November 2021. The term 'child' is defined in the Children's Act no. 38 of 2005 as a person who is under 18 years of age (SA Children's Act 2005:12). A paediatric patient is usually defined as a patient younger than 14 years of age (RSA DoH 2012: online). The research included paediatric patients under the age of 12 years. For that reason, the researcher obtained ethics approval from an ethics committee (cf. Section 3.9.1 & Section 3.9.2) and signed informed consent from the parent or guardian of each paediatric patient.

3.6 PARTICIPANT SELECTION (SAMPLING)

A sample is a selection of the population elements obtained by a sampling procedure representing a population (Dattalo 2008:3). The standard rule used throughout sampling is that the bigger the sample, the better (Lues 2016:46). The bigger sample size indicates a robust research study, therefore indicating that the end result is a true reflection of the population. For non-complex examinations such as CXR imaging, it is recommended that at least ten patients per patient group and procedure type be performed on each radiology department's x-ray equipment (EC 2018: online). Therefore, the proposed sample size included 30

patients for each weight-based group for each radiology department, resulting in a total sample size of 750 patients. Thirty patients in five weight groups, ranging from zero kilograms to 80 kilograms, would make up the planned sample size for the five x-ray machines. During the pilot study and the actual main data collection, the researcher had to adjust the sample size due to numerous unforeseen limitations (cf. Section 6.3 Chapter 6).

Daniel (2011:132) describes stratified random sampling as a sampling method that uses smaller groups, called strata, to sample a population. Stratified random sampling or stratification divides participants into groups based on similar attributes or characteristics. The study population were stratified according to the radiology department where paediatric CXR examinations are frequently performed. The researcher subsequently used cluster sampling to sample 30 AP paediatric CXR images from each of the strata.

Cluster sampling is used in statistics when natural groups are present in a population (Glen 2019: online). Further, for cluster sampling, the entire population is divided into groups or clusters or bands, from which random samples are taken (Glen 2019: online). The researcher divided the different groups into age and weight-based groups. Weight, rather than age, is a more accurate indicator to link to the DRL quantity (Järvinen, Vassileva, Samei, Wallace, Vano & Rehani, 2017: online). The chest imaging included all paediatric patients imaged in the radiology departments' x-ray rooms. Table 3.2 depicts the grouping of paediatric patients for the calculation of PiDRLs.

TABLE 3.2 Summary of weight groups versus age-based groups for PiDRL (Vañó, Miller, Martin, Rehani, Kang, Rosenstein, Ortiz-López, Mattsson, Padovani & Rogers 2017:93)

Description	Weight group intervals for CXR examinations	Age groups intervals for CXR examination
Neonate	<5kg	<1 years
Infant, toddler and early childhood	5kg to <15kg	1 year to <5 years
Middle childhood	15kg to <30kg	5 years to <10 years
Early adolescence	30kg to <50kg	10 years to <12 years
Late adolescence	50kg to <80kg	

Abbreviation: kg, kilogram.

3.7 INCLUSION AND EXCLUSION CRITERIA

The inclusion and exclusion criteria are a set of specific assertions about the characteristics of studies that will or will not be included in the meta-analysis (respectively) (Card 2015:38). The major aspects of the target population that the research will employ to answer a study question are defined as inclusion criteria. Demographic, clinical, and regional factors are common inclusion criteria (Hulley, Cummings, Browner, Grady & Newman 2007:29).

Paediatric patients up to the age of 12 years were included in this study. Another requirement was that each radiology department's paediatric patients be divided into weight groups ranging from less than 5kg to less than 80kg. Adults usually vary in size by a factor of 4 (40 – 160 kg bodyweight), whereas paediatric patients vary in size from premature babies (e.g., 300-400 g) to obese adolescents (> 80 kg body weight), representing a factor of more than 200 (EC 2018:29). Therefore, children weighing up to 80kg were included in this research study. A child may be subjected to medical treatment or surgical procedures only if an agreement for such treatment or operation has been provided in line with Section 129 of the

Children's Act No. 38 of 2005 (Medical Protection 2021: online). If the child is (a) under the age of 12 years; or (b) over that age but of insufficient maturity or cannot understand the benefits, risks, and social implications of the treatment (Medical Protection 2021: online), the parent, guardian, or caregiver of the child may, subject to Section 31, consent to the child's medical treatment. Therefore, the parent, guardian or caregiver had to consent to the procedure and the inclusion in the study.

The exclusion criteria were adult patients for radiology imaging, namely patients whose age falls outside the population's sub-groups, i.e., above 12 years of age and weighing over 80kg's. Another exclusion criterion was radiology departments that did not conduct paediatric imaging in their departments. Paediatric patients whose parents or guardians declined to give permission for their participation were excluded from the study. The DRL for AP CXR projection was calculated, and the lateral projection of the CXR examination was excluded. This is because AP projection is the most common and is therefore viewed as reliable (Arthur 2000:41).

For a radiology department to be included as a research site, the radiology department manager had to confirm that paediatric patients were referred there for CXR imaging. Radiology departments requiring the researcher to travel further than two hundred kilometres to collect data were excluded as research sites were purposely chosen within a radius of two hundred kilometres to minimise the travel time and cost to each research site. The distance between study sites and the amount of time the researcher would spend on the road was taken into consideration when choosing a research site. Since numerous trucks use the NC roadways, the researcher's safety was taken into account when selecting the research locations.

3.8 RESEARCH METHODS

A study's validity is judged by the information contained in its methods section (Kallet 2004:1). The specific materials and methods must be appropriate for

answering the research question and providing clear, adequate, and detailed information to scientists, readers, and reviewers reading the scientific article (Erdemir 2013: online). The behaviour and instruments used in selecting and creating research approaches are referred to as research methods (Kothari 2004:7). The methods and materials will convey how the research study was planned and how the research question was formulated in this study. The researcher designed nine steps included in the methodology to achieve the objectives of the study (cf. Section 1.4.3). Figure 3.4 illustrates a summary of the nine steps.

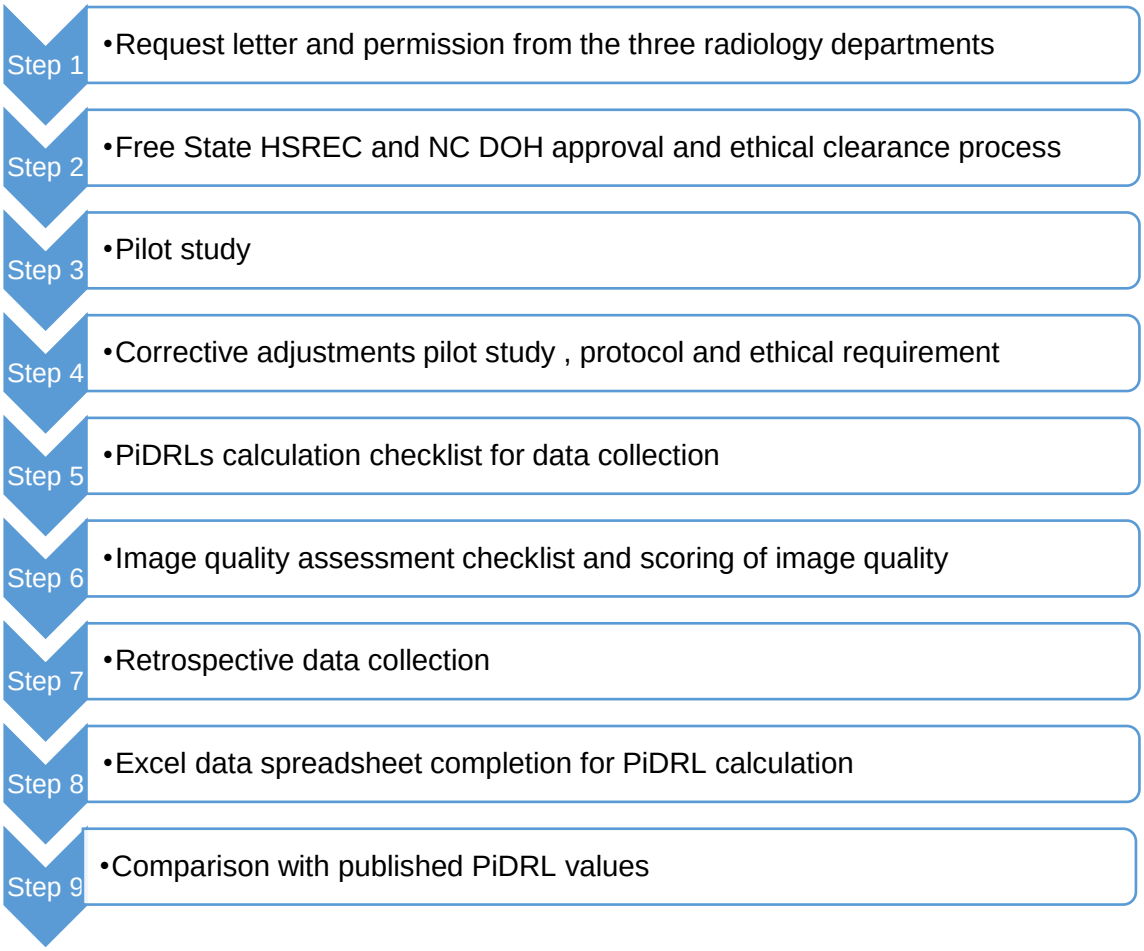


FIGURE 3.4 Flow chart to illustrate the methodological steps that were followed to calculate PiDRLs

The following are the nine steps used to determine the PiDRL at the three NCP radiology departments:

- The **first step** was writing letters to the three radiology departments to request permission to collect data at these sites. Subsequently, permission was provided by the three radiology departments [cf. Appendix 2(a) & (b)].
- **Step two** entailed obtaining permission from the UFS HSREC [cf. Appendix 3(a)] and the Northern Cape (NC) DoH (cf. Appendix 3(b)] to start with the data collection. Permission was obtained from the UFS HSREC on 17 August 2020 and the NC DoH on 7 August 2020.
- **Step three** was conducting the pilot study. The PiDRL calculation checklist described in Section 3.10.1 was used in the pilot study to capture the data. After that, the researcher captured the data in the Excel spreadsheet to calculate the PiDRL.
- **Step four** was corrective in nature and involved adjustments made after the pilot study to the protocol, checklist and ethical approval. The researcher postulated that by including this step in the design, adjustments and corrections could be made to improve the data collection process to answer the research question, thus ensuring the research instruments' validity. The researcher made no changes to the checklist after completing the pilot study. Notably, the researcher observed that during the pilot study, many paediatric patients were not accompanied by their parents or guardians but were rather accompanied by the referring physician due to COVID-19 pandemic restrictions. Consequently, the researcher designed a telephonic consent form and procedure, which was submitted as a study protocol amendment to UFS HSREC. The telephonic consent form was approved in November 2020 by the UFS HSREC (reference number: UFS-HSD2020/0456/290901 cf. Appendix 3).
- **Step five** involved the PiDRL **calculation checklist** (cf. Appendix 7), which the researcher utilised to collect x-ray equipment specifications. DRLs are x-ray equipment specific (EC 2015:9), and therefore, the researcher populated the checklist for the specific x-ray equipment. Further, the researcher captured the patient data on the checklist. The

ICRP recommends a sample size of 10-20 participants to calculate a DRL value (ICRP 2016: online). The researcher recorded technical imaging elements like exposure settings, x-ray tube output, and source-to-image distance (SID) on the checklist. As indicated on the checklist, for each radiology practice, the requirements were the recording data of 30 participants per weight group when undergoing AP chest imaging in a specific room.

- **Step six** included the **image quality assessment checklist** and assessment image quality scoring card described in Section 3.10.2 for newborn babies visiting the radiology departments. The image quality data collection was conducted during the PiDRL checklist data collection period. Paediatric patients were referred for CXR examinations to the radiology departments; thus, the researcher could capture exposure factors for the image quality assessment checklist (cf. Appendix 8). The same exposure factors were used for the PBU-80 Newborn Whole Body Phantom investigation as used by radiographers used for the CXR examination of the AP chest projection of the newborn babies for the less than and up to 5kg weight group. The researcher used the image quality assessment checklist to capture the exposure factors and check the image quality as specified by the guidelines of the (EC 1996:29) criteria for the image quality of newborn babies. The quality assessment checklist and scoring card indicated very clear and specific criteria to evaluate radiological images and, therefore, can be used independently as a guideline by technical and clinical staff (EC 1996:13). The checklist was used in Hospital 1, Hospital 2a, Hospital 2b and Hospital 3 when paediatric patients were referred to departments for paediatric CXR examination. The image checklist was also used on the mobile units in each hospital. After the researcher acquired the images, the assessment image quality scoring card was utilised, and each radiological image was scored based on the EC (1996:61) (cf. Appendix 10). The scoring card consisted of a 7-point rating scale developed by the EC (EC 1996:61). The researcher scored the radiological images and viewed the images on either the viewing lightbox or on a digital platform of the CR or DR monitor.

- **Step seven** entailed retrospective data collection. As described in Section 3.9.3, the telephonic consent letter was utilised to collect data for weight groups where the sample size was not adequate to calculate the DRL.
- **Step eight** included capturing the paediatric data from the PiDRL calculation checklist into the Excel spreadsheet. Formulas were entered in the Excel spreadsheet to calculate the PiDRL with the assistance of a medical physicist for each specific type of x-ray equipment for the respective radiology departments. The x-ray tube output had to be obtained to calculate the free air exposure (FAE) before the ESD_{air} could be formulated. Therefore, the researcher acquired a calibrated dosimeter from a manufacturer to read the dose at different kVp settings. The researcher obtained two dose readings at kVp settings, consistent with the kVp settings the radiographers in the department used to image their paediatric patients for CXR. An explanation for obtaining the x-ray tube output value is found in Chapter 2, section PiDRL calculation steps, Step 3, Calculation of the x-ray tube measurement. The researcher used the following formula in this research to calculate the ESD with backscatter (ESD_{air}):

ESD_{air} (mGy) = FAE (mR) X 0.008 77 X BSF (Tung, Tsai, Lo, Guan, & Chen 2001:851)

Where ESD = ESD in air, including the backscatter factor (BSF)
FAE = incident air kerma without BSF
BSF = BSF of 1.32
0.00877 = where 0.00877 converts the exposure, in units milliroentgen (mR), into the absorbed dose to air, in units mGy.

- **Step nine** involved the discussion of these research findings and comparing findings that were in line with other published data of other countries (see Chapter 5).

3.9 ETHICAL CONSIDERATIONS

In this section, the researcher will discuss ethical approvals, informed consent and telephonic consent.

3.9.1 Ethical approvals

Ethical permission was granted for the study by the UFS HSREC (reference number: UFS-HSD2020/0456/2909) [cf. Appendix 3(a)]. The researcher sent permission request letters to the three radiology departments identified as research sites. The study was registered on the National Health Research Database (NHRD) to obtain permission from the NC DoH to conduct the study in the public radiology department [cf. Appendix 3(b)].

3.9.2 Informed consent

Each parent or guardian of a paediatric patient (research participant) received an information document from the researcher that included a detailed and easy-to-understand explanation of the study (cf. Appendix 5). The information document [cf. Appendix 5(a) (b) & (c)] and the informed consent (cf. Appendix 6) were available in Afrikaans [cf. Appendix 6(a)], English [cf. Appendix 6(b)] and Setswana [cf. Appendix 6(c)]. The population in the NC province mainly speaks these three languages. The parent or guardian signed the informed consent or gave permission through telephonic consent to the researcher so that the paediatric patient's information could be accessed and recorded to calculate the PiDRL. The document stipulated that all information gathered would be kept private. No personally identifying information about the research participant was collected, such as his or her name, surname, date of birth, hospital number, home address, or phone number. Only questions of a technical nature were required from the departments for the calculation of the PiDRL.

3.9.3 Telephonic consent

The parent or guardian was not always present when the paediatric patient was brought to the radiology department for the CXR examination; hence telephonic consent (cf. Appendix 4) had to be obtained from the parent or guardian. During the COVID-19 pandemic, the general physicians accompanied the paediatric patient to the radiology department because only a few people were allowed in hospitals as per COVID-19 regulations. Therefore, the researcher introduced a telephonic consent letter in the methodology. The letter stated that all information would be kept confidential. The researcher described the study over the telephone in the presence of the general physician or medical staff. The researcher was in the administration office sitting next to the administrator. The telephone was not put on speakerphone, and the conversation was loud enough so that the administrator could hear the conversation between the researcher and the parent or guardian. The parent or guardian had to indicate if they understood the reason for the telephonic discussion and could ask questions if they needed further clarity about the research study procedure. After that, the medical personnel had to sign as a witness on the form as proof of consent. The researcher obtained permission to use the telephonic consent letter for the participating parent or guardian of the patient in November 2020 from the UFS HSREC (reference number: UFS-HSD2020/0456/290901). In Section 3.8.4.1, the main researcher mentioned that the radiography personnel in the radiology department, who were willing to assist, were trained for data collection. The patient influx in hospitals and radiology departments rose once COVID-19 restrictions were relaxed. The researcher could only utilise the telephonic consent retrospectively because the trained radiography staff were engaged with patient examinations in the department and could not collect data telephonically. When the COVID-19 restrictions were eased, the researcher collected data retrospectively from those patients where prospective data collection could not be obtained.

3.10 THE RESEARCH INSTRUMENT AND DATA COLLECTION TOOLS

Mangal and Mangal (2013:304) defined a research instrument or tool as a technique or tool to collect evidence or information for answering the research question. A checklist is a form used for quick and easy data recording or identifying actions or requirements. The data can usually be easily extracted in a useful manner from a checklist (AHRQ 2019: online). The advantages of a checklist include that the data is faster and easier to document and access, and it also saves time (Tripathy 2017:66). A disadvantage is that checklists are specific to a particular situation (AHRQ 2019: online). The researcher used two checklists as research tools: the PiDRL checklist (cf. Appendix 7) and the image quality assessment checklist (cf. Appendix 8). The third tool, the Assessment Image Quality scoring card (cf. Appendix 10), was used to score the radiological image quality.

The researcher used a checklist to gather the data to calculate PiDRL in the various radiology departments. The PiDRL calculation checklist (cf. Appendix 8) included the exposure parameters, patient age, patient weight, and x-ray equipment information. Data captured in the PiDRL calculation checklist was anonymised and numerical. No personal information was disclosed about the patients or radiographers during the data collection. A second checklist, the image quality assessment checklist (cf. Appendix 8), was utilised to assess the x-ray image quality of newborns referred to the radiology department. The image quality assessment checklist contains exposure parameters and the image criteria described in Section 3.10.2. The exposure of the PBU-80 Newborn Whole Body Phantom for this purpose was to evaluate the image quality. The image quality assessment checklist data collection was conducted during the data collection of the PiDRL calculation checklist. The researcher imaged the PBU-80 Newborn Whole Body Phantom when the radiology departments were less busy during the day.

Further, the researcher assessed the image quality based on the image quality scoring card during the control investigation on the phantom (3.5kg) for the

weight-based group of less than and up to 5kg. This control investigation of image quality was performed for paediatric imaging patients for the less than and up to 5kg weight group, a similar weight as the phantom for each room used. The researcher used the same exposure parameters used by the radiographers in the department on the mobile units for each hospital. The quality assessment checklist is very specific and clear, and therefore the researcher could utilise the checklist to evaluate the radiological images obtained during the image quality investigation. The scoring card utilised to score the radiological images (EC 1996:61).

3.10.1 PiDRL calculation checklist

The researcher formulated the PiDRL calculation checklist through guidelines documented in the ICRP (2017:103). According to the ICRP (2017:103), PiDRL is defined for the types of equipment used by each radiology department for typical exams of age groups and weight-based groups ranging from less than and up to 5kg to less than 80kg. The exposure parameters are fundamental in establishing entrance skin kerma (ESK) or entrance skin air kerma (ESAK) with backscatter to calculate PiDRLs. This calculation must be performed for the specific radiographic examination in the specific radiology department for the specific x-ray machine.

The researcher used the PiDRL calculation checklist (cf. Appendix 7) to calculate DRLs for each NCP radiology department. The primary researcher collected data by shadowing (observing) the radiographers in the radiology departments without disturbing their normal workflow. Each AP paediatric CXR image parameter and patient measurement was documented on a separate checklist. The x-ray images and related checklist were given the same study number. Section A of the checklist included the equipment information, such as the manufacturer name, inherent filtration of the x-ray tube, type of digital system, and whether the cassette or image receptor was used with or without a grid. The PiDRL calculation checklist indicated when the annual and monthly quality control tests were performed. Section B of the checklist included patient measurements, e.g., the

patient's weight and age sub-group in months and years and the patient thickness at the level of thoracic vertebrae number seven. Section C included the technical imaging factors such as kVp, mAs and the SID in centimetres. The time required to complete the checklist would be approximately five minutes.

3.10.2 Image quality assessment checklist and scoring card

DRLs are not sufficient in optimising radiation protection when used as a quality control tool on their own (Vañó *et al*. 2017:14). Image quality includes post-processing effects, which are indirectly attributed to dose evaluation quality (Muhogora, Ahmed, Almosabihi, Alsuwaidi, Beganovic, Ciraj-Bejelac, Kabuay, Krisanachinda, Milakovic, Mukwada, Ramanandraibe, Rehani, Rouzitalab & Shandorf 2008:1453). Therefore, image quality in conjunction with DRLs should be considered during optimisation methods. The researcher included image quality as part of the research method utilising the exposure factors and checking the image quality as specified by the guidelines of the EC criteria for the image quality of newborn babies. The EC (1996:29) image criteria for newborn babies provide a valid guideline for an erect AP CXR projection free from pathology. The guidelines contribute to dose optimisation in the radiographic imaging of a newborn baby. Table 3.3 illustrates the diagnostic requirements for a good quality x-ray image for newborn babies.

TABLE 3.3 EC x-ray image criteria recommendation for newborn babies (EC 1996:29)

No.	Criteria
1	Performed at the peak of inspiration.
2	Reproduction of the thorax without rotation and tilting.
3	Reproduction of the chest must extend from the cervical trachea to thoracic vertebrae 12 and lumbar vertebrae 1 (part of the abdomen may be included for special purposes).
4	Reproduction of the vascular pattern in the central half of the lungs.
5	Visually sharp reproduction of the trachea and the proximal bronchi.

6	Visually sharp reproduction of the diaphragm and costo-phrenic angles.
7	Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum.

Abbreviation: no., number.

The image quality of the CXR images of newborn patients was then assessed using the image quality assessment checklist (cf. Appendix 8) acquired by exposing PBU-80 Newborn Whole Body Phantom. Section A includes the equipment information and exposure parameters when the researcher performed image quality assessments on the PBU-80 Newborn Whole Body Phantom's chest images. Section B includes the criteria for image quality as stated by the EC (1996:29). After the AP CXR images were obtained by the investigation, the images were rated and scored. The image quality scoring card (cf. Appendix 10) consists of a 7-point rating scale, and the questions are based on the image criteria assessment (cf. Appendix 8). There are 13 questions. The total possible score is 13 points to achieve 100% image quality. According to the scoring, "1" indicates "Yes" it can be seen on the image, and "0" indicates "No" it cannot be seen on the image. According to the EC (1996:29), it is challenging to obtain 100% image quality because of patient imperfections, pathology, or technical factors. The scoring card was used for each AP CXR radiological image obtained during the image quality investigation. The steps are described in Section 3.8.4.2.

3.10.3 Excel spreadsheet for PiDRL calculation

Excel is a well-known standard spreadsheet tool that lets you quickly calculate and recalculate data using a variety of built-in functions and formulae (Held, 2006: xv). The researcher created a Microsoft Excel version 2016 spreadsheet with specific formulas that produced and calculated the value of the PiDRL. The formulas were implemented with the help of a medical physicist, guided by the calculation method mentioned in Chapter 2. The ESK value was calculated, including backscatter, for each patient in the specific weight groups. Utilising the statistical formula in Microsoft Excel, the seventy-fifth (75^{th}) percentile of each weight group could be obtained. Table 3.4 depicts the Excel spreadsheet that

was used to calculate the DRLs for each weight group per x-ray equipment utilised for each radiology department.

TABLE 3.4 An example of the Excel spreadsheet the researcher read the data into to calculate the PiDRL value

Machine information									Pt. measurements			Technical factors												
Room no.	Manufacturer	Grid ratio	Inherent filtration	CR/DR system	Bucky (yes or no)	Mobile (yes or no)	Incubator (yes or no)	Paediatric ward/ ICU/ Casualty	Pt. height	Pt. weight	Pt. age (years) (months)	kVp	mAs	SID	Pt. thick-ness	Gap between pt. and detector	Out-put K @ mAs used	SSD cm	SSD cor-rection	y =output/ mAs , x=kV	SSD correc-tion	ESD in mGy at 100 cm	ESD at cor-rected SSD (mGy)
									Centi-meter (cm)	kg	Year (y)/ months (mos.)/ days			cm	cm	cm	mAs/100* output	SID-(pt+gap)	(SSD/100)^2	y = 0.0015x -0.053			
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	44	2.5	16 days	50	1.8	100	9	2	0.000	89	1.26		89	0.0396	0.049994
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	40	2.9	3 days	60	3.2	100	10	2	0.000	88	1.29		88	0.1184	0.152893
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	22	4.3	1 mo.	55	2.5	100	8	2	0.000	90	1.23		90	0.07375	0.091049
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	45	1.3	3 mos.	50	3.2	100	8	2	0.000	90	1.23		90	0.0704	0.086914
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	51	3.5	2 mos.	75	2.8	100	7	2	0.000	91	1.21		91	0.1666	0.201183
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept	50	3.54	1 mos.	80	2.2	150	10	2	0.000	138	0.53		138	0.1474	0.0774
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	40	3.4	1 mos.	88	2.2	150	9	2	0.000	139	0.52		139	0,1738	0.089954
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	50	4.02	3 mos.	70	2.8	110	9	2	0.000	99	1.02		99	0.1456	0.148556
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	61	3.53	3 mos.	80	2.2	110	11	2	0.000	97	1.06		97	0.1474	0.156659
1	SHIMADZU	12.1	1.0 Al	DR	Y	N	N	Dept.	58	4.5	3 mos.	75	3.5	110	9	2	0.000	99	1.02		99	0.20825	0.212478

Abbreviations: Al, aluminium; no., number; cm, centimetre; CR, computed radiography; DR, digital radiography; Dept., Department; ESD, entrance skin dose; ICU, intensive care unit; kVp, kilovoltage peak; mAs, mill Ampere per second; mGy, milligray; mos., months; no., number; pt., patient; SID, source-to-image distance; SSD, source-to-skin distance; Y, yes; y, year,

3.11 PILOT STUDY

A pilot study is a smaller version of the major research project that allows the researcher to identify and address some of the challenges that may arise during data collection by gathering information to improve the project and making adjustments to the research instruments, research plan, protocol, and time schedule, resulting in a feasible study (Tripathy 2017:47). Recruitment, randomisation, retention, evaluation processes, novel methods, and implementation can all be evaluated by employing a pilot study (Leon, Davis & Kraemer 2011:626).

After ethical clearance was granted, the pilot study commenced in three radiology departments. In this dissertation, the hospitals selected as the research sites are referred to as Hospital 1, Hospital 2, and Hospital 3. Further, Hospital 2 has three separate radiology departments located in two separate hospitals, and they will be referred to as Hospital 2a, Hospital 2b, and Hospital 2c. Three participants representing each weight band were included, and the informed consent form was signed and approved by a parent or guardian of the paediatric patient.

The data collection proceeded after the completion of the pilot study. The data collected during the pilot study was included in the larger-scale research study as no changes or adjustments were required for the PiDRL calculation checklist (cf. Appendix 7). A medical physicist assisted in calculating the DRLs for the pilot study. Amendments were made to the information documents by simplifying the sentences and making the document easier to read and understand [cf. Appendix 5 (a), (b) & (c)]. For the pilot study, informed consent had to be obtained from a parent or guardian of a paediatric patient. South Africa was under COVID-19 restrictions during the pilot study period and on Lockdown Level 2. As previously stated, paediatric patients referred for CXR imaging were accompanied to the radiology department by the referring physician and not the parent or guardian of the paediatric patient as initially anticipated.

Consequently, amendments had to be made to the initial protocol to include a telephonic consent document (cf. Appendix 4). The researcher obtained approval

for these amendments from the UFS HSREC. Data collection continued while awaiting approval for amendments, but the researcher included only data from paediatric patients accompanied by a parent or guardian while awaiting the approval of the amendments. The data was captured using the checklist. The X-ray equipment information, patient measurements and technical imaging factors for calculating PiDRLs were documented for only seven patients who met the inclusion criteria. Further, the PiDRL calculation checklist (cf. Appendix 7) also stipulated the date on which the quality control tests on the radiographic equipment were performed.

3.12 DATA COLLECTION

According to the literature, DRLs should be included in a radiology department's program for quality assurance (Paulo, Vao, & Rodrigues 2015:1). Notably, DRLs should be recalculated and compared to the baseline on a quarterly basis. By having a checklist to indicate exposure data and then analysing the data, one can identify special-cause variations, thus getting to the root of the problem, especially when the DRLs are exceeded (Jones, Heintz, Geiser, Goldman, Jerjian, Martin, Peck, Pheiffer, Ranger & Yorkston 2015:9). A medical physicist is responsible for various tasks, including evaluating dose patterns by utilising dose analytics tools (Gingold 2017:1). Thereafter, the findings are compared with benchmarks such as DRLs and other published, summarised registered data to identify examinations and protocols that have the potential for further dose reduction.

In this study, the researcher collected data prospectively as well as retrospectively. Some radiology departments do not have well-automated data collection systems available to directly document the kVp and mAs on the digital equipment software. Therefore, the researcher scheduled visits to the radiology departments at least once a month. The hospitals where the researcher collected the retrospective data were Hospital 1 on the Shimadzu and Siemens x-ray equipment and the Shimadzu x-ray equipment at Hospital 2a. The PACS for Hospital 1 and Hospital 2b did not have all the data required to collect information

for the PiDRL checklist. While the data collection process was taking place for this study and the researcher was visiting research sites to collect data, the South African government applied Lockdown Level 2 and Level 3, which included strict regulations to minimise public and patient access to the hospitals, to curb the spread of COVID-19.

3.12.1 Retrospective data collection

The researcher implemented retrospective data collection as part of the methodology to try and achieve the required sample size. The reason for collecting data retrospectively was that radiographers could no longer assist with prospective data collection due to departmental staff shortages or a sudden surge in patient traffic. The researcher collected the data, even though those radiographers who were willing to help with the data gathering had been trained. The researcher had already taught radiographers how to complete the PIDRL calculation checklist.

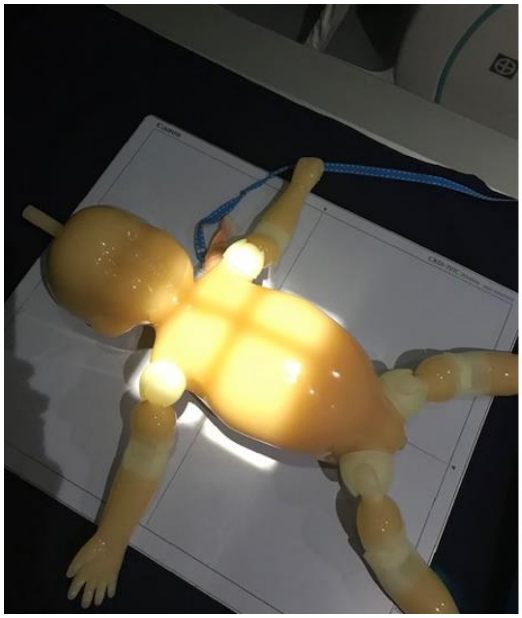
South Africa's COVID-19 lockdown levels were adjusted to allow frequent admission of patients, and the trained radiographers were occupied with an influx of x-ray referrals to the radiology departments. Therefore, the researcher had to utilise the telephonic consent letter and call each parent or guardian. The telephonic consent was implemented when the paediatric patient visited the radiology department, but data of that specific paediatric patient was not collected. The telephonic consent was obtained in the presence of witnesses.

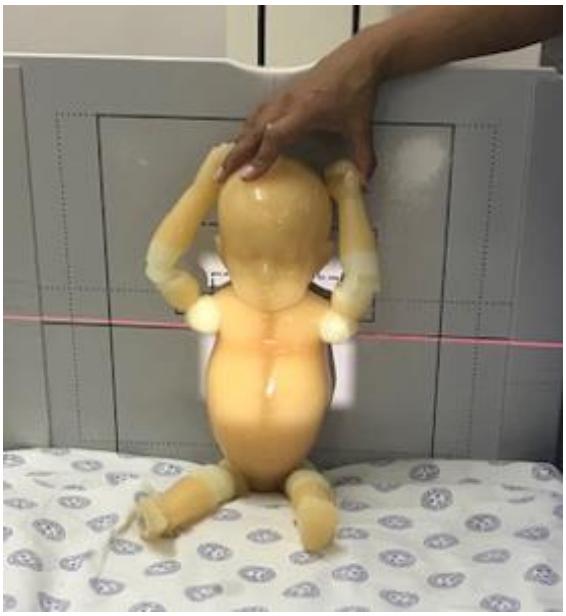
3.12.2 Image quality assessment of phantom CXR images

Image quality is defined as the feature of an image that affects a clinician's certainty to visually distinguish the necessary diagnostic features present in the image (Tompe & Sargar 2021: online). Contrast, dynamic range, spatial resolution, noise, and artefacts are all significant aspects of radiographic image quality (Williams, Krupinski, Strauss, Breeden, Rzeszotarski, Applegate, Applegate, Wyatt, Bjork & Seibert 2007:372).

DRLs are not directly related to image quality (Muhogora *et al*. 2008:1458). However, it is vital to ensure that patient doses from diagnostic imaging are kept ALARA and maintain good quality to execute optimal diagnostic outcomes. Physical parameters such as contrast, noise, and resolution, as well as picture display parameters and observer impression of image quality, characterise image quality during the main image formation stage (Conradie & Herbst 2016:1369).

To achieve a good quality image with dose optimisation in mind, a PBU-80 Newborn Whole Body Phantom was imaged, using the same exposure parameters that the radiographers use for the AP CXR projection at the research sites (radiology departments). This is specific for the AP CXR projection for the weight group that is less than 5kg. The PBU-80 Newborn Whole Body Phantom was in this specific weight group. Figure 3.5(a) and Figure 3.5(b) below depict the use of the PBU-80 Newborn Whole Body Phantom during image quality assessment at the research sites.





(a) **(b)**

FIGURE 3.5(a) and **FIGURE 3.5(b)** Images of the PBU-80 Newborn Whole Body Phantom used during the AP chest x-ray image quality data collections in the departments

The PBU-80 Newborn Whole Body Phantom specifications used in this study are: 53 cm tall, 3.5kg in weight, and composed of polyurethane and epoxy resin. The phantom was placed on top of the CR cassette with a SID of 100 cm. The primary beam was centred to the middle of the chest, and collimation was applied to include the whole chest area. Image acquisition was performed in accordance with the manufacturer's recommendation at each radiology department. The ESK with backscatter was calculated using the method described in Chapter 2, Section (Step 5: Calculating the entrance surface dose with backscatter) for the PiDRL calculation steps. The researcher used the assessment checklist to determine the image quality of each image acquired by the researcher for each respective radiology department as well as the mobile units at each hospital. Hospital 1 had three mobile x-ray units, namely mobile 1, mobile 2 and mobile 3. Hospital 2a had one mobile unit, and Hospital 2b had one mobile unit. Hospital 3 had one mobile unit. The image quality assessment checklist (cf. Appendix 8) was compiled based on the guidelines of the EC, as mentioned in table 1. The assessment image quality scoring card (cf. Appendix 10) was then used to score each radiological image when viewed on the lightbox or on the CR or DR acquisition monitor. Table 3.5 shows the various hospitals, including the departments, during the image quality assessment. The parameters captured included the manufacturer, CR / direct digital radiography (DR) systems, SID, kVp, mAs, and incubator:

TABLE 3.5a Departmental x-ray machine demographics and the exposure parameters used during image quality assessment

Hospital	Manufacturer	CR Digitiser	DR Digitiser	Inherent filter (e.g. mm Al eq.)	Additional filter	SID (cm)	kVp	mAs	Incubator	Grid	Collimation/ (cm^2)
Hospital 1 room 1	Shimadzu	N/A	DR Shimadzu	1.0	None	150	75	2.8	None	Stationary grid	16 x 16.5
Hospital 1 room 2	Siemens	N/A	DR Siemens	1.5	None	150	79	2.8	None	Stationary grid	17 x 18
Hospital 2a	Shimadzu	CR Agfa		1.0	None	150	96	5.6	None	Stationary grid	21 x 18
Hospital 2b	Siemens	N/A	DR Canon	1.5	None	150	96	2.5	None	Stationary grid	14.8 x 19.7
Hospital 3 room 1	Dell	N/A	DR Fudji	0.9	None	110	65	2.5	None	Stationary grid	16 x 16.5

Abbreviations: Al, aluminium; cm, centimetre; CR, computed radiography; DR, digital radiography; kVp, kilovoltage peak; mAs, mill Ampere per second; mGy, milligray; N/A, not applicable; SID, source-to-image distance

TABLE 3.5b Mobile unit demographics and the exposure parameters used during image quality assessment

	Hospital 1			**Hospital 2**		**Hospital 3**
Mobile number	Mobile 1	Mobile 2	Mobile 3	Hospital 2a Mobile 1	Hospital 2b Mobile 2	Mobile 1
Manufacturer of the x-ray machine	Villa Visitor AR 30	Radiologia Mobilette	DR 100e AGFA	Siemens	Shimadzu	IMD BASIC 100-30
DR/CR	CR / Agfa	CR / Agfa	CR / Agfa	CR / Agfa	DR / Canon	CR / Fudji
Inherent filtration of the x-ray tube (e.g. mm Al eq.)	0.5	2.0	1.1	1.5	2.0	2.0
Additional filter	None	None	None	None	None	None
kVp	55 kVp	55 kVp	55 kVp	55 kVp	52 kVp	50 kVp
mAs	2.5 mAs	2.5 mAs	2.5 mAs	2.5 mAs	2.5 mAs	1.6 mAs
SID (cm)	110	Maximum height	110	100	Maximum height	110
Incubator	None	None	None	None	None	None
Focal spot	Small	Small	Small	Small	Small	Small
Collimation (cm^2)	16 x 17	17 x 21	16 x17	19 x17	17.5 x 17.5	16 x 16.7
Bucky/grid	None	None	None	None	None	None

Abbreviations: Al, aluminium; cm, centimetre; CR, computed radiography; DR, digital radiography; kVp, kilovoltage peak; mAs, mill Ampere per second; mGy, milligray; SID, source-to-image distance

Table 3.5a illustrates the demographics of the x-ray equipment in the rooms of the hospital used during paediatric CXR imaging. The exposure factors outlined in Table 3.5b are similar to those used by the department's radiographers. Therefore, the researcher utilised the same positioning technique and exposure factors to conduct the image quality investigation on the x-ray machines in the x-ray rooms. Further, Table 3.5b demonstrates the mobile unit specifications and the radiographers' exposure factors when imaging paediatric patients for CXR examinations. The researcher duplicated the same positioning technique and utilised the same exposure factors when conducting the image quality assessment on the mobile units.

3.13 DATA ANALYSIS

Statistics can be defined as a "language" that gives meaning to numerical facts (data) collected using special symbols (Lues 2016:30). The researcher coded and captured the data obtained from completing the two checklists electronically in Microsoft Excel (cf. Appendix 9). A statistician also performed statistical analysis on the paediatric data using the SAS Version 9.2 programme. Descriptive statistics, namely frequencies and percentages, were calculated for categorical data. The Shapiro-Wilk test was used to investigate if the numerical data followed a normal distribution or if the data was skewed. For numerical data, mean and standard deviations, as well as medians and percentiles, were determined. For proportions, means, and medians, inferential statistics, such as 95 % confidence intervals, were calculated. All data are presented in tables and graphs to illustrate the information in a simple and easy-to-understand format. The DRLs are higher than the mean value for the given number of examinations dose distribution in diagnostic radiography. Therefore, the 75^{th} percentile is the value above the median (50^{th} percentile) in the dose distribution of the sample size (ICRP 2016:34). A significance level (α) of 0.05 was used.

3.14 VALIDITY

The degree to which a concept is precisely quantified in a quantitative investigation is known as validity (Heale & Twycross 2015:online). The Picture

Quality Assessment checklist was utilised to evaluate the image quality, while the PiDRL calculation checklist was utilised to collect data for calculating PiDRLs in the various radiology departments. The researcher recorded the data gathered by electronically in Microsoft Excel filling out the research instruments. Excel formulas were constructed for each type of x-ray machine to determine the PiDRL. The PiDRL calculation was overseen by a medical physicist, confirming the legitimacy of the research study. A statistician managed the collected data and provided descriptive statistics, such as frequencies and percentages. Means and standard deviations or medians and percentiles were presented as numerical data. The research instruments contributed to the validity of the data collected.

3.15 RELIABILITY

A research study is more stable or dependable if its results can be duplicated more frequently (Cypress 2017:online). To put it another way, it alludes to the idea of the repeatability, consistency, and reproducibility of results or observations. The ICRP recommends using DRLs as a quality assurance tool annually, based on the results of the original DRL calculation (ICRP 2016: online). According to the ICRP (2017:online), DRLs has been shown to be a useful instrument that helps with protection optimisation when patients are exposed to medical treatments for diagnostic and interventional procedures. By utilising a valid research instrument, the data collected improved the reliability outcome of this research study.

3.16 CONCLUSION

In Chapter 3, the research methodologies employed in the study, as well as the procedures and actions that were followed, were discussed, as well as the method for determining the PiDRL for three NCP radiology departments. The results and analysis of the data will be presented in the next chapter, Chapter 4.

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4 CHAPTER 4: RESULTS AND FINDINGS

4.1 INTRODUCTION

In Chapter 3, the methods and the study design were discussed. Chapter 4 will outline the results and findings of this research. The findings support the objectives of this study by calculating PiDRL for three NCP radiology departments. The three radiology departments were located in four hospitals in the NCP. In addition, the problem statement was addressed by ensuring that a lack of PiDRLs in SA and the lack of calculated PiDRL in current or recent literature in the NCP's three radiology departments were optimised. The results also address the objective of determining the image quality of the CXR radiographs taken during the radiological examination of paediatric patients.

The quantities that were used to set PiDRLs are milligray (mGy) or microgray (µGy). The 75th percentile represents the PiDRL per weight-based group as shown in Table 4.6 and the PiDRL per age group in Table 4.7. The quantities are dose indicators that characterise radiation exposure for each x-ray equipment in each radiology department. The dose indicators do not reflect radiation dose per individual but a value of a distribution of the values obtained from a specific equipment type for a standard size patient (ICRP 2016: online).

Three radiology departments in the NCP were included in the research study. Retrospective data was collected in Hospital 1 and Hospital 2a. Prospective data were collected in all of the hospitals. The total number of paediatric patients whose data was collected in this research study was n=375 The recommendation stated by the EC (2018: online) for each institution's (radiology department) x-ray equipment should have a representative sample of at least ten patients per procedure type and per patient group required for non-complex examinations such as chest imaging (EC 2018: online). Therefore, the proposed sample size included 30 patients for each weight-based group for each radiology department. Paediatric patients of certain weight groups visited the radiology departments

more frequently for CXR imaging than other weight groups. Completed PiDRL checklists were only excluded when the weight groups were fully populated, and the sample size of n=30 per weight group was reached. The other reason for excluding some paediatric patients was that if the parent or guardian did not sign the consent document. The research study was performed prospectively as well as retrospectively. This was because in certain weight groups, 30kg to <50kg and the weight group 50kg to 80kg, paediatric patients did not visit the radiology departments frequently for CXR imaging. The result was a smaller sample size during the data collection period. The retrospective data were collected to add to the weight groups in which the required sample size could not be reached during the prospective data collection period. The data will be presented by means of tables and figures in this chapter.

4.2 RETROSPECTIVE DATA VERSUS PROSPECTIVE DATA

As stated earlier, it was difficult to obtain a sample size of 30 patients per weight group during the prospective data collection. Therefore, retrospective data were collected to add to the total number of patients in those weight groups where the required sample size could not be reached with prospective data. A statistician used the Wilcoxon two-sample tests for weight variables to determine if there were major differences between the prospective and retrospective studies. If the p-value was greater (>) than 0.05, then there were no significant differences between the mean values of the retrospective compared to prospective studies. However, if the p-value was less (<) than 0.05, then there was a significant difference between the median values of the retrospective and prospective studies. Table 4.1a below indicates that a p-value greater than 0.05 was calculated for all weight groups. Table 4.1b below depicts the p-value greater than 0.05 calculated for the ESD with backscatter per weight group. Therefore it is safe to say that there is no significant difference between the data collected during the prospective and retrospective phase. The data collected retrospectively and prospectively can be seen as one sample per weight group. Table 4.1a below depicts the p-value for the hospitals where retrospective data was also included.

TABLE 4.1a Comparison between the retrospective and the prospective data collected per weight

Hospital	Equipment type	Weight group	p-value
Hospital 1	Shimadzu	<5kg	0.5603
Hospital 1	Shimadzu	5kg to <15kg	0.4529
Hospital 1	Shimadzu	30kg to <50kg	1.0000
Hospital 1	Siemens	<5kg	0.2632
Hospital 1	Siemens	5 kg to <15kg	0.6009
Hospital 1	Siemens	15kg to <30kg	0.7626
Hospital 2a	Siemens	<5kg	1.0000
Hospital 2a	Shimadzu	15kg to <30kg	0.0579
Hospital 2a	Shimadzu	30kg to <50kg	0.3940

Abbreviation: kg, kilogram, < smaller than, > greater than

If $p<0.05$, then there is a significant difference between the mean values of the two groups (prospective compared with retrospective).

If $p\geq0.05$, then there is no significant difference between the mean values of the two groups (prospective compared with retrospective).

Table 4.1b depicts the retrospective and prospective ESD with the backscatter factor value calculated for the different weight groups. A p-value >0.05 value was calculated for each weight group, where data was collected retrospectively and prospectively.

TABLE 4.1b Comparison between the retrospective and the prospective data of a weight group for which ESD with backscatter were calculated

Hospital	Equipment type	Weight group	p-value
Hospital 1	Shimadzu	<5kg	0.7
Hospital 1	Shimadzu	5kg to <15kg	0.1
Hospital 1	Shimadzu	30kg to <50kg	1.0
Hospital 1	Siemens	<5kg	0.7
Hospital 1	Siemens	5kg to <5kg	0.1
Hospital 1	Siemens	15kg to <30kg	0.8
Hospital 2a	Shimadzu	<5kg	0.1
Hospital 2a	Shimadzu	15kg to <30kg	0.7
Hospital 2a	Shimadzu	30kg to <50kg	0.8

Abbreviation: kg, kilogram.

If $p<0.05$, then there is a significant difference between the mean values of the two groups (prospective compared with retrospective).

If $p\geq0.05$, then there is no significant difference between the mean values of the two groups (prospective compared with retrospective).

4.3 TOTAL DATA PER X-RAY EQUIPMENT

The data collected, retrospectively and prospectively, could be added together and displayed as the frequency of paediatric AP CXR imaging during the data collection period. Table 4.2 depicts the amount of data collected retrospectively and prospectively in each radiology department per x-ray equipment. The frequency indicates the total data collected per x-ray equipment. Hospital 3 had the highest frequency.

TABLE 4.2 The total data collected per x-ray equipment

Hospital	Frequency (n)	Percent (%)
Hospital 1 / Shimadzu	63	17
Hospital 1 / Siemens	64	17
Hospital 2a /Shimadzu	88	23
Hospital 2b /Siemens	66	18
Hospital 3 / Dell	94	25
TOTAL	**375**	**100**

4.4 TOTAL DATA PER WEIGHT GROUP

Data were collected per weight group at the three NCP radiography departments. As stated in the introduction paragraph, the radiology departments were housed in four NCP hospitals. The graph in Figure 4.1 shows the data collection per weight group for the total population. The most frequent data collected per weight group is shown in the figure to be 5kg to <15kg.

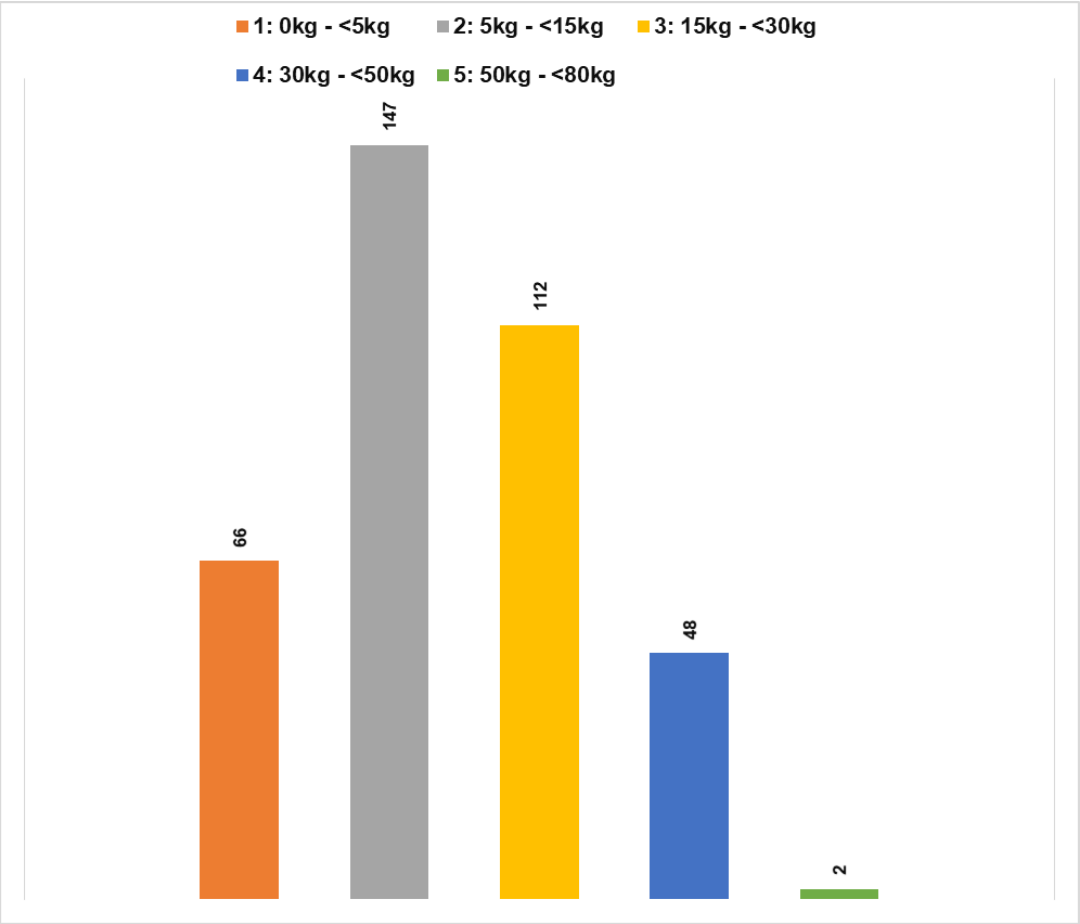


FIGURE 4.1 The frequency of the weight groups for the total population

4.5 TOTAL DATA PER AGE GROUP

During the data collection period, the age of the paediatric patient was documented on the PiDRL checklist. The total population per age group could be calculated from the data analyses. The most frequently collected data was for the age group 1 year to less than 5 years. Figure 4.2 depicts the total population per age group.

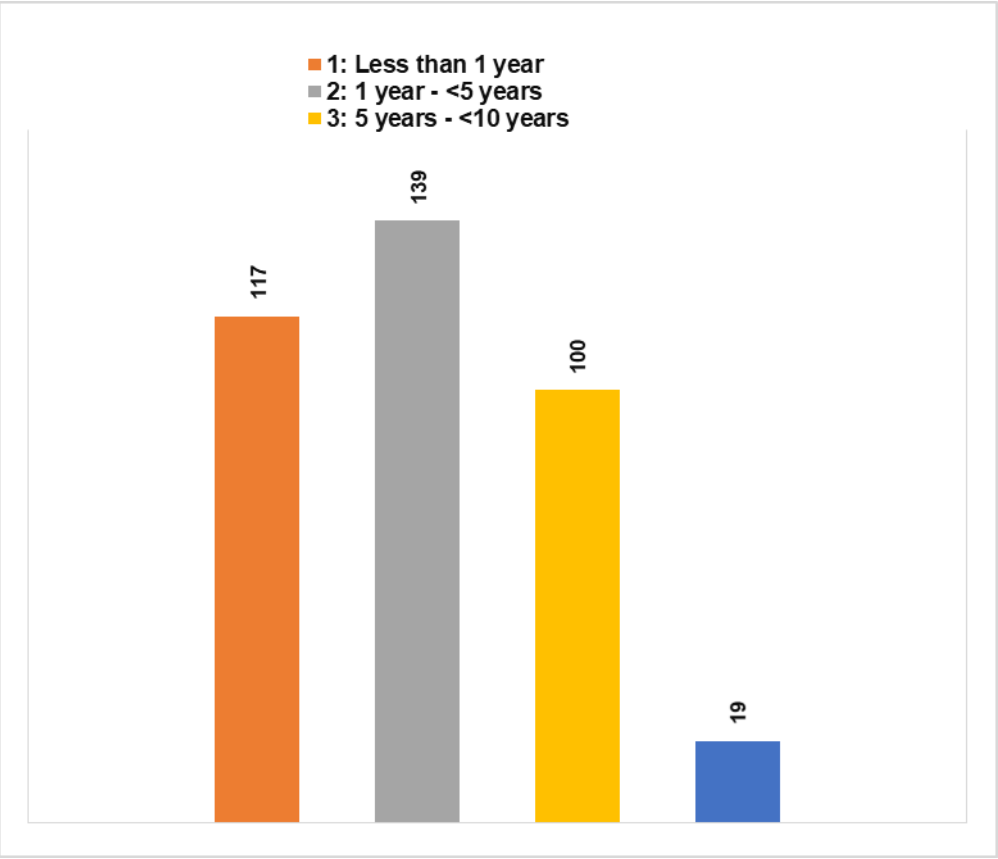


FIGURE 4.2 The frequency (n) of the age groups of paediatric patients for the total population

4.6 TOTAL OF WEIGHT GROUP PER HOSPITAL

The ICRP (2017:103) advises that PiDRL should be calculated per weight group. Table 4.3 depicts the data collected per weight group per x-ray equipment per hospital. Table 4.3 below indicates the frequency of data collected in various weight groups. Weight group 5kg to less than 15kg was the most frequently documented. Hospital 3 had the most frequent data collected.

TABLE 4.3 Data collected by weight group per hospital

Weight group	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell	TOTAL
<5kg	15	15	13	10	13	66
5kg to <15kg	30	30	30	30	27	147
15kg to <30kg	14	17	30	24	27	112
30kg to <50kg	4	2	15	2	25	48
50kg to <80kg	0	0	0	0	2	2
TOTAL	**63**	**64**	**88**	**66**	**94**	**375**

Abbreviation: hosp., hospital.

4.7 TOTAL OF EACH AGE GROUP PER HOSPITAL

The most frequently imaged age group was 1 year to less than 5 years during the data collection period. The total data collected at Hospital 3 was higher than the other hospitals. All age groups were populated with data except for the age group 10 years to less than 12 years in Hospital 2b, where no data could be collected. Table 4.4 shows the data collected for the three NCP radiology departments per age group.

TABLE 4.4 The age groups for the three NCP radiology departments

Age group	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell	TOTAL
<1 year	31	24	27	19	16	117
1 year to <5 years	17	27	22	37	36	139
5 years to <10 years	12	12	34	10	32	100
10 years to <12 years	3	1	5	0	10	19
TOTAL	**63**	**64**	**88**	**66**	**94**	**375**

Abbreviation: hosp, hospital.

4.8 MEDIAN PER WEIGHT GROUP PER HOSPITAL

Table 4.5 illustrates the median of each weight group per hospital. Maximum and minimum weight values were calculated for each weight group per hospital. The weight in kg was evenly distributed per age group per hospital. Data was not collected in the weight group 50kg up to 80kg in Hospital 1, Hospital 2a and Hospital 2b, but it was collected in Hospital 3, with a mean weight of 58kg.

TABLE 4.5 Median weight per weight group for the three NCP radiology departments

		Hosp. 1 Shimadzu	**Hosp. 1 Siemens**	**Hosp. 2a Shimadzu**	**Hosp. 2b Siemens**	**Hosp. 3 Dell**
Weight group	Variable (kg)	Median	Median	Median	Median	Median
<5kg	Weight	4	4	4	3	4
5kg to <15 kg	Weight	9	10	9	11	10
15kg to <30kg	Weight	21	18	18	18	18
30 kg to <50 kg	Weight	32	37	36	39	36
50 kg to <80 kg	Weight					58

Abbreviations: hosp., hospital; kg, kilogram.

4.9 MEDIAN kVp, mAs, PATIENT THICKNESS AND SOURCE-TO-IMAGE DISTANCE PER HOSPITAL

The following figures will indicate the median kVp, mAs, patient thickness, and SID. Figure 4.3 shows the median kVp values. Hospital 3 had a lower kVp value compared to the other hospitals, ranging from 55 kVp to 65 kVp. Hospital 1, Hospital 2a and Hospital 2b kVp ranged between 66 kVp to 104 kVp.

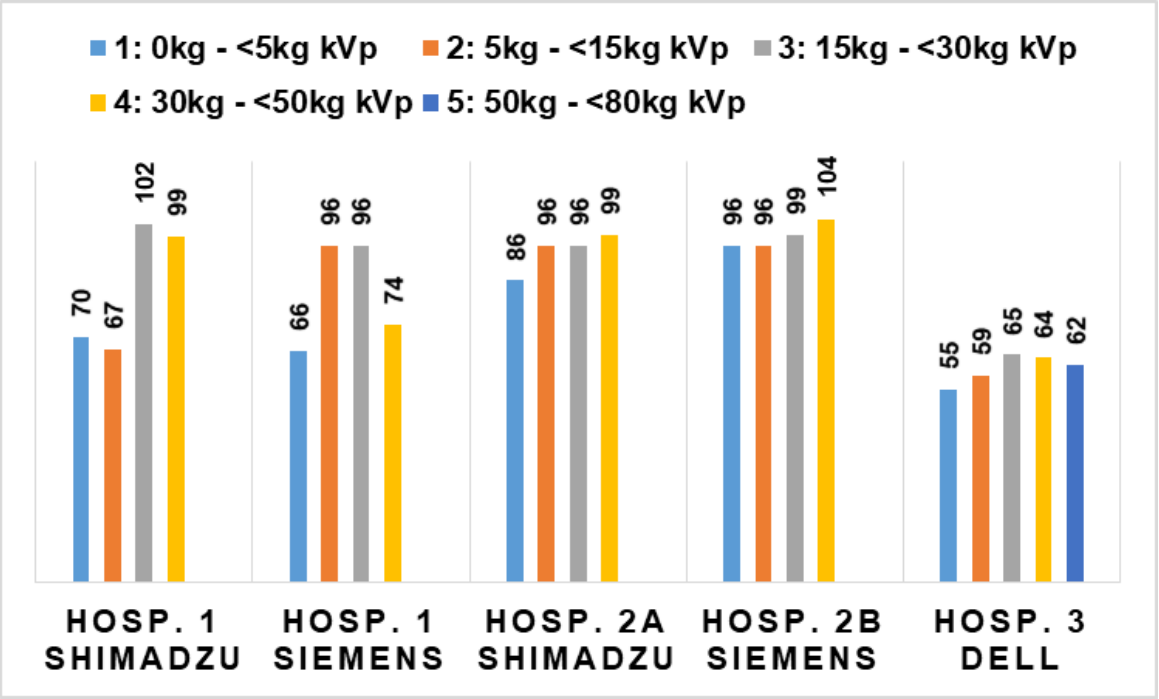


FIGURE 4.3 Median kVp values per weight group for the three NCP radiology departments

Figure 4.4 depicts the median mAs value per weight group per hospital. The values were evenly distributed per weight group for Hospital 1, Hospital 2b and Hospital 3, but not for Hospital 2a. For Hospital 1, Hospital 2a and Hospital 2b, no data was collected for the weight group 50kg to 80kg. Hospital 2a in weight group 5kg to less than 15kg, 15kg to less than 30kg and 30kg to less than 50kg were higher in value ranging from 3.2 mAs to 6.3 mAs.

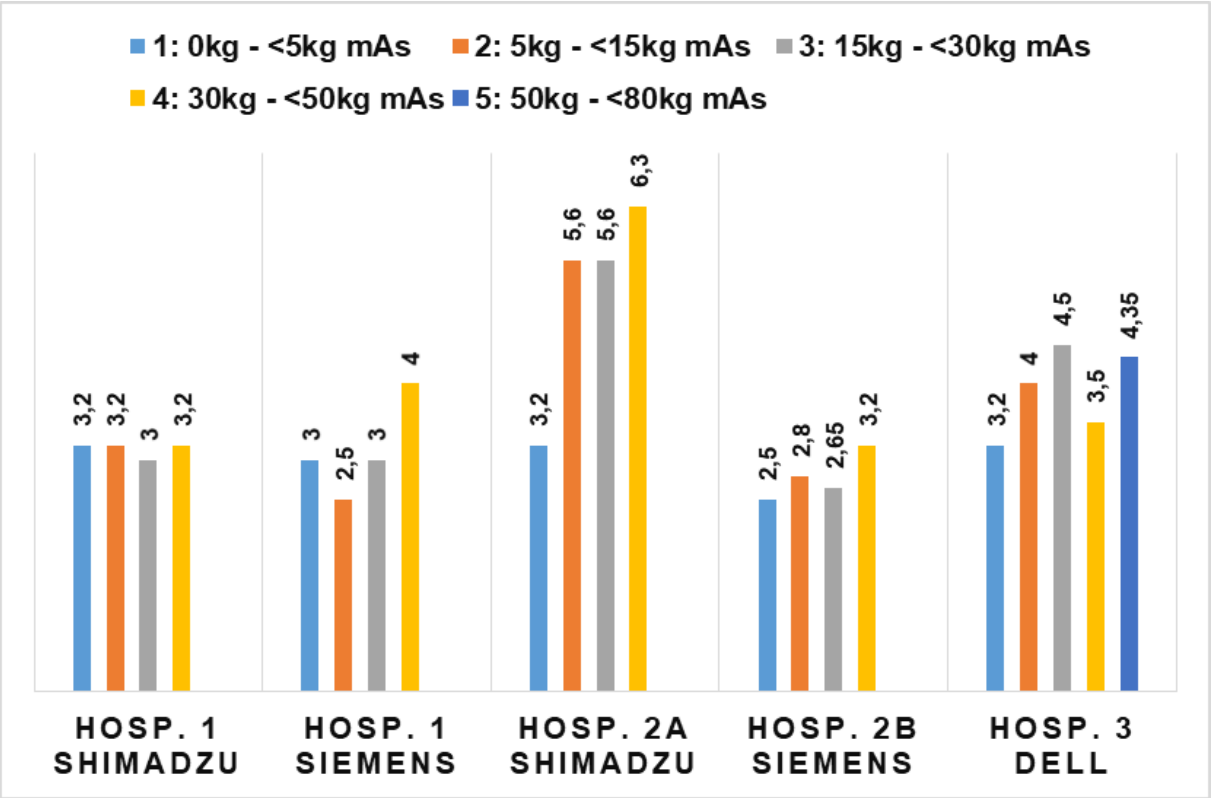


FIGURE 4.4 The median mAs values per weight group for the three NCP radiology departments

Abbreviations: hosp., hospital; kg, kilogram

Figure 4.5 illustrates the median value of the patient thickness per weight group at all hospitals during data collection.

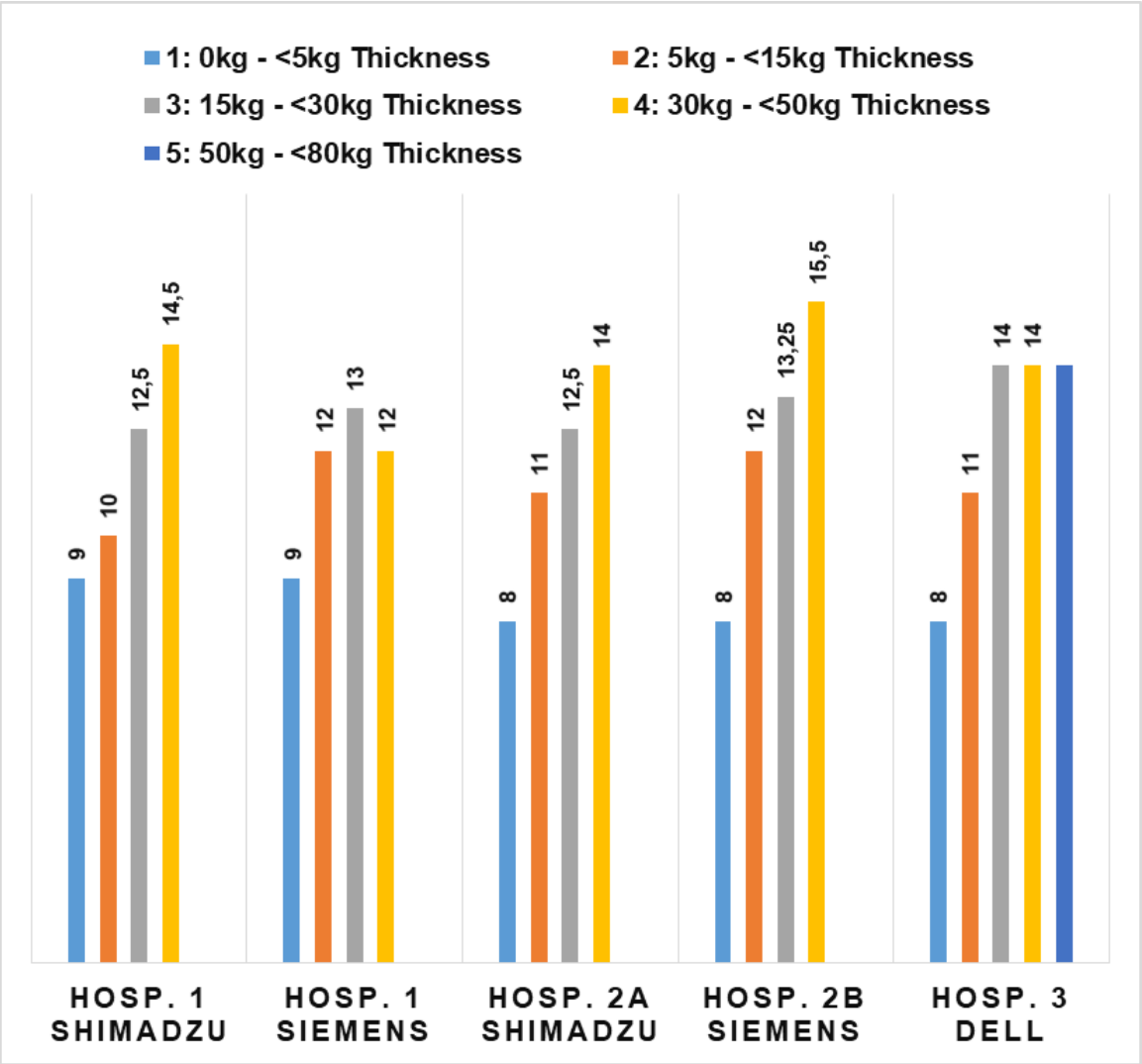


FIGURE 4.5 The median value of patient thickness per weight group

Abbreviations: hosp., hospital; kg, kilogram

The SID was measured during the data collection period at the three radiology departments using the PiDRL checklist. Figure 4.6 depicts the SID in cm for three radiology departments per weight group. The SID value was constant in all the weight groups and hospitals. The SID remained constant.

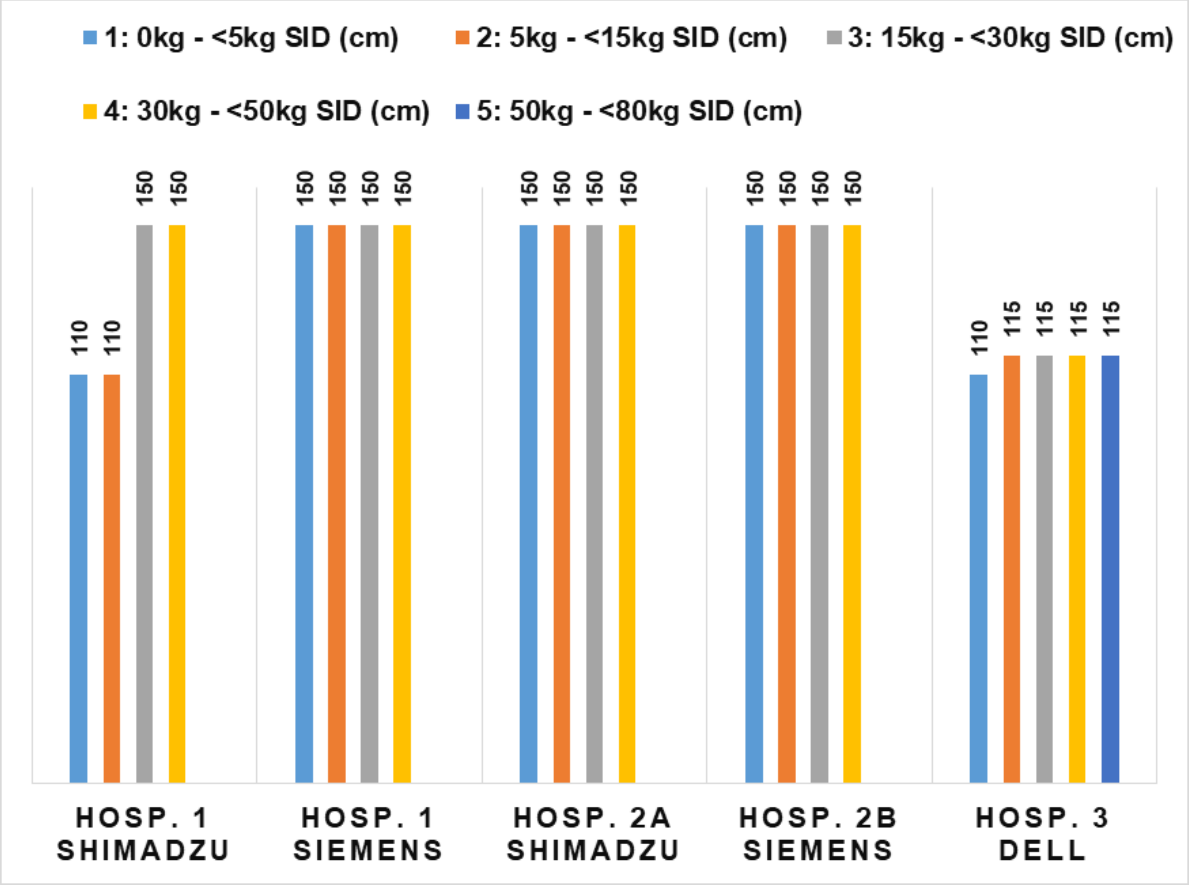


FIGURE 4.6 The median SID per weight group for three NCP radiology departments.

Abbreviations: hosp., hospital; SID, source-to-image distance

Hospital 3 shows a lower value of SID compared to the other hospitals. The SID stayed constant for all the weight groups within the radiology department in Hospital 3.

4.10 THIRD QUARTILE PER WEIGHT GROUP PER HOSPITAL

Table 4.6 depicts the third quartile (75th percentile) of each weight group's ESD (unit mGy) for the three NCP radiology departments. The ESD value includes the backscatter factor, which was calculated with the help of a medical physicist. The third quartile represents the DRL value of the specific weight group.

TABLE 4.6 The third quartile of the ESD per weight group for three NCP radiology departments

	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell
Weight group	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**
<5kg	0.3	0.3	0.1	0.1	0.1
5kg to <15kg	0.2	0.1	0.2	0.1	0.1
15kg to <30kg	0.3	0.2	0.2	0.2	0.2
30kg to <50kg	0.3	0.1	0.3	0.2	0.1
50kg to <80kg					0.1

Abbreviations: hosp., hospital; kg, kilograms. Values are measured in units of milligray (mGy)

Data for the weight group 50kg to 80kg could only be collected at Hospital 3. No data could be documented for the other two hospitals, as shown in Table 4.6. The mean range for the weight bands and age groups was calculated as 0.2 mGy for weight bands ranging from 0 to 80kg and 0.2 mGy for age groups ranging from 1 to less than 12 years of age. The DRL is expressed in the mean for these weight and age ranges.

4.11 THIRD QUARTILE PER AGE GROUP PER HOSPITAL

Table 4.7 depicts the DRL for each age group for three NCP radiology departments. Data for Hospital 2b, age group 10 years to less than 12 years, could not be documented.

TABLE 4.7 The third quartile of the ESD per age group for three NCP radiology departments

	Hosp. 1 Shimadzu	Hosp. 1 Siemens	Hosp. 2a Shimadzu	Hosp. 2b Siemens	Hosp. 3 Dell
Age group	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**	**75th percentile**
<1 year	0.3	0.2	0.2	0.1	0.1
1 year to <5 years	0.2	0.2	0.2	0.1	0.1
5 years to <10 years	0.2	0.2	0.3	0.2	0.2
10 years to <12 years	0.3	0.2	0.3		0.1

Abbreviation: hosp., hospital.

Data could mostly be collected in all the age groups and hospitals except in the age group of 10 years to less than 12 years in Hospital 2b. Paediatric patients in the age group 10 years to less than 12 years were not imaged at Hospital 2b during the data collection period.

4.12 MEDIAN ESD WITH BACKSCATTER PER WEIGHT GROUP BY HOSPITAL

Table 4.8 shows the median as well as the amount of data collected (n) for the different weight groups. As stated in the literature, an LDRL is based on the median value of the patient dose distribution for a specific radiological task for patient groups (Granata, Soratin, Seuri & Owen 2019:703). The values of the median and 75th percentile are measured in units of mGy.

TABLE 4.8 The median and 75th percentile for the ESD value with backscatter factor per weight group for three NCP radiology departments

Hospital 1 room 1 Shimadzu			
Weight group	**n**	**Median**	**75th percentile**
<5kg	15	0.2	0.3
5kg to <15kg	30	0.2	0.2
15kg to <30kg	14	0.2	0.3
30kg to <50kg	4	0.2	0.3
Hospital 1 room 2 Siemens			
Weight group	**n**	**Median**	**75th percentile**
<5kg	15	0.1	0.3
5kg to <15kg	30	0.1	0.1
15kg to <30kg	17	0.2	0.2
30kg to <50kg	2	0.1	0.1
Hospital 2a Shimadzu			
Weight group	**n**	**Median**	**75th percentile**
<5kg	13	0.1	0.1
5kg to <15kg	30	0.2	0.2
15kg to <30kg	30	0.2	0.2
30kg to <50kg	15	0.3	0.3
Hospital 2b Siemens			
Weight group	**n**	**Median**	**75th percentile**
<5kg	10	0.1	0.1
5kg to <15kg	30	0.1	0.1
15kg to <30kg	24	0.1	0.2
30kg to <50kg	2	0.2	0.2
Hospital 3 Dell			
Weight group	**n**	**Median**	**75th percentile**
<5kg	13	0.1	0.1
5kg to <15kg	27	0.1	0.1
15kg to <30kg	27	0.1	0.2
30kg to <50kg	25	0.1	0.1
50kg to <80kg	2	0.1	0.1

Abbreviation: kg, kilogram.

4.13 MEDIAN ESD WITH BACKSCATTER PER AGE PER HOSPITAL

Table 4.9 depicts the median ESD (measured mGy) value and the 75th percentile for the different age groups.

TABLE 4.9 The median and 75th percentile for the ESD value with backscatter factor per age group for three NCP radiology departments

Hospital 1 room 1 Shimadzu			
Age group	**n**	**Median**	**75th percentile**
<1 year	31	0.2	0.3
1 year to <5 years	17	0.2	0.2
5 years to <10 years	12	0.2	0.2
10 years to <12 years	3	0.2	0.3
Hospital 1 room 2 Siemens			
Age group	**n**	**Median**	**75th percentile**
<1 year	24	0.1	0.2
1 year to <5 years	27	0.1	0.2
5 years to <10 years	12	0.1	0.2
10 years to <12 years	1	0.2	0.2
Hospital 2a Shimadzu			
Age group	**n**	**Median**	**75th percentile**
<1 year	27	0.1	0.2
1 year to <5 years	22	0.2	0.2
5 years to <10 years	34	0.2	0.3
10 years to <12 years	5	0.3	0.3
Hospital 2b Siemens			
Age group	**n**	**Median**	**75th percentile**
<1 year	19	0.1	0.1
1 year to <5 years	37	0.1	0.1
5 years to <10 years	10	0.1	0.2
Hospital 3 Dell			
Age group	**n**	**Median**	**75th percentile**
<1 year	16	0.1	0.1
1 year to <5 years	36	0.1	0.1
5 years to <10 years	32	0.1	0.2
10 years to <12 years	10	0.1	0.1

4.14 MEAN PiDRL FOR WEIGHT GROUPS

For weight groups, the mean PiDRL is shown in Table 4.10 below. The 75th percentile is therefore expressed as the mean range for the weight groups.

TABLE 4.10 The mean PiDRL for weight groups

Weight groups	75th percentile in mGy
<5kg	0.2
5kg to <15kg	0.2
15kg to <30kg	0.2
30kg to <50kg	0.3
50kg to 80kg	0.1

4.15 MEAN PiDRL FOR AGE GROUPS

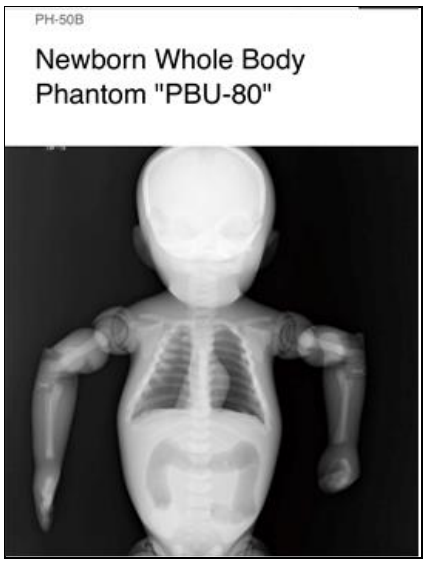
The mean PiDRLs for each age group are shown in Table 4.11. The 75th percentile is therefore expressed as the mean range for the weight groups.

TABLE 4.11 The mean PiDRL for age groups

Age groups	75th percentile in mGy
<1 year	0.2
1 year to <5 years	0.2
5 years to <10 years	0.3
10 years to <12 years	0.3

4.16 IMAGE QUALITY RESULTS

The image quality assessment checklist was utilised during phase 2 of the research process (see Figure 1.3). The image quality investigation was performed with the PBU-80 Newborn Whole Body Phantom on the x-ray equipment at the three NC radiology departments and on the mobile units that were utilised for paediatric AP CXR imaging. Figure 4.7a shows the actual phantom and Figure 4.7b shows the x-ray image of the PBU-80 Newborn Whole Body Phantom used during these investigations.



4.7a **4.7b**

FIGURE 4.7a Image of the actual PBU-80 Newborn Whole Body Phantom and **4.7b** x-ray image of the phantom

The PBU-80 Newborn Whole Body Phantom is made from polyurethane substituted for the soft tissue and epoxy resin for the synthetic bone of the phantom. The phantom is equivalent to a life-sized newborn baby, 53 cm tall and 3.5kg in weight. As stated in Section 3.8.4.2 (Chapter 3), the EC image quality criteria were utilised to evaluate the image quality of the AP CXR projection acquired with the PBU-80 Newborn Whole Body Phantom. The baby phantom was exposed to the same parameters that the radiographers used in the radiology departments for paediatric patients undergoing an AP CXR. Table 4.12 specifies the seven image quality criteria used to assess the image quality of the chest

radiographs for each department. The image criteria evaluation process was scored by utilising the Assessment Image Quality card (cf. Appendix 10) as indicated by the EC (EC 1996:61).

TABLE 4.12 EC radiographic x-ray image criteria recommendation for newborn babies (EC 1996:29)

No.	Criteria
1	Performed at the peak of inspiration.
2	Reproduction of the thorax without rotation and tilting.
3	Reproduction of the chest must extend from the cervical trachea to thoracic vertebrae 12 and lumbar vertebrae 1 (part of the abdomen may be included for special purposes).
4	Reproduction of the vascular pattern in the central half of the lungs.
5	Visually sharp reproduction of the trachea and the proximal bronchi.
6	Visually sharp reproduction of the diaphragm and costo-phrenic angles.
7	Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum.

Abbreviation: no., number.

The chest radiographs below were obtained using exposure factors utilised by the radiographers in the radiology departments and in the mobile units. Afterwards, the image quality was assessed using the criteria checklist in Table 4.12.

4.16.1 Image results per radiology department

The following results represent the investigations during the AP CXR imaging of the PBU-80 Newborn Whole Body Phantom on x-ray equipment in radiology and mobile units.

4.16.1.1 Image results Hospital 1

Figure 4.8a and Figure 4.8b show AP CXR projections that were taken in Hospital 1. Exposure factors are indicated in Table 3.4 (Chapter 3). The exposure factors for Room 1, Shimadzu machine, were 75 kVp and 2.8 mAs and the SID 150 cm. The phantom was positioned in a sitting position to simulate the procedure used by the radiographers in Hospital 1, depicted in Figure 4.8a below. The score calculated from the scoring card of the EC 1996 for image quality was 10 out of a possible 13.

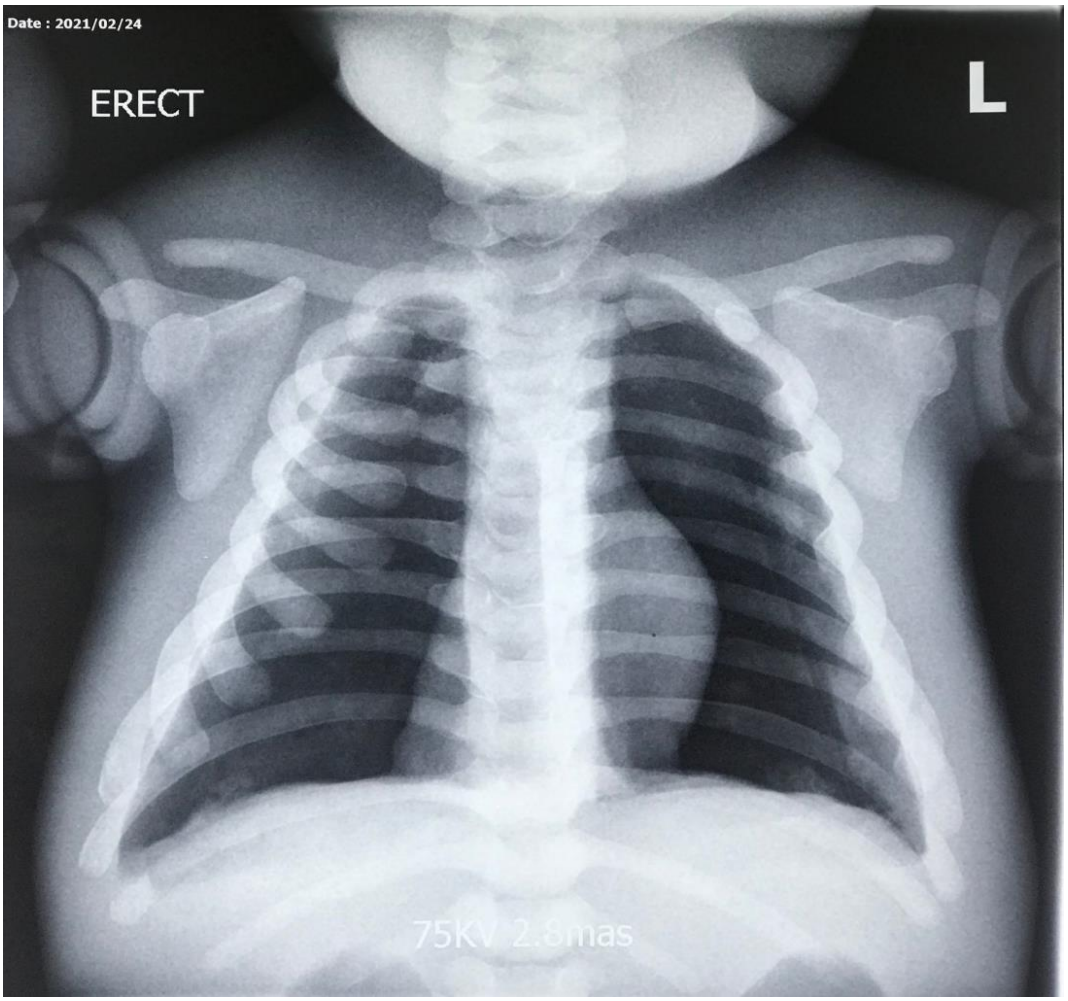


FIGURE 4.8a The AP CXR projection acquired at Hospital 1, room 1, on the Shimadzu x-ray equipment with the PBU-80 Newborn Whole Body Phantom

Figure 4.8b shows the image quality of room 2 of Hospital 1, taken on the Siemens x-ray equipment. Exposure factors used by the researcher were 79 kVp, 2.8 mAs and SID 150 cm. The AP CXR projection taken at Hospital 1 was taken on Siemens x-ray equipment in a simulated erect sitting position. The anatomical marker was noted on the radiological image. The score calculated from the score card from the EC 1996 was 11 out of a possible 13.

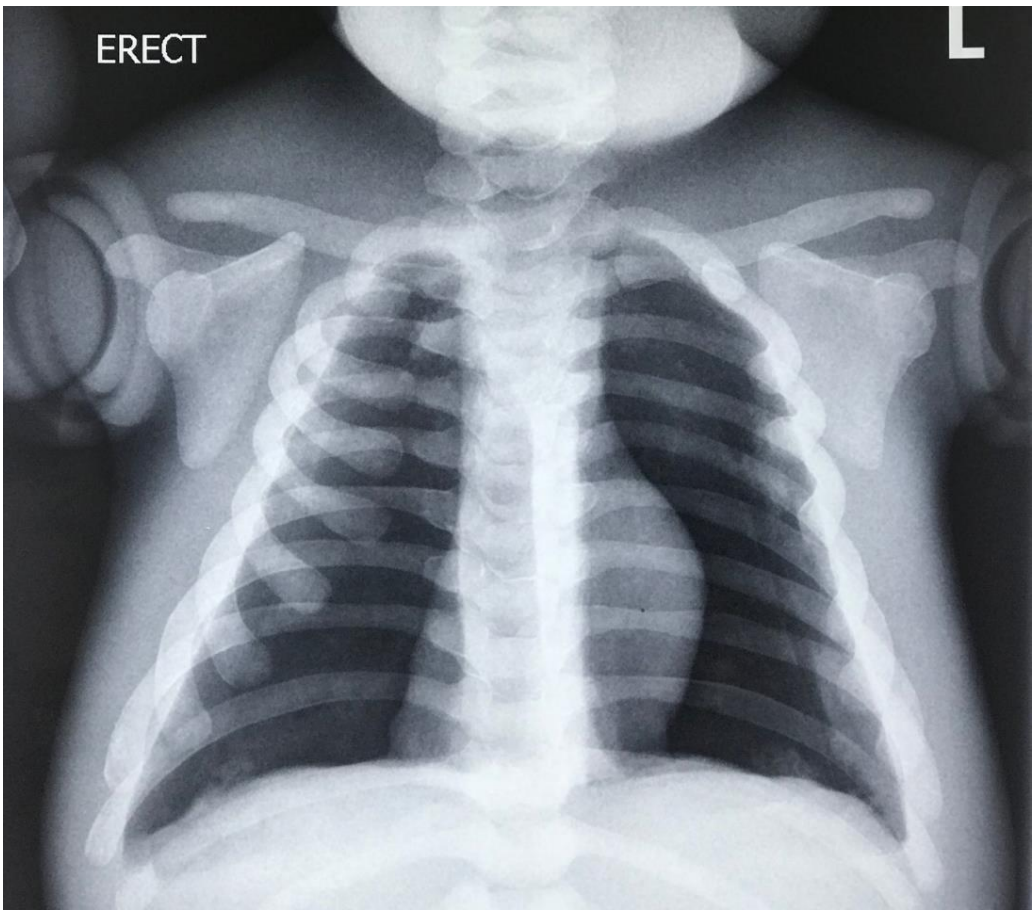


FIGURE 4.8b The AP CXR projection was acquired in Hospital 1, room 2 on the Siemens x-ray equipment with the PBU-80 Newborn Whole Body Phantom

4.16.1.2 Image results Hospital 2a and Hospital 2b

The AP CXR projections acquired for Hospital 2a and Hospital 2b for the x-ray equipment in the x-ray room are shown in Figure 4.9a. The exposure factors utilised are indicated in Table 3.4 (Chapter 3) of the x-ray machine demographics

while conducting the image quality assessment on the PBU-80 Newborn Whole Body Phantom.

Figure 4.9a shows the AP CXR projection results of Hospital 2a taken on the departmental x-ray equipment for the investigation of the image quality assessment. The exposure factors were 96 kVp, 5.6 mAs and SID 150 cm. The score calculated for Figure 4.9a was 10 out of a possible 13.

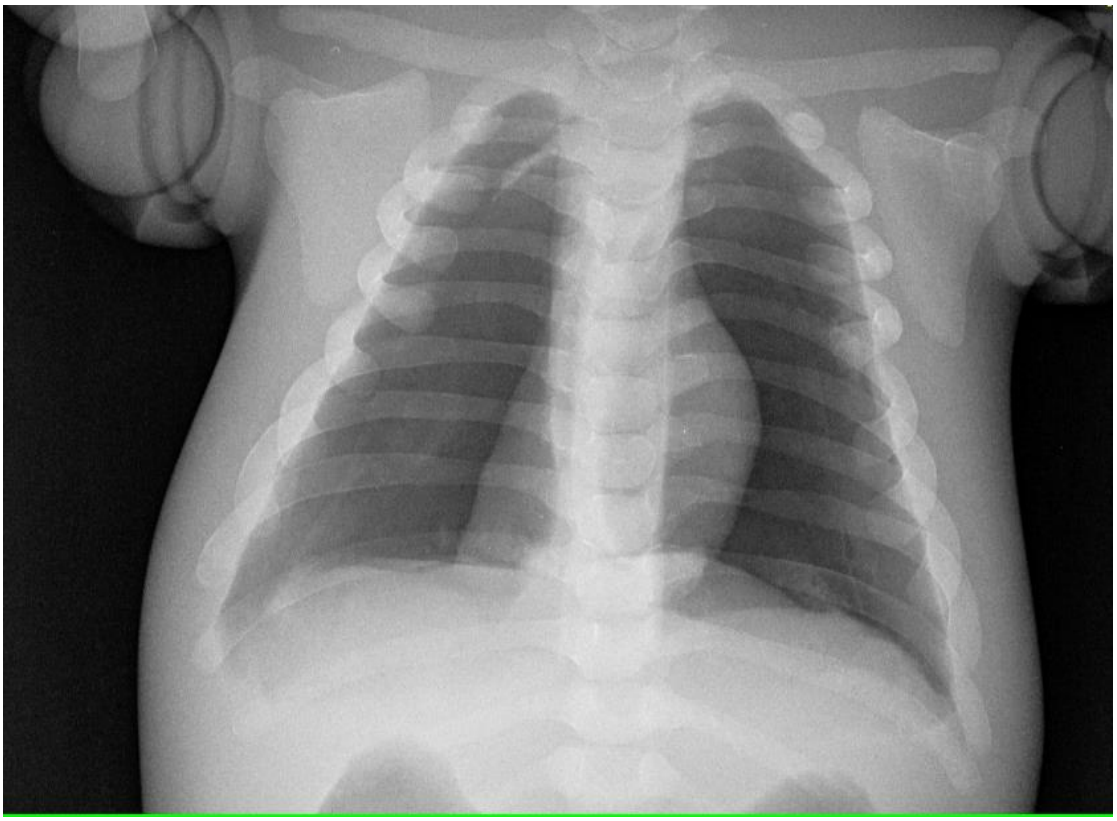


FIGURE 4.9a The AP CXR projection acquired in Hospital 2a on the Shimadzu x-ray equipment with the PBU-80 Newborn Whole Body Phantom

The phantom was placed in an AP sitting position, as shown in Figure 4.9a. The anatomical marker was cut off due to the post-processing of the digital image. Hospital 2b x-ray image quality assessment results are shown in Figure 4.9b. Exposure factors utilised during the investigation were 96 kVp, 2.5 mAs and SID 150 cm. The PBU-80 Newborn Whole Body Phantom was placed in a sitting position (Figure 4.9b), duplicating the method utilised by the radiographers in the departments. The score obtained for Figure 4.9b was 10 out of a possible 13.

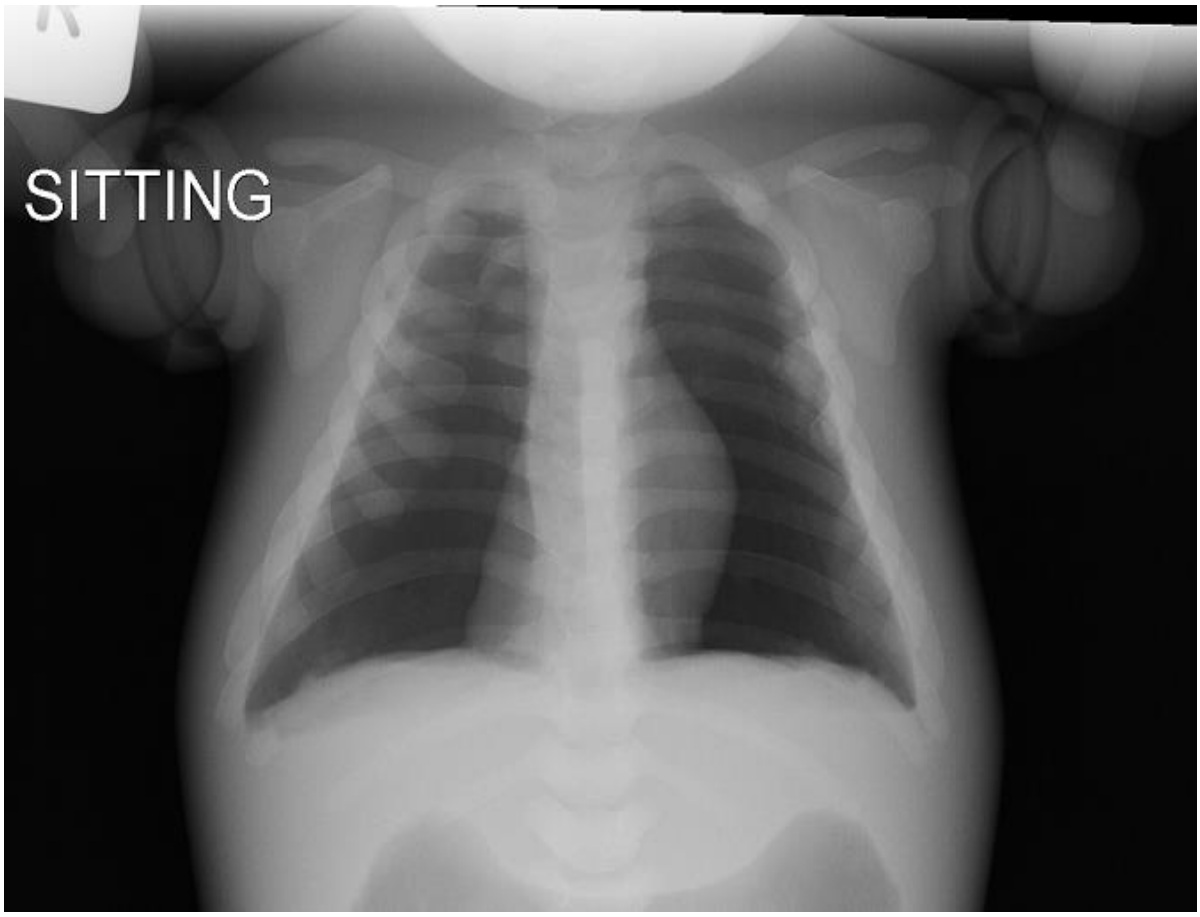


FIGURE 4.9b The AP CXR projection acquired in Hospital 2b on the Siemens x-ray equipment with the PBU-80 Newborn Whole Body Phantom

4.16.1.3 Image results Hospital 3

For Hospital 3, the AP CXR projection results are shown in Figure 4.10. The researcher used the exposure factors 65 kVp, 2.5 mAs and SID 110 cm for the AP chest x-ray projection acquired for the image quality assessment. The same exposure factors were utilised to image the PBU-80 Newborn Whole Body Phantom as the ones used by radiographers during paediatric patients' chest imaging.

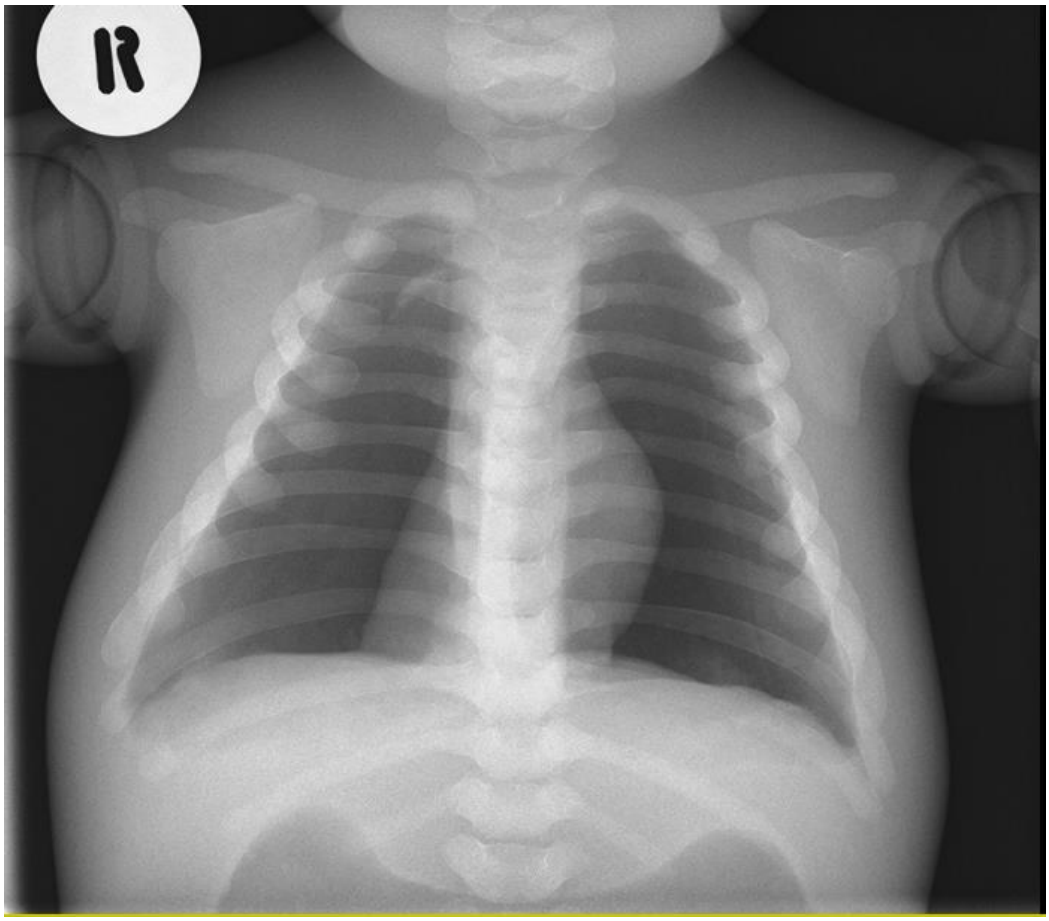


FIGURE 4.10 The AP CXR projection as acquired in Hospital 3 on the Dell x-ray equipment with the PBU-80 Newborn Whole Body Phantom

The PBU-80 Newborn Whole Body Phantom was positioned in an AP supine for the acquisition of the AP CXR projection shown in Figure 4.10. The right anatomical marker can be clearly seen. Table 3.5a (Chapter 3) depicts the x-ray equipment demographics and exposure factors utilised during the investigation. The score for Figure 4.10 was 10 out of a possible 13, as calculated using the scoring card of the EC 1996.

4.16.2 Image results per mobile unit

The exposure parameters that were used to acquire the AP CXR projections shown in this section are indicated in Table 3.5b (see Chapter 3). Mobile x-ray units were utilised during this part of the x-ray image quality investigation. The image quality investigation, positioning and exposure factors were duplicated the

way the radiographers utilised the mobile units when paediatric patients had to be examined.

Figure 4.11a below shows the AP CXR image quality results of mobile unit 1 utilised in Hospital 1. The exposure factors were 55 kVp, 2.5 mAs and SID 110 cm utilised during the investigation for mobile unit 1.

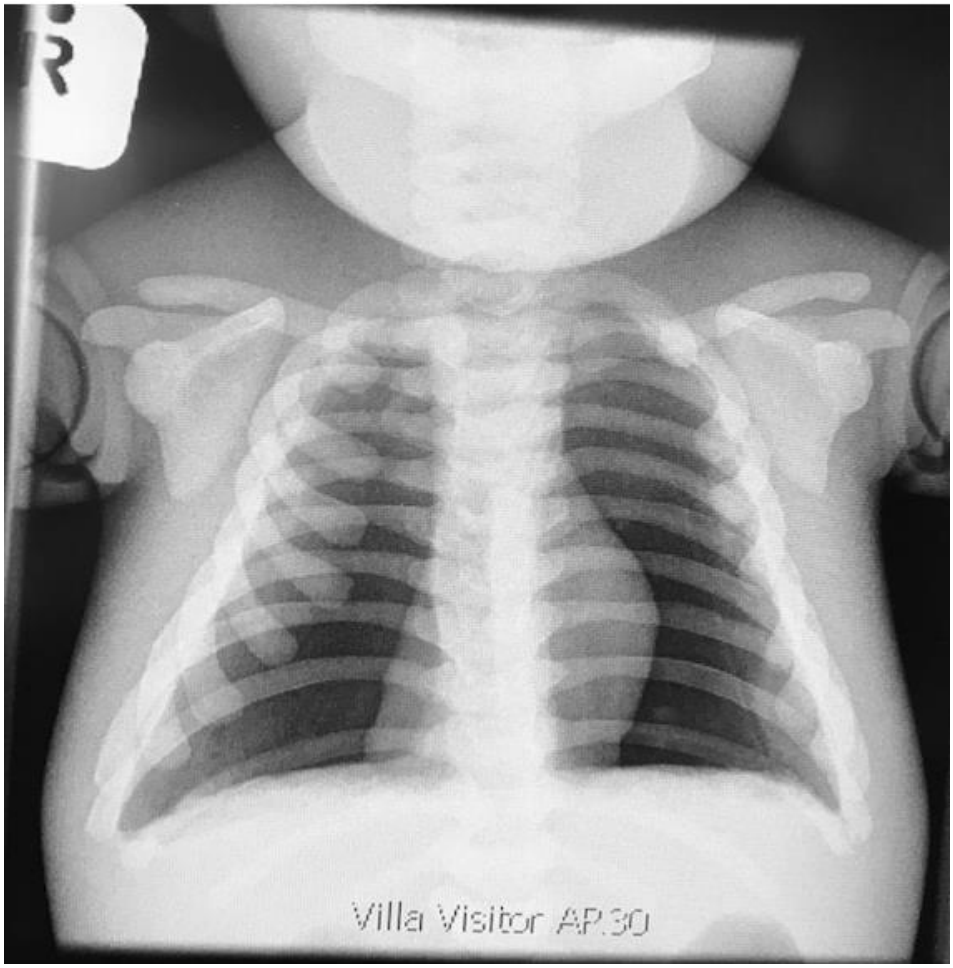


FIGURE 4.11a The AP CXR projection result as acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit 1 Villa Visitor AR 30 at Hospital 1

In Figure 4.11a, the phantom was placed in an AP supine position, duplicating the method that the radiographers in the department would use to conduct an AP supine CXR examination on a paediatric patient. The score was 10 out of a possible 13, calculated using the evaluation score card.

Figure 4.11b shows the AP CXR projection result for mobile unit 2, Hospital 1 of the investigation. Exposure factors of 55 kVp and 2.5 mAs were applied, with the x-ray tube lifted to a maximum height (distance from the patient) during the investigation.

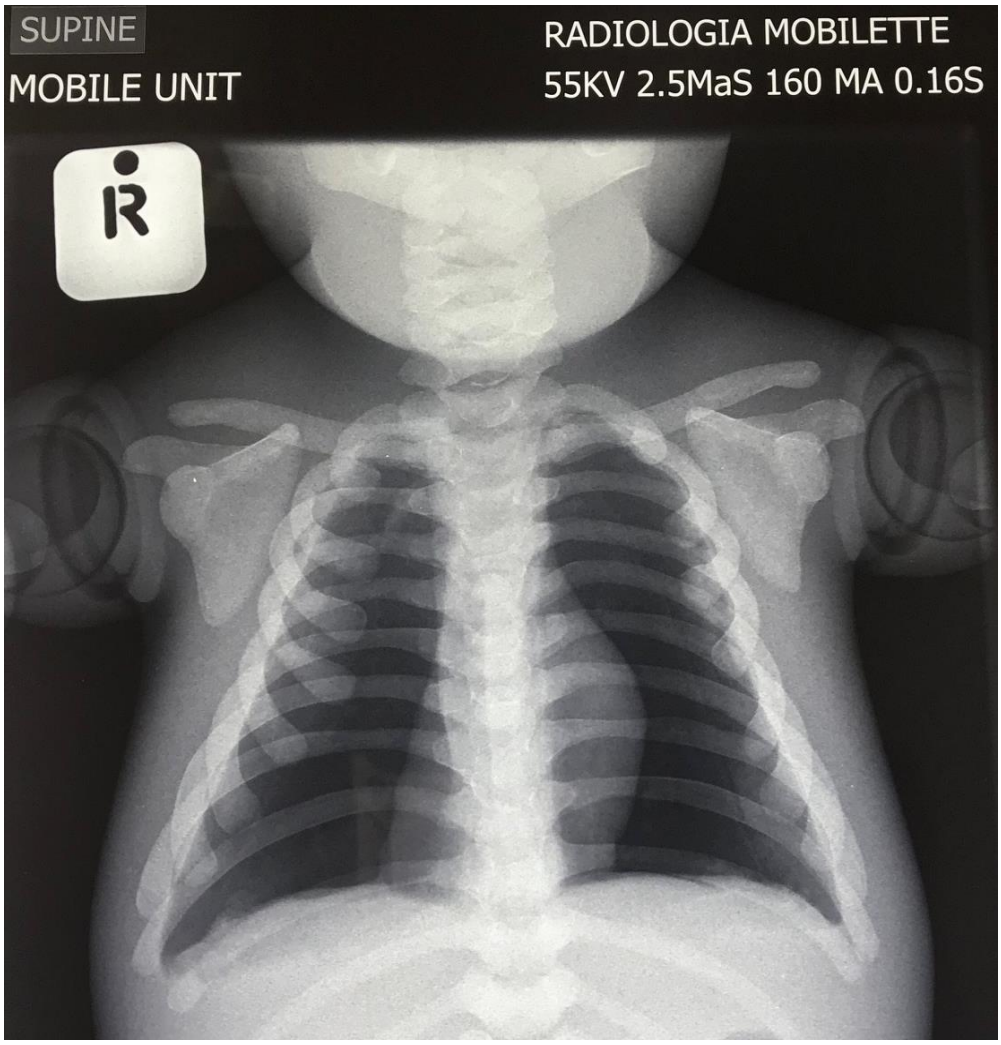


FIGURE 4.11b The AP CXR projection result as acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit 2 Radiologia Mobilette at Hospital 1

The investigation depicted in Figure 4.11b was performed in an AP supine position. The researcher replicated the exposure factors and imaging technique as the radiographers would perform it in the department. The anatomical markers are clearly seen. The score for the image quality in Figure 4.11b was 9 out of 13.

Figure 4.11c depicts the AP CXR projection image quality of mobile unit 3 in Hospital 1. The exposure factors utilised for this x-ray image quality assessment on the mobile units are indicated in Table 3.5b (Chapter 3).

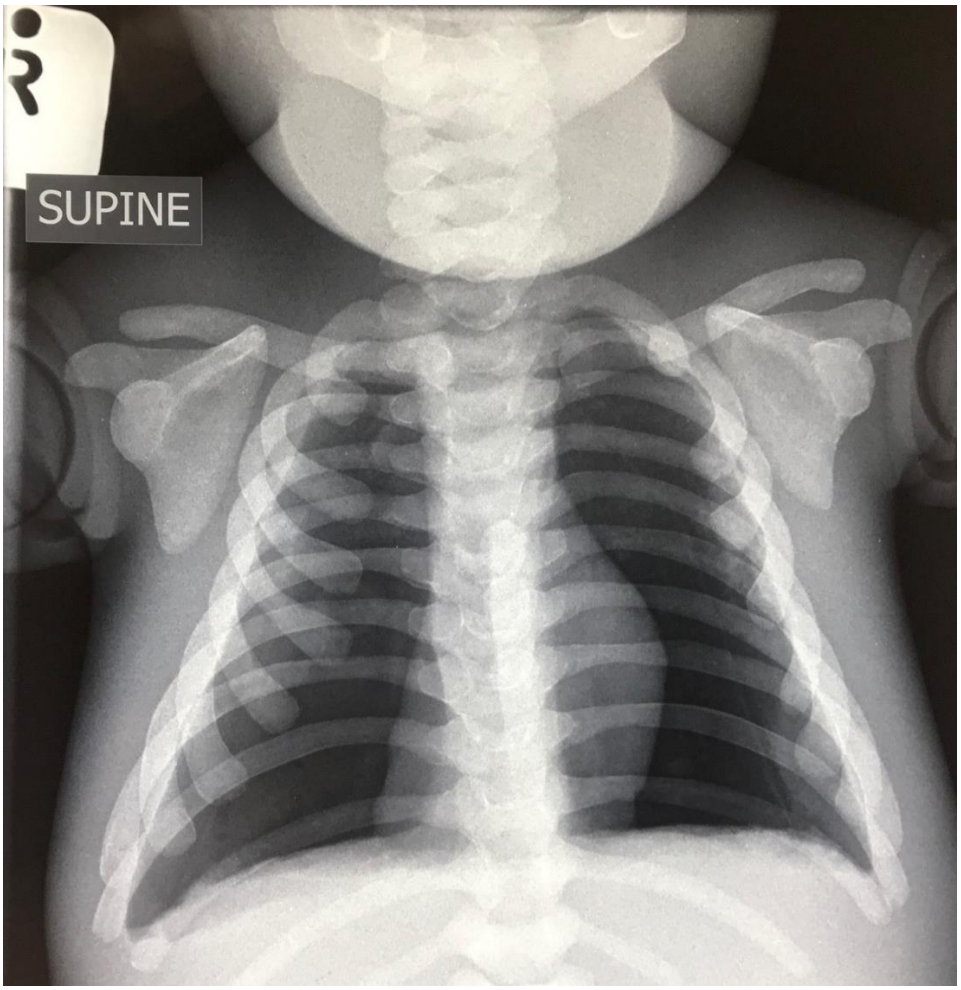


FIGURE 4.11c The AP CXR projection result as acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit 3 DR 100e AGFA at Hospital 1

The positioning depicted in Figure 4.11c was duplicated for the AP supine, as demonstrated by the radiographers in the department. The letters and markers are clearly visible. The exposure factors for mobile unit 3 Hospital 1 were 55 kVp, 2.5 mAs and SID 110 cm. The score calculated by the scoring card from the EC 1996 was 8 out of 13.

In Figure 4.12, the AP CXR projection acquired with the mobile unit in Hospital 2a is shown. The researcher duplicated the position method and used the same exposure factors as the department's radiographer.

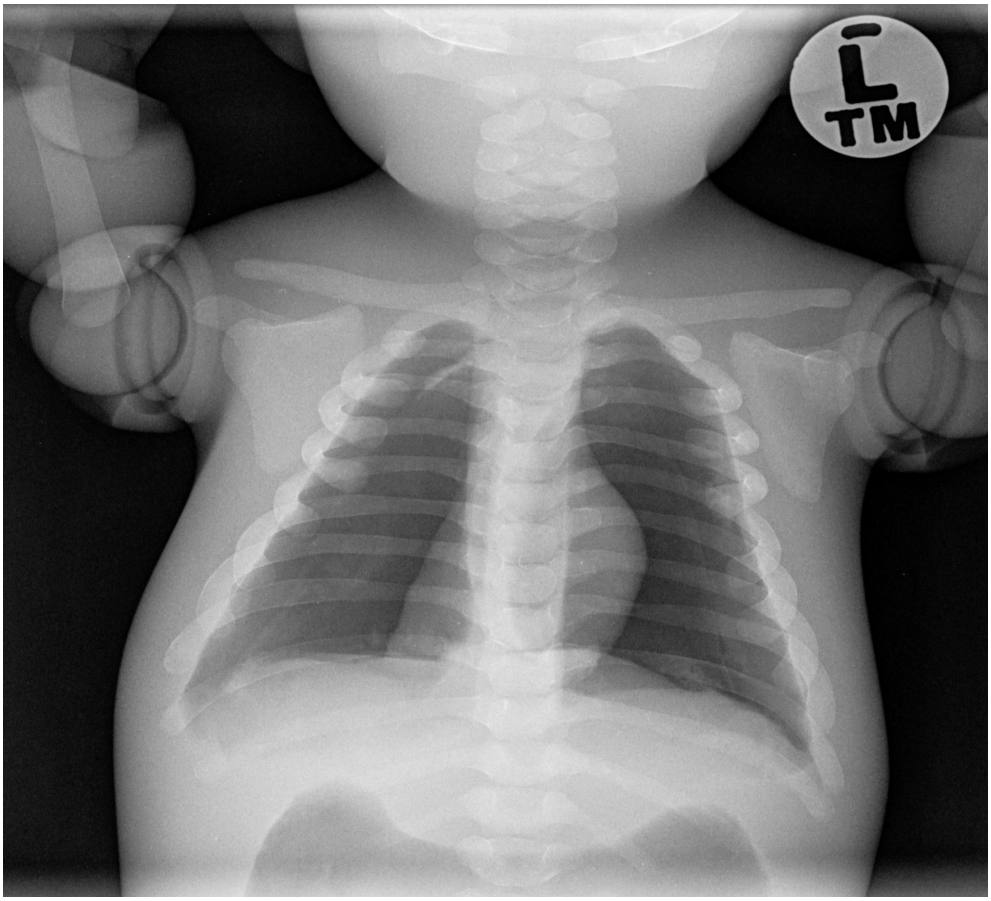


FIGURE 4.12 The AP CXR projection result acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit Siemens at Hospital 2a

The PBU-80 Newborn Whole Body Phantom was placed in an AP supine position. The exposure factors were 55 kVp, 2.5 mAs and SID 100 cm to acquire the AP chest x-ray image. The score obtained was 7 out of a possible 13. Mobile unit demographics are depicted in Table 3.5b in Chapter 3.

Figure 4.13 shows the AP CXR projection results of the mobile unit in Hospital 2b after the image quality assessment investigation was conducted. The mobile unit demographics are shown in Table 3.5b in Chapter 3. The mobile unit is a direct digital radiography unit.

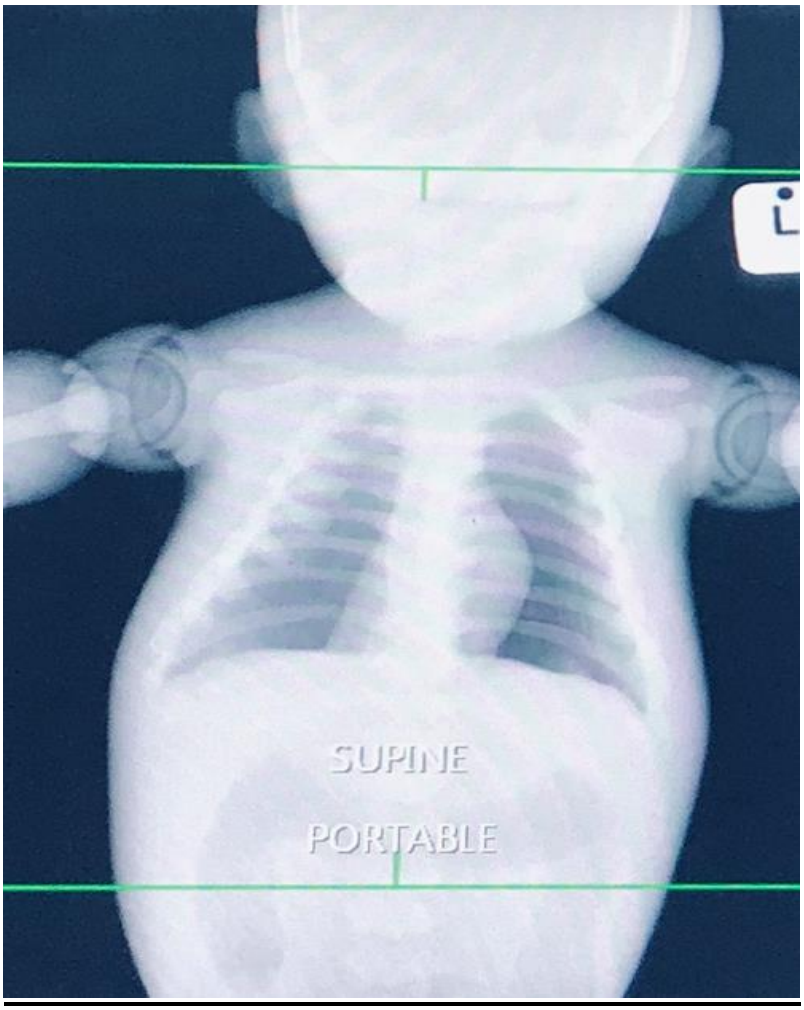


FIGURE 4.13 The AP CXR projection result was displayed on the Hospital 2b mobile unit console Shimadzu. This image was acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit at Hospital 2b

The images are displayed on the mobile unit console and then transferred to the radiology reporting monitors. The post-processing of the x-ray image was performed on the mobile unit console before transferring it to the reporting monitors. The exposure factors utilised were 52 kVp, 2.5 mAs and SID at the maximum height of the x-ray tube. The image quality score was 8 out of a possible 13.

Figure 4.14 depicts the AP CXR projection results of the mobile unit in Hospital 3. Table 3.5b (Chapter 3) indicates the exposure factors and mobile unit demographics utilised during the image quality investigation.

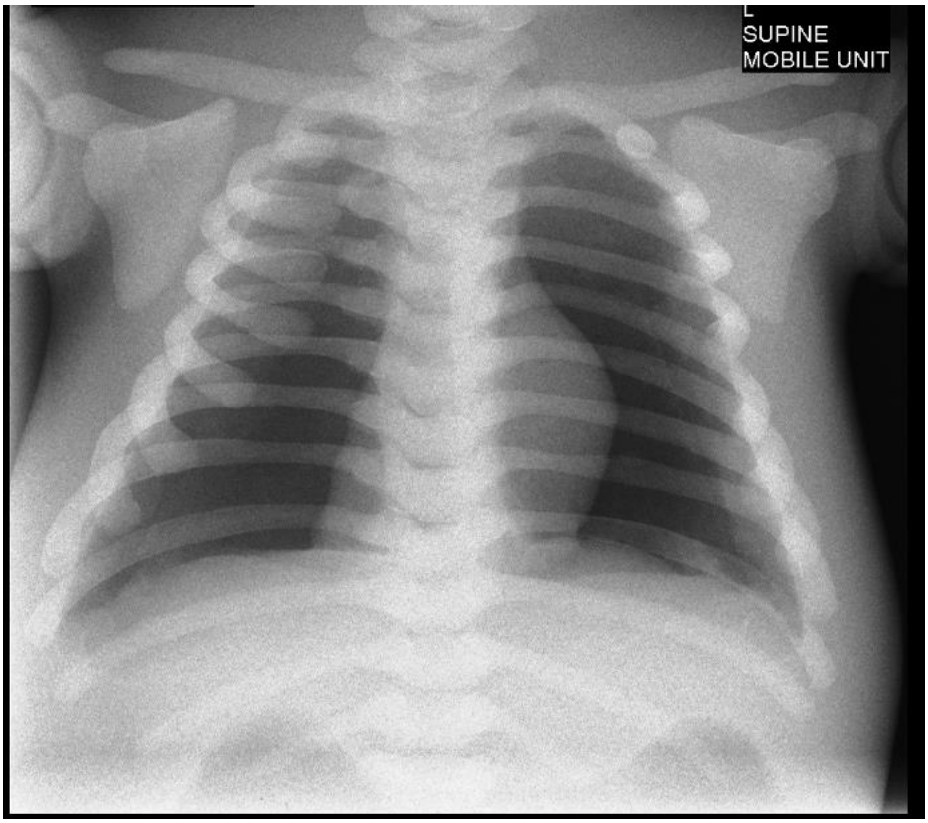


FIGURE 4.14 The AP CXR projection results as acquired with the PBU-80 Newborn Whole Body Phantom with the mobile unit IMD BASIC 100-30 at Hospital 3

The researcher duplicated the positioning method and exposure methods utilised by the radiographers in the department. The PBU-80 Newborn Whole Body Phantom was positioned AP supine, and the exposure factors used were 50 kVp, 1.6 mAs and SID 110 cm. The score calculated based on the scoring card of the EC 1996 was 8 out of a possible 13.

4.17 CONCLUSION

In conclusion, the results support the objectives of this research study by allowing the calculation of PiDRLs for the NCP radiology departments. The 75th percentile of each weight group was calculated. Furthermore, the median and 75th percentile values of specific age groups were calculated. The image quality assessment results were demonstrated using a PBU-80 Newborn Whole Body Phantom for the mobile units and on the x-ray equipment in the department's rooms. The

Assessment Image Quality scoring card was utilised to calculate the score of each AP CXR image obtained during the image quality investigation. The result of the scores indicated that all the AP CXR images were of good quality. In the next chapter - Chapter 5 - the researcher will discuss the results.

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Granata, C., Sorantin, E., Seuri, R. & Owens, C.M. 2019. European Society of Paediatric Radiology Computed Tomography and Dose task force: European guidelines on Diagnostic Reference Levels for paediatric imaging. *Paediatric Radiology*, 49(5):702–705.

International Commission on Radiological Protection (ICRP). (2016). Diagnostic reference levels in medical imaging. Available at: http://www.icrp.org/docs/C3WPDRLDraftForPublicConsultation(011116).pdf. Accessed 16 February 2021.

International Commission on Radiological Protection (ICRP). 2017. *Annals of the ICRP. Diagnostic reference levels in medical imaging.* ICRP Publication 135. ICRP 46(1).

5 CHAPTER 5: DISCUSSION, MAJOR FINDINGS OF THE DISSERTATION AND CLINICAL IMPLICATIONS

5.1 INTRODUCTION

To address the research problem (cf. Section 1.3 Chapter 1), the researcher formulated a research question (cf. Section 1.3 Chapter 1) and specific objectives (cf. Section 1.4.3 Chapter 1). The researcher constructed a design framework (cf. Section 1.9 Figure 1.2) for the study to achieve the desideratum proposed for this thesis. As outlined in Chapter 4, the results will be discussed in Chapter 5. Figure 5.1 illustrates the layout of Chapter 5. A summary of the data collection findings and an interpretation of the results will be presented after the introduction. Lastly, the study's clinical implications will be discussed and concluding remarks will be made.

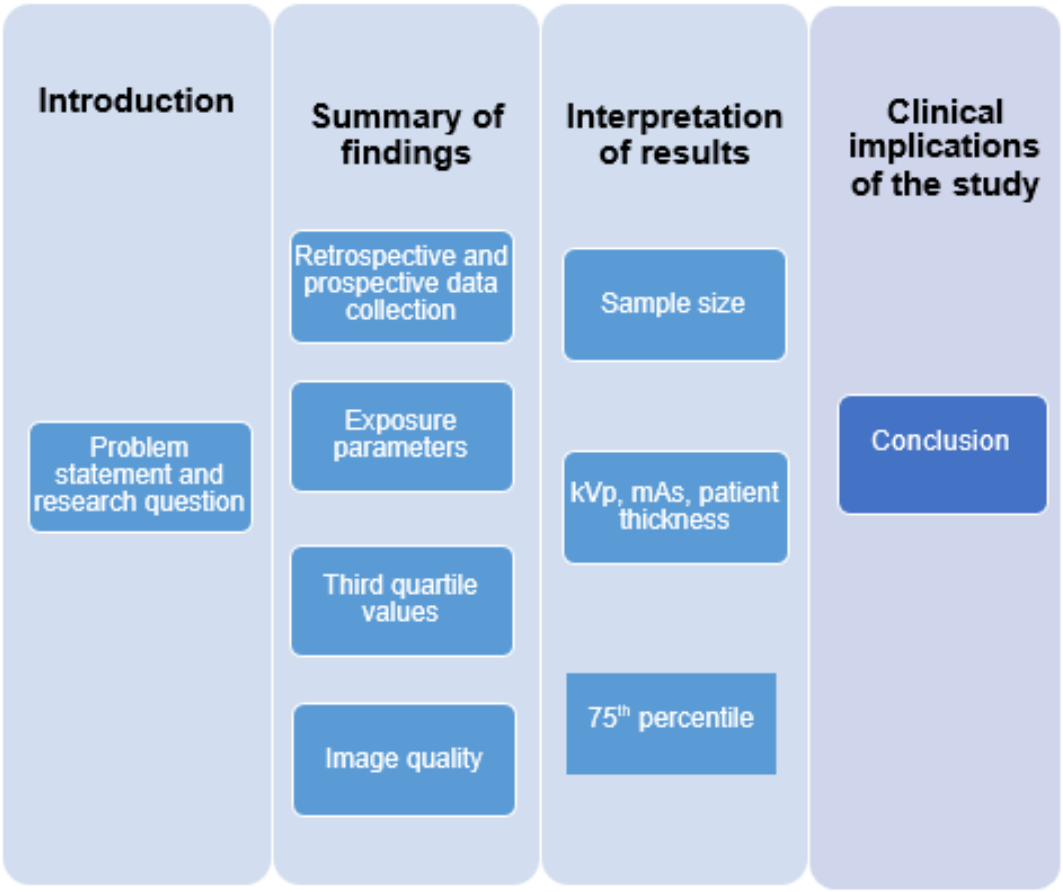

FIGURE 5.1 Layout of Chapter 5

5.2 SUMMARY OF FINDINGS

In this section, the summary of findings will be discussed under the following subheadings:

- retrospective and prospective data collection
- data per weight groups and age groups
- median kVp, mAs, patient thickness, and SID
- third quartile of weight and age group
- image quality

5.2.1 Retrospective and prospective data collection

During the data collection period, the world experienced a COVID-19 pandemic. The SA Government enforced the State of Disaster protocols according to the Disaster Management Act, 2002 (ACT NO. 57 OF 2002): MEASURES TO PREVENT AND COMBAT THE SPREAD OF COVID-19 (RSA 2020: online). The researcher experienced challenges collecting data for certain weight groups during the COVID-19 pandemic. As a result, the researcher had to make amendments to the initial study protocol and include retrospective data collection. The researcher, therefore, collected both prospective and retrospective data. During the data analysis, the prospective and retrospective data were compared to evaluate if differences between the two sets of data values were present. The Shapiro-Wilk test was used to evaluate if there was a significant difference between data collected retrospectively or prospectively at the research sites. According to the analyses, the data collected retrospectively had p-values >0.05; therefore, no significant difference was noted between the retrospective and prospective data. The data in each sample could thus be pooled as one sample for each weight group. The findings are illustrated in Table 4.1a, with Hospital 1 and Hospital 2a indicating p-values higher than 0.05. The researcher could only use the collected retrospective data obtained from Hospital 1 and Hospital 2a. The other hospitals included in the research study were omitted from the

retrospective data collection because telephonic consent was challenging to obtain. The telephone numbers were out of order, or calls were not answered. The reason for grouping the retrospective data with the prospective data was to add the sample size of those weight groups that could not meet the targeted sample size of 30 per weight group. The researcher included the data for 375 paediatric patients, using the PiDRL checklist in calculating the PIDRLs. Table 4.2 outlines the total data collected on the different x-ray machines at the one provincial hospital and three private hospitals in the NCP.

5.2.2 Data per weight group and age group

The researcher collected data for specific age and weight groups to calculate the PiDRLs. The total numbers of patients per weight group were: 0kg to less than 5kg (n=66), 5kg to less than 15kg (n=147), 15kg to less than 30kg (n=112), 30kg to less than 50kg (n=48), and 50kg to 80kg (n=2). The weight group 5kg to less than 15kg had the highest frequency of data collection for paediatric patients. The corresponding data of the total number of paediatric patients per age group are displayed in Table 4.3; 0 to less than 1 year (n=117), 1 to less than 5 years (n =139), 5 to less than 10 years (n=100), and 10 to less than 12 years (n=19). The age category with the highest frequency of paediatric patients for which data was obtained was 1 year to less than 5 years. The high data collection in the weight group 5kg to less than 15kg and age group 1 year to less than 5 years could be because children in this age group possibly are sick more frequently and therefore referred for radiological chest examinations during the COVID-19 pandemic. The reason could be that these age groups are commonly in preschool or day-care centres where co-infection happens more frequently and, therefore, illness can spread easily (Health University of Utah 2021: online).

5.2.3 Median kVp, mAs, patient thickness and SID

Table 4.5 depicts the median of each weight group per hospital. The data confirms that the median weight increased with age. During the data collection, there were no outliers for each weight group. Figures 4.3 to 4.6 illustrate the

median kVp, mAs, patient thickness and SID per weight group. Hospital 3 had a lower kVp value in all the weight groups than the other hospitals, with the highest being 65 kVp in the weight group 15kg to less than 30kg. The reason could be the difference in x-ray equipment manufacturer and, therefore, the difference in the equipment's exposure settings (Muhogora, Ngoye, Byorushengo, Lwakatare & Kalambo 2015:3). Hospital 1, Hospital 2a, and Hospital 2b kVp values ranged between 66 kVp and 104 kVp. The highest kVp in Hospital 1 for the Shimadzu unit was 102 kVp, and the highest kVp in Hospital 1 for the Siemens unit was 96 kVp, both for the weight group 15kg to less than 30kg. The highest kVp in Hospital 2a, for the Shimadzu unit, was 99 kVp, and Hospital 2b, for the Siemens unit, was 104 kVp both in the weight group 30kg to less than 50kg.

The mAs values were evenly distributed per weight group for Hospital 1, Hospital 2b and Hospital 3, except for Hospital 2a, as depicted in Figure 4.4. The mAs value ranging from 3.2 mAs to 6.3 mAs were higher for Hospital 2a in weight group 5kg to less than 15kg, 15kg to less than 30kg and 30kg to less than 50kg. The data in Figure 4.5 displays the patient thickness per weight group. The patient thickness increased with weight increase, as the data demonstrates. In Hospital 3, the patient thickness median value seems to stay constant for the weight group 15kg to less than 30kg, 30kg to less than 50kg and 50kg to 80kg. Figure 4.6 indicates that the SID stayed constant in Hospital 1, Hospital 2a and Hospital 2b, but Hospital 3 had a lower median value.

5.2.4 Third quartile of weight and age groups

Table 4.6 shows the third quartile (75th percentile) of each weight group's ESD for the three NCP radiology departments. The ESD with backscatter was calculated for all the weight groups except 50kg to 80kg for Hospital 1, Hospital 2a and Hospital 2b. For Hospital 1, Hospital 2a and Hospital 2b, no paediatric chest x-ray referrals were received for the 50kg to 80kg weight group during the data collection period. Only Hospital 3 reflects data for this weight group. Therefore, the 75th percentile of the 50kg to 80kg weight group could be calculated as 0.1 mGy. The data shows that the 75th percentile for Hospital 1 was

the highest at 0.3 mGy in the weight group 0kg to less than 5kg. Further, the weight group 5kg to less than 15kg in Hospital 1 for the Shimadzu unit and Hospital 2a for the Shimadzu unit had the highest ESD value of 0.2 mGy. The weight group 15kg to less than 30kg in Hospital 1 for the Shimadzu unit had the highest DRL value of 0.3 mGy. The weight group 30kg to less than 50kg in Hospital 1 Shimadzu unit and Hospital 2a for the Shimadzu unit had the highest ESD value of 0.3 mGy.

Table 4.7 illustrates the 75th percentile value per age group, ranging from less than 1 year to less than 12 years. Data was not collected in Hospital 2b for the age group 10 years to less than 12 years because there were no paediatric chest x-ray referrals. In the age group of less than 1 year, Hospital 1 for the Shimadzu unit has the highest DRL of 0.3 mGy. In the age group of 1 year to less than 5 years, the highest DRL of 0.2 mGy was calculated in Hospital 1 for the Shimadzu unit, Hospital 1 for the Siemens unit, and Hospital 2a for the Shimadzu unit. For the age group 5 years to less than 10 years, Hospital 2a for the Shimadzu unit had the highest DRL, 0.3 mGy. The age group, 10 years to less than 12 years in Hospital 1 for the Shimadzu unit and Hospital 2a for the Shimadzu unit analysis, demonstrates the highest DRL of 0.3 mGy.

Table 4.10 and Table 4.11 depict the mean PiDRL for weight and age groups. The 75th percentile for each weight and age group is expressed as the mean range for weight and age groups. The PiDRL remained constant and only increased for the weight group 30kg to less than 50kg. In the weight group 50kg to less than 80kg, the DRL was 0.1 mGy. The same trend reflects in Table 4.11 for the age groups. The PiDRL remained constant and increased in value in the age group 5 years to less than 10 years. Thereafter the PiDRL was constant in the age group 10 years to less than 12 years.

5.2.5 Image quality

As previously mentioned in Chapter 3, cf. Section 3.8.2.2, DRLs should not be the only method of dose optimisation. Good image quality is obtained by applying

the correct exposure parameters and, therefore, indirectly contributes to radiation safety (Muhogora, Ahmed, Almosabihi, Alsuwaidi, Beganovic, Ciraj-Bejelac, Kabuay, Krisanachinda, Milakovic, Mukwada, Ramanandraibe, Rehani, Rouzitalab & Shandorf 2008:1458). DRLs are designed to produce images of sufficient diagnostic value using the lowest radiation dose possible (Kim, Do, Goo, Yang, Oh, Kim, Hyeog Ju, Lee, & Lee 2012:615). Nevertheless, a DRL value is set to provide the lowest possible radiation dose that can produce images of sufficient diagnostic value (Kim *et al*. 2012:615). Therefore, the image quality assessment checklist (cf. Appendix 8) was applied during the image quality investigation performed on the identified x-ray equipment and mobile units for this research study. The purpose of the image quality investigation was to indicate if the current exposure values utilised by the radiographers are consistent with the EC image quality criteria set out in the 1996 guidelines (EC 1996:29). The assessment of image quality (cf. Appendix 10) is by means of a scorecard that was developed by the EC (1996) for scoring the image quality of each AP CXR image acquired during the image quality investigation.

In Chapter 4, the image quality results were presented. (cf. Section 4.14). The outcome of the image quality results obtained on the x-ray equipment in the departmental rooms, as well as the mobile units, was evaluated on the 7-point EC image criteria (cf. Appendix 10) recommendation for paediatric patients older than 1 year (EC 1996:29). The exposure factors utilised during the investigation resulted in good image quality. According to the score calculated from the assessment scorecard, all of the AP CXR images acquired during the study had a value, with the lowest score being 7 and the highest score being 11. The highest score of 11 was noted for the images produced on x-ray equipment in the room, and the lowest score of 7 was noted for the images produced in mobile units. The x-ray equipment in the radiology rooms produced images that scored higher than the mobile units' images. The reason could be that images were obtained through DR. Another reason could be that the phantom was placed erect against the erect Bucky, whereas on the mobile units, the phantom was supine, and the detector or cassette was placed directly under the phantom. The scorecard added up to a total value of 13, indicating perfect image quality according to the EC standards

(1996). The kVp range 55 kVp and 96 kVp for weight group 0 to less than 15kg and weight group 15kg to less than 50kg with a kVp range from 96 kVp to 104 kVp were in accord with the EC recommendation of tube potential for paediatric patients (EC 1996:29). This research study's SID from 110 cm to 150 cm adhered to the EC recommendations.

All the images collected during the study showed the cervical trachea, thoracic vertebrae, lumbar vertebrae, and upper abdomen. No vascular patterns were noticeable on any of the images acquired during the image quality investigation. This is due to the PBU-80 Newborn Whole Body Phantom anatomical imperfections. Findings of a study conducted in Korea showed the same image quality with a phantom representing a 5-year-old child (ATOM® dosimetry phantom, model 705-D, CIRS, Norfolk, VA, USA) (Kim *et al*. 2012:611). The Korean study used an average of 96 kVp and 4.30 mAs. An acceptable image quality according to the radiologist's 5-point rating scale was acquired during the investigation. The results indicated that good quality radiological images were obtained with exposure factors utilised by the radiographers in the department. Based on the recommendations by the Image Wisely program, Reference levels act as 'trigger levels' to initiate image quality improvement (Toossi & Malekzaheh 2014:305).

5.3 INTERPRETATION OF THE RESULTS

DRLs are defined for a specific radiological examination based on a well-defined radiation quantity specific to a given modality (Almén, Guðjónsdóttir, Heimland, Højgaard, Waltenburg, & Widmark 2021:65). In the clinic, the distinctive dose for the typical patient is assessed and compared to other DRLs (Almén *et al*. 2021:65). DRLs can be calculated as LDRLs, NDRLs or RDRLs according to the EC (EC 2018:70). The EC has released guidelines for European paediatric diagnostic reference levels (EDRLs) (Granata, Soratin, Seuri, Owens 2019:2). The EC guidelines recommend that PiDRLs be calculated in weight groups; however, the number of children per weight group is limited and therefore, data collection can be difficult to complete. In practice, it is difficult and challenging to

collect sufficient data for each weight group (Almén *et al*. 2021:66). Furthermore, collecting data takes a long time due to the limited number of paediatric patients referred for chest examinations, and this has been further aggravated by the COVID-19 pandemic.

In this research study, a total number of 375 paediatric patients participated. The data was collected in three radiology departments situated in four hospitals in the NCP. The PiDRL were calculated for weight groups with corresponding age groups. The researcher will discuss the data collected in this research study in line with other international studies where PiDRLs were calculated because, at the time, the researcher could not find local, regional, or national published PiDRLs for the AP chest examination in conventional radiography.

5.3.1 Sample size

The EC recommends a sample size of 10-20 patients per weight group (EC 2018: online). The aim of this study was to collect 30 patients per weight group. The reason for the sample of 30 was to get an accurate PiDRL value for the population. Figure 4.3 and Figure 4.4 (cf. Section 4.6 & Section 4.7 Chapter 4) illustrates the amount of data collected per hospital. The following section will be discussed in relation to corresponding sample sizes of different age groups in international studies. Findings from this study show that the highest value of data was collected in the age group 1 year to less than 5 years, n=139, and weight group 5 to less than 15kg, n=147. Even though the targeted sample size for each weight group could not be reached, it was significantly higher than the other weight groups in this research study. The higher frequency in certain weight and age groups could be attributed to their involvement in playgroups or schooling environments where cross-infection can play a role (Wambani, Korir, Korir & Kilaha 2013:471). Nevertheless, the sample size was difficult to obtain. During the early stages of the data collection period, the COVID-19 pandemic restrictions were implemented, which could be a reason for limited data in other weight groups. Restrictions on patient admissions to hospitals played a significant role, and referrals for radiological chest examinations to radiology departments were

very selective (RSA 2020: online). Even though the data collected was much less compared to other international studies, it is worth stating that collecting data for PiDRL for conventional chest examinations was difficult; hence, the minimal published data on conventional AP/PA chest examinations are available. Table 5.1 illustrates the variation in data collection for specific weight groups and age groups.

TABLE 5.1 Total data collected for this research compared to data collected for international studies

Country	This research study NCP, South Africa	Asogwa *et al*., 2021 Nigeria	Omojola *et al.* 2021 (only neonates) South Nigeria	Kim *et al*., 2012 Korea	Almén *et al.,* 2021 Europe (four countries)
Sample size	375	50	40	149	1722
No. of hospitals	4	1	NS	135	29
No. of radiology departments	3	1	NS	NS	NS
0 - <1 year	117	21	40	NS	NS
1 - <5 years	139	12	NS	NS	NS
5 - <10 years	100	NS	NS	NS	NS
Phantom 5 - <10 years	NS	NS	NS	147	NS
5kg - <15kg	147	NS	NS	NS	128
15kg - <30kg	112	NS	NS	NS	148
30kg - <50kg	48	NS	NS	NS	131
50kg - <70kg	2	NS	NS	NS	84

Abbreviations: NS, not stated; NC, Northern Cape.

5.3.2 kVp discussion

Exposure techniques vary between radiographers. The reason could be to obtain a good image result (Mesfin, Elias & Melkamu 2017:488). Other reasons could be variations in equipment settings (Muhogora *et al*. 2015:3). In the following section, kVp settings are discussed in relation to international studies utilising the exposure factors to calculate PiDRLs. The researcher found a variation in the kVp setting per weight and age group for each hospital in this research study. In Hospital 3, the kVp settings used were much lower than in the other hospitals in this study.

Contrary to the findings of a study done in Southwest Ethiopia, where the kVp increased with weight and age groups (Mesfin *et al*. 2017:488), in another study in South Nigeria, in weight group 0 to less than 5kg, the kVp was lower than the kVp in this research study. On the other hand, a study done in Japan indicated the same kVp settings for 0 to less than 1 year and 1 to less than 5 years of 75.1 kVp and 90 kVp, respectively (Asada, Ono, Kondo, Sugita, Ichikawa & Shibata 2019:5). A possible reason for the difference in exposure settings by radiographers could be the training and skill level of the staff (Alatts & Abukhiar 2014:188).

5.3.3 mAs discussion

The following section discusses the mAs values found in this study in relation to international mAs values. The NCP study's median mAs were much lower than the mean mAs in a study in Nigeria (Asogwa, Chiegwu, Omojola & Onwughalu 2021:157-159). A study in Southwest Ethiopia also had higher mAs values than this research study. The EC 1996 recommends high kVp and low mAs, aiding in lowering the ESD and absorbed dose to the patient (Mesfin *et al*. 2017:488). Another study in Japan had much lower mAs values for age groups 0 to less than a year and 1 to less than 3 years, 2.1 mAs and 2.4 mAs, respectively, compared to this study, which had 3.02 mAs and 3.62 mAs, respectively. Medical imaging equipment differs; therefore, the same imaging parameters cannot be used on

other x-ray equipment (Sun, Lin, Tyan & Ng 2012:284). Radiographers' exposure techniques can vary widely due to inadequate training, variations in patient appearance, different types of equipment, and the use of different techniques in different hospitals (Mesfin *et al*. 2017:489).

5.3.4 Patient thickness discussion

One study indicated that patient thickness contributes to the ESD value (Asada & Ichikawa 2019:385). Another study in Finland revealed an increase in ESD value with the increased patient thickness (Kiljunen, Järvinen & Savolainen 2007:455). Furthermore, the Finland study had a lower ESD value than this research study. Contrary to this study, the ESD stayed consistent with the increased patient thickness. The reason for the finding could be variation in exposure settings demonstrated between the various hospitals and between departments. The difference in DR and CR imaging equipment could also influence the ESD value (Siebert & Morin 2011:577).

This study showed that patient thickness varied from 8 cm to 14 cm. Asada and Ichikawa (2019:385) defined the age group 0 years as 4-11 months with 11.3 cm, while in this study, patient thickness for 0-11 months was 8 cm. The standard subject thicknesses for infants and toddlers set out in DRLs in the Japan study in 2015, utilising a phantom, are 10 cm and 15 cm (Asada & Ichikawa 2019:385). This was consistent with the findings of this study.

5.3.5 Third quartile discussion

The combined distribution value for the weight group 0kg to less than 5kg has a DRL of 0.2 mGy. For the weight group, 5kg to less than 15kg, the DRL was 0.2 mGy. The weight group 15kg to less than 30kg had a DRL of 0.2 mGy. Further, the weight group 30kg to less than 50kg had a DRL of 0.3 mGy, and the weight group 50kg to less than 80kg had a DRL of 0.1 mGy. The combined distribution value of age group 0 to less than 1 year has a DRL of 0.2 mGy. The age group 1 year to less than 5 years has a DRL of 0.2 mGy. In the age group 5 years to less

than 10 years, the DRL was 0.3 mGy. The age group, 10 years to less than 12 years, had a DRL of 0.3 mGy. The values were therefore expressed as the mean range for the weight and age groups. The following section describes the calculation of the 75th percentile and the methods to acquire the PiDRL. The following formula was utilised in this study:

ESDair (mGy) = FAE (mR) X 0.008 77 X BSF (Tung, Tsai, Lo, Guan, & Chen 2001:851)

Where ESD = the ESD in air, including the BSF
FAE = incident air kerma without BSF
BSF = BSF of 1.32
0.00877 = where 0.00877 converts the exposure, in units mR, into the absorbed dose to air, in units mGy.

While this study obtained the ESD value by utilising the exposure factors and patient anthropometric measurements, other studies used TLDs for ESD calculation (Karami, Zabihzadeh, Gholami, Shams, Fazeli & Nezhad 2016:2185). TLDs are sensitive to variations in room temperature and are not always accurate, as calibration needs to be done frequently (NRBP 1992:3).

The researcher could not find published data on the 75th percentile for conventional AP/PA paediatric chest examinations in SA. The findings of this research study and the method used to calculate the DRL were compared with the findings of international studies utilising similar methods. A study in Japan indicated 0.14 mGy for age group 0 up to 3 years, which was much lower than this research study's 0.2 mGy. Another study in Austria showed the ESD for age groups less than a year, 1 to less than 5 years, 5 to less than 10 years and 10 to less than 15 years as 0.055 mGy, 0.069 mGy, 0.82 mGy, 0.108 mGy, respectively, 0.112 mGy lower than this research. The DRL of certain age groups in this study was consistent with the DRL values of the EDRLs. Findings of the EDRL in groups 0 to less than 1 year, 1 to less than 2 years, 2 to less than 3 years, 3 to less than 8 years, 8 to less than 12 years and older than 12 years,

were 0.131 mGy, 0.240 mGy, 0.146 mGy, 0.228 mGy, 0.434 mGy and 0.455 mGy respectively (EC 2018: online).

Table 5.1 provides a summary of the findings of international studies where PiDRLs were calculated. Some research studies calculated by weight group, and other studies calculated by age group. Studies conducted in Finland (Kiljunen, Järvinen & Savolainen 2007:455) and Japan (Asada & Ichikawa 2019:385) calculated the ESD by patient thickness. In international research studies, various European DRLs were compared with LDRL, NDRL and EDRL.

TABLE 5.2 Summary of international studies where PiDRL were calculated.

Reference	Country	Methodology	Sample size	No. of hosp.	No. of dept.	Body part & projection	DRL measurements	Weight group	DRL/ Weight	Age group	DRL/ Age	Pt. thickness	DRL/ patient thickness
Lackay, OL., Horn-Lodewyk, JL., Muller, HM.	SA	Retrospective & prospective	30 per weight group	4	3	AP chest	mGy/ESD with backscatter	0 - <5kg, 5 - <15kg, 15 - <30kg, 30 - <50kg, 50 - 80kg	0.2 mGy, 0.2 mGy, 0.2 mGy, 0.3 mGy, 0.1 mGy respectively	0 - <1 year, 1 - <5 years, 5 - <10 years, 10 - <12 years	0.2 mGy, 0.2 mGy, 0.3 mGy 0.3 mGy respectively		
Billinger, J., Nowothy, R. & Homolka, P. 2010. Diagnostic reference levels in pediatric radiology in Austria. *Eur Radiol*, 20(7):1572-1579.	Austria	Prospective	1910	14	25	AP/PA chest	mGy/ESAK with backscatter			0 - < 1 year, 1-year old, 5-, 10- and 15-year-olds	0.05 mGy, 0.069, 0.082, 0.108, 0.112		
Kiljunen, T., Järvinen, H., & Savolainen, S. 2007. Diagnostic reference levels for thorax X-ray examinations of paediatric patients.*BJR,* 80(954):452-459.	Finland/ NDRL	Prospective	700	6		AP/LAT chest	mGy/ESD & DAP					Patient thickness; less than 12 cm, 12 - 14 cm, 14 - 16 cm, 16 -18 cm, 18 27 cm	40 µGy, 48, 71, 64, to 83 µGy

Toossi, B., Taghi, M., & Malakeh, M. 2014. *Local Diagnostic Reference Levels for Common Pediatric X-Ray Examinations in Khorasan Razavi Province, Iran.* Iranian *Journal of Medical Physics*, 11(4):301-307.	Iran/ LDRL	Prospective	627		10	AP chest & abdomen	ESD			0 - <1 month, & 1 - 12 months, and 1 - 5 years	77, 126, and 138 µGy for chest		
Asada, Y. & Ichikawa, T. 2019. Consideration of diagnostic reference levels for pediatric chest X-ray examinations. *Radiol Phys Technol*, 12(4):382–387.	Japan/ LDRL	Prospective	163		1	AP/LAT chest	ESD			0 - <5 years with correspon ding patient thickness	0.2 mGy in all age groups		
Morales, J., Jaramillo, W., Puerta, J., Arrieta, A., & Moncada, L. 2012. A comparison of age-dependent	Colombi a	Prospective	471	1		AP/LAT chest	ESD			0- <13 years	0.033 mGy		

entrance skin doses in pediatric chest exams with diagnostic reference levels for the Antioquia region of Colombia.*Radioprotection*, 47(4): 575-582.														
Seung-Youl, L. & Sang-Myeong, P. 2019. Establishment of Diagnostic Reference Levels for Radiography in 10-year-old Pediatric Patients in Republic of Korea. *Journal of Magnetics*, 24(4):781-788.	Korea/LDRL	Prospective	Phantom	211		AP chest	ESD/ Dosimeter			10 year old	0.20 mGy			
Almén, A., Guðjónsdóttir, J., Heimland, N., Højgaard, B., Waltenburg, H. & Widmark, A. 2021. Establishing paediatric	Sweden, Iceland, Norway & Denmark	Prospective	1722	29		chest, abdomen, pelvis, hip/joints and CT thorax and abdomen	Pka	Supine: 5 - <15kg and 15kg - <30kg. Erect: 30kg - <50kg and 50kg - <70 kg	0.040 mGy, 0.055 mGy, 0.028 mGy, 0.050 mGy,					

diagnostic reference levels using reference curves – A feasibility study including conventional and CT examinations. *Physica Medica*, 87(2021):65-72.									0.097 mGy				
R.RADIATION PROTECTION No 185 European Guidelines on Diagnostic EC 2018	Europe/ Austria, Belgium, Cyprus, Germany, Denmark, Spain, Finland, France, Ireland	Retrospective				chest				0-<1year; 1-<2years; 2-<3years; 3- <8 years; 8-12 years; <12 y	0.131, 0.240, 0.146, 0.228, 0.455 mGy		
Asogwa, C.O., Chiegwu, H.U., Omojola, A.D. & Onwughalu, E.M. 2021. Assessment of radiation dose to pediatric patients during routine digital chest X-ray	Nigeria	Prospective	50	1	1	paediatric AP chest	ESD/TLD			0 - <1 year, 1 - <5 years, 5 - <10 years, 10 - <15 years	1,54 mGy, 1,53 mGy, 0,55 mGy, 1,30 mGy		

procedure in a government medical centre in Asaba, Nigeria. *Medical Science and Discovery*, 8(3):155-160.													

Abbreviations: AP, anteroposterior; CT, computed tomography; DAP, dose area product; dept., department; ESAK, entrance skin air kerma; ESD, entrance skin dose; LAT, lateral; LDRL, local diagnostic reference level; mGy, milligray; NDRL, national diagnostic reference level; pt. patient; SA, South Africa; TLD, thermoluminescent dosimeter

Table 5.1 shows that some countries calculate DRLs by weight bands, whereas others calculate DRLs by age group. As mentioned, one study calculated DRLs by patient thickness. Bodyweight and thickness values vary from country, and therefore it is challenging to compare DRLs with international values. It is therefore recommended that a baseline DRL should be set within an individual country and then these values can be compared.

5.4 CLINICAL IMPLICATIONS OF THE STUDY

ESD values found in European countries in the age group 0 to less than 1 year (0.131 mGy) are lower compared to this study, but for age group 1 to less than 5 years (0.240 mGy), they are consistent with this research study (EC 2018:70). Results from a study done in Ethiopia found much higher ESD in all the weight groups compared to this study (Mesfin *et al*. 2017:487). The findings of this study demonstrate a higher ESD value for all weight groups and age groups compared to certain international research studies. On the other hand, the findings of this research study were consistent with other international studies for specific weight or age groups. The ESD value should increase as the weight or age group increases, but the mean ESD stayed consistent in this study. Most of the international studies calculated ESD by age groups. The ICRP (2017: online) and EC (2018: online) recommend grouping by weight group. In this research study, PiDRL were calculated by weight group with corresponding age groups, therefore making the study more reliable (Järvinen, Vassileva, Samei, Wallace, Vano & Rehani, 2017: online). Weight groups are a more reliable factor to link to exposure (Célier, Roch, Etard, Ducou Le Pointe & Brisse 2020:1188). Even though weight groups were utilised for grouping when calculating DRLs, the 75th percentile for this research stayed consistent within higher weight groups and corresponding age groups. One possible reason could be the variation in exposure techniques between radiology departments and differences in x-ray equipment demographics (Alatts & Abukhiar 2014:188).

Image quality improved in a study in 2008 when quality assurance was assured by implementing DRL in the radiology departments (Muhogora *et al*. 2008:1453). Another study indicated that the image quality decreased with the increase in kVp

and decrease in mAs for weight band 1kg to 2.5kg (Martin, Ruddlesden, Makepeace, Robinson, Mistry, & Starritt 2013:629). Image quality, together with the implementation of DRLs, is imperative for dose optimisation.

5.5 CONCLUSION

Even though no published data was found on PiDRLs in South Africa, a comparison was made with international studies. The findings of this study were high in some instances, compared to specific international ESD findings, while in other international research studies, the findings of this study were on par or even lower based on the ESD value. The PiDRL were calculated by weight groups and corresponding age groups, making the research study more reliable. Based on the PiDRL values of this study, the findings were slightly higher than the international value. Lowering the PiDRL for this study can therefore be recommended.

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6 CHAPTER 6: LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

6.1 INTRODUCTION AND OVERVIEW OF THE STUDY

Paediatric patients are more sensitive to ionising radiation because of their longer life expectancy, during which radiation-induced pathology can emerge (IAEA 2012: online). An increase in medical imaging such as CT and interventional radiography over the past decade and the convenience of digital radiography have raised concerns about dose optimisation, especially in paediatric medical imaging. Radiation optimisation and justification of radiographic exposures are essential (Hardy & Boynes 2003:22). The ICRP in 1991 and the European legislation in 1997 by the Medical Exposure Directive 97/43/Euratom (EC 2018: online) introduced the concept of DRL as a quality assurance tool.

Trauernicht and Pitcher (2021: online) highlighted that limited research had been performed on DRLs for different imaging modalities in SA. Furthermore, most DRL studies conducted in SA were for fluoroscopy and interventional radiographic procedures for adults and paediatric patients (Trauernicht & Pitcher 2021:291). The researcher found no published data on general radiography for paediatric patients at the time this study was conducted. Therefore, the researcher formulated the research question: “What DRLs for AP chest imaging of paediatric patients at different hospitals in the NCP will ensure optimisation of protection in the radiation exposure of these patients?”

To answer the research question, the researcher pursued certain objectives to establish DRLs for paediatric AP CXR imaging for the different public- and private radiology departments servicing the NCP. Further, the investigation led to the calculation of PiDRLs for various weight-based groups for AP CXR imaging for the radiology departments that were included in the research. The categories for the weight groups ranged from 0kg to less than 80kg from each radiology department. Corresponding to the weight groups, the age groups were also

included in the PiDRL calculation. To determine whether the 75th percentile value of the mean exposure settings for a specific weight group results in optimum image quality, a checklist was used after imaging a PBU-80 Newborn Whole Body Phantom (3.5kg).

6.2 METHOD OF INVESTIGATION

A descriptive study design was followed by collecting quantitative data prospectively and retrospectively. The three radiology departments included in the research were located in four hospitals in the NCP. The prospective data were obtained from paediatric patients that were referred to the radiology department for CXR examinations. The retrospective data were collected telephonically. During the image quality investigation, the researcher acquired radiological CXR images from the x-ray machines in the rooms and the mobile units. The CXR images used to assess image quality were obtained by exposing a PBU-80 Newborn Whole Body Phantom using the same exposure parameters the radiographers in the radiology departments used. PiDRLs were calculated on the x-ray machines in the rooms but not on the mobile units in the radiology departments.

6.3 RESULTS AND FINDINGS

The calculation formula utilised in this research study for setting the 75th percentile of weight-based groups and comparing age groups was:

ESD_{air} (mGy) = FAE (mR)X0.00877XBSF (Tung, Tsai, Lo, Guan, & Chen 2001:851)

The ESD with the BSF was utilised in this research study. Various external factors, as well as patient demographics, contribute to radiation dose. Exposure factors such as kVp, mAs, SID, patient thickness, and x-ray tube output needed to be obtained to calculate the PiDRL. A medical physicist was consulted to ensure the correct calculation of PiDRL. The results of all four hospitals were

calculated for each weight and age group. The image quality results were evaluated on a 7-point scoring card based on EC (1996:61). The scoring card consisted of 13 questions to attain a 100% score for image quality. The scores for radiological images evaluated during the image quality investigation ranged from 7 to 11. This range in the score indicates that the images were of acceptable image quality and met the EC guidelines on image quality (EC,1996:61).

6.4 LIMITATIONS DURING THE STUDY

During the research study, various limitations were experienced during data collection. The COVID-19 pandemic had a negative influence on the data collection process. Data collection for PiDRLs is challenging but obtaining the required sample size for each weight or age group is even more difficult (Asada & Ichikawa 2019:386). The reasons for this limitation include minimal referrals for paediatric CXR examinations as a result of the restriction of paediatric patient admission to hospitals in the early stages of the COVID-19 pandemic (Personal communication, Dr N. Cupido, 25 August 2020). Another reason for not reaching the targeted sample size was that staff members also contracted COVID-19 during the pandemic, and because of these work constraints, the radiographers who could help with data collecting were unavailable (Personal communication, Ms E. Cornelius, 24 February 2021). When restrictions on hospital admissions were reduced later in the pandemic, an influx of patient admissions occurred. However, this resulted in hospital employees being overworked, and as a result, radiographers did not have time to assist with data collection.

As a result of the limitations mentioned above, the researcher included a retrospective approach to reach the desired sample size for each weight band. The research sites were equipped with picture archiving and communication systems (PACS), but not all sections on the PACS were populated, making it difficult to obtain relevant information. Technical resources proved to be inadequate, with outdated equipment, lack of dosimetric equipment, and lack of convenient data handling resources, such as PACS and dose management systems, contributing to insufficient data validation (Järvinen, Vassileva, Samei,

Wallace, Vano & Rehani, 2017:3). The retrospective study was conducted via telephonic communication with the guardian or parent of each paediatric patient that was admitted to the hospital and referred for CXR examination. During this informed consent process, challenges that the researcher experienced included non-existent telephone numbers or the parent or guardian not answering the telephone call. If the parent or guardian was not sure of the child's weight, height or chest thickness, that specific patient was excluded from this research.

Due to limited funding and time constraints, the researcher could not collect all the data unaided and therefore requested the assistance of the radiography staff. The researcher trained the radiographers and demonstrated the use of the PiDRL checklist. However, some PiDRL checklists were incomplete and had to be excluded from the data collection. A further limitation of the retrospective study was that certain radiographers did not document their exposure parameters, so the data could not be used. Furthermore, the PACS did not include the exposure parameters of historical images, so the researcher had to search in the x-ray register for the name of the radiographer who worked that particular day and who completed the radiological chest examinations. As a result, the total amount of collected data excluded was 96 due to the limitations mentioned above.

One of the objectives of this research was to include PiDRLs on mobile units. The researcher did not have enough time to collect data for the PiDRL calculation checklist for the mobile units because the data acquisition in the radiology departments was time-consuming. Therefore one of the limitations of this study was that PiDRLs for mobile units could not be calculated for the three radiology departments in the NCP. Another objective of this research study was image quality assessment. The PBU-80 Newborn Whole Body Phantom was used to acquire images from the mobile units and fixed x-ray machines in the radiology department rooms. Only images of the specific weight band could be obtained because the phantom weighed 3.5kg, limiting the image quality assessment of the other weight groups.

No published data were found on PiDRLs for AP CXR examination in the NCP and South Africa, so a comparison could not be made between the findings of this research study with other local or regional DRLs.

6.5 RECOMMENDATIONS

The researcher requested and trained radiographers who were willing to help with the data collection. Unfortunately, the pandemic caused staff members to be booked off sick. Other radiographers could not assist with data collection, which resulted in smaller sample sizes in certain weight bands. A recommendation for future studies would be to enlist the services of two or three dedicated radiographers for data collection by communicating through their Head of Department or supervisor.

The retrospective data collection had limitations in obtaining the exposure parameters necessary to calculate the PiDRL for the CXR examinations performed on paediatric patients. Therefore, it is recommended that exposure factors should be easy to access retrospectively, which means that the kVp, mAs and the SID need to be added to the PACS to be available on the historic x-ray images.

One of the objectives of this research was to obtain PiDRLs on mobile units, but this data could not be included due to time limitations. Government or provincial hospitals have more than one paediatric ward, and therefore, a mobile unit would be stationed at the entrance of each paediatric ward. Some private hospitals also have more than one mobile unit near a paediatric ward. It is recommended that further research studies be undertaken to establish PIDRLs on mobile units.

The mean PiDRL for the weight groups 0kg to less than 5kg, 5kg to less than 15kg, 15kg to less than 30kg, 30kg to less than 50kg and 50kg to less than 80kg was 0.2 mGy, 0.2 mGy, 0.2 mGy, 0.3 mGy, 0.1 mGy respectively. The corresponding age groups 0 to less than 1 year, 1 year to less than 5 years, 5 years to less than 10 years and 10 years to less than 12 years were 0.2 mGy, 0.2

mGy, 0.3 mGy and 0.3 mGy. The literature demonstrates that the ESD should increase as the weight of the paediatric patient increases. The PiDRL value remained consistent in some of the weight groups and age groups in this research. The reason could be because of different x-ray equipment manufacturers and the variance in the exposure settings of each radiographer. A recommendation would be to revise the exposure factors and then recalculate the PiDRL for the smaller weight-based groups for the radiology departments in the NCP. This implies that radiographers should either be trained to calculate DRLs or the medical physicist of the department will need to establish DRLs for each x-ray unit. It is recommended that radiographers should use exposure charts as added reference to their discretion on exposure factors. A standardised exposure chart, which is regularly updated for the different x-ray equipment, is recommended for dose optimisation.

Due to limited human and financial resources, the researcher could only calculate the PiDRLs for four NCP hospitals. It is recommended that a larger number of hospitals in the province should be included in future studies. Regulatory bodies in SA should incorporate DRL as part of a quality assurance program. The Regulatory Body should enforce and evaluate compliance by hospitals and, thereafter, regular quality control checks must be performed by radiology staff and, reported to the Regulatory authorities. Radiation workers have to understand the importance and urgency of dose optimisation.

6.6 CONCLUSION

For this study, PiDRLs were calculated for three radiology departments in the NCP. The PiDRL focused on conventional AP CXR examination for paediatric patients. The data (e.g. exposure parameters) used to calculate the PiDRL is from the current practice in this region. The researcher compared the findings of this study to specific exposure factors and patient thickness in other international studies. Even though it is advised not to compare PiDRL with other international findings because of the variation in x-ray equipment manufacturers, the DRL of this study was also found to be on par with international studies. However, this

research study indicated that the PiDRLs could be revised and lowered in certain weight groups.

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APPENDICES

Appendix 1 Frontpage of the published article (Literature review)

ELSEVIER

Journal of Medical Imaging and Radiation Sciences 53 (2022) 123–137

Journal of Medical Imaging and Radiation Sciences
Journal de l'imagerie médicale et des sciences de la radiation
www.elsevier.com/locate/jmir

Continuing Medical Education

A practical guide for paediatric diagnostic reference levels (PiDRLs)

Olivia Lackay, Je'nine Horn-Lodewyk* and Henra Muller

Department of Clinical Sciences, Faculty of Health and Environmental Sciences, Central University of Technology Free State, 1 President Brand Street, Bloemfontein 9300, South Africa

ABSTRACT

This guide was designed to provide a foundation for developing paediatric diagnostic reference levels (PiDRLs) for conventional radiography. In principle, the calculation of diagnostic reference levels (DRLs) is recommended for diagnostic x-ray imaging examinations for radiosensitive patients, such as paediatric patients. PiDRLs are fundamentally important when considering dose optimisation in diagnostic radiology, computed tomography and interventional radiology for paediatric patients. DRLs can assist to point to non-optimised practices and the improvement of paediatric dose optimisation. The purpose of this continuing medical education article is to give medical radiation professionals an overview of PiDRLs for conventional radiography, an understanding of the benefits, the data collection process and some of the calculation methods. The readers can use these steps to establish and implement PiDRLs for different examinations.

RÉSUMÉ

Ce guide a été conçu pour servir de base au développement de niveaux de référence diagnostiques pédiatriques (NRDP) pour la radiographie conventionnelle. En principe, le calcul de niveaux de référence diagnostiques (NRD) est recommandé pour les examens d'imagerie radiologique diagnostique destinés aux patients radiosensibles, tels que les patients pédiatriques. Les NRDP sont fondamentalement importants lorsqu'on envisage l'optimisation de la dose en radiologie diagnostique, en tomodensitométrie et en radiologie interventionnelle pour les patients pédiatriques. Les NRD peuvent aider à identifier les pratiques non optimisées et à améliorer l'optimisation des doses en pédiatrie. L'objectif de cet article de formation médicale continue est de donner aux professionnels de la radiologie médicale une vue d'ensemble des NRDP pour la radiographie conventionnelle, une compréhension des avantages, du processus de collecte des données et de certaines méthodes de calcul. Les lecteurs peuvent utiliser ces étapes pour établir et mettre en œuvre des NRDP pour différents examens.

Keywords: diagnostic reference levels; paediatric diagnostic reference levels; conventional radiography; chest radiography; paediatric; dose optimisation; PiDRL

Learning objectives

After reading this article, the reader will be able to:

- explain the purpose and benefits of PiDRLs;
- state the contribution of PiDRLs to image quality;
- describe the considerations prior to data collection for PiDRLs;
- clarify the data collection steps for PiDRL calculation;
- identify the imaging parameters to calculate PiDRLs; and
- list the steps to calculate PiDRLs.

This is a CME article and provides the equivalent of 1.0 hour/credit from CAMRT that may be applied to your professional development credit system (self reporting). A 10-question multiple choice quiz (and answers) follow this reading.

Declaration of Competing Interest: The authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, nor other relationships or activities that could appear to have influenced the submitted work.

CRediT authorship contribution statement:

Olivia Lackay: Conceptualization, Funding acquisition, Formal analysis, Methodology, Writing original draft, Writing review & editing.

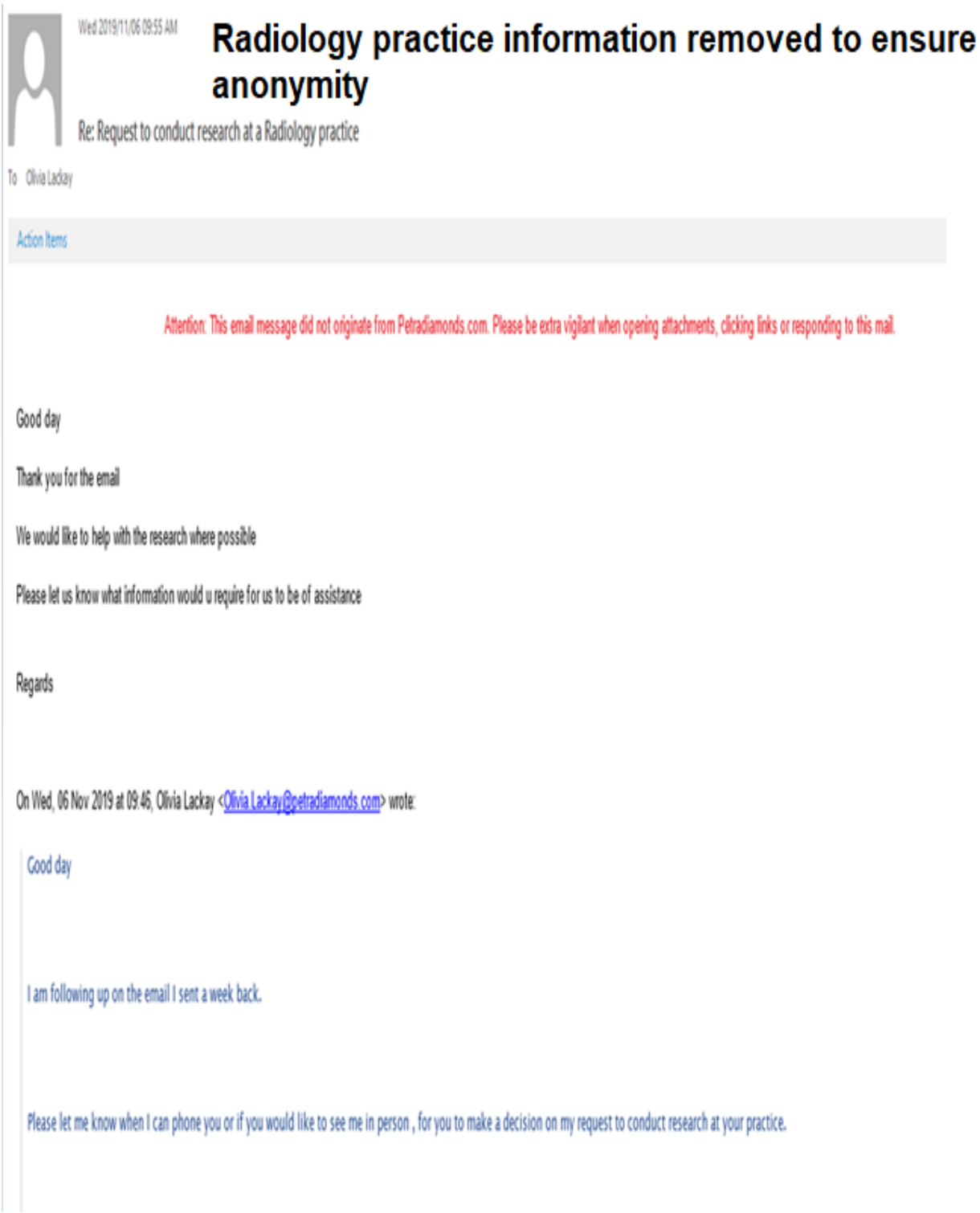
Je'nine Horn-Lodewyk: Conceptualization, Funding acquisition, Formal analysis, Methodology, Writing original draft, Writing review & editing.

Henra Muller: Conceptualization, Funding acquisition, Formal analysis, Methodology, Writing original draft, Writing review & editing.

* Corresponding author.
E-mail address: jhornlodewyk@cut.ac.za (J. Horn-Lodewyk).

1939-8654/$ - see front matter
https://doi.org/10.1016/j.jmir.2021.12.005

Appendix 2(a) Permission to conduct research at a private hospital



Wed 2019/11/06 09:55 AM

Radiology practice information removed to ensure anonymity

Re: Request to conduct research at a Radiology practice

To Olivia Lackay

Action Items

Attention: This email message did not originate from Petradiamonds.com. Please be extra vigilant when opening attachments, clicking links or responding to this mail.

Good day

Thank you for the email

We would like to help with the research where possible

Please let us know what information would u require for us to be of assistance

Regards

On Wed, 06 Nov 2019 at 09:46, Olivia Lackay <Olivia.Lackay@petradiamonds.com> wrote:

> Good day
>
> I am following up on the email I sent a week back.
>
> Please let me know when I can phone you or if you would like to see me in person , for you to make a decision on my request to conduct research at your practice.

Appendix 2(b) Permission from radiology department DoH

□

PO Box 152
Lime Acres
8410

20/01/2020

Mrs
Kimberley Hospital Complex
Radiology Department
Kimberley
8300

Dear Madam

REQUESTING PRELIMINARY PERMISSION TO ACQUIRE RESEARCH DATA

I, Olivia Lackay hereby kindly would like to request preliminary permission to collect data for research at the Radiology Department. I am registered at the Central University of Technology for the master's degree in Radiography: Diagnostics. My research topic is "**Paediatric chest diagnostic reference levels for three Northern Cape radiology departments"**. The aim of the study is to develop paediatric diagnostic reference levels (PiDRL) for the anteroposterior (AP) chest examination for radiology departments in the Northern Cape Province (NCP).

In order to establish PiDRL's, I need to obtain specific information from radiology departments that service paediatric patients. A paediatric patient can be considered from new-born up to fifteen years. The information needed to calculate the PiDRL, will be **exposure parameters such as, kVp, mAs, source-to-skin distance as well as age, weight and height of the paediatric patient**. The parent or legal guardian of the paediatric patient will firstly receive an information document in their home language. Secondly, if the parent or legal guardian is willing to give permission to submit necessary information that person will be asked to sign the informed consent form. Informed consent will be obtained before data can be collected. A checklist will be the research tool, to document data.

Central University of Technology, Free State

Myself, with my supervisors Dr Je'nine Horn-Lodewyk and Mrs H. Muller will firstly obtain permission from the University of the Free State (UFS), Health Sciences Research Ethics Committee (HSREC) by submitting a comprehensive protocol to ensure all ethical issues are addressed and ensure that the research will be performed in line with the Declaration of Helsinki (protection research participants). The study will need ethical approval as patients will be involved and patient data will be accessed. This study is seen as a minimal risk/low risk research project, as none of the participating patients will receive any additional radiation dosages or radiological examinations.

The confidentiality and anonymity of the practice will be respected and identifying information like "private practice" will be excluded from the protocol that could also be an identifying characteristic. The researcher will be willing to collect data over the weekends or after hours as it suites the practice.

Please find attached a concept note on the planning of the research study. I will be willing to also submit a full research protocol to the practice but need preliminary permission to continue to the next phase of obtaining ethical permissions. I need the preliminary letter from the practice in order to obtain approval from the UFS HSREC. After obtaining this letter I will first submit the approval letter to your radiology practice to inform you that ethical approval for this research was obtained. You are also welcome to contact one of my two supervisors Mrs Henra Muller (henramuller@cut.ac.za) or Dr Je'nine Horn- Lodewyk (jhornlodewyk@cut.ac.za) should you need more information on the study. Please e-mail the letter with the outcome of your decision on granting permission to perform research at your radiology practice to Olivia Lackay, email: Olivialackay@yahoo.com .

I would like to thank you in advance for your time and hope to hear from you soon relating to this matter in order to continue with obtaining ethical permission.

Yours faithfully,

Signature

Signature removed for anonymity

20/10/2020

Dep. Director: Rad.

Signature of approval and date

Olivia Lackay

Cell: 082 8259605

E-mail: olivialackay@yahoo.com

Dr Je'nine Horn-Lodewyk

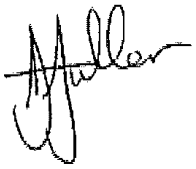
Lecturer and Supervisor

Department of Clinical Sciences

Central University of Technology, Free State

Cell: 0828594533

E-mail: jhornlodewyk@cut.ac.za



Mrs Henra Muller

Lecturer and Supervisor

Department of Clinical Sciences

Central University of Technology, Free State

Cell: 0845060004

E-mail: henramuller@cut.ac.za

Appendix 3(a) University of the Free State, Health Sciences Research Ethics Committee approval letter

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

17-Aug-2020

Dear **Olivia Lackay**

Ethics Clearance: **Paediatric chest diagnostic reference levels for three Northern Cape radiology departments**
Principal Investigator: **Olivia Lackay**
Department: **Radiography - CUT**

APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2020/0456/2909**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

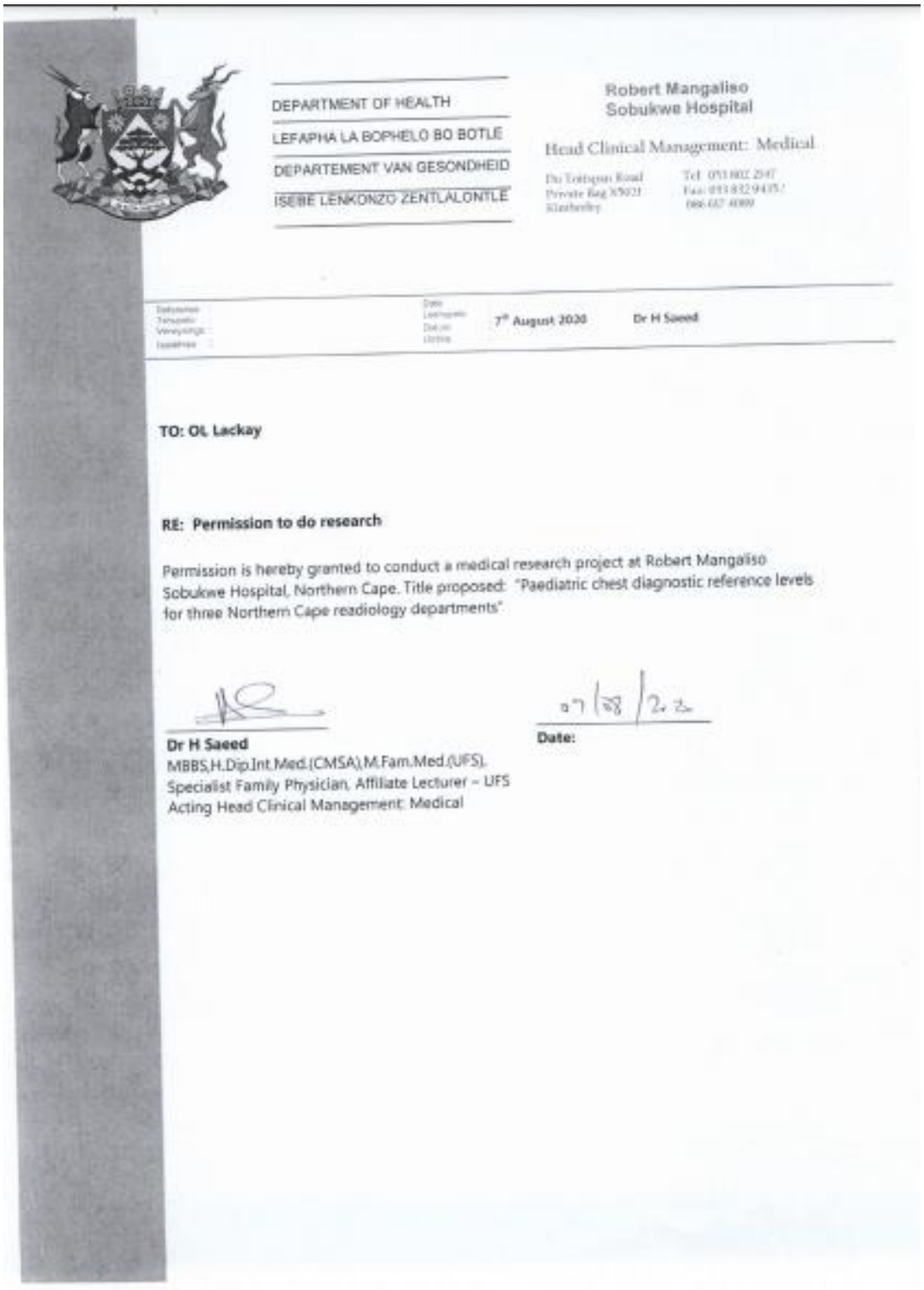
Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
IRB 0001992; REC 230408-011; IORG 0010096; FWA 00027947
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

Appendix 3(b) NC Department of Health approval letter



DEPARTMENT OF HEALTH
LEFAPHA LA BOPHELO BO BOTLE
DEPARTEMENT VAN GESONDHEID
ISEBE LENKONZO ZENTLALONTLE

Robert Mangaliso
Sobukwe Hospital

Head Clinical Management: Medical

Du Toitspan Road
Private Bag X5021
Kimberley

Tel: 053 802 2947
Fax: 053 832 9435/
086 637 4089

7th August 2020 Dr H Saeed

TO: OL Lackay

RE: Permission to do research

Permission is hereby granted to conduct a medical research project at Robert Mangaliso Sobukwe Hospital, Northern Cape. Title proposed: "Paediatric chest diagnostic reference levels for three Northern Cape readiology departments"

07/08/2020

Dr H Saeed
MBBS,H.Dip.Int.Med.(CMSA),M.Fam.Med.(UFS).
Specialist Family Physician, Affiliate Lecturer – UFS
Acting Head Clinical Management: Medical

Date:

Appendix 4 Telephonic consent approval

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

19-Nov-2020

Dear Olivia Lackay

Ethics Number: UFS-HSD2020/0456/290901

Ethics Clearance: **Paediatric chest diagnostic reference levels for three Northern Cape radiology departments**

Principal Investigator: **Olivia Lackay**

Department: **Radiography - CUT**

SUBSEQUENT SUBMISSION APPROVED

With reference to your recent submission for ethical clearance from the Health Sciences Research Ethics Committee. I am pleased to inform you on behalf of the HSREC that you have been granted ethical clearance for your request as stipulated below:

- Minor Amendment:
  Written informed consent will be obtained if the parent or guardian accompanies the paediatric patient to the radiology department. If the paediatric patient is not accompanied by a legal parent or guardian telephonic consent will be obtained.
  Changes made in protocol to indicate this.
  Telephonic consent form included.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this request for ethical clearance and we wish you continued success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7785/7794 | E: ethicsfhs@ufs.ac.za
IRB 0001992; REC 230408-011; IORG 0010096; FWA 00027947
Block D, Dean's Division, Room D304 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

Appendix 5(a): Information document to the parents or guardians of the participating patient in English

PATIENT INFORMATION DOCUMENT

STUDY TITLE: PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS

Good Day

I, Olivia Lackay, and I am a radiographer that takes x-rays. I am doing research to establish paediatric diagnostic reference levels (PiDRLs) in the Northern Cape Province (NC). I will provide you in this document with information on the research I am going to perform.

What are diagnostic reference levels?

Diagnostic reference levels can be defined as a tool to measure if the radiation dose that is applied for the specific radiographic imaging is as low as possible, but will still produce a quality image.

Where will the study be conducted?

This study will be conducted at three radiology departments in the NC province, SA which include paediatric patients as part of their imaging. The study proposes to establish PiDRLs for chest images at three radiology departments in the NC.

Who will participate in the study?

Paediatric patients ranging from new-borns to under twelve years of age, who are referred for chest imaging to the three radiology departments, will be included in the study. In order to establish PiDRLs, the researcher will need to collect specific information of 30 chest images of each age group ranging from 0-1 years, 2-5 years,6-10 years and 11-12 years from three radiology department. The PiDRLs will be calculated with the assistance of a medical physicist.

How many patients will take part in the study?

30 patients for each age group for each of the different radiology departments which will account to a total sample size of 450 patients.

Why is it important to do this research?

The established PiDRLs can form part of future quality control of these radiology departments. By including the PiDRLs as part of the quality control, can contribute to the radiation protection of paediatric patients and can thus contribute to best practice in the radiography profession. **The purpose and aim of this research are to ensure the correct dose for the specific chest image, and also to ensure that the radiology departments included in the study are operating optimally.**

What are the benefits?

This study will be beneficial to ensure that patients do not receive more radiation dose than is necessary.

How will my child's privacy be protected?

All efforts will be made to keep personal identification confidential. There will be no mentioning of the patient's name or identification number (ID number).

Kindly note that participation is voluntary and that your child may withdraw from the study at any time. No costs are payable by you for participation in the study, neither will you be remunerated for your child's participation.

The results from the study may be presented at seminars/conferences related to the research and/or published in an applicable journal.

What will happen during the study?

The researcher will stand by and observe the radiographer who will be taking the x-ray. The researcher will document the exposure settings on the x-ray machine, and then measure the chest thickness with a caliper.

What preparation is required?

The radiographer doing the x-ray examination will explain the procedure to the parent or guardian of the child.

How long will my child be in the study?

The radiographer doing the x-ray examination will explain the duration of the procedure. This examination should take about 10-15 minutes.

Who can answer my questions?

The radiographer will explain the x-ray examination and the researcher will explain the reason for the study your child is participating in, if you wish to participate.

What are the possible risks for my child by participating in the study?

There is no risk regarding injury to your child. The study is beneficial in terms of radiation safety.

What other choices do I have if I don't participate in the study?

If you choose not to let your child participate, the usual course of medical care will continue. You may remove your child at any time during the study.

The ethical aspects of this protocol have been reviewed by University of the Free State (UFS) Health Sciences Ethics Committee and the Northern Cape Department of Health. **Contact details of Secretariat and Chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State – for reporting of complaints/problems: Telephone number (051) 4052812.**

You can contact me, Olivia Lackay on Tel: 082 825 9605 or Email: olivialackay@yahoo.com

16/05/2020

Signature of researcher Date

Appendix 5(b): Information document to the parents or guardians of the participating patient in Afrikaans

PASIENT INFORMASIE DOCUMENT

STUDIE TITEL: **PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS**

Goeie dag

Ek, Olivia Lackay, en ek is 'n radiograaf wat x-strale neem. Ek doen navorsing om pediatriese diagnostiese verwysingsvlakke (PiDRL's) in die Noord-Kaap Provinsie (NC) te bepaal. In hierdie dokument sal ek u voorsien van inligting oor die navorsing wat ek gaan doen.

Wat is diagnostiese verwysingsvlakke?

Diagnostiese verwysingsvlakke kan gedefinieer word as 'n instrument om te meet of die stralingsdosis wat toegepas word vir die spesifieke radiografiese beeldvorming so laag as moontlik is, maar steeds 'n kwaliteitbeeld sal lewer.

Waar sal die studie gedoen word?

Hierdie studie sal by drie radiologie-afdelings in die Noord-provinsie, SA, uitgevoer word, wat pediatriese pasiënte as deel van hul beeldvorming insluit. Die studie beoog om PiDRL's vir borsbeelde by drie radiologie-departemente in die NC te vestig.

Wie sal aan die studie deelneem?

Pediatriese pasiënte, wat wissel van pasgeborenes tot jonger as twaalf jaar, wat na die drie radiologie-afdelings verwys word na borskasafbeeldings, word by die studie ingesluit. Om PiDRL's te bepaal, moet die navorser spesifieke inligting versamel van 30 borskasbeelde van elke ouderdomsgroep wat strek van 0-1 jaar, 2-5 jaar, 6-10 jaar en 11-12 jaar van die drie radiologie-afdeling. Die PiDRL's word met die hulp van 'n mediese fisikus bereken.

Hoeveel pasiënte sal aan die studie deelneem?

30 pasiënte vir elke ouderdomsgroep vir elk van die verskillende radiologie-afdelings, wat verantwoordelik is vir 'n totale steekproefgrootte van 450 pasiënte.

Waarom is dit belangrik om hierdie navorsing te doen?

Die gevestigde PiDRL's kan deel vorm van toekomstige gehaltebeheer van hierdie radiologiedepartemente. Deur die PiDRL's as deel van die gehaltebeheer in te sluit, kan dit bydra tot die stralingsbeskerming van pediatriese pasiënte en kan dit dus bydra tot die beste praktyk in die radiografieberoep. Die algemene doel en doel van hierdie navorsing is om die regte dosis vir die spesifieke beeld van die borskas te verseker, en ook om te verseker dat die radiologiedepartemente wat by die studie ingesluit is, optimaal funksioneer.

Wat is die voordele?

Hierdie studie sal voordelig wees om te verseker dat pasiënte nie meer stralingsdosis ontvang as wat nodig is nie.

Hoe sal my kind se privaatheid beskerm word?

Daar word gepoog om persoonlike identifikasie vertroulik te hou. Die naam of die identifikasienommer (ID-nommer) van die pasiënt sal nie genoem word nie.

Let daarop dat deelname vrywillig is en dat u kind te eniger tyd aan die studie kan onttrek. U betaal geen koste vir deelname aan die studie nie, en u sal ook nie vir u kind se deelname vergoed word nie.

Die resultate van die studie kan aangebied word tydens seminare / konferensies wat met die navorsing verband hou en / of in 'n toepaslike tydskrif gepubliseer word.

Wat sal tydens die studie gebeur?

Die navorser sal bystand hou en die radiograaf sal die x-straal neem. Die navorser sal die beligtings stellings van die x-straalmasjien dokumenteer en dan die borskasdikte met 'n caliper meet.

Watter voorbereiding is nodig?

Die radiograaf wat die x-straalondersoek doen, sal die prosedure aan die ouer of voog van die kind verduidelik.

Hoe lank sal my kind aan die studeer wees?

Die radiograaf wat die x-straalondersoek doen, sal die duur van die prosedure uiteensit. Die ondersoek duur ongeveer 10-15 minute.

Wie kan my vrae beantwoord?

Die radiograaf sal die x-straalondersoek verduidelik en die navorser sal die rede vir die studie waaraan u kind deelneem, verduidelik as u wil deelneem.

Wat is die moontlike risiko's vir my kind deur aan die studie deel te neem?

Daar is geen risiko vir u kind se besering nie. Die studie is voordelig ten opsigte van bestralingsveiligheid.

Watter ander keuses het ek as ek nie aan die studie deelneem nie?

As u kies om nie u kind te laat deelneem nie, sal die gewone kursus vir mediese sorg voortgaan. U kan u kind te eniger tyd verwyder indien u dit gaan ondersoek

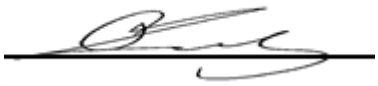
Wat is die koste verbonde aan toetse en prosedures?

Daar is geen finansiële voordeel om aan hierdie navorsing deel te neem nie. Die navorser sal u nie vergoed as daar 'n besering ontstaan as gevolg van deelname aan hierdie navorsingsprojek nie.

Kontakbesonderhede van Sekretariaat en Voorsitter: Etiekkomitee van die Fakulteit Gesondheidswetenskappe, Universiteit van die Vrystaat - vir die rapportering van klagtes / probleme: Telefoonnommer (051) 4052812.

U kan my kontak, Olivia Lackay

Tel: 082 825 9605 of Epos: olivialackay@yahoo.com



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30/10/2019

Handtekening van navorser

Datum

Appendix 5(c): Information document to the parents or guardians of the participating patient in Setswana

PATIENT INFORMATION DOCUMENT

STUDY TITLE: PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS

Madume.

Ka leina ke Olivia Lackay tiro yam eke go dira ekeserei.Ke dira di patlisiso mo maseyeng a gofitlhelwang bana le dikarolo tse dirileng tsa (PiDRLs) mo Kapabokone (NC).Ketla gofa tlhagiso Lesedi motokomaneng ya patlisiso mo go se kentse ke sedira.

Karolo ya diphitlhelelo e mo selekanong se sekae?

Selekano sa diphitlhelelo tlhagiso Lesedi go ka lebelela (Radiology) e e sekasekilweng ka setshwantsho sa marang enna ele kotlase mme e tlhagisa boleng jwa ditshwantsho.

Dithuto ditla tshwarelwa kokae?

Dithuto ditla tshwarelwa kwa Lenmed private Hospitalle le ko Kathu, NC Radiology Kimberley le Kimberley provincial Hospital mo Kapabokone.SA etla akaretsa balwetse ba masea jaaka karolo ya ditshwantsho.

Dithuto di leka go ka simolola (PiDRLs) ditshwantsho tsa mafatlha mo karolong dile tharo mo lefapheng la marang mo Kapabokone.

Kemang yo otla tsang karolo mo dithutong?

*Masea a eleng gone abonwang le ba dingwaga tse some pedi, ba eleng gore ba rometswe go ya ditshwantshong tsa mafatlha kwa lefapheng la karolo tse tharo tsa marang.

*Retla akaretsa dithuto go simolola (PiDRLS), Mosekasiki otla kgobokanya tlhagiso Lesedi gotswa mo ditshwantshong gotswa mo masome ale mararo modingwageng kgobokanyo ka go farologana ka dingwaga gotswa go 0/1, le 2/5 le 6/10 le 11/12 gotswa mo mafapheng a mararo a marang (Radiology).

PiDRLs) e tla tlhakanya ka thuso gotswa go kalafi moitsefisikisi

Ke balekae ba bagotsang karolo mo dithutong?

Ke balwetse bale some amarataro ka dingwaga tsa bone ka ditlhopa tsedi farologaneng.

Lefapha la marang letla bala disampole ka goya ka disease go balwetse bale kgolonne some amatlhano (450).

Goreng gole botlhokwa go dira dipatlisiso tse?

Ke go similola PiDRLs go kanna karolo mo bokamosong go laola tekatekano mo bokamosong mo lefapheng la marang, goka akaretsa PiDRLs jaaka go laola tekatekano.

Ekathusa go sireletsa balwetse ba masea go Radiation, le go thusa bogatlhamela masisi jwa Radiology porofesion.MAITLHOMO LE MAIKAELELO A TSHEKATSHEKO KEGO NETEFATSA GORE SETSHWANTSHO SA MAFATLHA SE NETEFETSE LE GO NETEFATSA GORE LEFAPHA LA MARANG LE AKARETSA DITHOLE GO KA DIRA KWANTLWE GA MAITEMOGELO A A LEKANENG.

Ditsholofelo ke eng ?

Ditsholofelo gotswa mo dithutong ke gore molwetse ga a na go amogela marang (Radiation) e feteletseng gosa tlhokagale.

Kesireletsa jang sephira sa ngwana waka?

Matsapa otlhe atla tsewa ka boitshupo kakaretso.

Gagokitla go umakiwa maina a mokudi kgotsa di nomoro tsa makwalo itshupo, Elatlhoko gore karolo ke ka goithaopa, gape ngwana wa gago aka ikgolega morago nako nngwe le nngwe serutweng se. Ga go tuelo epe e o e duelang tebang le serutwa se, legone go lebogiwa ka go tsaya karolo ga ngwana wa gago.

*Dipholo gotswa go serutwa ditla tlhagisiwa ko disenara/khonferense e amanang le dipatlisiso kgotsa e gatisitswe ka mokgwa wa mokwalo.

Go tla diragalang fa gare ga serutwa kgotsa thuto?

*Ba batlisisi batla tlhagisa le gore go lebelela motsaya marang a ekeserei o a tlabeng a dira ekeserei. Mobatlisisi o tla boloka boemo ba go tlhagisa mo motshining wa ekeserei gape a be a lekanye selekano sa sefuba sa ngwana wa gago ka calliper.

Ke boitukisetso bofe jo bo batlegang?

*Motsaya marang ekeserei yo o dirang tlhatlhobo ya ekeserei o tla tlhalosa nako ya tsamaiso. Tlhatlhobo e ka dira go lekana motsotso ele sometlhano go ya go masome a mabedi.

Kemang yo otla arabang potso yaka?

*Motsaa ditshwantsho wa marang otla tlhalosa diteko tsa ekeserei mme mmatlisisi otla tlhalosa lebaka la diteko tsa dithuto.

Ke eng se seka ba kang dikotsi mongwaneng mo go tseng karolo ga ngwana mo dithutong?

*Gankitla gonna le dipaka kotsi mo ngwaneng. Dithuto pabalesego tsa radiation dimolemo thata.

Ke eng se seka ntswelang molemo gake sa tseye karolo?

*Fa osa rotloetse ngwana go tsaya karolo, Se se agang sediriwa sa boitekanelo setla aga sediriwa.O ka emisa ngwana goka tsaya karolo modithutong.

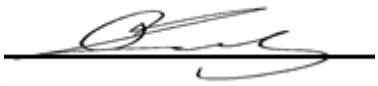
Ditokelo tsa me ketsefe mo go tseyeng karolo ga ngwana?

*Go tsaya karolo game ke ka goithaopa keka gorata game.

Maitlhomo le maikakaretso a tlhomamisitswe ke dithuto tse dikgolwane tsa(Univercity)UFS. Balefapha la bo rasaense le bo maitsanape le ba lefapha la boitekanelo la Kapabokone.

Dinomoro mogala tse oka dileletsang modulasetilo le mokwaledi: bomaitsanape ba Boitekanelo, Go ka baitsese ka di tletlebo o ka ba leletsa mo nomoro mogala e (053)4052812.

O ka leletsa nna O.Lackay mo go: 0828259605 kgotsa Imeile: olivialackay@yahoo.com



16/05/2020

Signature of researcher Date

Appendix 6(a): Consent letter from the participants in Afrikaans

STUDY TITLE: PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS

U is gevra om aan 'n navorsingstudie deel te neem en u het die inligtingsbrief oor hierdie studie bestudeer.

Let daarop dat u deelname aan hierdie navorsing vrywillig is, en u sal nie gepenaliseer word of voordele verloor as u weier om deel te neem of besluit om deelname te beëindig nie.

As u instem om deel te neem, kry u 'n ondergetekende kopie van hierdie dokument, sowel as die inligtingsbrief, wat 'n skriftelike samevatting van die navorsing is.

U kan enige tyd die navorser, Mev Olivia Lackay by 0828259605 kontak as u duidelikheid oor die navorsingstudie benodig, of alternatiewelik die Sekretariaat van die Etiekkomitee van die Fakulteit Gesondheidswetenskappe, UV by 051 4052812 as u vrae het oor u regte en oor die navorsingsonderwerp.

Die navorsingstudie, wat bogenoemde inligting insluit, is mondelings aan my beskryf. Ek verstaan wat my betrokkenheid by die studie beteken en stem vrywillig daartoe in.

8/03/2020

Handtekening van navorser Datum

…….. ……

Handtekening van deelnemer Datum

Appendix 6(b): Consent letter from the participant in English

STUDY TITLE: PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS

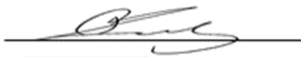
You have been asked to participate in a research study and you have studied the information letter about this study.

Kindly note that your participation in this research is voluntary, and you will not be penalised or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the information letter, which is a written summary of the research.

You may contact the researcher, Mrs Olivia Lackay on 08282596 at any time if you need some clarity concerning the research study, or alternatively, the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at 051 4052812 if you have questions about your rights as a research subject.

The research study, including the above information, has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.



30/10/2019

Signature of researcher Date

…….. ……

Signature of participant Date

Appendix 6(c): Consent letter to participants in Setswana

STUDY TITLE: **PAEDIATRIC CHEST DIAGNOSTIC REFERENCE LEVELS FOR THREE NORTHERN CAPE RADIOLOGY DEPARTMENTS**

O kupilwe go tsa karolo mo tlhotlhomiso kitsong ena me o tlhaloganya lekwalo kisto ya tlhotlhomiso ena.

Ka gore jaalo,itsi gore go tsa karolo mo tlhotlhomiso e, ke ka go ithaopa, le gore ga nketla o latlhegelwa ke morokotso kgotsa ditswanelo tsa gago ha o gana go tsa karolo kgotso o ikhutlwa go tlogela go tsa karolo mo tlhotlhomisong ena.

Ha o dumalatsana go tsa karolo o tla neiwa tokomane e signilweng ya dintlha tsa tsekatseko ena le tshobokanyo ya tlhotlhomiso ena.

O kgona go leletsa motsamaisi, Mme Olivia Lackay, mo dinomorong tsena 0828259605 ka nako engwe le engwe ha o tlhoka thuso ka tlhotlhomiso, me gape o nale tsono go botsisa mo Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS mo dinomoro tsena 0514052812 fa o baatla goitsi ditswanelo tsa gago jaaka motsakarolo mo tlhotlhomisong ena.

Tlhaloso ya tlhotlhomiso le dintlha tse di umakilweng mogodimo mona di tlhalositswe mo go nna ke motsamaisi ka puo ya molomo, me ke tlhalogantse.

Ke a tlhaloganya go tsa karolo mo dithutong tsena le go ithaopa go dumelana go nka karolo, go raya enge.

-  ---------- 8/03/2020

Signature ya motlhotlhomisi Letlha

---------- 8/03/2020

Signature ya monkakarolo Letlha

Appendix 7: PiDRLs calculation checklist

Paediatric chest diagnostic reference levels for three Northern Cape radiology departments *Entire checklist should be completed for each chest image taken.*	
Assigned Image number	
SECTION A: x-ray equipment information	
Room number	
Manufacturer of the x-ray machine	
Erect Bucky grid ratio	
Inherent filtration of the x-ray tube	
DR/CR	
For CR which Digitiser system used	
Out Bucky (yes)	
In Bucky (yes)	
Annual QC tests date	
Monthly QC tests date	
Mobile Radiography (Yes/No)	
Incubator (Yes/No)	
ICU or Paed Ward	

SECTION B: Patient measurements	
Patient height (in cm)	**cm**
Patient weight (in grams)	**g**
Patient age (in months)	**months**
Patient age(in years)	**years**
Patient thickness at T7	**cm**

SECTION C: Technical radiographic factors	
kVp setting	
mAs setting	
Source to image distance (in cm)	**cm**

Appendix 8: Image quality assessment checklist

SECTION A: X-ray equipment information		
Room number		
KV		
MAS		
Manufacturer of the X-ray machine		
Erect Bucky grid ratio		
Inherent filtration of the X-ray tube		
ADDITIONAL FILTER/ copper filter		
Digitiser system used		
Out Bucky (yes)		
In Bucky (yes)		
Mobile radiography (Yes/No)		
Incubator(Yes/ No)		
ICU or Paed Ward		
SECTION B: CRITERIA FOR QUALITY ASSESSMENT		yes/no
1	Performed at peak of inspiration	
2	Reproduction of the thorax without rotation and tilting	
3	Reproduction of the chest must extend from the cervical trachea to T12/L1. (part of the abdomen may be included for special purposes)	
4	Reproduction of the vascular pattern in the central half of the lungs	
5	Visually sharp reproduction of the trachea and the proximal bronchi	

6	Visually sharp reproduction of the diaphragm and costo-phrenic angles	
7	Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and mediastinum	

Appendix 9 Coded data for statistical analysis

Patient ID	Hospital	Machine	Weight Group Age_months	HEIGHT	WEIGHT	AGE	kVp	mAs	SID_CM	THICKNESS	ESDwith Backscatter
1	HOSP1-SHIMADZU	SHIMADZU	0KG- <5KG	44	2.5	16DAYS	50.00	1.80	100.00	9	0.659916682
2	HOSP1-SHIMADZU	SHIMADZU	0KG- <5KG	40	2.9	3DAYS	60.00	3.20	100.00	10	0.201818182
3	HOSP1-SHIMADZU	SHIMADZU	0KG- <5KG	22	4.3	1MTH	55.00	2.50	100.00	8	0.120185186
4	HOSP1-SHIMADZU	SHIMADZU	0KG- <5KG	45	1.3	3MTH	50.00	3.20	100.00	8	0.114725926
5	HOSP1-SHIMADZU	SHIMADZU	0KG- <5KG	51	3.5	2MTH	75.00	2.80	100.00	7	0.26556213
1	HOSP1 SIEMENS	SIEMENS	0KG- <5KG	50	3.4	1mth	96	2.5	150	12.3	0.095984195
2	HOSP1 SIEMENS	SIEMENS	0KG- <5KG	48	1.9	14days	52	2.5	150	7.5	0.022669419
3	HOSP1 SIEMENS	SIEMENS	0KG- <5KG	63	4.8	4mth	85	4	150	8	0.117346939
4	HOSP1 SIEMENS	SIEMENS	0KG- <5KG	62	4.9	2mth	102	5	150	10	0.20452636
5	HOSP1 SIEMENS	SIEMENS	0KG- <5KG	64	4.5	3mth	66	4	150	9	0.071838932
1	HOSP 2A	SHIMADZU	0KG- <5KG	56	4.3	4MTHS	86	4	150	8	0.086938776
2	HOSP 2A	SHIMADZU	0KG- <5KG	71	4.9	9MTHS	96	5.6	150	10	0.151732829
3	HOSP 2A	SHIMADZU	0KG- <5KG	29	3.29	1MTH	86	4	150	6	0.084507042
4	HOSP 2A	SHIMADZU	0KG- <5KG	40	4.5	3MTHS	96	2.5	150	8	0.065816327
5	HOSP 2A	SHIMADZU	0KG- <5KG	50	2.8	10DAYS	86	4.5	150	7	0.096423721
1	HOSP 2B	SIEMENS	0KG- <5KG	66	3.2KG	2MTHS	93	2.5	150	8	0.078061224
2	HOSP 2B	SIEMENS	0KG- <5KG	50	2.8	2DAYS	96	2.5	150	8	0.082270408
3	HOSP 2B	SIEMENS	0KG- <5KG	68	3.2	4MTH	96	2.5	150	8	0.082270408
4	HOSP 2B	SIEMENS	0KG- <5KG	62	3	1MTH	96	2.5	150	9	0.083456413
5	HOSP 2B	SIEMENS	0KG- <5KG	65	3.2	4MTH	96	2.5	150	8	0.082270408
1	HOSP 3	DELL	0KG- <5KG	65	3.3	3MTHS	65	3.2	115	10	0.64850599
2	HOSP 3	DELL	0KG- <5KG	63	3.1	14DAYS	55	3.6	110	7	0.044113322
3	HOSP 3	DELL	0KG- <5KG	60	3.2	2MTHS	55	3.6	110	8	0.045
4	HOSP 3	DELL	0KG- <5KG	63	4.5	3MTHS	55	4	110	9	0.251015203
5	HOSP 3	DELL	0KG- <5KG	60	4.8	4MTH	58	4.5	110	9	0.069788797

Appendix 10 Assessment image quality scoring card

Assessment of Image Quality — CHEST PA/AP

Image criteria assessment	Film - No.										
1. Performed at peak of inspiration, except for foreign body aspiration											
2. Reproduction of the thorax a: without rotation											
b: and without tilting											
3. Reproduction of the chest must extend from just above the apices of the lungs to T12/L1											
4. Reproduction of the vascular pattern in central 2/3 of the lungs											
5. Reproduction of a: the trachea											
b: and the proximal bronchi											
6. Visually sharp reproduction of a: the diaphragm											
b: and costo-phrenic angles											
7. Reproduction of a: the spine											
b: and paraspinal structures											
and visualisation of c: the retrocardiac lung											
d: and the mediastinum											
Total score											
General assessment											
Appropriate film-blackening *											
Contrast *											
Sharpness **											
Appropriate field size **											
Correctly centred over the region of interest **											
Film acceptable for the given clinical question ***											

Name of radiologist and hospital code

Scoring

image criteria	1 = yes	0 = no	↓ = too little / too low
*	+ = optimum	↑ = too much / too high	0 = unacceptable
**	+ = optimum	↓ = sub-optimum	3 = unacceptable (give reasons)
***	1 = fully acceptable	2 = only acceptable under special conditions	

Appendix 11 Letter of the statistician

Maryn Viljoen
Statistics Consulting Services

maryn.viljoen@vodamail.co.za
082 823 5731

Protocol and research methodology consultation • Ethical consultation • Database construction and capturing of data
Analyzing data using statistical software packages (SAS Version 9.1.3) • Statistics consultation services to analyze and interpret data
Conveys results with statistical tables and figures where needed

The Chairperson: Health Sciences Research Ethics Committee (HSREC)
For Attention: Mrs. M.G.E. Marais
Block D, Room 104
Francois Retief Building
Faculty of Health Sciences
University of the Free State

11 November 2019

Title: "Paediatric chest diagnostic reference levels for three Northern Cape radiology departments."

Researcher: O.L. Lackay
Magister Technologiae in Radiography (Diagnostic)
Department of Clinical Sciences: Programme Radiography
Faculty of Health and Environmental Sciences
Central University of Technology, Free State

I have seen and read through this protocol. I gave input and recommendations and will be the biostatistician responsible for the analysis of the data.

Maryn Viljoen
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Appendix 12 Letter of the medical physicist

Dear Olivia

I am willing to help you where necessary, but with no charges.

Best regards

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
'YUNIVESITHI YA FREISTATA

Susan Acho
Lecturer/Principal Medical Physicist: Medical Physics
Lektor/1E Geneeskundige Fisikus: Geneeskundige Fisika
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Appendix 13 Letter from the language editor

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konibo communications

CONFIRMATION OF PROFESSIONAL EDITING

Date: 18 June 2022

I hereby confirm that I have done comprehensive technical and language editing of the following dissertation:

Student:	Olivia Lackay
Title:	Paediatric Chest Diagnostic Reference Levels for 3 Northern Cape Radiology Departments
Degree:	Master of Radiography
Faculty:	Health and Environmental Sciences
University:	Central University of Technology

I started my career as a Lecturer in the Department of Communication at the University of Fort Hare and I am an Applied Linguistics specialist with extensive, senior-level writing and editing experience in a broad spectrum of disciplines, including editing of academic dissertations and journal articles.

Kind Regards

Kefilwe Makhanya
Editor

Appendix 14 Turnitin report results excluding the published article

Final Turnitin report

by Olivia Lackay

Submission date: 30-Jun-2022 03:42PM (UTC+0200)
Submission ID: 1865015048
File name: OL_Lackay_DISSERTATION_29_June_2022.pdf (4.26M)
Word count: 47894
Character count: 256448

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Final Turnitin report

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